

History

of the

U. S. Food and Drug Administration

Interviewee: Robert W. Sauer

Interviewer: Robert A. Tucker

Date: March 6, 2001

Place: Rockville, MD

INTRODUCTION

This is a transcript of a taped oral history interview, one of a series conducted by the Food and Drug Administration's History Office. The transcript is prepared following the *Chicago Manual of Style* (references to names and terms are capitalized, or not, accordingly.)

The interviews are with persons, whose recollections may serve to augment the written record. It is hoped that these narratives of things past will serve as one source, along with written and pictorial source materials, for present and future researchers. The tapes and transcripts are a part of the collection of the National Library of Medicine.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857CASSETTE NUMBERS: 1, 2, & 3GENERAL TOPIC OF INTERVIEW: History of the Food & Drug AdministrationDATE: March 6, 2001 PLACE: Rockville, MD LENGTH: 150 minutesINTERVIEWEE:INTERVIEWER(S):NAME: Robert W. SauerNAME: Robert A. TuckerADDRESS: [REDACTED] ADDRESS: Rockville, MD[REDACTED] FDA Headquarters - Parklawn BuildingFDA SERVICE DATES: FROM: June, 1961 TO: March 31, 2002TITLE: Director, Office of Management & Communications, CVM

(Last FDA Position)

INDEX

Tape	Page	Subject
1 - A	1	Personal & educational background
	2	Overview of FDA career
	3	Early Bureau of Radiological Health experience
	4	Conference of Radiation Control Officials
	7	PHS Radiological Health Program
	10	Color television radiation problem Radiation Control Act of 1968 (PL 90-602)
	12	Radiological Health function: to FDA & EPA
1 - B	14	WEAC (Winchester Engineering Analytical Center)
	✓ 16	EPA environmental radiation sampling program
	17	FDA field radiological health specialists
	18	FDA preparation for medical device legislation and program implementation

Tape	Page	Subject
1 - B	20	Device legislation role: Dr. Ted Cooper NIH, Heart, Lung & Blood Institute
	23	Establishment of BRH in FDA - 1974
	25	Utah Biomedical Test Laboratory (devices)
	26	Sen. Kennedy hearing - Dalkon Shield
	27	Bureau of Medical Devices & Diagnostic Products
	22, 28	John Villforth, director of merged units
2 - A	29	Personnel director experience
	31	OMB Circular A-76
	32	FERS (Federal Employees Retirement System) FAME (Formula for Achieving Managerial Excellence)
	33	Generic drug scandal
	34	Title 38 authority NTEU (National Treasury Employees Union)
	35	CEPHS (Consumer Environmental Protection Service)
	38	PDUFA (Prescription Drug User Fee Act)
	40	Congressional inquiries + FOI (Freedom of Information Act responses
2 - B	41	Hoffman-LaRoche + PHARMA assistance
	43, 46, 63	Dr. Jane Henney
	42	Dr. Frank E. Young
	35, 42, 57	Dr. David A. Kessler
	37	Gerry Meyer
	44	Dr. Frances Kelsey
	47	Associate Commissioner for Planning

Tape	Page	Subject
2 - B	50	Agency program impacts: '70s, '80s, '90s Leadership, merges, RIFs)
3 - A	55	Food program changes
	57	Tobacco issue
	59	FDAMA (FDA Modernization Act) - impact on funding resources
	60	Summation remarks (various commissioners)
	61	Centralization - decentralization
	65	Presidential Meritorious Award recipient

RT: This is another in the series of FDA oral interviews for the history program.

Today the interview is being held with Robert W. Sauer, Director, Office of Management and Communications in the Center for Veterinary Medicine. The interview is taking place on March 6, 2001, in the Parklawn Building, and is being conducted by Robert A. Tucker.

Bob, as we begin these interviews, we like to start with a brief résumé of your birthplace, where you were educated, and what degrees you may have earned in that process.

RS: I was born in 1943 in Elizabeth, New Jersey. My folks moved to the Washington area shortly thereafter, so I am, for all practical purposes, a Washingtonian, living most of the time in Montgomery County, but some time in the District and Prince George's County as well.

I went to Walter Johnson High School in the local area. I then went to Montgomery College and actually went under a grant from the Bureau of Radiological Health, and received an associate's degree in radiologic technology.

RT: And you finished your college work in what year, Bob?

RS: '63.

RT: Was that a master's or a doctorate?

RS: Associate.

RT: Associate degree, okay.

RS: In fact, I started working for the Bureau of Radiological Health while I was going to school. So when I started in June of 1961, I was a GS-2 working in the training program in the radiological health organization.

RT: As you came in, you were in the training element of the Bureau at that time?

RS: That's correct.

RT: What kind of training would you have been involved with there?

RS: What I'd like to do, Bob, if it's all right with you, is just kind of give you a brief synopsis chronology of all of my FDA experience, and then come back and talk about them one at a time, if that's all right with you.

RT: Sure. Let's go ahead with that.

RS: As I said, I was with the radiological health program in '61 and stayed with them through 1973, and that included the time that they were transferred into FDA. In '74, I

went to work in the Office of the Commissioner for Sherwin Gardner, who was the Deputy Commissioner at the time, on a special assignment having to do with developing a new medical device program, and we'll talk about that later.

From '74 to '81, I was in the Bureau of Medical Devices and Diagnostic Products, later to become the Bureau of Medical Devices, the start-up program for the device effort. In '82 and '83, I spent some time at OMB, the Office of Management and Budget, but most of the time I was in the newly merged Center for Devices and Radiological Health.

From '84 to '95, I was the Director of Human Resources for FDA. From '95 to 2000, I was in the Center for Veterinary Medicine as the Director of the Office of Management and Communications.

For almost a year in 2000 and 2001, I was the Associate Commissioner for Planning for FDA. In March of '01, I went back to my job in CVM, from which I will retire the end of this month.

RT: You had a rather broad scope of experience and, as you said, I'm sure you want to get into more details of that now.

RS: Let me start with the radiological health experience. Again, I started there as a GS-2. People wonder what a GS-2 can do in this world. It was fascinating. They had a real knack for taking people and giving them meaningful work. Several of us, including my wife-to-be, all started with the Bureau of Radiological Health on June 11, 1961. We were all part of this grant program at Montgomery College. We did a variety of things. The Bureau had a very active state radiological training program, which meant taking

training courses out on the road to various state health agencies and/or putting them on here in Rockville.

Just as an anecdote, when we were hired in '61, we were hired into the Chapman Avenue Building. What most people probably don't know is that in '61 that was only a two-story building. It was expanded to four floors a couple of years later, as the Bureau grew.

For the first four or five years, I was there on and off during summers while I was going to school, and they kept giving us a little more responsibility. We even participated in the conduct of a few courses. We put on some of the technical parts of the courses that they were giving. Got to do a lot of traveling. It was a great experience.

RT: Who was the person in charge of that particular activity?

RS: Elizabeth Baker was the director of the training program at the time.

RT: Later on that staff grew, as I recall. It probably had more folks later than it might have had at that point.

RS: Well, it's interesting. The reason for the growth in the rad health program at the time was not this training program; it was the X-ray exposure study. They commissioned a study, which I then started to work on in '63, having to do with X-ray exposure nationwide, and it was a major effort to try and find out what the actual medical radiation exposure was in this country. It was headed up by a fellow by the name of Joe Gitlin,

and several of us, lots of us, were working with Joe on the X-ray exposure study, which was finally completed in '64.

It's interesting to note that in '64 the radiological health program was over 1,200 people. It was a massive program, and when you think about where the radiological health program is today, that number seems even higher.

RT: Part of the Bureau's activities over the years, as I think you have suggested already, involved a lot of training and professional development for state personnel or perhaps assignees to a state program from the Bureau. Is that accurate?

RS: That's correct. We also did a lot of state assistance. We were out there helping the states get started, get programs started, or teaching them how to do things like surveys of X-ray equipment. I went out to do survey work in Nebraska. I spent time in the District of Columbia getting those survey programs up and running to where the states would take them over and do them themselves.

RT: Did the Bureau have any kind of grants or financial assistance for state programs?

RS: Absolutely. And that, you know, over the years dried up. The events of September 11th have kind of resurfaced the importance of having that radiological health capability in government, though. The problem is you can't just turn on the faucet. You can't just go out and hire these people, and because the radiological health program nationally has slowly eroded to the point where we don't even have a critical mass at

either the state or the federal level, we are not even graduating people in the health physics area anymore.

RT: Perhaps with the Bureau and later FDA support, there was a Conference of Radiation Control Officials. In your work in training, were you tied in with that organization?

RS: Yes. Actually, I think the Conference actually started later in time chronologically, and maybe Jim Terrill did start that, but I thought it was John Villforth that actually started the Conference. That would have been much later on, and I was off doing something else at the time. I don't recall the Conference being an active entity at the time.

RT: It probably wasn't in that period of time.

RS: Right.

RT: Now, a gentleman's name you just mentioned, a predecessor of John Villforth.

RS: Jim Terrill.

RT: Jim Terrill, yes.

RS: Yes. Jim has passed away, but he's kind of recognized as the father of the radiological health program. He's one of the people I'll mention later on in terms of leadership. He had a knack of not only making people work hard or wanting to work hard, but also playing hard. At that time, I was one of the younger folks around, and he was very interested in softball and bowling and all kinds of sports. He would always stop by and we would talk about how the Radiological Health softball teams and the bowling league were going. He would get out to them as often as he could. In fact, he bowled for a couple of years in the league.

