History

of the

U. S. Food and Drug Administration

Interviewee: Thomas L. Hooker

Interviewer: Robert A. Tucker

Date: December 16, 1994

Place: Palmyra, VA

DEED OF GIFT

Agreement Pertaining to the Oral History Interview of

Thomas L. Hooker

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INTRODUCTION

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

The interviews are with persons, whose recollections may serve to augment the written historical record. It is hoped 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
Rockville MD 20857

TAPE INDEX SHEET

CASSETTE NUMBER(S) 3

GENERAL TOPIC OF INTERVIEW: History of FDA

DATE: Dec. 16, 1994 PLACE: Palmyra, VA LENGTH: 150 minutes

INTERVIEWEE	INTERVIEWER
NAME: Thomas L. Hooker	NAME: Robert A. Tucker
ADDRESS: [redacted]	ADDRESS: U. S. Food & Drug Administration
[redacted]	Rockville, MD 20857

FDA SERVICE DATES: FROM June, 1964 TO April 1, 1993 RETIRED? Yes

TITLE: Director, Baltimore District (FDA)
(If retired, title of last FDA position)

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RT: This is another in a series of interviews in the FDA oral history program. Today the interview is with Thomas L. Hooker, former director, Baltimore district, Food & Drug Administration. The interview is [redacted] and the date is December 16, 1994. Present, in addition to Mr. Hooker is Robert A. Tucker. The transcript of this interview will be placed in the National Library of Medicine and will become a part of FDA's oral history program.

Tom, to start these interviews, we usually like to begin with a brief autobiography. Would you please start with some of your early years, where you were born, raised, educated, work experiences you had prior to coming to FDA.

TH: Bob, I was born in Excelsior Springs, Missouri, fifty-seven years ago tomorrow, and we lived most of the first seven years of my life in Kirksville, Missouri. In 1945, the family relocated to California and lived in San Bernardino, where I went to school through high school.

During my time in high school, I very much enjoyed chemistry and decided that would be the subject I would major in at college. I was also very sure where I wanted to go to school--UCLA was the only college to which I applied. After being in school for quite a bit of time majoring in chemistry, for a variety of reasons it became appropriate to take a couple of years off during which I met my military obligation by serving in the army, being stationed at the Army Chemical Corps Research and Development Lab in Edgewood, Maryland, working in a laboratory as a chemist. That experience convinced me that I really didn't want to be a bench chemist. So when my army career was completed after a couple of years, I went back to UCLA and changed my major to economics. I thought that combining a business education with chemistry would be useful in the future.

While majoring in economics, I was particularly interested in labor law, and so I spent most of my time and course work in that field.

With my interest in labor law, upon graduation with a bachelor's degree, a major in economics, I took the FSE exam, with the intention of going to work for the

Department of Labor as an investigator. As it turned out, I never heard from the Department of Labor, but did hear from the Food & Drug Administration. I got a call one day asking me to come into the Los Angeles District to be interviewed for possible employment with FDA as a Food & Drug inspector. Because I was also qualified to be a chemist, I also interviewed with the laboratory director, but the position of an inspector was much more appealing to me, and ultimately, I accepted an offer for employment as a GS-5 Food & Drug inspector. My employment with FDA began in Los Angeles in June of 1964.

RT: Who was the director then, Tom, out there?

TH: The district director at the time was Gordon Wood; the chief inspector was Les McMillan; and my first supervisor was Gene Spivak.

RT: So you spent several years there at L.A.?

TH: Yes, I was there for three years as GS-5, 7, and 9. About the middle of 1967, Les McMillan, who had gone to New Orleans as the district director, came back to Los Angeles and told me that I had applied for and been accepted as a resident at a new office to be opened at Jackson, Mississippi. This was at a time when employees were no longer directly told where their duty station was going to be. The merit promotion system was just coming into use so that employees had an opportunity to apply for positions. I had not applied for the opening in Jackson, but I felt that at least I had the opportunity to accept or reject the offer. I was also interested in going to San Diego, because the Los Angeles District was looking for help down there. But I felt the opportunity to go to Jackson where I would be by myself in a brand new office was something that was particularly challenging to me, and so I accepted the offer and moved to Jackson as a GS-11 in July of 1967.

RT: Let's see. Was Jackson a resident post then?

TH: It was a brand new resident post. There had previously been no one stationed there. I would be the first person there. Being by myself in Jackson gave me an excellent opportunity, in being the first person there, to really develop the territory, if you will, to get to know the state officials in Jackson and to get around to some of the establishments that hadn't received too much coverage in the past. Most of the work in Jackson was food related. There were egg breakers, some pecan shellers, vegetable canneries, lots of pesticide problems with eggs and particularly with chickens. The only significant drug work was a Travenol plant in Cleveland, Mississippi, where they manufactured parenterals, large volume parenterals for the most part, and some medical devices. I had no previous experience to any extent in that field, so I learned fast with the help of the folks at Cleveland, Mississippi.

RT: Were the state people in that particular location involved with problems that the FDA was concerned with?

TH: Yes. The state, as I recall, had pretty much split our work into two major phases, at least the food work: the Department of Health and the Department of Agriculture. Of course, this was long before the era of state contracts, but there was a great deal of interaction between myself and those two state agencies and others. The State Chemist's Office had worked and continued to work closely with the New Orleans district laboratory, and we had some involvement with the Board of Pharmacy. But for the most part, it was cooperative work, and I just felt that the state people there were extremely helpful and willing to work with FDA.

RT: As I remember, Jim Minyard was an official at the State Chemist's Office, who later was quite cooperative with the agency. Was he there at that time?

TH: Yes, he was. He was appointed to the position of state chemist before I left, and I got to know Jim pretty well and very much enjoyed working with him, and, of course, seeing him in later years after I had left Jackson.

RT: Well, as a matter of fact, Minyard was one of the state officials that the commissioner recognized in more recent years for his help in pesticide data action and summarizations.

TH: Right. One of the other state officials that hung around for quite a while after I left was the commissioner of agriculture, one Jim "Buck" Ross. One of my favorite stories about Jim "Buck" Ross, whom I had met once or twice just in passing, involved a visit to Jackson by the district director of New Orleans at the time, a gentleman by the name of Nevis Cook. Nevis was fairly new to his position and, of course, was getting around to meet all of the state officials. I took him by the Department of Agriculture to meet, among others, Jim "Buck" Ross. That was one of the more interesting meetings I ever had with a state official. We walked into Mr. Ross's office, and the commissioner stood up, and Nevis introduced himself as the new district director of New Orleans, to which Mr. Ross immediately said, "Well, it's been very nice to know you and come by again sometime." So that was one of the shortest meetings that I can recall with a state official. Nevis for once didn't know what to say.

RT: That does sound like Mr. Ross. I know in later times Mr. Kinslow went over to meet him, and somehow he did that with Mr. Kinslow in the same cursory manner, which left a little bit to be desired as far as state interest in interagency cooperative work.

TH: But certainly the officials under commissioner Ross devoted a lot of time and effort to working with FDA. One of the more important activities that I recall from

the years I was stationed in Jackson was Hurricane Camille, which hit the Mississippi Gulf Coast in 1969. Of course, that was one of the most devastating hurricanes to strike the United States, with some two hundred miles per hour winds and a tidal surge of I think about thirty feet. I was in Jackson at the time of the hurricane and spent the first several days simply surveying relatively limited damage in the area south of Jackson down towards the Gulf Coast. But the immediate response from FDA in the Gulfport area itself was being managed initially by Richard Davis, who was my supervisor at the time out of New Orleans, and by Tony Whitehead, who was the resident in charge at the Memphis post.

