

History
of the
U.S. Food and Drug Administration

Interviewee: James L. Tidmore

Interviewer: Robert Tucker

Date: March 20, 2003

Place: Rockville, MD

[Tape 1, Side A]

RT: This is another of the series of FDA oral history interviews. This morning we are interviewing James L. Tidmore. Mr. Tidmore is Director, Office of Facilities, Acquisition and Central Services in the Office of Management and Systems. The interview is taking place in the FDA Headquarters at 5630 Fishers Lane, Rockville, Maryland, and is being conducted by Robert Tucker. The date is March 20, 2003.

Larry, would you please begin with a brief review of where you were born and educated, and your federal service prior to joining the Food and Drug Administration?

JT: Thank you, Bob. I was born in Oklahoma City on August 27th, 1943. I lived in numerous places around the Midwest part of the country. I graduated from high school at Kemper Military School in Booneville, Missouri, in '61. I attended the University of Missouri, Columbia, Missouri, where I graduated in 1966 with a bachelor of arts in public administration.

My first government position was with the Soil Conservation Service from March 1964 to June of 1964. After I graduated from the University of Missouri, I applied for the Federal Service Entrance Exam and I received several invitations for interviews from the federal government. I interviewed with the U.S. Army Tank Automotive Center for three positions -- one, which was to be a computer specialist, the other was to be a procurement intern, and the third, I believe, was in the finance area. I did accept the position as the procurement intern, and I started working for the Army Tank Automotive

Center in June of 1966.

I stayed there until October of 1966, at which time I had enlisted in the army. I was in the army for about 170 days, and I received an Honorable Discharge at Fort Dix, New Jersey, for medical reasons.

Following my discharge, I came to the Washington, D.C., area. I did a walk-in to the NIH [National Institutes of Health] and asked them if they had any contract jobs available. They sent me to an interview, and I was hired by the National Institutes of Health. I started working there in May of 1967, and I stayed there until I came to FDA in 1974.

My first supervisor here at FDA was Lloyd Sunquist, who as the director of the Division of Contracts & Grants Management. I was the branch chief for the Negotiated Contracts Branch. After Lloyd Sunquist's retirement, I competed for his position and I was selected for the position of Director, Office of Contracts and Grants Management in September of 1976. I occupied that position until June of 1995, and over the years the activities under that position grew substantially.

In June of 1995, we had a reorganization, and the Office of Contracts and Grants Management and the Office of Facilities and Administrative Management were combined into the Office of Facilities, Acquisitions and Central Services. At that time, my supervisor was Robert Byrd. And that is a position which I am currently in.

RT: Larry, that's a good overview. Now if we could go back and go over in a little more depth your experiences in the agency. When you came to the agency, what was your entry grade level?

JT: When I came to FDA, I was a GS-14.

RT: Your earlier service, had you worked up from a lower grade?

JT: When I started with the Department of Agriculture Soil Conservation Service, I was a GS-2, making \$3,620 a year.

RT: Well, I'm sure that you had ascended the ladder a little bit before you got to FDA, obviously.

JT: That's less than \$2 an hour.

RT: The nature of work that you first started in federal service was as what type of position?

JT: I was in a position of mail clerk in the state Office of the Soil Conservation Services in Columbia, Missouri, and I was responsible not only for the mail for all of the state office and thirteen district offices, I also maintained a fleet of eight GSA vehicles, which were distributed around the state. I was responsible for keeping those all running and maintained and clean for the people who use them.

I was also responsible for all the forms in the office and keeping track of about 200 different forms we had, and distributing those out to the district offices as they

needed them. I did all the copying in the office, using a Wet Paper Process [Kodak]. We had about forty people in the state headquarters and many more out in the district offices.

RT: At that point you were not yet at a supervisory level. When did you first move to a supervisory capacity?

JT: I first became a supervisor at the National Institutes of Health. I started as a GS-5 at DOD [Department of Defense], and at the National Institutes of Health I was reemployed as a GS-5. I received ladder promotions and rose to the rank of an acting 14 at NIH before I came to FDA. I became a GS-13 supervisor in January of 1972 at the National Institutes of Health.

RT: At NIH, Larry, what was the nature of your assignment there?

