

# History

of the

## U. S. Food and Drug Administration

Interviewee: Robert C. Wetherell

Interviewer: Ronald T. Ottens  
Arthur J. Beebe

Date: September 15, 1986

Place: Davisville, RI

DEED OF GIFT

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Robert C. Wetherell

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## INTRODUCTION

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

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



CASSETTE NUMBER(S) 1 - 3

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

DATE: Sept. 15, 1986 PLACE: Davisville, RI LENGTH: 150 min.

INTERVIEWEE

INTERVIEWER

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RO: Interview with Robert C. Wetherell, former associate commissioner for legislation and information, presently chief of the Northeast Technical Services Unit of Shellfish Sanitation (Division of the Cooperative Programs of the Office of Compliance of the Center for Foods and Nutrition), conducted by Ronald T. Ottes with Arthur (Jim) Beebe, for the FDA Oral History Project on September 15, 1986, in Mr. Wetherell's office at North Kingston, Rhode Island.

Bob, we'd like to start by asking you to give us a brief resume of your career, starting back as far as you want to go and bringing us up into FDA and all of the positions you held with FDA, and whatever else you'd like to tell us about some of the incidents that happened along the way.

RW: My, that's a big order. I'm a graduate of the University of Missouri in agricultural chemistry back in 1949. I then went to Montana. In 1952, I became an employee of the Montana Department of Agriculture. The department was headed by Mr. Albert Kruze, commissioner. His office was in Helena, Montana, but I worked at Montana State College down in Bozeman, in the Department of Chemistry. My job was the feed and fertilizer control official for Montana at that time. The most interesting thing, at least in my memory, about that job was that I was the only person. I did all the field inspections; I did all the analytical work; and I did all of the reporting of violations and reviewing of applications.

During that time, I became active to some degree in the Association of Official Agricultural Chemists, AOAC, as it was known at that time. In that connection, I became acquainted with a number of FDA people, including Ralph Kneeland. As that association progressed, I became acquainted with others in FDA, including Jim Pearson, who was at that time director of the Division of Federal-State Relations. Also, Bill McFarland, who was Jim's deputy, and several of the other individuals in that division.

As a result of knowing them and knowing what FDA was concerned about, I began to think about trying to join FDA, and discussed that possibility with some

folks out at the Seattle FDA office. Nothing came of that at the time. In 1960, I left the state and went with a private firm in Montana. This firm was doing some interesting things with barley that had never been done before--that is isolation of the barley starch. Of course, barley's been used to brew beer for years, but had never been broken down to market the individual components. Incidentally, barley starch is one hell of a beautiful starch. It does better than the starch you buy in the store for your clothes.

But nonetheless, in late 1962 and early 1963, Jim Pearson and one or two others advised me that it appeared that there would be opportunities for employment with FDA in the Division of Federal-State Relations. Since the commissioner of agriculture in Montana was only making five thousand dollars a year at that time, and I was subordinate to him, a GS-9 looked good, even if it meant moving to Washington.

So in June of 1963, I did have a job offer from Jim and accepted it, and reported for duty, I think it was about June 28, 1963, in Washington, D.C. That's where I started in FDA. I started as a food and drug officer in the Division of Federal-State Relations. They had not yet established a registry, as I recall, for food and drug officers at the GS-9 or GS-11 level. So we were temporary employees for a year while they did that. In 1963, they did get a registry established. Most of us got appointed that had come in in 1963 to a GS-11. Other folks who were already in included Bob Tucker, who is still in the division; Charlie Pogue, who's still in the division; Charlie Orr, who was there; and Glenn Kilpatrick. All were already on board in 1963 when I came in.

RO: The division was a part of what unit in FDA?

RW: Ron, I can't recall anymore. It seems to me it was a division of itself, attached to the commissioner's office.

AB: It wasn't part of BFA (Bureau of Field Administration).

RW: No, it was not. It was a separate entity. In fact, I know it was. It stayed that way. It changed title from Division to the Office of Federal-State Relations in those times.

It was a pretty good life. We got involved in doing a lot of training for state officials. I guess because of my background and experience with animal feeds, I got involved with Glenn Kilpatrick in developing training courses for the state people in the inspection of medicated feed mills. That was the time, right in 1963, 1964. I think that was when I first met you, Jim (Arthur Beebe).

AB: We went to Purdue University, you and I.

RW: That's right. It was a lot of fun. I'm not sure how much impact we had; though most of the state people were enthusiastic and interested in doing a better job. We had training courses throughout the Midwest down into Oklahoma. I can't even remember, Ron, now that I think about it, whether we had one in Texas. But we had a cadre of instructors from Minneapolis District, from Baltimore District, and from I believe Chicago District, too.

AB: Perhaps Detroit.

RW: That's right. Maybe it was Detroit, Jim. I can't remember for sure. That progressed for two to three years--something like that.

During that time, FDA was expanding, as I recall. Other than the early constraints back in the Dwight Eisenhower years, where the agency got cut back pretty heavy, in the mid-1950s, the Second Citizens' Advisory Committee Report to the secretary around the beginning of 1960, apparently, had a lot of impetus to expansion of the agency. So grades were not much of a problem. They seemed to



move along, because most of us in Federal-State Relations wound up moving within a couple of years to a GS-12 and then to a GS-13.

The next major thing that happened was in the mid-1960s--1966, someplace along that time. There had been some problems with, I think, Abbott Labs in Chicago. George Larrick was still commissioner. John Harvey was deputy commissioner. There began to be a big brouhaha that involved the Fountain committee at that time. The agency was having trouble with some mislabeling or something with some of the Abbott drugs.

AB: May I ask a question first?

RW: Yes.

AB: Before that happened, there was a reorganization in FDA. The Bureau of Enforcement became the Bureau of Regulatory Compliance.

RW: That's right.

AB: Did Federal-State Relations become a part of that Bureau at that time?

RW: No, it did not, Jim. I'm sure.

AB: It wasn't until EDRO (Executive Director of Regional Operations) that Federal-State Relations was a part of the field organization.

RW: That's right. I think this will get at that. It was called, I think, the Office of Federal-State Relations in the mid-1960s. They had changed emphasis because of the second Citizens' Advisory Committee Report. Also, there was a big study done by the agency on the need for state cooperation. That was someplace between 1964

and 1966. One of the big things that was talked about was an establishment of a training institute, having money to do grants to states or contracts with states. It was almost pie in the sky. It was everything anybody wanted to have in terms of developing more help from the states.

RO: Was Jim Pearson still there?

RW: Jim was still there, but Bill McFarland was the prime mover on that particular report.

RO: Bill came in about 1958 or 1959.

RW: *Nineteen fifty-nine, yes. Going back on that, I believe Bob Tucker and Chuck Pogue came in in 1962 or thereabouts. I guess Glenn Kilpatrick and Charlie Orr were already there. They must have come in shortly after Bill McFarland did. I hadn't thought about this too much.*

It was an interesting time because the location of the Office of Federal-State Relations--whatever its exact title was at that time--was such that there was a lot of interaction, at least at Jim Pearson's level, with other components in the agency.

Going back, I'm trying to pick up the thread of what happened to Mr. Larrick and Mr. Harvey with the Fountain committee.

AB: Harvey's brother worked for Abbott Laboratories.

RW: Yes, that's right. The agency was doing an inspection. One of the upshots was that there was an allegation that Mr. Harvey called the district office and told them to get out of the plant for whatever reason. Well, the Fountain Subcommittee on Intergovernmental Relations was the oversight for the agency at that time. Up until that time, FDA (at least in my recollection) had not had much exposure on

Capitol Hill. There had been a few instances going back to the involvement with the enactment of the Delaney Clause, the Durham-Humphrey Amendments in the 1950s, and the Pesticide-Chemical Amendments in the late 1950s. But it was all on legislation. There was not really much oversight--at least when you look at the record of those things. There had been some, but the intensity did not, in my mind, develop until the mid-1960s because of a number of things. One, FDA was growing. Its budget was moving up. The impact of the additional authorities with the Color Additives Amendments, Food Additives Amendments, and things like that, were beginning to have an impact on the industry that was regulated.

So Representative Lawrence H. Fountain and his investigators--W. Donald Gray was the principal one--became somewhat concerned about this allegation of Mr. Harvey's having made that phone call and taking the FDA inspectors out of the plant.

RO: Excuse me, Bob. But at that time, did the Office of Federal-State Relations have a responsibility for congressional liaison? Or did that come later?

RW: That came later, Ron. The reason I'm mentioning it is because I think the thread is that the outcome of the Fountain investigations were that the leadership of the agency began to change. With that there came a reorganization of the agency. We got our first Public Health Service officer in to run the agency, Dr. James L. Goddard. Dr. Goddard had concerns about the agency--how it ought to be run, and there were a number of changes that occurred. One of the changes was to merge the activities of Federal-State Relations with International Affairs and with Congressional Affairs.

