

History

of the

U. S. Food and Drug Administration

Interviewee: Ronald G. Chesemore

Interviewer: Ronald T. Ottens
and
Robert A. Tucker

Date: July 7, 1999

Place: Darnestown, 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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Date: July 7, 1999

Place: Darnestown, MD

Interviewee(s): Ronald G. Chesemore

Address:

Last FDA Position: Associate Commissioner for Regulatory Affairs

FDA Service Dates: January 1979 - January 1999

Interviewer(s): Ronald T. Ottens & Robert A. Tucker

Number of Tapes: 3

Length: 158 minutes

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DEED OF GIFT

Agreement Pertaining to the Oral History Interview of

Ronald G. Chesemore

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RO: This is another in FDA's oral history recordings. Today we are interviewing Ronald G. Chesemore, retired Associate Commissioner for Regulatory Affairs, in his home in [REDACTED] The date is July 7, 1999. Also present is Robert A. Tucker and Ronald Ottes. The transcript of this interview, together with the tapes, will be placed in the Library of Medicine and become a part of FDA's Oral History Program.

Ron, to begin with, would you give a brief biographical sketch of where you were born, raised, educated, and what brought you to FDA.

RC: Sure. Well, I was born in 1943 in Paris, Tennessee. It's a small town of about 10,000 people in western Tennessee right on the Kentucky line. Educated locally there, and then went to college at Memphis State University, where I got both a bachelor's and a master's degree in biology. It was while I was in my master's program that FDA was recruiting on campus, and a fellow by the name of Don Voight--remember him?--recruited me, interested me in the Food and Drug Administration.

At that particular time, west Tennessee was part of the then St. Louis District, and Don was a resident there at the Memphis FDA resident post. So it was through that means that I became interested in FDA and started work for FDA in January of 1967. I moved from Memphis to St. Louis.

In his recruitment, Don told me that if I wanted to get ahead in the FDA that I probably would have to move around considerably, as that seemed to be a requirement for advancement at that time. I remember saying that was all right by me because there were parts of the United States I'd never been to and I was interested in moving around. What he didn't tell me, and I don't know if he knew at that time, was that FDA was going to close the St. Louis District Office.

So within three months of when I started in St. Louis, I was informed that they were closing the district office and that they gave me a choice. I could either transfer

to Chicago or to Kansas City. Of course, the third option would be to leave and find employment elsewhere.

RT: Was Roy Pruitt the director at that time at St. Louis?

RC: That name doesn't ring a bell. You know, I can't even tell you who was the director at that time. I just remember my . . . Bill Conway was there. Forrest Aull was my first supervisor.

At any rate, I chose to go to Kansas City rather than Chicago as a GS-7. I was recruited as a GS-7. So by April, then, I had moved from St. Louis to Kansas City in the same year. That's really where I did any of my inspectional work, and I was only in the field for a couple of years.

In 1968 or 1969, FDA advertised a management intern program, recruiting across the field. Even at that point in my career, I already knew that I didn't want to be an inspector all my life. I wanted to be a supervisor or a manager. The program looked interesting to me. I applied. They had someone from headquarters go to Chicago to interview me for that program, and then I came into Washington and interviewed with Mickey Moure, who at that time was the associate commissioner for administration and his deputy, John Droke. I was fortunate enough in being selected then to the first FDA management intern program and moved to the Washington area in November 1969. There were three of us in that intern program. The second was Art Norris. Art was an investigator in Atlanta District, actually working I believe in the Tampa resident post at that time. The third was Linda Horton. Linda was a graduate of the University of Kentucky, and had not previously been in the FDA.

But the only reason I mention their names is because all three of us were fortunate enough in advancing in the FDA. Linda through first the Office of Legislative Affairs and then the Office of General Counsel and now in the Office of Policy. And,

of course, Art Norris went on to work for the Public Health Service and then came back and worked as the deputy director for the National Center for Toxicological Research (NCTR) at FDA. So it was a good program for all three of us, and I enjoyed that very much.

RO: Can we back up a little bit to the inspections? You said you didn't care about inspections. What kind of inspections were they?

RC: Well, in Kansas City, they were primarily food. It wasn't that I didn't care for it. In Kansas City they were primarily food or medicated feed oriented. Of course, being the new kid on the block, you got to go out and do the feed mills, you got to do the grain elevators, you got to crawl up into the grain cars in the heat of August out there in Kansas City and sample grain out of those cars. There were some cosmetics; a few small medical device firms; and there was one or two drug firms. Back then, of course, everybody pretty much started off in the food arena. Since my background was primarily biology, I felt like I was suited for food inspections, but I also felt like that as far as I was concerned, even at that early stage, this was not something I wanted to do for the rest of my life.

Part of it, too, was that you were traveling two weeks out of the month in that particular district. That can get old, depending upon where you were, and usually you were either in northernmost Iowa or westernmost Nebraska or Kansas, you know, something like that.

RO: Did you get any formal training or was it pretty much on the job?

RC: No, I never had formal training. When I started in St. Louis, they sat me down in a room, gave me some tapes on the Food and Drug Act. I listened to those, and

unfortunately they didn't mean a whole heck of a lot to me. I was scheduled to go to bacteriological school at about the same time I got selected for the intern program. So, of course, I did not go to training. At that point I think the bacteriological training was in Madison, Wisconsin. So all my training turned out to be on-the-job training.

RT: The intern program at that time, was that a year or was there a . . . ?

RC: It was a two-year program with the understanding that if you did well that you would be eligible for promotion at the end of each year. So I was a GS-9 when I came into headquarters, which was late November 1969. Then when I came out of that program, I came out as a GS-12. Had I remained in the field, I probably would have spent ten years before I became a GS-12.

RT: Did you go from that program into financial management?

RC: Yes. During my program, we were encouraged to . . . Well, the whole thing was based upon rotational assignments, and I think I was to have five or six rotational assignments varying in length from one to three months. You thought about what it was you wanted to do, where you wanted to go, and you had Mickey Moure and John Droke as advisors.

I got assignments in the Contract Office and then with the Office of Pesticides & Consumer Product Safety. This was at the time that the product safety program was still a part of the FDA. Sam Hart had come in from Chicago, and I remember working with Sam Hart in that program. I also had an assignment in the cosmetics program in the then Bureau of Science under William Ligon. Bill Ligon.

RO: Who?

RC: Bill Ligon.

RT: Liggitt, wasn't it?

RC: Ligon, Liggitt. One of the two.

RT: Bill Liggitt.

RC: It could have been Liggitt. Yes, it could have been. I don't know why I think Ligon, but it was one or the other. A crusty old fellow. He smoked constantly.

RT: Was he the one that was into sensitivity of rapid eye testing and so on?

RC: Yes, he did all that.

RT: That was Ligon.

RC: OK. Yes, Ligon. Yes. OK. I remember doing a little management study for him, because he was the most unorganized person I've ever seen in my life. Bright, brilliant, but totally unorganized and paper just stacked everywhere, and he couldn't keep track of any assignments that were coming in, and he was obviously one of the reasons why, you know, people who were out collecting samples and sending them into headquarters never found out what happened to them, because he had no idea where they were.

Let's see. I went into contracts and grants, and also I know or I remember financial management. It was in financial management . . . The only reason I took that assignment was because I felt like no matter what I did, if I was ever going to be a

program manager of some type, I really needed to know about budgets and how to handle your operating expenses. So I kind of took that in preparation for maybe someday being a program manager.

As it turned out, it was a nice fit for me and the people in financial management, in that they didn't really know anything about agency field programs, or science. Even though while I was only in the field a couple years, I was able to bring some of my experiences to this group.

They in turn were able to teach me about financial management, and the people who were there at the time were just tremendous people. They made you feel right at home; they had great personalities; they worked real hard, but they had a lot of fun, too. I'm talking about people like Don Brown, Ed Steffee and Don Helm. This was under Moure's area as well. So it just worked out very well for me in that area, and I liked it so much that I knew when I completed the program that that's where I wanted to end up.

So I remember too that somewhere in that program I would go to meetings with Paul Hile and Sam Fine. I remember one time Paul saying, "Well, Ron, are you ready to come back to the field?" And I said, "Well, you know, I think I like it here in headquarters," and I'll bring that back up a little bit later. You probably remember this, Mr. Ottes.

At any rate, so I came out of that program a GS-12, a year later got a thirteen as a budget analyst, then competed for a job of the branch chief in financial management--it was called Budget Formulation branch chief--and was fortunate enough to be selected for that. So that was my first supervisory job, and I guess that was in 1973. So from '67 to '73, I was now a GS-14 supervisor. I liked being a supervisor. I liked working with the people. I enjoyed that.

As events happened, people moved on, the opportunity became available then to apply for the director of Financial Management. I applied for that, and in 1975 was selected for that job. So that was a GS-15.

RO: Well, who did you replace then?

RC: I replaced Jim Walsh at that point. Ed Steffee, who was there when I was first branch chief . . . At that point in time, Moure and Droke had moved on to go with Charlie Edwards, Commissioner Edwards, to the Public Health Service, OASH (Office of the Assistant Secretary for Health), and replacing them was Gerry Meyer and Ed Steffee was Gerry's deputy.

So Gerry Meyer then selected me to be the director of the Division of Financial Management. Jim Walsh went on to be the executive officer of Health Resources Administration.

So I was in Financial Management then as director of that office from '75 to 1980. After five years, Frank Claunts and I just happened to . . . He was a co-division director as director of Management Services. He and I were talking one day, and I found out that he had a master's degree in finance. I had a master's degree in biology. And we both thought, gee, it would be nice if we could swap jobs, because we were both kind of looking for new challenges at that point.

So we went to Gerry Meyer to talk about it, and he was very enthusiastic over it. I don't know if it was because he really thought it was a grand idea or he thought it was time for me to get out of financial management and Frank to get out of the management of facilities or whatever, but at any rate it worked out, and we swapped jobs.

So I was then in that job as director of Division of Management Services in 1980, and at the same time I was in that job, the department came out with a Senior

Executive Service (SES) training program. The Senior Executive Service had been created sometime in the late seventies. I can't remember exactly when. As a part of that law, departments were creating opportunities for people to get into the Senior Executive Service. So I applied and was fortunate enough to get into the program, and that was a two-year program as well.

Prior to that, I had Gerry Meyer . . . Gerry Meyer left the agency for a while, and I had acted in his job as the associate commissioner for Management, but Gerry came back to the agency. Actually, that was before Frank and I swapped jobs. I kind of left that out. But that was my first experience on the fourteenth floor as an acting associate commissioner. Don Kennedy and Sherwin Gardner were the commissioner and deputy commissioner at that time.