JT: I was a contract specialist through the entire period of time, and I was a contracting officer when I left NIH. I was responsible for about eight individuals under my supervision.

RT: The contracting work there, was it similar to what you came to in FDA, or was it in a different area?

JT: It was all contracting for research services for the National Institutes of Health and the National Cancer Institute. When I was at the National Institutes of Health, I

supported all of the different institutes, including the National Heart and Lung Institute, the National Institute of Allergies and Infectious Diseases, the National Institute of Dental Research, and so forth. So I had a good overview of what the NIH programs were.

When I came to FDA, I was very impressed with how the programs of NIH paralleled the activities which the Food and Drug Administration regulated in many capacities, so there were more great similarities in the two from a science mission-related basis.

RT: The contracts at NIH, were those with universities or were they in the private sector?

JT: They were both, Bob. They were probably about fifty-fifty with universities and others with profit-making organizations.

RT: At NIH, I assume that the funding levels were rather large in that activity. Were you dealing there with larger sum contracts than when you came to FDA, in terms of dollars?

JT: Yes. As a section chief at the National Cancer Institute, I had the responsibility for planning and executing contracts, which totaled about \$30 million annually, and when I came to the Food and Drug Administration, our contract program was about \$21 million annually.

RT: When you came to FDA, what was the general field of contracts? Was it broad across the agency's interest or in specialized categories?

JT: I was the chief of the Negotiated Contracts Branch in the Division of Contracts and Grants Management, and I was responsible for all of FDA's contracting nationwide.

RT: From my own experience working in the field organization, I recall that you were involved with the EDRO [Executive Director of Regional Operations] and the Division of Federal-State Relations with regard to a relatively small contracting program with state governments. That was probably small in terms of the total scope of your work at the time.

JT: Numerically it was probably about one-sixth of the activity. Dollarwise, I'm not sure what the dollar was for that particular program at that time, but it was a small portion, yes.

RT: You had worked in cancer and some other areas at NIH. What were some of the scientific-related contractual programs that you encountered in FDA?

JT: For example, at NIH we had a lot of research contracts involving animal research, and I was very familiar with the contractors who provided both the research and the animals themselves to the research communities. At CBER [Center for Biologics

Evaluation & Research], when I came here, CBER had a very large primate program to support the polio vaccine program, certification program. Those were two areas which were very intertwined, and today NIH and FDA still share the offspring which come from some of those primate contracts, for research purposes that they have joint funding of those contracts. That is one example.

I was very involved in the National Heart and Lung Institute artificial heart program, and when I came to FDA, of course, at that time the Bureau of Medical Devices was regulating the artificial hearts which were being installed at that time. So I had an intimate familiarity with how those devices had been developed and the people who had developed them. The University of Utah was doing testing of artificial heart devices in conjunction with the artificial heart program.

RT: As a contracting officer or contracting manager, were your duties at all involved in the auditing of the contracts, or is that done by some other entity?

JT: We were responsible for coordinating the audits of all of our contracts, both the cost analysis -- or the pre-award cost analysis was performed by FDA staff. Post-award audits -- after the performance, or in the midst of performance, would be performed by different components of the government, either the Defense Contract Audit Agency or the Department of Health and Human Services' audit function.

RT: As I recall, you mentioned Department of Defense a moment ago, is that correct?

JT: Yes.

RT: What was the tie-in of FDA with DOD [Department of Defense] in contractual matters?

JT: You mean the Defense Contract Audit Agency?

RT: Yes.

JT: If the Defense Department is the predominant funding agency for a commercial organization, they are responsible for the audits of all of the organization's contracts, so that they have a consistent audit. That's the tie-in. Then Health and Human Services would do most of the university audits, whether they were funded by the Defense Department or other agencies or if they were funded by HHS [Department of Health and Human Services].

RT: In your experience in contracting with outside entities, were there occasions where there were problems with performance, or did they usually meet the requirements?

JT: For the most part, contract audits would find maybe some procedural issues or strictly accounting issues, but the performance was not something which was usually brought into question by the financial audits.

RT: I was thinking, I guess, of problems. It's a little bit different avenue, I suppose, where in the pharmaceutical industry we've had some problems with correctness of data, submissions to the agency. Maybe that's not related directly to the matters that you were concerned with.

