History

of the

U. S. Food and Drug Administration

Interviewee:	Joseph Paul Hile
Interviewer:	Fred L. Lofsvold, Ronald T. Ottes, Robert G. Porter
Date:	October 22, 1986
Place:	Fairfax, Virginia

INTRODUCTION

This is a transcript of a taped oral history interview, one of a series conducted by Robert G. Porter, Fred L. Lofsvold and Ronald T. Ottes, retired employees of the U.S. Food and Drug Administration. 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 will become a part of the collection of the National Library of Medicine.

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

DEPARTMENT OF
HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration

TAPE INDEX SHEET

CASSETTE NUMBER(S) 1-7

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

DATE: 10/22-23/86 PLACE: Fairfax, Virginia LENGTH: 402 Min.

INTERVIEWEE	INTERVIEWER
NAME: Joseph Paul Hile	NAME: Fred L. Lofsvold Robert G. Porter Ronald T. Ottes
ADDRESS: [redacted]	ADDRESS: U. S. Food & Drug Administration

FDA SERVICE DATES: FROM 1/6/58 TO: 6/30/86 RETIRED? Yes

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

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DEED OF GIFT

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Joseph Paul Hile

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Chief, History of Medicine Division
National Library of Medicine

RP: The date is October 22, the place is Tyson's Corner, Virginia. We are interviewing Paul Hile, who retired on June 30, 1986, as the associate commissioner for regulatory affairs of the Food and Drug Administration. The interviewers today are Fred Lofsvold, Ron Ottes, and Bob Porter, all of whom have retired in the past few years from the Food and Drug Administration.

Paul, welcome to our oral history project; it's great to have you here. I wonder if we could get started today by asking you to give us a thumbnail sketch of your career and education so that people who read this will have a sense of who you are. And then we can go on from there.

JH: Okay. I was born in Denver, Colorado, on June 11, 1930. I graduated from what was then Colorado A & M and now Colorado State University at Ft. Collins in June of 1952 with a degree in animal husbandry. I went immediately into the service and remained there until May of 1954. After I came out of the service, I wasn't able to realize my objectives in agriculture, and I went to work in Denver for Sears, Roebuck and Company. I worked there for several years, but I was not really utilizing at all my educational background. So I took the FSEE, that is, the Federal Service Entrance Examination that was necessary at that time for certain federal jobs, and among those jobs that came to my attention and were made available to me for my consideration was one of Food and Drug inspector in Denver District. The job sounded interesting and challenging and would utilize, I believed, my college background, and some of my own job experience. I went to work at Denver District office on January 6, 1958, as a GS 5 inspector.

I stayed in Denver for several years and progressed to GS 9 and GS 11 inspector. Meantime, they began to establish some additional positions in the inspectional branch. They established the position of supervisory inspector and I was transferred in March of 1962 to Seattle District to fill one of those positions. I really did enjoy that job. I think as an aside, it was one of the most enjoyable jobs that I had, as I reflect back on my career.

Then in July of 1964, I was transferred to Washington. You'll remember in those days, you didn't apply for jobs. You got a call and were advised that you had been appointed to another position and transferred to another location, and you were told when they expected you to arrive. The position that I was appointed to in Washington was that of an auditor. Now you'll remember that supervisory inspectors at that time were GS 12's, and so I came to Washington with a promotion to GS 13, and joined a very small group, four persons, in a branch assigned to conduct management audits of field offices. It was the Management Audit Branch. I think that was the name of it, Bob. Do you remember?

RP: I think so; I think that's right.

JH: And it was one of two branches. Bob, you were in the other branch, the Programs Statistics Branch, in the Division of Review and Appraisal in the Bureau of Regulatory Compliance. The other three persons in the audit branch were Jim Beebe, Donald M. Johnson, I believe it was, to differentiate him from the several Donald Johnsons that have been in the agency, and Bob Sager. Bob

Sager and Don Johnson both had been chemists in the field, and Jim Beebe and I had been inspectors.

We began a program of conducting management audits of the district offices and ultimately the resident posts. That program grew in its importance and value over a period of time of about a year and a half, so that ultimately a decision was made to formalize the structure enough to have a branch chief. They had not had a branch chief prior to that time; we reported directly to the division director, and early on that was Ken Lennington. When they established the branch, they appointed me as branch chief, GS 14. Ken Lennington took another position in the bureau. Tom Brown, who had been the branch chief of the other branch, became the division director, and Bob, you became the branch chief of Programs Statistics Branch.

I held that position as branch chief till Dr. Goddard was appointed as commissioner, and that was in 1966. But for whatever reason, I don't remember the exact date that Dr. Goddard came on board.

RP: We all try to forget (laughter).

JH: There might be cause for that. Because Dr. Goddard approached his new responsibilities in a way different from what we were accustomed to, as far as management style was concerned. And I remember, Bob, that he asked each of the managers--bureau division and branch chiefs--over a period of several weeks to meet with him and Winton Rankin who was acting as his deputy and became his deputy, to discuss their program and how it contributed to the overall objectives of the agency. And that was a difficult time for the agency,

a real time of transition from one style of management and character of organization to another. But I remember you, Bob, and Tom Brown, and I went up and met with Dr. Goddard and Winton, and we described what we were doing.

I remember they were not convinced that the management audit process was really worth the cost. By then, the branch was composed of five professionals, including myself and a secretary. They asked me to carry out a cost-benefit study and report back to them on how I felt about the cost of the audit program compared to the value of the audits. I remember vividly this was a Wednesday. So I returned to my office and called the branch members together, and we began the process of planning to conduct a cost-benefit analysis of our activities.

The following Friday morning I came into the office, and I had no sooner gotten to the office than the phone rang. It was Tom Brown, and he asked me to come over to his office. I don't remember that you were there, Bob. Tom advised me that a decision had been made by the commissioner to abolish the division. The Program Statistics Branch was transferred lock, stock, and barrel, into another part of the bureau. But my branch was to be broken up and the individuals reassigned to various parts of any number of other offices within the bureau.

RP: Scattered to the four winds.

JH: Yes, and in a sense, they literally were. Because some took opportunities soon after that to get back into the field. So the group really was scattered. I remember that morning and what Tom and I were going through, because of

course, Tom's division was gone and my branch was gone. In order to kind of absorb this, and before we talked to our staffs, we took a little walk. We walked up to Constitution and passed the old Tempo R which they were tearing down at the time, to Tempo S, which you'll remember was just a block up. The Bureau of Drug Abuse Control, which was still part of FDA, was housed in the Tempo S buildings.

RP: That was one of the old temporary buildings on the mall that were used as government offices?

JH: Yes, they were the ones built in World War II, but that stayed on. There were other tempos on the other side of the mall and much closer to the Lincoln Memorial end of the mall that had been built in World War I and were to be temporary, and they were still there too. But now all of those buildings are gone. But I'm trying to recall the fellow's name that was the bureau director of the Bureau of Drug Abuse Control.

FL: John Finlator.

JH: Yes, thank you, Fred. So we went in and saw John and told him what was happening. He commiserated with us and showed a sense of concern for us. We felt better after that and walked back down to our office in FOB 8 there at 3rd and C Streets southwest. We called our staffs in and gave them the word that the division and branch had been abolished.

RP: See, I stood aloof from all this because I was the survivor (laughter).

JH: Yes. Well, that's right. I was assigned as a Food and Drug officer (now called a compliance officer) in the Division of Case Supervision under Morris Yakowitz.

I floated among the branches there. Chester Hubble was still there, Van Smart was still there in that division. Those were men, a number of whom in the following months made changes or retired, as a consequence of the organizational changes that were being made. There had been built up over a period of time in—it must have been in Van Smart's Drug Branch—a backlog of the old over-the-counter cases, that is the illegal sale of prescription drug prosecution cases. There must have been a couple dozen of them there waiting review, and some pretty old. And so I reviewed cases there for some several weeks while we worked that backlog down.

Meanwhile, as part of the whole change of organizational structure and approach, which included a much greater independence and autonomy for the field, the division undertook a new initiative to formalize and issue additional administrative guidelines, what they called Action Guidelines. They were the ones that for several years continued to be withheld from the public, but ultimately, you remember, we had to abandon that policy. I remember the other person that was working on that project with me was a fellow that had been in my branch, in the audit branch, and that was Joe Mamana. So Joe and I, then, began to draft these guidelines. And they included such things as insects in flour, and rodent pellet and urine contamination of bagged goods in warehouses, and that sort of thing.

FL: Criteria for legal action.

JH: They were criteria for legal actions. We didn't get very many of them done before I was reassigned to another project, but they became the defect action levels and that sort of thing that we know today. I did that for some several weeks, during which time the agency changed appreciably. Fred Garfield left and went to the Bureau of Drug Abuse Control; Alan Rayfield retired —well, you probably have a lot of that history on other interviews, and we don't want to go into all those details, at least now. But the agency was changing.

Meanwhile, before Dr. Goddard was appointed as commissioner, the agency had advertised for a contractor to conduct a management study of the field organization. And this is something we may want to talk more about later. The major contract of that study ultimately went to Booz, Allen and Hamilton. Once the contract was let, they were looking around for a project officer. I suspect by then there was some concern that I was a GS 14 branch chief without a branch, and the other Food and Drug officers were mostly GS 12's and 13's, so they needed a place to put me. They assigned me as the project officer for the Booz, Allen and Hamilton study.

That study was conducted principally in 1967 and 1968; it turned out to be a two-year study. The functional oversight responsibility for that study was initially placed in the assistant commissioner for administration's office. That was Ray Lannon. Ray had come to the agency at the time Dr. Goddard came, and I think had most recently been in the Social Security Administration. I

stayed there and reported as a special assistant to Ray for some number of months.

Meanwhile, in the reorganizational effort, with the carving away from the Bureau of Regulatory Compliance the responsibility of managing the field, the district directors reported directly to the commissioner. It became clear that the commissioner just couldn't be first-line supervisor for that many people: all the bureau directors and office directors at headquarters, and all the district directors. So they established an office called the Field Liaison Office. It was originally just Harris Kenyon and his secretary, Marie McNulty. It had become obvious, I think to everyone, that a study of the field organization should more appropriately be in whatever office was most regularly interacting with the field, and that certainly wasn't the Office of Administration. And so I then was reassigned to the Field Liaison Office, but with the same responsibility of project officer for the Booz, Allen and Hamilton study.

I remained in the Field Liaison Office, even though my assignments changed—they were influenced by some intervening reorganizations. But I think that from the very beginning, there was more in the way of the possibility of restructuring within the department of the various Public Health activities than met the eye when Dr. Goddard was appointed as the commissioner. Because it seems, in retrospect, that it was not too long after that, that in addition to making major changes in the Food and Drug Administration, there began to be identified changes to be made in the old Public Health Service--changes involving air quality, environmental pollution like noise pollution, and product safety—all programs that had been part of the earlier Public Health Service. And the concept of a new organization, the CPEHS—Consumer Protec-

tion and Environmental Health Service--began to develop. It was clear to all of us from the beginning that Dr. Goddard was hopeful that he would be appointed the head of that new organization. FDA was only a part of that organization, which also included several other programs from the Public Health Service.

It also became increasingly clear through day-to-day activities that it just wasn't reasonable for the commissioner of Food and Drugs, in addition to carrying out his responsibilities of managing the headquarters organization and immediate staff, to also have eighteen or so district directors reporting to him. You had budget concerns and program concerns, and all that sort of thing. Part of the activity was in what had become the revised Bureau of Regulatory Compliance, part of it was in the assistant commissioner for science's office--it was really a problem. A decision was made to enhance the Field Liaison Office position by elevating it to the assistant commissioner level. So they established the assistant commissioner for field coordination.

At about this same time, Harris Kenyon left FDA to join the newly established EPA.

FL: Wasn't the order of it that they established the Consumer Protection and Environmental Health Services? They combined FDA with the environmental structure of Public Health Services. And then the EPA succeeded the CPEHS organization.

JH: That's right, Fred. Yes, and took parts of what had been the CPEHS organization. But my remembrance was that Harris went with part of CPEHS

and never was the assistant commissioner for field coordination officially. And Sam Fine, who came in from Dallas, came in as the assistant commissioner for field coordination. They brought back direction of the field into his office, even though it was still on paper a staff office. The district directors' solid line on paper was still to the commissioner but the heavy dotted line was from the field offices to the assistant commissioner for field coordination, to the commissioner. And of course really, the assistant commissioner for field coordination's office carried out the day-to-day activities of managing the field. And Bob, that was when your branch came over and Don Martin and the inspection group came back over. By that time, because Doc Lipscomb was killed in a car accident before that reorganization took place, Hi Eiduson and the lab group came back from the associate commissioner for science's office. And Don's group, the inspection group, had come back from the associate commissioner for compliance's office.

RO: That didn't happen while Goddard was still commissioner, did it?

JH: No, it did not. Because in looking at the organization as a whole and not focusing directly on what was happening to Paul Hile during these tortuous times, Goddard did not get the job of director of CPEHS, Charles Johnson did. That was a terrible disappointment to Goddard, and Goddard left. And Herb Ley was appointed as commissioner. So all of these changes were taking place in that year or so that Herb Ley was commissioner.

That would have brought us to the end of 1968, early 1969. Sam came up as the new assistant commissioner for field coordination. And we pulled those

branches back in and made them staffs. And of course, I had stayed in the Field Liaison Office during that time, and we had picked up Roy Keeney. Roy had been the chief inspector for the Interstate Quarantine Program in the old Public Health Service.

Those quarantine programs had been part of the CDC, and you'll remember the Interstate program ultimately came to FDA. Roy had been the chief inspector of the Foreign Quarantine Program. But they moved the program to Atlanta when they moved CDC to Atlanta in '68, '69. Roy's wife also worked for the government, I think for the Public Health Service, in another program. They had their home here, their children were established in the community, and Roy didn't want to leave. So as Roy had been an inspector, and since we had inspectors, it seemed reasonable that he come into the Field Liaison Office.

The Field Liaison Office came into the transition with three professionals and a secretary: Harris Kenyon, who moved on into other program responsibilities, Roy Keeney, and myself. As the assistant commissioner for field coordination's office was developed by Sam Fine, he looked to those who were there, who had experience, and to what their roles had been, and he selected me to be his deputy. And so I became in early 1969 the deputy assistant commissioner for field coordination. We began then to draw together back into a single organization the headquarters functions that are necessary in an organization like FDA to manage the field offices, although ACFC was technically a staff office.

I enjoyed working for Sam, and I think we had a good office. All of the persons that came back into that unit, Hi Eiduson and his group, Bob, you and

your group, Don Martin and his group, were glad to be back, associated together in an organization that interacted daily with the field offices. We all felt a responsibility for managing the field, even though the management was indirect in concept.

RP: Of course, you realize that I found myself working for you at that point (laughter).

JH: Well, it just emphasizes the importance of the old adage about being good to someone, because you never know when you might wind up working for them. And perhaps all of us can reflect on experiences of that kind in our careers. I have always been grateful that it wasn't the other way around (laughter).

It must have been in early December of 1969 or along in there, when Dr. Ley was notified that he was being replaced as commissioner. I didn't take time to look back at this date; I should have.

FL: That was December 1969. Paul, on any of these dates, if necessary, we can correct them on the transcript if you missed or didn't get it exactly right.

JH: I appreciate that. But I knew it was about then because I think Winton had remained as the deputy commissioner. And I remember Winton made his famous speech, I guess it was probably before FDLI, the Food and Drug Law Institute's annual meeting. So it had to be in early December.

Sam probably was at FDLI, because I was attending the commissioner's weekly staff meeting with Dr. Ley--and it might have even been a special staff meeting as I reflect on it, because it was late in the afternoon--when he reported to us that he had been notified that he would no longer be the commissioner. He had met the new commissioner-designate, and it was Dr. Charles Edwards. I'm certain I'm correct in this: in that same meeting, Dr. Edwards came in and just kind of made a whirlwind walk around the table. It happened literally in a moment's time, as compared to other transitions of earlier times and later that seemed to be more orderly, taking more time.

Dr. Edwards came on board and immediately undertook a review of the organization. I'm sure he was charged with determining whether or not some changes needed to be made in the organizational structure to perhaps, in his view, make the agency more responsive to its responsibilities, especially at a time of rapidly changing technology in the businesses we regulated. He drew together a group of individuals as a review team to give him recommendations. Meanwhile, persons who had been part of the earlier administration--Ken Kirk, as the associate commissioner for compliance; Winton Rankin, as the deputy commissioner--retired from the agency.

With the associate commissioner for compliance position open, Dr. Edwards asked Sam Fine to accept that position, which he did. This was in the very early days of February of 1970. I remember Dr. Edwards called me up late one afternoon to his offices, and he asked me if I would accept the position of assistant commissioner for field coordination. So I was then appointed as the assistant commissioner for field coordination.

The study of the organization continued, and as there had been some major changes in 1966 under Dr. Goddard, there were even greater and I guess more traumatic changes under Dr. Edwards in those early months, with the creation of the new bureaus: the Bureau of Foods, the Bureau of Drugs, the Bureau of Vet Medicine, the Bureau of Product Safety.

Within a few months of Dr. Edwards coming on board, we agreed that it would be appropriate for him to meet all of the district directors in kind of a "go-away" session so that he could begin to gain an insight into their problems and concerns. It must have been in the early summer of 1970 that I called a meeting of the district directors at Minneapolis. Dr. Edwards came to Minneapolis to meet with us. You'll remember, Fred, the deputy district directors were there as well, because you and Pitt Smith were both there, I remember, rooming together, I think. And I remember we had some conversations about fair packaging and labeling, and some other things at that meeting. And you'll remember--and I don't mean this in a critical way--but we were staying at that hotel down the street from the district office. It had the Tudor architectural styling, and it's still there. We had reserved a suite for Dr. Edwards, but he swept in late the evening before and went directly to the Hilton.

Now, it's important that I say that ultimately, Charlie Edwards was one of the nicest men I've ever known, and one of the finest men to work for. But that was a little different kind of a situation for us, I remember. And he called and asked me to meet him for breakfast the next morning at the Hilton coffee shop. So I dutifully went over there and met him. We sat at the counter, though, and had breakfast. And during that breakfast conversation, he said that recommendations of the persons that had been reviewing the organi-

zation and his own perspective of the organization dictated a change in the way the field offices should be managed. It was not reasonable or fair for the field managers to report directly to the commissioner. He just didn't have the opportunity to be their first-line supervisors. And he asked me to undertake the assignment of establishing a new organization that would direct the field offices.

I accepted that assignment, and I began to talk to persons within the agency that I felt could be of help to me. Among those was Mickey Moure. Now Mickey also had kind of an interesting career with FDA after he had joined the agency, but by then he was the assistant commissioner for administration. We agreed, then, that it would not be appropriate to recreate the old Bureau of Field Administration, which had some problems in the way it had managed the field through its years of existence. Nor did we want to, in a sense, recreate the stigma that we thought some of the older field managers might still attach to the old Bureau of Field Administration.

So I worked with a team of field managers and others to establish an organizational concept to recommend to the commissioner that would assume line responsibility for managing the field offices. Then Mickey and I literally sat down one afternoon and took the government organizational manual off the shelf and went through that book, looking for reasonable titles that would make some sense. I'm not sure I want any of the three of you to comment on whether it made sense ultimately or not (laughter), but at least it wasn't the Bureau of Field Administration. We established the Office of Regional Operations. And the director of that was the executive director of regional operations. And so the acronym of EDRO came into existence, and I was appointed

as the executive director of regional operations when that new organization was put into effect. The time that it took to do that would have had that structure coming into existence in mid-1971.

That was an interesting time, because there were field managers, then, that had become accustomed to greater autonomy, and were less willing than others to feel comfortable with a new organization and with someone placed between them and the commissioner. It was about that time, too, that we were required to literally conform the field organizational structure to the department's regional configuration. And that was a difficult time: the EDRO organization was new; we ultimately established the regional director position; and we abolished the deputy district director position. It took some time to get that all sorted out.

I remained the executive director of field operations until in June of 1976, Sam Fine announced his retirement. I was asked by Commissioner Mac Schmidt if I would accept the position of the associate commissioner for compliance, and I did that. I was appointed as the associate commissioner on July 4, 1976, a date that had other importance around the nation, but certainly not nearly as important as my appointment as the associate commissioner (laughter).

At that time, the principal role of that position was to provide coordinative management to the agency's regulation development process, be chief advisor to the commissioner on regulatory policy, and establish informal regulatory policy when it was appropriate to be elevated to the level of the commissioner's office. And we supported the general counsel's office in developing the pleadings. We literally had what had been the old pleading section; we recreated that.

Over a period of time, the office functions changed as the organization of the agency matured. We had a number of different bureaus whose focus by then became increasingly parochial in their product areas. It became clear that the role of the associate commissioner in that office needed to become increasingly active rather than reactive, and even proactive rather than reactive. So over a period of time, the role changed, and we became increasingly involved in the development of cases as well as reviewing cases at the time they had gotten to the general counsel's office.

But I remained in that position without change generally in the character of the office. There was a change in the name of the office to the associate commissioner for regulatory affairs in 1977 under Dr. Don Kennedy's administration. And the functions matured and changed as I mentioned, but overall, it was a principal staff position to the commissioner and continued to be, as it had been through the years, the third-ranking position in the Food and Drug Administration.

In the fall of 1982, as an extension of some several reorganizational initiatives that he undertook in his commissionership, Dr. Arthur Hays had been viewing the field organization and became concerned that it was perhaps as parochial in its viewpoint as the headquarters bureaus. Just by its character, it didn't have as often an opportunity to interact as the bureau and center directors had to interact with one another. So at a meeting in September of 1982, he asked me to undertake an initiative to consider the reasonableness of combining the Office of Regional Operations with the Office of Regulatory Affairs. He asked me to do that in a way that would not be disruptive or raise concern on the part of the staffs of either office. And so I worked with a

small group of persons, and as a consequence not a large number of individuals were involved in that particular initiative.