So as a result of getting into this training program in the SES, I came out as being certified in the SES. In 1983, there was a reorganization that took the old associate commissioner for Regulatory Affairs and executive director for Regional Operations and put them together in something called the Office of Regulatory Affairs (ORA). Paul Hile, then the ACRA, asked me if I would be interested in joining the Office of Regulatory Affairs, and I knew as soon as he asked me that I wanted to. So I was fortunate enough then to come into the Office of Regulatory Affairs first as an executive officer, or became the executive officer. It was called the director of the Office of Regulatory Resource Management (ORRM). Paul had to have "Regulatory" in everything. Since then it was changed to Office of Resource Management, but same thing.

Then when fellows by the name of Ottes and Celeste left, I was fortunate enough to move laterally to be the director of the Office of Regional Operations. Then Paul Hile left and John Taylor took over as the associate commissioner of Regulatory Affairs.

RT: Now when you came into this SES, were you . . . ? You have traced the steps of your career progression. In the SES program was there an assignment type thing like there like you'd had at the lower level management?

RC: Yes. It was broader in scope and you were expected to get assignments in areas that you had never been in before. One of the assignments I took was when Dan Michaels, who was the deputy director of the Office of Compliance for the Center for Drugs, went to Harvard for three months to that program, and so I took his job; I filled in for Dan. That was my real first compliance officer experience working in the Center for Drugs. I also had an assignment with the Social Security Administration up in the Boston Region and worked both out of the Boston office and the "Wooster" office of the Social Security Administration.

RT: Wooster? (Laughter)

RC: Wooster. Worcester.

RT: Yes, I know. (Laughter)

RC: I did a study for them up there. A year later they wrote me back and said they'd implemented three-fourths of my recommendations, which was like twenty-something. It had to do with how often you kept this little satellite office--they had several satellite offices open--how long you kept them open, whether or not you consolidated them; and, of course, you know, this was when everybody used to have to go to the social security office to get their check or to fill out their form or whatever.

So I was real pleased that they bothered to write me back and actually implemented some of the recommendations that I made, because I figured it would be

just another study that would, you know, be in somebody's in-box or on the shelf and never see the light of day. I also had an assignment with the Office of the Inspector General during that program. Richard Kusserow.

RO: Richard . . . ?

RC: Kusserow, former FBI man from Chicago, and he stayed longer as the department's inspector general I think than anybody else ever had. He was the first, and then he didn't leave until, gosh, sometime in the early nineties he finally retired. So we're talking here now like '81, '82, sometime during that time that I was working for him. So he was the inspector general for the department probably ten to fifteen years. I don't know exactly how long it was, but he was appointed as HHS ([Department of] Health and Human Services) inspector general after they created the IG (Inspector General) Act of 1970-whatever it was. It created all those IG's offices.

RO: Before he left, didn't he get interested in FDA?

RC: He got very involved in the FDA and wanted, you know, to help us out in doing our criminal enforcement activities. So, yes, we could get to that in a few minutes, because I know you want to talk a little bit about the Office of Criminal Investigations.

RO: You mentioned very briefly your stint in Facilities Management. Anything really exciting that happened with facilities while you were there?

(Interruption)

RC: Well, yes. Even when I was in Financial Management . . . As a matter of fact, probably from the first day that I can recall coming into headquarters, Food and Drug Administration was always trying to get new facilities both in headquarters and the field. Even at that time in the early seventies it was felt that FOB 8 (Federal Office Building), which was dedicated I think when Kennedy was president, so in the early sixties, it wasn't even that old, was not the right building to be in with respect to animal experimentation. The field had really upgraded some of their facilities to the so-called "Rayfield" Buildings. But in many other locations, like New York and Chicago and Seattle, they were in very old government buildings, and so there was a need to try to get to new facilities at that time.

In addition, in many cities around the country, FDA owned some property where we wanted to build a facility. Money had been appropriated in some cases to either build a facility, to do the planning of a facility, et cetera. However, in 1973, FDA's appropriations chairman in the House, who was Jamie Whitten, decided that FDA needed more inspectors than they needed more buildings.

So Whitten then declared that a great deal of money at that time, twenty-something million dollars I believe it was, should be transferred from FDA's buildings and facilities appropriation to its salaries and expenses appropriation so that we could hire more people. Out of that came something that was called Project Hire. Also out of that came the FDA State Contract Program, where FDA would contract with the states for certain inspections primarily in foods and veterinary medicine. But as time went on, that was expanded into the radiological health area as well.

So all those facilities issues carried on in . . . FDA also owned land in Beltsville and had planned to consolidate its headquarters operations in Beltsville back in the seventies. That got delayed.

When I was in Buildings and Facilities Management, Division of Management Services, I specifically recall we were still trying to get a new facility in Seattle, and I

went out to Seattle to accompany then the chairman of the House facilities committee—I don't even remember what it's called now—and Jim Swanson was regional director there. We took this congressman through, and he got to see firsthand how poor the conditions were in that old federal facility in downtown Seattle. Then a few weeks later I testified before this committee in the Congress. I don't think it was my testimony, but eventually we were able to get out of that building and into a brand new facility that actually is not in downtown Seattle but is north of the city in Bothel, Washington.

I think the facilities issue has probably been one of the most frustrating for FDA and for those of us who have been involved with FDA over the last twenty-five or thirty years because you have such little control over that. You're totally dependent upon in many cases the GSA (General Services Administration), in other cases the Congress, of getting the money, getting the buildings, and it just seems to take forever when you have one plan in place, all of a sudden the administration changes, new commissioners come in, and they have their own thoughts, their own ideas in some cases about what should or should not be done with respect to facilities. You never had enough money, so you were constantly battling between whether headquarters or the field would get money for facilities, and, you know, it's still true today. Nothing really has changed that much, although we were able to make a considerable change in total facilities, which maybe you want to talk about later under laboratory consolidation.

RT: As a matter of fact, it's my recollection that in some cases we've had money set aside for new facilities, and because of the delay in its use, inflation has really made that figure inadequate. I think Chicago was one such facility, as I recall. Part of that escrow money was really applied to Project Hire and/or State Contracts at that time because it couldn't be used anymore for its original purpose because of inflationary influences.

RC: Well, not only that . . . That's true, but also when Ronald Reagan became president, his administration undertook an effort to sell surplus government property. So FDA then at that time had land in the state of Washington. I think we owned some property maybe in Illinois and a couple of other places. We knew we'd never get the money to build or the money that had been there, like you say, wasn't enough anymore. So basically what we did then was we had to surplus some of those . . .

(Interruption)

RC: . . . effort to reduce unused federal property.

RO: Wasn't it true, Ron, too, that some of that property that FDA owned was in undesirable areas?

RC: It was because, again, as various administrations came in and went out, in some cases the administration would want the federal government to be located in the downtown business area, so you'd find a piece of property in the downtown business area, which perhaps wasn't really suitable, but you were desperate, so you would take it. Before you could start construction there, the administrations would change, the policies would change, and federal government didn't have to be in the downtown business area, but it could move within the city limits or outside in the suburbs. So these things all impacted upon FDA being able to get new facilities for its authorities.

RT: I think that element may have also impacted on use of personnel. It's my understanding, for example, in New York, when they moved from Manhattan over to Bush Terminal in Brooklyn, there was a little problem with some of the female support staff not wanting to go to that area because of personal safety considerations. Is it

correct to say that perhaps Los Angeles' office also was in an area where there was some concern about matters of that kind?

RC: That has turned out to be the case, absolutely. It wasn't when that was built. Because the Los Angeles facility was one of the "Rayfield" Buildings that was built in the sixties. However, after twenty, thirty years you need to renovate buildings, you need to get to new places, and during that time frame, the L.A. facility was in a neighborhood that totally changed the characteristics. It became a neighborhood that was affected by drugs, by violence. We did have situations there of shootings right out in front of our facility. We've had situations where glass was broken, cars vandalized, et cetera. So, yes, not only . . . As a matter of fact, I think both male and female employees didn't feel very safe going out for lunch on some days.

RT: In New York as I recall, or in Brooklyn I should say, I remember visiting up there one time not too long before I retired, and they had that big wire netting just above the first floor to catch falling cinder blocks and so on that might strike pedestrians.

RC: Yes, the facade was falling right off the building, so we had no choice but to put up that wire netting. Plus we were next door to what is now a prison. I mean, we were the last people to occupy the old Bush Terminal, because the Navy was in there at one time with us; I think maybe Customs had some people in there. Also, I can't remember for sure, but it was another federal agency, and they were able to leave and we weren't. It was really in large measure because we were looking for a facility that would house not just investigators, but laboratory personnel as well. So when you're looking for that type of facility, it's not as easy to find as is just office space.

So that impacted upon us, plus the politics of other agencies such as the General Services Administration where regional directors were appointed based upon political patronage. Some of them wanted to work for the Food and Drug Administration and acquire new facilities and others had other agencies that were higher priority than us. So I think all in all it was just not a very good situation.

[omitted discussion of Rayburn vs. Rayfield and changed references above]

RO: Well, then you left Facilities Management and you came to the ORA organization. What was one of the first things that you had to tackle?

RC: I'll never forget my first week on the job as the director of Resource Management, and I got a call . . . Well, there was to be a meeting of all field administrative officers, and I was informed that it was taking place in Cherry Hill, New Jersey. And I thought, "Well, okay," you know, "it's right up there by Philadelphia." I got a call from the regional director from New York. Do we mention names?

RO: Sure.

RC: OK. Who was Caesar Roy. I had known Caesar from past experience, but didn't know him well. Caesar informed me that this administrative officer conference was taking place in his region, because at that time New Jersey was part of the New York region, which was Region II at that time, and he hadn't been invited to make opening remarks. But Dick Davis, who was the regional director of Region III, which was in Philadelphia, had been invited to make opening remarks, and Caesar just didn't think this was right. This meeting was going on in his region, and he felt like that he should be there.

I remember thinking, and I think I said to him, "Caesar, I can't believe that this is that important to you that you don't have other things that are more important than this, but I'll be delighted to look into it and see what can be done." And I remember thinking, "What in the world is going on in this organization?" (Laughter)

So in exploring this particular conference, I found out that it had originally been scheduled for Philadelphia, but they couldn't find any hotel accommodations in Philadelphia. So they moved it across the river to Cherry Hill where they got a good deal on a motel. As a result, you know, it just by happenstance turned out to be in Caesar's region.

Well, as I recall, both guys came and the conference went on and it was a good conference and all that stuff. But, you know, it was my first experience in politics within ORA, the internal politics of ORA, and even though folks had the same title, there certainly was a protection of individual regions and, as some might say, fiefdoms. So that was my first experience that I can remember:

The other thing that I really enjoyed being in that first job in ORA was because the field was always in need of more resources, and at this time, Paul Hile was trying to reorganize and balance ORA. What became ORA was the old EDRO and the ACRA. And as such when you reorganize, you're putting different groups together. We had some movements of offices in headquarters. This created some interesting problems for the, I'll call myself the administrative officer at the time, in that Paul wanted to consolidate some areas, but, you know, he was the type of guy that played everything very close to his vest, and he didn't want anybody else exactly knowing what their plans were.

