

History

of the

U. S. Food and Drug Administration

Interviewee: Francis J. Flaherty

Interviewer: Ronald T. Ottens
and
Robert A. Tucker

Date: June 14, 2000

Place: Parklawn Building
Rockville, MD

DEED OF GIFT

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Francis J. Flaherty

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INTRODUCTION

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

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



CASSETTE NUMBERS: 3

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

DATE: June 14, 2000 PLACE: Rockville, MD LENGTH: 160 minutes

INTERVIEWEE:

INTERVIEWER(S):

NAME: Francis J. Flaherty

NAME: Ronald T. Ottes & Robert A. Tucker

ADDRESS: [REDACTED]

ADDRESS: FDA Headquarters Office

Rockville, MD 20857

FDA SERVICE DATES: FROM: January 1962 TO: December 31, 1999

TITLE: Director, Strategic Initiative Staff

(Last FDA Position)

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RO: This is another in a series of the FDA oral history recordings. Today we are interviewing Mr. Frank Flaherty, who retired as the director of the Strategic Initiative Staff. The date is June 14, 2000. Interviewing Mr. Flaherty are Bob Tucker and Ronald Ottes. The transcription of this interview, together with the tapes, will be placed in the National Library of Medicine and become a part of the FDA's oral history program.

Frank, to start this interview, we'd like to have you give a brief description of where you were born, educated, and any relevant work experience prior to FDA.

FF: I was born in Lynn, Massachusetts, attended school there, and graduated from St. Mary's Boys High School. I then attended and graduated from the Massachusetts College of Pharmacy with a bachelor's degree in pharmacy. I worked as a registered pharmacist in a family-owned retail pharmacy for ten years before coming with the Food and Drug Administration.

I started with FDA in the Boston District in January of 1962. At that time, the district director in Boston was Nevis Cook. My first chief inspector was Les McMillian. The first supervisor I had was George McDonald.

RT: What led your interest to FDA? Did they have a recruiting drive or something?

FF: No. After ten years in retail pharmacy, I simply tired of it. My long weekend for those ten years began at 6:00 p.m. on Saturday until Monday morning; my short weekend began at 9:00 p.m. on Saturday evening until Monday morning. So I simply got tired and bored of retail pharmacy.

I took two Federal Service Entrance Exams (FSEE), one for the Bureau of Narcotics and a general one that you took for FDA. I knew virtually nothing about

FDA except there was such an organization that regulated drugs, and having been in pharmacy, I felt perhaps a little affinity for that.

Interestingly enough, I scored much higher on the Bureau of Narcotics than I did on the general exam, and I looked seriously into going with that agency. But I wasn't ready to be transferred around the world as they did with their people. I had a family at that time, small kids, and I simply didn't want to go to Bangkok or Sicily or some such place as a narcotics agent. So I looked into the Food and Drug Administration interviewed with the folks in the Boston District, and decided that I would go with them.

RO: As an investigator.

FF: As a GS-5 investigator making \$4,200 a year at that time. My career fortune, I think, may have been determined by my first day on the job when a citizen brought in a carton of prescription drug vials that came from a family member who was abusing prescription drugs and buying them illegally at a retail pharmacy. My supervisor asked me, since I had just come from practicing pharmacy, if I would look at those containers of drugs and identify what they were. So I did that, and that led to my becoming involved in doing a great deal of work on the illegal distribution of prescription drugs.

We focused primarily on pharmacies, but also I got involved in some street activities and illegal sales on the street of amphetamines, barbiturates, hallucinogens, and other prescription drugs.

RO: This program was commonly known as the OTC (over the counter).

FF: That's true, yes. Yes, "OTC work" it was called.

RO: Well, what would you do, Frank? You said primarily with pharmacies. Would you try to get a prescription for the pharmacy to fill and then see if you could have them violate the terms of the prescription? Or how did you go about that?

FF: No, no. We would go in cold and seek to buy some Bennies or some penicillin or some other drug that required a prescription. We would always have some reason to believe that was being done by the pharmacy. We wouldn't just pick out any store on the street and try that, but we would get leads from citizens, from the police, from other pharmacies, which would cause us to focus on a particular drug store. I believe that when I left Boston District in mid-1965, I had thirteen prosecutions in federal court of pharmacists and pharmacies.

RO: What year did you leave Boston?

FF: In '65.

RT: In the early phase of that type of work, were you personally involved in truck stop surveillance and so on?

FF: I did virtually no truck stop work. Trucks weren't that big in New England like they were in some parts of the country where they did a lot of truck stop work. It was primarily pharmacies. That did get me into some other kinds of work, like we had an undercover operation that involved horse meat being sold as beef, and we had a big case up there in Boston. It was kind of interesting. We ended up raiding the warehouse where the meat was being kept in large drums, wooden barrels.

We had followed the trucks that were carrying drums from up in Maine down into Boston to a warehouse not very far from our offices. One Saturday we followed

a truck on which we had seen this stuff being loaded in Maine. We followed it to the Boston warehouse, went in with a Notice of Inspection that we used, and opened up the barrels that were stored there.

In that business, there was a government requirement that horse meat be de-characterized, and charcoal is what is used to de-characterize it. So the legitimately de-characterized horse meat is sprinkled with charcoal, and it turns it black, and no one could mistake it for beef. We opened up the drums, and sure enough, in the top of the barrel was blackened meat which was the de-characterized horse meat. We dug down below the top layer, and there was a sheet of plastic across the top. You pulled that off, and there was non-de-characterized horse meat that was being sold as beef.

Obviously, the people who ran the warehouse knew what they were doing, and they ultimately got prosecuted in federal court as well. But that was an interesting caper that we had there.

RT: Since you had the pharmacy background, I'm not sure that there are very many pharmaceutical firms in the New England area, but were you ever involved in inspection at that juncture of pharmacy manufacturing and processing?

FF: Yes, I was. But in addition to spending a good deal of time on OTC work. The chief inspector was there to see that the routine regular FDA work was done, which was bakeries and warehouses and that kind of stuff, so I did all of that. I often did the OTC work in between or on my own time. I did some of it on the weekends, because the regular work had to get done. There were one or two drug manufacturers in Boston District, and I did some inspections of those.

But the way you went along in an FDA career at that point, you started out with warehouses and bakeries and other food commodity-related activities. After you did your job doing those kinds of inspections, then you moved on to the higher level stuff,

which was the limited amount of drugs and drug manufacturing that existed in Boston District.

RO: Did you ever try to build a case against the retail pharmacy that you had worked in?

FF: No.

RO: That was a legitimate operation.

FF: Yes, yes, and, of course, you wouldn't . . . There are some restrictions. You wouldn't want to go where you were known anyway. The idea was to not be known, because you were posing as something else. I would pose as a truck driver, for example, wanting to buy Bennies.

RO: OK. You said you left Boston then in 1965. Where did you go?

FF: Yes, I reported . . . Well, let me back up just a little bit. When I got hired, I was hired as a GS-5, as I mentioned, and I was told that I might get my GS-7 without transferring, and I might not. I might have to transfer to get promoted as you had to do--everybody had to, in those days. But I certainly wouldn't get a nine without transferring, I was told.

Well, I did get promoted to a seven, and indeed I got promoted to a nine without transferring out of Boston District. That was extremely unusual. But I could not get promoted to an eleven without transferring.

So I did transfer and went to New York District. I reported there on June 6, 1965, as I recall. The chief inspector there was Weems Clevenger, and my supervisor

was Ed Wilkens. At New York District, I did exclusively undercover work in the drug area. Again, some pharmacies, some street sales, and some manufacturers who were illegally selling drugs.

RO: And who was the district director?

FF: Charlie Hermann. Yes, old Charlie was the district director.

One of the interesting cases while I was in New York involved my buying amphetamines and some hallucinogens from a couple of street characters, one of whom was named Tony Canepa, as I recall.

RO: How do you spell that?

FF: C-A-N-E-P-A, just like it sounds. It turns out, we later found out that he was the son of a very wealthy furniture manufacturer from Cincinnati. But I managed to get myself introduced to him, posing as a drug peddler, made several buys from him, and then set up a close-out buy to take place at the apartment in Williamsburg--the Williamsburg section of Brooklyn--where he and his partner actually made these drugs. They were doing it on the kitchen stove, making amphetamines and some hallucinogens.

