

History
of the
U.S. Food and Drug Administration

Interviewee: Charles H. Parfitt

Interviewer: Robert A. Tucker

Date: January 5, 2006

Place: Rockville, MD



National Institutes of Health
National Library of Medicine
Bethesda, Maryland 20894

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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.



CASSETTE NUMBERS

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INTERVIEWER(S):

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Interview with Charles H. Parfitt

January 5, 2006

TAPE 1, SIDE A

RT: This is another in the series of the FDA oral history interviews. Today, January 5, 2006, the interview is being conducted with Charles H. Parfitt, former senior scientific coordinator, the Division of Field Science, Office of Regulatory Affairs. The interview is taking place in the Parklawn Building in Rockville, Maryland.

Charles, in these interviews, we like to get underway with a brief overlay or review of your personal history, your educational history, and then get to your employment history as we progress. So I'll let you start with that earlier information.

CP: Okay.

I was born in Philadelphia, Pennsylvania, March 20, 1947. I grew up in the Philadelphia metropolitan area, spent all of my early years through college and my early employment history in the Philadelphia area. Through my tenth birthday we lived in Rockledge, Pennsylvania. In 1957, we moved to Riverside, New Jersey from Rockledge. I graduated from Riverside High School in Riverside, New Jersey, in 1965, and I went to college at Rutgers University, Camden College of Arts and Sciences in Camden, New Jersey. That's one of the three major locations within the state where Rutgers has campuses. And I graduated from there in 1969 with a bachelor of arts degree in chemistry.

After graduation, I went to work with Whitehall Laboratories in Hammonton, New Jersey, and I worked with Whitehall for two years. I guess my official title was senior analytical chemist. And I was involved doing pharmaceutical quality control, testing of incoming raw materials and finished products for compliance with compendial and company specifications.

RT: Did you begin this employment pretty much immediately after graduation?

CP: Yes, within a month or so after graduation. I had gotten a part-time job with a company that made cardboard barrels, and quickly determined that I was sure glad I had gone to college. Assembly-line work wasn't my cup of tea – I was not cut out for that. I did not like it at all.

So I did go there. I started there, oh, I guess it must have been – I graduated in May and I think I might have started at Whitehall around the first of July, something like that. I don't remember the exact date I started.

RT: Were you approached by an FDA representative doing recruiting, or how did you come to decide to affiliate with FDA?

CP: I was just looking for other opportunities. I had always had in the back of my mind, wanting to work for the government. So I filled out a general U.S. government application. At that time I was, because of my, I guess it was the GRE scores and such, I was qualified for a GS-7, so I could either start at a 5 or 7. I did receive one inquiry prior

to FDA from a water quality lab in Charleston, West Virginia, but they were only offering a GS-5 and I wasn't going to relocate for a GS-5 salary at the time.

And then I got a call from FDA in Baltimore. Bob Chamberlain was the supervisor there.

RT: When you applied, though, you hadn't necessarily targeted FDA but made a general . . .

CP: It was just a general application for federal employment.

RT: Right. So FDA was . . .

CP: I guess I was aware of FDA, but I really didn't know anything about FDA.

RT: That seems to be the history of most persons who come to the agency. They weren't necessarily familiar at that time as many people are now with the agency. It has become a household word now, but it wasn't earlier.

Was that at a time when FDA was adding, recruiting many persons, or just sporadically?

CP: This was about a year before the big Project Hire, which I think was in 1972 or thereabouts, I recall. I know shortly after about a year or so after I started, they hired a large number of investigators.

RT: Well, Philadelphia was a logical place to begin.

CP: But I didn't start there. I started in Baltimore.

RT: Oh, that's right.

CP: I started in the Baltimore district lab down in Baltimore, Maryland, so we had to relocate.

RT: The first move is on you, too, isn't it? At least I think it used to be.

CP: Yes. I got some – I forgot what, exactly what they paid me, but it was some minimal compensation for moving. But basically I, with a couple of friends, we hired a truck and loaded the truck up from our apartment and moved it down to an apartment outside of Baltimore, Bel Air, Maryland.

RT: You entered as a chemist?

CP: Chemist.

RT: In the laboratory in Baltimore.

CP: In Baltimore. And I spent most of my first year in training.

RT: Who was the chief of the lab then? Do you recall?

CP: Oh, yes. Tom Welch was the lab director – chief chemist, not lab director; chief chemist back then.

RT: Yes, I should have said that.

Would that have been during the time when George Sooy was still there as director?

CP: No. Lee Strait was the district director. I don't know what his title, official title was back then. I don't think it was district director.

RT: He became one eventually.

CP: Yes, eventually. He was in that position, which became, which is known today as a district director. And he was there the entire time I was there.

I spent four years in Baltimore. I started in June of 1971 and left there in September 1975.

I guess the last year I was in Baltimore, the chief chemist was – I just drew a blank on his name – a tall, slender black guy, and he went down to Atlanta and eventually became RFDD. He came to Baltimore from Detroit. John Turner.

RT: Yes, right.

CP: John Turner. He was the chief chemist when I left for San Francisco.

RT: You transferred, then, from Baltimore to . . .

CP: To San Francisco.

RT: That was quite a jump, wasn't it?

CP: Yes.

RT: During your period in Baltimore, of course, there was an orientation and training. Did you get into any specific laboratory analytical projects while you were there?

CP: Well, the first year I was working – after I finished training, I spent most of the time doing, which they call now toxic element analysis; we called it heavy metals back then, and lead, cadmium, etc., so I spent that time doing that.

I started working in the pesticide area and found I liked the pesticide area a lot better than I did the toxic-elements area. I did considerable work in the pesticide area, and was selected to go to a four-week training program that Center for Food Safety and Applied Nutrition (CFSAN) put on to develop pesticide specialists. I was selected for

that and spent a month down at CFSAN, or as it was then the Bureau of Foods, I guess, back in those days.

RT: It probably was then.

CP: Working with Laverne Kamps and Jerry Burke. Laverne was the supervisor; Jerry I think was a, I'm not sure if he was a branch chief or something like it back in those days. And I spent four weeks there with intensive training with another chemist from Dallas District, Billy McGill. He and I were the two people from ORA, or as it was then, EDRO.

RT: Yes.

CP: Executive Director of Regional Operations, down there for training and development as a new pesticide specialist.

RT: These pesticides, were they drawn from any particular industry or area?

CP: Well, in Baltimore, we did the analyses for both Baltimore and Philadelphia districts, so we covered the states of Pennsylvania, Delaware, Virginia, West Virginia.

RT: During your training as a chemist, did you ever get out into the field with an investigator?

CP: Only one time. During my training program, there was one orientation time where I got to go out and do an inspection, and it was essentially related to what became the Consumer Products Safety Commission. It was looking at a store selling turpentine in reprocessed soda bottles, which wasn't a very smart thing to do. But it was a . . .

RT: Would that have been primarily under the hazardous substances program?

CP: Yes, the hazardous substances program, and I think that responsibility probably went to CPSC when they were formed sometime in the mid-'70s.

RT: In the course of your experience, were you ever involved in litigation or as a witness?

CP: No, I never was. Only one time was I – I was prepared to go, and then I guess it was about two weeks before we were scheduled to go to trial, they plea-bargained it, so we didn't have to. They pled guilty to the charges and settled, so I never did have to testify in court.

RT: That was good training, wasn't it, in terms of preparation?

CP: Oh, yes, being prepared to do it.

RT: When you went to San Francisco, were you, again or still, primarily involved with pesticide work?

CP: Well, that was the primary reason I went to San Francisco, as Baltimore then had a pesticide specialist, and most district labs only had one specialist in each area. The opportunities to get a 12 appeared to be very slim staying in Baltimore.

And I had also had a two-week training stint up in Buffalo district, working with Ron Laski, and I had met a supervisor up there by the name of John Wiskerchen. And John had left Buffalo and gone out to San Francisco. He was supervising the pesticide group out there, and he recruited me to come out there. So it was a lateral reassignment to go to San Francisco. And we look at it as kind of an adventure. My wife and I thought, "Well, hey, we're young, let's see what happens, see how this goes," it gave us a chance to see a new part of the country, because we were both from the Philadelphia area and then we moved out to Baltimore. I think I was the first person in my family to leave the Philadelphia area.

RT: That move, going to San Francisco, may have been kind of a sticker shock in terms of housing and the cost of living. Did that occur in your case?

