

History

of the

U. S. Food and Drug Administration

Interviewee: Heinz G. Wilms

Interviewer: Ronald T. Ottens

Date: December 7, 1994

Place: Rockville, MD

DEED OF GIFT

#1

Agreement Pertaining to the Oral History Interview of

HEINZ G. WILMS

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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.

TAPE INDEX SHEETCASSETTE NUMBER(S) 1,2,3GENERAL TOPIC OF INTERVIEW: History of the Food and Drug Adm.DATE: Dec. 7, 1994 PLACE: Rockville, MD LENGTH: 135 minutesINTERVIEWEEINTERVIEWERNAME: Heinz G. WilmsNAME: Ronald T. OttensADDRESS: [REDACTED]ADDRESS: Food and Drug Adm.FDA SERVICE DATES: FROM 1971 TO 1994 RETIRED? YesTITLE: Director, Division of Federal States Relations, ORO, ORA
(If retired, title of last FDA position)

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RO: This is one of a series of oral interviews on the history of the Food & Drug Administration. Today, Mr. Heinz Wilms, retired director of the Division of Federal-State Relations, is being interviewed in the Parklawn Building, Rockville, Maryland. The date is December 7, 1994. I am Ronald Ottes. This interview will be placed in the National Library of Medicine and become a part of the Food & Drug Administration's oral history program.

Heinz, to start this, would you briefly sketch where you were born, raised, educated and any work experiences prior to coming to FDA, and then we'll cover your career in FDA.

HW: OK, fine, thank you. And I hope this December 7, the day that President Roosevelt viewed as the day of infamy, will not extend to this particular interview. (Laughter)

Having said that, first of all I want to thank the oral history program for allowing me the opportunity and the honor for being interviewed in this what I consider to be a very important program and something that hopefully both the students of the Food & Drug Administration and members of the Food & Drug Administration will find of value to either examine what the agency has done or will be doing, and hopefully it might prevent either bad decisions from being made or help augment the good decision-making process.

RO: You know, that's interesting Heinz, because what we try to do in these interviews is to get something that's a little more in depth than what is part of the official record, and there are people that have been involved in when certain policy decisions have been made, and they can give some insight into really the pros and cons of what resulted in that policy.

HW: OK. Well, I was born September 4, 1937, in LeMars, Iowa, son of an immigrant shoemaker from Germany, who had left Germany in 1934 to get away

from what was going on over there, and either lived in town or on the farm in Plymouth County, Iowa, until I left to go to graduate school. I was educated in the LeMars public school system. Later, during my freshman and sophomore years in high school, I went to Concordia Academy in St. Paul, Minnesota, but returned to the public school system for the remainder of my high school years in LeMars and did the usual things, you know, active in various school activities.

But our financial situation was such that I did have to work, and I worked at J C Penney Company, and for the final year of my high school year, I began work with the brand new radio station that was just opening up as a cleanup boy and in general whatever duties needed to be done and gradually worked into within the year doing radio announcing. That allowed me, then, to work my way through college at Westmar College, which was the local college in town, where originally I was going to go into radio and business, but having been exposed to science courses like chemistry and physics, I found them so interesting that I changed my major and focused on the sciences. It was there that I . . . I spent about five years at Westmar College, because I had changed my major, but I majored in physics with a minor in math.

In 1960, I was awarded--actually '59--but beginning in 1960, I was awarded an Atomic Energy Commission (AEC) Fellowship to study health physics at one of eight schools around the country, and I chose the University of Washington in Seattle. There were probably eighty such students, eighty or ninety such students, selected each year from around the country to go to those universities, and it was a multidisciplinary program for one or two years where you would wind up getting your master's in health physics or radiological science or whatever it was called at the university. At the University of Washington, it was radiological science.

So I was at the university for two years, spending a lot of time in the second year just on my research topic and spending the summer between those two years at the Hanford Research Station, which was run by General Electric for the Atomic Energy Commission. It was there that they did an awful lot of biological effects

work, and it was, of course, associated with Manhattan Project in which they produced plutonium for later assembly into nuclear weapons. But they had a very active nuclear reactor program there as well. It was also in association with the University of Washington where they had a research reactor. My master's work was in radiation exposures to radium therapy, which was still being used at that time. It no longer is; there are better alternatives. Upon getting that master's degree . . . In fact, in my second year in graduate school, I got married. My wife, Sue Ann, is a girl from Akron, Iowa, and she had just gotten her nursing degree, so she worked at the local children's orthopedic hospital during my last year in graduate school.

After graduate school, I took a job with the United States Geological Survey (USGS) in Denver at the Federal Center. We were very fortunate coming out of that program, because there were a lot of job opportunities for us. In fact, I had almost selected a career in the Public Health Service and had gone so far as taking my physical, but the offer financially was better from the U.S. Geological Survey. I can remember starting there as I believe it was a GS-11.

RO: What year was that?

HW: This was in 1962. There was some resentment on the part of the old hands there at the U.S. Geological Survey. The geologists of which there were many and cartographers and hydrologists and those folks, as well as earthquake specialists, you know, it was a conservative agency. They didn't give out those kinds of grades for somebody just coming fresh out of graduate school. But they needed a health physicist, and I was also named the agency's safety officer. So I got involved in occupational safety as well, which I had gotten a lot of training at the university in industrial hygiene. So it worked out that my training there at the university was very well suited to USGS.

One of the reasons they wanted me to work there was to consolidate all of their licensing activities with the AEC (Atomic Energy Commission) and to put us

under what they called a broad license, which gave the agency more flexibility in using radioactive material. We were just entering the lunar geology program which had begun only a year or so before. You remember, this was 1962, and President Kennedy had announced the race to the moon, and we were really competing with the Russians at that time. The Federal Center or the USGS there was planning on installing a nuclear reactor, and so I was to be the health physicist for that and to prepare that.

So it was an exciting challenge. A young kid just out of graduate school, a lot of neat things to do and some more pedestrian things like mercury poisoning and preventing the poisoning of mercury and handling of mercury properly, working with the folks out at Canoga Park in California. That was the earthquake center out in Canoga Park with the USGS. They have three main centers, Canoga Park, the Denver center, and, of course, here in Washington. But most of my work was in Denver, and that's why I was sited there, even though I was the agency's safety officer and health physicist.

It was about that time . . . I can remember vividly the Cuban missile crisis kept us all glued in our seats. But that winter, or actually that following spring in '63, the appropriations were cut for USGS, and they X-ed out the research reactor, which made me start looking for some other job, because I felt that, you know, I really wanted to stay in the nuclear reactor or those kinds of activities rather than shift into some more things like lunar geology. The State of Nebraska had made an overture to me, but the money wasn't worth it.

Pan American World Airways was hiring health physics engineers to run the health physics protection or radiation safety program for a new agency called the Space Nuclear Propulsion Office, which was a joint AEC and NASA program. The country had been trying to develop various applications of nuclear energy in space for a few years. Some were fairly simple devices, like the SNAP devices, which are really nuclear thermal electric devices to produce electrical power to power satellites; and others were much more elegant, like RamJet airplanes, the old nuclear airplane

project which was shelved. But there was one called Nerva, that's a nuclear engine for rocket vehicle applications, which was the one I was hired to work on for Pan American Airways, which was the prime contractor for this project in Nevada, as well as the space station in Florida.

There were a number of us folks hired to run that program, and that was a very exciting time. We spent many, many hours, days without time off babysitting the reactor programs. I was in charge of the reentry teams that went in after the test shots of these reactors to make sure that we were handling the activated wires that would tell us what the flux of the reactor was during start up time, as well as I was in charge of industrial radiography for the Pan American World Airways, in which we were examining welds on all of the equipment there. For example, they had I think the largest stainless steel welded tower in the world there as well as an aluminum tower. These materials were selected because they were less neutron activation prone than other materials. But welding was difficult, and so they spent a lot of time checking those out.

It just so happened that these . . . I mean, these tests were very exciting. These small, basically barren shielded reactors were very powerful. They were intended to heat up hydrogen, liquid hydrogen and then expel them out the back. So from a physics standpoint, they were very efficient. They could be turned off and on in space, unlike a lot of the rockets at the time that were chemical rockets. So that's why they were really looking for them, and . . . It just so happened, however, that NASA made a decision that for the deep space probes, for which this engine was designed, they were not going to go to manned flights; they were going to go to instrument packages. So, once again, just like the previous program, it was "disfunded." (Laughter) And I could see that things were going to not be as rosy as I thought they might be for the future.

RO: So this was really done by Pan American under contract for NASA?

HW: For NASA. We actually had several . . . We were the prime contractor to run the site to provide all the services. The engineering was done by several firms working with Sandia, working with the Lawrence Livermore Radiation Lab out in California, and several others. So it was a consortium, both of universities and engineering firms that were putting this together. They had to do everything from scratch. But from an engineering standpoint, it was a great success. I know that just about a year or so ago there was some talk about reviving that project. So maybe there still will be life in that in my lifetime yet, because it was very impressive. A small reactor like that put out as much power as Hoover Dam. It was really, really impressive. And, of course, it was all classified secret stuff. One of the things I was responsible for were the dosimetry sites in the five- and ten-mile arcs around the test site. So it was a lot of fun to be out there and checking all of the dosimetry and coming across old cinnabar mines and Indian caves and things that a boy from the flatlands had never run into, so it was exciting.

