Winton B. Rankin

HISTORY OF THE
U. S. FOOD AND DRUG ADMINISTRATION

Interview between:

Winton B. Rankin, Retired

Deputy Commissioner of Food & Drugs

and

Dr. James Harvey Young
Robert G. Porter

Zebulon, North Carolina

September 30, 1980

INTRODUCTION

This is a transcription of a taped interview, one of a series conducted by Robert G. Porter, who retired from the U. S. Food and Drug Administration in 1977.

The interviews were held with retired F.D.A. employees whose recollections may serve to enrich the written record.

It is hoped that these narratives of things past will serve as source material for present and future researchers; that the stories of important accomplishments, interesting events, and distinguished leaders will find a place in training and orientation of new employees, and may be useful to enhance the morale of the organization; and finally, that they will be of value to Dr. James Harvey Young in the writing of the history of the Food and Drug Administration.

The tapes and transcriptions will become a part of the collection of the National Library of Medicine and copies of the transcriptions will be placed in the Library of Emory University.

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DATE: Sept. 30, 1980 PLACE: Zebulon, N. Carolina LENGTH: 246 Min.

INTERVIEWEE	INTERVIEWER
NAME: Winton B. Rankin	NAME: Robert G. Porter
ADDRESS: [redacted]	ADDRESS: U.S. Food & Drug Admin.
[redacted]	Denver, Colorado

FDA SERVICE DATES: FROM 1939 TO: 1969 RETIRED? Yes

TITLE: Deputy Commissioner of Food and Drugs
(If retired, title of last FDA position)

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BP: This is a recording of an interview with Winton B. Rankin, retired Deputy Commissioner of the Food and Drug Administration. The interview is taking place at Zebulon, North Carolina on September 30, 1980. Present, in addition to Mr. Rankin, are Dr. James Harvey Young of Emory University, and Bob Porter.

BP: Winton, I would like to start out the interview, if you don't mind, by asking you to give us a thumbnail sketch of your career in the Food and Drug Administration.

WR: Bob, I came with the Food and Drug Administration in 1939 as a Seafood Inspector. I was assigned on the Atlantic Coast of Georgia and Florida, and then in 1940, I was transferred to Atlanta and then to New York as a Food and Drug Inspector. After two and a half years in New York I was sent to Norfolk, Virginia as resident inspector. From there, I went to Boston, Massachusetts as Chief Inspector and then was transferred in 1946 to Washington to administrative drug work. In 1948, I was made Deputy Director of the Division of Field Operations, the division that then looked over the activities of the field districts. In 1954, I was transferred to the Commissioner's staff as Assistant to the Commissioner in charge of the

pesticides work. We were then implementing a new amendment to the law that gave better control of pesticide residues on food. After that, still as Assistant to the Commissioner, I was assigned to general operations, and for a period of time leading up to the enactment of the Food Additives Amendment of 1958, I was Commissioner Larrick's representative on the Hill, as we sought to get good food additives legislation. My assignment to deal with the Hill continued during the enactment of other items of legislation--the color additives amendment, the hazardous substances amendment, and the amendment dealing with habit forming drugs, barbituates, and amphetamines--I don't recall the technical name. I became Assistant Commissioner for Planning then Assistant Commissioner for Legislation and, in 1966, under Dr. James Goddard, became Deputy Commissioner, a post that I held until late 1969, when I was transferred to the office of the Assistant Secretary for Health and Scientific Affairs of the Department of Health Education and Welfare. I retired in February, 1972.

BP: When you came in the Seafood Service, who were some of the people that came in during that period, that later we all know?

WR: Well, I don't know that they came in at exactly the same time that I did, but some of the Seafooders were Lowry Beacham, I believe he preceeded me a little bit, Shelbey Gray, Allan Rayfield . . . I'm not sure whether Jim Pearson came in that way, I believe he did. Chet Hubble, I recall was a Seafooder. Quite a crew of folks came in in those days. That was the tail end of the Depression, you know. The salary that the government paid its Seafood Inspectors looked mighty good in those days.

JHY: You had finished Pharmacy School shortly before?

WR: Yes, I had.

JHY: And you attended?

WR: Ferris Institute, now known as Ferris State College, in Big Rapids, Michigan. I was working in a drugstore in Wilson, North Carolina, just a few miles from Zebulon, here, when I got a telegram from Bill Wharton, the Chief of the Eastern District, saying report for duty in Brunswick, Georgia on a given date. It was only about 3 days later. So I quit my job in the drugstore and piled my few belongings and my wife into the car and we drove down to Brunswick to see where I was going to work for the Federal Government.

It was at a seafood packer known as L. P. Maggioni & Company. I'd never heard the word before, so I went around Brunswick asking where the Maggioni (pronounced with a hard g) plant was. It took some time before I hit into a man who could interpret my question. They sent me down to the Maggioni Plant, this was on a Saturday afternoon; the plant was closed down. It was about as weatherbeaten, run down, an old frame structure as you've ever seen. I came within an ace of turning around and heading back to Wilson, North Carolina to see if I could get my job back as a pharmacist, but fortunately I stuck it out, and didn't have to stay at the Maggioni Plant too long after all.

JHY: Now, many of the inspectors who came in through the Seafood group were Southerners, because of the nature of the responsibility under that Amendment.

WR: Also because the salaries in the South for college graduates were not very high so that, whereas some of the folks in the Northeastern states could get jobs that would pay them essentially what the government was paying or even a little more, it was hard to get a job like that in the South. Even the folks that had masters or PhD degrees. We had a bunch of PhD's under the Seafood Service, during one period of time. Henry

Fishback came in that way. I believe he got his PhD later.

JHY: I've been interested in North-South sentiment and the interface between people from different regions. I wonder if you, as a Southerner who came into the Food and Drug Administration in the South at a time when a great many were coming in through the South, and who then went on to national leadership within the Agency, have any feeling in connection with the way you were viewed as Southerners within an agency which, when you came in, was more dominated in the leadership by Northerners. Was the regional legacy a source of any kind of tension or misunderstanding in any sense at all?

WR: It may have been for some of the fellows; it was not for me at all. I grew up in the mountains of western North Carolina where even the old-timers didn't worry too much about the Civil War or its aftermath. They didn't get too involved in that part of the state. So I didn't have the strong feeling of apprehension, you might say, that some of the fellows did when they were transferred to the Northern Districts for work. No I didn't have a bit of problem.

JHY: And you'd been at school in the North.

WR: I'd been to school in the North also. So it was not a traumatic experience for me. For some folks I believe it was.

JHY: Can you remember any incidents or examples of this that lead you to the conclusion that it was for some folks, traumatic or is this just a residual impression?

WR: Oh, there was a fellow that was assigned up in Buffalo, and I don't recall his name right now--who found life in Yankeeland so distasteful that he resigned after very few months up there. A pretty good inspector, but he didn't like the North.

JHY: It wasn't because of hostility; it was because of a different environment . . . or, do you know?

WR: I was not assigned in Buffalo at the time. So far as I know, it was not because of outright hostility. He just didn't like the North.

JHY: Can you decribe any incidents that are memorable from your early days in the Seafood Inspection that illus-

trate the nature of the Seafood Inspectors tasks. The kinds of problems that caused that amendment to be passed, and so on?

WR: The problems that arose in the seafood industry, and I'm speaking now about the shrimp canning industry almost entirely, were problems of insanitation and failure to maintain the quality of the product by applying enough ice between the time the shrimp was hauled into the boat and the time that it went into the can in the cannery. The seafood packers along the Gulf and South Atlantic Coast were putting up a pack that was just plain rotten and insanitary. And, for a period of time, this was in the early 30's, before I came in with the government, the Food and Drug Administration was seizing about half the pack of shrimp. The canners couldn't stand that; they said we've got to have some relief. The relief that was worked out was a law--the Seafood Amendment which provided that the Food and Drug Administration could furnish continuous inspection service to oversee the canning process and be sure that the final product was a good one. Each canner bore the cost of inspection at his plant. So, as soon as that law passed, some of the canners began signing up for the service. The Food and Drug Administration put on a big recruitment campaign to get people who could inspect shrimp. I'd never seen a

shrimp in my life before I was hired as a Seafood Inspector, but it doesn't take too long to learn what one of the little animals looks like. At that time the kind of shrimp being caught off the South Atlantic Coast fortunately looked gray when it was fresh and turned pink when it got too old. So you didn't have too much trouble telling when the raw material had gone bad. The Seafood Inspector had absolute authority over the seafood plant. No shrimp could come into the plant off the boat unless the Seafood Inspector approved it, and no canned product could leave the plant unless the Seafood Inspector signed a certificate of quality entitling it to leave. You can imagine that, with that kind of authority, and with a bunch of youngsters still wet behind the ears, there were some pretty rough conflicts. We were dealing with Portuguese fisherman and with Italian and Portuguese plant operators who didn't like to be told what they could or could not do, especially when a few tons of rotten shrimp were involved that would be worth thousands of dollars if the inspector would just let them come on into the plant and be canned. So there were occasions when you wondered, as Seafood Inspector, whether you were going to end up in the drink, being pitched off the dock when you told some Portuguese shipowner, "you can't unload those shrimp,

you've got to dump them". Fortunately I never did get thrown into the drink. We also dealt with some of the help in the plant. Really we weren't supposed to. You were supposed to say to the plant manager, "now you take care of this". It was easier, especially in dealing with the southern plant workers that recognized you as a fellow Southerner, to go over and say, "Hey, order some more ice, the ice is getting low". So I think we stretched the point a little bit and maybe helped run the plant once in a while. It was interesting work, but I was glad to get out of it when I did.

RP: It was probably before your time, but why did they go the route of the Seafood Inspection Service instead of maybe following what they did on the Alaskan salmon, shortly after the first World War, where it was an industry operated sort of inspection service?

WR: I think the reason would be the character of the people, the plant operators. In Alaska, as I understand it, there were a group of canners who could be depended upon once you told them what needed to be done, to do it voluntarily. We didn't have that on the South Atlantic Coast and the Gulf Coast. The operators, some of them at least, were rather unsavory

characters, and they'd get by with anything they could. I don't believe it would have been possible to put in a voluntary service on the shrimp canneries that would have accomplished the purpose.

JHY: Ultimately, the level of the industry got so elevated that they were able to stop the system.

WR: Yes, there is no Seafood Inspection Service now. It got to the place that the canneries didn't need the government help. That was a few years later.

RP: It was voluntary in the sense that they didn't have to subscribe to this seafood inspection.

WR: The law said it was voluntary, but in practice it was an absolute requirement for a period of several years because the larger food distributors would not buy shrimp without a government certificate. So if a man wanted to sell his canned shrimp, he took the Seafood Inspection Service and paid for it.

JHY: And that was a club, that really kept an eye on it.

WR: Yes, yes it was. When the industry improved to the point that the food distributors were willing to buy

shrimp that didn't have the government certificate and the government label, then of course, the service dwindled away rapidly.

JHY: Now it wasn't because of the dwindling of the Service that you left it? You were spotted as a capable man, deserving greater responsibility. Who was it who spotted you and that led to your leaving this service and going on to other things?

WR: Well, the man that took me in for temporary assignment on full-fledge regulatory work was John MacManus, who was then the Chief of our Atlanta Station, we called it at that time, the Atlanta District.

JHY: Will you describe him as a person? We do have an interview with him that I conducted a number of years before his death on tape in which he gives his recollection, but I would like to have your vignette of Mr. MacManus as a Food and Drug official.

WR: Mr. MacManus was a genteel Southerner, who grew up in the North. I believe he was reared in Rhode Island, but he was transferred years before I knew him to Atlanta and, unless you had been told that he grew up as a Yankee, you would never have believed it. He was

sort of a fatherly man, as far as the new inspectors were concerned. He didn't come across as a supervisor that was telling you, now you've got to do this or you've got to do that. He'd come into the inspector's office and pull up a chair and begin talking to you about the inspection trip you were going to take. Just chatting as one inspector to another. The first thing you know, you forget he was the boss. Here was a guy who wanted to help you get ahead and was trying to. I've heard him sit down and start talking to a young inspector before that fellow's first court appearance, at a time when the inspector was bound to be nervous. First thing you knew after Mr. MacManus had talked for a while, the inspector was getting relaxed. Getting rid of some of his tensions. I regarded Mr. MacManus very highly. I corresponded with him until his death. He was a perfect gentleman.

JHY: That certainly coincides with my impression.

RP: You know, in that interview, Harvey didn't have time to finish processing it, so Fred Lofsvold and I finished it in Denver. One of the problems we had was spelling all the botanical words. He was really a specialist in botanical drugs.

JHY: Up here in the mountains of North Carolina . . .

RP: And he still had all the words in his head whenever this occured, and they just flowed out of him. We had a hard time getting references where we could even learn this . . .

WR: He was trained as a pharmacist. He came up in pharmacy at the time that a knowledge of botany and, of course an understanding and grasp of the names was important, so that's why he was throwing all those words at you.

RP: It was interesting that in Denver District there was really not an adequate reference anymore that we could -- we did eventually find them all, but we had to search.

JHY: The books just weren't around.

RP: What references they had had been thrown away over the years.

JHY: He felt worried at times up in the mountains of North Carolina, somewhat like you felt around the shrimp factories. They feared he was hunting bootleggers instead of people who were adulterating the raw botanical.

RP: You know, going back to your question that you asked Winton about the Southeners in FDA, when I came in a few years later, out west, I gradually began to meet people, important people who came out and so on, like Winton, I was fully convinced that everybody that amounted to anything in Food and Drug was a Southerner.

JHY: Well, it is true that a good many of you came in through this seafood group rose into positions of authority in FDA.

WR: Yes, and then after the Food, Drug and Cosmetic Act was passed in 1938, there was a great influx of Southerners. Again, for economic reasons; in the South, you didn't get quite the salaries that you did in the East and the North. So there was a preponderance of Southerners in the Agency.

JHY: The same thing probably was true of Westerners, in terms of their salaries--there just weren't as many people out there, I guess.

WR: Right.

JHY: Did you work on any of the landmark cases in the days that you were an inspector?

