History

of the

U. S. Food and Drug Administration

Interviewee: Donald C. Healton

Interviewer: Robert A. Tucker

Date: June 19, 1995

Place: Orlando, Florida

DEED OF GIFT

Agreement Pertaining to the Oral History Interview of

Doanld C. Healton

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INTRODUCTION

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

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

CASSETTE NUMBER(S) 4

GENERAL TOPIC OF INTERVIEW: History of FDA

DATE: June 19, 1995 PLACE: Orlando, FL LENGTH: 225 minutes

INTERVIEWEE	INTERVIEWER
NAME: Donald C. Healton	NAME: Robert A. Tucker
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FDA SERVICE DATES: FROM: June 27, 1955 TO: January 28, 1994

TITLE: Regional Food & Drug Director - Pacific Region - FDA
(Last FDA position)

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RT: This is another interview in FDA's oral history program. Today, June 19, 1995, retired Regional Food and Drug Director Donald C. Healton of FDA's Pacific Region is being interviewed at the Sheraton-Plaza Hotel in Orlando, Florida. In addition to Mr. Healton, Robert Tucker is involved with the interview.

Don, when we begin these interviews, we like to start with a brief personal history, such as where you were born, educated, and any work experience that you had prior to beginning your FDA career.

DH: OK. At the time I was born, my parents lived in a small house on 63rd Street in Los Angeles. I was actually born in a hospital in Huntington Park, California. We lived in that little house for the first six months and then moved to a house in Montebello, a house that my grandfather had built. He had been a builder in Illinois and moved to California to build houses. Interestingly, he built them with roofs that were designed to shed snow. So it was clearly the highest peak roof in the neighborhood. We lived in that house until I left home. So I went all through school in the Montebello school district through grammar school at Washington Elementary and Montebello Junior and Senior High Schools.

My father ran for school board when I was a freshman in high school and was elected. So throughout my high school career my father was on the school board, which made life very easy for me. A very political school district, so by the time I was a senior, he had been elected as president of the school board, and I always thought the awards I received had more to do with his position than they did with anything academic that I did.

The result of that was that I really didn't work very hard in high school, and when I got to the junior college, I had to learn how to study, because I had never had to study in high school. It was kind of a rude awakening.

RT: What was the junior college you attended?

DH: I went to Fullerton Junior College in Fullerton, California, which is now part of the Cal State system. That is the system of California State Colleges. It's now called Cal State--Fullerton. It was a good school, but it was only a two-year school. It was designed strictly as a feeder into the University of California universities.

While I had been living in Montebello and attending church there, I met a young blonde at the youth group at the church. She was fifteen and I was seventeen, and we began dating then and dated exclusively for the next four years and eventually got married. She also went to Fullerton Junior College, and we would ride back and forth on the Greyhound bus to school from Montebello, occasionally studying, but not often.

RT: How far was the college from Montebello?

DH: It was about an hour drive on the Greyhound. It was there at Fullerton Junior College I learned that my original goal in life to be an automobile designer was not going to work out, because the first few math courses convinced me that I did not have the facility for math required to become an engineer. In casting around for some new goal in life, I concluded that chemistry was so easy that I might as well be a chemist. So I switched my major to chemistry at that point.

RT: Was your father in the automotive business?

DH: My dad was an automotive mechanic. He had originally worked for the Ford Motor Company, and, as a matter of fact, had been not only a mechanic in a Ford dealership, but had been a part of the pit crew for their racing team. They quit racing when their driver got killed.

RT: Automotives was kind of a special interest of yours?

DH: So I grew up with automobiles and working on automobiles.

RT: As I recall, even to this day, you have a rather unique Ford.

DH: Well, I had a unique Ford until I moved south after I retired. I didn't move the Ford.

RT: That was what model?

DH: A 1926 Model-T touring car. In junior college was, I guess, the first time that I ever played tennis. I had to do something for physical education as a part of the California state system, so I played tennis for a while there. I'll come back to that a long time later.

RT: Yes. I believe you have even chosen as your retirement residence Tennis Villa Drive or something like that.

DH: That's right. I do live at the Tennis Villas at Monarch Beach.

When I got out of high school, or as I was graduating from high school, the Korean War was a real thing, and I decided that I didn't want to sleep on the ground. So if I had to go into the military, I would prefer to have a clean bed every night, so I joined the Navy Reserves, thinking that I would never have to go, but at least if anything ever did happen, I'd have a clean bed.

I completed the junior college in June of 1950 and enrolled at UCLA. Actually, I moved into a co-op at UCLA, which later proved to have been the wrong thing to do, because it created some interesting aspects of the security clearance, because they were apparently a communist group or thought to be a communist group. But I was only there for a couple of months, because in October . . . As a matter of fact, on Thursday, October 12, 1950, having just started school in

September, I received notice from the Navy Reserves that I would be allowed to present myself for active duty one month later. So on Thursday, November 12, 1950, I reported to San Diego to the USS Laffey, Destroyer No. DD724, where I was allowed to spend the next two years.

I had signed up to be an electronics technician, so I spent a fair amount of time learning how to fix and repair and play with electronic gadgets, which later proved useful when I started with FDA. But I did go through the Panama Canal from San Diego, then to Norfolk, Virginia, where we finished getting the moth-balled ship back in operation, and then back through the Panama Canal, and then on to Japan and Korea. We spent our time circling in Wonsan Harbor, north of the 38th parallel, in order to provide a safe haven for any pilots that were shot down. They always knew that somebody was there and would pick them up out of the water and take them back to their aircraft carrier. So they did a good job of protecting our position, because they wanted us to stay there.

Occasionally we would see shells begin to walk across the water toward us. The advantage of being on a destroyer was that when you had six 5-inch guns, we had more fire power than they did on shore, and we could invariably silence the gun before they got close enough to us to do us any harm.

From there, we went on around the world, so that I did circumnavigate the world in 1952, which was a useful experience, I guess. Although, crossing the equator was not my favorite part of the trip.

Just before I started that trip, Doris and I had decided that four years had been long enough, and that we just couldn't wait any longer to get married. So we did get married. I wanted to get married on Sunday . . . No. I guess it was Friday. I wanted to get married on Friday. Doris wouldn't hear of getting married on Friday the thirteenth. So she moved the wedding to Sunday the fifteenth. So we were married on the fifteenth of July, 1951.

We then had a romantic honeymoon. We spent one week at Big Bear, and then got on a Greyhound bus and rode coast to coast on a Greyhound bus to

Norfolk, where she spent a couple of months through the rest of the summer with me. Then she had to go back to school. She was studying to be a school teacher. So she rode the bus back across the country; went back to Long Beach, what is now Long Beach State University--at that time, it was Long Beach State College--to complete her training to be a teacher. As I say, I made my circumnavigation of the globe the first time.

Our first wedding anniversary, I was on the Indian Ocean. She had no idea where I was. So it was kind of a difficult first year of marriage. We got back to Norfolk, and then August of '52, I was released and allowed to go home, which worked out beautifully, because I got to join my wife again.

RT: Had you finished your college education?

DH: No. I had only finished the first two years, and I had just started that at UCLA. So I was . . . When I came back, I would have been a junior or entering my junior year again. But I didn't have any money, and I had a wife to support. So I worked at Standard Oil Company's service stations for a year, while Doris finished her training to be a teacher. I eventually became an assistant manager in the service station and continued that for a year until she got out of school. Unfortunately, she wasn't able to find a teaching job when she got out of school, so she had worked for Dunn & Bradstreet for a year before she could be a teacher.

But when she finished college and did start work, then I went back to school. This time, however, instead of living on campus, we continued to live in an apartment on the East side of Los Angeles, near Montebello but actually in Los Angeles, and drove back and forth twenty-five miles each way to school for the two years that it took me to finish.

One of the joys of studying chemistry is the fact that they expected you to study German. So I had studied beginning German in junior college. Unfortunately, it was three years later when I went back and took the third year's course which was

scientific German reading, and I wasn't at the junior college anymore. I was now at the big university. I couldn't remember German to save myself. I'm not quite sure *how I got such an understanding instructor at* UCLA. But the instructor finally, after having me struggle the first time or two at oral recitation, told me that as long as I came to class everyday and diligently studied that she wouldn't call on me again until such time as I indicated I was prepared to participate.

I have never worked so hard in my life as I did in that course. I finally did manage to get a C and was relieved of the need for any further study in German, but Lord, that was hard work. I used to spend anywhere from three to four hours a night just on German. Luckily, I didn't have to work that hard in the chemistry part of it, because there wouldn't have been any time left.

RT: You did this German study on your own? You didn't have a tutor or anyone.

DH: No. All on my own, studying the books. The accent was never the problem. It was just figuring out what the words meant. But . . .

RT: That's a prerequisite in most medical school curriculum. I wasn't aware it was in chemistry as well.

DH: Oh, yes. But most of the chemical literature was in German at the time, because that's where most of the research work had been done, so German was the language of preference for chemists.

RT: Did that help you in your later FDA career?

DH: Absolutely not. It was of no value at all. But it was a prerequisite, so you did it, and I was just happy to eventually get through that course.

I was not a good theoretician in college. I did a lot better in the laboratory courses where you actually got to do some hands-on stuff. The two courses that I particularly remember in a positive way: one was instrumental analysis with Dr. Trueblood, and the other was quantitative analysis with Dr. Donald Cram. Cram subsequently was to win the Nobel Prize, and Trueblood was nominated, but I don't think he ever actually got the award. But they were both really outstanding instructors.

We had a teacher in physical chemistry who prided himself in the fact that 40 percent of his class failed, and he thought that was a wonderful tribute to him. I just figured it meant he was a poor instructor. But I guess of all the chemistry courses I ever had, that was the biggest struggle. At least I wasn't part of the forty percent.

RT: What was Dr. Cram's Nobel Prize awarded for?

DH: Well, it had to do with a method of separating materials based on the physical shape of the molecule that you wanted to separate from other things. You built a sub-strate that had holes in it that fit the shape of this particular molecule so that it was simply trapped mechanically. It was interesting in reading the alumni magazine. I know that that particular write-up about his Nobel . . . At the time that happened, actually I was then regional director in Dallas, and that became the focal point of a research project in a New Orleans laboratory, looking at ways of trying to separate natural toxins, and it worked.

RT: Well, that's interesting that it kind of carried over into your FDA career.

DH: Yes, it is. I was never certain why I was in Cram's class, but I guess it was predestined to come out that way.

RT: Now, I think you graduated in '56, didn't you?

DH: I graduated in June of '55. In the spring of that year, all the various potential employers came on campus and interviewed people as to their interest in employment. One of the joys of being at a large university is that it does attract a lot of potential employers. I had several interviews. The interview with FDA came about simply because there was somebody there, and I had the time available that day. So I went down to be interviewed as a potential place of employment. I knew absolutely nothing about the Food & Drug Administration. As far as I know, I had never heard of it before.

RT: Do you remember who your interviewer was?

DH: Oh, I certainly do. It was Louis C. Weiss. Louis was somebody who was later to be my lab director and lifelong friend. So, yes, I remember Louis Weiss.

Subsequently, I was offered jobs by two potential employers. One was the Food & Drug Administration, and the other was Dow Chemical. Dow offered me a job in Buffalo, New York; FDA offered me a job in Los Angeles. It was really a very easy decision. The pay would have been approximately the same. So it really was kind of a no-brainer to decide to go to work for FDA. I didn't have to move anywhere.

It was also supported by the fact that during the previous year, my wife had gotten pregnant, and as I was approaching graduation, obviously I needed a job, because I was trying to support not only a wife who was about to quit work, but I was going to have to support a baby as well, and it didn't seem like a good idea to move across country when I was about to become a father for the first time. So I went to work for FDA.

At the time, the FDA laboratory was on the top floor of the California Medical Arts building on South Hope, 1401 South Hope. A building interestingly that is still there. Although, it certainly doesn't have a laboratory on the top floor anymore.

RT: Did I understand you to say that it was a California State building?

DH: No. It was called the California Medical Arts building, which was a private building with doctors' offices and that sort of thing in it. But the Food & Drug Administration had two floors, the laboratory on the top floor and the administrative offices on a lower floor.

RT: And that was at San Francisco?

DH: No, it was Los Angeles, at 1401 South Hope in Los Angeles. Which is really walking distance from where the laboratory is now.

There were only--to the best of my recollection--there were only chemists in the laboratory at the time, one laboratory helper, and a lab director.

RT: Who was the director of the district at that time?

DH: Gordon Wood was the district director; Howard Bollinger was the laboratory director; Louis Weiss was the senior chemist, GS-11 at the time. Laboratory directors were people who had massive lengths of experience. I don't think there had ever been anyone become a laboratory director with less than thirty years of experience in the laboratories, and my goal at the time was that some day, you know, I'd like to be one of those. I'd like to be a lab director.

RT: And you actually started as a chemist then at Los Angeles, and when did you come on board into that position?

DH: Three days after I graduated. The twenty-seventh of June in 1955. July 1 I got my first pay raise, because they had an automatic pay raise that began at the first of the fiscal year. So I thought this was a great place to work. I went to work at

$4,044 a year, and got a pay raise to $4,480 three days later. So this was a great place to go to work.

This laboratory with really four working analysts hired three brand new chemists, which was a massive influx of people. I later came to realize that they really hadn't wanted to hire me. They had wanted to hire the other two people, but because of my military service, I had preference on the register, and I accepted the job. They couldn't get me to decline. Later in my career as I got into the business of hiring folks, it became clearer to me as to why they had hired me in the first place. It also became clearer to me later as to why certain events occurred that did occur. But we'll get into that in a little bit. But . . .

RT: Now you really didn't serve too long at L.A. before you were transferred, did you?

DH: Well, that's part of what later convinced me that they really hadn't wanted to hire me at all. But the training process there, all three of us were assigned to a single instructor. His name was Bob Baxter. He was a GS-9 in the laboratory. Bob was a young man in his forties, a very pleasant person, always had a smile on his face, enormous patience, and really carried us through the training program.

They had an interesting hazing procedure for new analysts there. Maybe they'd designed it just for us. I'm not sure. But they made sure that each of us went through the experience. They had some small Nigerian chilies that were imported, little red balls about the size of a cherry. They were the hottest things I had ever run across. The procedure was that you had to examine these chilies individually under a wide-angle microscope to determine whether or not they were insect infested or moldy. They had you operate under a hood, which should have been a clue to any new person, but it generally wasn't. Everybody stood around and waited for you to go to the bathroom, because it wasn't until after you went to the bathroom that they

told you you should wash your hands in alcohol before you go to the bathroom. Everybody had to go through that experience.

RT: At least you didn't have to check them organoleptically, I guess.

DH: No, you didn't have to taste or smell them. You did have to burn yourself before they would consider you as having passed the test.

