

History

of the

U. S. Food and Drug Administration

Interviewee: Alfred Barnard

Interviewer: Ronald Ottes

Date: May 14 , June 4, 1987
March 2, 1989

Place: Rockville. Md.

INTRODUCTION

This is a transcript of a taped oral history interview, one of a series conducted by Robert G. Porter, Fred L. Lofsvold and Ronald T. Ottles, retired employees of the U.S. Food and Drug Administration. The interviews are with persons, whose recollections may serve to augment the written record.

It is hoped that these narratives of things past will serve as one source along with written and pictorial source materials, for present and future researchers. The tapes and transcripts will become a part of the collection of the National Library of Medicine.



TAPE INDEX SHEET

CASSETTE NUMBER(S) 1,2,3,4

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

DATE: 5/14, 6/4/87 & 3/2/89 PLACE: Rockville, Maryland LENGTH: 300 Minutes

INTERVIEWEE

INTERVIEWER

NAME: Alfred Barnard

NAME: Ronald T. Ottes

ADDRESS: [REDACTED]

ADDRESS: U.S. Food and Drug Administration
Rockville, Maryland

FDA SERVICE DATES: FROM 1941 TO 1970 RETIRED? yes

TITLE: Director, Bureau of Regulatory Compliance
(If retired, title of last FDA position)

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SUBJECT

Wrap Up.
End of interview.

DEED OF GIFT

Agreement Pertaining to the Oral History Interview of

ALFRED BARNARD

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Chief, History of Medicine Division
National Library of Medicine

RO: This is another in the series of FDA oral history recordings. Today we are interviewing Mr. Alfred Barnard, retired director of the Bureau of Regulatory Compliance. The recording is being made in the Parklawn Building. The date is May 14, 1987. I am Ronald Ottes.

Al, we'd like you to please briefly sketch your background: when and where you were born, where you were educated, and the various positions that you held with FDA during your career.

AB: Believe it or not, I was born in New York City. That was only because I wanted to be near my mother at the time. I left there as soon as I found out where I was. I was raised mostly around Asheville, North Carolina. I graduated from high school in Asheville. I went to Rensselaer Polytech for a couple of years in Troy, New York, transferred to Georgia Tech, graduated from Georgia Tech in '38 with a B.S. in chemistry. I did graduate work at Georgia Tech under a fellowship from the Georgia State Engineering Experiment Station. My work was done in the area of chemical physics, the X-ray structure of viscose rayon, to be exact. I then went to the University of North Carolina and worked on my Ph.D. under "Pop" Ruark, of Ruark and Urey fame.

World War II broke out, and I came about as close to winning an important raffle as I ever did in my life. I think I had national order number 62 for the draft, and it wasn't too long before the draft board was telling me if I didn't get out and start supporting my wife, I was going to wind up in the army. Food and Drug came along and offered me a job. The only reason I happened to be on the register was because everybody in the graduate school at Tech had been given the day off to take the exam, and I didn't have anything else to do. I

didn't have the slightest interest in going to work for the government at the time I took the junior chemist exam. Ed Holmes, who was then chief inspector in Atlanta, came up to Chapel Hill to interview me and convinced me that a Food and Drug inspector's job would be a good place for me to be; so I joined FDA in January, the twelfth or thirteenth or something like that, 1941.

I worked as an inspector in Atlanta. I very nearly joined the military before I left Atlanta. I was working with a colonel at an army depot down there, and he had a little scheme to have me come into Medical Administrative as a First Lieutenant, which would put me in ahead of all of the M.D.'s that were coming in as second lieutenants. I was going to stay in medical administrative and help him run the depot down there. FDA convinced me I could do more for the country staying in FDA than I could in medical administrative, so I stayed in FDA. Ultimately in 1945 they finally went to the Presidential Review Board to get me one more deferment after the war was practically over. I had been told by some damned colonel down at Fort Belvoir that I was going to be in the army as a buck private in thirty days; and this was after I'd turned down a first lieutenant's commission four years before. So I was busy making a list of people I was going to shoot before I went into the army.

I was in Atlanta as an inspector, spent some time in Florida as acting resident inspector in Tampa, went to Baltimore in July of '42, and then to Washington, D.C. as resident inspector in 1944. The resident inspector's post in Washington, D.C. was a very interesting and long story. I don't know that there's much point in going into it. I was one of the few people who ever made a success of the job, and that was primarily because I was fortunate or astute enough—I don't know which—to recognize what was important in the job. And

what was important in the job was what satisfied the local politicians and the congressmen and the senators, and not necessarily what was of most high priority to the Food and Drug Administration. That created some conflict between the Washington resident post and the Baltimore chief inspector, to whom I reported. But nonetheless, you had to gear your actions that way to succeed in the District of Columbia as resident inspector.

RO: Who was the chief inspector then in Baltimore?

AB: The chief inspector in Baltimore changed during that period. Allan Rayfield was my chief inspector when I went to Baltimore, and Allan and I had some very interesting times. As a matter of fact, when I became resident inspector in Washington, he got me aside in the garage in South Agriculture one day and he said, "Now listen to me, Barnard, God damn it," he said, "don't you ever let me down in this job." He said, "I got you into this job, don't you ever let me down." Well, I happened to know that he had recommended somebody else for the job and that I had gotten the job through the support of others than Mr. Rayfield. So I looked Allan straight in the eye and I said, "Allan, the only reason I'll never let you down in this job is because I can't figure out any way to let you down without letting myself down." So, so much for that.

Johnny Guill became chief inspector while I was resident inspector in the District, and Johnny and I got along very well. Johnny was put into the job of chief inspector much too green, and it seriously hurt Johnny's entire career. He wasn't ready for the job when he was moved into it. Johnny was a heck of a nice guy; I liked him very much.

From that job I transferred into what was then the Bureau of Field Administration, which was again headed by Mr. Rayfield. I was transferred in there, I guess, in '48, and worked for Rayfield. I reviewed all the drug and device reports and Larry Warden reviewed all the food reports; Larry and I, between us, reviewed all of the investigational reports, EIRs and other reports, that came in from the field.

RO: Was Jimmy Cribbett there?

AB: Jimmy was there. Julie Hauser came in there fairly shortly. Frank Vorhees was there. Gordon Wood was there. Somebody else was chief chemist after Frank Vorhees left. Fred Garfield was there. We had a wonderful car pool: Winton Rankin, Allan Rayfield, Al Barnard, Gordon Wood. Oh, that was a doozy (laughter).

RO: I imagine.

AB: From the standpoint of my own career, one of the highlights was that the Civil Service Commission offered what they called the Second Career Development Program, and they ran a series of both oral and written tests and suitability interviews to pick the twenty top people for the program out of the entire federal service for that year. Somebody in FDA, over the protestations of Mal Stephens and a few other people, decided that FDA would participate. FDA had not been noted for participating in endeavors of this kind at that point in history. Suddenly they woke up to the fact that they had four people who had

qualified for the first stage; they were Bill Wright, myself, Jack Radomsky, and some guy from one of the scientific divisions; I forget his name now. And they were scared to death, because it looked like they might lose four people for six months, and in those days we had less than a \$5 million total budget; they didn't have four people to lose.

To make a long story short, Bill Wright and I both qualified for the program, and I went through the Civil Service Commission's Second Career Development Program, which I found one of the most useful things I ever got exposed to in my entire career. It was basically a course in human relations. I did a several months' assignment out in NIH on budgeting by objectives, which I found kind of useful. Immediately after I returned from there they had "the big rif"; we had "the little rif" and we had "the big rif." When they had the big rif, I was "riffed" and I was transferred to Atlanta. I was a GS-12, I guess, at the time, and I was going to be transferred to Atlanta. I looked at the situation in Atlanta, and they had nine GS-12 inspectors, and I had fewer retention points than any of the rest of them. Or maybe I was a "12" and I was going back there as an "11"; I'm not sure. So I said, "To hell with this. I might just as well leave the service here as in Atlanta."

RO: What year was that, Al?

AB: This was in '51, I guess, "the big rif." Somebody would have to check back, but I think it was '51. So I just sat tight. I said, "To hell with it." I had two weeks' vacation planned at Ocean City; I had a cottage rented at Ocean City just about the time I was supposed to be separated. So I cut that down to one

week because I figured I couldn't afford two if I didn't have a job. So I set out looking for a job.

I would have gone to work with Lloyd Hazelton. I spent quite a bit of time talking to Lloyd, but Lloyd at that time was hellbent he was going to control the business. He wasn't going to let anybody else have any part of it, and he wouldn't give me a piece of the action. So we didn't get together. Nine hours before I was supposed to be rified, I got a call from Ramon Davila in the personnel office telling me that they had suddenly found a way to keep me on the staff there in Washington. Ken Milstead had the office right across from me, and when I came into work Monday morning, he said, "Boy, you sure did sweat 'em out, didn't you?" I said, "What the hell you mean, 'sweat 'em out'? I didn't want to go to Atlanta. I didn't mind being fired. I don't expect to starve to death." Shortly after that, Fred Garfield and I designed a trailer laboratory and got some kind of an award or plaque of merit or something from Larrick which was not grammatically correct and also contained typographical errors, so of which I was not appropriately proud.

Then in late 1954, I went to San Francisco as chief inspector. In San Francisco I replaced Russ White. And that was a very fortunate circumstance, because I could do no wrong. White had been such a lousy chief inspector, he'd done such a lousy job, that there was no way I could fail to be a success. Plus the fact Mac McKinnon was district director. Mac had been my district director in Baltimore, and I was kind of Mac's son that Mac never had himself. He had two daughters, so I was kind of under Mac's protective wing. Of course, Mac was in the doghouse, so being under Mac's wing wasn't really the greatest place on God's green earth to be.

San Francisco was a very interesting period of time. Working with the people there was interesting. It was my first supervisory job. We had a few little interesting things here and there. We had a chief inspector's conference in Cincinnati once upon a time, at which the two major foci of interest were the possibility of getting data automation in the districts, and what to do about inspectors who took coffee breaks on government time. I got up and said that I took my inspectors out for a coffee break every morning, and one of the older hands got up and said that he felt that any chief inspector that took his inspectors out for a coffee break every morning ought to be fired. So we got the meeting off to a pretty good start. The older hand was the same one who announced, "We already have data automation in my district; we have two electric typewriters."

As far as I was concerned, I found out more about what was going on at the coffee break than I did any other time in the day. I found it a better opportunity to exchange information, to get a feel for what the boys' problems were, and what they felt they needed help with. It was the best communications vehicle I had, and nobody ever told me not to do it, although I'm sure Rayfield's hackles ran up and down his back by the hour thinking about it. Early on in San Francisco, Frank Clark came out and chewed me out about not doing too good a job of something or other; I've forgotten what it was. And I said, "Damn it, Frank, if I wasn't so busy having to be a district director, I would make a better chief inspector." And he looked at me straight in the eye and he says, "What do you think we sent you out here for?" So that's the way it went.

I remember when Stan Glassner was transferred to Peoria--I've forgotten now whether it was Rayfield or Clark called me up and asked me, "Would Stan

Glassner like to go to Peoria to be resident inspector?" I said, "I don't know; I'll ask him." "Oh, my God, no. Don't ask him! Don't ask him!" I said, "What do you think I am, clairvoyant, a mind reader or something, for God's sakes? Why shouldn't I ask him?" "Well, what are you going to tell him if he doesn't get the job?" "I'll tell him he didn't get the job. That's simple." But that was not that simple in FDA in those days.

RO: Not then, no.

AB: But to make a long story short, I did get permission to ask him, and he said he'd like to go, and they made him resident inspector in Peoria. His wife committed suicide with some barbiturates that were at least rumored to have come from the office, which didn't help things any. But that's another story.

RO: The office in San Francisco or Peoria?

AB: San Francisco. I could tell you amusing episodes interminably about San Francisco and life there, but I don't know that you'd be particularly interested.

RO: I think it would be interesting, especially if you've got some special cases.

AB: I had an inspector there whose wife was extraordinarily jealous, and she called up one day and asked for her husband. One of his very good friends recognized her voice. She asked for Inspector Taylor. No, it was Inspector Dada. She asked for Inspector Dada, and this character who recognized her voice said,

"Well, I'm sorry, ma'am. He went out with his wife about fifteen minutes ago." It took me about a week and a half to clean that one up, you know (laughter). Other little things. You get a call on Saturday morning that says, "Who is this bitch that my husband is sleeping with?" The delights of being chief inspector.

We hired a new guy, Bob Bunker; I don't know what ever became of Bob. I hired him as an inspector in San Francisco and sent him down to work with Billy Cox. Billy was resident inspector in Fresno. He got started on some projects, and the next thing we knew, he was just off by himself, making inspections and flying his own cotton-picking kite. The guy's only been around for about a couple of months, and nobody knew where he was. About once a week I'd get a whole bunch of good reports from him. I had him lost down there for about six weeks. Producing? Yes. But not exactly in accord with established procedures.

RO: Must be like Ollie North.

AB: Somewhat. Yes. But I was never a stickler for that kind of thing. That's the kind of thing that would have driven Sam Fine crazy. If a guy's producing and I can keep him from doing the wrong things, if I can develop him and train him and yet let him tend to go his own way, I see some advantages in that. I finally had to rein that guy in, by the way. I don't know; I'll probably think of some other San Francisco stories as we go along.

Dale Miller was an inspector of mine in San Francisco. Stan Gilmore was at that time my only GS-12 inspector; he was one of the three or four GS-12s in the country at that time. Stan was never noted for having a sense of humor, but most people didn't know Stan's sense of humor. I know I called out to the office

one day and said, "Stan, are you free?" And he said, "No, but I'm reasonable" (laughter). Perfectly straight face.

We used to have an inspector's staff meeting once a week. Everybody would get together for an hour in the mornings. After we finished up a meeting one morning, Stanley slapped the table and said, "I want to talk about sex before we break up." Everything was quiet. Stan says, "Now that I've got your attention, I want that sample wrapping room cleaned up every time when you get through" (laughter). The second day I was there, we got in the car to go over to the Hall of Justice, and instead of going down Market Street and around the hill, Stan went right straight up to the top of the highest hill in San Francisco and started right straight down towards Sampson Street; and as he's going down this perpendicular hill, he says, "Well, I wouldn't have come around this way except I had the brakes on this car worked on last week and I wanted to see if they were okay" (laughter). Never a smile. This is breaking in the new chief inspector.

I mentioned Dale Miller. That got me into Stan Gilmore. When I first came to San Francisco, the first thing I did, I sat down with each inspector and asked him what he had been doing, what work he was primarily engaged in, what were his primary goals, where did he think his future lay in the organization. One guy told me he had been in charge of useless projects and wasted time. So I got a pretty good open response from most of them. I asked Stan Gilmore flat out if he was bucking for chief inspector, and he told me that from what he had seen of the policies and attitudes of the agency, he was not at all sure that he wanted to be a chief inspector. So I said, "That's all right, then. I'll give some-

body else time on my desk when I'm out and give them the opportunity to develop; and if you change your mind, don't hesitate to let me know."

As a consequence of that, I put Dale Miller on the desk quite frequently. Dale showed more administrative aptitude than anybody else I had in that place. And Dale got personally involved in this, and he tried to curry favor with me. He and his wife used to come down and visit us in Palo Alto just practically every damned weekend. They made a pain of themselves. Dale and I went on a trip to Reno. Dale is a very straitlaced person who doesn't gamble, doesn't drink, doesn't womanize, and he and I had absolutely nothing in common. Dale came back to San Francisco with the conviction that his career was totally ruined and he was wholly incompatible with his chief inspector. What he didn't realize was that I don't relate personalities to official performance. I know people in the agency that I cannot abide personally for whom I have a great deal of admiration officially, and that included Rayfield; and there are also people in the agency that are absolutely useless officially who are very nice people and whom I find it very pleasant to be around and associated with. I wouldn't promote them to #2 dogcatcher from #3. And Dale was in the first category. Dale and I had nothing in common; I had no reason to spend any time with Dale personally, but that didn't prevent me from later on recommending him for promotion to an administrative post in Washington. I think he nearly dropped dead. I don't think he could believe it.

Anyway, along in the spring of 1960, I guess, I got promoted to district director in Kansas City. I got some more flak from Rayfield about "you do it like I tell you to, now, and you behave yourself and you do what I tell you, and we'll make you district director of Kansas City." I told Rayfield the kind of things

I'm fond of telling him: "Look, if you make me district director in Kansas City, I'll do the best job I can do as district director of Kansas City. It's just that simple." It was kind of ironic, in a sense, because Mac had been saying to me for a year or more, "Look, son, we're going to get you a job as a district director." And I'd been saying, "Now come on, Mac, I don't know that I want to be a district director. Look, Mac, suppose I got transferred to Kansas City as district director and I had Ted Benjamin as chief inspector and Andy Allison as chief chemist. Do you think I could stand that?" So where do I get sent? Kansas City!

Well, I learned at least half a lesson out of that. Andy Allison was a very, very fine chief chemist; he was excellent. Now Ted Benjamin was a problem; Ted Benjamin had been chief inspector in Kansas City before I ever came in the service. Now I come there as his district director. You know, this is not calculated to make for the easiest operation. Benny was probably one of the poorest chief inspectors we ever had. I started to say I was forced to, but at least I did, take over more of the management of the better inspectors than I should have.

To Benny, the ideal inspector checked in at eight o'clock in the morning and checked out at four-thirty in the afternoon, and was never late, and was well-dressed, and did what was on his work program—that was the perfect inspector. He had a guy there by the name of Roscoe Moll, and he considered Roscoe was about the perfect inspector. I was district director in Kansas City from the latter part of '60. until early '66, and if Roscoe Moll ever developed a legal action in those five years, I'm not aware of it.

We had another kid there by the name of Johnny Johnson, who couldn't do anything right. Every time Johnny went out, he screwed up something. But every time Johnny went out, he had a violation. You had to send another inspector out to get adequate documentation and to get the job done right, but every time he went out, he had a violation. And of course that drove Benny up the wall, and Johnny finally quit.

But my time in Kansas City was probably the most pleasant time I had in the agency. I did my thing; things went smoothly. I followed Sam Fine. Sam is an excellent manager, but a totally diametrically different management style from mine. Sam does things by the book. He's a navy man, and there are pluses and minuses to management by the book, as you know. Sam did such things as charging the guys leave when they went out house hunting when they were transferred in, because that's what it said in the book. And the mere fact that they had worked till ten or eleven o'clock the night before didn't cut any ice with Sam. I had a little different approach. I'm not sure that I ran any better shop than Sam did. I ran an entirely different shop, but as far as getting the mission of the organization carried out, I'm not sure I did any better; I may even not have done as well. But I had a happier crew. When I first walked into that district, it was like a mausoleum. When I left there, everybody had an esprit de corps. Whether it contributed anything to getting the total mission accomplished, I really don't know for sure.

RO: They hadn't moved into the new building then.

AB: No. I moved the district into the new building. I had some interesting experiences in the process. At the dedication of the new building, we had as our principal speaker Mayor H. Roe Bartle. H. Roe Bartle is a legendary figure in Kansas City. He weighed about 325 pounds. As I say, he's really a legendary figure. After the luncheon, we rode over from the ceremony to the new building in his limousine, my wife and I in the back seat with him. I invited him to stay a little while for the festivities afterward, and he apologized. He said he had a councilmanic meeting. He said, "I can't believe it. I have the only city council in the United States that is composed entirely of the offspring of unwed parents." Then he looked at my wife and said, "You know, they are a bunch of bastards" (laughter). At the luncheon, he was the keynote speaker and I was sitting at the head table to his right. As he was introducing the head table, he had me stand up--and as I said, he weighed about 325 pounds. I was weighing about 230 in those days myself. He looked at me and he said, "Son, you look like I might have sired you."

We had a couple of tiffs with Rayfield, and finally I got Rayfield on the right track somewhere around '64, about the time we moved into the new building. He came out to the house for supper; it was the last time he ever darkened our door. I don't know; I'd had a couple of drinks and I'd given him a couple, and he started in on me and he said, "Now, Barnard, if you don't do this and this and this and this, I'm going to root you out of this job in Kansas City." I said, "Rayfield, let me tell you something." My wife was sitting at the table, and, of course, she went upstairs in a hurry. I said, "Any time you want me out of this job in Kansas City, all you've got to do is say so, and you can have my resignation. As a matter of fact, I haven't got a Form 57 here now, but I'll

write you out a resignation right now, if you want it. I don't want to hear any of this. Any time you're not satisfied with the way I'm running the district, just tell me and go out and get yourself another boy. But in the meantime, let me run the district, and you keep your greasy fingers out of it. If you're not satisfied, just tell me." So that's kind of the way we ran the district from then on. I got along real well with Allan, because I wasn't afraid of Allan. Allan cowed a lot of people. And Allan did not recognize his own importance; that was one of Allan's biggest limitations in the service: he never realized how important he was.

