

History
of the
U.S. Food and Drug Administration

Interviewee: Frank P. Claunts

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

Date: December 8, 2006

Place: Rockville, MD

Interview with Frank P. Claunts

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TAPE 1, SIDE A

RT: This is another in the series of FDA taped oral history interviews. Today, December 8, 2006, we are interviewing Mr. Frank P. Claunts, who is the Finance Coordinator for the FDA User Fee Program in the Office of Management. The interview is taking place at the Parklawn Building in Rockville, Maryland. Participating in the interview are Dr. John P. Swann and Robert Tucker of the FDA History Office.

As we begin, Frank, please give a brief review of your educational and earlier professional career, and then move ahead into your FDA career.

FPC: Sure. I went to college at Texas Tech in Lubbock, Texas, and got a degree in chemistry. Actually, I had a double major of chemistry and English. I started off in chemistry because I thought I wanted to go to medical school, but the summer between my junior and senior years, I worked in a hospital in Midland, Texas, and decided I really didn't have the stomach for medical school after all. I really enjoyed my senior year and ended up with a double major in English literature as well as in chemistry.

JS: By the way, if I might interrupt, were you born in Texas?

FPC: I was actually born in Bartlesville, Oklahoma. My dad worked for an oil company, and he moved about every three or four years while I was growing up. But we lived primarily in Oklahoma, Texas, and Colorado. We were in Colorado from '51 to '55, and moved back to Texas in the summer of '55. We moved to Houston. I went to high school in Houston and then in Fort Worth. Then my folks moved to Midland, Texas, where our President is from, in the summer of 1960, the year I graduated from high school. I went on to college at Lubbock, which was just 120 miles from where Mom and Dad lived at the time, and got my degree there.

At the time I graduated from Texas Tech, I wasn't really quite sure what I wanted to do, but I was very taken with John Kennedy, who was President and who'd just been assassinated the November before I graduated. He started the Peace Corps. I really liked the idea of the Peace Corps as a way of trying to do something and give something back, and so I volunteered for the Peace Corps and was sent off to a training program in Milwaukee, Wisconsin, in the summer of 1964, where I learned the Hindi language and a lot about Indian culture and traditions. I was in a teaching program where we were going to be training teachers in science methodology and in teaching English as a second language. Half of our group was focused on the science methodology and half on the teaching of English, and I was in the science-methodology part because of my chemistry degree. Our group was trained in the Hindi language, which was used by about 35-40 percent of the people in northern India, but over half of us were sent to sites where we spoke a different language, where they spoke a different language, so after I got to India, in September of 1964, I ended up in a Bengali-speaking area in the far eastern part of India.

Actually, India has a little arm on the far east side that hangs over what's now Bangladesh but was East Pakistan back then. I was sent to a little finger that sticks into the side of what was then East Pakistan, in a state called Tripura, as a Peace Corps volunteer. I lived there for two years. It was a very small village. It had a market two days a week, on Wednesdays and Saturdays, when you could go down and buy produce and meat. Those were the only times you could get groceries and provisions. And I was the only Peace Corps volunteer in that town. The nearest Americans were about 40 miles away, which was about a two- to two-and-a-half-hour trip to get there because of the conditions of the roads, and you'd have to go by bicycle or rickshaw to a place called Udaipur, about 10 miles away, and then take a taxi, where you were one of many passengers paying for a seat in the taxi, to get to Agartala.

I lived in Kakraban for two years, taught English and taught science in the local teacher-training college, science methods. To kind of get an understanding of what the teachers were up against, I also taught English in a primary school in a little village called Harijola, which was about a three-mile walk from Kakraban. So that was what I did right after I graduated from college.

And when I finished my two years in the Peace Corps, I was asked by the fellow who was the Peace Corps director in India at the time, Fran Macey, if I would be willing to stay on and work on the Peace Corps staff after that, and I said yes, I would. I loved India and I welcomed the chance to come back to India. And what's more, then I could work for a couple of years without having to wear a coat and tie, in a short-sleeve shirt. That was an opportunity that sounded wonderful. But I didn't want to come back to India single, and so I went home and married my college sweetheart, Nancy, and came back to

India in January of 1967 to work on the Peace Corps staff. I worked on the Peace Corps staff for a couple of years in India, living in Calcutta and in Patna in northern India.

And then, after that, I was asked if I would stay on in India. I said I really would like to get back to the States. I'd been away from the States for five years and I wanted to get back home. And so they asked me to come back and work on the India desk for the Peace Corps in Washington. That was my first opportunity to live in Washington. In 1969, my wife and I moved to the Washington, D.C. area. We rented a little house in Arlington, Virginia, sight unseen for \$125 a month. We had contact through another couple we knew in India. They knew the couple that was about to move out of that house, and we thought, hey, that sounds good to us, and so we made arrangements to rent the house and came here, and I worked in downtown Washington. The Peace Corps office then was right opposite Lafayette Park. So I worked there for a couple of years in Peace Corps headquarters, 1969-71, as one of three India desk officers. Because India was the Peace Corps' largest program, with 1,500 volunteers in India at that time, there were three India desk officers.

Towards the end of that time, I was asked if I would go back to India one more time to do another tour in Patna, Bihar, where I'd lived before. I went back to Bihar to be the state director for the Peace Corps in Patna and Bihar in 1971-72.

The Peace Corps has a rule that you can only work for the Peace Corps for five years, or a sixth year, at the discretion of the director, but then you have to leave. It's an excepted appointment, not career service, and they did it very intentionally because they didn't want to have a bureaucracy with its own perpetuation as its primary driving force. So at the end of that time, I'd run up against the maximum amount of time I could work

for the Peace Corps, and I came back to the United States unemployed in April of 1972. I talked with some of my colleagues in the Peace Corps who'd gone through a similar situation, and my wife and I decided, from our brief living in the Washington area, that we really wanted to continue to live in the Washington area. We love this area. It's not flat like West Texas, and it had trees and hills, and it's quite beautiful.

JS: The weather was a little nicer, too, wasn't it?

FPC: Oh, absolutely, absolutely, although we thought we could live back here without air conditioning at first, but after about one week of August in '69, when we first moved here, we went to George's and bought a window air conditioner for our little house that we were renting. The summers here were pretty brutal, too.

But we decided to stay here, and I decided I'd go ahead and look for work with the government.

I got a copy of the President's budget and went through it to see which agencies looked like they were growing, so I'd see where the best chances were to find employment opportunities. The budget showed that there'd been substantial growth in the Food and Drug Administration, in EPA [Environmental Protection Agency], and in the Law Enforcement and Assistance Administration of the Department of Justice. All three were agencies that I thought had a mission that I could relate to. I didn't want to work for an agency that didn't have a mission I believed in and could support. I didn't know much about FDA and EPA, but I thought I liked the missions of both of those agencies.