So we got a whole group of people to participate in the close-out raid at the apartment. I went in at about 5:00 in the afternoon wearing a radio transmitter under my clothes so that the people outside could hear what was going on and could know when it was time to come in, when I had made the buy and passed the money. So that happened, and we completed the transaction. I gave the signal over the transmitter I was wearing, and a bunch of people busted in through the door. We had U.S. Marshals with us, because we, at that point, did not have the power to arrest.

So as they came through the door, I grabbed one of the guys and put him on the floor, and the lights flickered and came back on. After a moment, the lights flickered again and went off and didn't come back on. We were in the midst of the November 9, 1965, blackout. We needed to seize all of the illegal products and equipment that was in that place. So we had a couple of flashlights and got some candles from I'm not sure where, and worked until about 11:00 by candlelight seizing all of the products and taking the individuals off to jail. They were ultimately prosecuted in federal court, convicted, and they went to jail.

In late 1965, Congress was recognizing that there was a real serious problem with non-narcotic drugs, such as amphetamines, barbiturates, and hallucinogens. Of course, this was in the sixties when hallucinogens were really taking off, LSD, etc., and Timothy Leary was in his prime.

Congress passed the Drug Abuse Control Amendment in 1965, late in that year, and created a unit—actually, it was a bureau in FDA—called the Bureau of Drug Abuse Control (BDAC). It was under the FDA umbrella, but it was essentially a separate organization of agents dedicated to fighting the illegal distribution of these drugs.

I applied for and got selected for that new organization, and I was in the first training class of new agents. We went to the School of Criminology at the University of California in Berkeley. I was there from January until March, I guess, of 1966. That was right in the middle of the free speech movement at Berkeley, and the daily riots that they had there, all the upset. It was a real interesting time.

We set up the Bureau of Drug Abuse Control, which is known by the acronym of BDAC. That office was set up in New York, in downtown Manhattan, and we worked out of there.

RO: You were physically separated from FDA?

FF: Yes, yes. Yes, and there were a lot of people with a "we" and "them" kind of attitude.

FDA did a poor job of staffing that organization. They hired, with offers of promotions, a number of Federal Bureau of Narcotics agents, many of whom had been working in the New York City office of the Bureau of Narcotics.

What FDA didn't know, because the Bureau of Narcotics didn't tell FDA, is the Bureau of Narcotics internal security people were in the midst of a big corruption investigation of their own agents, and many of them, they just passed all them off to FDA. So we hired some fairly unattractive people, some of whom subsequently got arrested while working for FDA. One of them became the district director of the Bureau of Drug Abuse Control office in Baltimore. He got arrested for peddling drugs.

You may . . . Were you there then?

RO: Yes.

FF: Yes. Well, those were the characters that came over from the Bureau of Narcotics.

It's a reality that to successfully do that kind of work, you have to at least be a very good actor that you're dishonest and a crook, because you're dealing with real bad people, living among them, and with them, and in defense of those Bureau of Narcotics guys, it's easy to become like them. I suspect that nobody starts off that way. But it's like, I always thought it was like the cop on the street who takes an apple off of the cart, the fruit and vegetable cart. It starts out by taking an apple, and you go on from there. Probably the lesson, if there is one, is that you don't take the apple--you don't ever take that first step.

But these guys were hardened folks, and they kind of took over this FDA bureau. There was that "us" and "them" attitude that they had toward anybody who was an FDAer—they were pansies.

In any case, I worked out of the New York office of the new bureau, the New York City office. I became a supervisory criminal investigator there, supervising a bunch of these former Bureau of Narcotics people, among others.

I then transferred to Buffalo to open the office of the Bureau of Drug Abuse Control in Western New York.

RO: Before you went to Buffalo, do you happen to recall a drug raid in Englewood, New Jersey, involving a cosmetic firm there?

FF: Yes, yes, yes, I do. That was afterwards though. That hadn't happened yet.

RO: Oh, then you went to Buffalo and then came back to New York?

FF: Yes.

RO: Oh, OK. We'll pick it up later.

FF: I went to Buffalo. I wasn't thrilled about it, but in those days, unlike now, you do what you're told. I guess maybe if there were a union then, I wouldn't have gone to Buffalo, but I did. I opened a separate office in Buffalo from the FDA office. I had two people, two agents, working for me. We covered twenty-seven counties in Western New York, which is an area we couldn't possibly cover properly, as well as the Canadian border. I worked a lot with the Buffalo City Police. They had a drug

enforcement organization, and we cooperated a lot. Worked with the Canadian, with the Toronto Metropolitan Police on cross-border stuff. That was . . .

(Interruption)

FF: That was in 1967, late '67. I enjoyed Buffalo a lot, both the people and the work I was doing.

RT: These people that you had in your resident post, were they former FDA investigators or from the Bureau of Narcotics?

FF: One was a former FDA person. Indeed, he had been a chemist. He had been a chemist in Buffalo District. His name was Walter Behrens. He and I became real close friends, and still are.

It was a subsequent reorganization where under President Nixon there was a combining of all the diverse federal agencies that had responsibility for illegal drugs, and they reorganized into what is now DEA (Drug Enforcement Agency). That combined the Federal Bureau of Narcotics, the Bureau of Drug Abuse Control, some Customs people or a customs organization that was involved in illegal drugs, and maybe some other agencies, but into one entity called DEA.

Walter stayed on with DEA and ultimately retired from DEA after spending, I guess, seven or eight years in the Far East working for them in Thailand and other places.

The other guy who worked for me was a former Treasury agent--not an FDAer.

RT: So when this chemist came in from the Buffalo laboratory, was he provided investigational training, since he had been a chemist?

FF: Yes.

RT: Were you responsible for that or was it done elsewhere?

FF: No, I was in first class of new hires for the organization. He perhaps was in the second class, and he got trained. He had been working in the New York area as well, and he got transferred back to Buffalo.

In 1968 I had an offer to come back to regular FDA. Weems Clevenger was then the district director in New York, and I had stayed in touch with him, more or less, and I had an opportunity to go back to FDA, and I decided I would do that. So I moved from Buffalo back to New York, became supervisory inspector. About that time they were starting to call inspectors investigators. So I became a supervisory investigator in the Newark section of New York District.

RO: What grade? Thirteen?

FF: Thirteen.

RO: Well, what grade had you been when you were in this BDAC work? Were you . . . ?

FF: Gosh, I'm not sure I was . . . I think I was . . .

RO: I was just curious.

FF: Yes, I'm trying to remember whether I was a thirteen as a supervisor, if they had thirteen supervisors. I think probably I was a thirteen in Buffalo, came back to FDA

as a thirteen, and became a supervisor in the Newark section. That was before there was a Newark District or a New Jersey District, and it was a resident post, a major resident post of New York District.

The section chief at Newark was Ed Wilkens, so I was reunited with him back in FDA. Ed had gone to BDAC as well, back in 1966 when the organization was formed, and he had been the chief investigator for the BDAC New York office. He too went back to FDA-regular FDA.

So I then spent four years as a supervisory investigator at Newark supervising people who did all of the routine kind of FDA work, both foods and drugs. There was very little medical devices work then. We did hardly anything in medical devices.

I had a couple of real good cases there that I recall. One came about when we got a call one day, a poison control center who reported that a poisoned individual had been administered Ipecac syrup, which is the treatment to cause people to vomit when they've ingested some poison, and nothing happened. The person did not vomit. I found there were a couple of other similar reports like that. The Ipecac syrup had been manufactured at Dr. Madis Labs just outside of Newark.

RT: What was that name?

FF: Madis, M-A-D-I-S. Dr. Madis. I should have brought along a newspaper, the *New York Times* story about all of this. Let me finish. But . . .

So I sent one of my drug inspectors out to visit the Madis plant to do an inspection to find out what was going on. He made the inspection, came back, wrote it up, nothing wrong. . .

Well, come on now. This drug forces people to vomit. People are taking what purports to be this drug, and they're not vomiting. There's something wrong someplace.