RO: He didn't?

AB: No. He came out to San Francisco when I was chief inspector and spent half a morning telling the boys how they ought to arrange their desks. Now, the reaction of my group after he was gone was, "Well, for God's sakes, a guy in his position? Hasn't he got anything more important to devote his efforts to than coming out here telling us how to arrange desks?" Allan would say something, make some little casual remark to somebody like Ralph Horst or Wendell Vincent or somebody like that, and they would take it like the word of God, and Rayfield never recognized this, never. You're right, Ron, an awful lot of people thought that Rayfield thought himself far more important than he was. That was not true.

Rayfield has a difficult background. I don't know how much of it you know. He was raised on the wrong side of the tracks in Mobile, Alabama. His father was killed in a train accident in the Gulf, Mobile, and Ohio yards before he was

ever born. And the Gulf, Mobile, and Ohio Railroad never compensated his widow at all. He was caught between the couplers on two cars. Whether it was his negligence or the railroad's negligence, nobody knows; but he had his resentment deeply engrained from birth as a consequence of that. As I say, I have no personal use for Rayfield, but I can understand where some of him came from. And I have a great deal of admiration for his abilities.

RO: You were in Kansas City at the time of our big expansion, as far as recruiting was concerned.

AB: Yes.

RO: Andy Allison was a recruiter.

AB: Well, Andy was the top recruiter in the country, and we recruited some really top, top people. He brought in a young black prospect for an inspector who's still in the service somewhere; he was in Baltimore the last time I saw him. His name was Jim White, and he was not really black black. He was obviously Negroid, though. He was a candidate for inspector, and Andy brought him down to my office and we were chatting. I like to get casual with these guys if I can. I said, "What do people usually call you?" He said, "Well, Whitey, but not very often" (laughter). I said, "You're hired." That's my type of guy.

Something I always had to recognize as an administrator, as a manager, anybody who's an introvert has two strikes against him when I'm interviewing him for a job, and anybody who's an extrovert has a couple of strikes in his favor.

I've always had to be very, very careful about that in trying to select people for promotions and select people for employment. You have to recognize your own biases, and it isn't easy. I've always said that in selecting personnel, particularly for advancement, if you're right 50 percent of the time, you're a genius. It's a very difficult thing to do.

Back to Andy. I could sit here for thirty minutes and name the people who are still in the agency that Andy, I, and Boland Shepherd recruited. Boland was an inspector and was one of our better recruiters in the inspectional area; but Andy was our primary recruiter. Dick Ronk you know we pulled out of the Post Office Department in Omaha. Ed Frye we recruited. I could just name them by the dozens. They're all over the place. Some of them have retired by now. This gal that was a chemist who was district director in San Juan is in Chicago now. What the heck's her name? I forgot.

RO: Mary K. Ellis?

AB: Yes. Just as I say, gobs and gobs of them. He developed Don Healton. Of course, we got Don from San Francisco. He also developed Tony Celeste; Tony came there just about the time I was leaving, so Tony worked for me for a very short time. I don't know, I'll probably think of some interesting things about Kansas City as time goes on. The crises in Kansas City were mostly official-type crises.

I came to Washington in January 1966 to set up the Bureau of Drug Abuse Control with John Finlater. John and I had a little interview, and then we

walked into Jim Goddard's office; and John looked at Jim and said, "Well, the fat boy's decided to hire me." So that's how I became Deputy Director of BDAC.

RO: Where did John Finlater come from?

AB: John came from GSA. He had been in Labor at one time, or associated with Labor, and a lot of the people we picked up were from the criminal side of Labor. The people who were in criminal investigation work in Labor were fed up to the ears, because the labor unions were calling all the shots; they were developing all kinds of evidence of outright crookedness, and they couldn't get anything done about it, so they quit in droves to come with us. Some very good people. Then John brought some good people from GSA. Of course, I brought some good people from Food and Drug. Initially, we had a pretty good operation. When they went into Narco, it became a different situation. Let's see, we started in January to set it up, and I only stayed there until early September. John left to go to the International Narcotics Agents meeting in Geneva, and I don't think he'd gotten airborne before Jim Goddard called me and asked me to take over the Bureau of Regulatory Compliance.

RO: How did that come about, Al? That's something I wasn't clear on.

AB: After they kicked Rayfield and that bunch out, Larrick retired—essentially Larrick was kicked out—and with him went Harvey, and Rayfield, and several of the old gang. Winton Rankin stayed. Winton was about the only top-ranking guy, I guess, in the mess that stayed.

RO: Was Kirk still there?

AB: Oh, yes, Kirk stayed right up to the bitter end.

RO: What about Malcolm Stephens?

AB: Steve retired about the time we set up BDAC. I never understood Steve. That's an interesting thing. Steve was supposed to be my official liaison when I was in that career development program that I was telling you about. The career development program was run by a guy by the name of Franklin in the Civil Service Commission, and Steve was supposed to be his interface with FDA participants in the program. Franklin and I were talking about Steve one day, and Franklin told me that I needed to understand Stephens; and I never did succeed in understanding Stephens.

One of the first things we did in the career development program was to sit down and write out our career goals, and sit down and write out a set of realistic steps whereby we expected to achieve those goals. It's a good exercise; it's an exercise I would recommend to anyone who is in an agency who has ambitions. I get too many people like the guy who came in my office in Kansas City one day, complaining about his lack of advancement. I said, "Where do you want to get?" "I want to get ahead." I said, "Look, fellow, you've already got a head. Let's talk about your career." You hear too much of this. Anyhow, obviously at that time my objective was to become commissioner, and I outlined the steps by which I might arrive at being commissioner, all of which I completed,

by the way, except the last one. I don't think I would ever have become commissioner, because by that time you had to have an M.D.

This is a different story. Herb Ley and I were on a parity, and I told the secretary when Jim Goddard left that I was not interested in being considered for the position, because I was not at the point of time we're talking about.

Now, in '50 or '51, I had to present my career objectives to Steve, because he was my interface with the program. Steve was in the line of succession that I was going to take to get to the commissioner's office, and so far as I could tell, he bitterly resented it. He told me, "You're never going to get anywhere in life until you achieve some humility." I've never quite yet understood exactly what Steve meant by humility, because Steve himself has never precisely fit my definition of a totally humble person. I'm one of these people that kind of feels like they say, "the meek shall inherit the earth"; and when the meek inherit the earth, I'm not sure but what they'll be welcome to it (laughter).

So when they broke things up and Larrick left--and everybody else but Rankin, virtually--Goddard came in with a mission to change the direction of the agency. The department, the powers that be, the secretary--I guess the political administration, too, but primarily within the department--were dissatisfied with the narrow, case by case, "we're a cop agency; our role in life is to enforce a law just as though we were the cop on the beat." That kind of approach the department repudiated; whether rightly or wrongly is immaterial. Jim came in with a mandate to change the direction of the agency.

A great many people in the agency resented Goddard very much. They resented everything that Goddard did. I guess I was one of the few old-line people who worked successfully with Goddard and enjoyed working with Goddard.

Goddard's like everybody else; he's got shortcomings. But if Goddard had had the commissionership of FDA as his career goal, Goddard would have made one of the greatest commissioners the Food and Drug Administration ever had. But he had no intention of remaining commissioner of FDA. He took the job as a steppingstone to the Surgeon General's job, and when they moved "C. Square" Johnson in on top of him, and he found out he wasn't going to become Surgeon General, he quit. It was just that simple.

But in the process, having gotten Rayfield and all the old hands out, they abolished the old BRC, the BRC which had master control of the entire field, the BRC that sat up in the middle of the web and pulled all the district strings. They spun the district directors loose on their own responsibilities. Each of them was to develop his own work plan within certain guidelines that were supposed to be supplied from Washington.

RO: Al, let me ask you this. Fred Garfield was kind of Rayfield's deputy under the old BRC before.

AB: That's right.

RO: And then when you went over to head up BRC, Fred went over to BDAC.

AB: I'll get into that in a minute. Where was I, now?

RO: You were kind of spinning the field off.

AB: Okay. Harris Kenyon was brought in and assigned the job of being a one-man overseer, with instructions not to develop a staff and kind of coordinate things. Now this was supposed to be delegation, and there was much to be said for this that was good. Goddard wanted to delegate to the district directors a degree of responsibility he thought the district directors ought to have. Unfortunately, he had a few district directors like Ralph Horst, who couldn't go to the toilet without calling up first and asking whether he should do #1 or #2 or both. So that was one problem.

The other problem was that, unfortunately--and this may have been . . . I don't know, it's difficult to analyze exactly who's at fault; it may have just been the fault of the circumstances; it may have been because of the presence of Rankin; I may have played a contributing role in it. But it became more of an abdication than a delegation. Nobody gave the field the guidance that they needed in order to handle the decentralization. There was a kind of a hiatus between mid-1966 and mid-1967 while things were in the transitional stage, and Goddard would have done much better, in my 20/20 hindsight, to have reorganized Washington, gotten the structure in place, and then done the delegation, instead of doing the delegation and then trying to set up a structure to make it function. This may have been in part because of the mandate to take the agency in a different direction, a mandate that was not appreciated by most of the people who resented the things that Jim did.

RO: But if each one of the district directors was supposed to report directly to the commissioner, the span of control was just horrendous.

AB: That's true. That's one of the things that I had in mind when I said he would have done better to have established some kind of a central structure to have handled the thing a little better. Jim had too many other things to do. Jim had too many daughters whom he would rather have smoke marijuana than drink a martini, and little problems like that that drove poor old Paul Pumpian right straight up the wall.

But then to the Garfield thing. When Jim asked me to take over BRC, Fred was acting director. I don't think he had ever been officially designated as director. There was nothing they could do to fire Fred; there was no basis upon which they could fire Fred. There was no obvious place for Fred at his grade level. He was kind of like some other people. He was kind of like Reo Duggan and a couple of other people that turned up. So Goddard just summarily reassigned him to Finlater as his deputy. As far as I know, he didn't ask anybody; I'm not even sure he asked Finlater. Once he put me in the BRC post he told me to get my own deputy. He didn't ask me if I wanted Garfield. He did not like Garfield at all. I think this was primarily Fred's fault. Fred would not change from the old mold. Fred was an old-line Food-and-Druggery, and he wasn't about to change his way of doing. Goddard found that totally unacceptable. Of course, that's not a basis for which one fires someone in the Civil Service System, but that does get you, let's say, out of the flow of promotions.

So that's how that took place. I mean, he was just summarily transferred, and it was not until a luncheon about last Tuesday or whenever it was that Fred has been civil to me since. He and I sat beside each other. I deliberately sat by him, and we buried the hatchet, I think. We actually got friendly. I was very disappointed because, as I've already said on the tape once, I don't involve

personalities with business. I was very disappointed. I was called up to Michigan to serve on an oral interview panel to select candidates for the laboratory director in the state of Michigan to head up all of their laboratories. It looked to me like an ideal job for Fred. I knew Fred was unhappy in Narco (where BDAC went); I knew that Fred had kind of wanted to get back to the Middle West area; and I called Fred to tell him about it. "I don't need you to help me find a job!" and hung up the phone. Yes.

I got very much the same deal from Winton Rankin. After I retired I was offered a job that would have been ideal for Rankin. I didn't want a full-time job. These people wanted somebody for the job, and Rankin would have been a good man for the job. I contacted Rankin, and he acted like he was insulted that I would be offering him a job, as it were. Some people are funny. Anyway, that's how that took place.

I stayed as director of BRC. I hired Eric Stork as my deputy. I got Eric from HUD. Eric had set up the airports system for FAA, got it running; and once he got it running, he didn't have anything left to do except either tear it up and do it over again, or go somewhere else. He went and tried to work at HUD, and he said that was like trying to work with a bunch of eels in a barrelful of snot, I think was the way he put it. He said it was absolutely impossible. So he came over as my deputy and, as far as I was concerned, was an excellent deputy. Eric had a lot enemies scattered around the place.

RO: There were a lot of people in FDA that didn't think much of your judgment in selecting Eric Stork.

AB: I know. A lot of people never recognized Eric's ability; and Eric is today doing a hell of a lot better than any of those people who were very critical of my judgment, incidentally. Eric's too outspoken for his own good; that's one problem. Eric has no tact. You're talking about something very delicate with Eric and you say to Eric, "Now, Eric, you know how it is." Eric says, "No, how is it, Al?" Just like that, no smile or anything; he's going to dig to the bottom of it. And this'll irritate the hell out of you. I taught Eric not to do those kinds of things in public. I said, "Look, if we're in a meeting with ten people and I want to smooth something over by saying, 'Hey, you know how it is,' I don't want you sitting over there saying, 'No, I don't know how it is.' Just keep your mouth shut if you don't know how it is." But Eric had, as I say, a lot of ability. Personality problems, yes. The way it shaped up, I let Eric essentially run the Program Planning and Evaluation Group, and I ran Enforcement, and Ted Byers the Compliance Group.

I brought Ted in from New York; I brought Loftus down from New York. You know, you win one, lose one. Like I said about personnel selection, 50/50. The biggest mistake I think I ever made in my career was selecting Mary Dolan instead of Paul Hile for the job in Program Planning and Evaluation. The main reason I didn't select Paul was because the Booze-Allen people had warned me that Paul was an empire builder, and at that particular time I did not want an empire builder in that job; I didn't realize I was getting a useless lush instead.

RO: Was she already in headquarters or was she still in New York?

AB: She was in New York. That's one I owe Curly Clevenger. Curly never told me of her other problems. See, I had known Mary when she was a chemist in Kansas City; I knew her there very briefly. She was transferred to Denver very shortly after I got there. Then I had occasion to work with her when she was in Denver. At that time, Mary was kind of an abnormal person, but she was not on anything. She went to pieces after she went to New York. She was emotionally unstable from the start. I've never known the whole story. I think she lost a lover in the war, is the story I've heard. But whatever it was, she never recovered from it emotionally.

Anyway, in late '69 they fired Herb Ley. When Goddard left, I went over to see Wilbur Cohen, and I said, "Mr. Secretary, I've known you now for ten or twelve years. I don't know whether you would consider me for this commissioner-ship or not. I would just like to let you know that I'd like to remove my name from consideration before you have to worry about it." He didn't ask me any questions. He just thanked me for advising him; he didn't say, "Why?" or "What's on your mind?" or anything. Very secretarially distant, shall we say.

RO: Wasn't the Bureau of Voluntary Compliance established during that period of time?

AB: No. It had been established long before that. It had been established under Larrick. Shelby Grey was the first head of that group.

RO: When did General Delmore come in?

AB: The General came in when Shelby quit. They brought the General in and they were going to put the General in charge of what Shelby had been in charge of, and Shelby went right through the ceiling. He wasn't going to work for that retired demagogue. Oh, the words he used on Delmore, you wouldn't believe. And quit. Shelby was kind of an impetuous sort of soul, anyway. My first training trip out of the district in Atlanta as an inspector was with Shelby, when Shelby was resident inspector in Charlotte. I could tell some stories on Shelby, too, but they wouldn't contribute much to the history of the Food and Drug Administration (laughter).

Delmore came in then. There are several amusing stories about him. Delmore was a waste of public funds, and Goddard resented Delmore's presence. So one of the first things Goddard was going to do was fire Delmore. He tried to fire Delmore, and Congressman Sledgepump up here from Pennsylvania--Flaherty. Well anyway, it began with an "F." He was one of the most powerful men in the House. Delmore had taken him hunting and fishing on all the military reservations, and he and Delmore were in each other's back pockets up to their ears. It didn't take Jim Goddard very long to find out that he was not going to fire Fred Delmore.

Jim had some very interesting ideas. Jim said, "I'm going to abolish this damned tea inspection. It's an anachronism and a waste of time." I said, "Jim, you can't abolish tea inspection." "Why can't I, Al? Why can't I?" I said, "Well, in the first place, it's mandated by law, and in the second place, the entire tea industry in this country is totally dependent upon it." "Well, I'm going to do it, anyway." He found out he couldn't do that. But that's one of things I always liked about working with Jim. Jim would come to me and say, "Let's do so and

so." "Jim, you can't do that." "Why can't I do it?" I'd explain to him. "Well, all right, if I can't do it that way, let's see, can we do it this way?"

Incidentally, speaking of Eric Stork, before I forget it, as an aside. One of the big pluses with Eric: Eric Stork is one of the few men I've ever known who would go the way the boss said go, when the boss finally made the decision. Eric would scream and yell until the decision was made. Once a decision was made, he would wholeheartedly support it. I've never forgotten, once upon a time he and Jim Goddard got into a hair-pulling argument in a small staff meeting: "Jim, this cannot be done," Eric Stork said, and Jim Goddard said, "I don't care. We're going to do it anyway." And, you know, it worked. And the only reason it worked was because Eric Stork, the man who said it couldn't be done, went out and made it work. And there's not a hell of a lot of people around who will do that; just deliberately make a liar of yourself. That's what he did, and I've seen Eric do that on other occasions.

Eric had a cute little saying. Eric even would use this in meetings. I'd say, "Well, we're going to do this." We'd have an argument. Finally Eric would say, "Well, Boss, it's your cow." It goes back to the old story about the boy and the girl, and they're watching the cow and the bull out in the pasture. And the bull mounts the cow, and the guy kind of hugs the girl a little bit and says, "Gee, I'd love to be doing that." And she says, "Well, why don't you? It's your cow" (laughter). So Eric would pull that on me every once in a while. But he could be counted on that way.

The last year was pretty rugged. When Jim left and I told the Secretary I didn't want to be considered for commissioner, it had an impact on me that I really hadn't anticipated. You know, you spend your entire career in one place

and you kind of have one goal in mind, and when you suddenly surrender that goal intentionally, deliberately, it has an internal impact. Your approach to the agency or to the organization, I think, can never quite be the same. They had technically abolished my job, so I could have taken involuntary "retirement" any time I wanted to. If you have over twenty-five years' service and they abolish your job, you have the option of taking involuntary retirement. Or did then; I don't know what the rules are now.

RO: You can.

AB: The last year, I stuck around for two reasons. One, I had an abiding curiosity to see what the hell was going to happen next. I just couldn't resist. Secondly, it was during that year that we took over the Public Health Service functions. I had Shellfish Sanitation under my control. They all came into my bureau: Milk and Food Sanitation; Interstate Carriers; Jack Fritz; Dave Clem and all those guys; Harry Haverland. They all came in to work for me. So I spent much of that last year just integrating those guys, or trying to integrate those guys, into Food and Drug. They all thought that Food and Drug was going to rape them on the spot, and Food and Drug felt they were cancers joining the society and ought to be excised as promptly as possible; and I was trying to bridge the gap between the two. I went out on two or three road trips with Jack Fritz. We visited almost all of the PHS establishments in the field. We missed one. I had that trip scheduled when Charlie Edwards came in as commissioner, which Charlie told me to cancel.

You know, when people get old, they get loquacious. So any time, if I'm too loquacious, you just say so.

So that last year, Ted Byers was running Compliance pretty well, with the aid of Ken Kirk. Ken's role was an interesting one. Goddard never concerned himself with food problems, and Kirk was acting commissioner for foods. I know of only one significant food decision that Goddard made, that Kirk didn't make, and that was the one that involved Kava Coffee. Kirk wanted to attack Kava Coffee on the basis that this acidity bit was false and misleading; Goddard wouldn't let him. And as far as I know, that's the only major decision Goddard made in the food area that involved Kirk. Many of them came from Goddard, of course. Goddard appeared commissioner, but Kirk was really the commissioner for foods.

When Jim left, they kicked Rankin and Kirk out at the same time. Rankin couldn't retire, so they put him in a little isolated cell with no windows over in north HEW, and Kirk took retirement. It sort of momentarily left me the highest ranking unfired man around the place. I just wasn't quite obnoxious enough or important enough to be fired, but it was quite apparent that I was not the fair-haired boy. This is at the time when they kicked Ley out. I kind of skipped a year in there, because I was originally talking about the time when Goddard left.

When Goddard left, Ley became commissioner. That year was an administrative nightmare from my standpoint. It's one of the reasons I became involved in integrating the Public Health Service functions, because I could not get Ley to make a decision. And I could not get Ley to let me make decisions. I would tell Herb, "Look, Herb, damn it, if you don't want to make this decision, just leave

it up to me. I'll make the decision; don't worry about it." "Well, Al, you know, I like to keep my fingers in these things." Herb Ley is a nice guy, but I wouldn't go to Herb with an infected toe for fear I'd die of blood poisoning while he's trying to decide which antibiotic to use. He's much too thorough to be an effective administrator, I guess may be one way to put it.

