

History

of the

U. S. Food and Drug Administration

Interviewee: Philip B. White

Interviewer: Ronald T. Ottens & Robert A. Tucker

Date: July 15, 1998

Place: Parklawn Building;
Rockville, MD

DEED OF GIFT

Agreement Pertaining to the Oral History Interview of

Philip
Phillip B. White

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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.

INTERVIEW INDEX

General Topic of Interview: History of the Food & Drug Adm.

Date: July 15, 1998

Place: Rockville, MD

Interviewee(s): Philip B. White

Address: [REDACTED]

Last FDA Position: Director, Office of Standards & Regulation, CDRH

FDA Service Dates: 19961 to 1994

Interviewer(s): Robert A. Tucker, Ronald T. Ottes

Address: Food & Drug Administration

Number of Tapes: 3

Length: 135 minutes

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RO: This is another in a series of FDA oral history recordings. Today we are interviewing Philip B. White, retired FDA official. The interview is taking place in the Parklawn Building, and is being conducted by Robert A. Tucker and Ronald T. Ottes. The date is July 15, 1998. This interview will be transcribed and be placed in the National Library of Medicine and become a part of FDA's oral history program.

Phil, to start the interview, we'd like to have you give a brief biographical sketch of where you were born, raised, educated, and what brought you to the FDA.

PW: OK. I appreciate the invitation and look forward to discussing FDA issues with you, and I guess some personal issues also.

I'm going to be sixty this year. I was born in 1938, August 1938. I was born in Kingston, Pennsylvania, which is a small town in Northeastern Pennsylvania, close to the Wilkes-Barre/Scranton area, it's an anthracite hard coal mining area. My dad was a Pennsylvania state policeman. He and my mother lived at the time I was born in Wyoming, Pennsylvania, another small town, and both coincidentally close to West Pittson where my wife, Jeanne Devers White, who is still with FDA on a part-time basis, was born and raised.

I lived in Wyoming until approximately the age of six, which was around 1945, and at that time, I moved to Trucksville, Pennsylvania, which is more of a rural area, again, not too far away from the Wilkes-Barre/Scranton area. I stayed . . . I went to school in elementary and right through to seventh grade in the Trucksville area. Then we moved to Luzerne, Pennsylvania, when I was in my eighth grade. I stayed in Luzerne and graduated from high school there.

Upon graduation from high school, I started in college. I started at Penn State but transferred over to Wilkes College (University) after the first semester, because I just seemed to like a smaller college rather than a big university. I lived in Luzerne and

commuted to college. Wilkes College is now Wilkes University. It's located in Wilkes-Barre, Pennsylvania. I majored in biology.

After finishing the second year of college, my mom and dad inherited a farm in Meshoppen, Pennsylvania, which is about forty miles from the Wilkes-Barre/Scranton area. They moved to Meshoppen, and I moved into the Warner Hall dormitory. I stayed in the dormitory and finished my college career and got a bachelor of arts degree of all things in biology because of the curriculum in my college with a heavy emphasis on liberal arts. While my major was in a science, I actually got a bachelor of arts degree.

The summers I spent working in the Catskill Mountains as a busboy and a waiter. During the winters, based on the fact that I had become proficient in playing the piano, I used to play the piano to make some extra money. Towards the end of the college year I used to run out of money, so that's how I made my money by playing in bars, getting some free beers, passing the hat and getting a couple bucks.

RO: You didn't play in a band then?

PW: No, I didn't play in the band. I did play in the band . . . I played the trumpet very poorly in the high school band, but I never really became very proficient on the trumpet, although I still have one today and play it once in a while. Piano was my thing. In fact, I almost majored in music, but I decided that a better way of making a living was to get into the science area. So that's what I chose to do. So to this day music is my hobby.

I joined FDA for two reasons. Number one, Frank Fiskett, who is now deceased but at the time was a Food and Drug officer in the Philadelphia District, came to Wilkes University recruiting for people to become interested in FDA inspector positions. He spoke to our biology club, I believe, at the time, and this was in my junior

year of college, and I thought, you know, if you ever wanted to apply science to a non-laboratory kind of thing, that might be an interesting job to consider. Plus my dad, of course, being a state policeman, I guess, you know, part of that was sort of ingrained in me that investigative work might be something to consider at some time.

It came time for my senior year, and I started looking . . . I didn't really want to go to graduate school. I wanted to go out and work for a while, and quite frankly, although I interviewed with some people in private industry, it was kind of hard, because it was in 1961, and I was definitely eligible for the draft and subject to being called by the draft, and it was kind of hard to get placed in industry. So I looked for positions in the federal government. I took I guess it was the FSEE (Federal Service Entrance Examination), and I got a grade, and I asked them to send my application to the Philadelphia office, to FDA. I forget how I did all that. But somehow they got in touch with me while I was still in college.

Joe Belson, again another retired FDA person, came to interview me and also to do a reference check on me, and Joe evidently was satisfied with me, and he recommended that I be hired. I was offered a position shortly after I graduated in June of '61, and I reported for duty in the Philadelphia office on July 10, I think it was, or something like that. Yes, I think July 10, 1961. The first day I met George Brubaker, who is still a dear friend and also an ex-colleague of mine. He and I both started together. Fred Lofsvold was the district director. He swore us in. Leonard Blanton was our chief inspector. Frank Fiskett was a Food and Drug officer. Herb Ayres, another retired FDAer, was also a Food and Drug officer. Charlie Wood was the lab director, and Sid somebody--I can't remember his last name--he ended up in foods. Sid Williams, I think it was, was the supervisory chemist.

So we started. The first day was interesting. We sat in a room and read inspector's manuals. We didn't really have anything else to do until about 2:00 in the afternoon Tom Price said one of us could go with an inspector to do some net weight

surveys. I was the one that ended up going, and I went with Richard Fisher, who I think is still somewhere in this building. I think he's in the OTC drug program. Dick Fisher took me over to Camden, New Jersey, right across the river, and we found some short weight Quaker puffed wheat and Quaker puffed rice. This was a follow up to an inspection that Tom Kingsley, who was at that time a resident inspector in Harrisburg, Pennsylvania, had done at the Quaker Oats firm in Shiremanstown, Pennsylvania, and found short weight. Shortly after, there were multiple seizures of puffed wheat and puffed rice, because they were just consistently about 5 to 10 percent short weight, and I think they ended up a couple of years later getting a fine for violation of the Food, Drug & Cosmetic Act.

I spent most of the summer on training inspection and sample collection assignments. Joe Belson took me on my first road trip. He was a pharmacist, but we did nothing but cannery inspections. So that was kind of interesting. I went through the on-the-job training, which most of the training at that time was on-the-job, and finally I was allowed to go out and do some inspections on my own, about the fifth or sixth month, and I really did most of my work independently then. I very rarely . . . The only training we got formally was . . . I started in July. In December, I think we went down to FDA headquarters at that time in . . . I guess we were in the HEW Building, and we received some formal classroom training in the FD&C Act and evidence development and a couple of other things.

At that course I had met Cliff Shane—he was one of the instructors. Hy Eiduson taught the Food, Drug & Cosmetic Act for us, did a very good job. I met Allan Rayfield, who was, you know . . . (Laughter) There he is up on the wall there. He looked just like he does up on the wall there. A very stern, direct, authoritarian person. I met Ken Lennington, much the same way. Fred Garfield, I think I met, too, at that time; he was in charge of all laboratory operations. Reo Duggan had something to do with laboratory operations. And I got acquainted with some folks. I did not meet the

commissioner at the time. I forget who the deputy commissioner was at the time, but we did meet him.

RT: Was that John Harvey?

PW: Yes, it was John Harvey. Exactly. Why I remember that, I don't know. But, anyway, that was an interesting week. I really enjoyed it.

I went back to Philadelphia, and most of my work the first year or so was primarily food, and bakeries, and traveling, things like that. Gradually, I got into the drug area, but I always kept my options open and did other things, too.

RT: What was your entry level?

PW: I was a GS-5. My salary was \$4,330 a year, and I remember I used to take \$127 every two weeks. The thing that really made an impression on me was when I had worked in the Catskills the summer before, I was making more money per week than I was with FDA, but I knew I had to get started somewhere. I got promoted to a GS-7 in six months. Then I got promoted to a GS-9 about a little over a year after that.

And then, I don't know, I seemed to hit it. I got some good assignments in the drug area, and they seemed to like my work, and I got a GS-11 when GS-11s were not a journeyman level. It was very hard to get a GS-11, but I was able to get promoted. I got that around 1964 or so, I think it was.

And then by that time, Leonard Blanton had retired . . . Or, no, he had moved to Atlanta, OK? And Fred Lofsvold had left to go to New York, and George Gerstenberg was one of the supervisors, and Frank, I think . . . Oh, Frank Fiskett moved downstairs to become a supervisor, and Irv Berch came in as a district director. We had districts then; we didn't have regions. Jim Green was our chief inspector, and

I don't know . . . When I first started working for Jim, he . . . You know, we very rarely got appraisals. We got this statement once a year that we were satisfactory. Then all of a sudden, when Dr. Goddard became commissioner, they became a little more management/communications oriented. The only thing he said to me the first time he did an appraisal was he thought that I was more of a compliance or food and drug officer mold than I was the supervisory inspector kind of thing. But he just said that's what he thought. It wasn't a criticism. He just said if he had to pick a direction for me to go, that would be the direction he would pick out. That wasn't what I wanted to hear, but, while I wasn't that disappointed, I didn't think that was a good career ladder. I thought you'd just stop somewhere and that would be the end of it.

But, anyway, for some reason George Gerstenberg was sort of a mentor for me, and we seemed to work together very well. He put me in charge one or two times when he wasn't there, and he seemed to like what I was doing. Then I seemed to have caught Jim Green's eye. He seemed to like me. Around I would say 1965, I was promoted to supervisory inspector, which did not go over too well for . . . It's hard to get promoted in the same district, I think. There were people older than me that really felt that they had been pushed aside, and that they had played favorites with me to get the job and, you know. So there were some uncomfortable feelings, but it seemed to go away after thirty days or so. You know, it seemed to go away, at least from my perspective--who knows.

Anyway, I was a supervisory inspector, and I worked with Wadsworth Grey, Joe Phillips, George Gerstenberg, and myself. Jim Green had moved onto BDAC (Bureau of Drug Abuse Control), and Jim Nakada came in as the chief inspector. Jim was a delegator, so we were completely on our own. At times we had trouble getting along, because we really didn't have a leader. George Gerstenberg and Joe Phillips and I got along. Wadsworth Grey didn't get along with any of us. I don't think it was a black and white situation; I just think it was different philosophy, as I think about it through

the years. I don't think any of us ever complained about being discriminated against, including Wadsworth. I think we just didn't agree at times, you know, on work plans, on assignments, on assigning people, on following up on working with each other, we just didn't seem to . . . We got the job done, but it wasn't the most pleasant situation.

George left and transferred to New York District. At that time, for me to go from a GS-12--by that time I was a GS-12--to go from a GS-12 to a 13 absolutely would not happen in the same district unless it was a miracle. You really had to transfer.

Weems Clevenger was reorganizing, had a lot of money, and a lot of positions open in the New York District. I saw some openings advertised, and I just called him up and told him I was interested. I just called him directly. I didn't really know him, I just knew of him. He asked me to come up for an interview. I went up, got interviewed, and was selected for a supervisory position GS-13 in Newark. I left the Philadelphia District around the summer of 1967, and I worked in Newark . . . Well, it wasn't the Newark District then; it was Newark Section.

RO: Phil, before we leave Philadelphia, it was during the time I think that Nakada was chief inspector, there was a little problem of discrimination. Were you there when . . . ?

