

**History**  
of the  
**U.S. Food and Drug Administration**

**Interviewee:** Russell J. Abbott

**Interviewer:** John P. Swann, Ph.D.  
Robert A. Tucker

**Date:** March 23, 2011

**Place:** Rockville, MD

## INTRODUCTION

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

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

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RUSSELL J. ABBOTT

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CASSETTE NUMBERS: 1 and 2

GENERAL TOPIC OF INTERVIEW: History of the Food and Drug Administration

DATE: March 23, 2011

PLACE: Rockville, MD

LENGTH: 150 minutes

INTERVIEWEE:

INTERVIEWER(S):

NAME: Russell J. Abbott

[REDACTED]

NAME: John P. Swann, Ph.D.

Robert A. Tucker  
Parklawn Building  
Rockville, MD

FDA SERVICE DATES:

FROM: December, 1969

TO: December 31, 2011

LAST FDA POSITION HELD: Deputy Commissioner for Administration, Office of the Commissioner

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Interview with Russell J. Abbott

March 12, 2011

TAPE 1, SIDE A

RT: This is another in the series of FDA oral history interviews. Today, March 23, 2011, the interview is being held with Russell J. Abbott, recently retired Deputy Commissioner for Administration in the Office of the Commissioner, FDA. In addition to Mr. Abbott, Dr. John Swann and Robert Tucker of the History Office are participating.

Russell, we like to start these interviews with a brief review of your personal history, where you were born, raised, educated, any interim employment that you might have had prior to joining FDA, particularly if it related to your career in the agency, and then pick up your career with FDA, going through the various responsibilities and positions you've held up to the present time.

With that introduction, we'll let you start, Russell.

RJA: Okay. I was born in Ft. Riley, Kansas, in 1943. My dad was in the mounted cavalry, imagine that, actually rode a horse in World War II. From there, after the war, a few years after that, we relocated to -- my dad was in the restaurant business, and so we relocated to Virginia -- and I ended up going to grammar school -- they didn't have middle schools then -- and high school in McLean, Virginia. Finished McLean in '61, went to Virginia Tech, then known as VPI, graduated from Tech in 1965.

My dad, by that time, and my mother and my brother all worked for the Central Intelligence Agency, and since they had gone through a long, very long period of background investigations, I was approached by the agency in my senior year and asked if I wanted to work for them. I graduated, and I did. I spent I think a few years there, two or three years working for them in a variety of places in Europe and Southeast Asia and a few other places.

Then went to graduate school at American University, got my MBA in 1970. I then saw an advertisement in *The Washington Post* for a position with the Food and Drug Administration. At that time I interviewed with an unknown company called Data -- I think at that time it was called Data Control Corporation? [Note to editor: Should this be Control Data Corporation (CDC)?] It became a very big, important company in the computer industry, and I suppose if I'd stayed with them, I would have retired quite wealthy if I'd bought their stock.

In any event, I went with FDA, thought I'd try the feds out, and went to work for them in, I believe, the end of '69 in Crystal City, Virginia.

JS: You might say something about what your major was in college. Also, you mentioned you spent some time with Central Intelligence, and if there was any interest in continuing a career there, if there's anything you can say about what you did, that's fine. If not, that's fine too.

RJA: Sure. Well, my undergraduate degree from Virginia Tech was in business

administration with a major in personnel administration, and my MBA was Master of Business Administration, and it was a . . . My area of study was information systems.

Actually, I had considered staying with the agency, but I'd spent a lot of time overseas and I was probably ready to come back to the States, and I wasn't sure that's what I wanted to do as a career or not, and I was weighing my options at that time. The Food and Drug Administration just had some kind of appeal to it, and to this day I'm not sure. But I wanted to try it out and see what it was about.

Interviewed with a gentleman named Charlie Coffendaffer, and was offered a position, started my career in the Commissioner's Office and ended my career in the Commissioner's Office, oddly enough, with the Division of Management Systems, I believe it was called.

RT: So, your work at that time was still in the field of information management?

RJA: Well, it was. There wasn't much around, if you think about it. I mean, it was 1969-1970. The machines were as big as this office. There really wasn't much in the FDA or any other place in the federal government where you'd actually be doing the kind of work that I'd studied. I suppose you could get some type of programming or writing programs, but that really wasn't my interest and I wasn't really educated to do that. The gentleman I interviewed with, Charlie Coffendaffer, was interested in me from a management standpoint, use my skill set doing studies, analyses, that kind of thing, and that's primarily what I did when I first came to FDA.



In fact, the first study that I was involved in was when FDA switched organizationally. You probably remember that FDA was organized much different than it is today. So, for example, an organization, the Bureau of Medicine, which had the compliance function, was located in a Bureau. So the compliance function and the regulatory function were separated from each other, so part of this giant reorganization of the FDA involved setting up organizations that were self-contained, where they had the compliance function and they had their marketing function and they had the communications function all organized in one organization, so they weren't focused on medicine, they were focused on drug products. That was before biologics and before medical devices and before rad health, so it was mostly foods, drugs, veterinary products.

JS: Right. And I think there was a study, the Malek Study, in the late '60s . . .

RJA: Yes, late '60s.

JS: . . . that looked at the way we were set up, but, as you said, it focused on functional systems rather than by commodity. It sounds like one of the early things that you worked on was how this reorganization was really going to take place and get implementing.

RJA: Yes. I was a young Grade-9 management analyst, and the entire study was, I remember, being run by a GS-13, and the grade structure was much different back in those days. It seems like we were much lower graded and responsibilities were much

higher at the lower grades as opposed to what I see across the federal government today. The gentleman who ran the study became a Catholic priest later on after he left the FDA, and I'm not sure it was because of the study or not that drove him into the priesthood.

Getting off-topic, he was a very bright management guy, and they actually used him to do exactly that; he was actually in Richmond, Virginia, as a manager doing, you know, because they have lots of assets and lots of money and lots of stuff to be managed, so that's what he actually became. He was a man of the cloth.

JS: Everybody needs good organization.

RJA: Yes. That was the first thing I did in the FDA, and that study took, I think we did it almost for an entire year.

JS: Now, you lived through those reorganizations. What became the new entities, the Bureau of Medicine and the other bureaus -- how did they accept this change?

RJA: I was pretty far down the pecking order. There was the study. There was a lot of interest on the part of the Department, a lot of interest on the part of the current administration of FDA at that time, but I was pretty far down the pecking order at that time, so I was really a go-fer guy. And I would go to places, interview lab chiefs -- at that time they might have been bureau directors or whatever -- so I really am not that familiar with the political aspect of it at that time. I was way down the pecking order.

RT: Do you recall who was Commissioner during that time?

RJA: You know, I actually don't, unfortunately. I probably should have gone back and looked that up, but I don't remember who was Commissioner.

RT: I believe George Larrick might have been.

JS: Maybe Charlie Edwards.

RJA: I think it was Charlie Edwards. I think he left and went up to the Department later on or something. It was Charlie Edwards. I think Charlie Edwards was my first Commissioner. Although Larrick rings a bell. He might have been going.

JS: Or Goddard. Goddard came in '66 or so.

I appreciate what you're saying about not being in a position to appreciate sort of the political ramifications of a change like this.

But you were involved in something else early on in this period when you were in the Office of the Commissioner, and I think you might have had more of a sense of this, and that was in the transfer . . .

RJA: Division of Biological Standards.

JS: Yes. The transfer of the biologics function from NIH to FDA. And it's interesting because we're going to be going through another transition here pretty soon when Biologics moves from the NIH campus to White Oak. It's going to be a few years.

But that's always something you were closely involved in during your time at OC, and I think one of the things we wanted to explore early on in this interview is your sense of what challenges that were faced in moving an entity from a primarily scientific institution . . .

RJA: Science to regulation.

JS: Yes.

RJA: Well, the interesting thing about that was, there was all of the turmoil surrounding killed vaccine/live vaccine. There was all the turmoil about the polio vaccination, and there were congressional hearings and so forth. And someone in the Department or some politician thought that biologics should be regulated like drugs, that they should be a regulatory piece rather than a scientific piece. So, again, I was about a grade 11 by that time, pretty far down the pecking order, but I do remember that the charge was that the Division of Biological Standards, a scientifically based research organization, was going to be moved to the Food and Drug Administration as a regulatory agency. So I got sent down from the Commissioner's Office to work on that transition. And, believe me, I actually moved to the campus, had an office in Building 29, and it was the damnedest

sight. Three years later, they still didn't think they belonged to the Food and Drug Administration. There were scientists who never admitted the fact that they worked -- if you asked them where they worked, they worked for the NIH. They never believed that they were part of the FDA because they saw themselves as scientists, bench scientists, and the trick for FDA was to bring them administratively, organizationally, and from the perspective of turning them into a regulatory agency, and these were all doctors, scientists, and Ph.D.'s and they didn't want much to do with regulation. So that was quite a challenge.