CP: Actually, we got there just before the housing really went skyrocketing in the Bay Area, so we got in kind of just on the beginnings of that fast rise in value. We bought a house. I think we paid \$41,500 for a house, \$41,500 for a house out in Concord, and I thought that was – I could never, I would have never figured a couple of years before

paying anything, a price like that for a house. That was just so ridiculous. But in hindsight, I wish I had gone for a little better house. But hindsight's always 20/20.

RT: In San Francisco, who was your supervisor?

CP: John Wiskerchen was the supervisor of the pesticide group. Paul Bolin was the laboratory director.

RT: The district director at that time was . . .

CP: Billy Hill.

RT: Okay.

CP: I transferred out there as an 11 and essentially was given the job of running the pesticide group. At that time, San Francisco had a large pesticide program with the Central Valley. L.A. covered only the southern part of the state, Los Angeles district. So we had the northern part of the state plus Nevada and Hawaii, and I was given the job of running the pesticide program there under John.

RT: Now, imports from Mexico, were they a part of the workload there?

CP: No. We didn't have the imports coming in from Mexico. They went to L.A.

They went to the L.A. laboratory.

RT: Sure.

CP: But we got a lot of stuff coming out of China. It was at that time when I was out there that we started getting a high volume of imports from the People's Republic of China. So we got involved with that, and we got involved with a lot of what I considered to be weird products. These were salted, preserved duck eggs and dried lily flowers. These were all specialty Chinese foods that we got in that had residues of the pesticide BHC. This is a chemical that's relatively easy to synthesize and was widely used as an insecticide in China. And, unfortunately, when you use it, it does result in residues, and most of these commodities had no tolerances in the U.S. So we were involved with a lot of violative samples coming out of China, but mostly it was BHC. And also, we started getting in fish from China at that time.

But it was during this period of the late 1970s where we started getting a lot more imports coming into the country from the rest of Southeast Asia.

RT: Those violative products, Charlie, that came in from the Orient, being imports, what disposition, in a regulatory sense, was made of them? Were there seizures or were they just kind of turned . . .

CP: Well, these were detained.

RT: Detained.

CP: They were detained. And I guess they'd have to re-export or destroy it, one or the other, but the broker was responsible for it.

RT: That kind of product certainly couldn't be reconditioned.

CP: No. There was no way to recondition the stuff.

But the other interesting thing I got involved with back there is we were doing the fish program. There was a catch coming out of the Monterey Bay that had violative levels of DDT in it, and we kept finding these violative levels of DDT. This is an ocean fish, and it's caught in several thousand feet of water. And one of the interesting facets of that was that we actually, I along with Tom Cairns, who was the mass spectroscopist in L.A., they were doing the confirmations for us on this because we were trying to get seizures and stuff on it. And there was extremely high levels of DDT in these fish, and we actually identified the source of this, working with the investigator.

RT: So, what was it?

CP: Eldon Delanina was the investigator out in San Francisco. He got involved with a Navy research group down in Monterey and arranged for FDA to borrow one of their ships to do some sediment sampling in Monterey Bay, in several thousand feet of water. And they went out and collected these sediment samples, and we actually found the DDT

in the sediment. Apparently these fish were living in the area of an ocean dump, where they had dumped 55-gallon drums of waste materials out there, and there was a lot of DDT that went out there. And so these fish were being exposed to high levels of what was the parent DDT. Most of the time what you find in fish is the weathered residue, the metabolite DDE. Well, we were finding the parent compound.

RT: In interagency cooperation in that sense, did the National Marine Fisheries or Coast Guard or anybody . . .

CP: I think it was with the Navy, as I recall, and there was a report written on it.

RT: To restrict further . . .

CP: And whatever happened beyond that, that was toward the end of the time I was in San Francisco, and then I left and came back here to Washington eventually.

One other thing I got involved with out there in San Francisco district was another fish program that we were running. We were looking at Clear Lake, California, where there was catfish and carp fish, I believe, in the waters up there. And this was a lake that was treated with another DDT-related compound, TDE, and we found violative levels again of the pesticide in the fish. And this was the one where I worked with Tom Cairns down in L.A., and we actually identified a new metabolite of DDT that had never been – it was known to be a metabolite but had never been found in a natural environment. And Clear Lake is famous because it was one of the key incidents that triggered Rachel

Carson's *Silent Spring*.

RT: I see.

CP: It was where the grebe population up there went into a precipitous decline because of the thinning of the eggshells. So that was . . .

We had shown that 10, 15 years later, the stuff was still there and it was still a problem, and the fish contained violative levels of the pesticide.

RT: Well, there was probably rather focused attention on that type of fish coming in.

CP: Yes.

A couple of other incidents that I got involved with out there that were of, I think, interest is that there was a group of pesticides that were soil fumigants, used as soil fumigants: dibromochloropropane and ethylene dibromide. And these were two separate incidents. The first one was dibromochloropropane and second was ethylene dibromide about a year later. The tolerances that were written were written on residues of inorganic bromides, well, because the data supposedly show that you never found the parent compound. Well, lo and behold, the state started looking, and they started finding residues of the parent compound, and these were supposed to be carcinogens, so this caused a great deal of furor. And I worked very closely with the state lab up in Sacramento, and we had a cooperative effort going on. And what we did was I worked with them, and we were confirming each other's results. They asked us to look at the

samples and confirm that what they were finding was actually there. So we worked very closely with the state on the dibromochloropropane. And then about a year later, that was replaced by ethylene dibromide, and, sure enough, they were finding levels of EDB. And then several years later, this became an even more widespread problem in the '80s.

RT: You mentioned the state lab. Was that a state lab by itself, or was it associated with the Department of Health?

CP: It was a California Department of Food and Agriculture laboratory, a CDFA lab.

RT: I see.

CP: And they had a very big program. They had a program that was – that state program, at that time, was probably about the same size as our national program is. That was just involved in looking at the state.

We also got involved with them, and they had mobile laboratories, and I spent a week working in one of their mobile laboratories down in Watsonville, California.

RT: California, of course, has been really at the forefront, I guess, on analyzing and identification and regulation of carcinogens. Were you involved in any collaborative work in that area?

CP: Well, I think the EDB, the ethylene dibromide and the dibromochloropropane

stuff were probably the first incidents that probably resulted eventually in the regulations that they currently have. They certainly were some of the contributors to developing these.

RT: In fact, you see a lot of products labeled, in general interstate commerce, that under the California statute are required to bear an alert about the presence of carcinogens.

CP: Yes. I believe it was one of the . . . California had this thing where you could put a proposition on the ballot by getting a sufficient number of signatures. The public could actually draft a law that didn't go through the legislature and would be balloted, and I think that was Prop – I can't remember the name of it. It might have been Prop. 65, but I'm not certain of the exact number that it was. But it became that law, and it was through the proposition process that that became law, not through any act of the legislature.

RT: That's interesting, a different legislative . . .

CP: That's my recollection of how it happened.

Let's see. What else did I get involved with in San Francisco?

Oh, one of the things we got involved with out there was setting up a training program. California had a big program for analysis of pesticide residues, but the State of Nevada did not have a program, and their health lab wanted to get involved.

So I developed a training program, a state training program, and trained one of their analysts in our laboratory in San Francisco. He was down there for a month working in our laboratory in San Francisco. And then I went up to Reno – the laboratory was in Reno – and spent two weeks up in Reno working in their laboratory to help them get their new lab started doing pesticide analysis. They had a brand-new laboratory that they had just opened. So I got to see this new laboratory. It was a very nice state-of-the-art facility, and . . .

RT: What department had that lab in Nevada?

CP: It was the Health Department there.

And then, subsequent to that, we got involved with the State of Hawaii, and I believe it was the Health Department there sent one of their analysts over who were training in pesticide analysis.

I tried to convince Billy Hill that I needed to get back over to Hawaii for a couple of weeks to finish up the training, but that never flew. I don't know why. I just never got approved for that, to go over to Hawaii, two weeks in Honolulu, working in the state laboratory out there. I guess it was looked on as being too much of a boondoggle.

And then also, there were two analysts from the territory of Guam who came to our laboratory in San Francisco. Now, they were there for a considerable amount of time. I think they were there for like three months. And I think they spent three weeks doing pesticides, but they were learning not only pesticides, but they were there doing a wide variety of different chemical analyses. Learning that we do in the San Francisco district

laboratory at that time. We did toxic element analysis, we did colors, we did filth and aflatoxins, etc. Now, they spent a good deal of time in the other areas as well as pesticides.