I went through that process, along with everybody else. I think I disappointed them though, because I did wash my hands before I went to the bathroom.

The one lab helper there was Louie Hamm. Louie had been a professional prize fighter, and he obviously hadn't won a whole lot of fights, because his nose was pretty well distributed around his face. But it hadn't affected his sense of smell, and Louie eventually worked over fifty years for FDA before he retired. But even though he was the lab helper, Louie was the primary examiner of imported seafood for decomposition, and Ed Stiegel would simply confirm what Louie had to say about a sample, and then Ed would sign the reports as the analyst. But the reality of things was that he was the one that did the primary examination.

Merle Gnagy was the other analyst in the laboratory at that time, and, I don't know, it seemed like Merle did most of the work. I remember he would set up several racks of . . . These wooden racks that they use for testing condoms, and would have this great row of condoms full of water, and Louis Weiss would sit across in his desk, and invariably he would get an orangewood stick and imbed a pin in the end of it, and get out a three-foot length of glass tubing, and make a blow gun. Every time Merle would set up a row of these prophylactics for testing . . . You always knew that when you observed a hole, you had to see if it was uniform and spurting out both sides, because if it was, Louis had probably shot the thing.

(Interruption)

RT: All right, Donald. You were talking about Merle Gnagy when we dropped out of the last . . .

DH: Yes, well, as I mentioned, the thing you always had to look for in that laboratory was that you may have been sabotaged when you were doing an examination of condoms, and you always had to look for symmetrical holes on the opposites sides.

RT: How about training . . . ?

DH: We had a lot of fun in that laboratory.

RT: Mr. Weiss, in addition to having all the fun, probably was teaching you all to be very meticulous in your examination and careful.

DH: Yes, you could be charitable and say that. I think he was just having fun.

Louie also introduced us to the concept of research in an FDA laboratory. Kenton Harris and O'Dean Kurtz had assigned the south end of a northbound cockroach. He was supposed to learn if there were any parts that could be recovered and recognized after normal food processing procedures. He didn't find any. Louie also was an excellent glassblower. Flasks with ground glass connectors weren't available off the shelf, so he made up any we needed.

The chief inspector was Irv Berch, and he had an interesting crew. I carpooled with Jim Nakata for the entire nine months in Los Angeles District. Jim's wife helped at my son's birth as a nurse. My first experience with an inspector in the field was a trip to a rendering plant with Johnnie Cox. We were to oversee the destruction of some frozen turkeys.

We all lunched together out of brown bags. One day Johnnie Cox came up to J. Kenneth Kenny during lunch and said, "That is an ugly tie," and he cut it off.

Everyone, including lab people, wore white shirts and ties to work every day. Johnnie then went out and bought two really bad ties and offered Kenny either one he wanted. That helped me to understand why the Dried Fruit Association later sent MacKay McKinnion, Jr. a formal letter of congratulations when Johnnie Cox was transferred to the Midwest.

RT: All right. Was that sort of your introduction to FDA laboratory procedures, and then you . . .

DH: We were also associated with three very unique people. We had a West Coast general counsel attorney, Arthur Levine, Esquire; a Bureau of Medicine physician, Dr. Ralph Weilerstein; and a microbiologist, J. Paul Elliott. They did everything needed by FDA in their area of specialty for the entire West Coast. They just floated around where they were needed. All three were delightful people and exceptionally good at their jobs.

Well, I had been there just a short time when our son was born. He was born on the fifteenth of October, and I started work in June. A week after he was born I was called into the district director's office, and was given what I think is probably the most unique opportunity ever provided to an employee of the agency at that time. One of the conditions for employment was that you were subject to transfer, and I didn't know at the time, but I subsequently obtained a copy of what was then the official written transfer policy of Mr. (Allan) Rayfield. I don't know that anyone I ever heard of was given the kind of opportunity I was given. I was told that I could go to New Orleans, Atlanta, Baltimore, New York, or Buffalo. I didn't matter where I was going, but I was going somewhere.

RT: From what I know of early FDA management, that was unique, because many people were just told to report somewhere the next week.

DH: Yes. The general practice was that you were informed that your next pay check would be at a certain location, and you should be there.

RT: And if you declined to do that, was there a consequence?

DH: Yes. You were no longer employed.

RT: I see. I didn't know whether you were just passed over after that with regard to promotions.

DH: No, no. Your paycheck was there, and if you abandoned your job, you weren't employed anymore. It was a very narrow choice that you had available, and I could not understand why I was given the chance I was. I subsequently figured out that their intent was that I would resign my position rather than transfer, and they could have gotten rid of me. It didn't work. My wife and I decided that we would pick something in between the extremes, and we had narrowed it down to Atlanta or Baltimore, and eventually chose Atlanta.

The other two that they hired at the time . . . I can remember the name of one and not the name of the other one. But Chuck Earl was one. He didn't last through the training. He was a wonderful theoretical chemist, but he had, I think, three left hands. He really had no laboratory technique at all, and he shortly decided that he would rather go back to the university and go into research. So he didn't even complete the training.

The other fellow did complete the training and stayed in Los Angeles about nine months after I left, and then he was drafted and never came back to FDA after that. So . . .

RT: Your transfer to Atlanta was a lateral, no doubt, at the same grade?

DH: No, I was promoted at the time of transfer. As I say, it was just a week after my son was born that they raised this possibility or likelihood with me, and I told them that I would go to Atlanta, but that I simply could not move a week-old baby, and that it would have to wait until he was at least six months old. So it wasn't until the spring of '56 that I moved to Atlanta. When I finally did move, then I did get a promotion to GS-7.

RT: Well, that showed some consideration of family needs, even at that time.

DH: Yes. I still think that the desire, the expectation was that I would voluntarily resign my position. So they were bending over backwards to accommodate me so that I would have no complaint before the Civil Service Commission.

RT: Now when you got to Atlanta, did you get involved in other kinds of work in the lab?

DH: Oh, yes. Atlanta, of course, had a whole different kind of workload than you have in Los Angeles.

When I got to Atlanta, the laboratory director was Arthur Henry. There were seven people in the laboratory there. It was a bigger operation than we'd had in Los Angeles.

RT: Was John Sanders the director at that time?

DH: No, J. J. McManus was the director. Sanders came later. He . . . Three names really jump out at me among the analysts there. Clarence ("Schiff") Schiffman, who was transferred into Atlanta from the Savannah laboratory, when the laboratories were actually moved. Schiff had lost an eye in a laboratory accident (a peroxide explosion) in the Savannah lab. That had only been a two-person

laboratory. So working in a big lab like they had there in Atlanta was a new experience for him. But Schiffman became my mentor and close friend and somebody that I really looked up to. Our families also became very close. One of the things that he was particularly strong about was the need for accuracy and reliability in any work that you did. If anything, I would give him credit for whatever later success I had in the laboratory.

I had been in Atlanta about three months when I learned that Bob Baxter, who had been my trainer back in Los Angeles, had committed suicide. For a long time, I wondered whether I'd had any role in that. I subsequently learned that I had not. But my first thought when I learned of his death was that I might have played some role in that. It really bothered me for a while.

RT: You couldn't have been that bad of a boy. (Laughter)

DH: The first thing that happened when I moved into the laboratory in Atlanta was that Arthur Henry had to give up his workbench. He had always had a workbench assigned to him, and occasionally did look at samples. But when I moved in there, it had overcrowded the facility to the point that he had to give up his workbench. I'm not sure he ever forgave me for that. Nevertheless, he did give up his workbench, but the result was that I worked with the end of my workbench about three feet from the desk of the chief chemist. So you would have to say that I was under close scrutiny.

RT: During that period in your career, did you get involved in analytical work with regard to any significant regulatory actions?

DH: Yes. With Schiffman having been the jack of all trades as one of two analysts, he got into everything, and he really, as I say, was my mentor there. So pretty much everything new that came along that needed to be done that was new and unique,

he brought me into that process, and the result was that I learned to smell frozen eggs, I learned to smell fish, I learned to do all kinds of things in the laboratory.

I remember one episode where I had spent the entire day drilling thirty-pound cans of frozen eggs. You use a big power drill and a 1¼-inch bit and drill the full depth of a can of eggs. The result of that is that it tends to spray egg material around, and they did not provide any protective clothing at the time.

When I went home that evening, I always rode public transportation, and I found that I had the back half of the bus and the other forty people were all in the front half of the bus. When I got home that night, my wife burned all my clothes. So it . . . But almost every one of those egg cases became a court case. So we got into a lot of that.

But the biggest work that they did in that laboratory was filth analysis. So we got into a whole lot of insect identification and that sort of thing, and I . . . The first school that I recall that they sent me to was a training course in insect identification. O'Dean Kurtz and Kenton Harris were the instructors, and, of course, they were the gurus of insect identification.

Anyhow, we had this course in insect identification in Washington, D.C., and we were to bring a collection of insects as a part of the homework that we were supposed to do in advance of that. Most of the other people came to that course with collection of flies and little things like that. I don't think I had an insect that was less than three inches long in my collection, because one of the joys of living in the humid south was that we grew them big. So I probably had the most unique collection at that insect training course. I subsequently became pretty adept at that identification process and actually trained a number of other people in insect identification later.

RT: The work that you were involved in in Atlanta, was that primarily food oriented?

DH: Well, it was, yes, primarily food oriented until . . . I had been there about two years, I guess, when the nature of my work assignments began to change. A couple of things happened. One, the pesticides became more of an element in the work. At the time, we did primarily DDT, parathion, and lead arsenate. We didn't have much lead arsenate used down there, so most of the work was in parathion and DDT. Parathion was a colorimetric analysis, which was using instrumentation. DDT was done primarily by attacking the DDT molecules, you separated out the chlorine, and then you actually did a titration of the amount of chlorine present.

The earliest research project that I really can identify as being a research project that I worked on was trying to find a way to do that titration of the chlorine by electrometric titration, which was really the precursor of instrumental analysis of elements. We got to where I could do that pretty well. The instrumentation was pretty crude at the time, but I think really that was some of the early work that eventually lead FDA into other ways of instrumentally determining pesticide residues.

The basic method you used there to break up the DDT molecule was to cause it to react with metallic sodium. So we spent a lot of our time cutting metallic sodium into little tiny cubes, so that you could add it to the reaction mixture of the extract of the food product. Not the safest procedure. Metallic sodium left exposed to the air will eventually catch fire just from the moisture in the air. So life in those days, you kind of floated along without really recognizing how dangerous some of the work we did was.

Later, we began the extraction of pesticides with benzene, where you would put the food product in a big four-liter separatory funnel and shake it with liquid benzene, and then just drain the benzene off the bottom, and then go through a process of removing the pesticide from the benzene.

RT: Now, at that point in your career, did you ever become involved in litigation of the agency as a witness?

DH: Oh, yes. In filth analysis, we went to court several times. I guess the one that I remember the most of that kind of court testimony was . . . I lost my train of thought. Yes, it had to do with decomposed nuts. There is a kind of a reject nut that's a shrivel, and the U.S. Attorney asked me on the stand if a shrivel was edible. Not knowing the answer to the question, I answered it, "Yes, they're edible." The U.S. Attorney immediately called a recess, because that wasn't the answer that had been expected.

He asked Ken Harris, who was there as the expert, and Ken told them that, "Yes, sometimes my wife and I will sit around in the evenings and hunt through the nuts deliberately looking for the shrivels, because they have a nice sweet flavor. But they are rejects." So we . . . That was the first time that I was exposed to the concern of the attorneys that sometimes they forget to do their preparation, and they don't know the answer to the question when they ask it, and they get in trouble.

But then later in my career there, I switched to drug analysis for the last two years that I was there in Atlanta. One of the other analysts who had been doing all of the illicit drug work moved on. His name was--a name I always found fascinating--Joseph Colombo Monroe Griffin. A name that somehow just stuck in my mind as being a fun name. Joe had been the pharmaceutical analyst, and with his departure, I took over that function. So the last couple of years I was there I was pretty much involved in anything that had to do with drugs. That meant both legitimate pharmaceuticals and the illicit drugs, because at the time we were deep into the business of illegal distribution of amphetamines, and barbiturates, and antibiotics and all kinds of stuff. That became pretty much my exclusive province. This led to frequent court testimony. By that time the district director was John Sanders. John loved anyone who took part in successful court cases. I guess that is why I did so well there.

I also did some research projects in that area, one of which was to explore ways to separate the sulfa drugs one from another, because all of the official methods

use the same detection, and without being able to separate them, you really couldn't say which sulfa drug you had present.

Paper chromatography at the time really was limited to the little squares of paper which didn't give you a sufficient separation to be a very useful analytical tool, and there was some information in the literature about a different way of doing paper chromatography. They used a very long paper. It was called descending--going down--descending paper chromatography, where you used a piece of chromatography paper that was at least eighteen inches long, and it kind of started in a tray at the top and hung over a glass rod and then just dangled down. You had to have an atmosphere that you could saturate in the mobile solvent.

There wasn't any commercial apparatus available to do that kind of work, and we wanted to find out if, in fact, we could separate the sulfas that way. I managed to find a glass cylinder from an old gasoline pump, the old gravity-feed gasoline pumps, and by sealing that onto a piece of glass with another piece of glass for a cover, I was able to fill the chamber and demonstrated that it worked very nicely for the separation of sulfas. Unfortunately, it wasn't very many years later, actually only a year or two later that column chromatography was invented, and quickly displaced the need for descending paper chromatography. But that really was one of the things that I was proudest of in my work there. My notebooks with all of my research were provided to the FDA History Office when I retired.

RT: Did you get any recognition or reward for that?

DH: A publication in the AFDO journal or the AOAC journal, but other than that, no. And no one expected any.

RT: Well, you apparently got a relatively broad chemistry experience, because I think your next promotion put you at a supervisory level, wasn't it?

DH: Yes. Well, actually the work in the laboratory . . . You had asked earlier about court cases. The last two years while I was doing the drug analysis work, I don't think I went more than sixty days without being in court. In fact, you mentioned when I became a supervisor. I testified in eight different court trials after I became a supervisor in work that had been done previously. They had to fly me back and forth across the country to eight different trials. In one of those, in the middle of my testimony, they called a recess, and the defendant changed his plea from not guilty to guilty in mid-testimony. That was kind of an interesting experience.

But, yes, in 1961, I was transferred to San Francisco as a supervisor. While I had been in Atlanta was when they invented the position of first-line supervisor. Before that time, there had just been the chief chemists. There wasn't any such thing as a second level of supervision in that sense.

RT: So you were about one of the first supervisory chemists?

DH: Well, I was in there at an early wave, but the first group was probably two years before I became a supervisor. Then I was . . .