Larry Stern from the OC was reassigned to that group, and a gentleman in the Center of Veterinary Medicine -- Gesling I believe was his name . . .

RT: Jerry Gesling.

RJA: Jim, Jim Gesling.

RT: Okay.

RJA: Jim Gesling got sent down to be the, I believe he was the Compliance Director. The Director of the Division of Biological Standards left, and they appointed Harry Meyer as the Director, Paul Parkman and Hope Hopps and they had worked together.

JS: Right.

RJA: They actually got a huge Presidential award for their work in rubella.

They became the Directors. But what I can remember about them was they were never much enamored by the FDA, and that will surface again when the administration decided to combine the biologics and the drug group together. That was another very interesting story because I was right in the middle of that also.

So the thing was to sort of drag the scientists kicking and screaming into the FDA, and from my standpoint, since I was basically an administrator, and was to work on the administrative systems. It was a nightmare.

One time I can remember is that I saw one of the docs had a refrigerator strapped to the top of his van. I said, “Dr. Liu, where are you going?”

He said, “I’m lending it to my partner over in NIAID (National Institute of Allergy and Infectious Diseases).”

It was a culture shock, and it took years for those employees to turn over and be employed as FDA employees rather than NIH employees. I would bet you today, you could probably go down and still find folks who would say, “No, I worked for the NIH.” And that was the draw. The draw was, they were there because they wanted to work for the NIH. Working for the FDA didn’t really cut it for most scientists. To be on the NIH campus, that’s why they were there. They weren’t there to be a regulator in the Food and Drug Administration.

Eventually, from an organizational standpoint, we brought them into the FDA; and from a political standpoint, I think, over time, if you look at Biologics today, it’s

much different than it was then. But there were 250 scientists who were irate at being moved to the FDA.

The first thing the FDA did was put a big sign. They put a big metal sign over the Division of Biological Standards that said Bureau of Biologics. That's like the first thing that happened.

JS: Well, you raised a good point. I mean, what do you think worked and what do you think didn't work so well in this transition?

RJA: Well, they have a reviewer-scientist model which was not like anything else in the FDA, where the bench scientist who's doing the science is also the same person who's doing the application review. They have product license applications. They are one and the same. So when you would ask the question, "How many scientists do you have?" then ask the question, "How many reviewers do you have?" the answer is the same, because they saw themselves as scientists first and application reviewers second. The FDA, of course, I believe is quite the opposite. You are a reviewer first, and the science piece is secondary.

RT: Weren't they more inclined to be advisors or counselors to their clientele?

RJA: Well, that's what brought on the transition to the combined groups, was the Biologics folks had a much different relationship with their manufacturers or their customers than the drugs group did. It was much more collegial. They would have a lot

more up-front discussions. They might come in long before the application came in, which, of course, you wouldn't dare do today. They might actually bring them in, have a discussion about the product, have a discussion about the application, have a discussion about the process, and this would go on back and forth, and so there wasn't this more confrontational aspect, which the drug review part was like, where they were taking 3+ years to approve a product. In Biologics, there really wasn't, from my standpoint anyway. It seemed to me like the process didn't really have a start point. It might be a little bit grey at the front end, when the application came in and when they started reviewing and when they started having discussions. That was something that didn't actually change. That continued on until the mid-'80s when they decided that process works so well for Biologics; let's try that over in Drugs and see how that works.

JS: There was a real philosophical difference in how one enforces law. Their law, of course, preceded ours.

RJA: After the Public Health Service Act was 1902, I think, the Food, Drug and Cosmetic Act, 1906, so it did precede it. Interesting, the FDA now had two acts they could use. I mean, it's very beneficial to the Food and Drug Administration to have a Public Health Service Act also, besides the Federal Food, Drug and Cosmetics Act.

JS: One of the interesting things that might play -- by the way, we interviewed John Finlayson, and . . .



RJA: John, a friend of mine, absolutely.

JS: And a lot of things he was talking about . . .

RJA: He was there.

JS: Oh yes.

RJA: He was there.

JS: . . . came out in John's interview.

I didn't realize this until we were looking at the anniversary of the 1902 Act, but the first court case that we can find that came out of the 1902 Act didn't happen until the 1960s. That's over 60 years after the law was passed, so this is a very different kind of organization.

Interestingly enough, after the merger . . .

RJA: The '83 merger?

JS: No, I'm sorry, not a merger. When Biologics came into FDA, there was a real rush to ramp up blood regulations, and the Commissioner at the time, Dr. Mac Schmidt, said that, "The last three years, we've been trying to make up for the lack of regulations,

so they were bringing in intrastate blood banking and applying GMPs to those, so I guess that was maybe indicative of this whole different kind of approach to regulation.

RJA: Yes. The AIDS epidemic was cranking up back then, and so blood really . . . I mean, you're right, and John Finlayson was right in the middle of that. So they did GMPs, absolutely correct. It was bringing the FDA approach, the regulatory approach.

JS: Just one more thing that I have on this before you move on.

Were there many people who actually decided to leave the Division rather than move to FDA?

RJA: No. There wasn't a large exodus, no, not really, that I can recall. It was a very small organization. There was only maybe 250 people, I think, then, I believe, very small. Of course, FDA was only about 6,000 people when I got there, 6,000 people, and the budget was in the hundreds of millions. Hard to believe. It was under \$300 million when I got there.

JS: Different times.

RJA: I mean, really, and we got the request for supplement . . . It was influenza, swine flu, '76. The swine flu "epidemic" was approaching, and they were looking -- we put our budget request together. The entire budget request for our Bureau was \$4 million, and

like 10 people, so it's hard to imagine anybody making a request for that kind of small change now, really.

I spent a number of years in Biologics. I think I was down there until the axe fell again.

JS: You spent over 20 years in Biologics.

RJA: Yes.

JS: You mean while you were in the Office of the Commissioner.

RJA: Yes, and then I was permanently reassigned to the Bureau of Biologics from the Commissioner's Office.

JS: Right. During this short tenure that you were in OC, I'm assuming most of your time, pretty much all your time, must have been taken up with either the analytical work on the reorganization of the entire agency or on the whole Biologics issue.

RJA: Yes. Those are the two things that stand out. Although, don't forget, we also had products, we had consumer products that were part of the FDA back in those days.

JS: Consumer products.

RJA: Yes, which became the Consumer Products Safety Commission, it sort of spun off. The FDA had a huge range, a wider range than maybe even today, because by that time I think Devices and Rad Health had also come into the FDA. We'd added Biologics, Devices, and Rad Health to the FDA, and we had Consumer Product Safety spun off.

The only other thing I did of consequence, I think, was, somebody had asked the question from the Commissioner's Office about the impact that FDA had on the consumer in terms of the amount of money that consumers spent. So I did -- actually, I still have it, I think -- a study on the value of the products that FDA regulated. You could go DOL (Department of Labor) and find a code for drugs and a code for pharmaceuticals, a code for foods. You could add up the value of those in terms of gross national product, and you could weigh that against the FDA budget, and that would give you some idea of what the taxpayer was paying. Today, I'm sure you've heard in many a speech that FDA regulates 25 cents out of every dollar the consumer spends. Well, guess where that number came from? I actually did a study at the end of the day that said, well, it's 25 cents on the dollar. Now, I don't think anyone's challenged that number since. I am like 99 percent positive that's where that number was generated from that study.

JS: You know, I'm just surprised this hasn't, we haven't heard a query about where this number came from before, because we haven't in our office, although it's out there, as you said. Once I heard 20 cents, but, 25 cents . . .

RJA: Somewhere I think I heard 27 or 28 cents. But what I can tell you is I actually, I went to one of the departments and took all those codes and added up all the value of all those products. I don't know how good it was, but the answer was 25 cents on the dollar.

JS: It's a great figure.