So it was an interesting time in San Francisco.

RT: I'm sure Hawaii in particular would have had some of the same workload on imports from the Far East, analytical for pesticides and the like.

CP: Yeah. We didn't get very many samples in. We used to get some samples in from Hawaii. But we didn't get very many samples. There would be a few. Again, it was the shipping costs were . . .

RT: Might be prohibitive.

CP: Prohibitive. A lot of times what we did, like if we were going to sample something like pineapple, we would sample it after it was flown in on cargo planes into San Francisco International Airport and then sample it there. But about the only other things we got out of there, when we had to do the milk and egg samples and that type of thing, we would get those in from San Francisco.

RT: Hawaii, of course, produces various nut products. Are nuts, like macadamia and the like, susceptible of pesticide residue?

CP: We didn't do very many. We did some walnuts, etc., from the Central Valley area, but we rarely found anything in those. Those were always fairly clean. We never had a problem with any of the nut products, other than peanuts had aflatoxins, of course. That was another thing. Aflatoxins were done in San Francisco, too. I wasn't involved in that, but we did have the aflatoxin problems; we did find that, but not pesticides per se.

RT: California, of course, has quite a winery industry. Does the alcohol tax group regulate it?

CP: They handled most of that. We might look at the wine grapes; that's all. We did some; we did look at grapes and that type of situation.

But most of the stuff that we looked at was fresh produce coming out of the Salinas Valley and the Central Valley. The Watsonville area is a big truck-farm area where a lot of fruit and vegetables are grown. Of course, they have the major farms out in the Central Valley, Modesto, down in that area, and towards Bakersfield. So we did a lot of -- a lot of our samples came out of those two areas. That's where the majority of our samples came from, plus the imports that we would get in through the ports of San Francisco and Oakland.

RT: At the time you were developing training for these other state agencies, what was your stature in the lab in San Francisco.

CP: I guess it was about, after I was there about two years, they advertised a pesticide specialist position. I was selected for that, so I did get my promotion to a GS-12.

RT: So that would be a logical activity for you.

CP: And I'm trying to remember. It was, let's see, I was there in '75. I left there in '81. I'm going to guess around 1980 or so, Pete Bolin left our laboratory, and he got a promotion to become head of Winchester Engineering and Analytical Center (WEAC).

RT: I see.

CP: So he left. And then he was replaced by Barbara Dalrymple as the new laboratory director. And she was my laboratory director up until I left in 1981. She was there for about, oh, I guess, I don't know, a year, year and a half.

TAPE 1, SIDE B

CP: And then John Wiskerchen left before I left. He left to go to, as lab director in Seattle.

RT: Now, regarding the lab in San Francisco, how large a staff did you have there? Was that one of the regional specialty labs?

CP: Well, at that time we still had the district lab structure. And we had a pretty good-sized lab. I'm trying to recall. We had a large chemistry section. I'm thinking we had, let's see, three or four supervisors on the chemistry side, and we had one supervisor in microbiology, so I'm going to guess we had somewhere in the neighborhood of 40-some people in the laboratory, 50 people, thereabouts. It was a pretty good-sized laboratory.

And back in those days, it was a fun place to work. We had a good group and we all got along well. And we worked hard and we all got along very well. It was a great place to work.

RT: Your career, at least up to that point, and maybe beyond, your focus was primarily in pesticide analytical work.

CP: Right.

RT: Not to jump ahead, but is that pretty much the focus of your expertise through your whole career?

CP: Pretty much I stayed in that through the whole career. At the time -- I guess it was about 1980 -- a scientific coordinator position opened in Division of Field Science (DFS), here in Rockville, the Parklawn Building, and the person, my predecessor in that position was Lois Beaver, and she had left to go to the Office of International Affairs (OIA), and I'm not sure if she's still there.

RT: Maybe; I don't know.

CP: She was when I retired. She was still working there.

RT: Is that right?

CP: And so I applied for that position, and it was strange. It was just about the time, late 1980, when all of a sudden the interest rates just went through the roof. And we're trying to sell the house and were worried about selling the house. I'll tell you what. I was offered the job on a Monday. That weekend we had talked about it, and we had decided we were just going to have to withdraw. We didn't want to get involved in trying to move at this time. And I was going to call that morning, that Monday morning, and withdraw my application for the position. I was waiting for 11:00 Pacific time, because out there, at 8:00 Pacific, I'm thinking, well, that's 11:00 and people go to lunch, because in those days we worked 8:00 to 4:30 and there wasn't the flexi-hours that we have today, we didn't have the latitude that folks enjoy today of coming and going as they please almost. And you were there 8:00 to 4:30 five days a week, and that was your tour of duty. And I was way out there. Well, I'll wait till it's about 10:00 Pacific to call so it's after lunch. I figure if I call at 11:00, they're going to be at lunch and stuff, so I'll wait.

Well, about that time, the laboratory director came up to me and said, "Mr. Stephenson would like to talk to you." He was the director of DFS, Ken Stephenson. He

called and talked to me and he offered me the position, and I'm thinking, "Do I take it or not?" and I said, "Well, all right. I applied for it, I'll take it, since it was offered to me."

And, fortunately, we were able to sell our house in California. We made a very nice, healthy profit on it because of the thousands it had appreciated. It over doubled in value. So we had a good chunk of equity to work with, and we were able to move here. And then we were lucky. We were able to find a house that we had the cash to assume the mortgage, and with what I thought was a reasonable interest rate of around 12 percent. Of course, today that's -- the thought of it. But back in those days, that was a good rate, if you could get one around 12 percent.

RT: You'd been in San Francisco for several years.

CP: I was there from October '75 through -- I left San Francisco in January of 1981.

RT: In earlier times, at least in the investigative side of the field force, you really had to shift around quite a bit to move forward. And maybe we're starting to get out of that phase of administration by the time we're speaking of now.

CP: Yeah. That, moving people around, there wasn't much of that going on like I guess there had been prior to that. Up until the time I started, I guess there was a fair amount of that. But they kind of ended that, and I think that's when the cost of moving people around became quite prohibitive.

RT: Sure.

CP: And I think the rules changed where they had to reimburse you for moving expenses and . . .

RT: I think morale-wise, it was kind of tough on many people who had, shall we say, adolescents, the upsetting of their lives and friends.

CP: Yeah. I think during that time, too, it became a lot more of two-income families where both the husband and wife worked. Regardless of which one worked for the federal government, they had a spouse that was working too, and just moving wasn't an easy thing.

Fortunately, in my case, my wife was working at that time for Aetna Casualty Insurance Company and she was able to transfer from Baltimore to the San Francisco office. And then when we moved back here to Washington in 1981, she was also able to transfer into the Washington, D.C., office of Aetna. She was working in the claims area. So she was able to transfer both times, so she kept her seniority with Aetna. And, of course, that was nice because Aetna actually had a retirement program that's still in existence that she's drawing on now. So it was unlike the current situation. She was able to move, to transfer along with me, although when we made the moves, we weren't absolutely certain we were going to be able to move, she was going to get transferred, but it worked out that she was able to move on with me.

I came to DFS in 1981, and my responsibility was the pesticide program. I also became responsible for the dioxin program, all the organic contaminant programs. I was involved with pesticides, dioxins, etc., when I started with DFS.

And I guess by the time I got here, Ken Stephenson had already left DFS as director. And the director's position was vacant. I worked for Max Gibson, who had come into DFS from Seattle. He was a lab director in Seattle, and prior to that, he was the chief chemist in Chicago before he went to Seattle. Max was the branch chief that I worked for, and I worked for the Laboratory Operations Branch.

I guess about a year and a half or so, I don't know how long it was, maybe it was longer than that, but Arvin Shroff became director of DFS.

RT: Now, as you came from the field to headquarters, were you still involved in the same field, the same area of expertise? With regard to your responsibilities, concerned, were they now more a matter of reviewing field activities, or developing things here at headquarters?