I ended up reporting to Gulfport about the beginning of the second week after the hurricane came through. At that time, Tony left, and Richard Davis hung around for another day or two and ultimately departed, leaving me in charge of a rather large-scale FDA response. We had at least twenty to thirty investigators from several other districts who were helping, in addition, of course, to a major portion of the staff out of New Orleans. Some of the investigators were living in Mobile, and some were staying overnight in New Orleans, because there certainly were no housing accommodations around Gulfport. I and a few others who stayed in Gulfport slept and had our meals at the SeaBee base.

RT: At the SeaBee base . . . I think we had a lapse in our tape. At the SeaBee base? Is that correct?

TH: Yes. In Gulfport. One could cover this activity at great length, as I recall some of the things that happened, but the most unusual event, I believe, was authority that was given to FDA inspectors by the governor of Mississippi. No products could leave the disaster area without FDA concurrence. And so salvage operators who came down and would otherwise have swooped away with all kinds of damaged goods could not do so because they were stopped at roadblocks by the state police, and if the truck driver didn't have a release signed by FDA, those trucks

were turned back. This gave us a tremendous amount of control over the situation, and I first became aware of the opportunity one had to really practice frontier justice. One didn't have to go through the traditional FDA activities of making an inspection, collecting samples, trying to obtain voluntary compliance, and then possibly going to court. We simply told people what they had to do, and they did it. And in most cases, that involved destroying contaminated goods.

RT: Now, in that particular situation was the seafood industry a particular concern in the control of movement of food interstate?

TH: Yes. There were several shrimp canneries, for the most part in and around Biloxi, and all of those canneries were under water for a period of time, and so part of our job involved witnessing the segregation and ultimately the reconditioning when possible of hundreds of thousands of cans of shrimp.

I left Jackson in the spring of 1971, having applied for a position in Boston as a supervisory investigator. Richard Davis had by this time transferred to Boston as the chief inspector, and I was fortunate that he selected me as one of the new supervisors in Boston. So I moved to Boston in May of 1971.

As most people familiar with FDA history know, it was at about this time, I believe, in 1972 that along came Project Hire, which meant, of course, a huge increase in the staff of all districts across the country. So in the middle part of 1972, one of my most vivid recollections involves getting up in Boston District before a roomful of brand new investigators, who had been with FDA in some cases just a matter of days, and explaining to them what was a Class I recall. Boston at that time was experiencing a major outbreak of Red Tide, and we had to call on a number of seafood processors and enlist their cooperation in recalling food products that they had recently shipped. We had far more work to do than investigators who were trained, so as I said, I was trying to explain to a roomful of new investigators what was a Class I recall and how to try to get processors to conduct such recalls.

RT: Some of the sort of colorful figures in New England as I recall, one was Dr. George Michels of Massachusetts. I wonder if you had any particular experiences with state officials that would be worthy of mentioning.

TH: I remember Dr. Michels. Of course, he was with the State of Massachusetts. There were incidences that would occur involving food products that the district would request some help from Dr. Michels, and whether or not we got what we wanted was somewhat problematical. I had a lot more contact with officials in Rhode Island, because I supervised the resident post in Providence. I certainly did get to know the Rhode Island people. Fred . . . I'm having trouble thinking of his last name.

RT: Fred Siino?

TH: Fred Siino was there at the time, and we had good working relationships with Fred and his staff.

While I was in Boston, the Bureau of Radiological Health decided to cede to EDRO (Executive Director of Regional Operations) their laboratory at Winchester, and I was detailed to go out to Winchester during the first thirty days that EDRO took charge of that laboratory to assist in the transition. That assistance took the form of my writing procedures for the new lab so that they would become familiar with how a district lab or field lab handled samples, doing some work on staffing and functional statements and things of that sort.

RT: That office or unit was called WEAC. What was the acronym meant to describe?

TH: It stands for the Winchester Engineering and Analytical Center. I got to know the people there and their programs quite well, of course, from that thirty-day detail.

I believe the acting director at the time was Bill Clark. There were several that came through. Mike Rogers was one of them that comes to mind. I think Pete Bolin came out from San Francisco to serve as one of the first acting directors on a detail basis.

At any rate, what I was going to say was because I got so acquainted with the operations there and interested in what they were doing, I easily convinced my bosses in Boston to let me move the supervisory investigative group to Winchester. And so my last year or so in Boston District, myself and my whole staff of investigators were physically housed at Winchester.

RT: After the work at Winchester, I believe you then transferred into headquarters?

TH: Yes, I'd had a thirty-day detail into Keith Dawson's office that was, I think, arranged by Brad Rosenthal. Brad at the time was director of the Division of Planning & Evaluation--I believe that was what it was called--and he brought me in along with lots and lots of other people to work the thirty days for Keith Dawson. Brad had an opening at the time for the director of the Project IDEA activity. That function was placed under the supervision of Tom Hendricks, who had been brought in to take charge of the field data system. The position was as a supervisory management analyst at the fourteen level, and I competed and was selected for that position in July of 1974.

RT: Now, Project IDEA, I guess as the name implies, had to do with developing some new concepts in management?

TH: Yes. IDEA was an acronym that stood for Identification, Development, Evaluation, and Adoption, I-D-E-A. It was a brain child of Paul Hile, who was implementing recommendations made by Booz, Allen & Hamilton, who had done a

management study of the field, I guess, and through conversations between Booz Allen and Paul, the Project IDEA concept came into being. Project IDEA involved, for the most part, use of what was known as Measure-Act-Measure, a concept that involves measuring something, then acting to see through the final measure what the actual impact of your action was.

One of the first Measure-Act-Measures that we conducted after I came to Rockville involved testing the effectiveness of inspections in the medicated feed area, also testing the effectiveness of regulatory letters on improving compliance in medicated feeds. In getting that study underway, I got to know, for one, a lot of people across the agency, Gary Dykstra being one. I think Gary was in the Center for Veterinary Medicine at the time, and, of course, had a lot of input in this particular Project IDEA.

We did a number of other studies during my time there. The staff was very small originally. It was just myself and a lady by the name of Arlene Pauls. I then hired Larry Katz, and through a reorganization that occurred in headquarters during my tenure, I acquired the group of industrial engineers out of Field Investigations Branch, specifically Clarence Howard and Ric Garwood.

RT: Did you say Clarence Howard?

TH: I think that's his name. Certainly, I remember Ric Garwood very well. We did a lot of what we thought were interesting things. We studied, for example, the reliability of having drug manufacturers send surveillance samples to FDA, rather than have the investigators go out to a warehouse and pick up the samples ourselves. Just how reliable would that practice be, one that would save us a fair amount of time? It turned out to be interesting. But I must say that most of the things that we did, most of the studies that we conducted, were more of an academic interest to us than studies that led to any significant changes in FDA operations. I suppose they

verified the value of what we were doing, but our expectations were for a little bit more than that.

RT: I believe that was probably under the tenure of Commissioner Edwards. Is that correct? Or was that later?

TH: Well, I don't remember if Edwards was still there or not. Certainly Commissioner Kennedy was on the scene. There were many occasions that I remember having to conduct briefings for Sherwin Gardner, probably because he had more of a direct connection to the kind of work we were doing than Commissioner Kennedy.

RT: Now, as I recall, Sherwin Gardner had come to FDA . . .

TH: From Booz Allen.