It was then in the summer of '64 that I received another offer from the Nebraska Department of Health once again to join them and to be the person responsible for their radiological health program. The State of Nebraska had a couple of reactors either operating or planned to operate in that state to produce electrical energy, plus a research-type reactor that they wanted, and they wanted to sort of take advantage of a lot of the exciting Atoms for Peace Projects that were developing out of both the Eisenhower and the Kennedy Administration and, of course, the Johnson Administration.

They wanted the state to become an agreement state with the Atomic Energy Commission. The Congress had passed an amendment to the Atomic Energy Act that allowed the states to sign agreements with the Atomic Energy Commission to take over licensing of radioactive material. The federal agency knew it didn't have enough manpower to do that all themselves, and yet they wanted to encourage the use of radioactive material for feasible purposes, like in nuclear medicine. There was also an interest in states' rights at the time, for the states to do this kind of thing,

both the licensing and the inspection, the regulation. If it could be done in a uniform matter, then so much the better. There was also political desire of the State of Nebraska, because Senator Carl Curtis was a member of the Joint Committee on Atomic Energy, so I know that he wanted his state to be one of the agreement states.

So I went there in I believe it was July of 1964 to take this program, fledgling program, write the regulations for radiation safety for the state, and to work under the sort of broad supervision, policy supervision, of a newly formed governor-appointed radiation advisory council. We were located in the health department, we were a separate division, and we received that kind of guidance. So it was very interesting to work with the governor's office and these leading scientists and business people in the state to get this program going and working with the Atomic Energy Commission folks to become an agreement state. When we signed, I think we were the thirteenth agreement state to do so. I believe today there are some twenty-six or twenty-eight agreement states licensing radioactive material around the country.

It was also at that time that I renewed my contacts with the U.S. Public Health Service, which I had almost gone to work for right out of graduate school. It turns out that they had a formula grant program which was run out of an engineering unit of the Public Health Service and was known as the Bureau of Radiological Health, and it was administering a series of formula grants under the HEW (Health, Education and Welfare) to encourage the development of state radiation control programs.

They had a number of initiatives that they were pursuing. One was reduction of unnecessary x-ray exposure, both in the dental office and in the hospital for regular medical purposes and podiatric medicine, taking over and getting rid of radium. I had worked with radium in graduate school, so I knew something about it. Also getting rid of--but most of them had already been confiscated--those old shoe-fitting fluoroscopes and the old fashioned fluoroscopes that gave out tremen-

dous amounts of radiation were very inefficient for the kind of medical information they gave.

So at the time we developed the radioactive material regulations, we developed a comprehensive set of regulations for all kinds of radiation safety, whether it was material that would be regulated by the Atomic Energy Commission under the Atomic Energy Act and hence devolve to us, or naturally occurring radioactive material like radium, or radiation producing equipment like x-ray machines, and those kinds of things. We've developed a comprehensive set of regulations working with the representative from Public Health Service operating out of Kansas City.

In fact, it was during that very early stage that I first became acquainted with Jim Benson, who later became the deputy commissioner and for a while the acting commissioner of the agency, because he was part of a training cadre putting on training courses around the country at the various laboratories that the Bureau of Radiological Health had. They had one up in the Boston area, one down in Alabama, and one in Las Vegas. I had worked a little bit with the Public Health Service folks at the nuclear rocket station, because they were handling the radiation safety work along with Reynolds Electric Company at the weapons testing site, which was right next to us in Nevada. So some of the people I knew just from that old association and from the Health Physics Society that we all belonged to and went to a lot of their national scientific meetings.

Jim was teaching a course in handling radium needles, how to dispose of them, and had developed what we call the Benson Jar Method, which was a very simple method of seeing whether needles were leaking by placing them in cold cream jars and then reading the lid from the jar to see if any of the daughter products of leaking radium would be picked up. And that was how you could tell a needle was leaking. So it was sort of a very neat, low-cost way, and, of course, we were always looking for that.

We took about I guess it was a year to develop the regulations and put them into place. When I think of it now, we did it in an inordinate amount of speed there. It would be a very short time by today's standards. But, of course, we didn't have to engage in a lot of preambles and open hearings and things that became much more the standard of practice later. But we generally worked on models that were provided to us by AEC and by the Public Health Service and then our own radiation advisory committee. The Board of Health, I think, then passed those regulations according to their administrative procedures in '65, and we became an agreement state then.

We did the usual kinds of radiation protection things, such as x-ray inspections. We were one of the states that used the COSTEP (Commissioned Officer Student Training and Extern Program) trainees from the Public Health Service, which were student engineers, medical students, dental students. They were affiliated with the Public Health Service, getting perhaps some financial assistance from PHS (Public Health Service), but during the summer, were then farmed out on projects. It was great for their education and it was a very welcome set of extra hands for us to do special projects. And so we were involved in both the dental x-ray reduction program and the medical x-ray reduction program working with the folks from the Public Health Service, the Bureau of Radiological Health.

It was in about nineteen . . . It must have been 1967 I think at the American Public Health Association's annual meeting that several of us radiation control program directors got together and decided we needed to have an organization of state radiation control program directors to compete more successfully for federal funds for our programs. I think it was in 1966 or thereabouts that the formula grants, which specified certain monies could only go to radiological health, or to maternal and child health, or other things, were replaced with block grant monies by Congress. That meant that while the states could individually decide how they wanted to spend the block grants, you were not guaranteed a certain amount of dollars. So you had to, you know, compete more successfully. We felt that a unified

front and unified planning both within our state and among the states could be helpful to our continued financial support for the program.

RO: You were going to do this at the state level?

HW: We were . . . Yes, we were going to do this at the state level. So we got together an organization of state radiation control program directors, and we had our first session--a very unofficial meeting. I think it was at the 1967 annual meeting of the American Public Health Association. Thereabouts. I could be off a year, but I think it was in '67. Then we had a more, a little more formal kind of a session at the next American Public Health Association meeting. Some of the people that were involved in that were Ed Frye from Kentucky and Tom Jeruski from Pennsylvania. We had folks from Georgia, New York City. I think most of the folks that were in agreement state programs wanted to be part of this.

As it turned out, our timing was very fortunate, because Congress passed the Radiation Control for Health and Safety Act (RCHSA) in . . . I believe it was 1968. It was either that or early 1969, but I think it was '68. And in it, Congress specified that the Bureau of Radiological Health would have to, among other things, consult with the states in the implementation of this program. Well, here was a ready-made group of state officials who knew about radiation safety, and because of that the Bureau of Radiological Health then sponsored the first meeting of the Conference of Radiation Control Program Directors. I believe that was in 1969. I know I joined the old Bureau of Radiological Health of the Public Health Service in September of '69, and one of my first jobs was to get at the proceedings of that year's program.

While I was at Nebraska, I had a lot of dealings with the folks from the AEC.

(Interruption)

HW: I would lecture to the training courses of the AEC for the new folks who were becoming agreement state officials or staff of current agreement state officials to tell them how the system worked. Then I became more acquainted with the folks from the Bureau of Radiological Health--folks like John Villforth, Jim Benson, and others--who noticed that perhaps I might be a good member of their staff in the future. Dr. Jim Miller, a dentist, who'd been in charge of the state program, along with Dave Flora, who was his deputy, then made an offer to me to join the old Bureau of Radiological Health in the summer of 1969.

Again, it just so happened that the third biennial budget for our Rad Health program in the State of Nebraska had received no increases ever since the seed money was put in, and they were grossly inadequate. We had new duties, we had new people we had hired, we had been using all of these free people from the federal agencies to help us in our projects, that finally we got stretched so thin, we had to have more money. We didn't. I resigned, citing my frustration of not being able to get more from the legislature to run this program. It was a prestigious program to be one of the agreement states and to be out in front of radiation safety. Ironically, after I left, I think the legislature realized that the program needed more support, and they got more support. So maybe my leaving was helpful in that regard. (Laughter)

But I was hired to work for Jim Miller and Dave Flora to be sort of the liaison with the National Conference of Radiation Control Program Directors. I was one of the charter members, and knew all the people, and they knew me. That was my first experience into federal-state relations from the federal viewpoint. I can remember, as I mentioned earlier, my first job was to take all of these transcripts from the meeting of earlier that year and to edit it into something coherent and compact to the extent we could, and we did that. In fact, I edited those proceedings for the next two or three years, I think.

It was at that time, of course, that the Bureau of Radiological Health was going through some birth pangs of itself. The Public Health Service had been

reorganized I think in 1968 in what was called CPEHS. I don't recall all of the titles of that.

RO: Consumer Protection and Environmental Health Service.

HW: OK, Ron, thank you. And one of those organizations was the Environmental Control Administration. I think Chris Hansen was the director of that. It was under that that the Bureau of Radiological Health was located. That organization had taken over the buildings, or at least some of the buildings of the Bureau of Radiological Health, which had grown I think quite large. I believe there were some seven hundred or so employees in the Bureau of Radiological Health about that time and mostly scientists and engineers and biologists for bioeffects work and had laboratories in various places doing a lot of work. Of course, their wings had been trimmed a bit in this new organization.