CP: Well, I was more or less the liaison with CFSAN on the pesticide programs and the dioxin programs. So I was the headquarters contact. When the field folks had questions, they'd come to me, and I would coordinate with CFSAN, developing all the new compliance programs, or assignments would come through. I'd have to review all those. We would have to make recommendations on, if there was an assignment, which lab was going to perform the analyses, make sure the laboratories had the capabilities to do the work both in the equipment necessary and also having the people needed to do the

job. In some cases, even though they might have had the equipment, they didn't have the staff, so we would have to ship the work elsewhere. Instead of sending the samples to their normal servicing laboratory, we would have to make arrangements that it would go to another laboratory who had the staff to be able to handle the extra workload. So it was a challenging and interesting time.

RT: Were you ever detailed or assigned to CFSAN, or were you always in DFS?

CP: Well, I arrived here in February of '81 and I stayed here through April '87.

RT: I had the impression that maybe you had physically been down there.

CP: No. I was here in the Parklawn Building from '81 to '87, working for DFS. And then from '87 to '99, I was down at CFSAN. And then in '99, I came back here to DFS. So that's, let's see. My time in DFS -- I call it my first tour of duty in DFS.

It would seem like every year, we had a major pesticide crisis on my first tour of duty here. We had PCB's. We had a number of PCB crises, polychlorinated biphenols, in various products. We had a big crisis with aldicarb watermelon. That hit right around the 4th of July. We also had heptachlor in milk from the Arkansas-Texas area, mostly in Arkansas, where seed treated with heptachlor got mixed in the animal feed. It got into the feed and it wound up with heptachlor in milk. My responsibility was coordinating these emergency events for DFS. And as time went on, I found whenever these events came up, I'd find myself up in Dick Swanson's office, in the Emergency Operations

group, and usually wound up up there, whenever these crises started, as the science person up there advising. It was Dick Swanson and Irv Weitzman who were running that group up there then.

I even got involved heavily with the Tylenol tampering crisis when that came out. I was asked to go over and work with the folks in the Center for Devices and Rad Health. They had a lab over on Twinbrook. And I worked with them in developing a test using hospital x-ray machines to scan intact Tylenol. We would set just intact bottles in the box, do a hospital x-ray, and my job was to tamper the products, was to fill Tylenol capsules with cyanide, potassium cyanide, and we would plant them in there and see if they could find them. And they were able to do so using the hospital x-ray machine. You could x-ray the bottles, even end-on. And we used secretaries who worked over there and say, "Okay, you tell us. Look at this x-ray and see, is there something in there that shouldn't be there? And they would always be able to spot the contaminated bottle – it would show up as a white spot because of the potassium in the poison.

Fortunately, the person who did the tampering picked potassium cyanide or had access to potassium cyanide because potassium had a nice nuclear cross-section, which made it easy to spot in an x-ray, hospital x-ray machine. If they had used sodium cyanide, we'd have been out of luck. It wouldn't have worked. But because they used potassium cyanide, we had a tool to use.

Of course, that was when the folks in Cincinnati got involved, and they started trying to track where the cyanide, where the potassium cyanide came from. And, of course, that was the genesis of what became the Forensic Chemistry Center out in Cincinnati, and working with Fred Fricke and Karen Wolnick.

Well, it was then Cincinnati District Office, but it eventually became the forensic chemistry, evolved into the Forensic Chemistry Center.

RT: Now, was Three Mile Island or radionuclide contamination of milk ever something that you were dealing with?

CP: I was not involved with that. I'm trying to remember. I forget when Three Mile Island was. I think it may have been when I was in San Francisco. I didn't get involved in that. Although we did, when I was in San Francisco, get involved with the Kepone, which is out here on the East Coast, in the James River area. That was another pesticide. It was just breaking when I left Baltimore in 1975, just starting, and it became a major issue. I got involved with it when I was in San Francisco, because Campbell Soup had a plant out in San Francisco district. I think it was out in the Central Valley someplace. Well, they actually used oysters out of the Chesapeake to make their oyster stew. So I got involved in looking at those samples out there when I was in San Francisco. It was another one of these emergencies or crises. It seems like that was -- I got involved with those all the time when I was working here at DFS for the first go-around. We just seemed to have one every year.

Of course the big one was ethylene dibromide again. That was used as a fumigant in grains, and I worked with the folks at DFI. I was responsible for running the analysis program that we had going. And we were looking at, I think in the course of one four-month period, we looked at about 15,000 samples for EDB. It was a massive program. And I would have to prepare a status report every week on what we collected, what we

analyzed, what we found, how many violative samples, and where the violative samples were. And I'd have to prepare this report every Friday. It went up to the Commissioner's office.

And, of course, the following week, when the *Food Chemical News* come out, there would be my report. It was showing up in the *Food Chem News*.

And I worked with John Wessel then, who was the contaminants policy director for ORA. I did a lot of work with John and Cathy Carnevale, who were the contaminant policy staff under ORA. I guess by then it was ORA. During my first tenure in DFS, there was a merger between what was the ACRA office and EDRO office. Paul Hile became the head of the combined offices.

RT: That's right. So, organizationally . . .

CP: Don Heaton was the EDRO, and he went off and became the regional director out in Dallas, I believe it was, yes.

But I worked with, well, DFS was under -- I can't remember the title of the office, but Tony Celeste was the director, and Ron Ottes was his deputy.

RT: Your work through your career was focused on either doing analytical work, providing training opportunities for others and other governments maybe, and then management of field initiatives in the pesticides arena.

CP: Through that period of time, yes.

I also got involved with setting up pesticide workshops, and also training courses with the training group.

RT: Now, when you say the training group, are you thinking of the group . . .

CP: What's now Gary German's group, the organization that was . . . I'm trying to remember; I can't remember who was in charge of it back then. Well, Richard Baldwin was in charge of it for a while, and I forget who eventually replaced him.

And I guess it was probably in the late, '86, '87, I started to get burned out and felt I needed a change of scenery, and an opportunity came up to go down to CFSAN, go back on the bench and doing research at CFSAN, so I took that opportunity.

It was in April of '87 that I left DFS and transferred to CFSAN, worked downtown at FOB-8, at 200 C St., S.W., right in downtown Washington. I started doing methods development research down there, and worked down there from '87 to '99. I guess I left there right at January 1st or January 2nd, '99. I reported here to DFS again.

But during that time, I worked a number of years down there. I guess '87 till about '94, I was actually doing methods research work. I was associate referee for miniaturized methods, doing research under AOAC auspices, eventually became the AOAC general referee for multi-residue methods. I developed a couple of miniaturized methods.

I also ran a, I guess you would call it a methods validation study. It wasn't a full-blown collaborative study, but it was a methods validation study that got capillary gas chromatography into the pesticide program. This was based on work that was done at the

Total Diet Research Center out in Kansas City. And I set up a collaborative study to validate that procedure and got it into the AOAC book of methods.

In 1994, there was a reorganization at CFSAN, and a supervisory position became vacant. My branch chief down there at that time was Leon Sawyer. He went over to another group, so that position became open and I applied for it and was selected as the branch chief. So I stopped doing actual research work and became a supervisor at CFSAN and had at that time about eight people, well, seven or eight people working for me. But it was all involved with pesticides. There was, several folks were involved in doing methods development work, but I also had Bernadette McMahon, who was the editor of the pesticide analytical manual.

Also, we had a group that was involved with, I guess it was the 1986 or '87 farm bill, which mandated a laboratory accreditation program for labs that performed pesticide residue testing of fruits and vegetables, of foods. This group at CFSAN was given the responsibility of developing this program in conjunction with EPA and USDA. EPA very rapidly got out of the business. They didn't want anything to do with it. They just said, "You guys do it. Whatever you come up with is fine with us." That's in essence what they said.

We were working with, at that time, AMS, the Agricultural Marketing Service, and the Food Safety and Inspection Service (FSIS) to develop these regulations.

I guess as supervisor, my accomplishments were, we . . . As I said, Bernadette McMahon worked in my group, and we undertook a project to write a third edition of the pesticide analytical manual. The manual had been around for some time. That second edition probably was published in the, prior to my starting with FDA. And we felt that

the manual needed a complete revision, so we undertook a massive project. Anyway, it involved a lot of writing, and we had field analysts involved in the process. We did a lot of writing at CFSAN. We did get the manual actually published, and I guess it was '94 or thereabouts, '95. I forget the exact year that the third edition came out.

RT: Was there pretty good cooperation in this endeavor between FDA's CFSAN and AMS or USDA?