JT: The audits of those type were done on a specific contract basis. They were not performed as widely as they are today. In the recent years, there have become some situations, under both grants and contracts, where data has been brought into question in the performance of the research activities. The Health and Human Services has created an Office of Science Oversight, which does have a responsibility for auditing those, and I know that some FDA staff often participate in those audits today, both at universities, at pharmaceuticals, and other research institutions.

RT: Since large sums of funding have been involved in the contractual processes both at NIH and FDA, has that elicited congressional interest in terms of oversight hearings, and if so, have you been involved in those hearings?

JT: I think the FDA has been very fortunate over the years, that none of our contract activities have ever diminished to the level that they warranted any type of an oversight hearing of our contracts and our grants, unlike some other agencies where there have been major scandals. So the answer is no, Bob. Although periodically in budget hearings there will be questions asked about specific contracts which may be of interest to a congressman or a senator. But as far as oversight hearing of the contract program,

no, we have not had that.

RT: Have you ever encountered congressional influence to try to steer the agency's interest in a particular contractor?

JT: Occasionally, over the years, some congressmen, particularly some newly elected congressmen, might make a call to the agency and try to influence that, but we always declined to be influenced and made our awards as we deemed appropriate.

RT: Very good. I kind of touched on this, but the GAO, the General Accounting Office, of course, the investigative arm of the Congress, have they not at times done some studies of some of the contracts? I'm thinking now of an interest at one time in this relatively small area of state contracts where a field GAO team expressed an interest in oversight. Whether that was prompted by congressional instruction or just their investigative prowess, I'm not sure.

JT: Well, over the years we have become accustomed to numerous GAO inquiries every year, and we welcome them to come in and look at our files and our records. We just consider the matter routine, that GAO is going to come in, and we have never had anything that we considered a bad audit or a bad review of our activities. Sometimes the review is strictly programmatic in nature, and other times it is strictly financial or legal in nature. But I think all of our programs over the years have fared well and have continued. That doesn't mean there aren't occasionally some audits requested by

Congress or the Senate which have a political slant to them, and they're requested by a particular congressman or senator or a particular committee. Most of the audits focused on the program specifically, and the contract award and administration issues were secondary. Our procedures always were upheld by the audits.

RT: Within the administration of the agency over the years, has there been a change in direction with regard to contracting? Is it increasing or stable? Would you comment on that?

JT: Yes. Over the years both the contracting activity and the grant activity have grown proportionally with the agency's budget. Currently in fiscal year 2002, the total of the contract and grant program was \$477 million of the agency's budget. The total agency budget was \$1.6 billion. So that is somewhere at about a third, almost a third of the agency budget. In addition to that, of course, our facilities and our rent that we're responsible for is over \$103 million for the leases. So I have a total of about \$600 million under my responsibility.

The biggest change in the contracting, or acquisitions program, as we call it now, is the impact card programs, called the International Merchant Purchase Authorization Card, which is a program which was initiated by the General Services Administration, and in 2002 we did \$35.6 million in impact card purchases.

This has greatly reduced our need for what we used to call purchase orders, and the individuals in the centers can now make most of the purchases themselves of items that formerly were acquired by purchase orders. The program is about six years old. We

were the first HHS organization to embark on using the impact card, and we were pioneers and developed a very good program. Our procedures and policies were used as a model by the department for wider implementation.

RT: Was that an initiative of a commissioner, or who came up with that?

JT: That was an initiative of mine.

RT: Very good.

JT: That was one of mine. When the program was first mentioned by General Services Administration, they were looking for volunteers, and I quickly volunteered for FDA to be a pilot.

[Begin Tape 1, Side B]

RT: Larry, you mentioned that it was your initiative. I hope that some recognition was given for that idea.

JT: Well, I don't recall ever having any formal recognition of myself for the idea. I did recognize my employees who were actually carrying out the administration of the program. But I'm sure my bosses also took that into consideration when annual bonus time came around for me.

RT: Good. Well, at least you weren't oversighted entirely, then.

Larry, that's quite an impressive development of these initiatives. How does that compare dollarwise with the time when you first got into FDA in this area?