JS: What about the mission appealed to you? Can you say something about that?

FPC: I guess the consumer-protection nature of the mission, the fact that the whole purpose of the agency is to try and protect consumers and help them, and it did something that I thought was socially important for the country. It contributed to the well-being of the citizens. That's why both EPA's mission and FDA's mission appealed to me at the time.

So after I found out which agencies were growing, I started knocking on doors. I got the telephone books of the agencies. I'd been advised that the main function of personnel offices in the federal government is to protect executives from all the people who are looking for jobs, and so I quickly learned to avoid personnel offices. And I went through agency phone books and tried to pick, at medium to high levels, the names of people whose doors I might knock on and talk to about whether they had any vacancies there.

I came to FDA, and one of my first appointments at FDA was with a fellow named Dick Terselic, who was Deputy Executive Officer in the Center for Drugs at the time, and he looked at my resume, and my salary was about comparable to a GS-12 or -13, and he told me he didn't think I'd have any luck finding a job at that level because, with my experience totally unrelated to things at FDA, he just thought that I was way overpriced for the market. But he told me he'd been wrong before. His neighbor had a used Volkswagen that he was trying to sell. Mr. Terselic told him they could never sell it for the price they were asking, but he was surprised that they finally did get close to that

price. That was my worst day of looking for a job in that period, being compared to a used Volkswagen and being told I was overpriced in the market.

JS: This was also the time, though, around Project Hire.

FPC: That's right. The FDA was bringing on lots of folks. And that's why it stood out when I looked at the budget appendix, because Project Hire showed this tremendous growth in the last two years at FDA and plans to continue to bring on folks.

But one of the best days was when I talked to Phil White, who was in the field component of FDA headquarters. I can't remember exactly what Phil White's title was, but he told me that FDA was hiring a lot of people, and the person that I should talk to was Charlie Coffindaffer, who headed the Division of Management and Systems. He said Mr. Coffindaffer was hiring a lot of management and program analysts on his staff, had a good reputation in the agency, and he thought Charlie might be interested in talking to me.

I immediately called Charlie Coffindaffer, got an appointment, gave him my resume. Frankly, I didn't know what a program analyst or a management analyst was at that time, but I tried to convince him that I could be one based on the kinds of things I'd done in India, where we went in and met with state government officials, talked to them about what their needs were, and tried to put our heads together with them and see where the Peace Corps could do some things that would help them. Those were the kinds of things I'd done in India.

And I guess Charlie was impressed. He decided to hire me. This happened over about a two- to three-month period in the late spring/early summer of 1972. But he put a condition on hiring me. He only wanted to hire me if I was willing to go to school at nights and to get an MBA degree. He said the government would pick up the tab if I would do that. Well, I was ecstatic because I wanted to continue my education anyway. So I told Charlie that was a condition I would happily meet.

I was hired by Charlie in July of '72 and came on board as a management analyst. My first job was working in a newly formed branch, the Organization Planning Branch, and Tom Keough was temporarily the chief of that branch, but he left to go into the seminary to become a Catholic priest at the end of that summer. Barbara Porterfield then took over as the first permanent Chief of the Organization Planning Branch. Barbara was my immediate supervisor and Charlie Coffindaffer was my second-tier supervisor.

I liked the folks I worked with. Charlie had a pretty bright stable of young management analysts. There was -- I'm trying to go back and remember the names of some of the folks who were there -- Tom Perrelli, who later became executive officer in the Center for Veterinary Drugs; Russ Abbott worked in the group at the time and became the executive officer of CBER [Center for Biologics Evaluation and Research] and later CDER [Center for Drug Evaluation and Research]. And Jim Strachan, who later became the ORA Executive Officer, and Ted Searle were working this group. It was a very impressive group of folks.

And we did management studies in a variety of areas. I was involved in doing a management study for the formation of the new Bureau of Medical Devices at that time.

We interviewed some of the key people in the medical device area and did all the paperwork to establish the Bureau of Medical Devices in the early '70s.

One of the things I enjoyed the most, and one of the things that was very helpful in my career, was a study that I did with John Migliori and Jerry Gooden, of the review process for animal drugs for food-producing animals and how that process worked in FDA at that time. And this study was really commissioned by Sherwin Gardner, who was Deputy Commissioner of FDA at the time and the head of the Center, was actually the Bureau of Foods at the time. This was just after Virgil Wodika. It was a thin fellow, I can see him now. I'm drawing a blank on his name. He was the Director of the Bureau of Foods at the time.

JS: We can find that out in our list of directories and fill that in later, so don't worry about that.

FPC: I believe his name was Howard Roberts.

Anyway, we did a flowchart showing the process through which the animal-drug application flowed on its way to approval or a decision not to approve it. We documented how much time was spent in each office in the Center for Veterinary Medicine, and how much time was spent in the Bureau of Foods, in each office. And basically, as a result of that, some procedural changes were made in the review process for animal drugs that shortened the review time, and that study got the attention of Deputy Commissioner Sherwin Gardner and from the Bureau of Foods director at the time.

JS: I know this is a long time ago, but do you recall the way it was before the changes were implemented and what it was like afterwards? It must have been a substantial difference.

FPC: I remember that, it seemed like the process, once it hit the Bureau of Foods, could last somewhere between 18 and 24 months for review and approval, and they tried to make some changes and put in some controls to bring that down to less than a year. Ultimately, the foods part of that review was later transferred to the Bureau of Veterinary Medicine. It didn't happen immediately after that study, but a few years later. It was a step in the process that led to that change in how things went.

I got my MBA degree in the evenings at American University while I was working as a management analyst.

JS: That must have been difficult, doing this during the evening and then your job during the day.

FPC: It was, and we had one child when I started to work for FDA, and we had three by the time I got my MBA degree, so it was hard on my wife as much as me. My wife was very supportive of my getting this degree.

Once I got the MBA, I thought, oh, I'm feeling my oats. Let me see if I'd like to work some other places, and I put in an application at OMB [Office of Management and Budget]. I avoided their personnel office. I went down and met a few high-level officials

at OMB whose names I picked out of a phone directory and called and sent letters to. And I got a job there in their Legislative Reference Office, where I was responsible for the review of legislative proposals or legislation passed by Congress. I would coordinate the development of an administration position on each proposal or enacted legislation. We would look at both draft proposals that were getting ready to be sent by the Administration to Congress, and we'd look at the real bills. Once Congress passed a bill, we had to do a letter to the President that said what the administration position on that bill was. We would recommend to the President that he sign or veto it. I was responsible for the clearance and coordination of all the legislation dealing with national security, international affairs, and international financial institutions. That was pretty heady stuff.