CP: The Accreditation Program development was a long, drawn-out process because each of the three agencies had a different philosophy. We did actually draft regulations, and they went through the clearance process. I don't think they ever got published. It never got implemented. I don't know how many person-years of effort went into that effort. I'm going to say there had to have been 10, 15 person-years of effort between the three agencies that were involved in this. It went on for years, and it got very involved.

Of course, then we had to get it cleared through the chief counsel office at three different agencies plus two different departments. So it just died at that level. It never saw the light of day again, and I don't know . . . It just never, never got past that stage. I know it did get past FDA's chief counsel office. It did get cleared when we went through that. And I worked with the chief counsel office on that, and we finally got it cleared.

RT: Well, who was counsel then for FDA? Do you recall?

CP: Oh, gosh, no. I don't remember who was the chief counsel. I can't remember the

name of the staff attorney I worked with either.

RT: I just wondered if that was after Peter Hutt's tenure.

CP: Oh, yes, it was well after Peter Hutt's tenure.

RT: Because he did a lot of regulations.

CP: So it was a . . .

Then, of course, there was always the crises that came up that I got involved with. We had the Chilean fruit tampering crisis came up during my tenure down there. That was when I was still working in the laboratory at CFSAN.

I did get an award for that work-up, a Commissioner's Special Citation. We actually got fruit in the laboratory and injected the fruit with cyanide and then stored it in the refrigerator. And each day, I would take the fruit out and take pictures of it to see, when could we determine whether or not there was a change in appearance. How long did it take before there was visible evidence? I photographed the fruit every day. I'd have to run them down to Moto Foto and get them processed and bring back the prints, and these photos would go up through the CFSAN chain of command to the Commissioner's office. And I know one time senior management came through. At that time John Taylor was the ACRA. And I had worked with John a number of times in the past before, when he was at the Center at DRG. They were impressed with that work. So I was nominated for an award for that work.

It was important to look at the pictures to see how the fruit actually looked, what the fruit looked like. And most of the fruit, after a few days, you could actually see there would be a discoloration where you made the injection, so you could actually spot visibly. You know, you didn't have to just test it all the time with cyantesmo paper. You could actually see visual evidence that it was tampered. At least there was something there that caused a bruise.

RT: The initial detection, that wasn't a visual thing, was it? Wasn't that just a routine ...

CP: No, it was a visual thing. They actually spotted those grapes somehow.

RT: That's interesting.

CP: I've never heard the true story of what actually happened there. I have my suspicions of what happened, but that was always kept confidential as to what the real story was there. There had to have been some intelligence that directed them to that particular shipment, because you had a whole boatful of fruit coming in, and to be able to find that one crate that had those two tampered grapes. It's like finding the proverbial needle in a haystack.

It was an interesting time, though. I had an interesting time with CFSAN.

RT: I wonder if the visual procedure is still utilized which was developed at that time.

CP: Well, fortunately, we haven't had to deal with it, I don't think.

RT: Right. But I just wondered if that would be . . .

CP: Yes. You can still – I guess that visual evidence, it was . . .

RT: The initial clue maybe.

CP: Yes, yes. There was a lot of questions about whether you really could have gotten a toxic dose in a grape. There's a lot of questions involved there. How much of the cyanide remained.

Some of the other folks at CFSAN did some testing of the fruit, and they could always find cyanide. Again, it depends on how much was still left in the fruit, because when it's exposed to acid, it will react.

So when we were storing this fruit, we bought little what they call the under-counter refrigerator, and we set them up in a hood for safety concerns. We couldn't have just used a regular refrigerator sitting out in the open in the laboratory, so we had these. We bought the small refrigerators and set them in the hoods. That way, if there was outgassing of cyanide gas, that it would be taken care of by the hood and not contaminate the atmosphere in the laboratory.

RT: That's interesting. A lot of people don't know some of those background

activities, and I guess that's one of the merits of this oral history. It's an opportunity for researchers really to delve into what some of the background work is.

CP: Some of the unusual approaches that are taken to deal with an issue, a problem that arises. Yes.

RT: Exactly.

CP: Then in 1998, I had a tough time with a supervisor. I had a number of employees. I had employee personnel issues I had to deal with, and they weren't always pleasant to deal with, to have to deal with really heavy-duty personnel issues, and I had to deal with those and got through them satisfactorily. But it was tough on me.

Before I left DFS the first time, my boss at that time was Mike Olson. Max Gibson was branch chief when I started, and then he retired. Mike Olson came in as a replacement, and I worked with Mike. He was my branch chief during the last few years of my first stint at DFS.

He became director of DFS in 1998, after Richard Baldwin left. And the person he had working in the pesticide area had left DFS or was leaving DFS, and he called me up and asked me if I'd be willing to come back.

RT: The performance appraisal system was put in place. Was that helpful in management, or did that create additional turbulent waters?

CP: The old EPMS system, even though it was a lot of work, we spent a lot of time with it when I was a supervisor, and I found it to be useful.

TAPE 2, SIDE A

RT: With regard to the performance appraisal system, before we changed tapes, you indicated you thought it was a useful management system.

CP: Yes, I did. I did use it. We took it very seriously when I was CFSAN. We spent a lot of time developing the individual performance plans for each person that was in the branch. I expected each of my employees, when it became for the mid-year review and for the final year review, they had to provide me evidence of how they had met their individual performance plans, and then I had to review that material. And I used that to write what I thought was a very useful appraisal of where a person stood. And I had some very good people working for me and I had some marginal people working for me, marginal performers. And I think in both instances, it was useful. I was able to easily justify an outstanding rating for people, one of my people, and it was also useful to document the nonperformance or poor performance of those that were marginal.

RT: Did you ever have an occasion in your management experience where you had to more or less lead an employee to a separation?

CP: Yes. I had an employee who had a psychiatric problem. It got to the point where

the person could not get to work. We had flexi-hours, and the person was supposed to be in before 10:00, and this person sometimes would not show up until 2:00 in the afternoon. I had to put the person on leave restriction and was heading down that path. I was working with the Employee Relations group, trying to come to a resolution to the problem.

The person did something very stupid. They made a threat against another employee in writing, in an e-mail. And one of the most difficult things I ever had to do in the agency was essentially escort that person from the building, you know, take their I.D. and their keys to their office. We had keys to the offices down at CFSAN at that time. This was when we were still down in FOB-8. And this person was told by the agency physician that they were qualified for a disability retirement because of the severity of their psychiatric condition, but the person could not make a decision to do it. Well, this forced the issue, and the person did take a disability retirement.

But it's just as tough on the supervisor when you have to do this to a person.

RT: That's right.

CP: Especially a person that, five years previous, had been a coworker and a good friend. And to see this deterioration occur over a several-year period, it just was a steady progression. I had to write up a, to document everything and, gosh, it was a pile of paper that was four inches thick, the package I had prepared that just documented everything as the situation deteriorated, what I had done, the person's performance and inability to get to work.

RT: That certainly is the other side of management.

CP: Yes. There's the fun things and then there's the not-so-fun things. You enjoy the successes, but the other things are not making it fun to be a manager. And I think that's – I think I burned out on that, and that's when Mike offered me the position, the chance to come back to DFS.

Mike Olson was selected as director of DFS in '98, and the person who had been handling the pesticide program had left. And he saw an opportunity and he asked me if I'd be willing to come back. And, of course, I was a branch chief down there and got promoted to a GS-14, so I said as long as I keep my 14, I'll come back.

Well, he managed to finagle it through Debbie Ralston, and I came back here and started in January of 1999.

Now, right before I left CFSAN, I got involved in the beginning of the National Food Safety System project or the NFSS project. And I was made a member of the Laboratory Operations Work Group.

We had our first meeting in Baltimore of that group in December of '98, and I was elected to a leadership position. Bill Krueger was elected chair of the work group. He's director of the Minnesota State Ag. Lab. Bob Johnson was the deputy. I was elected chair of the Laboratory Accreditation Subgroup.

Well, anyway, I stayed involved with this group when I came to DFS. And, fortunately, I had a good boss in Mike Olson that I enjoyed working for. His philosophy was, you're a 14, you go do your job; just keep me apprised of what you're doing. So I

would, I had pretty much free rein to manage that pesticide program. I also got heavily involved with the NFSS project. Working with Bill Krueger, I got to know a number of really fantastic folks through that project: Pat McCaskey. He's the overall head of the FSIS laboratories, and I know he still works with Carl Sciacchitano, who's director of DFS now with the FERN project. So this was a multiyear effort, and I spent a lot, I devoted a lot of time in this project in my first year here back in DFS, 1999.