RJA: Yes. Like I said, I'm some junior analyst, but everybody bought it. I presented the data to the Division Director and then, from that point forward, that's the number I've heard. Now, perhaps somebody has gone ahead and done an analysis since then, but maybe not. But that's how that number was generated. I'm like 99 percent sure that's where it's generated from.

JS: Okay, that settles it. Glad to know that.

RJA: Somebody ought to go back and look, because the whole piece of the consumer products has gone up since then and we brought stuff in, so who knows what the value is.

JS: Well, that's the thing. We have so many functions that have come and gone, we lost tea.

RJA: Tea testers.

JS: Tea testers, that's right. Not that that contributed a whole lot to that figure, but that's a constant flux, it seems.

RJA: Absolutely. So I don't know whether anybody's challenged it or not since then.

RT: Well, they probably don't really have a basis to challenge it.

RJA: Well, why would they? It seems like it's been around for 30 years or 40 years.

JS: That doesn't seem to stop some people, though, does it.

RJA: No. I bet you I can find that somewhere. I think I saved one or two things over the years. I don't know. It may be around.

JS: Anyway, so in 1973, then, you start your permanent tenure in . . .

RJA: In Biologics. I spent about three years in the Commissioner's Office and then I moved to Biologics.

JS: As Director of Planning, Evaluation and Financial Management.

RJA: There were about as many people in the organization as there are words in the

title, because that was unheard-of. It was unheard-of to have a planning organization or somebody who did evaluations. This is a science group. There wasn't anything like that in the Division of Biological Standards.

JS: How did they fulfill those functions before then?

RJA: I'm not sure they did. I think that the Division was a relatively small organization, and I never saw any documents, I never saw any analysts or evaluators that would have done that, because the group that I actually brought in, they were all new to the FDA, so there weren't any management analysts or any program analysts. There were some budget folks, and they had these long sheets of yellow paper and they did it all by hand. They had every promotion, every within-grade. That's how they formulated their budget. At the end of the day, this is how much they needed for promotions and supplies. I guess that worked -- I really don't know. That was another big change of actually becoming part of the FDA process from the standpoint of planning, evaluation, formulation, execution.

RT: Prior to coming to FDA, in NIH, were they more operative on grants as a funding mechanism?

RJA: No, not Biologics. Not many grants. They were mostly, it was all appropriated money.

JS: But they had a lot more of it, being in NIH, than they would have in FDA.

RJA: That was a bone of contention in the FDA for years, because the per-capita value of the money at Biologics, in some cases, was twice what it was in other parts of FDA. They brought their budget intact. Whatever it was, they brought that entire budget to the FDA. Because for whatever reason, the NIH funds their scientists at a much higher level than the FDA funds their reviewers. I had used to get all kinds of grief from other parts of the FDA about how much money you guys down in Biologics have. And we had, on a per-capita basis, way more money than anybody else in FDA. That's because it was so heavily influenced by the science.

JS: I'm guessing you also had more scientists, more MBAs and Ph.D.s in proportion than the other FDA components.

RJA: Absolutely. Not as many docs probably as maybe other parts, like drugs, but certainly more bench scientists.

JS: What were the terms of advancement; how did those compare, the way it was done in NIH versus the way things were done in FDA, in other words, promotions and so on? Were things very different?



RJA: They required an adjustment. It was actually much different because they had a miniscule administrative staff, very small . . .

TAPE 1, SIDE B

RJA: I think from a promotion standpoint, a lot of it was tenure, and a lot of it was publications, because they were scientists. They were scientists first. I mean, at NIH it really was publish or perish.

RT: In the category of staff that came over, were there many Public Health Service commissioned officers?

RJA: Yes, but there were not as many Corps officers. To my recollection, there were a few, but not that many. We wouldn't know because nobody wore a uniform. I mean, you never saw a Corps officer at NIH in uniform, ever. I just don't recall whether there was a large contingent of commissioned Corps officers or not.

JS: We weren't thinking about that anyway.

RT: Well, if there were, that would have been another area of unhappiness, I guess, in terms of performance.

RJA: Yes. Well, there must have been, because they got paid monthly as opposed to the civilians, and those were the paper-check days. I remember when checks would come in, and we had a person who would go around and actually hand these checks out to people: “Here’s your paycheck.”

JS: I don’t mean to belabor the issue of this difficult transition from NIH to FDA, but there were other entities that went through the same experience. The Bureau of Radiological Health was in the Public Health Service. They came into FDA. I don’t know if they had the same kind of cultural or other problems.

RJA: I think one piece did and one piece didn’t. I think that the, one of the two, I don’t remember, but I remember somebody saying either the Medical Device folks or the Rad Health folks were more like the Biologics folks in terms of the transition. They had more trouble with it. I just don’t remember which. I really don’t know much about those groups.

JS: How was it for you, though?

RJA: I hadn’t been in FDA long enough, so it wasn’t a culture shock to me. I think that’s part of why I was able to do those different jobs. When I went back, I was just never bothered by that piece of it. I wasn’t troubled by the fact that lots of people were

unhappy and they were scientists, and I'm supposed to bring you guys over into the FDA, so that's what we're going to do.

JS: Did you have the support of Dr. Meyer and Dr. Parkman?

RJA: I have had the luxury of always working for M.D.'s, with the exception of the three years I was in the Commissioner's Office. My entire career I've worked for medical doctors, for M.D.'s, and they're about the nicest people you can work for, and I can tell you one reason. For the most part, they don't want anything to do with the stuff that I do. They don't want to hear about it, they don't want to deal with it, they don't want to know about it, especially the Biologics group more so than Dr. Janet Woodcock, for example, who is more into the budget piece and some of the administrative issues. But Harry Meyer and Paul Parkman, if I never talked to them about this, they'd be very happy.

Eighty-three rolls around, and someone with way more intelligence than I have decided that this Biologics thing was really working well, and they had this great relationship. Maybe we ought to try that with Drugs. So, let's put them together. We didn't know what that meant at Biologics. We weren't sure what that meant, pasting these groups together. What does that mean? We're going to stay here, the Drugs group is going to stay there? Who's going to run it? We didn't know.

Two things happened. Dr. Meyer called me into his office, and it was Meyer, Parkman, Hope Hopps, myself, and a phone call came in from the Commissioner, I believe, somebody on the Commissioner's staff, and said, "Here's how this is going to

work, essentially. You guys are all going to move to the Parklawn Building. We're kicking out the senior staff of the Bureau of Drugs. We're going to combine the two groups together. It's going to be called the" -- originally it might have been the National Center. Then NCTR (National Center for Toxicological Research) got all up in arms about, "We're the only national center." So there was a very short period of time where all centers were national centers, and that went away. "And we're going to form these national centers, and you, Dr. Meyer, will be the head of it, and you, Dr. Paul Parkman, will be the Deputy." They didn't mention me, which is fine. I figure, great, I'm going to stay down at NIH and run my group and be happy.

The next day, Sharon Holston, who replaced Gerry Meyer as the -- I don't know whether it was Deputy, it might have been Associate Commissioner back then, Deputy Commissioner or Associate Commissioner for Administration -- called me up in her office, and she has this huge organizational chart. I had about, I don't know, 10 or 12 people in my group at NIH. The Drugs group had a couple hundred people. I mean, that was the odd part about it, NIH, the Biologics group was very lean and really had a small administrative group, so I was -- and this was the group that I put together. So I'd never dealt with, from a Center perspective, the very thing we talked about large: numbers of budget folks, evaluation folks, planning people. We just didn't have that.

Sharon Holston has this chart, and there's this person, there's this organization over here that has a box in it that has all these people under it, like 200+ people. I'm thinking, "Gee, I wonder who that is." She says, "Well, that's you."

So, I got to move up there, up to Parklawn, too. Meyer, Parkman, Hope Hopps, myself left NIH reluctantly, moved to the Parklawn Building, and moved into the very

offices that had housed the people before us. I can't remember all of them, but I think that . . . I forget. Who was running Drugs at that time?

JS: Well, Dick Crout had left in 1980, around 1980, because we interviewed Dick. And Jerry Halperin was his Deputy.

RJA: Yes, Halperin was up there.

JS: He was, I guess, Acting.

RJA: Yes. He may have been Acting, and he was livid.

JS: Well, this is something, how this union was perceived on both sides, because I'm sure you heard both sides of it.

