History

of the

U. S. Food and Drug Administration

Interviewee: John M. Taylor

Interviewer: Ronald T. Ottes

Date: December 9, 1993

Place: Rockville, Md.

DEED OF GIFT

Agreement Pertaining to the Oral History Interview of

John Taylor

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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 Administrations History Office. 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration

TAPE INDEX SHEET

CASSETTE NUMBER(S) 1,2,3

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

DATE: Dec. 9, 1993 PLACE: Rockville, Md LENGTH: 107 minutes

INTERVIEWEE	INTERVIEWER
NAME: John M. Taylor	NAME: Ronald T. Ottes
ADDRESS: [redacted]	ADDRESS: U.S. Food and Drug Adm.
[redacted]	

FDA SERVICE DATES: FROM 1959 TO: 1991 RETIRED? Yes

TITLE: Associate Commissioner For Regulatory Affairs
(If retired, title of last FDA position)

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RO: This is another in a series of oral interviews on the history of the Food & Drug Administration. Today we are interviewing John Taylor, retired Associate Commissioner for Regulatory Affairs, in the Parklawn Building in Rockville, Maryland. The date is December 9, 1993. I am Ronald Ottes. This interview will be placed in the National Library of Medicine and become a part of FDA's oral history program.

John, to start this interview, would you briefly sketch where and when you were born, your education and so forth, and what brought you to FDA.

JT: I was born in Louisville, Kentucky on June 30, 1934. I attended college at the Central State University in Wilberforce, Ohio. In 1956, I graduated with a B.S. degree. After finishing college, I went into the army for two years in the U.S. Chemical Corps. After leaving college, I went to Wayne State University where I did some graduate work in organic chemistry.

At that time, in 1959, I decided it was time for me to get a job, so I applied to what was then called all the Civil Service Regions. I received an offer from the Detroit District of Food & Drug, at the GS5 level. I never will forget, because about a month and a half later, after I'd been interviewed for Detroit, I received an offer from the Cincinnati District for a GS7 level. And, of course, I wanted to change because Cincinnati was much closer to home, but I could not.

I think the first thing that really I remember about Food & Drug was my interview. It was by Howard Bollinger, who was the chief chemist of Detroit District at that time. And I had interviewed for other jobs in the private industry. But I spent five hours being interviewed by Howard Bollinger, and he really asked me every question that I can think of regarding chemistry. I remember one of my favorites. He wanted to know the reaction of aspirin with phenol. But that was Howard. I was hired on July 19, 1959 in Detroit. I was the first black chemist in the Detroit District. Detroit was a very unique place, because it was just opening, and most of the people were either transferred in from some other districts or newly

hired. So we had close-knit group of people because no one called Detroit home, which was a very positive thing.

My first supervisor was Garland Reed. And the training program was really unique, because every time you had a training sample . . . And they did not give you official samples. Most of the time the sample you received had been spiked, so they knew the correct result. You would finish the assay, and then you had to go into Howard and Garland and explain the chemistry of the method--I mean, of the procedures that you used. So . . . And they were always saying, "You're not going quite fast enough." But then I remember very distinctly, after being there about four months, we had the cranberry scare. And I can remember that we didn't have enough hoods in the Detroit District, plus the hoods we had were not very good. And I can remember ten hours a day extracting the cranberries with methanol. And I can remember going home like I had a contact high most of the time.

Garland always tells the story that they didn't know whether they were going to keep me or not. And I'll never forget, I was sitting at my desk doing my analysis, and Tom Welsh, who replaced Howard Bollinger as the chief chemist, came up to me and said, "You know, you're not doing too well. You're kind of slow, and we're not really satisfied with you." So I asked Tom what was my name, and he said, "You're Nelson." (Laughter) Well, he was referring to another black chemist which they had hired, and his name was Nelson Burgess. So I said, "No, my name is not Nelson Burgess. I'm John Taylor." I think Tom was kind of embarrassed about that, and I was kind of upset, because I'd been there for four months. When I first came there, Tom was a compliance officer downstairs, and subsequently promoted to chief chemist.

RO: That would have been disastrous to have been . . .

JT: Yes. So Garland always told the story about how I was almost fired. But then they really expected you to finish the training program in six months, and they

didn't take into consideration those times that they would have you doing extra things. For example, we spent over a month dealing with nothing but the cranberries. Or the times they would have you cleaning up downstairs in the basement, because either Mr. Rayfield, Mr. Garfield or somebody from Washington was visiting the district.

RO: That was the aminotriazole episode with the cranberries. Is that right?

JT: Yes. Yes. And I can remember we were one of the districts that actually found a few positives which was later determined to be a false positive due to problems with the methodology. But I guess I will never forget those days, because those were the few times that they were paying us overtime for working extra hours. For six days a week, that's all we did was analyze for aminotriazole. As I said, they want you to finish in six months. Well, I didn't finish the training program until about nine months. You couldn't get your promotion until you had finished your training program. After finishing training, I primarily worked on filth, because Garland Reed's expertise was in the filth area. Garland had developed a number of methods for both light and heavy filth, and I was actually . . . He actually let me do some of the research work for him in those areas.

I also had another unique experience. At the time, they transferred O'Dean Kurtz from headquarters to Detroit, because he had never been in a field district, and O'Dean was one of the outstanding experts in the filth identification area. So I got a chance to be trained and work with O'Dean, which was a real eye-opening situation.

After my filth experience, they decided that it was time for me to do some pesticides, so I did a number of pesticide analyses. And one of the requirements in pesticides in Detroit was that you go up to Benton Harbor in the trailer, and you would spend two weeks in Benton Harbor doing the analysis. And those were the

days before we had the new trailers, so there was no gas chromatograph; it was all paper chromatography.

After that, I finally got into doing some drugs, primarily the over-the-counter drugs and the undercover work. For about a year of my career, all I did was amphetamines, phenobarbital, butabarbital, and sulfonamides. They were illegal buys. One of the outstanding experiences I had was a trial in Fort Wayne, Indiana. And I tell you, when we got there, the section where the court was was not the best section in town, and after looking at the two defendants, I didn't know whether I wanted to testify or not. But we did.

I stayed in Detroit until 1966 when I was transferred to Kansas City as a supervisory chemist. I'll never forget the day I was at my desk, and I got a call from George Daughters, who was the district director, to come down to his office. So when I got there, Lipscomb, who was the chief chemist of the chief chemists at the time, was in the office, and they told me that I had been transferred to Kansas City.

RO: That was before the days when it was competitive, wasn't it?

JT: (Laughter) That's right. There was nothing competitive about this. They told me I was going, and I later found out that what each district did was send in a list of people that they thought were qualified for promotions up to headquarters, and headquarters made a decision of where and who they were going to promote. But no, there was nothing competitive about that. As a matter of fact, during the whole seven years I was in Detroit, the only performance appraisal I got was a piece of paper saying "satisfactory." So you never really understood, never really knew what they actually thought of you.

I'll tell you I had some real doubts about going to Kansas City, and I was not very happy about the situation. But one thing that I'll always remember--that I consider positive for both Lipscomb and Daughters and Welch, because he was in there also--they were very honest to me about the kinds of problems that I was going

to find when I went to Kansas City. They told me that I was going to have to prove myself before I became accepted, and they named a few people who were going to give me a problem because, to be very candid, I was black. And I was very surprised. They were right on the money. Earl Bloomingdale, Floyd Yarnell, Donna Bailey, Roberta Hoss made my life really miserable there for the first six or seven months I was there. But later on, it was very surprising. When I got there, they didn't believe anything I said, but I kept working with them. We kept having our little disagreements, and finally they learned to accept me.

RO: Who was the chief chemist then?

JT: Don Healton. It was my first experience with Don Healton, and it was a real learning experience, because Don had me writing position descriptions. I didn't know anything about writing position descriptions. So we went back and forth and back and forth on the position descriptions, and he always laughed about this, because he gave me fits, and we finally got the position description finished. One of the reasons they were writing new position descriptions at the time was that they were planning on having a specialist in other areas than pesticides--you would have drugs and so forth--and we were trying to put together PDs, position descriptions, which could be submitted to headquarters.

RO: This was at what--GS11 or 12?

JT: It had finally become a GS11, because when I started, the journeyman grade was a GS9, and eventually went to GS12--I mean the GS11. And supervisory level at the time was only a GS12. And the assistant chief chemist was a GS13, and the chief chemist was a GS14. Don also gave me fits about trying to write up promotion recommendations. I'll never forget we had this guy named Jim White, and I thought Jim was ready for a promotion. So I sat down and I put together the promotion

recommendation, and Don turned it down. Well, that bothered me, because here I am, my first promotion recommendation, and it was turned down. Well, you know, we weren't talking about a GS11, we were talking about promoting somebody from GS7 to GS9. Well, after writing it over about ten times, I finally convinced Don to let me promote the individual. We also have laughs about that still.

I stayed in Kansas City for approximately two years. The first year I was in charge primarily on pesticides and filth and medicated feed, which was very big in Kansas City. I'll never forget my second child was born in 1967, and I had to take off because we didn't have any relatives in Kansas City when my child came home. During the time that I was off, my laboratory submitted a quality assurance sample to headquarters, and they misidentified the G.C. peak. It really was heptachlor epoxide. Well, when I got back, I got my rear end chewed by not only headquarters, but by everybody in the district. Even though I wasn't there, it was still my responsibility. We shouldn't have made the mistake. What we had tried to do though, we tried to play by the rules. We did not have a pesticide specialist examine the sample. We did it just like we would do it normally and have an ordinary chemist. I'll never forget that. And he was just learning, and he just didn't measure the retention time correctly.

Then I was transferred . . . Oh, by the way, at that time I also met Tony Celeste. Tony was one of the other supervisory chemists, and also Tiny Silverberg. Kansas City was a unique district because they could hire a lot of chemists. So it was used primarily as a training facility, and you have people such as Richard Ronk, who spent almost his entire career in Kansas City as a trainer. After these people were trained, they were transferred to such places as Philadelphia, New York, and Chicago. So we had a lot of inexperienced chemists during that time. The second part of my tour in Kansas City, I did primarily drugs. Tony was transferred to Washington, and I took Tony's place in the drug lab.

In 1968, I was transferred to headquarters in the old Field Sciences Branch. At the time, it was under the assistant commissioner for field coordination, who later

on was Mr. Sam Fine. My supervisor was Hy Eiduson. It really was a very unique experience, because what you were trying to do was you were trying to coordinate between the field laboratories and the bureau laboratories. I always had a lot of respect for Sam Fine. As a matter of fact, as I look back on my career and look at managers in this agency, I would rank Mr. Fine high on that list. He could make a decision; he was very rational; and if you made a mistake, you got your rear end chewed. (Laughter)

I can remember Detroit District had sent in some pesticide analyses to us. Tom Brown was the district director in Detroit at the time. Tom was not happy with the results and the way his lab had performed. He sent them to us, and we didn't do anything. So, of course, he wrote a little letter to Mr. Fine. And then we get this call one morning that Mr. Fine wants to see us in his office. He wanted to talk to us about the way we were doing business. So he showed us the work and he showed us the deficiencies, and he asked if we had reviewed them, and we had, and we talked to the chief chemist. No, that's not the way it sounds. You shouldn't go back to the laboratory. You should have gone to the district director. The point was well taken.