PW: That happened after I left. I was aware of it, but I wasn't a party to it. There were all sorts of discrimination things. Both he and Irv Berch were really accused of being discriminatory about certain people and certain assignments and so forth. I think, as I remember it faintly, inspectors as well as people in the laboratory were involved, and there was an investigation. Because when I was in the executive development program a couple years later, one of the fellows that did the investigation shared an office with me. I didn't know too much about the investigation except it had been done.

RO: OK.

PW: The only thing that happened while I was there is for a brief period of time before I was the supervisor, we had Irv Pollack as a supervisor. Irv, I think, really had severe mental problems. He came in from, I think, Detroit District, and he just never hit it off with anybody. He and Gerstenberg just did not get along at all, and while George was a hard person at times to get along with, he knew the right way of doing things. He was very hard working and energetic. Irv Pollack not only gave out weird assignments, but he just acted very strange. One day he just went into a tantrum during an inspectors meeting--it was unbelievable--an investigation was done, some people wrote memos of what happened at the meeting. He was finally transferred to Boston, and I think he really got worse and worse, because when I ended up working for Winton Rankin in 1970 . . . No, it wasn't 1970, it was around 1969, word came in that he had been finally removed from the career service.

There were some discrimination accusations in the laboratory while I was there, centering around one or two people whose names I can't recall right now. But that was the only thing.

Both Nakada and Berch were very, very inflexible people, and I think at times that that was really not the modern way to deal with issues. To take a, to have a stiff lip and to deal with things, sort of like lawyer to lawyer, did not work with the kind of staff we had in the sixties, you know, especially after Dr. Goddard became commissioner. It just wasn't a modern way of management, and I think that was part of the problem. But, you know, at the time, even though the agency was growing, there were only so many ways to get ahead and so many positions, and I think that was part of it, too.

Anyway, I went to Newark. I worked for Ed Wilkens. At that time Newark was called a section. It was more like an inspection station. We worked in the old post

office, in a basement that had termites. It was an awful place to work. It was just terribly awful. Fortunately, they built a federal building across the street, and we moved to that, which was much better. I was only there a year. Wilkens was just the opposite of Nakada. Wilkens tried to micro-manage everything, and, you know, when you go from an atmosphere where you're completely on your own and then you're working for Wilkens, you really had to grit your teeth. We liked each other personally, but professionally I just had problems with that kind of oppressive oversight of everything that was going on. It bothered me at times, although it wasn't the worst problem in the world, you know. It was just part of maturing, I think. You know, you just have to deal with different people.

Anyway, while I was there I got assigned by Clevenger to go over to Brooklyn and help straighten out their data system, which was a mess. At that time, we really didn't have computers in the field. All we had were data cards, you know, and the operational data was just not going to the data processing unit very well, and it wasn't being transmitted to the FDA headquarters computer very well. I evidently said too much at a meeting one time: we had to discuss the problem, and Clevenger thought I was answer. So I got sent over to the Brooklyn office to work on the data system, as well as to try to make some sense . . . They had some planning responsibilities as a district to do, and they weren't being done very well. So I sort of helped deal with that, too.

I did not like that, because I was living way far away. You know, I was assigned to Newark, and I was living out in Morristown, New Jersey, and I had to take a train all the way to Hoboken, and then I had to take either the ferry or the tubes underground to Manhattan, and then I had to take a subway down to Brooklyn. It was just a terrible commute. At the same time, they wanted us to go to law school and take a law course. So I had to go to . . . I went to NYU at night, one night a week for two semesters. It was a wonderful law course, but I mean the drain on your time was just

awful, and that was even a worse commute, because that was down in Greenwich Village, and the commuting logistics were just awful.

Billy Goodrich taught the entire first semester, and it was wonderful, you know. Then we had Billy part of the second semester, and then we had some people from industry, and that was a wonderful course, I mean, it was really good. There was good dialogue. Some of the students that were in the course were FDAers. Some of them were people who ended up as industry attorneys. Steve Weitzman, for example, who was a character in himself, was there. To this day, he doesn't realize where I first met him, which was in that law course. He was going to graduate school and took it. Anyway, we all got four credits. I got A's. I don't know why, but I got them.

Towards the end of my first year, there were two things that occurred that got my attention. First of all, I was not too excited about staying in Newark for too long. I wanted to get ahead, but, you know, I also wanted to not offend anybody in the process, and, again, I was getting along fine. Wilkens and Gerstenberg did not get along, and it was terrible, because they fought with each other, and one was in Brooklyn, the other was in Newark. Arnold Morton was the director of all of this. He was there because he had been sent there I think by Goddard to spend some time there before he retired. He was a nonactive manager, and he could not referee very well between the two of them. Weems (Clevenger) was just disgusted with it, didn't want to do anything with it. Mary Dolan was his deputy, and she had her own agenda. So it was kind of . . . From a management standpoint, it was a mess. It was good experience for me, but, I mean, if you ever wanted to see how not to manage a railroad, that was the place to work.

At the same time, it was kind of exciting, because the industry was totally different. In Philadelphia, if you had a legal basis for asking for information from the regulated industry you could get it. In Newark or in Brooklyn, if you had a legal basis for asking it, that didn't mean you were going to get it. You know, I would send

inspectors out on assignments, and they wouldn't get the information. I couldn't understand why, and they said, "They just won't give it to us." So I went out with them one or two times, and I found that you really had to argue your way into it, and it was a very vigorous discussion to get what you wanted, and that's just the way it was. That was the New York climate as opposed to Philadelphia, which was good for me to learn that by going out with my people. But, on the other hand, it made it very difficult to do a thorough job at times, and at times I think we missed things that, because we just couldn't thoroughly document it, and . . .

RT: Were there any particular significant legal actions that resulted from your work at that point?

PW: Well, the main thing was . . . You know, I told you about this Arnold Morton position, and for some reason while I was over there . . . One time when I was over there, I had his job for a while, and I remember there were some big problems with counterfeit drugs. Weems was really interested in this stuff, because he was an old BDAC guy and so was Ed Wilkens, you know, so . . . You know, anything that smacked of counterfeiting they wanted to get into, because this is what they were comfortable with. All of a sudden, I'm in this job and the next thing I know is Ed Warner, who was the supervisor--just passed away recently--comes in and says, "I guess we better tell you. We have a warrant, and we're going to make a raid." And I said, "You're going to *what*?" "We're going to make a raid and seize these goods. We have a search warrant; we know it's there; we're going to get it." And I said, "Well, we've got to set up some system so that we keep people informed, you know. You've got everything set up. Go ahead and do it."

They had it set up all right. They get in there, and they couldn't find what they were looking for. They started knocking down walls, and holy God, you know, that's

just something we just don't do. I mean, you know, I was from a state policeman's family. You know, there's so far you can go. This was not one of those situations. Well, they started knocking down walls; they seized all this stuff; they brought it back; I called in the FBI to take a look at it. I was really trying to turn the case over to the FBI. This was just my hunch that we've got to get this out of FDA here. Let the FBI deal with it, because I knew that our people would not know how to deal with us. It was just instinctive in me. I mean, we weren't trained to do that stuff. That's what BDAC and these other people were for.

So that was a significant thing. That was a real significant thing. And that's the thing that really sticks out. Most of the rest of the stuff was . . . This was the beginning of IDIP (Intensified Drug Inspection Program). You know, I was only there a year, Bob, and we really got IDIP started, but nothing was finished by the time I left.

What happened to me at the end of the year was that there were two training possibilities. There was a long-term training program and there was an executive development program. So I applied for both. I told Ed Wilkens, I told Weems, and they said, "Fine. What do you really want?" I said, "I don't know what I want." I said, "I'd like to be interviewed if I can be for that, and then I'd like to make my choice."

So I was . . . And I have to have . . . You know, you hear funny things about Ed Wilkens and all that stuff, but I must say that he pushed it through. It was at the end of the deadline. I think the application got in past the deadline, but they still agreed they wanted to interview me. So I was called down for an interview. Gale Wyer, who was in the laboratory in New York, and I were called in for an interview. Mickey Moure, Jack Markowitz, Danny Banes interviewed us. We may have had another person there, but I can't remember who it was. But, anyway, at least those three did the interviews. Gale went in and did his thing. I went in, and I must have talked a good game, because I was pretty sure I had done well. I learned later that they did not have enough slots, but they found one for me.

So I was given my choice of going to graduate school for a year, you know, and staying in Newark and then coming back, or going to the executive development program. I chose . . . I really felt pragmatically, even though it would be good to go to school for a year, that in terms of getting ahead and moving up the ladder, I thought that going into the executive development program would not only be good experience, but I could probably get a GS-14 faster and pragmatically. So that's what I did.

So I left after a year and came down here.

RO: What year was that when you left New York?

PW: I left in 1968. Let's see. I went to Newark in '67--in the summer. I left in the summer of '68, and started in the executive development program either late August or early September of '68.

(Interruption)

RT: Did you say Jack . . . ? Was Jack Markowitz one of the ones that you had initially interviewed with?

PW: Yes, yes. He was part of the group that interviewed me.

OK. Anyway, Jack sort of oversaw things, Rico Sturniolo was the day-to-day coordinator, and we were told to come up with some assignments. Billy Hill, myself, Jim Adamson, Gale Wyer, I think, were the ones that were in the program--that class anyway. There was a class ahead of us and then there was us, and the idea was we would stay for a year or so, get as much experience as we could, and then move onto another position.

I wanted to do something different that I had never done before. The other guys all wanted . . . Oh, Larry Ormsbee was the other person. The other guys wanted to go work in what was then . . . I guess it wasn't EDRO. It was something, the precursor to EDRO. What was it?

RO: Field Coordination.

PW: Field Coordination. ACFC. OK. Assistant Commissioner for Field Coordination. Sam Fine was in charge of it. They wanted to go work in ACFC, work on the field work plan, and then go back out to the field. I wanted to go back out to the field, but I didn't want to work on the field work plan. I wanted to do something . . . I just wanted to learn a little more about the agency.

I really enjoyed interacting with Moure, and I think he sort of reached . . . He either reached out for me or I reached out for him. Anyway, we connected, and my first assignment was with Moure. John Droke was his deputy. I really worked for John. We decided I would do a survey of administrative activities and help them come up with, you know, as an outsider make recommendations for streamlining or adding here or whatever.

At that time, FDA had just become part of CPEHS, the Consumer Protection for Environmental Health Services. The FDA management all of a sudden had a layer over them at the CPEHS level, and they really had to make some hard decisions as to what they were going to do and what CPEHS was going to do, and actually, pragmatically, they wanted to hold on to as much as they could and give CPEHS as little as possible, because they just were afraid, quite frankly. It wasn't just a bureaucratic thing, They were afraid that the agency's resources were going to be drained and transferred to another part of CPEHS. Both the commissioner's office . . . I mean, the commis-

sioner's office as a whole was worried about that, and they thought that it would really have a detrimental effect on the programs of the Food & Drug Administration.

RO: Who was commissioner?

PW: At that time, Herbert Ley was commissioner. Goddard had left. It was Goddard's idea to have CPEHS. I mean, I read all of the task force papers while I was in Moure's office. Of course, the task forces had met before I got there. But basically Goddard and people on his staff . . . Oh, a fellow was there who was in charge of planning who had left, he was a . . .

RT: Was that Ed Tuerk?

PW: Tuerk was really pushing it. He and Goddard had it all figured out that they could create--and the PR guy that was with them, and I forget who he was. He went somewhere else, too. But they had an idea man that was . . . I remember at one time he was . . .

RT: Wasn't that Ted Cron?