One time, during a flap about the Arab oil boycott, the Commerce Department wasn't quite toeing the administration's line on what should be done. I raised their resistance up to the folks in the White House, who were our immediate policy supervisors. I got called over to a meeting in the West Wing of the White House with Stuart Eisenstat, who was President Carter's Chief of Staff at the time. He called in the General Counsel and other folks at the Department of Commerce and had a little come-to-Jesus meeting right there in the West Wing of the White House, and I got to be there for that. It was kind of heady stuff for a young guy to be operating at those levels.

It also was very stressful stuff, and while I enjoyed the excitement of it, I guess I didn't enjoy the fact that, as a legislative analyst down there, usually I was the guy who knew the least about the issues of anybody in the room. After four years as a management analyst at FDA, I usually knew more about the issues of the particular program that I was focusing on than anybody else in the room. I enjoyed that position of

having knowledge of the program. And here I was kind of flying at a very high level at OMB, being the person who knew the least about the issue, trying to be an honest broker and get people together to reconcile their differences. I didn't find that as satisfying as knowing a lot more about the programs and being more intimately involved with them.

So I called Gerry Meyer, who was the Associate Commissioner for Management at FDA at the time. This was '77, after I'd been at OMB less than a year. I said, "Gerry, I really would welcome an opportunity to come back to FDA at any time that there's an opportunity for me to come back there. I've had fun down here, I've found it interesting, but it's really not a place where I want to make a career or stay very long." And Gerry gave me a very warm reception, told me he was sure they'd have an opportunity back there for me, and he had me come back and work as a special assistant to Mary McBride, who was head of personnel for FDA then.

I did some things for Mary, such as some studies on retention and employee relations problems for about three months.

Then there was an opening for the position of Director of the Division of Management Services. Lloyd Sundquist, who was director of the Division, retired, and a GS-15 position was open. I competed for that job and was selected for it in the fall of 1977.

I served in that job for three years and was responsible for small purchases, contracting, administrative services, for FDA facilities nationwide. That was at a time when we were trying to get an FDA campus. We were very active in getting the land out on Muirkirk Road in Beltsville, and we got the Mod. I and Mod. II for Foods and Veterinary Medicine. That was originally going to be the FDA campus. That was one of

many false starts in getting an FDA campus established for the agency. But we got a couple of buildings built there. That was one of the more exciting things that happened when I was in the Division of Management Services.

After three years doing that, I got a little restless and decided I'd really like to do something else. When I got my MBA degree, it was with a major in financial management, and that's what I really enjoyed. And Gerry Meyer had mentioned to me a couple of times that Ron Chesemore, who was Director of the Division of Financial Management at the time, was getting a little restless. He'd been in that job five years and was interested in doing something else.

I called Ron and asked him if we could go to lunch. I told him I had a proposal I wanted to talk to him about. So Ron and I went to lunch in June of 1980. I proposed to Ron that we swap jobs. I said, "I understand you've been head of financial management for five years, you're getting a little restless and would like to do something else. I've been in charge of facilities and acquisitions and procurement in the Division of Management Services for three years. I'm getting a little tired of that and I really would like to get into financial management. Would you be interested in swapping jobs?" Ron said he wanted to think about it, but within a week I got a call from Ron and he said he would like to swap jobs. He'd enjoy a new challenge. He was tired of doing some of the same old things, and so he'd like to make the switch.

We both met with Gerry Meyer, the Associate Commissioner for Management, who blessed our arrangement and said, "That's terrific. I support you guys in making this change." So I became the Director of the Division of Financial Management in July of 1980, and Ron became the Director of the Division of Management Services for a couple

of years. And, of course, after three or four years, Ron moved out of that job. Later, Ron came into ORA, where he later became the Associate Commissioner for Regulatory Affairs.

JS: He was the head of, I believe, Regional Operations?

FPC: That's right. He was head of Regional Operations first. He went from there to being head of Regional Operations and then, after that, to being Associate Commissioner for Regulatory Affairs -- head of ORA.

RT: At the time of the swap, were you were both equal in grades?

FPC: That's right.

RT: That wasn't really a problem in the job exchange.

FPC: That's right. We were both GS-15's, we were both at the same level, and so that wasn't a problem at all. And I thought I'd just gone to heaven. I was happy as could be because I really wanted to work in financial management and I was getting the chance to do so.

It was fun because, as Director of the Office of Financial Management, you were in direct contact with every commissioner. I held that job for fourteen and a half years,

from July of 1980 until the end of December 1994, and came in close contact with every commissioner.

RT: That would have been starting with which commissioner?

FPC: Arthur Hull Hayes was the Commissioner when I first came into that job.

And I'll never forget. He did a videotape for the agency. We had some controversies with respect to, I think, antibiotic certification. Anyway, he did a videotape for the agency as kind of an introductory tape, and he mentioned in the videotape that he'd met with Frank Claunts and he understood all that he needed to know about finances. It was just like his own personal checkbook; you just added six zeroes to it!

It was heady stuff to work directly with the Commissioners. And we shepherded him through his preparations for his first appropriation hearing, because one of the things you do in financial management is you have to take the agency's request for appropriations to the House and the Senate Appropriations Committees, defend it in hearings before them, and work closely with the staff each year as that request for appropriations makes its way through the congressional process.

RT: I know in the Office of Legislation, where I once worked, there was testimony preparation about key agency issues. Would you or your staff prepare the statements of testimony regarding appropriations?

FPC: Absolutely. We prepared the statements of testimony for the witnesses at the table. We prepared a huge book, probably an inch-and-a-half to three-inch binder, of issue papers. When you're in an appropriation hearing, it's not like most hearings where you're there on a single issue, like drug-eluting stents or something like that. You're not looking at just one issue. Anything the agency does is fair game, so they can raise anything from radiation emitted from cell phones to yellow #2 or a veterinary drug that may be causing problems with antimicrobial resistance. So usually when the Commissioners go to these briefings and then the hearings, all the Center directors are present too, so you're constantly working with, in effect, the board of directors of the agency, with the Commissioner and all the Center Directors, to get ready for the hearings. We'd have several meetings to prepare them for that.

RT: Would General Counsel be involved in those discussions as well?

FPC: Oh, yes, General Counsel was involved.

JS: A lot of the people who are going to be reading this may not have an appreciation for the way budgets are negotiated within the agency and how these come about, or how the Office of Financial Management works with all of the Centers in the major offices. I wonder if you could characterize that for somebody who doesn't really understand the way that budgets are developed within the agency.

FPC: Sure.