Every year we put together a special workshop for the AFDO [Association of Food and Drug Officials] meeting. This went on just about every year that I was here in the second iteration in DFS. The first one we held was in San Antonio, Texas, in 1999, and . . .

RT: What was involved in that?

CP: We set this up to introduce laboratory accreditation to the state laboratory directors, the ag lab directors, and we got funding through FDA, through FSIS, and we even got some funding from CDC to pay the way, one person from each state ag lab to come, or at least the laboratory that was responsible for the food program.

RT: That's what I was wondering, because in many states, it's in health.

CP: It's in health labs. Right. So it was ag or health, but it was the laboratory that had the responsibility for the food program within that state. We funded one person from each laboratory to come to San Antonio. And what we were doing at that time was

promoting laboratory accreditation. That's how I got started in laboratory accreditation, other than the fact that I'd been involved with accreditation previously, the so-called NLAP, National Laboratory Accreditation Program.

And, unfortunately, I had a little accident down in San Antonio. I was going to cross a street at a crosswalk. There was construction going on in that intersection. There was a sewer grate that was recessed down six inches below the street level, and it was black, the asphalt was black. It was a hot day in the sun, it was a hundred degrees down there. I didn't see it, and I stepped off the curb into this thing, and I broke one ankle and severely sprained the other.

RT: That was a bad experience.

CP: I had to go to the hospital. They x-rayed it, said, "You've got a broken ankle," and I had to fly disabled by myself. I was carted around by wheelchairs down in San Antonio. They got me to the airport, and I will say Continental Airlines got me home. They took care of me.

I was out of work for two months because I couldn't drive. Of course, I live in Virginia, a 30-mile drive over here to the Parklawn Building, and for two months I worked at home.

I guess it was the second year we were involved in the NFSS project, that fall, we had our elections and I was elected as co-chair or deputy chair of the work group along with Bill Krueger. And some of the other folks who were involved with this were, of course, Carl Sciacchitano of DFS. Carl was the microbiologist, I was the chemist, so we

were kind of like a tag team. There was five of us that were really heavily involved, and we were the kind of the ringleaders of this work group. We had 20-some people in the work group.

RT: Again, the purpose of this activity was what?

CP: National Food Safety System.

So each year we got funding by hook or by crook to host these meetings, and we always tied them in with the annual Association of Food and Drug Officials (AFDO) meeting. We got funding to bring the state laboratory folks in.

RT: That's good, because some of them wouldn't necessarily get there otherwise.

CP: They wouldn't have gotten there otherwise. And I think it helped AFDO as an organization very much. And we pushed. We were the lab group.

RT: Were you involved on any of the science committees in AFDO per se?

CP: Oh, yes. I was involved with the science committee. I got involved -- through that, I then got involved with the science committee with AFDO. I think Gail Lancette was the chair of that. We were pushing for laboratories to become accredited.

We actually obtained funding through FSIS, and we established a pilot project on accreditation. We hired an internationally known expert in accreditation, Ken Stoub,

who worked with the pilot group of laboratories. It was the FSIS Eastern Laboratory. We had picked the Atlanta laboratory, the Atlanta Regional Laboratory with FDA. And then we had a number of state labs. And this consultant would work with the different groups to develop the necessary paperwork, their quality systems, and their quality program to enable them to become accredited. FSIS Eastern Laboratory was the first of their laboratories to become accredited.

RT: Has that program pretty much come to fruition?

CP: Oh, that was over within a year and a half. It went on for about a year and a half.

The major problem that state laboratories had is funding. Funding is always an issue with them, most of the state laboratories.

RT: Is the stipend or that assistance on travel to the national meetings still operational?

CP: I don't know what's happened with it since I've retired. It's been a year and a half now. I would suspect, with everybody under the gun these days on budgets, from what I hear, that it's not just the federal agencies but the states as well have had a number of cutbacks, etc.

RT: That's right.

CP: So I was involved with this project. Plus I still had my other activities within

DFS.

My second time around in DFS, I was named as a member of the U.S. delegation to the CODEX Committee on Pesticide Residues, so I became, had an international involvement. This was through the pesticide program. This is a very active group, CCPR group, CODEX Committee on Pesticide Residues. And we would meet, oh, gosh, at least half a dozen times during the course of the year as a delegation.

The delegation consisted of folks from FDA, myself and Bill Cooper from CFSAN; FSIS; EPA was the leader of the group. We also had folks from industry, both chemical manufacturers and pesticide manufacturing industry; also trade groups such as the California Citrus Quality Council and the Northwest Apple or Pome Fruit Association. I can't remember what the exact name of that group was now.

We also had, from the groups that are -- all different folks were involved in this in the consumer groups, such as . . . Oh, I can't think of the name of the group, the one that's always looking out with pesticides and everything nowadays.

We had annual meetings which I got to attend over in The Hague, the Netherlands.

RT: Oh, yes, interesting.

CP: So it was good to see a different side, the other side of the ocean. Sitting in one of these big meetings where you operate under the international rules, and you would have headphones on because you could listen in three languages: French, English, Spanish. You could dial in to which one you wanted to listen to. You could either listen to what

was actually being spoken, or you could listen to a translation of the other. If it was in English, it was a translation into French or Spanish. If the person was speaking Spanish, then you would hear a translation into English.

RT: I see.

CP: Or you could listen to the person per se. You operated under the delegation flag. There was a very specific manner of where you sat within the delegation by seniority.

Of course, the government representatives were always closest to the delegate. Only the delegate was authorized to speak unless he designated someone else to speak.

And so it was interesting to watch this, how the international bodies operate.

RT: Speaking of international, apparently through the years, we've had, at least in the appropriate districts, some sampling of pesticides from Mexico. What is the picture with regard to the liaison with the Mexican government? Has FDA and USDA worked cooperatively or they cooperatively with America?

CP: Yes. We've always had good relations and tried to work with the governments. I know that during the time I was at CFSAN, there was a Central American project of teaching people how to do pesticide analysis. I was not involved in that, but I know it was ongoing. A number of folks from within ORA were involved in that. This was because we had had problems not only with Mexican produce but also from other Central American countries. They were not aware of the nuances. Maybe the product had an

international registration but it wasn't registered in the U.S. on the particular product that they were growing. They were sending this product to the United States, but it wasn't registered for use on that product in the United States. So, therefore, when it would hit this country, we would find the residue and it would be illegal because there was no tolerance established for it.

So there was a lot of cooperative efforts ongoing, and John Wessel was involved in that a lot, the international efforts, as far as making them aware of what our regulations were. And I think that the industry got involved too in realizing that, hey, they had to advise these folks: you can't use this on that product if you're going to send it to the United States because it's not going to be legal. So you'd have to use a pesticide that was legal in the United States. And that helped a lot.

RT: With regard to our neighbors to the north, the Canadian officials, are they generally more sensitive to or responsible for pesticide control as compared to our neighbors to the south?

CP: I think that we're equivalent. They had slightly different regulations. But we got along well with them. We worked closely in the CODEX committee. The U.S. worked very closely with Canada, New Zealand, Australia. We worked together cooperatively on a lot of different issues that this committee was involved with.

My primary responsibility was an expert on methodology, and during the time I was involved with the committee, we were working on method-validation guidelines that are adopted internationally.

And one of the things I had adopted into the IOM was the international sampling guidelines for pesticide residues that were published through CODEX. We got those into the IOM. And the result of that is it greatly reduced the weight of produce that we collect. And since most of the samples now are shipped – the shipping costs went up in the ‘90s – they were killing us with the large number of samples we were shipping. The shipping costs were astronomical. So if we could cut the 20-pound sample down to a five-pound sample or thereabouts, the shipping costs went down, plus it’s a much smaller box. It’s not as much a hassle to ship for the investigators.

RT: Was there any particular loss in the reduced size? I mean . . .

CP: Well, these actually, I went through this, it was adopted by the CODEX Committee on Methods of Analysis and Sampling. I sent the proposal over to EPA to make sure. I mean, the EPA establishes tolerances; we enforce them. And to make sure that they were comfortable with us using this approach, that, how does that match up with the sampling protocols they use to establish tolerances, and they said that this protocol was closer to what they actually use than what we were using previously.

RT: Yes. That’s what I was after.