RT: Yes.

TH: And probably Paul Hile was . . .

RT: Paul was the project officer for the contract with Booz, Allen & Hamilton.

TH: One of the things that we did while I was on that staff was look at the consistency of legal action recommendations coming from the various districts. Paul became very concerned about what seemed to be some problems in that regard, and it was this concern which he had that led Paul to the conclusion, as far as I know, to develop the Quality Assurance Program relative to field operations. Paul gave that assignment to our staff, and I spent several months writing what came to be known as the EDRO Quality Assurance Program, a program that was intended to provide

some degree of evidence to field managers that their quality operations, or the quality function in the field, was operating as intended. Certainly it turned out to be not a particularly popular program in the field; although, as you well know, Bob, it was eventually extended to headquarters, EDRO headquarters, and that process had just begun about the time I left.

My departure from EDRO wasn't direct. I spent my last six months in Rockville on a long-term detail working for Ellen Williams, who had been brought into FDA by Commissioner Kennedy to the position of associate commissioner for policy coordination. When I went to work for Ellen, she had a very small staff, but she eventually acquired some other functions from various parts of the agency. But my principal responsibility during the six months that I worked for her was to chair an interagency task force, whose mission was to plan some public hearings relative to food labeling. This was in 1978, and I had a lot of interesting people on that task force. That was one of the first opportunities I had to work closely with Taylor Quinn out of the Bureau of Foods. Of course, I was always very, very much impressed by Taylor. He certainly knew more about food labeling than everyone else on the task force put together.

One of the jobs I had in addition to chairing that task force was to author the *Federal Register* document, which laid out the issues upon which public comment was requested. I certainly didn't have the technical expertise to start from scratch to do that myself, but served more as an editor than as the original author of what finally was published in the *Federal Register*.

RT: That was quite a milestone. Is that a forerunner somewhat of the regulations that have recently promulgated now on food labeling?

TH: Yes. And I guess I sometimes chuckle about how things keep coming around every few years, and food labeling is one of them. This was an activity that FDA

embarked on with the best of intentions back in 1978; although I'm afraid that it didn't go very far, at least from my perspective, until it was re-resurrected some ten or fifteen years later, and has led to where we are today.

RT: Well, certainly the requirements today are quite extensive and have been a real forward move for consumers. So you certainly deserve credit for the initial process in this activity.

I believe we'll now interrupt the tape to turn it because it's not functioning too well, so we'll turn to the other side.

(Interruption)

RT: We're continuing now.

TH: I might mention one other person that I got to know in the process of planning for these food labeling hearings, and that was Alex Grant. I had not had much previous direct contact with the Consumer Affairs Program during my career as an investigator and as a supervisory investigator. Working with Alex on what was obviously a consumer education program gave me a better appreciation for the involvement of his office and the importance of the program in general.

Actually before the first public hearing was conducted, it was in the summer of 1978 that Lee Strait, the director of Baltimore District, came by to see me one day to find out if I would be interested in a lateral transfer to Baltimore as the director of Investigations Branch. The compliance director had retired, and the current DIB, who was Don Sherry, was lateraling over to take charge of Compliance Branch, thus leaving the DIB vacancy open. I, of course, had been hoping for some time to return to the field as many field people who come into headquarters do, and so I jumped at the opportunity and transferred to Baltimore in July of 1978. Again, I was the newly-appointed director of Investigations Branch.

That, I must say, was one of the most difficult assignments that I've had during my career. I have often told people that I know of no other GS-14 position in FDA that is as tough as that of a DIB. Demands on you are tremendous, and the challenges, of course, are the same. But I considered it a great opportunity to get back to the field and enjoyed that position, even though I was in it for only about a year. Mr. Strait retired after I had been in Baltimore as the DIB for only about six months, and so I applied for and successfully competed for his position as district director and was appointed to that position in July of 1979. And, of course, that was the position I held until my retirement in 1993.

Even though I had escaped--if I may use that term--back to the field, because Baltimore is so close to Rockville and maybe for other reasons, I was occasionally tapped for special assignments back in headquarters. I think I should mention some of those before we go any further.

One of the first opportunities I had to come back to headquarters for a special assignment was in 1980. Paul Hile wanted to conduct a study of the staffing and functions of EDRO headquarters. So he asked three district directors to carry out that assignment. The three directors were myself, Al Hoeting from Detroit, and Ken Hanson from Seattle. Our work and ultimately the finished product became known as the "Three H Study"--Hanson, Hoeting, and Hooker. Bob, you were there at the time, and I'm sure you remember the uneasiness with which some of the EDRO headquarters people viewed our activities. I think the final product involved, as I recall, some recommendations to merge certain headquarters functions . . . I recall that we recommended that the State Training Branch be merged with the EDRO Training Branch. In my view that was one recommendation that made a lot of sense, but I noted as years passed that this did not occur. Fortunately, at some point in time, it did. I think two or three years ago, that merger actually came to be.

RT: It has come about now. Certainly, having worked in the Division of Federal-State Relations, there was some concern in our unit as well as others that perhaps

the study would very significantly alter the headquarters organization in a way that would be stressful for everyone involved. For the most part, I think they changed it where the revisions led to improved operations.

TH: Well, it was certainly an activity that the three Hs enjoyed very much and gave me a chance to get to know Al and Ken very well.

In 1983, Paul Hile asked me to chair an agency-wide task force charged with recommending how the agency could change the format and the focus of compliance programs. In 1984, I think one of the assignments that I enjoyed the most involved serving on an ORA task force charged with making some recommendations about regional structure. Specifically, our work led to reducing the number of regions from ten down to six. Of all the studies that I was ever a part of, that is one for which I believe something actually came out of rather quickly, and made a significant change in the field organization.

RT: Well, that certainly, I think, provided for a higher level manager reporting perhaps directly to Mr. Hile, the associate commissioner for regulatory affairs. The regional Food & Drug directors or RFDDs.

TH: Another activity of a special nature that I was involved in during the early eighties involved CASA. CASA is the Central Atlantic States Association of Officials. And, of course, you are very familiar with this organization, one that's actually larger in terms of membership than AFDO, the national organization.

I started going to annual CASA meetings as soon as I transferred to Baltimore and made the mistake, if one can call it that, of standing up in a CASA meeting to comment on a particular incident or issue that had come up involving non-uniform regulation by the states. Burton Love, who was president of CASA at the time, asked me to take charge of a newly-created committee within CASA called the Uniformity Committee. I really didn't know what I was getting into, and I must say

that the committee no longer is in existence, it was rather active for about four years, during which our principal task involved developing position papers for the CASA executive board relative to proposing more uniform regulations and laws to be enacted by the states, or making advice on that subject to FDA, in particular the Center for Foods.

Other activity of a special nature was in 1985, when I authored a document that Paul Hile used to request approval of the commissioner in changing the flow of case recommendations. That is a subject that I suspect has come up every few years throughout the Food & Drug Administration's history, and that is something I think is somewhat regrettable. Maybe we never really fully solve the problem for a variety of reasons. But we keep looking at the issue every year or two, and 1985 was just one of many, many times when Mr. Hile, or whoever happened to be the EDRO or the ACRA, tried to wrestle with that problem.

That completes some of the special projects of particular interest that I wanted to mention, and now I'd like to go back to the time when I was appointed director of Baltimore District and share with you some of my recollections about particular cases or incidences with which I was involved. Beginning in 1981, or about that time period, I was involved with the bioresearch program.