As an aside, the first Tylenol episode, which has become known as Tylenol I, the Chicago episode, occurred that fall, and so my report to Dr. Hays was postponed several times. And even the morning that I gave my report to him which was in early December, I remember, it was interrupted several times with the problems associated with that particular matter.

But he concluded, looking at both the benefits and drawbacks, that the value of the reorganization outweighed any problems that might result from it. He formally announced his decision in early April, and authorized me to establish an interim organization combining the two under a single head. Technically, I continued to be the associate commissioner, but was also the acting executive director of regional operations during the period of time that the new organization was to be approved.

It took much longer than we originally believed it would because it required secretarial approval and those things take some several months just by their nature. So it was wending its way through the process and had gotten down close to the secretary's office, when in August of 1983, Dr. Hays left. Meanwhile, Secretary Schweicker had left. And so you had a new secretary and then also you had no permanent commissioner. So the whole matter just was placed in abeyance. It remained in abeyance until some several months after Dr. Frank Young came on as commissioner and had a chance to learn what the field was, review the organizational logic behind the recommendation. After he made that review, he concluded that it was a meritorious recom-

mendation. He renewed the recommendation, and it was approved by Secretary Heckler in November of 1984.

But for all practical purposes, the organization was up and running. I had good support from the managers in the field. So it was almost pro forma by the time it was approved. At the time I retired on June 30, 1986, the function of the associate commissioner for regulatory affairs was not only as principal adviser to the commissioner on regulatory matters, coordinative manager of the regulation development process, coordinative manager and reviewer of enforcement actions, and developer of agency-wide informal policy, but it also included the responsibility for line management of the field organization. I retired from the agency at the senior executive level five.

(Interruption in tape)

RP: It is now October 23, and we are continuing the interview with Joseph P. Hile. Paul, you finished outlining your career in FDA, and I wonder if now you would go back to when you were hired in Denver and tell us about your training as an inspector and other things that happened during your years in Denver that would be of interest.

JH: Okay. I came in at a time when the agency was hiring to renew the staff that had been depleted as a consequence of the RIF in the early '50s. They were not hiring large numbers of people at one time, but they had started to hire in late '55 and '60. They were hiring along one or two people at a time,

at least it seemed to me based on the Denver District staff, to try and get up to the point where they had been when the RIF occurred.

RP: That's the Reduction In Force?

JH: Yes, thank you. That's the Reduction In Force that occurred in the early 1950s. I was the only person hired at the time I came on, but there were a number of other persons in the district office at that time that had been on board only a few months.

Training was very informal. I was shown my desk, given a copy of the Act, a copy of the inspector's manual, some other reading material, and it was suggested that I read through them, which I did. You'll remember that at that time the Act was printed in small print on small pages. It was a change for me; I'd been used to a job that was a little more active. I started on a Monday, and at the end of the week, on Friday, I asked Walter Kuska, who was an inspector at Denver District at the time, if I could go on an inspection with him, and I did. I began to get a greater insight into what inspectional work was like. It was an inspection of a small firm that popped popcorn, and then sold the corn to theaters so they wouldn't have to pop their own. It was not an extensive inspection, but at least I began to understand why we would be looking for rodent pellets and that sort of thing.

In fairness to Walt, he didn't expect to take a trainee with him, so he didn't have any extra equipment such as coveralls in the car. So I wound up making the inspection in my suit. As part of the inspection we went down into the basement where they stored the popcorn. It was an older building and the

basement was dirty. We were crawling around with a flashlight looking for evidence of rodent activity and insect activity.

And so, by the end of the week, after sitting at the desk for four days reading through that material without really understanding what I was reading or why, and then going out on an inspection without much preparation or support, I wasn't really certain that I had made a good decision to come with the agency.

FL: During that period, did anybody talk to you about what was in the Act or answer questions?

JH: Later, yes, but not in that first week. I reflected on that first week years later, when I was a supervisor at Seattle and again when I became director of the field organization and we had an opportunity to hire a large number of people in Project Hire in 1972. I made up my mind I would not handle a new trainee in the same fashion.

RP: I'd like to make just one point there, briefly. I was in Chicago at that time, kind of a senior inspector, and I was in charge of all the training. We made a very great effort to not let what you're describing happen. Men were taken in hand immediately, and there was a pretty well planned program.

JH: Well, I think there were a number of differences between districts in that regard at that time. I just raise it in that it was an interesting thing for me to reflect in later years on the fact that as a consequence of that first week, I

might have left the agency and not had an opportunity to have the career that I did and really the very rewarding time that I spent in the agency.

Within just a few days following that, though, we had a tip that there was an osteopath in Brush, Colorado who was selling prescription-legend drugs. Lew Lasher had an assignment to go up and see if he could buy some drugs, and he suggested I go along with him, which I did. Lew Lasher—you'll remember Lew passed away some number of years ago—was one of the two investigators at Denver who were doing quite a bit of OTC work, that is, the illegal sale of prescription drug work.

I mention this only because it's something, too, that I think about from time to time when I remember my very first days in the agency. I went up to the doctor's office a brand-new inspector with the admonition from Lew to go in and buy some yellowjackets—wasn't that what we used to call the phenobarbital in the little yellow capsules in those days?

FL: Nembutal.

JH: Nembutal, yes. All he did was sit me down on the examination table, and I told him that I really needed these and could I buy a hundred or so. And he sold me 100 or 120, I remember, without really any doctor-patient relationship of any kind. But my concern later was that I was shaking so hard during that first experience, he could have easily testified that he thought I needed those, that he diagnosed me from afar (laughter)! Lew, then, went in about an hour later, and he bought a bottle of a thousand, an original bottle, sealed at the top. So between my initial buy and his second buy and some later buys made by

other inspectors, we built a case. And so it turned out all right, but I reflect on that frequently as one of my early experiences.

My first road trip was with Ed Melton. Ed was a good trainer. We went down into the panhandle of Texas and inspected some warehouses and flour-mills and those kinds of operations that were typical of early inspections for new inspectors. He was very good; he taught me how to write a good report and make a good inspection. And I always appreciated what Ed did for me. He then turned my interest and my whole career on a better path than might have been after those first few days.

It turned out that those were interesting times in the Denver District for other reasons. I think that a number of the persons who were being hired at that time reflected a different attitude toward their job and toward what they expected from an employer than perhaps some of the older people who were in the district. As to myself, I had worked for some years before I started with the government. That experience and my own home life caused me to identify with those who had the old work ethic and attitude. We were pretty pleased to have a job, and if the employer asked you to do something that was within reason at all, you went ahead and did it.

We'd leave on a two-week trip on a Sunday afternoon, and then we'd come back on a Saturday morning two weeks later, and we'd be expected not to have any incompleted inspection reports to write up. We would have been expected also to make inspections over the weekend. And that was true even if you made a two-week trip, say to close-by areas such as Pueblo, Colorado, or down into the Arkansas Valley of Colorado. Some of the employees there researched and found that the regulations would have allowed the inspectors to

come home over those weekends, because it would have been less expensive to the government. Clearly there was no special reason or requirement that you leave on a Sunday and come back on a Saturday.

Furthermore, although the senior management of the district were very fine and dedicated men, they were not necessarily good managers of people. So it became apparent early on that there were some persons in that district office that were very, very unhappy. They were not disposed to leave government, but felt rather that it was their responsibility to undertake some initiatives to change the way in which the office was managed. As a consequence, there were some difficult times there for some number of months. Factions grew up and developed as well as hard feelings among the inspectors who on one hand felt they were on one side, and on the other hand, on the other side.

As I look back on the situation, it was almost trivia that was focused on on the part of some of them in regards to things that they didn't like that were going on. On the other hand, in the strict interpretation of the requirements and regulations, they were right. Denver District at the time included West Texas. On trips into New Mexico and West Texas frequently you'd find yourself in El Paso. You would get requests from people at the district office for you to bring things back from Juarez such as liquor, which of course was pretty cheap in Juarez. Some people were interested in that, but also many times they would ask for trinkets that you could buy in Juarez, because they might have wanted them for gifts or something of that kind.

RP: Some people bring things back from there through inadvertence, too (laughter).

JH: We always tried not to do that, Bob (laughter). And if that was the case, of course, nobody really ordered that at the district office (laughter). But some complaints that were raised by the individuals who were really very dissatisfied with the management of the district office at that time included allegations that we were misusing government cars by virtue of bringing that material back.

It was an unhappy time. Washington management was obliged to come out and pursue it and to carry out an investigation. I know Kenny Lennington came out. Each of us individually was asked to meet with him and to describe what was going on, whether we'd ever been asked to bring anything back, and that sort of thing.

At the same time—and I need to be very careful in the way in which I characterize this, because it's not my intention to indict anyone—some of the inspectors that were most critical of the way in which the district was being managed were the least meticulous in conducting their own affairs. And so the administration, sensing this, carried out some other investigations concurrently. This led to the resignation of some of the investigators who had been most vocal in their criticism at about the same time that some of the management there at Denver took advantage of their eligibility to retire. This made a complete change of management and atmosphere there at the district office.

My own position during this whole time was that my sympathies were principally with management. Although I would be the first to admit that there

were some inadequacies in the way in which they managed the office, in the whole broad aspect of how things were being conducted there, I felt more comfortable in supporting them than I did those who were in opposition to the management.

I think that was recognized especially by one of the two senior inspectors who were at the district office at that time. You'll remember there were no supervisors at the time, and the journeyman grade was GS 9. And so to be a senior inspector, you were GS 11. And the two senior inspectors at Denver were Johnny Winch, who had just come up some number of months before from Phoenix where he'd been the resident inspector, and John Akers. John had been the resident in Salt Lake City, and had just a few months prior to that time been reassigned back to Denver. I can remember John Akers especially during this whole time. His comment so often when somebody would come up and ask him about what was going on and what were his feelings, was, "Well, you're three times seven," the implication being, "You're old enough to make up your own mind."

I went on some training inspections and investigations with John Akers early in my career and early in these difficult times in Denver District history, and I liked John very, very much. He also was a very good trainer. I did undercover OTC work with him; we built some cases in Pueblo, Colorado, and then made a number of inspections of flourmills and grain elevators because he was expert in that field as well. I think it was clear to John where my sympathies were, and as a consequence, I suspect that it was known to management generally.

As a result, I was asked by Ken Lennington, who came to me directly, if I would work directly for him with the district director's knowledge. I would get my assignments directly from him, and conduct some investigations, on behalf of management, of allegations or suspicions of wrongdoing on the part of some of the inspectional staff at FDA. And I did carry out some of those investigations, two particularly. There was one allegation from industry that one of the inspectors was drunk on duty, and I made an investigation of that allegation. There also were suspicions that an investigator was misusing a government car by making unauthorized side trips over the weekend on a two-week trip. I made investigation of that as well.

As I mentioned a few moments ago, in the end, the turmoil resulted in changes in the district management. The district director retired, the chief inspector retired. At the same time, some of the inspectors, even some of those who had been most outspoken in opposition to the management of the district, left the office, some of them with the realization that they had not been conducting their affairs in the most proper fashion, either. As a consequence, there was a rather significant turnover in the personnel of the district, although the district was still pretty small.

Things settled down as a consequence. Sam Alfend came on as the district director; Joe North came in as the chief inspector. At about that time, they created the supervisor position, and George Goers came in as our supervisory inspector.

Concurrent with all of the troubles in Denver, the administration was beginning to grow and the "new" building plan was being implemented. New buildings were being built in Detroit, Dallas, and Los Angeles. And so a number

of the districts around the country were asked to undertake a recruitment initiative to recruit people into the district. Those persons would later be transferred into the new districts or the newly expanded districts.

This would have been about 1960. In Denver there weren't enough candidates on the Federal Service Entrance Examination registers, so we made arrangements with the Civil Service Commission to train some investigators, to give the FSEE test, grade the tests right there, and interview and recruit.

RP: Known as Plan B recruiting.

JH: Exactly right. Plan B recruiting. And I was one of the inspectors--I was a GS 9 then--who was selected to be a person who gave the test. I gave the test at a number of the universities in New Mexico and West Texas and especially Colorado. And we were pretty successful, the other inspectors and myself, in getting candidates. So it turned out that we grew from an inspectional force, after the turmoil, of maybe ten or twelve inspectors to forty inspectors. But we had, for instance, ten cameras, eight cars, and five sets of screens. And there was a period of time that as many as four or five new trainee inspectors would go out with an older inspector at a time on an inspection. And there were three or four sitting around one desk. It was not a very satisfactory circumstance. We lost some of the new recruits because things really were so poorly organized and structured. It was just clear that the agency had not done a good job of planning for that kind of recruitment effort.

On the other hand, some of those that we recruited during that period of time have stayed on and some have achieved some considerable recognition in

the agency. Some are still good, solid investigators at the districts that we staffed, particularly Dallas and Los Angeles. During that period of time, we recruited people like Adam Trujillo, who is now acting director of the Office of Enforcement in the Office of Regulatory Affairs, and is in the Senior Executive Service. We recruited Leroy Gomez who's the district director at Denver.

And so it was not a program without merit and without good results. But to come in on a Monday morning as a GS 9 inspector and have an assignment to go out and make a warehouse inspection or a macaroni inspection or something like that and have five or six inspector trainees wanting to go along with you (laughter) didn't make for the best training atmosphere. It was really a difficult time. But ultimately, as I say, many of those people went to those districts as they were opened and staffed, and they've become good, solid employees. That was an interesting time--different, too, I suspect, than occurred in some other districts, because Denver was so small to begin with.

FL: Why did they get so very many in a small place like Denver where obviously the workload was not large enough to accomodate such a big group?

JH: My sense, Fred, is that things then were not much different than they have been all through my experience in FDA in recruiting into the field offices: you are more often successful in recruiting candidates into the agency as inspectors or analysts in the western states. Now why that is true, I'm not sure. As recently as the Recruitment Initiative of the fall of '83, early '84--Ron, that was our Hispanic initiative, wasn't it?--we recruited about

sixty-five, seventy people in a very short period of time by going out and again visiting the universities around the country. Where we had the best registers and wound up hiring the most people was Denver, Dallas, Los Angeles, and San Francisco.

FL: Perhaps there was a lack of competition from industry for quality candidates, that there were not nearly as many jobs at that time other than government in those particular places.

JH: I suspect that's true, and that was particularly true in the early 1960s.

RP: I took part in it in Chicago; I'm convinced that everything you've said is true. But also, we had some districts that just didn't try very hard.

JH: Well, that could be as well.

RP: In Chicago, this was well illustrated. We could hire very few Chicago people. Wisconsin was in our territory and we did our most successful recruiting in Wisconsin and parts of Illinois and Indiana that were not heavily industrialized. What Fred said I think was sort of illustrated there within that one district.

JH: Yes. I think it's probably a multiplicity of things. We were focusing heavily on persons with agricultural and horticultural degrees and that sort of thing. And I suspect, regardless of where they were around the country, there were fewer jobs as such for those people than there would have been had we been

recruiting engineers or some other discipline. And remember, too, at the time, as far as chemists were concerned nationally, they were on that special program where we could pay them premium pay. So I guess that affected it as well.

But we were darn successful in Denver to a fault, really. Denver was an interesting district, though. It had a wide range of kinds of work, but it was principally food work. Very little in the way of drug work. But the district at the time, you'll remember, was Wyoming, the southeastern part of Idaho, Utah, Colorado, New Mexico, and West Texas. So it was a long way from one end of the district to the other. And you could go off and travel 2,500 miles or more easily on a two-week trip, down into West Texas or up into Idaho.

I think back on my own experience, and I guess that I'd like to comment on a few things that I think might be of interest. Ralph Horst was the district director at the time I started in Denver. Ralph was a good person, but you could never quite characterize him as whether he was a real strong enforcer or not. But the atmosphere within the district as far as the inspectors and analysts were concerned was, we were out looking for violations. Leslie O. McMillin was the Food and Drug officer then, and that was a newly created position; I think he was the first Food and Drug officer in Denver. He used to be waiting in the inspector's room when you'd come in in the evening, and the first thing he'd ask you is, "Did you take any pictures? And did you get any seizures?" So of course the byword around Denver among the inspectors always was, "Hey, did you take any pictures?" or "Did you get any seizures?" But that little characteristic of "Mac," as he was known, really made the inspectors conscious of the fact that when you were out and you found something that

was violative, you should be taking pictures of it as part of your evidence development, and clearly you should be sensitive to and interested in building cases.

I really had a great seizure on my first two-week trip alone. Now, it really wasn't alone; I went over to Salt Lake City and worked with the resident there. His name was Don Taylor, too--I think it was Donald L. Taylor. They wanted to transfer him back East or something, and he was from California. He quit and went back to Napa, California soon after my knowing him. But he was very, very helpful.

I was over there and I went to a firm named Bonny Nut Company. I learned a lot at Bonny Nut Company; it was a firm that roasted peanuts and cooked nuts in oil and packaged them. It was three stories high, and they had all of their peanuts and shells storage and roasting equipment on the second floor. They had all of their cooking and packaging operations on the main floor. And all their storage of shelled nuts--peanuts, cashews, and all that sort of thing that they cooked and packaged—were in the basement. I went in there, and I'll tell you, that place was just alive with insects and rodents. Here I was; I'd been in about five months, and I had before me what I guess later could have been characterized as a mass seizure, because we just about seized everything that was in there.

But it was a good lesson. For instance, there were moths floating in the oil; it was just, I guess, an inspector's dream as far as finding violations is concerned. But I raise it not only because it was a good challenge for me and I had to collect a lot of samples, nuts, bagging material, and all the kinds of things that you did in those kinds of inspections; but because it was almost

overwhelming. I called Don Taylor to tell him what I'd encountered. He said, "We ought to get the state involved in this and at least get the goods held."

So first thing I knew, in comes a fellow that I'd not met before. He introduced himself as Glen Kilpatrick. That was the first time I met Glen. Of course, Glen later came to work for the agency and had a very prominent career as the head of Federal-State Relations. I became a very, very good and close friend of Glen's. But he was head of the Utah Food and Drug Division at the time, and when I showed him what I had, he put it all under embargo, and it was later seized. The courts in Salt Lake City, though, I learned, too, through that experience, were not the most favorable to the federal position on matters. And one of the judges was Christiansen, and the other--who was the other judge? Fred, do you remember by any chance, or Bob?

RP: Willis Ritter.

JH: Yes. Both the judges there, although different in their character, very seldom were sympathetic to the government. And in Bonny Nut Company, I had all kinds of interstate records for my official samples, because they had cashews that were imports, they had peanuts from Virginia, they had peacans from one place, filberts from somewhere else. None of it could have been raised in Utah, because to the best of my remembrance, except perhaps maybe for some pinions down in the southeast corner, there aren't very many nuts grown in Utah.

But I got all of those shipping records, and most of them came in on the Union Pacific and some on the Western Pacific into Salt Lake City. When all

those seizures were filed in that court, my remembrance was that the judges involved themselves directly in those matters at the time. Because Christiansen I remember was the judge that reviewed the paperwork, and he wasn't satisfied with the interstate documentation, because in Salt Lake City, there was a railroad company that literally took all of the cars from the yards. It wasn't the UP or the Western Pacific; it was this small railroad company, solely owned by I suppose reasonably influential people in Salt Lake City, that literally took the cars from the yards and delivered them to the sidings. And I had failed to get that documentation. So my documentation was incomplete. And Don Taylor —thank goodness we had somebody there--he ran out, went down to the freight offices of that little railroad company there--I don't remember the name of it--and got all the freight bills and way bills and that sort of thing to move those shipments from the railroad yards to Bonny Nut Company. But it was a good lesson for a young inspector, not to be too certain without exhaustive inquiry, that you had all your interstate records.

We built a lot of cases in Denver, but a lot of them never really got along very far. I think Mr. Horst was more disposed after citation in a prosecution case to put it in Temporary Abeyance, giving the persons another chance, even though the inspectional evidence might have been that they had been conducting their affairs outside the law for some time. And in the over-the-counter illegal sale of prescription drug cases, he was anxious to have just a very, very tight and complete case. You didn't always get that in those kinds of investigations. As a consequence, there were a number of TA, Temporary Abeyance, cases in the district at the time that Mr. Horst left, and Mr. Alfend came on board.

Our sample custodian, Mr. William S. Sidney . . . Sid was a good man, and a helpful person, especially to young inspectors. He knew what you needed to go out on an inspection, and he was very helpful; but he was slow to throw out PA'd samples, that is samples involved in cases that were placed in Permanent Abeyance. So at the time Mr. Alfend came on board, our sample room was full of samples that had been PA'd under Mr. Horst's administration.

FL: And were ready for disposal.

JH: Ready to be disposed of, but not yet disposed. Well, one of the first things that Sam Alfend did was call for the files on all those cases, and boy, he really shook the cases back out of the sample room. Mr. Alfend, I guess, could be best characterized as an inspector's director, because notwithstanding some of his own characteristics as a manager that sometimes were difficult to deal with, if you had anything close to a case, why, he'd take it. And I remember one over-the-counter case in which the evidence was against a drugstore in Pueblo.

RP: You were really down on Pueblo, weren't you? (laughter)

JH: Yes, really (laughter). It was a good place in those years to build those kinds of cases against drugstores, where the evidence was pretty—I don't know how best to characterize it, but it really wasn't the kind of case that Mr. Horst was looking for. Sam picked that up. I had worked on that case, I think along with either Lew Lasher or Ed Melton. And he pushed that through and

we got prosecution on that. The fellow plead guilty and we got a conviction on that case.