So one of the things I remember quite clearly was that we had this total rearrangement of the offices laid out, and Hile said, "I don't want to see any names beside any rooms." So, anyway, whoever was doing the drawings came back and they had names. You know, there were two hundred or three hundred people you had to

find a place for, and I'm sure the kid who did it thought, "Well, I'll put this one there, this one there," so he could account for all of them, or she, whoever did it.

Well, it did not please Mr. Hile, and the meeting ended abruptly because there were these names on there. So, again, it was learning the personalities involved and how you deal with certain situations. So basically all we did was we took those plans, and redid them without the names, brought them back, and Paul thought it was great, and the reorganization, the relocation of the offices went on, and life went on.

One of the things that I think helped me in that job was that I had previously been in Financial Management, that I had previously been in Facilities Management, and that was probably one of the reasons that Paul was interested in me coming to ORA. So I was able then to go back to my old "haunts," if you will, and talk to the people there and get some empathy from them and sympathy from them for more resources or whatever, help in getting contracts, whatever it turned out to be that was specifically needed by ORA. So I think it was a good match. It was a good, new opportunity for me, and it was one that people in the organization appreciated. I felt they appreciated what I was able to do while I was in that job.

RT: That would have been during the tenure of what commissioner?

RC: Frank Young.

RT: Dr. Young?

RO: The merger was under (Arthur Hull) Hayes, just before he left.

RC: Right. Hayes blessed it. That's right. When did Frank Young come in? He came in when Bush came in, right? So I've got to think here a minute.

Well, it seemed to me like Hayes . . . By the time . . . Yes, that's right. I guess that's right. Hayes was there when I first started in ORA. Then he left and was replaced by Frank Young, yes.

RO: Well, one of the other things that I think happened about that time was when they started to reorganize the field and realign the regions. I think you were still in ORRM (Office of Regulatory Resource Management) when that took place, when they started to try to reduce the ten regions to five or whatever.

RC: I was still in ORRM at that time. That's right. Shortly after Paul came in, we did look to see if there was a way to reorganize the field. That's right. And we were successful in getting the department to agree for us to do this study. The field, I think, probably since creation of the regions had really never felt that they needed as many regions as they had--ten--but because of presidential edicts and other things we had ten.

It was recognized that in many cases you had what was called single district regions like Seattle where you had the district and the region together, and then you compare that with the New York region or Region II that had five districts, and it had, you know, a couple of laboratories, that type of thing. So you had this tremendous imbalance.

So we were able to do a study that recommended that we reduce the field from ten regions to six. The department agreed with that study, and it was done in such a way that as people retired and left, then we would not fill behind the regional directors and nobody lost a job, so then we were able to consolidate from ten regions to six.

RT: Now as a part of that, of course, laboratory consolidation was an element and some labs were closed, were they not?

RC: Well, now we came up with a plan to close laboratories, but the only we were successful . . . The only one we were ever successful with, as I recall--and if you all can remember differently, let me know--was that we took the New York lab which was in the same facility but had been divided into an import laboratory and domestic laboratory, and we did away with that artificial barrier and made it the New York regional laboratory. Oh, and we consolidated the Boston District lab with the Winchester, Massachusetts, lab. Even though they were both field labs and only 10-15 miles apart, they had separate management and separate administrative staffs.

RT: Well, did that result in the closure of the Buffalo laboratory?

RC: No. The Buffalo . . . That didn't happen then until after I became the ACRA (Associate Commissioner for Regulatory Affairs). But if you want to go in that direction now to continue the laboratory consolidation that's fine with me.

RT: Not necessarily. I just wondered about some of those things.

RO: I know you were in charge of the group that was working to realign the field with guys like Sterk Larson and Keith Dawson. I understood they were looking at various computer models on how to balance the field workload. That was one of the objectives I think of reorganizing the field was to balance workloads and staffing. But wasn't part of that study also looking at the field laboratories?

RC: Yes, yes, it was. We came up with an excellent plan because, not only was it a balance of workloads, but you had this tremendous imbalance in total personnel among regions. You had laboratories in various states of repair or disrepair, in various ages, et cetera. So we did come up with a plan to consolidate laboratories, but that was

never realized because of the GAO (Government Accounting Office) response to congressional interest that was generated by certain employees in laboratories that were scheduled to be closed.

RO: Like Minneapolis.

RC: Minneapolis would be one. There were others. And so the employees who have every right, of course, to petition their congressperson did. The Congress got the GAO to come in and critique our study. The GAO said, "Oh, gee whiz, you guys, you know, you missed on this particular calculation or you didn't factor in this particular thing." As I recall from my point of view, they were very minor considerations, but they worked. They were typical GAO reports in that the GAO doesn't come in usually to praise you for whatever you've done; they come in to find some little fault or criticism. So basically the Congress then put into FDA's appropriation report that there will be no money in a particular year's appropriation for any laboratory consolidation. So it was kind of dead on arrival, if you will.

I remember thinking at the time if I ever become the ACRA, I'll never do this study again. (Laughter) I said, "I'll be darned if I'm going to do this again," where you come out with something that I think truly would have saved the agency money, would have resulted in some positive effects, but was totally shot down for political reasons.

As it turned out, I did become the ACRA, I did change my mind, and we did further study on laboratory consolidation. The times had changed, the Congress was interested, everybody was interested in saving money, they were interested in reducing the size of government. This particular--why don't we just go ahead and go on into laboratory consolidation--this particular plan was similar to the plan back in the eighties, but there were some new wrinkles in it and things had changed in the field in the fact

that we were able to get a new facility in Seattle, we had one approved for Kansas City that was under construction at the time. So, as these changes happened, where new facilities would crop up, you then had to reflect this in your revised facilities consolidation plan because you don't want to throw away a new laboratory, for example. They're too hard to come by.

So we did make some changes from the original consolidation, plus we really looked at only the laboratories. We didn't try to at that point and time weave in some other things and make this reorganization any bigger than it needed to be, because we knew that selling the laboratory consolidation plan would be difficult enough without trying to say, "We're not going to have a district here," or "We're going to change regions there," or whatever, although subsequently we did reduce the number of regulations from six to five.

So we came forth with this plan that would consolidate the laboratories from eighteen to nine with what we felt like were five all-purpose laboratories--"mega-laboratories" was the phrase that was used for a while--and then four specialty laboratories, utilizing the existing facilities, adding on in places where we could add on, like in Atlanta, for example, but coming up with a new facility in Los Angeles. We wanted a laboratory in Los Angeles, and we needed a new laboratory in Los Angeles, and at the same time working to get a new facility in New York.

The other thing we took advantage of was the fact that the agency had recently, right before Dr. Kessler became commissioner, had a blue ribbon committee come in and do a study, and they criticized the agency for not utilizing NCTR (National Center for Toxicological Research) to the extent that we should. They said that NCTR was not a part of the FDA the way it should, et cetera.

So we decided to take a look and got working with Dr. Henney and Dr. Kessler's permission-agreement, rather than permission-agreement to go and look at NCTR and see if that would work for us as a place for one of our new laboratories. We

did this really because of the fact that the FDA owned that facility down there. There were top-notch scientists there that we felt like could interact with the ORA laboratory people, and in the final analysis you would have a much stronger FDA presence in one location than what you now had. We never envisioned combining the two organizations, because we didn't think that would work. But we felt like there was this synergy that was there and other things, personnel and facilities that could be utilized.

Quite honestly there was a lot of unused space in Arkansas. So we asked an architecture engineering firm to do a study and to see which was better: renovating existing unused space or building a new facility. Because we really didn't have any preconceived idea at that time.

They actually came back with a plan of new construction plus renovation of one building down there as the most cost effective means. We were able to get the resources needed, outside official budget channels--they were always added on by the congressional committees--to do that, and that laboratory I guess is going to be dedicated within the next six to eight months, I would guess.

RO: You know, I think that's interesting, because when FDA first acquired NCTR they were looking at whether or not there wasn't some field use for NCTR. We weren't thinking of it as far as a laboratory was concerned, but they thought the least we could do was to use some of the space there for investigators, have a resident post there. So we started in to explore that, and all of a sudden, why, forget it. They didn't want any regulatory aspect at all to NCTR. That was going to be strictly a research facility.

RC: Well, that shows you how, you know, twenty years and different administrations and circumstances can change. You know, it's unfortunate I think that that didn't

happen back in the seventies, because, again, it's twenty-five years of lost opportunities as far as I was concerned. But, yes, I remember that. I do recall that.

The other interesting thing that we got, you know, of course, everybody had criticized this. They criticized it primarily from the standpoint that the only reason we were doing this was because Clinton was president. If Clinton wasn't president, the FDA wouldn't be doing this.

Well, we started it before Clinton was even elected, and quite honestly, you know, I kept telling people, "Heck, if I had my druthers, I'd rather go to Tennessee, you know. I don't want to go to Arkansas." But it really wasn't because Clinton was president.

Now, it was fortuitous that he became president, and I think he certainly didn't do anything to keep us from going there. But really it was the local congressmen, it turned out to be Jay Dickey, a Republican, and Senator (Dale) Bumpers, a Democrat, who really helped—who both were on the appropriation committees in their respective bodies—and they, along with Congressman Thornton who was there, helped push this thing through, because the department and OMB (Office of Management and Budget) wouldn't support the money in the regular budget process.

So what happened was as the appropriation bills would leave OMB and go to the Congress, then the money would get added on. It would get added on in parcels of certain amount of money to make this happen. So fortunately it's happened, and I think it'll, in the long run, be good for the agency and be good for ORA. It won't be without its problems, but what is.

RO: Well, one of the things with laboratory consolidation, as always the personnel aspect of the thing, the people and, you know, a lot of the people weren't ready to retire. What about reassignment? Have they had any success in people being willing to transfer to Arkansas, for example?

RC: One of the things we were criticized for when GAO did their study of our laboratory report back in the eighties was that we were overly optimistic about people's willingness to transfer, and therefore we had miscalculated the amount of savings. So we knew that people for the most part didn't want to transfer. At least laboratory people historically were pretty much locked in to their location, their community, et cetera. But we knew some would. So we didn't anticipate a lot of people transferring.

But what we did do was that we offered an opportunity for anybody to transfer to almost any lab they wanted to in the 1990 plan. In the eighties plan, it was, you know, you're going to go here. Kind of like I went from . . . Well, they gave me a choice of Chicago or Kansas City basically.