WR: One of them. I'm not even sure I remember the. . . oh yes, two or three of them, I guess. There was the elixir of sulfanilimide case which was before my day, of course. And led to the enactment of the Food, Drug, and Cosmetic Act. And then, after that, shortly, we began to find other mix-ups with sulfonamide drugs. One I recall was a case in which sulfathiozole became mixed up with phenobarbitol. I don't recall that anyone was killed by an overdose of phenobarbitol, but the potentiality was there. We had a big drive to get that drug off the market. Where were you then? Do you remember?

WR: I was assigned in New York at that time. I may have left out my -- did I mention my assignment in New York earlier, I guess I did.

RP: You did mention.

WR: Because I was an inspector in New York, and I recall I got sent up in to central New York State, Albany, Troy, Syracuse. To see if I could apprehend all the supplies of that drug in that area. We did pretty good; the State furnished some people to help. We

just went into every wholesale drug house and, with the assistance of the wholesaler's personnel, when he'd give it, or without it, if necessary, we went through every invoice over a period of about six months.

JHY: This was one company?

WR: One company, yes. Looking for sales of sulfathiozole. We traced everything down except one bottle of 100 tablets. I began asking the wholesaler when we couldn't find that, well how could that bottle get out without your having a record? He says every day we have a dozen or even some days several dozen drug-stores that get out of supplies and they send somebody over here to make a cash purchase. And that's what happened, somebody made a cash purchase of sulfa-thiozole tablets that didn't get on our books. For-tunately, I reported that we had missed one bottle of sulfathiozole tablets, and I told why. Didn't hear anything for six weeks, and then the other publi-city--there was a great deal of publicity surrounding the case--led a druggist to turn in most of a bottle of 100 sulfathiozol tablets from near Albany, New York.

JHY: Do you remember the name of the manufacturer?

WR: I beleive it's Winthrop Laboratories, but I would wish that name checked, because I am not absolutely clear on it.

JHY: This is the quickest way to find the reference in the file.

WR: I think it's Winthrop. Well, Bill Wharton, the Chief of the Eastern District was absolutely incensed that one of his inspectors went out on an important assignment like this and muffed it. So he said, "Who was responsible for Albany, New York?" Winton Rankin. Bill sent Olie Olsen, the Chief Inspector of the Eastern District on the trail of Winton Rankin to take a piece of his hide out. And I said wait, Olie, I reported it, I told you I couldn't find it. Olie said, "You did?" So I pulled my copy of the report out and I showed him. He said, "I'll be damned." He went back and said, "Bill, he didn't muff it, if there was any muffing, we did, because he reported it." There wasn't any way you could get the doggone thing, but that convinced me it was wise to tell the whole truth when you're writing reports on Food and Drug matters. There was another case, and my involvement in it was down here in Raleigh, North Carolina. Merck put out

a preparation called Doryl. It was a muscle relaxant. It was used by opthamologists in the eye. And it was used by internal medicine men to give good relaxation under certain conditions. The preparation for intraveneous use was one tenth the strength for eye use. The Doryl for intraveneous use was put up in a little ampule, glass ampule. Break the neck of the ampule off and get your medication out. Unlike the one dose vials that you have now, or one dose needles. The preparation for opthalmic use was put up in a little vial that looked almost like the one for intravenous use, except that it had a screw cap. And the labels on the two products were similar in color and general appearance. What happened was that occasionally, a doctor would prescribe an injection of Doryl for his patient. The nurse would rush into the drug room and grab the wrong vial the one for opthalmic use, and inject ten times too much Doryl and the patient was gone. It killed him. All of us who were working on the Doryl matter were asked to be alert for injuries and deaths due to Doryl and we documented them when we found them. I was in Rex Hospital over here in Raleigh chatting with the pharmacist who had taken the state board the same time I did. We did not have a record of a shipment of Doryl for opthalmic use to Rex Hospital. So I wasn't even inquiring about this investigation. He said, I guess you heard about

this accident we had here recently. I said no, I don't believe I did. Yes, he said, one of the doctors killed a patient with Doryl. I said, the heck he did. How did it happen? Well, he said there were two patients, under the care of a urologist. They needed muscle relaxants. In this case, it was an intern, not a nurse, who decided that he would administer Doryl. He picked up the opthalmic vials, the ones with the screw cap, walked into the room where these two men were in bed, one bed beside the other. He drew out an injection of Doryl and administered it to the first patient, who stiffened, groaned, and died. The second man looked over and said, you ain't giving me any of that stuff doc. The doctor went absolutely to pieces. He began stating out loud that, "I killed him, I killed him". His supervising physician got hold of the vial; put it in his desk drawer and tried to get everything quieted down. In fact, I thought later he was trying to cover it up completely, but with the knowledge that such an accident had occured, and when it occured, it was possible to get the facts and even get the empty vial the doctor had put in his desk drawer. We prosecuted Merck & Company for that situation, the similarity of the drugs, the drug appearances. Oscar Ewing was the General Counsel for Merck & Company when we brought the prosecution. He believed and the firm believed very strongly that

there had been no violation of the law. But the government prevailed. And then it wasn't too long before Oscar Ewing was named Administrator of the Federal Security Agency in which Food and Drug was located. Matters were a little bit tense between Oscar Ewing and the Commissioner for a while after he came in. Though Ewing did say when he arrived, "Now the past is over, I'm no longer General Counsel for Merck. I didn't agree with the prosecution, but I'm not gonna hold it against you." However, he was very firm with Food and Drug for a while. He wouldn't tolerate any deviation from his instructions.

JH: Do you remember in connection with Ewing, the story, the feeling within the Food and Drug Administration, that, in connection with the Castleberry Case, I think it was, that involved Nutralite, that he compromised the case, he negotiated a settlement with the lawyers of the company in such a way that it undercut the Food and Drug Administration's ability to deal with nutritional supplements?

WR: I'm aware that the Mytinger and Castleberry decision, the negotiated settlement, did hurt Food and Drug's ability to deal with nutritional supplements that were

promoted too vigorously. I'm not aware that Oscar Ewing was responsible. I was not intimately associated with that case, but I think what happened was that the government witnesses, the nutritionists upon whose testimony the government case was based, had written articles for scientific journals that extolled vitamins for much the same purposes for which Mytinger and Castleberry promoted them. Thus, the government couldn't negotiate a better settlement.

JHY: That was the story that you heard.

WR: Yes.

JHY: I had heard a story that was a little critical of Mr. Ewing, I think, although this was all gossip and rumor.

WR: I also heard such a rumor. Now, my information, I believe comes largely from Bill Goodrich. Bill was being criticized by one of our scientists one time for the settlement that was negotiated and he said, "With the testimony that your fellow scientists gave, and the articles they put in the scientific literature we couldn't negotiate any better settlement." I accepted Bill's version at face value.

JHY: I'm glad to have your version of that because that does help in an area which is still a very significant area.

WR: Now Bill could have been covering for the secretary, of course, I don't know whether he was or not.

JHY: Well, I got you off the track.

WR: Oscar Ewing, as I mentioned was pretty firm with the Food and Drug Administration. He was the administrator when we were getting into the over-the-counter sales of prescription drugs area. A time when the Federal government was first beginning to exercise its jurisdiction over the retail druggist who mishandled dangerous drugs that were received in interstate commerce. The pharmacists of the country, the Pharmaceutical Association, were horrified that the federal government would even think of applying regulatory activity to the retail druggist. They brought great pressure to try to put a stop to it, to try to get Food and Drug out of this activity. They asked Oscar Ewing to stop it. Oscar Ewing directed George Larrick to stop it. Larrick decided that the issue was important enough so that we couldn't back down, so we continued our over-the-counter activities. We brought a case, I don't remember which one it was, that came to

Ewing's attention. And when he found that Food and Drug Administration was still involved in over-the-counter work with retail drugstores, he called Larrick in and said, "Now Larrick, I've told you to stop this foolishness, and I'm telling you now, if you don't stop it, I'm going to fire you." It wasn't long after that that the leadership of the Federal Security Agency changed. Oscar Ewing was out. Food and Drug Administration continued with its over-the-counter activities. A work that has lead now, of course, to the establishment of a new agency, the Drug Enforcement Agency made up from the old Bureau of Narcotics and the Bureau of Dangerous Drugs.

JHY: Are you saying that this was happenstance? Or was there some causal connection between the difference of opinion on this issue between Mr. Larrick and Mr. Ewing? Was he out and replaced because of this issue?

WR: No, no, that was by chance. That difference of opinion had nothing to do with Oscar Ewing's replacement. Oscar Ewing was supposed to form a department out of the old Federal Security Agency, but the medical profession and other important people believed that he was taking the first step toward socializing medicine. I think that's what got him out, no difference of opinion with Food and Drug.

JHY: It might have been interpreted . . .

WR: If it hadn't been explained. I think some of the most interesting work that I did, this was not while I was an inspector, had to do with drug recalls. It's customary now for the government to require recall of a dangerous drug. That was not customary when I came into the Agency. Only if you had an overwhelming problem, such as the olives with botulinas toxin or the elixer of sulfanilimid--something that was killing people--did the government get into a full- fledged recall activity. Starting shortly after I came into the Agency, and so far as I'm concerned, starting with this sulfathiozone tablet that was contaminated with phenobarbitol . . .

JHY: You were in New York in what year?

WR: I was transferred to New York in 1940, the fall of 1940, and I was there for 2-1/2 years.

JHY: So it was during that period that this episode occured?

WR: Yes, probably in the Spring of 1941. The realization began coming home to us that there were a lot of pro-

blems that arose in the drug field and later we found in the food field too, which might not be killing people, but which were potentially dangerous. Problems that warranted the complete removal of an offending product from the market. So, over the period of years in the early '40's, we had, I would guess, from 2 or 3 up to half a dozen recalls per year. Starting about 1948, when the Division of Field Services was formed, we began pressing recalls a little bit harder. This was when Dr. Paul Dunbar was Commissioner. We required the recall of a number of drug products. Dr. Dunbar began using press releases to alert the public to the existance of unfit material on the market. We sort of worked this recall business into the standard operating procedure of the Agency. It got to the point that we were having around 40 or 50 recalls a year there for a while. I think it's probably dropped off a little bit since then. Of great interest to me is the fact that this initial work by the Food and Drug Administration, in some small way, I believe, is responsible for the auto recalls that we are having today. It came about this way--there was a young attorney by the name of Jerome Sonosky, who was brought into the Department of HEW about the time the Food Additives Amendment was under consideration (that would be '57 or'58). Jerry Sonosky was serving as liaison between Abraham Ribicoff,

who was then Secretary of HEW and Capitol Hill. Ribicoff got out as Secretary of HEW to run as Senator from Conneticut. He won. He was looking for somebody to help him out on his staff, so he tapped Jerry Sonosky. Jerry told me later that they were talking one time about a bill that the Senator was thinking about sponsoring dealing with the auto industry. And Jerry said, "Well, Senator, you ought to put into that bill a provision that, when the auto industry manufactures a defective car, it has to recall it and correct the defect." Ribicoff says, "Jerry, you don't mean to say that there is any routine manufacturing of defective cars?" Jerry said, "Yes I do. You'll find that there are thousands of them, if you'll just put that provision into the law." So I have told myself that, because Jerry Sonosky had dealt with Food and Drug and knew how we deal with defective drugs, I think he was able to convince Mr. Ribicoff that the auto industry ought to be subject to the same provision.

JHY: So there was a precedent.

WR: There was a precedent, yes.

JHY: If I remember rightly, he was still around when the 1962 Kefauver Law was under consideration.

WR: Sonosky?

JHY: Yes.

WR: You were right. I gave the wrong date a moment ago, it was not the Food Additives Amendment he was concerned about, it was the Drug Amendments of '62.

JHY: When he became acquainted, so that the automobile law must be adjusted to that date?

WR: It would have come after '62, after Ribicoff became Senator.

JHY: And that was, of course, shortly after or about the same time that Ralph Nader wrote the book about automobiles.

WR: That ties right in.

JHY: Right. Where were you when that 1962 law came along? Were you in headquarters when Senator Kefauver began his investigation right at the very end of 1959?

WR: Yes, I was. I was Assistant to the Commissioner.

JHY: That's what I though I remembered. Were you present when Senator Kefauver came to the Food and Drug Administration? Do you remember?

WR: Yes.

JHY: Can you describe that episode as you recall it?

WR: The Senator said that he wanted to come down and talk to the Commissioner. That was an unusual request. Ordinarily a Senator phoned down or had his staff phone down and say, "You come up and talk to me." Senator Kefauver and John Blair, his staff economist, and two or three other people came down to visit Commissioner Larrick in his office. The Senator talked about the drug industry; about his belief that the drug industry was essentially a monopoly and needed control; about his desire to introduce legislation to grant some control over the economic aspects of drug distribution. Dr. John Blair did a lot of talking. I think he talked as much as the Senator, maybe more. What it amounted to, as I recall now, it's been a a long time since I've even thought about that situation, was that Senator Kefauver was asking Commissioner Larrick to support him in the introduction of legislation to deal with the economics of the drug industry. Mr. Larrick was polite and as noncommital

as he could be. He didn't want to get into the economic aspect of drug regulation at that time.

JHY: I have some recollection from other aspects that it was, as you say, primarily to Senator Kefauver, an economic issue when he came to the Food and Drug Administration. But, as a result of that conference, he first realized the health problems as apart from the economic problems that might be unsolved at that time in connection with prescription drugs. He went away from that meeting alert to the fact that, if he was going to pursue an investigation of drugs, he couldn't solve problems if he remained solely within the economics sphere, but he had to go into many aspects regarding health and promotion. Do you remember the conversation having aspects like that?

WR: Another one of the staff people that came with the Senator was Irene Till. I believe that Irene Till and John Blair were pressing ahead just as hard as they could on the economic aspects of drug regulation. Commissioner Larrick indicated to them that he did not believe that was an area that the Food and Drug Administration belonged in--that our area was health. I do recall that there was a discussion of health, and it's entirely possible that the Senator concluded that, if he incorporated health aspects under this

legislation, he might be able to get the support of FDA and the Department of HEW. You'd need to talk to others about that.