PW: Ted Cron. This was . . . The three of them were the people responsible for pushing this CPEHS idea. It was very clear in all the task force papers. I read almost every one that existed. This was part of my assignment to get familiar with how, you know, the administrative things. They gave me a lot of stuff to read, and I'm a pretty quick reader. But these guys wanted to create an umbrella for consumer protection programs as well as environmental health programs, and the idea was that Goddard

would be in charge of all this, and these guys would move up there and be a triumvirate running things.

But why, I don't know, but the decision was made probably because Goddard . . . I mean, I'm guessing now, but I assume that Goddard became too controversial for, you know, the department. He made some statements about marijuana, that he was, you know, more concerned about alcohol than he was the marijuana as far as his daughter was concerned, and that did not go over too well. I don't know what else he did, but . . .

RT: Well, he mentioned something about the demise of the corner drugstore.

PW: Yes. That's right, he did. You're exactly right. You're exactly right. And he did not get the main job. They put C. C. Johnson, who came out of nowhere, to get it, and C. C. Johnson must have had firm marching orders that this was a good concept, we were going to do it, it would make sense. The secretary at the time was Wilbur Cohen, I believe, and I assume it came from a high level that this was the way it was going to be.

Well, this is what I came into. Well, Moure, and Winton Rankin was the deputy, and Herb Ley and others really were very concerned about this--Ken Kirk was very concerned about it--because they really knew the history of the agency, and they were pretty open about it. They were just afraid that the agency's programs were going to disappear or be minuscule in comparison to what they were. They were just very concerned about the future of these activities.

So I was in an interesting situation where I was doing this survey, but I got drawn into the politics of this, I mean, the FDA politics of this. So it was a good experience for me to see all this. I did a very . . . You know, I did a whole bunch of interviews to do this survey, and I wrote up a draft which never went any further than

that. But I really was doing a lot of day-to-day staff work for them on a lot of issues like that. I just helped do things like that. Droke was involved in a lot of this, and I almost became his personal assistant in a lot of that stuff.

RO: Were there any administrative functions that were actually transferred from FDA to CPEHS?

PW: Well, they tried to . . . Well, one of the things--which wasn't a big thing, but it was an important thing--was the Art Davis function, internal security function. That was transferred up there, and quite frankly it was being used for . . . I don't know. At times we felt that it was being used to investigate the conduct of the people that were in FDA that were against, you know, this CPEHS thing, you know. It was just . . . There were just . . . There were weird . . . There were things happening that people didn't know what was going on. There was a vacuum that would exist. They would be investigating misconduct cases, and you'd never hear anything--you know, they'd never tell you anything.

And then there were some suspicions that . . . I'm moving a little further now, but while I was still in the program, I also worked for Winton Rankin and Herb Ley, and we were located in Crystal Plaza in Virginia. There were some suspicions that the phones were tapped. There were always people in working on the phones. Rankin couldn't understand that, and nobody else could understand it.

There were finally . . . To tell an anecdote that's weird, but Ley was kind of an interesting guy. Among other things he had worked in the military service for years, and he must have had something to do with intelligence at one time, because all of a sudden he comes in one day, and they told me to shut all the doors. I shut all the doors, and he had this thing to check for wire taps. So he was not only checking the phones, but he was going around checking the walls. I don't know if it was a metal detector or

what the hell it was. You know. It was kind of . . . I mean, this man was just so stressed out about this. He just really felt that people were watching everything they were doing. So he's checking Winton's office, and he's checking my office, and he's checking his office. It was the damndest thing you ever saw in your life. But, you know, we didn't find any taps, but we had a lot of suspicions, you know.

But I'm getting ahead of myself. Let me just tell you a little about myself, and then I'll get into that because that's really more interesting.

While I was working for Moure, all of a sudden the people, the commissioner's office was very concerned about the drug adverse reaction reporting program, which was a program in the Bureau of Medicine at the time--Drugs. OK? And they were really . . . They didn't think it was a good program to begin with, plus there had been an internal study that indicated it wasn't a good thing, and it got leaked to Congress, and Congress they thought were going to have hearings and make a really big deal out of it. And at that time, the Fountain Committee was raising hell about everything, you know, especially the fact that the agency wasn't moving out smartly and taking action against combination drugs and certain kinds of antibiotics. Chloramphenicol is the one that first comes to mind.

You know, throughout all this, as executive development trainees, we went to all the weekly staff meetings, and so we knew a lot about what was going on because Ley and Rankin were very candid about talking about things. It was interesting to watch that. The other thing that was interesting was to watch Al Barnard and--who was the voluntary compliance guy, the general?--Delmore fight with each other. One was in charge of voluntary compliance, the other was in charge of regulatory compliance, and they were each trying to blame everything on the other. It was kind of disgusting in a way, but it was interesting. So that was going on.

Dr. Van Houweling was in charge of Vet Medicine, and he didn't want to do anything about good enforcement. He just wanted to keep industry and USDA happy. If there was ever a man that had a USDA philosophy, it was Van Houweling.

Danny Banes was in charge of Science, and he was having . . . I think he was having emotional problems. He was sort of in a daze all the time. I remember that in training schools I went to, he was one of the best speakers I ever heard in my life talking about scientific . . . You remember how he was.

RO: I sure do.

PW: But he wasn't like that at all, you know. So we had a weird cast.

Anyway, I got sent over . . . John Jennings and Harvey Minchew were running the Bureau of Medicine. Minchew was the head of it and John was the deputy. I got sent over there to put together all the files on the adverse reaction program and get ready for hearings. I put together all the files, but they never had the oversight hearings. Winton Rankin had a special assistant position reserved primarily for people who were in the executive development program, and Mickey must have recommended me, because the next thing I knew is I was in there working for Winton Rankin, and that was the most interesting experience I've ever had in my life.

I went in there around 1969. I was still in the program, and went in there in the summer of 1969. This man was absolutely unbelievable. Everything that went across his desk went through me first. I had to review everything, I had to put notes on it, comment on it, and send it in to him before he would do anything about it. Very, very rarely did I not see everything that went across his desk. His door . . . My office was right next to his, his door very rarely was closed. I was allowed to listen or come into any meeting I wanted to. It was just an incredible experience, you know. And every action he took on something, he would explain to me. So it was a wonderful learning

experience. I don't know how he had the patience to deal with me, but he did, and I learned a lot from him.

That's when I got involved directly with his stuff and at times with Ley. I would do things directly for him. During all of this, these guys were not only dealing with Congress, and there was heavy, heavy pressure on them plus Goodrich to do something about drugs that were on the market that the Fountain Committee felt shouldn't be on the market. That's basically what the bottom line was. And also Harvey Minchew finally had it up to here, and he left. He went up to the Columbia Health Plan and is still there as far as I know. Jennings took over the bureau, and the bureau was very, very difficult to manage. They had all these responsibilities.

They did not have good managers. John was a wonderful, knowledgeable person, but he couldn't do it all by himself, and quite frankly he was more of a philosopher than he was a manager, you know. He really thought . . . I think it's kind of a doctor-to-doctor thing. Each doctor makes his own, has his own patients and does his own thing and is responsible for his own thing, and John would be the severe critic. He would be like a pathologist and really get after them if things were really screwed up, but he couldn't manage it that way, you know, and that's what he was trying to do. It didn't work very well.

But there were all these problems, and they would come into Ley on things that really should never have gotten to his attention. For example, things like the backlog, you know. Original NDAs--how long was it taking to review them? They were keeping all these charts, but they were still under tremendous pressure to do things faster. They were still implementing the Drug Efficacy Review for Prescription Drugs, and there was a lot of pressure on them to get it over with, because here we're talking about something that started in '62, and here it was, you know, '69 and it wasn't over.

At the same time, they had all the results of the OTC Review, they hadn't done anything with it, and had no strategy for doing anything about it. Finally, Winton was

so upset about it that he developed his own strategy and said, "This is the way it's going to be." He did it on a flip chart one day. He started developing strategies for everybody. Nobody had any clear sense of direction as to what to do. There was no enforcement philosophy, there was no mission for the agency, there was nothing. Everything was just, you know, crisis by crisis, you know.

At the same time, the programmatic crises were occurring. The management crises were getting worse because CPEHS was taking positions and money away from the agency, and basically they would take the salary dollars, so you would have these dummy . . . You know, you would have . . . It was kiting. You used to use the term *kiting*. You know what I mean. Well, basically I never knew what kiting was, but that's what it was. I mean, you would have all these vacancies, but you had no money to fund the positions, so you couldn't fill them. So then they would take those positions and say, "Well, we'll fill them." Of course, they had the money to do it because they took it from FDA to do it.

Finally, Rankin makes a speech at FDLI (Food and Drug Law Institute) one day and says, you know, "This is just terrible. Things are just awful." And that really got people's attention. Then Ley decides that he's going to form a task force of people that are going to investigate all of this. Maurice Kinslow was the head of it, and Marian Finkel was on it, and Tom Brown was on it, and I forget who else was on it. They came up with a draft report that was a real whopper, and they said things were pretty bad, you know, and that the agency really needed . . . And all of us helped leak that. It was a draft report, and between Paul Pumpian, who was your boss, and people in the press office and others, the draft report was printed and distributed liberally all over town. It made the news. It resulted in congressional hearings. It got the agency some visibility about this terrible thing with CPEHS--the fact they didn't have money, the fact that the agency was out of control. So it was good to get people's attention.

The hurting thing about it was the next thing we know was that Dr. Ley basically got removed from his position and offered a position in the department, and he chose to leave. Rankin got removed from his position and offered a position in the department. He chose to stay, because he wasn't quite eligible for retirement. So he went up to the Surgeon General's Office, who was Jesse Steinfeld. One thing that happened during all of that which was very important was cyclamates.

The most important calamity that occurred, and this is . . . I don't know if you've heard this story from others, but I'll tell you my version of it. Dr. Ley at times was very secretive and really . . . He supported everything that Winton did, but he tried to distance himself with it, and at times he did his own thing. At times, he really felt that Winton should be the heavy guy, I guess, and he should be the guy above all of that.

Well, all of a sudden we knew something was happening with respect to cyclamates, but we didn't know what, and it was all at the department level. Goodrich knew something was going on, but he wouldn't tell Winton what it was. Winton was trying to find out what was going on. All of a sudden Ley kept disappearing. He was just virtually out of touch and out of the office for about half a week. Nobody knew what was going on. We found out that the department had made a decision to ban cyclamates. Basically, it all came down to test data showing the occurrence of bladder cancer in mice and rats. The DHEW General Counsel (Bob Madigan) called Goodrich at the golf course and asked him what to do about it. "Well," he says, "without knowing too much," he says, "there are a couple choices. You could ban it or invoke the Delaney clause, or you could do some other things." I don't think it was much of a dialogue. From what I understand, he gave them a couple options, but I think what he was really saying is you ought to get some consultation before you make your decision, but people at the department made the decision.

RO: At the department?

PW: Yes. It was made at the department. Ley went along with it, but I don't know to what extent he went along with it or if he was just a good messenger afterwards. But basically he made it quite clear to us that it was not his decision, that it was their decision, and, you know, there was nothing more we could do about it.

So what happened was, I mean, that had a catastrophic effect on the agency, because it really showed that nobody trusted the agency to manage its own business and the people that were making the decisions didn't know what the hell they were doing. Banning cyclamates was the wrong decision. There were other ways of handling that. There should have been some more scientific input. There should have been some more studies. There should have . . . This was only one study. I mean, it was not enough information. FDA, through the Legislative Services Office and the Press Office and FDA fact sheets, clearly said this was a decision of Roger Egeberg, who was the assistant secretary for Health.