But then about a month later, during a grape crisis, we had published a laboratory information bulletin (LIB) regarding the analyses of grapes for pesticides. We were having some industry unrest in California, and there were some parts of it that were more political and more editorial than analytical. And so I got this call that I should recall all the LIBs, and that was the first time in the history of the Food & Drug that you recalled an LIB. I got them back, but I forgot to get one. I forgot to get one from a man named Kenneth Kirk. (Laughter) And that was another big mistake in my career, because he called me over . . . He called me and asked me had I recalled the LIBs. I said, "Yes." I gave him the count. He said, "Well, I know one you didn't get." And I said, "What's that?" "That's mine." Well, of course, to be very honest, I wouldn't ask Kirk for that LIB. Well, after that it was duly noted

that when he said recall, he meant recall everything and everybody. So we went over and got the LIB from Kirk.

I can remember another fascinating thing that happened during that time. There was this big push to consolidate all government laboratories under GSA. And that was one of my better experiences, because Paul Hile, myself, and Sam Fine went to the meeting. And to hear the dialogue back and forth, it was a very good experience. In the meantime, after we solved that problem, the Bureau of Drugs decided that they wanted their laboratories, they wanted to take all the drug analysis away from the field laboratories. By that time, Sam had moved up to the associate commissioner for compliance.

RO: Who was the push in the Bureau of Drugs for grabbing all the laboratories?

JT: It was both Danny Banes . . . And I was surprised, it was also Ted Beyers. Ted had been one of my first trainers when I started in Detroit.

RO: Of course, Ted was then in the Bureau of Drugs, and he . . .

JT: (Laughter) He had been with the Bureau of Drugs in charge of compliance. And we put together this . . . Paul Hile, who was then the Assistant Commissioner for Field Coordination, put together this task force, and the chairman of the task force was Bill Clark, who later on became the regional director in Chicago, Region V. I remember on it we had George Goers, chief inspector of Minneapolis District; Jim Swanson, who was later the regional director in Seattle; and we had Mike Truzzo, who is still in Buffalo as an administrative officer. We had a guy named Lou True, who is now an assistant administrator over in EPA--Environmental Protection Agency.

That was a very, very interesting time when we'd visit all the bureaus and tried to get all their ideas. We interviewed a number of people in the different districts

to try to come up with some recommendations on how the situation should be handled. Of course, we decided that there was no need to give the drugs their own lab analysis; but we felt it was necessary to have a generalist group, so if you had a crisis in one area, you could transfer all the people to that area and the Bureau of Drugs couldn't do that. For example, in the case of the cranberries, we could transfer everybody to do pesticide analysis.

Some of the other recommendations that were accepted--a number of them were not--because we had this elaborate plan for labs . . . This was in 1970. By 1980, we were going to have five major, I mean super labs with about three thousand people in the field doing analysis which never happened. But one of the things we did recommend, we recommended that a district be established in Newark. That did happen.

RO: But that was the first district that was established that didn't have a laboratory.

JT: Right. Then the second one was Orlando. Then Nashville. And all those three were recommendations made by the task group. One of the things that the task group really wrestled with, and I think we really made a big mistake, was where the district should be placed in the state of Florida because of land, and facilities, and the amount of money it cost to purchase the land. In hindsight, we should have recommended Miami, because that's the center of the district's universe, and also the number of imports that were coming in by the middle eighties. It is very clear that it should have been in Miami.

While serving on the task force, I applied for the executive development program. I remember one of the interviews was with Phil White and Maurice Kinslow, and I remember the question that Phil asked me very clearly. He said, "If you were in charge of the EEO program, what would you do?" And I said, "Phil, there's no way and not enough money that I would become the head of the EEO

program. I would quit first." But he kept pressing for answers, but he never got an answer.

One thing, going back in time, while Sam Fine was in charge of the field, they had a problem in Philadelphia with some of the problems in the racial area. It really wasn't only racial. It was with females, minorities, everybody. And he called me over to his office and said, "I'm going to assign you to a group with Voyce Whitley and--I can't think of his name--and you're going to investigate the claims in Philadelphia regarding discrimination." And I very nicely said, "I prefer not to go." (Laughter) He was very nice, too. He said, "I don't care what you prefer. You'll be leaving next Monday."

And it was a very unique experience, because what we found that there really wasn't a discrimination problem. Because what we did was interview minority males, minority females, majority females and other employees. We asked them the same questions. It was very strange, because everybody had the same answers. So what we were talking about was a management problem, not a discrimination problem. Because the majority and minority were saying the same thing. It was just that they felt that management was not paying enough attention to them, and that only a few parts of the district structure had anything to say about the management of the district.

RO: Was this overall district, or was it in one of the branches more . . . ?

JT: It was overall district, but the primary problems were in the investigations and the laboratory branches. But it did turn out that it was really an overall management problem.

Oh, and back to the point where I had applied for the executive development program, I was accepted to the executive development program, but then I got a call from Mr. Hile, and I had also applied for Chicago. But I really wasn't selected for Chicago. Another individual was selected for Chicago. His name was Louis

Schneider, an old friend of mine, who I had worked with in Detroit. "Felix," they called him. You know, we were very good friends. But then I get this call from Paul saying, "You know. Really we don't know the future of the executive development program, because we've had quite a few classes, and we're really running out of good places, jobs for these individuals who are graduating, and we need you in Chicago.

RO: That was as chief chemist?

JT: As chief chemist, yes. They had decided since Felix had been in Chicago for approximately five years now, they decided that it would be better that he went someplace else. So Felix was transferred to Detroit as the chief chemist, and I went to Chicago replacing Bob Martin.

RO: And that was in what? Nineteen . . . ?

JT: Nineteen seventy . . . The latter part of 1970. As a matter of fact, it was October of '70. I'd been to Chicago once, but I'd never really paid any attention to the laboratory. In fact, when I really got out there and had a chance to look at the laboratory, I said to myself, "What have I gotten myself into?" The district was not allowed to do pesticide analyses, because headquarters had decided they didn't have the expertise. And that was very common in the late sixties and seventies. If you did quality assurance samples and you got the wrong answer.

(Interruption)

JT: New York, Philadelphia, Chicago were some of the places that we yanked up. So my first thing was to try to find somebody to come in that could analyze pesticides. Well, the people we had, they were very enthusiastic, but they really didn't appear to know how to do the analysis, and under the program that had been

established back in the late sixties, every laboratory would send a person into the Bureau of Foods to learn how to do pesticide analysis, the individual from Chicago had left. So what we did, we transferred a guy in from Detroit to head up our pesticide program. After we were able to do three straight pesticide quality assurance samples, then they reinstated us and we could do pesticide analyses. But that was just one of the minor problems with pesticide analysis in Chicago.

It was in the old post office building. The ventilation system in the hoods was built in the mid-thirties, and when you were trying to analyze pesticides, you could smell the solvents all the way down the hall, and it was becoming the time when Chicago had a union, and they were really complaining regarding the fumes and the health of the employees. We finally got some fume hoods put in.

Also, the district was doing microbiological analyses. That was always questionable, because you had problems with contamination coming out of the vents and so forth. I remember one of the big things that happened while I was there in the microbiological area, we found salmonella in the chocolate. And I can remember when we reported it to headquarters, they went ballistic, because they said that salmonella would not grow in chocolate, and Dr. Olson, the director of the Division of Microbiology, B.F., said Chicago didn't know what they were doing, so therefore, Chicago should not be allowed to do microbiological analyses anymore.

Well, what we did, we packed up all the samples and we gathered additional samples from the firm, sent the samples to headquarters so Joe Olson could have his people analyze them, and they did find they were positive, and that was the first time they had found salmonella in chocolate.

In the meantime, headquarters decided they were going to give us some money to try to fix up the lab, because it was really a dismal place to work. And every time it rained, although we were on the twelfth floor, you'd come in on Monday morning, it had rained over the weekend, and you'd get your mop and mop the floor where it had leaked through the ceiling. And all kinds of money had been spent trying to patch the ceiling, but it just didn't work. So they say, "We want you

to do anything you want to to try to cheer the people up. Let them be involved in the redecoration of the laboratory." So we did that. And I'll be very honest, we came up with some colors that I think some people probably thought that I was kind of crazy, because we had a purple lab, we had a yellow lab, we had a green lab, we had a blue lab.

But the people really, really got involved, because what they said, you know, they had this chance to do it, as well as they bought us new furniture particularly for the micro lab. They said if the government would buy the paint, they would paint the lab. We came in on Saturday and Sunday--of course, not during regular working hours--and the windchill factor was a minus fifty-five, but everybody showed up, and we painted the labs on that Saturday and Sunday, and they were very happy. Commissioner Edwards was the commissioner at the time. So he and Paul Hile came out for a visit to the laboratory, and that was the first time that I'd met Dr. Edwards. And he looked at the lab, and he just laughed. But the thing that impressed me most was he said, "Hey, the people's morales are up." But Edwards was always in favor of closing the lab in Chicago based upon the recommendation of the Ritts Committee.

RO: Ritts Committee.

JT: Yes. But . . .

RO: Excuse me, John. Who was the district director when you went to Chicago?

JT: Bill Clark.

RO: Bill Clark was the district director?

JT: Yes. Right. He had . . . He . . . When he was on the task force, he was a deputy, and after that task force, he was promoted to district director, and then I went in as laboratory director.

RO: That was before they had established the position of regional Food & Drug director. Or it was about that time.

JT: About the same time. Because Don Healton came in from Boston to be the first regional director.

RO: I see.

JT: As commissioner, Edwards was walking through the micro lab. He said, "John, you've got a visitor." And here was this roach crawling up the refrigerator. (Laughter) That was another one of the problems in Chicago. You did have a few roaches and a few mice running around.

RO: What did you do about filth work? If you had some infestation like that, did you do filth work?

JT: We did filth work, but to be very honest with you, if we found any roach parts, we had to make sure they were not from the laboratory. Of course, the inspectors, if possible, had to pack everything in jars. But if we found roach parts, we had to be very careful that it was really from the plant and not from the facility. But we did have problems with our filth analysis. You had to start it in the morning, you had to extract the sample before the end of the day. You could read your plates anytime, but you didn't let anything set overnight. You didn't weigh out your wheat or your flour and so forth and let it stay overnight. You had to make sure that you had already extracted out any insect parts you had there.

This went on, and then Healton, who was regional director at the time, established a committee to look at how the laboratory structure was set up in Region V, or now the Midwest Region. And there was one thing that very evident that you just couldn't get around. Chicago really should not be doing the pesticide analyses, because even though we were given additional money to buy additional hoods and furniture for lab tests, it still wasn't working. So it was decided that we would have a partially specialized concept in the region, and that Chicago would lose pesticides, because still we had not gotten rid of the fumes, the union was screaming more, we did have an environmental engineer come out, and some of the levels of the solvents were above those recommended levels. So it was decided that Chicago would not do anymore pesticides or microbiological analyses.

The microbiological analyses were to be done in Cincinnati, and the pesticides would be done in Detroit and Minneapolis. Chicago would pick up additional drug samples from those districts. It really meant that the laboratory would become smaller, and one of the biggest problems I had was trying to find positions for the microbiologists. We transferred one of the individuals up to the Investigations Branch; another one decided she just couldn't take it, so she went to Consumer Product Safety Commission; and then we transferred the supervisor to Washington. We wanted him to go to MCMI, but he really didn't want to do that.