JHY: I just wondered if you did remember that, because, in fact, when the investigations did begin, the problems of the promotion and the problems of the testing--what was required in order to test drugs, not only for safety, which was already in the law, but the efficacy, the complex nature of each problem, began to emerge in the testimony. And this was something that the Food and Drug Administration was already recognizing, but they didn't have the legal authority to do anything about it, except that they were trying to apply an efficacy standard as an extension of safety in certain key drugs for life-threatening diseases even before this bill was passed.

WR: Under the new drug provision of the law, particularly.

JHY: Right, right. But they sensed that they did need more authority in order to attack the problem of some of the abuses that academic scientists were already beginning to point to in connection with promotion of drugs. And so I had wondered how pivotal in a chain of events that led to the 1962 law, this particular

visit to the Food and Drug Administration was in Senator Kefauver's mind. You do remember, at any rate, that the health implications of prescription drugs were, to some degree, discussed on that day.

WR: Well yes, they were brought up, I beleive, by Larrick. I wouldn't try to guess how pivotal that visit was for the Senator. The Senator would have made an outstanding poker player--you couldn't tell what was going through his mind by looking at him or listening to his conversation. There was no way I could say whether the particular meeting was the one that influenced his decision to go into the health aspects of drug distribution.

JHY: Let me ask you something about policy, at this time. In a meeting as significant as this, one would presume that somebody would have been assigned to write up a memorandum of what happened. I've run across memoranda when there were interviews between Food and Drug officials and other important figures. Would it be your presumption that, if I could find the place where it was located, that this interview between Senator Kefauver and his staff and Commissioner Larrick and his staff would have been written up and ought to be there for the records. Do you remember whether it was policy to do that.

WR: Oh yes, that was our policy. I would -- I'd guess you're not going to find a memorandum in the file of that particular meeting.

JHY: Why would you say that?

WR: At that moment, Larrick didn't want to have a darn thing to do with Kefauver's bill. He saw it as just a lot of trouble for Food and Drug that was not going to help the Agency. He didn't believe then, and none of the rest of us believed, that there was any possibility in the next few years of getting an efficacy provision in the drug chapter of the law. We didn't believe that we were going to get John Blair to modify the economic provisions that he wanted to write in the law. If there's any memorandum, I expect it's a short one dictated by Commissioner Larrick, himself, simply saying that Mr. Kefauver came down with his staff and discussed some legislation that he was thinking about introducing, and that would be about all.

JHY: Now the irony of it, from Kefauver's view, would be that what he was interested in basically was the economic side of things, but the end result several years later, was a bill which had hardly anything to

do with the economic side of things and had everything to do with the health side of things, except for the promotion, which might be considered economic, but also had its health aspect. So, as I remember, the Department which would have included Food and Drug, got out a competing bill to Kefauver's. Did you have a hand in that?

WR: Yes. I was involved somewhat in that. It became apparent to the Department that Mr. Kefauver had an issue that was attracting a lot of attention. He stood a good chance of getting a bill through Congress, at least he was going to keep on trying as long as he was up there in the Senate. The national administration didn't want Mr. Kefauver to get credit for an important piece of drug legislation. So the directive came down to our department from the White House, I believe, to come up with an alternative bill that we can call the administration bill. I was in on a number of conferences leading to the drafting of that bill.

JHY: With whom were you at the conferences, do you remember?

WR: Well Jerry Sonosky, the fellow that I mentioned earlier, Ted Ellenbogen was a lawyer in the General Coun-

sel's office assigned to legislation, a draftsman, Bill Goodrich was in a number of conferences, Wilbur Cohen in one or two of them, and I believe, on a few occasions, a fellow by the name of Dean Coston who was an Assistant to Wilbur Cohen.

JHY: Was Boisfeuillet Jones still around at that time?

WR: For a while--what would be called now, I guess, the Assistant Secretary for Health in HEW, well I don't recall that he was around at that time. He may have been. If he was, I didn't get in conference with him on this particular subject.

JHY: I think that Kefauver did believe that the White House had stymied him.

WR: Well they tried to.

JHY: On, at least the economic aspects of the bill, at any rate.

WR: They tried to stymie him on the whole thing. They didn't want a drug bill at that time, but when it became apparent that Kefauver was apt to get something, then they wanted an administration bill that was divorced from the economics provisions of the Kefauver legislation.

JHY: Were you in touch with the Congress yourself during the time that that bill moved along?

WR: Yes.

JHY: With whom did you discuss this in the Congress? Do you recall?

WR: Yes. On the House side, the key staff man with the Interstate and Foreign Commerce Committee was Kurt Borchardt. I dealt with Kurt, in fact Kurt almost worked me to death there for a period of a few weeks, when he was drafting and redrafting. I dealt with Alan Pearly, who was the legislative draftsman for the House. There were two or three others, I don't recall just now.

JHY: Were you the conduit for the Food and Drug Administration's views of what would be the best sort of bill?

WR: I was the conduit in part, but I believe Bill Goodrich was also a major conduit. On the Senate side, we dealt with Bill Reedy, who was a staff assistant to Senator Lister Hill, Chairman of the Health Subcommittee of the Labor and Public Welfare Committee of the Senate.

JHY: Would you say that the bill, as it finally was enacted, reflected fairly well the Food and Drug Administration's desire for provision, as of the time?

WR: Yes, it did fairly well.

JHY: The bill, as I remember, at one point, had much tighter controls over over-the-counter medications than it finally came out with. Now that was curtailed during the negotiations. Do you remember anything about that? I mean the industry people were bringing a lot of pressure . . .

WR: We would have preferred tighter controls on over-the-counter drugs, and we did propose stronger controls that were taken out in the legislative process. When you want to get a piece of legislation passed, you have to expect changes as the bill goes through the legislative process. The proprietary drug industry did bring pressure on Senator Kefauver to leave over-the-counter drugs out of his bill and he announced that it was his intent to have the legislation cover only prescription drugs.

JY: Do you remember anything else that was in your draft that did get traded away?

WR: Without reviewing it, I would say--I can give you a little bit of overall insight. The efficacy provision was put in as a trading point, initially. We in Food and Drug doubted that we were going to get authority to pass on the efficacy of drugs in that legislation. Mr. Kefauver grabbed that and began running with it. And it became apparent pretty soon that he might get the efficacy provision passed. About that time, the efficacy provision became a key point of the bill with us, and we were willing to trade other provisions, if we could keep it.

JHY: And of course the thalidomide events bolstered the ability to get the efficacy provision.

WR: That led to the efficacy provision. Without it, we would not have gotten it.

JHY: Right. One of the other things that gets wrapped up in this time period and certainly in the kinds of hearings which began with Kefauver and continued with Humphrey and have continued ever since, that very often became highly critical of the way that the Food and Drug Administration was operating--was the famous episode of Henry Welch--how much of an inside seat did you have with regard to that?

WR: For a period of time there I had pretty much of an inside seat.

JHY: Can you describe the kinds of conferring that went on, the activities that took place when it was revealed that his so-called honorarium really was so great for editing the magazines?

WR: Well, the revelation, of course, was made by Mr. Kefauver at one of the hearings before his sub-committee and Arthur Fleming was Secretary, at that time. Do you remember the day that this happened?

WR: Oh, I sure do.

JHY: Describe your conversations as you remember during the day and the way that your fellow high officials were feeling and reacting.

WR: Well, I was up at the Kefauver hearing, supposed to keep abreast of what was going on and relay the information back to Mr. Larrick. Mr. Kefauver came out with his revelation of the large honorariums that Henry Welch had received. As soon as I could get the information down, I headed back to Food and Drug to report to the Commissioner. It turned out that Mr. Kefauver

had sent an advance copy of the revelations to Arthur Flemming. When I got into the office, the Commissioner wasn't there; he was up talking with the Secretary. I would say that the reaction in Food and Drug was one of shock and almost disbelief. We found it hard to realize that this associate of ours, whom we were very fond of had engaged in activities that could be very damaging to the Agency. The question that was uppermost in our minds at that time, in mine certainly, was not whether Henry Welch would survive, but whether George Larrick would survive. And I believe that was the question in the minds in some of the other people that were associated with him. Mr. Flemming, Secretary Flemming, decided that he did not want to crucify George Larrick, that he just wanted to get Henry Welch out of the Department and then build back from that point. I believe he made the right decision. But, had he decided the other way, there was nothing on Capital Hill that would have saved George Larrick. Flemming could have gotten rid of him at a moment's notice.

JHY: This is speculating because, as far as I know, there never was a complete explanation of this on the part of Henry Welch. Ultimately, it was decided not to prosecute him, although that was looked into, as I recall. Did you ever have any comprehension about why he did this or was it kind of a mystery throughout, as far as his motivation was concerned?

WR: I'm always reluctant to try to tell what motivates a man when I am not sure. The records that I looked at covering a period of some years, from 10 years or more, leading up to the Kefauver revelations, formed a pretty clear pattern of a man that was greedy for money. I don't believe that Henry Welch intended to do anything illegal, but I think he was awfully anxious to get money. I believe that's what motivated him.

JHY: Well the committee that studied it found out that it hadn't affected his administrative decision-making, as I remember--you know, a way that was deleterious to the interest of the public. Although he had written editorials in favor of the combination anti-biotics which, in the long run, scientists generally didn't think so much of.

WR: The committee, I recall, found that Henry's judgment had not been influenced by the money. I don't believe it.

JHY: You don't believe it.

WR: No, I think that was not a correct finding.

JHY: Do you think that it was a little bit of a whitewash, then?

WR: Well, I can't say whether it was an intentional whitewash on the part of the committee. But as for Henry Welch, I don't think a man can go about acquiring the kind of money that he was acquiring using the means that he used without having it influence his official judgment. And the fact that you just mentioned, that he came out in favor of combination anti-biotic therapy against the advice of some of the leading physicians on anti-biotic therapy would be an indication to me that his decisions were being colored, I believe, by his extra-cirricular activities.

JHY: It did bring the whole Agency into question. It did require, of everyone, a form of accounting of their own economic investments and so on that had never been required before. It had always been taken that people had been assumed to be honest without requiring that kind of proof before. Indeed, I think I was early in my research in the Agency at the time and heard a good deal of grumbling among the people at the level of those sitting at the desks near where I was placed for my research, about the demand that they make this disclosure. But, it was decided, I suppose, at the very highest levels, probably by the Secretary himself, that this sort of accounting of everybody had to be . . .

WR: Secretary Flemming made that decision, yes. It was the only decision he could make, under the circumstances. He was trying to get the Agency out from under a very dark cloud, and he saw this as one step toward accomplishing that purpose. And, I think he made the right decision.

JHY: This was a tremendous blow to George Larrick?

WR: Oh yes, it was. He had had the greatest faith in Henry Welsh. He admired him as a scientist. Liked him personally as a friend. It was a trememdous blow to him.

BP: You know, I was in Chicago, I was just a mid-level inspector at that time and I often wondered if Larrick was getting adequate reporting from the field because we deeply resented the so-called anti-biotic inspections, which were usually made by one expert in the district, plus somebody from the Division of Antibiotics, and they played cozy with the industry socially, certainly. They accepted meals and things that we had always been taught that you not only didn't do, but you tried to even keep from having anything look like you were doing that. And yet the anti-biotic people just flew in the face of those instructions. And this is before the Henry Welch thing came to a head. I often

wonder--it has occured to me--because on many of these interviews the Henry Welch matter comes up--but why was this such a shock to Larrick? Why hadn't he gotten some feedback, because things that maybe weren't illegal but were--at least they weren't kosher in terms of the way inspectors were instructed to act--had been going on for several years.

WR: I don't know whether that had been reported to Larrick or not. If it had, I'm unaware of it.

JHY: This does bring us to a kind of judgment. You were very close through a number of years to George Larrick. Each commissioner has his style. Each comissioner has his total political environment, in which he has to operate. There were critics, in due course, in Congress and in the rising consumerist movement, of Geoge Larrick's style. Nobody ever accused him of the kind of relationship with industry which was revealed about Henry Welch, but the record will show criticism of him as having been too friendly, the criticism would have it, to industry. Eating with them at the Press Club and other places, and of being not arm's length, but genuinely friendly with industrial figures. Now, you observed him. Do you want to talk about that problem from your perspective and talk about Larrick's style as regulator, as Commissioner?

WR: Sure, I'd be glad to comment on it. George Larrick's fundamental objective, I'm satisfied, was to give the American public the best protection that he could in the Food an Drug field. Now, in order to administer a regulatory law, the regulator has to have a constituency; has to have somebody that will back him before Congress. If you don't have a constituency, then the first time your regulations begin to pinch, the industry will run up to Congress or run to the political arm of the Administration and get your decisions overruled. So Larrick had to have a constituency in order to administer effectively. When he was Commissioner, there was not a well organized consumer movement, such as there is today. There was Ruth Desmond, You will remember she was then just flying around making noises and not attracting much attention. Now, I expect Ruth Desmond, if she is still alive, or her successor, could get a lot of attention making the same comments that she did in those days.

Who was Larrick's constituency? It was regulated industry. That's the principal reed he had to lean on. When Charles Crawford decided to retire from his position as Commissioner, there were two people inside FDA that were hoping to get the job, John L. Harvey and George Larrick. Larrick won out, and he won out

largely because the drug industry came to his support. I'm satisfied that he did not compromise his decisions because of that support. I'm also satisfied that he had a very warm spot in his heart for the responsible members of the drug industry, because of that support. And that, no doubt, led to the close relationships you mention. But I believe he was just as firm with his friends - if firmness were needed - as with others in industry. I've thought about this a lot. I've wondered what Larrick could have done that he didn't do given the climate in which he served as Commissioner. I don't know what else he could have done. He associated with the responsible elements of the drug industry and, to a large extent, the food industry too. He did apply effective controls to all elements of those industries. He did not apply the rough shod brow beating treatment that some of the consumer advocates would like to see a government agency apply. That, I think, would be my thumbnail sketch of the situation.

JHY: When did he become Commissioner?

WR: I think in '54.

JHY: Right, so that his view of things must also have been conditioned to some degree by the first Citizens' Advisory Committee report, which was issued the next

year, which, I think, probably had been launched by Commissioner Crawford.

WR: That is correct.

JHY: But which actually reached fruition and was announced in 1955. Now . . .

WR: That was an industry report, in large measure. It reflected the wishes of the regulated industry.