I don't believe I really understood all of those machinations until after that was disbanded. I believe in 1971 or thereabouts that all was changed. Maybe it was '72. But it was at that time that the National Center for Radiological Health came out of that. But from that 1969 until about 1973 I was Jim Miller's deputy for those kinds of relations with the state. Jim was held in very high regard by all of the state folks, because he and the folks that worked for him were the primary life support, technical guidance from the Center--or Bureau of Radiological Health at that time--to the states.

We had regional representatives in each of the ten HEW regions. I think we had thirty or forty state assignees. These were full-time, paid by HEW, by Rad Health: engineers, dentists, physicists, health physicists, whatever, related to radiation safety, who were on loan for one, or two, and sometimes three years to states. Some in management positions to run the program; some in technical positions, whether they were running the laboratories, or whether they were doing x-ray inspections, or whatever it happened to be. Those state assignees were also

under Jim Miller. So he had a network of both assistants and technical help for the states and had his finger on the pulse of what was going on in the states. So I was part of that staff.

RO: Well, now these state assignees were salaried by the Bureau of Radiological Health?

HW: Yes. They were either . . . Most of them were commissioned officers in the Public Health Service. Some were civil service employees, but I think most were commissioned officers.

RO: Well, how did the bureau . . . ? Was it something in the bureau's statute that allowed them to pay for these?

HW: Yes, there was I believe funding for them under the Public Health Service Act of providing assistance to the states, and there were funds for that. The Public Health Service in lots of areas traditionally has provided assignees to state programs. A good example is the state epidemiologists, many of whom were CDC (Center for Disease Control) employees who were assigned to the states because the states didn't have the money to pay for epidemiologists, they were in short supply, and so they were assigned to the states to run the epidemiology program, many in fact wound up staying in that state and becoming the state health officer or . . . While in the same token, there were some of the state assignees who later left the Public Health Service and became state program administrators. But it was also a training program for the Public Health Service state assignees.

RO: FDA was never able to . . . ?

HW: No. No. FDA was not part of that equation at that time.

RO: It was still a part of the Public Health Service.

HW: It was still part of the Public Health Service, but their funds were not appropriated. You remember, too, that FDA's appropriations were made under the agriculture. The Bureau of Radiological Health's appropriations came out of the Health Appropriations Committee. Different committee. There was a legacy of providing that kind of direct support to the states. In addition to the funds that were going under either block grants or formula grants, there were the assignment of personnel to the states. It was all part of that assistance package. You know, there were a certain number of positions that were set aside for that kind of work. It fitted the strategy of the Rad Health folks very nicely, too, because much of what needed to be done had to be done at the grass roots level, and they just didn't have the people to do it, but they could augment the state staff, and they could also achieve a lot more uniformity that way, too. So things were being done in California like they were being done in Michigan or other places.

I mentioned the Atomic Energy Commission Health Physics Fellowship program that I went to graduate school under. Well, the Public Health Service had a similar program. In fact, they were training a lot more people in many of the same universities. I think they had a larger number of universities, all in the schools of public health: Michigan, Harvard, Johns Hopkins, you know. So some of those students that I went to school with were part of that program as well. Some of my colleagues in various jobs were part of that program. I think that a lot of the old guard in Rad Health at one time or another had gone through that master's program. They would get a master's in public health usually with, you know, a specialty in radiation science.

A number of folks in the old Bureau of Radiological Health at one time had been state assignees. Jerry Halperin was a good example. Jerry was, among other things, a state assignee in Kansas while I was in Nebraska. So we were neighbors to each other and at times met. We had meetings with our colleagues from the Kansas

City Public Health Service office. Jim Benson was a state assignee in Wyoming, although I think he was there at a different time than I was. But it was a different Public Health Service region, so we didn't interact all that much.

That experience gave the mind set, helped a lot in having strong advocates for state programs in the old Bureau of Radiological Health, because they had been there, they had seen the things that the federals were asking the states to do, and knew how difficult it was to implement them at times, and I think it made for good, you know, close and trusting working relationships. We had our usual disagreements, and battles, and all that kind of stuff, but basically it was all kept within the family, and what would come out of it then was a consensus, and everybody would pretty much do it the way that the group had designed it.

The Radiation Control for Health and Safety Act, I think of 1968, required that the standards that the federal government put into place would be identical around the country. So it preempted differing requirements for those kinds of products. It was . . .

RO: You mean the states couldn't promulgate their own?

HW: Well, they had different ones, but when the act was passed which gave the Public Health Service the authority to set standards for ionizing radiation, and microwave ovens, and lasers, and all, you know, radiation emitting electronic products, it required for the first time uniformity around the country. I think it was a wise policy decision, because obviously we couldn't have differing standards for the same equipment that was being manufactured for use everywhere in the country and, in fact, the world.

That was a real culture change for the Bureau of Radiological Health, too. It went from basically a state assistance, educational, developing guidelines with the professional organizations--all voluntary kinds of things--to a regulatory kind of an atmosphere. And this was a real change, a real culture shock, I think, for the bureau.

It was tasked also with developing a lot of reports to Congress and doing a lot of things it had just never done before. But they got some additional people, they got the additional monies to do it, and part of it, of course, was working with the Conference of Radiation Control Program Directors of which I had been a member and now was a liaison person.

Then a hallmark occasion was . . . I believe it was December of 1970 when President Nixon signed the executive order creating the Environmental Protection Agency (EPA). What that did was it took resources from a lot of federal agencies and put them into this new federal agency called EPA. So they took a lot of folks out of traditional Public Health Service programs, like water quality and safety, drinking water programs, air pollution, and radiation control was one of them, where they took about half of the number of people and two of the Bureau of Radiological Health laboratories--the one in Montgomery, Alabama, and the one in Las Vegas, Nevada--and transferred that to EPA. Then they split about down the middle for the headquarters folks as to who would go to EPA. I was given the opportunity to opt which side I wanted to go on, and I'll always appreciate John Villforth giving me that opportunity. I wanted to stay in public health rather than going to environmental work, because I always felt that radiation control would be much more important over in public health than in the environment.

So that was a time of real trauma, and for about a year, the Bureau of Radiological Health was sort of an orphan in the HEW Public Health Service regarding where it would be funded. I believe it was in '71 or '72, Ron, that the decision was made by the secretary that Rad Health would be placed into the Food & Drug Administration. That was my first exposure to the Food & Drug Administration, except for one brief visit that I had had from somebody operating out of the Kansas City office, you know, just a social visit to come by and say hello. I don't even recall who that was anymore. Probably long since retired.

But because we were part of the field side of the old Bureau of Radiological Health, and our organization was called the Office of Regional Operations (ORO),

Jim Miller was the head of that office--we were transferred, and the folks in the field offices were transferred then, to the part of the agency that dealt with the field. I believe when we first came there, that was the Associate Commissioner for Field Coordination (ACFC). It was all under Sam Fine, and it was shortly thereafter that EDRO (Executive Director of Regional Operations) was formed. I believe it was right about that time.

RO: Yes, I think it was.

HW: For the first time, there was, you know, line authority through an operating unit over all of the field organization rather than the direct lines to individual districts. This was part of that Booze Allen study that came out. At that time, Charlie Edwards was the commissioner of the Food & Drug Administration, and he met with all the folks over in Rad Health to try to allay their fears. Of course, Dr. Edwards was a very formal, stiff kind of person, and his demeanor was very sort of cool, and people were quite concerned about him. What would be our fate in Food & Drug?

In our case--in the field side of things--some good things were done. First of all, as I suppose part of our educational effort, all of the trade journals and all that kind of stuff was routed to us. I began reading the wide scope of everything that we were doing in the field: drugs, foods, even devices as it were, because we really didn't have a device program yet, but it was coming on. It sort of opened my eyes to a whole new horizon of things that would be of interest to me as a public health, consumer protection type person. So I was thoroughly enchanted by that stuff, and then we were also part of the management team, Dr. Miller was, but we would often attend the meetings for Dr. Miller and eventually became a regular sitting in the daily "stand-up" meetings that we had. Charlie Armstrong, and I guess you, Ron, and Hy Eiduson, who was the director of science, Dr. Post I remember was there, just a quick stand-up meeting of what was going on that day.

It was also in 1972 that Operation Hire--Project Hire--began. Congress was concerned that food safety had been sort of a stepchild to drug safety and appropriated a lot more resources and hiring authority to bring on hundreds of people, and so there was a special task force there to get all these people on board. All of this was happening . . .

(Interruption)

HW: All of this was happening at the same time. The new organization of the field for FDA; EDRO was being formed; new lines of authority were being worked out; new organizations were coming in, like the Bureau of Radiological Health; product safety was still, I think, part of FDA; federal agencies were feeling out how to split the environmental kinds of work between our agency, EPA, USDA, and the Atomic Energy Commission. So it was a time of a lot of change, a lot of exciting things, and really good people to make all those changes happen. When I think back to the sort of really tremendous changes that were occurring in our organization, the folks here in the FDA were handling that change I thought superbly. Everybody, you know, finds change uncomfortable, and yet I thought it went fairly well.

RO: Well, of course, about that time, FDA got the Bureau of Biologics as well.

HW: And yes, that Bureau of Biologics came to us in '71, '72. It was all part of that change. Then . . . I don't know how many people know this. I believe it was in 1970--'70 or '71--the Cooper Report came out. Dr. Cooper was from NIH (National Institutes of Health), was tasked with performing a study for Congress on if and how medical devices should be regulated. Up until that time, there was virtually no regulation on those kinds of devices, other than some of the fraud work that had been going on by FDA, E meters and those kind . . .