Prior to this time, as I understand it, Mr. Winton B. Rankin was the principal individual in the agency dealing with Congress. He and, to some extent, J. Kenneth Kirk and also Maurice Kinslow. If you haven't talked to Maurice, you need to talk to him. Because Maurice, to my knowledge, was the first person really involved with

congressional relations as a major function. He, I think, is the only FDA individual who's ever been part of the Congressional Fellowship Program, where people spend a year on the Hill.

With Goddard coming in, they brought in some other folks, too, including Paul Pumpian. This occurred at the time that the Dangerous Drug Amendments were being discussed on the Hill. The upshot was that John Finlater came in someplace in this general time frame--I haven't got it pinned down just exactly--along with Paul Pumpian.

Now, Paul was and still is an interesting individual. Clearly, Paul is a dyed-in-the-wool Democrat. He'd talk at great length about his relationship with another fellow pharmacist. Paul was a pharmacist. That fellow pharmacist was from Minnesota, by the name of Hubert H. Humphrey. Anyway, Paul I think was the first individual in FDA who was almost strictly a politician, if you will. So he was, with Goddard's blessing, given free rein to organize these three rather different units into one--that is, Federal-State Relations, International Affairs, and Congressional Activities.

Why International Affairs? Well, there had been some rumblings--and I don't have specifics--that things were not kosher, if you will, in the Office of International Affairs. I'm not sure what, really, the problem was.

So Paul, being ambitious and fairly competent, too, said to Goddard, "Well, let's put them all together," and he created the Office of Legislation and Governmental Affairs, OLGS.

Bob Tucker, for some reason, and rightly so, caught Paul's eye. Paul, in setting up this new organization, brought Bob over from Federal-State Relations to work with him. In addition, Paul took Marian Wong, who had been associated with Federal-State Relations as an administrative officer for a number of years, and brought her over.

I can't recall when Jim Pearson retired. It was someplace in that time frame that he did. But another reason for that retirement was the fact that Goddard felt

that there ought to be more visibility in the field for high-ranking individuals or individuals with big titles, if you will, to foster state cooperation.

One of the first ones that got that job was Bill McFarland. He went to Dallas. I can't recall the exact title. Do you remember it Jim?

AB: There was another reorganization where we were part of CPEHS (Consumer Protection and Environmental Health Service). There was a representative in each of the regional offices.

RO: They were regional assistant commissioners.

RW: Is that what it was?

RO: Yes.

RW: Okay.

AB: Nevis Cook had that job in Boston.

RO: George Sooy in Region III of Charlottesville, Virginia.

RW: That's right. The organization of OLGS, I think, occurred just prior to getting that in place. You're right, Jim. There was a lot of turmoil going on. One of the problems, in retrospect, is that Goddard was overly ambitious. He created, or was instrumental in creating--you're right, Jim--CPEHS. His hope was that he would become the head of it. When he didn't, he began to lose interest. The agency suffered like mad under CPEHS.

AB: What did CPEHS stand for?

RW: Go ahead, Ron.

RO: Consumer Protection and Environmental Health Service.

RW: That's right. Charlie C. Johnson became the head of that.

AB: Right, Charlie Johnson.

RW: Charlie Johnson--probably the first visible black associated with Food and Drug, at least in my knowledge.

AB: That employee that you're talking about, that was in the regional office, reported to Charlie Johnson, not directly to FDA.

RW: Is that right? Not having been in the field, the only thing I know is that Bill McFarland was very eager to have one of those big titles and get out to the field. So he went down to Dallas.

AB: I got interviewed for one of those jobs. It was Charlie Johnson and Harris Kenyon who interviewed me.

RW: Yes, that's right. Harris was the field coordinator?

RO: Field liaison officer.

RW: Field liaison.

RO: Well, he was before that.

AB: At one time he had it for FDA.

RW: Yes.

RO: He went up to CPEHS when it was established. But at one point Dr. Goddard felt that the agency should have more visibility in the DHEW regional offices.

RW: That's right.

RO: That was the reason they established some of those RACS.

RW: Thank you. I remember now. RAC--that's right.

Jim Goddard was an interesting person. My first meeting with him occurred when I came over to the Office of Legislation and Governmental Affairs. On the staff we had at that time, as we began to build towards a viable unit ("we" being the agency) to deal with Congress, were Jim Corrigan and Judy Moore. Judy has since gotten married. She was a little, petite, young lady--very vivacious and all. Jim used to come around and sit on the corner of her desk and talk to her. That's where I first met Jim.

As I said earlier, Jim Goddard seemed to lose some interest after Charlie Johnson got the top job in CPEHS. But the thing that he did in my book that the agency still suffers from is the fact that he emphasized the drug program and missed, I think, a great opportunity to really push the whole agency forward.

AB: IDIP, Intensified Drug Inspection Program.

RW: Yes, that's right. A combination.

AB: Who was the person he brought in? He was referred to by some as Batman and Robin. Did he come in to the public affairs job?

RW: I don't know, Jim. You know, Wally Janssen was still around then.

AB: I think it was the public affairs job.

RW: Well, for the life of me, I can't think of the public affairs guy's name. But Jim's right. It's Batman and Robin.

During Paul Pumpian's tenure as head of the OLGS, one thing that occurred was the inspection of foreign drug firms. One of the concepts at that time was to do agreement with foreign countries whereby they would let us check the inspections or do some inspections. The first one that Paul got interested in was with Switzerland. That became his crowning achievement. He just had to go over to Switzerland, and he and others worked with the government to exchange inspectional information. They wound up with the agreement with Switzerland on reciprocity of drug inspections.

That, in my mind, began to move FDA out of--I shouldn't say the shadow of Public Health Service. But it really began to put FDA in a much more visible arena. The intensity of the IDIP program began to get attention because manufacturers were concerned about what was going on. I think congressional interest began to increase in the late 1960s to 1970.

AB: Goddard came in January of 1966.

RW: Yes, that's right. Things moved rather rapidly for FDA, I think, in terms of external events about that time because of the drug situation. There was concern about the dangerous drugs, if you will. The Dangerous Drug Amendments with John



Finlater--the agency had that responsibility. Jim Goddard was right in the forefront of pushing those kinds of things.

AB: Somewhere along that line, product safety came into FDA.

RW: Yes, you're right, Jim. They did. I'm focusing on one thing. I haven't pulled CPSC (Consumer Product Safety Commission) into it. Well, the Child Protection and Toy Safety Act occurred about that time, with those responsibilities accruing to FDA, too.

(Interruption)

RO: Herb Ley came in as commissioner when Dr. Goddard left.

RW: Yes. We were still under CPEHS at that time. My acquaintance with Herb began when Paul Pumpian was still head of OLGS. Paul was out of town and, for some reason, he told me to stand in for him. Herb had the practice of having a stand-up every morning in his office. That was really my first close exposure to Winton Rankin, Ken Kirk, Mickey Moure, and the others that were really the power in the agency at that time.

AB: Was Allan Rayfield still there at that time?

RW: No.

AB: He had left.

RW: I never finished that thought about what happened.

AB: At the time of the Abbott hearing.

RW: I got sidetracked. But to go back, I think it was 1966 that this problem with Abbott came to a head with the Fountain committee. They subpoenaed a number of documents, including John Harvey's desk calendar, Allan Rayfield's desk calendar, and things like that, and all the telephone records. They had some very traumatic hearings. They brought in people from the field like Bill Conway and . . .

RO: Jim Nakada?

RW: Jim Nakada and others, to testify under oath. The essence of that was that Mr. Harvey retired. And that's what brought Goddard in. All this time, Winton Rankin and J. Kenneth Kirk were still there.

AB: Allan Rayfield retired.

RW: Yes, that's right. Allan retired. Did Shelby Grey retire at that time or a little bit later?

RO: It was about this time, I think. He wasn't as much involved in it as the others.

RW: No, he wasn't. But it was a changing of the guard of the agency.

AB: But Rankin and Kirk left much later.

RW: Yes.

AB: Harvey and Allan Rayfield left over the Abbott hearings.

RW: Mr. Larrick, too, left at that time or within a reasonable time there.

RW: We're coming close to 1970. Goddard had gotten in hot water and departed. Ley was commissioner.

The saccharin issue was heating up in terms of the Delaney Clause. There had been one or two studies done with rats. All at once, the report came in to the secretary.

AB: Cyclamates.

RW: I'm sorry. You're right. It's cyclamates--not saccharin. Scratch saccharin all through there. That's right. It was cyclamates. They put a bolus in the stomach of the rats along with saccharin. They combined the two, and the rats wound up getting cancer. That report came into the department. When the decisions were being made on that, the only one, as far as I know, in the agency that was involved with the secretary was Billy Goodrich, the general counsel for FDA. Herb Ley was not. Ken Kirk was not. Winton Rankin was not. When the announcement came out, Herb Ley was told about it, apparently, after the fact. He decided to leave.