Being in Baltimore carries some unusual experiences because of your proximity to Washington. There are a number of ways that plays out. But in particular under the bimo program, it became Baltimore District's responsibility to inspect FDA laboratories for compliance with bioresearch regulations. If you think inspecting private industry is tough because industry views FDA with some concern, you ought to try inspecting an FDA laboratory. It is far worse. You are really the bad guys, and more than once Baltimore District was not highly thought of by a particular headquarters organization because of our responsibility to have to inspect them and point out problems.

One headquarters unit that was particularly upset with us was Foods. Not that we found Foods' laboratories to be any worse than some of the other headquarters

laboratories, but for whatever reason, managers within the Center for Foods or Bureau of Foods, whatever it was at the time, looked at us with a degree of hostility, which I thought was certainly not warranted.

(Interruption)

TH: I think it was not so much hostility from Bureau of Foods employees as it was empty stomachs that they felt when thinking of Baltimore District, because one of our inspections of the food service facility in the basement of the FOB-8 building led the district to recommending that GSA close their cafeteria, a recommendation which GSA implemented, and although there's now a rather limited food service in that building, the cafeteria which had been there at the time has never reopened.

RT: That's interesting. That was somewhat of interest to me, because I, who used to come down to the Center for Foods, I wondered why the food service closed down, more or less.

TH: Well, Baltimore had to conduct an abnormally large number of inspections for GSA, because of the large number of GSA-run food service facilities in the Washington area. And we kept our food specialists busy almost full time just carrying out those inspections.

As I think back to the early 1980s, I'm reminded of a lot of activities that ORA pursued in an effort to improve management of the field, and one of those involved a series of courses taught by Walt Langdon. Walt was the training officer in the Center for Foods and had begun holding a series of Kepnor-Tregoe courses for field employees. These were the kinds of programs where each district would send one or two representatives to a central location, and Walt would present a particular program. One program that I remember was one on problem solving using the Kepnor-Tregoe approach.

What was unique in Baltimore was that for the first time, that series of Kepnor-Tregoe programs was presented to the entire management team of a single district. Walt Langdon, with the help of a clinical psychologist under contract to him, a fellow by the name of Larry Carroll, worked in Baltimore over a period of two or three years in presenting these K-T programs to us. Larry Carroll is of particular note, because his father had once been an inspector in Baltimore district many, many years earlier, and as I later began the process of writing the history of Baltimore district, I ran across this inspector Carroll, who had worked in Baltimore I think during the forties or maybe 1950s, somewhere in that time frame. Anyway, one of the best things that Walt did for us was a three- or four-day program that we went through up at Emmitsburg, Maryland, to learn, as a district management team, skills in leadership.

One of the things that Mr. Langdon noted about district problems was that we seemed to suffer from a low level of regulatory activity that was causing a degree of frustration within the district, leading to a lot of other problems. And he said at one point in time, "What you guys really need, beyond my course work, is a public hanging of some offender out there." And I must say that in looking back at the statistics of recommendations in that time period, certainly the numbers were not very high.

As it turned out, we had more than enough opportunity to increase our regulatory activity as the months unfolded. In particular, a case that began in 1984 that probably involved more litigation than any other case the Baltimore district had had to that point in time or since, and that case involved a company in Baltimore known as Kanasco, Ltd., run by a gentleman by the name of John D. Capanos. Briefly, this manufacturer of injectable antibiotics was the subject of a voluntary agreement signed in December of 1984 in Paul Hile's office after we had previously recommended an injunction. That, as I said, took place in 1984.

There was a seizure and eventual destruction of several million dollars worth of drugs across the country that occurred between 1986 and 1988; a permanent

injunction that essentially closed down the finished dosage operation; and the holding of several millions of dollars of products at the manufacturing site in Baltimore--that happened in 1985. The ultimate destruction of all of that inventory did not occur until about the time I retired, some seven or eight years later.

The criminal prosecution took place in 1989; also the defense of a multi-million dollar suit brought by Mr. Capanos against the agency and some of its employees including yours truly--that occurred in 1985 and through 1987; and the withdrawing of the approval of all of the firm's new drug applications--which occurred in 1987 to 1988. That was a very significant action. Plus, and possibly finally, several court actions brought by the agency to secure payment of fees that were due the agency in connection with other of these actions. That is a process that began in 1987 and continued through the time of my retirement in 1993. Certainly, all of those activities kept us and some general counsel's attorney very fully employed during that time period.

RT: Well, it's certainly an important case in my recollection.

TH: One interesting thing about it, the inspection that led to all of this took place in August and September of 1984, and the very next week following the completion of the inspection, our office requested that the Center for Drugs and the Center for Veterinary Medicine send a compliance officer over to Baltimore to help the district write the injunction recommendation that we were going to make. I say that because a lot is made these days, and on and off down through FDA's history, of the need for the field to work more closely with headquarters compliance units in order to ease the way for cases to get through headquarters. This was an example of something that we did a long, long time ago--1984, ten years ago--and I thought it came off fairly well.

From my perspective, not only did we need their help, but our strategy was in getting them on board early, they would have participated and, in a way, bought

in to the recommendation which they were later going to get on their desks to approve. As it turned out, that recommendation got kind of sidetracked because of the signing of a voluntary agreement. But, on the other hand, I think it was an example of how the centers and a district office can effectively work together from the very beginning.

I must say that the support that we had, particularly during the early years, was greater from Veterinary Medicine than from Drugs. Possibly that was in part because most of the case involved veterinary drugs, but CVM was fully supportive of all of the things that we wanted to do from the very beginning. The human drugs side was, they were there, they listened, they asked questions, they usually would raise issues that they felt would need to be addressed before they could support everything that was going on, and so we never felt like--and this is a matter of perceptions, so there is nothing to back it up--but we never felt like we had the full support from the Center for Drugs. They never said no to anything we did, but the way the case progressed, we got into court quickly and everything else just sort of flew from there and didn't really require the approval from centers about how the case progressed--simply awareness and advice.

RT: Now the Center for Drugs, or drugs for human use, has always seemed to have some problems, and it's my recollection, in processing seizures/prosecutions possibly because of the concern of the reviewers that they would be second-guessed in litigation. Even back to the days of thalidomide, when the action of Dr. Kelsey was given a lot of credit for having stopped a disaster, but that seemed to be kind of a rarity in that group over there.

TH: We certainly had the full support of general counsel. There are times when districts and GC are at odds on particular cases, but this was an example, the best I can think of, where we would never have gotten as far as we did in dealing with this

issue if we'd not had the full support of particularly Rick Blumberg and the general counsel's office in general.

I also would like to mention that, though I'm sure Mr. Capanos did not appreciate all that we were doing to him, one of his customers, his principal customer in the human drugs arena, was Parke-Davis owned by Warner-Lambert. There came a point in time somewhere in the 1985-1986 time frame when a number of issues at the plant directly involved the delivery of drugs to Parke-Davis, and the district worked very hard to ensure that what was released to Parke-Davis should be released, and I was very pleased to get a letter from the president of Warner-Lambert expressing his sincere appreciation for the support that the district gave in carrying out our mission, but still working with the company whenever possible.

Earlier on, Bob, you mentioned Jim Minyard and his involvement with FDA and the area of pesticide analytical data. That reminds me of a similar initiative that Baltimore district pursued with the state of Virginia. FDA, and particularly involved our district, had a longstanding, close-working relationship with state agencies, including the State of Virginia, that went back fifty, sixty, seventy years at least. What I was able to get started during the early 1980s was the computerization and exchange of pesticide analytical results between our office and the Virginia Department of Agriculture and Consumer Services, or VDACS.