Sam Alfend was very, very good. As an example, I met Leroy Gomez while he was a trainee. He'd been on the road for a week, and I went up into southern Idaho and I met him up in Pocatello, Idaho. We got an assignment to carry out an investigation because Seattle had found a bunch of seed-treated beans in commerce, and it was clear they'd just been blended in to get rid of them. We really worked hard for a week to ten days, because we had to trace those beans back to the farm and through a couple different elevators. We had one recalcitrant elevator manager who threatened to beat us up with a tire iron, and a few things like that, which made it a difficult investigation in a number of ways.

But we really had what we thought was a good investigation, and everything pretty well sewn up and all. And we came back and turned in our report, and it was extensive. I suppose we had maybe ten or twelve affidavits and all those kinds of things to move those beans through that process and to demonstrate how they'd gotten into commerce. We turned in our report right away, and Sam I guess tolerated chief inspectors because they were on the Table of Organization; but otherwise, Sam was his own chief inspector. And he was his own Food and Drug officer and just about everything else. Because a case like that, if he knew it was around, he'd go and get it himself and read it right away before anybody else had a chance to look at it. I remember he came storming out within hours after we'd turned that in complaining that it was not complete.

But here again, I raise it only because, well, first of all, the meticulous adherence to chain of command that we find extant in the district offices today did not exist in the Denver office there, under Sam Alfend. The district director was directly involved in the regulatory activities and what the inspectors were doing. Things were different then. The whole district was interested in building cases. As much as I hate to say it, and as hard as I think a lot of us tried to continue that kind of atmosphere, things changed through the period of years 1966 through today, so that kind of atmosphere isn't there anymore. For instance, you'd be on the road and you'd make an inspection of a cheese plant up in the Star Valley of Wyoming, and you'd pull all those sediment pads, and you'd find a bunch of dirty milk and other insanitary conditions, and you'd have your first inspection. Then you just set your schedule so that you went back there within a week and made your bracketing inspection, the follow-up inspection, and then reported shipments out in that intervening period of time. And if you had a good case and you found some filth in that cheese or whatever the product was, you had a prosecution case.

RO: Paul, you've mentioned prosecution cases and building them. Did you ever use injunctions, or didn't you have injunctions then as a sanction?

JH: Very seldom did you use injunctions. When I came into the agency, everybody that I talked to was concerned that the injunction obligated the agency to so great a burden of policing the injunction that it really wasn't a viable tool as far as the agency was concerned. Now it may well have been that there were some different attitudes around the country in other districts. It

might have been only that Denver District had had some unhappy experiences with injunctions, or some of the senior people had had unhappy experiences with injunctions elsewhere and brought that experience and that attitude with them. But I can't think of any injunctions, as I sit here and think about my years as an inspector, that I built; but I prided myself as being a good inspector, and I had a lot of seizures and I had a lot of prosecution cases that I built, because that was what we focused on.

FL: I think injunctions were not often brought because we had not yet learned how useful they were. They brought the injunctions that simply forbid the firm to violate the law, but did not go into specifics as to what improvements they needed to make to get into compliance, and as a result, as you said, we found ourselves designated by the court to make frequent inspections and that did use a lot of our manpower.

JH: That's a very good point, Fred, because just jumping ahead and focusing on injunctions, you remember when we had the Intensified Drug Inspection Program, the IDIP, that was started under Goddard in about '67 and went for '67, '68, '69, along there. We had several injunctions that resulted from this program. There was that big drug firm in Philadelphia that we enjoined. I don't remember the name of the firm, but I know the court literally appointed the Food and Drug Administration to become the quality control program for that drug firm.

FL: But that's really what got us into the Intensified Drug Inspection Program, the experience of that particular case. In that case, the court did allow us to charge the firm for the quality control services, but it still tied up manpower that could not be used anywhere else, where later injunctions then were written to require the firm to institute their system of quality control that we would then monitor and it would require much less time.

JH: Yes, that's right. We became much better at writing pleadings ourselves, in later years.

FL: The evolution of the injunction case, I think, was along that line. But the time you were speaking of, they were not very often brought anywhere.

JH: In my own experience, I learned the most about bringing injunction actions I think as late as the period when Rich Cooper was general counsel. Rich came into the agency fresh from criminal and civil litigation, and a lot of it. And he was, and I suspect still is, very, very good at it. It was only then that we really began to think about using the injunction even in broader ways than we had before: the approach that if a firm is doing business nationwide or in a number of states, you can choose your jurisdiction, especially in an injunction case. Or if several firms are operating outside the law, you can join those in single actions, like we later did in some of our approaches for regulating things like starch blockers.

But as Fred mentions, and in my experience early on, we just didn't use the injunction. But at least in Denver, and I think generally, throughout the

agency then, the focus was on building and taking enforcement actions. In that sense, there probably were some dimensions of our attitudes that were not as good as we would have liked them, because maybe the pendulum was too far in one direction at that time and later went too far to the other.

For example, I can remember Ralph Davidson and I made an inspection of a warehouse there in Denver, and we found four 100-pound bags of flour in cloth. They were sitting on a pallet out in an area of the warehouse that was used for making up small orders. It was clean and the warehouse was clean as far as that's concerned. We didn't find any rodent activity in the warehouse or anything. But in black lighting the bags, we found what appeared to be rodent urine stains on the bags. So we collected our sample dutifully and later the stains on the bags were demonstrated to be rodent urine. But we couldn't find anything underneath in the flour, and there was no evidence at all that they'd ever had any recent rodent infestation in the warehouse. So one could have been led to believe that they received it stained.

Setting that aside, the firm was ready just to open the bags and dump it all into a dumpster. That would have effectively denatured it, because it would just have mixed it with trash, there would have been no way it could have been reconstituted in any way. And furthermore, we had our official sample. But Davey said, "No. We aren't sure it's rodent urine; we've got to take it into the laboratory and make sure. We want you to hold it." We processed that through the district office and a marshal went down and seized those four 100-pound bags of flour.

Now, ultimately, that was really not in the interest of the taxpayer or even the consumer. The consumer's interest would have been protected by the

dumping of the flour. The government's interest would have been protected by the fact that we had our official sample, and had there been any actions taken, we had our evidence. The taxpayer's interest was not served in that the marshal had to go down and spend whatever time there was to get the four 100-pound bags of flour. But we had a seizure. That attitude has much to commend it, but management always has to be very careful that it isn't pushed to the extreme so that those kinds of things occur. On the other hand, if you're going to choose one side of the fence or the other, why, of course, I'd prefer always the side where you were more enforcement-oriented and focused. But I guess that reflects back to my early indoctrination into the agency.

FL: I think that at that time and before, that was the understanding that new employees were given, not maybe in so many words--that the law was to be enforced using those tools that Congress had provided in the statute by legal actions, and that the informal ways of enforcing the law would not be undertaken, because they were not legally authorized. If industry asked our opinion, we would give it to them, but we would not volunteer it, generally, unless they asked for it.

JH: Oh, yes, it was drummed into you as an inspector that you were not an advisor. Of course, I still ascribe to that. I think we're much more helpful now in pointing out to industry what the problems are, and our regulations and our guidelines now are much more useful to industry in better understanding what the Food and Drug Administration wants of them. But ultimately, it's the industry's responsibility to find the means of adhering to our requirements.

FL: Traditionally, from reading and personal experience, I believe that attitude went back to the original enforcement of the 1906 Act, and had continued throughout our history up to that time. Your other comment about the difference between Mr. Horst and Mr. Alfend in the way they handled cases . . . Horst's position of not taking a prosecution action on the first time a violation was discovered might be explained by his background. He came to Denver from New York, where he had worked for many years. When I got to New York in 1955, I found that it was a firm policy of the district, and had been for a long time, not to take action the first time we found them violating the law. The theory that they operated on was that you cited them and gave them a warning. That established a background of warning that you could later point out to the court if indeed they did not correct the violation and they were found in violation later. I think that was done for two reasons: first, because the courts in that area are more impressed by the cases when they are handled in that fashion; and secondly, the volume of cases that they had to cope with was far beyond what the staff could do, and if they could get a correction on a citation for warning and not have to go to court, they were happy to do so.

JH: I had heard that, too, in later times, Fred. Not so much attributed strictly to Ralph and thinking of the way in which he managed things, but thinking about the relative workload in New York versus some of the workloads in other district offices.

It was an interesting management policy under Mr. Horst, because as I mentioned, there was no sense that the inspectors slowed down at all building

cases; it's just that there was a disappointment that some cases that the inspectors thought were meritorious and should have gone forward did not. And then under Mr. Alfend, a lot of them were resurrected and filed, or pursued. I remember one day Sam came out into the office and he'd just gotten a letter back from headquarters. It was on a case, and I think the reviewing office in Washington had turned it down by letter. He said, "Well, I sent it in by airmail and they've now come back not happy with it by airmail, and the next I'm going to wire them, and then the next I'll call them" (laughter). But he wasn't going to give up just because he got a letter back turning down the case.

He was a very interesting man, and a demanding man. You had to learn to know him, and one of his characteristics was that he expected you to know what you were doing, do it well, and be in a position to defend what you did. But you learned that sometimes the hard way, because he was very good at chewing you out as well as praising you, if it was necessary.

I mentioned earlier that case that Leroy Gomez and I worked on, the bean case. We worked so darn hard on that case for so long, and it was so extensive and we thought we had so much, that when Sam came out to my desk . . . And he wouldn't go across the hall from his office to the chief inspector's office and say, "Joe, I've got a problem with this. Would you call Paul in and talk to him about it?" He'd come out of his office, come into the inspector's room right up to your desk right there and he'd start chastising you over the inadequacies of your investigational work. I remember that particular investigation, we'd worked so hard and thought we had such a good case. My sense was, "The heck with it. I don't care what happens, I'm going to react back," which was a little out of character for me.

(Interruption in tape)

JH: Ron wants me to add that that was a little out of my character in those days, anyhow. I kind of fought back and told him what we had done and why, how we had dealt with different aspects of the investigation. I laid out the affidavits and all. It turned out, not surprisingly, that of course he was right; there were some inadequacies in our investigation. But notwithstanding that, it turned out, too, that he thought it was a pretty darned good investigation. It was just his nature to come over and approach it in that way. And once I reacted in that fashion, he and I became in the business sense the best of friends, and he relied on me. By then I was an 11 and one of the two 11's in the district. And he gave me a number of assignments following that, as an example, building a support for his recommendation that they establish a resident post in Albuquerque again. But I think you had to stand up to Sam and show him that you believed in what you were doing and you thought you had done a good job and all. That's what he was looking for. And persons that would not do that, he would continue to browbeat, and that could be pretty difficult for some people to take. I've talked to others who knew Sam through the years that he was district director, and they found out the same thing I did, and always, as I did, the hard way.

I don't want to speak too long on those years. I guess like all of us, I could talk a lot about those first years if it's of interest and useful information for the record.

You know, before I leave Denver, there's something I want to emphasize, because I've said some things about the district and the atmosphere that was

prevalent there that might make you feel that things were all bad. The fact of the matter is, in balance, things were very, very good. And there was a very, very good spirit at the district. The people liked each other. We looked for opportunities to be together and do things special when special things occurred.

An example was when somebody got promoted. When I got promoted from 5 to 7, Les McMillin said, "Okay, we'll have the party at my house. You have to buy the booze, but don't worry about any of the rest of it." So within a week or so, he had scheduled the party at his house Friday or Saturday night. And I went up to the old Denham Drug that was up there on the corner of about 18th and California, and I got a bunch of booze. But when I got there--and this was my first experience, because I had come in and they hadn't hired anybody since I came in. I'd been in a little over six months, and I was going from 5 to 7.

Just about everybody in the district was there. Dorothy McMillin had baked a ham and had a whole bunch of other things. Other people had brought food, soft drink, mix, beer. And we had just really a great, great evening in celebration of my promotion. And that happened, I found, regularly during those years, when anything like that occurred. And there was a great comradery and a great esprit de corps extant in the field offices at that time.

One final thing that occurred in Denver for me is that in the fall of 1960, they hired a new secretary by the name of Helen Neu. Helen and I, it turned out, walked up the street the same way every evening to catch the same bus. Well, we became friendly, and I found that she was raised on a farm in western Nebraska. I'd spent a lot of my growing up years on a farm in western

Kansas. We found we had things in common, and I asked her out and we started going together.

We went quite regularly because we enjoyed one another's company, and it became serious. But we also were sensitive to office politics and our obligation to be respectful of those. So we didn't tell anybody. We conducted our affairs so that nobody would suspect. And the only person that suspected was Alice Taylor, Don Taylor's wife, who came every evening to pick up Don. And she parked right outside the back door of the customhouse there on about 20th and California; we'd all come out in that direction in those days. One or the other of us frequently would leave earlier than the other, but we'd kind of slow our pace so I'd catch up with Helen or vice versa. But that was not necessarily noticeable to anybody in the office, because they might be coming at different times or whatever. They'd be catching up too, but to Alice who saw us all the time . . .

So later, then, in mid-1961, when I gave Helen her ring and everybody around the office was most surprised and didn't believe that we'd been going out those months prior to that time, Alice said, "I knew it all the time." Helen and I were married in October of 1961. And although Helen quit work then, she'd been with the agency long enough to have a sense of what it was about. She knew the people, and she knew what an inspection report was, and I was traveling two weeks in and two weeks out all through those times that we were going together. So in later years, I always admonished her that she knew what she was getting into (laughter).

I was transferred out of Denver the following March and the two of us picked up and went to Seattle. My experience in Seattle as a district was con-

siderably different from in Denver. Ken Monfore, as an individual, I suspect was ahead of his time, as far as having a regulatory philosophy that embraced not only the more traditional approaches to compliance--that is, the enforcement activities of the agency--but he also had begun a program of federal-state relations. He had very good relationships with the state officials in Seattle District, with several of the city enforcement organizations, and he not infrequently would look to those officials to undertake enforcement actions in lieu of the Food and Drug Administration. He also found when he got to Seattle the Better Salmon Control Plan, and had given it his full support and done a number of things to strengthen that program through the years. So as you looked at Ken, you saw someone that was considerably different in his philosophies of enforcement from say, Sam Alfend. Ken was a very pleasant man and a very pleasant person to work for.

The district itself had kind of a range of personalities. Art Steers was the director of the laboratory. Art was a very nice person to work with. Arnold Morton was the Food and Drug officer. John Kedzior, a character unto himself, was chief inspector. And I came up to a district that, based on their calculations, needed two supervisors. The other supervisor was Wally Rynerson. Now Wally also was an interesting character. He had joined the Food and Drug Administration in the early 1930s, and my memory is that he was at San Francisco District.

FL: He originally was at New York, and then went to Los Angeles. He was from Iowa. One of his claims to fame was that he and his father played in the town band that was conducted by Meredith Willson, who later had The Music

Man on Broadway. But he was appointed to New York, transferred to Los Angeles. He came to Seattle District as a Spokane resident, and then was the Portland resident before he came as supervisor.

JH: Was he not in San Francisco? Is that just my faulty memory?

FL: Not to my knowledge.

JH: It really isn't germane, but he used to tell stories about those early days in it must have been Los Angeles instead of San Francisco. But since they were only stories and they weren't very complimentary of the way in which they spent their time, I don't know whether I'll go ahead and repeat them here or not. But I guess what I want to emphasize is Wally had been in the agency for some long period of time by the time I met him, in contrast to myself, because I was comparatively new. And so our energies and interests were considerably different, one from the other. I guess John sensed that, and as a consequence, in making assignments, I got all of the trainees and Wally got all the experienced inspectors. The only non-trainee that I had was Ed Floyd, and Ed was a good inspector. He was a GS 11 inspector then, and a good one.

I mentioned earlier that there were a number of different personalities. I don't want to imply that there wasn't a concern over building cases at Seattle, but they weren't as aggressive in Seattle, it seemed to me, as we had been in Denver. I had just built a case as an inspector in Denver against a warehouse for bird excreta contamination of food products. The administration approved it, it was filed, got a plea, and a several thousand dollars' fine. I felt pretty

good and was convinced that you could build a case with bird excreta as the cause, the adulterant.

When I got up to Seattle and they divvied up some of the staff and I started reading some inspection reports that were coming in, I read one of an inspection of Associated Grocers there in Seattle. The inspector was Dan Beardsley. Although he wasn't a trainee, he hadn't been on board too long. And my gosh, if you'd been able to tie the warehouse to the feet of the sparrows there, why, they could have I think flown away with it, at least if his report was accurate in the number of birds that were flying in and out of the warehouse there. And as I looked at the file jacket, that had been a problem for some long time. But all of the earlier inspections were NAI, No Action Indicated. And in pursuing it there, the sense of the district was that the administration wouldn't take a case like that.

Now I know that even as late as probably June 29, 1986, there are attitudes in the field offices that influence whether or not cases come forward that include concerns over whether the administration will take the case or not. But I encountered several occasions like that where there seemed to be a sense, especially in the inspectional staff, that the administration wouldn't take the case. Maybe they'd had a similar one turned down for one reason or another and they were just hesitant to send them in again. But we pulled that case together and sent it in and the administration accepted it and it found its way back to the U. S. Attorney's office.

As an aside, apparently the officers of the Associated Grocers were influential enough in politics in Seattle there that the case was never filed. The fellow that was U. S. Attorney at the time later ran for public office and was

a representative from Seattle and I think is still influential in political affairs there. But he had us go back out several times and make inspections and come back and report to him. And just over a period of time, of course, they began to try and do something about the birds, and the case was never filed. Just an interesting aside.

Let me digress a moment. We always prided ourselves in the agency as not being influenced to any great extent by politics, and I think for the most part we were not. But we were not free of the possibility of that influence. Because I remember in one instance we built a number of OTC illegal sale cases in the Lubbock Leveland area of the Texas Panhandle. This is when I was still in Denver. John Akers and I had probably twelve or fourteen cases. That might have been our problem; maybe we had too many cases. But I remember, he and I were one of the teams doing the closeout inspections. You'll remember how you go in and make the last buy and then identify yourself and make an inspection. We were in this one drugstore in Leveland. The fellow was very, very cooperative, showed us all his records and everything. But during the course of the inspection, he says, "You're nice fellows and you're conducting yourselves professionally and all, and I'm going to cooperate with you. But this case will never come to trial." He said, "I am a personal friend of Lyndon Johnson." Lyndon Johnson was a Senate whip at the time. Of course, we didn't respond in any way to encourage the discussion or anything.

The interesting thing is that none of those cases ever came to trial, were ever approved. They were all PA'd at headquarters. And I don't say that as a criticism of the agency, because after all, the nature of our government is such that federal agencies are occasionally influenced politically, and particu-

larly by individuals who are in turn influential in the politics of the time. But that fellow's prediction came true; none of those cases was ever filed.

RP: You know, there's some background to that. A few years previously, we'd built many cases in that area and we had all kinds of problems with Judge Davidson, who was probably still the judge. I don't mean that that was the reason, but it would have made the administration a little bit more careful or maybe even reluctant to file cases.

JH: I remember Judge Davidson, and he was a very difficult judge to go before. And he was a very biased judge, racially biased. I mean, you couldn't bring a case in his court that had a black or Hispanic analyst or inspector and feel at all comfortable. And it may well have influenced the decision in that case. But for whatever reason—it may have been that or otherwise—it was interesting that was his admonition at the time.

But be that as it may, let me go ahead with a couple more examples of what I encountered. But you know, I learned some things, too, because things are not always what they appear to be. For those of you that were in the Denver District or in the western districts, you knew that one of the things you always looked for in a grain elevator was weevil. You used a dockage sieve extensively in grain work. Well, I got up to Seattle District and they had a lot of grain work there and they didn't have a single dockage sieve. I thought that was really interesting. But their response was, "Well, we really don't need them, especially, because although we have a lot of grain, we really don't have a lot of problems with insects or rodents, and we've just never really had to

use them a lot." But I was persistent, so John Kedsior said, "Okay, we'll buy some." So he bought several sets of dockage sieves.

By the time they came in, I thought I knew the inspectors pretty well, those that if there was a going to be a violation out there could find it, especially insects. Ed Floyd was one of them. So I set up some trips out into Montana starting from Spokane, involving principally grain elevator inspections. I armed them with those dockage sieves and sent them out. And they didn't come back with a single case (laughter). So I concluded either they weren't as good inspectors as I always thought they were—and I think that was not true, because they found other violations—or they were right: there wasn't an awful lot of insect activity in the elevators in the northern regions of the country, and they didn't need the dockage sieves as badly as I thought they did.

I want to be cautious about what I say here. On the one hand, Ken Monfore really was doing some things that were new, or new to me, at least, and different, in expanding the character and nature of a regulatory program. On the other hand, it was much more difficult to develop a case and get a case through Seattle District than it had been in Denver. And that was the full range of cases.

There was a fellow out at Moses Lake, Washington, as an example, who was taking the waters and the salts and that sort of thing from Moses Lake and making a soap out of it and shampoos and that sort of thing and making extravagant claims for it. It was just a typical quackery case. We'd made those kinds of cases in Denver, but I couldn't get that case pulled together, nor very much interest or excitement about it in Seattle. We finally called Washington. We talked to Harold O'Keefe, I'll always remember that. We talked to him and

he said, "Sure, of course we'll take that case." So we pulled that case together and sent it in.

But the voluntary compliance concept and the use of state and local officials as an adjunct in turning case work over to them to pursue, was much more popular and used much more widely in Seattle District than ever it had been in Denver. In fact, as far as state officials were concerned in Denver District, "Don't call me; I'll call you" was the policy, in contrast to Ken and his policies that went out and actively solicited their support and interest. And I learned to know a lot of state officials at that time that I knew later, that remained in the state program through the time I was stationed in Seattle, as contrasted to Denver. Some of them joined FDA, like John Mahre in Seattle.