RO: Well, that was probably about the first that there was any kind of centralizing that work in one laboratory and decentralizing . . . You didn't have . . . In other words, you didn't have a generalist laboratory in Chicago.

JT: No.

RO: That was the first then of starting into a region at least of decentralizing some of that work.

JT: That's right, and we didn't have a fully specialized laboratory in Detroit, because it was decided that Detroit would send their microbiological samples to . . .

RO: Cincinnati?

JT: . . . Cincinnati. So really the only full-purpose labs we had were Cincinnati and Minneapolis. But you could say that Minneapolis probably wasn't a full laboratory either, because at that time they hadn't combined the microbiological center with the district office. So it was still a separate entity.

RO: I was always curious as to why the microbiological samples went to Cincinnati rather than going to Minneapolis where they had the Center for Microbiological Investigations, I guess is what they were.

JT: Yes. At the time . . . This was just before the switch over. At one time, the center was a part of the Bureau of Foods and not of the field. I'm trying to remember the guy's name that was there. The one that used to wear the cowboy boots.

RO: Leininger. Harold Leininger.

JT: Harold Leininger. When Harold was there, he was a part of the Bureau of Foods. Later on, he became a part of the field, and then additional samples were sent to Minneapolis from Chicago and so forth. But at the time, we had to make sure that the Bureau of Foods was willing to accept the samples that we were sending, because during Leininger's time, they had a lot of research being performed. Only when there was a major crisis would the bureau be willing to take official samples.

It really changed a lot when Dr. Olson was replaced by Pete Reed as the director of the Division of Microbiology. Pete was more cooperative. The field was really involved with planning some of the work that the micro center was doing. So it was really a big change.

But, yes, that was the first concept of the partially specialized lab. You still had the same complaints then that you have now: that shipping samples take too long, and primarily they were worried about the import samples. Now, although most people would think that Chicago wasn't a big import district, primarily the things they got through air and mail were the only things they got, so you didn't really have a major problem with the imports out of Chicago. But take Detroit for example, particularly in the micro area. Detroit was a big port, you did get quite a few samples coming in, and plus Detroit had to find ways to send all of their people to Cincinnati, and there were a lot of complaints about the people being transferred. But at the time, Detroit didn't have a union; Chicago did.

But we felt that the program worked very well, and the laboratory directors would meet quarterly to make sure that everything was going right. You could call another laboratory director and say, "Hey, this sample must have the highest priority." For example, in the case of pesticides, if Detroit couldn't handle it, we would call Minneapolis to make sure that we got it in the speediest time possible.

During the whole time I was in Chicago, there were always plans for a new district office which never happened. They had the site near the V.A. depot at Hines which fell through. They looked at locations out in the suburbs that . . . One was Mary Knoll, a college that was being closed, and they thought that they could make a training center and have a district office out there, but that fell through because there was no money.

One of the things that happened during the late sixties, during the time of Dr. Goddard, we were primarily doing two things. We were doing salmonella analyses and drugs. And in the seventies, when we finally got back into the filth area, I can remember in Chicago, we were finding that even in the best warehouses in some of

our most credible firms contained rodents and insects. So when Senator Kennedy gave us the extra people and money we began to do more work in the sanitation area.

RO: That resulted in Project Hire if you remember. That was in about . . .

JT: Right. In 1972, right. Like I said, we were really getting prosecutions in the sanitation area at the time. I guess one thing that always bothered me, that's when I started to see the lab dwindling. Not only in Chicago, but all over the country. When I started in Chicago, there were fifty people in the lab, and they were all busy. When I left, there were about thirty. And at one time it went down to as low as about 14 people in the laboratory. Which meant that you had to do a lot of juggling on what you were going to do and what you were not going to do, which meant that we really just wiped out in Chicago primarily everything dealing with the economic violations.

But we used to have a lot of problems with pesticides in Chicago in a very unique area. In noodles, they would use the old wooden drying containers, and they would spray Lindane in the plant, and the Lindane would get into the wood. And I remember we had three injunctions going on with three different firms, but it really killed us, because we had to monitor all the shipments so before they could ship it out, we had to analyze for Lindane; but I can remember that Lindane problem drove us crazy until finally they decided they would stop using the wooden trays. But most of your experts in the field, those people who had been making noodles for a number of years, felt that something was added by the wooden trays.

RO: And this was primarily in noodles and things of that sort?

JT: Yes . . . Well, all different kinds of pasta.

I guess it was during that time in Chicago we saw a lot of different switches on how people felt about the laboratory, including some feedback from the bureaus. There was more of an emphasis on inspectional findings and less on the laboratory. I can remember Taylor Quinn, who subsequently became my boss, had the idea if you had a good inspection, you really didn't need to analyze the sample for filth. Because if you had to give him some good finding, he could win a case, a (A)(4) case, no analysis necessary. And that the inspector should be able to determine what kind of insect they found, whether it was a mouse pellet or rodent pellet. So those kinds of things began to cut back on the number of people you needed in the lab, and the labs were becoming smaller and smaller.

Another thing that was happening, money was not as easy to come by. During the late sixties and the early part of '70, we were getting all kinds of equipment, but it was beginning to slow down by '73 and '74. I was very happy when, after I left, that Chicago did get a new laboratory. They decided that they had to split out the district office from the laboratory, and they did get a laboratory there working. By the time they got the laboratory, though, they didn't have any people. So that was another problem. We had to try to find additional things for them to do so they could fill up the laboratory they had. After being in Chicago for almost four years, in the middle of '74, I got transferred to the Winchester Engineering & Analytical Center (WEAC).

RO: That was the first I guess, John, that the field had taken over that WEAC, as we called it. Is that right?

JT: That's correct. It was a Bureau of Radiological Health facility.

RO: And you were the first director.

JT: Right. And it was really a learning process. First, Winchester was not your traditional laboratory. They had a lot of space out there, acres of land. You had unique people. Like you had a driver for the director, you had a machine shop that turned out to be invaluable because they could make anything. I'm talking about analytical equipment and so forth. You had people that were not familiar with analyzing regulatory samples. Primarily what they had done before the takeover by the field was to run food samples for radionuclides, test microwave ovens over the lifetime. What they would do, they had this automatic door opener. If it was a home oven, they opened and closed the door 100,000 times to see if there was a microwave leak. If it was for commercial use, they would open and close the door 200,000 times and measure the microwave radiation. And, of course, they did the television sets where they would actually tear down a television set and then measure the radiation. And you had your x-ray unit and so forth. That was it.

RO: Your staff then had all come from the Bureau of Radiological Health. Is that right?

JT: That's right. When I first got there, it was all from Rad Health, and you had primarily physicists, engineers, and some chemists. But primarily you had engineers and physicists. And these people were very, very intelligent and very knowledgeable about the work they were doing, but the thing about it is they didn't know how to put together a work sheet. And at the time, devices were on the horizon, so they wanted to set up a medical device section at WEAC to test some of your more unique devices and so forth--those devices that were not radiation-producing equipment. And then it was also decided that since there was so much extra room, that we should do some drug analysis, particularly in the dissolution area. The people at WEAC had actually built equipment according to the USP specs for doing a dissolution unit.

The first thing that happened was that we transferred some people in. We brought in a guy from St. Louis to head up the dissolution unit. We hired new people. The problem was to train the people to put together a work sheet so if necessary we could take action. Because to be very candid, at the time, the Bureau of Rad Health really didn't believe in any regulatory action but rather in education and voluntary compliance. Oh, another thing is that there was no structure to the organization. They would come to work when they got ready, and they would go home when they got ready, because they were professionals. I had trouble buying that kind of a setup.

But I think the first big problem we had was with a General Electric x-ray unit, and General Electric was one of the biggest ones. So it was approximately a 155-page work sheet. And to be very honest with you, I was no engineer, and I stayed up all night reviewing this work sheet, because we had a conference call with the people in the Bureau of Rad Health, including Mr. Vilforth, regarding our findings. Because here we had this big firm, their piece of equipment did not meet the specifications listed on the label, and all we were doing was comparing the label against our findings. So I can remember having the conference call, and, of course, I didn't satisfy John, so that driver for the center director came in handy, because we packed up the entire General Electric--that entire x-ray device and sent it down to the Bureau of Rad Health so they could do a subsequent analysis. The sample was okay.

RO: It was all right? They didn't support your finding?

JT: No--yes, they supported our findings. It was violative. And the next big one was the Toshiba television, and they were coming in from overseas. And we had all kinds of television sets detained, and they had trouble believing our results, and we did send the TVs down to Bureau of Rad Health. They did confirm the results. I guess the one thing that I never understood about those situations, the people that

were actually doing the work were not people that had been trained by what was known then as EDRO. These were people that were former employees of the Bureau of Rad Health. I think they tried to pick out some of the better people to bring to Washington, but they still had a nucleus of outstanding engineers and physicists in the center.

I think another big problem at WEAC was trying to get enough work to do. Now EDRO had let us hire the people; we had sufficient people. They had given us all kinds of money to buy the proper equipment to do the analyses, including drugs and devices. But we could not get work to do. We could not get the Center for Drugs--or the old Bureau of Drugs at the time--and the Bureau of Medical Devices to give us any work. And I can remember coming down here lobbying with the people in both bureaus to try to get enough work so we could keep the people busy. In the case of drugs, the way things were going, we were doing a lot of content uniformity. The people at Winchester were able to do your automated analyses, and we were running in direct conflict with the work that was being done in the St. Louis lab. So we would beg them to give us what we call one of the studies and St. Louis one. And they really didn't.

In devices, it was even worse. At first, they said that they needed people to develop performance standards. So we had been able to even hire some new engineers, some biomedical engineers out of the University of Texas, and so forth. They were really good at performance standards and so forth, so we had asked them for some very simple things that we could do. For example, something that's still going on in the Food & Drug now, let us set up a standard for hearing aides and defibrillator. Devices--and (Dave) Link was the director--refused, because he didn't think we had expertise.

Then we asked to be able to do work on consumer complaints to try to determine whether there was actually some problem with the device or whether you had user error, where the person that was trying to use the equipment did not know what they were doing. And we even said that we would be willing to discuss the

kinds of analyses that we were going to do, the kind of tests we were going to do, prior to doing it with the bureau. That still didn't sell.

So I can remember that Don Kennedy, who was then the commissioner, decided he was coming up to WEAC and Boston, because he was giving some kind of a consumer talk. So I got him out to WEAC, and I outsmarted myself, because I had put together a list of how many people I had, what they were doing, and what work we weren't getting. So I'll never forget, he said, "You're *too* slick." (Laughter) Because I had everything there. He decided that he would have Jim Beebe, who was the regional director in the Northeast Region, Sherwin Gardner, who was the deputy commissioner at the time, and Dave Link, who was director of the Bureau of Medical Devices, meet at Winchester and decide what kind of work Winchester could do, and we wouldn't leave until we had come up with some solution to the problem.