AB: Do you remember who the secretary was?

RW: I almost said it a minute ago, Jim. I can't right now.

Anyway, why Herb Ley should have been involved is the fact that prior to that, the Kinslow Report (which I mentioned briefly earlier) had been completed. The Kinslow Report was the study of all of FDA programs--what needs to be done, how it should be done, what changes should be made. It was completed.

RO: This is the one that was commissioned by Dr. Ley, wasn't it?

RW: Yes. It was commissioned by the commissioner.

AB: Maurice Kinslow was the chairman of the committee.

RW: Right.

AB: Members included Tom Brown and Dr. Marian Finkel, a physician.

RW: And a number of others. All internal--not an external review group. It was done primarily to forestall what, in some people's minds, would have been another outside group coming in and mucking around with FDA.

Well, that was completed. People on the Hill and other places began to want to see it. Here again the politics were beginning to change. We were coming up to a presidential election. Finally, a strategy was either consciously or subconsciously--I don't know which--developed which says, "The way to get us out of CPEHS is to get that report out." It had been held under wraps. My recollection is that one Paul Pumpian leaked it to the Hill. As a result, a number of hearings were held, particularly with Paul Rogers, in the House, who was chairman of the Subcommittee on Health at that time. That led to a reorganization again of FDA coming out of CPEHS but keeping us in the Public Health Service.

I guess it's fair to say the Democrats in the department didn't like that. Paul left. Mr. Rankin was put under wraps and moved to the department.

AB: Ken Kirk retired at that time.

RW: Yes, that's right. Ken retired. Because of the importance of people in this life of FDA, when CPEHS was formed, Mickey Moure, I think, went up to CPEHS as their financial officer. Didn't he go up then?

AB: Yes.

RO: He was still there when Charlie Edwards came in as commissioner.

RW: Oh, excuse me. That's right. It was the guy before him that went up. Mickey became the principal budget officer for FDA. That's right.

RO: I think Ed Lannon.

RW: Ed Lannon went up there. Mickey then became more and more of a power, if you will, particularly as we got out from under CPEHS. But with Ken Kirk retiring, Rankin being put under wraps and moved to the department, and without much responsibility to allow him to serve his time out until he was eligible to retire (so I've heard), FDA got a new commissioner, another M.D.--Charlie Edwards. He brought in a whole new crew of people around him. Some of those are still around the agency today.

RO: You mentioned it was about this time that there was another reorganization of FDA.

RW: Yes.

RO: I think some of the changes were that the Federal-State Relations and Legislation and International Affairs were separated, weren't they?

RW: Yes. It was part of an overall reorganization. Charlie was a management type, although an M.D. Wasn't he from Booz, Allen, Hamilton?

RO: Yes.

RW: Ron, you're right. When Charlie came in from Booz, Allen, Hamilton, he brought in a number of other people. He also came in with a clear idea of reorganizing, once again, the agency. The main direction that he undertook--and I'm sure you'd get this better from other people--was to do away with the non-product-oriented alignment and organize the agency into product lines. It wound up with the Bureau of Foods, the Bureau of Drugs, and the Bureau of Veterinary Medicine.

Let me back up. I said he came in from Booz, Allen, Hamilton. I think that's a key point for folks to remember. Because back in the late 1960s, I guess, and maybe early 1970s, the agency let a major contract with Booz, Allen, Hamilton to undertake a review of the management and record keeping of the agency. That's when I first got to know Paul Hile--during the time he was serving as project manager for that contract. We also were faced with a big railroad strike. Paul Hile had some responsibilities for monitoring the status of that strike, and I helped him out on that.

In the process of the reorganization, and rightly so, Dr. Edwards decided to take OLGS and split it back into its original three parts: that is, Federal-State Relations, International Affairs, and Legislative Affairs. It wound up that Federal-State Relations went to the organization where it more clearly fit, which was the Office of Regional Operations. He put international affairs into the Office of Health, I think it was, and created then an Office of Legislative Services at that time. Part of that reorganization was premised on the Kinslow Report. Am I right, Ron?

RO: Yes.

RW: As a result, Maurice came in to help Dr. Edwards implement this reorganization. Maurice brought in one of his compatriots from Baltimore, Merl (Pat) Ryan, to head the Office of Legislative Services.

That gets us into a more current era of legislative activities of the agency.

RO: Bob, if I remember right, Pat Ryan was only in there in an acting capacity.

RW: Yes, he was. He stayed for about a year while they sorted things around. Mickey Moure began to play a bigger role in the management of the agency than he had in the past. Do you agree?

RO: Yes. That's right.

RW: One of the things Mickey did was to find someone to permanently head up Legislative Services. He identified such an individual and recommended to Charlie Edwards that he be brought on. He was Gerry Meyer, currently the associate commissioner for management and operations in the agency.

Gerry had served in the department (DHEW) on the budget staff. Prior to that, he had worked for (I'm not sure) more than a year on the House Appropriations Committee with the ranking minority member of that committee. Gerry stayed in OLS until the time that Charlie Edwards decided to become assistant secretary for health. When Charlie made that decision, he also took Mickey Moure up to the assistant secretary's office with him. That left the management and operations position open. Mickey recommended, as I understand it, that Gerry Meyer succeed himself. Sherwin Gardner was acting commissioner at that time.

RO: Sherwin became acting commissioner when Edwards went upstairs.

RW: Yes, that's what I'm saying. During the time that Edwards went upstairs, Sherwin was acting. Mickey had gone upstairs with Charlie Edwards. So Gerry (I gather selected by both Mickey and Sherwin Gardner) became the new Mickey Moure of FDA. Is that about right?

RO: That's about right. I think maybe to fill this in a little bit--Charlie Edwards' deputy, Jim Grant, had left. Sherwin Gardner was also from Booz, Allen, Hamilton.

RW: Oh, one of those.

RO: That's right. Charlie had brought Sherwin in for agency planning. When Jim Grant left, I think Charlie named Sherwin deputy commissioner.

RW: That's right. I keep forgetting about Jim Grant. He's kind of like the phantom secretary, David Matthews. There is a name there, but you never saw him, so you never paid much attention to him.

So, when Gerry took over Mickey's old job in the agency, the position of director of legislative services was open. About that time, they completed a search. Mac Schmidt came in as commissioner. This must have been about 1973 that Mac came in and they announced the job for director of legislative services. I applied and good, bad, or indifferent, I got selected. I continued on as director of that until Don Kennedy came in as commissioner. Here again you had a change in administration. So commissioners began to change with regularity as the politics changed.

Don brought in at least one person with him to serve as his special assistant. The first hearing that I really had anything to do with Don Kennedy on was with Charlie Rose in the House of Representatives on an issue. We put together literally a book as a statement. Don said, "Is this necessary?"

I said, "Absolutely." It turned out it was. I think that's what kept me from being replaced by Don Kennedy at that time. Two positions in FDA besides the commissioner that are becoming more and more vulnerable to political change are the Public Affairs Office and the Legislative Affairs Office. So that was my first inkling as to the sensitivity of my position.

We stayed as Legislative Services until the Senior Executive Service (SES) was created by Congress and the administration. The position was then upgraded from



a GS-15 to a GS-16 into SES. And they changed it to associate commissioner for legislative affairs at that time.

Under Commissioner Art Hayes, there had been again some . . .

RO: Excuse me. I think there was a commissioner in between Kennedy . . .

RW: That's right. It was just trying to sketch what happened to me. But Jere Goyan came in as commissioner when again it was a Democratic regime. Jere was a nice fellow, enjoyed traveling and all. He was pretty much in the hands of his staff. One of the more influential ones was the associate commissioner for public affairs at that time.

As a result of several things during Commissioner Hayes' regime, the associate commissioner for public affairs, Wayne Pines, somehow fell into disfavor with the department and perhaps with the White House. While everyone in the agency battled like hell to keep Wayne, they could not. So Wayne was transferred over to help run Saint Elizabeth's Hospital. I was asked by Art Hayes and the department to take on the additional job of public affairs. Rightly or wrongly, I did. I kept that responsibility until April 1, 1985.

It's an irony that Wayne Pines, one year before he left, got a PHS Award. One year before I left, I got the same PHS Award. I told Brad Rosenthal this year to watch out because he got the same one.

That kind of covers me up till this point, where I'm up here in Davisville, Rhode Island, where the sun is shining and the phone doesn't ring as often.

RO: Bob, that brings you up as far as your career in FDA is concerned. There are a number of changes that happened. I don't know what sequence you'd like to follow here and how much you'd want to say about what brought you into your present job.

RW: Well, that's an interesting subject. I've thought about it off and on for the last year and a half or so. I'm not sure I can put it all together, Ron. Some of it will be supposition; some of it may be my imagination. I don't know.