JHY: It reflected the issue of the wing of the regulated industry which was suffering from problems that came from the wing of industry that wasn't being as regulated as well as it might be, probably for financial reasons. In some considerable measure, for financial reasons, as well as for the associated reason of the inadequate staff, particularly in the scientific sense, that the Food and Drug Administration had at that point. And so, to get better scientists, get more money to the Food and Drug Administration so it can do its delegated job, I guess, is sort of the bottom line of that report, wasn't it?

WR: Well, there were two or three bottom lines, that was one of them, certainly, yes.

JHY: As you see it, what are the other key ones?

WR: I believe it was the first Citizen's Advisory Committee report that gave some emphasis to the idea that the industry ought to be self-regulating, or did that come on the second report?

JHY: Well, I don't remember.

WR: The bottom line that the Food and Drug Administration grabbed and ran with, was the one you stated--give us more money; give us more scientists. There were one or two other bottom lines that could have been run with, but we sort of ignored those. They did not fit in with our view of the way that effective regulation could be carried out.

JY: But the Citizen's Advisory Committee Advisory Report was sort of necessary to get more money. This was a powerful thing with the Congress, that major wings of industry themselves should say, "This regulatory agency ought to have more support from Congress."

WR: Yes.

JY: Why was this necessary? Why hadn't the Agency made its own case or sought to make its own case with the Congress for more adequate resources?

WR: In order to get funds of the magnitude needed by Food and Drug in order to do an effective job, somebody was going to have to say the Agency is not doing an effective job, and the various Commissioners up to that time of the first Citizen's Advisory Committee report, had been unwilling to come out and say in terms that really hit the public between the eye, "We aren't doing the job you expect us to." Oh, we'd said it, but we sugar coated it. Somebody had to say the Agency is doing a lousy job, and it's not going to do better until it gets more funds and more personnel. Now the Citizen's Advisory Committee didn't say that, but Kefauver and Humphrey and Fountain, and others on the Hill said it through their investigations of Congressional Committees. It was not until the public became convinced that Food and Drug was doing a lousy job, that the appropriation began growing the way it needed to grow. So I would say the reason the Agency had not presented its story adequately before, was the fact that it had not had a Commissioner who was willing to stand up and say, "I'm doing a poor job, I'm not protecting the public." They just couldn't bring themselves to say that.

JHY: What they did was say, "We're doing a great job with the money we've got.

WR: That was our standard pitch. And that's not the pitch that gets you vastly increased appropriations.

JHY: Were you close enough to observe, once again in the realm of motivation, why it was that the earlier Commissioners took that perspective?

WR: They were all proud men. They were all hard-working men, and it just isn't human nature for a man that is doing the best he can and is proud of what he is doing to say, "Look I'm doing a hell of a poor job. I'm just not doing what you expected me to." Somebody had to get hurt bad for the public to realize the situation Food and Drug was in, and no Commissioner was willing to hurt himself that bad. I don't know whether they ever thought it through in those terms or not.

BP: We all, right down to the very bottom of the administration, we had that pride in what we were doing.

WR: We kept emphasizing what we were giving you for the dollar that you let us have instead of emphasizing what you are not getting because you are not letting us have more dollars.

BP: Because of that attitude we, as individuals, accomplished a great deal more than they accomplish now, because it gave us a dedication that doesn't exist any more.

WR: I've heard that, yes. I've heard that the productivity per man was greater then than it is now.

JHY: And there's another facet to it, and that is that the nature of the job, potentially, was rapidlly changing. It was changing for reasons that we've already alluded to. In the drug field, when we talked about antibiotics, that is to say the chemo-theraputic revolution was bringing drugs in at a tremendous rate which differs quite markedly from what the drug task had been for Food and Drug Administration back when it got started and in the '20s and so on. And you've already indicated your own personal responsibility in connection with a whole series of amendments, some of which had to do with drugs, but mostly had to do with foods, food additives, the colors which were used in foods and so on, which meant that there was, as I once called it, a chemo-gastric revolution that was going on essentially at the same time. So both the food industry and the drug industry were becoming something that they hadn't been before, at least the change in degree was almost

enough to be a change in kind. So that the job that the Food and Drug Administration should assume was constantly enlarging. Do you have the feeling that the kind of agency it had been--relatively small, prideful in what it was doing, the Commissioner being able to know everybody by his first name . . . I guess the question is, with this kind of an agency, was it's planning arm adequate--did it neglect foreseeing the increase in the job, which its name should have implied, or did it foresee these things and just think it was politically impossible to get the added authority and the added responsibility so that it was events and events pressing on Congress that got these additive laws and that got the Kefauver Law and that eventually brought the resources so that the Administration could enter the new age and begin to try to tackle problems that it might be fair to say that it had neglected. I would appreciate if you would kind of address that sweeping question.

WR: I've been thinking about that question ever since I got your letter several days ago, so I will try to address it when we get back from lunch. Well, as you mentioned before the recorder was turned back on, basically the question that you ask is whether the Food and Drug Administration kept up with the times, or whether for some reason or other it failed to keep up and, of

course, if it failed to, you'd like to know why. I think it failed to. My answer would be that the Food and Drug Administration never has kept up with the times and possibly never will. It is in the nature of a government regulatory agency that the Agency gets funds with which to perform its function after the need becomes apparent, rather than before the need becomes apparent. So, what I'd like to speak to really is the question, "Did the Agency recognize the need at an earlier date, whether or not it was able to get funds." I think the answer is that, at one period of time the Agency did recognize the need that was coming up, certainly in the food field. When Paul Dunbar was Commissioner, and this would have been back in the '40s, he became concerned about the growing number of synthetic chemicals that were being used in food. And he became convinced that there was a potential problem here that no one was dealing with adequately. So he went to Congressman Frank Keefe, an influential member of the House Appropriations Committee in the period of roughly 1945 to 1948. Dr. Dunbar discussed the problem that he saw with Mr. Keefe, the problem being that immediately following World War II, partly as a result of the tremendous amount of research that had been prompted by the war itself, we were having literally hundred of new chemicals coming out of the chemical factories of the

nation. The industries were looking for uses for these chemicals, and one of the big potential uses is to incorporate it in food. We eat enough food in this country every year so that, if a manufacturer can get a small fraction of one per cent of his output incorporated in a big selling item like bread, he can amass a fortune in a short period of time. The chemical manufacturing concerns were beginning to try to promote some of these newer chemicals for use in bread as softening agents, for example. Mr. Keefe listened to Dr. Dunbar with interest and said, "Well, Commissioner, let me think about this and I'll be back in touch with you." Later he got back in touch with Dunbar. He said I've taken some soundings up here on the Hill. There's no way you're going to get any legislation at this time that would deal with the problem we discussed, because no one recognizes the need. There is just no sentiment on Capitol Hill that will deal with the problem you are faced with. Mr. Keefe believed it would be necessary to have a broad study of the use of chemicals in food to develop the facts and lead to more widespread understanding of the problem.

JHY: How did you learn about his trip up to the Hill and the reply of the Congressman? Was this discussed in the conference of high Food and Drug officials?

WR: It must have been discussed by the leadership of FDA. At that time I was in a relatively low staff position, and was not present at any sub discussions. My information comes second or third hand--I believe Charlie Crawford told me that story when he was Deputy Commissioner, or perhaps after he became Commissioner. Congressman Keefe decided to help Dr. Dunbar. He sponsored a Resolution, passed by the House, to establish a select committee to investigate the use of chemicals in food. The Select Committee was formed with Congressman John J. Delaney as chairman. (It came to be known as the Delaney Committee). Dr. Dunbar assigned the task of amassing pertinent data on the problem to Mr. J. O. Clarke, then in charge of the planning office of FDA. J. O. and his staff worked closely with the Select Committee and its staff.

You will recall that the report of the Select Committee painted a dramatic picture of potential danger from the widespread, poorly controlled addition of new chemicals to food, and called for strong legislation to establish stronger controls. This led to the enactment of the Pesticide Chemicals Amendment in 1954 and the Food Additives Amendment in 1958.

But that got away from the answer to your basic question. The answer I would give is that Paul B. Dunbar,

who was a scientist in his own right, a good scientist, recognized this need and took steps to deal with it. I believe that, after that time, the leadership of the Agency did not recognize growing needs in the same way that Paul Dunbar did. There were several reasons. One reason, as far as the next Commissioner was concerned, Charles Crawford, was that Charlie got completely embroiled in controversy with key members of Congress and his time was almost totally taken up trying to deal with that problem.

JHY: Parenthetically, can you indicate what some of the issues were that caused these conflicts?

WR: Economic, primarily. There was a Congressman by the name of Tabor who was requesting by one of his constituents to intervene with FDA at a time when FDA was saying to the constituent, "We're not going to let you make little beet balls out of big beets and sell them without indicating that they are made from big beets." Mr. Tabor felt that our position was totally unreasonable. He wanted us to relax. FDA declined to relax, and so Mr. Tabor took out after us on our appropriation. He happened to be on the Appropriation Committee. He cut the appropriation a little bit. I think it was $100,000.00, but in the budget we had at that time, $100,000.00 was a lot of money.

JHY: And you really think that this was the psychology as much as the economics of it, was a serious crimp on FDA being able to take any new initiatives?

WR: Yes.

JHY: And the time . . .

WR: One reason that it was such a serious crimp was that Commissioner Crawford could not bring himself to believe that the Congress, as a whole would ever allow Mr. Tabor to cut our appropriation. It became apparent to the business manager of the Agency, and I'm not sure now whether it was Fred Munchmeier or Bush Locknane, one of them, that there was a real danger that we were going to have a cut in the appropriation. Mr. Tabor had already indicated he was going to bring that about. So the business manager came to the Commissioner and said, "Commissioner, we've got a few months before the end of the year. We're apt to get a cut in the appropriation. We'd better curtail our expenditures for personnel. Stop hiring." Mr. Crawford said, "No, right will prevail. They're not going to cut our appropriation, because that's not right." This must have been January or February. We got on into March and April and the business and personnel people kept

coming back to Mr. Crawford and saying, we've got to make a decision. Look, at the rate we're going now, we're going to be over-staffed, and it will hurt us awfully bad if we have to cut back in the last month or two. Charlie Crawford wouldn't agree to cut back until the very last minute. So we finally had to run a reduction in force in late May, at which time many people in the Agency were given pink slips, a lot of them later withdrawn, who would never have been touched, had Charlie taken action a few months earlier. That shook the whole Agency up and did harm, very greatly, its ability to deal with current problems--to deal with anything except Congressman Tabor and an appropriation cut. Very shortly thereafter, Charlie asked the Secretary to form the first Citizens Advisory Committee, and that was basically the reason he did ask to have the Committee formed. He said, "Look, we've got problems. We see the problems and Congress doesn't see them. We've got to have some outsiders to look at our operation and say what is needed. (Intervening material restricted. For release January 1, 1996.

JHY: The following question is related to what you suggested, and that is, the reason why the next Commissioner after George Larrick did not come from within the Agency as had been the tradition, but was appointed from the outside. You were in the Agency during this most crucial transition, one of the very crucial ones in its

history, I think. Would you recount what you remember of the details of the choice of the new Commissioner and suggest your interpretation of this. Who made the decision? What was said why it was made?

WR: Well the decision was made, at least so far as I am aware, by Wilbur Cohen, who was the Secretary of HEW. I do not know whether he had help from the White House or not. I feel sure that he cleared the choice with the White House, but my guess is that Wilbur made the decision on his own. I don't recall exactly what statements were made at the time, but it seemed obvious to me that the new Commissioner had to come from outside the Agency. The Agency had been under intensive attack from the Congress for about six years, by that time, starting with Mr. Kefauver's hearings and continuing with one hearing after another before Congressional comittees. There was no way that a person from inside the Agency, whether scientist or not, could hope to stand that barrage of attacks, because he would be colored with the old policies and the old decisions. The Secretary obviously felt that way about it. The Secretary I believe, though he never told me this, felt too that the Agency was ingrown to the point that he had to shake it up a little bit and get some new blood in it. So he brought in Dr. James Goddard from the Public Health Service, who had been Director of the

Communicable Disease Center in Atlanta. He evidently gave Dr. Goddard a blank check in so far a shaking up the Agency was concerned. Dr. Goddard shook pretty good.

JHY: Do you think, if he gave him a blank check about shaking up the Agency, that from the Secretary's office or perhaps the White House, there was a bill of particulars with regard to policy that Goddard brought, that he should follow?

WR: I'm not sure I understand your question. What do you mean by a bill of particulars as to policy?

JHY: The kinds of things that he ought to do that hadn't been done in a regulatory sense. By shaking up the Agency . . .

WR: I dont' think so. I didn't detect it. If there was a bill of particulars of that type, I believe that Goddard did have a bill of particulars which said, "Jim, get this Agency out of the clutches of the Congressional Committee, doggone it. Get things calmed down with Congress. We're politically in trouble because of the Food and Drug Administration." Now I think that Jim Goddard, on his own initiative, had a bill of particulars, if you will, which said, "This is a golden

opportunity for Jim Goddard to make a name for himself, so I'm going to keep my name before the American public week in and week out." And he did that too.

JHY: Well, when you said "shook up", that could be interpreted as structural, and it also could be interpreted as programmatic. Both were true, I think. I thought perhaps you were referring to the structural. Will you talk about the reorganization, because certainly, a great many of the people who were in the Food and Drug Administration when he came along--when they think of his regime, they think, first of all, of the reorganizational plan that he inaugurated, which they tend to criticize very much. You were his deputy and perhaps even occasionally saddled with the responsibility of being a kind of hatchet man for the shake-up. Wouldn't that be even fair to say?

WR: I got credit for some of it.

JHY: You were given credit for it, that's true. Would you talk about that organizational change that he brought in and what the point of it was, and why it elicited so much criticism among those who were in the Agency?