I'll never forget one classic example. We had a request from Johnson & Johnson for an opinion as to whether an orange-colored three-and-a-half-grain aspirin tablet was or was not a New Drug. To me it was kind of ridiculous. Three-and-a-half-grain aspirin tablet's a New Drug? Billy Goodrich said he thought it was a New Drug. I said, "Billy, I think you're crazy." Billy's remark was that "as long as the wrinkle cases are under litigation, I'm not going to admit that there is anything that is not a New Drug." He stuck to that position, and he won his wrinkle remover cases. But the proposed response to J & J bounced around for literally months. Finally, Kirk sent a draft down to me to sign, saying that it's a New Drug, and left town on a two or three weeks' trip.

So I picked up the phone and called Herb Ley, and I said, "Herb, I've got this letter down here. If you instruct me to sign it, you're the boss, I'll sign it. But I don't want to sign this letter and issue it without your knowledge, because you're the commissioner and you're going to have to take the flak when it comes out that some idiot in the Food and Drug Administration is calling a three-and-a-half-grain aspirin tablet a New Drug when it's not being offered for anything but what aspirin has always been offered for. There's going to be some criticism, and you're the guy that's going to get it. And I just want you to know before the letter goes out." "Well, bring it up to me." So I took it up to him. We talked, and he said, "I've got a lot of admiration for Billy." I said, "Yes, I've

got a lot of admiration for Billy, too." "I'll tell you, leave it on my desk. Just leave it with me; I'll think about it." You know what happened? That was Volume #7 of the J & J A.F. (Administrative File). It disappeared. Volume 7 of the J & J A.F. was never found. And when I went to work as a consultant for J & J a year and a half after I retired, they still hadn't had an answer to that letter (laughter). Which is kind of a cute sidelight on how things went for that year.

When they fired Herb and Rankin, Charlie Edwards called me in and started talking to me about my future in his new Food and Drug Administration. I finally said, "Doctor, I think you have really got to be kidding." He said, "What do you mean?" I said, "Here I sit, with a comfortable pension, with almost thirty years of public service, an opportunity to get out and do all of the things I've always wanted to do all my life, and you're asking me to make a renewed commitment of probably some six or seven years to your "new" Food and Drug Administration. I don't think so, Doctor; I really don't." He was going to set me up in some kind of a job as a regulatory advisor to the Bureau of Foods, or something of that sort (laughter). I was a GS-17. I think I was going to be reduced to a GS-15, but I could keep my GS-17 pay, or some such thing as that. Which, of course, would have meant that I would have been at permanent salary ceiling. That didn't bother me one way or the other. I had a high, almost four years, at a GS-17, with a comfortable pension. Why should I go through that kind of mishmash? It didn't make any sense. So there is about my career in Food and Drug.

I stayed into April of that year for several reasons, not the least of which was that I wanted to work with the Hill. FDA moved out to Rockville in the

interval, and I worked with Bob Wetherell and those people in legislative liaison for about three months, January, February, and March, and made some contacts on the Hill, handled legislative correspondence, and developed a few precedents for them. I wrote some letters that actually told Congressmen the truth. It took a long time to get some of them signed. We had a letter complaining about some outfit up in Wisconsin that was labeling something blueberry jam when it wasn't really blueberries, it was huckleberries; something else said foxtail jelly and it didn't have foxtail in it, it had alderberries. You know, this kind of thing. I just wrote to a Congressman and said, "Yes, we know these things have been going on. This firm has been the source of complaints of this kind for many years, but we frankly do not have the resources to expend on this sort of minor economic cheat." It had to go all the way to the commissioner's office before it could go to the Congressmen.

RO: Let me back up just a minute.

AB: Anywhere you want to go.

RO: You had a pretty good working relationship with Jim Goddard that you've already said few in the agency didn't have.

AB: That's right.

RO: It has been said that Goddard was responsible for the Consumer Protection and Environmental Health Service (CPEHS). It was his brainchild of bringing that together, and then he wanted to be the head of it.

AB: As far as I know, that is totally false. CPEHS is an animal that was set up by the Secretary's office to ostensibly--and probably, actually--to relieve the Secretary of some of the responsibilities for the Food and Drug Administration and two or three other constituents of the department. The head of CPEHS was supposed to be a kind of undersecretary for those areas of responsibility assigned to CPEHS, and one of the biggest mistakes Bob Finch made was isolating himself from direct contact with the Food and Drug Administration. This got him into the cyclamate mess; it got him into about two other major messes. We had more than one instance where there would be a top-level conference in Finch's office with people like the president of the GMA, and nobody from FDA present. The phone rang one afternoon at five-twenty: "Who's over there? Who hasn't gone home? Get the hell over here to the Secretary's office and see if you can help out with some of these questions." Really, the Secretary just left his tail hanging totally out in the wind with no cover.

"C. Square" Johnson was an absolute disaster as far as any competence is concerned, from the Food and Drug standpoint. I don't know anything about C. Square's competence in other areas. The only real brush I ever had with C. Square was when he explained to me that we should not put things in the Federal Register; it wasn't necessary. When he was operating in New York City, if he had a dirty restaurant, he just turned the information over to the newspapers, and that got it cleaned up. I told Mr. Johnson that it seemed to me that I

recalled when I became a Food and Drug inspector I held up my right hand and took an oath to support the Constitution of the United States, and I didn't have any intention of abrogating that oath. Which I don't think Mr. Johnson greatly appreciated, but that was neither here nor there. That was the kind of relationship that existed between Food and Drug and the Secretary's office.

Personally, I think Johnson—and perhaps it may have been more accurate to say Johnson's office—made a point of being certain that nothing went from the Food and Drug Administration to the Secretary. They were an absolute non-bypass; I don't know exactly what the proper word is, but they were a total screen. And if Jim Goddard had anything to do with the genesis of CPEHS, I'm not aware of it.

RO: What about the demise of CPEHS? It didn't last too long.

AB: I don't know anything about the demise of CPEHS. I think the demise of CPEHS came along with the demise of Bob Finch. I think that Finch's successor probably had sense enough to see that some of Finch's problems stemmed from the existence of CPEHS. By that time, I was busy enough with what I was doing so that I had kind of gotten loose from the Secretary's office. When I first came in to BRC, after I got out of BDAC, I was considerably involved with the Secretary's office because Goddard wanted me to replace Kirk and Rankin as far as the management of regulatory affairs was concerned.

I don't know exactly what was lacking in me, but somehow I was not able to do that. Now whether I had just known them too long, whether I had been #2 to them too long, or whether I didn't know exactly how to go about it, or whether

the two of them, having the commissioner's ear twenty-four hours a day, were simply in too powerful a position, I'm not really sure. But I know I was never really able to fulfill what Goddard, I think, had hoped for at the beginning. I think Goddard would like to have seen me in essence replace both of them in the regulatory areas.

In the other areas, particularly in the areas where Rankin excelled, in department relationships, and Hill relationships, and those kinds of things, I don't think he viewed me as material at all. But in the regulatory areas, I think this is what Jim had kind of hoped for, and for whatever reasons, it didn't pan out. Probably it was as much my shortcomings as anybody's. As time wore on, I got less and less exposure to the Secretary's office, and by the time CPEHS broke up, about all I did was clap my hands and say hallelujah. But that was about the time everything blew up. I mean, CPEHS blew up about the same time that Jim left.

RO: That was the reason, I think, that there were a lot of people that thought Jim decided to leave, because he didn't get to head up CPEHS.

AB: Jim's goal was Surgeon General. I don't know that Jim ever wanted CPEHS. I've heard Jim express bitterness about working for "C. Square" Johnson. How much this was related to the fact that "C. Square's" black and how much of it was related to Johnson's lack of ability to do the job, I really don't know.

RO: Or it could have been, too, the fact that Goddard wanted that job and Johnson got it.

AB: That is also possible, but I never sensed that.

RO: As a commissioner, what kind of an enforcer was Goddard? There's those that feel that he was pretty weak, and there were others that said he was quite a strict enforcement official.

AB: No, Goddard was a strong enforcement official. Goddard didn't have the same concepts of what is important to the consumer as certain people in the Food and Drug Administration did. Somebody would say, "This mayonnaise contains 20 percent fat and this mayonnaise only contains 18 percent, Commissioner." And Goddard would say, "Can the consumer tell the difference?" And this really upset the old-line Lowrie Beacham types, going way back to the guys that used to populate the Yellow Dog Club. That would just turn Heine Lepper's hair if Heinie had still been around.

But Goddard felt very much as my wife felt when we ran out one time and seized a whole bunch of peaches that were labeled "mixed pieces of irregular sizes and shapes" because they were really badly trimmed halves. My wife said, "If the Food and Drug Administration hasn't got anything more important than that to do, your \$5 million budget is too big." So Goddard had a different sense of what was important. Goddard felt that the nation's drug supply had a hell of a lot more potential for killing people than mayonnaise and canned peaches that didn't meet the standards. . And given the agency's limited powers and limited funds, Goddard was willing to turn that kind of stuff over to the states. Goddard was not naive enough to think that the states were really going to be able

to handle it, but it was a politically expedient, comfortable way to get rid of something that he did not have the resources to do a really effective job with. In my opinion, it was a well justified series of decisions. Goddard was adequately enforcement-minded. I mean, he was not another Harvey W. Wiley by any stretch of the imagination, but he would support enforcement action.

RO: Of course, it was under him that we started to notify firms immediately when we found any of their products deviating from labeled claims; rather than try to get a seizable size lot, you'd ask, "What are you going to do about it?"

AB: And you get a lot more protection for the public that way.

RO: It was Recalls that really got popular under Goddard.

AB: Well, you get a lot more public protection that way, too. If you know there's something out here that may be a serious hazard to health, this business of running out and trying to find a lot so we can wait six weeks to get the marshal to go out and seize it, and in the meantime the public is using it, really doesn't make much sense when you stop and think about it.

Goddard brought in another concept that was difficult for me to work with, and in some respects is still difficult to work with, and that is the class action concept. Goddard didn't feel that all of the issues before the Food and Drug Administration were suitable to be settled on a case-by-case basis, that we ought to be able to do some of the things of the general type that the Federal Trade Commission does, issue a rule that applies to all of these products. That

is what has come out of the DESI review thing; that's what has come out of the OTC review thing. Goddard is the guy who was the genesis for all of this concept of dealing with products as groups and as "classes," as opposed to trying to get somewhere by one lawsuit at a time. Here again, I think this is sound.

RO: Coming out of CDC (Center for Disease Control), he changed us, as far as foods were concerned, to think about microbiological contamination. Of course, trying to clean up the food chain from Salmonella was something that we were never able to do. And poor Kenny Lennington was frustrated with that.

AB: Still to this day we haven't succeeded in doing that. Everybody's blabbering about Salmonella on the television right now.

RO: That's right, it's up in the front again.

AB: They're now telling us things about how to handle chicken that I was teaching my wife thirty years ago.

RO: The other thing is, it was during this period Goddard's time of self-certification. What did you think about self-certification, the possibilities of it as a tool?

AB: I think that self-certification is a workable concept. I think it may have been ahead of its time. I think we may yet see some form of self-certification. One of the reasons I say it was ahead of its time--it was not only ahead of its

time, but it was somewhat ill-timed—because here there had been a period during which the Food and Drug Administration had done relatively little enforcement in the food field. The food industry was at a relatively low ebb, in comparison to the general standards, let's say, of the preceding fifteen years. It was at a relatively low ebb from the standpoint of overall sanitary compliance. This is not the time to start a self-certification program. The time to start a self-certification program is when the industry is at its best, and then you select those industry leaders who are willing to make certain commitments. Then set up a check-like-hell procedure to see that they are carrying out their commitments.

This is the way that USDA has handled foreign meat inspection for years. It hasn't been totally successful. There has been canned corned beef come in here with blowflies in it, and other problems from time to time. But it is a workable concept, and it puts the burden, the expense of surveillance, on the guy who's making the profit rather than on the taxpayer. It's like one of the best principles of management I know: make it plain, keep it simple, delegate everything, and check like hell. Now the piece of that equation that is frequently missing is the "check like hell" piece, and this was one of the problems with the self-certification thing. It was not kept very simple. The agreements were made too complex to begin with. That was the fault of having Delmore involved, and Delmore's staff involved, in that. Delmore's office was not the place to put that program. Of course, it was a voluntary compliance program, so by name there wasn't any other place to put it. But if that program could be laid out, made simple, kept simple, thoroughly delegated, and then a mechanism set up to check, and you go in and you do a specific audit to see that these guys are

doing exactly what they're committed to do, this would work. And it would save the regulatory agency a lot of money. And this would not only work in the food industry; this would work other places as well.

RO: The trouble was, as you said, it was so complex that the only firms that could really abide by it were those that we didn't have that much trouble with. They had pretty good quality control.

AB: That's right.

RO: The other thing that they wanted was to be able to advertise the fact. Of course, we wouldn't let them put it on their label, and we wouldn't let them put it on their invoices.

AB: This is one of the real problems with the program. You shift the burden, you shift the expense to somebody else, and he gets zero benefit.

RO: I was involved with the first pilot program with General Foods at Dover, Delaware. I thought it had a lot of potential, that eventually you were going to go all the way down the supplier chain, because every one of the suppliers were going to have to abide by certain things, and their suppliers in turn. So if you could have ever gotten that thing working . . . But it was one of those things that, as you pointed out, was so complex that it kind of just died.

(Interruption in tape)

RO: What was the relationship between Goddard and Rankin? Did they get along?

AB: Rankin and Goddard, and how they got along. Rankin got along with everybody because Rankin made it a business to get along with everybody. In my own personal opinion, Rankin is a totally intellectually dishonest person. The best example I know of is when I was working with Rankin in BRC. In the early '50s, before I went to San Francisco, George Larrick was commissioner, and George sent a memorandum in to the two of us, to Rankin and thence to me, asking for our views on something. Rankin brought it in to me and said, "Now, what does Larrick want us to say?" To me, if the commissioner asks for your views, the commissioner is paying you for your views, not for you to try to figure out what the commissioner wants you to say. I think that reflects Rankin's basic attitude. Certainly there was never any overt friction between Rankin and Goddard. There were times when Rankin advised Goddard of things that he couldn't do, which was not at all uncommon. As I have said, Goddard took that sort of thing very well. He would argue with you, but if you could convince him he couldn't do it, it was agreeable.

RO: Do you have any idea why, if Goddard was given the charge when he came to FDA to clean house of at least the top staff, he retained Rankin?

AB: I have no idea. I've thought about that a number of times. I've even wondered to myself whether his retaining Rankin was good or bad. And even with

the benefit of hindsight, I'm still not able to really come up with an answer to that question. I'm sure that Goddard wanted to retain some degree of continuity with the past and with the way things were done in the agency, because he came in with, really, no knowledge at all.

You say his mandate was to clean house. I don't think his mandate was so much to clean house as it was to change the direction of the agency. He probably felt that he could change the direction of the agency and still retain a few people in the second echelon who knew where the bodies were buried and which switches to turn. He kept Kirk, of course, and he kept most of the people in the bureau. The only places where he really made significant changes early on were in those areas that directly impacted the pharmaceutical industry. He didn't mess around with personnel in the Bureau of Foods, for example.

RO: It was during this period, too, I think, that we started in with the idea for the Intensified Drug Inspection program (IDIP).

AB: Yes. I remember what it was now. It was food GMPs (Good Manufacturing Practices). That's what it was. Make a little side note there, and we'll get into IDIP first.

With all of my usual modesty, I have to laugh at the fact that Irv Berch got the FDA Award of Merit for the IDIP concept. The IDIP concept had its genesis in Ed Tuerk's office, and it came about this way, if anybody's interested. Tuerk was explaining to me in a one-on-one meeting that the only way to regulate the drug industry was through certification, and that we should move promptly to place all drugs, not just antibiotics, under the certification system. I told Tuerk,

in effect, that he was out of his mind, that the certification system didn't do any more to ensure perfection in the drug supply than any other system, and that what we really needed was some kind of an inspection system that stayed with an operation long enough to really learn how the operation was conducted, and what went on, and whether or not the process was one that could be consistently repeated. And we chose an inspection program designed along those lines rather than an effort in the Congressional direction to obtain certification for all drugs. It was out of that concept that the IDIP program was born. Tuerk took that and turned it into the IDIP program, and I'm still not sure exactly how Irv Berch got credit for having been responsible for its genesis.

RO: I don't know.

AB: I'm sure Irv would be willing to unburden himself on that subject. Irv is a peculiar character, too, by the way. I talked to him on the phone the other day.

We were talking about food GMPs. I think the record might show that I was the originator of the concept of food GMPs, and when I took the concept to Ken Kirk, he thought it was an excellent one and he supported me 100 percent right straight through to fruition. An implementation of the concept of food GMPs I consider to be one of the major contributions I made to the agency during my career. The original concept was presented in a paper I delivered to AFDO in St. Paul in June 1967, later published in the September 1967 issue of Food, Drug, Cosmetic Law Journal.

I think it's to be regretted that something that is potentially useful has been to some extent prostituted. The original concept of an umbrella GMP with

individual sub-GMPs for individual products I still think is a very good one and a very workable one. The only problem is that the sub-GMPs have to be developed with a great deal of care, and they're difficult. To give you some examples, some of them have been slapped together by people who didn't know what they were doing, and they have led to, generally, the downfall of the concept of separate GMPs.

On the other hand, when we did the breaded shrimp GMP, I had a meeting in my office in which I had represented over 95 percent of the world's total production of shrimp. We started from there to develop breaded shrimp GMPs, and we got our microbiologists and their microbiologists and we got out of Washington and went down to Tampa, Florida, and held a week's meeting. We got where nobody could bother us, and we sat there and really let our hair down and fought over what we can do and what we can't do, and what's practical and what's not practical. Off the tape, you were talking about Bartram. Bartram was one of the microbiologists that was in on that. We came out with a GMP regulation for breaded shrimp that then stood up perfectly; nobody ever had any problems with it until they finally abandoned the concept of individual product GMPs. It takes a lot of hard work, but most things that are worthwhile do. I don't know; it's a difficult area, and it's not one that is going to be resolved by going back to the concept that God, motherhood, and the flag constitute GMP if you're going to really treat GMPs as how-to regulations.

RO: Aside from a workload standpoint, do you know of any reason why the individual GMPs were abandoned?

AB: No, I don't. I was a little bit puzzled when the decisions were publicized to abandon them. I really don't know. I think that there may have been two or three reasons. It may have been the anomaly of having only a few when there was a need for so many, and no capability to develop them. The problems in developing them are reflected in the fact that we had some people who insisted on trying to write individual GMPs without ever having visited the plant, or any plant producing the product about which they were going to write GMPs. And some of them refused to travel. Now when you've got people who are trying to write GMPs to cover an industry and they've never even seen the product produced, it's not hard to figure out why the GMPs are not really all that useful. There are at least some GMPs that were put together in that fashion. I mentioned earlier that some of them were just slapped together.

And I think, too, in one or two instances, the GMPs sort of got out of the context in which they were supposed to have been originally. Writing GMPs involving things like pesticide residues--this wasn't really the original intent. The concept was that GMPs were really definitions of insanitation as the term is used in Section 402(a)(4). And when you started getting outside of that, you began to get into some other difficulties. You got, in my opinion, into perhaps some legal questions. I never had any question in my mind about the legality of food GMPs as long as you stayed within the scope of 402(a)(4), and I think most of the lawyers agreed with me. Not initially. Some of them didn't agree with me initially. In fact, the Food and Drug Law Quarterly, that published my original paper from Minneapolis had in it, I think, at least two attacks from the legal profession on the concept.

RO: I know when we first started those umbrella food GMPs, the little manufacturers said, "It's going to put me out of business. It's just going to destroy me, because I'm not going to be able to do it."

AB: And yet there wasn't anything in there that wasn't strictly God, motherhood, and the flag. Keep the floors clean, wash the dishes, that kind of thing. It wasn't that difficult.

RO: To begin with, when we started to apply some of those requirements, I think some of our inspectors got a little bit aggressive in trying to hold things to the letter here, as often happens.

AB: Well, we've got that problem in the drug GMPs. This is a very real problem in the drug area. We've got too many drug inspectors who think they're God, and they interpret the GMPs, and "you either do it the way I interpret it or else." Everything's either black or white. We've got some where they don't use any judgment. I've got a situation up in New Jersey where there's a bulk pharmaceutical production operation. The guy came in a couple of years ago and wrote a four-and-a-half-page FD 483, following the finished pharmaceutical GMPs. And, of course, management got its finger on the panic button and I had to drop everything I was doing. There were about four things on there that needed to be taken care of, and they were very valid criticisms. And we took care of those and we simply wrote the district and said that "the rest of this stuff is in the finished pharmaceutical GMPs; it doesn't apply to this operation." That's the last we ever heard of it.