JT: As I said earlier, Bob, the contracting activity, when I first came to the agency, was \$21 million. Now, that does not include small purchases, which at that time was in another part of the organization. That was in the Division of General Services. Our grant program was only about \$3 million. Now our grant program in FDA has grown to \$30 million, and largely part of the orphan product growth is attributable to that. I believe the orphan product program now is about \$20 million of our grant program.

RT: And that's orphan drugs?

JT: Orphan products.

RT: Does it include more than drugs?

JT: It includes both drugs and devices. So it used to be the orphan drug program, but now it's referred to as the orphan product program.

RT: For reviewers of this transcript, an orphan product would be defined as?

JT: An orphan product, I think the definition has been somewhat fluid as far as population goes, but at one time the definition was any disease which fewer than 100,000 people had in the United States qualified as an orphan product. I'm not sure what the precise definition is right now. The product addressing those diseases that were had by less than 100,000 people.

RT: Those are the kinds of products that would not necessarily be incentive products for development by the industries, right?

JT: Correct.

RT: Was some stipend available to the developing industry? Is that the way these funds were used?

JT: No, the funds were actually used for the research itself, and the researcher might be someone in a university or in a nonprofit organization who is taking an existing drug and doing research to try to apply that existing drug to the application to an orphan disease. That's where a lot of the research is done, rather than the actual development of new drugs for application for those diseases.

RT: In recent times there has been a lot of interest in developing some therapy, or hopefully a cure, for such maladies as AIDS. Have some of those monies found their way in the AIDS-related research?

JT: The AIDS-related research, I think, is a program unto itself, for the most part, at NIH, although the Center for Biological Studies is also doing some AIDS research.

RT: What would be some of the other categories of products, or categories of problems, where these contracts or acquisition funds may have been applied in recent years?

JT: Well, of course, the state contract program has grown substantially. However, most of our funding, not necessarily the largest number of contracts, but the highest percentage of dollars, goes into information technology acquisitions today, which is the mainstay of most of the aspects of the agency today.

RT: Larry, you just mentioned again the state contract program. Initially that was primarily a look to the states for inspectional assistance. In more recent times has that changed to other areas, informationwise, for example, adverse drug reporting and so on, do you recall? That's kind of far back in your immediate involvement, I'm sure.

JT: The program has grown with the mammography inspections. As far as adverse drug reactions, and I don't believe that is part of the scope of the contract program. But my day-to-day involvement in that in the last two years has been pretty minimal, unless there were problems in a particular area.

There was quite a large activity with the states when the tobacco program was an initiative. Dr. [David] Kessler in time has told us to cease and desist funding that

program, that it was beyond our authority, that that program was terminated. But that was quite a large expense of the part of the state program.

RT: Are there any other areas historically that might be mentioned here where contract and acquisition funding has been involved?

JT: We have had a fairly active construction program over the years, particularly over the last ten years. The construction of the Arkansas regional lab at NCTR [National Center for Toxicological Research) has been a major effort and a major funding target, although it has been a drawn-out process with regard to getting the funds from Congress. We are currently building a new facility in Irvine, California, to replace the Pico Boulevard facility in Los Angeles. We have other contracting activities involved in construction or renovations all over the United States and the headquarters.

I'd like to go back to talk about the information technology contracts. At one time -- I'm going back about fifteen years -- when what is now called the Parklawn Program Service Center in the Parklawn Building, was the contracting office that did all the information technology acquisitions for the Public Health Service, and FDA did not have authority to acquire those things. I instituted a program as information technology grew, that we started out with the small purchases, which had been moved under my authority at that time, and is still under my authority. But that was an effort when I had to convince the agency that all the contracting activities belonged together.

Once I had the small purchase authority, we started to do all of the information technology purchases in FDA. Very soon we were getting a much better purchase for

each dollar that we executed than was being performed by the Parklawn Service Center. Gradually we expanded this into contracts. We went to the department and did make the case for our own authority for information technology procurement, and there were a couple of instances where their contracting activities were improper, and this helped us in getting our own authority. As the IT area grew, it became essential that FDA manage its own programs and have the contract authority to award our own information technology contracts.

RT: The issue of user fees has come up increasingly. Is that of any involvement in regard to the management operation of your office?