RT: The Bureau of Radiological Health later was brought into the Food and Drug Administration, but historically what was the origin of the Bureau? Was it under another part of the Department?

RS: Correct. It always was a part of the health arm of the U.S. Government. I believe it had its origins in the late forties and early fifties in the atomic testing program.

Because of the concerns about environmental and public health exposure, the radiological health program was formed, and there was created a network of federal agencies and the state agencies, and they were primarily concerned with monitoring the air, the food, the milk, the water, for contamination that might be coming from other people doing testing or related to U.S. testing as well. The Public Health Service also did some offsite surveillance for the AEC [Atomic Energy Commission] testing facility in Nevada, and that is the main reason the radiological health program had a significant laboratory facility just outside of Las Vegas, Nevada.

RT: Putting that into perspective of time, about what year would that have been, Bob?

RS: Well, I think that this was probably all in the forties and early fifties, when this got started, and then the radiological health program, I'm not sure when it was originally established as an organizational entity, but it was in the Public Health Service, which was in the Department of HEW [Health, Education and Welfare] and then became HHS [Health and Human Services].

Now, again, to show you a little bit of how this radiological health mentality was, they gave people lots of opportunities to do lots of things, and I took advantage of that. They asked me if I wanted to go out to do some of this work with the Atomic Energy Commission doing some of the offsite surveillance work out at the Nevada test site. I was out there for several different tests in the mid-sixties. It was just kind of an exciting place to be, and participated in just about everything that was going on out there.

RT: In terms of your career, you came in at the entry level of GS-2. Did you have an opportunity then to get some promotions and move along?

RS: Sure. Keep in mind, I was going back to school and then back to work. So I think by the time '65 rolled around, I think I was all the way up to a GS-6. My future wife and I decided to get married. So we got married in '65. And that was another interesting thing about the rad health organization. It was a very young group of people in the Bureau at that time, and there were a lot of marriages within the organization,

people working together getting married. It was very commonplace, and you'll see a lot of that left over in the old rad health community and the device community as well. It was a very interesting phenomenon and created a literal family atmosphere.

But in '65, when we got married, it was pretty clear that I didn't want to continue to do this technician work for the rest of my life, so I decided to try getting into the administrative area. I often think about those days. Mr. Terrill found out that was what I wanted to do, and he personally went to the Office of Personnel Management on my behalf and wrote them a letter on my behalf. When all was said and done, I got a job as an Administrative Assistant, GS-7, in the environmental control program of Bureau of Radiological Health. This meant I had to travel downtown because that's where the program was housed.

I'm sure you're aware that the radiological health program in the sixties was actually housed in the old Tempo buildings on the Mall. We were in the Tempo R building until Lady Bird Johnson decided that she wanted to beautify the Mall and tear down those old temporary Quonset huts that we were working in.

RT: I came into the Division of Federal and State Relations, and we were in Tempo S, so we were in that same series of buildings, which I believe had been there since World War I.

RS: No, it was World War II. They were literally set up as temporary housing quarters then, and I'm sure no one expected them to be used into the sixties.

RT: I guess that would have been true, because we did have an old central air conditioner, and they wouldn't have had that back in the First World War.

RS: Right.

So I was given an opportunity to go into that program, and that was a lot of fun, too, because that program handled the environmental surveillance network for the Bureau. We had three regional laboratories. There was one in Las Vegas, one in Montgomery, Alabama, and one in Winchester. The Winchester lab eventually wound up coming to FDA, but that was at a later time.

So I worked with the environmental program for, I guess it was, about two years. The director of that program called me into his office one day—I think I was a GS-9 at the time—and he said, "There's some really big stuff happening, and we're going to set up a new program. I think you're the person to go work with Jack Nelson and help get this program set up." This was the color television radiation problem, the cathode ray tube problem with color TVs. This started to emerge in '67, I think.

The Bureau had asked Jack Nelson to set up the program, and Chuck Weaver, who would have been Jack Nelson's peer, kind of said to Jack, "I think Bob's the guy to help you get this thing going." So I did. I went out and worked with Jack, and we got the program set up and we got legislation passed. This was PL 90-602, the Radiation Control Act of '68. I think we were reasonably successful in getting it going and getting the program up and running, doing a lot of hiring and setting up, implementing regulations.

This was a very new approach for the rad health program. They were used to dealing under the Public Health Service Act. They weren't dealing with much

enforcement authority. They did most of their work through the states. They did most of their work by giving money away or giving assistance away, and now they were becoming a regulatory agency. It was a very different environment because now they were in the standards setting and enforcement arena.

RT: Time-wise that would have been about when?

RS: The law was passed in 1968.

RT: When other units of the traditional public health program came into the agency, they, too, had sort of a change of venue in terms of being in an enforcement-focused agency rather than the more supportive and program developmental work. So it was probably a little stressful in your bureau as well as in these others to change step.

RS: Well, we hadn't come into the FDA yet. We were still part of the Public Health Service and not part of FDA yet. It was interesting, in '69, I think it was, Jim Terrill called me and said, "There's a group being put together at the Department, and I'd like you to serve on it." It was a group that [HEW] Secretary Gardner was putting together. It was headed up by a fellow by the name of Ron Linton. So I said, "Sure, I'd love to." So I went down and joined the group. Again, I was a fairly young guy, and I wasn't the policy guy. I was a research associate for this task force.

The report that we put together in '69 was entitled, "The Strategy for the Livable Environment." And it was, in fact, the legislative blueprint for the formation of EPA

[Environmental Protection Agency]. Terrill understood that the EPA might come out of this working group, and he wanted somebody there on it that could let him know where this thing was heading, because he knew the radiological health program was going to be a major piece of this environmental group, if the EPA ever got set up as a separate entity. Of course, he was right.

So, in '69—I think it was '69—the legislation was introduced, EPA was set up in 1970, and the radiological health program was split almost in half. Half of it went to EPA. That was the environmental radiation programs, all the sampling that they were doing, the offsite work they were doing with AEC, and the other half stayed in HHS, and that was the medical X-ray and the electronic product radiation associated with the 90-602 activities.

For a few months there, we were just kind of sitting there in the Office of the Secretary reporting directly to the Secretary, which was kind of an interesting set of circumstances. Well, that didn't last very long, and that's when the decision was made to transfer those elements of the radiological health programs that stayed in HHS to the Food and Drug Administration.

RT: Was that a part of the Nixon administration reorganization of government agencies?

RS: Boy, that's a good question.

RT: I don't know either.

RS: I'm not sure.

RT: It might have been somewhat in that period of time.

RS: The action to set up EPA was a separate legislative action. I don't recall it being part of twenty-nine other things, but it may have been.

So what happened was when Terrill called me and asked me to go work on this Linton committee, I was with what was then called the Division of Electronic Products. That was the group that was doing the new law.

When I got back from this committee work, I was asked to help with the negotiations regarding the split, because I knew the thinking that had gone into what was going to EPA and what was to stay in HHS.

Then when we were moved into FDA, what happened was I was in a division. We didn't have offices back at that time. It was just divisions. I was moved up to the Deputy Executive Officer position, and my job then was to work with people like Gerry Meyer and Mickey Moure and folks like that in trying to get the Bureau of Radiological Health FDA-ready. I think that's about the only way I can say it. Remember, we had just gone through the trauma of splitting ourselves in half, and people sitting side by side, one went to EPA, one stayed in HHS. Very, very traumatic experience for everybody.

That had only just gotten done when we had to go through this transfer into FDA, which also was traumatic and became more traumatic. It took a while for the radiological

health folks, much like the biologics folks later, to get used to the culture of FDA. It really was a different way of thinking.

I like to think that the radiological health program, when it came into FDA, not only was significantly impacted by FDA, but it in turn also had some lasting impacts on FDA. Clearly there was a strong FDA enforcement posture that the rad health people just were not used to. On the other side, I think a lot of the senior leadership in FDA, when the rad health program came in, began to see the merit of a strong educational component for industry and users rather than just 100 percent focus on the regulating solutions.

So I really think, at least in the case of rad health, I think it was a mutually beneficial marriage. I do think the agency learned a lot from the rad health approach to doing business, and I give a lot of credit for that to John Villforth. I think John was a real visionary, and I think he made the transition into the Food and Drug Administration a whole lot easier than it otherwise would have been. But I was also asked to work with the agency and the Bureau to ease this transition, particularly for the administrative areas.

For example, one of the things that we had to do was we had to give up our laboratory in Winchester. When we split with EPA, two of our field labs, the one in Montgomery, Alabama, and the one in Las Vegas, went to EPA, and we kept what is now the WEAC [Winchester Engineering Analytical Center] facility. That was part of the Bureau at the time. Well, that just isn't the way that FDA did business. It was a laboratory and it was outside of Washington. In those days, all field labs reported to the ACRA [Associate Commissioner for Regulatory Affairs]/EDRO [Executive Director of Regional Operations], and there just wasn't any if, ands, or buts about it. And our folks, who were very specialized folks, doing very specialized radiological health work, wound

up being another ORA [Office of Regulatory Affairs] lab expected to do all of the myriad of testing for all FDA-regulated commodities.

[Begin Tape 1, Side B]

RT: Bob, you were speaking about WEAC and some of the consolidation problems with FDA.

RS: That was part of the negotiations that we had with the field folks at the time that this happened. We had developed some pretty sophisticated—at least at that time they were sophisticated—testing facilities at WEAC for doing microwave testing. I don't know whether you ever saw them, but you'd go in and you'd see a row of twenty microwave ovens that the doors were just being opened and closed automatically. The issue was, were the seals wearing down and therefore creating an opening where the microwave radiation could leak out and cause damage to people, particularly the eyes. That was the concern.