Virginia has a very, very active analytical pesticide program, and one which impacted significantly on Baltimore, because to the extent that the state was looking at a particular commodity and not finding problems--that was generally the case--there was no reason for Baltimore District to sample similar products. The problem was that all of that information was on hard copy and not computerized, and so the district undertook to acquire that information from the state to code it and to put it into FDA's pesticide data base. Then, of course, that information was fed back to the state reflecting not only what the state had done, but the samples that Baltimore District had collected and analyzed.

I later tried to interest VDACS in another manner of using FDA's computerized information through direct access by them to our official establishment inventory (OEI). In fact, on one of my visits to Richmond, I actually, using the state computer, dialed into the Baltimore District computer and demonstrated how, with access allowed by us, the state could check the OEI, which would give them an opportunity to know the last time the district had inspected a particular establishment and what the inspection classification was. To my knowledge, the state never pursued that for a variety of reasons, one being the difficulties in computers talking to one another when they are set up to speak different languages or something like that. But I nevertheless thought it was another opportunity that someday will be expanded.

Baltimore, as I mentioned, had an outstanding working relationship with state agencies long before I got there. That relationship has always been particularly significant with Virginia. I remember early on as the district director meeting on many occasions with Ray Van Huss, who was head of the food inspection program in Virginia at the time. Ray subsequently retired, went to work for Gerber Foods, and unfortunately passed away some years ago. Replacing Ray was Don O'Conner, and later Art Dell'Aria. Art still heads the state food inspection program, and whoever was in charge, I can't say enough about the close-working relationship that developed there--in part, I think due to the interest and support of our supervisory investigator in Richmond, Lloyd McEwen. Lloyd has been Mr. FDA in Virginia for a long time, and although the state probably from time to time sees more of Lloyd than they would like, which is one way of putting it, nevertheless Lloyd thinks a great deal of the state, and the district, you know, just had an outstanding relationship with that agency.

With Maryland, we also had a lot of good working relationships. I particularly recall Dave Resh, who headed the food program within the Department of Health and Mental Hygiene. Our principal contact with Dave was through state contract inspections.

Another person on--I'm not sure that she was on Dave's staff, but she was certainly in that department, that we had a lot of interaction with--was Mary Jo Garreis. Mary Jo at the time was one of the principal managers in the state's shellfish sanitation program. Because the regional shellfish specialist, Mr. Brands, was stationed in Baltimore, there were numerous occasions when the Baltimore district and Mr. Brands would interact with Mary Jo. Sometimes that interaction took the form of trying to separate warring parties from attacking one another. Ms. Garreis and Mr. Brands tried diligently to work together, but they had their problems.

West Virginia Commissioner of Agriculture Gus Douglas headed the agency with which we dealt with a great deal. Also we had some contract inspections with the Department of Health and a few in the medicated feed area.

Cooperative relationships with the District of Columbia are so few that I frankly don't remember any positive ones. To an extent, our resident post covering Washington, D.C. would often interact with that staff, but for a variety of reasons those relationships never took the shape or the extent of our contacts with other states.

RT: Well, I remember in the past, the District of Columbia representative that attended the AFDO meeting had to pay his own way, and that sort of was indicative that the department wasn't committed to sponsoring their staff's participation in such national organizations.

(Interruption)

RT: This is a continuation. Bob Tucker was speaking and observing that the District of Columbia in the past has failed to sponsor their representative nationally in regional conferences of cooperating state officials.

TH: Yes. I don't think that the relatively small number of contacts that we had with District of Columbia government were necessarily a result of lack of interest on their part, but more likely one of lack of funding. The agency was very small, had no money to send anybody anywhere, had in effect no laboratory, and I think money was their principal problem.

Bob, as I think back on the accomplishments of Baltimore district, they are the result, of course, of the hard work and dedication of a lot of great employees. One unit that I was always very proud of is the microbiological laboratory in Baltimore that is supervised by Ted Wazenski. Ted has announced his intention to retire in a couple of weeks. Ted was instrumental in implementing a lot of technological improvements in the laboratory, and some of the instrumentation that he was able to bring to the lab was put to great use in the identification of listeria monocytogenes in a number of food products.

I specifically remember a couple of large scale Class I recalls that resulted from isolation by Ted's group of listeria in Gold Bond ice cream and Carnation Bon Bons. Ted's group was to my knowledge the first in the country to isolate this particular organism in crab meat. We collected one day a sample of imported crab meat from Mexico and, of course, detained the entry because of the presence of that organism, and that started us looking for listeria in domestically produced crab meat, of which there is quite a bit in the Baltimore area. We would occasionally find a problem, and that led to a couple of injunctions later on in the 1990s. The finding of listeria in sandwiches at a Stewart sandwich plant in Norfolk, Virginia, led to the first injunction pursued by the agency for that particular problem.

Another incident that I recall without a lot of satisfaction was the finding of listeria in some cheese products made by a Mrs. Giles plant in Lynchburg, Virginia. Mrs. Giles at the time was owned by Campbell's Soup, and the parent corporation vigorously pursued what I might characterize as lobbying efforts with CFSAN management in an effort to forestall any regulatory action that they could see coming from Baltimore. The district was annoyed by the extent to which Campbell's Soup

would meet in private, if you will, with CFSAN officials, the district never being invited, even though those meetings were a direct result of our inspection and analytical findings. We were also annoyed by--and this certainly bothered CFSAN officials--the fact that one of their employees got an invitation from Campbell's Soup to visit the Mrs. Giles plant after our inspection. He went down to the plant, spent a couple of hours or a day or whatever in the plant, and basically said he thought everything looked fine, and his "testimony," if you want to call it that, was certainly going to be an embarrassment to FDA, if nothing else. At any rate, that case eventually went away and did not become a case, but the good news is that Campbell's Soup did devote a fair amount of effort to improving the sanitary conditions in that plant and recalling everything that we found to be contaminated. Of course, that required us to do a lot more sampling than we would have otherwise preferred to do.

Another activity or industry that Baltimore district had a lot of involvement with was in vitro diagnostic devices (IVD). That activity kind of got started in a way by the involvement of the laboratory in working for the center in establishing performance standards for a variety of IVD products on the market. For example, pregnancy test kits, glucose tolerance kits, and so forth.

This kind of brings us up to 1985, when the district and the agency successfully concluded two very large scale mass seizures of IVDs manufactured at plants in the Baltimore area, specifically Flow Labs and M. A. Bioproducts. The cases involved, at least in part, a failure to comply with device GMPs. The center was at that time or shortly thereafter in the process of trying to develop some GMPs that would be specific for the IVD industry. Of course, at that point in time, all we could do would be to apply, if you will, the generic device standards for GMPs.

Because we had been successful in the two mass seizures, it was the district's position that we should apply those same standards, the same level of expectation to other manufacturers in the Baltimore district, and as we would encounter similar problems, we would make similar recommendations.

One of those cases involved a firm in the Baltimore area known as Bioclinical Systems. Unfortunately, when the injunction recommendation that we pursued got into court, the issues were considerably narrowed by the court--narrowed to the point, in my opinion, that the agency lost the case. The judge refused to grant the injunction. It was that incident that prompted a number of very vocal parties within certain portions of the industry to launch a campaign alleging that the Baltimore district was unfair, was holding the industry to standards that didn't exist, was trying to enforce GMPs for IVDs that didn't exist, et cetera, et cetera, et cetera.