This has to go back to the time when Mark Novitch was acting commissioner, following Art Hayes' rather sudden departure. A search committee was out for a new commissioner. Keep in mind the Republicans were in the White House and were in the department. Contrary to what a lot of people felt, Dick Schweicker, who had been secretary of the department, was a friend of FDA's. No question about it. Compared to other secretaries that I've seen, he was. With his departure and the advent of a new secretary, things began to change.

I think it needs to be said that Art Hayes and Dick Schweicker had a one-to-one relationship that was helpful to the agency. With Dick Schweicker's departure and a new secretary on board, that relationship no longer existed.

The new secretary brought in a number of people. The new secretary was a creature of Congress. A Republican, Margaret Heckler, had served the President quite well in Congress. But she was also part of that "ole boy, ole girl" network, if you will. So when she came in, she perhaps inadvertently, unconsciously--I don't know, maybe it was forced on her--began to select people as her staff who were proteges of other people on the Hill. One of whom was Mac Haddow. There was not a strong undersecretary at that time. There never has been, really, when you think about it in the department. There's never been a strong undersecretary. There was a continuing battle with the White House over who Margaret Heckler would have as staff. The people that Schweicker had brought in, for the most part, left their staff positions and new ones came in. Mac Haddow was one of those.

At the same time, FDA was being badgered, if you will, unnecessarily, but nonetheless badgered by Congress--particularly the Ted Weiss committee. Ted Weiss had taken over the committee that Mr. Fountain used to chair. The staff under Mr. Fountain who were sympathetic to the agency, albeit rather critical, had, for the most part, departed. That was Gil Goldhamer and Delphus Goldberg; the name that

sticks with me is the "Gold Dust Twins." It was Gil and his compatriot up there. They left.

Ted Weiss, when he took over, brought in some very young people who were desirous of making names for themselves. They were just hammering the living hell out of the agency over a number of issues.

The department said, "Why don't you stop all that leaking of information to the Hill?"

The young staff in the department, what they did not understand is you can write all the memos in the world, if you will, saying, "Don't give this stuff away," and there will always be people in an organization the size of FDA who have some grudge, some personal vendetta that they want to carry out, who will leak stuff. You can tape the doors shut and everything, but it will still get out. What the department people did not understand, and still do not, is that it does happen and they can't stop it.

My perception after an early meeting with Mac Haddow, in response to what I guess was not quite a subpoena issued by Weiss, was that Haddow perceived me to be the reason that things weren't shut down tight out there, and that I was personally responsible for everything getting leaked to the Hill. Keep in mind Congress has no deterrent under Freedom of Information. The only deterrent they have at getting at agency records are the 301J stuff--trade secrets. Beyond that, they demand and can get everything. Haddow didn't think that was right. I don't think he ever understood, though, the actual ramifications of what he was talking about.

That went by and things went along. Frank Young began to get a hold on the agency. I guess it's a little to my own chagrin, when I think back about it, that I know probably more about Frank Young's appointment than anybody in the agency.

As I started to say, they were having difficulty finding a new commissioner. I know who finally thought of Frank Young outside of the agency. I was asked, "How do I put somebody's name in the pot for the search?"

I said, "Send it to me and we'll put him in the pot." Little did I know that the papers I got and put in the pot were Frank Young's.

As a result of that, Dr. Young came in as commissioner. We had several long talks. One of the things I advised him to do, rightly or wrongly . . . Well, there were really two. One, you need to build yourself a network in Washington that is in the department, in the White House, and in the community of Washington. You need to have a network of people--OMB, IRS, the Treasury, wherever, as well as Congress. Those of you who have seen Frank operate, you know that he has a tendency, at least early on, to whip out a little tape recorder and jot things down right now.

In addition, I told him . . . And people in the agency when they read this probably will have mixed emotions about it.

(Interruption)

RW: The other thing I told him, I said, "If you have an agenda that you want the agency to follow, you have got to get that agenda in place early on. Because if you don't, FDA is the world's best at capturing commissioners and making them one of their own. If you don't, you're going to have each center presenting its own agenda for you to dance to, and they will compete with each other in this. You will have a hard time sorting it out. So if you really mean to stay and move the agency, get your own agenda thought out, announced, and in place. And then you will not be faced with trying to judge whose agenda is the best."

I guess I need to say with that kind of introduction of my relationship with Frank Young, Frank Young began to pay very close attention to what Mac Haddow said--not the secretary, Margaret Heckler, but what Mac Haddow said. It was interesting that the Weiss committee and one or two others (Mr. John Dingell, for example) were still getting after FDA--which is part of their right to do--on several issues. But material was getting out that had not been cleared, which you can't stop.

There will be people in the bowels of the agency who will Xerox something, take it home, and hand it to them at night.

In addition, I'm not sure what really precipitated it, Ron. I really haven't thought about it. It's been too much fun up here for the last year and a half. Well, I guess what really precipitated it was the Commissioner's Action Plan.

I had thought that our office had been doing a pretty good job of kind of leading the agency with the center into the area of food safety. But in his action plan, the commissioner did not have any responsibility assigned to the Office of Legislation and Information. That bothered me. Quite honestly, it bothered me--perhaps inappropriately so, but it did. My ego may have been showing a little bit at that time. And then some time after that, things cooked along and cooked along. Boy, it's hard to reconstruct now. Mark Novitch was out of town. Dr. Young was out of town. Tom Scarlett, I guess, was in town, as I was.

Tom Scarlett called me on the phone and said, "Bob, have you heard the latest rumor?"

I said, "What?"

He said that three FDAers are going to be asked to leave.

I said, "Oh?" This is not uncommon in Washington--to have rumors. You kind of toss it off lightly. "Yes, well, who are they, Tom?"

He said, "Mark Novitch, myself, and you."

Well, that got my attention in a hurry. That kind of bothered me. I got a hold of Mark and told him. He hadn't heard it. He said he had called Dr. Young.

The next day, I asked Mark if he had, and he said, "Yes. And he said he would call us."

Well, it turned out that Young talked to Mark about it and talked to Scarlett, and did not call me. The first thing I knew about it was he came back and called me into his office. Then he began to talk about things and saying, "You know, I've been noticing you don't look well. Have you had a physical lately?"

I said, "No. I feel fine. I'm just a little disappointed about these kinds of things."

Basically, what it boiled down to was: Haddow did not like the way things were going in terms of dealing with Congress. The second is that I think Young also wanted to be more flamboyant in terms of public relations than is my style, which is try to be factual about it and don't try to beat people over the head with things. One of the interesting sidelights: We, thanks to Paul Hile and Roger Miller, got the Drug Advertising Council Group out of New York to co-sponsor the quackery ads with us. One of the first things we did with Frank was to set up that press conference. Roger got it set up.

Frank walked up there, apparently, in New York, and lit all over Roger. "I didn't know there was going to be more than one camera!" These kinds of things. He had his own way of doing it. I'm not saying that our way was any better or any worse, but he had his own way. As commissioner, he's entitled to try that.

In talking with Frank, I said, "Does Haddow want me out?"

"Oh, no, no. Just give up the public affairs job and you can keep the legislative affairs job."

I said, "I don't think Haddow wants me in that job."

Frank did not answer that directly. He said, "Well, I'll talk to Haddow. It will be all right."

I said, "Without the confidence of all the people in the department, and your confidence, I can't do that job." So we were left at that.

I had better than twenty years in. I was over fifty-five. I asked Gerry Meyer, I said, "Gerry, the commissioner, in essence, is abolishing my job if he's going to split it back to two units.

He said, "Yes."

I said, "I could retire, couldn't I?"

Fortuitously and unknown completely to me, Jim Verber, who had been up here at Davisville, was retiring July, 1985. I didn't know that when my situation

occurred. Only by happenstance (I guess by talking to Gerry about abolishing the job), Gerry knew that Verber was retiring. Or maybe Gerry didn't. I guess what happened is that Gerry and I talked about it and I had jokingly in the past said, "Well, if they ever get a grounds keeper job or just a floor sweeper job up at Davisville, I'll take it."

RO: You'd been heckling me for about four years about a resident post up here.

RW: Yes! That's right! I had, hadn't I? Yes. That's before I tumbled between the difference between a resident post and Northeast Technical Services Unit, Ron. (Chuckles)

Anyway, Gerry said, "I think we can do something on that." They looked at it. Gerry was ready to create a position. Downgrade, but what the hell. He said "Well, I've got to talk to the Center just so they'll know I'm going to give them a position and what it will be." And that's when Gerry found out that Verber was retiring. Then, apparently, Sandy Miller (bless his heart), Dick Ronk, and others said, "Oh, my God." So on April 1, 1985, I came up here.

Does that, in a very roundabout way, answer your question?

RO: That answers it. Bob, one of the things I would like to have you do is to go back and, from your perspective, talk about the relationship that the various commissioners that you worked under had with Congress and with the department. All tied in there is the difference in the secretaries in HEW and HHS, and the involvement that they wanted with Congress.