WR: Yes, I'll be glad to. As sort of a preamble, let me tell you of a conversation I had with Dave Senster, who

was Jim Goddard's deputy at CDC and when Jim left, took over as Director of CDC. I was talking with Dave, I guess 9 months or so after Dr. Goddard became Commissioner. He was sort of sympathizing with me. I said, "Dave, this guy is really turning things upside down for us." "Well," he said, "don't worry about it, that's the way he operates. He came into CDC and did the same thing. He turned it upside down. We're still trying to get the pieces together." Well, that gives you another man's viewpoint on how Dr. Goddard operated. In my opinion, Dr. Goddard believed when he came into the Food and Drug Administration that there was an urgent need for new blood in the agency. And I believe he saw the need for a complete restructing of the plan of organization to jolt the old employees out of any complacency they may have had. His approach seemed to be if they did it before or if they were organized this way before, or if he held this job before, then it's wrong--change it. I thought at the time and still believe that Dr. Goddard exercised the power of the Commissioner with unnecessary brusqueness -- even rudely at times. Perhaps the Agency is better off today because it happened. But it was a very unpleasant time. I mentioned earlier that I believe one of Dr. Goddard's goals was to keep his name before the American public. He didn't want to be Commissioner of Food and Drug for the rest of his government career.

He regarded this as a stepping stone, I think, to some higher position. The thing that happened, which he had not anticipated, was that he stepped on Hubert Humphrey's toes in the process of trying to reach that higher position and Mr. Humphrey, who was then Vice President, told Wilbur Cohen to get rid of him.

JHY: Was that the remark about the corner drugstore?

WR: Yes. The corner drugstore will not be extant in 20 years or some such comment.

JHY: So that was more crucial than everything else?

WR: That's what wrecked Goddard. He had been leading up to that on two or three occasions before, and Willard Simmons, the President of the National Association of Retail Drugstores was becoming concerned about this new Commissioner who apparently had taken aim on the retail drugstore for publicity purposes. And when Goddard finally mentioned his view that, in 20 years the corner drugstore would be out, Simmons publically came out against Goddard and, obviously, he privately went to the Vice President and said, "Hubert, you've got to help us." So Hubert did get in touch with Secretary Wilbur Cohen and asked him to take care of Goddard. A few weeks went by, maybe 2 or 3. Goddard was still

in. Secretary Wilbur Cohen was over at a Cabinet meeting one morning, when Mr. Humphrey came in, sat down beside him, leaned over and said, "When are you going to get rid of that son of a bitch Goddard, anyway?" About 10 days after that cabinet meeting, Goddard told me he was going to retire. (You will understand that the material about the Secretary and the Vice President is rumor. I was not there and neither of them talked with me about it.)

JHY: Goddard had a vision of politics. I mean you're suggesting that his administrative structural organizational approach was one of tearing up old roots and establishing new things. You are also suggesting that he was interested in his own future in headline. But there isn't any doubt at all that he had a policy especially with regard to putting into effect certain things in connection with the control of prescription drugs that had been forecast by the 1962 law, but which might not have been going into effect as rapidly as some people thought maybe they should be. So he had a set of firm convictions and these convictions were to be carried out with regard to prescription drugs. In somewhat less a collaborative conversational way with industry, rather in a more arm's length way with a lot of public criticism, the pharmaceutical industry, that made Goddard sound somewhat more like Kefauver and

other critics. Indeed, like even Humphrey, at the time. . . So that it wasn't that he didn't have a policy and it wasn't that he didn't have a style. The policy was more aggressive than Food and Drug had had before, and the style was more flamboyant. But he did bring a more vigorous sense of mission and changed priorities with regard to where the mission lay. Is that not so, or would you comment on what I've just said?

WR: Your question reminds me that, when I closed my earlier comments I had not given Dr. Goddard his due. Dr. Goddard had a philosophy, it is true. I may have indicated that he didn't. Dr. Goddard did have a philosophy. I think the philosophy that he brought to the Food and Drug Administration, which has the most lasting impact, was the philosophy of tapping responsible scientists and others outside the Agency and getting their input as the Agency developed its own policies. Dr. Goddard had come up through the Public Health Service which, for years has done that. He did proceed, almost immediately, to begin contacting responsible outsiders to get them to feed their views into the Administration before the plans were finally put together firmly.

JHY: And even brought in bodies from outside on loan, occasionally. Public Health Service doctors were brought in.

WR: Oh yes. He brought in personnel who were familiar with this process and who were able to contribute to Goddard's view that we ought to tap the outsiders to a greater extent. I agree with your comment that Goddard's method of operation was much more flamboyant than had been used before. I come back to the comment, which I may have made earlier that Dr. Goddard was not considerate of individuals. He was a very ruthless individual in dealing with personnel, whether the personnel happened to be inside the Agency or heads of industry. In that respect, I think he harmed the Agency. I think he was unnecessarily ruthless and harsh in dealing with people. To some extent, one of the most notable achievements of Dr. Goddard's career, the step in which he got the National Academy of Sciences to review drugs that were on the market in the United States and suggest activities that should be take to control them better, was in part at least, the result of a happenstance. The happenstance was that Food and Drug Administration had, I believe, a slight increase in its appropriation for that year. The old-line personnel in the Agency were so jittery as a result of the new Commissioner's activities the changes that had

taken place, that they did not pay attention to the financial end of the game quite as closely as they had been doing. Near the close of the fiscal year, FDA had a significant amount of funds unspent, Dr. Goddard believed the public would be well served if the money were used for some useful purpose rather than returned to the Treasury. So he contracted with National Academy of Sciences for this study, which turned out to be very worthwhile.

JHY: I see. So this was shooting from the hip, you are suggesting, rather than this carefully long plan delivered policy . . .

WR: Shooting from the hip with the understanding that Goddard obviously had been doing an awful lot of talking with outsiders who were knowledgeable of FDA's problems. He also obviously realized that this was a significant problem that ought to be dealt with, but the idea of getting the National Academy of Sciences to assemble a large group of scientists to review the drugs on the market at just this time was stimulated. I believe, by the surplus of money at the end of the fiscal year.

JHY: He was succeeded by his Medical Director, Herbert Ley, who had quite a short reign as Commissioner. Will you evaluate him?

WR: Dr. Ley is a scientist. He was trained as a scientist. I believe he thought as a scientist. He was much more considerate of personnel than Dr. Goddard. He was quite protective of medical personnel. He came to the job, it seemed to me, with the attitude that you don't tell a doctor what to do. He wanted to let the doctors in FDA operate the way doctors do out in medical practice. Each one makes the best decision that he can and then he lives with it. In that particular regard, I though he fell a little bit short as an administrator, but overall I thought Dr. Ley was a very capable individual and one who was doing a good job as Commissioner.

JHY: What was his trouble? Was it almost entirely the cyclamate case that caused him to get out, or be forced out?

WR: His trouble was that he was put in by a Democratic administration and the Republicans, when they came in, I'm satisfied, had Herbert Ley on their hit list. They were just waiting for an opportunity to kick him out and get someody else. I think that's the whole story. It wasn't the cyclamates that got him out, that was just the excuse.

JHY: So that there wasn't any doubt that the decision to bring Goddard in, as these two examples show, did politicize the Commissionership in a way it had not been before?

WR: No question about that in my mind, it did. I think the job will remain a political job from here on out.

JHY: You're suggesting then that the Goddard change in structure was changed for change sake, and that the criticisms of it that were made from previous personnel who were forced to modify were proper criticisms?

WR: No, I don't believe that's quite the impression I wanted to convey. Certainly there was a large element of change for change sake in the reorganization, but I don't believe that it was all completely blind. I think that Jim Goddard had been schooled in administrative procedures, that he had some concept of what kind of organization could be made to work successfully. I think he came into the job with instructions to change that agency--stir it up, thoroughly. The criticism that I would give is that Goddard made the changes without very much compassion.

JHY: What was the administrative rationale behind the kind of basic changes that were made?

WR: I think that what Dr. Goddard was trying to do when he came into the Agency was to build a structure that had a number of almost independent operating units under the overall supervision of the Commissioner, to replace an earlier structure in which essentially all key decisions had to come from one point, from the Commissioner or his office. So Dr. Goddard, wanted a Science Unit that made science decisions for the FDA, within broad policies that the Commissioner established. He wanted a Medical Unit that made broad decisions in the field of medicine. He wanted a Public Relations Unit that dealt with public releases almost independently, and he wanted a Congressional Liaison Unit that did a much better job of keeping in contact with Senators and Congressmen. The organizational structure that he developed was one that tended to achieve this objective. He had an Assistant Commissioner for Science, and I've forgotten what the fellow in the medical field was called, I guess it was still Director of the Bureau of Medicine--but he had much greater responsiblity than the older Director of the Bureau of Medicine. What Goddard was never able to achieve however, and I don't know whether any Commissioner can, was a situation in which he was able to escape individual picayune questions from the Congress about every action that the Agency takes. The job is such that, when a Congressman or a Senator wants an answer to a question that is very

important to him, he's not going to be satisfied till he gets that answer from the Commissioner.

JHY: How much of the structural problem within FDA do you think was a matter of increasing size and complexity as resources did come and the Agency did grow, so that the decision-making was more dispersed and had to come from different angles so that fewer people really were constantly privy to what was going on and in which the sense of loyalty was diminished as the scale of things grew, so that it became a big bureaucratic operation, regardless of the structure, more difficult to control, more difficult to manage than in the earlier, more poverty-stricken days when the Commissioner could call everybody of the smaller group by his first name? You kind of went through the tremendous growth that came after the proverty of the '50s, certainly up to a certain crucial point at your retirement. I've often wondered if the increasing complexity of the problems, including the complexity of the science of the problems and the size and complexity of the Agency so that no matter what structure was applied to it, it might have made administration more difficult and the problem of accomplishing the mission more difficult. Here I've given a postulate. I'd like your critical judgment from your lifetime of experience upon that.

WR: I think (I'm not sure this is a direct answer to your question, but it bears on it anyway) the biggest mistake that the Agency made in the field of personnel over a period of years extending from the time I first entered it until Dr. Goddard became Commissioner, was to insist on advancement to key positions from within the Agency. I think that hurt us seriously. We needed the viewpoints, experience, and training that were available only from outside from the Agency. In restricting advancement to key positions largely to promotion from within, we deprived the Agency of those broader viewpoints. We needed management abilities that were not developed within the Agency and that we didn't really get from outside with the limited recruitment we had from outside. Now did that answer your question, or was there more to it?

JHY: Well, I'm just thinking that it's harder with bigger more complex structures to get clarity of purpose and precision of decision-making than it is with simpler structures. What you're saying is that the simpler structure had a kind of lack, that is to say fresh blood, fresh ideas. Though it was able, within its own lights, to function more precisely than maybe the bigger complex structure.

WR: It's true that the bigger your organization becomes the more skill is required to manage it successfully, but when you consider the size of the Food and Drug Administration even today after its very significant growth since I retired, as compared with the size of other organizations that are very successful, I can't believe that the agency has reached the point where size itself is an impediment to good management. I think what we lacked, and I have no knowledge as to whether the Agency has it today, was the management skill that has been developed to deal with larger organizations. To answer the question I think I heard you ask, I don't believe size alone was much of a problem. I think lack of skill is the problem.

JHY: Thank you. Can we go back to 1948? Earlier you did refer to that reorganization. Was that not the date?

WR: There was one in '48, yes.

JHY: When the regions, or what were they called then?

WR: The stations, I believe we called them, were made districts. The whole field structure of the Agency was reorganized.

JHY: Do you regard that as a significant change and, if so, good or bad?

WR: That was a significant change, and I believe a change for the better. What we had prior to 1948 was a field structure broken into three geographic areas: the eastern part of the country, the central part and the western part. Each area was managed, rather complete, by what was called a District Director in New York or Chicago or San Francisco. Under each one of those directors, we had managers of the individual field units, the stations, who for practical purposes were not allowed to deal directly with Washington. They had to go through New York or Chicago or San Francisco. That was not a very satisfactory structure for an organization that was growing and beginning to meet more complex problems. The reorganization eleminated the, what was then called, a District Level in New York, Chicago, and San Francisco levels, and allowed the field units to report directly to Washington and deal directly with Washington. In that regard, I thought it was a beneficial change.

JHY: It was definitely a centralization of policy change?

WR: Yes, it was. It was centralization of policy and direction. The three earlier district offices had interpreted and sometimes modified the policies set forth by the Washington headquarters to such an extent

that over a period of time we came to have differing enforcement activities in various parts of the United States.

JHY: So that industrial complaints about differing kinds of types and weights of policies might have been one of the reasons for the change?

WR: I expect that that had something to do with it, yes. I expect the complaints were justified, to some extent.

BP: As an inspector, when you did have occasion to meet an inspector from another district and you talked, you sometimes felt you were with different organizations.

WR: Yes, I noticed that.

BP: Particularly the West and East, and Central stood not only geographically between, but in many attitudes it was somewhat middle groung.

JHY: So, in a sense, the policy was a lengthened shadow of the District Director for these 30 years or so from the time that this system was set up until the time it was changed?

WR: Well I would say for 16 to 18 years, anyway. From the early '30s, as I understand it, until about 1948, this situation had been developing and growing more acute.

JHY: I'd like now, if you wouldn't mind, vignettes--I asked you for a vignette at one point of Mr. MacManus who was your first boss, so to speak--I'd appreciate it if you would give me vignettes of the Commissioners you knew and maybe Mr. Wharton, whom you've mentioned, who was the Director of the district that you went to work for. Would you mind running through chronologically and describing the man and the way they went about their task and their personalities and so on?

WR: What I'd start with . . .

JHY: Perhaps using characteristic anecdote, if one comes to mind, that displays the man as you did with Mr. MacManus sitting with the young inspector.