As I mentioned earlier, I was transferred to Atlanta, I later concluded, in an effort to get me to leave the agency. While we were in Atlanta, we moved into a new laboratory building, and a couple of incidents might be worth recalling from that process.

The first had to do with the period when we were checking the place out before the grand opening. We decided we ought to test the safety showers. Clarence Schiffman and I were in the process of doing that, and he pulled the chain and I was holding the bucket, and we turned one of them on in I think it was Lab A, and it wouldn't turn off. If you know anything about safety showers, their intent is to deliver a lot of water in a hurry. It's about a one-inch pipe that you just open it up,

and it really dumps water. And there is no floor drain under them, because they are only intended for emergency use.

So we're standing there with this hand-held bucket trying to catch this massive flow of water and do something with it, and it just wasn't going to turn off. One of the characteristics of an emergency shower is that you don't want anybody to accidentally shut the water off, so the shut-off valves are hidden and the hidden location is not known, because they don't want you to turn them off. So, after a few minutes, it became obvious that we needed help. I think there was a chain of three of people trying to hold buckets and dump water, and I ran down and finally got a hold of the building contractor, who got me in contact with the plumbing contractor, who finally told me to go down to the ladies' restroom on the first floor and get up in the ceiling, lift the ceiling tiles over the second stall to the left, and that's where I would find the shut-off valve. And there it was.

RT: Since then, that probably was a unique experience, is there a plan now for drainage?

DH: No, they're still done the same way.

RT: That was an exciting moment, I'm sure.

DH: That was an exciting moment. Then when they did finally have the grand opening, it was planned on the open front steps of the building there at . . . Actually, it's the same physical location where they are located now. It rained that day, but they decided they were going to hold this ceremony on the outside anyhow. Mr. Allan Rayfield didn't change his mind very easily. So my assignment that day was to stand in the middle of the street right along side of the building and direct traffic away from the crowd gathered in front of the building long enough so that they could

have this reception. So I spent the grand opening ceremony standing in the rain directing traffic.

After that they did have the reception, and somewhere, somehow during that reception, my wife and Mrs. Rayfield got connected. Mrs. Rayfield said to my wife, "Oh, you're Don's wife. Allan talks about him all the time over dinner." I guess somewhere along the line, and I have always attributed it to Schiffman's instruction, and John Sanders' love of people who succeed in court testimony, the idea of getting rid of me had changed to a considerably more positive attitude on Allan's part. A lot of folks had problems with Allan Rayfield. Obviously, I didn't, because from that point on, it was obvious that he was pushing my career and not holding it back, and I've certainly been grateful to him ever since then.

RT: Your work directing traffic for the celebration, I guess that would come under the position description of . . .

DH: Other duties as assigned.

Anyhow, I was transferred to San Francisco then to be a supervisor in the laboratory. I had not been a GS-12 long enough to be promoted to a GS-13 supervisor. So I was transferred to San Francisco to become a supervisor, but I was not able to be put in that position, so I worked for almost a year under the designation of acting supervisor, until such time as they got around to deciding that I was ready to be promoted to the GS-13 supervisor.

RT: I assume that MacKay McKinnion was the person in charge of the district.

DH: McKinnion was the district director; Harold Gerritz, Dr. Gerritz, was the laboratory director; and at the time I was the only first-line supervisor. FDA had gone through an interesting evolution from the time that . . . Actually, two years before I was hired, FDA had suffered through a ten percent reduction, always the

result of a fuss with Senator Tabor from the state of Maine and an entrepreneur in Maine who decided that you could make baby beets by taking . . .

(Interruption)

RT: All right, Don.

DH: OK. Senator Tabor's constituent thought that the use of a cantaloupe ball cutter applied to big beets to make little beets out of them was an appropriate thing to do, and the FDA didn't think so, and we had to, in fact, seize the product. Senator Tabor, in his efforts to convince the Food and Drug Administration that that had not been a wise move, had caused the agency a 10 percent reduction in budget and a 10 percent reduction in staff as a lesson. The reason for the hire in 1955 when I was hired was that (we had been Taborized in 1953, and it wasn't until 1955 that they were allowed to rehire) we had learned our lesson. So, in a way, I owed my job to the senator for having caused a reduction in the first place. Otherwise, there wouldn't have been the chance to be hired at the time I was.

RT: OK. Were there any particular things that come to mind in terms of significant milestones in your career at San Francisco?

DH: Oh, a lot of things happened in San Francisco. The hiring process that had begun in '55 was a minor thing compared to the kind of expansion of the agency that began to take place just a few years later. Just about the time that I went to San Francisco in '61, we really started hiring, and I mean hiring big numbers.

RT: Was that Project Hire or was that something later?

DH: I don't remember what we called the first one. In that first year that I was there, I ended up supervising, as a first time supervisor, twenty-one people. The other half of the laboratory was supervised by Dr. Gerritz directly, because I was the only supervisor.

This was a very busy time. Among the people that I was supervising were the microbiologists. I didn't know a thing about microbiology, except that they stared a lot through microscopes. But, anyhow, I was their supervisor, and the result was that they were certainly allowed to pretty well manage by themselves. And most of these were new hires.

RT: Were these people more in need there? I mean, was San Francisco a district that required more micro work than Atlanta, or was it an expansion all over the field force in this discipline?

DH: Well, I think it was an expansion of the discipline. At the time when I started, in '55, just six years earlier, there had only been one microbiologist on the whole west coast, and he used to travel back and forth between San Francisco and Los Angeles to do his work depending on where the samples were located. Now San Francisco had a staff of several. So, you know, it was just a massive increase in the use of that discipline. But I did end up, as I say, with twenty-one people--most of them new hires--in need of training. So I spent a good share of my first year really running training projects.

RT: Now, was the agency at that time moving into more programs relating to microbiology nationally?

DH: Yes. I think it was a considerable increase in the use of the discipline of microbiology. But, also, it was just a general expansion of everything. Everything we did was bigger and better and grander.

RT: So it wasn't selectively microbiology.

DH: No, it wasn't selectively in microbiology. It was just everything was getting better. It was a wonderful opportunity to do more of what we'd always been doing.

One of the stories that I remember from San Francisco was the fact that you'd always have the policy--and it certainly was Allan Rayfield's policy--that all sample had to be destroyed after it was used, that the samples were not to be consumed. They certainly weren't to be taken home. When I got to San Francisco, there was a kind of sampling going on there that I had never run into before. That was the examination of wines for filth. The instruction for the handling of wine was that it was to be poured down the drain after examination. I found that they had determined that with the better wines, one removed the trap from the sink, placed a receptacle under that, and poured the wines through a sieve and down the drain and into a receptacle at the bottom. That was generally reserved only for the better wines. But that was an interesting process that I hadn't run into before.

I also remember one cheese sample that came in there. It was not being held for sale. I mean, we were curious as to whether or not we had any jurisdiction over it, because it had been brought in to be used as gifts by the importer. But when you looked at the cheese, it wasn't clear when you looked at it. It was like something was out of focus. If you looked at it under a wide-angle microscope, it was alive. The whole surface was covered with mites about a quarter of an inch thick. I had never seen anything quite like that. The whole surface was just moving. We finally came to an agreement with the importer, and he just trimmed the outsides off and threw it away. He was able then to give away the cheese. It was a real good cheese, but . . .

RT: San Francisco no doubt had a lot of import work, as perhaps L.A. did, too. I suppose San Francisco requires quite a bit of lab work in relation to imports.

DH: When I first arrived in San Francisco district office, all of the case work was handled by a single Food and Drug officer, Bud Kerr. After a while Reggie Jang joined Bud and handled the imports. Reggie is still there and still involved in imports. The chief inspector was Monte Rentz. Shortly, we got a new supervisory inspector from the commissioner's staff. His name was Henry Roberts. Eventually he became the chief inspector and then later the district director in Minneapolis. Henry and I had a lot of fun together. Henry was different.

MacKay McKinnion, Jr., was the district director. I later found his first performance evaluation where he was described as "a bit of a playboy." He never got over it. He took me on my first federal-state encounter. He paid for our rooms in Reno with his roulette wheel winnings, then we met with the state folks and returned home.

Dr. Harold Gerritz became a close personal friend as well as boss. The staff was so big that there was no time for personnel work. We carried it on the Greyhound commuter bus and did that business on the bus to San Bruno/Millbrae on the peninsula.

San Francisco also did a lot more pesticide work at that time. Of course, in the six years between when I was in Los Angeles and when I was in San Francisco, the size of the organization had changed dramatically. I went from a situation of four analysts and three trainees in Los Angeles to where I was supervising half the laboratory, which was twenty-one people. So it's hard to compare the amount of work being done in the two places. But San Francisco did a lot more pesticide work, a lot more import work than I had seen in L.A. But by then, L.A. was doing more work, too. So I don't really know what the comparison was between the two.

But we did also have the West Coast vitamin analysis. All of the examination of enriched breads, for instance, was done in San Francisco for the West Coast with a single analyst.

They also had the tea examiner there, which was one of the things that I supervised, which really concerned my wife, because she was a tea lover, and I can't

stand the stuff. She was concerned that I would be causing the rejection of some of her favorite product, and that was often the discussion at home as to whether or not I was letting in good tea.

RT: Is there anything else of note you recall about San Francisco?

DH: Well, there were some things associated with massive growth that went on in San Francisco at the time. Instrumentation became a reality. You know . . . Before 1961, we hadn't really done much in the way of instrumental analysis. In the early 1960s, we moved to doing pesticides by gas chromatography, we had several new kinds of spectrophotometers, and . . . The laboratory in San Francisco was designed in 1932 by Carl Vorhees, and he strangely enough had somehow had the foresight to bring in enough electric power that we never did have to pull additional power into that laboratory, but there was no place to put instruments. So we began to nibble on space that had been used for other things at other times or by other agencies and began to considerably expand the laboratory areas. I was the one that ended up really drawing the floor plans and providing oversight for most of, all of that expansion.

RT: Was that facility located where the current FDA office is or were you at another location then? The Federal Plaza or whatever it is.

DH: Well, this was the 50 U.N. Plaza building, which was built by WPA in 1934--it was completed in '34--and occupied by FDA as a laboratory until they moved to Alameda a year ago. But there were, you know, all kinds of other agencies in that building, and every time anybody abandoned any space on the fifth floor, and it turned out in the attic on the sixth floor, we moved laboratory into it. That meant putting new benches in, meant new plumbing and new electricity and all that kind of stuff. So I ended up, as I say, spending a lot of time drawing floor plans for our

new space, and that did include a room that was devoted strictly to the instrumentation and particularly for pesticides plus my desk. We even moved laboratories up onto the sixth floor where there had never even been plumbing before, and they ended up moving the tea taster, Tony Daly, up there as well. A terrible space.

RT: That gave you some direct experience in planning lab facilities, and later we're going to talk about some organizational things you did at the national level. As I recall, you were at San Francisco about five years, weren't you?

DH: Yes. I was there from '61 until the end of '65.

RT: And then you moved to Kansas City?

DH: I moved from there to Kansas City as a laboratory director. I finally reached my career goal, took over there on January 1 of '66. Actually, Doris and I and Bruce moved over the Christmas holidays. We left home on the twentieth of December, spent Christmas at our folks' homes in Montebello, and then drove on to Kansas City and arrived there about New Year's Day.

RT: Well, that's a cool time out in that country.

DH: We had no place to live, and Andy Allison was retiring as the laboratory director. He and Esther invited us to live in their home until such time as we had found a place to live. This was just about the time that GSA changed the rules on transfers and offered some minimal assistance in the cost of transfer for selling a home. That's about the time that FDA employees were finally allowed, really, to buy houses; because before that time, you couldn't afford to buy a house, because you couldn't afford to sell it, because you got no assistance from the government. So we

did buy a house in Kansas City for the first time we'd ever been in a position to be allowed to do that. We stayed with Andy and Esther for about a month.

We learned that Esther Allison had long provided boxes of cookies for staff members every Christmas. The staff suggested that if I was taking Andy's job, then my wife had to take over Esther's cookie job. Doris loved to bake, so she was happy to oblige. From Christmas 1966 until I retired, we produced a "Cookie Day" Christmas party for whatever office I was with. When Doris died in January 1993, I decided to do the last one by myself in her memory. I managed to produce 133 dozen cookies using 26 different recipes. Then I sold the freezer.

RT: Was Sam Alfend the director?

DH: No, Al Barnard was the director. Interestingly, I started on the first of January. Leonard Blanton came in as the new director of investigations, the chief inspector, about two weeks after I got there. We had been together in Atlanta district office earlier. A week after Leonard arrived, Al Barnard left. He went in to headquarters to be the director of the Bureau of Regional Compliance, and I was appointed as the acting district director. So three weeks after achieving my career goal to be a lab director, I was acting district director. Luckily that didn't last too long, and Charlie Armstrong came in.

Eventually, after we had . . . We had some actors move through for a while, but eventually Charlie Armstrong came in there as the district director. We also absorbed St. Louis District into Kansas City District.

RT: Well, you weren't in Kansas City but about a year, as I understand.

DH: Well, I was there a year and a half. When I arrived, Andy Allison was a supreme recruiter. I don't think I've ever seen anybody who could hire people like Andy could, and he'd been pretty well given free reign to hire as many as he wanted.

So when I arrived there, they had laboratory space for thirty-six, but he had seventy-two people on board, most going through the training process. My first assignment from Granville "Granny" Lipscomb was to move them out. My assignment was to reduce the group from seventy-two to thirty-six.

I also found a very strange supervisory arrangement when I got there. The laboratory director--or chief chemist as they were still called then--Andy Allison, had seldom been there. He spent all of his time recruiting. He not only recruited chemists; he also recruited investigators. But the main thing was the recruiting of chemists. Minneapolis was the recruiting mecca for investigators. So those two districts were massively overpopulated.

RT: Was there work for that many people? There wasn't space. But was there enough work to do?

DH: No. It's just that they could hire them and train them. So they did. They hired them, and then . . . The concept ahead of time had been that they would be moved on. But, as it turned out, Andy got to hire them and I got to move them. So when I got there, I found that one of the supervisory chemists was, in fact, designated as the acting laboratory director. One of the supervisory chemists was assigned to operate the laboratory data system. They had, fairly advanced system for that time, a data tracking system for samples. It was all on IBM punch cards. Before the advent of any kind of desk-top computer system. So one of the supervisors did nothing except operate the data system--sat in the library, and did that.

RT: Kansas City became the sort of national lab center for the Total Diet Program. Was that in place when you were there?

DH: No, that came later. Just about the time that my transition began from San Francisco to Kansas City was when we began the process of having science advisors.

We had had a science advisor in San Francisco, but he really didn't do much for the laboratory. He was a national expert in pesticides and was mostly used to bolster the FDA position in testifying with Congress. But when I got to Kansas City, it was just about the time their first science advisor was sworn in. Again, recruited by Andy Allison, but sworn in under my management. That was Clifford Malone from Kansas State University. Cliff probably has seniority over all other science advisors in FDA. He's still there.