So that had become a radiological electronic product testing facility up there, and the folks there weren't real crazy about picking up some of the more traditional Food and Drug work that the field did, but we got them to agree to keep our radiological testing component up there intact.

RT: Did the Winchester laboratory ever get involved in the traditional agency laboratory work? Wasn't it always pretty much a specialized laboratory?

RS: No, I think it really did turn into doing some more routine Food and Drug work, because you've got to remember, and in fairness to everybody involved, that group had been doing a lot of environmental surveillance work, so there was a lot of basic chemical analysis work that was being done. It was looking at different commodities for different problems, but it was chemical analysis.

RT: They did have the expertise?

RS: Absolutely. That function went to EPA. The environmental sampling work went to EPA. So you had a capability there that the field wanted to use for its traditional work, but there were some parts of it, as I mentioned, like the microwave oven testing facility, that we wanted to make sure was retained for that purpose, and it was.

RT: Did that laboratory ever get much involved in the medical device testing activity?

RS: Probably not much more so than any other field laboratory. They did the consumer product work, but I don't think they did anything in ultrasound or lasers or medical X-ray or anything like that, any more so than any of the other field laboratories did.

One other concession that came out of this negotiation was that we wanted to have in each one of the regional offices—and I think there were ten at the time—a radiological health expert person that could continue with some of our work with the

states, and we wanted that person to be a trained radiological specialist. We wanted that person to have a place of privilege in the organization and report to the highest level, the district director or the regional director, and that is the way it was set up.

RT: As I recall, a number of the state cooperative or state liaison activities, including radiological health, were sometimes absorbed in a state services or state cooperative unit, probably in the compliance parts of the field office. Is that how you recall it?

RS: My recollection is we kept one person as a radiological expert, and that person stayed in the regional office or the district office, depending upon where they were. Those weren't the only people doing radiological work in the district, but there was one who had this position of the radiological specialist.

RT: I was trying to recall, as the office I was in worked a lot with state cooperative activities as well, and I thought that the rad health rep, if you will, did become a part of that cadre of people like the milk and food specialists.

RS: Yes, I think you're right, Bob.

RT: That's what I had in mind.

RS: Yes, that is correct. At least that's my recollection.

RT: So they were able to continue in their specialty field and not be diluted off into all kinds of other enforcement matters at the field office.

RS: But all of that was decided as part of this negotiation for absorbing rad health into FDA in 1970. So for the next couple of years I served in the capacity of the deputy to the executive officer in rad health. His name is Bob Neal.

Everything was going along fine, and then one day I got a call from Gerry Meyer, and Gerry said, "Mr. Sherwin Gardner needs some help, and I think you could help him."

So I went over and talked to Gerry and then I talked to Mr. Sherwin Gardner. What they were doing at the time was anticipating medical device legislation. They had set up a small staff in Dr. John Jennings' office, Associate Commissioner for Medical Affairs, to begin getting this medical device program started.

What Mr. Gardner wanted was basically two things. One, he wanted an organization that could be set up to handle the device program. He didn't want to leave it as this little component in John Jennings' office. But he also wanted a legislative implementation plan for the device amendments, which they were expecting pretty soon. Sherwin asked if I would be interested in working on it for six or seven months, and I said, "Sure."

I worked with Sherwin. I worked with Gerry. I worked with Dave Link, who was running the device program in John Jennings' office. I worked with Dr. Eloise Eavenson, who was running the *in vitro* diagnostics program that was housed in Drugs at the time, because by the definition in the device legislation, it was clear that *in vitro* diagnostics would be regulated as medical devices.

RT: By that time, I'm sure, Bob, you had risen to a higher grade.

RS: I was a 14 in rad health, and I was given a temporary promotion to a 15 when I went to work for Sherwin.

RT: Because of that level of work you obviously had progressed quite a distance from your entry.

RS: I have a funny anecdote about that time I went to work for Sherwin. He was here in the Parklawn Building, of course, and my office was right next to his. I came in one morning, and I guess I was noticeably wet. Sherwin's secretary said, "What happened to you?"

And I said, "Well, I just had a long walk, parking the car over at Twinbrook."

And I didn't say another word.

So about an hour later she comes in and she says, "You now have a parking place in the Parklawn Building."

I said, "Oh, that's wonderful. Thank you very much."

So that afternoon, I had a meeting with Dave Link. I went into his office, and he was over in the Chapman Avenue Building at the time. He was really, really ticked about something. It was very obvious. I asked him what was wrong.

He said, "Some day you're going to have to explain this bureaucracy to me."

I said, "What happened?"

He said, "I just got a call from so-and-so, and they took my parking place away."

[Laughter]

Guess who they gave it to? Well, guess what. We quickly fixed that and gave him his parking place back. I didn't mention the story to Sherwin's secretary. But it was an interesting set of chain reactions that occurred.

RT: And you were, I presume—

RS: I was very dependent upon Dave for making this implementation plan make sense, and there I was and they were taking his space away to give it to me. So I thought that was a bad idea.

RT: Probably.

RS: Bad plan.

We worked for, I don't know, six or seven months and put together a plan for both putting together a bureau and a legislative implementation plan.

What happened in devices—I'm sure you know this—Dr. Ted Cooper from the Heart, Lung, and Blood Institute at NIH [National Institutes of Health], was asked to put together a legislative strategy for the device program, and he did. That was done in '72 or '73. So there seemed to be pretty much unanimous agreement about the approach, and the approach was, the first thing you've got to do is you've got to classify all these devices and decide how you're going to regulate them, and then you have this three-

tiered system of regulation. All devices aren't the same, and they shouldn't be treated the same. So we knew pretty much how things were going to play out. There were just going to be some details that had to be worked out.

Interesting part about that law was the timing of it, and I'm convinced that Watergate had a very significant impact on that law. You may have heard it referred to as the Advisory Committee Act of '76. Everything that the agency does in devices is subject to review by an external advisory committee. It was just kind of a sign of the times of opening up government and not allowing anything to be done behind closed doors. So I'm convinced that Watergate had a huge impact on the way that legislation was structured.

Dr. Ted Cooper's plan said you've got to rely on experts, because you're never going to have enough people in the agency to handle all these sophisticated devices. But they went a little further than that. Just about every substantive decision by the agency had to have an advisory committee review it.

So we put together the plan. We put together the proposal for a bureau, came and presented it to Mr. Gardner and [Commissioner] Dr. [Max] Schmidt at the time. And they said, "Let's do it." So we set up the Bureau, and I think we started with about fifty people. It was the end of '73 or early '74. By the time the device amendments passed in '76, we probably had about 150 people onboard, and then we grew to a little over 300.

RT: This probably was a relatively rare occurrence in the agency's history where anticipation permitted preparation rather than reacting to a sudden enactment with no funds and no personnel.

RS: Exactly. Even in the Radiation Control for Health and Safety Act, we could see that coming, and there was some technical work that was going on with the Hill on the Radiation Control Act. Once you have consumer products that are really hurting people, like the TVs and the microwave ovens, it was only a question of how fast it was going to happen, but it was going to happen. But in the device area, you're right. We did have the luxury of time, didn't have all the resources that we would have liked to have gotten, but we did have the luxury of time and could set up an organization and get some growth in before we actually had to start enforcing the law. That allowed us also to do a lot of the "classification" work on devices and set up a lot of the committees of outside experts.

RT: John Villforth, sort of the spectacular-type leader that he was, was he a visionary in this regard, or was it the management team seeing the larger thing?

RS: I'm not even sure. Well, first of all, this whole legislative approach, remember, came from Dr. Ted Cooper. It didn't come from within FDA. He came from the Heart, Lung, and Blood Institute. I think there was a general concern at the time that they wanted to regulate devices. They knew they had to regulate devices. The Dalkon Shield was very, very high on people's radar screens. There were hearings before [Senator Edward M.] Kennedy. And it was very clear that there had to be some regulation done on devices. But they also understood that this was a very small entrepreneurial industry, and they didn't want over-regulation. And there is a difference between a tongue depressor and a heart valve, and there had to be some give-and-take between regulation

and practicality. That's what led to the Cooper committee report thing, and that's what led to the device program regulation as all know it today.

Now, having said that, I give Dr. Ted Cooper the credit for the creation of the device program. But I give Dr. John Jennings, Dr. Max Schmidt, and Sherwin Gardner the credit for saying, "We know this is coming. Let's go ahead and get ahead of this curve." And they didn't give it to the rad health program or give it to the drug program and say, "Do this as a collateral duty." They had John Jennings set up this little group that included Dave Link and Larry Pilot and a few others to start working with the Hill on the language to start the device program. That was all being done in '73.

When we set up the Bureau in '74, they had a lot of this pretty well thought out. It was just a question of me helping them put it all on paper and sequencing things in a way that seemed to make sense.

It was interesting, too. When the law was passed in '76, we went down to OMB. We did a lot of work on trying to get resources for it. We went down to OMB and the director of the health programs at OMB at the time was [Victor] Vic Zafra. Vic just grilled us unmercifully, grilled me unmercifully for hours, about his sense that we didn't need the kind of resources we were talking about. Congress had already passed the legislation, and we knew we were going to get something, but we knew we weren't going to get everything we asked for either. Eventually the administration and Congress got together and resourced the new law very well.