RJA: Well, I heard more from our side because my perception is they pretty much stonewalled Harry Meyer the entire time that we were there. If you look, nothing really changed dramatically. The things that sort of made the Biologics process work effectively, according to the people that thought that, wasn't part of the Drugs' culture and were never going to be part of the Drugs' culture. I mean, they were just more like regulators, and NIH was more like scientists, and I didn't think it was ever going to change.

We moved up there, and what I spent the next probably two years doing was putting, pasting these two groups together, because here's what you had. You had a compliance group and you had a compliance group, put them together. Who was going to run it? You had an EEO group and an EEO group. Put them together. You had an Office of the Center Director, you had an Office . . . So you had all these parallel organizations that I got to paste together and try to figure out who was going to run them. Who was going to run the compliance, because you had two directors. Who was going to run EEO? Who was going to run -- what were we going to do with the now two secretaries that worked for the Center Directors? What do we do with them? So, you talk about headaches!

And, of course, the *Pink Sheet* was all over me. And it was different then. You could just walk in -- this was the age you could just walk into the Parklawn Building and just walk into my office. Literally, the stuff that went in the *Pink Sheet* were variations of this organization that I was working to. The strange part about it was, as soon as I got to the end of it, guess what happened? They started taking it apart and ripping it in half again and building what became the Bureau of Biologics. So it was this sort of crescendo, work, work, work, work, get it together, scotch-tape it, scotch-tape it, make the selections, export a lot of people, and hurt a lot of feelings.

JS: The Executive Officers.

RJA: The Executive Officers for the Bureau of Drugs. I had two. We had two of everything, essentially.

They tried to patch together some of the scientific divisions with some of the review divisions, and that just didn't, wasn't going to happen, was not going to happen.

But people still here today, Bob Temple, for example, lived through that. He's still here. He would be one you really want to talk to when he does finally retire. He may never retire, but . . . He's a great guy. I've always liked Bob Temple.

We would have these staff meetings, and I bet you there must have been 30 people in there. That's how many organizations we had. You would go around the room and it would take hours and hours. I would see Parkman and Meyer back there. They were used to having their lunches together. They would meet in his office, the three of them, and they would bring vegetables in and wash the dishes, and put their stuff away, so it was . . . Now, all of a sudden, they're in this huge conference room listening to 30-plus staff discuss mostly drug issues.

JS: This isn't what scientists do, is it?

RJA: Yes, and they weren't really scientists in the biologics sense, you know. It didn't last long enough to effect any change. I never saw any real change, to be quite candid with you.

And the drugs -- Jerry Halperin, just literally before he left, just was not going to change. He even called me in his office and he said, "These folks work for me, they don't work for you, and that's the way it's going to stay." And that's the way it was.

To this day, I don't think anything productive came of that reorganization. They finally saw the error of their ways, which maybe was the only positive thing about the

AIDS crisis. It gave them a reason to separate them apart and form an AIDS Division.

That was the basis of it.

JS: And, of course, they stayed together.

RJA: Yes.

JS: Maybe John Villforth had a lot to do with that. I don't know.

RJA: Yes.

JS: But the Center for Drugs -- and it was Drugs and Biologics, not Biologics and Drugs. Right?

RJA: It was Drugs and Biologics, absolutely.

JS: Okay. That did come to a halt, didn't it?

RJA: Yes.

JS: Can you say a little bit about how that came about and why?

RJA: It wasn't working; it just wasn't working. I mean, it was not working. There



wasn't -- again, being an administrator, I just didn't see any major change, and I don't think Meyer and Parkman saw any change.

Harry Meyer was about to retire, so the agency was faced with either selecting Paul Parkman for the job -- he was the Deputy -- recruiting somebody from outside -- Carl Peck came in -- and then you would have an even worse situation where you'd have a group of Biologics folks now being governed by a Drugs person or an outside person. And you had the AIDS epidemic really becoming critical.

I think that gave the FDA the ability to split the organization back and say, "We now need to form a group to focus on the AIDS crisis. We want them to be at NIH, and we want Paul Parkman to run it." I think Dr. Parkman was torn between wanting, because I think he felt he was the Deputy and they were sort of passing him over for the drugs position. I don't know if you talked to him or not [unclear].

JS: We have not, and that's somebody that needs to be on our list.

RJA: Yes. He's getting on in years now. He's probably got to be in his eighties by now, and his health wasn't that good the last time I saw him.

I think he was a little bit hurt by being passed over for the Director job of either the combined group or even the Drugs job. It's quite possible that he might have stayed if they'd asked him, in what became the Bureau of Drugs. But he was not offered the job.

I said, "Now, guess what you get to do? Now you get to unpaste them." Now I've got to go back. I've got to go to the Compliance group and pick out the piece that

I'm going to take to Biologics. I've got to go to the management group, take out the piece I want to take to Biologics. I've got to go to the scientific group, the sort of hodgepodge, find out the groups that go back to Biologics. And, oh, by the way, here's how many FTEs you get to have. It wasn't like I would move folks and that would become the ceiling. They said, "No." I forget what the number was. It wasn't very many. It was like maybe 275, 280, 300, something like that.

Again, you had a lot of people that got left behind who weren't very happy about it, and some people who went that weren't very happy about it. Again, I'm in a position of dealing with an organization that is unhappy for a whole number of reasons.

And so they kicked us off the fourteenth floor, and the thirteenth floor, and we went over -- I think we might have been the first FDA people ever in the A wing. We were like castoffs, and that's how Parkman saw it.

So I'm now the Executive Officer for the Bureau of Biologics. I was in a room this size on the fifteenth floor of the A wing. The door came into my office from the hallway. I've never been one for trappings. But we really were treated with a little bit, I think, a little bit of disrespect, and I think Dr. Parkman was very hurt by that. He moved down to NIH and spent the majority of his time there. I was going to most of the meetings and all the Commissioner staff meetings, whatever they were called back in those days.

JS: But you were in the Parklawn Building.

RJA: I got to stay in the Parklawn Building, yes. Never went back . . . Don't forget, I

moved to the Parklawn Building when it opened, in 1970, from Crystal City, so I was like one of the original tenants.

JS: You talked a little bit or you mentioned briefly the AIDS crisis. How do you see that as affecting the separation of biologics and drugs organizations?

RJA: The AIDS supplemental went to Biologics. We hired more staff. Dr. Parkman brought over Debbie Henderson from the NIH to be his AIDS person. She now runs the Executive Operations staff for Janet Woodcock. Janet had left Biologics to go to be the Center Director for the Drugs group. She remembered some key people from Biologics and brought them with her. That's how I got to Drugs, as a matter of fact.

Now we had the Bureau of Biologics and we had the AIDS crisis and we had an AIDS group and a Therapeutics group, and it never went back to the way it was because by now we had folks over that five-year period who came into FDA as FDA folks. But you still had scientists like John Finlayson, you still had a lot of old-timers. From their standpoint, nothing had really changed. They'd stayed in their labs. This reorganization had taken place, and now had come back, and they just, to them, I mean, John would probably say, "It didn't affect me, either one, either coming into FDA or going to Drugs or coming out of Drugs. I did the same thing I did for the previous 10 years."

John was an interesting guy. What I found universally is that these are some of the smartest folks I've ever met in my life. They know everything about -- you can pick a topic, and nothing used to intrigue me at the smaller meetings in Biologics, is they'd be talking about sailing one day, and they would know everything about boats; and then they

would be talking about cars, they knew everything about cars; and they'd be talking about science, and of course they knew everything about science. They knew everything about art or about music or whatever it was. They were just, they had these, you know, things were firing off in their brains, and I guess that's how they got to be doctors. But I was fascinated by some of those conversations.

So that was, the next four or five years or however long that lasted.

JS: Something comes along, though, before you make the transition to the Bureau for Drugs in 1995.

RJA: Is that when that happened?

JS: Yes, 1995. That is a huge shift in the way FDA gets funding.

RJA: Absolutely. This is the PDUFA negotiations.

JS: That's right, the Prescription Drug User Fee Act.

RJA: Nineteen ninety.

JS: Nineteen ninety-two?

RJA: We negotiated in one year, but we didn't get the money until the next year, so

you're right, '90, '91, '92, so somewhere in there. But I forget what year we actually, the first year we got user-fee money.

JS: I know you were very closely involved in that. We want to hear about that, but also if you could just say something about where this came from, because I know there's a long history of opposition to this by Congress, by the industry, and by FDA, a pretty vocal opposition to this concept, even though there are some precedents, like antibiotic certification.

RJA: Very small corresponding ones.