Well, to make a long and interesting story short, I proved that rather than extracting the active ingredient alkaloid from Ipecac, this guy was using ephedrine instead of Ipecac. He was able to get away with that, because the only test for Ipecac syrup in the U.S.P. at that time was a total alkaloids, and that test could not distinguish between the active ingredient alkaloid in Ipecac and the alkaloid in ephedrine. So if you tested the syrup, the Ipecac syrup, for total alkaloids, you found there were alkaloids there, but it was the wrong alkaloid. This guy was a goddamn crook, a flat out crook.

RT: So presumably the ephedrine was much cheaper.

FF: Precisely. That's exactly the story. It was much cheaper. He had records purporting to show that he was importing the raw material in bulk Ipecac from Canada. I wound up going to Canada and working with the Mounties up there at the plant that supposedly had been sending him Ipecac, Dr. Madis' documents were all counterfeit, phoney as hell.

He got prosecuted, and even the *New York Times* editorial commented at the lack of jail sentence that the judge gave this guy. When it went to trial, the judge was named Fred Lacey, who had been the former U.S. Attorney in Newark, and I thought that he would see that justice was done. No. Gave him a suspended sentence. But that was a fun case, a challenging case.

Another thing I worked on was—I used to like to get involved in things—was the vichyssoise soup case. That broke on a holiday weekend. I don't know if it was . . .

RO: The Fourth of July.

FF: The Fourth of July. So I got called at home by my boss to see if I would come in and go with somebody to interview an employee of the company, the retort operator.

So by then it was Fourth of July night. I found out where the guy lived and went to his house, the second floor of a three-story tenement, someplace in the Newark area, and interviewed him in his kitchen. He admitted underprocessing. That was one of the big recalls, nationwide recalls with lots of publicity, because that stuff had killed somebody, I believe. It maybe paralyzed another couple of people. That was a big FDA case.

RO: That was with botulism.

FF: Yes, yes, underprocessing of the Vichyssoise soup. I've never eaten it, but it's something that you don't cook. You eat it out of the can, cold, so that . . . Well, normal heating of a soup would kill the botulinum, or would destroy the botulinum toxin. If you don't heat it, then you get that toxin, which is highly toxic.

Then the one you mentioned, Lorraine Cosmetics. That was another fun case that I was heavily involved with. My friend Ken Silver called me about that a year or so ago. He was writing something up or something.

This was a firm, again just outside of Newark or maybe even in Newark. Lorraine Cosmetics was the name. They had a scam where they would collect physician sample drugs in large quantities. They would buy them from the salesmen, the companies; and they'd buy them from doctors; they'd buy them from pharmacists. They were processing large quantities of prescription drug samples. They'd unpackage them from the little sample packages that they were in, foil packages or whatever.

In those days, many of these samples were imprinted with the word "sample" right on the tablet or capsule. In the operation that they had going at Lorraine, it's kind of an assembly line type of business where they would have people unpackage the samples, and then they'd pass them on to the next station in the, you know, storefront place where this was. If it was a hard, coated tablet and it had "sample" imprinted or

"sample" printed on it, they would use a swab of acetone or some other solvent to rub off the "sample" lettering. If it was a hard table that maybe had "sample" stamped on it right into the tablet, they had a file, sandpaper, and they would sand that down to eliminate the word "sample." Whatever it took to restore these to the appearance of the regular drug, they would do.

RT: Even though it was labor intensive, I guess they were making money?

FF: Oh, yes. They had shoe boxes all over the place, and the shoe boxes were filled with all these tablets and capsules. They would then pour them into plastic bags and put a little sticker with the name of the drug on the plastic bag, and they were then selling them all around New York to pharmacies.

We would trail their distribution truck over to New York to see what pharmacies were buying this stuff, and then we set up a raid. The Marshals were with us.

We went into Lorraine Cosmetics and did a close-out inspection. Simultaneously, we had people over in New York who went to a number of the drug stores who had been customers, where they got affidavits from the pharmacists stating who had been selling them the drugs, along with pictures and all. We seized all of the drugs, the limited amount of equipment that was at Lorraine, cartoned it up, and the Marshals took possession of it all and stored it away for the trial.

While we were in there, I was going through a desk of the guy who owned the place, and I found a bottle of cocaine. So we brought in the local police and had him arrested for possession of cocaine. That charge went to trial in the local court, and I went and testified there. He got off on that count on the basis that he was not in possession of it. It was in his desk, in his building, in his business, but the judge concluded that we couldn't prove that it was his. So he walked on that one. But he and Lorraine Cosmetics got prosecuted in federal court and got convicted.

RO: Was this a legitimate cosmetic firm?

FF: No, they weren't . . .

RO: They weren't. It was just a name?

FF: No, they were not a manufacturer of anything. There was a storefront. I don't recall if they'd ever been in the cosmetic business. If so, it was a distribution point; it was not a manufacturer of cosmetics.

RT: In terms of profit, was it a large sum that they were deriving from this activity?

FF: I don't recall the numbers. It was obviously enough to sustain the business and to make money on. I suppose they were paying the workers very little. But there was a heck of a big volume of drugs, and they would put a thousand tablets in a plastic bag and sell it to a pharmacy, and undercut, obviously, the legitimate product.

RT: The source would have been what? Physicians' offices, or where did they get these samples?

FF: Physicians, nurses, salesmen. Trafficking in physician samples was a big business, until sometime after that, when the federal government made distribution of samples illegal . . . Highly controlled—I guess it's not illegal—but they're controlled almost to the extent of narcotic drugs today, where you've got to have a written request for them and all the steps are tracked.

But I had seen situations where salesmen for major drug companies would sell cases of samples, because that's how they got them. Salesmen could get samples in

almost unlimited quantities from their companies. If they were producing business for their company in their territory, then there was almost unlimited amounts of samples available to them. So they had a lucrative business going on the side of selling these samples.

Well, in any case, I spent four, exactly four, interesting years in Newark doing what is the toughest—at least used to be—the toughest job in the Food and Drug Administration, which is the first line supervisor. To do that job right, you have to bust your tail. You've got eleven or twelve or thirteen people working for you—at least we used to have—in a busy district. The most important job in the Food and Drug Administration in my judgment.

I'll say parenthetically here that some . . . I think it happened after you left, Ron, but I'm not sure. If it didn't, so be it. But when ORA (Office of Regulatory Affairs) management decided to eliminate the first line supervisor's job, and the person who ultimately made that decision was somebody who had never been a first line supervisor in the field and didn't have the foggiest idea of what he was doing to the field. Then after some time went by when they eliminated the first line supervisor, they suddenly were mystified that quality and production both went downhill and they had a big problem. Why? Because the first line supervisor tells somebody who's working for him, "I want you to go out and get these three samples this morning. When you're done with that, you come back and see me because I've got four more for you to get this afternoon."

So the job of the supervisor is to get the work done. The job of the supervisor is also to ensure the work is done properly, the quality of it. So you look at the collection reports that come back, and you look at the inspection reports, and you make sure that the job was properly done. What happens when you eliminate that position? You get a bunch of people sitting around in a circle, "Well, let's see. Shall I get a sample today or shall I get it a week from tomorrow?" And who's reviewing the work?

All that stuff. A big mystery why quality and production went to hell? Not really, if you knew the job of a first line supervisor.

That's a little diversion. I'm not sure how we got into that, but it's sure in the heck true. It was predictable. As soon as they eliminated that position, you knew what was going to happen. Boy, it came back to haunt them.

RO: Well, do you think some of that had to do with reinventing government and doing away with some of those mid-level jobs?

FF: That was the reason given, but, you know, if you want to cut back government . . . If you want to cut taxes, your local taxes, are you going to eliminate the fire department? No, I don't think so. You don't cut what shouldn't be cut, and that was the basis for it, I guess. But that goes to what I'm saying, that the people who made the decision didn't know what they were doing and didn't know what the implications were guaranteed to be.

Well, in any case, after four years of blood, sweat, and tears and sixty-five hour weeks in Newark, I got bored again, and I became aware of an opportunity for detail in headquarters in the Field Compliance Branch. So I applied for the detail and got selected and came to Rockville in August of 1972 for detail in that branch, working for Pat Ryan. I primarily handled compliance programs, the clearance of compliance programs. I coordinated that through the EDRO (Executive Director of Regional Operations) organization with the field. My detail—I think it was for sixty days—got extended for another sixty days, and maybe for another sixty days after that.