But as you probably know, then just a couple of years later, Vic Zafra wound up coming to the Medical Device Bureau from OMB as the Deputy Director to Dave Link. So we knew Victor very well before he even walked in the door. But I think the

visionaries, in terms of the preparation for this work, were clearly Jennings, Schmidt, Sherwin, and Link.

RT: We've jumped from the time you entered to where you're really in key planning and developmental work. So that would suggest that if you went along from your entry at GS-2 through when you mentioned your progression from GS-7 or GS-9, you had through these years been in increasingly responsible roles and you apparently had progressed very well along time-wise in that career track.

RS: Been lucky, right place and the right time. I mean, I really was. I've been very, very fortunate.

RT: If you hadn't had the abilities, of course, you wouldn't have been moving ahead like that.

RS: Well, I appreciate that. But, you know, one of the interesting things is, and I give Chuck Weaver, who I mentioned earlier, he's the one that kind of kicked me out of a nice, comfortable little—you know, I was an assistant to somebody else—and said, "I really think that you can help them set up this new program," for what was the Radiation Control for Health and Safety Act. I give him the credit. I mean, I was a Grade 9 at the time, and he just kind of threw me out there and said, "You can do it, and you ought to do it."

So I didn't know any better, and I just said, "Okay." [Laughs] But I give him a lot of credit. He was not thinking about himself or his own program; he was thinking of the larger organization, and he was thinking of my career development.

As a result, I was able, at a very young age and modest grade, to participate in the development of a legislative program, a brand-new program known as the Radiation Control Act, and we had to do the planning for it. We had to do the hiring for it. We had to do the regulations for it. So, I mean, I really got exposure to it all at a very early age. So when Deputy Commissioner Gardner wanted this done five years later for the medical device program, it was my second time around, even though I was *still relatively young*.

RT: That was a good experience base, I'm sure, that's helped you on through the rest of your career that we're going to touch on now.

RS: Absolutely.

Okay. A couple of things about the device program in its early development. I mentioned to you we grew from like 50 to 150 in the first year and half, as a bureau. We obviously couldn't stay in the Chapman Avenue Building, and the best space available for us was in Silver Spring [Maryland], so all moved there. We had no laboratory capability at all. We were begging and borrowing lab space wherever we could get it.

We even went so far as to contract with an outfit out in Utah, the Utah Biomedical Test Laboratory just outside of Salt Lake City. This was a large animal testing facility that the Heart, Lung, and Blood Institute had set up, and they were starting to back out of their funding of it. So we basically used it as our laboratory. We had some fairly large

contracts out there, and they would do just about anything, any kind of research or testing, for us that we wanted done. They were doing heart implants, artificial heart implants in large animals back then in the mid-seventies. Without them, I'm not sure where we would have been.

Finally, we got ahold of some space in the USDA Building on Independence Avenue. That's where our laboratory was for years and years. Not an ideal setting, but we got a lot done. We had some very creative lab people at the time who got more done with practically nothing.

I think the hardest part about the device program for me was the reality of the device problems at the time. It was hard for me going from the rad health program to the device program, because in the rad health program you had people like K. Z. Morgan from Johns Hopkins [University] who would say, "Unnecessary medical radiation exposure accounts for somewhere between three and 30,000 deaths a year worldwide." Wasn't real specific. You couldn't really point to people dying very clearly. I went to Devices and people were dying. I had a tough time with that. But it was a place where all of us felt like we were all on this major public health mission together. Until that time the agency had been almost powerless without the device amendments to do anything about anything.

Then when we had the hearings before Senator Kennedy on the Dalkon Shield, those were tough. I think the senator wanted—to make sure that the device law eventually got passed, but he also wanted to make some people look bad, and it was a very difficult thing. He wound up having to subpoena Bureau employees to testify before

him, because they didn't want to testify against the agency. They were afraid, and it was hard, very hard.

The other difficulty we faced was that we had cultures from two different parts of the agency. You had the diagnostic products program coming into this new organization that came directly from Drugs, and they thought differently than the new device people. Getting those people together, to work together, to think the same, was almost impossible. It was a real struggle.

RT: Who in the agency would have been trying to effect that better cooperation? Would that be from the commissioner's office?

RS: No, these two were pulled together and made up the Bureau of Medical Devices and Diagnostic Products. So when the Bureau was set up, these two cultures were brought together under one roof and that was under Dave Link. The answer to your question, it was Dave Link.

There were some tough times in Medical Devices. Toxic shock syndrome was a huge problem. Dave Link left. Victor Zafra came in about, I'm not sure when it was, '79-'80, and Dave Link left shortly thereafter in '80 or '81, I think, and that was hard. That was very hard, because Dave had been the real leader of this program from birth to this point. When he walked out, a lot left. Victor was a wonderful man, strong manager, but he wasn't a scientist. He wasn't an engineer. He wasn't a physician. He was an economist and good writer and good manager, but everybody knew it wasn't going to last with him running the device program.

Well, somebody then got a bright idea. You've got to remember the timing of this. This is now in the beginning of the Reagan administration, and the eighties were some pretty dark days for FDA. So it was clear you had this device program that was in need of lots more resources. You had this device program which needed a new bureau director. And then you had this radiological health bureau that most people at that time in the agency felt was probably overstaffed for the kind of workload they had compared to the rest of the agency. And you had a very dynamic leader of that bureau in John Villforth. So the solution was obvious: Let's put them together. And you've got to remember, they had already done that with the Center for Drugs and Biologics. They'd already merged biologics and drugs with some of the same objectives in mind.

So Villforth was put in charge of the new merged organization. John was very familiar with all of his people in the rad health area, so when the two organizations merged, they no longer needed two compliance directors or two executive officers or two anything. And if you were John, who would you pick? John picked his radiological health people to run this merged organization. Well, that's the time Vic left and went back to OMB, and it was about that time that the administration passed or got passed the Tax Equity Reform Act, TEFRA [Tax Equity and Fiscal Responsibility Act]. Vic had gone back to OMB, and he was up to his eyeballs in TEFRA and trying to get the regulations cleared to be published. He asked me to come down. I went down and spent a few months with him at OMB.

Then I came back and Gerry Meyer called again. So Gerry, at this time, called and said—

RT: Okay, I've got to stop here.

[Begin Tape 2, Side A]

RT: All right, Bob. You had mentioned you had spent some time at OMB, and Gerry Meyer then gave you a call.

RS: Yes. By this time, Gerry and I had been working together, because even when I was in the device program or with rad health, we worked together on bringing rad health in, and as an executive officer I was working very closely with Gerry almost on a daily basis for all the administrative things. So he knew that I was looking for other things to do, and he called me just after I got back from OMB and said, "I'd like you to come over and take over the personnel office. I'd like you to come over and be my Director of Human Resources."

So I said, "Well, let's talk about it." And we did. Gerry was a very persuasive kind of person. At that time, Tom McFee was the Assistant Secretary of HHS for personnel, and Tom had kind of an iron-fist control over just about everything that was going on in HHS having to do with personnel. So he always had the right of first refusal for any of the agencies hiring a personnel officer.

So I went down and spent some time with Mr. McFee. After talking for a while, his only question of me was, "Why in the hell would you want that job?" [Laughs]

RT: Would that move be a promotion in your career?

RS: No, I had been a 15 when I took the executive officer job in the Bureau of Medical Devices. That was a 15, and that was in '73. The personnel job was a 15 at that time as well. So I stayed as a 15. It was a lateral transfer.

It was interesting. When I went there, I told Gerry that I was considering leaving government at the time. I had been offered a couple of things outside of government, and I was pretty close to being eligible. Let's see, was I eligible at that time? No, I was getting close to being eligible for a discontinued service retirement. So I said, "I'll take the job under one condition, and that is, instead of making me the personnel officer on paper, make me a manager reporting directly to you that can in that capacity run any of the organizations that reports to you."

My thinking was that if I decided I wanted to retire, they'd be able to abolish that job, but it's kind of hard to abolish the personnel officer job. So that's why I was acting director of the personnel office for a long time. So Gerry convinced me, and Tom said it was okay with him, if I really wanted to do this, to take the job, and I did. I started there in, I think it was in 1984.

Those were very difficult times for FDA. You've got to remember that's, again, the Reagan administration. They set up a series of clearances with OMB on regulations that kind of squashed anything happening that was new or viewed as additional regulatory controls. You saw an awful lot of impediments put in the way of the agency doing its job. It also was not, obviously, a time of growth for the agency. The agency had had a lot of change in the seventies with new programs coming in and additional resources with its bioresearch monitoring program. But, boy, during the eighties, it just

dried up. And it's one of the things I'll talk a little bit about later, because the impact of that decade is still being felt today.

We basically lost a generation of hires, and with those of us who are retiring now, you look to find the people who have those twenty years of experience in the agency, and they're few and far between, because we *did* lose a whole generation.

But in the personnel arena, we got some things done. There was some hard times. We had the one and only A-76 effort that came to fruition in the agency's history. We actually wound up contracting some jobs down at NCTR [National Center for Toxicological Research]. That was hard. It was the first and only time, and it concerns me that we seem to be going in that direction again. But it was very difficult. We actually wound up having to put a lot of people out.

RT: For the researcher or reader of our transcript, you mentioned the A-76. Could you clarify what that is?

RS: The A-76 is an OMB circular, and basically what it says is that there are certain kinds of jobs that are *inherently governmental*. There are other kinds of jobs that probably should be performed by the private sector, and A-76 describes the process by which the government goes through to determine whether or not a particular job should be contracted out. If the government can do the job as cheaply as it can be done by the private sector, it can stay government. If they can't, then it should be given to the private sector.