Well, I can remember Sherwin . . . We met, I guess, for nine straight hours, and knowing Dave Link, we still hadn't decided anything. The only thing that Dave was willing to let us do was clinical thermometers--testing the accuracy of thermometers. But he just couldn't say flat no, so he said that he would look into it. So he let us do work on the hearing aides and defibrillators, but then they never accepted any of the tests. So twenty years later--almost twenty, about nineteen--we still have a problem with performance standards on that.

(Interruption)

RO: Did the Bureau of Medical Devices at that time have a laboratory in headquarters here? Is that what they were trying to protect or . . . ?

JT: Yes, they did. They had a laboratory . . . They had a laboratory down in the old agricultural building--the Department of Agriculture Building--at the time. But they were very limited on the kinds of things that they could test. What we finally

decided to do with some of the engineers was to make them available for inspections on medical device plants. Now, of course, they would not be the lead investigators. The district would ask for these individuals, they would go out with one of the investigators from the district, and they'd be primarily looking at technical type things, like design and so forth, to see if they could find anything that they would know would cause a failure in the system. We kept them busy that way.

After Dave left, it got a little bit better, because I guess Vic Zafra was the acting. And we did do more work regarding pacemakers that had failed and so forth. Some of the things that they were able to determine were bad batteries, poor connections and so forth. It was a very, very talented group. And I'll tell you when I got there, I was worried about it ever becoming a regular laboratory, but they really started to do some good work. You had the expertise and the knowledge; it was just that they were used to a different system.

RO: Do you know why they put a "Food & Drugger" in there to head up that laboratory rather than an engineer or someone like that?

JT: Well, the guy that was my deputy, Bruce Burnet . . . I think if they had done that, then the purpose of the lab, the purpose that EDRO wanted to make of the lab, would have been lost; because although Bruce and myself worked well together, Bruce never agreed fully to what was necessary on a work sheet. They just couldn't see the necessity to making sure you had a continuity of how the samples were handled. That to them was just petty work. Their work was to do research. Even on every sample they figured that they have to do research. They could perform tests on a particular x-ray unit, rather than using the test that they had developed. The next engineer would want to reinvent the wheel and start from scratch to see what they could find and do better.

RO: Well, a lot of their things like you're talking about, television sets and x-ray units, weren't they submitted for . . . ? They weren't collected in the true sense that FDA collected a sample, were they?

JT: That's right. All the bureau TVs and x-ray units were submitted. And, you know, it always amazed me that somebody would submit something that didn't meet the standard. You would call . . . Well, the Bureau of Rad Health would call over and say that, "We want you to send 'X' number of units to Winchester this month, and we want you to send 'X' number of these devices." So . . . And then they would have them shipped to Winchester, and then after we were finished, we would send some of them back.

Now the ones that we didn't send back were the microwave ovens that we had done a lifetime test on and those TV sets that we broke down. We tore them apart and put them back together. The Food & Drug had to buy those. But if you just do a normal test, you just bring them in and check the radiation; or in the case of the x-ray unit, you weren't breaking it down, you were just checking the radiation levels and making sure that the dials and so forth were accurate. After you finished your analysis, you called the firm, and we had to box them back up, and they were shipped back to the firm. We never collected any samples in the Rad Health area.

RO: So your charge really when you went up there was to bring this group into the Food & Drug Administration?

JT: That's right. I'll never forget I made one snap judgment when I first got there. I said, "One thing we've got to get rid of is this group of people in the machine shop, because we just don't need that." Well, to be very candid, after I was there for a while, I realized that I was wrong, because if you needed a piece of equipment that would take some time to get, you didn't have the money, if you could draw it on a napkin, those people could put it together for you. And if anything was wrong with

it when you got it, then they would make the change. So they designed equipment for every laboratory in the country. So they really turned out to be worth their money.

Winchester had their own janitorial service. GSA was not involved with WEAC at all because it was owned by Food & Drug, and that was very unique, because you didn't have to worry about the GSA, but you did have to worry about ROFEC, what was the HHS regional facilities office, because they had to approve any changes that you made in the building. And, you know, it was nice having the people that cleaned the building accountable to you, because you could make sure you'd get it done. But they had a painter and . . . But that painter could do everything. They had a lot of cross-training, and that's what made the unit so valuable. Just because you're a painter, you might be out there drilling or you might be welding, because they made sure that there was cross-training. And also they were very good at designing buildings and other kinds of things. So if someone really had a hood problem in another district, we did send those people out to look at the hood system and give them suggestions on what should be done.

One of my best friends, oldest friends in Food & Drug, was Lou Gershman, laboratory director of Boston District at the time. And every time there seemed to be a major crisis, I would be on detail and Lou would be in charge. For example, when the Chinese exploded their nuclear device, and we had all of the samples coming to WEAC to be analyzed for iodine and other radioactive substances, he was in charge. I guess what we found during that time that was really a problem. We kept finding radon in the samples, and it was really, really bothering me. Then we found that in the area on which WEAC was located (the border of Winchester and Woburn) the water had radon in it. And so you had to really be careful reporting our findings of radon.

But those people worked day and night during that time--also with the Three Mile Island problem. They were heavily involved in the analyses of the samples. And, of course, I had left by the time of Chernoble, but I was down at the Bureau

of Foods, and they did an outstanding job analyzing the samples being brought into the country. They were working twenty-four hours a day, because I can remember having meetings on Saturday mornings with Dr. Young and others. The individuals at WEAC were feeding us the results as we were having our meeting. So they did an outstanding job in the radionuclide area.

I think another program that always fascinated me was the analyzing products grown around your reactor sites. We were running for tritium. We really never found that much, but it really was a useful program, because if you saw any rise, even though it was not at the level of concern, you would report back to the reactor site involved. We got into some very interesting work with the EPA, because EPA does radioactivity analyses also, primarily in milk samples. So when I wanted to check to make sure that there was a quality assurance program, we would buy some of the samples from EPA that had been frozen, and WEAC would analyze them to see what kind of results they obtained. One time WEAC results did not compare with EPA's, so I stopped all analyses until we were able to obtain satisfactory results. The EPA samples were done out at the Las Vegas laboratory, which is one of the most outstanding laboratories in the radionuclide area.

RO: Well, John, you remember when we first got into the Total Diet Study, a lot of that was checking for radionuclides. The Total Diet sample went to Kansas City District for analyses, did WEAC get some of that to run for radionuclides?

JT: Yes. They would send portions of the market basket to WEAC. Also, at one time, we proposed to analyze for heavy metals; however, Kansas City had the expertise to do them. But we did run all of the market basket composites for radionuclides. We frequently had problems with the tea and coffee composites, because there was a possibility where some of the tea was grown in an area where there was radioactive contamination. So those were the kinds of composites you'd

always have to look at very carefully. But, yes, yes, they did the market baskets. I don't know whether they are still doing that or not.

RO: Well, when did you leave the WEAC?

JT: In 1977, Richard Davis, who was the district director at Boston, was made regional director at Philadelphia, and I was transferred from WEAC to Boston as the district director. It was good to have WEAC in the Boston area, because when I got to Boston what I found was that the device industry was really growing rapidly in that area. As a matter of fact, at one time it was the largest area for device manufacturers. But it was good to have WEAC because the engineers were available to accompany investigators on device inspections.

Boston had grown so fast that we had two different facilities. We had a facility which was the old district office for the Compliance Branch, the Administrative Branch and the lab, and then we had the investigators about four blocks down the street. And the bulk of the work was in imports and medical devices. You had very, very little drug work. As a matter of fact, you had next to nil. I think we had one prescription drug manufacturer in the entire area, so you really didn't get too much experience in the drug area.

I found Boston another unique experience. It was something similar to Chicago, because you had a lot of people that had been there for a long time. They had never left Boston. And then you had a number of younger people primarily out of your Project Hire that were there. So you had a lot of experience, then you had a little bit of experience, and there was a big hole in the middle, because it was such a long period of time that Food & Drug was not hiring. I think if I look at the Laboratory Branch, Lou Gershman had been there for a number of years, so he really added stability and experience to that area. You had Earl Burton as the director of investigations, and he had been around for a long time. And then you had Jack Hamilton, who had been around a number of years, who was head of

compliance. So you had a very experienced group of branch directors, and the same with their supervisors. In the Investigation Branch, they had some outstanding supervisors come through during that period, and they're still making their mark in the Food & Drug area.

We were known for taking regulatory action against what they call the 301K small bakeries. As a matter of fact, it got so bad that Arthur Levine of the General Counsel Office told us he wasn't going to take anymore prosecutions on these small bakeries, because the interstate commerce in some cases was less than ten percent.

But another big area that really had some problems was in the seafood area and in two aspects. Number one was species substitution. We had a number of prosecutions, because they would substitute haddock for cod. They would substitute for red snapper anything you can name--any red fish. So we had one of the few guys that was really an expert in electrophoresis, and he was also an expert in decomposition, and that was Tony Laterza. And he would actually do species identification for most of your district offices. The only other expert we had at the time was an individual in San Francisco. But we did have a number of prosecutions in that area.

The second area was in the mercury in seafood area. It was a problem because, number one, the State of Massachusetts refused to set an action level or tolerance. So you could ship anything into Massachusetts. You wouldn't get any help there because they had no tolerance. Canada had no tolerance, and everything was coming down from Canada, so I can remember us working weekends to get the detentions regarding the mercury in seafood. And it got so bad that the people were very wise. They knew that a fish above a certain weight was going to be over the level. So they would commingle, you know, put small and large so the lot average would be below the action level.

RO: At what level, John, were we taking action at that time?

JT: At first, we were taking it at 0.5 ppm, but then the judge in the Anderson Seafood case said that we were full of baloney, so it was raised to 1.0 ppm.

RO: What seafood case was that?

JT: The Anderson Seafood case in Florida. He raised the action level to 1.0 ppm. But at first we were going at 0.5 ppm, and we were detaining a large percentage of the fish attempting to enter the country. After it went to 1.0 ppm, it was recognized that the Bureau of Foods or the Center for Foods was only willing to take action when the level was above 1.1 ppm, because of the methodology and so forth. So when they started to commingle the lots, we said, "Ah-ha. We'll outsmart them. We'll only sample the big fish now." Now of course, that wasn't a proper regulatory sample, but we would sample the big fish and say, "OK. You can recondition by separating out the large from the small." Well, the Bureau of Foods statisticians and some compliance people didn't quite like that, so they made sure that we had to take a representative sample, something from both the small and the large.

The agency was almost ready to raise the level when some research was published that showed mercury did affect the fetus, it crossed the placenta; and therefore, it's still at 1.0 ppm, and there are a lot of studies going on to ascertain if the level should be lowered.

RO: What fish were these primarily in, where we were finding mercury?

JT: Swordfish, mahi-mahi, shark. We had a very interesting case. We had these people from Hawaii saying that the mercury found in their fish, their swordfish and so forth, was not like the mercury found in the swordfish coming from the East Coast. They were saying that ninety percent of their mercury was inorganic; whereas eighty to ninety percent on the East Coast are organic. Well, we did a big study, and in this particular area in Hawaii, for some reason, it is primarily inorganic, and that's

when we really stepped up our method for doing not total mercury, but looking at the inorganic versus the organic.

RO: Any explanation why that . . . ? Was it a metabolism or what?

JT: They say it was metabolism, and it's something to do with the kinds of plants that are found around that particular area that causes the organic mercury to be converted into the inorganic mercury. I just could not believe it, but, of course, found that I was wrong.