WR: I'd start with Walter Campbell, who was Chief of the Food and Drug Administration. I did not know Walter Campbell intimately. I was an inspector way down the line and he was Commissioner way up high in Washington. I met him a few times, and I know how he was highly regarded by folks who knew him better. Walter Campbell was a lawyer, a man who read the law literally and

applied it literally, who liked to insist on strict obervance of the requirements of the law. He was sort of an aloof figure, so far as I was concerned. That would be about what I could tell you concerning him. Bill Wharton, who was the Chief of the old Eastern District, when it covered the Eastern part of the United States, was an inspector originally. He was a cop in the Food and Drug field. He liked to think of himself as a tough cop, and perhaps he was, in many respects. I liked him personally. Some folks disliked him intensely. He played favorites. He had his favorites on the inspection and analytical staff, and if you were one of his favorites, you couldn't do any wrong and, if you weren't, you couldn't do any right. I was fortunate enough to be in the good graces of Bill Wharton. I guess Wharton's approach to management was best described by a story that Ben White used to tell. Ben White was in charge of the New York State Food Laboratories for years. And then Food and Drug needed somebody to head up its Food Laboratories in Washington. This was one of the times that it recruited from outside the Agency. It evidently didn't have a man that it felt could handle that job. It approached Ben White to take the job on, and Ben did. Before reporting for duty in Washington, Dr. White stopped by New York to talk to his friend Bill Wharton. He said,

"Bill, give me a little bit of advice. Now, you know what goes on down in Washinton. How do you recommend that I get along?" Bill's response according to Dr. White who told me this over a couple of bottles of beer one evening, "Ben, you've got to be ruthless; you've got to be ruthless." That was sort of Bill Wharton's approach to personnel management. He could be very ruthless when he wanted to, and he could be very kind when he wanted to. I think Bill Wharton served a valuable purpose in the early days of the districts. I think he and the other district directors did. They were able to stimulate the field staff to new inspectional and analytical approaches that would not have been accomplished by broader, less intense direction from Washington. I believe the three district organizations had outlived its usefulness a few years before it was changed. The next Commissioner that I knew was Paul B. Dunbar, who became Commissioner when Campbell retired in, I guess '44, or thereabouts. Dr. Dunbar was a scientist, a chemist. He was a very likeable individual, very human individual. His staff liked to work with him. He was effective in dealing with the Congress, very effective. He'd go up on the Hill and sit down and talk with the Congressman and Senators

that he knew and seemed to get along well with them. He got along very well with industry. I don't think that he was as cozy with industry as George Larrick, but the responsible elements of the food and drug industry regarded Dr. Dunbar as a friend, rather than an enemy. I knew him first when I was out in the field, and he was in Washington. Then I was later transferred into Washington and had the opportunity of working directly with him upon occasion. I was assigned to George Larrick, but frequently I'd have to go into Dr. Dunbar's office individually to deal with him. He was intolerant of poor work or sloppy work, very intolerant. For that reason, we kept on our toes when we were around Paul Dunbar. Toward the end, I think Dr. Dunbar became less and less enamoured of working with the political supervisors that he had to deal with. He got to the place that he disliked dealing with the key people in the Federal Security Agency. He let them know it. I recall that, it was within the last year before he retired, Dr. Dunbar and I went up to see John Thurston, who was then acting Administrator of the Federal Security Agency. I don't remember what the problem was, but Dunbar was dissatisfied with something the Agency had done. Thurston, in a sort of resigned way, after we'd taken our seats, looked over

and he said, "Dr. Dunbar, what have we done now?" Obviously the Dr. had been there on of other occasions complaining, and I believe Thurston thought that the complaints were getting petty. Dr. Dunbar still was an effective administrator when he retired. He retired at a good time. Things were going well. We had good relations with industry and with the Congress. Charlie Crawford was the next commissioner, and I guess I've sort of given you a vignette of Charlie already, but I'll repeat it, in case I left something out. Charlie was a scholarly individual, a student more than an administrator. He enjoyed taking a complex problem, a question as to whether a certain section of the law could or should be used to apply to a certain problem, and mulling it over for an hour or two or longer if need be. Sometimes he had one or two others in the office with him, but frequently he wanted to be completely alone until he had sorted things out to his own satisfaction. He was a good legislative draftsman. He had played a big role in drafting the 1938 law. He enjoyed, I believe, sitting down and just toying with the different ways you might write a piece of proposed legislation to get what you wanted. He was an expert at deciding what charge to bring when there had been a violation, that would ensure your winning in court. In short, I would say that Charlie was an excellent

technician. I don't think he was very heavy on administrative ability. Certainly he was not heavy on establishing good relations with Congress. I liked Charlie very much, personally, but I think the Agency was better off because he got out when he did. The next Commissioner was George Larrick. I expect I've pretty well described him already, would you like for me to go ahead and . . .

JHY: Can you tell some incidents that reveal him in his major characteristics that come from your close association with him through the years?

WR: Well, Larrick was a man who, despite all the rumors that you've heard about his close association with industry, would not, in my opinion, allow his association with industry to bend his judgment at all. He was straight-laced on adhering to the rules that he thought applied to a situation. He was an opportunist, as an administrator to a considerable extent. He almost shot from the hip upon occasion in making decisions.

I recall the episode of the cranberries, you remember years ago. We found some pesticide residue, we thought, in cranberries from New England. We were trying to decide what to do about it. We were trying to decide, among other things, whether the analytical

procedure was accurate. Larrick and someone else, one of his staff, went up to see Secretary Flemming, and when they came back, it was with the word that Secretary Flemming had announced publically that he wouldn't eat cranberry sauce that year--essentially a stop sale order. Well, that was premature. As it turned out, the cranberries did contain the pesticide residue, but for a couple of months after that stop sale order was issued we still were not absolutely sure that our analytical method had detected the herbicide aminotriazole. That was an uncomfortable two months.

JHY: It was the Secretary who, as I recall, got the greatest criticism for his precipitousness in connection with that episode. Are you suggesting that Larrick was shooting from the hip on that occasion and going too quickly to the Secretary and influencing him to take a public step?

WR: I believe that Larrick had been summoned to the Secretary's office. I don't believe that he initiated this particular meeting, or perhaps it was a series of meetings. No, I think, if Larrick had had the decision left to him, that he would have followed the advice of his staff and would not have made a public announcement

at that time. All I'm suggesting is that, when the Secretary heard the story of what we had found and said, "Well, we've got to make a public announcement," it would have been mightly helpful if Larrick had said, "We aren't ready, Mr. Secretary, I cannot assure you that we have found this herbicide in the cranberry sauce." He obviously didn't say that, or Flemming wouldn't have shot from the hip. I don't know why. I wasn't present at that particular meeting.

JHY: I might just say, at this point, that one thing that certainly George Larrick had was a sense of being part of a long tradition of honorable service. He held his predecessors in the greatest respect and esteem. It just happened that I was at his home on the Potomac to interview him when he became ill and went to the hospital, a week or so before his death, and it was my responsibility to get the ambulance that took him to the hospital. He became sick at lunch, before we had gotten to the task of interviewing, but before we sat down to lunch, we went into the front room from the dining room, just as we were about to sit down and he shut the front door so that it didn't cover the wall beside the door on which he had hung the photographs of

all his predecessors. Virtually the last thing he said to me was to remark at the respect and admiration he had for his predecessors and that he had sought to fulfill the obligations that were place upon him in the way that they had done, which he obviously held in high respect.

WR: I certainly agree with everything you said. He had a sense of mission for the organization. He was a very warm individual in contrast to some of the individuals we discussed who, I believe I've characterized as ruthless. Larrick was not ruthless. He tried to keep the personal problems of his staff in mind and he worked with them to try to make things easier for them in a personal way. In fact, I think that might have been a possible drawback in the Welch situation. Larrick liked Welch personally, as many of the rest of us did. He was reluctant because of that to demand before the Kefauver hearing that Welch disclose all of his involvement with the publications of which he was editor. Some time (I guess it was a month and a half or two months) before the Kefauver revelations, maybe even a little more, some of us who were studying the situation wanted Larrick to call Welch in and simply ask him to give a full story of his involvement with the publications--a total story. I know Bob Roe was present.

Bob was nominally Welch's supervisor at that time. Jack Harvey was present, and I was present. The three of us had been individually studying the situation, and each of us had come to the conclusion that we just had to know more about what Welch was doing. Larrick heard our views and said, "Well, I understand the way you feel about it. Welch is a scientist. He is a friend. I don't believe he would do anything wrong. I'm just not going to ask him now." I wish he had. It would have helped if we could have broken that story instead of Kefauver.

JHY: There had been the hint in the Saturday Review, I think, and I think at one point . . .

WR: It was after that that we had this meeting.

JHY: And Larrick did ask Welch, at one point, I think the record shows, and he said that he received an honorarium, but Larrick didn't go a further point and ask . . .

WR: We wanted him to ask, "What are the details; let's have the whole story, Henry." He was unwilling to do that.

JHY: So it just really must have been a crushing blow to him when that episode occured--when the details were . . .

WR: I'm sure it was, yes. Well, let's see . . . Personally, I thoroughly enjoyed working with Larrick. He was a very close friend of mine, I feel. I prize the association. Now I haven't characterized Jim Goddard. I did not enjoy working with him. I was uncomfortable with the gentleman. I didn't like the way he dealt with people. I thought he was unnecessarily brusque. If you get an interview with Milstead, get Milstead to start on Goddard. You'll get an earful.

BP: You know, the only time I was in Goddard's presence--you probably attended so many meetings you might not remember--but Tom Brown and I went up to brief you on something we'd worked out in the Division. Tom was making the presentation. There were you and Kirk, there were a number of people all of them bigshots to us--Tom got up to make his presentation and, it was very uncharacteristic for him--his mouth opened and nothing came out. He had stage fright. Do you remember that?

JY: No, I'd forgotten that.

BP: I remember it very well, because I knew if Tom was permanently disabled, I was going to have to get up and do it. But anyway, Goddard said, in just the kindliest way, you know, Tom, just relax a minute. This happens to all of us. You just take a deep breath and relax and start over. And Tom did and he went right ahead. And that's the only time I've been in Goddard's presence--he handled it in a kindly nice way. Yet--you know--I'm not saying you're wrong--because I didn't know Goddard, and I've heard things from many other people who've known him.

WR: I'm glad you put that in because I had forgotten that an incident like that ever happened. My memory of Goddard is illustrated more by a situation that happened to Paul Hile (I don't recall what job Paul had right then--working, I guess, in the Bureau of Field Administration somewhere)

BP: Chief of Auditing Branch

WR: I'm not sure. Anyway Paul came in with a number of other people. There must have been 7 or 8 people in the room. Goddard wanted the answer to some question that Paul was supposed to have. Goddard asked him a question and Paul sort of beat around the bush. He

didn't come out with a direct answer. Goddard listened for maybe 40 seconds and he said, "Paul, let's just cut out the bullshit and answer the question." Now, that's a rough way for a Commissioner to talk to somebody that is down the line. Maybe to a Bureau Director, but not to a fellow in Paul's position. That was more characteristic than the story you told, of Goddard's approach to personnel. Paul couldn't have been any more shaken if Goddard had hit him. Herb Ley was a very likeable fellow. I mentioned earlier, I think he was a good scientist. I think he was a pretty good administrator. I believe he was a little bit easy on the MDs.

JHY: You mentioned something when we were talking off the record about his becoming Commissioner. Would you put that on the record?

WR: Oh yes. When Wilbur Cohen had told Goddard that it was time for Goddard to retire (that's how Goddard reached his decision), Wilbur, of course, asked for Goddard's recommendation as to a replacement. I learned later--let's see how I learned it--learned it from Ley--Goddard asked Ley if he would like to be recommended as Commissioner of Food and Drug. Ley was mulling the question over and Goddard said, "Now I'll tell you, Herb, there's a good chance you won't be in

the job for a year. If the political administration changes, you'll be out, and it looks like the Republicans are going to win." Ley decided that, even so, he would like to have the job but, from the time that the Republicans won the election (that would have been in '68), it was fairly evident to Herb Ley, I believe, and it was evident to me, that his tenure in that office was limited. I believe that the Republicans, when they came into power, had already decided that they were going to search for a convenient opportunity to replace the Commissioner of Food and Drugs.

JHY: And you were there when he was replaced, still?

WR: Yes. He and I were clipped at the same time.

JHY: So did you get acquainted with Dr. Edwards at all?

WR: Not well. I knew Dr. Edwards--I met him, I should say. You may recall that the Department, at one swoop, transferred--or offered transfers to Ley, Kirk and Rankin from their positions in Food and Drug to positions in the Department. Herb Ley resigned. Kirk retired, and Rankin transferred to the Office of the Assistant Secretary.

JHY: Can you explain that? The background--was this in order that the new Commissioner could have his own people in those high places?

WR: Well, I cannot speak for the Department, of course. The cyclamate decision had been reached. Cyclamates are the artificial sweetener that was produced by Abbott Laboratories and was being widely used in 1969. Some tests raised the question as to whether cyclamates were safe. So Secretary Finch, I believe in October of '69, issued a statement that cyclamates were going to be banned in food or banned from food. But, as things developed, the Agency--the Department was going to allow cyclamates to be used in certain foods and other foods it wouldn't allow them to be used in and the foods would have to be destroyed. It looked like a decision that hadn't really been thought out. In fact, I think it had not been thought through thoroughly. The Department placed the blame for that decision on Herb Ley (tried to) and on his top staff. And that was the excuse that they gave for easing Ley, Rankin and Kirk out, or I should say booting them out. As a matter of fact, I was advised by Jesse Steinfeld, who was Deputy Assistant Secretary for Health and Scientific Affairs, that the decision on cyclamates which he didn't agree with, although he was present and I pre-

sume spoke, was made by Secretary Finch. It was really not Herb Ley's decision. In any event, the Department had become dissatisfied with the management of Food and Drug. It wanted to take some action that would dramatically illustrate the dissatisfaction, and the action was to remove the three top people at one fell swoop. Charlie Edwards--rumor had it--had been brought in some weeks earlier to be groomed to become Commissioner of Food and Drugs. Dr. Edwards made that statement one time, not to me, but to others.

JHY: From where? To a spot within the Department.

WR: Yes, to a spot within the Department, and as I recall, he was brought in from some management consulting firm, but I'm not positive on that.

JHY: Boose-Allen, I think.

WR: I believe so. In any event, if he had been brought in for that purpose, things moved a little bit faster than the Department had anticipated, because Charles Edwards was not acquainted with the problems of Food and Drug when he needed to take over. I met the gentleman, possibly a day or two after the change. I wished him well, and I told that if there was anything I could do

to help in the transition, I would be glad to do so. Well he said, "You can help. I need somebody there just to help me hook up faces and names and tell me who does what. If you'd be willing to stay for a week or ten days for that purpose, I'd welcome it." I said sure, I'll stay if you'll clear it with the Assistant Secretary. He evidently did. So I stayed for, I guess 10 days and tried to ease the transition. Of course, I saw Dr. Edwards in action during those ten days. He is a polished individual, certainly not gruff in dealing with personnel. He's very smooth in dealing with personnel. He impressed me as being an unusually intelligent man. I was favorably impressed with him on that limited association.