But no systematic kind of pre-marketing approval program existed. And when the Cooper Report came out, various agencies were asked to examine the report and to decide or to make recommendations as to what role they might have. Radiological Health--remember, this was before FDA came into the picture--was asked whether it would be interested in taking it over. After all, they had the engineers, the physicists, the biologists, and they were already handling some of the medical devices, those related to radiation anyway, under the newly passed Radiation Control for Health and Safety Act of 1968. So it was sort of a natural. But the policy makers were very fearful that if Radiological Health got that program, that Radiological Health would suffer. This big universe of products would basically overwhelm the old BRH (Bureau of Radiological Health), and the folks in BRH were very much wedded to radiation protection and really not terribly interested in a broader scope of responsibility.

RO: When you say policy makers, you meant policy makers in the Bureau of Radiological Health?

HW: The Bureau of Radiological Health, that's right. They were very concerned about, you know, would this overwhelming responsibility basically swallow up Rad Health. It was because they were so interested and concerned about radiation protection that they really didn't want to have those efforts diluted.

RO: Well, John Villforth was the director at this time?

HW: I believe John Villforth then was the director. That's right. Who was his deputy?

RO: Andy Anderson, wasn't he?

HW: Andy Anderson was, but then there was also . . . Oh, the fellow that hurt himself and then went to work . . .

RO: Bob Elder.

HW: Bob Elder, yes, went to work for Cosmetic Toiletries & Fragrance Association later. But they were implementing this very complex act, all the standards that needed to be . . . They were concerned about having too much on their plate. So they had had an opportunity to actually take over this whole program and design it properly, *I think*; but because of their concern about what would happen with Rad Health, they really didn't push for that. So out of that, over the next several years came hearings and plans to do something with Congress to write a law for medical devices. Ultimately the Medical Device Amendments of 1976 were passed, but it took a couple of hearings. We had a group in the agency, a smaller group, that wasn't, obviously, a bureau or national center yet. I think it was an office of medical devices. Dave Link, I believe, was running that. But they were sort of gearing up for what ultimately became the Center for Devices.

RO: But before that it was the Bureau of Medical Devices?

HW: It was the Bureau of Medical Devices, and then later, of course, Rad Health and Devices were merged into a single center.

RO: Well, I heard that when that was merged into the Center for Devices and Radiological Health that Villforth resisted that move at that time.

HW: He might have, but I don't have any direct knowledge, because by that time I was fully enmeshed in the regular Food & Drug kinds of things. It was because of

my exposure to all the Food & Drug stuff that was going on, that I was very much interested in applying for an executive development program, Jim Miller recommended me for it, and I was one of the selectees in the group that started in 1973, I believe, and most of the graduating class I think graduated in '74. But I was kept on in the program under some temporary assignments to exec. sec. and to legislative affairs after the summer of '74 until '75, when I joined the EDRO again to run the State Services Branch in the Division of Federal-State Relations. It was during that time that you, Ron, were my advisor in the Executive Development Program, which we lovingly called the "charm school." (Laughter)

RO: Were you Jim Miller's deputy?

HW: Yes, I was his . . . I didn't start off as his deputy, but Dave Flora was Jim Miller's deputy, but Dave actually transferred to Seattle as the Region X Radiological Health representative, ultimately retired there. When Dave left--and this was probably, I think, in '71 or thereabouts, I don't recall exactly--I became Jim Miller's deputy. So all of the regional Rad Health reps reported to Jim prior to the time we came to FDA.

RO: Well, that was quite a trauma for not only you folks in the Office of Regional Operations in BRH, but also for the John Villforths and others who had had these . . .

HW: . . . their own cadre.

RO: That's right, out in the field and . . .

HW: Right. Yes. So obviously we're all involved in culture shock for quite a while. You know, for several years, you're trying to serve two master's and two cultures, and

I think it all sort of evolved pretty well, but it was a difficult time. Because, you know, who were their bosses, really? They were used to . . .

(Interruption)

HW: They were used to being directed centrally from headquarters, and then all of a sudden their operations, daily operations boss were the regional Food & Drug directors. The regional specialists, rad health specialists, generally were fairly senior people, with good, wide experience. The rationale for that was that, one, they had to be a technical resource for the state, so they had to be fairly senior people and have a broad range of experience, and they needed to operate on their own frequently without much guidance. So those regional specialists were fairly high level, either commissioned officer or civil service type folks at the O-5 or O-6 level in the commissioned corp or 13-14s in the civil service. I think most of them handled that transition maturely, but I know that it was traumatic for some of them, because old ways of doing business and . . .

RO: Sure. Well, then they got into the regional office, and they had to report to the regional Food & Drug director rather than directly to headquarters.

HW: All of a sudden their budget wasn't their own and, you know, all that kind of stuff that goes on. But some of the folks that I worked with in headquarters, Bobby Dillard and Jim Kraeger, who . . . Bobby just retired a couple of years ago, and Jim Kraeger still is the regional rad health rep in Chicago. I guess he's the senior rad rep now. It's interesting. Jim Kraeger and I went to the same small college in Iowa, Westmar College, a small college of about six hundred people. When I was a senior in my physics major, I had him in some of my physics classes, and we were fellow students in German classes together, and in math classes so . . .

RO: Well, we digressed here a little bit. You got into the Executive Development Training Program. Do you want to tell us a little bit about some of the assignments in that program?

HW: Yes. That was very interesting, because while I'd had a grounding in some of the projects that were being done in headquarters, it really wasn't in depth, getting into the history of the agency and the law, how the field operated, the kinds of things it did, the management culture, all those kinds of things. While I'd had management courses both in the State of Nebraska and at the BRH, there wasn't really any kind of a planned program. FDA had had an executive development program for some few years, and a few of the graduates were already, I think, regional directors or district directors at the time. It occurred to me that, "Gee, here's a good way to move up the ladder and to get some good training skills and that kind of stuff at the same time and to learn about the culture."

RO: You came into the program as a GS-13?

HW: Yes, I was a thirteen. I didn't really pay too much attention.

RO: Well, it was either a thirteen or a fourteen.

HW: It was either a thirteen or fourteen. But when I graduated from the program and was selected for a job as the State Services Branch chief, then that was a fourteen. I just can't remember whether going into the program I was a thirteen or fourteen. I think I probably was a thirteen. We were competitively selected, I mean, for the executive development program; that meant that we could then be placed non-competitively once we successfully completed the program. There were a number of agencies that had those executive development programs, and some continue yet today.

In my case, and this was what was so good about the program, for each student or fellow of the program, a training and experience program was developed for that person based on what they felt that person's strengths and weaknesses were. Each had an advisor, and in my case, Ron Ottes was my advisor, and that worked out very well. Ron and I sat down, and we developed sort of a plan of what we needed to do. It was clear that I needed to get more experience into how the field offices operate, because I really didn't have any experience with FDA field offices; I had them with the Public Health Service and with the Atomic Energy Commission, but not FDA.

So I had a series of assignments. I think I spent a month in Chicago under Don Heaton, and during that time, I was acting district director and I think acting like a deputy regional director for Don. I think I might have spent some time in the Investigations Branch and Compliance Branch. I'm not sure about the laboratory, but I don't think there was enough time for that. I spent another month down in Atlanta later on in that year as director of investigations unit. It was not a branch. They were set up differently in that region, and it was sort of a regional position. So I spent a month down there. But that was separated by a number of other assignments.

For example, I spent time in the headquarters Budget and Financial Management Office. I spent a month down in the Center for Foods. At that time, it was the Bureau of Foods. Now, of course, it's the Center for Food Safety and Applied Nutrition. I worked in their planning and budgeting office to see how all of the various kinds of projects that were vying for resources were put together into a plan, and we did that over in the summer months, prior to the time that the budget would be developed. I spent time in exec. sec., in executive secretariat. Mac Schmidt was the commissioner then.

I spent time in Office of Legislative Affairs. It wasn't called that then. Office of Congressional Affairs or something like that. I think I spent about three or four months there ultimately, because the job that was planned for me really didn't open

up until January or February of the following year. So I spent more time in legislative affairs than I would normally have--that and executive secretariat. But those two kinds of assignments were great because, again, it was a broad overview of what the agency was doing, and attending hearings, and writing reports and analyses.

During part of that time, I took training courses. We laid out a four-week series with the American Management Association. That was a very good experience, because I was taking courses with corporate types primarily. Very few governmental types in that, and there were both U.S. and foreign business types were taking that. There was a lot of analytical kinds of corporate strategy work. Given a set of facts, here's what you do. But there was an awful lot of how do you deal with employees, how do you deal with labor unions, public affairs, all of which was very useful here in FDA in any kind of management setting. I took several executive seminar courses from the Civil Service Commission in Oak Ridge and Denver, I think. Wherever the courses were most conveniently offered at the time and could fit it into the schedule.

I did some, I think, special projects for you, too. I think I did one on labor relations, where we looked at the various union agreements that we had around the country, and what kind of guidance should we give to field management on operating with the unions. At the time, in the seventies, the unions were really rapidly growing in popularity and influence, and so it was very important that we had some uniform advice to the extent we could around the country.