But the trauma! The FDA people don't realize how much trauma they can cause. You know, "Let's send him a citation." But you're sitting out there behind a desk and you get a letter from the Federal Government that says, "You've got to come in and tell us real quick why you shouldn't be prosecuted in the federal courts," it has a hell of a lot more impact than the guy that wrote it thinks it does. He ought to get a letter from IRS saying, "We want you to come in immediately to tell us why we shouldn't throw you in the penitentiary." It would give him a feel for how it is when the shoe's on the other foot.

RO: Al, was it during your regime as the director of BRC that we did away with the cite "for warning," or was that done before then?

AB: That was done after. We were still citing "for warning." There was a lot of debate going on about the desirability of citing for warning. There were those who felt that we ought to cut it out; there were those that felt that it served a very useful purpose. I, for one, have always kind of felt that it serves a very useful purpose. I'm not really sure how ethically honest it is; it's kind of bluffing. But back in the good old days, we used to write letters to firms. If you got a letter from the Food and Drug Administration saying, "Gentlemen, we really seriously question the legality of this. We suggest that you take it up with your lawyers," or something of this sort, "very truly yours," you damned well better do something. If you got a letter from the agency saying, "This is the most horrible violation we've ever seen, and if you don't do something about it, we're going to throw you in jail next week," forget it; throw it in the wastebasket. It used to be SOP; if it was something we weren't going to do anything further

about, we'd write the harshest letter we could write. If we really planned to take some action, we'd simply put the guy on gentle, formal notice that we considered it actionable--just the reverse of what you might expect.

RO: Now those things have been legitimized into a regulatory letter, a post-inspection letter.

AB: Or adverse findings letter.

RO: It's a fine line that divides some of those.

AB: Yes, and the districts have never figured out what that line is.

RO: No. It depends on how you head the letter.

AB: (laughter) Anytime they want to issue one, they call it something that they're authorized to issue; it doesn't make any difference what the content is.

RO: Al, I want to back up into some of your early career at Food and Drug, because I know there were some probably interesting cases that you were involved in. But before we do that, so that we don't miss it along the way, whatever prompted you to come into headquarters from director of Kansas City District to head up BDAC, which was a brand new bureau within the agency?

AB: I had been far more involved in trying to control the illegal use of barbiturates and bennies (amphetamines), primarily in the trucking industry, than any other district director. I had a group of about four inspectors out there who were, for all practical purposes, reporting directly to me, who were doing undercover work. We were developing some really spectacular cases for FDA at that time, involving wholesale peddling of bennies, particularly, and some other drugs, to truckstops and to the trucking industry.

So I had been involved for about a year and a half very directly with that kind of work; and when the Drug Abuse Control amendments were passed and the decision was announced to set up a separate bureau, because of my known involvement in the matter, I was considered as a potential candidate for the directorship. It's just as well I wasn't chosen, because I would not have made a good director; I would have been too tied to the old-line FDA way of doing things, and that would not have worked in the bureau. But when Jim Goddard brought Finlater in, I was one of the candidates that was made available to Finlater as his deputy.

Now, in the meantime, I had been doing some thinking on my own about what really constituted drug abuse problems, and I had sort of decided by the time I came in to talk to Finlater and Goddard about the job that I would like to come to Washington and really make some kind of an effort to do something about the problem of drug abuse. By this time, we had gotten beyond just bennies at truckstops; we had gotten into addiction and addicting drugs, and of course the Drug Abuse Control amendments brought us into everything but narcotics, and it brought us so close to hard narcotics that it didn't really make much difference.

To make a long story short, by the time I came in as deputy director of BDAC, I came in with the idea of spending the rest of my federal career trying to combat drug abuse as a national problem. Not by kicking down doors and making criminal cases and arresting pushers and that sort of thing, but really trying to look into the roots of drug abuse and see whether or not there is really an appropriate federal role or whether we're really talking about personality defects that we can't do anything about. Then we might just as well leave the federal role out it entirely. There are those who point out, and perhaps with some justification, that some people are going to become addicted to something; it doesn't make any difference what it is. And if you make one thing unavailable, they'll become addicted to something else. This is a personality defect and not something that really is an appropriate area for federal regulatory action.

My goal got truncated for two reasons. When BDAC was originally set up, we set up three divisions. One of the divisions we called the Division of Drug Studies and Statistics, and that was a division that was designed to cope with the kinds of problems I'm talking about or to explore them. We hired a competent--or at least I thought so at the time--doctor from NIH by the name of Fox. Dr. Fox--Jim Fox, I believe it was, but I'm not absolutely positive--came with us to head up that division, and the thing was just getting well underway when Fox was taken with a heart attack and later died. He didn't die at the time, but he was out of service. And at about the same time, Goddard approached me to take over BRC, and Jim Goddard was the kind of a guy that if he says, "I want you to take over BRC," you don't say, "No, Jim, I would rather stay where I am

in BDAC." If you do that you might just as well quit, from a career standpoint. So I never did get to fulfill that desire.

RO: So your interest was to look at the social aspects of addiction.

AB: Yes. The origins: not how people get drugs, but what motivates them to get drugs. If you're going to cut off drug abuse, this is really, in the last analysis, in my opinion, the only way you're going to cut it off. As long as you've got people who generate a demand for something, you're going to have people who will supply that demand. This has always been true, and it always will be true.

RO: Sure, as long as there's an economic advantage.

AB: That's right.

RO: Now I'd like to back up, if you don't mind, to the time that you started as a GS-5 or GS-7 inspector.

AB: GS-5.

RO: Yes, that's usual.

AB: Eighty dollars and forty-one cents twice a month. Not every two weeks, but twice a month (laughter).

RO: You were involved in some interesting cases. If you can think of them from each one of the stations you were at, that really highlight the investigative techniques that you used and some of the outcomes, from a legal standpoint.

AB: Somebody might be interested in the number of times that an ordinary little Food and Drug inspector had occasion to look down gun barrels (laughter). When I was still working as an inspector in Atlanta, Nevis Cook and I made a couple of buys of I guess it was diethylstilbesterol. I'm not sure; some prescription legend drug from a pharmacy out in east Atlanta called Delameter's Pharmacy. I don't know why I remember it. In preference to citing the guy, at that time we had a little program where we went out and called the attention of the management to what they had done and the fact that they had violated a federal law, and that they had better take better notice of what they were dispensing without prescription. We walked in, and this pharmacist was about half-drunk, and he reached in his drawer and he pulled out a pearl-handled .44 that had a barrel that looked to me like you could have put an orange in it comfortably. And he sat there and played that gun back and forth between the two of us like he was trying to decide which one of us to shoot while we were sitting there talking to him. It took us quite a while to get him calmed down. That's nerve-wracking.

In later years, we used to, on crabmeat programs, both in Atlanta and later in Baltimore, stop trucks at night to sample crabmeat in transit en route to the northeastern markets. And almost every time you stop a truck, you're looking down a gunbarrel. You don't walk up to the truck and then reach in your inside coat pocket for your credentials. You already have your badge or your credentials out when you walk up to the truck, because the guy's got a little gun lying

right there across the window; you're looking right into it. That never bothered me. But this guy that was drunk, that kind of upset me.

RO: As far as the crabmeat, what were you stopping the trucks for?

AB: To get samples. We had a program—I don't know whether they still have it or not. Filth in the crabmeat industry has long been a problem. The primary route of contamination is rodents. There are others, but what happens is, crabs are cooked at night, from four to seven in the evening, and then they're shoveled out on picking tables or cooling tables, or they're left in retort crates if they've been retorted, or whatever have you, overnight; and then the pickers come in early in the morning and start picking them. Well, overnight the mice have foraged back and forth over them, and you've got nice, fresh rodent droppings all over them. And then you put them on the picking table, and with a little water it doesn't take long to spread *E. coli* all over the whole damned mess, and typhoid organisms, and whatever else as well.

So we used to make those inspections. We would set up at night. All of them shipped by wildcat trucks. That's not true. All the stuff out of Florida used to come by railway express, and we used to work on the express platform in Jacksonville. It was transshipped from one car to another in Jacksonville, and we'd sample it during the transshipping, which worked very well. Coming out of North Carolina, it all came out by trucks, and we'd get where the roads coming out of the lowlands intersected the main highways, and we'd wait there. The truckers were all cooperative, because all of them were violating the ICC (Interstate Commerce Commission) rules. We had a little pact with them that we

wouldn't tell the ICC. See, none of them had any manifests that you could find. I mean, they were all hauling their own stuff, supposedly, and of course they weren't. They were operating as interstate carriers without being licensed as interstate carriers, but we had a little pact with them: we wouldn't tell the ICC, so they were all pretty cooperative with us when word got around that we wouldn't do anything.

I had a very amusing episode one time that might get a laugh. Johnny Guill and I were sampling crabmeat over on the eastern shore, and we had some brand new slipcover cans. You know, you get the crabmeat as aseptically as you can and drop the pound can into one of those pre-sterilized slipcovered cans and put the lid on it. We had some brand new, shiny ones and we had a whole bunch of them in big garbage cans in the back of the government car. When we got back up to Sandy Point, we got on the ferry over to Annapolis. This was before we had the pleasures of the Bay Bridge. So we were on the ferry and we opened up our cans and we were re-icing our samples, putting fresh ice on them, and some grease monkey came up out of the bowels of the ship and was looking at us while we were working. "What are you doing?" I says, "Oh, that's nitro in those cans. You have to keep that stuff cold; it's liable to go off on you if you don't keep it iced." That was the end of that. We got all through. We started up to the deck, and about the time we got halfway up, here comes the skipper down. "Who in the hell is this that's got this nitro on my boat?" Boy, you talk about somebody that was upset! (laughter) Brother, was he ever upset. And did he chew us out after we explained to him!

RO: Where were those samples analyzed, then, because the districts at that time didn't have microbiologists?

AB: We brought them directly into micro.

RO: Into micro in headquarters here.

AB: Yes. In Florida, we had a trailer lab. When we were working in Jacksonville, we had a trailer lab. When we worked in North Carolina, we had the trailer lab set up in Little Washington, which leads to another interesting story. Pete Caluccio and I were working together. Did you ever know Pete? Pete's still around.

RO: No, but I've heard of him.

AB: Pete's an inspector up in New Jersey, East Orange. We had been working twenty-eight hours; we'd been up twenty-eight hours. See, you have to get to the crab plant in the morning, before the pickers start on the crabs. We'd been working all damned day. So we'd been up about twenty-eight hours and we were leaving Oriental, North Carolina to drive back to Little Washington, which was forty or fifty miles; I was driving. Pete was asleep before we got past the second filling station, and there are only two in town. Somewhere up the road, Pete tapped me on the shoulder and he says, "Barnard, it's time to wake up now; we're coming to a curve." Whatever waked him up, I'll never know. He was sitting over there, dead to the world. He woke up, looked over, and saw me

sound asleep. We were going down the road fifty-five or sixty miles an hour, down this straight stretch of road, and I'm sitting up there, sound asleep. He's scared to say anything sudden, I'm liable to jerk the car off the road. He reaches over and taps me. "Barnard, we're coming to a curve now, it's time to wake up." It shows somebody was looking over our shoulder that morning. This was about seven o'clock in the morning. We made it back to Little Washington and went to bed.

RO: I would hope so.

AB: The whole time I was chief inspector in San Francisco, I never drove to Sacramento and back without sleeping by the side of the road. There's something about that road that is totally soporific. The first time it ever happened, McKinnon says, "Where have you been? You left Sacramento at one-thirty. The California people told me so. You got some babe up the road?" I said, "Now come on, Mac, I haven't got time for that. I went to sleep up there under a tree." He started to chew me out. I said, "Look. Would you rather have me asleep up there under a tree or wreck that automobile in a canal down there somewhere?" "Oh, well," he says; "I guess you got a point." I learned, when I get sleepy driving, I go to sleep.

RO: You mentioned that you were resident at Baltimore district. Was this when you were doing some of that work? You were the resident in Washington, D.C.

AB: I did one or two crab trips when I was resident here. And then I did one crab trip after I came back here with BRC. We had an outbreak of typhoid in New York that was related to crabmeat, and Will Swain and I, and Bartram, went down to Jacksonville and spent a couple of weeks working the crabmeat industry there; and then we went over to New Orleans and worked crabmeat over there with Jimmy Hyndeman. Remember Jimmy?

RO: Sure do.

AB: On crutches? See that guy bounce in and out of a trailer . . . He'd get in and out of a trailer on crutches better than I can get in and out with two good legs. Bryan Eggerton was chief inspector down there at that time. There was a guy that didn't know what was going on, too. We spent a couple of weeks down there, flew back in here in a blizzard, one of those fall snowstorms. We had about eight inches of snow and we didn't even have an overcoat; we had summer clothes on.

RO: I think of all the work we did on crabmeat, trying to establish some standards for coliforms, E. coli to enable us to take regulatory action on objective samples, we never really were able to, without any correlating factory inspection.

AB: In our day, positive E. coli was adulteration, period. Morris Osterlink and I worked a long time on crabmeat, and Morris worked on the various fecal streps. We did a lot of work on the fecal streps, but they were too ubiquitous. But iso-

lated and speciated *E. coli* has always been considered, as far as I know, the basis for alleging adulteration. Speaking about work on food standards, the work that was done on watered oysters is the real horror story in the food standards area. First trip I ever went on in my career was a food standards trip with Willie Stokes. We went over to the University of Georgia to work with the Home Economics Department over there on something--I don't even remember what it was now. Did you ever know Willie Stokes?

RO: No.

AB: Willie came in here in the twilight of his career. I don't remember what his job was. Willie was, with the possible exception of Ted Benjamin, the most naive man I ever met. One of the favorite stories on Willie Stokes is, he was investigating a patent medicine manufacturer somewhere down near Macon, Georgia. This guy had a product, and the main feature of the product was that it had a new, secret ingredient. Willie was making this inspection, and he asked this guy, "What is this new, secret ingredient? It's not declared on the label, and under this new law, you have to put the ingredients on the label, you know." And he said, "Oh, that's just a lot of applesauce." Willie said, "Yes, sir." He had his notebook out, "And how much applesauce do you put in, sir?" (laughter) We were at a party one night, and I was making passes at the chief inspector's wife; and Willie sent his wife over to me and says, "Come on. If you've got to make passes at somebody, make up to me, don't make up to her. You'll get yourself in trouble." He actually sent her over to keep me from getting in

trouble. I mean, he was that good. He was one of the "goodest" guys I've ever known.

RO: You mentioned the problems we had with trying to get standards for watered oysters. Remember the GICORP (Government/Industry Cooperative Oyster Research Program) study, a big study that went on, and we were going to find out how much the oysters really bled after packing?

AB: That was probably after I left the oyster area. But we started that. The first long road trip I ever took, one of the first, was with Bill Barbour, and I went to Apalachicola, to pack oysters for just that purpose. Because the Gulf Coast oysters will bleed. You can take these salt-water oysters from up here in the bay area and you pack them out of good salt water and they will drain dry; they just won't have any liquid unless you water them or blow them. If you just shuck them out and drain them, and don't wash them, don't blow them, or anything, you will have zero free liquor. But down there, you can take them right out the shell--I've done it--pack them in gallon cans, and you'll drain 2, 3, 4 percent free liquor after they've been shipped to this market. Bill Barbour and I went down and did a lot of packing of oysters down there. I remember one night he and I ate a gallon of oysters. That's a lot of oysters. With a pound of crackers, a gallon of oysters, and a bottle of catsup. We were packing some oysters, and somebody stuck an icepick through the top of the can, and that's not very good for an experimental pack.

RO: No, not at all. I'm surprised that your digestive system withstood that gallon of oysters.

AB: Oh, I can sit up and eat oysters all night, if you give me a little time and a little beer and a few crackers.

(Interruption in tape)

RO: This is a continuation of an interview with Al Barnard that was begun on May 14, 1987. Today's date is June 4.

Al, we have covered some of the highlights of your career in FDA, and when we closed the interview on May 14, we were discussing some of the interesting assignments you had during the early years of your FDA career. Before picking up on some of your more interesting early assignments, perhaps we could cover some of the events early in your headquarters assignment that we may have missed.

AB: As I said last time, when I came back to headquarters in 1966 to start BDAC with Finlater, I came back with the idea of doing something fundamental about the problems of drug abuse rather than just kicking down doors a la narcotics agent procedures. I was more interested in really looking into the basic problems that lead to drug abuse as opposed to just making cases and trying to put peddlers in jail. This sort of evaporated for a number of reasons, not the least of which was that it wasn't John Finlater's primary goal. But also Jim Fox, whom we had hired to head our Drug Studies and Statistics group (a psychiatrist/psychologist from NIH), had a heart attack about the time I joined BRC, and he dropped out of the picture; so that went by the board.

Another thing that might be interesting to trace a little bit, and that is Clevenger's history, as it were, in BRC. I brought Clevenger in from New York to head up what we called our Division of Case Control, and we also had a man by the name of Anderson who was in charge of case development. Over time, I think Anderson, at least, felt that there was some conflict between the two positions, and it never did work as smoothly as Finlater and I had envisioned it.

The thinking was that Clevenger would handle things like the librium and valium, controlled substance classifications, which we were litigating with Hoffman LaRoche at the time, and that Andy would handle field prosecutions and arrests and things of that sort. Clevenger stayed in his role until after I went into BRC, and then—I'm not sure of the exact timing--Goddard shifted him back to New York as district director, so I think that sort of cleared that up. Now, where do we want to move from there?

Well, there are one or two more things that I'd like to say about the BRC era while we're in Washington, as it were. In the old three district days, the chiefs used to engage in a process we called lemon swaps. If you had a lemon and another district had a lemon, you'd make a deal to swap the two lemons and see if either one of them would ripen somewhere else, or rot. When Rayfield took charge of the field as head of BFA, he got rid of his lemons another way. He used to, whenever a Washington division needed somebody with field experience, give them one of his lemons from the field. After he became head of BRC and really began to have the headaches of the whole administration, he made what I thought was a very appropriate comment at one time. He said that every damned turkey that he had shipped from the field had become a buzzard around his neck.

When I came into BRC, I inherited a fair number of those buzzards. We'll leave them charitably unnamed, but one of the alleged missions that I had, according to Goddard and Rankin, was to clean up BRC and get rid of the deadwood and the buzzards. So I set about initially to do that, and early on I had one of the more smelly buzzards lined up to be transferred to New York. I'd made a lemon swap deal with Curly Clevenger after Curly went up there, and lo

and behold, when we got ready to make our move, the guy didn't want to transfer and Rankin and Goddard wouldn't back me up on transferring him. So this started a long series of events which resulted in a number of things never getting done in BRC under my management that Goddard, at least--I'm not sure about Rankin--had anticipated would be accomplished. I think to some extent this played a significant role in the fact that ultimately my performance didn't totally satisfy Goddard. Rankin, I think, was never satisfied with me, I think partially because he saw me as a potential threat to his position. Goddard was never that disappointed, but there were areas where Goddard was not pleased with my performance.

RO: What did Goddard really want you to do with BRC?

AB: Goddard wanted three things out of BRC. He wanted the BRC to provide the policy leadership for the field, the policy leadership that Goddard himself really abdicated when he moved towards the idea of putting the district directors so much on their own. I think we talked a little bit about that last time. I think he wanted BRC to fill that gap, and I think this was maybe possible under somebody else, but not possible under me. I had too long and too close a relationship with Kirk and Rankin, and then we had guys like Walter Moses that we talked about on the tape before. The lines of communication weren't drawn on organizational charts; they were buried deep in history, and there was no disrupting them in any satisfactory sort of way. Yes, we could write policy in BRC and we could disseminate it to the field, but that wasn't really policy. Policy was what Kirk and Rankin, influenced by Moses, Duggan, et. al., decided to do.

Goddard's concept was that if a district director wanted to bring prosecution, that was his prerogative, let him bring it. Deeply engrained within Kirk and Rankin and most of the people in my division of Case Guidance was the concept that our primary role was to screen cases and see that there was uniform application of the law, and that the cases were justified, and that the cases were well prepared. The division had gotten the reputation of being very negative and killing everybody's recommendations and being very hard to get cases through, and this is one of the things that Goddard wanted changed. Goddard stood almost alone in wanting this change, and lacking any kind of real support from Rankin and Kirk, it was impossible to get a change. Rankin would give lip service to it because that's what Goddard wanted to hear, but when it came down to really getting anything done in that area, it just didn't get done.