RT: That's helpful.

RS: Another thing that happened in the eighties, while I was in this personnel job, that I think was huge, was the introduction of the new federal retirement system, the FERS [Federal Employees Retirement] System. It changed a lot, and I'll come back to that later on. But it was a new opportunity for government employees to participate in a 401(k)-type program. But it also meant substantially increasing the portability of government employment, and you could take a lot of things with you now that you couldn't before, and it really made a difference. It made a difference in terms of longevity of government careers and FDA careers. It put us in a position where it was clear we had to be doing some things to make FDA employment more attractive to recruit and retain people. That's why FDA was one of the early organizations to jump on this quality-of-worklife bandwagon. When OPM announced the Flexi-Place program, the work-at-home program, FDA was one of the very first agencies to participate in the pilot program, and I think there are some targets this year for there ought to be 25 percent of the workforce participating or the eligible workforce participating in Flexi-Place. We were well beyond 25 percent when I was personnel officer. So since we felt that we couldn't hire, we were not growing. We were, in fact, losing. When you couple that with the advent of the portability of FERS, we had to do some things to try to make FDA a more attractive workplace, and that's why things like Flexi-Place picked up some steam and were embraced.

We also put together the FDA leadership development program, the FAME [Formula for Achieving Managerial Excellence] program. We felt that if managers were

going to have to work with fewer resources to get the job done, we ought to put more time and energy into developing some of their managerial skills, and that's when we started the FAME program, which is still running today.

We also had the generic-drug scandal. It was probably one of the bleaker times in the agency's history. Of course, in the personnel office we were smack dab in the middle of it, because all of the actions against the individual employees had to be taken. As horrible as the things were that were done, it's still tough when they're going to jail or when they're being fired. It's not a fun situation to live through, and it was not a fun situation for the leadership to live through. I think Jim Benson did a superb job in keeping the agency together during that time, and it was a tough time. It was a very difficult time, because that's basically all we worked on for a long, long time.

But we also had some positive things that we were able to get done, again because we were so focused on trying to make the FDA a more attractive employer. We were able to get on the new pay system, the Senior Biomedical Research Service. When that first was proposed, it was strictly an NIH program. We found out about it, and we were able to make some inroads and get some people's attention. It was strictly going to be few research programs, and we got them to include in the legislation that it could be for review work as well as research work, and it's been pretty successful. For a couple of years it was basically the only game in town for getting some higher-level pay. It also basically freed up a lot of SES [Senior Executive Service] positions. By putting people into SBRS, that freed up SES positions for jobs that had not previously been allowed to be filled in SES.

We also got Title 38 authority. This was an authority that the Veterans Administration had to pay their practicing physicians in the VA hospitals. We worked very hard and finally got agreement from VA and DOD [Department of Defense] and OPM to make that available to FDA M.D.'s, and it has changed the statistics of the turnover of physicians. All in all we got a lot of things done, but it was a difficult decade, the eighties and the early nineties.

RT: These initiatives that you've just been addressing, were those helpful in recruiting physicians from private practice to research in the agency or research review?

RS: Review, in particular, yes. Yes, they really were. It used to be you could get physicians up to the Grade 14 or 15, and then pay them a physician comparability allowance, which altogether was a reasonably good sum. But Title 38 opened up new doors. Now, what the agency decided to do was to keep Title 38 for its managerial positions. They were a little concerned. You've got to remember, this was in the early nineties. They were a little concerned about budget-busting decisions. So we got that authority in the early nineties. Then they only gave it to the team leaders and supervisory physicians.

I personally think that that decision had as much to do with any that the agency ever made in terms of leading to NTU [National Treasury Employees Union, NTEU] being successful in organizing the agency. The physicians who were not team leaders or supervisors were some of the most aggressive groups favoring unionizing the agency. I think because of the way organizing a union works, it's not what percentage of the

workforce votes for a union, it's what percentage of the people that vote, vote for a union. My understanding is that there was a large block of physicians that voted for the union, and there were less than a thousand people that voted in total.

Most of this time when I was personnel officer, Dr. Frank [E.] Young was the Commissioner and John Norris was the Deputy. We did a lot of work with Dr. Young's Action Plan, and a lot of new personnel initiatives that came out of the Action Plan, some successful, some not so successful. But Dr. Young just wanted to see us try. But some of these pay initiatives were the direct result of that kind of thinking, that kind of pushing to do more for our workforce.

Then, of course, we had generics, and we had Jim Benson as Acting Commissioner, and then Dr. [David A.] Kessler came in. Well, I don't have to repeat history. Kessler's solution was bring a whole new superstructure for the agency, and he did. It was relatively quick and it was relatively painless. Nobody else lost their job or anything else. Talk about taking control quickly, it was done.

RT: Were you in a place where—I'm speaking historically—where CEHPS, Consumer Environmental Health Protection Services, was interposed between the agency and the department? Were you involved in any problems emanating from that particular initiative?

RS: Charles C. Johnson was the Director of CEHPS. When was this? '68?

RT: Yes. Late sixties, I think.

RS: Yes. The Bureau of Radiological Health was part of CEHPS when it split, and then half of us were hanging—not part of CEHPS, but reporting directly to the Department—and the other half went to EPA. We were involved in CEHPS in that they took some of the resources from the organizations that were put into CEHPS to provide central services in the personnel and facilities, etc.

RT: This is certainly a digression from where you were. It just occurred to me that that was another time in the agency's history where structurally there was some added steps in the administrative process.

RS: Absolutely, and it's one of the points I was going to make later about the pendulum on centralization and decentralization. It's never still. It's always going, and everybody always feels that wherever they are, it's better in the other direction. [Laughs]

RT: Well, if you wait long enough, it will change.

RS: Exactly. That's exactly right. So just wait until it comes by again.

RT: The real irony of it is, I suppose, in a circular process we kind of come back at times to almost where we were before. I don't know whether that really happens. I guess it doesn't happen literally. But the government is always dynamic and changing.

RS: Absolutely.

RT: I'm sorry for the interruption. You were speaking about Dr. Kessler, and that's more current.

RS: I was in the personnel job until '95, so I had quite a bit of time under Dr. Kessler.

RT: About how many years?

RS: I was in personnel for eleven years, from '84 to '95.

RT: That was a period that you saw obviously a lot of changes.

RS: Yes, it was Dr. Frank Young, Jim Benson acting, and then Dr. Kessler came.

Our situation in personnel and all of the people that worked in the administrative area had been significantly changed when Gerry Meyer went to CDER [Center for Drug Evaluation and Research]. We had all reported to Gerry, and Gerry was a strength. He had a lot of years in that job. He knew how to deal with commissioners. He knew how to help commissioners, and he wasn't afraid to sacrifice his own skin a little bit to make sure they understood when they were thinking about doing something that might get them in trouble. I have enormous respect for Gerry because of that, and because he and I have been friends for a long time.

Gerry went to CDER, and Sharon Holston took Gerry's job and became my boss. Sharon and I were very good friends, and we are friends today. She's the best person I think I've ever met in my life. She's just extremely good in handling of people, and she was good for that job. She was a good interface with Kessler for the administrative activities.

But the minute Mary Jo Veverka came in, that changed. Good, bad, or indifferent, I think Mary Jo brought a very different set of knowledges and skills to the agency. I don't think FDA would have been able to implement the User Fee Program, PDUFA [Prescription Drug User Fee Act] as well as it did without Mary Jo. But she left a lot of litter, too. That's just a fact. [Laughter]

Sharon suffered as a result, and Sharon eventually took the job in constituent relations work, and Mary Jo recruited for and replaced Sharon with Bob Byrd. So in a relatively short period of time, I went from working for Gerry Meyer to Sharon Holston, to Mary Jo Veverka, to Bob Byrd. Talk about four very, very different kinds of people. [Laughter]

RT: It took a little acclimation, I'm sure.

RS: Well, and you didn't have much time to acclimate, because they all had various needs, and as the personnel officer, they needed a lot from me quick. By the time Byrd came in, I had been in the personnel job for eleven years. I have enormous respect for personnel officers. Anybody that can do those jobs for careers, I just take my hat off to them. But by '95 I was tired of it, and I just really wanted to do something else.

We had just spent an incredible amount of personal time and energy on PDUFA. I was running two different parts of the PDUFA development program at the time. I was obviously responsible for the hiring of the 700 people, but I also was given responsibility to make sure we had facilities for the 700 people. So I had the space as well as the HR [human resources] work. It was a real strain, but I also think we were very successful.

Part of the problem that people don't [I don't think] realize is that when PDUFA happened, both biologics and drugs were totally out of hiring practice. They had gone for a long, long time without any growth. And to all of a sudden to say, "Go out and hire as many as you want," they weren't ready. They just weren't ready at all.

During this time we were working very closely with the pharmaceutical industry on PDUFA I. Len Silverman was the human resource director for Hoffman-LaRoche at the time. He and I talked about them helping us out. I was trying to get some impetus for jump-starting this recruiting effort. So they agreed to do some survey work for us and come in and talk to physicians about what was good or bad. They gave us some reports about what might improve recruitment. They went back and talked to some people that we had talked to about jobs and they decided to turn us down. We were very short-handed, so I was looking for people that could help, and Len agreed to put some troops together to do a lot of the staff work for us and find out what we could do to make life easier and better.