Basically, the agency budgets are always using the last appropriation as the baseline, so whatever was appropriated for the most recent year is your starting point. What you're doing is negotiating differences between those numbers and what you're asking Congress to approve for the next year. We went through periods of zero-based budgeting and other things like that, but it never really took root. Everything is started from the baseline of the most recent appropriation. So Congress sets that line every year when they pass an appropriation.

Now, within the agency, in preparation for developing the budget, the Office of Financial Management asks each one of the Centers and Offices what their priorities are for the next year. What are the most important things for them to accomplish? The Centers are then asked to submit how much they think is needed to accomplish those priorities. The Office of Financial Management will get that wish list from each one of the Centers and Offices and provide a consolidated list for the Commissioner.

Then, how that list is vetted changes depending on the Commissioner and how the individual commissioners operate. Some Commissioners like to convene all their Center Directors together to have them talk publicly about the list and have kind of a public vetting process. Some Commissioners, like Dr. Kessler, are introverted, and like to have very small meetings and kind of vet those lists with a small number of staff. But the most crucial thing is that the Commissioner, the head of the agency, is the one who ultimately decides what priorities are going to be budgeted for the next year. He gets the wish list from each one of his components. He will be responsible for a process that somehow takes the wish list from all the components and decides, these are my top priorities, and these are things that I'm going to ask money for next year.

Almost always, the staff recommends that his top priorities be the cost of the pay raise and the cost of inflation, because if you don't get the cost of the pay raise and the cost of inflation, you're moving backwards from year to year. Usually the staff and financial management will say, "These should be your top two priorities." Then after that, if there are program increases you want, if this is the year to go after a particular food-safety initiative and add resources to the foods program, the Commissioner will ultimately make that decision. He'll, either with the advice of the Center directors or with the advice of a small staff or on his own, make the decision that these are my priorities. It's the Commissioner's ultimate decision.

RT: That's a developmental phase of budget planning.

FPC: Yes.

RT: The Congress has on many occasions imposed additional responsibilities on the agency and sometimes has not provided additional funding to cover those added responsibilities. Can you speak a little bit about the decision process which is involved in those situations?

FPC: Sure.

But even before it gets to Congress, there are other cuts that occur in this process.

Whenever the Commissioner says, these are my highest priorities and this is what I want to do, that's always the high-water mark for what that budget request will look

like, because for most of the years that I was in the Office of Financial Management, we had an Office of the Assistant Secretary for Health that was the next echelon, and their role was generally not to enhance our budget, but to cut it back.

TAPE 1, SIDE B

FPC: And so the Commissioner would make his pitch to the Assistant Secretary for Health. The Assistant Secretary for Health would ultimately decide, this would be an embarrassment to me if I ask for everybody's wish list. The increase would be too high, the difference between what was appropriated last year and what we're asking for this year. So the Assistant Secretary for Health, Ed Brandt or Jim Mason or Bob Windom, whoever it happened to be, they'd make the decision: No, FDA, you're going to get to ask for your first priority, and I like your fourth priority better than your second and third, so I'm going to give you your first and fourth priorities. Those are my decisions of what I'm going to let you ask for.

Then it would go to the Department, and then we'd maybe go up there with CDC's first priority and Indian Health Service's second priority, but they'd all be enhancements. Then once it got to the Department, the Secretary would then make a cut. The Secretary would say, "Oh, Ed Brandt, you've got too many things here. We can't support all those things because we've got Medicare with these needs and we've got other components with needs, so we can't put it all in health. We've got to give other programs some increases."

So there's a constant vetting and reduction and appeal process that goes on.

We used to prepare our budget in March and send it to the Assistant Secretary for Health. Then they would make cuts and the revised budget would go in June to the Department. The Department would make cuts, and the final budget approved by the Department would go to OMB in September, and that was the budget for the year that was already a year from that September. Then OMB would make its final decisions in usually December or January, just before the president's budget is submitted to Congress. What happens at each level, of course, is there are cuts.

Then it goes to Congress in January. FDA's appropriation comes under the Agriculture Appropriations Subcommittee, unlike the rest of the Department which is under the Labor-HHS Appropriations Subcommittees. There, under Labor-HHS, NIH [National Institutes of Health] and CDC would often have their budgets added to. But for us, whatever OMB asked for was rarely added to. It was usually reduced from, so there were further changes made in Congress. And, in addition, Congress would put on certain earmarks. Congressman [Joseph] Skeen would ask for earmarks for particular educational institutions in his home state of New Mexico, for example. We'd have certain grants that we were always required to make out of the funds available to us to places in New Mexico put in as earmarks in the appropriation language. So the congressional will plays out in this process, too.

Plus the, you know, money is politics, and the congressional committees or the appropriations committees would decide, if they didn't like something we were doing, and they would decide what we cannot use any funds for. So they could put restrictive language in the appropriations saying that you can't use any funds for certain purposes.

RT: I was going to ask you if the fact that FDA is regulatory, perhaps more than some of its sister agencies in the Department, if that is a problem in that sense.

FPC: Well, I think it is, because regulators aren't very popular folks, and the congressmen always hear from the regulatees about the problems they've had with the regulators, so they're overly suspicious of us when they make decisions. So we're pretty much in an adversarial environment.

And the reason FDA was under the Agriculture Appropriations Committee was because back in the days when FDA regulated pesticides, before EPA was created, we were moved there because the folks on the Agriculture Appropriations Subcommittee thought we were far too aggressive in regulating these wonderful pesticides that were available to the agricultural community, and they wanted to ride herd on us a little bit.

JS: But hadn't we been under Agriculture since even after 1940, when we were switched administratively to be under the Federal Security Agency.

FPC: That's right. We started off under the Federal Security Agency.

JS: Wasn't our budget still under Agriculture at that time? I mean, we started out, obviously, in Agriculture before 1906, but we were moved to FSA in 1940. But even after the move, when we joined agencies like the Public Health Service and NIH and others, didn't our budget continue to be overseen by the Agriculture Subcommittee?

FPC: I can't answer you for sure, but I have the impression that FDA was moved into the appropriate committee for the Federal Security Agency and then later for Health, Education and Welfare, and that in the '60s it got moved back under the Agriculture Appropriations Committee, but I'm not sure about that. That's an impression I have from things I've heard, but I couldn't say that for sure.

JS: But that historical issue aside, one question I wanted to ask is, since we're under the Ag appropriation, what's the reasoning here why we weren't moved under Health with all the other health agencies? Was it a case of the Agriculture Appropriation Committee wanting us rather than the health departments not really caring?

FPC: Absolutely. They wanted us, particularly when we still regulated pesticides. Before that rib was taken from our side and EPA was created, they wanted to control the regulators of pesticides, so that was the strongest reason for FDA to be there.