JT: We do award contracts which are awarded with what we call PDUFA [Prescription Drug User Fee Act] funds. We have other user fee programs, of course, now there are being implemented. But they are just another accounting code, as far as we're concerned, and they're handled the same as all of our other contracts, just that it's a different accounting number. But we have many, many different accounting numbers and what we consider different types of funds.

RT: Larry, I think there are some other initiatives which would be good for the historical record, and maybe you would like to proceed with those.

JT: One of the activities which I have thoroughly enjoyed being a key player in, having watched it grow for years, was the planning, development, and implementation of the

Moffett Center, which was sponsored by the FDA Center for Food Safety and Applied Nutrition. This is a joint venture with the Illinois Institute of Technology [IIT] and with the State of Illinois, and was centered around a building which was donated by the Corn Products Corporation, CPC, International, to the Illinois Institute of Technology. The Illinois Institute of Technology approached the agency and did not want to accept this building unless they had a clear purpose and a commitment from some other entity to help them develop a concept of having the academic, the federal, and the private sector perform research in the food safety arena.

At that time, Brad Rosenthal was the executive officer of the Center for Food Safety and Applied Nutrition, and he approached me. He wanted to give them a single contract for all this activity which was going to involve construction. It was going to involve having FDA staff on site and numerous activities involving the private sector. I counseled Brad, and at that time the director of the Center for Food Safety, which was Fred Shank. I counseled them that a contract was not the appropriate mechanism for this activity. We had a new instrument at that time, which was called a Cooperative Research and Development Agreement, which we are still using, and it is an instrument which was created under the Technology Transfer Act and the Stevens-Wildner Act. That allowed us to enter into agreements with both the private sector and the academic sector, to accept services from them without our funding them ourselves.

I also counseled them that we could not occupy space which was being paid for under a contract, so we needed to have a lease agreement for the space that FDA personally were going to occupy. Then we needed to have what is called a cooperative agreement, which is a form of a grant, where we would provide funding to the Moffett

Center itself.

This took at least two years to lay out the program that we were going to embark upon. We published our intents in the *Federal Register*, we met both with FDA general counsel, with the commissioner of FDA, who at that time was Dr. [Frank] Young, and we met with HHS general counsel for grant and procurement law. It took a great deal of time to explain to all parties what each of the different instruments involved in this would accomplish and how we would keep those financial programs separate from one another so that our contract was not supplementing our grant, and vice versa.

It did take about two years to get all this up and implemented. However, that was in the late eighties when we carried all that out, and the Moffett Center is still operating today with all of those different instruments still continuing, and it is used as a model for other things, such as the GFSAN agreement with the University of Maryland, and there are other agreements which have been modeled from it.

At the groundbreaking, or the dedication of the Moffett Center, Dr. Kessler was there, and this was early on in his tenure as commissioner, and he cut the ribbon for the opening of the Moffett Center.

RT: Do you happen to remember what year that might have been? It was early in Dr. Kessler's time here, you said.

JT: Bob, as I recall, that was in the spring of 1990. Dr. Kessler was just recently on board.

RT: The term "Moffett Center," was that term Moffett named in honor of some

individual?

JT: Moffett was a formal head of the Corn Products International Company.

RT: Larry, maybe we can say a little bit more about the prime purpose of the Moffett Center initiative.

JT: The Moffett Center was unique not only in the arrangement of having involvement of both the academic, federal, and private sectors, but the facility itself was unique. The facility, which was several hundred thousand square feet, was actually a series of three buildings, was the core of the Corn Products Commission pilot plant, which they used to develop their food processing lines whenever they would come up with a new food product. The plant included a four-story laboratory and two pilot plant buildings. This facility is located in Chicago, Illinois, and it is adjacent to the Corn Products International Building.

The pilot plant was unique in that there were only two of those in the United States of that nature, and CPC International had constructed a new pilot plant and was no longer going to be using that particular one. It has provided a place for both FDA and IIT and industry researchers to do many successful research projects since 1990.

RT: Did some of our laboratory people go over there, possibly from Chicago district?

JT: Actually, the people who occupied the facility had been located in Cincinnati, and

they were performing research in what was an old Quonset hut in Cincinnati.

RT: Was that out at the Taft Center where they had been located in Cincinnati? Possibly so?