As a result of that, we made some pretty dramatic changes. We shifted some resources out of the central personnel office to the two centers, so that there could be quicker turnaround time from the time a candidate came in till the time they made a job offer, that they would be dedicated resources within the center. And the center, in fact,

added resources to those resources. We moved our people geographically so that they were part of the center's physical space, all designed to try to improve the recruitment process. But we also found some interesting things about how the reviewers looked at their jobs in drugs and biologics, what they spent their time on. Amazing how little time they spent on review work.

RT: Is that right?

RS: Yes. They were responding to congressional inquiries. They were responding to FOIs [Freedom of Information Act]. They were doing all kinds of other things. So it was little bit of effort to kind of re-engineer jobs and take some of that work away from them to allow them more time to do what they really wanted to do and what the agency really needed them to do.

RT: Those distractions then probably were a serious contributing factor to, if you will, approval lag or whatever.

RS: Well, I don't want to put it that directly, because the problem was, they simply didn't have enough resources. We had to get more resources in to get the job done. When you think about it, when you say they were responding to congressionals; well, when somebody writes in about the decision you made on this particular drug and why did you make it or why didn't you approve it, you've got to get the people who are most knowledgeable, preparing the responses. So the physicians had to do that. It wasn't a

question that they didn't have to do this. If they were working on the reviews, they had to respond to the congressionals.

RT: Yes, congressionals are certainly a priority always.

RS: So it was just another, I think, demonstration of the fact that what they really needed was just more of everything. They needed more physicians so some of those physicians could do some of the congressionals, but the aggregate of having several people meant they'd also increase their review time or the amount of time spent on reviews.

[Begin Tape 2, Side B]

RT: Do you want to pick it up where you were?

RS: I think I was just saying that using Hoffman-LaRoche and the folks at PHARMA to help us in this way was just another example of how far we were trying to go with very constrained resources and trying to figure out how to make FDA a more attractive employer. We were trying to figure that out, and we knew with the PDUFA program and trying to fill so many jobs so quickly, we had to figure out a way not only to make it an attractive place to work, but also once we got people who were interested, finding a way to get them in and up and running as fast as we possibly could.

Because I was involved in both facilities and the HR side, I served on the PDUFA steering committee, and I was also trying to run a personnel office with a fairly substantial workload there for other non-PDUFA related things. It was fun, but eleven years was about all the fun I could take. [Laughs]

RT: In the personnel office function, which you spent that period of time, did that entity as well increase in personnel and capability to deal with these burgeoning problems, or did you have to work with the same level of staffing?

RS: During the Dr. Frank Young time, which was the first quite a few years of my time in there, the agency was in a downsizing mode. It was very clear. And that wasn't Dr. Frank Young; thinking that was the sign of the times. The eighties were just tough in terms of growth in the agency. The generics problem started changing the thinking a little bit. As bad as some of the things were, it also indicated there was some need for additional resources. So that started turning the corner a little bit, but no growth in the human resource arena.

When Dr. Kessler came in, we didn't get any increases, but what happened was, when PDUFA was being planned out, it was very clear that the human resources and all of the administrative areas throughout the agency were going to have to take some part of the PDUFA increases in order to be able to support the expansion of the program. And we did. So there was some growth as a result of PDUFA and other increases as they came to the agency later on.

RT: Very good.

RS: So now we're kind of up to '95, and I'm feeling like it's time to try something else. I had spent most of my career in centers, first the Bureau of Radiological Health and then Bureau of Medical Devices, and I really was interested in getting back to a center. The toughest part of going back to the center, though, to be honest, was Dr. Jane [E.] Henney had come in as the Deputy Commissioner. She was the best combination scientist-manager that I've ever seen, and at least in this agency I've seen a lot. She was far ahead of everybody else, and I think just the two short spans of time that she was here, I think she had more lasting impact on this agency than anybody else I can think of. But, anyhow, her being there made it tougher for me to think about leaving, but she wound up leaving anyhow, so I started looking for a job.

At that point I was aware that Billy Don Weaver, Executive Officer of the Center for Veterinary Medicine, was going to be retiring, and a new center director had come in over there, Dr. Steve Sundlof. Dr. Sundlof was fresh out of the academic world and needed some help in figuring out his way around the administrative management world in FDA. So Steve and I got together and we talked and hit it off and decided that would be a good fit for me. So I went to work with Steve in March of '95.

Working in a center again was a blast. It was a lot of fun. Steve was a change agent. He was a change agent in a lot of different ways in that organization. He was changing the paradigm about how they thought about their jobs programmatically, particularly the review function. He got them thinking that they ought to look at themselves as the people responsible for getting new technology to the market, as

opposed to the people responsible for preventing bad technology from getting to the market.

You know, it's interesting, when I think about that, it really is a traditional problem that I think the agency suffers from. If you stop and think about it, we've had only one FDA employee ever get the Congressional Medal of Honor. That was Dr. Frances Kelsey. And she got it for not approving a drug. [Laughter]

RT: That's right.

RS: So maybe the most revered action that this agency has ever taken, you know, was not approving a drug. I don't mean that as any discredit to Dr. Frances Kelsey, but it's true that people getting recognized and rewarded don't usually get it for getting drugs approved.

RT: They certainly get criticized and admonished by Congress and the press.

RS: The easiest thing to do is not approve. It's what all of our natural instincts probably drive us towards.

But, anyhow, it's just been a wonderful ride with CVM and Dr. Sundlof. He's probably the best read, management-wise, person that I've ever worked with. He knows an awful lot about management theory, and I try to help him turn it into practice.

The other thing about CVM is it's astounding that such a small center has such huge public policy and public health issues to deal with. I think antibiotic resistance is

just a good example of how complex the agency's responsibilities have become over time. Antibiotic resistance is obviously affected by the human drug use of antibiotics and the animal drug use of antibiotics, the less than prudent use of antibiotics on both sides. And yet measuring the antibiotic resistance is one of the more complicated things that we try to do. How do you force people to demonstrate to us before they market an animal drug whether or not it's going to contribute to antibiotic resistance in humans? The complexity of the situation is incredible.

BSE [Bovine Spongiform Encephalopathy], another case. Most of the BSE is an animal-feed issue, but you find the potential for it in so many kinds of products. It's everywhere, and the challenges facing the agency from an import standpoint, as well as the domestic control, are staggering, and all of this falls to the Center for Veterinary Medicine.

It's been a wonderful time. We've gotten a lot of support in the center over the last few years, and the center is not so little anymore. It's growing, and growing, I think, efficiently. I think this center is just in a whole lot better shape now than it was six years ago.

RT: With the term of Dr. Lester Crawford as Deputy, at least for now, I suspect the center will be recognized. He had top management responsibility over there earlier.

RS: Sure did. And that can work in a couple of different directions. We could get a lot more second-guessing on the fourteenth floor or a lot more support on the fourteenth floor.

RT: Well, hopefully the latter.

RS: Yes, we're optimistic as well.

So I was with Steve for the first five years, from '95 to 2000, and then Dr. Henney came back to the agency as Commissioner. After she came back, Paul Coppinger, who was the Associate Commissioner for Planning, decided to retire. Dr. Henney called me and asked me if I would come over and do that job. I told you my enormous respect for Dr. Henney.

RT: Yes, I was going to ask you if you could elaborate a little bit. You indicated, I believe, you felt that she may have had a more lasting contribution than some other top managers of the agency. How would you quantify or define that?

RS: For example, when she was the Deputy for David, I believe the record will bear this out, she's the one that put just about every one of the center directors in their jobs. I know she put [Bruce] Burlington in. I know she put Sundlof in. I know she put [Janet] Woodcock. I know she put [Cathy] Zoon in. I think [Joe] Levitt probably was not her appointment. And when you think about the collective impact that group of center directors had on this agency, it's enormous. That's what I mean by the long-term impact of what she did.

I think when she left, she left the absolute strongest Policy Board, if that's what you want to call it. When she left, I think she left the strongest Leadership Council in

place this agency has ever seen, and that was Dr. Henney's doing. She's the one who ran all the centers at the time, and she's the one who put those people in place. That's one indication.

I think when she came back, I wish she had been here longer, because she's the one who really put the wheels in motion for some of the major changes in the food programs for this agency. What you're seeing now is support, a lot of support, for major increases in the food program. The food safety initiative has made CFSAN [Center for Food Safety and Applied Nutrition] a much more viable public health program than it has been for two decades, and all of that comes back to Dr. Henney.

RT: I see. Well, that's wonderful, as you say.

RS: That's just two examples.

So she asked me if I would come over and help. I was already eligible to retire, and I think I had added value to CVM and Dr. Sundlof, but I agreed to go. I told her I'd spend six or seven months there, and I wound up spending almost a year there.

RT: You went over in what capacity?

RS: I went over as Associate Commissioner for Planning, working for Bill Hubbard and the Commissioner. Like I said, I was planning on staying there just a few months while they recruited and filled the job, but then I wound up staying almost a year. Part of the reason that I decided to go back to CVM was that I really did want to retire, but I

didn't want to kid them into thinking that I was going to stay much longer. And, secondly, Dr. Henney left. The lack of courtesy and the way those things get handled is tough under any normal circumstances, but with her it was even tougher.

The election came, and it was pretty clear something was going to happen, but nobody could find out. She left January 20, and then I went back to CVM in March of last year. I announced shortly thereafter that I was going to retire at the end of last year, December, and then Dr. Sundlof asked me if I would just stay on to kind of help fill my own job and leave the center in good shape. So I agreed to stay on until the end of March, and that's where we are.

RT: Is it clear yet who may succeed you?