Another big area we hit was shrimp. It hit when I was there, and it hit in three areas. Shrimp for salmonella. We took the position that salmonella has no reason to be in shrimp. And if it's there, it's due to something that's being done by the individual harvesting the shrimp. So the salmonella was added.

Then there was the area of filth. We were finding quite a few samples of shrimp which contained rodent hairs, rodent pellets, portions of rodent pellets, roach parts, fly parts, and decomposition. And the funny thing about it is we got into this big disagreement with India, because we said there was no way to recondition shrimp containing filth. If it was decomposed, unless you're willing to smell and separate every part, it couldn't come in. But in the case of salmonella, if it was positive and you were willing to cook it, it can come in.

The big debate was whether you could wash the filth off of the shrimp. And Paris Brickey, whom I really respect, kept saying that you can't do it. The soluble filth still gets into the flesh of the shrimp. Well, I'll be very honest with you. I looked at that theory, and I couldn't quite believe it. So what they did is they radio-tagged some soluble filth. They ground up filth and radio-tagged it, and then they mixed it with the shrimp. It's not the normal way shrimp would be processed. The prepared shrimp was analyzed, and the soluble filth was still there. Therefore, the policy is still if you find filth in a sample, it cannot be reconditioned.

But the shrimp really became a major problem, because New York and Mr. Shane didn't agree with Boston regarding all of the time we were spending on the shrimp. But eventually every district was sampling shrimp for filth, salmonella, and decomposition. But, anyway, eventually everybody was on the same wave length, because we did find some major problems with shrimp, and they're still going on now. During my time we were never able to come to agreement with India on the methods to be used for testing for salmonella. Therefore, they would have to cook their shrimp before they were allowed in the country. In the other areas, decomposition and filth, we would accept their analytical certificates.

RO: Most the problem with the shrimp, then, was imported, not domestic. Is that right?

JT: Right. We ran no domestic shrimp. Ninety-five percent of the shrimp coming into Boston was imported, and we had no problem with the domestic shrimp. And it really got to be a hassle because . . . Well, I say hassle. Congress was hassling and so forth, because in some instances, until we worked out this deal where they could cook it, we were just wiping out firms left and right. Senator Kennedy and a few of the others, Governor Dukakis, they were not too happy with what we were doing, but after we said they could cook it, they didn't want to start a problem. Also, a number of those firms went together, and they did send people to India to look at the conditions there to see if they could be improved so we wouldn't have all these kinds of contaminants. Some of the firms did hire people to go to Southeast Asia, and some kept people over there to make sure that the individuals didn't go back to the old system of processing shrimp once you left. The shrimp problem improved slightly.

Another one of my exciting times in Boston was one day . . . It was 1978. It snowed in February. I think we had a total of about fifty-eight inches. In some places, the drifts were up to eight or nine feet tall. During the time we received this

call that some Israeli oranges had been injected with cyanide. Well, the problem was the boat was on it's way, and the governor had closed the entire city. There were no automobiles allowed on the streets period. So we had to try to find out how we were going to get an investigator down there to check the oranges; and number two, how were we going to get to the office and open the safe to get funds so we could make the trip. (Laughter) I will never forget that trip.

I finally made it down to the district office. We got the money. We checked, and we had three or four inspectors go to check the shipment. We checked on this left and right: a visual inspection looking for holes, prick holes or injection holes, because they said they'd been injected with a big bore hypodermic needle. We didn't find anything, but it was my first experience with tampering, and I'll tell you everybody was very, very upset. Some employees from the Connecticut Board of Health helped us perform the checks. They volunteered. Some of the inspectors down there volunteered to help us to check the entire ship.

RO: And this was with cyanide, you say?

JT: Yes. Israeli oranges. Supposedly with a solution of cyanide. Now what we know is as soon as the acid from the orange hit the cyanide compound it would have been changed to a gas. I doubt we would have found anything anyway. But we were neophytes, and we couldn't take a chance. Plus, I guess every embassy and everybody in Washington was screaming for something to be done.

One of the good experiences I had in Boston was working with Jim Beebe, the regional director. I first met Jim for a short time when I was in Detroit, and Jim was transferred--I guess it was to Atlanta, because he didn't stay in Detroit too long. Jim really got around in those days. He really transferred quite a bit. But during my time at WEAC and at Boston, it was a real pleasure working with Jim. He used a common-sense approach to everything he did. And, you know, he would joke, but

you had to be able to tell when he was really joking and when he was really serious and he wanted it done. (Laughter)

I'll never forget when I was still at Winchester, we had this big warehouse with about $8 million of material in it. And this was one of our first processes of seizing the entire warehouse, and the owner was a constituent of Senator Kennedy. So, of course, we filed a mass seizure. But then the Boston District office came in with a prosecution recommendation. So I was out at Winchester, so Beebe gave me all the documents, and said, "I want you to give me a recommendation of whether we should prosecute or not." He knew that was a no-win situation, as far as I was concerned, because if I would have said, "Hey, we should prosecute them," Beebe was going to say, "Did you use any common sense?" If I'd said not to prosecute to them, Jack Hamilton, Boston District compliance officer, wasn't going to speak to me. (Laughter) But after reviewing it, I looked at it, and I said, "No prosecution."

But, no, very seriously, Jim really taught me a lot about dealing with people, although we had our problems in Boston with the union. We eventually had to unionize at WEAC as well, and some of the things in the union contract in Boston were totally ridiculous. But the union wanted them, and eventually, we were able to work better with the union. But it was a real unique situation.

(Interruption)

JT: OK. I transferred out of Boston in 1980.

RO: John, before you go into that, were you still at Boston when you headed up the task force for establishing research centers in the field?

JT: (Laughter) Some things I'd like to forget about. I wasn't the chairman. No, the science advisor from San Francisco was the chairman, but Felix Schneider and myself did all the work. I can't remember the chairman's name. It was another one

of my exciting assignments. And it really got home to me how widely the disagreements were between the bureaus and the field. The whole project was to look at the field and see if we could improve the science in the field labs and see if we could establish a small group in certain laboratories that would become known as the Centers of Excellence that would really do research in particular areas. The idea was then Commissioner Donald Kennedy's.

RO: Was that science advisor Dr. Cangliosi?

JT: Yes. And the first thing we found is that the resistance from your different bureaus at the time was really outstanding. They wanted nothing to do with the project, because they felt that it was taking away from their scientific capability. They figured they were already the experts. They didn't need any neophytes in the field. One of the things that we tried to get them to realize is, "Hey, you have your people in the bureau; they're experts. But we also have to keep the science capability up in the field." And we figured that one of the ways we would attempt to sell the idea was to say, "OK. We'll have a small nucleus of people in the Centers of Excellence, but we would transfer people in and out to make sure that their expertise was still available to everyone."

We went around and around and around, and we finally did establish some groups. Since there was such great fighting regarding the name Centers of Excellence, it was changed to Research Centers. I can remember that the Bureau of Veterinary Medicine director, Van Houweling, he was so totally against the concept that he would not even meet with us to talk about it. The people in the Bureau of Foods were the same way. In Drugs, they tended to be totally uncommitted. Because really we weren't thinking too much about having a Center of Excellence for drugs, because we realized it would be very difficult to have the St. Louis laboratory and the field laboratory performing the same functions.

We finally decided to recommend that we have research centers in the areas of total diet, which would be in Kansas City, pesticides which would be in Detroit, aflatoxins which would be in New Orleans, your vitamins and minerals which would be in Atlanta, your tissue-residue-type analysis which would be in Denver. We decided that the minimum staffing for these groups should be at least six people. One of the things that happened, we really didn't have enough money to properly fund the groups. They were established. As a matter of fact, most of them are still in operation.

RO: John, isn't there a microbiology center in Minneapolis.

JT: Right.

RO: And we also have a shellfish, don't we? Or a seafood?

JT: Oh, that's right. The seafood in Seattle, right.

RO: And I wonder if the fact that Foods was so opposed to this was the fact that they were being impacted on more than any other, because we were talking about seafood, pesticides, and you had total diet.

JT: Yes. You're right. That was one of the reasons they were upset, because it seemed that we were attempting to take over their areas of responsibility. Maybe we should have gone after drugs, but we really couldn't see us getting anywhere with the amount of resources they were already putting into the drug research area. Although they had an outstanding pesticide research unit in Foods, there were still some of the individuals that were still living in the fifties and sixties. They felt that they had developed most of the pesticide methods, and these methods were good, and any new methods tended to be just a take-off on the old methods. We felt that

we needed something new, because we needed additional methods to determine more of the newer pesticides.

For example, we were very well set up for the organophosphates and the organochlorines, but not in some of the other areas or where the new pesticides were being developed. Also, there was a disagreement between the Bureau of Foods and Los Angeles District regarding the Luke Method. In the Luke Method, you use a smaller amount of product and supposedly you could perform the analysis faster. Everybody complained that Luke changed the method every time he used it, and the method had not been properly validated. Although since that time, Luke has published his method in the literature, and a number of people are using it.

We also recommended a committee meeting for scientists from the research center and in the Bureau of Foods to determine the kinds of research projects to be conducted so there would be no duplication of effort. The kinds of work Detroit was doing was in the smaller areas of pesticides that were not being researched in the bureau. So really there was no duplication of effort. And I guess it worked pretty well in the pesticide area.

It worked better in the pesticide area than it did in the aflatoxin area, because Lenny Stoloff of the Bureau of Foods didn't like the idea of New Orleans District developing methodology in the mycotoxin area, and particularly when they started to use the robots. At least the people in the pesticide area could sit down and talk about the project. Steve Walters was the first research center director in Detroit, and he could talk to the people, and he developed a good relationship with the individuals in the Bureau of Foods. The individuals from the New Orleans District attempted to cooperate with the individuals in the Bureau of Foods, but the individuals from the Bureau of Foods did not feel they were competent enough to perform research.

I think one of the big things that helped us out with the project was the selection of Dr. Sanford Miller as the director of the Bureau of Foods. Sandy realized that he would never have enough resources to do all the research he wanted

to do, and he had no problem with the field participating in these areas. When I was dealing with Dr. Howie Roberts, the acting director, some of his office directors were giving him fits about accepting the proposal. Whereas, when Sandy got there, there was really not that big of a problem. He believed in it.

RO: Yes, there's some of the staff in the Bureau of Foods that felt that Sandy sold them off.

JT: Yes. Yes, they did. Yes, they did. But, you know, one of the things he did though, Ron, he put together this book of research projects of what everybody was doing, because he felt that you had people down there that had been working twenty years on the same research project, and they hadn't been fruitful. And he was right. He was right on target.

Yes, they thought Sandy sold them out, but Sandy always had a soft place in his heart for the field. He felt we should work together to get the job done. When Sandy was appointed bureau director, I was still up in Boston. So we sent Sandy out with one of the district investigators to inspect the plant. And he lost his wallet, and the investigator, who's now in Falls Church resident post, found it and gave it to him, and Sandy was always our friend. But one of the first things we did when we heard that Sandy had been selected, we called M.I.T. and asked him if he wanted to go out on an inspection, and he did. He was very interested in learning all the responsibilities of FDA. After I transferred to the bureau, they still felt that Sandy had sold them out.