JT: These were CFSAN employees. They relocated from Cincinnati to Chicago, and there are approximately thirty employees at the facility now. They are full-time and reside in Chicago.

RT: Larry, you've worked for the agency for a number of years and thus have served under several commissioners. Do you have any impressions about these commissioners, either personally as to their style of management, or the program initiatives they pursued in greater interest than had been done before?

JT: When I first came here, [Dr.] Mac Schmidt was the commissioner, and Gerry Meyer was the Associate Commissioner for Management and Operations. Actually, Gerry was the individual who encouraged me to apply for the job of branch chief of the Contracts Branch. Gerry and I had known each other at the Cancer Institute early in both of our careers. But Dr. Schmidt was the commissioner at that time.

I think that one of the things that I reflect on in my years is the ability of commissioners to rely on their staff and to follow their advice, particularly in areas where the commissioner was not an expert, and none of our commissioners have ever been what you would consider experts in the area of contracts. Some of them did have familiarity

with the grant process because they had been in the academic community.

As far as the commissioner which was the best at following the advice of his staff, or seeking the advice of his staff, David Kessler was by far the best. There were many activities which we embarked on with Dr. Kessler which were ideas which he had created and which he wanted to support programmatically. But he would always call me into his office, or into a meeting, and would ask me to listen to the presentation on the program of what the program would be, and then he would ask me how was it feasible to carry out the funding of these different programs. He, on several occasions, made it very clear to his staff that unless Mr. Tidmore agreed with the approach, that FDA was not going to go forward with the activity.

This was very wise on his part, because it did make the individuals pay attention to my recommendations, and all of these activities went forward and were carried out in a very smooth, efficient fashion.

RT: Did you have any particular experiences with commissioners that were more headstrong-minded in doing something without getting counsel of management teams?

JT: We had an activity, which was before I had the grant activity, and I believe it was under Mac Schmidt, where he wanted to fund a grant with the organization which was called the Nutrition Today Society. What he was, in essence, trying to do was to provide funding to prop up a failing organization. I was not responsible for the grant activity at that time, but a grant was funded for an amount of money that was probably twenty to fifty thousand dollars, somewhere in that neighborhood. What the agency received in

turn were boxes of brochures, which, unfortunately, the Nutrition Today Society was giving these away to the public. So we received, for that amount of money, something which other people in the public could receive for free.

[Begin Tape 2, Side A]

JT: There was an investigation, and there were *Washington Post* headlines, and there may have been hearings, I think, is ultimately one of the things which resulted in Dr. Schmidt leaving the agency.

RT: You served under several other commissioners. You've mentioned two of them. Any others come to mind that were of significant impact on the agency as you managed your part of it?

JT: I think Dr. Kessler had the most impact and most involvement with us. Although Dr. [Jane] Henney, also, as both a deputy commissioner and then as commissioner, was involved in several of our activities, like the technology transfer program. She was very instrumental in pushing what is called the leveraging program, or partnering program, with outside activities.

RT: When you mentioned leveraging, was that implying funding incentives?

JT: The concept is multifaceted, but one of working with outside groups, as well as other

government activities, to partner with them where they may have a common interest and are interested in bearing part of the expenses of an activity which would benefit both partners. So it covers a broad range of agreements, from informal memorandums of understanding all the way to formal contracts.

RT: For the Food and Drug Administration, was this a new direction?

JT: It was not that new a direction, but what it was, was a recognition of what the agency had been doing for many years in pulling together a compilation of those activities.

Leveraging was an initiative of the [William Jefferson] Clinton administration.

RT: Larry, during your tenure with the agency, you have worked under a number of commissioners and other administrators, and you've also been involved either directly or in some way with several reorganizations of functions. Would you care to comment about reorganization issues?

JT: Sure, Bob. Because we are currently undergoing a reorganization, it's something I've given a lot of thought to in recent months. We have been working on developing an organization called an Office of Shared Services, which will include the procurement activities and facilities and all the things which are under me currently, and will also include some of the information technology and other things. But this is probably my tenth reorganization since I have been in the Food and Drug Administration, and some of those reorganizations I initiated myself, particularly when I first came to the FDA.