CP: Yes. So they actually highly encouraged or were very supportive and stated very explicitly in their memo back to me that this approach was preferable to the one we were currently using for enforcement. So we did make the change in the IOM shortly before I

retired.

RT: I think we've come pretty much to where you were when you did retire. Is there any other . . .

CP: Well, there was always 9/11.

RT: Oh, sure.

CP: And that got me involved with the last major project I got involved with at DFS. Shortly after 9/11, Mike Olson, who's the director, came to me. He said, "I think we need to start looking at mobile laboratories again." Now, we had mobile laboratories back in the '70s, and they were a failure. They weren't supported financially or program-wise, and they just languished. But we felt, he felt we needed the ability to be there, and to be there on the spot, in an emergency. So he gave me the chore, assignment, to investigate mobile laboratories. And I knew about the problem we had back in the '70s with the mobile laboratories, and I was a little bit leery of this project, but I said, "Okay, I'll go look into it," and I started doing some online searches.

And lo and behold, I saw this one on the Internet. Virginia Tech University has a chemistry mobile laboratory that they send around to high schools throughout the state of Virginia that don't have a chemistry lab, so that they can actually teach chemistry.

RT: Is that right?

CP: Yes. And actually provides them -- they can have the lecture in the school, but it provides the laboratory setting for the students to actually get involved in the scientific experiments. And it moves from high school to high school.

Featherlight was the name of the company out in Iowa that manufactured this unit, and I contacted them. And they were very interested -- of course, this was right after 9/11. This was in December of 2001. They happened to have that unit, could make it available. And they had another mobile unit. These are both tractor trailer-based units, 53-foot tractor trailers. The second had multiple slide-outs. Now, it wasn't a laboratory, and it was owned by the Medtronic Company, which is a medical device manufacturer. They used this trailer to go out and train surgeons on surgical procedures. They don't work on live people; they work on cadavers, train surgeons on how to install their medical devices. These were like spinal devices for treating scoliosis, etc.

They arranged for both these two laboratories to come to the Parklawn Building. We had the Virginia Tech lab parked out front. We didn't have room to park the other one because it took up a lot of room due to the slide-outs. So we had it over by the Ramada Inn on Rockville Pike. We had it in the parking lot behind that. And I arranged for the senior managers in ORA to visit each, and also invited the senior managers from the Centers. Some of them did come around, and they actually toured these units.

And about the same time, Mike Olson had been at a counter-terrorism meeting, and he had mentioned the mobile laboratory. He had met this person from the Air Force. She was a lieutenant colonel or something. She was involved in counter-terrorism activities. And he gave me her name. He said, "Talk to her. She might have a lead for

you, who could build these for us” because I didn’t want to go right to the manufacturer per se, Featherlight, because then you’re going to get involved in procurement with bids and the whole nine yards.

Well, anyway, she put me in touch with this group up at Edgewood Arsenal, a lady by the name of Monica Heyl, H-e-y-l. Well, I called Monica, and she said, “Yeah, we’d love to talk to you about this. We’re involved in building mobile laboratories, and we’ve got them in several federal agencies.” So we set up an appointment in January 2002. Tom Savage, who was the deputy director of DFS, and I went up to Edgewood, Maryland, to the Edgewood area of Aberdeen Proving Ground, and met these folks up there, and they spent most of the day with us.

We walked out of the building afterwards, and I looked at Tom and Tom looked at me, and I said, “Pinch me. Is this for real? Because these are the exact people we need.”

These people, what they do is they design the mobile laboratories and they contract to have them built. And how it would work is we would set up an interagency agreement with them, transfer them the money. They would have the laboratory built to our specifications. We don’t have to get involved in the contracting-out process.

Well, anyway, we found that they have built mobile laboratories for the FBI. They also built them for other classified customers. And their primary interest was in chemical weapons, chemical warfare agents. And when they say mobile laboratories, they took a mass spectrometer, mated it up with a generator, and would take it out in the field, I mean out in the field, set it up and be able to analyze for nerve agents and mustard, etc., any of the chemical warfare agents.

They were doing these analyses, and they were involved in a number of classified operations. I know they were involved in Desert Storm and the last war with Iraq. They were also involved in the Kuwait war. So they were involved in all of these, looking for the chemical warfare agents. Their units were used by the U.N. when they were doing the inspections in Iraq before we had the latest war with Iraq.

So, anyway, we had counter-terrorism money in 2002. I was given \$3 million to set an IAG with the Edgewood folks to build all the laboratories. I was the FDA project officer on it.

RT: I was going to ask you, just ballpark, for the kind of laboratory that this agency would consider, is it a big-bucks . . .

CP: It's a big-buck issue.

RT: I bet it is.

CP: And I was responsible for working with the Edgewood group for the design and construction of the mobile laboratories. The process we used was to have their lead engineer, Charles Henry, and Monica, who is the leader of the group, visit our New York laboratory to look at our microbiological laboratory up there. And then we went out to Cincinnati, to the Forensic Chemistry Center. Because what we were looking at at that stage was, after the 9/11 situation, we were looking, not at just program work, but we also had one of the focus on the counter-terrorism issues.

So what we decided to come up with was a mobile laboratory for microbiology and a mobile laboratory for chemistry. The chemistry laboratory was set up to be able to screen for the chemical warfare agents and other poisons. What we tried to do was set up the same methods that the Forensic Chemistry Center devised that were used by our fixed-site laboratories in doing their CT analyses.

Now, we could do most of that work. The only thing we couldn't do was looking for toxic elements because that just was beyond the capacity of a mobile laboratory. We felt it would be too much.

Then, on the microbiological side, we wanted to look at the select agents plus. We felt that there were also the normal food-borne pathogens could be used in a terrorist event.

RT: If we went into that type of laboratory facilities, what number would we like to have? A mobile laboratory, of course, can move, but I would think that West Coast and East Coast geographically would require . . .

CP: Well, what we did, we costed it out and we came up with a cost of, we estimated \$3 million. Actually, we had to give them another half million a couple years down the road because of cost increases and just changes in the way we designed the laboratory. We initially were thinking of a 53-foot tractor-trailer type base. But in looking at the analytical requirements and isolation of the various stages and the method, you want sample preparation separate from the analysis so you don't have cross-contamination issues. Plus you have to have an office area for people to work that has to be out of both

of those.

Creating those barriers, I mean, physical barriers in a 53-foot tractor trailer, to be able to safely handle select agents, we felt undoable and we needed to move away from the one-unit concept. So what we came up with was a three-unit design. We had three different vehicles. Two of these were in trailers, and the third, the office, we used just essentially a motor home that was modified into an office, just like an RV-type motor home.

With the two trailers, one is the analytical unit, which does the analysis, the other is sample prep. We set the sample prep up with a glove-box system that would enable us to safely handle extremely toxic chemical and biological agents. The prep units were designed to meet Bio Safety Level-3 requirements.

TAPE 2, SIDE B

CP: And we were fortunate that they had a contractor they could go through to buy these units. They already had a contract with a private company to do this type of work. So we didn't have to go out on the open market, bid the stuff out. What we did is we interviewed. We checked out a number of different places to have the laboratories built, and basically decided that we would go with Featherlight out in Iowa. I made several trips out to Featherlight in Iowa along with Edgewood personnel, too, and talked to them about how we were going to do it, then during the course of the construction to see how things were going.

They built the two trailer units, and they're 40 feet long, eight and a half feet

wide. The analytical units have slide-outs that come out so that you have more floor space in there when they're parked. The sample-prep units, we couldn't include slide-outs. We wanted to control the atmosphere in there. All of the air inside both the units is filtered with carbon filters and HEPA filters, so it's pure air. They're designed for the safe operation. There's a specific airflow so that the sample comes in the back of the lab, moves through the lab towards the front, but it's against the flow of the air in the laboratory because the air goes from the front to the back. That's the way they have designed the system. So if anything was released in the laboratory, it would be contained in there. Any of the air that is incoming is filtered; outgoing air is filtered before it goes out so that we would not release anything into the environment. They were built to very strict safety standards.

These were completed just before I retired.

RT: If I understand you, Charlie, we have three units.

CP: A laboratory consists of three vehicles, two trailers and a motor home as the office.

RT: Let's say we have an incident in Albuquerque. We physically drive them down there from wherever they're . . .

CP: Right.

RT: Are they centrally located perhaps?