RO: You went to the bureau then in what year?

JT: Eighty.

RO: Do you remember, John, while you were still in Boston, we needed a director of our compliance group in the old EDRO organization. I talked to you, and I said, "John, why don't you come down and head that up?" You said, "No. I don't think compliance is my bailiwick." And what do you do? You then go down to Foods.

JT: I remember that very well, Ron, and I really felt that way at the time. I really didn't feel that compliance was my thing. I didn't feel that I knew enough about the area, and I really felt worried about the whole thing. My one job I always wanted was the director of field sciences, which I never got.

RO: Well, I remember that. And I'm sure you remember it very well, too. Don Healton was the EDRO then, and I was his deputy, and it upset us very much that Sherwin Gardner just felt at that time that we needed a Ph.D. as the director of field sciences.

JT: Right. But, no, I look back at that, Ron, and I guess I had more courage when I applied for Foods, because I really didn't feel that I wanted to go into compliance. And I'll be very candid with you, I didn't think that I was going to get the job when I applied for the director of the Division of Regulatory Guidance. As a matter of fact, Taylor Quinn didn't even interview me. So I knew that I didn't get the job, because I hadn't even had an interview, you know. I knew they selected the panel, and I knew that other people had been interviewed. I never got an interview to this day. And then he called me one day, and said, "You got the job." I said, "Taylor, you didn't even talk to me." "I talked to Beebe." "OK." Well, I knew Taylor, but that was the way that I was introduced to working for Taylor. And one of the things I once asked him, "Why did you select me?" He said, "Well, common sense. If you've got common sense, you can do compliance. But some of the people on my panel didn't have common sense."

Every morning we would meet to discuss issues facing the office. Some of the people felt very upset because Taylor had brought in an outsider. Because that job had always been held by somebody within the old division. Taylor was the division director, and after he left, Caeser Roy was the director. Both those people had grown up in that division. They'd been in there a long time. So some people felt that Taylor had sold them out by bringing me in, but that didn't last too long, because we didn't have time for it to last long.

When I walked in, I ran into two big things: infant formula. And infant formula was driving us crazy. And the second one was salmon and botulism. In the case of the infant formula, the commissioner was also very much involved. When I got there, Dr. Goyan was the commissioner, and San Juan District analyzed the sample of infant formula and found it violative. It was very high in one of the heavy metals. So my people came in and told me, and I reported it to Sandy, and Sandy reported it to Goyan, and he called the firm and said, "Quit selling." And then Sandy called back, "John, did you look at those work sheets." I said, "No, I haven't looked at those work sheets yet." "Well, John, I think you better look at those work sheets." So I looked at the work sheets, and sure enough, we did make a mistake. We made a calculation mistake. It was twice what it should be.

Well, Dr. Goyan was not too happy, but after that, anytime there was a problem, he would come down and ask me very specifically, had I looked at the work sheets? I found Dr. Goyan, in some instances, would make a decision very quickly, even after that mistake. And in the case of the infant formula, that was just the first one in a series where I either worked with Dr. Goyan or with Dr. Mark Novitch, who was his deputy. We had one where it was a snowy day in Michigan, and the regular people who manufactured the infant formula couldn't get in, so the substitute forgot to put any vitamin B_6 in the product. So we had a Class I recall on that. There was another one where another ingredient was left out. There were a number of Class I recalls during that period in the infant formula area.

At the same time, there was a consumer group called Formula. Most of the members were involved in the Syntex episode where their children had taken the formula, and either they failed to thrive or they had other kinds problems. We spent hours with them, because they were suing the agency and the firm, because they felt that neither one of them had performed their job correctly. So I really got to know the commissioners. I always felt that even in trying to put together the infant formula good manufacturing practices, how to manufacture the product was a major project. Analyzing the product was another big area. The people in the industry probably knew more than Food & Drug about the proper methods to use. We depended very heavily on the industry personnel in both these areas.

I remember the director of Q.A. from Mead Johnson. He's retired now, and I can't remember his name. But we'd be sitting in the room hour after hour after hour, and that guy really had a good system, and he really was a stern task master. And it took us months to determine the proper analytical methods to use for infant formulas.

And then when we found something low, you never knew whether it was a real hazard or not. I can remember when we found the vitamin B_6 problem, Dr. Sandy Miller getting on the telephone to some of his experts, some of the people that had actually developed the RDA for the vitamin B_6, and he wanted to know what kind of safety factor was built into the number. Because you usually have a safety factor built in. But the guy told him there was no safety factor at all built into the number. So what you see is what you get. Which meant that it turned out to be a Class I recall rather than a Class II recall.

RO: I guess that Syntex was the one that really led to the regs, wasn't it.

JT: Yes. Syntex led to the Infant Formula Act, and that left a big scar in the Bureau of Foods and now the Center for Foods. The firm decided to remove the salt from the product, because the firm felt that to remove the salt would aid the

infant because of all the talk about high blood pressure and so forth. And they didn't realize that by removing the sodium, they removed the chloride too, which the baby needed. The thing that really compounded the whole problem, Food & Drug got the product; they analyzed the product; they didn't find the salt; they sent the product to the scientist for evaluation, "What does this mean"; and the scientific people said Class I. At the time, the compliance people could overturn the scientific decision. Well, going back to the scientist, so they overturned it. The compliance people decided on a Class II or Class III. That was just before I got there. But when they had the congressional hearing, all the details were reported.

So Congress passed the Infant Formula Act so that situations of this kind would not happen in the future. The Act included the authority to force recall, the ingredients and amount which must be present, how the products must be tested during manufacturing, required notification to FDA before marketing a new product, etc.

We had put together a recall regulation while Jimmy Carter was President, and Goyan was still commissioner, but we didn't get it through OMB and the Department of Health & Human Services. So once the Reagan administration took over and Tom Scarlett became general counsel and Schweiker became the HHS secretary, they sent back the regulation, and Tom Scarlett actually rewrote the entire regulation. The center had nothing to do with it. They were totally unhappy with the regs. So when they sent it back, Tom rewrote it and sent it out, and that's how it was approved.

Senator Metzenbaum wasn't too happy about some of the things in the regulation, particularly when the problems continued to happen in the infant formula area. We actually tried to prosecute a few people. In the case of Syntex, the prosecution was not approved by the U.S. Attorney. But the Wyeth case in Michigan was approved. Well, we recommended prosecution in both cases. The U.S. attorney wouldn't buy it in San Francisco. In the case of the Syntex, there was no regulation there. So the guidance wasn't that good. In the case of Wyeth, the Act was there;

you knew what you were supposed to have there; there's no excuse. So they copped a plea. In the case of salmon . . .

RO: That was canned salmon.

JT: . . . canned salmon. The first one started--and I say the first one, because there was a series--the first one was started by a death of a Dutch person. Some of the cans of salmon were not properly sealed which meant that Food & Drug was going to have to go out and check a number of cans to attempt to determine the extent and cause of the problem. Seattle was always the leader in this area. They have worked so hard with the National Food Processors in setting up the Better Salmon Control Plan, that we really felt we had this whole situation solved. And every time we felt that we had it solved, some other problem came up.

So we went out and we looked at all the cans in bright--when I say in bright, it means that they hadn't been labeled yet. And when you put these things through the weight detector, if it's short weight, it's supposed to kick the can right out. But in the case of some of these containers, the skin would cover over the hole so you would get your oxygen free atmosphere and you wouldn't lose any of the juice or product. So the detector would not eject the can. So we got that solved, but then all hell broke lose. And it was probably the largest recall I've ever been involved with, besides the mushrooms.

They found that in a number of the cans, there was a strange little hole, that was unusual, and it wasn't directly related to the sealing of the can, but it was being sealed by the product, and botulism could grow. So the experts started to look at the problem. We had National Food Processors, the people from Seattle District and others in the plants and warehouses. What we found was that the equipment that was reforming the cans was making the little hole, and since all firms were using the same type equipment this meant that all canned salmon had to be recalled, and all cans of the product had to be examined. So the agency and the industry looked at

recalled salmon from all over the world, and boy, you'd be surprised at the number of salmon that goes to the U.K. And they were really hard on us, because they said, "We aren't going to buy any salmon until they look at it."

I went to Seattle, and the district personnel took me to one of the plants, and they showed me what normally happened when they're checking the cans. However, since the hole was sealed, the cans would not be ejected, and they had to look at every can individually. And that bothered me too, because I wondered how long a person could look without beginning to get blurry-eyed and missing things. So they were making changes of personnel about every forty minutes. But we looked at every can of salmon, and the only other time that I can remember looking at every container of a product was when we had the mushroom problem back in the seventies, and we looked at every can at every warehouse. And it was the same way with the salmon.

That was something that no one expected. No one had any idea when the problem started.

RO: Do you know, John, if they've changed now? Are they shipping cans whole or in the round rather than flat?

JT: In some cases, most of the cases now, they're shipping round.

RO: Round?

JT: Yes, they're shipping round. The can is formed but does not have a top lid. But they're shipping round now, which should limit that problem unless they come up with another one. Well, it was the largest recall that I was ever involved with, because you had more salmon than you had mushrooms. What we did by that mushroom recall, a number of the domestic firms went out of business, and most of the mushrooms were imported. When we have problems with the imported

mushroom people, they'd always say, "Hey, but you never found the serious problem with our products that you found in domestic product." But now they're finding all kinds of bacteria in the product coming out of China. But we really have very few mushroom manufacturers in the U.S. now.

(Interruption)

JT: While I was in the Division of Regulatory Guidance, we changed from Secretary Pat Harris to Secretary Schweiker and Commissioner Goyan to Commissioner Hayes. One thing that struck me most about Secretary Schweiker, and it was the first time in my experience that you found people at this level getting involved in regulatory areas. Secretary Schweiker was really, really, really heavy on infant formula and any other Class I recall-type situation. You had to let him know, and he wanted to be involved. He wanted you to take the most rigid action possible. He just didn't want this to happen. No matter what time it was, eight, nine, ten, eleven o'clock at night, you had to call Secretary Schweiker. But he didn't hinder you. In some of the recalls, as a matter of fact, in the infant formula, due to him, I think we really in some instances classified the recall too high. I didn't have any problem working with Secretary Schweiker because, like I said, he never stopped me from taking a regulatory action or requesting a recall.

The only thing that we were not very happy with was that we had no money to pursue economic violations. The field had to send us all their proposed economic projects for review since we only had about two person-years for the entire field, so we didn't do much work in the area.

But then something else happened. We got a new secretary, Margaret Heckler, who I'd met and worked with in Boston, and her chief of staff was Mac Haddow. When he was selected, my fun at FDA diminished. I can remember the first instance, we had a petition in from a firm in Utah that wanted to reuse soft drink bottles. You would take the bottle to a retail establishment, the bottle would

be filled from a fountain and you would take it back home. The bureau reviewer denied the petition, because he believed the practice could be hazardous. And I'll never forget, here Sandy Miller was my boss, Taylor Quinn's my next boss, but we get this call from Haddow's office saying that he wanted Art Banks, who was in charge of the retail food program, and myself in his office at 5:00 P.M.