RO: Paul, you mentioned earlier the Better Salmon Control Plan. What really was that?

JH: Well, that started many years prior to my ever coming to the district. It was a joint program between the government and the industry and the trade association to assure the quality of canned salmon coming from Alaska. The Alaskan salmon industry and fish industry generally presented some special problems for regulating commerce. It did then, and it continues to represent things different from the norm. It's highly seasonal; the canneries sit there all through the year otherwise unused, and subject to deterioration; the location of the canneries not infrequently was then and continues to be in reasonably primitive areas, making sanitation more difficult to maintain; and the condi-

tions on the fishing boats varies widely as to how they treat the fish and how long they hold the fish, before they ever get to the canneries.

And so, one of the approaches that was considered and pursued and resulted in the development of the Better Salmon Control Plan. Although the name has changed, it's still extant. There was agreement among the signees—not all the firms participated—but it allowed for the sampling of canned salmon that was shipped unlabeled to big warehouses, the salmon terminals in Seattle, for later labeling. It allowed for those lots to be sampled and examined jointly by the industry through the trade association and the FDA. It helped establish standards. And I think over a long period of time, it really has been a very effective program in steadily increasing the quality of canned salmon and improving the salmon-canning industry. And notwithstanding periodic problems.

Now after I left Seattle, there was a problem that resulted from or at least was attributed to the re-rounding of cans, improper seaming, and that sort of thing. And then more recently, the problem in the early 1980s was again in the re-rounding equipment tearing a little hole in the side of the can. But setting those problems aside, all in all I think it was a very successful program, and was reflective of the kinds of things that the management in Seattle was willing to try. And so I want to be fair; I don't want anyone to sense that I'm being hypercritical of the management there because of my finding situations where they were not as aggressive in developing and bringing cases, as I had been accustomed to in Denver, when, on the other hand, they were looking for and finding other ways to bring about correction and compliance that in later years of my career gained greater favor and, in fact, had to become part of our arsenal because of resource limitations and other reasons.

I mentioned that I had all the trainees. That put a special burden on me. At the time, I was a little distressed about it. But later, when I look back at my experience as a supervisor in Seattle, out of the several number of jobs that I had in my career, being a supervisor in Seattle was one of the most rewarding. I was able to see and feel at least that these trainees were maturing and growing into productive inspectors, inspectors that enjoyed their work and were building cases, doing good work. And that was very, very satisfying to me.

FL: At that time, Paul, about what proportion of the inspection staff were trainees?

JH: Well, that's an important thing. I'd say we probably had a staff of about twenty investigators total and probably twelve, fourteen of them were trainees.

FL: This was at the height of our expansion following the First Citizens Committee Report, I guess.

JH: Yes. Really, that expansion initiative spread over some number of years, but started slowly and peaked in about 1961, '62.

FL: And resulted in the agency becoming four times as large as it was when it started.

JH: Yes. We learned a lot of things the hard way. I mentioned the problems in Denver. It was very difficult to keep pace with the new investigators coming in and having investigational equipment for them. We were trying out new things at the time, as well. And it was during that period of time that, much to the dismay I think of some of the older inspectors, we began to get a lot of new cars (laughter), and get them more frequently. And we were getting good cameras, and we were doing good work with cameras.

It was an exciting time; it really was. You had to work feverishly to keep up. I can remember I'd look at inspection reports very quickly to have a sense whether there was anything there or not. If there wasn't, I'd stack them behind my desk. It got to where I'd have two or three stacks of NAI inspections a foot and a half high just stacked behind me there. Those inspectors were out doing inspections and bringing things in. There was so much work, you just couldn't keep up. And none of us were clock-watchers, but you just couldn't get it all done in those times.

One of the things that in a sense complicated training, although I'm a firm believer in standard practice around the country, and especially in an organization like FDA, is that during all this time, when I came in in 1958 and into the early '60s when I was then a supervisor and had a number of trainees, you had a standard training program where each of the trainees had to do the same kind of work during the first six months of their career. We still had, during that time, a training agreement with the Civil Service Commission that allowed inspectors and analysts to be promoted from GS 5 to GS 7 in six months rather than going through a full one year's experience, which was the requirement under any other circumstance. But during that first six months, you had to have

inspections of bakeries and you had to have inspections of grain elevators; certain kinds of things were laid out. You had to go through a series of sample collection experiences of different kinds, including documentary samples and so forth. That was all very good. But the complicating factor was that all the decisions on promotions from 5 to 7 were made in Washington. And I remember for my own self, and later then for all these trainees, having to work to prepare the paperwork necessary to send to Washington so that they could make the decision as to whether or not the individual should be promoted from 5 to 7. And you had to be meticulous in making sure that that report reflected that the person had done all of the different kinds of work that was described in the training program.

First of all, it made things complicated; secondly, it slowed things down; and thirdly, it made you wonder about the way in which things were being managed at the time. After all, who would know better whether an individual could do GS 5 work and be promoted to GS 7 than the supervisor and the chief inspector and the district director on site? And yet, that kind of authority was still held at headquarters. You knew that except in rare instances, they wouldn't have known the individual from "Adam's off ox," so to speak. Notwithstanding that, it had to be sent into Washington for approval.

In my later experience, and I think, as an example, when Dr. Goddard became commissioner, those kinds of policies influenced the changes which were made in the way the field organization was managed. Because field managers felt they could hardly go across the hall to the mens room, to make it very graphic, without calling Washington. That was just the way things were handled in those days.

We've lost some people. I remember a couple fellows that I had as trainees. Once they understood what the business was, they came to me, sat down, and said, "You know, I just can't be an inspector." And in my talking with them and pursuing it, it turned out that they just couldn't go into a plant, find a violation, and gather all the evidence that they knew might later be used to prosecute someone when that individual was standing right there watching them do it. They just couldn't quite bring themselves to do that. It emphasizes that being in the Food and Drug Administration at all, and being an inspector in the Food and Drug Administration specifically, takes a special kind of person. At least I think all of us believe that, and have prided ourselves as being special through all these years.

The work in Seattle still continued to be mostly food work. Lots of new experience for me. All the fish work was new; we had very little fish work in Denver. Much more fruit work in Yakima Valley of Washington, down in the Willamette Valley of Oregon. That was interesting and challenging. I always use as a good example of poor planning the fact that I was the work planning supervisor in Seattle for the couple years that I was there, but I never got to Alaska. I could have at least gotten myself a trip to Anchorage.

RO: You had an opportunity to go to Alaska in later years, but you sent me instead.

JH: I remember that. I was older and wiser and made the decision for a different reason, maybe. Something of interest that occurred while I was in Seattle was that we had a reasonably significant earthquake in Seattle. That is of in-

terest mainly for those who know the Seattle office building and the surrounding buildings. It was strong enough that a lot of the gingerbread on those older buildings around the federal building fell off into the streets. But I remember I was standing by my desk on the fifth floor there. That building you'll remember was built during the WPA days, and it's a good, sturdy building--heavy, thick brick and plaster walls. I was standing by my desk and my desk all of a sudden just moved away from me by about a foot. I looked up and those walls were just waving as if they were made out of rubber. That's an interesting experience for someone that's never had it, and it's one that I'm glad was not any more severe than it was in Seattle. There was very little damage. There were cracks in the floor in the building, though, that are still evident as a consequence of that earthquake.

More serious, and of greater importance to us in FDA was the earthquake in Alaska that occurred while I was there. Especially in Anchorage and all through that area. There was a lot of serious damage to the city as a whole, but of course, of special concern to us, food and drug supplies there were seriously damaged. We had several teams of inspectors in that area following the earthquake, and all through those difficult times afterwards assisting state officials in going through and making determinations as to whether or not food and drug supplies could be used. The difficulties of traveling to Alaska and traveling around Alaska that are significant enough under normal circumstances just made that kind of an inspection responsibility all the more difficult.

There are two subjects that I'd like to cover regarding my experience in Seattle that I think are significant before I leave Seattle. The first is that while I was a supervisor there, the administration took its first cautious steps

into providing automated data processing equipment for district offices. The administration, as I remember, asked the National Archives to conduct a study of the activities of the field offices, particularly as it related to work planning, and the recording of investigational findings. We had been using manual systems in the past such as the Flex-site system. They were asked to make recommendations as to how those systems of work planning and inspectional finding data could be converted to automated systems.

In subsequent discussions with persons more knowledgeable than many of us were at the time about the equipment we got pursuant to that study, there was a sense that the administration got sold a bill of goods. Because we bought systems that were characterized as 870 document writer systems that were keypunch systems, and they were based solely on punch cards. And the rate at which the equipment could punch cards and read cards and print out cards was much slower than what even was available at the time that the equipment was purchased. But for us, it was new and different and presented some new challenges.

The approach was to hold training sessions in several district offices around the country where they had put this equipment in place. Those of us in the western part of the United States went to Dallas for our training. It was IBM equipment, and there was a fellow from IBM there. By that time, John Kedzior had gone to Washington and was in the planning area. He was there in Dallas. And I met for the first time, as an aside, persons like Pitt Smith, Kurt Noah, and others who were supervisors in the western districts at that time.

We were advised that once we got this system in place, all you'd have to do was push a couple buttons and your work planning would be done for you. I

suspect now, more than twenty years later and with twenty years' more experience in computers and other automated data processing equipment, that we know that even today in the most sophisticated systems you just don't push a button and have things done for you. But we had great expectations at the time, only to be later disillusioned at how ineffective that equipment really was. And it's too bad, because I think it colored the way in which many of us viewed computers and related equipment for many, many years following that. And we could have had an entirely different kind of experience. But it was a pretty bad experience; the equipment was not very good, and we struggled for some long years working with that equipment before we discarded it for something more sophisticated. And to think about the fact that it was probably outdated at the time we bought it, it really was not a very good or effective program for the agency.

RP: For one thing, I think there was a lack of systems analysis, and we didn't really do anything but try to mechanize what we were already doing, and that was in itself a mistake.

JH: Absolutely, and a mistake that we repeated on several occasions in the years following, Bob, as you and I can remember. Yes, you're absolutely right. It kind of leads me into the next topic that I want to mention. The agency had a tendency then more than it has in more recent years to look within itself to solve its problems, to look for its strength. And generally speaking, that's not all that bad. And to the extent that the Food and Drug Administration continues today to be more unique in its character than many other government

agencies, and even though some argue that our spirit is not what it was in years past, the spirit that exists in FDA as compared to many, many other federal agencies around the country is—well, it does set us apart.

But we were so prone to look to ourselves. And even though we went to the National Archives for assistance, we probably would have been better served to go outside of government totally at that time to get some sense of what we really needed in the way of automated data processing equipment. But we repeated the same kind of mistake for years. Once we got the equipment, the people that we had work it, use it, were persons from within the agency that we gave a little bit of training to, and then they became the basis for our data processing units in the field and that sort of thing, rather than going outside and hiring persons who were trained in this field from the very beginning. Some of those people are still in the business and have learned the hard way what it means to be expert in data processing. It was not a very good start, but it clearly jumped us into modern times when they made that change in about 1963.

Also in 1963, the agency for the first time focused on the fact that more formalized managerial training would be helpful to managers. Now, I've mentioned that I worked for Ralph Horst and Sam Alfend and Ken Monfore as district directors. My chief inspectors were Leo Cramer, a prince of a man, Joe North, John Kedzior, and Bill Kupp. Each of those individuals brought their own personality and their own abilities and character to managing those offices. And ultimately it's true under any circumstance, no matter how hard the agency strives to assure uniformity of action around the country, by our very

nature, the personalities of the individuals who manage our field offices are going to be reflected in the local policies of those agencies.

But those men learned how to manage on their own. And for better or worse, and whether they were good or bad managers, they really had no opportunity to benefit from formalized management training. The first managerial training given to supervisory or managerial staff, at least in the field organization, was given to supervisory inspectors and analysts in about 1963. I took the entire course myself while I was at Seattle. I got there in the spring of '62, and left in the early summer of '64. So it was during that period of time it took place.

We were all directed to take a USDA, U. S. Department of Agriculture, graduate school correspondence course on basic management techniques. It was designed purposely for an introduction to management techniques. It was a good course. That's not surprising, because later, Bob, you'll remember you and I took a seminar course as part of the USDA Graduate School program. It was an excellent course as well. It was directed toward the first-line supervisor and had, oh, ten, twelve lessons that you completed at home. You sent in your answers and they were graded and sent back. At the end of the course, there was a two-day classroom setting summarization of the course. And that was held, as I remember for us on the west cost, in a USDA facility outside of San Francisco; I don't remember exactly where. But it was very, very useful and helpful for a first-line supervisor.

My only criticism now would be, in looking back, that they didn't require the branch chiefs and district directors and others to take the same course. And so there was some considerable frustration among all of us at the first-

line supervisor level in coming back all excited and primed to begin to use new and ideally more effective managerial techniques only to, not infrequently, have our enthusiasm dampened as a consequence of the failure of our supervisors to be willing to go along with these new techniques. Certainly, the agency is no longer that way. By that I mean they've encouraged and sponsored and fostered managerial training at all levels for some number of years. But that was their first tentative step into the business of providing management training for supervisors.

I don't know whether the motivation was their own recognition of the need or changes that were beginning to occur in Civil Service requirements. Later it became a requirement that supervisors have forty hours of supervisory training, but that was many years later. It may well have been just a recognition on the part of administration management that that kind of training was necessary. And I guess the natural tendency was to begin to focus it at the first-line supervisor level. It could have been well-used at some higher levels as well, but was not.

RP: Do you think somebody like Leo Miller might have had an influence on our doing that?

JH: He may have.

RP: I believe he was the first person that had a job that would be equivalent to the associate commissioner for management.

JH: Yes. And wasn't it along in there somewhere that the BFA hired Mickey Moure as a training officer?

FL: Mickey had come on before that. I don't know what his interest was in management training. I'm only guessing, but I think perhaps Winton Rankin for one and perhaps Harris Kenyon, who was by then director of Minneapolis, began to do some reading on their own in management. There began to be talk about it among the district directors. And in fact, management training generally had not been all that common until just a matter of some eight, ten years before the date you were talking about. Scientific management is a relatively new field.

JH: Yes. I didn't want to attribute it, say, to Mickey that it was his idea as much as to reflect the fact that the management of FDA was beginning to recognize the need for greater attention to managerial training, and other kinds of new training.

FL: I'm not sure when The Man in the Grey Flannel Suit was published, but that popularized the kinds of things that were going on in management.

JH: Well, I look back on that training, and it was very, very good. It was either very, very good because, without realizing it, we were kind of starving for that kind of training, or it was good, and/or both. But it certainly started all of us out on a trail of greater and greater interest in being good managers.

I now come to my first job after I was transferred to Washington headquarters. I arrived in early July 1964 and joined the group charged with conducting management audits. It consisted of Jim Beebe, Bob Sager, Donald M. Johnson, and myself. As we think about what the genesis of that organization might have been, it could probably be attributed to several things: a growing recognition on the part of the administration as a whole for the need to implement additional, new managerial activities. The new organization of the Bureau of Regulatory Compliance was reflective of the recommendations of the Second Citizens Advisory Committee. So there were a number of factors that might have influenced a decision to establish a group of this kind.

But we came into the job none of us having ever done anything like this before, and with really no tools at hand giving us a sense of how we should conduct a management audit. Two of us had been inspectors and to that extent, we had gone in and inspected things and evaluated things. The other two were analysts, and so I guess they clearly had that analytical mind. But we also, I guess, were seen as persons who were acquainted with how the field offices carried out their affairs as far as making inspections. And a couple of us had held hearings and, as I say, the others had been in the laboratory.

One of the first things we were confronted with was that we really didn't have a set of criteria against which we would measure performance. You'll remember that policy, and particularly operational policy, had been issued through the years through district director memorandums. But there was no formality about that system; they weren't numbered or anything else. So one of the things we had to do was begin to pull together district director memorandums, and we went just about everywhere we thought we could go. There

were a number of persons around that had files that we were able to utilize. But we then made copies of those memorandums and tried to categorize them into different kinds of operational procedures so we'd have that as a basis.

We pulled together a complete set of the old Bureau of Enforcement guidelines, because a lot of those were still in effect. We tried to pull together even the old Trade Correspondence. And we got the Administrative Guidelines, that was the confidential system. By then, BEVC and BRC guidelines had started as far as giving guidance on program matters. We just attempted to draw together in one place all of the kinds of guidance that might have issued to field managers on how they should be conducting their affairs.

And then we began a program of conducting management audits. We also did some other things. We began to inquire as to whether or not there were books on how to conduct management audits. And there were some books. So we ordered several of those, and began to read on how to carry out these kinds of reviews. We went across to the library at North HEW--quite a large library there at the time--and sought out books on management and management audit and made notes on how to approach it.

We learned that there are several ways in which these audits can be conducted, and one is to have a full-time audit team, and whoever had decided on how to approach the program had clearly concluded that was what they would do. We concluded that for the most part, the teams would be composed of one inspector and one analyst. We began to develop outlines of approach, and they would include looking at laboratory operations; an on-site inspection of how the laboratory was being maintained; a review of paperwork in the laboratories; and looking at some worksheets.

In the inspectional side, we'd inquire as to how work planning was conducted; we'd look at representative inspection reports; and we'd look at some case work. We decided we'd look at how vouchers were maintained and other formal paperwork in the administrative side of the house, and draw some conclusions about overall management policies and techniques through just general observation and description on the part of managers as to how they conducted their affairs.

Well, it was an interesting experience, because here we were, four newly promoted GS 13's, persons who, from the standpoint of individuals like Charlie Herrmann, weren't dry behind the ears yet; and we were being asked to go out and evaluate how well they were carrying out their responsibilities. So it's not surprising that from the very beginning, our reputation was not very good. And as the program moved along and some of the actions began to be taken and reactions to our reports revealed, we literally were seen as the henchmen of the management of the Bureau of Regulatory Compliance, and the axmen as far as that was concerned, when you looked at some of the kinds of things that occurred. And I can talk about that more in a few minutes.

But we were doing the best we could. When we'd get on site, we'd sit down and we'd meet with management. We'd go over the program and describe what we wanted to achieve. We'd have people designated to work with us, and they'd pull out various files for our review and make them available. We'd sit in the library, as an example, and go through different kinds of files, inspection reports as I mentioned, case work, and so forth, and use our understanding of the guidelines that were out there for the field to use in reaching their decisions.

For our on-site inspections, we'd choose an evening to make the physical inspection, and we'd do it after everybody left. We'd walk through the laboratory and be concerned about such important issues as how many lab coats were left lying around on chairs and benches; were there any samples left out; were the drawers where samples were kept locked; how clean was the laboratory; how clean were the premises generally; and so forth, cleanliness that could be attributed to the workers there and not necessarily to how well the facilities were maintained by GSA or something of that nature.

As I look back on that experience, I can see how, at least in some instances, we were reasonably petty on things that we brought to the attention of management. On the other hand, I think some important inadequacies were revealed. But those kinds of things might not have been ones that were originally in the minds of the individuals that set up the audit team. By that I mean, there were some situations that, had management taken different approaches to evaluating what was going on, the end result might have been the same, but the audit program would not have been damned generally by the field managers and personnel as it ultimately was, as being the causitive agent.

I'll digress enough to give as an example the audit that Bob Sager and I were assigned to make at St. Louis District. You will both remember that Roy Pruitt had been ill for some long period of time. And we found that he had not been in the office for months. That was, I suspect, clearly understandable. But what was revealed was that Roy Pruitt continued to sign all of the paperwork, and of course, it was not Roy, it was Joe North who was the deputy director then or the clerk, or whatever. And the only thing the poor auditors could do was report that during all of this period of time, the district director was not

Planning and Appraisal, and part of which was this new initiative of management audit.

Morris Yakowitz was the director of the Division of Case Supervision; Fred Garfield was the director of Field Operations; and Ken Lennington was the director of the Division of Review and Appraisal. That division had two branches: the Program Statistics Branch, and Thomas W. Brown was the director of that branch. But the other branch early on did not have a branch chief, and Ken Lennington acted as the branch chief. So the four of us literally reported directly to Ken. We got our directions and guidance from Ken. But it was clear he was feeling his way as well as to what would constitute a management audit.

We used to laugh; we'd come back from audits and we'd sit down and dictate our reports. And they were lengthy; I mean, the audits took a week for the most part of a district office. And we had lots of notes and exhibits of what we had found. We would sit down and report the way we went about it or what we found and our conclusions. And, boy, those reports were long and detailed. The first transcription, ordinarily, would undergo considerable rework before it ever saw the light of day. We all felt like we had the blue pencil madness, because we really edited them extensively before they were completed.

But that's the way in which it was managed. And the reports, as a consequence . . . The first level of review was Ken Lennington, and then they went directly to Allan Rayfield. You never quite could anticipate what the reaction would be, because sometimes they saw things that we reported to be much more serious in their consequence than we did; and other times, things

that we felt were relatively significant, they did not. I think that, although they might not have purposely undertaken the review in this fashion, ultimately the personalities of those that were being audited, that is the district directors and the staffs, and how they were viewed by bureau management influenced what was seen as significant and what was not.

To give you an example of that, Sam Fine was the director at Dallas at the time we made the audit there. And we had already made audits of districts where there was a reasonably extensive program of federal-state activity. When we got down to Dallas and made the audit, we reported in a straightforward way that Sam would share the FDA work plans with state officials before they were implemented. And he received the most stinging letter you could imagine as a consequence of that. Now, for better or worse, that had to be colored in some way, I think, as to how Sam was viewed, perhaps, as a district director, rather than having a serious concern over whether a state official had gotten our work plans beforehand. Because there were other districts that were doing a lot of federal-state work, but they didn't react in that fashion.