JY: What about the reorganizatin that the CPEHS period that wasn't tied in in any way with you, was it? Or was it?

WR: Yes, it was. When Goddard was Commissioner and he hadn't been Commissioner for too long, there came talk--rumors about reorganizing the regulatory activities of the Department into a new unit. Take Food and Drug, Air Pollution Control, a new agency; Water Control, Milk Control and put them all in a new outfit

to be called Consumer Protection and Environmental Health Services.

JHY: When you say "there came", came from where? Was this from the Secretary's office or was Goddard himself responsible in some measure for developing this concept?

WR: I don't know the answer to that question. I have suspected that Goddard himself was responsible and that Goddard had hopes that he might be chosen to head up that new organization, but that's purely guesswork. No one ever told me that, and I pass it on with that caveat. The Secretary did establish CPEHS, the Consumer Protection and Environmental Health Services. He chose a fellow by the name of C.C. Johnson to head it. Now this new office had not been provided for in the budget. But Mr. Johnson, with the Department's approval recruited a lot of high powered people to help him set up the organization and they had to be paid. The only place to get the money for them was out of the budgets of the Agencies that were being placed under CPEHS. So Air Pollution Control, Food and Drug, Water Control, Radiological Health, perhaps one or two others, were tapped for funds and for position slots to staff this new agency. I thought it was a mistake from

the word go. I thought it was unwise (if not illegal) to take funds and position slots that had been appropriated to Food and Drug Administration and turn them over to a new agency wiithout clearing it through Congress. The other agencies that were tapped for funds and positions felt the same way about it. So we started off on a bad note. And things never did get any better. I guess you would say that the regulatory agencies just declined to be regulated by C. C. Johnson. We gave him whatever bit of lip service we had to but didn'f offer much cooperation. He finally went under. My view was that, if this new agency, CPEHS, succeeded, the Food and Drug Administration would cease to exist as an entity. Our operations would become scattered among a lot of other things that were of greater interest to the Public Health Service personnel and staff of CPEHS. So, to the extent that I could do so without getting fired, I failed to cooperate with CPEHS.

BP: You know, you took me with you to a couple of meetings of that committee that had responsibility, I guess, for organizing CPEHS. I don't know exactly what was happening - you were presenting something and I had some maps and some data that you wanted to use. You might

not recall because you were probably involved in those every day, but I remember sitting there, I had nothing to say. I was just there to furnish anything you might need. I was kind of appalled at the whole atmosphere of that group sitting there. It was kind of frightening, in a way.

WR: Well, the personnel that were selected to head up CPEHS were, some of them were, I believe, incompetent. And, if others were competent, they certainly didn't use good judgment. As one example, there was a unit in CPEHS that was to deal with legislation in the regulatory area. The operating agencies were instructed that they were not to deal directly with the Congress. Now, we'd established relationships over a period of years that enabled us to get favorable consideration from certain members of Congress. To suddenly order a halt to such contacts was not only offensive, it was potentially destructive to the Agency. We were also advised that we should list in writing the key members of Congress that we dealt with and the areas in which we had been able to be successful. I can't think of a more stupid request coming out of a government administrator. I did as instructed. I listed the chairmen of the various House and Senate committees that we dealt with, and that was all.

JHY: That brings up the question of the relations between the Agency and the Congress. There was a special branch of FDA that had liaison with Congress. Was this, from time to time, part of your responsibility?

WR: Yes, my responsibility in dealing with the Congress started about 1956, when the Food Additives Amendment was under consideration. I had been working on pesticides, and George Larrick asked me to start working on proposed legislation regarding food additives. So I became, I guess within about a year along with Bill Goodrich, the liaison man with the House Committee on Interstate and Foreign Commerce, the staff of the Committee. From that time until about 1962 or 1963, I was involved in Congressional relations rather actively in connection with the Food Additives Amendment, the Hazardous Substances Amendment, the Color Additives Amendment, the Dangerous Drug legislation (I can't recall the exact name of it).

JHY: But not, I take it, during the period of the early '50s when the hearings had been held.

WR: The Delaney hearings? No, I was not involved at that time.

JHY: So that the laws were kind of separate--maybe depending to some extent on the evidence brought forth in those hearings, but it took a while to get Congress around to the point of legislating in this area.

WR: The Delaney hearings followed this conference that I mentioned earlier between Dr. Dunbar and Congressman Frank Keefe. They alerted Congress and the public to the need for some better control of these chemicals that were coming into the environment. The Delaney hearings did not, themselves, propose legislation. Other hearings led to the drafting of specific legislation. And there were hearings on each of these laws that I mentioned.

JHY: I'd like you to talk about your activities in connection with securing these bills, because this, to me, is an unstudied area. Before I forget it, I want to ask one particular question. Someone suggested to me once that the famous Delaney Clause in the Food Additive Bill--that's become increasingly famous or infamous since that time--was gotten into the bill by the National Health Federation. Do you have any recollec-

tion of this, or any feel for whether or not such an allegation might be the case?

WR: Well it was, of course, gotten into the bill by Jim Delaney, as you would guess from the name of the thing. I don't know why he decided to put it in. At that time, I don't recall that the National Health Federation was very powerful politically.

JHY: It was a fairly new organization, certainly. I'm sure it wasn't very powerful politically, but now this allegation was made to me by someone who perhaps had a right to know. I just thought it was a thing I ought to check out, particularly because of the future significance of both the clause and the growing political strength of the National Health Federation.

WR: I just don't know why he put it in. Could we take a brief break?

Coming back to the Delaney Clause, there is a little bit of background that may be of interest. When the Pesticide Chemicals Amendment was enacted in 1954, it did not have a provision specifically barring residues of cancer producing pesticides in food. Our scientists wanted to administer the law so that it did bar any carcinogen from foodstuffs, and they did so administer

it. The whole Agency did. One of the pesticide manufacturers, Naugatuck Chemical Co., a division of U.S. Rubber Company, had a chemical that was used to combat mites and red spiders on crops. I believe it was called Aramite. On animal testing, that substance was found to produce cancers in some of the test animals. So, on the basis of our pharmacologist's recommendations, we refused to grant a tolerance for residues of Aramite on food and crops. The U.S. Rubber Company called for the formation of a scientific advisory panel of outside experts to review the evidence and make recommendations to the Commissioner. (This was provided for in the pesticide chemicals amendment.) The panel was formed. Scientists were recommended by the National Academy of Sciences, as provided in the law. The panel considered all of the evidence, and it recommended that an interim tolerance be granted for Aramite while further studies were made by U.S. Rubber Company on the toxicity of this chemical. I learned later--I did not know at the time--that there was an intense amount of lobbying by U.S. Rubber Company among the scientists on this panel. That may have influenced the recommendation. I can't say. In any event, acting on that recommendation, the Food and Drug Administration did establish a tolerance level that allowed small residues of Aramite in food. It was later rescinded,

after further animal testing confirmed the carcinogenic potential of the pesticide. That is the background. Now, as the Food Additives Amendment was moving through Congress, for what reason I do not know, Congressman Jim Delaney requested that a provision be written into the Food Additives Amendment barring the approval of any level in food of any substance that produced cancer in test animals. We felt, in Food and Drug, that the provision was unnecessary. We spoke with Mr. Delaney about it. We told him that that was the recommendation our scientists would make, and that was the policy we would follow. It was not necessary to write that into the law. He said, "Did you follow that in the case of Aramite?" We explained what had happened. He said, "I want to put you in a situation where, no matter what an advisory committee recommends, you don't allow a cancer producer in food." Mr. Delaney's influence was great enough so that the people dealing with the legislation on Capitol Hill said, "If we wanted the law, we would have to take the Delaney Provision." Under those circumstances, of course, we agreed to it. It wasn't a bad provision, at that time.

JHY: And he told you that, specifically, so that he did use history as a guide.

WR: He was aware of the fact that we had been required to establish a tolerance for a carcinogenic pesticide on some food crops.

JHY: What kind of a man was he? You dealt with him during this period.

WR: I'd rather not characterize him, really, unless it's particularly important.

JHY: No.

WR: My contacts with the gentleman were not sufficient for me to feel comfortable about characterizing him.

JHY: Will you go a little more extensively into your activities during the enactment of this series of laws, which, in one area after another, buttressed the protection of the consumer in connection with different kinds of additives?

WR: What role I played as an individual? Well, my role with the Food Additives Amendment was to serve as liaison between Commissioner Larrick and the two Congressional Committees that were considering the legislation, the House Committee on Interstate and Foreign

Commerce and the Senate Committee on Labor and Public Welfare. I dealt, at that time, largely with the staff of those committees. Kurt Borchardt was the key staff man on the House side. Kurt was a skilled legislative draftsman in his own right. A very knowledgeable lawyer and a man who had a sincere desire, I believe, to protect the public--to enact good legislation in this field. The Department had a lawyer, Ted Ellenbogen, who was the draftsman for HEW. Ted was an individual that did a lot of nitpicking. He was not an easy man to work with. Borchardt didn't like to work with him. Instead of relying on the Department's legislative draftsman, Brorchardt wrote his own legislation, and he'd clear it with the Commissioner through me. We'd do our best to keep the Department happy. But, because of this relationship, direct from Borchardt to the Commissioner, the views of FDA certainly were before the House Committee without the attenuation that might have occurred otherwise. I think we got a better law because Kurt was doing our drafting than we could have if the Department had done it. Bill Goodrich worked with Kurt Borchardt too, in a very smooth fashion. Kurt and Bill would draft the language, and I'd have to help draft material explaining what had been done in non-legal, non-technical language. The material that I prepared was submitted to Commissioner Larrick and Bill

Goodrich for review and when satisfactory all around was delivered to Kurt Borchardt. Sometimes Borchardt would need more background material or different material and I was responsible for getting it to him.

Later, when the Committee had decided that it was going to approve a bill (this is still the House committee) and it was meeting in executive session to put the final touches on it, I was privileged, along with Goodrich, to be available to answer questions Borchardt might have about the Food & Drug position. After the House passed the bill it went over to the Senate side and I had somewhat the same relationship with Bill Reedy over there, though Bill and I never did get to the place where we worked as closely together as Kurt and I did. Bill was friendly; he was favorable. We got essentially what we needed through on the Senate side. I guess the next amendment was the Color Additives Amendment. Secretary Flemming, when the Color Additives Amendment was under consideration, came forth with his aminotriazole in cranberry pronouncement. He came in for a lot of criticism. At about that time, and I would guess this was in January or February after the Thanksgiving on which he banned cranberry sauce, Food and Drug was scheduled to testify on the Color Additives Amendment. Secretary Flemming, my judgment

now based on what later happened, decided this was his opportunity to justify what he did on aminotriazole in cranberry sauce. So the Secretary told the Commissioner, "I'm going up there with you, George. I'm going to testify on that." Well Larrick was delighted. The bill wasn't having too much acceptance on Capitol Hill, anyway. If you have read Secretary Flemming's testimony on the Color Additives Amendment, you wil have noted that he didn't testify about the Color Additives Amendment, he testified about cancer in food. That was the whole testimony. But his testimony was so eloquent, that it got the Color Additives Amendment passed. As I say, I had very little to do with that.

JHY: You didn't have the liaison of the drafting on that amendment that you had had on . . .

WR: No, I did not. I had some liaison, but it was relatively minor because the Secretary was carrying the principal burden of testifying. Ted Ellenbogen had the principal burden of drafting and, I beleive, Kurt Borchardt was still there in the Committee and whether Kurt liked it or not, he had to work with Ted that time. I could not help him out.

JHY: The precedent of the other bill was important, however, in the second bill . . .

WR: Yes.

JHY: The pattern had been laid down.

WR: Yes. Then the Hazardous Substances Amendment, I believe, came along next. It wasn't a very complex drafting job. I worked on that essentially as I had on the Food Additives Amendment, with the Committee staffs. Then came the Dangerous Drug Amendments. I'm trying to remember just what happened there. I didn't didn't have quite the intimate involvement with the drafting. I believe Bill Goodrich carried the major drafting responsibility for our department. I was involved more in preparing testimony for departmental witnesses and developing back-up information. I may have done some testifying myself on that. So that would be a thumbnail sketch.

JHY: Your role is most intimate and significant in connection with the Color Additive Amendment, I mean the Food Additive Amendment.

WR: Yes. Now the next legislation, after the Dangerous Drug Amendments would be the drug amendments of, was it '62?

JHY: '62 was the Kefauver Amendment. Was that the one you meant?

WR: Yes. Ribicoff was Secretary in '62. Sure, it was the drug amendments of '62. I was heavily involved in that too. At that time, Ribicoff had Jerry Sonosky, who I mentioned earlier, as his legislative aide. Or perhaps Wilbur Cohen who was Assistant Secretary for Legislation had Jerry. Anyway, Jerry was up there in the Department. It was obvious from the Kefauver hearings, that we needed some good input into that legislative process to get what we wanted. John Kennedy was President. The drug industry, for a period of time, darn near had a funnel into the White House, I think. Because we'd propose something and it would get knocked down at the White House. We were especially anxious by then to get the Efficacy Provision in the drug amendments. Jerry Sonosky was sold 100% on getting the Efficacy Provision in. We thought we had it in, and somebody got to the White House and they said take it out or water it down, I don't recall which. There were several versions that were so watered down they would have been impossible to administer effectively. Jerry and I were working one night, after that decision had come down. Jerry had been asked, I guess, by Wilbur Cohen to draft an appeal to the White House. He came up with an eloquent appeal. I was helping him

draft that thing. Jerry got through with it, I guess it was about 2:00 in the morning, and he looked at me and he said, "Winton, what are you going to do if this doesn't work?" I said, "Jerry, I'm going to tell them what happened. I'm going to tell everybody what happened." He said, "You'll get fired." I said, "Yes, but everyone will know who killed the efficacy provision." Jerry told Wilbur Cohen that Food and Drug was getting ready to kick over the traces if they took out that provision. Wilbur went over to the White House with the appeal the next morning. Whether my statement had anything to do with it or not, I can't say. But, after that, the White House stuck with us on the Efficacy Provision, and we got it in. But, boy, for a while, it looked like we wouldn't. John Lear wrote about this whole episode. I'm sure you've read his series of articles on the Kefauver Amendment.