But even after EPA was taken away from us, Congressman Jamie Whitten, who was chairman of our appropriations committee for many years, felt he really wanted FDA in his committee. He liked having jurisdiction over the mission of FDA. He felt we had an important mission, and he liked that, so he wanted to keep us there. And there'd been a lot of talk about moving us out of that subcommittee, but clearly the subcommittee so far has had enough muscle to keep us right there. That could change over time.

JS: But as far as you know, the Health Committee would certainly welcome FDA under its wing, but it's really more the strength of the Agriculture Appropriation Committee.

FPC: That's right. They pick and choose their fights up there, and they don't want to alienate the folks on the Ag Appropriations Committee if they feel strongly about keeping us there. Clearly, Congressman Whitten felt strongly about keeping us there. His successor, Dick [Richard] Durbin, who was chairman for a couple of years, felt strongly about keeping us there. That was before he moved over to the Senate and moved up to the number-two spot in the Senate now. So there's been a strong feeling about wanting to keep us in the Ag Appropriations Committee.

But the fun thing about working in Financial Management was it's where FDA policy is created. Money drives policy, and the appropriators were the levers to make sure that policy went in a way that they were comfortable with when they approve our appropriation bill, so they can restrict it from doing things, or enable us to do things.

In fact, one of the ways they did this was they didn't much like the idea of user fees, and user fees came on as a very powerful idea basically from the time there was a User Fee Act passed in 1950, in the General Appropriations Act, 1950 or '51, that gave federal agencies the authority to collect some of their funds from user fees. If the things that were done by the agency were for the good of a particular identifiable beneficiary rather than for the public welfare overall, agencies were supposed to collect user fees from these beneficiaries.

JS: Do you know what prompted this Act, any of the social, cultural, or economic issues?

FPC: It's strictly an economic issue. It's always been an effort to keep expenditures down, by transferring some cost to user fees instead of paying for them out of the general funds. OMB was the driver of this. And so once that Act passed, OMB almost immediately turned to FDA and said, "Hey, can't we put some of your things under user fees? How about putting the drug-review process under user fees?"

JS: You're talking about from the 1950s era?

FPC: Yes, from the 1950s. This is documented in that 1983 study that I wrote called the "User Charge Study of 1983," and I'll provide you a copy of that.

But from the early times -- our Chief Counsel at that time was a fellow named Billy Goodrich -- Billy Goodrich said, "Hey, before that Act passed, Congress had specifically created within FDA some fees for specific activities, like insulin certification and antibiotic certification. So it's my view as Chief Counsel of the agency that Congress has to specifically authorize fees for FDA activities. We can't use that general authority of the Independent Agencies Appropriation Act of 1950." So that was Goodrich's approach back in the '60s, to say, "No, we don't think the general user fee authority applies to FDA."

But every year or two, OMB would re-raise this issue, trying to force FDA to get some of its money through user fees. When I was in the Office of Financial

Management, as our budget developed for 1981 or one of the early years I was there, we got pressured to charge user fees for some drug approval activities. We were charged to do a study of that. I authored a user-fee study. I worked with Paul Coppinger on it, but I did most of the work. We documented the history of user fees from the past, from the Independent Agencies Appropriation Act, to 1983. We documented how FDA rejected user fees at various times for various reasons, and we expressed our concern that if we ever got user fees for anything, even for a small part of a program, over time the pressure from OMB would grow to make all of that program supported by user fees.

RT: In regard to user fees, of course, that was kind of imposed, as you're indicating, externally. Internally, how were user fees defined or formulated, on the basis of what criteria?

FPC: Well, first of all, let me just give you a little bit more history about the resistance to them, because for a long time we'd opposed them. Both Dr. Arthur Hull Hayes, Jere Goyan, the commissioners early on before Frank Young, opposed user fees.

JS: Charles Edwards?

FPC: Charles Edwards.

JS: Goddard.

FPC: They opposed user fees, constantly resisted them.

The break came when Frank Young was appointed Commissioner. Frank Young was more open to user fees and was willing to go ahead and consider user fees. I can remember in one of our budget discussions, when I'd gotten some feedback that Dr. Young had said, "Okay, I'm putting some user-fees monies in our budget." And, of course, they still had to be approved by Congress if we believed in the Billy Goodrich principle that we needed specific authorizing legislation. I couldn't believe Dr. Young made this decision. I tracked him down by phone to a motel in Utah, where he was attending some meeting. I got him on the phone and said, "You didn't really mean to do this, did you?" And he said, "Yes, I really did, Frank."

JS: But what about the opinion of the General Counsel, Mr. Scarlett or whoever was General Counsel at the time? Regarding the interpretation that Billy Goodrich had made, which I imagine was shared by Peter Hutt, his successor, did the General Counsel's office at some time make a determination that this was something that wasn't necessarily the case?

FPC: I don't think it was ever made in a written determination. Basically, Frank Young, Frank Young agreed that we would put in the budget that we would get less money from appropriations and we would start collecting user fees for drug approvals. This was proposed for the first time when FDA submitted its budget for 1986. Tom Scarlett was Chief Counsel when that user-charge study I mentioned to you was

published. He looked at it before it was published, and wanted to deny later he had. And so I reminded him of the meeting he was in where it was cleared.

But Frank Young finally, in 1986, in our budget, said, “No. Let’s go ahead and put in there that we’re going to collect some user fees under the Independent Agencies Appropriation Act.”

So we put that in our budget submission in 1986, that we were going to do that, and we published a notice in the *Federal Register* that we were going to do that.

Well, when our 1986 appropriation was passed, Congress included a new line in it. It said something to the effect that no funds made available in this Act can be used for the development or implementation of any user-fee program under the authority of the general User Fee Act, period. So Congress killed it right there. And the administration proposed it again the next year, and Congress killed it again. And so we went through that dance. All the time that Young was Commissioner, it kept getting killed because the Congress would say, “No, we’re not going to let this happen.”

JS: But was there discussion about Congress’s view in opposition to this during appropriation hearings.

FPC: There was, and Jamie Whitten and others were incensed that we would keep making our budgets based on proposed legislation instead of on what the law really was. And OMB forced us to go ahead and put these budgets out based on changes in law they wanted, because OMB wanted to make the budget look like it was asking for less appropriations. It was strictly driven by appearances from OMB.

JS: I'm probably getting ahead of you here, but there's, of course, another side in this story, too, and that's industry.

FPC: And I'm going to tell you how the tide changed.

What really happened was, after Kessler became Commissioner, he started working closely with some of the folks on the Appropriation Committee, and Kessler was philosophically supportive of user fees, too, as long as the fees didn't look like FDA was beholden to the industry.