RW: Oh, my Lord, Ron.

RO: And along the way, some of the more interesting hearings that you participated in, which was a lot of them, and what were some of the axes to grind that the congressmen had against FDA.

RW: I guess, probably, I ought to start a little bit with Jim Goddard, because he enjoyed Congress. He thought it was a great forum, as I read him. He was a good witness--no question. But I wasn't that close to Jim. Up until the time that he ran into his alcohol and marijuana flack, it was pretty much roses up there. My relationship . . . There wasn't much of one with Jim.

Herb Ley was kind of the same way, except Herb wasn't there long enough. Herb was very laid back. He was kind of, to his credit, always willing to listen to people. But whoever talked to him last probably got their way, if you will.

Winton Rankin and Ken Kirk, while never commissioner, were the power behind the scenes. I never will forget the first time I had to go in and see Winton, late in an afternoon. It was on the Animal Drug Amendments that were passed on the Hill and ready to go into the whole Bill Report, which is the last stage before it goes to the White House. Somebody on the Hill called the office about 6:00, and wanted to know whether or not there should be a three-letter word or a two-letter word in one of the last sentences of the bill. Should it be "and" or should it be "or"? I looked at it. Right now I can't tell you which way it should have been. But the point is, I went into Winton. He said, "Oh, my God. Thank God we caught it," and went on. I mean, he was that kind of person--not much frills with him. J. Kenneth Kirk was even a little more austere, if you will. Except, when he did get a twinkle in your eye, you had fun with him.

Charlie Edwards was the next one. Charlie struck people as a little aloof. He was a tremendous delegator, though. I think, while he was not a palsy-walsy type person with people on the Hill, during his tenure as commissioner he probably was as well-respected as any we've had. He was a manager. He was willing to wade in though, late at night, on weekends, to resolve issues. We had several of those, while



he was commissioner, that got the White House involved. He was probably overall, in my book, one of the better commissioners the agency has had.

AB: Is it true that he was relaxed enough so that he could sleep during the hearings?

RW: He never displayed much emotion, if you will, Jim, in the sense of really paying attention. But keep in mind that he had somebody by his side later on that (I don't care who it was) would out-talk him. That's Peter Barton Hutt, the general counsel. If you wanted to just relax and enjoy a hearing as much as you can, get a question and then phrase it, "Well, I'm not sure, but I'd like to ask . . ." or "Counsel will respond to that." And Peter could obfuscate and twist words just all over the place. People would say, "That sounds like a good answer," when, in fact, they never knew what the hell he was talking about because he was very clever at that.

He always appeared, Jim, very relaxed. I agree with you. But I've never seen him quite go to sleep up there.

Mac Schmidt was a delight to work for. He loved commas. If you ever wrote anything for Mac Schmidt, you could never put enough commas in anything. I would say that Mac probably had the toughest time of any commissioner. Because here was a Republican White House of which Mac had been part and parcel, if you will, facing a very hostile Democratic Congress--particularly in the Senate--and where Ted Kennedy was in charge of our oversight committee on Labor and Human Services in the Senate. There was never an opportunity, particularly on the Senate's side, for Mac to develop the kind of relationships that he could have because of the kinds of things that the Kennedy staff undertook to develop in hearings: that is, the investigation of what is now the Center for Drugs. I think Mac Schmidt had more pressure on him, both internal and external, than any other commissioner. He carried it off with a great deal of grace in some very trying times. He has a

tremendous sense of humor. Thank God he did, because it served him a time or two.

I think the neatest thing I ever had to do with Mac . . . We had three hearings in one day on the Hill. Mac testified at two of them, and I guess Virgil Wodicka testified at the third one. One of Mac's daughters was there at the hearing. He turned to me in going from one hearing to the other. Here you think, "Oh, my God. How did I do?" and all these kinds of questions. He said, "Do you think you could get Ted Kennedy's autograph for my daughter?" He was thinking about people. He really was.

After Mac, Don Kennedy was a different cat. As I mentioned earlier, I almost got replaced by Don. There's no regrets about that. Don was probably the commissioner who worked the hardest at trying to develop good relations on the Hill. He was tremendous at developing good rapport with the staff people. Keep in mind, though, here's a dean again. In contrast with Mac Schmidt, Don Kennedy is a dean in academia. Don was very much involved with graduate students. After a while, the perception--at least mine--was that Don Kennedy looked around the agency and tapped a lot of young people to work on things of interest to him because he viewed them as his graduate students.

AB: Operating people in the field were certainly very impressed by him; he had a lot of charisma.

RW: Yes, Jim, no question. That same kind of charisma stood Don well on the Hill--but with the staff people. You have the old thing. A doctor's peer group is doctors--nobody else above them or below them. Well, Congress, they've got their own peer group, and that is Congress. Everybody else is below them. Don had a tendency, on occasion, to lecture on the Hill a little bit--probably more than Mac Schmidt.

Anyway, the most telling thing about Don Kennedy . . . I don't know whether Don ever knew this or not. When you talk to a member of Congress who is chairman of a subcommittee or a committee--I don't care whether it's in private or in public--you call him Mr. or Mrs. Chairman. Well, Paul Rogers, one of the best supporters the agency ever had, was chairman of the House Subcommittee on Health. There was a lot of activity with that committee. The staff on that committee just adored Don Kennedy--Steve Lawton and JoAnn Glyson.

I am told by those two individuals that Don made the horrendous mistake of calling Paul Rogers "Paul." While the staff adored Don, Mr. Rogers got turned off. It's little nuances like that that make commissioners stand out in my mind.

Jere Goyan was just (it doesn't sound good) a good old boy. He did a lot of good things. But he just knew he was here for a short while, and was going to ride it out.

RO: Of course, with Jere Goyan, he had Nancy Buc as a general counsel, who was such a friend of the secretary at that time. He never had much of a chance, did he?

RW: I guess he didn't. Because you had Nancy Buc and . . .

RW: I'm talking about the general counsel of the department, who was also a woman, Jody Bernstein. Her husband was in the commissioned corps.

Anyway, Jere never had a chance because he's a gentleman and a retiring person. He's not aggressive. I think that if it had been Charlie Edwards or Mac Schmidt there with Nancy Buc, you'd have a different set of circumstances that would have been most interesting. Because I think Nancy just saw somebody that she could just run over.

You know, a lot of people hated Nancy. They disliked her intensely. I enjoyed her probably more than most people because she was willing to fight Congress when the fight was needed. She would go to bat for us. I can understand

other people saying, "Jere just bows to Nancy." If he would have had (excuse me, Jere) a little more backbone and stood up, I don't think it would have happened.

RO: Wasn't it when Jere first came in that he was confronted with the Infant Formula Hearing? Was that Goyan?

RW: Jere's first hearing when he came in was the Infant Formula Hearing. Absolutely right, Ron. It really was. And that's one of the worst hearings I ever put together. I let congressional staff do something that should never have been done. And I've regretted it ever since. But we had two people in the agency who said different things on the record. So they sat one of them at one end of the table, and one at the other end, and they began to get going at each other. Here's poor Jere sitting in the middle. It was not a good scene.

We put the question squarely to Jere. "Here you're only on board a month. Do you want to do this? Do you think it's appropriate?"

He said, "That's what I'm getting paid for. I'll go do it."

I guess I didn't have enough backbone to say, "Jere, don't. You haven't been here long enough." You learn these things as time goes on. We should have said no. We should have had either Paul Hile or Howie Roberts in the Center for Foods do it.

Jere had a very unsettling introduction to congressional hearings.

Art Hayes was probably the easiest commissioner I've known to introduce to Congress, who was respectful of it and worked hard at trying to understand it and was always willing to go do things. I mean, he learned early on to call everybody Mr. Chairman.

Of the three recent M.D.s, he was probably the less pretentious of all three of them. A slight fellow, but, oh, did he love to talk. And he could talk. But that came from his father who was a radio announcer.

Then, of course, there was Frank Young.

Interspersed all through this, Ron, keep in mind that there was Mark Novitch as acting commissioner about three or four times.

RO: And Sherwin Gardner.

RW: And Sherwin, too. I guess of those two, Sherwin was probably more of a manager. He had some slight style concerns of his own. If the facts were there and it was presentable, he left it in the hands of his staff to get the job done once he agreed with the facts. Mark, though, had his own style and was great at rewriting things at the last minute.

I don't know how Frank Young is because I didn't have that many hearings with him. In working with him, he seems interested in how Congress works. I understand that his networking may be paying off a little bit in terms of support for the budget this year for the agency and getting the National Food Processors and others to actively become involved on behalf of the agency on the Hill.

RO: Bob, you've talked about the way that some of the commissioners seem to be able to handle Congress, or not handle Congress. We've had a number of different general counsels in the agency that you've had to deal with. If you could give us some insight into their different styles as far as dealing with the commissioner, with the secretary, and with Congress.