Also, I think I did an analysis for one of the other offices of the agreements that we had, the Memorandums of Understanding. So we had sort of a uniform list of all of them that were in existence. I began doing work on the freedom of information regs and the Peter Principles, as it's named after Peter Hutt. We, as an agency, were adopting a new way of issuing regulations with the preambles and notice and comment rule making that was becoming the vogue. The agency was picking up on the recommendations of the Administrative Conference of the United

States. All the federal agencies really were supposed to do that, but I think FDA was out in front and making these things very complex. We were at the time, I think, issuing a lot of regulations, Good Manufacturing Practices that were very specific kinds of industry practices, and so we were engaged in a lot of rule making that evolved . . . Later, I know I was involved in the writing of our regulations on the Freedom of Information Act, how we dealt with the states and what kind of information could be given. I know that was one of my first jobs when I was the new States Services Branch chief.

RO: Well, you did that when you went into State Services?

HW: Yes. I think, though, that there was some work I did during the executive development program, but it spilled over into there. We issued those regs in '75-'76. I was branch chief starting about January '75 there, so . . .

RO: What were your responsibilities in the State Services Branch?

HW: This was for Glenn Kilpatrick, who was the director of the division at that time, and a very prestigious individual and well thought of all around the country. He had two branches. One was run by Bob Tucker, which was the State Program Coordination Branch, and it was responsible for administering the state contracts that FDA had and some other things. And the State Services Branch, which I was named the head of, was responsible for communications and issuing the commissions for state officials. We were the information side, and Bob Tucker's branch was the program coordination side.

We had program specialists working for us at that time, but I believe that was on Bob's side, and that was the rad health, the milk, the food service . . . Those kinds of programs were under Bob. One of the things that we had in my branch was the teletype NRSTEN (National, Regional, State Telecommunications Exchange

Network) system. We also developed the state inspectors manual that was patterned after the FDA inspectors manual. Any summaries of legislation or regulations, we put them together and sent them out to the states.

RO: You mentioned under Programs Branch, under Bob Tucker, Radiological Health. Now, what had happened then to Jim Miller and the group under him? Jim left; is that right?

HW: Jim transferred back to Rad Health. Jim for a while was still part of the field organization, but transferred back sometime in the seventies to the center. The center decided they would still have a unit that dealt with the states but would work through the field organization. Jim, of course, being a dentist, also had some interests on the dental side of things. I believe Jim might have been also doing some graduate work at Johns Hopkins at the time, too, because he was working on a Master's of Public Health. But, anyway, they had a small group of state coordination that some of the folks in our office transferred to. But some of the other folks stayed with us. We had . . .

RO: Herb Klein?

HW: Yes, Herb Klein, Lois Miller, and Lavert Seaborn. All of them, those few individuals were then assigned to the State Program Coordination Branch, and in that branch were other program area specialists, like the milk and food service and feed, that had some very specific program technical expertise.

RO: But now in State Services Branch, was there . . . ? You administered the commissioning program for state officials?

HW: We had commissioning; we had the communications program; we had a number of manuals, guidance manuals; and then we handled all the inquiries that came in from the states on what was FDA's position; or if there was information, guidance information that was needed for our consumer affairs officers in our field offices, we would develop them.

We also provided liaison in my branch, as well as Bob Tucker's branch, to certain state organizations. Very much like today, there were a number of state organizations that we were the liaison for the agency. Glenn Kilpatrick was the FDA advisor to the board of directors of the Association of Food & Drug Officials or the Association of Feed Control Officials. Folks either in my branch, or myself, or Glenn, or the other branch and Bob Tucker would serve on those boards and be a contact point for them, a one-stop shopping service as it were, so they didn't have to find out who in the agency to go to. Or if the agency needed some assistance from these kinds of state officials, they could come to us, and then we could arrange it. So very much like today, we would have meetings with the executive boards of those organizations or attend their meetings wherever they were in the country, and represent the agency. It was a time, however, when we were not working as closely with the states as we are now.

We also had the Intergovernmental Personnel Exchange Program that we were basically just keeping track of who was assigned to various states or the state folks assigned to the regional or district offices. But it was about that time that the funding for IPA (Interagency Personnel Act) basically stopped. We had a few sort of special projects where somebody would go there and work on a new set of regulations or something. But most of that really was tailing off, and by 1976 or '77, there was just no funding.

RO: Now that had nothing to do with the state assignees that we talked about before?

HW: No. This was a different act that applied to all of government. The state assignees in Rad Health were at the states under Section 351 or 361 of the Public Health Service Act that calls for the secretary to provide assistance to the states. But the IPA, the Interagency Personnel Act, gave authority to federal agencies anywhere if they had the funding to share expertise with one another. But it operated pretty much the same. However, I think the IPA assignments were intended to be short term and not long term--two, three, four months generally.

RO: Well, you left the Division of Federal-State Relations then?

HW: Yes, I did.

RO: What position did you leave for? (Laughter)

HW: Well . . . By the way, I want to mention just a little bit about something. It was interesting that in 1975 . . . You've got to remember the state contract program really didn't get started until about '72.

RO: Yes. That was part of this Project Hire with all the money . . .

HW: Yes. All those new monies for food control work and all that kind of stuff. And the communications program was all teletype. We were leasing all these lines and paying for a teletype machine in every state. There was one per state, and then in some of the trust territories of the United States. We had to type every one of those messages out by hand, and then get on a teletype machine and get them to Western Union, and then they would send it out. So it was a very laborious, time-consuming process. But the FDA was paying for that machine, and the states could send in inquiries to us. It was the first step in a nationwide communications program

which later, you know, became all computerized. But changes really were significant by the time I returned in 1985.

Well, in '77, the agency received a bunch of new resources from Congress to monitor the conduct of clinical trials and pre-clinical trials. They were concerned about the quality or the lack thereof of those studies coming to the agency. There were a number of horror stories of really bad science or fraudulent science being done, which then, of course, eroded the base on which we approved or did not approve drugs and other products.

The agency was given hundreds of positions and multi-millions of dollars. I can't remember now how much it all was. But part of it was for us to develop regulations and then inspect or audit clinical trials around the country, and also to make sure that the trials were conducted in accordance with concerns for human rights under the Helsinki Agreement. Institutional review boards all rose out of that. The program was run in a fledgling sort by Dr. Kelsey over in Drugs, and there was some other work done in a couple of the other bureaus, but really most of that was in drugs. And they had developed some regulations already, or guidelines, but they were translated into regulations in about 1977-78.

They had this big mass of resources and people. They went from a staff of about three, or four, or five to thirty or forty. The field had gotten new positions, too, to conduct those field audits of those scientific studies. They were supposed to be scientific, at least. Dan Michels, I believe, was the deputy to Dr. Kelsey and had just been promoted to a new position in drugs. Dr. Crout was the director of the Bureau of Drugs at the time, and Jerry Halperin was Dick Crout's deputy. He had come out of an executive development program at Harvard, gone to the Winchester lab up in Boston, and then was selected for this job as Crout's deputy. By the way, Jerry Halperin had also been a rad health rep I think in Chicago and Philadelphia.

Anyway, one day in the hall down by the elevator, I was going to the post office, and Jerry said, "We've got a vacancy here. I know you; I know you could manage this; and we need somebody bad. And Dr. Kennedy, you know, really has

the heat on the center to keep this program going, and he's getting heat from the Hill to make sure that these resources are used properly. And we've got, you know, hearings coming up and all of that." Dr. Kennedy by that time, of course, was the commissioner. I said, "Well, I'll look at it and compete with the others." And I applied for the job and was given the job as deputy to Dr. Kelsey, and took that job in August of '78.

RO: And that was the Division of, what, Scientific Investigations?

HW: Division of Scientific Investigations, and it was part of the Office of New Drug Evaluation, which was run by Dr. Marian Finkle. It was not part of the Office of Compliance at that time. Logic was that we were basically the quality control people for the reviewing scientists to make sure that the data and the pre-clinical work as well which they were looking at were valid before they made a decision to approve a drug. So we had a pre-clinical group, we had a clinical group, and we had the institutional review group, all either inspecting against the regulations or developing the regulations and guidelines that later would come into effect. Some of those regulations never did go into effect, but a number of them did.

One of the sanctions that we had, of course, was disqualification of clinical investigators, either permanent or partial disqualification. We would not accept the studies of work being done by those. And that was a very powerful compliance tool, because the drug companies had a lot of money and time invested in these, and they wanted to make sure that the data were right. And, of course, we came across fraudulent, poorly done, or sometimes just sloppy work. But, unfortunately, we saw quite a bit of very bad work being done. We had a group in drugs of about . . . I think we had a total of about sixty people, fifty to sixty FTEs (full-time equivalents) that were assigned to us, and some twenty or so of those were field FTEs, and the rest were in our Division of Scientific Investigations.

So I handled the program manager aspect of the Bioresearch Monitoring Program, and Frances--Dr. Kelsey--handled the scientific aspects of it, dealing with the review divisions, looking at the studies themselves for flaws, deciding what we would recommend to the review divisions, or taking enforcement actions against the clinical investigators, in which, of course, Office of Health Affairs was involved, too. There were similar units, but not as well organized and funded in most of the other centers. And then there was a coordinating group which Ernie Brisson ran in the Office of Enforcement, which was part of the Associate Commissioner for Regulatory Affairs.