RT: What kind of educational background did he have?

DH: Chemistry. Analytical chemistry. He was a marvel at teaching instrumentation to the analysts, but he has also used FDA problems in his teaching at the university since that time. So he's been an integral part of that operation there since '66.

RT: Now, is he a full-time FDA person?

DH: No. He's part-time. He's a full-time professor at Kansas State University in Manhattan, but at least one day a week in the laboratory at Kansas City.

RT: Don, you then, I think, joined the first class, I guess you could say, of the executive development program.

DH: Yes, that was an interesting process. They . . . I had been there about a year, and, as I said, spent my time moving people away, force transferring people. You'll find folk all over the country today that can remember being moved out of that laboratory. Because a lot of them, interestingly enough, made one move and then just stayed there for the rest of their career. But you'll find occasional ones that are scattered all over the country.

RT: Can one say that would be more likely to happen to a lab person to stay at one location than the investigating staff?

DH: Oh, yes. Yes. There were probably more people in the laboratory side of the house who decided that family situation, quality of life, style of life was more important than promotion, and that being a GS-12 for the rest of their career was acceptable. Maybe it's a personality difference. People who are investigators, I think, had more of a tendency to feel that they wanted to move on, move up, than laboratory folk did. Yes.

RT: Investigators, in a sense I suppose, had more P.R. or public relations contacts than many lab people. So maybe they were more people oriented.

DH: Well, I think, as I said, there's a personality difference.

RT: Yes. That's what I was suggesting.

DH: Sure.

RT: Now in this first group of the Federal Executive Development Program, there were just a few of you folks. You were in the . . .

DH: Well, what happened is they changed their mind in the middle of the process. The Executive Development Program was to be a year-long process, and they asked a number of folks if they would be interested in applying for that year-long procedure. I was one of those who had been asked, and we (Doris and I) had been agonizing over it. We had some questions about personal arrangements and that sort of thing as to . . . Could my wife and son come with me? Could, you know . . . Would they then guarantee a job somewhere else afterwards? A lot of that kind of

questions. The same kind of questions that people ask today when they talk about Executive Development Programs. Those were unanswered questions.

I had come in to work then after we had spent an agonizing weekend thinking about whether or not I wanted to apply for the year-long program. I got on the telephone and called headquarters to try to ask these questions, and I was on the phone, and they raised a new possibility that had not been even discussed before. They wanted to know if I would be willing to come to Washington for a six-month detail beginning the next Monday for an abbreviated Executive Development Program, and that they would attempt to work out some kind of a mechanism by which I wouldn't have to be in continuous residence in Washington. I put them on hold and got on the other phone and called home. I'm talking to my wife. So I've got a telephone connection going on here in which I suddenly had to make an instant decision as to whether or not I would accept this six-month detail. Before we got off the phone, we had said yes. So then unexpectedly, what should have been I thought three or four months down the line, became a "Report to Crystal Plaza next Monday and begin a six-month detail." In fact, there were six of us who were in that group. It was an eclectic group.

RT: Well, Curtis Joiner was one of those, wasn't he?

DH: Curtis Joiner, Charlie Coffindaffer, Sam Hart, Frank Clark . . .

RT: What was the last one? Frank Clark?

DH: Frank Clark. And me. How many's that?

RT: Let's see. I have one, two, three . . . No. One, two, three, four, and, of course, yourself is five.

DH: And myself. OK. Maurice Kinslow was the other one.

RT: Maurice, yes. Now were all of them given the same arrangement as you? A shortened executive development program?

DH: Yes. This was somebody's bright idea at the last minute. You know, all of this occurred right after we had moved from a career commissioner to a politically-appointed commissioner, and, you know, things were pretty fluid in Washington at the time.

RT: That was Dr. Goddard as commissioner.

DH: Yes. Somewhere in that thought process, they had suddenly gone from a year-long program to a six-month program. As far as I know, it was the only six-month program they ever ran. But whether it was a sense of urgency or what, I don't know. But they just decided that the first group would be a six-month program.

RT: So that was kind of the unique part of that first class, if you will.

DH: Yes.

RT: And then after that . . .

DH: Well, it's unique in also that we were essentially a part of the commissioner's office. We met with the commissioner fairly often. I don't remember now what Ed Turek's formal position was, but . . .

RT: I think he was the head of planning, wasn't he?

DH: Yes, it was planning and evaluation. But the result was that we spent a lot of time talking and meeting with the commissioner, being aware of what was happening at that level. Each of us had a special project that we were assigned to. Oh, two of them worked on one project, which was the self-certification procedure. I ended up with the assignment to work on the laboratory data system, and since one of the prime models that was out there was being studied by the contractor, which was Booz, Allen & Hamilton--as far as I know that was also FDA's first encounter with Booz Allen--but the fact that the Kansas City system was one of the systems they were looking at as the future of how that management would take place, I was allowed to go back to Kansas City from time to time, not only to visit my family, but with the excuse of studying what they were doing there.

RT: Good. Paul Hile, I think, was project officer for this study that Booz, Allen & Hamilton . . .

DH: Paul became the project officer in mid-stream, yes.

RT: Now after that program was completed . . .

DH: Well, as the program was being completed . . . I don't think any of us really knew when it was supposed to be over. Nobody had ever told us what the endpoint date was. They had told . . .

(Interruption)

RT: OK. All right, Don.

DH: OK. Although we didn't know when the program was going to come to an end, we did know that we had been there about six months, and that none of us were

aware of any likely positions being available. We also, I guess, had some sort of blind faith that somebody was going to do something good for us.

Unbeknownst to me, there was an exchange that took place between the then-director of the Boston district office and the commissioner. Nevis Cook was the director of the Boston District, and I don't think he had ever accepted the concept that we ought to have a politically-appointed commissioner. But even if he had, he was by nature an overly outspoken person and a very folksy humorist. I think he thought he was being funny when he sent a message to the commissioner, which was essentially ended up below with "what hath Dr. Goddard wrought." Dr. Goddard was not amused, and made sure that Nevis was aware of that. And Nevis's response was, "Hey! If you don't like the way I'm running this place, replace me!" And apparently, that afternoon, I was called in and asked if I would accept the position of district director in Boston.

That, I think, was the episode that created the associate regional Food & Drug directors, I think they were called, an ambassador without portfolio and nothing to do, but a place to park people. They created these positions, as I say, as a holding pen for folks they wanted to move out, and then they in fact moved Nevis to Denver and told me that I was going to go to Boston as the district director.

However, they had not actually done the necessary paperwork to make that happen. So I was told and actually was given a letter that said that it is appropriate for you to put your house on the market, so that I could in fact sell my house under the GSA rules, but I was not to tell anybody where I was going. Although I was allowed to go on a secret house-hunting trip. So Doris and I went to Boston to try to find a place to buy, but we were prevented from asking anybody in the district office where was a good place to look, because I wasn't supposed to be there.

It was also interesting because prior to having received the letter, I had the house on the market anyhow, because I knew I was leaving. The wife of one of the supervisory chemists was in real estate and lived right around the corner. So there was certainly no way to keep it secret that I was going somewhere. Even though I

was not physically in Kansas City at the time, the fact that my house was on the market was certainly well known. That lead to the issuance of this letter authorizing me to sell my house, so that all I could tell people was that, "Well, I'm going somewhere, but . . ." So I had my house on the market. Eventually I came back, and we did find a buyer.

On the day that we were loading our furniture to move to Boston, we went to closing on the house, and we actually signed the papers for closure on the hood of the car, while the moving van was being loaded. I was afraid I was going to have to leave my wife behind to take care of that, but we were able to go to closing on the day that the moving van was moving us out.

We then drove to Boston. We still didn't have a place to live. I remember we stopped at Niagara Falls and wanted to go across the bridge to the Canadian side, but we had our dog with us. The dog had a rabies tag, but we did not have the dog's certificate for the rabies vaccination. So we were not allowed to take the dog across. So we had to leave her tied to the car while we went across.

One of the questions they asked us when we came back was, "Where do you live?" And the three of us just broke out in gales of laughter, because we didn't live anywhere. Our furniture was in a moving van going into storage, and we lived in the car. So we finally retrieved our dog and drove on to Boston.

The move to Boston was equally interesting. We finally did get to Boston without a place to live. We lived in a North Reading motel for the first six weeks or so that we were in Boston. But at least by then I was able to talk to the people in the office about being the district director and getting some advice on places to live and such. So we ended up buying a house in Reading, and I rode the train every day to work. The first time I'd ever commuted other than by automobile. But it was a pleasant place to work and live.

RT: You were district director when you went there. I don't know just when this happened. You can fill it in. You became among the very first of the regional Food & Drug directors or RFDDs.

DH: Well, Mr. Nixon was in the White House and determined that the socioeconomic agencies should all have regional structures and should have a regional director. The Food & Drug Administration did not believe that there was a need for such a position and resisted for some time. Even though we did have a politically-appointed commissioner, it just didn't seem to make sense to FDA.

Eventually, the political pressure reached the point that it was obvious that we were going to have to do something. So FDA selected one of the district directors in each of the ten HEW regions, and actually, that was just about the time that they produced ten. There had been nine, and there was a plan to reduce them to eight. Then as a political payoff, it was decided that it was politically expedient to have a region in Seattle. So instead of going from nine to eight, they went from nine to ten. So we were determined to need to have this title, if not a position. So one district director in each of the ten regions was designated as the regional director, which carried absolutely no functions other than the fact that you had a title. It had no function, no authority, or anything to it. It was just a sham to try to convince the White House that we had one.

RT: So this was really a decision from the White House level rather than from the commissioner's office.

DH: Oh, the commissioner fought hard against it, and was still fighting it even though we were named in title. As I say, it had no function or authority associated with it. It was just a sham title.

RT: Well, of course, in your case, you were in Boston, and you became the . . .

DH: I was the only district director in that region.

RT: I assume in some other areas that involved the relocation of the new RFDD from where he currently was serving?

DH: No. There was no movement of anything. It was just an existing district director was given a second title. He was both district director and regional Food & Drug director. So I had the dual title. But it didn't do anything, except that I was expected to go to the region's departments, regional directors' meetings.

RT: Now that later changed, didn't it?

DH: Yes. It changed in '70, I think, right after I had moved to Chicago, where I had the similar dual title. In April of '70, I moved from Boston to Chicago. I was the district director of Chicago District and the designated regional director as well. My wife and son finally followed me there in June when school was out.

RT: Well, I want to ask you a question a little later, but maybe we ought to wait for that, and that would be in the various districts and regions in which you've served, were there significant regulatory problems? But if there are some with regard to Boston, maybe we could touch on those now.

DH: When I became district director in Boston, we had a unique situation. Dr. Goddard was really tuned to what was happening in the field organization. We had a coordinator for field operations, but the district directors were directly supervised by and reported to the commissioner. Now you talk about fun and power. If we wanted something, we called the commissioner, and he directed it to happen. This didn't last long, but it was sure fun.

In Boston, the biggest problem that I recall was the sardine industry, the canned sardine industry, had a severe problem with leaking cans. That flat can is one of the hardest cans in the world to seal properly. The courts, in their wisdom, had concluded that the can company's monopoly over the canning systems had to be eliminated. At that time, the canning companies actually did the maintenance . . . The can manufacturers did the maintenance of all the canning machinery in the factories. The courts decided that was wrong, that they shouldn't be able to do that because that gave them a monopoly over the canning operations. So it was left to the manufacturers of the finished product to do their own machine maintenance, and they weren't particularly good at it.

The flat can that sardines are packed in is particularly susceptible to leakage. There was a very high percentage of those cans that were leaking. We began to observe some problems with the bacterial contamination of canned sardines. In trying to find a way to do something about that was one of my first real excursions into trying to work with the state on a regulatory problem.

RT: What state did you work with?

DH: It was the state of Maine, of course, where most of the sardines are canned. I guess my first real episode would have been in Kansas City, but was kind of short-lived. That had to do with pesticides in chicken. But . . .

RT: Out there you would have been working with what state?

DH: It was the state of Iowa that had a problem. The state of Iowa at the time . . . Even the front line inspectors were replaced every time the administration changed from Democratic to Republican, which was every two years. So you didn't really have any kind of continuity of state program management. That was, I guess, terribly unsatisfactory debate for me to enter into, particularly since this was in my first

month as the acting district director, in my first two months as a branch director. But that had kind of faded from my memory.

But the first real regulatory effort that I got into, I think, with a state was with the state of Maine on these canned sardines. We did finally work out a voluntarily agreement with the industry. We had concluded that if you could find the leaking cans and remove the leaking cans that you would have, in fact, eliminated the majority of the bacterial problem. Eventually we figured out that if you turned the cases upside down, the leaking oil would stain the cases, and by segregating out those cases, you could then go through can by can in those cases and find the leakers, and then repack the good ones.

So we really worked out what was essentially an industry-wide voluntary agreement, which was monitored by the state of Maine on our behalf, and that was Clayton Osgood, who was the director of the program at that time. I think that was really something that I got some satisfaction out of. I thought that we actually accomplished something. We changed the industry in a positive way. I think it was demonstrated to me that working together with the states, we could accomplish good things.

RT: I know in New England there were several states you worked with. Massachusetts, of course, was rather unique in that Dr. George Michaels was there. As I recall, he was one of the first state persons or perhaps the only state official that ever convinced a state legislature to give him a lifetime appointment to his position.

DH: George is the only person I know of who was in his position because the law said he was in his position. The law in Massachusetts, the health law, actually designated him as the director, and the only way he could be removed was for the legislature to actually amend the law.

RT: Well, I think he was an unusual official in some respects. As I recall, he was removed from office because of some improprieties, the acceptance of gratuities, et cetera.

DH: That happened long after I had left there, but it was certainly obvious at the time I was there that that was going on. Yes.

RT: Some of the other states in that area I'm sure were easier to work with.

DH: Well, Connecticut and Rhode Island both had good programs and were very cooperative with us, and we got along fine with them. New Hampshire and Vermont essentially didn't have any program.

RT: Well, I know that some states had very limited resources.

DH: Vermont didn't even own an inspector.

RT: In 1968, at the 72nd Annual AFDO Conference in Hartford, you presented a paper on federal-state relations, so it was evident at that point that you were getting involved in the intergovernmental sphere.

DH: Well, I was involved in a large part, I think, because headquarters had directed us to become involved. I'm not sure that I would have had much of a relationship with the state of Massachusetts if we hadn't been directed to build up our relationship with the states. But it was certainly a very spotty thing. It was . . . As I say, there were three of the states out of the six in New England that we got along fine with and three that we didn't. I think that the rest of the country kind of saw federal-state relations the same way, that states on the average probably were thought of as not being capable of doing the job.