RW: Boy, Ron, that's a big load.

RO: You were mostly involved, I guess, from about Charlie Edwards' era on. Bill Goodrich left and Peter Hutt came early in Charlie Edwards' tenure.

RW: Yes. I didn't have that much to do with Billy at all, in terms of that relationship. Peter Barton Hutt loved to deal with Congress. He recognized that it

was here to stay whether the agency liked it or not. That being the case, we had to learn to deal with it. He was more than willing to spend whatever time it took to educate people on the Hill. Basically, that's what it has been for the last dozen years or more--getting people to understand FDA, what it is, how it goes about its business, and what impact it has on consumers. Heretofore, I think people on the Hill just felt, "Oh, Food and Drug is out there doing whatever it is they do. Except when it comes time when they put somebody in our district out of business, we won't pay any attention to them."

Peter was very aggressive about it and worked well with committees. As most people know, who have been in the agency when Peter was there, he can talk your arm off. He'll work you to death. He worked nights and weekends. When the agency moved into Parklawn, the air conditioning went off on the weekends--those of you who have not had that fortune to know. So Peter decided that, by damn, he still had to work Saturdays and Sundays, and he needed his air conditioning. And he got it. That's about the only place in the Parklawn Building for years that was air conditioned on Saturdays and Sundays.

Peter, as I said, worked extremely well with the staff people on the Hill--willing to do whatever he could. He'd make commitments on the part of the agency that we'd all have to turn to and work Saturdays and Sundays, too. So be it. It's a team effort.

In contrast to Peter, Dick Merrill was more of an introspective person--not that he did not willingly involve himself with agency issues. Here again, he was more of a dean, if you will, than a real advocate for the agency.

(Interruption)

RW: It's hard to say what I'm about to say about Rich Cooper without demeaning other general counsels. In my book, whether it was because his personality fit with mine or what it was, Rich Cooper was the most effective general counsel that I've

seen in Food and Drug. He had practiced as a trial attorney, which I had not thought of as being necessary till I became acquainted with Rich and saw how he operated. I think it is imperative that the agency have that kind of ability in its counsel, because he was able to thwart any number of things in a most pleasant manner. But, when he found out somebody had had him, that person got it. It made you feel good to be around Rich. It really did. He was thoughtful. He wrote extremely well. He was not given to long explanations, if you will, of what was going on, but got to the point with a lot of sound logic. He was just a joy to be around and to watch him work. He worked well with the Hill--no question about it. I think the agency has been very fortunate. Here again, I have no firsthand experience with Billy, but I understand he was the same way. The agency has been very fortunate to have the caliber of chief counsels that they've had up to and including Tom Scarlett.

People underestimate Tom a great deal of the time. He is very thoughtful. Next to Rich Cooper he's probably the best writer as far as a counsel the agency's had. He is more than willing to work with the Hill and does it well. He's not as enamored of it as, say, was Peter Barton Hutt, but he is very effective when he puts his hand to it.

Nancy Buc was, in her own way, good for the agency during the time she was here, as far as congressional relations.

Keep in mind, there's a whole mix of things that are going on when the agency is represented on the Hill or in public. One of the things that FDA has to recognize (always has been, still is, even though the field particularly has made great strides forward in it) is that it's a male organization. It always has been. Look around Policy Board now. Is there a woman on it? No. Nancy Buc broke that. In order to do that with a bunch of male chauvinist pigs that we had sitting on Policy Board at that time, it probably took somebody with the nature of a Nancy Buc to carry it off.

Nancy, in her own way I think, made some contributions that we might not have otherwise had. It told the world a little bit that yes, a woman can operate in

that capacity. Now, albeit she may have rubbed some folks--and I'm sure she did--the wrong way with some of her acrobatics and language from time to time.

RO: Bob, you mentioned something about Peter Barton Hutt, and recognizing the need to educate Congress--probably the staffers more than the Congress.

RW: Yes.

RO: Part of your job and your staff's job was kind of behind the scenes in dealing with congressional staffers, wasn't it? I know you had to prepare all the testimony for the hearings. But it was a key part of your job to have good liaison with congressional staffers. Is that right?

RW: Oh, absolutely, Ron. I think that office has a role that is very important for the agency. I used to describe it as: It's the agency's ear to Congress, and it's Congress' ear to the agency. You want to tell them what the agency's doing, but you want to do it in a way that they're going to tell you what Congress is doing. I think it is intelligence. And it involves building confidence that the people on the Hill know that when you give them an answer it's straight. Whether they like it or not, you're not hemming or hawing. Too often, people want to tell Congress only what they think Congress wants to hear. Well, for FDA to function, in my book, in terms of public benefit, it's got to be honest about how it responds to inquiries. I don't care how distasteful the issue is, you have to deal straight up with it.

In order to get people to recognize that you're telling it like it is, they've got to know you and understand that you're not out there to cut a deal or do things like that. And that takes time. It is compounded by the fact that staffers change on the Hill, as is quite often the case with members, particularly in the House. They change every two years. So you have a continuing job of building trust. It's not just once a



month or maybe once every two weeks. It's phone calls every other day to keep them apprised once you know something they're interested in. Keep checking on it.

I'm sure I made a nuisance of myself and the agency, calling people to ask them what the status of this is about every three days or four days, from time to time. But it was important. That way, they know that you're concerned about them. Whether the people on the Hill can ever do anything for the agency, I don't know. I don't know if they can. But they sure as hell can cause trouble for the agency if they don't get what they want. Keep in mind Congress holds all the cards as far as the agency is concerned. The only way you can get them to be into play there is to play straight with them.

The only time I ever ran afoul with the agency, Ron, it was you and me one time. Do you remember that? With Marsha McCord and Senator Thomas Eagleton about an imported drug. Yes. But it worked out.

RO: Oh, yes.

RW: Yes, I made a few mistakes like that from time to time. But for the most part, people in the agency began to understand the need for Congress to know. Once we began to get over that and get away from the old syndrome, "If they didn't ask the question, don't answer it" . . . If you can go a little beyond and still be based on fact, do it.

RO: What you said a while ago, that seemed to have gotten you into trouble with at least . . .

RW: With Marsha? Well, yes.

RO: Maybe you felt that Congress had more of a need to know than some of those in the secretary's office.

That leads me to another thing. FDA is really under the assistant secretary for health.

RW: Yes.

RO: But I think most of the dealings that we've had, at least with the department that you've mentioned, has been directly with the department rather than with the assistant secretary for health.

RW: Yes. That's kind of a dichotomy in the organization of the department, at least from my experience in the positions I was in.

On the legislative side of it, the assistant secretary for legislation in the department has no (and I use this in spite of what I said earlier) line authority over legislative offices in the agencies. There is, if you will, a dotted line, on the organizational chart. There is a communication thing and a need for clearance, if you will. Clearance amounts to a number of things--whether it's a letter, whether it's a piece of testimony, or whether it's going to visit somebody or somebody's coming out to visit you.

The assistant secretary for health's office has a dotted line from the assistant secretary for legislation's office over to the health office. The legislation for PHS is handled by the assistant secretary for legislation. There's an advice and comment relationship between PHS and that office, just as there is between that office and the agencies.

On the legislative side, if we told the assistant secretary for legislation's office, they would take care of telling PHS.

Public affairs was different. There was an assistant secretary for public affairs. But, also, the assistant secretary for health had a public affairs officer who was much more aggressive and very, very supportive of the agency. On public affairs things,

press releases, and all, you'd send them to PHS, who would clear them and send them on to the department--not like the legislative matters.

So you had two different routes to go, both of which worked well. I don't know what other folks might think about it. Early on, I was told the department on legislative matters, on working with Congress, will want to babysit you all the time, do everything. I decided (probably unconsciously, without any really conscious thought given to it) okay, we'll begin to tell them every little thing that goes on, just overwhelm them. We started that back in the early 1970s. As time went on, they began to accept for fact that we were telling it like it was. We'd just tell them every time we went up to almost literally wipe somebody's nose on the Hill. There were so many of those little things going on that I (and I may be completely wrong, and it may be the problem that I got myself in with Haddow) began to feel that they felt that we were telling them all that there was. So I could do a few things that they didn't need to know about on occasion--nothing to hurt the agency, nothing to hurt the department, but some things that would from time to time prevent a catastrophe hitting the agency or the department or would somehow help us. That worked, Ron, as far as I can tell. Nobody ever complained about us not keeping the department informed about important things, and who we were seeing, and things like that.

Holding both those jobs at one time, it did give you pause so you had to stop and think, "Well, am I doing public affairs or legislation?" and based on which one it was, which way I had to go.

But I had excellent staff in both those operations. It was more fun than you can shake a stick at.