I remember Winton was charged with deciding how the agency was going to respond. So we had I remember Taylor Quinn and Walter Moses in our offices almost every day. They were seeking guidance on just what we were going to tell the food industry. Everything was coordinated by them with Winton. They were up in his office every day, and they basically worked through it on a case-by-case basis until they came up with enough guidance to satisfy people. It had a terrible economic effect on the food industry, because everybody was using this stuff. It just wasn't sodas; it was used in jams, jellies, all across the board. It was considered very, very safe and very good for what it was . . . That was a terrible thing to happen.

RO: What you've said supports the rumor that Ley was dealing with the department on the cyclamates, but he was supposed to have been charged with, "Don't discuss it with any of your FDA staff."

PW: Yes, that's true. And that is true. That's exactly true; that's what he told us. He was told not to say . . . And, you know, Winton could never, ever understand that. It was not a personal thing; it was a professional thing with him. How in the hell a commissioner could ever tolerate that. That was just inexcusable. The people that knew the most about it were kept completely out of it, and Goodrich, I think, was just trying to, you know . . . I think he gave them some real quick off-the-cuff advice, and all of a sudden they just took it and did it, you know. And then I don't know . . . He would be the one that would have to answer to his part of it. I never asked him quite frankly. I think he would have told me; I just never asked him. There were certain things you just didn't ask him about unless you really felt you had a need to know.

RO: Do you think that the cyclamate decision really was the demise of Herb Ley?

PW: I think that was the straw that broke the camel's back, because that really showed the public, as well as the department, as well as the White House, as well as the Congress, that everything was kind of screwed up, you know. I mean, not only was FDA being criticized for the drug program; now they were doing things that affected society, and then, you know, they had all these task force reports that showed things weren't being done very well, and I think they . . . And then I think the department realized this CPEHS thing was a big mistake. It just wasn't working. I think they just decided that was it.

So basically Ley got called up to the department and was told that that was it for him. He came back, stayed for about three or four days, and resigned. Rankin stayed

a little longer than that, about a week, and then he left. The next thing we know Dr. Edwards walks in to be introduced to the FDA staff by Rankin. I was told to get out of the building.

RT: I remember that because in the Legislative Office we thought Winton Rankin protected you.

PW: Yes, Rankin . . . I just . . . I was just told to get out of the office and just get away for a while. Which was kind of interesting, because I didn't tell anybody I was told that except . . . But John Droke was sort of my supervisor, even though I was working for Winton, and he kept asking me for leave slips, and I said, "You've got to be kidding." He's probably still asking me for them.

So, anyway, I was told to get out because it could really . . . You know, why should I be involved? I mean, I was the staff assistant, let's put it that way. I helped out, but I was not a policy maker, you know, so why should I get cremated with the rest of them--which was very thoughtful.

RT: That was very decent of Rankin.

PW: Yes.

RO: What about Ken Kirk? Was Ken Kirk still here then?

PW: Oh, yes. He was still there, and . . .

RT: He elected to leave.

PW: That's correct, he retired.

RT: No, he left as part of this.

PW: Yes, he left as part of this, too. Yes, he left as part of this, too, and immediately gave some scathing interviews saying that everybody in the Bureau of Medicine was nothing but a bunch of people that were cardiac retreads or people who should have retired a long time ago, and they couldn't practice medicine.

I remember what I did--it was probably not the smartest thing in the world--but I ran into Weems and Charlie Wayne on my way out, and we went and had a couple drinks, and I told Weems what was going on, and Weems immediately changed his plans and stayed an extra day or two. The next thing I know, I'm in the office the next day, and Weems walks in and starts talking to Rankin, and Rankin looks at me with a dirty dagger-like, "You big mouth you. You said something to Weems."

Anyway, Mickey came in and says, "I've got to get you out of here. Go back, start working for me and John for a while; stay away for a while, you know." So that's what I did. I was working for them. I was slated to go out . . . I had been selected for a position as deputy director of Boston District, and that was going to be my next assignment. Winton had approved it. He said if that's what I wanted, he thought I'd be good for it, and that would be good for Boston.

I would have worked for Don Healton. He had not officially selected me, but I knew he was going to because that's just the way it worked. Sam Fine says, "How would you like to go to Boston?" I said, "Fine." He says, "That's what I have in mind for you." I said something to Winton. Winton said, "I'll talk it over with Sam." He went and talked it over with Sam; he came back and said, "I think that would be good for you if that's what you want to do." So that was just a matter of working out a reporting time. Well, then this happened, you know. So I'm . . . They felt that, I

think, if I just worked for Mickey until it was time to go to Boston, that would be the best thing to do.

So I was there for a couple days, and Maurice Kinslow was asked by Commissioner Charlie Edwards, through Winton Rankin's maneuvering, to serve as his special assistant to get started. Well, they . . . Maurice reached out to me, I think at Winton's suggestion, to help do some of the staff work. Maurice was not the most trusting person in the world until he really got to know you. I mean, he really had to make up his own mind about you. Even though I was okay as far as Winton was concerned and, you know, he and I lived in the same neighborhood and I had given him rides home once in a while, we really had . . . He was not anything more than a fellow FDA colleague, and that was it. He really had no more time for me than he did for the man in the moon. That's the way he was until he really got to know you. I don't know how he was with you, but that's how he was in general at that time, and he probably still is the same way.

So, anyway, I did some staff work for him. He must have liked it, and he asked me to continue doing it. OK? Then . . . And I hope you don't take any offense of this. He and Edwards did not like the quality of work that was coming out of the legislative area--not in your area, Bob. You were in the . . . I'm talking about the getting ready for hearings and answering congressionals. You were doing the bill reports. They had no problems with you, but they didn't like . . .

RT: I know the other side.

PW: All right. So they asked me, and I don't think Bob Wetherell will ever forgive me for this. God bless him, he's dead now. But I was asked to review everything that came in and critique it before it went to Maurice, and Maurice said, "If you say it's okay, it goes right into Edwards and that's it." So I was in an impossible situation, you

know. I know Wetherell never forgave me. It was not my idea. So I just did my job, you know.

Well, he was the kind of guy that was always wanting to get things done. It wasn't the quality as much as the quantity. He wanted to keep it moving. Thank God, in a way, that we had somebody like him. But the quality was sometimes just awful. It was just terrible. It was just not . . . The problem was they got lazy, because Winton used to rewrite everything and make it perfect. So they just took advantage of his willingness to do that, even though it irritated him at times. He did it so well that they never learned from it, you know, and unfortunately they were in a situation where there was no more Winton anymore, and I could only help so much. So I just kept bouncing back stuff at times, and it really used to . . . He almost used to cry. It put me in a very awkward situation, but I did the best I could, you know. They finally decided to bring in Pat Ryan to run the legislative, you know, the whole thing.

RO: When Edwards came in, where did Winton go?

(Interruption)

PW: Winton Rankin was transferred to Jesse Steinfeld, the Surgeon General's Office, and served as his special assistant. This was all late '69 and getting into early 1970. And Winton retired right before I went to Dallas. So he left in '72.

RT: I think while he was over there, one of his principal duties was to explore the possibility of Fort Detrich in Fredericksburg, Maryland, being acquired for FDA purposes.

PW: Yes, he had that assignment. He had a couple others. At times he got . . . There were one or two times when he got between the agency and the department, and it wasn't his fault, he was just doing his job he was asked. Somebody would . . . You know, the industry had a tendency at times when they didn't like what the agency was doing to go to either Egeberg's office or Steinfeld's office and complain, and a couple times he was the person that would call Edwards' office and say, "We've had this inquiry; we want you to come up or give us a paper about it." Well, Edwards soon made it . . . You know, he wanted to manage the agency a little like Kessler in a way. He wanted to get the agency in good shape and run his own show, and he really resented that. So Winton stopped doing any of that. He didn't want to do it to begin with it; he was just being a good soldier. But that was a problem.

Edwards brought in . . . I might not be going in the same sequence here, but I think it's important to say that the agency hadn't permanently detached from CPEHS but did shortly after he arrived. During that period of time, Edwards really decided that there needed to be a reorganization, there needed to be a team put together, you know, that could manage the stuff. Mickey Moure was a big influence on him, and he started bringing in people. Jim Grant came in as the deputy commissioner. Maurice served as an assistant for a few months, and then, you know, moved over to this assistant commissioner for program coordination job.

Glenn Kilpatrick was running things as best as he could for the whole Office of Legislative and Governmental Services, but Glenn was a state guy. I mean, he was interested in that, and he was just doing it as a favor, and they eventually brought Pat Ryan in to do that. And, by the way, Glenn did a great job, I thought, he was a good soldier, and I think he did the best job he could at the time in terms of managing that whole program, and I think people respected him for it. I really think in terms of quality of effort and doing something that he didn't want to do, he did about as well as anybody.

RT: Let's see. Before Pumpian was in there. You mentioned his name earlier.

PW: Yes. Pumpian was very political, and you probably know this better than me, but my impression while I worked for Ley and Rankin was Pumpian would take your bill reports and go and give speeches about them all over the country. Finally, Rankin caught him at it and said, "You're not supposed to be doing that. That's not your job. Cut it out," and, you know, he grounded him.

RT: Pumpian also, I think, kind of became involved in this vendetta with C. C. Johnson perhaps as a sort of a sacrificial lamb, if you will, because they wanted somebody to do that, and Pumpian was willing.

PW: Yes. Well, Pumpian, from what I understand, did himself in. I saw a written evaluation of Pumpian, which was stolen from my desk by the way. I should never have kept it. But when I inherited this job, there were a whole bunch of performance evaluations in writing of a lot of people. I don't . . . You know, it's one of those things where I should have just taken them all and said to Winton, "We better get rid of these," and I didn't. They were stolen from my desk. Somebody knew they were in there and stole them, and it was subsequently leaked, some of the portions of that about Pumpian.

But basically what it said in writing was when the CPEHS thing was going, Pumpian went all over Congress ingratiating himself about this. He also tried to get a BDAC job and was in tight with Humphrey and a lot of others when Humphrey decided they weren't going to support Pumpian--he was out. But he was still doing a lot of stuff directly with the Democrats.

RT: Yes, he was.

PW: Yes. You probably know this better than me, but that's my recollection of that.

RT: Well, as an aside, I was on his staff, and he suggested that I could be his contact over on the Hill. I didn't really want to do that, because I don't want to be political. I want to be career, not just transitory.

PW: No, no. No, you were definitely a career guy and a good one at it. He . . . You know, he was a likeable guy though, you know. I sort of liked him. But, I mean, he was really a political animal and, you know, out to get what was good for him. But I sort of liked him at times, but he was . . .

RT: He was the predecessor to Pat Ryan.

PW: Yes.

RT: I don't know whether we kind of got that in sequence.

PW: Yes, well, Glenn was in there for a little while after he left, and then Pat moved in, as I recall it, you know.

So Pat comes in, and he's in charge of all that. He had a horrible job. I mean, there were nothing but hearings after hearings after hearings, and he did the best he could. Oral contraceptives came in, and Larry Pilot came in from the department. He was . . . I think he actually--as I understood it--he was the head of the Pharmacists-for-Nixon thing, and he ended up working for Steinfeld, and the next thing he knows . . . Edwards, of course, was our first sort of political appointment. Larry did the work on

that oral contraceptive hearing and decided on its own or led a discussion that resulted in the commissioner, without clearing it with anybody, saying we were going to have patient labeling for oral contraceptives. That really created a big stink. I mean, it was a very good decision, but it hadn't been cleared with anybody. So the industry's complaining, the department's complaining, everybody's complaining. But that was the end of Larry. Larry was no longer a candidate for the OLGA or whatever it was, the OLS job.