Of course, we were competing for resources out in the field, and there were never enough resources out in the field, and we had studies that needed to be looked at by the field and so did the other centers. So there was always sort of, you know, tension going on and bartering for that limited pie that we all were part of.

RO: Was there any appeal procedure? If you found out that there were fraudulent reports coming in, did a clinical investigator have any appeal?

HW: Yes. The process was something like this, once we got the report in, if it was a clinical investigator, we would send the clinical investigator a letter. A copy of that letter went to the sponsor of that study, whatever the drug company was, stating what our problems were with that study and asking the clinical investigator to respond to that letter. It wasn't really a regulatory letter, but we were asking them to respond to it to . . . Maybe we were wrong in our analysis of it, and what explanations did they have? If they were not forthcoming or if their response was not suitable, and we felt that the violations were egregious or really bad, we would indicate to the individual that they were in danger of being subject to disciplinary action, say disqualification. And they would be offered the opportunity for a Part 16 hearing to . . .

(Interruption)

HW: . . . to explain why we were wrong and they were right or whatever extenuating circumstances there were and what offers of correction they would make. At the same time, of course, we would be working with the review divisions to make sure they didn't use the work of that clinical investigator, and usually the drug companies themselves would be trying to find out what went wrong or use other studies . . . They had their own groups of monitors that were supposed to keep track of the clinical investigators' work.

RO: That Part 16 hearing, did you conduct them or . . . ?

HW: No, we did not. That was conducted by the Office of Health Affairs, Dr. Nightingale's office. That was a fairly formal, long, drawn out kind of a thing. What would usually happen is we would offer them the opportunity for either a settlement, where they would consent to being on a disqualification list, or do some corrective measure, whatever it happened to be. I did not get involved in that. That was really Dr. Kelsey's side, and then her branch directors, like Alan Lisook or George James, depending on whether it was clinical or pre-clinical or whether it was an institutional review problem perhaps, and then we might be dealing with the institution, or university, or hospital.

If we felt that there was some really intentional fraud involved here, we did work with the field and with let's say the U.S. Attorney's Office to bring actions under both Title 18 and Title 21. Title 18 was a very good title to use, because that was providing false information to the government, and you could get U.S. attorneys to be very much interested in those kinds of cases when perhaps they might not have been interested in a Food & Drug case under Title 21. So we did have a number of convictions of people that were truly engaged in fraud or doing what we call table top research, graphite research. Those were the particularly egregious things that

took many years to get adjudicated. But ultimately the individuals, some of them spent time in jail and fines, et cetera, and of course, their work was not acceptable.

RO: Heinz, do you remember any specifics about any of the really public things that happened, some of the more important things that you were involved in?

HW: Well, let's see. I remember that we were very much concerned about DMSO, and while it was already approved then for interstitial cystitis, a very limited use, it was being touted by a bunch of "health fraud" people for a wide range of things. I believe its sponsor was Dr. Stanley Jacobs from Utah. I'm really going off the top of my head here, so . . . But that was one I remember.

In another case, I can't remember the doctor's name, but he was a clinical investigator who had fraudulently conducted the work, but he had conveniently lost his records. It turns out he hit himself over the head to appear like he had been robbed and all of his records had been stolen, which was an obvious dodge to what he was doing.

Another one was a fellow who had done work in Mexico, but he didn't have any of his patient records to back it up, because in Mexico, the doctors were taxed, at least at that time, on the number of patient files that they had. So he just destroyed all of his patient files so he wouldn't have to pay as much tax to the *federales* in Mexico. I mean, a lot of crazy stories like that. They were inventing cover stories basically for their kind of work.

The conduct of clinical investigations is very expensive, and so many times there was a lot of money involved, as well as professional prestige, because they would be writing these things up in the journals. And so that . . . If a person was a well-known clinical investigator, it was quite a profitable business to be in, and there was a lot of pressure on some of these folks to produce research that would be favorable to the drug company seeking to get that drug approved. So there again

was, you know, some built-in human bias to produce studies that were favorable but not necessarily that they were conducted scientifically, and that's what we were tasked to do, to make sure those studies were scientifically valid.

RO: Were any of these clinical investigators involved in work of more than one drug for more than one company at the same time?

HW: Yes. You would have clinical investigators that would be doing multiple studies on different drugs, or chemicals really at that time, or substances, test articles, and sometimes, if they were not good at record keeping, they would get that mixed up. They would get patients mixed up, or they would be applying the test articles or numerous test articles to the same patient, and that would be getting in the way of, you would have concomitant medications that would basically ruin the results of the scientific tests, and sometimes they would try to hide that when mistakes were made instead of, you know, correcting it properly.

And, of course, you had people, individuals out who were sort of in the business of being clinical subjects. They would get paid for this. Again, that was another problem, too. They had to make sure that they weren't improperly induced to becoming test subjects. But under the best of circumstances, there was some money involved for some of those folks, and they would be less than honest as to what their medical situation was. It was sort of like the problem with the old blood donors, you know. They were in it for the money, and they would do whatever they could to be involved in more than one test. Some of them were, of course, unwitting subjects.

RO: How was Dr. Kelsey to work for? She's such an interesting--and I say this very affectionately--character.

HW: Well, people told me that she would be very difficult to work for, but I found that that was not the case. In fact, we're very close friends today. I'm retired, but she's still working, and I think she's over eighty now. She just had her eightieth birthday earlier this year. We had a very good working relationship, because she really wasn't interested in the management side of things, and keeping track of resources, and fighting for resources, and planning, and all that other kind of stuff that comes with that kind of a job. She wanted to focus on the science, and that was fine by me. But we both had the same goals in mind: we really wanted to make sure that these studies were valid and to punish the bad guys or women, if that were the case. So we worked pretty well, and it just so happens that we . . . She spent some time in the Midwest, and we knew some of the same people, so there was some camaraderie there as well.

She did not like the administrative kinds of problems and personnel problems, and generally I had to deal with those, and that was OK. In fact, I can remember when I first took that job over in August of 1978, the very week that I came there, all of our GS-13 consumer safety officers had been downgraded two grades. OPM had gone through and done an analysis of overgrading jobs. This was happening throughout the agency, and I suppose in other federal agencies too, but it was a terrible time in both the morale and anger and resentment. Of course, they took it out on me or others who were, you know, happened to be around, very understandably. We were able to find jobs for a lot of those folks so that they could preserve their grades. But I think in the first three or four months that I was there, I had something like thirty or forty personnel actions. I certainly questioned whether or not I had done the right thing. In fact, I remember feeling so bad about it, I talked to you and I talked to Paul Hile to say, "What have I done," you know. "I mean this wasn't worth a grade promotion, you know, really to do this."

But it was a promotion for me. I went from a fourteen to a fifteen. I learned a lot out of that. We had a very good close working relationship, and I had some very exciting experiences. In addition to the work, it was good to see some of the

people develop. We had one person for instance who started as a GS-3 typist, a female, who had a general education, and she was so sharp and so dedicated and helped to bring order out of chaos there. Some of the folks that had been there before hadn't really paid attention to record keeping, so we didn't know what assignments were out and what their status was, and we had to get that all in order. She was very helpful in that regard, as well as others. She now has progressed along the ladder where she is a GS-13 and has gotten her graduate degree in the sciences, you know. And she's assistant biology prof at one of the colleges, as well. I mean, those kinds of things really does your heart good when you see that you were able to help people like that along.

So I had a very good, I think, relationship with them, and they keep inviting me back to the Christmas parties, so it must have been all right.

RO: And then you left that position for a new challenge.

HW: Yes. Well, I left because . . . Now, this was in 1985. One of the things I missed was interacting with the state folks. In my job for the seven years I was over in drugs, '78 to '85, I really didn't interact much with state folks at all, and I did not travel much at all either. That was all done by our staff, and I missed that. As a former state official, I sort of wanted to get back into that kind of thing. So I was interested in intergovernmental affairs. It didn't have to be just federal-state stuff, but intergovernmental affairs. The directorship of the division came open when Bill Cobb left . . . Glenn Kilpatrick had died and Bill Cobb had taken over from him, and then he left to become the state chemist in Texas, so that job was open. I applied for that job. Although it was a lateral transfer, it was sort of a new set of things that offered some excitement.

I will say one . . . I want to get back to one thing that I remember from my first stint in Federal-State Relations at the State Services Branch. You know, I mentioned that we responded to inquiries from states. We got an inquiry once from

one of the states on whether the agency could help them write a negative or positive formulary. Now, a formulary is really a list of drugs that are approved or disapproved in the state. I believe the state was New York, but that's really not important, because at the time several states were considering either positive or negative formularies. The reason being they would use those formularies to determine whether or not the state was going to pay for the use of those drugs.

RO: Under a Medicaid program?

HW: Yes, under a Medicaid program or some other public assistance kind of program, or use in their own state institutions and purchasing of those, et cetera. I believe this was about in nineteen . . . It must have been 1976 or '77 perhaps. So Glenn and I--Glenn Kilpatrick and I--sort of scoured around and we found that the agency had no listing whatsoever of all the drugs that it had ever approved since the '38 drug amendments. So we couldn't help the state in that regard, and they said, "You've got to be kidding." Well, what about the Drug Listing Act. Well, we had a listing of drugs, drug companies and their products, but, again, it was not really complete, and certainly didn't have the grandfather drugs in, but it was for different purposes, and it did not make any distinction about whether or not they were approved.