So we opened it up, and we had in the first year, year and a half, I think we had over a hundred people willing to transfer to these various locations. Very few wanted to go to Arkansas, but I can understand that initially because we didn't have a facility open down there. When we advertised for a director and then when we advertised for some of the vacancies down there, after we got it approved, we had quite a number of applicants. Plus we made a tremendous effort at letting people know what's in Arkansas. We provided people an opportunity to go down there; in some cases they went on details and on some cases they just went down for a visit, which again was not something that we had done much in the past. So we tried to make it a more people-friendly thing, because you really did have to be concerned about people and their families.

RT: That in itself is a marked change in the agency's history because years ago it was an edict that you go here and go there. The agency has lost some good people along the line who were not able or willing to move for various reasons. So I think maybe it was during the Hile era that maybe that started to be changed.

RC: Well, I think there was a lot of factors, too, that . . . Maybe if you recall that's when real estate became very, very expensive. More families became more two breadwinners in a family rather than just one. A lot of things started to change. I think from a personal standpoint, that's much better. From a management standpoint, it makes it more difficult to achieve some of the things you want to, because it would be a lot easier just to say, "OK. Tomorrow your job is in so-and-so, and your paycheck is there. If you want it, that's where it will be."

RT: Do you think, having been a manager at the upper level, the morale of the agency can be generalized as changed for the better?

RC: I've never been one to generalize the morale of the agency . . .

(Interruption)

RT: I can remember, in my early career at the state level where I used to work closely with FDA personnel from Chicago, I always greatly admired these inspectors who had such a commitment and dedication to their job. They'd sit in hotel rooms and prepare reports and samples for sending to the laboratory, far beyond the usual workday, and that was just a given. I don't know whether that's true now or not. Perhaps it is.

RC: I think it's still true for some, but--especially those who travel and make those kind of inspections--but I think it's changed from the standpoint that people now want more time to be with their family, they want to start work earlier in the day, leave sooner, and if you provide those opportunities, morale still can be high. But I think people now are looking more for, Do I enjoy the work that I'm given? Is it meaningful

work? Do I know the results of my work? I mean, I can remember not that long ago when people would do these inspections, they would spend all this time writing them up, and then never hear whatever happened to their report, or whatever happened to their sample. You know, these are the types of things that can affect morale as well. So . . .

But I think if you did generalize, to me, the field morale for the most part was always high. It was high because people felt that what they were doing was important. It was important to the consumers of this country. Now if you were in an area where the laboratory was going to close, certainly the laboratory morale would not be high, but that doesn't mean the investigators might not be, and you . . . I think a lot of that, too, had to do with the personalities of the district, of the leadership within that district, what they did as far as, you know, whether they were team players or whether they were out there on their own and saying. "This is not my thing, this is another thing headquarters is ramming down your throat." You know, this went on—I'm not talking just in my time as ACRA, but I'm sure forever. You always had this we/them mentality to some extent, and you tried to break that down as much as possible.

(Interruption)

RC: Go ahead. Ask me that question.

RO: Before leaving this laboratory consolidation, what's the status of closing some of the laboratories and having the big regional laboratories or whatever you call them?

RC: OK. We've been very successful in pretty much completing this laboratory consolidation plan. We now have—or FDA; I still talk like I'm still there! (Laughter) FDA will dedicate a new laboratory in New York, will dedicate a new laboratory in

Arkansas, and now it looks like we'll have money appropriated in the FY2000 budget to build a new laboratory in Los Angeles out in Irvine at the University of California, Irvine.

Laboratories which have closed or will close this year include the Buffalo laboratory, the old Cincinnati regulatory laboratory, the Detroit laboratory, the Chicago laboratory, Minneapolis laboratory, the New Orleans laboratory. Those either are closed or soon will close in the year 2000. Once the laboratory in Los Angeles is completed, then plans are that the San Francisco laboratory will close and work will be transferred then from San Francisco to either Seattle or Los Angeles.

In addition to the labs that I mentioned, Cincinnati, the Forensic Chemistry Center, was designated . . . These nine laboratories that I mentioned, five of them were all-purpose and four were specialties. So the one in Cincinnati was to be especially for forensic chemistry and it was to be a new facility, and that has been completed. The Philadelphia lab is doing nothing now but drug work, and we had renovations completed in the 1990s to make that happen. The Winchester laboratory in Winchester, Massachusetts, is to do specialized work in radiopharmaceuticals and medical devices, and that has happened. The Puerto Rico laboratory is to do only drug work; all of their food work has been transferred to the Atlanta laboratory. There's still a renovation plan for that Puerto Rico laboratory, but I understand the money is there, and I'm sure they're proceeding with that.

When the Arkansas lab opens, the Dallas laboratory will officially close, and it's pretty much out of business now, I think; the same is true for Baltimore. So the agency . . . This consolidation plan has been realized and hopefully it will be more advantageous to the agency in the future. In my talking to folks that lost laboratories from their location, it really hasn't impacted the work of that district at all. They've been able to ship their samples elsewhere which, of course, we've often done since time in memorial, we've had laboratories, and life goes on.

The receiving laboratories have become more customer oriented. They realize that if they're serving more than one district that they have to set priorities and they have to work with the district management. And that's, as far as I know, happening pretty regularly and I think in a pretty orderly fashion.

RO: Is the Arkansas laboratory going to be a general purpose laboratory or a specialized one?

RC: It's going to be a general purpose laboratory. I think eventually there, too, the plan was to close the Kansas City laboratory and the Denver laboratory and move those operations primarily to Arkansas. So they'll be doing a lot of the medicated feed work and the vet drug type work that had been done by both Denver and Kansas City. That'll eventually move to Arkansas.

RO: What about the microbiological work? Are each one of these central laboratories going to do microbiological work?

RC: Yes, each one of the central labs will have a microbiology capability.

RT: In terms of overall staff, numbers of personnel, this new configuration, has that reduced the numbers of people overall?

RC: The field has suffered a reduction in personnel for a number of years during the Clinton administration in general, which then has had an impact I think proportionately on both the laboratory, the investigations, headquarters, you name it. Plus the fact that since a number of people did opt to retire rather than transfer, you had some vacancies in these laboratories. I think the net result initially will be fewer personnel in these

consolidated laboratories. But hopefully, the agency will be allowed to hire again and bring in new people to some of these locations.

RT: With this reduction that you've cited during the Clinton administration, is that all related to the vice president's reinvention of government?

RC: Sure. It's related first of all to the fact that the budget was not balanced, the big budget. The administration said we've got to reduce the size of government. Reinventing government was then one way of reducing the total size of the government. Our laboratory consolidation plan met the criteria for reinventing government, reducing the size of the government--as I mentioned earlier, I think that's one of the reasons we were successful in doing it--plus, we could show that there would be savings by doing this, not only immediate savings, but savings in the future as well. If you consolidated these facilities, you didn't have to buy all this equipment and, you know, all those things that went into that plan. So . . .

But, yes, it was a part of the reinventing government, the reduction in the size of government. Now the last couple of years the agency has gotten some addition of resources through its appropriation process, but they've been targeted primarily in the foods area and in the tobacco area. While these programs have grown, other programs have had to shrink in order to help these programs grow. So you still have the selective part of the agency that is still terribly underfunded and undermanned, and it has impacted both field and headquarters.

RO: You mentioned the tobacco program. What is the FDA's tobacco program?

RC: Well, as I understand it, FDA's tobacco program, after the rule was promulgated, was to have the enforcement part of that program carried out by the states. FDA

would contract with the states, and they in turn would utilize individuals within a state to go and try to get buys at retail outlets to see if these retail outlets would sell cigarettes to minors and/or if they didn't sell them, would they check their ID cards, and this was the program. This, as far as I was concerned, was the best way to do it in that I never felt like that it was appropriate to take ORA personnel who were trained in, you know, have degrees in biological sciences and make them cigarette police, where all they did was to go and see if they could watch the buy, somebody selling cigarettes to minors.

So from that standpoint . . . And most of the states I understand, not all, but most of the states had contracted with the FDA to carry out that program, and some of these are not the typical state agencies that FDA has dealt with in the past. In many cases, it might be the transportation or the State Highway Patrol who actually got this contract. Or it might be the health department, might be the ag department, but it might be another department with an interest in it too, which was an interesting thing I think for people who actually did let the contract, because this was a whole new way of doing business that they had to learn about as well. Do you want to talk more about it than that?

RO: Well . . . Go ahead.

RT: Now, I was just going to say that for many years the position of the EDRO or the head of the field organization was more or less third following the deputy commissioner. In more recent administrations there have been changes in the upper management structure. Would you care to comment on that?

RC: Well, I used to joke when Dr. (David) Kessler came in and he made those changes creating all the deputies, that I or the ACRA then had gone from being third in the agency to thirteenth. I don't know whether it was third or thirteenth or ninth or

what it was, but certainly Kessler's reorganization made a tremendous change in the traditional way that the FDA had done business.

He created another layer, if you will, of management, of deputy commissioners. So instead of the ACRA and the center directors reporting directly to the commissioner, we reported to the deputy commissioner for operations. Then there was a creation of a deputy commissioner for management, a deputy commissioner for external affairs, a deputy commissioner for policy, and one other than I can't even think of right now. Maybe when I do the transcript I can fill it in. So that changed the way that the agency had done business.

Now even though Kessler created this, and this layer of management was created at the same time the rest of the agency was undergoing a downsizing through the reinventing government operation, and so it didn't sit well with a lot of people for a variety of reasons, and it was unusual too from a management perspective. I don't know what textbook it came from. I've been unable to find that in any textbook. But he had his reasons for doing it, and, you know, of course, he's the commissioner and he could do that. He got the permission from the department to do it and he did it.

One of the things he was able to do in adding these layers was that he did bring a lot of diversity to the immediate Office of the Commissioner which had not been there before in terms of certainly women having higher positions within the FDA, which we had been criticized for. He was not successful in bringing a lot of minorities in initially when he created the first group of deputies, and he took some flack from the department on that. Yes, Kessler, you have changed the makeup of the Office of the Commissioner, but even though you brought women in there's not a minority, either men or women. So as time went on, he tried to address that issue as well.

With respect to the job of the ACRA, yes, that changed considerably, some of which was done on a structural basis. When you created the office of the deputy commissioner for policy, many of the things that former ACRA's had been involved in,

as far as setting policy on certain new types of things, I was not involved in them. Some of that was because of policy; some of that I think was by design. I think Dr. Kessler's motivation . . . First of all Dr. Kessler is a brilliant person, and when he came into the agency, he came in with a lot of zest and a desire to strengthen the enforcement arm of the agency, and we were successful in doing that. I think in some cases we perhaps went too far on one end of the pendulum, from one end to the other, and then as time went on we pulled back a little bit.