JS: But this whole culture of opposition to this was eventually overcome.

RJA: Here is my perception, and it's only my perception.

At that time, it was still taking like a really long time to get a drug product approved in FDA. I mean, really, if you think about it, it was over 30 months. It might have been 36 months. I believe that pharma said it's in our best interest if we can shorten that time frame. I mean, I heard all kinds of numbers about what that means to them in terms of dollars. For every day, every week, every month that they can get a product on the market sooner, there's a direct correlation to how much money they make. By shortening the time and getting some, getting guarantees from FDA that certain things would happen by certain dates, six months for approval for some drugs, for example, whatever, I think that was a huge advantage, and they probably saw that as a reason.

From FDA's standpoint, when you look at the budget history of FDA, we weren't very successful in getting huge budget increases every year. I think from a financial standpoint, that probably had a lot to do with it. I don't think anyone envisioned it turning out how it did turn out today, where the Center is, in some cases, 99 percent funded by user fees in some of the Divisions. If you look at the accounting system, the review divisions in CDER are like 99 percent funded out of user fees -- almost no appropriated money. I think, as a Center, it might be in the 60 percent range now total. That's really pretty dramatic.

But the biggest thing I remember about the user fees, after we negotiated, the money came in, was that they split Biologics, and we got like nine or 10 comparative applications compared to CDER. But, for whatever reason, the science was so expensive. In other words, running a lab is 10 times as expensive as running an office, obviously. So the thinking was that Biologics needed that money to support science, but the user fees specifically excluded research in the second year. The first year, it had research. Then pharma said, "No, we don't want to pay for research." So they excluded research from user fees.

Now, I wasn't involved the last time, but it seems to me like it's sort of back in research. So, Biologics eventually lost probably 20-25 percent of their PDUFA funding that got moved over to Drugs.

JS: That must have been an interesting dialogue that led to that, though, because I think Biologics has always argued that our products are different. It's all part of the

process of approving or evaluating product; you have to understand it, and to understand it, you have to do this research.

RJA: People argued that, they successfully argued that, and they have maintained this hybrid reviewer-scientist model.

JS: But it didn't work as far as the user fees were concerned, eventually. That part of the process was basically exempt from the funds, wasn't it?

RJA: Well, part of it also, but I think there is some science in Biologics that really is either basic or directed towards the betterment of the person doing the science, because a lot of it involved published research papers. Many of the staff fellows don't stay. They come in, three or four years, they leave. They're doing science that may or may not be directly related to an application. I'm sure that some people would argue that's not true. My sense was that's sort of where pharma was coming from. But, again, I can't judge whether a science project is directly related. They would say it was.

RT: Now, you received a commendation from the Commissioner for developing the PDUFA financial system.

RJA: Yes, and I had to present it to a congressional staff in a very hot room on a Friday at five o'clock. And the room was about 90 degrees. And I thought, okay, "You've impressed me that you're always busy on Friday at five o'clock."

That was a system used to actually go and find out the value of the person's time, how much time they were actually spending on PDUFA, so the accountants could determine how much of each individual's pay and operating budget would be funded under PDUFA. That system eventually got implemented. CDER and I think other parts of FDA use something similar to that now.

Part of the challenge was that pharma demanded an accounting system. They wanted to know how much time was spent doing what.

#### TAPE 2, SIDE A

RJA: Anyway, that was the accounting system that in some respects is actually still used today.

JS: Did you get a sense that -- I know you were in these hearings, in these congressional hearings, for this specific purpose -- there was a little pushback from some of the members of Congress about what this new kind of funding might mean?

RJA: Not, no. The reason they dragged us down there was they were not happy with the Drugs' accounting system, because at that time the Drugs group didn't really have one. The folks in Drugs said, "I'm not filling out any timesheets." I don't know what process they used at that time, but whatever it was, it wasn't something that folks on the Hill thought was sufficient to actually account for the use of PDUFA. They were very concerned about how the money was being spent, because, interestingly enough, what



PDUFA says is that there's a base amount of money in the FDA already appropriated to do the drug-approval process; we call it the process. You've always got to have that much appropriated money every year. You can't go under that. So, I forget what the number was, but there was some, like, 700 FTEs and some hundreds of millions of dollars that were already funding the drug process. PDUFA has always been seen as additive, so you weren't supposed to use PDUFA funds on activities that were already in place. You could improve them, but you couldn't replace them. In other words, you couldn't start replacing appropriated money with PDUFA money. That's what the Congress was most concerned about.

JS: Sort of technical things.

RJA: Right. So you have a line. Here's your appropriated money. PDUFA is up here. But this can't start to go, this can't go down so at the end of the day you're funded 100 percent out of PDUFA and there's no appropriated money in the process.

Now, it started to turn like that, and now that's one of the huge concerns in Drugs, was that the new product review side was getting hundreds of millions of dollars; the generics group was getting nothing. All of a sudden you had this disparity in CDER about certain groups having lots of additional money, certain groups having no additional money. They could travel, they could train; other folks couldn't do anything.

In FDA, you had the Drugs group getting lots of PDUFA money and the CVM folks getting nothing and the Device people getting nothing. So, again, it's the same old thing. It's Drugs people. It's like when I was at Biologics. You Biologics people got all

the money. Now it was the Drugs people have all the money. Until other parts of the FDA got user fees, that was . . . Again, I was always getting grief. Well, you've got PDUFA money; of course you can afford to do that. You've got this, you've got that. So that caused a little bit of strife in the FDA.

JS: There were other Centers that did not, in fact still don't, for the most part, get user fees. Right?

RJA: Yes.

JS: I guess this has created some issues and strains cross the agency.

RJA: It did originally. When CDER, CBER, and, of course, OC got their finger in it. And ORA. So there were four groups. The predominant groups were Drugs and Biologics. The money, it was like there's about a billion dollars in user fees now in FDA, a huge amount of money.

JS: Those costs do have to be directly connected in some way through the negotiation process, right?

RJA: It is the, pharma absolutely mandated only for the process, the approval of human drugs. Eventually, they saw the value of the post-marketing piece, and so now you see, even on the post-marketing side, there are some drug-safety PDUFA dollars used. That

was unheard-of initially. They didn't want anything to do with compliance or anything to do with inspections. This is for the review of drug products only, no science, no compliance.

JS: You could do an inspection as part of an NDA process, but not follow-on.

RJA: You couldn't do a follow-on study.

JS: Even as part of the post-marketing process?

RJA: Yes. That's what the push was for the accounting system. They wanted to make sure that these folks were accounting for what they were doing against a specific set of projects, and that only those were then given to the accountants, who would then fund a percentage of your pay, percentage of your operating budget. So it really is how PDUFA operates generally across the FDA, generally, better in some places than others.

JS: This was the way the law was written, I think. It has to be renewed every five years.

RJA: It might have been three years the first time; it might have been five.

JS: But it has to be renewed.

RJA: Yes, there's a renewal process.

JS: Now, because of your experience in this initial one, were you also involved in the subsequent renewals and the application to other products too?

RJA: I did two, PDUFA 2 and PDUFA 3.

JS: I know you're not on that side of the equation, the sort of industry side, but what's your feel for what's being extended by a company to get a product approved as opposed to what the back end is, what they're making? Is this known?

RJA: Yes, well, it has to be. It has to be cost beneficial. It has to be cost beneficial because I think the numbers for a new chemical entity, new product on the market first time, are astronomical. At the end of, getting it on the market at the end of six months, approval, instead of 36 months, you can imagine what that means in terms of profitability.

JS: Right. I mean, what it costs to bring a drug to market has become almost a political figure. I know a pharmaceutical economist's debate about what it really costs, and we know what we see in the *Post* ads, on the "Fed Page" and other places. Who really knows? But, you know, one is guessing at the cost.

RJA: FDA can't even tell you what it costs to review a drug anyway. You know, as hard as we try, it's really hard, it's hard to figure that out. We tried to do it on a couple of drugs and we tracked them to see how much time was spent on this. You could make some estimates, but there isn't a number that says it costs the Food and Drug Administration this amount of money to approve a product. You won't find that number anyplace, as hard as I tried to do it. Maybe because the products are so different, the drugs are not alike. Maybe an NME costs this much, and a me-too costs this much. But, for whatever reason, I think they might be scared of that. I think it's going to be a pretty big number. Look at the size of the FDA and the amount of money in CDER and in Biologics.