I was pretty low when I went over there. But I will never forget, when I went over there, he made it very clear that he wanted me to change my decision. It really made me angry, and so I tried to lay out the rationale of why I said no. Are you going to be the one to make sure that the bottles are cleaned? You'll have a little child that picks up one of these bottles that might have cleaning solution or something in it and take it to the establishment to be refilled. We attempted to explain our rationale.

But he started to yell, and scream, and talking about firing us and everything else. Then he asked me if I was going to change, and I told him, "No, I can't change, because I'd be violating the law. That's not how I'm supposed to approve it." I said, "I'm not going to change. You can do whatever you want to to me; but I just can't do that. My conscience won't let me do that." Well, he screamed and yelled some more. I guess I was really depressed after that, because I didn't care what he did. I was . . . To be very candid with you, I was very depressed. But I never heard anything else about the situation.

RO: I am curious, didn't he elevate that up to Sandy Miller or higher?

JT: No, he didn't. Not on that one. He didn't elevate it. But I always kind of thought, if he wanted something, why didn't he go to Sandy? But, no, he never elevated that one to Sandy, and there were a few other situations that he did. And it really bothered me that more and more I was seeing the secretary's offices getting involved in the regulatory area. I am referring to specific cases, but I realized it was their responsibility to establish policy. But I think it always bothered me when we

were dealing with a safety issue. I had no problem if they do not want me to pursue economic violations or even sanitation violations. But when you're talking about safety issues, I think you have to draw the line.

The second situation happened when the field collected some samples of lobelia. Lobelia is used as a smoke deterrent. It's supposed to be a substitute for nicotine. The toxicologists felt the product was hazardous, and the district office recommended seizure. But we didn't seize it. We were told to put it on hold. In this case, he did go all the way up the line. He went on up the line, so I kept those seizure recommendations on the top of my cabinet until the day that he resigned. The recommendations were then sent to GC and approved.

RO: Was this a Utah firm?

JT: Yes, it was a Utah firm. Another time we got in trouble was when the Utah firm came in, and this time they wouldn't meet with Taylor Quinn and myself. They decided they wanted to meet with Sandy, myself and Taylor, and Sandy turned them down. So two minutes later Sandy got this call from Haddow regarding the turn-down then. Also, we got beat up pretty bad. And this one didn't really bother me, because it was with the alcohol in the candy. Our previous GC had refused to approve seizures for alcohol in candy.

But those weren't the only kinds of things under his sphere of influence. I know when we were trying to determine which colors to list he was heavily involved. If you tried to delist a color, you got all kinds of flack, because Ms. Heckler was the secretary and she used lipstick. But when you were trying to determine what was the deminimums, I and some of the toxicologists thought it should be 1×10^{-9}, but it came out 10^{-6} and, of course, the courts overturned that level.

I guess another low point was with the raw milk. This wasn't Haddow, this was another one of the assistant secretaries that I think was an economist. We had recommended that raw milk in interstate commerce be banned. And everybody up

the line, the commissioner and everybody else, approved it. It gets over to HHS and they sent it back saying rewrite the regulation. So we rewrote the regulation, and allowed the shipment of raw milk in interstate commerce. Well, of course, we were sued by a consumer group, and the judge overturned the regulation. As a matter of fact, we did not have to rewrite the regulation because we used our original regulation.

That was another low moment also, because with our original regulation and the action memo, we had laid out all of the known injuries, particularly in the State of California where they had some huge dairies, such as Altadena, that were selling the raw milk. We had a number of deaths of elderly people and immune compromised people due to the consumption of raw milk. We were not playing a game. We had proof of a hazard.

Well, before I left, we had completed all of the colors with the exception of Red No. 3. However, they should have been completed earlier.

RO: What was the cause of the delays?

JT: There were about six colors that the agency had recommended to be banned because they caused cancer in the rats studied. When the recommendation reached the secretary's office, the department's personnel would disagree with the recommendation. They would send it back and say find a way to approve it. Someone from outside the agency found this letter from Sandy Miller to the last assistant secretary for health in the Carter administration, Dr. Brandt. The letter or memo stated we had disapproved the colors, and he'd gone through the commissioner's office and so forth, and Brandt had no problem with it. But before anything could be done, the administrations changed. So that was a long delay. There was evidence, like in some of the other areas, there were regulations written with the agency's conclusions, but the problem was that the people in the secretary's office didn't agree. And I learned to love Mary Frances Lowe, but while she was in the secretary's office, she checked

every one of our regulations, and if she didn't like the regulation, it came back. So it was months and months and months. After she got to FDA, she was a real advocate, and I really learned to like and work with her, but Mary Frances drove me wild while she was at the department.

RO: Were you there when we were dealing with Herb-a-Life?

JT: (Laughter) Now that's another low point of my life. (Laughter) Yes, I was there when we worked with Herb-a-Life. As a matter of fact, Ron, I remember coming out here that Saturday up in the EDRO conference room, and us looking at each piece of paper. Also, I never . . . I always felt kind of bad, because, if you remember we had this hearing, and one of the people on the hearing was our good vice president Gore. And they had decided that they didn't want Sandy to attend. Don't ask me why, you know. They didn't want Sandy to go for the hearing, because Sandy didn't make a good representative for our nutritional system. So they sent Forbes, myself, Dr. Young, and Dan Michels.

The Center for Foods--we had written a notice of adverse findings on some of Herb-a-Life's products, primarily on the food area charges, the illegal food additives and so forth. The rest of the products were considered drugs because of the claims. And I've never been beaten up so much, because Gore kept pulling memos out of his briefcase from Los Angeles District to both centers regarding the inactivity toward Herb-a-Life. And I swear I'd never seen any of the memos. I kept looking at them. Then I found out that Rudy Apodaca of the Center for Drugs had some of them. But, yes, I was there at the hearings, I can never forget all the women that were over there, because we were very bad people. We were trying to bother Herb-a-Life. At least we didn't come out blank on Herb-a-Life. We forced them to change some of their labelling. At first, it looked like that we were going to give up everything, that they were just going to walk.

I remember some of the senators during the hearing. I remember Rudman in particular. He was upset because he considered some of the products as hazardous, because at the same time we were taking the action against Herb-a-Life, there had been some consumer complaints regarding some of their products. We could never tie the injury to the product. But Rudman made it very clear. He didn't care what product a person wanted to use. But if it hurts you, we were supposed to make sure that it didn't get on the market. Yes, Herb-a-Life was not only pushed by Haddow; it was also pushed by Senator Hatch.

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RO: John, if you have a little more time. There are a couple of other things. One . . . Health claims on foods. You were I know in the center then, and shortly after this came up, I think Taylor Quinn decided to retire. There were some that said that Taylor got so upset about the decision to allow certain health claims on food, he retired. You probably know better than I that he was adamantly opposed

to it, and when the agency decided to allow certain health claims on food, he decided to retire.

JT: Taylor was extremely upset about the whole situation. So to be very honest with you, Ron, we had actually written a proposed notice of adverse findings to Kellogg regarding its health claim. And I really don't know whether Taylor left because of that, but it happened right after that. He was very, very upset. I think he got more upset with some of the comments that were made. Of course, we knew that we were in trouble when the National Cancer Institute had approved it, and now you had FDA, one part of the PHS, and NCI on the other side. So we knew we were in trouble. But everybody watches everybody. I think Dr. Frank Young has said that he was with us, Sandy was with us, and Sandy stayed with us. We were working on proposed information that we were going to use to fight this situation because we knew it would open Pandora's box.

Well, when statements were made that this situation didn't pass the Hee Haw test, it kind of hurts our feelings, because nothing was said about the Hee Haw test when we had all the private meetings down at FOB 8. The Hee Haw test was applied to a cereal being called a drug . . . For seventy-five years, we had said that if a food product made drug claims, it's a drug. You know, and the Hee Haw test doesn't mean anything. But, yes, Taylor quit right after that, because he felt very strongly that the agency was completely sold out. But you've got to realize that this was only a result on the backs of a lot of other things. Herb-a-Life, some of your color decisions, your lobelia and all that stuff. I was the most surprised guy in the world, because I thought Taylor would stay on forever, and one day he just came in and told me, "Hey, I'm retiring."

RO: What was it like to work with Taylor? I've heard general counsel say here that, "One thing about Taylor Quinn, he stakes out his position and that's that."

JT: (Laughter) I enjoyed working with him, but that's very true. Taylor would say, "This is it." And no matter what you say, no matter how long you argued it, it didn't change. I remember one instance that really typifies it all. It was a case that Buffalo District had sent in, and Buffalo was taking exception to our decision regarding (A)(4) evidence. But Taylor really liked Pitt Smith. You've got to realize, he really liked him. So Pitt called Taylor and asked for a hearing to appeal it. And, of course, since Pitt wanted it, Pitt got it. But Pitt couldn't come down, so he sent his Compliance Branch chief. And his Compliance Branch chief brought Robert Spiller from GC. So we're discussing it and so forth, and Spiller opened his mouth to say something that he agreed with Buffalo, and Taylor just threw him out. He said, "The agency made policy. Not GC."

(Interruption)

JT: "This is our decision, this is our discussion, end of comments. And furthermore, Spiller, you weren't even supposed to be here. It was just out of the goodness of my heart that I let you come in." So after they left, I said, "Taylor, I think you were a little bit harsh." And he thought about. He said, "Yes." But one thing, Taylor trusted his memory, because he had been there so long. And he had worked on these things, and nobody was supposed to dispute him. But one thing about it, we had disagreements. And if he said he wanted it done a way, I said, "Fine." But sometimes he would come back. People don't realize this. He would come back the next day and say, "You know, I thought about. You're right. Let's do it your way."

Another one of the big cases--once again this involved Pitt--was with Beech Nut. Because Taylor did not think--and he was right--we had enough proof to go for a prosecution on Beech Nut, primarily because New York District had not sent in their investigation on their companies that were involved with Beech Nut. So he and I went back and forth. So I called Pitt and said, "Hey, you call Taylor, too." He finally decided, "OK. We'll go with the case." But the reason he wasn't happy was

because we didn't have an abundance of evidence. Now, what really happened in that case, they went to the Grand Jury, and the Department of Justice got all kinds of information. But he will change his mind. He was not very happy because he didn't have enough to go on at that time with Beech Nut. But he did finally say, "OK. We can go with the prosecution."

RO: Well, this was that intentional adulteration.

JT: Yes. It was intentional. But what we really needed was the information from the New York District, their companies were the ones that were actually involved in the adulterating of the apple juice. With their information, we could tell the amount they were charging and that somebody knowledgeable would know the produce was adulterated, because it had been sold so much below the going rate for your pure apple juice.

But Taylor, I'll never forget, they wanted him to be deputy director of the Center for Foods, and he said the only way that he would accept that job is that he could be the director of the Office of Compliance also. So since they said, "No, that can't happen," Mr. Ronk was selected as deputy. But Taylor, he really loved his job. I still talk to Taylor. We keep in contact. But it was a real treat to work for him. He's a very hard man to get along with sometimes, and some people really found him to be . . . Well, let's put it this way. Taylor could be very, very stubborn at times, and sometimes he would see only his way.

RO: You know, he was a very good friend of Sam Fine's. Sam was still the associate commissioner for compliance. Several times I had gotten into a little bit of a disagreement with Taylor, and he said, "Well, should we go to Sam Fine?" And I said, "Taylor, we shouldn't have to go to Sam Fine."