I think Goddard genuinely wanted the house cleaned out of the turkeys, and there were six or seven or eight of them. Goddard really genuinely wanted them cleaned out. He hadn't been able to clean his own nest. He had General Delmore and he had announced publicly that he was going to fire Delmore. And Delmore had this guardian Congressman from Pennsylvania. At a lower echelon, I was having exactly the same problem. It didn't take me very long to find out I wasn't going to transfer some of my turkeys. I think Goddard expected me, by some kind of legerdemain or magic--of which he would be blissfully unaware--to just make these people disappear. It doesn't work that way, as you well know. I did manage to make some of them disappear. I palmed two or three of them off on the Bureau of Medicine, and I did induce one of them to move, but it was not an overwhelming success.

RO: Did he identify those that he wanted you to move?

AB: They didn't need to be identified. Everybody knew who they were. There may have been two or three that were marginal, but there were five or six that there was no question about. Some of them I could still name for you. No, there was no doubt about it. Then, of course, there was the unfortunate situation that Kirk had a personal antipathy towards a few people, and Kirk tried to take a few guys like Tenny Neprud and John Lupien, and lump them in with the turkeys. In my opinion, at least, it was a product of personal distaste, because those were guys with substantial competence. So that kind of became involved in it, too. As a matter of fact, Kirk went so far as to send somebody out to find these guys playing pool at lunchtime. It's like I told Kirk and Rankin, "They get thirty minutes or something for lunchtime; I don't give a damn what they do with their lunchtime, as long as they don't bring disgrace on the agency." "Well, they shouldn't be playing pool. That might bring disgrace on the agency." I said, "Well, I play pool, too."

RO: Al, we had hazardous substances under Product Safety. Did that come under BRC at that time?

AB: Yes. And we talked a little bit about Dale Miller's career with me in San Francisco. It's interesting. Dale came in and took that thing over until . . . It was in there for a while. And then they moved it out; they set it up under, I guess under Delmore, and they brought this idiot in--he's dead now--from what became Consumer Product Safety. Mac . . .

RO: Mac Jensen.

AB: Mac Jensen. Yes. Mac's a character, impractical as all get-out. And we had another guy in there working in that same group. Mac took the thing over eventually. I'm trying to remember the name of the guy we had. I'll never forget. We were sitting in Herb Ley's office when Herb was commissioner and we were working on his testimony on the Toy Safety Act, and we kind of leaned back and took a break and Herb says, "I think I better slip out and buy a couple of pocket knives for my kids before we make them illegal." And this guy looked at Herb and he says, "Dr. Ley, you don't really think children should play with knives, do you?" Just as serious as all get-out. Yes, that's Product Safety. It was in Ted Byers' shop, actually, for a while.

RO: Before it got to be a bureau, didn't it go into what was the old Bureau of Medicine?

AB: No, not to my recollection.

RO: Do you remember Sam Hart?

AB: Sam went through the charm school and then came down here and took that thing over before Jensen took it over. In fact, he and Jensen, there was a lot of bitterness there, a great deal of bitterness. I don't think either one of them was a competent manager, if you want my candid opinion.

RO: Mac never really wanted to be in the Food and Drug Administration. He was happy when CPSC (Consumer Product Safety Commission) was created.

AB: That's true.

RO: Before we leave headquarters again, I think you mentioned earlier that you were very interested in management, and maybe you were interested in it all of your career; but it seemed that you became more interested in management while you were in headquarters here. Was that a result of when you entered the Civil Service Second Career Program?

AB: Yes, it stemmed directly from the Civil Service Commission's Second Career Development Program. Previously, I had had no interest in management. I really had no concept of management or the problems of management, or of people-related problems until I was exposed to that training. And it came at a fairly opportune time, because I had just a couple of years in which to really digest it, and then I went into my first supervisory role as chief inspector in San Francisco. I recognized as a consequence of that training that as you get anywhere above the role of a first-line operator, the most important skills you can have are management skills. Once you get off the bench, technical skills become secondary very quickly. I see you smiling, but I still think that's true. I recognized early on the need to develop management skills, and that's whence my interest in management came, a self-serving interest if there ever was one. People are the most expensive and most important machines that we have, and

managing them, and keeping them adjusted, and keeping them running smoothly is the most critical job that supervision has; and there are not a whole hell of a lot of people in supervisory roles that seem to fully appreciate that.

RO: Would you care to comment, then, on some of your colleagues, as far as their management abilities? You can start at any level and go on through the commissioners that you served.

AB: Successful management styles vary a great deal. Unsuccessful management styles, I guess, are myriad. I don't know that I would care to comment too much. Rayfield has a reputation of being probably the agency's worst manager, at least among the rank and file. This is because Rayfield never learned anything about the human aspects of management. If Rayfield had taken the time or trouble to learn a little bit about the human aspects of management, I think Rayfield would have been a successful manager.

Sam Fine, I think I said earlier, managed by the book, and Sam had a better feel for the human side of management. He didn't have a very good one, but he had a better one than Rayfield did. Sam would expect a guy to work for him till eleven o'clock at night and then charge him an hour's leave the next day while he hunted for a house to live in, because that's what it said in the book. Things of that sort.

Speaking of commissioners, Goddard's management style I think I've already mentioned bordered more on abdication than delegation. If Goddard ever gave it conscious thought, I think his feeling was that he would abdicate and then delegate to the next echelon to pick up that which he had abdicated. That's what I

said earlier; he was looking to me to provide certain kinds of things to the field that he had abdicated.

A lot of people in what ought to have been management roles in the Food and Drug Administration were never managers. They carried out instructions, or what they perceived to be instructions, and cried bitter tears when they didn't get better instructions.

RO: What about Larrick?

AB: Larrick was naive. Larrick was a small man. I liked George Larrick very much personally. I don't think that Larrick was a poor manager; Larrick did a fairly decent job of managing the agency. Larrick was people sensitive. As long as he stayed within the boundaries of his experience, background, comfort zone, Larrick did a pretty good job.

The kinds of things that lead me to comment the way I do on Larrick are, for example, Congress asked Larrick to take the Poultry Inspection when the blowup came in Poultry Inspection. Congress wanted to transfer it to the Food and Drug Administration, and Larrick stood up in public and said the Food and Drug Administration can't handle it. And this was terrible. There was a time when there was concern about filth in chewing tobacco and poisonous additives in tobacco, and Congress wanted to turn the regulation of the whole tobacco industry over to the Food and Drug Administration, and Larrick says, "We can't handle it." This was terrible, too. This is an agency that is crying for Congressional support, saying it needs more funds to get its job done. Here it's given greatly broadened opportunities, and the commissioner says we can't do it. In

this world of ours--and whether it's right or wrong, it's true--you either grow or you shrink. It is almost impossible to successfully stay where you are. We take the best teachers we have in our schools who don't want to be principals, and we make principals out of them, and they make lousy principals, and then we wonder why. It's the old saying, we promote everybody to their level of incompetence.

I always admired Crawford. I guess I admired Crawford in part for his stubbornness. As long as Crawford was right, or thought he was right, nothing changed his direction. Common sense, lightning, thunder, or God Almighty, Crawford said, "This is the right way to do it and I'm going to do it this way, and if you, Congress, cut all my funds off, I don't give a damn, this is the right way to do it." This general approach is what ran the agency into the problems that it ran into.

I always regarded Paul Dunbar as a very poor manager. He was not good at making decisions. Crawford picked up the decision-making process for that pair. Dunbar was, again, a very little man. It always disturbed Dunbar that for all the years he knew Harvey W. Wiley, Dr. Wiley never remembered his name. That really upset him. I've heard him say that half a dozen times.

Walter Campbell, I greatly admired. I have to confess that part of my judgment of some of these guys is playing poker with them. You can learn a lot about a guy playing poker with him, and I've played poker with Crawford, and I've played poker with Campbell, and I've played poker with Larrick, who was a very poor poker player, by the way. I've always had a great deal of admiration for Walter Campbell. Walter had an insight into the goals of the agency, the significance of the goals of the agency, and something of a feel for how to

accomplish them. Now, as a day-to-day manager, I didn't have enough contact with Campbell to know whether he was people sensitive or wasn't people sensitive. I really don't know how good a manager he was, but as a top-level administrator of the agency, I admired him. In fact, it was at my behest that the building in Kansas City was named the Walter G. Campbell Building, and I invited Mr. Campbell to come to the dedication. Unfortunately, he was too ill to come. I guess that sort of covers most of the commissioners.

RO: What about Jack Harvey? How did Harvey and Larrick get along?

AB: Harvey and Larrick got along very well, because they complemented each other. The places where Larrick was weak, Harvey would pick up the slack. Harvey was totally unable to change the idea that the agency couldn't take on additional responsibilities. There was no way Harvey could intervene in that sort of thinking, but Harvey was hardheaded, practical, very pragmatic, as most good lawyers are. Larrick was much more the dreamer. Larrick was capable of being hurt. Larrick was very much hurt by the Fountain hearings on the Abbott affair. Harvey's attitude was "to hell with them." It ran off of him much more like water off a duck's back than it did off Larrick.

Tillie Cecchi could probably discuss Harvey's management styles and capabilities with you a lot more accurately than I can. I knew Harvey very well. In fact, Harvey served as my personal attorney. We had a very interesting relationship. When we were on Food and Drug business, it was always "Mr. Harvey," and when he was my attorney, it was "Jack and Al." It just took care of itself; nobody ever said anything about it. We were on a first-name basis when he was

my lawyer, and he was "Mr. Harvey" when he was the Food and Drug Administration (laughter).

Of course, I've got a little amusing story as an aside on Jack Harvey. We got an injunction against a raisin packer in California. The firm had a whole lot of raisins, and we were trying to hammer out a temporary restraining order in the judge's chambers, and the judge threw us out and said, "You guys hammer this out and be back by one-thirty, because I've got to be somewhere by two o'clock." So we're in there with Arthur Dickerman and the defendants and a bunch of lawyers, sweating it out. We get down to the question of exporting these raisins under 801(d). They can get a certificate from the Dried Fruit Association that they comply with the specifications of the foreign purchaser and everything. Under the gun with ten minutes or less to go, I acceded and agreed to this. So Harvey got very upset about it, and he and I had quite a discussion over my having done it. I pointed out to him all the reasons. Finally he said, "Look, Al. Let me tell you something. I probably would have made the same decision in the same position myself. I just wanted to have the opportunity to make it." Of course, he was deputy commissioner at the time, and here I'd made this apparently earthshaking decision at much too low a level. Jack never said so, but I think secretly he kind of admired me for making it, because he'd been living a long time with Ralph Horst, who called up and asked him whether or not he should go to the toilet. So Jack had his problems on both ends of the chain.

RO: You mentioned the Fountain hearings and the problem we had with Abbott Laboratories. Where were you when all that happened? You were in headquarters here in Washington, but what position did you have?

AB: Most of the time I was. See, I was resident inspector in the District, which I will say without hesitation that up until the change in the agency I was the only successful resident inspector they ever had in the District. And that was mostly because I sloughed off most of the important work. It's a question of "important to whom." When you're resident inspector in the District, if you get an assignment that says, "We just had a food poisoning and eight people are dead," and while you're reading it, the phone rings and Senator Sludgepump's wife has just found an alligator in a can of peas, you don't say, "Oh, hell, there's no alligators in peas" and go start looking at the food poisoning. You go out and take care of Senator Sledgepump's wife first, then you look after the food poisoning. That's the only way you survived successfully in those days as resident inspector in the District. When I left that resident inspection post, I left a whole bottom left-hand desk drawer full of uncompleted assignments of miscellaneous kinds from Baltimore District. But I kept Washington happy as resident inspector, and I was the only resident inspector they ever had that didn't cause the District constant problems from headquarters. I moved directly from there into Rayfield's shop in . . . well, I guess, let's see, we called it . . .

RO: Probably BFA.

AB: Yes, Bureau of Field Operations. BFO? I don't know; Bullfrogs' asses . . .
BFA, I guess it was, yes.

RO: Bureau of Field Administration.

AB: That's it. As I think I may have mentioned earlier, Larry Warden and I handled all of the reports coming in from the field in their originally. We had Julie Hauser in there. I stayed in there from approximately '48 till I went to San Francisco in '54. During that period, we had a lot of the Abbott hearings.

We had some other interesting things. I remember one time Chet Hubble had a case out in Cincinnati involving a tomato packer that put up some filthy and rotten tomato products. The case came to trial in the dead of winter, and they were testifying and they got into some kind of conflict of testimony about how some packing line was set up. So Hubble and one of his minions went over in Indiana and broke into the plant, and they got caught. Hubble escaped back out of Indiana, and they had a warrant out for his arrest in Indiana for breaking and entering. It was an utterly ridiculous thing to do, because anything they found there in the dead of winter wasn't going to be admissible as to what happened last summer, anyway. I mean, you talk about managers. Here's a district director! So he's got Milstead on the phone wanting to know "My God, what to do, what to do," and Van Smart was working as a kind of assistant to Milstead at the time as kind of a legal advisor or something. Van says, "Tell Chet to go down there and give himself up and plead innocent on the grounds of an insane impulse." Milstead told Hubble on the phone, and Hubble nearly blew his stack (laughter).

But you were starting to say about that period. We had lots of interesting things during that period. That was when we had the Nutrilite case, and that's when I wrote the notorious Barnard skit. That's the last skit that we ever had. I wrote that skit on "Regulatory Management at the Washington Level, or How's Your Nutrilite Tonight?" It was too close to home. It was funny as hell, but it was too close to home. It was a takeoff on Jack Harvey, primarily, and the commissioner. While the case was being developed, Rayfield had gone into Harvey, complaining about the money that was going into the Nutrilite case. "Jack," he says, "can't we settle this damned case and save some money?" And Jack says, "Settle, hell! I wouldn't give 'em the sweat off my balls."

I had Julie Hauser playing the part of Dunbar, and Julie sat there with a telephone, taking the call from Harvey in California where they had settled the case. Julie had a hearing aid, like Dunbar did, and he'd twirl that hearing aid. "Yeah, yeah, Jack. It'll cure cancer, I see. Oh, only if it's caused by a nutritional deficiency. Oh, I see. Hmmm." He looks around at the audience and he says, "I wonder if he saved the sweat off his balls. (Hesitates) I wonder if he saved his balls" (laughter).

They settled the thing; they allowed them all kinds of claims that a lot of people didn't think should have been allowed. This skit was the settlement, after the Supreme Court had ruled.

The case was an interesting one. I spent hours and hours and hours in a locked room putting together tapes. We had recordings that came in from the field, and we had them on just about every medium you can imagine. We had them on the old Pierce wire recorders; we had them on various kinds of disks, recordings that were taken at sales pitches and that kind of thing. Being the

only one in the agency who'd had any electronics savvy, it fell to me to put those things together onto tapes that we could present in court, and take these pieces and those pieces, identify them, and assemble the master tape, which was quite a chore.

Other interesting things in Washington. I was up on the Hill. I guess that was after I came back, though. Larrick and I went up on the Hill once or twice while I was in BRC. No, BFA. Once, I guess. It had something to do with a Congressman from New York. I don't remember the details of that one. Rosenthal, I guess, was his name. He was running up and down our backs about our alleged negligence in letting the stuff that the military was turning loose get into civilian channels. Another 20/20 hindsight hearing. Benjamin Rosenthal-- that was that Congressman's name. He's been a pain in some people's necks since.

RO: What about earlier in your career, Al, going back to some of the things that happened along the way up?

AB: As I said before we put the tape on, it was really fascinating to sit and listen to John McManus talk about the old days in Food and Drug, when he was in the so-called Savannah Station before they moved it to Atlanta. McManus used to do his inspecting in a horse and buggy, and to hear him tell tales about getting around from place to place in a horse and buggy was fascinating.

Some interesting little things have happened from time to time. The way we go at things today as opposed to the way we used to go at things . . . I spent five days, I guess, in Albany, Georgia, just sitting in Albany waiting for a guy

to ship some pecans, because Lennington had made an inspection and concluded that the pecans were going to be polluted with E. coli. This guy finally made his shipment, and it was NAI. But I'd sat around there and had nothing to do but stay undercover, because they weren't supposed to know anybody was in town. This guy wasn't going to ship until he knew that the Food and Drug inspectors were elsewhere.

Of course, we lived with that in the crabmeat industry in Crisfield, too. Whenever we took the trailer laboratory to Crisfield, as soon as we crossed the Matapeake Ferry, everybody in Crisfield knew we were coming; the Western Union operator down there took care of them. So that wasn't that unusual. Of course, the guys with the crabmeat had to ship it anyway.

An interesting sidelight on crabmeat, and it's an interesting sidelight on why I don't think it's possible to write checksheets for factory inspections. We had a little plant down in Florida. I don't remember the name of the town; it may come to me as I talk, but it was down south of Jacksonville, between Jacksonville and Melbourne, on the east coast. Oak something. This plant was built like a little dairy; it was a model plant. The Florida Health Department had supervised the engineering of it; it was all brick, and stainless steel, and concrete, none of the wood and junk you traditionally found in crab plants in those days. They kept putting out polluted meat. And we were getting samples, and we were supposed to be getting samples to prove that a clean plant will put out clean crabmeat. This had people, to say the least, disturbed.

Lennington and, I guess, Will Swain—somebody else with Lennington-- happened to be in the plant one day about lunchtime, and the manager's wife came down to the plant to bring him his lunch. And she had the baby with her. While

she was there, she spread the baby out on the picking table and changed the baby's defecated diaper on the picking table (laughter). This, apparently, was a daily occurrence. She'd stir the baby up from its nap, go take the boss's lunch down to him, and by that time the baby had done his business; so she changed the baby. And everything that was handled on that table from there on out was polluted. Now you can't write that into a checklist. No way.

Other interesting asides. We had a prosecution, I guess, against R. L. Albert up in New York City for deceptive packaging of Christmas gift packages, and I was one of the witnesses. We went up to New York and we stayed, I think, five days before we got around to testifying. You know how court cases drag on. Jake Fittleson was testifying. Did you know Jake Fittleson?

RO: Yes.

AB: Jake was a very competent witness, as you well know, and the defense attorney was trying to harass Jake. We had a female United States attorney. Edith Glennon was her name and she objected. "He's harassing my witness." The judge says, "Oh, come on now, Miss Glennon. He seems to be able to take care of himself. Let 'em rough each other up a little bit." It was kind of interesting what was going on. But the five days we sat around, Ole Olsen, who was then chief inspector of the Eastern district, couldn't stand to see all this time go to waste, so he put us to work. He assigned me to John Cain, and John Cain sent me down with Zaic to the docks to sample chinchona bark. Now here I am with the only damned suit of clothes I've got; I'm down on the dock sampling chinchona bark. And when I got back to 201 Varick Street about six-thirty in the

evening, my suit was filthy and my ears were ringing from the quinine to the point where I couldn't even hear the subway. And I've never forgiven John Cain for that deal. You know, you would think at least under those circumstances they could have found some decent assignments, things to clean up, not that.

I guess one of my more protracted and intriguing experiences was in Florida my first year. I went to work in January, and the following winter I went down to Florida to do experimental packs of oysters, as I mentioned, with Bill Barbour. We were coming home from there and we stopped off in Jacksonville at Western Union to pick up any messages. I was told to proceed to Miami and contact George Fowler. Hank Cragin was resident inspector in Jacksonville at the time. I contacted George Fowler, and Barbour was sent somewhere else. I got home some time in June. That was the breaking of the Winthrop sulfathiazole case, and I worked in Tampa and Miami on that. And by then the Willett hairwave deaths had occurred. And by that time, Cragin was so far behind with his citrus plant inspections that I stayed down and made citrus plant inspections for about three weeks to help Cragin out.

RO: What was this Willatt hair case?

AB: Permanent wave solution killed several people. It was one of these sulfides that was absorbed through the skin. We had one death in a beauty shop in Fort Lauderdale. Not in Fort Lauderdale. Somewhere in the Miami area, anyway. That thing was pulled off the market. It happened right on the heels of the Winthrop sulfathiazole thing and sort of partially got lost in the shuffle. I think

the outfit was in either New York or Chicago; I forget. But that was a serious one.

RO: Was this marketed primarily to beauty shops?

AB: Yes, it was marketed entirely to beauty shops. This was really before the home-permanent thing set in. Home permanents hadn't really been developed at that point; this would have been in '42. You can go back. You can find that one in the records if somebody wants to know. W-I-L-L-A-T-T. Willatt Permanent Wave Solution.