(Interruption)

FF: My detail got extended and extended, and I never went back to work in Newark District. I got hired by Pat Ryan to work in the Field Compliance Branch. That was in . . . Let's see. Charlie Armstrong was Pat's boss. We had a small group of people there. There was . . . Well, there was Chuck Everline and Dick Klug. Lloyd Lehrer was there for a while.

RO: Who was that last one?

FF: Lloyd Lehrer, L-E-H-R-E-R. Remle Grove. Remle was handling recalls at that time. So I stayed there permanently doing compliance programs.

I found Pat Ryan to be a great guy. He had been previously the director of . . .

RT: Office of Legislation.

FF: . . . Legislative Affairs, I think it was called. The Office of Legislative Affairs. After he did a stint there, he became the branch director in EDRO. So that was the guy I worked for, and I liked Pat very, very much.

One of the noteworthy things about Pat was I went to him one time, coordinating and rewriting compliance programs and trying to get things done and make things happen, and I recall saying to him, "You know, I don't know how much authority I have around here to get things done." I'll never forget, he said, "You have as much authority as you want to exercise." I never had to ask that question again, and that proved to be true.

I was working there for a while, and . . . Let's see. In early 1975, I was asked if I was interested in a detail in the Office of the Associate Commissioner for Compliance, who was Sam Fine. There was a new program that needed to be developed that came to be named the Government-Wide Quality Assurance Program.

That came about following some congressional hearings into the awards of contracts by the Department of Defense (DOD) for drug products.

DOD utilized standards for the products they wanted to buy, quality standards, that were different from the quality standards for the very same drug that the public utilized. Some of the theory on the DOD's side was that, well, these drugs are going to be used by soldiers, so they need better drugs than ordinary citizens need. Drug "X," for example, it has a USP monograph potency range from 90-110 percent, but DOD wanted it to be 95-105 percent, because soldiers are going to take these drugs.

Some manufacturers were complaining they had to run two separate lines in their plant: one for products going to DOD and one for regular commercial distribution. There were also some charges of intimacy between some of the DOD drug procurement people and some of the drug companies and some hanky-panky along those lines and all. There were hearings chaired primarily by Senator Nelson.

RT: Gaylord Nelson?

FF: Gaylord Nelson, yes, and he beat up badly on some of the DOD people. In fact, there was one guy they wanted to prosecute from DOD for some stuff that he was alleged to be doing.

It was decided that there should not be separate, tighter quality assurance determinations for drugs made for sale to DOD and to VA (Veterans Administration). DOD had its own little FDA. They had a cadre of inspectors who would inspect those drug plants who had or sought DOD contracts. VA had a similar thing on a smaller scale, but they had some inspectors who inspected drug plants for VA contracts. Manufacturers would complain that at times in their plant there was an FDA inspector, there was a DOD inspector, and there was a VA inspector, all at the same plant at the same time, and the manufacturers didn't like that.

So it was decided that all of this quality assurance responsibility for drugs sold to the government would be consolidated within FDA. The organization that managed that was going to be in the Office of the Associate Commissioner for Compliance. I had the opportunity to work on the development of that program. The person who helped a great deal was Tom Brown, who was a staff director working for Sam Fine. Gary Dykstra was in that organization at the same time, and he worked on helping lay the groundwork for the development of this program.

I became the acting director of the staff that was going to run that program, and then I became the director of that staff. Sometime in I guess it was the early fall of 1975, I got the permanent job.

But I set up a process and an organization. I took some people from both DOD and FDA to work on my staff. The people who had been the DOD drug inspectors were offered the opportunity to come to work for FDA. A number of them did; one or two lasted.

What we did was before any contract was awarded for any drug product, DOD and VA would come to FDA in a formal process that I set up, identify what the product was, who the supplier was, both the manufacturer and the raw material manufacturer, any packager or packer or labeler, and we would then determine whether there were any problems from a quality assurance perspective with any of those organizations, those companies who had a hand in manufacturing and delivering the drug to DOD.

We threw out all of the standards that were inconsistent with the public standards. So no longer was there a 95-105 percent of potency requirement for a drug. The 90-110 (percent) is what prevailed.

And the understanding was that if FDA said there was a problem with this manufacturer, DOD should not award that contract. The contract didn't get awarded, and DOD would then go on to the next lowest bidder until they had one where FDA said, "There are no problems. The quality is satisfactory."

RT: In that process, Frank, was there a period of time when there was a colonel as a representative of DOD in residence, if you will, here in FDA?

FF: Yes, there was. As a matter of fact, there were a couple of them.

This was not a friendly takeover in everybody's mind, as human nature would cause you to expect. DOD did not want to lose this authority and responsibility that was taken from them and given to FDA. So for the most part, they didn't like us, because we took something from them that they didn't want to give up, and that's understandable. So I think it's pretty fair to say that there was organizational animosity.

RT: How about the VA? Were they part of that resistance?

FF: Definitely, definitely. At least as strong. The thing is they were smaller, a much smaller organization.

We built relationships with individuals in the other agencies as a way to overcome the organizational animosities, and some good relationships, very good working relationships developed. I had hired an individual from the Philadelphia headquarters where DOD had previously handled this work, and he was on my staff. He helped with the people-to-people relationships that we tried to establish.

There were numerous times where DOD alleged that FDA was too slow, taking too much time to do these quality assurance evaluations. In the process that I had set up, we had a 10-day maximum for turning around the requests from DOD. Many times they made a big issue of claims that we were taking too long, taking sixty days. I knew that was bull.

So I confronted them on each of these occasions and said, "Give me the project numbers that you say are taking all this time." You know, put up or shut up, in effect. So they would give us a long list of projects that they claimed had exceeded, long

exceeded the agreed upon 10-day turnaround time. Almost without fail, I would say 99.8 percent of the time, we were able to document that, "We got this request from you on this date, we responded to you on this date, here are copies of the documents, and we turned this around in four days, in six days, and you guys up there just don't know what you're doing. You don't know when you sent it to us, you don't know when you got it back." We came out smelling like a rose every time.

RT: Was the person or the individual, we raised the question about the uniformed person? What was the role or the duties of that person?

FF: Yes. They provided a full colonel who had worked up there in Philadelphia to come down and be a resident in my office, to smooth out some of these things that were causing problems between the two organizations. The first guy was Marc Vigneault, M-A-R-C, V-I-G-N-E-A-U-L-T, and a real nice guy. He was pretty much on our side. He knew that things were screwed up in Philadelphia, and he saw that things were working very well on the FDA side. So he was an ally. You couldn't ask for a better situation where their own person was down here working on my staff and saying the problem is in Philadelphia, not in Rockville.

RO: He was still a DOD employee.

FF: Yes. His duty station was Rockville, but he was being paid by DOD.

RO: Frank, before we go on, did VA and DOD have analytical capabilities prior to FDA taking this over? Or did they base it pretty much on inspectional evidence?

FF: DOD had a lab in Philadelphia, a small lab. They didn't do very much. VA had some testing capability as well out at Hines, Illinois. But you couldn't compare their analytical capabilities with an FDA lab. The amount of work they did was very, very small as far as analyzing the drugs. The DOD lab was more into looking at surgeons gloves, looking at simple device products, than they were drugs. They relied mostly on the manufacturers' own test results.

RO: Maybe you could go through this a little bit because I'm really not clear on this. When FDA got a request from DOD for these certain drugs from these manufacturers, you would go to the inspectional evidence or at least what we had on those particular firms.

FF: Yes.

RO: Was there a recency factor that FDA would have had to inspect that firm in the last ninety days or something like that?

FF: There was, but it wasn't ninety days. Initially, we had set it up as one year. After a period of time, we made it two years. We not only had to have been in that firm, we had to have looked at the type of product that they were buying. Not the exact product, but we had to have inspected their tableting process, for example, if the contract was for a tablet.