RO: Every year, it seemed to me, there was an increased number of oversight hearings from, let's say, 1970 on. I think that was about the time (1970 or somewhere in there) where you got more involved with legislation than you were with federal-state relations.

RW: Yes.

RO: Would you mind going back and kind of picking up some of the key hearings that we've had that had the most impact on the agency?

RW: I think, as we mentioned earlier, the hearing in the mid-1960s that involved Mr. Fountain, Commissioner Larrick, John Harvey, and others, was one of the critical hearings in terms of turning congressional interest towards FDA. People began to look at us. Couple that with what Jim Beebe mentioned some time ago--the implementation of the 1962 Safety and Efficacy Amendments. Congress had passed a major statute. We had "a scandal," if you will. Those two combined to begin to raise interest in Congress on how FDA was doing its job. You would find a series of hearings with Fountain on implementation of Kefauver-Harris, if you will.

The Democrats had been running the country for a while in the House, the Senate, and the White House. And then, all at once, you came in with a change in politics. The White House went Republican, and you still had large Democratic majorities on the Hill. As new things, new organizations in FDA (as we talked about) going to a product-oriented system under Charlie Edwards, the push coming to increase productivity in terms of reviews, things began to build to a crisis a little bit in the Bureau of Drugs.

I think the next really major hearings that had an impact--any may still be having an impact on the agency--were the Kennedy hearings during Mac Schmidt's regime as commissioner, where allegations were made by a number of aggrieved Bureau of Drugs employees, that a number of things weren't being done right and that the health of children was being jeopardized by some of the drug approvals. A whole series of things. Those took more steam out of Mac Schmidt than most anything. I think if Mac hadn't had those kinds of hearings, he would have been a very effective commissioner. But that just turned him into knots. He had great help out of the chief counsel's office in terms of Bill Vodra. It still was a turning point.

I shouldn't say 'a turning point.'" But clearly, it was a significant set of hearings-- when you had, for the first time, large numbers of employees coming up and criticizing the agency openly. There have been a few in the past, but nothing like this. At least I'm not aware of them. Are you, Ron?

RO: No.

RW: I think that was a major set of hearings. I skipped over one. I think the hearings back in the late 1960s, before Paul Rogers, on the Kinslow Task Force Report, on the problems with the agency, were another significant set of hearings in the fact that it did have some impact on where the agency was relocated out of CPEHS. How it related to the department was undertaken at that time.

You can pick out a hearing here, a hearing there, that would have some impact on the agency. Oh, my. I can't quite remember. I think one of the ones was the Fountain hearings, or was it Zomax where allegations were made that a number of deaths had occurred. Am I right, Ron? Zomax, right? But these had not been reported by the firm. We knew nothing about it. Other people had data. They presented that at the hearing. The agency had been working with the firm to revise its labeling and to do some things. During the hearing, it became evident (at least to the firm and to FDA), based on information from Europe and Great Britain, that there were a number of adverse reactions that we should have known about but did not. So the firm stopped marketing. I think that did a number of things. One, it pointed out that our adverse drug reaction system in the agency was not what it should have been. That's gotten beefed up now under Gerry Feist. That is a very viable, ongoing, aggressive operation. It also put the drug industry on notice that they'd better damn well start playing straight with us and get their own house in order a little bit better. I think that was a significant hearing.

It depends on how you look at it. I think the hearings on sodium or salt in food, in terms of public health protection, probably have been very important over the last four or five years. I think there's no question about that.

I think that another area, going to the drug side of it, is the series of hearings that probably started back in 1981, maybe 1982, that dealt with pharmaceutical innovation and patent life. One of the things that has come out of that has been the bill passed in 1984 which became Public Law 98417, which is the Patent Term Restoration and Generic Drug Statute, which allows abbreviated NDAs--my nomenclature may be completely wrong now--for generic equivalence of drugs on the market. It could have, over ten to twenty years, a tremendous impact on people buying drugs because it says to the world, "The generics are subject to an approval system, and they're just as good."

The other thing, as we mentioned during lunch, the bulk of the hearings on FDA are oversight and are critical. Now, I don't know why that is per se, because the agency does a lot of good things. But one observation is that Congress is subject to the whims of the people, of the electoral or electors (whatever you want to call them)--the voters, if you will. The one way that members of Congress can keep their image in front of those voters is by having hearings criticizing somebody. How many times do you pick up the paper and the headline is a good news headline? It's never. It's always bad news that makes the media. I fault the media for this a lot. They play up the bad, play down the good, because only bad news sells; good news doesn't sell. The way Congress plays to that is to find out that somebody isn't doing their job quite right in FDA, call up the media, tell them, "So-and-so is not doing the job. He's let three food additive petitions go without adequate safety tests," or "He's approved an NDA that only had ten patients in it, and it should have had a thousand. And we're going to have a hearing." They come up and they film it, and they put it on and go. Congress seeks publicity. The media fosters that.

Hopefully, both House and Senate now being televised (at least in the floor sessions) will begin to provide another side to that story for the public. But I'm not sure.

You can't really say this was a hearing where FDA came up and got patted on the back. However, there was one that stands out in my mind. The issue is still not dead. It involves ourselves and the Bureau of Alcohol, Tobacco, and Firearms (BATF). And it involves the labeling of alcoholic beverages. Dear old Ben Rosenthal was chairman of a Subcommittee on Commerce, Consumer, and Finance of the House Government Affairs Committee. BATF and FDA, as I recall, had an agreement that we worked together on labeling of alcoholic beverages. Apparently, there was a petition submitted to BATF wanting an ingredient listing. They said no. So Ben Rosenthal said, "Well, FDA's got joint jurisdiction. Let's call them up." Sam Fine was the associate commissioner for compliance at that time. I went and saw Sam. He saw what was going to be done.

He said, "We're going to do it."

Would you believe we got a statement which says, "If they're not going to do it, FDA will require it."

Ben Rosenthal, for the first time, really patted us on the back. It's the only one I believe we came away clear winners on. Since then, that's fallen into disrepair because of the courts and the solicitor general's ruling and a number of other things. But those kinds are fun.

AB: Did you have a role, Bob, in any of the reviews made by GAO?

RW: Not really, other than tracking their origin, Jim--trying to get back and see if it came from a member, and if so, what the member was really about. No. Those have been under Gerry Meyer's jurisdiction--the actual interplay with GAO all the time. However, I understand that's changing now and my old office is going to have it. But I don't know for sure.

RO: Probably because a number of them are initiated by Congress.

RW: And also, they have fallen off, too. You raised a good question, Jim, because GAO (an arm of Congress) is an investigative body. Albeit, they don't have people who really have too many smarts in some things--particularly FDA things. So it does make some sense to have it associated, Ron. But the number of GAO audits, as I understand it, in the last three years have fallen way off in FDA.

AB: I'm not sure that's correct.

RW: Is that right?

RO: It was on the increase before I left. That's interesting.

RW: Yes. But they've got a new one out. Doug Bernard from Georgia, chairman of the old Ben Rosenthal committee we just talked about, has requested GAO to do a pilot study on the safety and health effects of fish and shellfish. They are to talk to the National Marine Fisheries Service folks, states, and industry. That letter did not mention FDA yet.

Jim, going back to your point about GAO--Congress would initiate a study, monitor the hell out of GAO as to where they were. And when they got ready to finalize a report--in the case of FDA and other agencies, too--the committee that asked for it would say, "Okay. We'll have a hearing. Now don't you give that report to FDA until the day before the hearing or until the day of the hearing." So we'd go up there and be hit in the face with something we hadn't seen.

RO: The one that I remember, GAO at least gave us additional resources--back about 1972.



RW: Yes, that's right. On food inspection. Mr. Jamie Whitten.

RO: Yes.

AB: Food sanitation.

RW: I'm trying to think of some other ones, Ron. For a while, we were running hearings about one every two weeks or so. They all kind of fade together sometimes.

Some of the people that stand out were dear old John Moss from California, who chaired the Oversight Committee of the House Interstate and Foreign Commerce Committee. He was a great man with the gavel. He did not tolerate one bit of nonsense by a witness. I remember some of our witnesses getting gaveled down. We always made it a practice, from Peter Barton Hutt on, to have an attorney with our witnesses. I remember on more than one occasion that John Moss, as chairman of that subcommittee, after people were introduced, would turn to our counsels and say, "For what purpose are you here?"

(Interruption)

RW: "To advise my client, sir."

"You are to advise your client only on things concerning self-incrimination. You cannot sit here and interpret the law that you, Mr. Commissioner, are responsible for enforcing."

I think another key hearing was (as much as I hate to give credit to him) the hearing that Ted Weiss held on E-Ferol. In getting ready for that hearing, it was my view--and I think it was shared by others--that the agency had made a mistake. Dr. Novitch, to his credit from my perspective, shared that view.

RO: Excuse me, Bob. What was involved in that E-Ferol hearing?

RW: It was basically a failure to report, as I recall.