The sulfathiazole thing, of course, was incredible. I sat in the Tampa Wholesale Drug Company day after day after day, going through their customer invoices and picking out sulfathiazole sales just off the invoices. And then Hank would phone in every so often and I'd give him a new list, and he'd go to the drugstores and try to find this stuff. What happened was, when Winthrop finally put the freeze on the lots, some of it slipped through here and there for various reasons. One batch at Tampa Wholesale--oh, I forget now how it slipped through, to tell you the truth. But there was one at McKesson-Grover-Stewart in Miami that we followed up on. This was one of the sub-lots. The original lot was MP095, I think, and the cripples from that lot were ground into the next lot, so the next lot (MP118) also killed a couple of people. None of these people would have died had they been healthy, but they were giving this to people who were on death's door with pneumonia anyway, and it didn't take much phenobarbital to put the finishing touches on them.

I walked into a drugstore down south of Miami, in Homestead. The druggist was standing there with a bottle of MP118 in his hand when I walked in, so I collected it from him, got a statement, and headed back to McKesson-Grover-Stewart because we had thought that McKesson had gotten it all. In other words, we had thought that McKesson had quarantined all the stocks before any got out, until I found this bottle. So I took off to get back there to catch George Fowler, and a cop picked me up and stopped me. I said, "Look, I've got this stuff here. It's killing people. I'm trying to get back to get my partner to get it stopped up there at the wholesaler." "Well, let's go!" he says; and he turned on his siren and then we went through Miami about sixty-five miles an hour! I came up to McKesson, and George Fowler's standing there waiting for me with his mouth hanging open. Here I come with a police escort (laughter).

What had happened was, they had a holding room. After they inventory the stuff and check it in, they put it in what they call the tally room. And this damn stuff had been in the tally room. The Winthrop representative came in and checked the receiving room stocks, checked the shelf stocks, and reported there wasn't any; and this shipment was sitting in the tally room. So then we had to run that shipment down all over the Miami area after all the time I spent in Tampa. That was a spring shot, really. Let's see, what else?

We had a couple of interesting cases in Kansas City. We had the big condom seizure when the judge wouldn't believe the statistics. God, I think there were 10 million condoms or something like that we seized in Puerto Rico. We had samples of, I guess, 200 or 300 or something like that from various shipping cases. We had a very sound statistical estimate of the number of holes. After the case was essentially closed—the judge hadn't rendered his decision—I talked

with the judge. I had talked to the statistician on the phone. I offered to get for him one of the nation's top statisticians from Ohio State University to testify to the statistical adequacy of the sample. The judge looked at me and he said, "Mr. Barnard, I may be narrow-minded or stubborn, but we might as well save the government the money, because no amount of testimony is going to convince me that that size sample is representative of that many units. I'm just not going to be convinced. I know that in my own mind." That was the end of it. That's when I met Johnson and . . . what's his name, that wrote the book? Johnson and Masters. He came over and testified as an expert on the pressures and energies and stuff involved in sexual intercourse, and the significance of holes in condoms. He's a character. He is really a character, that guy is. I spent several hours with him, briefing him about testifying. Very interesting character. Interesting case.

We had another interesting case. That's one of two cases that I recommended not be brought. We had some idiots in Washington at the time. Chet Hubbel and Sid Weisenberg, between the two of them, they insisted on bringing this case even though the district director had recommended against it. As Billy Goodrich told them later, "You should have had better sense than to bring a case in Barnard's district when he didn't recommend it." The case was an absolute disaster. We had Ellis Arnold, who was the former governor of Georgia in as the chief defense attorney, and we had a little simpleton for an assistant United States attorney that left everything around where they could find it. They went through and rabbit hunted all our confidential files. This guy was terrible, absolutely terrible.

I had put Baldy (Norman) Kramer in charge of the case, because Baldy was my Food and Drug officer, and I have never, as a principle of management, believed in putting somebody in charge of something and then jerking him out of it in the middle of it. During the disaster, Rayfield called me up and said, "How's this case going?" I said, "Terrible, and it's likely to get worse." He said, "Well, why don't you step in and take charge of it?" I said, "Rayfield, look. I put Kramer in charge. I put Normie in charge of this case, and I'm not going to jerk him off of it." "You think that was smart?" I said, "If I hadn't thought it was smart, I wouldn't have done it. I'm not going to second-guess myself." So that was real terrible.

Prendergast came out finally from Washington to try to help out, but it was far too late for that. They sent Herbie Friedlander out, and Friedlander was in a state of absolute blue funk. Ellis Arnold would just rip these witnesses to tears. We had a colored chemist out there, McCullom or something like that, and he had done some protein analyses. Ellis Arnold messed him up to the point where he didn't know what he was testifying to. Then they had some associate professor from the University of Minnesota; they called him in to review this poor chemist's work, and he said, "Well, I'd give him a grade of 'C-,' maybe." And there wasn't anything wrong with the guy's work. The assistant United States attorney wasn't willing to put this guy back on to cross-examine him about the basis upon which he graded him, because he didn't know anything and he didn't have any confidence in anybody that did. It was a disaster from the word go.

RO: What was the product?

AB: I'm trying to think of the name of the product. I was trying to think of it coming over on the subway, and I cannot think of the name of it. You won't have any trouble finding it, though, because it had huge overtones; it made headlines all over the nation. We had some new electronic eavesdropping equipment, and these people were selling this product in a supermarket. They had a little promotion and they were handing it out. You know, the sampling-type thing you see in supermarkets. And they had a few little claims about it nutritionally, but nothing significant. We weren't that much concerned about the claims. The principal issue was low protein. So we decided, though, that this would be a good place to try out this new equipment. So we did try out the new equipment. And somehow in pawing through the files, Arnold found out that we'd made recordings and that we'd had this gal in there, "this blonde super-spy," he called her. Long, the Senator from Missouri, got involved in it and with the aid of some of his Mafia connections, really made a cause celebre out of the damned thing. There were headlines all over the place. I will think of it if you give me enough time, but there's no problem identifying it. This was in '64, approximately.

RO: We'll have a chance to enter it. But how did this case ever go forward if it wasn't recommended by the district?

AB: I think Normie recommended it. I don't remember now exactly how that so-called case supervision--what did they call themselves then? Case supervision or something. I don't know exactly how they did get hold of it. And then the worst

part of it was that at the last of it, we had an offer to plead the corporation if we dropped the individual. And they wouldn't drop the individual! Oh, boy. And what that cost the taxpayers, and what it cost the poor guy they prosecuted. He had Ellis Arnold up there from Atlanta with his crew. He told me later it cost him over \$200,000. There was no smoking gun; there was no desire of anybody to do anything really heinous. As a matter of fact, if you believe the other side, the stuff wasn't even deficient in protein. But I won't accept that; I was willing to grant that.

The other one that they brought over my protest was when I was in here in Washington on a temporary assignment. They used to rotate the district directors in when they got behind in their work to help them review things, and I reviewed a bunch of cases. One of them that I reviewed was the Dow Corning silicone fluid, Medical Fluid 360 case, where they prosecuted Dow Corning for distributing that Medical Fluid 360 for mammary augmentation. That, in my opinion, was a lousy case. They finally settled that one on a plea. They had a medical director who was going out saying more than he should have been saying, but this was not an overt attempt to sell this product. There wasn't any profit in this product; there never was any profit in this product. I've been a consultant for Dow Corning almost ever since I retired, and I know now even better than I knew then that there was never any profit in the product, particularly for that application.

This guy they had for a medical director was going out and talking to plastic surgeons and people like that about what could be done with this material, and again Weisenberg and Hubble parlayed that into a criminal prosecution, partly because Dow Corning was a big company and they felt like they could

get some big headlines, get some big name for themselves. I thought it was an ill-judged case from the standpoint of there being no need for it, really.

Those are the kinds of cases--particularly that one, not so much the one in Kansas City. The one in Kansas City was a judgment call. If I had been sitting in Washington looking at the case, I might have said go ahead with the case, too; it was that close. It was a bad case, and from a hindsight standpoint it never should have been brought; and certainly they should have accepted the plea on the part of the corporation. But the Dow Corning case is the kind of case that got the agency a bad reputation over time. It's the kind of case that led to the kind of criticisms about the agency being a cop agency and not interested, really, in consumer protection, but just interested in making cases for cases' sake, and that sort of criticism.

We had some people at that time in compliance areas who had that bent of mind. It was an outgrowth, I think, of the basic philosophy. I know it went as far back as Campbell, and it may have gone back to Harvey Wiley. Early on, the agency recognized that they did not have anywhere near the resources necessary to regulate the entire food, drug, and cosmetic industry, and they felt it was necessary to carefully select cases so that the case selected, if you won it, would have an impact on the entire industry. It's now the kind of thing that we would call a class-action type of thing. Jim Goddard was the first one to bring the class action concept into focus in FDA. But you chose your case not solely on the basis of the violation itself, but on the calculated impact that that case would have on that whole area of regulatory problem. This spilled over, I think, into the kind of thing that I'm talking about later on. It became a matter of

making cases that would make splashes without really evaluating the kind of broad picture that I'm talking about.

RO: Bill Goodrich was general counsel at that time, wasn't he?

AB: No. Bill didn't become general counsel until probably '55, somewhere along in there.

RO: I was thinking of some of the cases you were talking about when you were in Kansas City.

AB: Goodrich was general counsel by the time I was in Kansas City, yes.

RO: Bill was credited with wanting to set some of the enforcement policy by selected test cases.

AB: Well, that's true. But these didn't fall in the category of test case. No, no, no. Cases like the wrinkle remover cases, those were test cases. There were some other cases. And then Bill and I fought repeatedly--this was one I won. Bill always wanted me to bring an action against Nyquil when Vick first brought out Nyquil, because Bill's position was that they were running big ads: "This is a New Drug." Bill said, "Either it's a New Drug, in which case they ought to have an NDA, or the ad's false and the label is false and misleading." Because it had appeared everywhere where you could call it labeling; it wasn't just advertising. Bill wanted to take that on as a test issue, and I told Bill I thought it was a

kind of a trivial issue in the over-the-counter field. At that time we didn't know what to do with over-counter New Drugs anyway; they're not sure what to do with them yet, for that matter. They were still smarting from the effects of saying that x milligrams of antihistamine has to be Rx, but half that much you can sell over the counter; so that you can take two of them. There are some little anomalies that are really written into the law; those are not things you can solve by administrative intelligence; there are few of those.

Pat Cronin was general counsel when I came into the agency, and then Pat was succeeded briefly by this guy from Minnesota who died of cancer. It was an amazing thing. He worked on the Koch cases. He spent most of his career in Food and Drug working on cancer quackery, lived in constant terror of cancer, and then died of cancer. I can't remember his name. Tall, towheaded. It might come back to me eventually.

Billy was in Food and Drug for a while as an attorney before he became general counsel, and wielded some influence before he became general counsel. Pat Cronin was pretty well settled back and relaxed, a snug-harbor-type approach, by the time I got associated with him to any degree. When I came into Washington as resident inspector, I had the delightful opportunity to work directly with the general counsel. We got a temporary restraining order against the Connecticut Baking Company; they put out some Boston cream pies that were loaded with staph, and we jumped in there and made a quick inspection. The place was filthy. We made an inspection on Tuesday, and on Thursday we were in the judge's office asking for a temporary restraining order. Now that kind of thing was unheard of in Food and Drug. We got it through the Eastern

district, and I sat down with the general counsel's office and I drafted the papers with this guy. Bernie Levenson was his name. Bernie and I drafted the pleadings and the affidavits in that case.

We filed the affidavits with photographs, and somebody in the general counsel's office jumped on it and said, "You can't plead evidence." We didn't care whether we could plead evidence or not; we were going to put the photographs in with the affidavits. The marshal that took the judge upon the elevator back to his chambers after we had our first session, said, "You know, after the judge looked at those photographs, you had your injunction. He didn't have to read anything else." He just looked at those photographs; that was it. The hell you can't plead evidence!

That was an interesting period. We also did the K & R Bakery, which was the one that stood for the authority under Section 301(g), to regulate commerce wholly within any territory not organized with its own legislative body. The K & R Bakery was a local bakery; they claimed they did no business outside the District of Columbia. And we had one of these District of Columbia activists defending them, Bernie Wiener. He's a guy that's saved all the historic buildings in town, but he wasn't going to let the monstrous federal government engulf some little local business. The judge told him, following the appellate court decision in the Carmen Beach case, "It may be naught but pernicious oversimplification, but I find that this section of the act applies." In the Carmen Beach case, these idiots in the appellate court here for the District handed down a decision in which I think it was old Champ Clark stated that "even though the language of a statute may be clear and simple, it is naught but pernicious oversimplification to assume that the meaning to be drawn therefrom is likewise

clear and simple." Now will you tell me how Congress can say what they mean other than in clear and simple language? The Carmen Beach case was a notorious white slave case here in the District. So this guy was hanging on Carmen Beach, see, to save his client's skin.

Did we talk about the food GMP regulations swinging around a full 360?

RO: Yes, we did.

AB: Good. I didn't know whether we had or not.

Speaking of test cases and the kind of cases we've just been talking about, they're examples of the old truism that bad cases make bad law and good cases make good law. We were very, very careful in the Food and Drug Administration for many years to bring only very good cases. We were acutely conscious of the res adjudicata doctrine. And, I think, probably a little too conservative. Even Billy. Now Billy wanted to push out the frontiers of the act, but we were very, very chary as a general rule, with a couple of exceptions. One of the reasons the exceptions I mentioned stood out so blatantly is because they were exceptions and because we were very, very chary as a general rule about bringing cases we felt we had any serious likelihood losing. This philosophy is one of the things, I think, that Goddard wanted me to turn around in the regulatory milieu when I came into BRC. And, given that it was engrained in everybody in the organization except Goddard, it was unlikely to be turned around overnight.

(Interruption in tape)

AB: Let's talk just a moment about deceptive packaging cases. I don't think that the Food and Drug Administration ever won a contested one. And in my opinion this is totally due to the tunnel vision exhibited by the scientists in the Food and Drug Administration. We were talking about the Delson Thin Mint case. I'm not sure whether this was the Delson case or not, but there was a case tried in New England—Rhode Island, I believe; I'm not sure—involving deceptive packaging. We had all this testimony about how many grains of mustard seed you could pour in the box, and how many you could pour out, and how many you could pour in with the product in it, and all this kind of stuff. Hours of "scientific" testimony.

About two weeks after the judge dismissed the case, the resident inspector, Cassidy, got a telephone call from the judge. The judge asked him to come into his chambers; he wanted to talk to him. He says, "Mr. Cassidy, I want to tell you a story. I was in the grocery store the other day with my wife. We got to the checkout stand and she asked me to go back and get something that she had forgotten. I went back and got the package and came up to the cash register, and she looked at it and she says, 'Oh, no, no. That one's only about half-full.' That is the first time that I realized what the Food and Drug Administration was driving at in that case that you had before me." Now, that's what kind of a job we did in presenting our case, from a practical standpoint. That's my view on that. Why did you bring that up? You mentioned the Delson case from some other standpoint.

RO: I was just curious to know where you were at that point.

AB: Speaking of presenting cases, A. G. Murray for many years was the Mr. Drugs of the Food and Drug Administration. Murray was a very, very devoutly religious man, a very conservative man. He used to tell a story about a case years ago when we were trying a seizure of a diphtheria remedy. The remedy was some kind of a gargle, and they had all kinds of expert doctors testifying with respect to diphtheria. The defense was testifying that, after all, this mouthwash and gargle did kill some germs. The doctors were having a great deal of difficulty, and Murray went out and got an old country doctor from in town there, with no credentials except a long practice in the community, put him on the witness stand, and the defense attorney started questioning him. "Now, doctor, this will kill some organisms, won't it?" "Yes, it'll kill some organisms." "Well, then, it'll be of some help, won't it? It'll help the patient, won't it?" And the doctor looked at him and he said, "Mr. Lawyer, when the house is on fire, you don't run into the vestibule with a teacup full of water." And that was the end of the case. That was all the jury needed to hear. And we need more of that kind of common sense in lawsuits.

The Abbott matter. The Abbott matter dragged on a lot longer, I think, than a lot of people thought it did. Some people thought it was primarily responsible for the demise, if you will, of Rayfield and Larrick. I don't think so. It may have provided kind of an excuse to weed them out; it may have been sort of the trigger. But as you and I have said before, Goddard was brought in to change the direction of the agency, not to clean up the Abbott mess.

RO: For the record, what was involved in the Abbott matter?

AB: The Abbott matter involved, over time, the production by Abbott of large volume parenterals, which were non-sterile, or which had a reasonably high likelihood of being non-sterile. The thing really got its momentum from the old Cutter episode, when Cutter put out some large volume parenterals that were contaminated and actually, I think, resulted in a few deaths. Abbott had developed what was probably the first high-speed production line for large volume parenterals, and there was real reason to question how effective the sterilization techniques really were. Of course, we had the old USP system for testing: if you examined it and found it adulterated, you examined it again and proved that it was adulterated; then you examined it a third time and released it if you didn't get any more non-sterile units in the third sample. It was patently ridiculous, and end-product sampling still is, in products of that kind. Fortunately, we can't get the world to that state, but at least we've got some people in the Food and Drug Administration where they realize that end-product sampling doesn't tell you any more than that you didn't miss the sterilizer with that particular batch.

The Abbott pattern continued over a long period of time, which is really, I guess, what caused the flak. A lot of it was politically motivated. Fountain and Don Grey, his chief investigator. Don and Fountain saw an opportunity to make some good headlines at the expense of a well-known, profitable company. Rather than go quietly, Larrick, particularly, and Billy Goodrich kicked up their heels and tried to defend all of FDA's indefensible positions.

One of the things that the agency never learned until, I guess, Paul Pumpian came in . . . I think Paul was probably the first one that taught the agency a little bit about dealing effectively with Congress. If some Congressman wants

to make a headline, the best thing to do is get together with him and say, "How can you best make this headline you want to make?" and go in there, and let him beat you over the head and make his headline, and get out and go on about your business. Don't get into a big fight with him. Recognize what his goals are. Recognize what he's trying to accomplish. Help him get it accomplished at minimum expense to you, then get out. Don't fight a continuing, long-term battle with him. The Food and Drug Administration through the years has lost so many of those battles that it's been a disaster; the Administration was once cut down to less than \$5 million total appropriation as a consequence of losing those kinds of battles.

Anyway, as the fight wore on, Abbott continued from time to time to put out questionable materials. I don't think they ever did kill anybody. Everybody said they were about to, they were going to kill somebody next week; but I don't think anybody actually provably died. They began to look into the fact that there had been some relationships between Jack Harvey's brother and Abbott. They never were able to find anything; there was more innuendo than anything else. If there was anything ever proven, I'm not aware of it.

An interesting sidelight to that is, Tommy Riggs, who's dead now, God rest his soul, was working for Abbott. Tommy used to pick up the phone and call me at home when I was in BRC and tell me where to send the inspectors in Abbott to find things, and which lines to look at; and I would then send the inspectors to those lines and they wouldn't find anything. That's how I first got to know Don Martin, by the way. Don was in Chicago, and I got hold of Don on the phone. He and I had quite a little session, which Don has never forgotten.

But the Abbott thing, as I say, was kind of used as something to hang somebody's hat on. It wasn't really the reason that Rayfield and Larrick got out. Larrick was run out, and Rayfield along with him, primarily because the department was not pleased with the direction the agency was going. The Abbott thing was used to focus on the concept that the agency was soft on big drug companies. That's one of the reasons that Goddard came in and turned the spotlight on the big drug companies, much of it totally unjustified. But, nevertheless, that's what his mission was, to dispel the idea that FDA was in league with the big drug companies, which was, in part, an outgrowth of the Abbott thing.

RO: Al, I believe we have covered many of the events in your career, and unless you have anything additional for the record, we can close this session. We will still have an opportunity to add other topics after we review the transcript.

(Interruption in tape)

RO: This is a continuation of an interview with Mr. Alfred Barnard. The date is March 2, 1989.

AI, we covered rather thoroughly, I think, your career in the Food and Drug Administration and a number of the programs that were a priority of the agency during your career. But there were several compliance programs and personnel initiatives that I believe we failed to cover. One of the programs in particular was one dealing with the improvements in handling raw materials--milk and cream--in the dairy industry. Would you care to discuss that program in detail: the objectives, how we inspected, the places, some of the cases resulting from the program, and your general reaction to the agency's accomplishments?

AB: Yes, I'd be glad to, Ron. I was not as active in the cream program as your opening statement might lead the listener to believe. But down in the southeastern United States--I think this was probably even more true in the Indiana, Illinois areas but I never worked in those areas; that's hearsay--the sour cream butter industry was based on cream collected from small farmers. Cream was a by-product. It was how the small farmer got his spending money. He had a little can of cream and he usually kept it in the chicken house. When he had some cream left over, he'd go out and add some to the can. Then the mold would grow over it until the next time he added some. About once a week, the creamery would come by and collect it, or maybe once every ten days. During hot weather, you can imagine the kinds of things that happened to that cream.