But on the other hand, there was a lot to Dr. Kessler that, I don't think he felt comfortable in dealing with bureaucrats. He did feel comfortable in dealing with his deputies, which he brought in; he felt comfortable in dealing with people that weren't necessarily in the management chain at FDA; he felt comfortable dealing with individual investigators, but I don't think he felt comfortable in dealing with their management, either at the district level or at headquarters level.

His modus operandi was also to incorporate public affairs and legislative affairs in a lot of what went on in the agency. He totally changed the way the agency was operating under Frank Young and previous commissioners the agency had, what was called the policy board, which included associate commissioners and center directors and a few others. We would have weekly staff meetings, and it was called the Commissioner's Staff Meeting. Pretty much everybody had a place that they were to sit around this table. There were pictures of center directors and associate commissioners up on the outside of the door there on the fourteenth floor.

Shortly after Dr. Kessler came, why those pictures came down; there was no more policy board, because he had created these new deputy positions; and the so-called Commissioner's Staff Meeting got changed to just called a Weekly Staff Meeting. I think the reason that it was called the Weekly Staff Meeting was because the commissioner was never there. He just really wasn't interested in some of the things that were related to during those weekly sessions, and part of that was because a lot of

it was what somebody used to call tales about their trips: I went to here and I gave this talk, I went there, you know. That's not interesting. It could have been used for much more useful purposes about talking about specific problems, how you're going to approach certain things, et cetera.

So there was this total change then in the way the agency did business. With respect to . . . So then Kessler used the deputy commissioners and he used his associate commissioner for public affairs and his associate commissioner for legislative affairs to really talk about what was going to go on in the agency, how to best portray the agency in the public's light, in the congressional light. Many times there were actions taken that included publicity which would not have occurred in older days of the FDA. The FDA was one of I think, yes, we will take action to protect the public health, but we didn't want a lot of publicity about what we had done. Dr. Kessler was just the opposite way. He felt a need to show what the agency was doing, and for the most part, that worked quite well.

He got some criticism for the seizure of the orange juice, because that was a labeling issue and not a health issue. And I think maybe, looking back on it, we probably should have done something different as far as the big first seizure. But again that was something that very few people knew about, and it just happened.

We were talking a little bit about the difference in the ACRA position between Frank Young and David Kessler. Frank Young was a very outward going, optimistic fellow, but he liked to get involved in a lot of things, especially--but so did Kessler--especially emergencies. I remember Frank Young, being a pathologist, he loved to talk to fellow pathologists around the country anytime that there was a crisis dealing with a poison, be it cyanide, be it whatever it was.

RT: Would you say he was more of a micro manager?

RC: He was . . . Yes, he was more micro management oriented. Plus he made a lot of . . . Frank's biggest downside as far as I was concerned--and I didn't work directly for him but just for a few months--was that he always promised more than anybody could ever deliver. He would go off and he would meet with somebody, and he'd come back and he'd say, "We're going to do this, this, this, and this," and you hadn't even had time to complete other projects that he'd asked you to get started before he wanted the new ones done.

Kessler, in contrast, was . . . He liked to . . . He micro managed emergencies initially when he got there, because, as I said, I don't think he trusted the agency. He didn't feel like maybe the agency knew what it was doing. It took about a year, year and a half for him to feel comfortable in dealing with then Dick (Richard) Swanson, who was head of the emergency operations, and he finally realized that Swanson wasn't going to, you know, go off and do something that the agency shouldn't do. But then that's when he kind of delegated that to Mary Pendergast. He didn't get as involved.

But Kessler traditionally was much more interested in what's going on outside the agency, was more interested in particular projects, such as drug advertising and tobacco, that he thought the agency should be involved in, and was constantly working press and the Hill and the department and external units and really wasn't that interested in the day-to-day operations of the FDA. He left that, the tasks, if you will, to the deputy commissioners.

RO: What was Kessler's relationship with the field? One of the things I always tried to do was to get the commissioners out into the field offices to see what they were all about.

RC: His relationship with the field for the most part--especially the investigators--was good, because initially he did go out and visit a lot of places right away. But then that

slacked off, and that has to do with a lot of factors. I'm not faulting him for that. But I think he could have made efforts to visit more. He would go to certain cities where we had offices and deliver a talk and could have taken the time to just drop by and say hello or meet with the staff, and I think that would have done a lot more to help bolster his relationship with the field.

I think he was always very supportive of the field in the standpoint that the field needed additional resources. He knew that. But his last few years he was more interested in getting the user fee passed for the drug approval process, and he spent more time involved in center activities and other activities besides the field.

RO: Did he routinely meet with the senior managers, field managers when they came in?

RC: Not the last few years. Initially he did. I remember the first day he came in, we were meeting in Annapolis, and I drove him over there, and he met with us. He spent some time to talk, you know, a little bit with us. When we would have annual conferences, he would initially come in and talk. But towards the end, that wasn't as important or he didn't have the time as well. I think some of that was he just wasn't interested. He was so focused on the tobacco issue the last two or three years that he was commissioner that he spent his entire time doing that; and such things as breast implants. You know, those were the types of things that he was engaged in--not the day-to-day run of the mill, how's the field doing, how's your morale, et cetera.

I don't mean to imply that he lost interest or that he wasn't supportive. He was supportive. But I think, you know, he had other . . . He was not the kind of guy that liked to sit around and talk shop. He didn't feel comfortable sitting around the table with a bunch of folks just talking about what's going on and how's it going and these types of things. He was always a very, very focused individual. You might see him

in the hallway and he would be constantly thinking about something, his mind would be off someplace else, and he would barely acknowledge you, and it wasn't because he didn't like you or he was mad at you or whatever that day. It's just that that was the way he was and probably still is.

RO: You mentioned he was really focused on breast implants. Didn't you?

RC: Yes, that was one issue that he was focused on. Yes.

RO: Now I understand some of the more recent studies have suggested that the implants aren't the big problem that they thought they were.

RC: Yes, well, I think his whole . . . I don't know what all went on there, because, again, that was one of the areas that the ACRA was not included in. There was an awful lot of political pressure on the agency at that time. There were all these different sides, and I think the agency felt like, you know, let's have a call for the data. Well, the data has now come in and evidently it's not the problem that some people tried to say it was. I'm not sure that he couldn't have made the same decision based upon the information at the time, but he chose to ask for more data, and that's just the way it went.

RO: The Red Cross during . . . I think it was during Kessler's.

RC: Yes.

RO: Several years ago, the agency had a lot of correspondence with the Red Cross. Was it about blood? Do you want to comment?

RC: Well, again, I think this too goes back to the Frank Young era where we tried a voluntary approach with the Red Cross, and that didn't work. There was still a tremendous amount of concern over the condition of Red Cross operations and finally during Dr. Kessler's tenure . . .

(Interruption)

RC: Well, before we initiated the consent decree, this is an area where I was involved with general counsel and the commissioner. We got investigators like Ellen Morrison and the one in Buffalo, Mary Carden, in to actually talk to the commissioner about what they were finding during these inspections. We also got the Center for Biologics more attuned to the fact that we needed to actually bring about an enforcement action against the Red Cross. The voluntary efforts just weren't working.

Kessler and I paid a courtesy visit to Ms. (Elizabeth) Dole before all this, and then she was also present when we made the decision, when we brought members of the Red Cross out to the Parklawn Building to present them with the consent decree.

The consent decree required the agency to spend an awful lot of resources, an awful lot of time in helping the Red Cross change its operations. It took about two years for the Red Cross to finally change their own internal management, change their operations so that they could comply with that consent decree. I think now that they've--you know, five years now have gone by--and I don't know if they've been released from the consent decree yet or not. The thinking was that that would happen sometime during the first part of 1999. Certainly this month, maybe next month they probably would petition the agency to be able to get out from under the consent decree. The agency was making a number of inspections, I know, last winter and this spring, and if those inspections turned out to be okay, they probably would be relieved from being under the consent decree.

RO: Would you care to comment on what some of the specific problems were?

RC: Well, yes. They ranged from the lack of SOPs (standard operating procedures) to the failure to follow SOPs, training, also computer problems. The Red Cross had a tremendous problem with their data integrity. I don't mean by that that they were falsifying data. It's just that you couldn't rely on the data to make management decisions.

Also the fact that the Red Cross operated pretty much independently from one Red Cross chapter to another around the country. They weren't really operating under a national uniformity. So all those things were addressed in the consent decree. The Red Cross spent a lot of money. They had to spend a lot money, they had to spend a lot of time, they had to hire new people, et cetera. But today I think they've got one of the better operations going of any enterprise the agency inspects.

Of course, blood was such a unique component and such a unique product, I should say, and since Red Cross was . . . You know, 50 percent of all blood handling was done by the Red Cross, and we felt like in order to make sure that the rest of the industry would do what was necessary to make the safest blood supply possible, we needed the Red Cross under consent decree. After the Red Cross came under consent decree, two or three other blood organizations also entered into a consent decree. So for a while there, I think we had 75 to 80 percent of the entire blood industry under consent decree.

RO: That's interesting. You mentioned along the way user fees. The field organization really don't get much out of user fees, do they?

RC: We got a little bit out of user fees under the Prescription Drug Marketing Act, but it was, everything was additive. What the field was doing routinely didn't count;

it had to do more in the way of preapproval inspections to get any money from the user fees.

User fees had been put forth during the entire eight years of the Clinton administration as a way to help in balancing the budget. For anything other than the approval of new drugs and biologics, the Congress has frowned upon it. It was put forward for medical devices; it's never been approved. It's been put forward for imports, you know, how to do import operations better; it's never been approved. In fact, the Congress has really been upset with the department and with the Food and Drug Administration for bringing these budgets forward that have user fees in them. But, as part of the department and the administration, the agency goes along with this and puts user fees in. I think maybe in the year 2000 that didn't happen, but I'm not sure.

RO: Generic drugs. Just . . . I think you were probably the ACRA or shortly after the agency encountered the generic drug problem.

RC: Shortly after that. I remember John Taylor was the ACRA when the initial discovery that people within the Center for Drugs had taken bribes from the industry, and we both were commenting to one another that, "Well, thank goodness, it's not ORA. Gee, that's just a few people in the Center for Drugs, and it's their problem." Well, of course, it wasn't just their problem; it was an agency problem. It became a fixation of the agency probably for the next two to three years.

John Dingell, who was the congressman, head of the House Commerce Committee, held a number of hearings. He had his own staff investigators and he had GAO and the IG totally infiltrate the Food and Drug Administration, both headquarters and the field, trying to find areas where perhaps other attempts at bribery had taken

place, perhaps the agency was falling down, we were too cozy with the industry, you name it. Dingell was having somebody investigate all of that.