Ultimately, their complaints, which were directed to the commissioner and to members of the Maryland congressional delegation, led to a lot of meetings--not only with the commissioner, but also with Senator Mikulski. These meetings ultimately led to a great deal of initiative on the part of the district and Richard Davis, our regional director, in meeting with members of the industry to assure them that their complaints were being taken seriously and that the district was doing everything it could to apply equally the standards that we perceived the agency to have.

This narrative brings me up to the spring of 1989, a point in time when I made a decision to reorganize the Baltimore district staff. This was not a major reorganization, but one which I think had some significant impact on the district.

It was really in two phases. The first phase involved the import program within the district. What I did was to combine all of the inspection and compliance phases of import activities into one unit called the import operations group, and I placed that group under the direction of the DIB. In effect, I have taken the import compliance function out of Compliance Branch and put it under the direction of the DIB, in the process creating a unit whose sole responsibility was to cover imports from the review of entry phase, the sample collection, wharf examination, making decisions on release or detention, the supervision of reconditioning, et cetera, et cetera. All of that was under the direction of one supervisor, specifically Carl Neilson, working for the DIB.

The effectiveness of that change, I think, is in one respect measured by the number of detentions that the district was able to affect. Within a year of this reorganization, the import operations group was detaining up to two thousand entries per year, compared to two hundred to four hundred detentions that had been accomplished three or four years previous. And certainly the number of complaints that I got from importers went way down, again because I had a specific unit that they could talk to and that could dedicate essentially all of their attention to just imports.

The other phase of that reorganization involved the creation of a criminal investigations unit, and I put that unit within Compliance Branch. At that particular point in time, the district had several investigators who worked essentially full time doing grand jury work for U.S. attorneys across our district. In effect, we had the equivalent of about six investigators who did nothing else but grand jury work, and that made them unavailable for more traditional investigational work. One of the problems in FDA's planning process is that such work is not planned, and positions are not allocated to cover grand jury work. I understand difficulties associated with why that doesn't happen, but the effect of it is to significantly reduce the real number of investigators that our district had to do the work that the agency expected.

RT: Well, Tom, was this, to your knowledge, the only district that has moved that way in its organization?

TH: Well, at the time, I think the answer would be yes. But an event which has occurred subsequent, that kind of makes this problem go away in effect, is the creation of the Office of Criminal Investigations (OIC). OIC may have been thought of; I don't know. But it certainly had not come into existence in 1989. The other reason I had for creating this unit was that the poor DIB didn't have access to those investigators, didn't even know what they were doing, and certainly couldn't manage their activities, because of the fact that they were working for U.S. attorneys. I just

thought it would be desirable to try to get control of what they were doing to the extent it is appropriate and to place that control within Compliance Branch, where the Compliance Branch director is more directly involved in working with U.S. attorneys and grand juries anyway.

RT: At the time you created such a unit, those staff persons were not authorized to carry sidearms, were they?

TH: That's right. They were not.

RT: That has since been authorized for this new unit. Is that correct?

TH: Yes. The creation of that Criminal Investigations Unit may have been, as it turned out, one of the most prophetic changes that I ever made as a district director. I did this in April of 1989, and in the summer and fall of 1989, the generic drug scandal evolved. The connection of that problem with Baltimore district was pretty well established, in part because of the location in Baltimore City of a firm called Pharma-Kinetics, a company that was doing and continues to do a lot of clinical testing of drugs under development for manufacturers across the country.

I might also mention that the drug manufacturer that was directly responsible for the exposure of this scandal, if you will, of course, was Milan, a drug company located in Morgantown, West Virginia. That meant a lot of sticky contacts, if you will, because we knew that every time we walked into Milan, the activities that took place were going to be looked at by Milan management as possible retaliation on the part of FDA for their having gone to the House of Representatives to Congressman Dingell and exposed the scandal.

At any rate, because the generic drug problems involved at least to some extent Pharma-Kinetics, the department's Office of Inspector General (OIG) created what you could call a task force working with the U.S. attorney in Baltimore to

pursue an investigation that focused originally on agency employees, but ultimately on drug manufacturers. The district was requested to supply some manpower to assist the OIG in their investigations of the industry, and we supplied such personnel. Ultimately, of course, that evolved into a full-blown task force working for the U.S. attorney, and I believe that organization is still in place.

Another activity of the newly-created import operations group within Baltimore district involved a major investigation into the importation of counterfeit veterinary drugs. In June of 1991, our import group got a call from the resident inspector in Omaha, Nebraska, who had run across some drugs purportedly made in China--it was an antibiotic--at the Long-March facility in China. That facility was the only firm that FDA had approved for the manufacture of this particular product, which I think was oxytetracycline. But it turned out that the resident in Omaha had inspected the Long-March facility and was quite convinced that the product labeled as coming from Long-March was in fact not Long-March product, and the entries had been made through the port of Baltimore. That's why we were contacted. Within a matter of days, our office had elicited the support of the customs officials at Baltimore, and customs had made some major seizures of the product that was out in Nebraska, as well as product that was at the present time still coming through Baltimore.

It turned out that what we had stumbled across was a worldwide network involving a number of counterfeit antibiotics. Certainly veterinary drugs, but possibly that extended over to the human side. To my knowledge, that investigation that was pursued under the direction of a number of U.S. attorneys across the country is still going on.

It did uncover some difficulties that I think the agency has in keeping track of what firm overseas has been approved to make what product. That seems like a simple issue, but for whatever reasons within center activities, through the paper trail, if not through computers, it was pretty tough to tell. And if you didn't know, if you were sitting at a . . . If you were an FDA inspector sitting at a port of entry, and

here's a product, an antibiotic or a new drug coming in from a particular plant overseas, the major question is, "Is that company, is that source approved?" And if you can't find the answer to that question, you can't make an effective decision on whether or not to permit entry.

Timewise, we are now moving to my last few years with FDA, and there are two or three cases that were particularly significant to the agency that I don't want to ignore. In some respect, they point out both the positives and negatives on this question of center/field relationships, which is so important to what we do.

American Red Cross (ARC) is kind of on the negative side. In 1990, Baltimore district was asked to support an inspection to be conducted of the national headquarters of the American Red Cross. The lead investigator was Mary Carden, an ORA headquarters employee working out of Buffalo district, and assisting her on that inspection in the summer of 1990, was our Ellen Morrison.

The inspection disclosed a number of problems which, as you may recall, came to the attention of Congressman Dingell, and some of those problems were of such concern to Baltimore that we felt a follow-up inspection was needed. The district worked, or tried to work, for many weeks with the Center for Biologics in planning for that follow-up inspection. The center might have felt somewhat left out during the course of the 1990 inspection. We wanted to be sure that didn't happen again. We wanted to know how the center thought we should pursue a follow-up inspection, what issues they wanted us to focus on, what was most significant, what was least significant, and so forth. I'm afraid to say we were not very successful in getting that kind of input from the center for reasons which I will probably never know--certainly never understand.

Nevertheless, I recall in the spring of 1991, where it was passed on down to me through the chain of command, more or less, that the ACRA would like us to delay conducting that follow-up inspection for a period of time. Eventually, the word was that it was now ripe or certainly okay for us to continue that planning process.

And, ultimately, we did conduct a follow-up inspection of national headquarters of ARC in the summer of 1991.