JHY: I've read some of them, but I would need to refresh myself. I did have a student who did a dissertation, Richard McFayden, did he ever talk to you?

WR: Oh yes, I've met him. He interviewed me on something.

JHY: Yes, he did. And he did his dissertation on this. Then later on tried to get the White House point of view, after he had finished his disseration. He got a

grant from the National Library of Medicine to continue some interviewing. I can't remember it was before he got the grant or as part of the time he had the grant that he came to talk with you. But he tried to find out what went on in the White House. I think, not with very successful results.

WR: Well I was never sure myself whether the decisions that I was told were being made by the White House were being made by the White House or by Wilbur Cohen. I know Wilbur Cohen, who was--I guess he was Assistant Secretary for Legislation at that time--Wilbur was greatly disturbed about the John Lear articles. He said about them, "that's just not accurate, that's not what happened at all." Well, Lear's reports of happenings of which I had personal knowledge were pretty accurate. I don't know whether Wilbur Cohen was making the decisions and saying, "This came from the White House, we can't help it." I just don't know.

JHY: So, it's kind of a mysterious thing. Certainly Richard McFayden had very great difficulty trying to figure out who was doing what.

WR: Well, you'll never get the story out of Wilbur.

JHY: So the relationships between the White House and the Secretary's Office and Food and Drug still have some mystery in them.

WR: With respect to the drug amendments of '62, I should mention that the White House, at least on the record, became more intimately involved with this legislation than with any other piece of Food and Drug legislation, in my experience. Allegedly, I was told at least by people in the Department of HEW, that decisions with regard to what would or would not be included in the legislation had been made at the White House at a conference the night before, or a few hours before. I do know that just a few days before the final bill was agreed upon in the Congress, when the trading was underway to see who would give what, I saw a letter from the White House. I believe it was signed by John F. Kennedy. It stated an administration position that was revised from an earlier one and a position which, in my opinion, would have emasculated the Efficacy Provisions of the Drug Additives Amendment. And whether that letter was actually drafted in the Department of HEW for signature at the White House, I can't say. I do know that the administration's position changed later after further discussion and after the realization that the Food and Drug Administration was going to place the monkey on the White House's back, if the Efficacy Provision were gutted.

JHY: I think there is some indication that this bill was being used in the White House as trading fodder in connection with other bills that the White House wanted to get. And I think perhaps the book that Harris wrote, if I'm right, suggests that maybe Senator Eastland was was one of the people the White House was trying to influence on other bills. They might have been yielding to his very conservative approach on this bill.

WR: I have heard such reports, but I have no facts that would support or refute them.

JHY: Any more on this series of bills?

WR: I believe I've pretty well covered that.

JHY: Well, I looked at the kind of queries that I wrote to you ahead of our gathering today to see what points we hadn't already covered in this extensive conversation. I have a few things here that might be used to mop up, perhaps. You talked about several cases in the early part of your career with the Food and Drug Administration when you were an Inspector. I had asked about important and/or intriguing cases. What about later on--on the regulatory side of things? Were you at an inside seat and might have fresh, interpretive or

colorful sidelight information on important and/or intriguing cases?

WR: Well, for a period of time just after my assignment to the Washington offices, I was involved in dealing with drug cases particularly. And this was during the time that the administration was developing the position, in part through several court actions, that promotional material that described a drug constituted labeling, even though it was not shipped across the state line in the same box with the drug, so long as it became associated with the drug at the other end. This was a fascinating period of court actions. I can't claim credit for developing the theory. There are others who did that. But I had the opportunity to observe first hand the development of the court cases that gave real teeth to the labeling provisions of the drug law. A. G. Murray, an Administrative Officer did the spade work on those cases in the Washington offices and, for a considerable period of time right after going to Washington, I was located in Mr. Murray's office. Sat right across the desk from him to try to learn the ropes of the Washington routine. So I was privileged to get a first-hand look at many of those cases as they were being developed.

JHY: Did you have anything to do with the Krebiozen case?

WR: Not very much to do with the Krebiozen case, no. Others worked on that.

JHY: Another query I put had to do with turning points in FDA's history. We mentioned a number of turning points, possibly. I want to bring this up again. When you were thinking over the kinds of questions that I had written in this letter, I wonder if you thought of any others that you hadn't mentioned?

WR: Well, I think the key turning points in FDA's history, as I know them, tie right in with key personnel changes in FDA's history. The change from Walter Campbell to Paul Dunbar, as I observed it from the field, was not a significant turning point. If it was, I didn't detect the significance. We went along pretty much, after Dr. Dunbar became Commissioner, as we had before. The change from Paul Dunbar to Charlie Crawford as Commissioner was, in my view, a very significant turning point. We lost a man who had excellent relations with Congress, who, while he hadn't gotten big appropriations, hadn't lost ground on appropriations. The new Commissioner Crawford ran into an unfortunate situation in which he encountered some heavy opposition in Congress that hurt the Agency

financially. However, he brought about some much-needed organizational change when he eliminated the 3 geographic centers of decision making in the field and had the inspection/laboratory field offices report direct to Washington. The formation of the Citizens Advisory Committee, the first one, and its report constituted another step that lead to changes in the organization. The change from Charlie Crawford as Commissioner to George Larrick was a very significant one. We changed from a couple of scientist Commissioners to a layman Commissioner. We changed to a Commissioner in Larrick who gave the apearance of being more friendly to the industry than some of his predecessors had been, and we came to a Commissioner during whose term some intense examination of FDA by congressional committees was destined to take place. And that series of congressional committee examinations, in my view, led ultimately to the almost explosive growth of the Food and Drug Administration in recent years. When Larrick retired, and Jim Goddard was named as Commissioner, there was a most significant change in the Agency. The old organization was taken away and a new organization was established. The old personnel were shuffled around, some of them encouraged to leave the Agency. New personnel were brought in. Then the change from Commissioner Goddard to Commissioner Ley was one brought about by political pressure from the

White House, which reflected political pressure from the NARD, and finally the removal of Herb Ley from the Commissionership was one which I believe was politically motivated. Jim Goddard's and Herb Ley's appointments established the precedent of making Commissioners of Food and Drug political appointees. I am not sure it is a bad precedent; the job is important enough so that whoever holds it must have political support, otherwise he is not going to do a good job. I do believe that it is not good to have the political level extend a far down into the agency as it does now (in 1980).

JHY: We talked a lot about the very top spot, and you certainly were right next to the Commissioner through the later part of George Larrick's and Goddard's and Ley's administrations. What about the administrators below the Commissioners and their relationships with each other? I raise the question, were there wounding rivalries and tensions that hurt the top team and perilled decision making, or was this, as far as an agency was concerned, fairly compatible, cooperative and sense of good team through the period in which you were watching things from a high level.

WR: I'll have to qualify my answer at the outset by saying that, aside from a brief period of service in the

department just before I retired, my entire government career was in Food and Drug Administration, so I do not have a first hand feel for the relationships that customarily exist between key personnel in other government agencies. Oh, I have seen some of them from the outside, but you don't get the same feel there that you do from the inside. There always were rivalries and frictions between the key staff. I guess you always will have, as long as you are dealing with human beings. For the most part, I thought they were not destructive, and I am referring now to the time that George Larrick and L. D. Elliott were Assistant Commissioners. For example, there were minor frictions between them between their staffs, but I believe it did not interfere with the progress of the Agency. When Crawford became Commissioner and George Larrick Deputy Commissioner, we had new group of people brought in to fill key spots, Jack Harvey from San Francisco, and J. O. Clark from Chicago.

JHY: This was at the time that the district system of change, that district directors were accommodated in Washington.

WR Yes, and Bill Wharton retired, but Alan Rayfield was brought in from the Eastern District. These people had been operating in the field as rivals and, to a consid-

erable extent, they continued to operate in Washington as rivals. Perhaps, Jack Harvey and J. O. Clark, not as intense rivals, but both of them I believe regarded Rayfield as sort of a "Johnny-come-lately" interloper. There were frictions there in the top staff that carried on for quite a while. Rayfield later made his peace with Harvey and got along pretty well with him. In fact, Rayfield got along better with Harvey than he did with Larrick. He and Larrick had a personality clash that made it difficult for them to work together, and when Alan needed a key decision, he tried to take it up to the Deputy Commissioner instead of the Commissioner, with Harvey instead of Larrick. We also had in the associate commissioner spots, for a period of time, Bob Roe and Malcolm Stephens. I did not observe hurtful conflicts between Bob Roe and others, but there was destructive conflict between Malcolm Stephens and the Deputy Commissioner, John Harvey, also between Malcolm Stephens and Alan Rayfield. At one time, I'm told, Malcolm Stephens visited the principal staff man of the second Citizens Advisory Committee, Dr. George Y. Harvey, to criticize the leaders of the Food and Drug Administration, especially John L. Harvey and, to a lesser extent, George Larrick. It was after that that Larrick and Jack Harvey, the Commissioner and Deputy Commissioner, reorganized the Food and Drug Administra-

tion to get rid of the posts of Associate Commissioners. Bob Roe was made Director of a Scientific Bureau, and Malcolm Stephens was made Director of the Bureau of Enforcement. Malcolm Stephens never forgave Harvey for that reorganization. I believe there were destructive conflicts and cross currents between them from that time on, until Harvey and Stephens retired.

BP: Kirk was in there too, it seems to me. He expressed some resentment of Stephens when I talked to him.

WR: When Stephens was made Director of the Bureau of Enforcement, he and Kirk had to work closely together because Kirk was passing judgment on whether we would file for legal action cases that had been developed under Stephens' direction. Yes, there was conflict there. I'm glad you reminded me.

BP: Well I just happened to know that because Kirk, this was about the only conflict of that kind that Kirk mentioned specifically.

JHY: Were these mainly personality and power matters, or were they matters of judgment about policy about which people felt deeply? Or can you distinguish?

WR: Well of course ostensibly, they were matters of policy about which people felt deeply. There is no way I can say what really prompted them. There was one other conflict there that was important, involving Leo Miller, Assistant Commissioner for Administrative (Business Manager) of FDA. Leo Miller had occupied a very important position with the Federal Security Administration. He had been brought in in the early days of the FSA. When the Federal Security Administration became a department, I guess in 1952, Mrs. Hobbey was brought in as Secretary. She and Leo Miller didn't get along together. I was in no position to know why and never did hear exactly why, but Leo Miller was stripped of his responsibilities. He was given an office where he could sit all day long and do whatever he wanted to--doodle or brood or telephone, but given no responsibililty. After a little bit of that, he got fed up and transferred to the Department of the Army as a financial or planning officer over there. Later, when the Republicans were out and the Democrats got back in, Leo wanted to get back with our Department. He considered that his home department.
So he applied to George Larrick for a position and Larrick hired him. For a couple of years I would say, maybe longer, Leo did a yeoman job with FDA. He brought some improved business practices in that were much needed. He was a great asset to the organization.

For some reason, I'm not sure I know the answer, Leo became thoroughly disenchanted with FDA's top management, with both Larrick and Harvey. (Intervening material restricted. For release January 1, 1996.) He and Jack Harvey had some deep misunderstandings during this period of time. The result was that Leo Miller, and for the last year, perhaps year and a half that he was with the Agency, was a destructive influence also.

JHY: You used the word destructive. Were these rivalries the tension, such as to hamper the mission?

WR: Yes. I think so.

JHY: Can you give examples of how policies weren't developed or cases weren't brought, things of that nature?

WR: It is not possible to say what new or improved policies might have been developed in the absence of these personality clashes, or what cases might have been brought that were not. I do believe that when the leaders of an organization become preoccupied with personalities they then have less time to devote to enlightened leadership. Just as there are times in your personal life when you look back at some decision point and wonder what would have resulted had you made a different decision, we can look back at the rivalries just mentioned and wonder whether the agency would have been

greatly improved had they been absent. We'll neverknow for sure; you can't turn the clock back and try another approach. I do believe that on many occasions some of the FDA leaders were spending time worrying about each other that could have been devoted to furthering the mission of the agency. Others might hold that some irritations on the job are good in that they keep you alert, that you do better because you have to guard against possible attack from your enemies.

One thing I would like to say for the record is that, while I've been quite frank in my evaluation of a number of people associated with the Food and Drug Administration and the policy decisions they made, I think FDA is one of the better government agencies with which I am acquainted. I think FDA had personnel who, on the whole, were a cut above the average of federal employees. I would not wish my frank remarks to be taken as an indication that I dislike the Agency or its personnel. I think it is, or was at the time I was associated with it, and I certainly hope it still is, one of the best agencies in the Federal government.

JHY: Certainly, throughout most of the time period, to judge by all the remarks that I've heard, the esprit de corps and sense of mission of the Agency on the part of all and sundry was very high. It was often remarked

upon in the kinds of comments that were made at different kinds of meetings when people were brought together. And it has been remarked upon in various interviews that we've had.

BP: Almost every one. I was trying to think . . . I've interviewed 20 odd people, most of whom had either very important or at least fairly important jobs, and everyone has said something like you did. Just almost to a man.

WR: If I were going into the government service today, I don't know any agency I'd rather start with than the FDA I knew.

JHY: We pushed you toward the difficult, toward the hard and toward the critical. That's on purpose, because those things don't show up unless you probe for them. And what you're saying is you wouldn't want to have the interview which is unbalanced for this reason--seem to be your full perspective.

WR: That's true. I do not wish this interview to be taken as an interview of an unhappy disillusioned ex-employee. I was a very happy employee. I enjoyed my work, and I'm proud of it.

JHY: That is good to have on the record, and we appreciate very much both your willingness to talk and your willingness to talk as honestly and candidly and straightforwardly as you've done.

BP: It's been a real opportunity for us. A very pleasant one too.

WR: I've certainly enjoyed it myself. I've enjoyed seeing both of you again.

BP: I believe that then completes the tape.