One of the big concerns was this thought that "he who pays the piper calls the tune." We wanted to be sure it was done in such a way that FDA was not beholden to industry, that industry was not going to be looked at as our puppet masters if we started collecting fees from them. This was a key concern.

And what happened to change things? Industry had been staunchly opposed to user fees consistently, right up until Kessler became Commissioner. Well, Gerry Mossinghoff took over as the head of the Pharmaceutical Manufacturers Association [PMA, now PhRMA] in the early 1990s. Prior to that, he had been Commissioner of the Patent Office, and he'd been at the Patent Office when they instituted user fees there. Mr. Mossinghoff told the folks in the drug industry, "Guys, you're missing the boat here. FDA's resources for drug review are inadequate. They're never going to be able to meet the kind of time frames we want. They're never going to have the resources to do the job unless we put some money up too. And if we can find a way to guarantee that the money we put up will be in addition to appropriations, and not in lieu of appropriations, then we

can see the resources FDA has for drug review increased. We can get more of what we want out of it, too.” And so Mossinghoff really was the guy who was responsible for changing the view of the drug industry from consistently opposing user fees to being supportive of user fees. That was the seminal thing that happened.

Kessler basically supported user fees, once Mossinghoff turned the drug industry around, and Kessler and Mossinghoff and folks from the biologics trade organization -- I don't remember who that was at the time -- worked with the congressional staff. Bill Schultz was on the congressional committee staff at that time and was the chief staffer we worked with in the House. But we developed the Prescription Drug User Fee Act [PDUFA] in 1992, and it passed in 1992, because finally there was industry support. And that law put into place a provision that the fees had to be in addition to FDA appropriations, and that if FDA didn't spend the minimum from traditional appropriations, they couldn't keep and spend the fees for that year. So those are called the triggers in the PDUFA law. They require FDA to have to have a certain amount for appropriations. Basically, they have protected the program so that, by and large, the fee money added by the industry has been in addition to appropriations.

Now, they haven't been perfect protections because the rate at which the appropriation increase was triggered was geared to the CPI [Consumer Price Index]; FDA's appropriation had to go up as much as the CPI goes up. But our costs over time have risen at a much higher rate than the CPI.

JS: So it has not been the case that our appropriations have diminished over time because of the increase over time of user fees. Is that correct?

FPC: I think that's fair to say because, basically, what we spent from appropriations had to go up by at least as much as the CPI or we couldn't keep and spend the user-fee money, so that appropriations for the drug-review process haven't gone down.

Now, there is another view that said, because we had to protect the appropriations from the drug-review process, when we got harsh marks from OMB about how much we could ask for, we always managed to be sure there was enough in the drug-review process to meet those triggers. So sometimes, particularly in the early years, the budgets for foods and for devices and for other organizations got reduced to be sure that we had enough budget authority in the drug process to meet the triggers in PDUFA. So there was some harm to the other Centers done budget-wise in PDUFA I, in the first five years of PDUFA.

After that, most of the reductions, if they had to be made, were absorbed within drugs and biologics in their non-drug-review activities, in their compliance activities or in the field portion of those programs. Those were the ones that took the cut in order to protect the drug review funding.

JS: Okay. And I gather that under the term provisions of the '92 Prescription Drug User Fee Act, that there are very key areas where money can be spent on user fees within the agency and where they cannot be spent. Could you say something about that?

FPC: The Act defines the process for the review of human-drug applications, and money can only be spent on things that are part of that process as defined in the act. And

for the first 10 years of PDUFA, that included only pre-market activity. You couldn't spend a penny of it on any post-approval activities.

In PDUFA II in 2003, we got permission for the first time to use some of the money on post-approval risk-assessment activities, and that was specified in the Act. It was only things in the first two or three years after the drug was approved that we could spend the money for.

In PDUFA IV, which we just negotiated with the industry but which hasn't been enacted by Congress, at least the agreement we have with the industry is to expand substantially the post-approval activities we can spend the money for.

PDUFA has a five-year sunset provision. It has to be reauthorized every five years. We have linked the reauthorization negotiations with the industry every five years, and I've been a party to the negotiations in PDUFA I and to the renegotiations in PDUFA II, III, and IV for all the financial aspects of PDUFA over the time I've been here.

JS: Can you say something about any substantial differences when PDUFA was reauthorized in 1997? Was there any major difference between that law and the original law, that maybe we had recognized there were problems that we did not anticipate?

FPC: There were some differences. Unfortunately, we had a flawed negotiating process in 1997, when PDUFA was renegotiated, and the agency didn't fare well in that.

Mike Friedman was our Acting Commissioner at the time, and he insisted on being at the table during negotiations, and that really put him and the agency at a disadvantage. Friedman was too quick to make agreements with the industry. He would

agree on proposals they would make without having a chance for his staff to tell him what the downsides or the upsides were of these agreements. And the agency really suffered under PDUFA II because we didn't have enough money to sustain performance. We were insufficiently funded. We couldn't keep things up at the level as industry expected by the end of PDUFA II.

In PDUFA III, we got the agency to use a different negotiating process. Only at the staff level personnel would negotiate with industry. Then we'd go back to our ratifiers, who were the commissioner and his senior staff, and tell them, "This is what industry has proposed. This is what we propose. We've had a chance to analyze what industry wants. This is what we recommend." Then we got feedback and decisions from our ratifiers, who were better informed before decisions were made. By not having the Commissioner at the negotiating table, but having him a step back, he had a chance to get staff advice before making decisions. We had a much better arrangement under PDUFA III than we had under PDUFA II.

JS: When PDUFA II was passed, this was also the same time as FDAMA, the 1997 FDAMA Act. I can't even remember what the acronym stands for, but . . .

FPC: Food and Drug Administration Modernization Act.

JS: Modernization Act. Thank you.

Was there any interplay? Was one delayed by the other? I seem to recall that there was an issue.

FPC: They were both a package. I mean, we didn't want many of the provisions of FDAMA, but political forces at the time led that to happen. I mean, it happened over the agency's protests and resistance. We wanted what you call a clean reauthorization bill and we didn't get that.

When we got PDUFA III, we pretty much got a clean reauthorization bill. It didn't have a lot of other statutory changes embedded in it.

PDUFA IV is going to be very interesting because we have the Enzi-Kennedy bills being considered in Congress right now, which would substantially revamp our drug-safety operations. And I think there's some nervousness that we may see PDUFA IV changes wrapped into some kind of larger FDA reform bill again, and you're always nervous about what that's going to bring.

JS: Well, the timing is such that it's going to happen during what's been going on for the past few years in terms of drug safety.