Needless to say, that inspection disclosed what we considered to be a number of significant problems, particularly the ineffectiveness of national headquarters in managing their blood centers across the country. In September of 1991, the district recommended--formally recommended--that the American Red Cross be placed under an injunction. We realized, of course, that such an recommendation was a very significant one and would require the close review of agency officials. Certainly that's what happened, because the agency elected to create a task force to look not just at our recommendation for regulatory action, but a whole gamut of ARC problems. We were invited to participate in that task force and did. Unfortunately, as most task forces go, a lot of time passed, and in effect, it was a year and a half from the date of our recommendation before we began to get very clear signals that the recommendation had the support of the commissioner and was going to get forwarded to the Department of Justice.

I recall reading after I retired, a statement that Commissioner Kessler made, that he considered this injunction which lead to a consent decreed to be one of the most important and difficult issues that he had had to deal with up to that point in time. So it's something that I think the district has cause to be particularly proud of, even though it didn't go very smoothly. It certainly did not go quickly.

I would like to contrast that experience with ARC to our experience with what was really a very similar problem involving Amtrak. Blood banks are nothing like trains, but in both organizations we had a quasi public entity that affected in some significant way American citizens.

The initiative leading toward the injunction of Amtrak came to us from the center early in 1992. I got a call one day from Janice Oliver. Janice had been my DIB in Baltimore for a number of years. She had moved into the center to be responsible for regulatory guidance. She called to discuss the fact that a serious rodent problem had been found during a special survey of Amtrak food service cars,

and she indicated that the district ought to look at that information, and if we did and felt an injunction was warranted, the center would certainly favorably review that recommendation.

I couldn't help remembering ten years earlier when a senior agency official, specifically Mr. Paul Hile, had come out to Baltimore on one of his regular visits, and one of the problems that we talked to him about was the serious problem with Amtrak food sanitation. At that point, we were directly involved in getting reports in from all the districts about Amtrak sanitation and could see a serious problem. We bounced off of Paul the idea of an appropriate regulatory response, specifically an injunction. I remember him saying that such an action would return the nation to an era when sandwiches would have to be hocked to passengers by track-side vendors, which he thought was beyond the realm of reasonableness.

Interestingly enough, the compliance program was very shortly thereafter changed to remove any responsibility by Baltimore district in supervising Amtrak national headquarters. What happened next, I need not go into, but suffice is to say that for the next ten years I basically felt, If someone else wants to worry about Amtrak, fine; I've got plenty of other things to deal with. Then ten years later, here comes CFSAN saying, "We've got a problem." And the center worked very quickly in approving that recommendation, met promptly with Amtrak officials, and just in an incredibly short period of time a consent decree was signed. Of course, that didn't lead us to sandwiches being hocked to passengers by track-side vendors, but rather to a significant effort by Amtrak to get their act together.

RT: Now, Tom, a number of years earlier, with regard to Amtrak, and I don't know that this ever led to any involvement of your district or perhaps to any legal action of sorts, but there was at least a discussion about the aesthetic if not sanitation problem of human waste deposit on track beds. Do you recall being involved in that issue with Amtrak headquarters at all?

TH: Yes. I don't remember much about the conversations that we had. Mike Casnia was our ITS specialist at the time, and Mike dealt with Amtrak national headquarters frequently. That issue was part of these discussions.

RT: Yes. I don't know that it really ever led to a regulatory positioning of the agency, but it . . .

(Interruption)

RT: OK. Well, Tom, that certainly has given us a breadth of your experiences as a manager at the district level, and, of course, you've been at the headquarters level as well. Do you recall the various commissioners in terms of their differences in either direction or management style that impacted on you or the field organization?

TH: In answering your question, Bob, let me refrain from commenting on what I've read. It was a subject I followed very closely. I would read everything coming out of FDA, listen to people who had opinions on that subject, but I don't think it would be appropriate for me to just pass on perceptions I had that were based on what someone else told me, but try to answer your question from personal experience rather than anything else.

RT: That would be appropriate.

TH: Commissioners that were around during my early tenure, of course, I had little contact with. I met Dr. Goddard during my last week in Los Angeles district. I was in the process of kind of wrapping up things and not starting anything new, and so I was around and probably viewed as someone who was safe enough to serve as a chauffeur for Commissioner Goddard. I had to take him from the district office back to his hotel in Beverly Hills. It's just amusing to me, a little incident. I remember

as we were driving towards his hotel, we were passing down Wilshire Boulevard, and went past a new car dealership that had some very fancy looking imported European cars in the window, and Dr. Goddard said, "Well, I'd like to go take a look at those cars." So we parked the government car and spent a few minutes going through the new car showroom, and I guess that was my first exposure to something that you ought not to do, at least as an inspector; you shouldn't stop in the course of your official duties to go car shopping. It was all right for the commissioner, so it was all right for me.

Commissioners would come to visit offices where I was stationed, but I wouldn't have much personal contact with them. I did get a little bit acquainted with Sherwin Gardner, because, as I said earlier, from time to time I would be asked to provide briefings to him on Project IDEA work or the EDRO Quality Assurance Program. It was always a challenge to try to make those presentations informative and entertaining enough to keep Sherwin awake. He had a tendency . . . And I don't blame him. I'm sure he had to sit through a lot of very boring presentations, and he would nod off from time to time.

Commissioner Kennedy I got to know fairly well. Not personally, but I certainly was exposed to him often, because during my detail as a policy analyst I would be present in a large number of meetings that he would have with members of the staff throughout the agency, two or three meetings a week at least, and I was very impressed with him. He certainly was committed to what I was involved with, specifically the food labeling assignment.

I was intrigued even as a GS-14 at the influence of politics at that time. My first direct encounter . . . The issue was where to hold these public hearings--which cities--and the task force, which had an assistant secretary from USDA, a representative from the Federal Trade Commission, and Taylor Quinn, and Alex Grant, and lots of other people from FDA. The task force had made some recommendations on some cities where these hearings should be held. Well, I sent my list into the commissioner, and he probably passed it on to OLS, and it wasn't long before I was

told--the task force was told--which cities these hearings would be held in. And, of course, the decisions had to do with particular congressmen who were up for reelection or things of that sort. One city was as good as the next. It didn't really matter in terms of public input where you held the hearings, but the decisions were certainly politically determined.

RT: Well, I would pick up on that. Having been a state official before coming to FDA, I used to work with FDA personnel out of the then Chicago district. They gave me the impression that, you know, in FDA there was no politics. And later years when I came into Washington and indeed worked for a time in the legislative office, it became clear to me that between the inspectors level and the upper management level, the latter needs to be more cognizant of political considerations in welfare of the agency's funding and success.

TH: Yes. I never had any great problem with the politicalization of FDA to the extent that commissioners and their deputies would come to FDA from the outside, rather than having grown up throughout their lives within FDA. Part of that was, I think, my six months with Ellen Williams. Here was a lady who had never worked for FDA in the past, didn't know much about what we did. But I spent hours and hours and hours during those six months talking with Ellen, and she was as committed to FDA's mission as I was. So I didn't feel that sense of great concern that bringing people in was necessarily bad.

RT: We did mention her name earlier. Just to bring it back into focus, Ellen came from where and worked with you in what capacity?

TH: I don't remember where she came from. She was appointed by Commissioner Kennedy to be the associate commissioner for policy coordination.

RT: That's correct. I recall that now.

TH: That unit for a period of time was disbanded after she left, but . . .

RT: Well, while we're thinking about the influence of the Congress, were you ever involved, Tom, as an FDA official in presenting testimony or being directly involved in any of the hearings the agency was called to appear at on the Hill?