Kind of as a sequel to that, later, when I was working in Baltimore station, we used to see cans of cream come through Wheeling, West Virginia, with

the lids wired on because otherwise the escaping gases would blow them off (laughter). That's the way sour cream was handled. I'm skipping to the end of the story perhaps, but as far as improvements are concerned, about the only improvement that really came was when the sour cream butter business stopped. The Southeast, at least, never developed a volume of cream that would have permitted a decent sour cream butter operation. I think, as far as I know now, virtually all, if not all, of the butter produced in the United States is sweet cream butter. I don't think there's any so-called sour cream butter produced at all anymore.

RO: What were we trying to do, as far as controlling the use of sour cream was concerned?

AB: We were trying to clean up the raw material source. The plants themselves were not objectionable. Swift had a plant in Macon, Georgia. The Americus Creamery had a plant in Americus, Georgia. I think they had—I'm not sure--one other plant. Armour had had a plant in Georgia that they finally closed because they couldn't tolerate the kind of raw material they were able to get. Swift, at that time, wasn't nearly as picky. The Americus Creamery made a point of buying anything that the farmer wanted to sell. I think I may have mentioned before the "reverse" food and drug guarantee that Americus Creamery used to use. Their invoices had a statement on them that the undersigned, Americus Creamery, will in no way be responsible for any seizure or criminal action undertaken by the Food and Drug Administration as a result of subsequent introduction of this butter into interstate commerce.

RO: For the record, Al, you mentioned a "reverse" food and drug guarantee. What is a Food and Drug Guarantee?

AB: The FD & C Act Guarantee is the guarantee provided under Section 301(c), I guess it is, which states that the seller hereby guarantees that the product is not a product which is adulterated or misbranded under the Food, Drug, and Cosmetic Act or which may not be introduced into interstate commerce under Section 404 or 505. That protects the purchaser, like a wholesale grocer, for example, who buys canned goods or anything else in the food, drug, or cosmetic line and subsequently ships it to his customer across state lines. Now, if he has that guarantee from his supplier and he, in reliance on that guarantee, ships an illegal product, he is immune from prosecution. That does not keep the merchandise from being seized, and he has to straighten that out with his supplier. But it does give him immunity from criminal prosecution provided he doesn't do any manipulation--if he ships the goods as received, if he doesn't repack them, relabel them, or anything of that sort. If he just buys them and sells them as is, that gives him immunity.

This reverse guarantee is guaranteeing that you will not be immune but that you will suffer the consequences if you ship this stuff in interstate commerce. As I say, even the Americus Creamery, despite its policy, was still a decent operation as far as the creamery itself was concerned. The problem was the raw materials.

The program consisted largely of trying to, one way or another, interdict the flow of filthy and adulterated cream to these creameries. We would send

out crews of cream tasters who would take glass rods--they called them cream rods--and dip them down in the cream and slap it into their mouths and taste it. I remember once the inspector got a chicken gut strung across his teeth while he was tasting cream. I remember Ed Hoshall cracked his cookies and lost his false teeth in a can of cream down in southern Maryland (laughter). It was beginning to become a matter of concern about the health of the inspectors: what kind of diseases might a man catch or what kind of food poisoning might a man get from tasting cream? And yet, as far as I know, there was never an instance where cream tasters suffered any known ill effects from tasting cream.

RO: Other than a queasy stomach.

AB: Yes, other than a queasy stomach. I think Ed had a hangover that morning (laughter). I think that may have contributed to the problem.

The examination of the cream supply provided evidence of the use of rotten cream over and above the mold counts. Of course, the laboratory mold count was the . . . What the heck was the name of the mold count?

RO: Howard mold count.

AB: The Howard mold count was the primary method of determining that type of adulteration in butter. I remember when I was in Florida once I sampled a whole carload of butter for Chicago. I was a neophyte then, and I was still capable of making mistakes. I got over that later, of course (laughter). But I forgot to send them a list of the churn numbers that were related to the subsamples of the

shipment. I was very, very happy when I got a wire back from Chicago: "All subs 100 percent adulterated. Proceed with seizure" (laughter). They didn't have to decide which churns or what. Often, with the butter that we sampled from that part of the country, you would find some churns very clean. I didn't know enough about the industry to know why, but you'd find some churns very clean and some churns 100 percent positive fields on mold count.

RO: Do you know if there was any chemical index then that you used to support the mold count?

AB: No, not that I recall. They would run them for gross filth: insect fragments, worm fragments, that kind of thing. There were standards for "dirt." You had standard pads. You'd run a little filter pad on the butter and then examine the pad and compare it with a standard.

RO: I think later it was determined that water-insoluble acids were an index of decomposition.

AB: Yes, I think you're right. Some of the higher chain fatty acids.

RO: What happened to the sour cream, then? There was surely sour cream available. If it wasn't used for butter, what happened to it?

AB: I don't know. To be honest with you, I really don't know what became of it. I think, really, it was part of the change in economics of the South that took

place during World War II. The small farmer really quit being a dairy supply point. He didn't keep enough cattle anymore to have cream left over. He'd go ahead and consume it himself or churn it and make his own butter. We always made butter on the farm. When I was raised on a farm down in the Southeast, we made all our own butter. We never had any surplus cream. The surplus milk went to the hogs. But dairying really had not been an industry in the Southeast. You didn't have these large dairies with dairy herds and that sort of thing. The whole dairy industry was scattered small farmers, mostly. I think that as the economy evolved down there and you began to develop some dairy farms, you got away from the demand from sour cream. I think most of it, what there was, was used on the farms.

RO: I was born and raised in a small town in North Dakota. There were several what we called cream stations. They received cream from the farmers in five-gallon cans which, like you say, was probably the week's cream obtained from separating the milk. It was often sour. I often wondered when you couldn't make sour cream butter anymore what happened to the sour cream.

AB: I really don't know.

RO: Did the agency have any cooperation from some of the dairy associations, like the Butter Institute?

AB: Not that I'm aware of. I'm not even sure the Butter Institute was really in existence. I guess it probably was, but I think they sort of looked the other way

as far as the southeastern United States was concerned at that time. There were other dairy problems too. They were mostly of a local, noninterstate nature. You know, fresh milk, fluid milk problems. If they were involved, I don't recall it.

RO: There were, apparently, some pretty good cases that resulted. Some of those would be of interest.

AB: Well, we got an injunction against Swift. Also, we got what was a large fine; I think it was \$1,000, which was about as large as fines went in those days, against the Swift plant in Macon. I don't believe we ever succeeded in getting a case on Americus; I'm not sure. We got several seizures of Americus stuff that had been moved over either into Florida or into Alabama. But we never were able to establish their guilt in connection with the distribution.

But I know we got an injunction against Swift. But that didn't make any difference either because Swift didn't ship any butter. I mean, the injunction didn't matter. The only thing we got against Swift was that Swift's trucks would work Alabama and Florida out of the Macon plant and, every once in a while, somebody would throw some butter on the truck, probably by mistake rather than intent. We would occasionally find Swift butter in interstate commerce that had, in fact, been shipped by Swift. So we sought an injunction. It didn't do any significant good because I'd say anywhere from 97 to 99 percent of that butter stayed in Georgia anyway.

RO: FDA's program must have been effective, then, if it spelled the demise of sour cream butter.

AB: Well, I'm sure that our program was a contributing factor but I think that it may have been an increasing aesthetic consciousness on the part of both the industry and the public. When I grew up, when you ate flour in the springtime, your flour had bugs in it. If it didn't have bugs in it, you worried about what the hell happened to it to cause it not to have bugs. Nowadays, people don't cotton comfortably to eating buggy flour and those kinds of things. There's been a change in the housewife's attitude toward what constitutes adulteration. There's been a very substantial change in attitude. I think that nowadays you'd be hard put to find a plant manager who would be willing to run a plant and accept that kind of garbage and put it in human food. That was not the philosophy in those days. Not that those people were any worse than people today; it's simply a different approach to things. What is attar of roses to you may be . . . et cetera.

RO: I don't think oleomargarine was quite as popular then as it is now.

AB: Oleomargarine was much vilified in those days, partly, of course, due to the dairy lobby. But it was attacked as being unhealthy. In fact, one of the things I've got a little note here on the whole philosophy of the arrogance, if you will, or totally undemocratic nature of successful Food and Drug law enforcement. We can get into that later. But the objections to oleo were promoted, as you say, by the dairy industry. Now we find ourselves having come full circle. We're

saying that the short chain fatty acid oleos are much better for you than the animal fats in butter. Much was made in the forties of the terrible things that these nondairy fats would do to you.

I got to thinking about food standardization and things like that. The Supreme Court in Dotterweich, I think, said that this law provides protection, reaches into areas, where the consumer in the circumstances of modern industrialization is totally unable to protect himself. That is undoubtedly true. But when you accept that, you have to accept that there is somebody out there who can do the protecting. Now, you have "Father is all," and he tells me what's better for me. He knows a hell of a lot better what's better for me than I do. When you put that kind of power into the hands of a federal agency, you begin to run into some funny kinds of things.

The saccharin thing is a good example of it. I remember sitting and listening to Walter Campbell and later to Charlie Crawford discussing food standards and food standardization. We were talking about the farina case, which was the lead case before the Supreme Court in the food standards business and, subsequently, the benzoated catsup case, and the fact that you can't permit the marketing of catsup with added sodium benzoate without violating the fundamental precepts of food standardization.

I've had trouble with that concept all my life because I can so easily see both sides of the coin. If a guy wants to buy catsup that's labeled "sodium benzoate added." Of course, you and I know the benzoate thing had nothing to do with benzoate or food standards either; it was to keep them from using rotten tomatoes. But leaving that aspect of it out, that spilled over into other things.

There are a number of other things where a similar line of reasoning was followed.

It's something interesting to philosophize on: just how far does government go to protect the citizenry against real vis-a-vis perceived ills and who determines what constitutes an ill? I remember when Jim Goddard first became commissioner, one of the very first staff meetings that we had, somebody was there from the Bureau of Foods. I think it was Lowrie Beacham, maybe not. Maybe whoever was heading Foods at that time. But something was said about some food standards item, and I think it had to do with mayonnaise versus salad dressing—I'm not sure--and it was considered to be an important problem. Jim Goddard said, "Can the consumer tell the difference?" "No, the consumer can't tell the difference." "What does it matter?" "That's just the point, the fact that the consumer can't tell the difference is what's important." "Well, if the consumer can't tell the difference, I can't see what difference it makes," says Jim (laughter).

RO: You have to protect the consumer, though.

AB: It's fascinating, too, you know. In the days when I was working in Kansas City and Evan Wright was running Food and Drug in Kansas, the idea of selling what he called bellywash, diet soda, was repugnant to Evan. The idea of somebody spending their money for something that didn't provide nutrition! Nowadays, the fewer calories it's got, the better it is. I mean, we've come full circle on this one too. If you can sell somebody nothing for \$5 a bottle, they're a lot better off than if you sell them good hydrogenated fats or nice coconut oil for

\$2 a bottle (laughter). All of which goes to show that we're a long ways from solving all the problems of governing our society.

RO: That's right.

AB: I guess. What else did you think about getting into?

RO: You said you had several other interesting cases that you thought we hadn't covered earlier.

AB: Yes. There are two or three odds and ends that I thought maybe we hadn't covered. I did mention the fact that we had the egg school in Kansas City on the NBC "Today" program. I think we got that in. I don't think I talked much about the work we did on food standards on ice milk in North Carolina. I guess this was probably my first or second road trip. We did a lot of work on how the consumer perceived ice cream. We were trying to set a standard for ice cream, and at that time there was much hassle about low fat ice cream.

North Carolina had a state standard for--I don't think they called it ice milk but it was the equivalent of ice milk--4 percent fat. The primary proponent was Coble Creamery or Coble Dairy, and Coble was all over piedmont, North Carolina, and probably down to the coast. Their big pitch to everybody was what a tremendous public service they were doing by putting dairy products in the stomachs of these poor children who wouldn't otherwise be able to afford dairy products. We were doing some investigating of how these products were marketed and how the consumer perceived them. We were doing some question-

naire work and that kind of thing. We started running some samples and we found that these buggers were giving them about 2 percent fat at the same time they were bragging about what wonderful things they were doing! Of course, fat was the money constituent in those days. Milk solids, you couldn't give away; the fat was where the money was. That changed too over time, as you know.

But I thought that was kind of interesting. That was one of my early introductions to some of the things that generate cynicism about the goodwill of industry. I'm generally pro-industry but I can get pretty cynical about some of the things that industry does at times.

Did we dwell at all on John McManus?

RO: I don't recall.

AB: John was station chief in Atlanta and kind of my guardian angel, in a way. John was a very kindly, elderly gentleman by the time I met him. He was totally shocked when my wife called him up and told him her water sac had broken. Mr. Mac thought you found babies under cabbage leaves; at least, that's what he thought nice women were supposed to think. I was down in Savannah. This was our firstborn, and my wife thought I ought to be there. Speaking of firstborn, let's go off the record for a second.

(Interruption in tape)

AB: Mr. Mac used to tell some fascinating stories--it's too bad you can't get them for your history--about the days when you did Food and Drug inspection work in Georgia with a horse and buggy.

RO: I think you did mention that.

AB: Did I mention that? We may have as much as I know on that one. Did I talk about the botulism case here in the district involving home canned okra? Do you recall? That was an interesting case. I was in a laundromat in Arlington, Virginia washing clothes with a neighbor. The laundromat operator came over and asked me to come to the phone. My wife had gotten Rayfield in touch with me. They had a couple of people over in Baltimore, a minister of some negro church, who was in the process of undergoing a tracheotomy as a consequence of acute botulism intoxication. He had been at a supper party the previous Sunday--this was like a Wednesday or a Thursday--at a home over in southeast Washington in a real rough neighborhood. So I was to find out, as soon as possible, what the story was.

So I headed for southeast Washington. By now it was eleven o'clock at night. As luck would have it, I picked up a police car, so we went to the house together and we knocked on the door, and a lady came to the door and she was sick. She'd been throwing up and she was really sick. When she first started getting sick, she'd taken a whole bottle of castor oil, she said, which is probably what saved her life. But we looked around a little bit and then arranged to take her over to what was then Gallinger Hospital, got her over to the hospital and got the story from her. She had canned okra in half-gallon mason jars by

setting them in pans of water in the oven. There were no jars left, but I managed to get some empty jar lids and a few little things like that, and the lab picked up the organisms off those.

I think the preacher died; there was somebody else in Baltimore that recovered. There were a total of eight or nine people involved in the thing. There was one jar of okra that she had sent to a friend in South Carolina by another friend, and we managed to get that one intercepted before anybody ate it. I never knew what became of it.

One of the amusing sidelights: I got back home about two-thirty or three o'clock in the morning, and I hadn't more than gotten home than the phone rang. "This is Gallinger Hospital, 'Dr.' Barnard. What treatment do you want given to this patient you had admitted here this evening?" (laughter) I told this dame that the woman is probably suffering from botulism. She said, "The only doctor we know that knows anything about botulism is Dr. So-and-So, and he's a very important man. We don't like to disturb him." I said, "If you don't want that woman dead on your hands, I suggest you better give him a ring." So they got hold of the doctor and he got some bivalent antitoxin to her by about six o'clock, I guess, in the morning. It took that long. But she recovered uneventfully. So that was kind of an interesting one. I'm sure you've got some of the other botulism cases on the record, the same type of follow-up thing.

RO: The one I thought you might have mentioned was the one that the state of Virginia reported to us—I think you were here then—of finding botulism in anchovies, which just seemed almost impossible because of the salt content. It turned out that it wasn't.

AB: We did have one here of botulism in figs. There was a lot of work done by Micro. They finally concluded that the botulism was encapsulated in rot spots in the figs. But that one was tied down pretty nicely. That was the one where we chased—Food and Drug, not "we" in the personal sense—that damn fig preserve down in about fourteen states. This woman here had packed it and she had sent a jar to about every friend she had. She was very much upset with the idea that there might be anything wrong with her fig preserve. I don't remember many of the details of that case.

I did tell you the famous story on Nevis Cook and anchovies, didn't I? The first trip I ever went on with Nevis . . . We'd sit down and order a meal, and whatever I ordered, Nevis would say, "Make it two." After about two days of this, it begins to get on your nerves because you begin to wonder, "I wonder if I'm ordering what he wants. I wonder if he's going to like this." It sort of gets to you!

Be that as may, we were in the Hotel Columbia in Columbia, South Carolina, and I ordered an anchovy salad, among other things. So Nevis said, "Make it two." He never tasted anchovies before. He ate a piece or two and he looked up and he said, "Well, the damn things didn't spoil for the want of salt, did they?" (laughter) That got to be a very famous saying. There was another guy there who became a chemist because he couldn't stand being an inspector. He'd started out as an inspector and he saw more filth than he could stand. Bob O'Neill was his name. Bob had been on a road trip for about four or five days and he hadn't eaten anything. He'd gotten around to where he wasn't eating anything but canned soup. Of course, he didn't know what was going into canned soup.

One morning, they talked him into ordering some cereal. He ordered Shredded Wheat, broke up his Shredded Wheat, and when he poured some milk on it, out swimming across the top comes a sawtooth grain beetle. And that was the end of that (laughter). Poor guy.

EEO problems. I could tell you three funny stories about EEO problems, for whatever they're worth. Nevis, as far as I know, never had any real EEO problems. Nevis was a good north Georgia country boy, as you know, and he went to Boston as district director. The EEO people, of course, were genuinely concerned about what a good Deep South boy might do in the EEO area. They did an EEO study up there and they asked Nevis some question about his attitude towards bias and what have you. Nevis says, "Well, we don't have any prejudices at all up here. I hired five Protestants last month" (laughter).

Teddy Maraviglia was being picked at in a rather irritating way when he was district director in Cincinnati by some EEO officer from some outside survey. Teddy got irritated enough so finally he looked the guy right straight in the eye and he said, "Listen, I've been listening to all this concern you've got. I'd like to know, what are you guys doing for the damn Wops?" It embarrassed the guy, obviously. Finally, he guy looked at Teddy and said, "Well, Mr. Maraviglia, let's be honest about it. We're really talking about Negroes."

In my own experience, which I thought was kind of amusing, I had an EEO team out when I was district director in Kansas City. They did a nice job. They patted me on the back very kindly for what I had done, not only in the EEO area but also in the physically handicapped area. I had a chemist out there who worked out of a wheelchair. My sample custodian and storeroom supervisor was a guy who'd been put on full physical disability by the army. So they were

pleased with that. Right at the end, this fellow said to me, "Mr. Barnard, you're doing a nice job in a lot of areas. But I don't see that you've done anything for the mentally handicapped." I looked him right straight in the eye and I said, "You just didn't stay around here long enough." He never cracked a smile but he never put a thing about it in his report, either (laughter).

You know, I have my prize story on the mentally handicapped or mentally retarded or whatever they call that program. When they put the HEW payroll on the computer for the first time, you remember all the problems they had for a year and a half? All the ridiculous things they did? Like people living in Florida getting Wisconsin income tax taken out of their paycheck twice the amount of the paycheck? That unit, the first year, got a special award for hiring the mentally handicapped.

RO: I recall.

AB: Now, what kind of mentality does it take to launch a new program that requires probably a higher level of intelligence than's available in the department in the first place and then concentrate on the mentally handicapped?

RO: Yes, that's right.

AB: I guess they should have been complimented on putting a manager in charge who was mentally handicapped. Anyway, that's so much for that area.

I got to thinking about my history as resident inspector of the district. I don't know how much of this we got into. But there were two things I thought

might merit mention in addition to those that we did mention. One was the K & R Bakery case. That's K & R; it's also known by the name of Rubenstein. This is a case that went to the court of appeals for the District of Columbia. This was, as far as I know, the first application of Section 301(g), which provides FDA with the authority to regulate commerce within any territory not organized with a legislative body, which included the District of Columbia and places like that.

We got an injunction against a filthy bakery down in Southwest, a small bakery, on that basis. There was an activist around here, one of the early home rule activists, who was a lawyer, and he took the case to the appellate court on the basis that this was an unwarranted invasion of the District of Columbia's privacy by the federal government, and lost hands down.

I guess the most amusing thing about it, from the fun standpoint: the Carmen Beach case was a white slavery case. She was actually a madam who was hauling prostitutes around the area, and they prosecuted her under the White Slave Act. Appellate Court Justice Champ Clark was drinking his lunch (and supper) in those days. I don't know whether Champ wrote the opinion or not but the court of appeals, in ruling on the case, made the comment, and this is, I think, a direct quote; if it's not, it's not far off: "While the language of a statute may be clear and simple, it is naught but pernicious oversimplification to conclude that the meaning to be drawn therefrom is likewise clear and simple." The Supreme Court later overturned them in the Carmen Beach case. But the judge who wrote the opinion in the K & R case was the judge who had written the dissent in the Carmen Beach case. In his opinion in the K&R case, he said, "It may be naught but pernicious oversimplification but we hold that the statute

applies as written" (laughter). The idiocy of some courts! How can congress make its meaning any clearer than to put it in plain and simple language? Would you tell me? It's hard enough to communicate in this language at best.