JT: That's Taylor. You know, I remember one thing that really hurt him. If you remember when Dr. Young first became commissioner, he had these committees to prepare his action plan. They had one on compliance and they had the head of the compliance from each center, as well as Ron Johnson, who was the director of San Francisco District. Well, they wouldn't accept Taylor's name to be on the committee, and that kind of hurt him, and they appointed me. The reason that was given by Sandy Miller was they felt that Taylor would control the meeting because he wouldn't be flexible enough to really look at the big picture and see what should be done.

RO: Yes, he had a reputation.

JT: Yes, he really had a reputation.

RO: Well, we jumped a little bit when we got into this Chilean grapes, because after you left Foods, you went into the Office of Enforcement in ORA before you went up to be the ACRA. But you weren't in that position very long, were you?

JT: No, I really wasn't. I got here in March of '86, and I left in July of '86 and then I performed my first detail upstairs. I was very surprised when Paul (Hile) announced his retirement. Because I'll be very honest with you, I don't know whether I would have taken the job had I known that Paul Hile was planning to retire within the next several months. I'll never forget, it was the day after Thanksgiving in 1985, Paul said that he wanted to talk to me and let's go and have lunch. Well, over the years, there's one thing I've learned about Paul Hile starting with the time I first met him when we were on a committee studying radionuclides back in the late sixties: if you listen to him, you're going to do what he wants. You know if you stop up your ears, you've got it made. But if you listen to him, you're going to do what he wants.

So he called me, he said that Merv (Shumate) was retiring, and that Merv had been one of the people that had recommended me to come out there and take his job, and he would like for me to come out. So we had about an hour's talk, and I said, "Fine. I'll go back, and I'll tell Sandy that I decided to go." But then when I got out there, Paul deserted me which was a big disappointment.

I really didn't get a chance to do too many things while I was in the Office of Enforcement. I think one thing--there were a number of things that always bothered me--I always wondered about the interplay between the divisions down in the office, primarily the Division of Compliance policy and the Division of Compliance management and operations. I always thought that there was quite a bit of overlap, and I always wondered if it would be more efficient to have one big group perform both responsibilities. I found the people down there--at the time I had Bill Jackson in one division, Ernie (Brisson), and Bob Spencer in the regulations group--I found them very competent. I will be very honest with you, if I had stayed in the Office of Enforcement, I would have abolished Ernie's group. I tried to abolish Ernie's group, because I just didn't see the need for that and I thought it was an overlap. Then when . . .

RO: I was really surprised--of course, I had retired by then--but I was surprised that Sandy Miller would let you go.

JT: Well, we had this long talk about the whole thing, and I really had mixed emotions. We talked about it and talked about it, and he said, "Well, if you'll try to help me get somebody else from the field, you can go." Well, of course, we were not successful, although we really tried hard. We talked to a number of the field Compliance Branch directors, but no one was interested in coming to headquarters during that time. Now field personnel is transferring to headquarters. So after Sandy and myself talked, he said, "Fine. You go and stay our friend," as he put it.

RO: And then you went into the ACRA (Associate Commissioner for Regulatory Affairs).

JT: Yes, and that was . . . I'll be very honest, I was ambivalent about that job, too. As a matter of fact, I don't know how they decided on who was on the panel, because I didn't even apply for the job. I think they had a search committee which is normal, and they had a number of names . . . They had a number of names, and we were interviewed by a large number of people. The commissioner, the deputy commissioner, the general counsel, et cetera, et cetera, et cetera.

And I'll never forget my first interview was with John Norris, who was the deputy commissioner, and I flunked. How do I know that I flunked? I was home one night, and I got this call from a man named Mr. Hile, saying, "What in the hell are you trying to do?" So I said, "What do you mean, Paul?" He said, "Come on, John, you're not trying. Do you want the job?" I said, "Well, Paul, I feel kind of ambivalent about it." But we talked. I said, "OK. I'll tell you what. I'll give it my best shot." If you ask me from my heart why I really got the job, I think it was your regional directors. Dr. Young did talk to the regional directors. Because I'll tell you who I really would have liked to see become the associate commissioner for regulatory affairs was Jim Swanson. You see, I didn't know Swanson was getting ready to pull a disappearing act on me, too. But Jim was very adamant that he didn't want the job.

RO: Yes, he . . .

JT: And after that, I was worried, because I didn't know who was going to be selected. I could have accepted Beebe, who I knew wasn't coming; Davis, I knew he wasn't coming, because I had talked to them about it; or even Cliff (Shane). But I think by that time Cliff had really had it. I had a lot of respect for all of them. As a matter of fact, all your regional directors I had a lot of respect for at the time.

And when I first talked to Dr. Young, I thought we were going to be able to do more things than what we actually did. I could realize that we'd had some problems early on when Haddow was there, but under Dr. Bowen, secretary of HHS, and I can't even tell you his chief of staff's name. But when he called me, it was not you can't do this, it was really calling for information and how, you know, what's the meaning of this, and so forth. So Dr. Bowen really let the agency handle its affairs, even though he had some problems with DMSO, he wouldn't even get it for his wife--he did not even get involved in the situation. I had a lot of respect for Dr. Bowen.

We really felt that we could do more, and Dr. Frank Young seemed to be very interested in compliance actions. I did not know John Norris', deputy commissioner, compliance philosophy. However, I felt I could get around that hurdle. So once I got the job--and I'll be very honest with you, I was very surprised that I got the job--I felt that we could get a lot of things done. And we did try to do a lot of things in the action plan way of changing things in the import area and compliance area.

But there was one thing that wasn't fixed, and that was the relationship between ORA and the centers. We had very little problems with CVM. I went down and talked to Gerry Guest, no problem. Sandy Miller was no problem. But when you got to medical devices with John Vilforth, he didn't want to ORA to be involved in any of his work at all. He was still education to the bone. So was Jim Benson at that time. Benson changed once he became deputy commissioner. Paul Parkman and the guy before him in biologics were not very cooperative in the compliance area.

RO: Meyer.

JT: Meyer. Hank Meyer. We would get into these huge fights. I can remember in the blood area when we were trying to negotiate an agreement with Red Cross. I was very, very unhappy because I didn't think we were strong enough, and Paul (Parkman) thought we were too strong. So we ended up right in the middle

somewhere. But as you can see, it didn't do the job. And in the case of devices, even when you try to make a simple decision on whether it was a device or a drug, and the two centers couldn't agree and you were the mediator, it was the fact that they didn't want ORA involved. They wanted to be the primary decision maker as far as cases were concerned.

And, of course, I would take the matter to Dr. Young, and we would never get a decision. Even in the case of personnel evaluations. I always felt that ORA was being short-changed, because I would always look at the people in drugs, and they always received the largest percentage of the bonuses. Devices not too much, because a large number of the individuals were in the commission corp. And I never will forget, John Norris got so mad at Richard Ronk and myself, because we kept bringing up the point that he told us to be quiet regarding personnel evaluations. But I still . . . And even though we set up a system on how the personnel evaluations should be performed, we never really accomplished our goals. I had a lot of respect for Dr. Frank Young. He did a lot of good things for the agency. I think that one of the low points was the problem we had with the I.G. (Inspector General).

I believe wholeheartedly the inspector general should review all the agency's programs and tell us where there are operational problems. I lived with that when I was in Boston, you know, when they evaluated our shellfish program. However, I did not believe the Office of the Inspector General should perform our criminal investigations. But, anyway, when we got into this whole exercise on what we were going to do and what they were going to do.

And I can remember the day that Dr. Frank Young took Tom Scarlett and myself down to meet with Kusserow, HHS inspector general, and we stayed in there for about two hours in his office. I really felt depressed when I left that meeting. And then as we went back and forth, and we could see that we were losing the war regarding the activities that the inspector general was going to be able to do, and they told me to write a memo on what I could give up, I did that. I didn't give them anything meaningful. They could have the compliance of human tissue, donated

tissues and those kinds of things. The agreement memos went back and forth for months. I felt very bad when John Norris would say he was going to support me, and then the next thing I know Kusserow had taken one step forward, and I didn't think that I was doing the kind of job that was necessary. And then when Jim (Benson) became the acting, Jim said, "Let's make a deal." And, of course, I was only with the agency about two more months after that. They made that deal which was overturned.

But I really felt there could be cooperation, but I didn't feel that it was right for the I.G. to be making some of the statements they were making when they had no facts. They had this big thing about a situation which happened in Denver. Well, when we went to the U.S. attorney to see if this was true, whether Denver really screwed up the investigation and I.G. was a savior, you got a different story. Another incident they referred to happened in Newark. When you went to the U.S. attorney, you got a different story. It was always they were the great savior, and Food & Drug was the bad guy which was not true. In each case we were talking about the investigation of clinical investigators. Now, I had no problem with if they're really going to look at something involving their areas of responsibility, but I didn't think they had the expertise to perform routine FDA inspections.

The thing most people don't realize, they were taking most of our areas of expertise. They were even talking about the normal criminal prosecution, and everybody wants to forget that. They thought, oh, they were talking about specialized violations. No, they were talking about the normal prosecution, because they could get it done faster. Granted they probably could, because their recommendations didn't have to go through the department of justice and then to U.S. attorney. Granted, they could. But if you want to solve the problem, why not give Food & Drug the same kind of authority?

RO: Do you think if they'd have come up with FDA's criminal investigators that FDA has now that you'd have stayed, John, or were you to the point where . . . ?

When it was decided FDA would have criminal investigators, then didn't Kusserow back off a little bit or . . . ?

JT: Not really. Oh, he did back off some, but not on the important issues.

RO: Well, he left eventually.

JT: Yes, he left. I know there was a lot of pressure from Congress and the industry, because they didn't want people coming out to their firms who were not qualified to perform an inspection. They don't think Food & Drug knows everything, but they didn't want anyone to come out and do less than Food & Drug. But I really don't know, Ron, whether I would have or not. I really don't know the relationship between your criminal investigators and your regular investigators. Has that caused any problem?

RO: I don't know. I think it's too early to really tell. There are some I know that feel that this is going to be an elitist group, and it's going to be like back in the earlier days when you had the OTC group, and they didn't want to go out and collect pesticide samples because they were . . . The one thing that the criminal investigators did, I guess, is when they had that Pepsi-Cola tampering problem. They got in right away and were able to obtain a number of confessions.

JT: Yes, it was a real job.

RO: But I know that there's some question about whether or not there's going to be enough of that kind of work for them to do. So I guess it was really, John, what prompted you to chuck it in was the incursion of the I.G.

JT: Well, and there were a number of other things behind it. Besides, I'm getting old. We're getting old. I guess sometimes I really didn't know where I was going and what we were going to do in the health fraud area. We would tell a person one thing, and then we'd do another. I think that Dr. Frank Young tried to give the field a fair share of the few resources we were receiving.

RO: He was a supporter.

JT: He was really a supporter. It was just the fact that he really loved this agency, and he really believed in it, and he stretched himself too thin.

RO: Well, one thing he said, I know even before I retired, that he wanted to be the top cop in the agency.

JT: That's right. That was definitely . . . (Laughter)

RO: Well, John, I want to thank you for giving of all this time, and you've been very, very candid on this. We'll get a chance to review this, and thank you very much.

JT: OK, Ron.