In conjunction with all of that, we developed firm profiles in order to make that evaluation. Because it always bugged me, even when I was in the field, that the status of acceptability and non-acceptability for a drug firm was based on the last inspection of that firm. A major manufacturer, Lilly in Indianapolis, for example, makes eight or

ten different dosage form drugs, tablets, capsules, ointments, solutions, injectables, or whatever.

The way FDA used to inspect and reach conclusions on firms was the last inspection. So if the last inspection of Lilly covered . . . This is back before profiles, before an FDA drug quality assurance program. If the last inspection of Lilly had covered ointments and solutions, and that inspection had been classified in compliance, then Lilly Indianapolis was considered in compliance for all their dosage forms. Small volume parenterals may have not been inspected for six years, because we had inspected solutions and ointments there. Lilly would also have been considered an acceptable supplier of small volume parenterals.

When I was in the EDRO Field Compliance Branch, this had troubled me, and I had done some work then on developing a firm profiling process that came to be known as the firm profile system, where you could identify clearly discreet dosage forms and inspect the process for that dosage form and conclude that they knew how to make tablets, or they knew how to make ointments. Therefore, any ointment they made that came through that process was acceptable.

RO: So supposing then that a request came in for parenterals, and the last inspection had not covered parenterals from this particular firm, would FDA go back and inspect this firm for parenterals in order to get that category?

FF: Yes, we would look at when parenterals were last covered and what the conclusions were. Now if the last inspection had been a year ago and had looked at their parental process and it had been fine, then we would say they're fine for parenterals. If it had been two years or three years since anybody looked at parenterals, then we would have to inspect their parenterals. Or if the last inspection--no matter how recent it was had been violative--then it was time to go back and do a new inspection to

see if they were still unacceptable, because you can't turn down a multi-million dollar contract for a firm based on six-months-old negative findings without confirming that there was still a problem.

This was a new day for the drug manufacturing industry, to deal with FDA on their contracts. We knocked a number of them off contracts, and they weren't happy about that and would come and complain. But we were able to demonstrate that there was a violative inspection, and we told them, "You need to get your place in order if you want government contracts."

So that's how that process worked. As I say, we relied heavily on profiles. We had meticulous records. We knew exactly when every request . . . And we would get I don't know how many thousands of evaluations we would do a year for DOD or for the VA—many thousands. But we had meticulous records, files on every evaluation we did. We could show precisely what we did, when we did it, who did it, and why. So we were able to answer any questions that anybody had anytime about why we were doing what we were doing.

RT: There may have been differences between civilian distribution requirements and military in terms of temperatures and conditions in the military. Were those significant and a part of your deliberative inspections?

FF: No, because the military had storage facilities the same, maybe even better than the commercial facilities.

RT: That wasn't really a factor then?

FF: No, it wasn't.

RO: I guess maybe some of the requirements that DOD and VA may have put on was the packaging of it that may be different than what the ordinary consumer would get?

FF: There are many people who believed that the requirements that DOD put on were designed to keep generic drugs out of government procurement. The DOD people--particularly Max Feinberg in Philadelphia, who was the head guy--were opposed to generic drugs. And he was the one who designed the special specs for their products. There were a lot of people who concluded that he designed them in such a way that it kept generic products from being eligible for sale under government contracts. Indeed, when we first got involved, there were no generic products being bought by DOD.

When FDA said the same standards must apply to everybody, generic drugs then began to be procured, because they were the low bidder, and if they met the public standards, then they couldn't be turned down for some fanciful reason that somebody might have wanted to apply. I think we gave generic drugs a tremendous boost to where they are today, through the procurement of them by the government.

The USP monograph standard for aspirin was 90-110 percent . . .

(Interruption)

FF: . . . if with the aspirin tablets having a monograph potency range of 90-110, I could agree that if DOD needed some aspirin tablets to shoot up to the moon, and they were going to leave them there for fifteen years until the next moon shot, then I could probably agree to a 95-105 percent potency range to help better ensure that they would retain their potency, because they were ensured to be closer to 100 percent potency when they manufactured them. But other than some special need like that, there is no justification for special potency or other quality requirements.

They used to require or request bids on a particular drug or tablet; for example, the color had to be Fuchsia No. 123A, the color of that tablet. It just happens to be that only one manufacturer could produce that tablet, because he's the only one that knew what that color was. So DOD was often very restrictive, and they would direct contracts to favorite manufacturers. There was a lot of stuff going on that shouldn't have, that wasn't right. The taxpayers were paying for that.

I should say that Vigneault was good. He knew what he was doing. He wasn't too popular with his DOD people in Philadelphia because he would tell them that they were wrong and that the problems were there and not here.

After four years with us, he moved out. He didn't eventually have anything to do. They replaced him with another full colonel, Harold Varnex. He didn't have the background that Vigneault had, because Vigneault had worked in Philadelphia in DOD procurement, so he knew the business. His replacement who came along didn't know anything about that. He had never worked in that area. He literally had nothing to do. He was just there some of the time. But overall, DOD having a rep here was good for us, and it helped with things.

While I was in the position of running the Medical Products Quality Assurance staff, I developed relationships with any number of military medical people in the various services. We would work together.

One example, I got a call one day from the Air Force Surgeon General, who I had known and worked with before he became Surgeon General, and he asked if I could help him. This was in the 1980s, in the midst of the Cold War, and there was a great concern about nerve agents and the use or the possible use of nerve agents by the Russians against our pilots. There was a drug that was being used by NATO as a nerve agent prophylactic and antidote, but it was not approved in the United States for that purpose. He wanted to know if I could help get FDA approval for the Air Force to use that drug or at least to have it available for use by our pilots if it was needed.

There was and perhaps still is a policy that no drug can be used on military people that doesn't have FDA approval. So I told him I would see what I could do. He had some top secret material that described--it was from NATO--that described the drug testing that had been done on animals to show the drug was effective against nerve agent drugs. I had previously got top secret clearance, because I had attended from time to time some meetings at the Pentagon where they were talking about classified information.

So he sent this top secret package over to me by courier, and I had to scurry around to find facilities, a safe or whatever, in FDA where this stuff could be stored safely. Indeed, there was one. Linda Bottlemeyer. Do you remember her? She was in some part of OMO (Office of Management Operations), and sure enough, they had this big safe with top secret capability. So I was able to use that.

In any case, I needed to get somebody in CDER (Center for Drug Evaluation and Research) to review this material. It turned out there was only one person in the whole center who had top secret clearance, and that was Bob . . . God, his name escapes me.

RO: Temple?

FF: Temple, Bob Temple. So we would go through the ritual of I would get the documents out of the safe, and I would hand-carry them to him, and he would be able to look at it, and then we had to get it back into the safe for overnight storage.

But Bob looked at it over a period of time and concluded that it appeared to be safe from the studies that were done, but he was shaky on the efficacy of it. No testing had been done on humans, because it wouldn't be ethical to give humans a nerve agent and then see if this drug was effective enough to save them, and these nerve agents, just a minute drop, kills you like that, they say. So he wrote up something that we gave to

the Air Force and satisfied what they needed in order to be able to give the drug to their pilots.

Another call I got from the Air Force Surgeon General's office had to do with a GAO (Government Accounting Office) investigation that had been done in western Europe at U.S. Air Force contingency hospitals. The Air Force in the 1980s had a number of pre-positioned, fully-stocked contingency hospitals, and these were ready to be deployed. They had everything except staff, but they were fully stocked with all equipment, drugs, devices, everything that was needed to take it to someplace, set it up, and begin treating patients. They had bought millions and millions of dollars worth of drugs to stock these hospitals. Most drugs have a thirty-six-month expiration date on them from the date of manufacturing.

RO: Do you know how that's arrived at?

FF: Yes, it's a good round number based on commercial distribution practices and on marketing strategy, because you make money in business by turning over your product. If they could put a one-year date on it and get away with it, that would be even better. But traditionally they've used three years. In order to meet FDA's requirements for labeling the drugs with an expiration date, you must provide data to FDA that shows that the drug will retain its potency and other quality characteristics for the period on the label. So if you choose two years that you want to put on the label of your drug, then you've got to give FDA data that shows it will retain its potency for two years. If you choose three years, as nearly everybody does, then you give FDA that data. FDA doesn't care how long the expiration date period is; they only care that you've got data to support that expiration date.