RO: That's right. Al, some of the early work that was done in recording some of the pitchmen. I don't know whether that was while you were in Kansas City or here or wherever.

AB: No. That's while I was in the District of Columbia. I think probably I did some of the very first surreptitious recording work that was done by the administration. We were working in those days on the health food pitchmen. I was trying to think of the most famous one, the one that went to the Supreme Court. Kordel. The Kordel case. We had a guy here by the name of Nelson West, and West promoted seaweed for all kinds of diseases. We had a couple of others that used to lecture here in the District of Columbia. We had problems presenting to the court what these people had said. We usually proceeded by seizure of their stocks, and in contested seizures we had a great deal of difficulty conveying to the court what had been said during the oral presentations.

You see, the significance of the oral presentation is that a drug--and these products were drugs, by law--is required to bear adequate directions for use, and that includes directions for use for all of the conditions for which it's offered or purveyed by its promoter. So if you're going to charge that the drug fails to bear directions for use for cancer, you're going to have to prove that the promoter recommended it for cancer, which means that you've got to have

something, somebody who can testify, and you have to have something that will testify in contravention of the guy's statement that he didn't do that.

So what we used to do occasionally, we'd get a good stenographer who would try to take down the lectures or the spiels. That didn't work because you couldn't get anybody who could take it down verbatim. They never knew what was important and they were too busy taking down things that didn't matter, when the important things were being said.

Then we had Charlie O'Neal. Charlie was an inspector in Baltimore who lived in the District and commuted to Baltimore. Charlie had been a court reporter and he could do a real good job. I'll never forget once upon a time we had a case on trial, and Charlie kept testifying as to what the guy had said in the lecture, and he's testifying from his notes. When the defense attorney got him on cross-examination, he thought Charlie was making most of this up and he's beating Charlie over the head about how you remember all this. He finally said, "Let me see those notes!" and he grabbed Charlie's notes, and here's pages full of this beautiful Pittman shorthand, just dots and squares and dots and squares. His face fell. Of course, when the judge saw his face fall, he said, "I believe you might show his notes to the jury, sir" (laughter). Then his face fell further.

But to resolve that problem, we went to tape recordings. I remember one of West's first spiels was in a church up on Sixteenth Street, around the Columbia Heights area, somewhere in there. Right at the top of Meridian Hill. I was up in the church loft with an old Pierce wire recorder. I don't know whether you've ever seen a Pierce wire recorder or not.

RO: No.

AB: It's got two spools; one fits on one side and one on the other, and it's this fine magnetic wire. Once it gets loose from you, God save you (laughter). You're liable to get snarled up in it and never get it back. That was one of the very, very early ones. Then I moved from that to tape recorders. By the time I got into the Bureau of Regulatory Compliance, Frank Clark and I were really investigating what kind of tape recorders we wanted and what kind we needed. We finally browbeat GSA into letting us purchase some pretty good tape recorders for the purpose. It was not until I got to, I guess, San Francisco that we first started playing around with wireless equipment, radio type equipment. By the time I got to Kansas City, we were using some that, in those days, was fairly sophisticated radio equipment.

This case that we had, the famous case that I still can't remember--the Allerjoy case, the one that I talked about our superspy and all that kind of stuff--the whole reason that recordings got involved in that was not really for the purpose of recording what was going on. It was for the purpose of testing the equipment. That never really came out in the trial because Ellis Arnold, the defense attorney (ex-governor of Georgia), made so much of the surreptitious recording that nobody ever managed to get across to the court that that wasn't really the purpose at all of the recording. The purpose of the recording was to test out some new equipment. We had bought a kit that was really quite a sophisticated surveillance equipment. It was something you could bug places with and that sort of thing, which capability we hadn't had before.

RO: That required two people, didn't it?

AB: Not necessarily. I mean, somebody could plant a microphone in here and sit downtown and record everything that's going on in here. That sort of thing. More often, it was on somebody because the locus of the action was moving; so you had to have somebody to carry the microphone.

Usually, our big concern, one of our early uses, was protection. You put it on an undercover agent so if he got in trouble, you could move to protect him. If he were attacked or if he were held at gunpoint or something of that sort, you could move to protect him. That was a more important aspect of it, actually, than getting evidence because in the undercover drug investigations, you always wound up with physical evidence; if you didn't, you really didn't have a case. The recordings of what led up to the buy were useful, really, only in thwarting a defense of entrapment. If the guy pled entrapment, you had a recording here to show how the thing came about, which should, if it was conducted properly, serve to show that there was no entrapment.

RO: What led to the curtailment of our use of them? Do you remember specifically the . . .

AB: The do-gooders, I guess, as much as anything else. There were people who didn't feel right about it, and then they began to pass laws prohibiting recordings without people's knowing about it. The laws became more and more inhibitory. You know you've got to post a sign in a room that says, "This room's bugged," otherwise it's a criminal offense, and that sort of thing. As far as I

know, that sort of equipment is still used in some types of undercover work as a means of protecting agents. But as a means of evidence gathering, it . . . You're shaking your head. You say you don't think it's . . .

RO: No. I was wondering . . . You'd almost have to have a court order in order to do that, wouldn't you, now?

AB: To bug a place?

RO: Yes.

AB: You almost do now, I think, if you want to bug an installation or tap a phone or something like that. Of course, the wiretap laws, you see, spilled over into this too because what really constitutes a wiretap? A wiretap isn't really a wiretap 99 percent of the time. You pick up by induction and not by tapping. But the do-gooder atmosphere.

If you want to know what fundamentally led to it, it's the same damn thing that fundamentally led to the restrictive things like the Miranda rule and things like that, and that's abuses by law enforcement officers. The courts wouldn't have gone to these kinds of things had it not been for abuses by law enforcement officers, and at all levels. It was worse at the local police level than it was anywhere else. That's why Miranda arose where it did.

But hell, I sat in a district court one time waiting for a case of mine to come to trial right here in the District of Columbia. A defendant came up who had been arrested for public drunkenness. Those were the days when we

frowned on public drunkenness. Nowadays, we give them housing. But this guy was arrested for public drunkenness, and the officer who arrested him had gone fishing and somebody else was standing in for the officer and testifying for the officer. This guy wasn't as drunk as they thought he was and he looked at this officer and he said, "Your Honor, that's not the officer that arrested me." The officer responded, "Your Honor, that just shows how drunk he was." "Thirty days." That's the kind of thing that led to the kind of problems we're talking about. It's unfortunate. It's like a lot of other things. DDT's one of greatest blessings we ever had. We haven't got sense enough to use it right, so we ban it.

RO: The toxicity of DDT, or at least what they thought the toxicity of it, has changed from . . . Good grief, the way that they used to spray people during World War II, or dust them for lice and things.

AB: It didn't kill anybody. Very many people, anyway.

RO: No.

AB: But, you know, when you get to the point where 47 million pounds of chlorinated hydrocarbon pesticides were used in Fresno County, California in one crop year . . . That's 47 million pounds of chlorinated pesticides in one county. That's the kind of pesticide problems we were looking at in California. Then you wonder why you have problems.

Then, of course, the stupid people that you had using pesticides was another problem. We had a guy using parathion in an orchard down in San Jose, and somebody told him he better protect himself and wear some gloves and stuff. "Oh," he says, "this stuff won't hurt you," and reached down and took a dipper, dipped some up and drank it. He lasted about a minute and a half.

RO: I was going to say he probably didn't last long.

AB: Just about a minute and a half. But when you've got that class of people handling those kinds of materials, you've got problems. No educational programs to go with them.

RO: Let me ask you a question, Al. I was thinking when we were talking about the recording and the changes in being able to do that. I couldn't help but think about the ability to take photographs during our inspection. I'm sure that you fought ardently for that right when you were still with the Food and Drug Administration. Now that you're a consultant on the other side, what do you think about that?

AB: We'll talk about two things. A) I advise all my clients to refuse to permit photographs. If there's a document or something that the inspector wants copied as a courtesy, we'll be glad to copy it for him. Anything to be helpful. A photograph, if there's a real reason for taking the photograph, it's nothing but giving evidence against yourself because the inspector wants it for evidence. So I can argue with you that it's an invasion of my Fifth Amendment rights to make me

give you a photograph, because all I'm doing is giving you evidence against me. If we're dealing personally, I think it's fairly clearly a Fifth Amendment invasion.

On the other hand, looking at it from the compliance standpoint, I've never insisted on taking photographs where there was not need for it. For example, I inspected the Maryland Baking Company in Baltimore that makes cones; ice cream cones is the only thing they made. I think they've sold out now. They had some equipment that was so highly proprietary that they didn't patent it because they didn't want it patented because they figured there would be enough information in the patent so somebody could come close enough without infringing it. They asked me not to take any photographs that would show any of those pieces of equipment. Other than that, they didn't have any problem, and I didn't have any problem with that at all. I know some inspectors wanted to get search warrants and this kind of stuff. Well, this is silly, in my opinion.

The same thing is true of this hassle that's going on between the pharmaceutical industry and FDA about photographs. There is not one time in a million that FDA has a really legitimate reason for taking a photograph in a pharmaceutical operation. There may occasionally be something but it's very remote. It's not like rats in a bakery or bats on the wall or roaches or something of this sort. Now, if you find rodent infested sugar in a pharmaceutical warehouse, sure, that's a suitable candidate for a photograph. But generally speaking, there's not the need for photographs, and FDA is putting themselves in a difficult position if they really try go to court to force the right to take photographs in innocuous situations. They will be wise to wait until they have a situ-

ation where the facts are on their side, where there was a real need for a photograph.

Now, the thing about it is, by the time you send the inspector back to go get himself a warrant, the kinds of things that really make good photographs are going to be gone, if anybody's got any sense at all. So it's a difficult . . . You're asking me for my views. I'm just kind of giving you my views on both sides of the subject. I never ran into a situation in my entire inspection career where I wanted a photograph, felt that I needed the photograph, and was denied the right to take it, never. I've been in several situations where I was asked not to take photographs and, in every instance, I didn't see any--just like the Maryland baking incident--reason to contest the issue.

RO: You never sent an investigator back to take photos that should have been taken or that you thought should have been taken.

AB: Yes, but not because management refused us. It was because the inspector didn't have sense enough to take them.

RO: That's what I'm getting at.

AB: Yes. As chief inspector, I have done that on occasion. I guess I did it more often when Bennie was my chief inspector and I had Bennie send somebody back to take some photographs that should have been taken. I only recall once in San Francisco. Most of the guys I had in San Francisco were eager beavers. Once they found out they could get some results from what they did, I had very few

inspectors out there who wouldn't take photographs at the drop of a hat or do anything else essential to a case.

RO: I guess, though, Al, since you've retired and are consulting that your attitude about the right to take photographs has changed a little bit.

AB: I don't think my attitude about the right to take photographs has really changed, Ron. I think that, well, it's always been said that your point of view depends on where you sit. It's like the old story about the Chinaman in the outhouse. You've heard that one, haven't you? The Chinaman was always fond of telling his son about George Washington, who wouldn't lie to his father. One day the Chinaman grabs his son by the nape of the neck and says, "Did you throw the outhouse into the river?" The kid says, "Cannot tell lie. I like George Washington. Yes, Father." And the father beat the living hell out of him. When he got through, the kid says, "George Washington's father didn't beat him." "George Washington's father wasn't sitting in the cherry tree" (laughter). So your point of view, as I say, depends on where you sit.

I always pressed for photographs because they were part of the job. I don't think I really ever gave any serious, mature consideration when I was in Food and Drug to the question of right. I never encountered enough obstacles to force me to face what I would do in the face of an obstacle. In the first place, being a pragmatist, as I said earlier, what you want to photograph isn't going to be there by the time you force a photograph if a guy refuses to let you take a photograph. Where you tend to run into problems is when no cameras are per-

mitted on the premises in the first place. This kind of gets a little bit more difficult.

I don't know. The Supreme Court has repeatedly refused to come directly to grips with this issue. Every time it's come up, they've taken some little narrow strip of the particular case and made an ad hoc decision that couldn't be expanded to anything else. I think the FDA is being totally ridiculous when they say that this recent EPA case where the court upheld taking photographs of a plant from an airplane proves that they have the right to take photographs inside of a plant. This is like saying, "Well, I can stand off and take a picture of the bathroom window of your house. This gives me a right to get in the shower with your wife and take her picture in the nude, obviously, doesn't it?" (laughter) One is on public display and the other is inside of my premises. I won't say "private" because it's an industrial enterprise but at least it's not out where everybody can look at it.

RO: I don't recall that EPA one but I assume that was on a pollution problem. That's the reason they were doing that.

AB: Yes. EPA rented a helicopter and flew over the Dow plant in Midland and took some pictures, and the right to take those pictures became an issue. I don't remember the details but the court held that EPA had the right to take those pictures. The FDA general counsel's office has, as I understand it, translated that into a ruling by the Supreme Court that as compliance officers in the public interest, they have the right to take photographs in a plant. At least one of my client's general counsel's office says, "B.S." (laughter)

RO: Al, is there anything else?

AB: Let's see. I was going to talk one other aspect I thought was kind of interesting. I was brought into Washington as resident inspector in part because the existing resident inspector was retired but still on pay, shall we say. He had once been chief inspector of Baltimore and been demoted and moved to the District of Columbia as resident, so he was not really highly motivated. He was a nice guy; I always enjoyed working with him.

But I got involved in things as resident in the District that were not the customary Food and Drug things. See, I never was in the war. I turned down a commission as a first lieutenant right at the start of the war at the urging of FDA people who convinced me that I could do more for the country protecting the military drug supply than I could in the Medical Corps, which is where I was about to get a commission. Along towards the end of the war, my draft status became a very hairy thing. FDA had gotten me several deferments, and finally I took a preinduction physical out at Fort Meyer, and some damned old colonel assured me that I would be a buck private in the army within thirty days. Now, you know a guy who's turned down a commission as a first lieutenant . . . Here I've got a wife, one child, and another one in the oven, and this guy's telling me that I'm . . . Well, I'm making a list of people I'm going to shoot before I go into the army.

The FDA went to the Presidential Review Board and got me one more deferment, and that got us past . . . One of the bases upon which they went to the Presidential Review Board was my importance in maintaining the health of

the key inhabitants of the District of Columbia. I'd been put in the position of doing a lot of restaurant sanitation work. I did all the government building cafeterias, every one of them; I did them once every six months.

We had a Salmonella outbreak here down at the New England Seafood Restaurant on Maine Avenue, which is where the restaurant center used to be before they changed it all. We had a Salmonella outbreak down there. Everybody went down there one Friday afternoon, and the Department of the Navy was virtually devoid of personnel Monday morning.

Somebody woke up to the fact that a real good widespread food poisoning case could seriously impair the ongoing war effort because you had a whole bunch of key navy people that were down with Salmonellosis instead of keeping the navy afloat. So, as I say, I did all of the government GSA cafeterias in all the government buildings, every one of them. I did a lot of the major, popular eating places, particularly the places that were frequented by large numbers of high-ranking brass. I did all the fancy restaurants up and down Connecticut Avenue.

You wouldn't believe some of the things I found. You'd be amazed at how many mouse pellets you find in sugar bowls on the tables. I found accumulated rodent feces on a drainboard that must have been at least three inches deep. You dig it out with a knife in, literally, chunks of rodent excreta just accumulated over the months in a rat infested restaurant. I found a guy right on Capitol Hill, just across Independence Avenue from the Capitol, a small restaurant there on the corner of First and the Avenue, I guess, or First and South Capitol, maybe, or East Capitol. He's got a big barrel of flour and he's dipping flour out to make gravy. Down in the barrel is a big rat. I got a sample of the gravy;

the lab found fleas off the damn rat in the gravy. He's not bothering anybody; he's just dipping flour. The rat's down there; he isn't bothering anybody.

One of the most common problems I found that the D.C. Health Department wasn't bothering with at all, was putting cold meat on the bottom shelf of the refrigerator and then bringing in dripping wet vegetables and putting them on the upper shelves and letting the stuff on the roots and the outside of the vegetables drip down on the cold meat. Then you wonder why you had food poisoning cases. Of course, the biggest Salmonella case we had was a carrier, the Typhoid Mary type. She worked in a couple of restaurants before they got her pegged. But the district at that time was not doing very much.

I worked with a very interesting guy by the name of McCrayon. McCrayon was a World War I veteran. Mac put it very nicely. He said, "It may be a hell of a thing to say about your own job but when you pay \$1,500 a year, you get \$1,500 a year men, mostly" (laughter).

I was working up here on Georgia Avenue one afternoon in a small establishment, and the guy offered me a \$20 bill. He was very surprised when \$20 didn't buy me off. Of course, I immediately went down and told George Larrick about it. George was sort of my mentor even though I was working for the Baltimore district, which I'm sure Baltimore appreciated. George said, "Why would he do that?" George was a naive person in some ways. I said, "You know, you don't fish with worms because fish don't eat worms. People know that fish take worms; that's why you fish with worms, George" (laughter).

Enforcement in the district was not what it ought to be. I don't know what it is today but in those days, 'tweren't what it ought to be. So I wound up doing

a lot of that kind of work: small establishments, small delis, and that sort of thing that didn't fall to the lot of the usual Food and Drug inspector.

RO: I'm surprised the restaurants didn't fall under the Food Service of the Public Health Service.

AB: Public Health Service and Food and Drug didn't speak to each other.

RO: Not at all.

AB: You know that.

RO: Yes.

AB: Since they weren't doing the job . . . you know. As far as I know, that work was never used anywhere to show up the Food Sanitation Service, which it might well have been, I suppose.

We talked about the oleo thing. Government cafeterias. That was the one thing I thought might be a worthy mention.

RO: So that was really the prime reason why you weren't drafted then, was that you were doing the restaurant inspections.

AB: Yes, ultimately, it was. No, I think that gets about all of it. We talked about sampling crabmeat, stopping trucks, and working on railroad docks and

those kinds of things. Watering scallops. We used to have some interesting stories about watering scallops. They used to keep them in tubs under the floor. You'd walk in the plant and there were no scallops. "We haven't got any scallops." "What's under the floor there?" "Oh hell, what do you mean, 'What's under the floor?'" Lift the floor up and there's tubs of scallops soaking (laughter).

RO: Scallops or oysters?

AB: Scallops. Oysters, they blew them. That wasn't as easy to conceal as scallops. But they'd just shuck out scallops and put them in tubs of fresh water and put them under the floor.

RO: Well, Al, if that covers everything, I appreciate this additional interview.

AB: I hope this turns out to be useful. As I say, I think the first time we did this, I tended to focus more on personal things, stories, the inside dope, you know, the inside poop, the little things that I knew that other people didn't know. Then, I got to thinking about it. I talked to a couple of other people who'd been involved in this endeavor, and I got a feel that you really more wanted some things of genuine historic value.

RO: Both.

AB: So that's why I thought about these things.

RO: Some of the things, the people that are involved in some of the issues, see things a lot differently than what really came out as far as the official position of the agency. It's some of the little things like that that it's always nice, from a historical standpoint, to get on the record.

AB: Yes. This interested me. The guy that wrote the book on the persecution of Wilhelm Reich. I've forgotten his name now. He was up at SUNY (State University of New York). I've got a copy of the book. He interviewed me in connection with the preparation of that book. His view of the Food and Drug Administration's approach to Reich and my view of the Food and Drug Administration's approach to Reich are a fascinating contrast. We never got into any significant disagreements but he was never able to envision Reich as someone who was peddling accumulators to cure disease. He felt--and I think with some justification--that there was a certain amount of almost vindictiveness caused by Reich's approach to sexuality. I recall Bill Wharton screaming that this guy was teaching young kids to masturbate. Wharton, for all of his foul mind, loved to set himself up on a pedestal as being the guardian of the public morals. He was very upset with this sort of thing.

The guy that wrote that book, I think, feels that it was Reich's leanings in those directions that led the Food and Drug Administration to attack him on other grounds. You know, like putting Al Capone in jail for income tax evasion. I was never able to convince him that, in my view, at least, such was not the case. I will admit there may have been individuals in FDA who were motivated that way and by that but that doesn't gainsay the fact in my mind that there

was a genuine violation of the Food, Drug, and Cosmetic Act, both in fact and in intent, by Reich, which he was never willing to accept.

RO: Well, Al, thanks a lot.