FPC: Right.

JS: Can you walk us through, now, how the user-fee acts were applied to other product categories FDA regulates in subsequent years?

FPC: You're talking about medical devices and animal drugs?

JS: Yes.

FPC: Sure.

Basically, we had a model that was working pretty successfully for human drugs, and let me just talk a little bit more about the fees for human drugs.

But we have three basic fees, three legs to that program. One is an application fee that's paid any time an application is sent to the firm. But that only generates a third of the revenue. Two-thirds of the revenue comes from annual fees that the firms have to pay. Any firm that manufactures a prescription drug product has to pay an annual establishment fee, and they also have to pay an annual product fee for any product that was marketed that year. Those were annual fees that generated two-thirds of the revenues, and those two-thirds of the revenue are fairly stable from year to year. The third that comes from application fees could be pretty unstable. It could fluctuate a lot depending on whether we got a lot of applications that year or a few, and we don't have any control over that. There's not a steady stream of application fees from year to year.

JS: But the fees themselves, the charges for an application and so on, are those set?

FPC: It's specified in the law that a third of the revenue comes from product fees, a third from establishment fees, and a third from application fees, and the laws have been different at each time. PDUFA II set the actual fees in the law, how much we could charge for an application fee, and everything else was tied to that. In PDUFA III, we got away from that and went back to the way PDUFA I was, where the law sets a revenue

target for application fees. We can adjust that revenue target for inflation and for changes in workload. The revenue target for establishment fees and the revenue target for product fees is also adjusted for inflation and workload. Every year, by notice in the *Federal Register*, FDA does the inflation adjustment to those revenue targets, a workload adjustment if necessary, and then publishes what the fees have to be to meet those targets.

JS: I know you didn't bring numbers with you and so on, but it would be interesting to find out what this amounted to, what specific amounts of money we're talking about in relationship to the appropriated amounts.

FPC: Well, for the drug program, we're currently at over 50 percent. We're at about 58 percent coming from fees and 42 percent from appropriations in 2006, the most recent year. That started out in 1993 where we spent about \$8 million out of \$128 million for fees, and so it's gone up from \$8 million in fees in 1993 to over \$300 million, I think, for fees, or close to that, in 2006. I don't have the exact numbers.

JS: No, but it grew from a very small percentage.

FPC: It was about \$87 million from fees at the end of PDUFA I, and so it's continued to grow substantially since then.

One of the things you have to realize is that the cost to FDA per staff year, per person that we pay at FDA, over the last 10 years has increased at an average of about 5.9 percent each year. Most people think, "Oh, gee, if we get the President's pay-raise

amount, we'll be made whole," but we're not because our costs, the cost of benefits and other things, are going up at a higher rate than the pay raise. And so just to maintain a staff year, the cost increases every year about 5.8 percent, and when you compound that over 15 years, that's reason for significant increases.

RT: Has user-fee implementation resulted in or reduced, shall we say, drug-approval lag time by . . .

FPC: Oh, it has definitely reduced time lag. We've gone from an average review time of over 30 months prior to the passage of PDUFA in 1992, to an average review time of 10 to 12 months. And, of course, the ones that are the significant breakthroughs get approved on an average of about six months now. So it substantially reduced the time. The United States is now the first market entered for over half of the new drugs on the world market too.

Now, we've also added other fees to this, too. We, I had the medical-device user fees passed in 2002, which was the first major additional program to get user fees. We collect a lot less in medical-device user fees. I think this past year we collected about \$33 million in 2006 in medical-device user fees, less than 17 percent of the total program resources.

Those have been more troublesome fees because the industry would only let us collect fees for applications. They wouldn't let us put in establishment or product fees. So the revenues fluctuate substantially from year to year, and most of the years they've been far below what we projected, so we have a lot of volatility in those fees. We're in

the process of negotiating with the device industry for reauthorization of the medical-device user-fee program.

JS: You touched on this earlier, but I wonder if you could say just a little bit more about what impact the user-fee laws have had on the components of FDA that don't have user fees. Could you say a little bit more about that, the Offices and the other Centers, for example?

FPC: Well, the main impact they have right now is that there are triggers about how much has to be spent from appropriations to keep the user-fee programs intact, so if we don't meet those triggers, we'll lose over \$300 million worth of revenues that we count on. So FDA makes sure that when appropriation increases are divvied up, the programs that have user fees get whatever increases they have to have to keep the fees coming in. That means that the programs that don't have user fees often take disproportionately larger cuts, so programs that do have user fees get increases in appropriation needed. So the fees not only give programs that have them the fee revenue, but they provide some extra insurance of enhanced appropriations as well. Those programs that don't have user fees usually are on the short end of that stick, and appropriations have to be cut to the programs that don't have user fees.

JS: And any, can you give us any specific examples about some of the Centers or Offices that have been in that position? For example, to what extent their lines have been reduced because of that need to meet the triggers for the Centers that do have user fees?

FPC: I know I've seen some figures on the Center for Food Safety and Applied Nutrition that show that it's dropping in its capacity to retain staff. It might look like it's straight-lined if you just look at the real dollars, but in terms of accommodating inflation of 5.8 percent each year, the number of staff it can keep on board goes down significantly. I can't give you the exact numbers, but . . .

JS: I understand that.

Has there been any discussion of perhaps having additives, food additives, user fees for those?

FPC: Well, there's been discussion of that. It's been proposed a couple of times. But the only way that user-fee programs have happened, have become law, is if the industry supports it. In 1992, when Mossinghoff got PMA to support drug fees, that happened. In 2002, when AdvaMed and MDMA [Medical Device Manufacturers Association] supported medical-device user fees, they happened. When the animal-drug industry supported animal-drug user fees in 2003, they were passed. The food industry hasn't supported user fees yet, and until they do, I don't think we'll see user fees enacted. In the way Congress functions, if you don't have the industry support along with the government support, Congress is not likely to enact fees.

TAPE 2, SIDE A

RT: We've just changed tapes.

Frank, you've served under quite a number of Commissioners over your extensive career. Do you have any impressions or recollections of incidents or issues that might be noted?

FPC: Well, I've served under a lot of commissioners, you're right, Bob, and I've really enjoyed the association with them.

I guess there are two little, two things I'll mention. One involves Dr. Lester Crawford long before he was Commissioner, and another involves Dr. Kessler when he was Commissioner. Let me start with some recollections of Dr. Crawford.

The first time I ever met Lester Crawford was when he was director of our Center for Veterinary Medicine in the early '80s. Frank Young was Commissioner. And if anybody goes back and looks at the testimony given to appropriation hearings in about '83, in that era, they'll notice some curious testimony.