One of the things that came out of that which we touched on just briefly before was the fact that FDA had no designated criminal investigators at that time. The agency had always conducted criminal investigations to a point and felt like if it needed to have a criminal investigation conducted that we could do it. We didn't have anybody in the series called GS1811, which is the criminal investigator series, but the IG's office did. The Office of Inspector General folks were 1811s. So Frank Young initially got Dingell to agree--well, Dingell perhaps got Frank Young to agree I should say--that the Office of the Inspector General should come in and help the FDA.

So this was a gut-wrenching experience at the FDA for a while in the fact that we were pressed upon to come up with a memorandum of understanding between the FDA and the IG's office about their helping us and what they would look at, what we would refer to them, and this just did not set well with us at all. It was our opinion that in order to make this not happen, if you will, we should create our own Office of Criminal Investigations and that FDA should hire its own criminal investigators, because we were concerned that the enforcement part of any action that was criminal would be taken away from the agency, and we didn't want to do some initial investigations just turn that information over to the IG's office, let them then run with the ball, and the agency be left high and dry.

So during this time, Frank Young departed. There was an interim time when Jim Benson was the acting commissioner. Then David Kessler became the commissioner. It was shortly before Kessler got there, I think, that we decided that we would create this Office of Criminal Investigations. Yes, I'm sure it was. I think Benson was there when we decided to do this. But Kessler really got involved in making that happen and agreeing that it was a good thing to do and got behind it and supported it.

It was given to me, I mean, it was an ORA function, I should say, to create this office and make it viable.

This was one of the more challenging assignments that I think I had as the ACRA, but also I think it was interesting and as far as I'm concerned ultimately rewarding because you had the traditional people in the agency who felt like we didn't need criminal investigators; we could do it ourselves. You had external factors such as the Congress and the IG wanting us to either establish them or give the job to . . . If we didn't establish it, the IG was going to take it over. So it was a necessity.

So then what we tried to do was involve as many people as we could in ORA to help in recruiting and selecting a director in setting up this office. We went through some reiterations as to what was the best way to make that happen. But as it turned out, we recruited Terry Vermillion to be the director. Terry had twenty-plus years of experience with the Secret Service, and we set up our separate Office of Criminal Investigations. We decided not to co-locate them with other field personnel within ORA, and we really created a regulatory side of ORA and a criminal investigative arm of ORA.

Initially, of course, there were places where that worked well and places where it didn't work at all. I think a lot of the problems had to do with poor communication or a lack of trust. Over the years many of the initial concerns have subsided because it has shown that it can work.

Well, it just so happened that shortly after the office was created, there was the Pepsi tampering incident. Those guys from the Office of Criminal Investigations went in and conducted investigations much faster than what we had done traditionally. They got the results much faster. They had the network set up. The interesting part that made this work so well, I think, was they had a network already established with other criminal investigative offices, with state police offices, with U.S. attorneys that we just didn't have in the traditional FDA, and they brought that to bear not only in the Pepsi

tampering but in other tamperings as well. So they showed results early, they were positive results, and I think people started saying, "Gee, maybe these guys can do this work. Maybe we can work with them."

It has developed now, I think, into a pretty good working relationship, and the Office of Criminal Investigations says, "Look, we don't know a thing about drug GMPs, and we don't want to know about drug GMPs. That's somebody else's responsibility. But if during an inspection of a drug GMP the regulatory inspector finds that perhaps somebody's been keeping two sets of books, that's when we're interested." And that's when that type of investigation gets referred to the Office of Criminal Investigations, and that has worked very well.

RT: Now one of the differences in the 1811 series and the regular Food and Drug consumer safety officer series is the authority to carry firearms.

RC: I thought that's where you were going when you started this, yes.

RT: So, of course, back in the days of the Bureau of Drug Abuse Control in the agency, apparently there was a recognition at that time when they took that function over to the Department of Justice that there were some situations in which self-protection and so on was in the interest of the investigator for the agency.

RC: Yes, the bearing of arms was one of the big controversies also when we established this office. There were many people who felt like this is not the FDA. The FDA doesn't need to have gun-toting investigators.

In talking to Terry and in talking to other agencies that had criminal investigators--because one of the things I did was to talk to other agencies to see how they would set up an office--it became quite obvious to me that you needed to have individuals who

were trained in firearms and who could carry them when necessary if you were truly going to do criminal investigative work.

One of the negatives here also was that right before we created the Office of Criminal Investigations, the agency conducted a raid on Dr. Jonathon Wright. We actually supervised it although it was done by one of the county sheriff's offices in Washington. The FDA didn't have any weapons, but the county sheriff's office did, and one kid from the sheriff's office, or one person from the sheriff's office, went in to Dr. Wright's office with his gun drawn. He never pointed it at anybody, but he did have the gun drawn. That got a lot of negative publicity, and, of course, at the time that made people in headquarters all nervous and wringing their hands, worrying about is that what we're going to turn into when we create this Office of Criminal Investigations.

The office has existed, I guess, since about 1992. Fortunately, no one has yet had to fire their weapon. There have been many instances where the Office of Criminal Investigations in carrying out their activities have encountered subjects who did have weapons. They have had to make arrests, which they have authority to do; they've had to seize weapons, which they have done; and had they not been in a position to use that weapon if necessary, I don't think they would have been able to do what they did, nor would I have wanted to put them in harm's way without those weapons.

So if you're truly going to have a criminal investigative unit--this is what was told me and which I now believe--you've got to have people who are trained in firearms and know how and when to use them. One day there will be an occasion when they will have to use that weapon, and I just hope that whoever is at the helm of the agency will realize that there will be inquiries and there will be press, and they'll have to handle it appropriately.

RO: What kind of workload does that group have?

RC: They are busy. They want more people than what they have.

RO: How many people do they have?

RC: They have about 150, of which about 120, 110, 115 are actual investigators out there doing the work. They're involved in everything, in every area of FDA business, from food imports, to the importation of body parts, to fraud, to methamphetamines, to misuse of . . .

They were involved, for example, in some breast implant activity when the agency said, "No more latex implants," and we found out that folks were importing breast implants. The Office of Criminal Investigations got involved and actually a doctor was arrested and sent to prison because of his illegal activity in this area. So there's plenty of work for them to do.

RT: Now as far as foreign inspection activities, do you care to comment about how that's changed in the recent past?

RC: Sure. I think just the world itself changing and that truly we are more global now as a society, not only in drugs but in foods—especially in foods. People want whatever food they want whenever they want it, and there's only one way they're going to get them, and that's through imported products. The same is true with foreign-made drugs that are approved for importation into this country.

So the agency has had not only to take its resources and inspect domestic plants, but now we've got to inspect foreign manufacturing and processing plants as well.

RT: Initially we had a pretty small cadre of folks doing that.

RC: We had a very small cadre. I think when I went to ORA there was maybe twenty-five, perhaps fifty people doing that kind of work. Then we had to up that number, and we eventually had like three hundred people who were available to be on the foreign inspection cadre. We changed some of the parameters, where before I think you were gone a month at a time or something like that. Anyway, we made it more conducive for people to want to join the foreign cadre and to make the workload a little bit better and not such a drudgery.

But the other thing that has happened too is the congressional passage of the FDA Modernization Act which now requires the agency to work with foreign governments to establish a system whereby we will allow a foreign government inspection to take the place of the FDA inspection. This is something that I think the agency has felt was needed for years. But we've always been concerned about whether or not the inspection will be equal to the inspection that the FDA would make and whether we can rely on that country's inspection report. Will they even share their inspection report with us? Will they do training with us? These types of things had to all be in place before these--as they want to call it under the act--"mutual recognition agreements" will be put in place.

So the agency has started down that path in both the drugs and device area. There's activity going on now in the foods area as well. So I think in the future there's going to be much more cooperation between U.S. agencies and foreign agencies in Food and Drug work.

Also during this time, we had the creation of the European Union. So the agency went from dealing with not just individual countries in Europe, but now this European Union and all the politics that went into that. Also, Australia, China, Pakistan, India. These countries--China, India, Pakistan--are now producing a lot of bulk drugs and also some medical devices that come to this country that we have to be concerned about and we have to spend resources examining.

All these things have added to the workload of the field organization, and unfortunately, we never got the corresponding resources needed to really do all the things that were required. The domestic inspection program has suffered at the expense of the foreign inspection program--not that they need to be equal, but certainly you would want to have resources to do the type of inspection program that you need to do in all areas. Of course, foods took the brunt of that. The food programs suffered a loss of resources for years, primarily because we transferred resources from foods to medical devices and to drugs.

RT: I think it was the GAO study earlier that focused attention on deficiencies in the food and generated the state contract program.

RC: Exactly. You could go back to the sixties, seventies, eighties, nineties, every time GAO did a report on foods . . . And Dingell had a lot of them done, especially if you remember the pesticide reports too in the eighties and the nineties. You know, FDA needed to be doing more. Well, at the same time we were being criticized for not doing enough in the drug and device areas. Plus when you had the new program come in on the approval of drugs and biologics within a certain time frame that again put more emphasis on making inspections and doing them in a timely manner, and you were expected to do them. It didn't matter if you didn't have all the resources you needed.

So the agency, I think, has always been faced with, ever since I can recall, a task that demanded more resources than what they had.

RT: They had a few initiatives, although they've never come to fruition, to take the food regulatory function from this agency and combine it with another existing agency. Do you see that as dormant now or . . . ?

RC: It might be dormant, but it's not dead. I think that will continue to resurface. It's something that Vice President Gore, when he started reinventing the government, pushed for a single food agency. It is now something that the National Academy of Sciences, in their study of the food safety in this country, has recommended that, if not a separate agency, then at least a separate person to run the food safety program, and have control over the budgets of Ag Department, FDA, and other agencies involved in foods. There's a part of me that says I think you could probably do a better job in the food area if you could combine a number of these agencies, because I think at one count there was twenty-five different programs or something like that involved in food safety.

I do believe that there's a tremendous waste of resources between FDA and USDA in the inspection of some of these plants. I don't know if that can ever be overcome as long as you have two separate agencies. We tried to come up with a Memorandum of Understanding this past year, my last year, with them on avoiding duplication in plants that are under dual inspection, and we didn't get very far, to be perfectly frank, not nearly as far as I would have liked for us to. Maybe the next generation will. I hope so, because it's just ridiculous.

But you've got to change some laws to make the food program better, in my opinion. USDA has got to be able to get out from under this continuous inspection program that they have to pursue because the law mandates that they do. They've got a tremendous employee union. And their employees don't believe that they should have to do some of this work that the FDA investigators and inspectors do, or that they need to be better trained to do that and that type of thing.

So there's a lot of obstacles to overcome before any major changes are going to take place. But still the program is underway, and I do think that it's about time that more attention is paid to food safety, and for the last two years it has, and I'm glad to see that in food safety.

RO: We used to be quite concerned about making our mandatory inspections in drugs. Are we concerned about that anymore? Do we make them? Or aren't we concerned?