So DOD had bought these drugs. We had approved the purchase of them on contracts, and they had used them to stock these hospitals. That whole process had

gone underway when Reagan came into office. You'll recall that Reagan campaigned on readiness and the need to build up the military. So when he came into office, there was very quickly a big surge in procurement of drugs and other military material, guns and boots and everything else. The drugs had gone into these contingency hospitals and sat there for three years waiting for a war to happen and it didn't. So the Air Force was now starting to throw away those drugs because they had reached their expiration date. GAO had gone in there and looked at that, and had written a report that was highly critical of the Air Force because of this great loss. Hundreds of millions of dollars worth of drugs were being thrown away. GAO told the Air Force, "You've got to do something."

So I got the call from the Surgeon General's office saying, "Is there anything that you guys can do to help us in this situation?" Well, knowing a little bit about drugs, I knew that at the stroke of midnight on the last day of the month of the labeled expiration date, the potency doesn't dramatically fall off the edge of the table. Drugs degrade on a curve; in most cases a long, slow curve.

So I thought there was something that could be done. I believed that the drugs would retain their quality for a lot longer than the labeled expiration date. So I got together with Joel Davis, who was in CDER and who worked with us on ensuring that the manufacturers bidding on drug contracts indeed did have data to support the expiration date they were using.

Joel and I had a long history of working together on this type of thing. I went to him and said, "Can't we design something that would avoid throwing away all of this stuff because it reached its label expiration date?" He said he thought we could.

Joel is the scientist in this part of it; I'm not. I don't pretend to be a scientist. Working with Joel and using his scientific expertise, we designed what came to be known as the Shelf Life Extension Program. I went back to the Surgeon General's office and said, "We may be able to help you. We're willing to try under two

conditions: One, that what we do is recognized to be just a pilot test, because we don't know if it will work; second, you've got to pay us to do it." They agreed. They were very pleased with our offer to help them.

We ran the pilot test, sixty or seventy lots of drugs that had been stored over there in those hospitals. Joel designed a test that used some various scientific principles, like the Arrhenius equation that you probably know something about; it is applicable to testing drugs for loss of potency. What we would do is get a sample from each lot to be tested for possible extension of its shelf life. These were all previously unopened containers. We would put containers into an oven at high temperature and high humidity for ninety days and cook them. We had other samples of the same lots of the same products and we would also test them. We would test both the cooked and the uncooked drugs, and the lab or Joel was able to draw a degradation curve. The ninety days at this precise temperature and humidity was equivalent to "x" number of years at ambient temperature of storage. When that was all finished, you could draw a curve—potency at the end of three years, potency after being cooked, and you could extend that curve, and it would show at what period of time at ambient temperature would the potency of that drug fall to the lower level of the applicable potency standard. We tested other things besides potency; hardness of the tablets and other applicable quality characteristics. But the important one was potency.

RO: Bioavailability or . . . ?

FF: The dissolution testing which equates to bioavailability was done, yes. In the manufacturers' original submission to FDA for new drug approval, there is the bioavailability data and that equates to a bench test of the dissolution profile of the product.

We would find that this curve almost without exception would not hit the lower level of potency standard for seven, eight, nine, ten years in the future. I was, though, not entirely comfortable relying on that curve. So I built into the program an annual retest to confirm the extension we approved.

We would extend the shelf life by three years based on this analytical curve. But I wasn't comfortable enough to just do that. So while we would extend it for three years, we would make each extended lot come back for testing every year—not cooking anymore, just testing of the product stored at ambient temperature. And we would find that the curve was even lower. The actual potency would be even better than what the curve projected. That gave us the confidence that we were right when we made those projections, and we would extend and extend the life of drugs in many cases for ten years. The annual testing would confirm that it was still good.

In any case the pilot test worked out fine, and the Air Force wanted to continue it, go into a full formal program. We didn't object, and we did that. We charged the Air Force for the time that we spent, both the administrative time and the lab time, and everything we did. We charged them for equipment. We bought ovens, we bought many kinds of equipment for the lab that was needed for this, and we charged them for all of that. So FDA got reimbursed pretty nicely for what we did. And that program is still going on.

RO: Is that published anyplace or was it just released to DOD?

FF: Was what published?

RO: The results of this Shelf Life Extension Program.

FF: No, it wasn't published anywhere. Industry knew about it. I talked about it to industry; Joel Davis talked to industry about it. So they knew what we were doing. We were never challenged. We were very conservative in what we did. We wanted to be certain we had good lab data to back up what we did. And, as I say, where it showed it was going to be good for ten years, the most we would extend it was three years at a time, because I felt that if we were challenged and shown to be wrong one time, the credibility of that program would go in the can.

No manufacturer ever challenged us. They asked questions about it, but never argued, and here they were losing millions upon millions of dollars in sales because the government was no longer replacing these drugs. We quickly brought into the program all of DOD's stored drugs. Not just these Air Force contingency hospitals, but the other services. The navy had tons of stuff stored in some island in the Indian Ocean, and we tested and extended the expiration dates of that. FDA's still doing it.

RO: This study then was probably the basis for your appearance on at least one of the national networks talking about shelf life.

FF: Yes, the Peter Jennings show. I got a call out of the blue from a reporter last September while I was still working for FDA. Actually, I got the call from an FDA Public Affairs person, who said a reporter wanted to talk to me about the shelf life program. They referred the reporter to me, which made the whole thing legitimate as far as talking to the press about something.

This lady called me from *The Wall Street Journal* and asked some questions. I answered them, and she called me any number of times over a period of months. She did a lot of work on it. I had a copy of a speech I had delivered to some DOD officials describing the shelf life program. There was a paper that Joel Davis and I--mostly he--wrote, more on the scientific side of it, that he delivered to a pharmaceutical

scientific organization. I supplied her with copies of those two papers. She talked to many people in FDA, in DOD, and in industry. I was amazed at all the people that she followed up with and all of the research she did for her story.

I even referred her to Mary Pendergast, because Mary got us doing some of this work for drug products that were being shipped to Russia. Mary got involved when she was working for Kessler on some Russian activities. This was after the Soviet Republic fell. Manufacturers were shipping products over to Russia to help them, and they were in some cases shipping expired drugs, and, some believe, taking full tax credit for the donations. But the Russians were upset that we were dumping crap on them. So Mary had us do some testing on some of that stuff so that we could prove that the drugs were still good.

The reporter went to visit our Philadelphia District laboratory, which is where the shelf life testing is now being done.

(Interruption)

FF: The reporter called me in February and told me the story was going to publish the next day. She said that there were likely to be people in the media who would want to talk to me, and was it okay if she gave them my home phone number. I said, "Well, exactly what are you talking about?" She said, "Well, when we publish these front page stories, the people who are involved often get called from all over the country." I said, "Well, I don't want to get called from all over the country." She said, "Well, *The Wall Street Journal* has a working relationship with ABC," and she said, "I'm sure that they're going to want to talk to you." So I said, "Well, okay."

Sure enough the next day I got a call from a producer for the Peter Jennings nightly news show. He asked me questions and wanted to know would I be willing to

be on that show. I said, "Yes, I guess so." They sent a crew to my house, the lighting people and sound people and an interviewer and all.

The interview went for about an hour and twenty minutes, and they had about thirty seconds on the show. (Laughter) But that was fine.

Then I got a call the same day from a Dateline producer, and we talked for about a half an hour. He wanted to get me to say the same thing that the ABC people tried to get me to say during the interview. They wanted me to say that drug companies were ripping off the public by putting a three-year expiration date on the labels of commercial drugs, and I wouldn't say that. The drug companies would be ripping off DOD and the government if the shelf life program hadn't come along and showed that the government doesn't need to throw away stored drugs after three years. But that's different from saying the public is being ripped off.

One of the main differences is that what people throw away, prescription drugs in prescription vials that are sitting in their medicine cabinet. What we did with the shelf life program was to test previously unopened containers; we have no scientific data--and I don't think anybody does--on what's the effect of long-term storage on drugs that have been repackaged at a pharmacy and the user opens that vial every day and takes one out, keeps it in a steamy medicine cabinet, and then the unused portion sits there for however long. I tend to think that they retain their potency, that they're still good. But I don't know that for sure. No testing was done on that.