RT: Yes, I believe that's true. Now, Don, you left Boston I think to take another RFDD position in about two years after coming to Boston?

DH: Well, I went to Boston in August of '67, and in the spring of '70, I moved on to Chicago. The one thing we haven't talked about really that happened while I was in Boston that will always be with me is that's when I had my problems with my gall bladder and ended up in the hospital with an undetermined problem. The only thing I knew was that I was bright yellow and that I hurt. Eventually, an expert from Mass. General sat down with me and told me that I had surgical hepatitis. I questioned that, because there is no such animal. He said, "What it means is that you're bright yellow, and we don't know why. We're going to cut you open and find out why." (Laughter)

The surgeon that worked on me was about 6' 8" and had the biggest hands I've ever seen on a man, and the resulting scar I thought was probably the result of him having to get both hands and his head inside my body to find out what the problem was. It turned out to be a gangrenous gall bladder, which when removed, everything cleared up in a hurry. But that was an episode.

RT: Yes. Well, you'd remember that. I know. From personal experience, you'd remember that kind of surgery.

DH: In 1969, when I went to Boston, we were still in the truck stop business. During my time there, this work was removed from FDA, and DEA was formed. They like publicity about their raids. Unfortunately, the press hadn't caught up with the change, so I got three or four calls a week in the wee hours wanting the scoop on the latest drug raid. FDA had never really sought that kind of notoriety. I moved to Chicago and escaped the phone calls.

I moved on to Chicago in the spring of '70, with the dual title of district director and regional director. Doris and Bruce joined me in June after school closed. Bruce was between freshman and sophomore classes in high school.

RT: During the time there, I'm aware of your work in the central states area and recall that you attended some of the conferences of the Central States Regional Association of Food & Drug Officials, when you were director. You were pretty active in working with state problems and with the City of Chicago, as I recall.

DH: Well, that particular region had, I think, a unique situation in that the states involved--all of the states involved--were pretty active in the regulatory sphere, were active in the Association of Food & Drug Officials (AFDO), and all had good, strong programs. At the same time also, each of them had a personality in charge of their programs that were kind of the folks that were easy to deal with. It made it easy to follow the edicts that were coming out of Washington in terms of working with the states, because the people who were there were the kind of folks that you could be very comfortable working with. The difference between being there and being in New England was like night and day. So that even though we were working with the states by direction from headquarters, it was a lot easier to do that simply because of the kind of folks we had to deal with.

RT: In Chicago, you had a little different universe of firms to regulate.

DH: Well, yes. I got into the drug industry, which I had never really had much to do with before, and certainly imports were a different kind of an animal.

RT: Imports would have been coming from where there? Primarily Canada?

DH: Well, you get a lot of stuff from Canada, but amazingly there's a lot of oceangoing ship traffic that comes up through the canal and the Great Lakes and into Chicago. So you get an eclectic mix of product coming in there from everywhere.

RT: Were there some problems at the time you were there with alefish and other contaminated or chemically contaminated fish products in some of the major rivers and lakes?

DH: Well, originally, it turned out that the major problem was DDT in the fish products in Lake Michigan. I remember we had a number of meetings with industry in which we were certainly not popular, because the fish were being dried and shipped to New York primarily. The chubs were the big fish, and they were all going to New York to be sold as a gourmet product, and we were seizing them right and left for pesticide contamination. Over time, the DDT contamination was eliminated, mostly because DDT was eliminated from use. But they never were able to recover that industry, because as the curve of DDT contamination went down, the curve of PCB contamination went up, and they intersected just about at the violative level so that by the time they were no longer violative for DDT, they were violative for PCBs.

I think a lot of that was, it was really the bulk paper industry that was dumping all the PCBs in Lake Michigan. Unfortunately, Lake Michigan's water is almost stagnant. There is no natural drainage out of that lake, except occasionally there is some artificial drainage into the Illinois River. It's something like ninety-seven years for the water to turn over in that lake. So that once you get a contamination in that water, it's there forever, and one of the wonders of both DDT and PCB is that they are so chemically stable that they don't go away. That's . . . Once you get the contamination in that lake, it goes on forever.

I do remember a meeting in Gary, Indiana, where I met unprotected with a group of fish boat captains, and I frankly was not at all certain that I was going to

survive the evening. That was as scary of a meeting as I've ever been to. They were . . . Those were rough and ready men, and I wasn't sure I was going to survive the evening. (Laughter) When I finally left there, I was given a trophy, which was a lake trout mounted with a sign underneath about the PCB contamination. That was one of the highlights, I guess is the correct term, of having been there.

But another of the regulatory episodes that I remember there was the testing laboratory. About this time, during the time period '70 to '76, when I was in Chicago, we get into the inspection of laboratory testing, and Abbott Labs and IBT were the big cases. These really were among the first cases in which laboratory tests that had been falsified or changed or modified somehow and then used in support of petitions came to light. That had to do both with drug testing and with the testing of the safety of pesticides. That investigation is still having repercussions.

For whatever reason, it was determined that that investigation would be directed really out of headquarters rather than out of the Chicago District. There were questions in some people's minds--never in mine--as to whether or not some of the staff in Chicago might have been somehow compromised in this investigation. I don't think there was ever any proof of that.

RT: Did this have anything to do with Abbott Laboratories?

DH: Well, Abbott happened at the same time, and they had these two investigations that were kind of stumbling over each other. They were both being managed out of headquarters. Myself and one or two other people in Chicago were the only ones that were really privy to what was going on. Management was pretty much all at on headquarters. As I say, there was . . . The district was certainly vindicated in the end and was in no way compromised. But it was a terribly uncomfortable process to go through. I was never really that convinced that headquarters knew how to run an investigation. But . . . We did get the investigations done, and we did find the

problems, and we did pin things down. So I guess in the long run, the investigation . . .

(Interruption)

DH: OK. Now we're recording.

RT: Yes, we are.

DH: The process of finishing those investigations was, I guess, a milestone for the Chicago District and for FDA, I think, because they certainly had brought implications, because IBT, among other things, was also involved in much of the safety testing of pesticides in addition to pharmaceutical testing, and the echoes of those adverse findings and then--that really is what we found was that they were cheating on the tests--was very broad.

But a lot of other things happened about the same time. The Food & Drug Administration's deception in the appointment of regional directors was noted by the White House, and the White House informed the commissioner that he had a choice. He could either appoint real regional directors as separate and distinct from district directors, or they would appoint a commissioner who would take care of that. And the commissioner, seeing the wise position, decided that, in fact, we would appoint regional directors, and that they would have authority over the budget, positions, and dollars for the district offices under them. So I became the regional director for Region V, headquartered in Chicago, and responsible for Minneapolis, Detroit, Cincinnati, and Chicago Districts, and Bill Clark came in as the district director for Chicago District.

It's about this same time that the new badges came in for FDA. The old badge was a small badge, only about an inch and a quarter in height, and the new badge was the size of a regular police badge. There were a lot of mixed feelings as

to whether that was good or bad. But a lot of the folks who had had the badges for years wanted to have their same number. There were a number of us in Washington the day the new badges arrived, and those that who had badges for a long time as investigators wanted mostly to duplicate their old badge number, and they did, in fact, go through the series and then pluck out the one that had their old badge number on it so that the number continued.

I had not had a badge because I came out of the laboratory, and all the rest of them had come out of the investigative side, and those of us in the lab had never been graced with a badge. So I didn't have an old number to fall back on, and I got to thinking about what would be an appropriate number, so I selected "007." I had about twenty-five years of fun with that number, because I was frequently introduced in speeches and that sort of thing as being FDA's agent 007, so I got a lot of mileage out of that badge.

Chicago District was located in . . . At least the laboratory was on the top floor of the post office building. They had been there for a very long time, and that building was in terrible condition. New laboratory space had been promised for years and years and years. The paper plans for a replacement laboratory were yellow with age when I got there, and I kept those around for a long time. They even had the physical location set aside on the VA hospital grounds. But that planned laboratory was not built. Sometime after I left there, they did finally get a replacement laboratory, but not while I was there. So we had to do some interesting and innovative things to try to make the space a little more acceptable.

One of the things that I did, I didn't like the office that I assigned to myself, and I wanted to redecorate it. Of course, GSA said that paneling was inappropriate for someone of my rank, and could not be installed. Maybe it was indicative of where I was going in my career, but I decided that I wanted it paneled anyhow. So I went out to the local lumberyard and bought the paneling and some two-by-fours to make furring strips and proceeded to panel two walls of the office. I also . . .

Since GSA didn't dictate the carpet color, I had red carpet installed. So folks thereafter talked about being called on the red carpet from time to time.

RT: Did you also purchase the carpet or . . . ?

DH: No, GSA bought the carpet. They didn't dictate the color, so I could pick whatever color I wanted. So they did furnish the carpet.

Also, that was when we first received what we called the red phone. The initial conference capabilities of that system were excellent and were somewhat unique within government, I think, at the time. But the switching device was all mechanical, not electronic. I got to where I could guess that my telephone was about to ring just by listening to the series of kicks as the relays kicked in. The switching device was in the closet in that room, and each location that had a red phone had one of these big boxes. It's about three feet high and eighteen inches deep and about, oh, two feet wide, I guess. It took up a lot of space because it was strictly a mechanical switching device. But it allowed us to have group conference calls among all of our offices and was really a most handy tool.

One day Bill Clark came to me and said that he wanted to release one of his analysts, one of his chemists from service and assign him to a long-term research project. The research project involved the exploration of whether or not a computer could prove useful in the laboratory. We thought about this for a little bit, and then concluded that it was worthwhile to conduct such an experiment. So we did, in fact, set aside one chemist position. Subsequently that was increased to two chemists' positions, and they got a Digital PDP-12 computer, which is six feet high and almost that wide, very deep, and had a lot of mechanical switching in it, rather than little chips and . . . It was just a monster. But, nevertheless, was the beginnings, I think, of the real computerization of our laboratories, which has now reached the point where you can't hardly buy a piece of equipment that doesn't have a built-in computer.

But we didn't know at that time whether they would be valuable at all. So we essentially devoted four analyst years, that is two people for the next two years, to the exploration of the potential value of a computer in the laboratory. Obviously, it did in fact prove to be useful, and those two persons who were involved in that, Larry Albers and Mark Overton, are still listed by the central office computer staff as members of their team, and they are still active in the process. So I think that the time spent in their training and in experimentation did in fact prove to be useful.

Bill Clark was an innovative kind of person. And he came forward also with a suggestion that a strange, new electronic typewriter kind of thing might eventually prove to be useful in the investigations branch. We ended up with I think it was six different brands of a new device called a word processor in the investigations branch, none of which would talk to each other obviously, and they all had different qualities and different capabilities, and none of which proved to be the one that the agency eventually bought. But, nevertheless, it was an interesting experiment to try the various different pieces of equipment in the laboratory and in the investigations branch.

RT: You were the only regional office that was experimenting that way at the time?

DH: I think we were the first one that started it. But, as I recall, there were two others that eventually were doing the same thing we were, and they weren't using a variety of brands as we were. Most of them stuck with a single brand, and eventually ended up with systems that they kept. The collect of systems that we were using, several of them proved to be so impractical that they didn't end up being used. Actually, Chicago was then not among the first to really be automated with typing systems, simply because most of what we experimented with didn't work.

RT: Well, that later became a problem in headquarters, as well as the field, which was later resolved as having incompatible data systems.

DH: Yes. That certainly was part of the reason why it failed was that we had so many different brands that were not interchangeable. Nothing was interchangeable. The tapes were interchangeable. It could read them. The programming was different. It was all just a jumble.

RT: Well, it was pioneering anyway.

DH: Yes. Part of the problem with the physical location there was that we were overcrowded, particularly as the laboratory expanded. One answer to that that we explored was that we move the investigations and compliance staff out of the office into a separate office building. We used a messenger to run the files back and forth, because the central file remained in the Chicago district office where I was. That was a bad idea. It really did not work well when we had the investigators off in a different location. It was, you know, one of those things you try that you hope will work, and it didn't work.

Eventually, we moved the investigators back into the building, but into what had formerly been attic space up above the laboratory. I'm not sure that was a good idea either, but at least it gave them more physical space and got it back together.

The biggest problem I think was trying to use records, because the factory files were never where you wanted them when the two offices were in different buildings. That was a failed experiment.

RT: Well, that's the way we learn, I think, in government as well as in everything else.

DH: In walking through the laboratories, it was very easy to get depressed. The ceilings leaked, and in many places in the building, you'd walk through the laboratory, you'd find a giant sheet of plastic arranged under an open spot in the ceiling tiles where the tiles had been removed and the big sheet of plastic was formed into a funnel that generally would attempt to redirect the roof leaks at least into a sink so that it wouldn't mess up all the experiments. That went on for a long, long time. It was probably a four- or five-year process to finally get the leaks in the roof stopped.

Partly that was finally improved when some wag decided to upend trash cans over some of the vents on the roof, which kept some of the water at least from coming down around the vents and into the ceiling.

RT: Was the agency ever challenged in any of the litigation about the sanctity of, shall we say, of the laboratory?

DH: Well, we were very careful not to encourage visitors in the laboratory. Occasionally we would have someone in for a hearing, and they would be sitting in the compliance officer's office and would observe significant numbers of cockroaches running through the compliance officer's office. But we generally kept them out of the laboratory. We did not encourage public visits to the labs.

Part of what I did was in trying to encourage the staff, I felt they needed encouragement because despite the physical inconvenience of the place, they kept doing excellent work, and we wanted to try to do something about the morale. So we concluded that perhaps decorating the place, making it a little more lively looking might help. So I made an offer to the lab staff that I would buy the paint to repaint the laboratories, which GSA was not willing to do. So since we were buying it ourselves, we didn't have to go through the GSA supply store, so that we would go to Sears and buy any color paint they wanted to buy. The only caveat was that all of the people who worked in a particular laboratory--it was broken up into small

labs--that everybody who worked in a particular laboratory had to agree on the colors. I didn't care what they were. I'd buy whatever they wanted, but I didn't want any complaints about the colors. So it had to be a consensus color scheme.

We had one that I used to refer to as the Chinese restaurant room, because it was bright yellow and bright red. There was another that was the grape room, because it was two shades of grape, a dark and a light color, and there was the blue room, and there was a green room.

The lab director got even more exotic in his . . . That was John Taylor at that time. John decided that he wanted to do something really distinctive. Interestingly, he painted three . . . Two of the walls he painted white, the third wall was all windows, the fourth wall then became black and white stripes that were about six inches wide, vertical stripes. I never did figure out the origin of the idea, but there were baby-sized footprints in red that looked like they walked up the side of the wall at about a forty-five degree angle. It was never clear to me what those footprints represented, but John liked it.