RT: Now later, and this is jumping a bit, but wasn't he quite a bit later involved the device program?

PW: Yes. Yes. He ended up working in the device area and stayed there until he left government. But basically he really wanted the Pat Ryan job, and he didn't get it. They just felt he was a loose cannon. Edwards had to clear most of his appointments, you know, with people in the department. There was this character called Mastrangelo. I forget his first name, but his last name was Mastrangelo, and he was the political guy that worked for the secretary, who at that time was Secretary Richardson. Richardson has this political guy there, and they were constantly calling Edwards to take this one, take that one, take that one, you know. Of course, nobody in the agency had ever dealt with this before. So I knew about this stuff going on, too, and I heard Edwards had some very heated discussions with this guy once in a while. I mean, he would really tell him off, and I'd say, "Why?" He says, "That's the only way to deal with him." But we had some doozies, I'll tell you, that were sent to us during that time.

But basically I started working for Maurice. I think the reason we started working together is one Sunday afternoon, right before Christmas, something really leaked that shouldn't have leaked, and Maurice was assigned by Edwards, who at that time was still commuting from Chicago and was home, to find out what happened. I

was the guy that knew exactly what had happened, but I was assigned to call people and figure out what happened. And after I did that, Maurice liked me, and that's how I started doing staff work for him.

Actually what happened was Josh Zatman, who is now deceased, was in charge of public affairs, and he leaked something that he shouldn't have leaked. I think he just did it accidentally and didn't know he shouldn't have done it, and word got out on something that had not really been cleared with Edwards, and the department had complained, and you know . . .

At that time, the commissioner had to clear all substantial things with the department. That's just the way it was. Eventually, Edwards made damn sure that that wasn't going to be the case. But, I mean, until he got control, I mean, this was in the early days of his regime in 1969. It started to change as he got his own people in place and established some credibility with the Congress as well as with the department. He was very, very good at that, and did it the right way. I mean, he made the calls, he made the visits, he stayed in touch with people, he kept them informed, you know, he stayed on top of things, and let basically the agency do its thing but with some leadership.

Jim Grant came in from the White House Conference on Nutrition. They picked him out of that, and he was the deputy. He was very management oriented and kind of a peculiar guy to work for, because he had some personality quirks at times. He had a big case on himself, his big ego. But he was a very smart man, and actually I did some staff work for him and I was offered a job with him, but Maurice made sure that didn't happen.

I always had people looking out for me at that stage, you know. I had Winton, and then I had Maurice, and I had Mickey, and I have, you know, I have to thank them for protecting me at times from things I might have jumped at myself.

Anyway, Grant set up a decision-making survey, looked at the vertical and the horizontal alignment of things. We didn't always understand what he was doing, but what came out of it was a concept of reorganizing the agency on a product-oriented basis instead of a discipline-oriented basis, and that's what it ended up doing. They brought in Henry Simmons to run the drug part of it, and then they brought in Virgil Wodika to run the food part of it. Van Houweling stayed where he was. Dave Link and Larry Pilot were brought in to start something going in the device area. I'm going to go now to the Cooper Committee.

When Ley was still commissioner, Nixon had made an announcement in his State of the Union message that he was going to call together a group of people to develop recommendations for medical device legislation. I remember when that . . . When I showed that statement to Winton, he said, "Well, we have to thank Maurice for that, because," he said, "his task force, his Consumer Protection Task Force probably . . ." Because they did make a big mention of the fact that the agency had to establish regulatory control over medical devices. FDA was doing everything on a case-by-case basis by calling them drugs, and there was a need for definitive legislation.

So Dr. Ley came to me. Ted Cooper, who at that time was director of the National Heart, Lung & Blood Institute, his position . . . Ted Cooper ultimately became assistant secretary for Health and then went out to industry and passed away a couple of years ago. Anyway, Ted Cooper was put in charge of this, and I was very flattered. I knew Dr. Ley was going to ask me to do it because Winton had warned me. He came and said to me that, "I would like you to be my staff assistant on this committee." He says, "Quite frankly, I'd prefer to take somebody from the drug area, but," he says, "they're not only too busy, but they're not as sharp as you. So I'm going to take you with me to do my staff work."

So I went with him to the first meeting, and it was just an organizational thing. I remember Mark Novitch, who was in the department, came on behalf of the surgeon

general and gave a presentation of why they felt that legislation was important and so forth. But it was really . . . The main message that was coming in at the first meeting was, "Let's be careful how we do this and let's not treat it like drugs. Let's just treat devices the way they should be treated, and let's not overdo it here." I went to the second meeting with him, but then Dr. Ley got fired. (Laughter)

So I got Dr. Edwards ready to go to the . . . Then they sort of recessed it for a while until the dust settled a little, and then they started their meetings again. I got Edwards ready to go to the third meeting, and then he . . . I forget how he took care of it, but I wasn't involved after that. After going to the first two meetings of the Cooper Committee, that's when things started to descend upon . . .

One of the reasons I knew he was going to get fired is all of a sudden he wasn't in his office too much, and he started getting calls early in the morning, and I used to pick up the phone because I was there early, and the director of NIH was calling--I forget who it was--and I said, "Dr. Ley is not here. He's out of the office." He says, "I have something important to tell him." I says, "Mr. Rankin can call you back very shortly or take the call now if you want me to interrupt him." "No, I want to talk to Ley directly." I knew something was happening then. You know, somebody knew something. And I think we had heard some things anyway, you know how these things go. Things started . . .

You know what always happened with the department? The press office would start leaking things about twenty-four hours ahead of time. The press office at the department level or Bob Wetherell would hear something. (Laughter) That's the truth! Bob Wetherell had his own channels or it would come through the press office, and I think one of those channels was active, and we started hearing some things, and then he got moved out.

Anyway, the Cooper Committee . . . From a program thing, there's one other thing to remember. We had people come in from industry at one of those two meetings

to make it very clear that they were very concerned that this legislation would be written like drug legislation, and also that the concept was already on the table to have device classes. Class I, Class II, Class III--the opposite way of the way they came out by the way. Class I was going to be premarket approval Class II was going to be standards, Class III was going to be, you know, general controls. And they wanted to make it very clear that there were so many things coming on the market that FDA could really have a negative effect on the application of technology if they didn't do it right, and that was pretty clear in my mind. That was the big message I gave to Edwards when I was getting him ready for this, and I felt, you know, it should be done on that basis. That was my involvement with the Cooper Committee.

I got involved in another committee very briefly on drug abuse. There was another drug abuse thing where they were trying to come up with a cohesive policy on drug abuse. And at that time, I tried to get Paul Hile, who was Sam Fine's deputy, involved in it, but Paul was more looking at it from a BDAC standpoint and not from a national standpoint. So I really . . . He wasn't of much help to me, so I recommended Sam go to one meeting, and Sam figured out . . . I said to Sam, I says, "I don't know who the right person is for this, but somebody needs to go that has got a title, not me." Because I didn't have a title. And so Sam went. He quickly found out who the right person was. I think Jennings or somebody went like that. So that was another thing.

Anyway, the first couple months getting started, you know, Edwards was trying to get to know people, had a lot of meetings, didn't want to do much paperwork. Maurice and I handled most of that, and Maurice went to the meetings at the same time. It was very hard on him.

Then they brought . . . As soon as Jim Grant came in, all of a sudden really Jim and Edwards took hold, and Maurice was sort of detached from the commissioner's day-to-day activities. At the same time, we knew, because it had started before Ley

left, that there was going to be a critical report coming out from the Nader Committee. Because Nader had started a study in '69 of the agency and was going to not, was going to critique the things that Nader cared about the most, which was food sanitation, bad drugs being on the market, and stuff like that. He had a whole bunch of young people all over the place asking for information and getting information and there was no control over it.

And we knew that Maurice was going to get killed in that report, because he was a friend of Winton. He was a working associate, with Goddard as well as with Rankin, and had worked in the congressional area before he went to Baltimore as the district director and then came back to headquarters. We knew Maurice was going to get pilloried in this.

Edwards and the others decided to create this position for Maurice, the assistant commissioner for Program Coordination. Nobody knew what the hell it was going to be. He was going to be in charge of the computer functioning because there had been some criticisms that Mickey, because of his concern about administrative activities, was too central-minded, so they took away the computer function from him and gave it to Maurice, who knew as much about them as I did. And they gave him the policy management function, which was the Art Davis internal security function, and then they established this program coordination function, which I ended up in charge of, and . . . But no definition as to what we were supposed to be doing, you know. This was the craziest . . . And, you know, he could get promoted out of it.

So he wanted a promotion, and he felt . . . Actually, he really felt that they wanted him to stay there and help out, you know. They probably did, although he and Jim Grant never really got along. They just didn't. It was just a personality clash. There was some jealousy and . . . It wasn't so much Maurice's fault as it was Jim's. Jim just didn't want him around, and I think Jim knew that he was going to be in trouble anyway with the Nader report.

Shortly after Maurice moves into this position, they asked me to stay, and I really wanted to go to Boston. I wanted to get away from all this stuff. But, you know, the commissioner called me in, and it's kind of one of those things where they said, "We know you want to go out to the field. We'll get you out there someday. Please take this job right now. This will be good for all of us," and so I took it. But I didn't know what I was supposed to be doing. I did it because they asked me to do it, you know.

Well, I quickly discovered Maurice was going to be kept in the closet and kept out of sight, so to speak. I don't know how he tolerated it, but, you know . . . I came up with a concept for program coordination which everybody agreed to, but nobody really wanted me to do. By that time I had a staff of George White and Earnie Brisson, you know.

We had this computer function, and we had nobody running it. It was an awful mess, because first of all, there were still fights with CPEHS as to equipment, and programmers, and this and that, and Eisenhart I think was the guy . . . Eisenhart was his last name. I think it was Don Eisenhart. I'm not sure about the first name. But, anyway, he was in charge of the computer, but he knew nothing more than how to operate a computer. He didn't know how to plan. He wasn't modern. He just didn't know . . . He wasn't . . . He just didn't have the breadth of experience to go beyond what they had already, which was just a simple machine that did accounting and did some data processing and that was it.

So Maurice has all these functions, and he basically served as an advisor to others. Mickey and Sam Fine would come to him for things and Pat Ryan would come to him for help. He helped Edwards decide what speeches he was going to give. I mean, that was a very elaborate thing, because for a commissioner to decide whether to do things and what to say and all that stuff. He didn't write the speech, but he coordinated the commissioner's public appearances and his speeches.

Then he had me doing some things while we . . . My staff took notes at staff meetings, and we did a couple studies of our own trying to push for some attention to areas that we felt were being neglected. National Center for Microbiological Analysis was one; the facility up in New England . . . The Radiological Health . . .

RT: WEAC (Winchester Engineering and Analytical Center).

PW: Yes. There were some things involving WEAC before it even came to us that we got involved in, and I don't know why we did, but we did. There were some other things. The need for attention to disposable devices. The need for attention to some nutrition things that came up through the McGovern Committee that had never been fully acted on. McGovern had had hearings on monosodium glutamate and a couple other things and was still raising Cain because nobody was doing anything about them.

So we tried to look for areas where we felt there was some problems, and even so it was not a great job for me. I just didn't feel like I was . . . I didn't know what I was doing.

RO: How did your office and the bureaus get along?