That was a difficult program to carry out. Sam had remained active in the naval reserves. And talk about managerial training, I think Sam had begun to get that kind of training through the military as well. He was very proud of the way in which he managed that office down there. And when we came in to make a management audit, he was quite receptive and helpful and supportive of it. In contrast, some of the others were just very, very negative, and we could hardly get the time of day out of them, and they were not helpful at all. And even some were very, very sarcastic about it and belittling to us about

the whole initiative and our being there and not knowing a single thing about running a district; we had never run a district in our lives, how the heck could we come in and report on how a district was being managed and all?

Even though, I think, in toto, good came from that program, it could have been a much better program. There could have been greater participation on the part of the field managers on what kind of a program it would be and what the auditors would look like. Some additional inquiry into how management audits could be conducted would have revealed that local people could have been assigned to be part of the audit team so that it wasn't persons from the outside coming in and "spying" on them, so to speak. It could have been a much better program, a much more effective program, but it was not.

RP: What could have been done? Were the districts properly prepared for this?

JH: I don't believe so.

RP: Or did you just arrive suddenly; this was something new and different and here you came?

JH: Yes, I think for the early ones, this was something new and different and here we came. And then we made a report of what we found, and some people were admonished that they had not been conducting themselves properly. And you know that the management of the Bureau of Regulatory Compliance at the time was capable of giving a reasonably severe tongue-lashing to those that

they thought were conducting themselves in a way different than management thought they should.

RP: I guess what I was thinking about is, if we would assume that the audits were done well, and I'm willing to assume that, then something that should have happened before either didn't happen or didn't happen the right way. And then the use of the results of the audit was poor in terms of really coming out with a product that helped everybody.

JH: The audits may not have been done well, at least early on, because we were neophites ourselves. But they were not done with malicious intent. Yet I think that, a a consequence of our audit reports, bureau managers took management actions that gave the impression that we were sent there to get the goods on people and thus justify aggressive, punitive actions. That compromised any value that could come from the program at all. You get off on a bad foot on a program like that, why, you can never overcome it. We could literally never overcome that. I remember talking to people like Jim Swanson, who was a chief inspector at the time, and my remembrance was that our reputation preceded us to the district. And, man, it wasn't a good one. So it's very difficult to carry out an audit in that way.

Furthermore, we never really did have a good sense of what was important and not important. One of the things that Ron Ottes, as an example, remembers best of the audit at Baltimore, was that he had injured his toe mowing the lawn just a few days before the audit and was in the hospital. And Bob Sager felt that his findings in the laboratory were so significant and important

of the moment, he pursued Ron to the hospital bed. You know, that kind of action on the part of the auditor—even if the auditor thought he was doing the best job he could in what he was being asked to do—really had a very detrimental effect on the program.

It was too bad, because as a part of that program, I became a firm believer in the management audit technique. And in later years, when I was the executive director of regional operations, I attempted to reinstate some kind of useful management audit program. But even to that time, the bad feelings that had resulted from that earlier initiative really stood in the way of any real good program being undertaken. And it's too bad because management audit is a recognized, useful management tool, and the fact is we build it into our own GMPs and GLPs. We require management audit and record of management audit, and record of improvements that were taken as a consequence of that. And yet, that one experience has really compromised field managers in trying to undertake that kind of activity now. I feel rather strongly about it. It's clear in my discussion of that activity.

FL: Paul, I do not recall that any attempt was made to involve the persons who were to be audited in helping to select criteria or give weight to criteria.

JH: None whatsoever, Fred; that's correct. The four of us were sat down in our offices and were literally told, "Go forth and conduct management audits." And two inspectors especially, Jim Beebe and myself, we viewed ourselves as pretty decent inspectors. So we applied our inspectional techniques: you go out and gather evidence of wrongdoing. That was the way in which it was ap-

proached, and the consequences not infrequently were like a seizure or prosecution might have been to somebody in the industry as far as our own managers were concerned. And then, like I say, the way in which the management reacted to our finding of what was going on in St. Louis District and some of the others--it's too bad.

FL: And the uses to which some of that data was put a few years later.

JH: Absolutely, Fred. After Dr. Goddard got on board, he—well, not he, but others—dug that material out and clearly that was influential in . . . Well, they closed St. Louis, Kenny retired under less than favorable circumstances, and—well, we could go to a number of those kinds of examples. I remember at one of the Christmas times, it must have been Christmas of 1964, we were sitting around and talking about it. I drew a little Santa Claus. It was about eighteen inches tall. He had a sack on his back, and we drew packages there and we wrote the names of the districts that we had audited; but in Santa's one hand was an ax, and in the other hand was a noose. We cut him out and Scotch-taped him to the door of our office. Well, Allan Rayfield came walking by, saw that, and, boy, within just a few minutes we got a call from Kenny: "Take that down off the door" (laughter).

But the whole concept of having a management audit group—if it had been properly conducted, as you suggested, Fred; if people had understood what the objectives were; if the persons who were to be audited had participated in the criteria for audit; had local people been made a part of the audit team; had the results been used in a positive way to bring about correction rather than

not infrequently as they were used in really a punitive fashion to somehow carry out activities that really should not have been part of that program; then it could have been a very worthwhile program. Because once we finished all the districts, we started to audit the resident posts. And we started specially focused audits, like the administrative activities or maybe just the inspectional activities, or whatever, so that we were focusing on special kinds of things, and the audits were of shorter duration.

It came to a sad ending. As I characterized in my introductory remarks about my own career, by the time Dr. Goddard came on board, the branch had grown a little bit and I was the branch chief. Goddard had asked all of us in the early days of his administration to describe what we were doing. I had described to him the activities of that branch. And he had asked me to undertake a cost-benefit analysis of it, but before we even got that underway, within two days of the meeting, a decision had been made to abolish the branch. So the program came to kind of an infamous end. There were very few tears shed, I guess, by anyone over its demise, except for those of us that were in the branch (laughter).

There were good people in the branch. There were the four I mentioned, but I brought in people like Jim Davis who's now the director of investigations in Seattle and a recognized, competent director of investigations; Dick Hunt, who is now retired, but he retired as the director of the Division of Regulations Review in the Office of Regulatory Affairs. He was recognized as knowledgeable in the regulation development process and very, very good. I had brought in Joe Mamana. He's had a checkered career, but that's not necessarily been all Joe's fault through the years. He had been an administrative offi-

cer. And Leroy Gomez was a part of the staff. Leroy's the district director at Denver. So it was not a shabby group of people.

RP: I had kind of forgotten that until Leroy and I were talking one day. He just about barely got there when it was abolished. I don't think you hardly had time to give him a desk.

JH: Yes. It was a sad commentary. I can talk about that at some other time and on another tape.

FL: Don't you all think that the way they went about establishing and conducting this operation was very characteristic of the management of that bureau at that time? It was a dictatorial, "do it my way" sort of management that had very little input from people in the lower levels; it was all from the top down.

JH: Well, absolutely. I mean, you characterized it perfectly. In a microcosm of the audit was what in a macrocosm was the bureau's problems that led ultimately to the demise of that bureau as we knew it. It led to Allan Rayfield's retirement, Reo Duggan's reassignment, Fred Garfield's leaving to go to the Bureau of Drug Abuse Control, Lennington's reassignment to other activities, and Goldhammer's retirement. Something that happened at about the same time was that Abbott matter that resulted in all of the hearings, and where Allan Rayfield literally became, in my opinion, the sacrificial lamb of the administration.

RP: He would agree with you.

JH: And my sense is that that might have been true, although I was not privy to all of the things that were going on, and I never knew really all that went on. Maybe no one will ever know all that went on then. But he was the good soldier who, more than others who were party to it, were marched into the jaws of the lion or whatever analogy you want to use. And I saw Mr. Rayfield conduct himself in ways that frequently were disappointing, because as a manager, the impact and results were not what you would have hoped they would be. Certainly, my characterization earlier about training, having to come into headquarters to promote somebody from 5 to 7, was exactly an example of that kind of dictatorial direction.

FL: He was autocratic; there was no question about it. And he could be a mean son of bitch sometimes; but he was basically a man of good will who was conducting his job—this is my opinion—in effect the way he had been trained and had seen other people do.

JH: Well, and I think Allan Rayfield was conducting his affairs the way he thought Commissioner George Larrick and Deputy Commissioner Jack Harvey wanted him to.

FL: I think so, too.

JH: We're digressing a little bit, but it's all part of the whole matter. At the peak of those hearings, Rayfield needed staff support in pulling together information necessary for him to go up on the hill. And the one group that could be readily drawn into it without disrupting everything else was the audit group. When did that happen, in '65? It had to be.

FL: Sixty-four and '65.

JH: Because, see, the audit group was still composed of Johnson, Sager, Beebe, and Hile. The other three hadn't been sent back out, two to the districts and one to another job yet. And we'd go down on a Saturday morning--I mean, we did a lot of work in the week and in the evenings--but we'd go down Saturday mornings during that period of time, and we'd pull together information on the recall that occurred and how it was conducted and the problems associated with it, all that kind of information. We'd work it all up. Mr. Rayfield and Fred Garfield lived close together down in North Arlington. So Fred would drive down. But Fred would finish his work and then he'd go home. Well, here it would be maybe 4:30, 5:00 Saturday afternoon. We'd finish struggling through and Mr. Rayfield would ask for a ride home. Because all of us lived on further into Fairfax County and had to go right by his house to get home.

I learned more about Mr. Rayfield as an individual those few weeks and those few days when he'd be in the back seat of the car and you'd be driving, or you'd be back there with him because one of the other guys would be driving--because we carpooled down, too. He'd talk about the problems of the moment, the impact on his family, and all that sort of thing in that few minutes,

maybe twenty-five, thirty minutes that it took us to get from FDA back over to his house. Those were difficult times.

And I learned something about Mr. Rayfield, or at least what Mr. Rayfield had to tolerate as a manager, when I took over managing the field. You know how highly I regard the field managers and the field totally; but the group of managers in the field at that time was not without—there were those that caused some problems for me. And one of them that caused a real problem for me I later learned caused a real, real problem for Mr. Rayfield. He was not a director then, but somewhere in the senior investigative line; and he caused a real problem. And Alan absorbed all of that and none of it ever got to the commissioner. Had it, it would have caused major problems. Rayfield probably had his problems, too (laughter).

But notwithstanding all of that philosophical characterization of Mr. Rayfield and the problems of the time, he ruled with an iron hand; you did things his way or his chief lieutenant's way, or you were wrong. As I remember, when I was still in Denver, in the Plan B recruitment, I had hired a young man whose name was Howell. I can't remember his first name. He was from New Mexico. Nice young man. He'd been on board several weeks, and Rayfield came out for a visit. And you remember, for the most part, when they came for a visit, at least my experience was, they'd go into the district chief's office, close the door, and you never saw them. If you were part of the little crew that played poker in the evening, then you saw them, but you never saw them much during the day.

But this time I remember Rayfield came out into the inspector's room and was talking about some things that were going on. Here we were, and the in-

spectors' rooms were all pretty much alike. But that one in Denver was that one big, long room with the desks on both sides of it. He was kind of walking down, and here was this brand-new guy who had been working on a sample. It was on his desk and it was not properly done. But he was interrupted in the process of doing it and nobody really had had a chance to look and see whether he'd done it right or not before it was turned in. It was sitting on his desk. Well, boy, Mr. Rayfield saw that and he lit into that kid like you wouldn't believe. And the unhappy thing is that the next day the kid quit.

Heck, I'm not embarrassed to say that I and about everybody else that worked in the Bureau of Regulatory Compliance and before that in old BFA, if you were walking down the hall and you saw Rayfield coming down, you turned into the office. It didn't make any difference whose office it was, because you'd just as soon not meet him, because you had no sense of what you were going to encounter. That's a sad commentary. That's the way you felt about him in the daytime, in the office, and yet those few weeks when he was having all those problems in those Abbott hearings, we gained an entirely different insight into him as a man, an individual. He's an interesting person.

Eighteen years later, I was on the program on the twenty-fifth anniversary of the Detroit District office, as was Mr. Rayfield. He was the featured luncheon speaker. I hadn't seen him for all those years. And he looked great. Remember how thin and pale and fidgety and all he was all those years? When I saw him then in Detroit, in his later years he gained some weight, he was tanned, he was relaxed—looked good. If I look that good when I'm that age, I'll be darn glad. But we just had a nice conversation that afternoon because I sat next to him at the luncheon table, and then a lot of the people at Detroit

District twenty-five years later didn't know who Alan Rayfield was. They had an open house that afternoon and he had brought his wife. Then he has a niece and nephew that live in Detroit, so the niece was there. So it kind of befell me to be with them, because otherwise they would have been pretty lonely. They showed some home movies that had been taken at the time that the district was opened and all those kinds of things. And people thought they were great and all, but they were a bunch of younger people that weren't around twenty-five years ago.

During our conversations, he said, "You know, Paul, this is the first time in eighteen years that I've been contacted by the agency on an official matter." He walked away and he never heard from the agency again in any kind of official or semi-official kind of a thing. Well, he's an interesting man and those were interesting times. We could have a dozen or so tapes of my own remembrance of him and working for him and with him on matters, or scurrying away from his side because you'd just as soon not meet him in the hall and undergo whatever might have been the consequence of seeing him in the hall (laughter).

RP: You know, I went down and interviewed him in Florida three, four, maybe six years ago. He was extremely kind and gracious. He insisted that when we got all through he'd take me out and show me the town where he lived. His wife fixed lunch for us, and it was just a delightful day. But of course, I had grown accustomed to him in Washington and worked with him on budgets and that kind of thing.

JH: That's right; you had a different relationship with him.

RP: From really hating his guts, which I did when I was in the field, I grew to appreciate him quite a bit when I was in Washington working on a face-to-face basis. He could be quite different.

JH: Yes, he really could be. An interesting aspect of working in the Division of Review and Appraisal was that the audit group of four individuals was drawn upon by Ken Lennington as the division director to help out in a number of different division assignments, and particularly to work with Tom Brown and Bob Porter and others in the other branch as it related to field budgeting, planning and evaluation activities.

I remember particularly sitting in on a meeting with the Bureau of Budget examiner for FDA, probably in late 1964, soon after I'd arrived in Washington to talk about the budget that would have started with the fiscal year beginning July 1, 1965. The discussion went along the lines that the budget examiner was a little apprehensive over supporting (to his supervisors') requests on the part of the Food and Drug Administration to increase the resources for the field organization. Because the proposal of the Food and Drug Administration was to ask for additional resources only to increase the frequency of inspections of certain segments of the industries that we regulated.

I remember that we were proposing to get additional resources so we could inspect bakeries once every two years. And the concern that the budget examiner had was that first of all, there was really no clear reason presented in the budget proposal as to why we needed to inspect bakeries once every two years in the first place. But equally important was that there was no evidence

that the agency had looked at its own procedures to see if they could become more efficient in the conduct of inspections so that they could release already on-board resources to make inspections more often without having to ask for additional resources. His position was strong enough that it was clear that even though he was prepared to support the agency in certain increased resource requests for that upcoming fiscal year, unless it became clear that FDA was ready to do something different and try to improve its own procedures and release some resources, he wasn't sure he could support the agency in future budget requests. So the agency committed itself during that meeting, and I suspect subsequent meetings at about the same time, to undertake some studies of how it conducted its affairs with the idea that we could become more efficient in conducting inspections and make up at least a part of the budget increase request through our own efficiencies.

And so the Division of Review and Appraisal was given the assignment to develop some kind of a study. And I remember we also drew out of Division of Field Operations out of Kedzior's group because Frank Thompson participated in this initiative; Bob, you were in on it, some of your staff; Frank was in on it. That fellow that was a statistician; there were a couple statisticians—nice fellows, black fellows—do you remember those two fellows?

RP: The one you're thinking about was Matthew . . .

JH: Butler, was it?

RP: Butler.

JH: Yes. We sat down together, all of us, and the audit group, and we thought through how we might approach this. We came up with a program that we ultimately gave the name Program Managed Establishment Inspection, PMEI. It had, I think, four parts to it. In one instance, we were going to take . . . Well, let me back up a minute. Because at that time, we had a special Form FD-483 for inspector's observations for grain elevators. Remember that? It was 483-A. And it was a checklist. But you recall, too, that the agency's policies at that time were adamantly opposed to checklists. But we concluded that we would conduct a number of inspections solely on the checklist basis, and see if we could save some time, decrease the time per inspection, and still feel comfortable that the inspection results were satisfactory. That was one of them, I remember.

The second one was bakery. We had abbreviated inspection reports in the bakery area. The principal focus of this initiative was to see if we could cut down on the amount of time taken to prepare inspection reports and not necessarily reduce the time in the plant. And there were a couple others, Bob, but I'm not sure I remember all of them. There was the abbreviated inspection in bakeries, the checklist in elevators, the one in macaroni products, I think—principally all focused on abbreviated inspections, particularly if they were NAI.

We developed the program and got it approved and issued it, and the program was carried out early in that subsequent fiscal year. I remember the results came back and we wrote a report. And our conclusions in the Division of Review and Appraisal, that is, the group that was working on this initiative,

were that we could save time without sacrifice of quality by reducing the time spent on preparing inspection reports, and we could, in fact, submit abbreviated reports for Non-Actionable Inspections, and we could use effectively a checklist. In fact, we may have prepared another checklist for one of the other product areas, if we really focused on that. But the bottom line was that there were ways in which we could increase efficiency and save resources and accomodate a more frequent inspection of segments of the industry utilizing the resources we already had on board and not having to ask for all of them new.

Well, that report went forward with those recommendations, and the fact of the matter is it disappeared, and I don't think we ever heard of it.

RP: Rayfield just tucked it under somewhere, because he didn't like any of those approaches.

JH: No, it was clear he did not. We knew he and his associates didn't like the approaches before we ever started. But we thought that the results were persuasive enough, and we felt that perhaps the Bureau of Budget examiner's admonitions were forceful enough that it might have been persuasive. But it was not. I remember, then, that the following year, which would have been the fiscal year beginning on July 1 of 1966—but we would have been looking at the budget proposal and preparing for hearings in the fall of 1965—that the budget examiner, same fellow, was inquiring as to what we had done to improve our own procedures, and the bottom line was that we hadn't done anything. He was aware of the PMEI initiative, but it was clear that we hadn't changed our

processes at all. The exact timing of these events I just can't recall, but I remember a situation, Bob. You were by then the . . .

RP: I was a branch chief and Tom Brown was division director.

JH: I would have been by then the branch chief of the audit branch. We were in Tom's office for some reason and I think Tom was called out to the phone or to go up to Rayfield's office or whatever. But I remember within just a few minutes Tom coming back into his office where we'd been waiting for him, and he was concerned and kind of out of breath over the fact that we had been notified in the agency that we had no support that year from the Bureau of Budget for any increases in the field. The bottom line was that the Bureau of Budget was saying, "You promised to study ways to become more efficient, release some of your own resources toward the increase in the number of inspections you could make. You didn't do it, and so we're not going to support you for any additional resources."

It was out of that dilemma that Tom, you, and I and others that were a part of that whole initiative there of budget preparation and presentation began to consider what we could do to be persuasive to the Bureau of Budget that we were sincere in our efforts to improve our own operation. And out of that grew the concept of having a study of the field organization conducted by an outside management consultant firm. So an RFP, a Request For Proposal for bids on a contract for such a study, was prepared and issued, and a review committee was drawn together. I remember that, but I don't remember who all was on it. The bids were reviewed, and Booz, Allen and Hamilton was identi-

fied as making the best proposal at the most acceptable price. It was to be a complete study of the field organization, how it conducted its activities, to determine how the procedures might be changed to increase the efficiency of the field organization.

Now, imposed on the agency at this same time was Mr. Larrick's and Jack Harvey's retirements--departures--and Dr. James Goddard coming on as commissioner and bringing with him some persons that he had had either on his staff at the CDC or persons that he was aware of through other means as part of his staff--people like Ed Turk, as the head of his planning. And so they came in just as we were beginning to finalize the contract with Booz, Allen and Hamilton. Part of that contract focused on a review of the laboratories, and how the laboratories might be made more efficient.

First of all, I really think Goddard was not enamored of the idea of a study at all. But we were so far down the track that I don't believe we were in a position to back away. So his solution to his unhappiness, particularly about the laboratory aspect of the study--because he thought that people within the government could do an equally good job of study--was to in fact say, "All right, the study of the inspectional part of the operation and the overall way in which the district offices conduct their affairs and manage their programs can be studied, but the laboratory part will be carried out by a laboratory study group" that was then part of the Centers for Disease Control. That group had been established as part of the CDC's international program to assist emerging countries in preparing plans to develop and put into place Public Health Service kinds of laboratories. I remember one of the reasons why that was more easily done by Goddard was that the study of the Food and

Drug Administration by Booz Allen was to be conducted principally by employees of the parent firm, Booz, Allen and Hamilton. But the laboratory study was going to be done by a subsidiary firm that was principally a product testing laboratory firm. Do you remember that, Bob?

RP: That sounds familiar now; I didn't really remember.

JH: And so, in a sense, the subsidiary firm that was going to be doing the study of the laboratories was really not a management study firm; it was a testing laboratory. It was more reasonable for Goddard to say, "Wait, look. We have an organization that could do it as well or better in the federal service."