RS: Don Peterson. Don was the Director of the Office of Financial Management. Then he was the Exec Office for CBER [Center for Biologics Evaluation and Research], and then he was the Deputy to Jeff Weber for about eight months. He started with me in January. So he's worked with me for the last two and a half months, and he will.

RT: Well, it certainly is helpful, I'm sure, to both your center director and to your successor to have this—

RS: Transition period.

RT: Transition period. Yes, that's good.

RS: I'm at the point here in my notes, Bob, and I don't know what you want to do.

RT: My time is available as long as we wish to continue.

RS: All right. Let me just run through some of these things. What I did was to stop and ask myself, what is it about what has happened in the last forty years that were major impact items? And just to make sure I had captured everything, whether I was personally involved or not.

RT: Well, that's good. I think that would be a good dimension to this interview.

RS: In the sixties, now you've got to understand most of my sixties were not in FDA. They were part of the radiological health program. And I think I've covered just about all of these. But clearly the color television radiation problem, which led to the 90-602, that was huge. The creation of EPA and the split, that was huge. The integration into FDA, that was huge. All that occurred in the sixties to the rad health program. FDA, I believe it was in the late sixties that they had the major reorganization in FDA, the Malek Report.

RT: I think that's right.

RS: FDA was just kind of reeling from that, you know, a shift from the Bureau of Science into the functional bureaus, to the product-oriented bureaus. So they were still trying to feel their way into their new organization when all of a sudden they started getting these appendages thrown at them from the rest of the Public Health Service.

That gets me into the seventies. When I think back about what happened to the agency in the early seventies, they had rad health come in. They had biologics come in. They had NCTR come in. They had the bioresearch monitoring program expansion. They had the medical device legislation that passed. They had the swine flu vaccine problem, where they had all kinds of concerns raised about vaccinations. All of that occurred in about a five-year period. It's kind of staggering that the agency even survived that. You know, from like '71 to '76, all of those things happened.

I also think that was a time when we saw a major change in leadership, and I think it has had a significant effect on the agency. I was looking at this the other night to prepare for this, and there's probably stuff you already know, but the first seven commissioners served a total of fifty-eight years. So they averaged eight and a half years. The next seven averaged two years. Think about that. Think about what that does to the continuity of the organization. When you superimpose this over what I just described happened in the early seventies, because we were in the process of these turnovers of commissioners in the seventies that lasted from the middle sixties to the early eighties. It's also interesting, this is when we first started having acting commissioners. We never had acting commissioners before. So you had not just seven people averaging two years, but you also had these career people who were acting as commissioner for a fairly extensive period of time in between.

RT: Several of those.

RS: Yes. Mr. Sherwin Gardner, Dr. Mark Novitch on several occasions. So getting any kind of continuity into the running of this agency was difficult. I give people like Mr. Gardner and Dr. Mark Novitch incredible credit for keeping it together, and that's who did it. I mean, it was the Sam Fines and the Paul Hiles and the Mark Novitches and the Sherwin Gardners, the career leadership at the top of this agency, the Gerry Meyers. They were the ones that kept this agency together.

RT: Well, they were the ones that certainly had institutional memory to hopefully counsel the new leadership. And, of course, as you are suggesting where you have a constant turnover, the person who implements certain policies or certain directions isn't going to be around long enough to really be answerable to them. They will be gone.

RS: Absolutely.

RT: That is a contrast to earlier days in the history of the agency where the agency administrators were career people and they had to live through their decisions longer.

RS: I didn't look at this, but it would be interesting to look at the times that people came in and the time of year that they came in and left, to just match that with the budget cycle. I mean, if you were here two years, it's conceivable you only went through one

budget cycle with testifying before the Hill. So I just think the fact that we survived as well as we did during the fifteen-year period is just an enormous credit to those career folks who held the agency together.

RT: It's very remarkable.

RS: Yes, it really is. This gets us up into the eighties. There was an event that happened in the eighties that I played some role in, which I think had a pretty dramatic effect on the agency, too. I refer to the elimination of the drug certification program in the early eighties. It was like 120, 130 people. The agency was going to run a RIF, because they lost the support for the program, and the program was being abolished. These were tough times, because we already knew resources were going to be tough for the agency.

A group of us got together and talked through the RIF and all the ripple effect of the RIF, which would be catastrophic. The estimates were that for every person being RIF'ed, it would impact six other people. So you're talking about 700 people being affected by the RIF. Might not be out on the street, but they would be moved into different jobs.

So a group of us got together and said, "That's one possibility. The other possibility is we all get together and see if we can work out placements for these people into very scarce vacancies that we had throughout the agency." We convinced ourselves that was the right thing to do. It was right for the employees. It was right for the agency,

because of the impact of the disruption of that ripple effect on 700 people. So we put together a group and we wound up placing all the people and avoided a RIF.

I think something happened with that, that was a really good thing for the agency. I think it created a kind of a mind-set about how we want to treat our employees and to what extent we will go to, to make sure we protect our employees which I think has lasted to this day. I think this agency goes to extremes to protect its employee and that is a good thing.

RT: Sort of an *esprit de corps* of the agency, which I think through all of its history has been pretty strong.

RS: Yes, it has.

RT: Back in the earlier times when there weren't so many personnel, there was a lot of pride. Everybody literally was very proud of the agency and proud of what it stood for and did, and that is great and it's continued through all of the manipulations of policy and resources that have happened.

RS: Yes, I agree. But I think there was something about that RIF-avoidance work that went on then that had a very long-lasting, positive impact on the agency. I think it's paid dividends in many, many ways.

The eighties, I've mentioned some of these already. It was the decade of downsizing, and it was hard. There were always talks about and threats of 20 percent

reductions, planning for RIFs. It was a constant cloud hanging over our heads, particularly in the personnel office. Not only would we be affected by the RIF, but we would also have to administer the RIF.

The FERS system, I think, has changed the whole fabric of government, but it's really had an impact on FDA. People don't come to work for one employer anymore and make a career out of it.

RT: That's true. I guess that's even more true over in Japan where that used to be the norm. It has changed even there.

RS: PDUFA was monumental. It came in the early nineties, but a lot of work, preparation for it, came in the late eighties. The eighties saw the tremendous erosion of the foods program. The foods program in FDA eroded significantly through the eighties and nineties.

[Begin Tape 3, Side A]

RT: Bob, you were mentioning the relative smaller size of the food regulatory scheme.

RS: I think from the mid-seventies to the early nineties the food program just was decimated, and I'm not even sure it was as conscious a decision as much as whenever something came up that had to be done, particularly in the field, where all the food resources were, it was easy to just say, "Well, let's divert a small amount from our largest

program to do this new thing." Well, you do a hundred of those things, and you're diverting major resources, and I think that's what happened. I don't think anyone consciously said, "Let's significantly reduce the food program." But when we actually started looking at it in the mid-nineties and saw what had happened over time, it was staggering how much of the program had eroded.

That's where, I think, the efforts over the past several years that Dr. Henney started and Joe Levitt and Jeff Weber and Dr. Bernard Schwetz have carried, you're starting to see some revitalization of the food program. It's not just CFSAN; it is also in the field, which is where the greatest need is.

RT: In view of the recent concerns about security and so on, I'm sure there's going to be a further impetus to strengthen resources probably for our whole agency, but certainly in foods.

RS: Also in the eighties were the mergers. It was the decade of mergers, the merger of the device and rad health program, as well as the merger of the drugs and biologics program. Eventually the drug and biologics programs were pulled back apart again, but not the rad health and devices; they stayed together. The plan at the time was, "Let's move some of those rad health resources to the device program," and that is exactly what has happened over time. Now it's hard to find anybody in the radiological health program. As I said earlier, with September 11th, people are wondering how did we let that happen. Fact of the matter is, this was the plan.

Also, in the eighties, generics was awful. I think also, if you check the record, you'd probably see that the eighties saw an increase in the number of political appointees in the agency. I don't mean to say anything bad about the people themselves, but that made things different, when you started getting more and more political appointees into the agency. I don't mean the commissioner. I'm just talking about throughout different levels of the agency. That was hard, and I think the agency was not a better place for it, at least for a while.

The nineties were interesting, too. Dr. Kessler made things interesting, obviously. But we had some really devastating things happen budget-wise to this agency in the nineties. OMB stopped giving us pay raise money. Every year we had to absorb it. The overall impact of that on the entire agency can't be overstated. People think, "Gee, this year we got it and we're on our way to recovery." You never recover what you lost, and those are lost dollars and people.

The PDUFA trigger was also devastating to the agency. The impact of the PDUFA trigger on the rest of FDA, PDUFA was substantial. Then finally, I think it was Dr. Janet Woodcock herself who said, "This is ridiculous. We ought to absorb the impact of the triggers, in the drugs program and in the biologics program." And they did, which had major negative impacts on the non-PDUFA aspects of the CDER and CBER programs.

FDAMA [FDA Modernization Act]. FDAMA was tough. A lot of lines were drawn in the sand. It's had its impact on a lot of this agency. We are doing things differently as a result of FDAMA. And with PDUFA II being tied in with FDAMA, we

probably didn't get all of what we probably should have gotten in PDUFA II, because it was tied to FDAMA or vice versa, FDAMA was tied to PDUFA II.

Tobacco. I give Dr. Kessler enormous credit for trying, but we have paid a pretty heavy price for it for many, many years. I think the whole shift of the commissioner going through Senate confirmation changes the political landscape of this job substantially. I think we're seeing that now. We have a divided house between the administration and the Senate.