RT: Did you ever have any inquiry by building GSA managers about your decorating there?

DH: The GSA people really didn't spend much time in our place other than the cleaning crew. I don't think they . . . Most of them never recognized what we'd done.

RT: Well, that probably did help the morale a little bit, didn't it?

DH: Yes. It did amazingly help the morale. The staff came in at 6:00 on Saturday morning, and by Saturday evening the painting was done. They were intrigued enough by the idea that they gave up their weekend to come in and paint the place.

And, yes, it really made a difference in the way people felt about the place and about working there.

RT: Well, I remember at one time visiting Chicago, and the inspectors' room was one of the most crowded places I'd ever seen in an FDA field facility. Very small, little half desks.

DH: That was before we put them upstairs.

RT: And it must have been difficult in such close quarters.

DH: Well, it encouraged people to be out on the road.

RT: There's another spin off, I guess.

DH: During that same time period, we were doing what was called Project Idea, which was a headquarters-generated concept initially which was we would do some experimentation, and we could experiment with almost anything we wanted to experiment with. One such experiment was to combine compliance and investigation supervision into a single position. As I recall, that was Project Idea Forty-five.

It was thought initially that it would do a couple of things, that it would improve the management of cases by making sure that you had all of the evidence you needed before you concluded the investigation, because the person who was going to be the compliance officer was also the first-line supervisor. It was also thought this would save manpower. It turned out it didn't save manpower, because the people who were doing the work got to where they had to spend so much time in the actual case development that they would appoint a deputy to be the supervisor. So you ended up with the same number of people being separated from actual on-line work, and it eventually got dropped.

RT: Did the measure-act-measure philosophy come into that?

DH: It was all part of how you determined whether or not a project idea was working. It was the . . . You measured some attribute, then you did whatever this project idea was, then you measured it again. As I say, it worked as far as case development was concerned, but it was a total failure as far as the saving of person-power, which was supposed to be the selling point. So that one fell by the wayside.

By 1972, we were back into a more traditional relationship with headquarters and no longer had the luxury of reporting directly to the commissioner. Most of us had no trouble with this. My counterpart in New York, Weems Clevenger, however, never quite made the switch. Weems was a very bright and imaginative problem solver. He just didn't have much patience with bureaucracy. When he wanted something done, he insisted that it be done--no matter what. He devised a communications system for including Puerto Rico in on-line FDA discussions. Unfortunately, he didn't get proper authorizations to buy the system--he just bought it. It worked well, but was summarily removed, as was Weems.

In June of 1972, I received a call asking if I would move to New York to replace Weems. I respectfully declined on the basis that my son had already been moved once during high school, and I just couldn't ask him to make a second move going into his senior year. The commissioner accepted this refusal, but asked me to go to New York for sixty days to "clean it up." He said I could take anyone I wanted to be the district director for New York. I chose Henry Roberts because he was a quick study, brutally blunt, and had an exceptional level of integrity.

As we proceeded, we found some problems that could be fixed easily and some that were more difficult. Generally, we found people who wanted to do right but needed direction. Many of them are still with FDA and doing a great job.

Toward the end of this period, I received an emergency call from my wife. My father had suffered a major heart attack, including a complete stoppage in the hospital. I turned everything over to Henry and flew to California. My dad survived,

and I returned a week later. This was a very tough period of my career. I continue to recognize and appreciate Weems for the visionary he was and the friend that he was.

RT: Are there any other comments you'd like to make about your tenure at Chicago, or is that pretty well covered?

DH: Well, it was during the time I was in Chicago that we began to upgrade the position of the regional director. First, you know, as I mentioned, we appointed them. But then we began to take a look at those positions and began to wonder whether or not it was really fair to pay all of the regional Food & Drug directors the same about of money. There were some of us who were supervising as many as five hundred people. There were others who were supervising only eighty people. The big ones would have four and five district offices. A small region would only have one office, and they were all paid the same. That eventually ended up in having the regional Food & Drug director in New York upgraded to a GS-16. Shortly before I'd finished my tenure in Chicago, the Chicago position was also upgraded to a GS-16. Then just about that same time, we were also moved into the wonders of the new system, called the Senior Executive Service (SES). But that's a different story.

RT: I was wondering if that didn't occur about then. I was going to ask you.

DH: There was also, however, a system of in-house committees that had begun to evolve over this period in the seventies, with each one of these committees really focusing on a particular subject matter area, like foods, drugs . . . A system which incidentally continues today.

I served on the Steering Committee (our symbol was a veterinarian's castrating knife). This was pretty much what it sounds like--an overall policy recommending group. Later on, I served as chair for the Consumer Affairs Officer

(CAO) Committee and for the Biologics Committee. In this latter role, I negotiated the first field training efforts in plasma centers and in blood banks. When I then moved into the Executive Director of Regional Operations (EDRO) job, we began to actually implement field inspections of plasma centers. About a year later, I got a memo from Hank Meyer in which he noted that this had been a success. I thought that was a major triumph.

RT: And this was primarily set up for the field organization?

DH: The committee system was entirely within the field organization, and was really designed to try to resolve difficulties. If you think back to the makeup of the organization back when I started. The field organization represented 78 percent of the manpower of the entire Food & Drug Administration. In 1955, that predated about all of the requirements for pre-market approval with the exception of the fact that antibiotics had to be certified and drugs had to be safe. Which meant that there really wasn't much pre-approval, simply that the manufacturer had to make that determination that they were safe.

As product pre-approval became more and more a part of the responsibility of the Food & Drug Administration, as the new drug approval, new device approvals, and all of that sort of thing came along, the percentage of total FDA manpower devoted to the field organization dropped as low as 38 percent, which a lot of people resented that, and I was one of them. It seemed to me that there was far too much in the way of person-power being devoted to headquarters activities, which were-n't . . . A lot of us thought were separate from *real* Food & Drug Administration work.

RT: I'm sure as you came into headquarters as the executive director of regional operations or the EDRO, you, as I recall, made a number of changes, reorganization, and so on that I'm sure took that into consideration.

DH: Yes. You know, reorganization has been a part of life all along. I recall when I was in Boston, I used to get telephone calls at 2:00 and 3:00 in the morning from the local newspapers wanting to know about the most recent drug raid, because, in fact, FDA had been responsible for illicit drug sale reductions for a long time.

During the late sixties, the Drug Enforcement Administration (DEA) was devised, and that switchover took place. A number of our staff became a part of the DEA, and during my last year in Boston, even though that changeover occurred and DEA was the one making these raids, the local press hadn't really focused in on that yet, and we still got a lot of telephone calls at 3:00 in the morning about this latest raid, and I'd have to profess ignorance and fend them off on somebody else's phone number. But it still caused us to lose a lot of sleep.

Another reorganization was the short-lived disaster known as the Consumer Protection and Environmental Health Service (CPEHS) headed by C. C. Johnson. This additional layer of bureaucracy between the secretary and the FDA never did work and thankfully was short-lived.

RT: Well, the BDAC, Bureau of Drug Abuse Control, FDA's enforcement arm, had been transferred to the Department of Justice under DEA at that time.

DH: Yes, it became a part of DEA, but we still got the telephone calls, because the press still had us on the Rolodex, I guess.

RT: Well, I believe that wasn't it about 1982 when you came into headquarters as the EDRO . . . ?

DH: No, '76. Nineteen seventy-six when I went into Washington.

RT: Yes, 1976. And . . .

DH: Another thing that had happened, Bob, during the seventies was the evolution of the testing of consumer products outside of the normal, if you will, food and drugs area. I remember while I was there in Chicago that a product called X-33, which was a waterproofing material designed to waterproof basements and that sort of thing, became a very, very widespread, popular product. Unfortunately, the solvent in that product was so flammable that it burned up a fair share of the houses where it was applied simply because the flash point was so low that the pilot lights would set off an explosion and burn up the houses.

We attempted to figure out a way to actually measure the flash point without burning our laboratory to the ground. We were able to show that with a combination of alcohol and dry ice, you could get the product cold enough that you could actually measure the flash point. Certainly at any temperature that anyone was going to use it around home, that stuff was about as dangerous as any product I have ever run across. I think really this product hazard was a strong impetus in the eventual development of the Consumer Product Safety Commission.

(Interruption)

RT: I was about to mention that the Bureau of Product Safety, being in the Food & Drug Administration at that time, would have been the statute under which our interest in these products was drawn. Is that correct?

DH: Yes. A number of things happened all at one time. There was the transfer of some responsibilities from the other parts of the Public Health Service into FDA. Radiation for Control and Safety came into FDA, the Food Service Inspection, that

whole collect of things that came to us for management. We also picked up the biologics control from the Public Health Service. You know, the nature of our business began to change again.

RT: That was really a result of the executive reorganization of 1976, wasn't it? The presidential . . .

DH: Yes. Actually, I think it was just before '76. It was finalized then, but a lot of that came into FDA's structure so that the . . . There was a whole flux of things moving in and out. Eventually, the Product Safety thing . . . When the Consumer Product Safety Commission was formed, 10 percent of the FDA staff was reassigned to that organization, and a lot of those folks who were there, and many of them were still there, were former FDA employees.

RT: OK. I did mention a little bit ago your transfer in to head up the field organization. That was at the time when Paul Hile had been elevated to the position of associate commissioner for regulatory affairs, or the ACRA. Coming in at that time from the field, did that present any particular challenges or problems for you to deal with that were unique?

DH: Well, yes, one of them was Paul Hile. Paul was given the option of moving to this new position, but he really didn't want to give up the management of the field. So it was a very difficult decision, I think, for Paul, because there was a camaraderie to being a part of the field organization that he found very difficult to give up. I think he thought long and hard about whether or not the prestige of the new position was worth what he would have to give up and sacrifice to take that. But he did eventually opt to take the position as the associate commissioner for regulatory affairs or regulatory compliance. That left the position open for the EDRO, the executive director of regional operations. I didn't particularly want that job. I was

happy doing what I was doing, and, in fact, I did not apply for the position for a long time. In fact, this was to be the first position I ever applied for at FDA.

When I came into the Food & Drug Administration, one didn't apply for a position, one was told where their new job was, and the whole thought of deciding whether you wanted to apply for a position was really a foreign idea. I'm not really sure when that became the norm, but we did go through a shift in personnel practices. The whole idea of having a performance appraisal that the employee knew about is a relatively new concept. When I started in FDA, they did performance appraisals, but I was in my seventh year and a supervisor before I knew they existed.

RT: That was the management-by-objective philosophy, wasn't it, that I believe was started by secretary McNamara over in DOD and then spread somewhat down the line?

DH: Yes. It slowly spread, but as I say, I found myself very surprised in San Francisco where after I'd been there a year or so when Dr. Gerritz told me it was time to do performance appraisal, because I didn't know they existed. It turns out that every employee had an annual appraisal. That is every employee over GS-9 was the subject of a written, one-paragraph performance appraisal. It was just a one paragraph narrative that went into your personnel file, but you never knew it existed. It was never discussed with anybody or anything. So the whole shift from that mode to where you applied for a vacancy, and you had a performance appraisal that was to be discussed with you, that's about as profound a shift as I think you could ever find.

RT: So that would have occurred approximately at what year?

DH: Well, it occurred beginning in the mid-seventies, I think, as a thought, and by the eighties was the only way to do business.

Anyhow, as the opportunity to apply for the EDRO position was nearing its close, I was approached by Maurice Kinslow, who said that he was representing his cohorts, a number of the other regional directors. I don't know who. I didn't ask him who he represented, but he said he represented several of the regional directors, and that they wanted me to apply for the position. That made me rethink, I guess, where I was, and we got to thinking about who we might end up with if I didn't apply, and eventually, I did apply for the position and was selected. When that opportunity first came up, I had absolutely no intention of applying for the job.

RT: So you moved to Washington then?

DH: I moved to Washington in September of '76.

RT: Now, you came in as the EDRO. As I recall, it wasn't too long until you did undertake the reorganization of the EDRO headquarters. What prompted you to restructure these headquarters units? Did you have an edict from somebody or was this your initiative?

DH: Yes, it was all my own initiative. I think almost every manager thinks that he knows a better way to do things. I don't know whether it was any better or not, but it was different. Clearly, I thought it was a better way to organize things. A number of changes occurred after I left that position to reverse some of the things that I did, and I guess for a new manager they were better. I've always felt that actually I came more to recognize while I was in the EDRO position that almost any organizational pattern will work if the people want to make it work, and it won't work if the people don't want it to work. The real organizational structure had more to do with the informal lines of communication than it does with the boxes on an organizational chart anyhow.

RT: I believe one of the things that you were certainly instrumental in accomplishing as the EDRO was to restructure some of the laboratory operations in the field and the development of what became known as the research centers.

DH: The first three years that I was in Washington were fun. The organization was growing, our budget was growing, we were popular with the commissioner's office, almost anything we wanted to try that was new was blessed, and that was a fun time. We could do a lot of things. One of the things that we did do is what you just mentioned, Bob. It was a long debate. It was not easy to get this approved.

If you look back in the history of science in the Food & Drug Administration, initially, people in the field ran samples. The development of new analytical methods was done in Washington, and one of the things that I discovered when I moved into Washington I probably should have been aware of a long time ago, but it's never come to the fore. In studying the functional statement for the field organization, there was no component in that functional statement that called for or that provided the responsibility to the field organization to do research in the laboratory. It was not a part of our job. So it had long since moved to the point where most of the research was being done in the field, particularly research in new analytical methods. But according to the functional statement, we had no responsibility to do that.

RT: Did the regional research centers provide for a better way on a national basis to coordinate and control the research? I guess what I'm asking . . . Prior to that research center concept, were research activities somewhat independently pursued in the field?

DH: Yes. Research was based on individual personal interest. A person who wanted to work on a particular project became an associate referee for the AOAC for that particular subject, and if the referee on the broader subject area concurred, and then that person was allowed as an individual to do the research. But there was

never any concentration of expertise in any one place, and oftentimes you might have three or four people working on the same thing in different parts of the world, different parts of the country, and nobody knew what the other was doing. It was just sort of a disjointed thing, because it had just grown.

RT: Now did the establishment of the research centers effect some economies and equipment as well?

DH: I think that depends on who you ask. I believe the answer is yes. There were economies of size, and there were some real advantages to having multiple disciplines working on similar projects being in the same physical location. But that's something that came later. The first battle was to get the idea of research added to the functional statement for the field organization.

RT: Did the research centers program require some relocation of scientific personnel?

DH: Well, the research centers flowed out of the concept that once we had the responsibility to do research, then they had to look at what is the best way to do research. Part of what they concluded was that there were two real basic ideas to be pursued in the research. The first is the more basic kind of approach to researching things. The second is the practical application of those to individual problem resolution. It was that second that really does not require concentration. It's the first, the idea of doing the more basic kinds of stuff that benefits most from being grouped together in location.