RC: I don't think that the fact that we aren't concerned is the right way to put it. We just haven't had the resources for years—I'm saying five or six years—to do the mandatory biennial inspection of drugs, devices, biologics.

One of the things the agency did was, in the blood safety initiative, we decided that we needed to inspect those blood firms once a year. Well, how do you do that? Well, you take resources from other areas in order to do that. So once we did that then we started going away from drug inspections once every two years. The number of medical device manufacturers continued to proliferate, and yet our resources for inspecting them did not.

So I think in the drug and device area it's probably like once every four to five years now on the average of what the agency is getting to. This includes the veterinary drug area. Food inspections in the area of once every five to ten years, depending on whether you do include state inspections or not. So the agency has now . . . Over the last two or three years, what we started to try to do was say, "If we can only inspect 'X' number of firms, let's try to make sure that those are the firms that truly need to be inspected. What drugs are they making? Are they critical? You know, even though we haven't been in the plant in three years, does that matter? Are they making . . . ?"

(Interruption)

RC: In the FDA Modernization Act, there is again a requirement there for the agency to come forth and tell Congress how they're doing in meeting the statutory obligation and how they intend to meet that. So I think it'll be interesting to see how that plays out

in the next few years and whether or not the agency would ever get anymore resources to do this or whether the agency then will be able to change its modus operandi, go with the plans of setting a tiered approach to inspection that includes priorities based upon risk, based upon product, et cetera, and see if the Congress then will say, "OK. We'll buy that."

RO: You know in the last, oh, five, six years anyway, the agency's placed an awful lot of emphasis on approving drugs, and there's been an awful lot of drugs that have been approved on a fast track. Do you think the agency's going to run into trouble on some of those?

RC: I think perhaps it already has. You know, I think that there will be instances where there will be drugs that turn out to be approved that maybe if we'd had time to study them further would not have been approved so quickly. But that has to be balanced, I think, against the fact that at least there are new entities out there now that are available to people, and I really think when you look at the total health care between new drugs that are now available and new devices that are now available, the agency has an obligation to weigh the safety and effectiveness of those things against the risks, and based upon data that's available to them, they've got to make those decisions.

I think, yes, there will be times when that decision may come back to be the wrong decision. But you always find out more about a product after its approved, after you've had . . . Even before there was this Prescription Drug Marketing Act which required all this fast turnaround. The only way it's going to change is for--and I'm not sure it should--but you'll have to have another catastrophe in this country similar to what thalidomide was back in the fifties and sixties in order for that to change any.

RO: That's what I was going to mention. Thalidomide has been approved again.

RC: Now it's been approved again, but for a different use.

RO: I know.

RC: But the agency struggled on that one, too, from the standpoint that even though you've got all these restrictions associated with its approval and its use, I think deep down there is this fear that it's not going to be used for what it was approved for, and you will again have people misusing this product and catastrophes happening. But it takes a lot of people . . . You've got to screen your female patients before you use this thalidomide, and hopefully people will do that.

RO: And it won't be diverted for other uses.

RC: Yes, it won't be diverted for other uses.

RO: Off on another subject, ORA 21, which you are a father or uncle or at least a part of. What is it?

RC: ORA 21 was really created as part of reinventing government initiative from Vice President Gore. I mean, it developed into that. I think we might have actually started before that, but regardless.

We took a look at the organization and what was going on, and the fact that we weren't getting more resources, and we weren't having the impact that we wanted to. We were missing deadlines on biennial inspections; we had people that perhaps were doing things that were no longer necessary to do; and we said, "Let's create an environment of change to try to change the organization to adapt, to be able to be prepared for the 21st Century." And we called it ORA 21.

Part of that was a change in organization, which included the laboratory reconfiguration and perhaps district reconfiguration as time would allow, but it also included a change in attitude on how to look at what we did. For example, from an industry inspectional process, we tried to change the attitude from one of let's try to find a fault in this firm when we inspect it, a "Gotcha!" mentality, to let's just try to make sure that whatever inspection we do we're trying to achieve compliance as the end result. If that can best be done by a voluntary action on the part of the firm, let's give the investigator credit if he or she made that happen.

This wasn't necessarily a new philosophy from voluntary versus regulatory or nonvoluntary enforcement done and the subject has been debated in the FDA for years. Both of you know--one time I guess we had an associate commissioner for voluntary compliance or something like that.

But as I recall--even when I did inspections, and certainly, you know, it has continued--investigators were often criticized if they didn't get violations during inspections. If they didn't issue a 483, regardless if it was a one-item 483 or a hundred-item 483, they were criticized. If the firm was in good shape or created a situation such as voluntarily destroying things, we needed to create an avenue whereby instead of a seizure taking place, which the investigator would have gotten credit for . . . If a voluntary destruction achieved the same purpose and faster than any seizure ever could, the investigator would be given credit for that and thanked for a job well done. It was just as important for that to happen as it was for a seizure.

Well, we were able to do that and we created a system for that, but, of course, the number of seizures fell dramatically. So then you've got the outside critics--and some inside--saying, "See, the FDA's not enforcement minded anymore. It's obvious in their numbers. Their seizures went down. Their injunctions went down." So you had to deal with that type of look-see and prove to the folks, critics, that what you were doing was still just as important today as it was yesterday, and you really hadn't

changed your standards; you've just changed the way that you were trying to do certain things.

When you go back to the early nineties, and we talked about generic drugs, we must have had twenty or thirty generic drug firms under injunction between like '92 and '95. Well, you know how many injunctions you can bring against generic drug companies? You don't have to put every firm under injunction, and I think those that needed to, we did. Even some brand name manufacturers we put under injunction if we needed to.

The idea was if you need strong enforcement, fine, do it. If you don't, then look for other means of achieving compliance. We were criticized from the standpoint that some of the hard numbers dealing with enforcement went down.

Now at the same time that was happening though, the number of criminal investigations, the number of prosecutions for criminal violations were going up. But we made the early mistake of not counting those and publicizing them, because the traditional way of criminal investigative units, just like the old FDA was, "We're just doing our job; we don't want to publicize this," et cetera, et cetera, et cetera. We eventually were able to put some statistics into the annual report that I think showed a pretty good balance.

The other thing that then created an interest on the part of some people outside the agency was to start looking at the criminal arrests and prosecutions and whether or not they were the right thing. So, you know, it constantly changes from one way or the other.

But the biggest thing to think about also in ORA 21-I've strayed here a little bit-was, who are our customers? This is kind of what this new reinventing government came to be. The customer first and foremost has always been the consumer. But the customer of FDA's regulated products also includes health professionals who use those regulated products. There are times when even parts of the industry might be

considered a customer, even if it's a reluctant customer. So we had situations where we had people playing "Gotcha!" with the industry, and we wanted to change that.

We initiated a number of grassroots meetings with all segments of the industry that we regulated. We sat down; we listened to them; we talked to them. What is it you want the FDA to do? How can we do our job but maybe do it better? Are there things that we're doing that you feel like we shouldn't be doing, et cetera? We listened to what they had to say, and we made some changes in our operations. Probably the biggest area is the medical device area, and I can talk about that a little bit if you want me to.

RO: Sure.

RC: One was in inspections of the medical device industry. Whether or not the agency, for example, should preannounce its inspection. This was something that again has been a subject that's been debated in the agency for years. Is a surprise inspection the best mode of operation? I think the gut reaction of most people is, "Absolutely. You need the surprise inspection." But when we stopped and started looking at all the inspections that we do, we discovered that there were a lot of inspections that we called ahead and said, "We're coming," and we scheduled them.

That was true of every foreign inspection that we made. Of course, that was primarily logistically related. But it was also true of clinical investigator inspections, there were certain preapproval inspections that we had said, "Yes, we want to make sure the right people are there," et cetera. So when we got through, we said, "Heck, maybe if we can set forth some criteria here"--because this was something the industry wanted--"that, okay, we can try this out."

So we said if your previous inspection was No Action Indicated--or, as we called it, Voluntary Action Indicated--we would call and schedule an inspection with you. But

in return, we wanted certain people there, we wanted certain records available to the investigator or team of investigators before we made that inspection. We also then changed the way we did 483s, because many times when we would make the inspection and a firm would voluntarily correct something, we wouldn't necessarily annotate it on . . . We would not put it on the 483. We would mention it in the report.

Well, the report is not what hits the press. The 483 does. There was such a demand for one company to get another company's 483s under the Freedom of Information Act that we decided that it would only be fair if we annotated the 483 and said the firm made the correction. Or if the firm promised correction of this, we would say, "Fine. When are you going to do it?" And if they would make a commitment that by such-and-such a date they would correct this problem, we would annotate that on the 483.

The other thing we would do is we would send them a post-inspection letter. The industry said to us, "We have no idea whether we passed your inspection or not. We get this 483 and maybe months will go by before we get a warning letter. We know if we get a warning letter, we didn't pass. But what happened?" So we said, "All right. We'll send you a post-inspection letter."

So those three things were piloted, and we got good results both from the investigators and from the industry, I think. The agency is now trying this approach to other product lines, except for the food area, and there's parts of me that says, you know, even in some food establishments you could preschedule an inspection. But filth . . . You don't want an opportunity for somebody to sweep the floor clean if that indeed has an impact upon that operation or clean the pipes, et cetera, before we get there.

But there are many instances like that I think that the agency can and will be using in the future that is different from the old way of FDA doing things, and still, hopefully the end result is compliance with the standards and protection of the

consumer, which is what we're about. That's what we're there for. That's what it's all about.

RO: So essentially ORA 21 then is taking a good look at how we do our business.

RC: How we do our business, how we were organized, etc.

Now, having said all that, one of the down sides of ORA-21 was that for a while we had what we termed a change letter, and what we did was we allowed any employee of the organization--whether they were in California or Rockville or New York--to suggest things or to complain about things or whatever. Part of that grew into just a few people continually criticizing everything that we were trying to do with respect to change. Some of that criticism helped us and some of it was just the same old "stuff," you know, this back to your question hours ago on morale. (Laughter) After a while it affected my morale, and I said, "The heck with this. Enough of this change letter. We'll still get folks input, but I think we could do without this. We tried it, we got some good results, let's move on to something else."

At the same time, we had to create a little staff of three to five people to do this ORA 21 change. We created that staff with the understanding that one of the staff's job was to some day come back and say, "OK. I'm not needed any longer." Well, that hasn't happened yet, and it's still my hope that under the new ACRA that eventually that office will go on and do other things besides ORA-21.

RO: Is there kind of a measure-act-measure or something of what ORA 21 is accomplishing?

RC: That was one part of this, in that one of the tasks of each district was to pick a segment of the industry, no matter what it was, whatever was unique to that district, and

go out and see what the in-compliance status of that industry was. Then either have some workshops, do some inspections, take some act, and then measure again to see what impact they had on the compliance status of that industry. That's right. It worked very well, for example, in the medical gas area.