PW: Well, there was some resentment about our function, so we didn't always get the best cooperation. However, Wodika was very cooperative with me, and for the most part the people in drugs were. Some of the administrative people were very nervous about us. For the most part, because I had worked with a lot of these people when I was with Rankin, I usually got what I wanted, but it was with a great deal of difficulty for me. However, my staff had a terrible time. I mean, you know, whatever we would accomplish in terms of setting up a relationship was based primarily upon my prior contacts. I brought in two guys from the field, and they had a very difficult time getting

cooperation for the projects that we assigned to them. So it was kind of a difficult thing. The program coordination function ended up being more of the precursor to the executive secretariat than anything else.

Maurice finally decided he couldn't take it anymore. After the Nader report came out, he was really kept in left field, and he did the best he could. They did give him special things to do. We had some accusations of scientific misconduct in the food area, and he and Jennings did some work on that. There were a couple other things. There were a lot of fires occurring in the Parklawn Building, and he and his staff looked at that. There were certain kinds of bizarre . . . There was a dice and sex and vice operation going on in FOB 8 (Federal Office Building 8), you know, in the garage there, and there were undercover police involved; there were people from Art Davis's staff involved. It was really kind of weird, you know. Weird things like that, you know. But not what you would expect an assistant commissioner to be doing.

They sent me . . . I wanted to go to Berkeley and take one of these executive seminar courses, and I went to Berkeley for two weeks in 1970, which was good for me, by the way. It was . . . I never knew what liberals were until I went out there. (Laughter) Liberal Californians, you know. It was right at the time of all the Berkeley hippie stuff.

Anyway, I met a person out there, Ross Bainbridge, who I thought was a very sensible guy. One of the most sensible computer persons I ever met in my life. When Maurice was trying with great pressure from Edwards to get somebody to run the computer functions, I recommended that he at least interview Ross. I really thought, this is what he needs. So I called Ross up, and he was interested in the position. Eventually, they hired him. Right after he hired him, Maurice left and went to Atlanta. He had had it. He couldn't take it anymore. He went to Atlanta, because there was a vacant regional director position there. What's his name left.

RT: Sanders?

PW: No. It was after Sanders.

RO: McMillan.

PW: McMillan.

RT: Yes, Les McMillan.

PW: As soon as Maurice found out McMillan was leaving--Louis Weiss or somebody tipped him off to it, and he immediately said, "I want to go to Atlanta." He went to Atlanta.

So I was put in charge of this function, and if there was ever a mismatch . . . By that time I had gotten my GS-15, too. I got my fourteen and fifteen, and I was also promoted to deputy assistant commissioner for just a few months, and then Maurice leaves, and I'm in charge of this whole function. Well, if there was ever a mistake in the world, it was putting me in that function or me trying to make something out of it, and I really tried very hard.

Now, during this period of time with Maurice and before I . . . All of a sudden Edwards found out that I was unhappy, and I really didn't like the job, and I didn't want to do it anymore. In fact, I even went in and told him one time, late . . . You know, whenever you wanted to see him, the best time to see him was between 5:00 and 6:00, because he would always leave at 6:00.

So I went in one night, and said, "I don't know what I'm doing, and I don't know why you asked me to stay here. I don't know why I should be here, because," I said, "you're not doing anything with Maurice." He said, "Well, your problem's with

Maurice, not with me." I said, "It was your idea that I stay here." You know, I was kind of brash, and I just told it like I felt.

Shortly after that, he started tapping me for assignments, and I finally ended up being his special assistant while I was working for Maurice. Thank God we all got along, because, you know, I then almost spent all my time with Edwards while I was working for Maurice. I had my own staff, and I was almost doing what I was doing for Winton. I was going through all his paperwork; I was helping him with his appointments; I was sitting in on his meetings; I was serving as the devil's advocate. I think that could not have lasted forever, and I started to distance myself from it, because quite frankly I think after a while, he got sick of me doing it, but he was too polite to say it, because I was too direct for him. Because some of the bullshit that he used to listen to and put up with was just unbelievable to me.

But I was supposed to give him the FDA insight, and I gave it to him. But, you know, after a while, I thought, "I'm not going to be, you know . . ." There were times when I think I was wrong about my insights, because I, you know, I was not an MBA, and a lot of people were walking in there from Booze Allen, and they had a different outlook than I did. Although I admired them for it, I just didn't think it had anything to do with us.

But, anyway, I took over the assistant commissioner for Program Coordination job. I distanced myself from him, but I didn't like the job at all. I was just at the point of concluding that I didn't want to do it anymore when they came to me and they said they really felt that it would be better if I just ran the secretariat and gave Mickey back the computer function and the internal security function, and that's the way it worked. So I ran the executive secretariat. I was really the second director of it. Beulah Sink, who was the commissioner's secretary, ran it for a few months.

(Interruption)

PW: So, anyway, I . . . Beulah didn't like the job. She really, from the word go, from the time Dr. Ley left, wanted to leave altogether and go to one of the bureaus and become what is now considered a consumer safety officer position. He did not want to lose her, so he brought her back into his office. I ran the secretariat. Ross Bainbridge transferred and reported to Mickey, and Dick Bunoski--by that time, Art Davis had retired--and Don Henson reported to Mickey.

And this was the best decision, but I resented it in a little way, you know. I didn't like the way it was done, but it was done, and Mickey and I never got along after that. He felt that I had sort of never been loyal to him once I started working for Maurice. That was not true, but, you know, that's the way it was. To this day, I don't . . . We get along, but we don't really get along that well, but I think it's more his fault than mine. I mean, he married my secretary. I thought I gave him something great there. (Laughter) He married Carla, and they now live happily ever after on the eastern shore.

So, anyway, I found out from Maurice, who used to come in from Atlanta and visit with me once in a while, that he had seen Louis Weiss, the Dallas regional director, in the elevator, and he said, "Louis, why are you here?" He said, "I'm going to tell Paul Hile that I'm retiring." So Maurice tells me, I go to Edwards, and I say, "I want that job." I said, "You guys said you'd get me out of here. I want that job." Then I went to Hile, and I said, "This is probably the wrong way to do it, but I went to Edwards, and I want to tell you that that is the job I want. I want to go out to the field."

Now I had been previously offered the job that Bob . . .

RO: Wetherell?

PW: No, no, no. The guy that was a historian with Fred.

RO: Oh, Bob Porter.

PW: . . . Bob Porter had. OK? Before Bob went into that job, Paul Hile had offered me this job. Well, I was working with Maurice, and I had turned it down. At that time, Hile says, "I know you want to go out to the field, but do this job for a year or so, and I'll send you out to the field," and I didn't want that job either--planning and administration. That was . . . I really like the programs of FDA. I don't like . . . I mean, I have good experience in the other, but, anyway . . .

So, anyway, I go to Edwards, and I go to Hile asking for this job. I was very brash. I was in my thirties, you know, and I just wanted out of Washington, and I thought this is for me. Get me away from all of this craziness, you know, because I had been there for almost four years then.

So they finally decided I would be their choice for the job. I think they were glad to get rid of me anyway--not so much Paul, but I mean, you know . . . And they felt they . . . I think they really felt they owed me one. I had done my thing for them, and, you know, it's time to move on.

So Hile comes to me, and he says, "The regional HEW director"--because then it was the Department of Health, Education and Welfare--"has to also approve the selection, so you have to be interviewed." OK? Then he tells me LeRoy Gomez has applied for the job, and he really wants it, and Bill Clark had applied for the job, and he really wants it. And I don't know who the hell else had applied for it, but, you know . . .

And I said, "Well, as long as I'm your choice for the job, I certainly don't object to an interview." But they said, "Well, on the other hand, you still have to convince this guy," you know. But I said, "And I'm willing to do that. But," I said, "I think in the final analysis, let's cut the bullshit here. This guy is not the commissioner. He is the regional HEW director. So I expect to get this job." I mean, that's how I felt about

it. I thought, I've been playing the staff role for long enough. I told Edwards the same thing. He got *very* angry with me, but I didn't care. I said, "Listen." I said, "This is what I want, and I expect you to back me." I said, "I expect to do well in the interview, but I want the job."

OK. So Paul was very good. He set it up in such a way that I could fly out there on a Friday, get interviewed on a Monday so I could look for a house on Saturday and Sunday, and actually that's what I did. I went in and was interviewed on Monday morning. Howard . . . I can't think of his last name, but, anyway, he interviewed me. He asked me a bunch of things, and as it turned out, he ranked everybody from the interviews, and I came out number one.

OK. So he's . . . McMahon. Howard McMahon is his name. OK? He had been a city manager in Fort Worth, and then had become regional HEW director. After he left that job, he went up to Oklahoma City to become a city manager. I don't know what happened to him since. He's probably retired. Anyway, he was a decent guy. Anyway, he interviews me, and he recommends me for selection.

The next thing I hear is Hile says, "Well, that's all well and good," he says, "and you're going to get selected for this, but I just want you to know that LeRoy is very unhappy, and he's calling the White House." So he called some guy . . . LeRoy must have called some guy whose in charge of Hispanic affairs at the White House, and there was an inquiry from them, preselection, favoritism, blah-blah-blah-blah-blah-blah-blah, and LeRoy was pounding all over the place. So that was another thing.

Anyway, I finally get selected. One of my bosses at the time was Ron and the other one was Paul, and they called me up at the . . . I was in Ocean City a lot then. I was taking some time off. They called me up and they said, "You were selected., congratulations, and when are you getting out there?" You know, they wanted me out there sooner rather than later, so I said, "I'll go in September."

RO: And that was what year?

PW: That was '72. But I think . . . Ron probably doesn't remember this, but I think he wanted me there a little sooner. I wanted to take two weeks off, and then I wanted to drive there, you know. I think he really . . . He wanted me there. But I said, "I'll get there. I'll start the day after Labor Day." So, anyway, we worked it out.

And I don't know why, but they really didn't say too much about me to the Dallas staff. Nobody knew anything about me when I walked in there, and all they heard was preselection, favoritism, etc.

Joe Durham was the Dallas district director, and Nevis Cook was the district director in New Orleans. It was a five-state region. Texas, Oklahoma, and New Mexico were Dallas, and Louisiana, Arkansas were New Orleans. OK? Why it was structured that way is because of HEW regionalization, because as far as lines of commerce were concerned, it made no sense whatsoever.

So Joe introduced me to everybody, and then tried to get me and my immediate staff to move to another building in Dallas, because they had been working on getting the regional director office out of there. I don't know. I took a look at Dallas District, and Hile had told me to, you know, instill a sense of management there, because it just didn't seem to have much, you know. The personnel people told me they were very concerned because there had been some suicides in the laboratory. A couple of suicides and a couple of bad situations, which they felt, not knowing anything more, needed to be looked into. What was the reason why these people were having all these problems, you know?

Anyway, I went in there, I met . . . Fortunately, the state officials were there that day. Bob, you might even have been there. There was a briefing on state contracts, but somebody was there from your office.

RT: Oh, it probably was Bob Dickinson, I suspect.

PW: No, no, you were there, because you told me so. Because you came to me and said . . . Either that time or the next time I saw you, you said, "You've got this Joe North on your staff. He's in charge of Federal-State Relations, and he is a discredit to the agency." And I remember saying to you something like, "It's either my first week on the job or the first day of the job. What do you expect me to do about it?" And I didn't tell you that, but Ken Lennington had stopped me before I came out to Dallas and said he was a great guy if somebody could just instill in him what he used to be capable of. Sam Fine had told me he was worth nothing. He was on your side. Because I remember you telling me that.

Anyway, so I met the state officials the first day, because Maurice had told me, "The first thing you ought to do is go visit the state officials because," he says, "those are the people you're going to work with." Well, I didn't have to because they were all there for the state contract briefing. Burley Walker from Oklahoma, Jim Dougherty from Texas, and I forget who was there for New Mexico.