JS: You think it could be a big number.

RJA: I think it's a huge number. Maybe they don't want to know the number.

JS: That's interesting, because the Act is based on . . .

RJA: Well, figure how many products are approved. The number is going down. FTEs are going up. The dollars are going up from the PDUFA standpoint. Approvals are going down. On the Biologics side, you get two or three a year. On the Drug side, I don't know what the number is now, twenties now, I think.

JS: I think that's fascinating -- I've never run across that before, that concept.

RJA: They could certainly do it. Somebody could sit down and probably figure it out. We've got some very bright people in FDA. Theresa Mullins is one of the smartest people I know, and I guarantee she could do it.

Now, the scary thing is, when you do track a product -- we picked a couple when I was back in CDER -- and we actually did a separate timesheet for them, and was amazed about, not how little time, but how much time a reviewer actually spends reviewing the product as opposed to everything else that goes on. There's so much other stuff they're tasked to do that, really, the hardcore of actually sitting down and reviewing an application in most cases may not be the most time-consuming thing they do in a given day.

JS: They might not be doing just one at a time, too.

RJA: Yes, well, they're doing multiple things.

JS: Yes, so it would be tough to track.

I guess as long as we were satisfied with the negotiated amounts.

RJA: Well, pharma appears to be satisfied, FDA seems to be satisfied. It's hard for me to assess at this point.

JS: Right. Well, I just wanted to transition into your transition to the Center for Drugs, where you became the Executive Officer in 1995.

RJA: Janet Woodcock asked me if I was interested. I went up and we chatted, and I was absolutely interested. I had worked with Janet in Biologics when she was Director of a Branch. I liked her, so I went to CDER. Janet was the first real manager that I think Drugs ever had. She actually managed the Center, the financial piece, the application piece, I mean, all of it. She is a hands-on manager. But a manager in the true sense of getting into the budget piece, getting into the planning piece, something that others would not do to the same degree.

JS: Before we move to that . . . Well, let's go on.

Anyway, you've become the Executive Officer in Drugs, and you're faced with a number of interesting challenges then, like . . .

RT: Well, we're particularly interested, because we're recent new tenants of the White Oak campus, in terms of how that all came about.

RJA: Yes. Well, I'll tell you. The first thing that happened was the Drugs group didn't -- and Janet again was asking questions of their financial people and not getting answers, like basic questions. Well, how many FTEs do we have? How many PDUFA FTEs do we have? And she was used to, in Biologics, a very structured approach. We could tell

you exactly how many FTEs, who did what. I mean, it was very structured even though it was smaller. CDER doesn't seem to do any of that, so my challenge there was pretty much going in, dismantling this organization, sort of a budget group and the financial group, and putting in place administrative processes that she was more familiar with, so that's where I did that.

But White Oak -- well, this wasn't even White Oak then. It was either King's Farm or the FDA Taj Mahal. The FDA Taj Mahal made the paper, of course. But the first was Clarksburg. It was going to be Clarksburg, and then they decided they were going to have a prison there, and the FDA, and then it became King's Farm, and King's Farm would rather build townhouses and make a lot more money than putting a federal facility there, which they did. The thing about White Oak, there was a very interesting group called Labquest, which after BRAC, was looking for a tenant. Sharon Holston had a number of meetings with this community group who raised their hands that we'd like the FDA, so White Oak was chosen after the GSA got involved and so forth, as the location of the headquarters of FDA.

The problem was the Taj Mahal approach, which is when they needed, well, we need a billion dollars for the campus, and they said no. So they were going to build it one building at a time. Of course, we've been through a process every year where FDA is squabbling over the very next building. So the first building that was built was the lab building for CDER.

RT: Historically this was federal-owned land. Wasn't there a Naval research facility -  
- the Naval Ordnance Lab?



RJA: It was a Naval research lab.

RT: Had it been abandoned or dormant for a time?

RJA: BRAC.

JS: Base Realignment Commission.

RJA: Yes. But it was GSA owned.

JS: Yes.

RJA: It was owned by GSA. They owned -- it was a federal property, so that was part of the lure of getting another federal agency there.

JS: Also, not inconsequential was the fact that I think the Center for Drugs was spread out like FDA headquarters generally was.

RJA: Well, Drugs was in about, I think, 25+ locations.

But also, FDA was all over the map. I mean, when you look at Montgomery County, you go, my God, how did they get anything done? We were everywhere, and we kept adding buildings. As FDA grew, there wasn't any central place, so you would add a

building. We added Corporate, then we added another Corporate, then we added two buildings on Rockville Pike, Woodmont buildings, Woodmont One and Woodmont Two. Then there was Twinbrook. Then it was this and then it was that. So FDA was just adding and adding and adding.

The campus concept came about, and the first building was the lab building for the CDER folks. Unfortunately, by the time the building was finished, half of those folks had been disbanded and there wasn't enough room to fill the building. That's how CDRH got put in the top two floors. There wasn't enough CDER folks to fill the lab building.

There was a group -- it was the National Center for Antibiotics, NCAA, and the combined group, one of the first things we had to do was go down and abolish this group.

They were included that far back as part of the master planning for the building. The building was built to house more scientists than CDER actually had. The question was whether they were going to actually fit out the top two floors or not.

JS: Do you know what building number this is, the initial one?

RJA: Sixty-two, I think, either 62 or 64.

JS: The first building on the campus.

RJA: The first building.

RT: Those are GSA properties. Were special appropriations obtained from the Congress?

RJA: Yes, for each building, literally. Now we're going to build the lab building, and the next building they were going to build was the CDER office building, which was 21 and 22. The whole process goes through again, they get the money, they build the building. We moved folks from Parklawn, basically.

RT: This environment, this property, will all be FDA facilities? We're not sharing it with another federal agency.

RJA: Yes. Well, I think there's 700 acres, and FDA has only a portion of those.

RT: I see.

JS: We have room to grow if we need to.

RJA: No. We don't have room to go anywhere.

JS: Oh.

RJA: Let me show you. [see Figure at end of transcript]

What we see is that the campus doesn't have the whole FDA.

This is the whole -- let's try to get your bearings. New Hampshire Avenue is, here's New Hampshire. Here's the entrance of the FDA. Okay? This is the campus. This is the building 1. Here's the circle, and then you go around. These are the CDER buildings, this way is the parking lot, here's the CDER buildings, this is the piece they're constructing right now, the child center is going here. This is the FDA piece of this entire giant piece of property.

RT: I see.

RJA: See, this is White Oak. This is FDA. We're restricted to this campus here. So if we wanted to build beyond that, we'd have to actually get permission. We'd have to go through the whole master planning thing to get another property someplace on this. The Air Force base is over here someplace.

JS: Right. The wind tunnel and so on.

RJA: Yes, 660 acres. I think FDA has 70 or 80. I don't know exactly what the number is.

But if you look here, you can see what's going on. You've got, Percontee wants to build this giant village here. They've got -- here's Washington Adventist Hospital is coming, they're right here.

JS: Well, I know Labquest has been very diligent with monthly meetings and they have all their minutes up on their website.

RJA: Yes, very active. They play maybe a larger role in making decisions about FDA than probably they should. Who's to say.

Anyway, then 21, 22 got built. They were supposed to house all of CDER. Those two buildings were supposed to house the entire Center for Drugs.

JS: But in the meantime, something else had started going on in the agency, and that's historically a hiring surge, and CDER certainly was among the entities that benefited from that.

RJA: Yes. So these buildings -- don't forget the design for these buildings, the design and the money preceded this growth rate, so by the time the buildings were done, CDER didn't fit. They were too big. So the only people we could actually move to the building 21 and 22 were the reviewing staff. So the rest of CDER stayed behind wherever we were. Like I didn't move. They needed another building, and the next building was 51; 51 got built, going to house the rest of CDER. By the time 51 was done, Generics didn't fit. Generics had gotten too big. The only CDER staff now not on the White Oak campus are the Generics group and this management group.

Now, the other thing about CDER, they've already had to move folks off of the White Oak campus. They've gone off campus already in order to house the review

divisions as they continue to grow under user fees. Every time they're renegotiated, more people are added to the review process.

RT: As one goes out around the Beltway, before you get here coming from the west, there's an exit that says "FDA Research Center." Is that related to the Center for . . .

RJA: That is Betsy Bretz's side, and she named it. This is the Federal Research Center as named by Betsy Bretz.

RT: Okay.