Dr. Crawford convinced Frank Young that he should make a key piece of his testimony all the work that FDA was doing to help the catfish farmers in Mississippi. Now, this came over strong objections from Gerry Meyer, who was the Associate Commissioner for Management, and from me, as I was the head of Financial Management. We tried to talk Dr. Young out of it, but Crawford said, "No, you've really got to do this. You want to hit this guy where he lives. You want to let him know what we're doing for his constituents there in Mississippi." And Gerry and I were apprehensive about it, but Dr. Crawford prevailed, and Frank Young took his advice and made that a pretty significant piece of his testimony before the Appropriations Committee

in that year. And I'll never forget sitting there at the table with Dr. Young and Gerry Meyer, and Dr. Crawford was there too, at that hearing and watching the chairman, Mr. Jamie Whitten from Mississippi, the chairman of the full Appropriations Committee as well as of our Ag Appropriations Committee. When the Commissioner started talking about what he was doing for catfish farmers in Mississippi, you could virtually see the steam rising from Jamie Whitten's head. He was so annoyed at being pandered to by this talk about what we were doing for people in Mississippi when he had nationwide jurisdiction for FDA, for Agriculture, for all of the things we do. And he clearly knew what was going on, and he was not a happy camper. So I'll never forget that.

JS: Hopefully, that didn't too adversely affect our actual appropriations that year.

FPC: Fortunately, I don't think it did. We never got really fantastic appropriations, but it was an incident that I will never forget, and every time I see Lester Crawford, I always think about the catfish testimony.

The other thing with a commissioner that I'll just mention was I worked pretty closely with David Kessler when he was Commissioner. I tried and tried to talk him out of embracing prescription-drug user fees, because from the time I wrote that 1983 user-charge study until user fees finally became the law, I spent all my time at FDA actively opposing user fees. I was convinced that it was going to work against us, that it was going to put us and the industry even more at loggerheads than we traditionally were as regulator and regulatee. Obviously, history has proven me wrong because I don't think it's done that, although some people might disagree to some extent.

But in working with Kessler, he finally agreed to user fees and supported them, and once user fees became law, then I started supporting user fees. And I wanted to be sure that since I had worked so damn hard to try and keep user fees from actually becoming law, that once they became law and I was responsible for FDA's financial machinery, I wanted to be sure that I didn't do anything to make them not be a success, because people would look at me as somebody who might want to undermine the program. So I worked hard to try and make sure our financial machinery supported user fees and made them as successful as possible.

But the main piece of working with Dr. Kessler that I wanted to just reminisce about was when Kessler went before the House Ag Appropriations Subcommittee. Dick Durbin had just become chairman. Now, Dick Durbin inherited the chairmanship from Jamie Whitten when Jamie Whitten left Congress. Durbin's father died of lung cancer, and Durbin was an avid anti-smoking advocate and really couldn't understand why FDA hadn't been more aggressive in its approach to tobacco previously. So Dick Durbin was constantly getting the Commissioner to the side and trying to push him to oppose tobacco and take some active, aggressive stance against tobacco. And I'd been through the files on tobacco. I knew that we'd had a history of sidestepping tobacco for 25-30 years before this, maybe longer, because we recognized the politics of it were fraught with peril.

And I'll never forget, when I first heard the Commissioner say something publicly about opposing tobacco and trying to regulate tobacco and what was happening there, I was convinced that he must have gotten word that he was a short-timer and was just having fun in his final few days at the agency. I didn't think anybody in his right mind

would be able to carry off going up against the tobacco industry. And I was quite proud when he did take them on. I'm sorry we didn't win all the court cases that would have supported more aggressive regulation of tobacco, but I'll never forget my amazement when he finally did go ahead, with the support from Durbin to take on the tobacco industry.

JS: And we did. When we asked for money for that program, we had an Appropriations Committee -- certainly, an Appropriations Committee chairman -- who was supportive of these funds.

FPC: Right. Dick Durbin was the chairman, and he was the one who really goaded the Commissioner into being more aggressive on this, I think. If he wasn't the one to go to, he was certainly a very instrumental factor in Dr. Kessler's decision-making process.

JS: And did we get most of the money that we had requested for tobacco?

FPC: We did initially. Then Durbin left and went to the Senate, and then we lost some court cases and that money was redirected to other programs after that.

So those are the two anecdotes I wanted to share.

I left the Office of Financial Management in 1994, December of '94, after fourteen and a half years. I then spent two years in CBER. I was CBER Exec Officer for a good part of that time, but then finally decided that I had burned out. I had been a supervisor and a manager long enough. I didn't really want to supervise other people. I

just wanted to work on programs. And so I left CBER, went back to being a management analyst in the Office of the Commissioner. Over time I became involved full time in user-fee support, which is basically what I've done for the last 10 years. I worked on user-fee programs, the annual financial reports, the five-year plans, monitored receipts, proposed allocations, and all the financial stuff that supports the user-fee programs, and I've loved it.

RT: As you look ahead, Frank, do you see a further encroachment or development of user fees in some of the activities that do not now involve them? We've mentioned foods, and I think you've given reasons that isn't happening in foods. Is the trend going to stable, as far as you know, in this area?

FPC: You know, it's really hard to say what's going to happen. I'll be surprised to see user fees in foods. The drug industry was able to support a user-fee program that really helped them and the agency, and it's been a boon to both FDA and to the industry and to consumers, because we've been able to enhance our drug-review staff.

We haven't had as positive an experience with the user fees with medical devices. All that medical-device user fees really get done, because of the amount we've collected, is to help us stave off the erosion of appropriations, but we really haven't made substantial increases in our staff, and so our improvements there haven't been as dramatic as they were in the drug area. In fact, some components of the medical-device industry are talking about whether we should continue them in medical devices.

My own personal expectation is they will probably continue in medical devices, but at a much lower rate than the fees that we're getting in the drug area. I'd almost be surprised to see them take root in foods, primarily because it's an industry with tighter margins and it's going to be harder for the folks to find the resources to pay the fees.

RT: I suppose, comparatively, drugs, of the three disciplines you mentioned, devices and foods, drugs potentially are more hazardous if not cleared carefully.

FPC: Absolutely, absolutely.

RT: Whereas foods generally tend to be safe substances as far as life-threatening is concerned, generally.

FPC: I think that's probably a very reasonable observation, Bob. That's right.

RT: Is there anything else that we want to touch on during our discussion today?

JS: I don't think so. I think we've covered a wide area. And, again, thank you so much for your insights into this area of FDA history that we're just delighted now to have as part of the oral history program.

FPC: I appreciate the opportunity to share it. Thank you.

RT: It's a very significant contribution, Frank. Thank you.

END OF INTERVIEW