We didn't really move people to accomplish this. For the most parts, the basic researchers that we hired came from academia or from outside the organization. As I mentioned earlier, during this first three-year period that I was in Washington, that is from '76 through '79, we were growing and growing rather

significantly in numbers. It reached the point where we eventually had as many as 3,400 people in the field organization.

RT: Well, did you kind of evolve Centers of Excellence in this initiative?

DH: Well, Centers of Excellence was the first name that some people used in referring to what we might develop. There was a real reluctance on the part of the bureaus to allow this kind of thing to evolve in the field, and the . . . Actually, the most difficult hurdle to overcome in the establishment of what became known eventually as the research centers was to get the Bureau of Foods to agree to a management-of-research system that they felt comfortable enough with, because they saw themselves as being cut out of the process, and the eventual resolution of that was an agreement to a management system, a planning system at least for the research for these centers in which the center, the Division of Field Sciences in the EDRO organization, and the director of the particular research center would be a three-headed planning person who would decide on the individual projects to be pursued in a particular research center.

RT: With regard to the foods group, did they ultimately establish a laboratory in Chicago? I have difficulty recalling the name. It was a separate facility . . .

DH: The Moffett Center.

RT: The Moffett Center.

DH: That came long after all of this, and evolved out of a whole different process. It had nothing to do with what we're talking about here. That occurred long after I had left Washington and really grew out of a facility that was donated to the

organization--that whole physical facility. But that had nothing to do with anything I was involved with.

RT: Now, of course, during your tenure as the EDRO, you dealt with several different commissioners and, of course, bureau or center directors. You've already indicated that a lot of good management was necessary with the foods group. Were there other parts of the headquarters organization that were problematic in terms of moving this way to the research center?

DH: No. I don't think we had anywhere near the same problems with the other bureaus, with the possible exception of the Bureau of Medical Devices after it became an entity. They had a radiation laboratory up at Winchester, Massachusetts, that also did some medical devices work, and there was a long and often rancorous debate as to who should manage that place, what should they do, what kind of a relationship there should be between field people and headquarters people as far as the management of that organization. That took a long time to resolve, and it involved a lot of people besides me. But eventually that did become a field facility, after having been actually a dual facility for a long time, where the center had some people and the field had some people all physically in the same place.

RT: Now, did that organization you mentioned, the Bureau of Medical Devices, combine with Radiological Health at one point as a center?

DH: Yes. The Center for Medical Devices and Radiological Health.

RT: So that would have been under then John Villforth at headquarters.

DH: It did become John Villforth's task, yes. But if you go back before that, the whole device thing evolved separately and was . . . The inhouse management entity

is a device organization which was combined with the rad health business when they were transferred to FDA.

RT: As far as the . . .

DH: I've often referred to that as the "Bureau of Things."

RT: As far as the biologics group, they, I believe, were a little resistant to . . .

DH: Well, they were resistent to any field involvement at all. Not to the concept of us having a research center. They didn't think that there should be any field involvement in field inspection whatsoever, because they evolved within the Center for Disease Control and National Institutes of Health as a separate entity, having their own investigators, and that their investigators were in fact also research scientists and developed an interaction with the industry that was totally different than anything that had existed anywhere else in FDA.

RT: As far as laboratory or scientific elements, were their operations more technical than strictly laboratory?

DH: That's what they would have us believe. The fact is that they eventually came to us in the field organization because there was a development of some clearly criminal activity particularly in the blood area that they were simply not equipped to handle. One of the documents that I eventually ended up with while I was in the EDRO position was a letter from the director of Bureau of Biologics that . . .

RT: That was Dr. Meyer?

DH: Dr. Hank Meyer, yes. It was a little, short, single paragraph thing that said that we'd been through a year of field investigation and case development in the area of blood banks and plasma centers, and it hasn't been so bad after all. (Laughter) It was quite a concession I thought that . . . And we did go through a very extensive training program for field people. But the fact is that there was so much money to be made in the plasmaphoresis and blood donation business that organized crime got into it, criminal elements got into it, and it was just something that the scientists at the elevated level that they were in the Bureau of Biologics simply were not equipped to handle, and that was really when it began to become obvious that there was going to have to be a field involvement in those kinds of investigations, and it has evolved since then to where we have at least some kind of a presence in almost the entire industry. But it's been a very slow evolution of mind set and generally involved also almost a complete turnover of the staff in the Bureau of Biologics.

RT: Now, when you were EDRO, I know that you also did some coordination with some of the other federal agencies in a kind of a working group called the Interagency Regulatory Liaison Group, or the IRLG, and this was a coalition of several federal agencies. Do you care to comment on the objectives and who was involved and so on, the outcome?

DH: (Laughter) Well, I probably could comment on it, but I guess the best comment is that it didn't work, it probably never would have worked, and it wasn't really worth the effort. The presumption was that there was some kind of improved efficiency that would come out of that group working together. I don't believe that there was ever any real expectation on the managers of any of the separate entities, that that really was something they wanted to do.

RT: What were the agencies involved?

DH: I don't remember at this point, Bob, as to who all was involved.

RT: Well, in my footnotes I have here, the EPA, the USDA, CPSC, OASH, and FDA.

DH: It was a very short-lived effort.

RT: It might be interesting to observe that recently I was approached by somebody in the agency who was trying to find out about the IRLG, with the idea of presenting this concept to Mr. Chesemore, who is the current ACRA, and I told them that Gary Beard from the Division of Federal-State Relations, who sort of is your staff assistant, could probably give them info. So maybe the coming around the tree is in evidence again.

DH: Maybe it's Freudian on my part, but I've very carefully erased most of that event and series of events and efforts from my memory banks.

RT: As I recall from Gary's involvement, one of the objectives was to develop a system for cross referrals of violation discoveries between agencies. As you've already observed, there were some different orientations coming together there.

DH: I don't recall any case ever having been referred from one to the other.

RT: I see. Well, when the EDRO and the ACRA organizations were combined in 1982, do you have any thoughts on what prompted Dr. Arthur Hayes, the commissioner at that time, to move this way?

DH: I have no idea whatsoever. He never discussed it with me, he never asked my opinion until after his decision was already made. I had no part in the discussions

leading up to it. I was informed that the decision had been made, and if I wanted to submit a rebuttal, I had an opportunity. I was given one week to do that, and to the best of my knowledge, I suppose Dr. Hayes read it, but . . .

RT: Kind of made his own decision then.

DH: His decision was already made without any participation by our organization whatsoever. It left me in a very embarrassed position with my own managers, because it was clear that our organization was being eliminated, and I couldn't tell them what was happening. It was about as uncomfortable and embarrassing a situation as I could ever expect or imagine being found in. I don't think Dr. Hayes had any idea of how hurtful this was to me personally and to my managers.

RT: Don, well, we've really got quite a bit to cover, but later on, I'd like to get your comment about the various commissioners. But maybe we should wait on that one until we move across some other things that you were involved in.

Now you then went to the Southwest Region at one point in time as the regional Food & Drug director, that being a very large territory as I recall and . . .

DH: Well, at the time my position was abolished, the commissioner gave me an opportunity to select whatever position I might want. I told him at the time that I thought that Paul Hile and I were so far apart in our philosophies of management that there was no way that I could be his deputy, which was one of the possibilities that had been raised. I think that was obvious, because when the combination took over, a significant number of the changes that I had implemented were promptly reversed. At the time that was occurring, there were two vacancies available in the position of regional Food & Drug director, and since he had given me the option of any position I might want, why I told him I would accept the position as the regional director in Dallas.

RT: So that was the Southwest Region.

DH: Well, no, it was Region VI.

RT: Well, was that before the agency had reduced the number of regions?

DH: Yes.

RT: At any rate, I do know personally from working in the Division of Federal-State Relations that you were instrumental in developing some good cooperative arrangements with state people down there. I think you, for one thing, developed a COPE agreement, which was a Coordinated Operations Plan for Emergencies agreement that involved twenty-two signatories and included three or more regulatory agencies in each of five participating states.

DH: Yes, it was . . . Dick Davis in Philadelphia had developed the basic concept of the COPE agreement, and as Dick . . .

(Interruption)

RT: OK. We were talking about COPE agreements.

DH: Well, the concept of the COPE agreement as Dick established it was an agreement between his office and a particular state. He brought together all of the regulatory elements in foods and drugs within a particular state and found that they frequently did not communicate with each, and that one of the benefits he saw to that was the fact that it provided a mechanism to bring about communication within that particular state.

RT: Well, as I recall, in addition to the states, you also had involved some federal agencies. Do you remember the ones that were involved?

DH: Well, that's what I did with it, yes. As I began to look at that and think about what the advantage of it was, I also noted that you didn't have much in the way of coordination and cooperation between various federal agencies or between similar agencies in different states. So what we decided that we would try to do was to take the concept that Dick had developed, where he developed an agreement between himself or his office and a particular state and all of the elements that went in a state, was to try to do the same thing with all of those same elements within our region.

RT: So the states that would have been involved would be Arkansas, Louisiana, New Mexico, Oklahoma, and Texas.

DH: Those were the states that were involved in old Region VI, which was the regional structure at the time I went there in '83. I guess that maybe the reason that I felt that way was that when I first went to Dallas, the first meeting outside of the office that I went to was a meeting where a number of the senior state officials from the state of Texas were present. It was a workshop that was being done jointly by state officials from Texas and FDA.

I had an opportunity over dinner that evening to sit down with the senior management from the Health Department of the state of Texas. We got to talking about the desirability of working together and concluded that communication between our organizations was really not very good and probably wouldn't change unless we changed the interpersonal relations between our people. We wondered how one might do that.

Neil Travis from the state of Texas proposed that we needed to get together in a social atmosphere away from the office and proposed that we attempt a go-away

kind of a meeting, and we agreed to do that. We agreed that they would bring their representatives from around the state, and that I would bring in my folks from around the various resident posts and the supervisor responsible for them and all of my managers from the region and district. And then we would just go away somewhere and spend the weekend together and work on the concept of improving the interpersonal relations between us as people, with the idea that it would then spill over into the workplace.

That worked so well that we did it every year for the rest of the time I was there. I think there was a whole lot more that happened after the formal sessions during the day when we were just together playing in the evenings, and that turned out to be a really superior interaction between the two organizations and led over time to a significant number of regulatory actions in which we took joint action or in which the state took action based on federal testimony, FDA testimony, and the other way around, where FDA used state investigators' work as the basis for legal actions.

RT: I believe that you also pioneered, at least in that area, the first issuance of an FDA commission to the State Attorney General's office in Texas.

DH: Yes. That all came out of that same process, because we were using each other's evidence. We reached the point on one particular case where I was developing a regulatory letter to issue to a firm, and I could not share the drafts of that with the Attorney General's office who was in the process of developing an injunction against the same firm. The way around that seemed to be to go ahead and commission that person, which then allowed us to share that kind of preliminary information in case development, and we subsequently expanded that to include all of the attorneys general in the region, and it worked very well.

That kind of interaction proceeded from Philadelphia's development of the COPE agreement. We kind of put those two together and said, "Hey. We've seen

the advantages within one state, between one state and FDA. We also see the failure between states to communicate with each other. And we know that Dick's right, and that within a state people don't talk to each other. Maybe we can use this as a mechanism to fix all of that."

One of the things that happened, for instance, is that a product would be condemned in one state, the owner would want to recondition it in a second state, and there was no automatic mechanism for communication between the states, and that was happening more and more often. So we saw the hole as being the way to fix that.

RT: I believe that in Texas, as I recall, a cottonseed meal problem emerged. I forgot the adulterant there . . .

DH: Aflatoxin.

RT: Yes, that was one of the problems they worked out.

DH: Yes. Actually, that was cottonseed meal that came out of Arizona.

RT: Arizona. I see. Now, just to touch back for a moment to the COPE agreement, I think . . . My recollection is that you had USDA, EPA, and the Indian Health Service as federal agencies tied in.

DH: Yes. As we began to look at who all needs to interact, the states pointed out that USDA in particular was often a party to recalls such as you mentioned, the aflatoxin in the cottonseed meal. The other place where we ran into a problem was the fact that if you looked at the state of New Mexico, which was one of our players, a big chunk of the square miles of New Mexico is Indian reservation, and if you have a product recall, we can't go on the Indian reservation. We have no jurisdiction on

the Indian reservations. But those consumers have every bit as much right to know about recalls as anything else.

The mechanism to let them know is to get the Indian Health Service to inform them. So that's how we brought in the Indian Health Service, and, in fact, even though we were talking about Region VI, which did not include Arizona, the headquarters for the Indian Health Service that dealt with New Mexico was in fact in Window Rock, Arizona. So, yes, we expanded well beyond our own borders in order to get the right players involved.

RT: From the international cooperation . . .

DH: I might point out that it took almost a year to get all those people to sign that document. Just the signature part took almost a year.

RT: I'm sure it did. I think that while you were in leadership at southwest, you also strengthened or worked on Mexican liaison to deal with some of the problems.

DH: When I went there, there was a headquarters unit physically located in Dallas District called the Mexican Liaison Office. I was given a task by headquarters to reexamine the liaison with Mexico and to make some recommendations as to how we might improve it. When I looked at one of the issues, it turned out that the majority of the issues between the FDA and Mexico had to do with actions being taken by the Los Angeles District and Dallas District against products of Mexican origin; and a headquarters unit could not resolve those issues, because they didn't have direct access to the information on what was going on.

So, among other things, I recommended that the organization not be a headquarters organization, and that the responsibility for liaison with Mexico be transferred to the two regional directors, you know, from San Francisco and Dallas,

and that the focal point for that be Dallas, but that it be in the regional director's office in Dallas and not in the headquarters unit physically located in Dallas.

RT: And you did have a staff person there that . . .

DH: There had been two staff people there actually. Bert Guerarro and . . .

RT: Roman Longorio?

DH: Yes. Anyhow, just about the time I got there, one of the two departed so that it really came down to a question of should that person be replaced, and my recommendation was no, and that the individual remaining, which was Bert Guerarro, be reassigned to the staff of the regional director. Subsequently, Bert decided that his own career interests lie in getting back to the laboratory. So we were able to get him reassigned as a laboratory supervisor in New Orleans.

And Roman Longorio moved on. He actually left the Food & Drug Administration and entered his own business as a consultant to importers bringing product in from Mexico.

RT: So Roman is still, in a way, serving the interests of the regulatory community.

DH: Well, he's involved in the process anyhow. It's . . . Whoever's best interests he's serving.

RT: And then, of course, you served as RFDD of Pacific Region then or Region X?