RJA: And there's no argument.

JS: But you're pointing out something there that must have been just very frustrating to somebody who's obviously, among other things, dedicated to planning and anticipating, because you have a discrete amount of space here, yet you have people coming on, buildings to house them that have less than a guarantee of funding . . . In other words, the long-term plan for White Oak is a very malleable one. Is that right?

RJA: A long-term plan it is really not -- it was a very short-term plan, because when buildings were ready, others decide to move. In building 51, Generics was really slated to go, and the building was built to house Generics. Why would you have a document room in a building that doesn't have any documents? Well, guess what? There was a

document room built because we thought Generics was going to be there. Generics wouldn't fit. Generics would have filled the entire building by the time that happened.

JS: So, where is Generics?

RJA: Generics is on Metro Park. The beauty of them being there is they're in a location that has as much space as they need, as much parking as they need, as much document space as they need. Now, they ought to be on campus, clearly. There isn't a plan to bring Generics on campus even in the next iteration. In other words, the last piece of the campus they're building, this piece right here, the southeast corner . . .

JS: Where Biologics . . .

RJA: Yes, where Biologics is supposed to go. I don't know if we're going to have enough money to finish that. But that's going to house ORA, the Biologics science group. The reason it's so big is because you've got scientist-reviewer model, so they need a lab and an office. At the NIH, they were in basically the same location. You'd walk into a lab, there'd be an office in that lab, unless you were a branch chief or a division director, for the most part.

JS: Right now, Biologics occupies buildings 29, 29A, and 14D, so there are three buildings on the NIH campus?

RJA: Well, 14D is where they house their animals; 29, 29A, 29B -- 29B was the AIDS building.

JS: Well, for example, when the Center for Tobacco Products became part of FDA, the Commissioner at the time said it was certainly the intention to bring them onto campus. But all of this is contingent upon getting the funding from GSA.

RJA: That's right. I'm not a political person. The reality of it is, you'll never get Tobacco on campus, not in your tenure as a professional.

JS: Probably the same might be said for parts of Drugs, then, too.

RJA: Might be, right. Because this next iteration is the last quadrant. As I said earlier, there isn't enough room. The last quadrant, when filled, Tobacco will not be there and Generics will not be there. So you'll still have, Generics could be 300 or 400 people; Tobacco could be 600 or 700. You'd have 1,000 people still off campus, which means they've got to go outside this, go to the National Parks and Planning Commission and start the process to get enough land to build on.

JS: Even though there's space that's coded there as FDA space, you just can't go and build on it.



RJA: FDA is limited by the amount of space right there, that grey area, that white area.

JS: To get more space, we'd have to get permission from . . .

RJA: Montgomery County, go through the Master Plan. That process has started right now.

JS: Well, speaking of funding and such things, I want to talk a little bit about what's happened in the last few years with the agency's funding and the FDA Alliance. I wanted to talk about one other thing that, I know you got involved in, after you arrived at CDER, although this is something that affects the entire agency, and that's the provision of sort of a centralized support entity for the campus.

RJA: Office of Shared Services.

JS: The Office of Shared Services. I think you were closely involved in that, getting it started or proposed.

RJA: I mean, believe me, that was a concept I never . . . Two things. My involvement with the union and my involvement with shared services were for two reasons. My fear was that it would go a direction that I personally would not be comfortable with, so I had a vested interest in making sure that an Office of Shared Services, that whatever model

they came up with, actually worked. I didn't want Booz-Allen developing something that, when you actually tried to implement it, it would be a catastrophe. To be quite candid with you, it's not worked well.

RT: For the researchers that may review this record, what was the Office of Shared Services to encompass?

RJA: Well, the thinking was -- and FDA paid a lot of money to a consultant to come up with a concept where you would, every Center had a . . .

#### TAPE 2, SIDE B

JS: There's a lot of stuff to cover here, but we don't want to take up too much of your time.

RJA: No, no, as long as it's stuff that you'd find useful. I mean, that's another thing.

RT: We're continuing now regarding the Office of Shared Services.

RJA: Okay. So, every office had a service function that a very expensive consultant company thought that we would be better served in a shared concept, and the FDA thought it was a good idea because they figured that we would get lots of kudos from the Department by doing this shared-services concept.

It turns out, at the end of the day, it's actually more expensive to do it that way than it was the other way.

JS: What kind of services are we talking about?

RJA: Well, basically, it was travel, it was facilities, contracts and acquisitions, it was some of the financial piece, library services eventually, and equal employment opportunity.

JS: Does IT support become part of it as well from the beginning, or . . .

RJA: IT from the standpoint of some of the functions. Most of the IT (Information Technology) functions became part of shared services, and a certain piece of it stayed as part of the Commissioner's Office. But that was the concept.

I think it took us about a year to do that, and eventually we got to the point where we had an organization, and then we had to transition people from the Centers to the Office of Shared Services, and that was the challenge that I had, was actually coming up with this concept where you had about 300-plus people located in the Centers that needed to now go to the Shared Service group, and the question is, who are they? What grade would they be? What would the organization look like? I had to develop the Shared Services, what it looked like, down to the actual positions, and then find the people that would match up with that.

We set the model up, and the first thing that happened was the Centers realized, well, we now need something to interface with this group. All of a sudden, the Centers started hiring an IT person to interface with the IT group, a procurement person to facilitate the procurement group, a facilities person to facilitate . . . At the end of the day, you had about 50 or 60 people hired across the FDA that did nothing but interface with the Shared Services group. Now you had a giant Shared Services group and you had services out in the Centers to interface. Then the Centers began to develop their own, so they began to grow, and eventually Shared Services clashed. The only thing that's left of the Shared Services now, I think, is the help desk, ERIC, and the IT piece. I think the rest has all migrated to other parts of FDA. It was a colossal failure from my standpoint.

Well, I haven't heard too much about the MEO (Most Efficient Organization). It's back there winding down. You hardly hear anything about it anymore.

We haven't talked about the union, but the union thing, when FDA, they had the vote and a few people decided they wanted to be a union in the FDA, voted, and that was enough. They needed somebody to negotiate with NTEU [National Treasury Employees Union], with the national group and the FDA employees who were part of their bargaining group, and nobody wanted to do it, so I volunteered because I was, again, most interested in making sure that there weren't things put in place that just weren't workable. I mean, I didn't want the union to have such a hand in the FDA that we couldn't do our work.

JS: This is in the late 1990s?

RJA: It might have been 1999; I think it was '99. Yes, it was '99.

JS: Some of the FDA employees in the field I know were unionized. But in headquarters, was that . . .

RJA: There too.

JS: This was at headquarters.

RJA: Yes, very few people. The local 282 also has mostly field people also. There are some field people that were in another union, not 282, I think because of the region they were in. But most of the field people were not unionized. They became part of chapter 282.

The first time I sat across from Frank Ferris, who was the chief negotiator for the union, who I'd heard was a tiger and who turned out to be a very nice gentleman, a very nice guy, it was just common sense from my standpoint. We negotiated each article you can imagine, and we wrote them from scratch. That collective bargaining agreement was the model that they'd used in other HHS organizations, would actually take the FDA one and model one as they became unionized, and it was the same one they used to model the HHS consolidated CBA (Consolidated Bargaining Agreement). It was actually a really good document. To this day, even though it's somewhat dated, it's amazing.

JS: This affected many.

RJA: About 5,000 employees.

JS: One thing I wanted to ask about is, because you're working with so many scientists, and you have throughout your career here, how has advancement for scientists changed, if it was, by the agreement? Because they could be members of the union, right?

RJA: Oh, they are, they are. Well, members as opposed to represented by. If you pay your dues, you're a member, but you're automatically represented by the union even if you're not a member. Even with, say, they have 5,000 members, I would say they have 500 members but represent 5,000 people.

JS: Just, very briefly, we happened to be in ORA at the time our boss Jerry Henderson was the Executive Officer for ORA. When OASH, the Office of the Assistant Secretary for Health, was disbanded in HHS, the staff went to different agencies within the Department.

One of the people that Jerry brought on was a labor specialist, George Bork, to help Jerry deal with the new agreement.

RJA: Well, Jerry had the field piece, so he had . . . And, don't forget, FDA probably

has a union because of the field. That's where 90 percent of the issues -- 90 percent of the issues are in the field, and they're always upset about something. They're always filing something, grieving something. They're always the ones who are most outspoken at the labor meetings.