Now if you did that testing, showed that those products--even repackaged like that--were still good, and that word didn't get out to the public, then the public would be getting ripped off.

But when I wouldn't say that the public was getting screwed, Dateline was no longer interested in the story, because they were looking for something sensational.

In any case, that shelf life program is still going on. As far as I'm concerned, the next thing that happened is one day I was sitting in my office minding my own

business, and I got a call from the Deputy Associate Commissioner for Regulatory Affairs, Mr. Gary Dykstra. Now this was November 10, 1993, as I recall, and he wanted to talk to me. I said, "Oh, shit, what have I done now?"

So I went to see him, and he asked me if I would take on a new assignment, managing the development in the fielding of OASIS (Operational and Administrative System for Import Support).

RO: And that is the acronym for . . . ?

FF: Operational and Administrative System for Import Support. I said, "Why me? I don't know anything about imports. I worked on imports when I was a GS-5 on the pier in Boston. I haven't done anything in imports since then, and I don't know anything about computers." You know, I can turn my on, my PC, and that's all I know.

RO: You did an awful lot of computer work in the Government Wide Quality Assurance Program?

FF: Well, no, not me. I mean, we were computerized, we were heavily computerized. But I had some excellent people, most especially Anna Colandreo, who did it. But I said, "I don't know anything about any of this stuff. Why me? You must be trying to get me out of the job I'm in."

He explained that, as everybody knew, the development of that system had been in trouble for years, there was a lot of congressional heat, industry heat. So he said they were looking for somebody . . .

Well, first of all he said, "You'll have a good learning curve." He said they were looking for somebody who could manage that whole effort and bring it together

and all. I said, "Well, let me think about it over the holiday." The next day was Veterans' Day. I said, "Let me think about it."

So I thought about it, and decided, why not, with some conditions. I went back to him and said, "I'll do it. But first of all I want to pick my own people who are going to work for me. Second, this isn't a detail. If I'm going to leave the job I've got, I'm leaving it permanently; I'm not going back to it. And third, there's got to be an organization set up to do this." He agreed to that.

I almost immediately took over the new job. I brought with me the two people that I had in mind, who had been with me for twenty-odd years, Anna Colandreo and Leslie Sweeney, and we went to work on trying to get this system developed and operational. It was a challenge.

Dykstra had talked about the learning curve. The learning curve was a vertical line for me. The toughest part of that job was the challenges from within FDA. The good part of the job was so many of the people that I worked with, so many good people from DHRD (Division of Human Resources Development), from DIOP (Division of Import Operations Program), the field almost without exception was just great. We developed a great operation, I think. The contractor was fine. There were some individuals and organizations within ORA (Office of Regulatory Affairs) that wanted us to fail. But things worked out well.

We put out the system. It was the first of its kind in FDA. Nobody had ever done that before. It wasn't perfect to start, it still isn't perfect. But with such a large national complex system like that, it will never be perfect. It works well, and it did the job. If you look at the volume of imports handled by FDA, before automation, before OASIS, FDA could not handle the workload and paperwork that they had at that time. There were big problems in New York and elsewhere with just the sheer volume of entries. They couldn't look at them all, they couldn't process them all. They were

taking weeks before they'd give a clearance for an entry, while all this stuff is sitting on the docks rotting.

The volume of entries has risen, I don't know, threefold, fourfold since then. The automated system is handling the work in a timely fashion. There is no way that FDA could be handling the current import volume without automation, and OASIS automated it.

RO: For the record, Frank, could you give a very simplistic explanation of what the system was designed to do, what it is doing?

FF: Sure. The system works in conjunction with U.S. Customs' automated system called ACS, Automated Commercial System. ACS is the acronym. The way the Customs system works is import brokers all around the country submit data electronically to an electronic system ABI (Automated Broker Interface). ABI connects thousands of import brokers around the country with the Customs system for processing import entries. Customs has to clear every import before it can come into the country.

FDA has to also clear every entry of FDA regulated product, which is about one-third of the total number of entries coming in. There's about thirteen million entries total now. So FDA processes about one-third of that. When I left, it was close to five million entries a year that we were processing, and we couldn't handle them when we were doing a million and a half manually back in the late eighties.

In any case, the import broker transmits electronically to the Customs system information about the shipment that he's bringing into the country, what it is, how much, where it's coming into, how it's getting there, where it came from, who's the manufacturer of the product, et cetera. That data gets transmitted and processed in the Customs system. For FDA regulated shipments, those data are forwarded to FDA and processed by OASIS.

RO: Is that at every port of entry, so that like New York it's called into the New York office for processing?

FF: No, it's all done centrally. Everything from around the country goes into the Customs computer, and then we have a dedicated line coming over from Newington, Virginia, to our computer in Rockville, and the data are processed.

All of our people around the country access the system, and they in turn from us get data on the entries that came into their ports. It's OASIS that sends it to them. They can view on their screen each entry. They make a decision based on the data that's on the screen. About 88 percent of all of those entries are now entirely paperless.

RO: Entirely what?

FF: Paperless. Prior to OASIS, for every entry, the importer or the broker had to submit to the local FDA office a package of paper, a 704 form, invoices, shipping documents, et cetera, a package of paper. We've eliminated almost all of that. Only in select instances when the data on the screen isn't adequate do we then need paper, and that's really the big savings because in New York and elsewhere, I'm sure, and I know in Los Angeles and elsewhere, paper was piled to the ceiling. People couldn't begin to get through it and review it. So now it's all data on the screen.

RO: And that's fully operational?

FF: Yes. After the decision is made on OASIS as far as the acceptability of the FDA regulated products, that decision goes back from OASIS to the Customs computer, back to the screen of the importer or the broker who entered the data in the first place. So he gets the clearance on the screen.

RO: What's the time lapse?

FF: Sorry?

RO: What's the time lapse back to the broker?

FF: For the majority of shipments, it is within fifteen minutes.

Now we still have to do testing on some entries, lab testing. And, of course, that slows the process, because that part hasn't changed. If you've got a bacteria test that needs to be done on some seafood, then it's going to take a couple of weeks before the answer gets back.

So that's briefly how that works.

RO: When that comes in to this central OASIS, is there any kind of a determination made here centrally on those things before it goes back to . . . ?

FF: Yes, the preprogramming is in the central computer.

RO: I see.

FF: And DIOP makes the determinations in conjunction with the centers on what products we're not interested in, and it's programmed into the system in advance. If we don't want to look at CD players coming in in cars from Canada, then it's an automatic, "May proceed," and it goes back (snap) like that.

RO: Well, it's a rapid determination when you have an import alert, for instance.

FF: It puts on an automatic hold, yes. That's programmed in automatically and the shipment is not released. One of the advantages of this centralized system is it eliminates port shopping.

RO: Yes, I can see that.

FF: It used to be the practice that for importers to send things to New York because they can get them into the country easy instead of sending them through Boston, because they're tough in Boston. They won't let stuff in. And, you know, Senator Kennedy and others have called FDA on the carpet for that because there was a big reduction in what was being brought in through Boston because New York was easy to sneak it through.

RO: Or if you're refused entry, then it eliminates them going to New Orleans or someplace like that.

FF: Yes, the automated system, OASIS, brings a lot of advantages.

After I got somewhat done with OASIS, there was another system that had been in the development stage since the late 1980s. The ORA division responsible for its development had not been successful. I am referring to automating the operational systems for domestic operations. It replaces PODS (Program Oriented Data System) and all of those ancient systems that came on line in the 1970s.

RO: What's the acronym for that?

FF: FACTS. Field Accomplishment and Compliance Tracking System.

RO: F-A-C-T-S?

FF: Yes.

RO: Where does FDA stand on that?

FF: That's fielded. It's out there, operational. We've done some good things towards being paperless with it. We have eliminated hard copy cover sheets and collection reports. It's all electronic now. We have an electronic signature feature, because as you know with the collection record, for example, you need an authentic, verifiable signature of the individual who collected the sample if you're going to go to court. So we have the electronic signature that people affix.