CP: Well, they would be co-located with each other. They can operate or they're supposed to be able to operate independently, but, in reality, they really do need to have access to electricity, water. And then, of course, you have to make the necessary arrangements for pickup of hazardous waste. They do use water in the work, so you have to have some type of way of connecting to like a sanitary sewer system to get rid of wastewater, etc.

RT: Right.

CP: Now, you can store it on board and then have it pumped out and hauled off that way, but that's inconvenient.

We were hopeful that we could use them also for regulatory work plus have them in case there was ever a terrorist event that required either a microbiological or a chemistry unit. Also, we wanted to be able to use them for our routine program work. Or we thought that they could be stationed at a port of entry and do a, focus on a product or a limited group of products for a short period of time, then move it to another port, and that was the intent behind it.

Unfortunately, the budget got in the way as budget cuts, and I, what's going to happen with them now, I don't know. I have a feeling, I have a sinking suspicion that they're going to go the same way the other ones did. We don't have the funds. The agency no longer has the funding to support them.

RT: Now, before, Charlie, how many of these did we have?

CP: One micro and one chemistry. Two units. And they are -- actually, what we did is, before I left, we arranged for them to be parked down in Arkansas because of the type of facility that is. At the Arkansas Regional Laboratory, they have a large facility physically. It's very secure. It's got an external fence and an internal fence. And they set up a spot where we could park them. They also have all the hookups there for them so that they could actually use them when they're not being deployed.

RT: Well, I maybe wasn't clear with my question. I understand what we're doing now. But historically, in the earlier phase of mobile labs, did we have more in numbers then?

CP: Yes, yes. We had several different types. We had some that were -- I know there was one on the Mexican border. L.A. had one that was basically a tractor trailer for doing pesticide analysis. Dallas had one that was built on a bus-type chassis. There was another one -- I think it was in a bus-type chassis -- that was designed for, that was for pesticides, there was one designed for microbiology. We also had some that were almost like step-van trucks something like UPS uses for deliveries and stuff. That type of vehicle we used for various things. I know we had one in San Francisco when I was out there, but it was used for mostly fill of container. I think it was used when we'd go out and do food standards, you know, fill a container, that type of work, go right up to a plant

and collect samples and do the analysis, and then move on to another plant, so they wouldn't have the shipping involved.

RT: Well, probably subsequent to that period I've addressed now, the earlier mobile lab initiative, have we regionalized or specialized since then?

CP: Those were in the '70s, and they just disappeared.

I know Seattle had the microbe lab, and they used it, I don't know, through the '70s, maybe even the '80s. Then it was transferred. I think CFSAN took possession of it. It was given to them, and they had it, I think it was down in Dolphin Island, but I'm not certain of all those details. And I don't know if it's still in existence down there, or the others. What happened to them, I don't know. I think they were surplus, probably.

RT: Well, this homeland security initiative, the initiatives that were taken in homeland security, probably this new mobile laboratory initiative then was sort of a complementary ...

CP: Right, and there was a big push on imports after 9/11, looking at imported foods, and it was recognized that there was a certain vulnerability with imported foods. So we had hoped to be able to use these at various ports of entry and move them around from port to port for a short period of time. They would be at, say, the Port of Miami for three weeks; then it would move on to, who knows where, Port Champlain, New York, or one of those Mexican ports, Laredo, Nogales, Otay Mesa -- pick one -- or other ports of entry

along either the Canadian or Mexican border, or even look at essentially something like Port Elizabeth up in New Jersey. Even though it's not that far across the river to the Northeast Regional Laboratory, samples collected today don't get to the lab until tomorrow. So mobile labs would provide a quicker turnaround.

RT: So this would provide for that.

CP: That was -- the point was that the sample, if the sample was negative, we'd have an answer within 24 hours after the sample was physically collected.

Now, if it's positive, then all bets are off, because then the results have to be confirmed, you have to do a check analysis. You have to meet the legal requirements to take a regulatory action. So we wanted to be able to say that we went in there and collected a sample at port X. We could collect five samples today. Twenty-four hours later, you're going to have a no answer . . . If the product is okay for what we're analyzing it for, you'll have an answer; the product is released within 24 hours, which I think would have made the importers very happy, because now, it doesn't get to the lab for 24 hours, at least.

RT: That's what I was going to ask you. And comparatively, the timesaving would be significant, then, for results on . . .

CP: Yes, for the importers and the brokers, that they would get faster turnaround on those analyses.

Plus they could be used for other things, like there's a lot of seafood that comes into the Port of Miami; fresh seafood comes in by air through there. And shipping fresh seafood up to Atlanta for organoleptic analysis is very difficult and expensive. There's a day delay from the time it's collected till the time it hits the laboratory, at least one day, if not more.

RT: That was a significant . . .

CP: So that's why we tried to develop these. Unfortunately, I don't know that the ORA has the money to run them. From what I hear, apparently not. It's just the vagaries of the budget.

RT: Yes, right.

CP: You know, after 9/11, we went out and hired a thousand new people. I suspect the size of ORA is back to where it was before 9/11 now.

RT: I suspect so.

CP: I don't know what the current staffing is, but I know, even in the few years after 9/11, before I retired in 2004, the attrition was taking effect. We weren't replacing people we were losing. And I don't think it's changed any since then.

RT: Probably not.

CP: From what I hear. I don't know.

RT: Well, Charlie, as a science-based regulatory agency, what's your sense of the direction? Are we getting further or farther away from being a science-based regulatory agency overall? What's your sense of that?

CP: I think we're trying to be as much as we can, but I think we're being hurt by the budget. We just don't have the funding required to keep on top of everything. And the technology changes so fast, it's not just acquiring new technologies, but you have to have the people trained to work with that technology, be they a chemist, a microbiologist, or an investigator, have to be knowledgeable about this new technology. And the training costs, you know. Gary German's staff, the training costs. Keeping people current is a very time-consuming and expensive process. And I'll be honest, I think my concern is we're not getting the budget anymore that we need to do the job properly.

You know, I was beginning to see it before I left. That was part of my decision to retire. I could see the frustration beginning to build. I would get frustrated by not being able to do what I thought needed to be done because we just didn't have the wherewithal to do it. And it's no fault of anybody here. It's the Congress.

RT: The Congress does add responsibilities and is not always forthcoming with funding.

CP: Usually not.

RT: providing commensurate funding.

CP: Yes. There's expectations made on the agency that we aren't funded to do, we don't have the funding for. I mean, it's not just the ORA; the Centers are the same way.

I saw the same thing down at CFSAN. I mean, when I started, when I was hired as a supervisor down there in '94, I had eight people. When I left there, there was four. Every time I'd lose somebody, I never got permission to hire a backfill. I never was given, I never had a chance to hire somebody down there. And, what, five years I was a supervisor. There was never an opportunity to hire anybody.

RT: Well, that's a significant erosion in help.

CP: Yeah. You'd have people retire and you couldn't replace them, just give up that effort, whatever projects they were working on. If it was important, maybe somebody else would pick it up, but more often than not, it would just sort of die off. And some of them were things that we should have been doing, but . . .

RT: Exactly.

Charlie, I appreciate your participating in this interview. Is there anything, as we close, that you would add?

CP: I know there was some frustration at the end, but I enjoyed my career with FDA. It was a rewarding career. I met a lot of great, great people, worked with a lot of great people, people I respect very much, and you always have to make do with less than you think you really need to do the job. That's the fun part of it, is getting the job done anyway.

RT: Many people in this agency have been very intuitive and inventive in doing more with less.

CP: Oh, yes. That's the name of the game. And in DFS, it was always, in working with DFS, many people would ask me about coming into work there, "Well, what's the job like?" and I said, "If you can't work on 20 things at once, you'd better not come here," because you're always juggling multiple balls. And what gets attention is the one that's yelling at you the most a lot of times.

RT: I'm sure that's true.

CP: And that's just the nature of the game. You're dealing, you know, you've got any number of responsibilities that are ongoing, many things I didn't talk about. Minor parts of your job become very time-consuming at times, and it always happens when you least expect it and least want it to happen, so you've got to deal with it. And that was, you know, it was always fun doing that. I enjoyed doing that.

RT: Well, Charlie, thank you very much for the interview, and we'll make sure that it gets finalized and gets over to the National Library of Medicine.

CP: Okay. Thank you.

END OF INTERVIEW