So out of that attempt to try to satisfy the desire of these states who were developing these formularies, we had met with the folks from Drugs and they said, "Yes, you know, we need that information, too." So out of that whole effort came what is now known as the "Orange Book." The "Orange Book" was the first time the agency had ever put down all of the drugs and the indications for it. I think the first "Orange Book" came out in probably '79. I know we were having a frustrating time trying to get this out, because Drugs kept telling us, "Well, yes. We'll have it. We'll have it." And it always took . . . It was a lot more work than they thought. But I can remember when the thing first came out, Glenn called me up and said, "Let's go

over to this Chinese place and have a drink to celebrate." It was one of those kinds of things that you sort of look back on. Yes, that was a direct result of that sort of innocuous inquiry that came.

But in '85, when I came back, we had . . . The programs were up and running. In some areas, we still had the same sort of set up that we had before, and some of the same people were still there. We were faced with trying to upgrade our communications system which had . . .

RO: Well, by that time, NRSTEN was in effect?

HW: By that time NRSTEN was in effect. It wasn't built on teletype, but we had switched over to some rudimentary computer stuff, but it really needed to be fixed, and the states were hollering about stuff was late, and it wasn't getting into the right places . . . And, heck, it was still getting there a lot faster than it used to be with the teletype, but still, you know, they wanted it faster. Even today, I'm sure it will continue to be a problem getting that information to them as quickly as we'd like it to. But today it's computerized. The agency had just gone through the EDB crisis, the ethylene dibromide, where the NRSTEN system was very useful in getting information out to the states for the Environmental Protection Agency, and for the United States Department of Agriculture, as well as FDA. It was the only system around that could do that. In fact . . .

RO: What was involved in that ethylene dibromide?

HW: That was . . . Some people called it the killer muffin. That was where ethylene dibromide was, I believe, used on some cereal grains, found the residue was above our tolerance level, or maybe there wasn't a tolerance established, as was the case so often. I wasn't directly involved. I was still over at Drugs. But our information system was used by all three agencies to get the information out to the

states. Some states, in the absence of information or a tolerance established by FDA, went ahead and established tolerances of their own. They were begging FDA to set a tolerance for EDB, but it was just taking too long. Or FDA setting an action level, or begging the EPA to establish a tolerance, because that's the way the system works.

RO: Well, that's a fumigant?

HW: It's a fumigant for grains, right. But . . . I don't know if the problem was that we didn't have a tolerance, or we needed a new action level, or what it was, because I wasn't involved. But I do know that had it not been for the NRSTEN system, we would have not been able to convey to the states what we were finding and what our guidance was in a prompt manner. Ultimately, that settled down, and I think out of that whole exercise came an increased awareness for the federal and the state agencies to get their heads together and decide what their positions were going to be on chemical contaminants before going off half-cocked. But it also said we need this information faster, better, more uniform, and we've got to network more closely together.

We did get some additional resources from the commissioner's office. Commissioner Young was commissioner about that time. He got some additional money for us to upgrade those systems, and today, there are . . . I think they are linked by fax or by E-mail, and there are many, many, many more offices at the state level that are directly connected into that system so they can get it faster.

That was also a time, though, that we were faced with some very difficult decisions on funding. Everything was going along swimmingly, and then the Gramm-Rudman-Hollings Budget Reduction Act came into effect. I think that must have been in '87. It impacted significantly on '87-'88 funding, and we basically had to cut state contracts in half. That was sort of a warning signal to the states that they should not depend as fully on federal funds and maybe have some alternative

funding, and also for us as a federal agency to not depend on those. States who were burned by that had to lay people off and were much more careful or reluctant to get into programs or at least to have positions hanging on those contract monies. Out of that, too, I think we probably learned that maybe this is not a relationship that should be built on the dependence on the dollar, but maybe a relationship on trust and making sure that we have the same information, and the training, and all those kinds of things. So when I came in there, we started to upgrade a number of those activities. One of my first tasks was to transfer the training group from Cincinnati to headquarters, which had been resisted . . .

RO: I had been accused of doing that. In fact, I was called some nasty names.

HW: Well, you know, we were changing other things elsewhere in the field too, but it made . . . I know for a long time that there had been suggestions made to move the training facility out of Cincinnati. The reason it was in Cincinnati was it was an outgrowth of the old Taft Engineering Center from the Public Health Service, and that's where the other training courses were: water pollution control, solid waste, all those programs that went over to EPA. The vestiges of that, from Food & Drug, were still there. But states had trouble getting their people to courses in Cincinnati. Well, we had taken the courses on the road to a large extent, but still it was sort of a small cadre of people. And being separated from headquarters, it was much more easy for them to be out of touch with what were the important things and what were some of the latest technology and latest issues that the agency was facing. Bringing them into headquarters and making a separate branch right here in the Parklawn Building was a very good move.

One of the first things I did was hire a very strong manager from the state of Pennsylvania, Gary German, to oversee all that training. He had been active in the CASA (Central Atlantic States Association) efforts in training, which was one of the regional associations of the Association of Food & Drug Officials, and they were

superb in doing lots of different training stuff. So Gary had both the experience of being a line manager and a trainer, and he assembled then a training cadre, because most of the folks in Cincinnati chose not to come to headquarters. And so we had to start off with a whole new cast of staff, and yet we had to still present the courses that had been scheduled that the states were depending on. That was a management challenge, but it came off well, and out of that came a much, I think, better, stronger series, new thinking, new expertise. We got folks on board that had hands-on experience at the state and local level, as well as FDA old hands. It worked very well, so . . .

RO: One of the fears of the group though at the time was that they were going to be merged with the training function that was here, and, of course, that happened.

HW: Ultimately, that happened, and there are still I'm sure pros and cons being weighed on that one.

RO: That was quite a loss for you, though, that training branch.

HW: Well, there were two series of events that happened before. We had three branches going on. Bob Tucker had a branch, Dick Moats had a branch--that was the State Services Branch. Dick had worked for me when I was the State Services Branch chief, and he was an outstanding commissioned corps engineer and sanitarian and was leading that group. And then we had the training group. So we had three branches in the division, and we had thirty-five or so people working for us.

I think it was about maybe five years ago, somewhere around '88 or '89, it was decided we would cut back on administrative or management overhead, and that we'd cut back on the number of branches to cut down on management positions. So we combined education and information. Instead of having three branches, then we had two, and we moved some of the functions around. And it was about that time

Dick Moats had retired anyway, so Bob Tucker was left and Gary German as the two branch chiefs. We still had the same number of responsibilities, to do training and information and program coordination, but we did it in two branches rather than three.

But Gary particularly, had a very broad span of control. I think he had sixteen or seventeen people reporting to him, both on the information and then on the training side. That was really a heavy load, but he did it very well. Which meant, though, that I had to do a little more liaison with the state organizations than he might have been able to do, because he was so involved with the training and information.

RO: Tell me something about voice mail.

HW: Voice mail? OK. We were searching for ways to get information out to the states quickly, to let them know that they had important messages waiting for them. While the old teletype system was slow, it had one good feature: you didn't have to call up and find out if you had a message. It was there, you know. It had typed out whether you wanted it or not. Whether you had asked for it or not, it was there. And if it was a real emergency, bells went off. Yet, with electronic mail, which the NRSTEN system had been converted to, if you didn't read your mailbox, you would not have known, nor the other agencies that depended on you reading it, they didn't know, and that was one of the big concerns we had. This was before fax technology took over. Fax ultimately became our solution.

But prior to that time, it was called to my attention that there was a way that we could use a computerized phone dialing service to phone up all the states that we wanted to, various subsets of a state, like state food officials or drug officials, and say, "You've got an important message. Read your mail. Read your NRSTEN. Do something with it." As opposed to our people sitting down and calling. It would do it after hours, and it was something that had been offered to school systems, and they

were using them, and I think IRS and some of the other federal agencies were considering it. So Commissioner Young thought this was a good thing, because we had told him about our need to get this information out. So he gave us some additional money--actually to the computer folks, they had this thing on loan to us--to actually send out messages to the states. Now, it could receive messages as well, but it never really worked out like I wanted it to.

RO: Well, does it just go to a telephone?

HW: Yes. Basically it was a computer . . .

(Interruption)

HW: It was a computer-driven telephone that had built into the computer different permutations, combinations of phone numbers for state officials. So that . . . And you could put a message in there and "say" to the computer, "I want this message to be sent, this voice message sent to this group of telephone numbers." And so it would do that. It would say, "You've got an important message," or "We are anticipating the release of a news release," or something like that. Of course, it depended on whoever was answering the phone on the other end to get the message to the right person, and, you know, that was a weakness in the system, and we still have the capability of doing it. The voice mails today are more a receiving rather than a sending mechanism. To send messages out to these folks, the fax technology came up, which is computer driven, you can automate it as far as who you want it to get to, and everybody has them. And the messages show up whether you ask for them or not. It's there.

RO: It's gotten cheap.