We've eliminated all of the paper, and some you'll be aware of, Ron. The accountability of samples within the district. We used to have that . . . There was a green form, and I forget the form numbers for them. But we've eliminated that. It's all now done on the screen. When the analyst picks up the sample at the sample room from the custodian, the analyst does an electronic signature. So there's a chain of custody, and when it comes back to the sample room, the same thing. It's signed back in electronically. So we've been able to do some pretty good things.

RO: Did this system then eliminate the need for the districts to track their own compliance? A couple of years ago each district almost had their own . . .

FF: Yes! There's a compliance component in FACTS. The labs' analytical work goes in the system. So all the laboratory findings are put in and maintained electronically so that somebody in the center can call up a sample that was analyzed in New York or wherever and get the sample results out of the system and view them on the

screen. The center can issue inspectional or analytical assignments electronically to the field. It shows up on the screen in the district that's going to do the work. The district gets the assignment out of the system, does the inspection, types the data back in. We did not eliminate the narrative portion of the inspection report, that still exists.

The center can track the status of the field's work when it's been assigned to somebody to do, and whom, if the work is underway, if it's been completed--so a center now can monitor all of that from any assignment that they send out to the field.

RO: What protection is there from invasion here by a virus?

FF: Well, I think the virus will try to attack a PC (Personal Computer) and then get into a system. All of the PCs have virus protection software. But new viruses come along, and I guess the protection has difficulty keeping up with the new viruses. I suppose in theory somebody could create a virus and send it to some FDA PCs and infect the system. But there's something called a firewall that is built around all the agency's systems, and that's intended to protect against anybody accessing any data in any electronic system.

RO: The hackers.

FF: Yes. I think almost anything is probably possible, but there are strong safeguards.

RT: Well, probably FDA's system wouldn't be any more vulnerable than many other systems in operation? It might not be as attractive as DOD or banking or something like that, but it could happen I suppose.

FF: I think anything is possible to happen with that kind of thing.

RT: Ron's point . . . I was thinking that before he asked it. We're so dependent on this system, and we have no paper writers anymore that . . .

FF: True. But what we do do is backup the data. And that backed-up data is offline and not vulnerable. So you can reconstruct the files. Even if it's not anything malicious like that, your system, in and of itself, can go down and destroy the data that's in there, which is why you need to have backups now to be able to reconstruct what you had.

RO: That's interesting.

FF: And FACTS . . .

(Interruption)

FF: . . . other reasons. We built these systems in segments. We couldn't afford to do it all at one time. We didn't have the money, and it is poor system development practice to try to develop a big system all in one package. You're not going to be successful, because new systems always have things go wrong with them. They're very complex, very difficult, and you need to take a bite at a time. So with FACTS, we did the sample collection and the administrative part of the work. Sample collections, some sample analyses, and the administrative part in the first bite. The second bite we added inspections and all the rest of the analytical work and the compliance module. What wasn't done and is I think being done now is consumer complaints and some of those other related programs.

RO: You said this replaced PODS?

FF: PODS is gone.

RO: PODS is taken care of.

FF: Yes, all of the data is in FACTS that PODS had, plus a lot more, far more than was ever in there with PODS.

RO: Interesting, Frank. Very interesting.

FF: So that takes us to December 31, 1999, when I retired. Although, if it's of any interest, I'm back working part time. It's a rather strange setup. There's something called ITDS, and that's the acronym for International Trade Data System. This is a concept that goes back to 1994 or so, to have a single nationwide system for processing everything relating to imports and exports. Every federal agency that's remotely involved with either imports or exports would be a player in this system, and that includes agencies you wouldn't ever think of. For example, the Census Bureau. They'd be a player, because they use a lot of import and export data, and Commerce agencies. I think there are one hundred and four federal agencies who will be involved in this system. It'll cover both exports and imports. The import portion of it will be very similar to what we now have with OASIS and what Customs has, but will involve many other agencies. So this system has been on the drawing board and not made much progress since 1994.

RT: Is FDA the pilot leader in it?

FF: Well, we were involved with it from the very beginning because we have such a big piece of imports. There is an ITDS board of directors, and it's chaired by somebody from ITC, the International Trade Commission. Gary Dykstra is on that board of directors. Gary has taken on a lot of responsibility in that area, and he has become responsible for doing a pilot of it. The pilot will involve Customs, FDA, INS (Immigration and Naturalization Service), and Department of Transportation (DOT), and the pilot will involve trucks coming across the northern border, at Buffalo. DOT, of course, regulates trucks; INS regulates the foreign drivers. So there's a pilot being planned for later this year, if things go well, and Dykstra is, as I say, responsible for that.

RO: You are now then a consultant to that?

FF: I'm sorry?

RO: You are now a consultant to that?

FF: Well, yes. I've got a funny situation where I have a contract from Customs, but I'm working for the board of directors, which is an interagency entity. But primarily I'm working for Gary Dykstra in helping to bring about the pilot, working primarily on the non-system development, non-technical things, like the training of users that's going to be needed and trying to get the Buffalo importers and the carriers, the truckers, to participate in the pilot. Many of those kinds of things. The same kinds of things that we were faced with both OASIS and FACTS in getting a successful pilot of it done.

RO: Sounds very interesting.

FF: So that's where I am at the moment.

RO: Well, unless there's something else.

FF: Well, let me tell you something. I thought you were going to ask me about changes that I've seen in the Food and Drug Administration.

RO: That's right.

RT: Very good.

FF: And I think I want to tell you about the changes I've seen in FDA since 1961. It will be brief.

There are probably three main changes. One is the bringing in non-FDA people to top jobs in the agency, and it, of course, started with Goddard. After I came in, Goddard was the first non-career commissioner. That has accelerated greatly, and we now have commissioners and deputy commissioners and associate commissioners who had no involvement in FDA before they got the job. We even have the ACRA (Associate Commissioner for Regulatory Affairs) who is a non-FDAer in an important position. So that's one of the changes I've seen, because that never happened when I first started.

Second change is the politicization of the agency. There was none of that when I started. I think that the politicizing of FDA goes hand-in-hand with bringing in outside people. I think what really accelerated it was Frank Young with the big ego, who pushed for and got a requirement for Senate confirmation for commissioners, which simply makes our commissioner more beholden to the politicians in order to get

confirmed. This agency is now rife with politics. Beholden entirely to Congress and powerful committee chairmen, and I think to the detriment of the agency.

RO: Well, it's no longer when Frank Flaherty can start out as a GS-5 investigator and think that he can be commissioner.

FF: Well, that's true. Frank Flaherty never thought that, but Frank Flaherty is surprised as hell he ever got as far as he went.

And the third thing is the change in people. When I started with FDA, people were dedicated FDA employees, who lived and breathed FDA. That changed tremendously. I guess it probably started in the seventies, and it's gotten to the point . . . There are still dedicated people; I don't want to suggest otherwise. Many new people coming in are dedicated, but for a heck of a lot of people it's just a job, a stopping place. That's so different from the way it was back when I started.

So those are the three significant areas that I see have changed from the time I was in FDA.

RO: And what is the prognosis for FDA? Is it going to revert? Or is it going to continue? Is it going to revert back to what it used to be or is it going to continue?

FF: No, I don't think it's going to go back. I don't think you can ever go back.

RT: Well, as far as the overall mission, what do you see there? You spoke of the changes of the players. How about the basic mission of consumer protection? Do you see that as something different from its historic roots?

FF: The mission is the same, I guess. It's been expanded, but essentially the same. How well FDA carries out the mission is what's changed in my judgment. In the old days, you didn't have a Senator from Utah calling up and saying, "Lay off the firm in my state selling these products. Lay off." But you have that now, and FDA reacts and does lay off. So I don't think FDA can carry out its mission like it used to.

RT: The agency has worked in the past with more politics at headquarters than perhaps many persons out in the field recognized. By politics I mean being responsive as an agency to congressional committees, appropriation leaders, and so on.

FF: Well, certainly there was always that, but I still don't think when I did an inspection of a firm and we were going to do something with them that back in those days that a Congress person would call FDA headquarters and say, "Lay off," and that that would cause us not to prosecute. Maybe some of that went on, but it's just blatant now.

RO: Well, Frank, we want to thank you very much. It's been very, very interesting and very enlightening. We really appreciate that.

(Interruption)