The first thing I did was to reorganize the Procurement Office, which had only been recently reorganized before I got there. But I think that the changes that I made were far more efficient and far more responsive to the program needs. But over the years I did modify the organization from time to time as other activities were added to my organization and as my scope of authority expanded.

But early in my career, Gerry Meyer, at a staff meeting, when I was the director of the Division of Contracts and Grants Management, ended up a quotation, which is attributed to Petronius Arbitor 210 B.C. It goes as follows: “We trained hard, but it seems that every time that we were beginning to form up into teams we would be reorganized. I was to learn later in life that we tend to meet any new situation by reorganization, and what a wonderful method it can be for creating the illusion of progress while producing confusion, inefficiency, and demoralization.”

That has shown itself to be very true in many occasions, and over the last five years, within the Office of the Commissioner, there have been multiple reorganizations. But for anyone heading up a large organization, such as the Food and Drug Administration, the only way they can really make an impact on the organization is to implement their own reorganization, and that may or may not contribute to the well-being of the taxpayers, but it is the number one way that any individual coming into this organization puts his imprint on the organization.

RT: Probably during the years you’ve spent at FDA we’ve had more frequent changeover of commissioners than in the early days of the agency when it was usually a long-term tenure. Perhaps one of the shortcomings of frequent change is that

reorganizations implemented, or ideas put forward, is that particular individual won't be here long enough to either benefit or suffer from some of those changes.

JT: Right.

RT: On the other side, I suppose, is the fact that by changing rather frequently you don't get a stayed inertia, which may have been a problem with the old system.

JT: The current reorganization just of the Office of Management and Systems is one which will go down, I think, as a landmark reorganization. In the past most of our reorganization, I think, were pretty much sketched out on the back of an envelope, and were through a series of meetings of the principals involved and so forth, and a little give and take, where the organizations were drawn up and then implemented, and new mission statements would be developed, and new directives developed for each of the components.

But today, as happened shortly before I came here in 1974, the reorganization is being led and managed by Booz, Allen & Hamilton. Booz, Allen & Hamilton did a major reorganization of the agency in 1974, and they split apart the facilities and contract organizations in some fashion. Of course, they were always under the associate commissioner for management and operations. It took us twenty years to get those two components back under one manager, a subordinate, to the assistant commissioner for management and operations. At the time that those two activities were put under me, I had 230 individuals working for me, and today I have 137 individuals working for me,

and I'm still carrying out more activities than I was five years ago when I started in this position.

So people bring in Booz, Allen & Hamilton, and we pay them \$3 million to find out why it's not providing the customer service that they want to have. So this will go down as this reorganization will have cost over \$4 million from the time it is finally decided what the organization is going to look like. Now, this will also involve bringing in people from the center back into headquarters, so it's a centralization as opposed to the last ten years of decentralization. That is a major step in the right direction, but it will be very expensive. It will never go to completion of the full reorganization, because to develop the shared services concept it is a five-year project as projected by Booz, Allen & Hamilton, and it will never go to completion because the principals involved, well, not even counting myself, but I'm talking about the associate commissioner for management and the commissioner, I'm sure, will all be gone before the five years has elapsed. So some other new organization will be implemented before it can ever truly bear fruit.

RT: Are there any other comments you wish to make, Larry? We've covered a rather broad range of subjects, as has your career.

JT: Well, I could go on quite some time, but I don't know if other things I would have to say are really historically significant, Bob.

RT: Larry, as you close your government career, do you have in mind continuing to be in the professional arena or are you going to just enjoy freedom now?

JT: Oh, no, I will continue working in various endeavors, Bob. Whether they are directly related to the procurement or acquisitions arena which I have always participated in, I don't know. But I do have several opportunities and they will be at least on the fringes of the acquisitions arena, I'm sure.

RT: Very good. Are there any particular awards or recognition by FDA that you've received that we might put on record?

JT: I have received several awards over the years, and I would actually have to give you a list of them, Bob, and I'd be happy to do that.

RT: We can add that as a supplement to the narrative.

JT: Okay.

RT: I want to thank you, Larry, for making yourself available for the oral history program, and I wish you, and my colleagues, Mr. Ottes, would wish you, if he were here, continued success and happiness in your retirement.

JT: Thank you, Bob. I've enjoyed it.

RT: Thank you, Larry.

[End of interview]