HW: It's gotten cheap. So fax technology along with electronic mail has sort of taken it over. Electronic mail is still useful for those states and others receiving the messages that want to take that information and send it to someone else on electronic mail. But even now, with the computer technology, that's taken, you know, the computer-driven faxes, that's even solving that problem.

So there are new things coming on the horizon that are going to be even better for communicating. But that was always a problem, making sure the folks read their mail, that they passed it on to the right folks. But it's a long ways from what it used to be. One of the chief results of it is that we get far fewer inquiries from the states on what FDA's position is, because they already have this via NRSTEN. And then we would put out periodic compilations of what we had written about, so that they could go back to it. And being in the computer, we could also tell who had read their mail and who didn't and all that kind of stuff.

RO: Another acronym, SAIL. What's that?

HW: State Action Information Letter (SAIL) was begun under my watch as well. I believe it was first proposed by Dick Moats to provide a service to states so they could tell their counterpart states about the new things that they were doing, the exciting things they were doing, and using the NRSTEN system--or telecommunications system--to send that information out to the states. So if they were encountering a problem, or they had established a new regulation, or developed a new piece of equipment, or a new training aid, or whatever it was, taken a new enforcement action, they could use SAIL to pass that information on to others. And we were just going to be a passive dissemination organ, as it were, for those states. It was real popular--it is real popular today.

RO: It's still ongoing.

HW: Oh, absolutely. It's, I think, gone into the next generation, however, in that it isn't just state stuff that's in there. I had my staff, and there's usually one person that's responsible for gleaning material from whatever source from the states to put in there. But we also have FDA things in there, and if you want more information, check this off, send it back to us, and we'll get it to you. So it's very useful, it's very timely, and I guess the only criticism that we get is, "How come you didn't have this item in there," or "We'd like to have some more." Well, the purpose is not to be too exhaustive with details. It's to get the information out. If you want more, here's how you can get more information. So the folks can learn from each other. And that's been a real success.

RO: One of the things that I always regretted, I guess, is that the FDA--I shouldn't say FDA--but at least the old EDRO organization and the ORO organization never got as involved in the conference as we have in say AFDO, for example. I'm sure there's a good reason for that. I know when you came into the division, I thought we were going to have some inroads into the conference now; but we never got that far.

HW: No, and while it would have been nice, it really wasn't terribly necessary. There were a number of reasons for that. When you say the conference, you mean the Conference of Radiation Control Program Directors. Because there were some other conferences, like the Conference of Food Protection. They have a number of federal agencies that are supporting their activities.

RO: Financially supporting.

HW: Financially. Oh, yes. And, in fact, the states are the primary implementation arm of now the Nuclear Regulatory Commission and the Environmental Protection Agency on a number of programs, just as it is now for FDA in the Mammography

Quality Standards Act (MQSA). The conference and its member states are the ones that are actually going to be doing the legwork on MQSA or the bulk of the legwork out in the field, inspecting the machines, certifying facilities. Thank goodness, too, because we don't have the people to do that work. So their interests were much broader but limited to radiation protection solely. They had no other interests than that, and they didn't want to increase their horizons. We had a group over in Rad Health that was satisfying some of their needs in terms of technical guidance, which we just did not have the technical resources in ORO to do. And so if it's working, you know, "If it ain't broke, don't try to fix it."

We had a working relationship, and a very positive one, over the last several years with Gary Beard as the latest one. Lavert Seaborn before, but Gary Beard in particular. Very positive and knowing where we can be helpful and where we really can't be helpful and not trying to be something that we weren't. Our field specialists, both of the electro-optic specialists and the rad health specialists, those folks have been very much involved in conference work, serving on their committees, operating on special projects with them, doing training for them. So as an organization, as a field organization, we are intimately and directly involved in the Conference for Radiation Control Program Directors. It's just that we didn't need to be as hands-on at headquarters as perhaps we are in some of the food programs. I mean, they've got their own fully paid staff operating out of Kentucky, and so that's worked well. I always figure if it's working well, leave it alone.

RO: Don't monkey around with it.

HW: Help it work better if they want it.

RO: Tell me about your involvement in the quackery program in the agency.

HW: Yes. OK. Well, of course, I don't think the bioresearch monitoring was quackery. That deals with fraud of a different type. But I've always had an interest in that, and when we had developed this sort of a . . . I guess we were recognized for being well managed and having a good operating unit and a close working relationship, and on my watch we developed a real strong working relationship with the attorneys general and their national association. It was felt that we would be an appropriate division to handle health fraud coordination, as opposed to some of the other units in the ACRA. I mean, they could go there equally well, but because a lot of what needed to be done needed to be worked with the states, it made a lot of sense to come with us.

So it was in, I think, '91 that we were given the responsibility to nationalize our health fraud coordination work. It had been located in the Kansas City office. There are some good people there, but they did not have some of the resources we had in headquarters, and if they're out in Kansas City, it's hard for them to relate to the folks in the centers. So having it here at headquarters worked well.

We were authorized to hire a health fraud coordinator, which we did, and that position has just recently been filled again. We have been lucky to get really good people in that position, but they've been so good they've been hired away by others. So we've always had to get new people. But by having the combination of the state attorneys general and the Association of Food & Drug Official folks involved in that, it's been real successful.

One of the first things I insisted on was that we would not take over handling inspection assignments and things like that. That would still be the purview of the centers and our Division of Field Investigations, the usual operating network that currently exists. No reason to get involved in that at all. Our job is to get all those various parties together and to make sure that they're understanding what the others are doing so that they can share their information and hopefully bring joint actions.

So one of the things we did was establish a regular monthly working conference call with a small group of--now it's about twenty--states, either Food &

Drug or attorneys general folks around the country. We do that monthly. We have a monthly call with health fraud coordinators in our field offices. There was some talk about going to quarterly, but that wasn't frequent enough. They want to share information about the various folks they're investigating, and it's investigatory information so we can keep it confidential.

Another thing we need to do is to upgrade our data system, and we were able to get funds to contract out for an intelligence service run by the Consumer Health Information Research Institute out of Kansas City to be a computerized data bank as it were for various practitioners and health fraud scams and things of that nature and find out what's happening in this country and elsewhere. So we're contracting that. Now we have information that we send out from our division to those operating units that tells them about what's been going on, minutes of those calls, or information, background information.

As a result, too, because we had this operating unit, we were involved with the commissioner's office in getting--and the centers--in getting ready for the dietary supplement hearings, which involved what do we know about the fraudulent claims or at least unsubstantiated claims being made by some segments of that industry. And so we were the unit to work with the field folks to gather information about what's being promoted, the kinds of materials that are being promoted, and to gather information for the commissioner's office, and we had a number of hearings last year where we worked with the centers in developing that information for the commissioner.

RO: Is this health fraud now? You know, the agency always had a problem defining fraud and quackery.

HW: Well . . . Yes. One of the things we did was to come up with . . . We finally had a definition. It took us a year for defining health fraud, but it's more than quackery. I mean, quackery is part of it. It's like trying to define pornography. I

mean, you know what it is. It's just hard to write an all-encompassing description. But when somebody is promoting, and it doesn't even have to be for sale, but promoting some sort of an unsubstantiated product, or scheme, or whatever, rationale, or irrationale, if it doesn't have a scientific basis for it, and it is regrettably diverting people away from proven treatments, treatments that have gone through scientific review process, that have scientific basis for it, that is getting to where we are talking about fraud.

Of course, fraud involves many different kinds. Some are just sort of well-intentioned individuals; some people are the true quacks that are in it for the bucks. So you've got both the charlatans and you've got the true believers but are uninformed. We've always had that; we always will. The important thing is that we get information early on these people and try to get other units who can help take actions to get involved--the Federal Trade Commission. We also, as a result of that, serve--I was, but others would be--serving on the Joint Task Force on Health Care Fraud that is operated by the Department of Justice. That involves folks from the FBI and Federal Trade Commission and just about every federal agency that you can think of. I mean, there's food stamp fraud, but there's also a lot of Medicare/Medicaid type fraud. Those kinds of things, too.

RO: Well, Heinz, we've covered a lot and kept you for longer than I had intended.

HW: That's fine.

RO: But we've covered a lot of things. Is there anything else you'd like to add? You'll have an opportunity to review this and . . .

HW: I suppose, but I just think that . . . Well, I couldn't have designed a career in advance, an exciting experience for myself.

RO: It sounds like you've . . .

HW: I'm just so thankful that I had this opportunity to, you know, work with folks, and there's such a dedication level around the country, especially in the field folks. I mean, they'll just turn themselves inside out for you, you know. That is so heartening, and particularly when you get out with the investigators and the analysts out in the field. It's exciting.

RO: Why did you retire? You were having so much fun.

HW: I was having so much fun. Well, I guess a couple things. First of all, you know, I've got about thirty-two years of public service, I've got forty years or more of work experience. But my wife's health was such that when the opportunity came along, it would be another three years before I could retire otherwise. I had the age, but I just didn't have the FDA service, federal service. So with her health condition, it was just the timing was perfect for it, and I felt that while I had the opportunity I should do it. But I'm hopeful that I'm not going to . . . I mean, I'm not going to divorce myself from FDA things. I still need to be involved and want to be involved and hopefully will be involved, whether it's association work or something else that will keep my interest peaked and maybe I can contribute something, too.

RO: We want to thank you very much for your time here, Heinz, and this will end the interview.

(Interruption)