Well, the contract was let. It was to be a year-long study initially, and I can remember they had a district directors meeting at which the study concept was presented. Booz Allen's representatives were there, describing what they thought they might do and how they might approach it. It was not very well received by the district directors. Particularly people like Gordon Wood were strongly opposed to the concept. I think Irv Berch was director at Philly by then, wasn't he, Fred?

FL: Yes.

JH: And you remember, Irv of all the district directors was always the one that at least seemed to be most interested in an understanding of things like statistics and that sort of thing. And he wasn't very pleased with that concept. But I remember especially Gordon Wood speaking out very strongly in op-

position to the kinds of general ideas that were being spoken to by the contractor. But notwithstanding that, the study was undertaken, and two districts were chosen as the principal sites for the study: Kansas City and Detroit. And between those two, Kansas City was the district at which the majority of the work was to be done. And then as concepts were developed and tested, the contractor would go to Detroit to also test them as a confirmation of their validity or otherwise.

The study team from Booz, Allen and Hamilton had on it one fellow that was a financial expert. There were a couple science advisors. But the vast majority of the consultants were industrial engineers. And their approach was the old time and motion study approach, to study just what we did and see whether or not what we did could be broken down into segments and those segments used to propose improvements in how we conducted our affairs, either by rearranging the segments or improving the way in which we planned for the segments or whatever.

As an example, one of their concepts was to break the inspection process down into parts. It would include things that we could think of--as an example, preparation, then the raw material inspection, and so forth, much of that drawn right out of the inspection manual. But we had never thought of them as segments to which time could be attributed. They saw them as segments that then could be used in planning, and that you would plan not only for an inspection, but you might plan to inspect only a part of the operation of a firm, an approach which they later characterized as "directed inspections." And as a consequence, you could save time, and you could predict the time that could be saved. So that was one of the approaches that they used.

They also thought that we could do better by collecting the time that we spent in conducting our affairs against a different matrix than we had been using traditionally. We had been using, you recall, the commodity code as the basis for dividing our time. So we would be reporting principally time against inspections of dairy and dairy product manufacturers or bakery and bakery products or fish and fish products. And they thought that if in fact we were concerned over safety first and sanitation second and economics third in our priorities—and those had been our priorities for some time—that we could break down those into different segments—different kinds of safety concerns and different kinds of sanitation concerns and so forth—and begin to attribute time against that kind of concern first and be worried about the commodity as a second cut of the data.

Another concept that they had was to gather data on our findings in a way that would allow us to focus better on where our inspections would be directed. As an example, ultimately they were recommending that if we made an inspection of a bakery, we would have concluded centrally within the agency and proposed to each of the district offices that there might be twenty-five or thirty aspects of that inspection that were important to the agency. And then the inspector would make some yes, no, or maybe kinds of answers against those twenty-five. And if we could collect those data individually and accumulate them, we would begin to see where the problems in the bakery industry were focused. In turn, you could characterize them as to whether they were safety or sanitation or economic, and if they were principally occurring in the manufacturing segment of the inspection as contrasted to the raw material. You could schedule inspections to look only at the manufacturing part and, at

least in theory, begin to become more efficient in the planning of inspections and cut down on the time that inspections take, and release manpower to be applied against other activities.

Well, of course to do all of that kind of planning, it was clear that the data gathering system, the automated data processing system of the field, would have to be more sophisticated than it was. And so another aspect of the study was to propose a more sophisticated automated data processing system.

Finally, there were a number of individual kinds of recommendations that were not as wide ranging as that, but would cover such things as increased analysis of finished product, but collecting specific information against attributes, and then using more sophisticated statistical analysis of those findings again to help direct inspections. As an example, they took a number of analytical findings of drug products and manipulated them against an individual firm to determine what kind of quality control problems that firm had.

Well, not surprisingly, the first year's effort only narrowed the kind of general recommendations that they were going to make and did not result in a lot of specific recommendations. Furthermore, they suggested that the study be extended to a second year so that if the agency agreed with the recommendations in general, then the specifics could be fleshed out and be part of a second-year study. The agency concluded that that was reasonable; they let a second study. So ultimately, it was a two-year study. And I think the two years totalled about $750,000, which at that time was quite a large contract, for the agency, especially.

All of this occurred in a pretty negative atmosphere. You'll recall that Dr. Goddard specifically was not happy with Booz Allen undertaking a study of the

laboratory aspect of FDA. But generally speaking, he was disappointed that he couldn't jump in and negate the study in the first place. But he wasn't able to do that, because it was so far down the contract line. But as a consequence, as Booz Allen would come to points in the contract schedule where it was appropriate for them to make reports to the agency, they would make the reports to Goddard and the senior staff and others. And those were always very, very acrimonious kinds of meetings. The fact is that during the course of the second contract, Dr. Goddard became so adamant in his unhappiness with what was going on and argued so strongly in opposition to what they were doing and whether or not it was satisfactory, that Booz Allen threatened to sue the agency for breach of contract.

I was the project officer for this contract and this was not a happy circumstance for a project officer to find himself in (laughter). Because I had to sign off every month that the contractor was doing their job and that they could be paid a monthly portion of the overall contractual fee. And just as an aside, I became so distressed over it at one time toward the end of the contract, that I went in to see Winton Rankin. I told Winton it just wasn't worth it to me any longer to be part of this controversy between the commissioner and the contractor: the commissioner unhappy on the one hand, arguing that they weren't doing their job and they weren't being reasonable and practical and all that sort of thing, and the contractor on the other hand threatening to sue the agency for breach of contract. If I had to I'd submit my resignation just to get out of the middle of it. Winton talked to me and the more level head of the moment prevailed. He persuaded me not to do that and to tough it through, which I did.

Although we'll talk more about the Booz Allen study, I must admit that of the number of different assignments that I had during my career in FDA, it turned out that being project officer for the Booz Allen study was one of the most educational. Because the way in which I participated as the project manager, I went regularly to Kansas City with the study team. I eventually had a couple people working for me, because Booz Allen would ask for information to assist them and I couldn't do it all myself; and in fact, there were really no other offices available to do that. Two young women were assigned with me. One was Arlene Pauls, and the other was a young black woman. She had her master's degree in mathematics. I've been trying to think of her name since we began to talk about this interview, and I just can't remember it. But remember the end-of-the-trail, ceramic Indian on the horse that I've had in my office through the years? That young woman gave that to me during the time she worked with me.

RP: Didn't she live in Alexandria and we got invited to her house for a cocktail party one night?

JH: I just don't remember, Bob. She was a very pleasant young woman, and a very knowledgeable one, but I just can't remember her name. Well, that's not really important as much as the fact that we literally found ourselves in a sense as an extension of the Booz Allen study team. I learned to know the study staff very well. One of the principal project managers was a fellow by the name of Don Messer.

My goodness, I was in Kansas City so often during that whole time. The Kansas City staff became intimately involved in it. They were doing all kinds of study work in support of it. It included Charley Armstrong, the director out there, and I remember Dick Ronk was a senior analyst at the time, as was Mary Anne Westoff. And I learned a great deal about management techniques, industrial engineering techniques, financial management techniques--all the kinds of things that were a part of that Booz Allen study I was exposed to those things, really, for the first time in my experience, and really in a very, very intimate way, for two years. So although it was a very traumatic time for me in a variety of ways, ultimately it was one of the most interesting and rewarding experiences of my career.

Meanwhile the CDC unit was looking at our laboratories and was preparing suggestions on how they might be configured physically and making suggestions as to how we might manage our workload. But the fact of the matter is that that group was not accustomed to dealing with regulatory laboratories. Public Health Service kinds of laboratories, where they were concerned over communicable diseases and that sort of thing, they knew. But not the kind of work we did. And as far as I am concerned, from all practical purposes, their report was really not very worthwhile to the agency, and didn't impact to any great extent at all on the way in which we conducted our laboratory affairs.

But notwithstanding the strong opposition to the study generally by Dr. Goddard and members of his immediate staff, and even after Dr. Goddard was gone, we were beginning to look at the recommendations and consider whether we could implement any of them at all. In the long term, as I look back at how we conduct our affairs now in the field and have for fifteen years or more,

the Booz Allen study had a greater impact on the agency's field offices and how they conducted their affairs than a lot of us really ever expected it would or was predictable at the time that the recommendations were being considered.

By the time the agency was considering some of the specific recommendations coming out of the second-year study, particularly, as an example, the recommendation that we ought to implement a much more sophisticated automated data processing system, Dr. Ley was commissioner. And I remember Charley Coffindaffer, who was in the assistant commissioner for administration's office at that time, making a presentation to Ley—and of course, I was there, because I'd been the project manager—on the amount of money it would take to implement the Booz Allen's recommendations for improved computer support to the field offices. This would have been in probably early 1969. I don't remember the exact figures, but it was something in excess of a million dollars to get it up and going. Dr. Ley concluded we just didn't have the money to undertake that initiative.

But meanwhile, you'll remember, Bob—this was while Dr. Goddard was still commissioner—you were asked to implement a program-oriented data system. There was a team of persons identified to assist you in doing that, if my memory serves me right. And they were drawn from that first group of persons in the Executive Devolopment Program. That was under Dr. Goddard. That included Sam Hart and Don Healton, Maurice Kinslow, Curtis Joiner, a doctor by the name of Kelly out of the old Bureau of Medicine. But that team did it in about two days or something like that. Here you had a two-year study with recommendations of far-reaching impact on the agency, and you had to do that

all within I think three months. I was being facetious with two days, but I think you had something like two or three months.

RP: Including development of a manual and going out and implementing it. Who knows? We maybe wouldn't have done a better job if we'd had a year. I suspect we would have, because it was an unrealistic time frame.

JH: But clearly, that grew out of the Booz Allen study.

RP: Well, yes, it was mostly Booz Allen. They worked with me in my office; they used the blackboard day by day practically. Of course, they were not the only ones. Anyway, it came from the Booz Allen study. That's the most concrete thing that came from it to my knowledge.

JH: Yes, because remember we tried for some time to implement the recommendation on gathering more discreet data from inspection reports. There was a name to that system, too.

We were collecting the data manually. Remember it had a name and we used the initials for that name. They were program information sheets. We collected data on inspection reports against maybe a couple dozen factors. And that was a direct outgrowth of the Booz Allen study. But because it was manualized, it became so burdensome that it literally died of its own weight; it was just too difficult to pursue.

RP: Well, as I recall, our data automation people were going to punch it for us and the sheets just stacked up to a point where it was too late to play catch-up.

JH: Yes. Although we'd never really implemented the planning of inspections by the discreet breakdown that they had, we did begin to think about directed inspections as contrasted to complete inspections. And ultimately, the kinds of things that went on as far as information gathering and data analysis at the St. Louis Drug Analytical Center reflected the kinds of suggestions that Booz Allen was making in regards to utilizing product surveys, analyzing marketed products in a statistical way.

I think some of the suggestions such as breaking the inspections down into such finite parts were really never practical. Booz I think ultimately realized that, but it was, in a sense, too late. Had the Booz Allen study occurred at a time when the agency was more stable, we might well have been in a better position to accept their recommendations for an improved data information system, and, as a consequence, been several years ahead of where we ultimately were in updating and improving the computer support for the field. And we might have been more receptive generally to the overall concepts of improved management than we were.

There was one other aspect of the study that I've not touched on that we did do quite a bit on, and for some several years following that. You remember one of their challenges was to devise some system by which we could measure our accomplishments. So they proposed that we use these data that we were gathering--as an example, the more finite information on inspections and that

sort of thing—not only to do a better job of scheduling inspections, but over a period of time to measure the character of an industry, and then after we had brought some kind of effort against that industry, measure again and see if it had changed. And that concept became known as Measure-Act-Measure.

As an example, you would measure the status of the bakery industry at a moment in time against a certain number of attributes. You'd get that information, assess what it reflected, that maybe there were major problems in raw materials storage. Then you'd develop a strategy to deal with that. If it was inspection, you might design specific inspections directed toward that part of the operation. You'd carry out that activity for a period of time with the objective of improving sanitary conditions in the bakery industry. And then you would measure a second time by conducting again, in a random fashion, a number of inspections with the ideal result that it would reveal that the industry had improved. But the concept was that over a long period of time, you would be doing these kinds of activities and you would build a library of experience that would allow you to also become increasingly astute at designing the strategies that you used to deal with problems. So that if you measured an industry's compliance, found a certain kind of problem, you'd know from experience that one of the most effective ways to deal with that problem would be, say, inspections or sample collection analysis and seizure, or whatever.

RP: Public notice, or it could be some sort of an educational campaign.

JH: Exactly right. Or industry workshops. Any number of things. And, in fact, ultimately it could be a combination of approaches to solve the problem. But

you would regularly in gathering this information become increasingly sophisticated at measuring the status of industry, determining what the problems were, developing strategies to deal with it, and then taking those actions and measuring again later to demonstrate that ideally there had been a change. Of course, what you'd want would be a change for the better. You would then be able to do a better job of demonstrating your effectiveness and attribute those gains to actions on the part of the Food and Drug Administration, or at least be more confident that you could attribute them to actions that the Food and Drug Administration had taken.

And you remember in the early '70s, we set up the Office of Regional Operations under the executive director of regional operations. We had that unit in the EDRO organization that carried out studies. And they did a number of pilot studies that were Measure-Act-Measure studies.

RP: Yes, I remember.

(Interruption in tape)

RP: It's now October the 24th, 1986, and we are continuing the interview with Joseph P. Hile. Paul, when we quit last night, you thought you might start this morning with a discussion of that part of the Booz Allen study in which you pulled together previous studies and that later some of this material was used by Dr. Goddard and others.

JH: Well, I thought it would be interesting to comment on the fact, as an aside to the Booz Allen study, that one of the first things that the Booz Allen representatives asked the agency to do and that I did as the project officer, was to pull together previous studies of the agency for their review and consideration. It included a wide range of studies. It started with the first Hoover Commission in I think it was 1948. And FDA was mentioned only so briefly there and really wasn't a matter of significance. But later as you got toward the end of the '50s and into the early 1960s, there were some several studies that were quite interesting and I think significant.

Of course, there were the First and Second Citizens Advisory Committee Reports, and those I'm sure are covered elsewhere in interview and are available. But there were some other studies, and I think as an example, one by the Senate in the early 1960s, that focused on the way in which the agency was being managed. And there was an internal study of special significance conducted by a fellow by the name of Art Davis and another person whose name I don't remember. Both of them were management analysts at the time. I guess I remember Art's name best because he remained with the agency for some number of years following that, where the other individual did not.

The study that those two fellows conducted was literally a management study of the agency, focusing on some of the significant management issues confronting the agency in the early 1960s. The study was conducted in 1962-63, and was directed to Commissioner Larrick. Several things that were recommended were of later significance. It focused some considerable attention on the way that the field organization was managed. And it concluded that the field organization was too closely managed, that is that the reins were in fact

a little too tight. It made a number of recommendations as to how greater authority could be delegated to the field managers without concern over loss of overall direction and the need to have agency policy implemented nationally in as uniform a fashion as possible. It was quite critical of the way in which the field was being managed at the time, and as we've said I think several times already in this interview, later, when changes were made under Dr. Goddard, one of the first things that he did was to make the change to give greater authority to the field offices.

The second interesting aspect to that study was a series of recommendations on how best to begin to implement the 1962 drug amendments. You'll recall the implementation of those amendments required that the agency begin to review for proof of efficacy the whole range of drugs that had been approved prior to that time based solely on safety. That ultimately became the so-called Drug Efficacy Study Implementation, or DESI.

But an interesting recommendation that was made right following the passage of those sixty-two amendments, and in this report, was that the Food and Drug Administration should use the short-term commissioned officers of the Public Health Service as an adjunct to the FDA staff for reviewing these NDA's. You'll remember at that time, as part of a means of serving their obligation under the Selective Service System, physicians and pharmacists could join the Public Health Service in lieu of being in one of the arms of the service and fulfill that obligation. So they would be in the commission corps for two years or so.

There were a number of recommendations of that kind, and to the best of my ability to pursue them, that is to see what happened at the time the report

was submitted, there was no evidence that any of them were given any serious consideration for implementation at that time. Interestingly, when Dr. Goddard came on as commissioner in 1966 with what I think, looking back, was a mandate for change in the agency, he brought with him a number of senior staffers that he had worked with at the CDC, that is the Centers for Disease Control.

FL: At that time, I believe it was the Center for Communicable Diseases, wasn't it?

JH: Yes, you're right. It was only later that they changed the name. Thanks. I've become so accustomed to now calling it the Centers for Disease Control, which has been the title of the group for the last three or four years, it's hard to get out of that.

FL: I think they used the initials CDC so it was Communicable Disease Center.

JH: Yes. One of those persons was Ed Turk, who became the assistant commissioner for planning. When Ed came on board and learned that the Booz Allen study was beginning and became involved in it, he learned of these studies as well, and asked that I provide them to him. Even though one can be critical of the way in which Dr. Goddard came into the agency and made the changes he made in its organization and staffing and programs, one must admit that a number of the things that he did, or that were done by members of his senior staff certainly with his concurrence, were to implement the good, solid recommendations that had been presented to agency management some several

years before and just set aside. And the interesting thing was that on a number of those studies, as an example the one by Art Davis and his colleague, there would be a little note at the top: "Good study. File" with Commissioner Larrick's initials, and no indication in the file itself that there had been any serious consideration of the study and to accept or reject any of the recommendations.

Looking back, it's a disappointment that they were not given more serious consideration in the early 1960s, and some of those recommendations implemented, or at least pursued to the extent that it was demonstrated that they were not appropriate for implementation. It might well have been that the later traumas of 1966 and '67 under Dr. Goddard might have been avoided, at least some of them.

Ten years later, when I began to think about the agency as a whole by virtue of being then the associate commissioner for compliance, I sought to draw together again all of those studies to see what might remain there in the way of good ideas or at least considerations that had been reviewed and set aside. Because you'll remember that we were in the middle '70s continuing in a time of transition with changes in commissioner, and we were beginning to implement the reorganization of Dr. Edwards. And I asked Bob Bell in the Division of Management Systems if he could pull those together for me. But we were never able to find them all or resurrect them all, and I never did again find the Senate study or the study by Art Davis. They had just somehow gone by the wayside during that ten years. I don't know how hard we ought to work to try and run them down, but it's something that Suzanne White might want to put in the "nice to do" list sometime.

RP: Yes, because they're almost for sure in the archives somewhere.

JH: Yes, because there would have to have been more than just one copy of it around, although I think I had in my hand in 1966 the commissioner's copies.

I suspect it's appropriate to now focus on the change from the commissionership of George Larrick to that of James Goddard, because that took place right about the time that the kinds of things that I've been talking about took place. As I look back at that particular time of my own experience and that of the agency, most significant was how abruptly the change took place and how drastic the changes were, and even in the view of some, how ruthless Dr. Goddard and his lieutenants were in bringing about these changes.

There had been a number of rumors around the agency and expressions of concern for some time. I was not in a position then to know whether there was any substance to them or not. And certainly I was not privy to what was happening in the immediate office of the commissioner in those days. But there were strong rumors that Senator Humphrey was not happy with the way in which the agency was conducting its affairs. He had been so much in the forefront of what was happening in the Senate, at least in those few years before 1966, that people were not surprised, I guess, when Mr. Larrick retired and Dr. Goddard came on board.

No one knew what to expect, exactly. Nobody knew him very well, at least at my level in the agency. And it was only as we began to experience the kinds of things that Dr. Goddard implemented did we begin to get any sense of the individual at all. I remember, and I've mentioned a couple of times already,

I think, that one of the first things that he did was to begin a series of meetings with senior staff, and then later with division and branch chiefs to be briefed on what was going on within the agency. And in my own experience, you'll recall within just a day or so of the briefing, the decision was made to abolish the unit of which I was a part.

The same kinds of results seemed to be evolving from all of those meetings. I think perhaps by now, within a few weeks, Allan Rayfield had retired. Fred Garfield was acting as the director of the Bureau of Regulatory Compliance. Reo Duggan was close to Fred, and they would go down and have these long sessions with Goddard and others. They'd come back, then, and call staff meetings of their own because they'd be getting all kinds of assignments to begin to undertake studies or initiatives to begin to do things differently and to restructure what the agency had been doing.

I remember in one instance they came back and Goddard had raised a topic of how we would approach the inspection of a segment of industry and how we might bring about change in that industry. Dr. Goddard characterized an approach that he thought had considerable merit, and had sent Fred and others back to give consideration to. That was what he characterized as a wolf pack. He suggested that a segment of the industry be selected and problems be identified and the entire field force of investigators just be turned out against that industry with a view to bringing that industry into compliance with our requirements. And I suspect, then, as you begin to look at what later evolved as the Intensified Drug Inspection Program, although I guess wolf pack might not have been exactly the way to best characterize it when it was ultimately implemented, certainly it was the concentration of a large amount of resource

against a single segment of the industry we regulated, and that resource was left there until the problem was solved, or at least appeared to be solved.

Also, they began to look at our procedures. And it seemed as though the policy that they were implementing was that if it was a part of the old Food and Drug Administration, it was bad and should be done away with. And you remember it was within a few months that they began to do away with long-standing regulatory tools like the Regulatory Procedures Manual and the Regulatory Management Notes—all of those kinds of useful, precedent-providing mechanisms. The Abstract Index—those kinds of useful, beneficial enforcement tools began to disappear because they were taking people away from those activities and putting them elsewhere without any concern as to whether they were worthwhile or not.

RP: And without supplying any substitute mechanisms for transmitting policy to the field.