DH: Well, before that happened, while I was still in Dallas, we went through a reorganization of the regional structure in which effective 1987, 1988, we reduced the

number of regions from ten to six, and essentially what happened is that what had been Region VI, VII, and VIII were melded into a single region called the Southwest Region. In that process, I lost Louisiana. From the collect, I also lost Montana which went to the Pacific Region, and all the rest of it then became a single region with three districts, which is Dallas, Kansas City, and Denver, became a single region. That was facilitated by the fact that both Region VII and VIII were without regional directors at the time that happened. So the only thing it affected was promotion opportunities for people that didn't get them.

RT: Well, you certainly had a large territory in Dallas and later in San Francisco. Probably the biggest piece of geography in the country--the biggest two pieces.

DH: Well, yes, when, you know, the Pacific Region was almost described as being from the Continental Divide to Guam, from the north end from Point Barrow to the southern end being the Samoan Islands. So, yes, it's a lot of territory involved. And, in fact, at the present time it's the largest, in terms of personnel as well.

RT: Now, within the regional organizations, the regional headquarters appointed some managers for these so-called state cooperative programs, or at least strengthened those dealing with the shellfish, retail food service, milk.

DH: Well, yes. They were kind of wandering minstrels without any kind of collective direction to go, without any collective management, and I did see the value of setting that up as a separate branch, and it did establish a situation where they all reported to a single manager for their organization.

RT: OK, Don, I think you had expressed earlier, off the tape, comments that you wanted to make on some new facilities in the field.

DH: Yes, when I took over down there, Dallas was in a fairly nice building, but old. Kansas City was in a fairly nice building, but old. Denver was in a very old building, not nice. This was all, I think, a part of what, over the years, had become the deteriorating nature of a lot of our facilities. The Dallas and the Kansas City laboratories were built during the flurry of building in the late fifties, and they're all known as Rayfield buildings, because they were all designed by Allan Rayfield and they all look alike. All a single design with some exterior differences, but inside they all look like the same building.

But you're talking about a physical facility that is subjected to considerable strain because of the changes in the kind of work we do. But also because plumbing gets old; electrical service becomes inadequate; air conditioners get old. All of which means that from time to time, you need to have a serious reconstruction of laboratories. That had not taken place in FDA for a long, long time, and there was all kinds of planning going on, all kinds of thoughts and ideas about what needed to be done, but it wasn't really physically happening.

As it turns out, in Denver a facility became available that offered a real opportunity to move out of a very old, very inadequate structure into a shell that could be designed to fit our own needs however we wanted it, and that was done. I think that was a very good thing.

In Kansas City, there was an opportunity to develop a new structure, a totally new, rebuilt structure, and the monies became available, and we were able to do that.

In Dallas, all the planning was done, but we never were able to get the money to do it. So a number of things happened. They did move into a refurbished facility in Denver. We were able to move into a brand new facility in Kansas City after I left the region, but we had done all the planning in advance. We even brought into the regional office the fellow who had been the laboratory director in Denver at the time that building was being designed and built. We brought him in to work on the

ongoing process involving both the Kansas City laboratory and in what might be done to help in Dallas laboratory.

RT: Was that David Root?

DH: Dave Root. So Dave has provided that kind of coordination for the entire region for the three labs within that region.

What happened in Dallas was that we managed to actually about the time I was leaving there, we were able to get an agreement that we would move the regional office out of the building into separate leased space. Since that time, they were able to . . .

(Interruption)

DH: OK. The rest of the district office moved also out of the structure, and they are in the process, or have been in the process, of converting the rest of what had been the old district office building into all laboratory, and all of that is building on the information that Dave was able to gather throughout the rebuilding of the other two laboratories. So they should be in passable shape for the next several years.

One of the things that had happened during the latter stages of my time in Dallas, I had been I guess you'd call it negotiating with Lloyd Claiborne, my counterpart in San Francisco, about the possibility of us trading jobs. We had been talking to the boss in headquarters about that possibility, but we hadn't really gotten serious about it, although both Lloyd and I, you know, were desirous of such a switch.

About the time we got into serious discussions with Ron Chesemore about that possibility, circumstances changed, and Lloyd Claiborne retired. I had made no secret of my desire to move to California--move home to California--so I made a formal proposal to Mr. Chesemore that I would be most pleased to accept a transfer

to San Francisco, and he was able to accommodate that desire. So I did, in fact, move to San Francisco.

RT: Well, just to put things in perspective, is it true that you came to Dallas in '82?

DH: Eighty-three, May of '83. I reported to Dallas on Sunday, May 10, 1983. On Wednesday, May 13, I received notice that my father, who was en route to see his first great-grandson, had been taken to a hospital in Joliet, Illinois. Before I could get there, he died. Doris and I handled the details and eventually took my mother back home. It was over a year before she actually got to meet Alex.

RT: And then you went over to San Francisco in '94, was it?

DH: No, it was January of '91. So I had seven years in Dallas, which was the longest I was anywhere.

RT: While you were at San Francisco, I'm sure that some more facility improvements probably occurred.

DH: Well, yes. We were able to accomplish a number of things, some of which I certainly can't take credit for. Seattle District, as I had just mentioned with Denver, had been in a very old, very inadequate building. They were able to get into a brand new facility designed for us outside of Seattle, on the north side, in Bothell, and moved the entire office out there. That building has subsequently become too small, and they are in the process of expanding the building. But that was a very useful kind of an improvement, I think. Certainly, it was an improvement of the working conditions for the people who were working there.

The San Francisco office . . . All the planning for a move to a newly renovated facility took place while I was still there, but the physical move occurred after I had retired. But they are now in a new building. I also started the process of moving the regional office out of the old federal building, and they have subsequently moved to a new federal building in Oakland. So we no longer have a presence in the old federal office building at 50 U.N. Plaza.

Los Angeles District . . . We started the planning a long time ago. Actually we created a new management entity which was the import unit, including both import compliance and import investigations, all of which is in a newly renovated office space in Terminal Island, which I think is working very well. The non-laboratory remnants of the district office have just moved into an office space in Irvine, California, and they have permission to negotiate for the relocation of a laboratory from downtown Los Angeles also to the vicinity of Irvine into a new facility, which again will relieve the problems of not only the deterioration of the facility itself, which is really bad, but also to get into a physically safer area, since they are currently located in south central Los Angeles and were directly and adversely affected by the riots there. There is some real question of the physical safety of the people who work there, and that can be relieved by the upcoming move.

So we were able to plan for and eventuate the move of all three offices in that region.

RT: While you were at San Francisco, you also worked, as I recall, with Canadian people to establish a rapport between the Health Protection Branch and FDA.

DH: That didn't start when I went to San Francisco. The Canadian people had been a part of the Central States Association. Actually they were at least visitors to the Central States Association before I got there in 1970 and had been active participants since that time in the Central States Association. I found that the provincial people from the western part of Canada were equally involved in the

Western Association when I arrived there, and I think we have significantly improved that relationship while I was there.

RT: That's what I was thinking of in this case.

DH: I can't take any credit for starting that. I think I could take maybe some credit for improving that.

RT: Nurturing it.

DH: Nurturing it. We also involved the folks from Mexico in both AFDO and in the Western Association, and I think that's a positive . . . During that whole time, we have also been able to foster the participation of Mexico, strengthened the participation out of Canada, and involved a number of other countries as well in the Association of Food & Drug Officials, which I think is a very positive event, and, you know, is represented by the fact that the Federal-State Relations Committee of AFDO changed its name to the Intergovernmental Relations Committee simply because it was no longer just federal-state, but, in fact, was a lot broader than that.

RT: Now I know you've been active in AFDO, the Association of Food & Drug Officials, having been involved in several of their committees through the years. What were some of the highlights of your involvement there?

DH: Well, I first got involved at the committee level. There was nothing to involve laboratory people. When I had first gone to Chicago, I observed the fact that there was a laboratory section in the Central States Association, and it seemed to me that something like that would be desirable at the national level. In fact, we started what we called the Science and Technology Committee, and I was the first chairman of

that committee and remained active in that committee throughout the rest of my tenure with FDA.

RT: And I think you've participated in some other committees and leadership as well.

DH: Well, the Federal-State Relations Committee, which subsequently became the Intergovernmental Relations Committee, I chaired that for several years as well.

RT: Right. And, of course, with regard to AFDO . . .

(Interruption)

RT: You were saying, Don, when we ended that tape, we were talking a little bit about the AFDO committee, and . . . Oh, yes. I remember now. I was about to mention that in 1994, you were the recipient of the AFDO's most prestigious award, the Harvey W. Wiley Award. Of course, this year you'll be the presenter to this year's recipient of this award. This award is very prestigious in that it identifies on a national basis individuals who have made very significant contributions to intergovernmental cooperation and/or achievements in their respective agency.

DH: For me, one of the real advantages, if you will, or the most meaning, I think, comes from an award like this, because it's awarded to you by your peers and not by your bosses. It's not a management kind of a thing. It's given to you by the folks you've worked with, and for me that's greater recognition, and I certainly was honored last year to receive that award. The interesting twist to that is that I'm one of the few people that was told in advance about receiving the award, because I wasn't going to be there, and the only way they could get me there was to tell me that I had to be there for the Wiley Award banquet. They didn't actually say that

I was getting the award, but they told me I had to be there for Tuesday night's banquet, and it wasn't much of a leap of faith to figure out that there was only one reason for that to be fact.

It's not the first time that that's happened. I remember when Don Mitchell had been nominated. I actually had to tell him to get his tail down here because he was getting the award. Otherwise, he would not have been present.

RT: Well, it usually is a secret process, and you feigned surprise enough to be convincing, I think.

DH: Well, except that I did also admit during the discussion that I had been told in advance. I don't think that will be the case this year.

RT: It's a very fine accolade to receive, and perhaps an appropriate culmination of over thirty years of service to the FDA and the nation.

DH: Well, very near forty years.

RT: Forty. I'm sorry.

DH: Thirty-eight and a half at the time of retirement.

RT: Great. Now, Don, we've covered a lot of ground, but one thing I might ask you is in regard to the fact that you served under quite a series of commissioners. As a matter of fact, there have been more commissioners in the last several years than the agency ever had before that post became politicized. Having served under a number of these folks, do any come to mind that you'd like to comment on either in an affirmative or otherwise way?

DH: Well, my first recollection, of course, was the last of the career commissioners, and I think the thing that . . .

RT: Who was George Larrick.

DH: That was George Larrick. The thing that jumped at me about Commissioner Larrick was the fact that everybody in the organization, from the local storekeeper to the highest official in Washington, if he met you, he could call you by name and knew something about your family. There were only eight hundred of us when I started, so maybe it wasn't as tough to do. But to me that was one of the most impressive things about being a part of FDA was the family. I think the field organization has managed much better than any other part of the organization to maintain that, and I think that was one of my earliest impressions of senior management was that they seemed to care about the rest of us.

Obviously when we went from a career commissioner to a politically-appointed commissioner, there were a lot of trepidations about that. I certainly had a positive reaction to that. I didn't particularly think that Jim Goddard was a great commissioner. But in terms of my own career, I certainly flourished as the result of his having been there, and I think in part because Doris and I had agreed when I came to work that one of the tenets of employment was that when they asked us to go we'd go, and we always did that with one exception. In 1972, when Weems Clevenger left New York, they asked me to go there and take over that job; I declined. That was only a year and a half after I'd moved my son already in high school, and I was not going to move him again while he was still in high school. They respected that on the proviso that I go to New York for sixty days and act as regional director instead. So that was, I thought, a cheap price to pay to keep from being transferred there.

We had a lot of almost what you'd call interim commissioners, people who were there for very short periods of time that didn't seem to have a whole lot of

effect on the agency one way or the other. Some of the acting commissioners have perhaps had more effect it seems to me than those interim commissioners. Sherwin Gardner and Mark Novitch come to mind, both of which I got along with very well, both of which I think did a great job for FDA, and both of which were put in what I would say is an untenable position of being given the responsibility to do the job while being told that they weren't qualified to have the job. How they were able to maintain the sense of professionalism that they brought to those jobs in those kinds of circumstances . . . Sherwin, more than once being put through that, is just . . . I thought that was an exceptional performance on their part.

I get along very, very well with Don Kennedy--in part, I think was an accident in time. He was there when I first went into the job as the EDRO, and we were expanding, we were getting bigger, we had more money, the budget was getting bigger all the time, and he was open to new and inventive and new operational kinds of things, and that was fun, and I got along fine with him.

That isn't to say that I agreed with everything he did, because one of the things I wanted to do was to close Minneapolis District, and he would not allow that to happen. I believed then, I believe now, that there is not enough work for that office to be in operation. The investigations part, yes, but they don't need a laboratory.

RT: That was in your jurisdiction when you were RFDD at Chicago, wasn't it?

DH: Yes. Most of what they do, you know, in that laboratory is work brought in from elsewhere simply to keep them busy, because they don't have enough local work to do. Otherwise, they wouldn't have anything to do in that lab.

RT: Coming now down perhaps to the more recent commissioners, do you see a difference in direction that is worthy of note--where we're going or where former long-time employees might feel we should be going or not going?

DH: Well, I had my say about Art Hayes. I don't agree with a lot of the things that he did. As far as David Kessler is concerned, I like a lot of the things that he's done; I like the activism involved. At the same time, I think that he has compromised the agency's position in a number of areas on the altar of politics. Maybe it's the price that a commissioner has to pay to stay on the job, but I'm not sure that it was worth it.

I was particularly surprised by his decision to take on the tobacco industry, which a number of other commissioners had very carefully and deliberately refused to do in the past. It's not that I don't think that we ought to do something about the tobacco industry as a nation. It's just that I don't think FDA ought to be the pawn to try to do that.

I still think that if I had to pick out one thing out of my whole career that I had done, it would be during the time of Kennedy's commissionership when we were able to officially make research a part of the function and to get the research centers established. I think it's time for a revision of the research centers, and that was included in my last task which I did for FDA, where I spent the last three months of my time on the job looking at the twenty-first century and where FDA ought to go and try to be in the twenty-first century: what the labs ought to look like, what investigations ought to look like, what the organization ought to look like.

I was pleased by the fact that Dr. Kessler pretty much accepted that report as it was submitted, and it is now the blueprint for the future. That does, in fact, include a restructuring of the research, the research centers, and the kind of research done, the size of them, the location and size of laboratories, and hopefully recognize the new directions that both inspection and laboratories are going to have to take.

RT: Well, that's something I'm sure that you can watch now as a retired regulatory official and observe whether those ideas are carried out.

We've covered a lot of ground. You've certainly covered a lot yourself, and probably have moved as frequently as anybody has who has risen so near the top of the organization.

We appreciate very much the opportunity to have a transcript of your work experience and your views. Thanks very much, Don.