So at the end of the week, Tucker Lightfoot, who was a supervisory inspector, says, "We don't know anything about you. Would you mind having an all-hands meeting to introduce yourself, tell us what your background is?" So that's what I did. Nobody knew anything about me, because Ottes and Hile had never even sent a resume out for them. (Laughter)

So I had to tell everybody who I was, and I got acquainted with everybody, and I decided that I would try to get to know the people and work with the people who were the strongest and come up with an organization. Maurice was trying out a pilot in Atlanta that sort of centralized the controls over investigations and science and administration, the labs, and I decided I would do the same thing. If I had to do it over again, I wouldn't have done it that way. But I decided to do the same thing and try it

out. Hile was willing to do that, and basically I put together a task force to do that. So we basically set up the same function. We selected Bob Bartz to run New Orleans, and Jim Anderson to run Dallas, and Tony Whitehead to run Houston station.

Bob turned out to be the best manager. Jim was a wonderful support to me and a good backup to me, but he was not the greatest manager in the world. But he got the job done very well, and his people loved him, and he got along with Bartz very well. So the three of us were a good team. None of them got along with Dale Hunter, who was my executive officer, but most executive officers don't seem to get along with anybody anyway. So that's my experience after thirty-three years of FDA. The money and the planning guy don't always hit it off with the program people.

The biggest disappointment I had was that Tony Whitehead and Jim Anderson just did not get along. As a result, Houston was not well served by their efforts, because the food and drug officer, Ken Ewing, really established a direct pipeline with Anderson, and I was not able to break it. I probably should have broken it. I should have just ordered them to stop dealing that way. Tony never really had control of that function, the compliance function, the way I wanted him to. And there were some personnel problems that occurred in San Antonio about the time I was leaving Dallas. The resident inspector and somebody else there were just a bunch of malcontents. Tony was not able to manage that very well, and Jim didn't seem to be able to get on top of it.

There was an investigation done of that after I left, and it was concluded that there would be some transfers and some things done. But the thing that really bothered me was, this was something way removed from me, and I tried to do what I could do to solve it, but I really left it to Jim to solve. But I ended up getting a letter of reprimand from Hile over the fact that I should have done something about it sooner, even though most of the things had occurred afterwards, occurred after I left. I thought that was very unfair, but I just took it and ripped it up, quite frankly. It was the only

reprimand I ever got in my life, I didn't think it was well deserved, and I've never discussed it with Hile since, and I've never actually told too many people about it except you two.

RO: You didn't frame it, in other words?

PW: No, sir. I really was very . . . You know, I just didn't think that was very fair. But, anyway, that's the way it goes.

Anyway, I was in Dallas for ten years, and during that time, I got a good management team in place. I think we did some good things. I think the districts operated fairly well together. I think that we were able to improve the morale. We gave Ken Hanson all the backing in the world to run the laboratory. We got some supervisory people in there that did a better job. But I never felt the supervisory people were as strong as they should be, although Darrell Brown came in and was pretty good, and he ended up on . . . Heaton wanted me to take him, and I took him. I didn't want to take him, but I took him, and he did a fairly good job.

The laboratory people did not want to move. They didn't want to really advance themselves, and they were kind of a . . . It was just hard to get them to show enthusiasm about anything, and I don't know. It was very difficult the whole time I was there carving out effective roles for the laboratories in that region. We set up the mycotoxin program in New Orleans, and we had an active import program, shut down the micro lab, got a new building, thanks in part to Ron Ottes and Bob Bartz more than me working very hard on it.

I just never . . . I was more disappointed . . . If I had to be disappointed about anything, I never felt the laboratories operated as well as they could. The only time I thought they really operated well was when we had crises in Mexico with illegal residues, illegal pesticides being used to cause residues, and we were examining a lot

of samples. The Dallas laboratory was coordinating very well with the Los Angeles laboratory and with the mobile laboratories, and that was . . . In a crisis, they were very good. When we had some drug mixups that were occurring nationwide, they worked very good as a team to do that. But in a non-crisis situation, they just were kind of blah, I felt.

It could have been the culture of the region as opposed . . . You know, coming from the East Coast to the southwestern part of the country. That might have been part of it, too. I certainly felt that it could have been a better effort, but I think I did as well as I could. I think that Louis Weiss and Joe Durham, quite frankly, were absentee managers. They did not tend to manage, and they just let things happen. They went to a lot of state official meetings, took their wives with them, were out of the office all the time, and both felt like that wasn't the job they wanted, but they would make the most of it. So, you know, I had to really instill a little sense of belonging and urgency to get things done, and I think I was able to do that.

I really didn't want to stay there more than five or six years--that was the deal I had with Hile--and then I wanted to move. During that time I got divorced, and I got remarried to Jeanne Devers, who had started in FDA in Philly, and had ended up as a consumer affairs officer--it was called consumer specialist. Anyway, she and I got married. The idea was for me to transfer to Philly when Ted Maraviglia retired, and she would then leave the agency and work somewhere else, and I would go back to the East Coast, and it would be a change of assignment for me. It would be great, you know.

Then John Byington, who was the chair of the Consumer Product Safety Commission (CPSC), offered Jeanne a position as regional director in Dallas. She got the job, so she moves to Dallas, and I ended up staying in Dallas longer than I wanted to. So I was there from 1972 to January 1983.

In 1982, Jeanne got detailed back . . . There was a change of presidents. Nixon was in . . . No, Reagan was in, and Nancy Steorts was the chair of the Consumer Product Safety Commission. Jeanne had known Nancy through a White House assignment she had had during the Nixon administration with Virginia Knauer, who was the White House Consumer Affairs Officer, and Nancy asked her to come in and help her get started. Jeanne loved working in Dallas, but did not like living there. She's an East Coast person like me.

So she went to Washington and really wanted to stay, and I said, "Well, if you want to stay, maybe it's time for me to move on anyway." So I went to Hile at the time, and I said, "I really want to move. Can you help me?" He circulated my resumes to some people, and I don't know if I said anything to Heaton or not, who was my boss then. John Villforth and Jim Benson called me and said, "We just merged the device and radiological health bureaus. We're in charge of it. We could use some help. How about coming here on a detail? And who knows, maybe something could work out permanently for you."

So I went to my last joint EDRO meeting. It was a regional and district director meeting, and it was at the Ramada down in Bethesda, and Ron Ottes made me take notes. I think he knew I was going to leave, but he made me take the notes anyway, because Fred Lofsvold had retired, and he made me take the damn notes. I was really burned about that, but I took them. I eventually gave him the draft copy of the notes. He never told me whether he liked them or not. But Maurice told me he thought I did a pretty good job for somebody stuck with taking the notes that didn't want to do it to begin with.

Anyway, January 1983, right after the first of the year, I started on this detail with Benson and Villforth, and basically they asked me to go outside of the center and survey people in industry as well as in the rest of FDA and find out what kinds of issues

they felt the new team should deal with. So I went to Hile's group; I went and talked to Ron; I went and talked to Healton.

I went to a whole bunch of different places and found out that there was a big discontent about the fact that the device program was felt to be managed by and for the device people, and it wasn't integrated with the rest of the agency. They weren't really doing enough, paying enough attention to clinical trials, and that the 510(k) program was a quick way of getting things on the market without rigid attention by FDA. The implementing regulations they developed were nothing but junk, and had to be rewritten by the lawyers, and as a result, they were way behind.

I went out to the . . . I went out to the trade associations. Neil Dunning, who was in charge of what was then the Office of Small Manufacturers Assistants, took me around to the trade associations, HIMA and a couple of the others. They felt they had a good relationship, but they were very concerned that the new center would not be responsive to the industry in terms of the way the industry should be regulated, ought to be regulated, and was not being regulated. So, you know, you hear different sides, different people.

So I basically started making some recommendations based on my interviews of things that should be done. After about six months, I said, "You know, I . . ." They really just were happy with me there, but, you know, it was costing a lot of money. Jeanne and I were both on per diem and both were not permanently assigned, and I had a house in Dallas that was just sitting there, which we never went back to, by the way.

So I said that I would like to stay, and I would be willing to take a . . . I was . . . You know, I was in the senior executive service, so I said, "If necessary, I will take a downgrade, because I really like working here and I'm learning something new, and it's time for me to change." So they offered me three positions. They offered me the deputy director of the Office of Device Evaluation or they offered me the job of deputy director of the Office of Training and Assistance.

RO: Oh, yes.

PW: They offered me this new position of Office of Standards & Regulations. They had put together the standards coordination function and the regulations function together, because neither one of them were working very well. I thought, well, that's more regulatory than anything else, so I'll accept that.

So basically I had a very small staff of people, about thirty people, and I was in charge of all the regulation development and was also to try to make some sense out of a standards program that was supposed to be developing mandatory standards but hadn't done anything, and . . .

RO: You were the director of this office?

PW: I was the director of the Office of Standards & Regulations. Alan Andersen was my deputy, who had formerly been in charge of the medical device standards program, and I had Jim McCue in charge of the standards staff. We called it the operation staff. And then I had a planning staff which was more of a regulations planning staff, with Mel Altman in charge of it. And then of all things I also had the FOI (Freedom of Information) function, and how I ended up with that I don't know, but I got it. That was another one that was in trouble, too. I guess they gave me all the trouble functions, because they knew I wanted the job, that I wanted to stay in Washington.

Anyway, so we were able to do a couple of things during those ten years. Number one, we got all the classification regulations done, because classification had not been finished in '82, even though the law had been passed in '76. We were able to get them done by about '86. We got all the fundamental implementing regulations done for things like the PMA (premarket approval) regulation, the 510(k) regulation. Those weren't as important as the medical device reporting regulation, which was a big

one, very hard to get through. We got some policies established for areas that needed some attention but not necessarily a lot of regulation. Color additives was one of them, software was another.

At the same time, I was assigned to maintain liaison with all the trade associations, and I think I did a pretty good job of trying to get their input into things, at least at the staff level. Also, because of my contacts outside, I . . . Villforth wanted a lot of attention paid to who represented the center at outside meetings, who spoke, what they talked about, and that kind of thing. So I sort of coordinated the center's participation, events held by FDLI, by RAPS, Regulatory Affairs Professional Society, and also by HIMA. I spent a lot of time personally on that.

Alan Andersen eventually left and became the head of the Office of Science and Technology and then the Office of Device Evaluation. I selected George Brubaker, my friend from the past who started with me, and brought him over from the executive secretariat to be my deputy, and he sort of ran the day-to-day activities, and I took care of the outside things.

Villforth left, and then we had a series of acting center directors. Villforth retired. Liz Jacobson was the acting center director; Kshitij Mohan did it for a while; Walt Gundaker did it for a while; and finally Jim Benson came back. He had left the center and went over to the commissioner's office and became acting commissioner--deputy commissioner and then acting commissioner. He came back and ran it for a while, and then Bruce Burlington came in and is still the center director to this day.

During that time, we had some very key events that occurred. One was that we had some oversight hearings from John Dingell from the House level really raising a fuss about the way the medical device amendments were not being implemented and felt that the center needed to really pay attention to the strict construct of the law, and get the regulations done and do the right thing, and get on with what Congress had intended, which was to get all the pre-amendments, get all the classification done, get

medical device recording done, get pre-amendment products on the market cleared for safety and efficacy, get the 510(k) program run on a more sensible basis. They had a series of hearings that were very, very critical of the center. Fortunately, most of it you could blame on the past and encourage the people that were there to do a better job.