JH: That is correct. And the fact is, you will remember there was a long period of time that there was no mechanism at all and nothing went out. And only then, after Sam Fine became the associate commissioner and I was the EDRO did we begin to try and resurrect some of those mechanisms, beginning in the early '70s. It was only within a few months of my leaving the agency in June of 1986 that we were ultimately able to get the Regulatory Management Notes system back up and going again. And it seems incredible, just as an aside, that it would take that long. But on the other hand, those systems or their predecessor's systems, had been in place since 1907, I suspect. And I

commented how abruptly the changes were made; all of a sudden they were just abandoned. I guess you just don't step back and get those kinds of things started again overnight. I can only hope that the agency will never go through that kind of an episode again.

Everything that was traditional and almost sacred to the agency seemed to be fair game. In the program area, many of us remember as an example the directive to step away from and forget the traditional sanitation work. It perhaps has been mentioned by others that Ed Turk, in one meeting that many of us remember, said, "We don't care if the inspector's walking through rodent pellets knee-deep. That's not our interest; that's not our concern." Our focus by then had been turned toward bacteriological contamination of foods. I guess none of us would argue that it was not inappropriate that the agency begin to concern itself about bacteriological contamination of foods; but it was the way in which the changes were made that seemed so significant.

It was true of all of the work we were doing as a part of implementing the drug amendments as it related to medicated feeds. You'll remember, he just said, "That's an economic problem; we're not going to do that anymore. We'll let the states do it." Well, of course, the folly there was that if the states thought it wasn't important to Food and Drug Administration, it wasn't important to them, either. And there was a long period of time during which nothing was done in the area of medicated feeds. I think that although one can agree with Dr. Goddard that the bacteriological contamination of foods is an important issue for the agency to be concerned about, and that continues to be demonstrated as of today, his decision that medicated feeds represented only an economic problem was clearly a mistake and a failure to perceive what the

real concerns were, the residue problems. And the agency has had nothing but trouble in trying to regulate that part of the industry ever since. But the rapid switch away from what we had been doing, the abandonment of our traditional program priorities and all was very traumatic for all of us.

I remember one of the first things that Goddard attempted to do after he had been there awhile in regards to enforcement policy, though, was to pull together a statement of his regulatory philosophy. Do you remember that? It really wasn't a very good policy and that whole initiative began to focus on individual procedures and the changes in some of those procedures. But it was at that time that we began to move away from using the citation for warning. You'll recall the Reo Duggan memorandum that spoke directly to the change in policy to no longer use the citation process as a means of warning industry of our concern, but rather said if we're going to use the citation process, we'll use it as it was intended originally, at least from the viewpoint of Dr. Goddard and others--as a sincere commitment to go to trial if we didn't have information presented to us sufficient to change our minds.

And we would use other means of warning the industry. One example was that he suggested to the field managers that if they had problems with a firm, as soon as they had that information in hand either from an inspector or from sample analysis, they ought to pick up the phone and call plant management or corporate management and advise them of the problem, call them into a meeting where they would sit down and attempt to resolve the matter right away and get correction made.

This was the beginning, too, as I remember, of our extensive use of letters. If you couldn't get them on the phone or if it seemed more appropriate to put

the matter in writing, send them a letter. And I think what evolved from that was what we first began to call the post-inspection letter. And of course, in the intervening years, we have a wider range of letters.

A number of things that we began to do then, although on longer experience not unreasonable ways of dealing with the industry when we have a problem, were so dramatically different from what we had been doing. It was in a sense just administered by gavage, I guess would be the best way to characterize it. It was very objectionable to the rank and file. We saw men whose entire careers had been spent with the agency demoralized, belittled, pushed out of the agency; we saw organizations, some that had been just recently created as a consequence of the Second Citizens Advisory Committee, almost arbitrarily abandoned; we saw individuals who had not really had an opportunity to prove their worth, or even in some instances with reputations that were not as sound and solid as those that were being replaced, at least in our view, being elevated into positions of prominence and given responsibilities that seemed way beyond their means.

Goddard was an interesting person, from my viewpoint, as well. I think he had a more than usually large ego. I think it's necessary for a commissioner of Food and Drugs to be somewhat egotistical. It's a tough job and unless you have great confidence in yourself, I'm not sure you could perform adequately. But I think Goddard's ego needed to be regularly fed. And he brought close to him as intimate advisors, persons that I think did that regularly, people like the fellow who was his public affairs--Ted Cron--as an example.

I hope it's not unreasonable for me to characterize some of the experiences in the way I am, but when you'd see Goddard walk through and Cron be-

hind him, it was almost like Cron was a little puppy dog running along behind his master, there to do every bidding. I remember one time on a personal matter, my mother-in-law was ill suddenly, and my family and I were caused to get airline tickets on short notice and that sort of thing to fly back to the Midwest. The only thing we could get at the time was first class, so we took it. At that time, our kids were small and when we got down to the airport and in the waiting room, the attendants were very solicitous to us. But all of a sudden, who was there but Ted Cron. The interest of the stewardesses and others in my wife and me was to get us on the plane early with our little children, which is something they traditionally do. But the purpose for Ted Cron to be there early was to let the person at the gate there know that the commissioner of Food and Drugs was going to be on this plane, and to arrange for him to get on early as well. So the interesting thing was, we got on early and sat down in the first class seats that were the only ones available to us on such short notice, and coming on right behind us before anybody else, was Jim Goddard, who got on and walked back to coach and sat down.

I don't want to make more out of it, except it was just kind of typical. For all the rest of us in the Food and Drug Administration, in all my experience both before and after, in those kinds of settings, it really didn't make any difference what you were within the agency. When it came time for a plane to be called, you and all the rest of the people got on at the same time and sat down. But Goddard had to be treated differently. And ultimately, I think his need to be something different, his need to be special, led to his downfall. I'm jumping ahead a little bit, but you'll remember Cron's statement attributed to Goddard about marijuana later. Do you remember that, Fred? It

was attributed to Goddard and I don't remember exactly: that it wasn't so bad to smoke some marijuana now and then; it wasn't really a problem.

FL: My recollection is that he made that statement in a speech to some group on the campus of the University of Minnesota. And he had said this at other places before, that he would not be as concerned if his young daughters used marijuana as he would be if they drank alcohol. But it was picked up there and happened to get on the wire dispatch and was carried all over the country.

JH: I didn't remember the circumstances, and I'm glad that you do remember the specifics of it. It's just that that was an area in which the commissioner of Food and Drug should have never ventured, in my opinion, and certainly not with those kinds of conclusions. You could speak about your concern over the abuse of alcohol without comparing it, necessarily, to the use of another drug.

FL: Especially when another agency of the government, the Bureau of Narcotics, which did have the responsibility for marijuana distribution, had that for one of their priorities.

JH: Yes. But getting back to the early days of Goddard and the impact on our compliance activities, Goddard liked to be perceived, I think, as a very strong and aggressive enforcer. And I suspect, if you teased out only what we began to do in regards to salmonella contamination of foods, or the way in which we approached the Intensified Drug Inspection activity, that's not an unreasonable label for him.

On the other hand, stepping away from the use of more formal notification of firms' problems; picking up the phone and calling the managers in for a meeting instead of having a seizure; ignoring sanitation; relegating economic issues to very low priority--I think for the most part, and in the field particularly, he was not viewed as a strong enforcer. It was an interesting dichotomy that existed within the agency as it related to Goddard.

FL: I don't think we perceived it at the time, but in hindsight, perhaps it was a step toward the Food and Drug Administration assuming the responsibility for telling the industry exactly what it had to do to comply with the law. For a long time prior to that, our attitude, I believe, was, it was their responsibility to find out what the law required and to do what it did require. But with this kind of campaign of direct intervention, we were taking on a responsibility for telling them how to run their business.

JH: Yes. And as I look back at that time, Fred, I'm not sure that Goddard and his immediate staff were conscious of what they were doing. I don't know whether their motivation was just to bring about change, and any change was their objective, or whether they were in fact conscious of an effort to move the agency more into what I think in later years has become characterized as a public health attitude--prevention--as a dimension of the Food and Drug Administration's responsibilities.

Now the Congress had pushed us that way a little bit with the 1962 amendments, because as a part of that, the concept of Good Manufacturing Practices evolved. And of course, I'm not sure that Congress had all those

ideas themselves. I'm not sure that Mr. Larrick and his administration might not have been instrumental in crafting some of that language, even, working with staff. But certainly, even though the agency might have been moving the direction of providing increased guidance to industry in regards to what we expected, Goddard and his associates just pushed us off the deep end, and we started thrashing around in the deep end of the pool.

FL: That was the philosophy that was being taught at that time in all of the schools in public health. And it was in many places the philosophy under which local and state health departments operated and still do.

JH: Yes. Well, and with the Food and Drug Administration becoming a part of the Public Health Service in the late '60s, then we too began to look at our programs from that viewpoint, and as of this moment talk about prevention as a primary objective of the agency. GMP's, that is, Good Manufacturing Practices regulations, in foods, drugs, devices, medicated feeds; Good Laboratory Practices regulations; a full range of guidelines on how to interpret the regulations for the submission of new drug applications; pre-market applications for devices; the so-called Redbook as guidance to the industry on submission of food and color additive petitions--the regulations that we've issued in the last fifteen years has increased the 21 CFR from probably two volumes of maybe 300 pages to I think most recently eight volumes of over 1,300 pages. I'm not sure all of that is necessary in looking back, but certainly these years have become years of being much more explicit as to what we expect of industry.

But that gets us into other things, and maybe I need to just mention briefly that it was not only the Food and Drug Administration being pushed and maybe dragged kicking and screaming into the Public Health Service and into the mindset of the Public Health Service that caused these changes to come about; but at the same time, there were strong forces government-wide through the Administrative Conference of the United States to bring about a change in the way government agencies administered their various statutes. And later, when we talk about my own experience with Peter Hutt and the contributions that Peter made to the agency, we just have to talk about the fact that Peter, in the same fashion, catapulted the Food and Drug Administration into the modern age of administrative law.

And so there was no one single force impacting on the Food and Drug Administration through those years 1966-1976. I guess I'll have to be a little philosophical now and say that except that the agency was as strong and viable as it really was down deep inside, and I think continues to be, it would have never survived that period of time. I think it could have easily disappeared, and we might now have food programs in the Department of Agriculture and Vet-Med programs in the Department of Agriculture. Who knows where the Food and Drug Administration might be, because as we all know, really, there is no Food and Drug Administration formally. I just think that notwithstanding its faults--and it had faults--and notwithstanding the values of the new ideas, many of them brought by Goddard and others in those later years, the Food and Drug Administration was a strong, viable, committed agency. It's interest was the consumers' interest. And it was that strength that allowed it to literally stay alive through all of those very, very difficult years.

Talking about abrupt changes, Goddard's departure was abrupt. And within a year or so, Dr. Ley's departure was abrupt. With the change in the way in which commissioners were selected from focusing more on either career or at least officials that were already within the government, like Dr. Ley, to drawing the candidates from outside the agency in 1970—we've had a series of changes. And I really do believe only a very strong agency with a very strong foundation could have persisted, and be the kind of agency it is today.

My own job responsibility during the early period of the Goddard era was principally that of being the project officer for the Booz, Allen and Hamilton study. And so on the one hand, I was not party to a number of the operational changes or having to implement some of the operational changes. On the other hand, I was in a position to be sensitive to what was happening, get the reaction of people that were being impacted upon by them. And then my office—not my physical office, but the office to which I was assigned early in the assistant commissioner for administration, and later with the field liaison officer—allowed me to be up and around the commissioner's office quite often, or have reason to meet with other members of the commissioner's staff as part of the Booz Allen thing.

The dramatic changes in a sense continued along through most of Goddard's tenure as commissioner. But perhaps they were a little more subtle and the changes weren't quite as frequent in later months. But I'm thinking, as an example, bringing Paul Pumpian in to be the director of Legislative Affairs and combining the Federal-State Relations activity with Legislative Affairs. It was about then I think that Glen became the Director of it under Paul. And they brought Larry Pilot in. Remember Larry came in and nobody knew exactly

what he was supposed to do. He acted for a while as a special assistant. But ultimately, he worked his way back into the Legislative Affairs side of the house.

So you had new faces coming on, and you didn't always understand where they were or what their objectives were. There was another fellow that was in the public affairs office in addition to Cron . . . Remember he was an older fellow and he became ill and I think later died of cancer. I just can't remember his name. But what I'm saying is he was from outside the agency. And Lannon was outside of the agency. Turk brought in people onto his staff. There was a fellow that came in later. He succeeded Turk as the assistant commissioner for planning. I can't remember his name.

FL: It was a French sort of name. He spoke with a British accent. Grandpierre.

JH: Yes.

FL: You wouldn't want to forget Eric Stork.

RP: I wouldn't let him forget Eric Stork.

JH: Well, that's right, and Eric Stork. You could look throughout the agency, and those kinds of things were occurring and continued to occur. In the field, from my perspective, you had a number of individuals who you sensed had just been out there chomping at the bit for an opportunity—some of them; not all, but some of them—to jump in and take a leadership role in the field, but had

been held down by the individuals that had been there for long years and had held those positions for a long time. And a number of them jumped into the breach and took full advantage of their reporting now directly to the commissioner. Not that that was necessarily bad, but it created a different atmosphere as well. Persons like Weems Clevenger, as an example.

You'll remember that one of Goddard's ideas, or his staff's ideas, which was really not a bad one at all and stayed with the agency for some number of years later, was to establish the Executive Development program. But if you focus on that first class, it was a group of individuals that represented a different basis on which to choose the potential leaders of the agency. One of the things that Goddard did was create an undercurrent that the inspectional side had been too prominent in its influence on agency affairs all through the years, and that it was about time that science and scientists began to take a leadership role in the management and direction of the agency.

That first Executive Development class, which was a six-month class, you'll remember was composed of Sam Hart, who'd been chief chemist at Cincinnati; Don Healton, who was chief chemist at Kansas City by then; Curtis Joiner from Atlanta; not a scientist, but certainly a different kind of person than ever before, Maurice Kinslow, who'd been head of the Legislative Affairs. And I think I mentioned earlier there was a fellow whose last name was Kelly, but was a doctor out of the old Bureau of Medicine. So you had a different group of people there who were identified as the future leaders of the agency.

Then you had some people evolving and emerging who were different in character from a number of the older people. And you began to see an initiative taken to move out and replace a number of the older persons who'd been in positions for some long period of time. At the time, the Food and Drug Administration was not required to configure itself to meet the departmental nine regions. But Goddard, because, I suspect, he'd been more familiar with the regional concept by virtue of having been a part of the Public Health Service--and many of the Public Health Service programs were administered through the regions--saw an opportunity to extend the agency into the regional program, and also an opportunity to move some people out of positions. They established that regional assistant commissioner job. And they began to move some people into those positions: older district directors, some branch chiefs, some division directors from headquarters.

It was clear that the primary purpose was to open up those positions, that is, the ones that these individuals vacated, for new appointees. Nevis Cook went to Denver, and at the conclusion of the program, Don Healton went to Boston to replace Cook. George Sooy went to Charlottesville to the regional office, and Maurice Kinslow replaced George at Baltimore. Some of the persons I suspect said, "I'm not going to take that kind of a move." Retzlaff, as an example, in Buffalo, did retire, and Curtis went to Buffalo. Guill went from Chicago to San Francisco and Sam Hart went to Chicago to replace Guill. Remember the fellow that went to Dallas was in the Federal-State program.

RO: Bill McFarland.

JH: Bill McFarland. And that was at that time when Pumpian came on and Glen moved in and Bill McFarland went to Dallas. And subsequently, although not as quickly, some of the other older managers like Ken Monfore and McKay McKinnon and Gordon Wood began to retire.

FL: Wood and McKinnon did not retire until after Goddard had left.

JH: Well, I've forgotten exactly when that was, but don't you think . . . It just seemed to me that they might well have retired anyhow. Certainly they were both at retirement age or past, but it was just that kind of a momentum was built, and it just seemed that they may not have otherwise retired. Maybe they would have. I don't know, Fred.

FL: I knew them both well. They both realized what was happening, and both of them singly and in concert made no secret of the fact that they intended to outlast Goddard, which they did. Neither of them retired until well after Dr. Edwards came.

JH: Well, I was just thinking of Monfore; and Pruitt, of course, had been ill for so long.

FL: For the others, there were efforts made to push them to retire, but they refused to do so.

JH: What I was remembering, and not as accurately as I should have, is that Goddard ordered a bunch of plaques for a number of those individuals. There was a plaque for Monfore; there was a plaque for Pruitt; who else was there a plaque for? It was clearly a "sop" to "honor these people for their years of service" and that sort of thing; and those men wouldn't accept those plaques. And I carried those around in my office supplies for years. For a variety of reasons, I didn't have the heart to throw them away, and I didn't know what to do with them. And I finally--I don't remember exactly when it was, maybe as recent as when I moved from up on one side of the commissioner's office down the hall to the other side; that would have been maybe five years ago or so--I finally just wrapped them up and took them home and then put them in the trash at home. I would not throw them out there.

I guess that whole period of time, those men I had known and respected, even though some of them were more difficult to get along with . . . Like Gordon, you know, he wasn't an easy guy to get along with, from my perspective. But I just remembered them, and it just seemed to me like when Goddard came on, that whole era of managers started to change. When I think about them leaving, I think about the whole process starting under Goddard, although, as you say, I remember that McKinnon received the Award of Merit at the first awards ceremony under Edwards, now that I've focused more directly on that. And he was characterized as the dean of the district directors at that time.

RP: We had a dinner party for him at that time, I believe.

JH: Yes, we did, at Blacky's House of Beef there over in Northwest.

RP: I was telling Fred about that assuming that he had been there; but it wasn't at a time when all the regional directors were in there.

JH: No, it was in relationship to that ceremony rather than . . . We later had a dinner up at the Rib. This really isn't germane to the interview, I guess.

Some of the other changes that occurred at that time were, Ken Lennington was assigned to Ken Kirk's office, the associate commissioner for compliance. Ken was identified as the Salmonella Project officer. Reo Duggan went with him to the associate commissioner's office. But then so did the Field Science Branch that had been part of the old Division of Field Operations. Fred Garfield had been acting as the director of the newly constructed Bureau of Regulatory Compliance, and he left to become the deputy of the Bureau of Drug Abuse Control. Al Barnard who'd held that position swapped and came over and became the director of the Bureau of Regulatory Compliance.

I remember as an aside, Al carried a BDAC badge, being a member of the Bureau of Drug Abuse Control, and it was a fairly large badge, certainly large as compared to what the Food and Drug inspector historically had carried and was still carrying, the small badge. And I think it was that influence, because Al was not reluctant to flash his big badge . . . I remember he flashed it in the first staff meeting (laughter). He called all those guys together, you know, Ted Byers and Taylor Quinn and all that crew that was part of the old Division of Case Supervision which became the Division of Case Guidance because that

bureau didn't supervise anything in the field. Al was showing them how big his badge was. Of course, later we got larger badges ourselves.

I'm trying to think of some of the other changes that took place during that period of time.

FL: Lee Cline left very suddenly.

JH: Yes. The fellow that was running the Vet-Med program—what was his name? He left about that time as well, too, didn't he? I can't remember his name, either, offhand. But there was quite a shakeup in the science side of the house, and that's when some of the persons that had been actively involved in the Public Health Service science programs joined the agency. Keith Lewis came into the agency at that time. And Angelotti came into the science part of the organization. There were really major changes.

The district directors would come into meetings, and I remember that at a lot of those meetings they were talking about major changes in the programs. I remember the pesticide program came under some considerable criticism by Ed Turk. Because I can remember in one meeting Sam Fine standing up and arguing strongly that there was a need for a strong pesticide program, at least in Dallas. And Irv Berch used to like to get into discussions, I think, with Ed Turk over the statistical significance of matters. Those were different kinds of meetings than any of us had been accustomed to in the past.

RP: I recall at Sam's insistence, a decision was made at one of those meetings that we would put a little more manpower into the pesticide program. And it

was of course my job, then, to go back and add the manpower and distribute it out to the districts. We made a little mistake in calculation and Sam Fine, who spearheaded the whole thing got less manpower than he had before (laughter). We had to correct that.

FL: There was a lot in the field, too. There was the emphasis on industry education, GMP seminars, and things of that sort.

JH: Yes, that's right, Fred. In fact, there was a major program of seminars. The districts had to build into their plans formal projections for seminars. I remember that. And we focused so heavily on salmonella in foods; you'll remember a major initiative in the dried milk industry; a major intiative in the yeast industry; we got into the gelatin industry; we began venturing into the animal feed industry, rendering plants specifically. I remember one time, Fred, I don't remember exactly the circumstance, but it was you I know, that we were talking about trying to eradicate salmonella in the rendered animal feed business, and you characterized that as an effort like trying to sweep away the ocean with a broom.

Ultimately, later, in the early '70s, after Goddard was long gone, it was under Virgil Wodicka in then the new Bureau of Foods, and his chief of compliance by then was Bob Angelotti . . . They were discussing the reasonableness of requiring that the bulk containers used to ship rendered animal feed around the country be sanitized. That was kind of the extreme to which that particular program ultimately went before things turned around a little bit, and although Virgil knew the human food industry real well—he'd worked I think for

Hunt Foods . . . And I don't know whether Angelotti had any knowledge of the food industry or not. But they sure didn't have any understanding of the farming business or that sort of thing. This is digressing a little, but they were thinking about publishing good agricultural practices regulations to regulate the way in which unshelled corn was stored on the farm.

FL: It was the rendering plant problem, that aspect of the salmonella, which was an important one, because it was a vector that carried salmonella to the food animals. Nobody seemed to recognize that rendering plants are really a service industry to the cattlemen. They operate on a marginal profit, and if we required, oh, sterilization and modernization of their equipment, they might well go out of business and leave the cattle-feeding industry and the cattle-raising states with no place to dispose of the 5 to 10 percent of their steers that die normally in the feed lot.