RO: Was this the one that was involved in this firm marketing what we considered was a new drug and they didn't think that it was a new drug?

RW: It's caught up in that. It's also caught up in the review of the DESI review. That is, the Drug Efficacy Review of the pre-1962 drugs that we were told by Congress to go back and look at the data. That is not completed. Until that's done, we aren't taking action or making determinations. In order for a drug to meet that, it's got to have the same labeling, as I recall, and indications, and same wording, and everything on it as it did when it first came on the market.

AB: We knew this product didn't have an effective NDA.

RW: Yes.

AB: We knew the firm was marketing the drug and also knew about some injuries.

RW: They knew about some, but there was also more failure to report by the firm.

AB: We didn't look too good either.

RW: No. That's what I'm saying. When that application or piece of paper came in, it was reviewed against the criteria that were in place at that time for saying, "Yes, it fits the old thing. No, it doesn't. Therefore, it's got to have a new drug application." I think it's clear we made a mistake when we said, "It fits the old criteria." It should have been labeled immediately as a new drug, and not put on the market until they had an NDA approved. It was a problem for infants.

AB: It had been on the market a long time.

RW: Yes, I think you're right, Jim. So Weiss had a hearing. It's the first time that I can recall that the agency went up and said in essence, right smack out of the box, "We made a mistake." That killed the hearing. The agency is so recognized by the Hill of coming up and defending itself to the point of saying in essence, "We FDA never made a mistake." When somebody attacks us we circle away, and then, boy, we just shoot them dead."

The easiest way to stop bad publicity, to kill a hostile hearing, is to once in a while tell a committee chairman or somebody up there, "Yes, we didn't do it right." It doesn't have to be done every day, all the time. Just once in a while. We're human. I don't care what you talk about. FDA's made up of humans and we act like humans. We are not infallible. We've got to admit that publicly from time to time.

We did almost the same thing with Mr. Fountain and Peter Barton Hutt way back on another hearing where they were going to indict us by a whole series of questions that went on for fifteen pages. Thanks to Peter Barton Hutt and a couple of the rest of us, we had kind of played out the possible scenario and asked ourselves some of the same questions--not exactly, but in the general areas. During the hearing, all at once, some of the questions that we had dreamed up began to show up. Peter was very fast on his feet while he was sitting there. Anyway, he began giving an answer for the fourth question ahead. We could pretty well predict what it was going to be. That threw them all off. They just threw up their hands.

So there are lots of little nuances that you can pick up to do. But you can't do it all the time. You've got to pick your spot to do it. It's a fascinating game with the Hill. I think the agency in Hugh Cannon has got a pretty decent guy there. With the staff that's there, he's got good support. But it's not going to go away. The agency's got to remember that. They cannot ignore Congress. I think Gerry Meyer and others will say from time to time, "I'd like to tell off so-and-so where to go."

And Gerry will say, "Yes, I'd like to, but I can't." Because they'll get you. They hold the money strings. When you go up to a hearing, they hold all the cards. It's a hard thing for people with strong personalities and egos to learn to deal with up there. But it can be done.

RO: Bob, is there anything else you want to add--either about the hearings or your career in FDA? Jim, do you have any other questions?

AB: No. I think we've pretty well asked the questions I had in mind.

RW: You didn't quite get the answer you wanted. (Chuckles) I'm not sure you got any of the answers.

AB: What do you say about the future of FDA?

RW: Oh, boy, Jim. That's a big one. I'm concerned about the future of the agency. It's something that's been discussed. I can do it, frankly, because I'm overage, too. The agency is aging in terms of its people. Given the constraints on recruitment that have occurred in the last four or five years, coupled with the Gramm-Rudman stuff, we're not recruiting the number of young people we need to. You're given another spur by Congress and the administration in terms of attacking the civil service retirement system. I would not be surprised to see even more of the older folks in the agency moving out like Paul Hile did this year. I think that is a very serious problem. How to overcome it, I don't know. With that kind of aging going on, you begin to get . . . I was going to say you lose your zeal for fighting somewhat, but I'm not sure that's the case. But without a steady influence of fresh, young, bright people, the agency is not going to have the vitality that it has had.

AB: I think you can address that to the government as a whole. With the environment today . . .

RW: I agree with you, Jim. However, there are a few places where I think they are attracting some people. I think the Sea Grant Program in the National Oceanic and Atmospheric Administration (NOAA) has had some influx of money, and some exciting things to do, bringing in a lot of young, bright scientists. I think that's one thing that FDA has never had, maybe never will--an image as an exciting agency, on the threshold of new frontiers of science, if you will; when, in fact we are that, but we haven't gotten that message out.

I'll go back to Congress. Maybe this is one of the things, among others, that I can be faulted for. Ron, you mentioned some time ago about dealing with the staff up there--very hard to get support for FDA across the board. FDA does not give money away like NIH does, like USDA can give money away. We're more likely to take it away. That's one of the things that is so nice about Paul Rogers when he was chairman of that subcommittee. We would do things in his district, but he had the understanding and good grace to know that we were enforcing the law. Many members of Congress don't take the time to understand that. While they'll support us one day, the minute we tell them the next day, "Hey, we're closing down a plant in your district because it's filthy," that hurts because it costs that member votes, because there's people out of work and he didn't do anything about it. So I guess the word I was looking for is: I don't ever envision FDA having a lobby in Congress like NIH, like NOAA does, like Sea Grant does, like USDA does. Because what we give them one day, we'll take away the next. We're walking a very fine line. Few people on the Hill really respect that and understand it. Those few that do don't say much about it. It's much more sexy to say, "I got a \$250,000 Sea Grant for my college down here."

AB: I think the role of the agency, or at least the emphasis, is changing too, and if we were able to hire more people now, I think that more of the people would be hired at headquarters than in the field.

RW: Jim, I've got two concerns among many others. One is the point that you make--the dichotomy in numbers between headquarters and the field. Clearly, the field is where the action is, where consumers are being protected; while, for the most part (and I was part of it), the Washington scene is a bunch of paper shufflers.

AB: Yes, but it has to do with pre-clearance and close surveillance now. Those are the two things that the commissioner has emphasized.

RW: Yes.

AB: Not going out and making a sanitation inspection and a drug inspection.

RW: No. That's what I'm saying. That concerns me. The second one is--and this has been for twenty years almost--the discrepancy between resources that are being dedicated to drugs and those being dedicated to foods. When I look at the numbers that have been put into the Center for Drugs and Biologics vis-à-vis the Center for Food Safety and Applied Nutrition, it scares me a little bit.

Sandy Miller said something, I think, a year and a half or two years ago that's very, very true: "All the talk about chemicals in foods being hazardous to your health doesn't seem to be panning out. Those levels we're finding are not very high. What scares the living daylights out of me are all the new bugs we're finding in foods."

That, coupled with the fact that you eat food three times a day--you sure as a devil don't take drugs three times a day--just bothers me that foods have suffered. When I say "foods," I'm talking about across the board, in the field, and everywhere else. It's not gotten what I think is its fair share of the resources given to the agency.

Jim, your point about Frank Young talking about things . . . You're right. They're all headquarter's activities. And that's wrong. In my book, that's absolutely wrong. Sure, those things have got to be done, but that's coming from two pressure points. One is from the drug industry which wants to make money and get approval. And the second is to help the drug companies monitor their experiences with drugs so they don't get caught in the same bind as the firm did with Zomax.

How do you see it, Jim?

AB: I think you can see the influence of the field has decreased over the years significantly.

RW: Yes. I've seen it, too, you know.

AB: And the regulatory function and the time spent on it is less and less each year. There is much more emphasis on getting correction. There are many ways to get correction.

RW: Yes.

AB: It doesn't always have the same impact. You have recall after recall. I think if you've had seizures or prosecution you would have more of an impact on the people involved.

RW: Health fraud, to me, is a good example of that, Jim. I think if we had brought a good, hard case five years ago on a big firm it would have had more of an impact than the kinds of things that we have been doing.

AB: One of the problems today is you have a real good case, but then you send a regulatory letter or you have a meeting with the firm. They make partial

corrections. They don't correct everything you wanted done, but they correct enough so you don't have a good case anymore. You cannot get the rest of the corrections that you want.

RW: I believe in telling people that they've done wrong and giving them a chance to correct. But I think you've got to draw the line someplace and just crack down on them.

RO: Do you think we've exhausted things?

RW: I could go on for another five hours, but you two want to get out and go to Fall River and to Boston. No. I think we've covered a lot. I'm sure I've missed several very significant things, but I can't think of them right now, Ron.

RO: This doesn't necessarily close the record. Because what we'll do now is get these transcribed. They'll be sent back to you for corrections and accuracy. If you see things that you've missed, we can add it then. Or if there's enough, we'll be glad to come up and have another session.

RW: All right. I enjoy having sessions--at least having folks come in and see us.