Art Hayes ceased being commissioner. He left, and we got Frank Young as commissioner and John Norris as deputy commissioner. They pretty much reflected a sense of, "We'll cooperate with Congress, but let's not be too tough on the industry, too," you know. Let's have a balance here. So Benson and Villforth had to do the best they could under the circumstances, and I think they did, and I think the subsequent people did, too.

The approved resources increased a little, because one of the problems was the device program never got funded right. From the minute the device law was passed, they got caught in the position freeze, and they had to come up with ways to do medical device regulations that were innovative and cost effective, and that was one of the reasons the 510(k) program operated the way it was. That's one of the reasons they didn't have much of a laboratory or a scientific basis for what they did. It was one of the reasons that they were so industry-oriented, because they had to rely upon the industry to comply, to get true attention to the spirit and intent of the law because they didn't have the resources.

Bringing the rad health function in helped, because the rad health people had, were composed of a lot of engineers and physicists which you need in the device area, and a lot of those functions, a lot of those resources were transferred from the rad health program into the medical device program to this day, that there really isn't much of a rad health program as opposed to a very visible, strong medical device program, and part of it is as a result of that merger and the transfer of those resources. The other reason is the law was really weak in a couple areas, and even though the center was being held accountable for it, it didn't make sense to do some of the things . . .

(Interruption)

PW: Well, the law had some weaknesses. For example, Class II devices were supposed to have . . . All Class II devices, and there were about fourteen hundred of them, were supposed to have mandatory standards, and that just didn't make any sense. Standards were a very elaborate, five-step rulemaking process. It took too long to do it, and it didn't make sense because the technology changes occurred so much that . . . We did one for apnea monitors, and swore we were never going to do another one again.

RO: One for what?

PW: Apnea monitors, infant apnea monitors. I think there's only been one done since then, and that had to do with how you plugged things into the wall so that there would be basically no way of shocking yourself if you plugged things in the wrong way. And that's the only ones they've ever done that I'm aware of.

But basically, there were other weaknesses in the law, and finally there was some legislation passed. The Safe Medical Devices in 1990 set up a little more reasonable balance, and then there were some amendments to the law right up through the Medical Device Improvements Act enacted recently that make the law a lot more flexible in terms of how you implement it.

It was very difficult for me from 1983 until I left, when I retired in 1994, very difficult for me to write regulations because there was no flexibility. Most of the rest of the Food, Drug & Cosmetic Act has enough flexibility that you can write regulations in accordance with what you think your best judgment is as to how you can do things. Unfortunately, the Medical Device Amendments weren't written that way. They were written during the Watergate times, and the people that wrote them told us that

Congress didn't trust anybody in the executive branch, and so they wrote the law a lot stricter. It didn't give us too much flexibility on how we wrote the regulations. But now there's better flexibility, and I think, you know, as a result, there's a better balance to how the law is carried out.

So basically, those are some of the things I did. What we saw through the years was more attention to clinical trials, more attention to requiring clinical trials, more attention to monitoring clinical trials, more attention to flexibility in how things were done, better science in terms of how things were evaluated. The laboratory functions in some of the areas were particularly good for ultrasound, and for x-rays, and for certain kinds of breathing machines there were some good studies done. When problems occurred with tampons, i.e., toxic shock syndrome, a wonderful analytical method was developed by the laboratories that's still used for tampon absorbency testing. The Commissioner's Office at times slowed down the pace that we really were trying to achieve in getting things done because of their own personal interest. Frank Young at times, for example, with toxic shock syndrome and the tampon labeling regulation, for some reason slowed everything down. We were criticized for not getting it done sooner. It was really his fault, because he kept fooling around with it so much.

But for the most part, I thought we moved at a smarter pace. Unfortunately, though, there was still that leftover concern that there wasn't enough medical science utilized in the device evaluation process. When the breast implant crisis hit, where the commissioner ended up banning the use of silicone gel, that really was another catastrophic thing that occurred. Bob Sheindan, the director of ODE (Office of Device Evaluation), was moved out. Susan Alpert came in from drugs and did a wonderful, still is doing a wonderful job. Some more medical people were brought in. Bruce Burlington was brought in as the director. Benson, in essence, left, because he had to take the heat. Somebody had to take the heat for that, you know. I think he decided

that he had fought the battle long enough, so he left. Basically, a brand new team came in.

I was at the stage where I was ready to leave. It's very hard to go through changes in bosses, and it was getting particularly hard on me. As much as I liked coming back to Washington, I didn't care for that job. The FDA regional director position was probably the best job I ever had. The CDRH job I was in was very hard, because there were a lot of responsibilities. It was a coordinating job, and we had to rely upon resources outside of our immediate office to get it done.

The fun part of the job was the international aspects. The last couple years I was there, there were a lot of things happening in Europe to harmonize the way they regulated devices. There was a need to coordinate what we were doing in terms of developing regulations with what they were doing. Villforth picked up on the fact that I had been very active when I was a regional director with the Mexican government on illegal pesticide usage and trying to help train their chemists. Sam Fine and Sherwin Gardner at the commissioner's level, and Paul Hile and others at the EDRO level, and I was at the regional level. We worked a lot on . . . We had a memorandum of agreement with one of the Mexican government administrations to sort of help them educate the growers, as well as train the chemists and accept certificates of analysis, and that worked for a while.

So, anyway, I think Villforth knew I had that experience, and he got me involved in the international stuff, and I really loved doing that. It took a lot of my time, but it was fun to do it.

But I got, again, in a very difficult thing where we were doing the right thing. Dr. Kessler was the commissioner at the time, and he really . . . He and Dingell and others didn't want too much involvement with harmonization, because they felt that--two things--number one, it showed collaboration with the industry; and number two, Dingell was concerned that anything that promoted harmonization would affect jobs.

He was very conscious of labor unions, and he felt that anything that would affect a positive trade balance that still exists with medical devices and American jobs of people that are involved in manufacturing devices was a bad thing to do.

So, again, I was in this, "Yes, go ahead and do it, but we don't like it, and we know it has to be done, but you go ahead and do it." So I was in a, kind of a . . . Again, I was sort of a point man, you know. I could see where Bruce Burlington was reflecting the same thing and called for a relook at the way stuff like that was done and all that stuff, and I thought, you know . . . And I was ready to leave. I wanted to leave when I was fifty-six. I had thirty-three years in, and it was just the right time. And I was timing it to the fact that we had gotten a tremendous pay raise in the senior executive service. All of a sudden we got like a ten thousand dollar raise, but we had to stay in three years before it would affect our annuities. So my time to leave then was in 1994, and I chose to leave in July of 1994, which was thirty-three years almost to the day that I started.

RT: In your work with international, the international arena, in devices is there any program for inspection by FDA of foreign manufacturers, such as in certain drug activities?

PW: You mean where . . .

RT: Where our people would actually go to a foreign plant?

PW: Oh, yes. It was very active.

RT: And that was developed then?

PW: Yes, it was very active. It was really increased. It was always there, but not very much. With the United Kingdom, there was a memorandum of agreement where we would accept some of their inspections, but then there was a difference of opinion on sterility. So we ended up getting their reports but not accepting their findings, because their interpretation of sterility was different than the U.S.'s. But basically there was a need to step up attention in the international arena, because people were complaining, quite rightly so, that these people were not being inspected with the same kind of vigor--if at all--it wasn't with the same kind of vigor, and they were really getting treated better than people in the U.S. who were being vigorously regulated. So to that extent, it was increased a lot.

The big thing, though, that we got going is we established a good working relationship with the European Union--it wasn't the European community, it was the European Union--and to this day, there's a good working relationship between FDA, the Department of Commerce, the White House Trade Representatives Office, and the European Union. There is now a formal memorandum of agreement to work towards reciprocity with inspections and also probably accepting the reviews that they do of new products, of devices, primarily Class I and Class II devices. It will take years to put it in place, but I think the efforts of a lot of us who set the foundation for that were good things to do, because now everybody thinks it's the greatest thing in the world to promote international harmonization.

RT: With regard to adverse reactions or injury similar to the drug program, there was one established for devices, wasn't there?

PW: Yes. There was a formal one established after the Medical Device Reporting regulation was put into place. It was attached to compliance, and then later on, it was broken off, and it's by itself now. It's a very strong, vigorous program.

When you hear criticisms about FDA and its adverse reaction reporting systems, remember that they're better than anybody else's in the world, but they're never going to be as good as they should be, because it takes a lot of time and manpower.

RO: Well, so much of it was voluntary.

PW: It's not entirely voluntary in the device area. It's . . . If you can show an association with a death, of a death, serious injury, or a malfunction that could lead to a death or serious injury, then it applies in the device area. But, you know, all those reports come in, and somebody has to analyze them, and that's the problem. There were . . . When I left, there were like twenty-five or thirty thousand reports there, and nobody to go through them. So it was a good early alert system, but it wasn't good for epidemiological baseline data.

Now they're getting a better handle on that by cutting down what devices, what kind of device reports they want to get. They have a little more flexibility with that now, but . . . It's still a better system than the rest of the world, but it's still not as good as it should be.

I probably could have covered some other things. The most important thing for me the last couple years was the international area. I was on the board of directors at ANSI (American National Standards Institute) because of the standards. See, standards became all of a sudden very important, and even in the law now, FDA has the right now to endorse standards. They never had that right before, and so our standards program was based on the fact it was a good thing to do, but we couldn't endorse what you were doing. FDA was involved, at least the center was involved, in about three hundred standards efforts, but it was very hard to justify those because everybody thought it was a good thing to do, but there was no legal basis for it. Now there is.

But standards became a very important thing for the European community. You could use standards to demonstrate compliance with the direct European Directives for the essential requirements or the legal requirements for marketing devices. Then they finally discovered in the United States it was the right thing to do here. So I served on two standards boards of directors, the American National Standards Institute, as well as the Association for the Advancement of Medical Instrumentation, AAMI.

I served on those two boards, and that was primarily to bring a focus on FDA's involvement in some of those international standards efforts that greased the channels, because the ways of developing standards are very slow, and we need to be getting standards out there real fast. So I did some of that. Linda Horton now does it for the ANSI in CDRH; Lillian Gill, represents them for AAMI now, but I started that. I was the first person to do that. I also served for a while on the board of directors of RAPS, because Villforth felt that that organization was a good way to get the word out because it had no trade association affiliation, so that was another one that . . . He really put me on the board for that, too.

I felt like I had a good career. I was glad to leave, though. I didn't always enjoy everything I did, but it was a great experience and good people, and a lot of interesting things, you know. You don't always apply them to consulting, but you have a good memory.

RT: In your present consulting role, are you kind of specializing in devices?

PW: I do mostly . . . Well, it's interesting . . . Now, 99 percent of my work is medical device consulting. I'm in charge of our medical device division. I have one full-time person that works for me, and I have one part-time person that works for me.

But interestingly enough, because of my standards background, for a while I was doing standards consulting for a software company developer, who was having trouble

dealing with standards issues, and I did this quite profitably for a couple years. But they finally hired, at our suggestion, hired a standards coordinator, so I don't have that anymore.

So that was an interesting offshoot of all this. I was hired because a lawyer for Covington & Burling recommended me because of my involvement with standards in government to handle this non-FDA issue. It was the biggest fun I ever had in my life. I really traveled all over the world and did this for a couple years. Now I don't do that anymore. It's all medical device consulting. I have somebody that does 510(k)s, and I do the audits, and I do most of the marketing and bringing in business and so forth. The two of us handle most of it. So . . .

So that's where I am four years later.

RO: Anything else, Bob or Phil?

RT: I think that covered it pretty well.

PW: No, I can't think of anything else. It's interesting.

RO: It is very interesting, and we really appreciate your giving us the time.

PW: OK. I'll look forward to getting the transcript. (Laughter)