TH: At the federal level, I never was asked to testify. There were several occasions when members of my staff were asked to testify. Mike Carpers on the issue having to do with the man in the plant. Congress was interested in this. Boy, you're really stretching my memory here. The question of drug manufacturers that produce products for other firms by simply providing the physical plant, and the other firm would run the plant making their own product, and that was a relationship that was of interest to the Congress, and I remember Mike Carpers being asked to testify on it.

The Red Cross problems were of concern to the Hill, and again, Ellen Morrison was a person that Dingell's staff got to know very well. The generic drug matter, and our relationship with Milan, some problems that I haven't gotten into on this oral history, but Mr. Dingell's committee was very much interested in what Baltimore district was doing, and I had several meetings with members of his staff never leading to me being required to testify.

RT: I was recalling you had earlier spoken of the fact that because of the proximity of Baltimore to Washington . . . I just wondered if you had ever been drawn into that, but I guess you were in an indirect way.

TH: Yes.

RT: Now, you spent . . . Let's see. Your career with FDA was how many years in all?

TH: Just short of twenty-nine.

RT: And with that kind of long service and a commendable one . . . As I look around your home office here, I see a number of accolades that the commissioner and others have given you for service well rendered to the agency. With that background, do you have any sort of perspective on either where the agency seems to be headed or maybe ought to be headed? The latter I know we have no control over, but do you have any kind of closing thoughts in that regard?

TH: Well, that's a very important question, Bob. Certainly I am very thankful for the fact that I went to work for FDA. I can't imagine doing anything else with my life than having worked for FDA. It was a tremendous opportunity, and the people I've come in contact with, I had a great regard for. It's just been a super experience. And I think about what was right and what was wrong, where the agency should go.

I must admit, just to digress a little bit from your basic question, I view with some apprehension all of the interest in tobacco of late. I don't smoke, and the more the government can regulate tobacco the better; but FDA's got enough to do, I think, without getting sucked in some way to that very difficult issue. We have enough tough issues to worry about.

RT: Well, with the recent change of chair in Congress committees, and we have a Virginian now for the chair, Mr. Waxman's group, that interest probably will be less intense for the foreseeable future.

TH: Certainly. That's true. I was thinking a little bit in general about this subject earlier today, and it occurred to me that one of the fundamental problems, not so

much from the agency perspective, but from the perspective of the field and our involvement in the overall agency mission, it kind of in my viewpoint starts from the fact, what are we supposed to do? What is our basic mission? I've heard ACRAs describe from time to time how difficult they have wrestling with that issue when meeting with center directors.

The field, I believe, is from the perception of centers, needed to gather information, to provide information. Bureaucracies need information. I mean, the whole fabric of our society centers now around the collection and handling of vast amounts of information. As I think back on all the compliance programs, all the assignments, whatever, that would come out of headquarters, 99 percent of them involved going and finding out what's happening, gather this information. And that is fundamentally different from the role that field people are trained to carry out. The role for which they're trained and for which is ingrained in Tom Hooker and lots of other people is gather evidence, not gather information. Big difference there.

Since we're trained to gather evidence, when we find evidence that indicates the need for regulatory action, we put that in a form of a case recommendation when we need to, and we send it into headquarters. Now, in headquarters, they hence become bombarded with huge numbers of case recommendations coming in from the field that they simply don't have the resources--if they have the interest--in handling. So all of these cases sit, and the frustration builds in the field, because nothing is done. That, I suspect, is as much true today as it was the day I left and the day I started with FDA, or close to the day I started.

Of course, I don't just think I have my finger on what is wrong; I think about what is the solution. As I mentioned earlier, ACRAs or EDROs from time to time have tried to streamline the case approval process. But, in my opinion, all of these efforts have been piecemeal and have never dealt with the fundamental problems that exist.

When I retired, I got involved in writing the history of Baltimore district, and that took me back through decades and decades of what was going on in Baltimore

and the kinds of cases they were working on. The numbers of cases given the size of the staff is just incredible. And yet I don't think that the people that are working in Baltimore today are any less hardworking or any less dedicated than were the ones thirty, fifty years ago; but the results of what they do can't begin to compare with thirty to fifty years ago. And why?

Well, at some point in time, headquarters, for a very good reason, determined the need to exercise more control on those cases, to make decisions, to set priorities--and that's appropriate. But the result of it has been that . . . Again, you go back to the fact that we're sent out to get information, you know, we kind of . . . We get the information, but in the process of that we often find problems, we gather the evidence, we submit the case recommendations to headquarters, and nothing happens. Tremendous frustration surrounds that.

I get to the point where I think if the agency can't for whatever reason or doesn't want to pursue all those cases, then we're too big. We've got too many people developing all these cases, gathering information . . . I won't pass judgment on the value or the need for that information, because I've been in headquarters. I know how you get to want it, but what are you going to do with it. Maybe we need fewer people. If all we're going to do, in effect--I'm oversimplifying it--but if most of what we're going to do is just get information, we don't need as many people. We'll have less information, but maybe we can do with less. We'll certainly have less frustration.

RT: Well, you certainly have identified a problem that I recall through my career as a state official where I would work cooperatively with FDA folks and gather information and so on, or samples. Even state samples sometimes were channeled through for FDA analysis, and it would take long periods of time before decisions were made as to whether this was something that regulatory action would be taken or it would not be. So it's been a ubiquitous and perennial problem.

TH: As I was preparing myself for this interview, Bob, I was going through some of my materials that I've kept, and I ran across a memo that I wrote. Now, if you talk to a few people around FDA that know me, I'm known for writing. I used to write a lot of memos. That was my favorite form of communication--much more favorite than oral. On my last day with FDA, I sat down and wrote a memo. It happened to be on the subject that we're talking about: the enforcement process and how it can be approved. I directed that to the Office of Enforcement. And if you don't mind, I'll read it to you. It's just one page in length. This is dated April 1, 1993.

> During this week's ORA conference call, districts were once again urged to offer comments on how the enforcement process could be improved. I believe that Carl Turner has already provided comments to your office. Although my own views are not likely to be different from other commentators, I'm providing them anyway, because I feel so strongly that the American public needs to be better served by more radical changes in our approval processes.
>
> The most fundamental change that is needed is to *greatly* reduce oversight by FDA headquarters. Enforcement action is taken only when the agency has evidence of violations and the will to act. In the present environment, there are just too many cases for headquarters to evaluate and then conclude that action should be taken. While it is true that the nature of violations these days is often far more complex than in the past, the agency is still able to cut through those complexities once a clear message is evident from FDA leadership that we will act. But that can only happen in a relatively few situations. The rest of the time case recommendations sit and gather dust. I understand the reasons why headquarters review is believed important. I also understand that the kind of change that I and many others believe is necessary will have some adverse consequences. However, the public's trust in FDA is misplaced to the extent that we allow turf, politics, and the fear of being sued because of mistakes to limit our response to conditions that ought to be stopped.
>
> Even though we should always strive to produce work of the highest quality, such work is of no value if it is fed into a stream so clogged with case recommendations that weeks, months, and years pass before someone decides to act. No sane person can expect employees

to strive to produce work at the desired level of quality if the effort invested goes for naught.

Well, as you can see, I have not offered anything new or specific. Nevertheless, I don't think that further tinkering with the process will be worth the investment unless the kinds of basic, philosophical change eluded to above is implemented.

RT: Well, Tom, that's probably a good note on which to close our interview. I want to thank you for contributing to the FDA oral history information.

TH: Thank you, Bob. It's certainly been my very great privilege to help out.