If you have a workshop and you have a thousand people at your workshop, maybe that thousand people represents five hundred firms. Well, how long is it going to take you to inspect five hundred firms? A heck of a lot longer than it is to have that workshop, and maybe the people will really take from that workshop and go away and make some changes, and that's another part behind it.

I think there's something else I wanted to say there, but I don't remember . . . Oh, the other thing was with this. Here, let me continue.

We traditionally in ORA had every district aligned the same way with the same type of branches. You had an inspection branch, a compliance branch, and you had an administrative branch, and that was true whether you had a district of fifty or sixty people or whether you had a district of 250 people. So we said, you know, let's try some experiments here. If you want to combine two branches, fine. We will give you the opportunity to do that. We will not criticize you for doing that. You don't have to do something in Nashville the same way you do in Seattle, if that's not right for you.

So in some cases we had branches that were combined. The reinvention thing required us to reduce the number of mid-level managers in our organization, which then meant branch chiefs, in some cases supervisors. So we went to some team approaches in certain places. The positive side of this is it worked in some places; the negative side is it didn't work worth a damn in other places. Especially we allowed too many supervisors not to be . . . We didn't replace enough supervisors when they left. Consequently, we now, in the last year, year and a half, have had to hire new supervisors, because the span of control was just too much. The teams didn't work in some places.

The actual combining of the branches for the most part has not been that bad. It was the team approach that didn't work in a lot of places. The team approach being you take four or five investigators and you create a team, and you let them schedule when they want to make inspections; you let them handle this, that, and the other thing. It turned out that somebody didn't want to be the leader, or somebody didn't want to take responsibility, or they'd have a meeting when they should be out making inspections, you know, these types of things, and management was aloof to a lot of this.

So that part of it didn't work, and hopefully we've realized that, and we're trying to correct that, which is part of what all this was about anyway. I think if you realize your mistakes and you learn from them and you can change them, then fine. If you don't, you're just going to be stuck. But every organization in my mind continually needs to take a look at what it's doing and try to reevaluate it.

RO: So are you now going to mandate more of what the field structure will be like?

RC: No, I don't think so. But we were saying, "If you need that supervisor, go ahead and hire him. Don't continue with the team approach if it's not working."

RO: You remember Sterk Larson. Something like this would drive Sterk Larson crazy.

RC: Yes, because it would . . . Well, for a variety of reasons. (Laughter) But Sterk and Keith (Dawson) were both very process oriented, and they were very analytical, and they needed to keep track of things to the nth degree. When you start fooling around with stuff like this, it would blow their minds.

RT: Well, change is inevitable I guess, and one change that seems to be evident, when you left, there was a search for a replacement and a selection was made outside the agency. Was that indicative of the need for continuing change and process?

RC: No, I don't think so. I think it was indicative of the fact that very few people wanted to apply for this job.

What I tried to do was I tried to get the regional directors to apply; I tried to get the district directors to apply. And I also encouraged Dennis Baker, who ultimately got the job, to apply, because I thought there were people at the state level who would be good candidates. I didn't necessarily think that they would get selected, but I could tell that people were reluctant to apply for the job and for a variety of reasons. Of course, that's an individual decision that people have to make.

Let me digress and just say the same thing happened when I was appointed the ACRA. Frank Young *I know* tried to get certain regional directors to come in and take that job, and they wouldn't do it. They said they'd hold Chesemore's coat, and they'd support Ron. "He's doing a great job. Let Ron have the job." And, you know, I kind of got that job I think probably out of default. So this time I told people that if you don't apply for the job, then be prepared for whoever gets it. "But," I said, "you're not going to have any influence over it if you don't try for it."

So I know a nationwide search was undertaken. I called Dennis Baker. He wasn't going to apply, and I encouraged him to apply. I said, "I think you probably could do this job." I know the three finalists for the job, and I honestly believe that of the three finalists that Dr. Henney made the right decision in selecting Dennis Baker, even though he wasn't from the FDA. He had a very similar job with the State of Texas. Texas is only one state, but I think its budget was probably bigger than the FDA's budget, and Dennis was involved in all the programs--not just foods or not just drugs, but in all the programs.

So I think he was a good selection, I think he'll do a fine job, I wish him nothing but success. Of course, it will take a while for him to know the agency. It will take perhaps even a longer time for people to feel comfortable with him. It's just, as you say, change is inevitable, but a lot of people don't like it. But I think his actions will speak for him.

RO: I think especially, Ron, that since now the ACRA is back in an agency policy role, an outsider in that position might raise some questions.

RC: Yes, but I wouldn't . . . Had Kessler not made such a tremendous change in the way business was done, I would say perhaps that would be more important than it is, because, you know, the ACRA really hadn't been involved in some of those . . . Like the tobacco program, I was not really involved in that and in its formations, et cetera.

So one of the things I regretted when I made the decision to retire--or after I made the decision to retire--was that Dr. Henney did get that job, because I knew that she would probably elevate the ACRA back. I enjoyed working with her before, but at the same time it was time for me to go on and do other things.

RO: If you had known Dr. Henney was coming back, would you have retired when you did?

RC: Well, she and I had a discussion. I was in Albuquerque in 1977, and she and I had lunch, and she said, "Can I count on you to be there?" And I said, "Well, I was" I had at least one more year to go before I was fifty-five, that was it. I said, "Well, at least for another year." But I had retirement in my mind then, and I said, "Why would you want to come back to the FDA?" And she said, "There's only one job that would bring me back to Washington, and that would be it."

Well, as time went on, it seemed more and more that Dr. Friedman was obviously the . . . He was doing a good job, and the secretary and he got along quite well. The Henney nomination continued to just pthh, pthh, pthh, and I had to make a decision.

I haven't really answered your question, but I think it was just time for me to go. But I did tell Dr. Henney that I would miss working with her. And I think both of us were looking forward to working with each other, and we did for a couple of months and that went well. But, you know, it'll go fine for Dennis, too.

RT: Well, of all the retirements that I've ever attended of FDA managers, yours was certainly attended by a larger number of people than I've ever observed. I think you had 540. So that's real accolade to be seen to you.

RC: It may be 450, I don't know. But it was a large turnout. I was very . . . You know, I felt very honored, Bob, and very fortunate to have worked with so many good people and that they, you know . . . Obviously, I guess they came because they wanted to—it cost them twenty-five bucks—and not because they had to. So it was a great evening, and I'm glad I had the opportunity to work for the Food and Drug Administration.

I'm sure none of us ever thought we would ever do the things that we did with the agency when we started. The only thing I remember was when I applied for that internship job way back when, the only people that told me, "You don't want to go to Washington," I later found out were people who had never been there. (Laughter) So I was a very lucky fellow from a lot of respects.

RO: Is there anything else you'd like to add? We've kind of structured you here a little bit. You must have some of your own topics you'd like to cover.

RC: Well, one would be the better working relationships we enjoy with our state partners. I and others worked very hard through AFDO and other organizations to increase the federal/state partnership. The new Food Safety Program, at least from the inspection standpoint, should benefit from this. I worked with a lot of very dedicated people in the states as well as FDA.

The only other thing I would add is that I was really fortunate in the early part of my career when I came into headquarters. In being in financial management, one of the things I really liked about it was you got to go and interact with the commissioner. I'll never forget when Dr. Edwards was commissioner and I had the cosmetics account in the Budget Office, and Mickey Moure I'm sure got him to call me about a question that he had regarding cosmetics and the budget for cosmetics and however many people there were, and I nailed it. (Clap) (Laughter)

But I tell you, just the fact that the commissioner would call, you know, a peon and interact with him meant the world to me. I never forgot that. But I was also able then to interact with other commissioners as time went on. But I also never forgot that, and in my own career, I tried then, you know, to make people, regardless of whatever grade level they were and whatever job they had, feel that they were an important part of the organization. I think it paid dividends, and I think it's how you get people to . . .

I used to relish the fact that I could remember a lot of people's names. It wouldn't matter whether I was in the field or at headquarters, I was just fortunate in having that ability. Now I wish I still could remember, you know, your name, Bob. Sometimes I can have problems with that.

RT: Speaking of commissioners--and you've served under a number--and we've talked a little bit about Dr. Young and Dr. Kessler, and you just mentioned Dr. Edwards. What about some of the other commissioners that you were the acting associate commissioner under?

RC: I was the acting associate commissioner under Don Kennedy. Don Kennedy was another extremely bright fellow and did really well in testifying before Congress. I thought he did the best job until Kessler came along; then I've never seen anybody testify better than Dr. Kessler.

Dr. Mac Schmidt, I think sometime in his career he was a teacher. I'll never forget, he used to do his own typing, and he also had a calculator. Every time we would send up a budget chart, and we'd go up then the next day and have a meeting or something, he had run through the numbers, and he would say, "Ahhh, I think you, you know, these numbers don't add in column 'X'." (Laughter) So that's when I first found out that whatever you send forward, the first thing you've got to do is make sure the numbers add. (Laughter) But these guys were all so . . . I found every one of them to be very personable. Art Hayes was very personable, too.

I'll never forget when I was at facilities, you mentioned . . . You asked me was there anything I remembered about that. We were trying to get, I don't remember whether it was New York or whether, maybe it was headquarters facility done, and Hayes said, "I want to meet with the head guy at GSA who's in charge of the buildings." So, you've got it. I set him up, had the meeting with, it wasn't the administrator at GSA, but it was a deputy administrator in charge of public funds or public buildings or whatever.

But we went down there for that meeting, and obviously this guy had no intention of ever meeting with the commissioner of the Food and Drug Administration. So we met with one of his, you know, probably third-ranking subordinates, and they put us in a little room that might have been an 8' x 10'. Hayes sat there and he talked to this probably GS . . . You know, he's probably in the SES, but he was a political appointee. And nothing ever came of it. I thought, so this is the way that the FDA commissioner gets treated. That's just what you had to deal with. That was some of the realities of life.

But I was fortunate enough to be around these guys and pretty much enjoyed all of them. They all had their passions, and they all had their quirks, which I'm sure we all do. So that, I think, kept me interested in staying with the FDA. I had so many jobs at the FDA that that kept me interested. As I said, I knew I didn't want to be an inspector all my life; I knew I didn't want to be in the finance area all my life; and these opportunities came along at very fortunate times, and I was lucky enough, you know, to be selected for the jobs and wound up as the associate commissioner for regulatory affairs which was never a dream. It just happened, and I'm glad it did.

RO: Well, Ron, we want to thank you for the time you've given us.

RC: Oh, my pleasure.

RT: Thank you very much.

RC: Thank you. My God, we went right on along, didn't we?

(Interruption)