JH: Well, and then all of the waste from the slaughter business. That's right. Well, Goddard really did bring about some major changes, and I often think about what might have occurred had Goddard become the director of CPEHS. Now I suspect he would not have been able to override the strong national move, and in Congress the move to establish the Environmental Protection Agency. With that having been created, so many of the environmental programs that were part of the CPEHS organization would have gone ultimately, anyhow. But it would have left Goddard still with perhaps becoming under those circumstances the surgeon general and maybe even the assistant secretary for health. No telling what might have happened. There might have been other

names on that list of people who were caused to leave the agency or decided to leave as a consequence of their own decision (laughter).

We named some of the people that went to the position that was created, the regional assistant commissioner position, but we didn't name Doug Hansen, who had been the director of the Division of Field Operations in the Bureau of Regulatory Compliance. And then with that major shakeup, he went to Chicago. I'm trying now to focus on some of the other changes that were in the Bureau of Regulatory Compliance. Eric Stork came in as the deputy from outside. They created the Division of Planning and Evaluation, and Mary Dolan was selected as the director of that division. I guess Ted Byers became the director of the Division of Case Guidance.

FL: Both of them were from New York.

JH: Yes. Ted, remember, had that period of time when he'd left the agency and then had come back.

RP: There was a period in there when Doug Hansen also had a division. I was in that division. I can't think of what they called it; I'm sorry. Something about program something.

JH: The Division of Program Analysis, DPA, wasn't it?

RP: Could have been. I don't know; I've really forgotten.

JH: We'd have to look for sure. That's right. Because I remember that was particularly true in those early months when we were changing the field data system over to a program oriented data system, literally the PODS.

RP: It was a very difficult time for me because I had the responsibility for doing that. But I was in Doug's division and Doug and Al Barnard had a history of not getting along with each other, and it made it extremely difficult for me at the working . . . Really, I was the one that had to produce what the division was doing with a lack of support because of personalities.

JH: Well, and that was also made it more complex for you because they were actively recruiting for a branch chief and you were acting as the branch chief, and it was clear that you were not going to be the branch chief. Because that's when they were interviewing that fellow that came on board, but later went out to the Bureau of Standards. Remember who I mean?

RP: Yes, he was a statistician, Peter Finkle.

JH: And I think he's still out at the Bureau of Standards.

RP: But he was being recruited to take Doug's place.

JH: Was that Doug's place he was being recruited for?

RP: Yes. He wasn't going to take my job. I was going to be working for him instead of working for Doug, and I in fact did when he came. And that's when Doug went out to be an RAC.

RO: Well, later he came and did some work for us.

JH: Yes, on contract, I remember that. Because he's part of a . . . He may not be there; he was really begging for money, because it was part of the Bureau of Standards program that was supported solely by outside contracts. And when they didn't get any, why, of course, that went by the wayside.

RP: He didn't get along with Eric Stork. I operated during that whole period in a division that had severe personality conflicts with the bureau office, and found myself many times going over my division director's head simply to get things done and going directly to the bureau, because I got along with them. I could even get along with Eric Stork, with great effort. And Al Barnard and I got along fine. That intervening division director was never a satisfactory situation.

JH: My whole focus was--because all through this time, I was the project officer on the Booz, Allen and Hamilton study. I had to bring that contractor in periodically to make presentations on what was occurring. And it was a most disruptive time. I can remember, and I've mentioned before the situation when Goddard, in a meeting, was so critical of what Booz Allen was doing, and Booz Allen was so adamant that they were doing exactly what they'd been

contracted to do, that ultimately Booz Allen was threatening to sue the agency for breach of contract. I was caught right in between that whole matter, and by that time I remember I had been assigned to the Field Liaison Office with Harris Kenyon. Harris's office was right next to Winton Rankin's, and there was a door between them. And every once in a while, if I was sitting in there for Harris . . . It was a very small office in number of staff and if Harris was off somewhere, I'd sit in there. For a long time, it was just three of us--Harris, his secretary, and myself--Winton would stick his head in unanounced. He'd just open the door and stick his head in and come in and see what was going on. And I remember on one occasion I was so distressed over that whole mess that I was filling out my 52 to kiss the agency goodbye (laughter). So Winton had me come in and we sat and we talked for a while. And Winton counseled me, advised me that "even that would pass," and I didn't resign from the agency. But ultimately, even in that very, very narrow job responsibility, things became so hectic that it was intolerable.

And that whole atmosphere, in my own opinion, prevailed in just about every office within the agency at my level, which would have been the GS 13, 14 level. Because we were continually being buffeted from one extreme to another with changes in policy, and of course our security of the old traditions was taken away from us. You never knew what to expect from persons like Ed Turk and Ray Lannon and others as far as what they would recommend. You felt in jeopardy all the time. It was a terribly, terribly difficult time.

Things were moving so quickly. I mentioned Al's big badge. We ordered badges for the agency, and we ordered them in anticipation of being part of the Consumer Protection and Environmental Health Service. The badges had

FDA across the top, Consumer Protection and Environmental Health Service across the bottom, and Public Health Service on them. And by the time we got the badges, by the time they were designed, ordered, made, and delivered, the Consumer Protection and Environmental Health Service had come into existence and gone out of existence. And so the manufacturer of the badge worked with us, and that's when that little piece across the bottom of the badge, kind of a ribbon effect, with FDA on it was designed and they slapped (claps) that over the top of the Consumer Protection and Environmental Health Service.

RP: No clapping within six inches of the microphone (laughter).

JH: (laughter) Sorry. I was not in a position to really have any understanding of how or why Dr. Herbert Ley specifically had been selected to become commissioner when Dr. Goddard left. He was not known to us well at all. It turned out that he was not a difficult man to work with or deal with at all; in fact, he was a very pleasant person to be around.

He had some interesting little idiosyncrasies. For instance, at a meeting, he always set the time of the meeting at the time the meeting began. And he had one of those little half-round kitchen timers that are popular still; you can buy them where you buy things for the kitchen. And he'd turn the time on that and set it up on the table. So all during the meeting with him, that little timer would be sitting on the table going tick, tick, tick, tick, tick, tick, tick, tick, tick, you know. And when the alarm went off, that was the end of the meeting. It didn't make any difference whether you'd completed your session or not.

Looking back at a lot of meetings I've been party to, maybe that wasn't all that bad (laughter).

But he was not a difficult person to deal with. But he really had no knowledge of the agency, and I think in the few instances that I had to work directly with him, for instance, as we began to consider implementing the recommendations of the Booz, Allen and Hamilton study, I never sensed that he really had a full, keen understanding or was willing to take the time to really gain a complete understanding of those issues. Now, that might be unfair, and clearly, I would have been biased in those meetings. I'd spent two years of my life as the project officer for that study and felt like the only soul in the world, let alone in FDA, that was at all supportive of some of those recommendations, and that I had to all by myself fight everyone else who was agin' it, just because it was Booz Allen. Booz Allen's reputation during that period of time was not good. And as a consequence, their study was not good and their recommendations were not good, regardless of whether on objective analysis they had merit.

I remember only a few things about Dr. Ley during that period of time that he was commissioner. And they're little things like his adherence to strict time frames during meetings. The one meeting that's most fresh in my mind yet is the meeting in which, I mentioned earlier, Charley Coffindaffer made a presentation on the computer system necessary to support the Booz Allen study. And I know Dr. Ley just concluded it was too expensive and we just could not do it. I can remember a few staff meetings which he chaired, and the one, of course, that left the most impression was the one in which he announced that he was being replaced and Dr. Edwards was coming on board. He, to me, even

more than, say, Jere Goyan, who was commissioner for about the same length of time, came in and was commissioner for a period of time, and leaves the least impression on me as commissioner.

FL: Of course, he became commissioner under difficult circumstances. Goddard had abruptly retired, and he became commissioner at the same time that we went into the Consumer Protection and Environmental Health Service with a new overlay of direction and management. And less than six months after he became commissioner, there was a national election in which Mr. Nixon, a Republican, became president, rather than the Democrats who had been in power. So a new secretary came on of a different political persuasion. So all in all, there were a number of problems within his first six months that probably occupied the bulk of his time rather than trying to manage the agency, although he had only a limited knowledge of us, because he had been only with the agency as Director of the Bureau of Medicine since Goddard had become commissioner.

RP: The political climate was such that from the very beginning he knew he was a short-timer, and that's bound to affect anybody's performance on a job, I think.

JH: I suspect so. And you need to be fair to him, and I don't mean to be otherwise. It's just that as I think back, of the commissioners that were commissioner during my tenure in the agency, Herb Ley is the least known to me. I know those were difficult times for him, without question. And it just

happens that for whatever reason, the kinds of things that Herb was doing and was involved in for the most part did not involve me nor the people that I was working with and in association with. You just don't remember him as being actively involved, particularly in field affairs, field activities, and that was where my focus was at the time.

FL: Well, by that time you were working with Harris and the Field Liaison Office. Pretty soon Harris left for CPEHS, and Sam came in when?

JH: Sam must have come in about January or February of 1969, along in there somewhere.

FL: So for a while, you were the Field Liaison Office.

JH: I was, yes. But not much was happening in that time. I guess, really, my best understanding of commissioners, from the perspective of having an opportunity to work directly with them as commissioners, started with Charley Edwards when I became a member of his immediate staff, and when a whole series of new initiatives began again. And as I look back at that last number of months, a lot was happening with Sam and myself. We mentioned earlier the assistant commissioner for field coordination position was established in that short period of time. The Field Science Branch that had been in the associate commissioner for science's office, Danny Banes's office, came into the ACFC organization. The Inspection Branch under Don Martin had been in Ken Kirk's

office, in the associate commissioner for compliance's office; it came into that organization. Bob, your branch of Planning, that had been in the . . .

RP: The DPO, I believe, the Divison of Program Operations.

JH: That's right. The Division of Program Operations in the old Bureau of Regulatory Compliance. Roy Keeney and I from the Field Liaison Office came in. I remember, I guess we were looking inward. We were building an organization anew that was beginning to assume greater responsibilities over the day-to-day affairs of the field organization. And that was so challenging and so exciting, at least for me, that you didn't necessarily know what was going on outside. You knew that there was trauma outside, because that was the period of time when persons like Leroy Gomez, who had been assigned to planning under Vaughn Choate, were just as unhappy as could be. And there were other circumstances like that vibrating around. Mickey Moure had moved in and become the assistant commissioner for administration. And of course, so many of the people that had been a part of the Goddard Administration were leaving.

I know that in the field things continued to go on, day in and day out. Inspections were being made, samples were being collected and analyzed, and all of those kinds of things. And some difficult things had been happening through there. Remember the "Spice of Life" episode had occurred earlier, not during that period. But what I mean is, the field was actively involved in matters. Things were going on. But it just seems to me that at headquarters,

especially in the commissioner's office, things were slow. Things were not happening.

RO: Well, under Ley's early days there, why, we had the Kinslow Committee that looked at the agency. Remember the Kinslow Report?

JH: Oh, yes.

FL: I believe that came while we were under CPEHS.

RO: Yes, but it was Commissioner Ley.

FL: But it was an accurate look at the way the agency was operated, and it was intended as a response to criticisms by Congressional committees.

JH: And the early consumers groups. Nader's Raiders were walking around the agency like they owned the place. Well, of course, it was the Kinslow Report that began to focus on the possibility of reorganization of headquarters along program lines. And in a sense, it elevated Maurice into a position of importance and recognition when Edwards came on board, again with the admonition to bring about change. But it's an interesting time for me, that period of time. Between the end of the Booz Allen study and when Dr. Edwards came on board is not quite a black hole, but it was a difficult time for me personally. And that might influence to some extent the amount of that period that I remember.

RP: During all that turmoil we were going through, it was really a great thing that Sam Fine was the one that came in. He was a cool head and a steady hand, and truly knowledgeable. I don't know what would have happened if we hadn't had a man of his qualities in there right at that time.

JH: I don't know, either, Bob, because you can think of some people that you admired highly and liked and had lots of experience in the agency that might have come in or might have been at headquarters and put into that job, and you would not have had that stability. Clearly, Sam brought a stability that was necessary.

RP: He brought a presence that was recognized by the commissioner so that the influence of that group on the commissioner's office was strengthened.

JH: Yes, without question.

FL: Is there a possibility that this period, too, was something of a reaction to the excesses of the Goddard regime which had so drastically changed things, and perhaps a planned effort to restore some central control over the field out there?

JH: Certainly that, I believe, is true of the Edwards time. Whether it began earlier than that, I don't know. Now certainly you could argue that creating the assistant commissioner for field coordination as contrasted to the field

liaison officer, one person, at least in concept, was moving toward a return of more line management responsibility for the field. But from my viewpoint, one can only speculate whether that would have occurred had Herb Ley remained as commissioner or not.

Let's argue that all the changes that you've characterized that brought about the change, and particularly the political change of the moment, didn't occur. Let's say a Democrat went in and Ley stayed on. The field managers, from my viewpoint at that time, enjoyed that autonomy, some of them. The most vocal of them, at least, I think. And I'm not sure Herb Ley as commissioner would have taken the initiative to change that.

RP: Did Sam come in under Ley?

JH: Yes.

FL: There was the possibility that they might lose control of the field because there had been established in the regions a regional administrator of CPEHS, and all of the other CPEHS programs reported directly to him. At this point, there was a sort of dotted line between the regional Food and Drug director and that person.

RP: I don't think Sam Fine would have come in without a pretty clear understanding that it was going to be far more of a job than Harris Kenyon's job.

RO: That's right, Bob. That's what I've heard, anyway, that when Sam was asked to come in, why, he had said "I'll come in, but not as a strictly liaison."

FL: I think it would be most interesting to know exactly the role of the deputy commissioner, Winton Rankin, who was thoroughly convinced that the agency should be kept as independent as possible of CPEHS in the idea of strengthening the field organizations so that it could be directed from FDA rather than from CPEHS. If you remember what happened the first of December of 1969, when Winton made his speech at the FDLI, Food and Drug Law Institute meeting . . . I believe you could characterize the speech as one in which he sought the support of the regulated industry to get Food and Drug Administration out of CPEHS. He laid his job on the line that day. It was a public challenge that they couldn't overlook.

JH: That's right. Well, through that period of time, and then clear to '76, Sam and I became friends. Helen and I would see Mary and Sam socially from time to time. We had any number of conversations about a wide range of topics. But I never had a sense of what the direction of the assistant commissioner's job might have been beyond what it was in those conversations. And it might well have been that Sam had an agreement with Ley and Rankin that over a period of time that position would assume increasing direct-line authority over the field. From a practical standpoint, we exercised it anyhow, as far as the control of money and resources, and we tried our best to represent the field's interests in agency affairs. But the fact is, it continued to be a staff position, and there was still considerable interaction, I suspect, initiatiated more per-

haps on the part of certain directors than maybe the commissioner himself, but between those directors and the commissioner's office. And there were strong, strong feelings of indepedence.

I even sensed in those days . . . Now Sam might have said, "I won't come in except that there's something more in it than just the Field Liaison Office." On the other hand, Sam, I think, when he was at the district office level, was not as outspoken as, say, a Clevenger on the other end of the spectrum. But certainly, I think he was a strong advocate of greater independence for district directors than perhaps others who felt more comfortable for whatever reason with an organization at headquarters giving line direction.

RO: But I think you had a range of the district directors out there from, let's say, a Weems Clevenger down to the others. And then in the middlegrounds, Sam was a good manager and wanted more freedom, but at the same time, living within some maybe undefined parameters.

RP: Sam would have stayed within whatever the organizational structure was at that time. He was a pretty much by-the-book sort.

RO: I can remember some assignments that issued from some of the more aggressive district directors at that time and Sam rescinding them because they were a little beyond what, I think, should have been undertaken. I can remember memos coming out from Sam: "Disregard the sampling assignment from so and so."

FL: And Sam was well respected by most of his former colleagues and trusted. When he called and asked somebody to do something, you knew that there was a darn good reason that it ought to be done. And most of the people in the field would be happy to accept Sam's judgment, because it was again the man rather than the position.

JH: That's right. Absolutely.

RP: He was a no-nonsense sort of man. He became my supervisor for that period of time, and although I'd known him for many, many years since the Denver days, when you did a piece of business with him, that's all you did. You didn't gossip or pass the time of day.

JH: When your meeting with Sam was over, it was over, and he had a way of signaling you, and you left (laughter).

RP: By picking up the next piece of paper in his "in" box and starting to read and paying no more attention to you.

FL: I think that was part of Sam's personality, but it was also shaped by his experience and training in the navy.

JH: Yes. You were dismissed. And it wasn't a mean thing on his part at all; it was just his nature.

RO: But you'd better get it the first time, because he usually didn't repeat those things; I remember that.

RP: He made it clear, you know.

JH: Well, I had the highest regard and continue to have the highest regard for Sam. And of course, I became his deputy during that period of time and learned a great deal from Sam, and a great deal from that experience. And, as I say, as I think about those months between Goddard's departure and Edwards' arrival, my remembrance is most of setting up the ACFC organization and dealing with Sam, dealing again regularly, Bob, with you, putting out work plans, and those kinds of things.

And Fred, you said there was a time of adjustment and slow down purposely maybe, and a time of healing. I always like to characterize the commissioners beginning with Edwards as bringing certain things to the job. And I always saw Edwards as the healer, coming in and healing the wounds of the agency, from my perspective. It might not have been true from other perspectives, but you see, that was the period of time that I was going through the building of a new organization to provide line management for the field. It was a time when I was fighting tooth and toenail people like Henry Simmons, who was campaigning actively and aggressively to take the drug portions of the field program and put them under the newly established Bureau of Drugs.

Danny Banes was an ally of his. Because Danny, if he'd not been successful in pulling the field laboratories into one of the bureaus, would have pulled them into his office under science. I just saw Edwards manage all of that kind

of activity. And there were other strong power plays going on in the agency at that time. He brought them to an end and established the concept of his senior staff meeting and working together to deal with agency issues. This was not the so-called Policy Board. That name was a created by Schmidt.

In my experience, in the period, say, 1964 to 1970, I had not seen a commissioner draw all of the senior staff people together in a room and start to deal with agency problems, and Edwards did that. He would listen to the arguments pro and con for just so long, and then he'd say, "This is the way it's going to be." I recall a matter that was of particular concern to me during that period of time. There was a move to really change the field organization of FDA completely so it would no long exist as we had known it all through those years. In such a situation, he listened to the arguments, asked for memorandums discussing it from the various parties, counseled with persons close to him--Sam I'm sure was one of those persons, because I think he and Sam had a special relationship--and made his decision.

I can remember at a go-away of the senior staff out at the Holiday Inn at Gathersburg, this issue had been raised again. Edwards said, "I've looked at it; I've considered it. There will be no change in the way in which the field organization is structured and directed, and that's all. I don't want to hear any more about it." But he did it in a non-offensive way. And everybody, even though they might not have liked some of the decisions, felt like they'd had an opportunity for their views to be considered.

RO: But it was early in those years, too, Paul, that you had to wrestle with the regionalization of the field.

JH: Sure, and Edwards, boy, he'd fight. We'd go down to the department and he'd yell—I mean, Charles Edwards never yelled and screamed, but he was adamant. He was fighting people like Buck Kelly, who were very aggressive at the regional level, and were reaching to draw all regional programs under their jurisdiction.

Those were tough times, too. But the difference between those difficult times, at least for me personally, and the tough times that existed between '66 and '70 is that the person you had leading the agency was a champion for the agency, and not a champion for himself. That may not be fair to Ley. But Goddard's interest, as far as I'm concerned, from the very beginning, was to further Goddard's interests, and the agency be damned. That was not true of Charley Edwards, and I think was not really true of any commissioner that we've had since, even though their personalities are different and some were more focused on their own objectives beyond the commissioner's job than others. But Edwards championed the agency, protected the agency as it related to the things that I was most intimately involved in, and that was the field organization. This included the outside pressures to take it over and the inside pressures to carve it up and divvie it up, foods to foods, drugs to drugs, and so forth.

RP: Paul, would you clarify your position relative to Sam during this period? Because you've gotten into the Edwards thing without ever quite finishing your discussion of Sam.

JH: Yes, I've kind of jumped ahead. It's hard; it's a continuum, and it's hard to not do that. When Sam came up from Dallas to take over the position, the newly established position, it was my privelege and I was very fortunate to be able to work with him and to be selected by him as his deputy. So I was for that period of about a year, the deputy assistant commissioner for field coordination. When the changeover came about with Dr. Edwards coming on board and persons like Winton Rankin and Ken Kirk and others leaving the agency and beginning to retire, Sam Fine was asked by Dr. Edwards to become the associate commissioner for compliance. The commissioner, at that time, also asked me to become the assistant commissioner for field coordination.

That relationship that I had with Sam for that period of time in the ACFC organization was fortunate, because I think it assisted in the strengthening of the field all during that period of time that Sam was the associate commissioner. Because I had established a relationship with Sam working with him that then continued all the time that I was the EDRO. I felt comfortable in going and meeting with Sam and talking about issues with Sam. We didn't always see eye to eye on matters, and I think there were times when Sam forgot that he was the associate commissioner and not still the assistant commissioner. But I guess that's true of all of us. Those were easily overcome. The field then prospered, I think, in part, because Sam was the associate commissioner, and because Sam and I had had that personal relationship. The relationship that we had with him was very beneficial to us.

RP: I know it's late, Paul, and that seems like a good stopping place. I want you to know that we all thank you very much for your time and for the effort

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RP: I know it's late, Paul, and that seems like a good stopping place. I want you to know that we all thank you very much for your time and for the effort

that you've put into this interview. I think it's going to be a very good one. This ends the interview.