JS: I know Jerry was very happy with the support he got from George in this regard.

RJA: Yes, yes. George retired. George was on the bargaining team, and when we got really tired of negotiating, we'd bring George in, because George would just talk in this monotone. You know George. He would talk for hours. They would go, can we take a break?

JS: Before going on to what became your last position in FDA, I did want to ask a little bit about funding for this agency. This has just grown incredibly, and I don't know if you'd care to comment on why you think that came about the way it did, what roles maybe outside groups did have in that or not, but there's no doubt that the agency's budget, just within the last five, seven years, has just grown astronomically.

RJA: It just sort of has bumped up gradually, to the fact where it became one billion, then a billion and a half, then two, then two and a half, then three. Now it's five, with the user fees.

I can't think of anything specific except that it seems like we're always on the front page. I think from the Drugs point it was the drug-safety piece, and it would be

products that got on the market, as opposed to putting them in 20 people, you're putting them into 20 million people. The post-marketing piece became way more important.

Then there was the food safety. It seemed to be some crisis somewhere, a food problem or it was a drug problem or it was a medical device problem or it was a . . . But that's the history of FDA.

Look across FDA. I'll go back to '76, swine flu followed by Russian flu, more money; followed by influenza, more money; followed by AIDS, more money; followed by a cranberry crisis or that poor potato soup company that we put out of business, Bon Vivant vichyssoise. I mean, a long history of spikes in our budget correlate exactly to some type of crisis going on.

RT: As a matter of fact, the elixir of sulfonamide was the original boost for the '38 Act.

RJA: Yes, absolutely.

RT: It's just continued.

RJA: Yes. Or implants or whatever. No, that I think may have more to do with it than anything. And Congress saying, "God, throw more money at it!" And FDA has always been very good when asking for money, in taking advantage of, saying we're going to have a big food-safety program, you can't do it with what you have, so you're going to need more.



JS: I'll have to look back at Mike Brannon's article on organizing and reorganizing FDA, this very useful piece that he did on the agency's organization and how it changed. I don't know if he talked about it, but that makes sense; it makes all the sense in the world because the world of crisis has a role in the story he tells.

RJA: Yes. I knew Mike, and we worked, I think, in the same group.

JS: In 2009, you moved on to -- you're back to where you started.

RJA: I don't move on exactly. The truth of the matter is that John Dyer had left, and the new Commissioner came on board, and Janet Woodcock suggested to her that, in the interim, this three- or four- or five-month period while they were looking for somebody, why don't you take my Exec Officer, Russ Abbott, and let him do that job, because he can bring a Center perspective to it, to a job that had never had a program person in it, ever. I said to the Commissioner, "Don't forget, I'm a program person. I've been fighting these people for years. I've been brawling with Contracts. I've been fighting with the financial people. I've been screaming at the IT people. Now they're going to work for me?" So I said, "Okay."

Walked in and I guess I was there five or six months maybe. They did the recruitment, they didn't like anybody. The Commissioner asked if I would stay. There's the Commissioner of the FDA asking me would I stay and work for her, and I said, "Sure, I'll stay for a year," because I wanted to retire at the end of 2010.

So I spent the last piece of my career in the Commissioner's Office, which is where I started. I said it's odd that I would, even in the same organization, I might add. So I spent the last year, and primarily it was doing battle with the very people that I had done battle with through most of my career.

The problem as I saw it was that they have forgotten their role. As I said, "The only reason you're even here is to support the Centers. If the Centers aren't doing contracts, you don't have anything to do. If the Centers aren't moving into White Oak . . . They're not building White Oak for you; you're building White Oak for the Centers." Part of it was the fact that they had just forgotten, I think, that their role was to support the Centers and the program person. That's the influence I tried to bring. I wasn't there long enough to make any change, really.

RT: The Commissioner that asked you to stay on, was that Dr. Margaret Hamburg, the current Commissioner?

RJA: Yes, the current Commissioner, Dr. Hamburg, a really nice person, I mean, very nice. I enjoyed working for her.

But from a political standpoint, as I said, I'm not the least bit political, so I don't mind being a little bit roughshod, but this is how I think I want it to work, and that's the way I want it to work, and you can do that, and they weren't used to that. Some of those folks started complaining to the Department, the Department started talking to the Commissioner, and I backed off a little bit, since I was leaving anyway.

JS: Interesting.

RJA: Oh, it was very interesting, very interesting.

RT: I see that practically all during your tenure, you've served as the Credit Union Chairman.

RJA: Yes.

RT: Chairman of the Federal Financial . . .

RJA: It's called Federal Financial. I volunteered a long time ago. I had this financial bent, so I was interested in how they did loan approvals, so was on the Loan Committee. Then the fellow who was on the Board had a heart attack and died.

JS: I remember that.

RJA: Yes. He was the husband of the head of EEO.

JS: Ed de la Rocha.

RJA: Ed de la Rocha was the guy. He had a heart attack and died.

JS: I remember that.

RJA: I was in this position on the Board, and then three or four years later I got elected to be the chair of the Board of Directors, and I've been doing that piece for at least 10 years.

JS: I can't end this without asking you about the Parklawn races.

RJA: The Parklawn Classic.

JS: You were involved in those from the start.

RJA: Thirty years I ran there. It says one thing about me. I'm the most boring guy in the world if for 30 years, on the same day of the same month, I was in the same place for 30 years. I was a member of the Parklawn gym, and we would try to run down to Twinbrook and back and we weren't very good at it, so we said, "Let's have a race, and we'll do the Parklawn marathon," not even knowing, of course, what a marathon was. Our t-shirts said Parklawn Marathon on them. Our first race was five miles, and we had no idea what we were doing, none whatsoever. We ran up, let's see, Fisher's on one side and Parklawn's on the back side.

JS: Well, you ran up Twinbrook.

RJA: Ran up Twinbrook, and then we ran down Parklawn and then Randolph to Viers Mill, down Viers Mill and back to Parklawn.

JS: Did you go through the park at all?

RJA: No. They changed it. Over 20, 30 years, they changed the course a number of times.

JS: But that was a pretty successful race, because a lot of people took part.

RJA: It got bigger and bigger and bigger, and then it got so big that they started bussing people in. It was very successful.

JS: Now we're doing it at White Oak.

RJA: I've done all three White Oak Classics. I had so many t-shirts, I had to quilt my own.

JS: Really? Where's that?

RJA: I have two daughters. So, not to insult them, I used, I gave one a quilt made out

of the Parklawn Classic t-shirts, and I gave one a quilt made out of my marathon t-shirts, and they're exactly the same size.

JS: Well, Bob . . .

RT: You're continuing as a consultant now for . . .

RJA: Well, I'm working as a Reemployed Annuitant on the new legislation under health reform. I wouldn't have come back otherwise, because the penalty on your retirement pay is so great. But under health reform, they included some language which allows a retiree to come back for one year without any penalty. Well, it expires in 2013, the Act does, with no penalty on your retirement. I'm getting my full retirement and I'm working 20 hours a week for CDER, doing special projects for Dr. Woodcock.

RT: You've had a remarkable career, a government career in money management, financial planning, and so on. Have you had enough, or do envision doing some post-employment work?

RJA: Had enough.

RT: Okay.

RJA: Forty years is enough. I'm not interested in doing anything else. I've had some

very good offers. I mean, I have had some good ones. But it requires me to keep working full time, and I really don't want to do that.

RT: Sure. You said 40 years, didn't you?

JS: Forty years?

RJA: Yes.

RT: That's great. Well, that's a good figure to retire at in terms of your retirement annuity.

RJA: Well, it was the right time to go. There wasn't anything else I could do. I wasn't going to go back to a Center, and I wasn't going to stay in the Commissioner's Office. The timing was right. I'd also accumulated a bunch of annual leave that I was going to lose if I stayed until January 1<sup>st</sup>, so I'd rather get paid for it.

RT: Russell, we really appreciate you granting us this interview.

RJA: Well, I hope it's helpful.

I think from your standpoint, PCY had to say what [unclear] John [unclear] to say with what, I mean, it's a different view.

JS: Very interesting, very different perspectives from the same entity in the agency.

RJA: Really, I bet.

JS: I don't know if you've seen it. I might send that one along.

RJA: Yeah, I would like to see John's. He's a very interesting guy.

JS: And he's one of a few -- when we get off, I want to try to get some contacts from you.

END OF INTERVIEW