RT: You just can't please both sides of the spectrum on the administration and the political.

RS: That's right. The litmus tests are going to be so severe that they're going to have a tough time finding anybody that's going to have all the right answers for the question, because nobody agrees on what the right answer is.

The mammography program. I think in the mammography program people talk about the PDUFA as being the big change resource-wise. I think mammography is an interesting program, because it's basically a state-run program. I mean, we're just kind of feeding the states money. That's something that we probably ought to be watching with the Republican administration. Interest in those kinds of programs where funds we passed through to the states just might be a little more supported, and I think our experience with the mammography program tells us it can work.

Dr. Henney, I've already mentioned. I give her enormous amount of credit, for many things. I mentioned that she appointed most of the center directors, and that I

thought that was the strongest groups of center directors I can ever remember. That group was interesting. This was in '98. I think both Drs. Henney and Kessler had left. David had left and Mike Friedman was the Acting Commissioner. Center directors had come together and said, "We think the agency is not approaching this budgeting the right way. They're low-balling everything. They always go in with a minimum request." They wanted a more aggressive approach to the budget request process.

So they got several of us together and they went to Dr. [Michael] Friedman and they said, "We, the centers, would like to put together something for you for this budget cycle." They asked me to head up this little group. We did a GAP analysis for the agency. Basically at the time the agency was pretty close to a billion-dollar agency. Our analysis indicated that in order to do the job the way everybody felt it should be done, and in many cases the way the law required, we would have to be a two-and-a-half-billion-dollar agency instead of a billion-dollar agency. Whether the funds came from user fees or whether they came from appropriated funds didn't matter.

Well, that occurred just at the time FDAMA was happening, and the agency was able to use the report to Congress on FDAMA, which was the first year that FDAMA had been implemented, to get on the record that the agency needed to be at least twice the size it was. From that day forward, the agency's request every year has not been two, three, ten, fifteen million dollars, but in the hundreds of millions of dollars. Some people think we've gone too far and we're asking for five and six and seven hundred million dollars each year, but we're being successful at it, too. We're getting larger and larger increases and that helps.

Resurgence of the food program in this early decade is incredibly important. We've got a long way to go to rebuild it to where it ought to be, but it is interesting. We got [HHS Secretary Tommy] Thompson agreeing and using a quote that FDA has 80 percent of the responsibility for food and 20 percent of the resources, and USDA has 20 percent of the responsibility and 80 percent of the resources.

RT: Well, let's hope his voice is heard in the higher circles.

RS: Well, it is, and that's evident in the budget. The counterterrorism budget is turning out to be the food-safety budget, and that's where all the resources are going to rebuild the food program, to protect the food supply.

Let's see, what else do I want to tell you? Major changes over the last forty years, the scope of the responsibilities the agency had. It's really funny. When you think back to '69 or '68, what FDA had responsibility for was foods and drugs, and now look at the agency.

I think the whole social atmosphere in the agency is different. We were talking about this before. People are interested in working at home. People are working flexible work schedules. People are interested in moving from place to place, industry to government, government to industry, at much greater rates than ever before. That's partly because of things like the FERS system. But it's just, I think, a general societal trend.

RT: Yes, possibly. Back in the thirties, some of the old stalwarts, as they later became in the agency, got their government jobs during the depression years. There was a totally different commitment about a job then than now, because if you had one you were very fortunate. Others equally or better qualified might not have one at all. So that is, I think, part of the dimension of the situation as well. Let's hope we don't go back to the economy of the thirties.

RS: Yes. FERS we've already mentioned. I think that's had a very dramatic effect on government employment and government careers. I think the change in the Senate confirmation of commissioner has had a major impact on this agency, and will continue to have. I think September 11th had a major impact on this agency and will for the foreseeable future, just like the rest of the country. And the lost generation of the eighties, I will continue to say, may be one of the most important factors that's affecting this agency today. We did lose a generation.

A couple of things. I'll do this quickly. I mentioned the centralization, decentralization. The pendulum just keeps moving, sometimes faster than others. We have just gone through in the last five years a tremendous decentralization program within the agency within the Department, and now here it comes back again. It's a little faster in turning around this time than normal. Like I said, the grass is always greener.

Just an observation. I have observed that a couple of centers seem to be proving grounds, fertile grounds for agency leadership positions. I think about CDRH [Center for Devices and Radiological Health], for example, and they produced Jim Benson; Linda Suydam; myself; my brother, Don Sauer; Bob Elder, who was Associate Commissioner

for Science for a while; Joe Levitt; Liz Jacobson; all of whom served in many other FDA positions. I think of biologics, that I believe produced Janet Woodcock, David Feigal, and Bruce Burlington came from biologics. I often wonder if that's coincidence or not. It's kind of interesting. I mean, stop and think. Jobs at that level are either filled from outside or they're filled from within the pipeline. Why is it that so many people from biologics and people from CDRH have made it there? I don't know. Might be interesting to study sometime.

The shift in the term expectancy for the commissioner. I hope that's behind us now. I mentioned the first seven and the second seven. Then came Dr. Young, and he was here for a substantial period of time, as was Dr. Kessler. Unfortunately, Dr. Henney was not. I hope that's not the beginning of a different trend, back to the short-term commissioners, because I think that really hurts.

Another anecdote, I mean, it's factual, but just to get it on the record. I did a study. I guess this was in the early eighties. We were constantly haggling about resources and who had how much money and everybody was poor-mouthing. So I did a study that basically looked at the spendable money, spendable dollars, for each of the centers at the time. The results were very interesting, and intuitively, I guess, if we had thought about it, we probably would have guessed this. What the study showed was that the organizations that grew up outside of FDA and came into the agency were resourced much better than the organizations that grew up in the agency. The rad health program, the biologics program, and the even NCTR all came in with a lot better dollars per FTE to support their mission, than those who had grown up inside the agency. The drug program, the food program, and the vet medicine program were the ones that were in the

worst shape, and that's where most of the field resources were, and the field was in bad shape.

RT: That's an interesting finding, which without the study probably would never have been noticed.

RS: What happened as a result of that? We looked at this as an agency, and the study was presented to the Leadership Council. Basically what they did was to decide that over time they would try to make some corrections. We saw some small adjustments in each year being made. When asking for *increases*, the FDA would be asking it for those programs that were under-resourced.

But I don't know exactly how that happened. I don't know whether it was a reflection of the Agriculture Committee in the Congress versus the Health and Human Services Committee. That's where the different decisions were made. I don't know whether that was a HHS decision on how much money they were going to request for FDA even though it's not even part of *their appropriation*, or whether it's an OMB decision, because there are two different branches in OMB that were dealing with the budgets. Regardless of the reason, the outcome was as I have said.

RT: The findings that you went over before *mentioning Dr. Kessler*, to what *commissioner* or what report or finding would have been time-wise?

RS: This would have been probably '81. So '80 or '81, but I don't think it was [Jere E.] Goyan.

RT: Would it have been Dr. Charles Edwards?

RS: Oh, no, no. This was much after Dr. Edwards left the FDA. The following are my wrap-up comments. Dr. Henney was the best combination scientist-manager and leader that I have ever seen in this agency. She had it all. She was a visionary. She was intelligent, articulate, and dealt with people very, very well. She was very clear in her direction and she held people accountable for getting things done. Her sensitivity to the political horizon was also superb. She just had it all. A lot of people have had some of those attributes, but I have never worked with or been associated with anybody else who had them all.

RT: You, of course, have been in a position where you could really see that. Do you feel that the larger community of agency managers and administrators perceived that in Dr. Henney?

RS: I do. Yes, I really do. I don't know of anyone who would dispute the fact that she was the best. Some people would go back to Charlie Edwards, for example, and say that he was in that mold, too. I didn't have much time in FDA before Edwards went to the ASH [Assistant Secretary for Health] position, I guess it was. So he may have been,

but since I'd really been in the agency and participated at various levels of the agency, I've never seen anybody as effective as Dr. Henney.

RT: That's interesting.

RS: It's interesting because I have had the privilege of working with some really, really super people. Most of them were really superb leaders. People like Jim Terrill, John Villforth, Bob Elder, Gerry Meyer, Sherwin Gardner, Sharon Holston, Sundlof, and Bern Schwetz. What Bern has done for the last year, what he lived through personally and yet kept this agency together and kept pushing back when in the best interest of the agency. The integrity that he has shown, that's just inspiring. So I've had great opportunities to work with a lot of really superb people in this agency, and I'm just very thankful that I was able to do it.

RT: You certainly have had a breadth of experience from really a very basic start.

RS: Clacking the erasers together, you know, to get the chalk off the erasers.

[Laughter]

RT: You've made a remarkable career, and we especially appreciate—

RS: We didn't mention the grades. I was a 15 for a long time, and then I mentioned to you some things had happened. Dr. Mike Freedman is the one that actually put me into

SES in '97, and then Dr. Henney, after I had done my stint in the planning job, Jane nominated me for the Presidential Meritorious Rank Award, and I received that this year.

RT: Wonderful. Congratulations.

RS: Thank you.

RT: It was well deserved.

RS: Well, I don't know about that. But, again, right place at the right time.

RT: You would not have received it had it not been well merited. And it all started out just doing the work.

RS: I like to believe that's true.

RT: I really appreciate very much your very thorough coverage of your career track and experiences. This has added some dimensions to our oral history that we haven't had before, and it's most appreciated that you've shared it with us.

RS: Good.

RT: Thank you.

RS: My pleasure, Bob.

[End of interview]