History

of the

U. S. Food and Drug Administration

Interviewee: Dr. M.T. Bartram

Interviewer: Ronald T. Ottes

Date: August 6, 1987

Place: Kennett Square, Pennsylvania

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. Ottes, 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

TAPE INDEX SHEET

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

DATE: August 6, 1987 PLACE: Kennet Square, PA LENGTH: 113 Min.

INTERVIEWEE	INTERVIEWER
NAME: Dr. M.T. Bartram	NAME: Ronald T. Ottes
ADDRESS:	ADDRESS: U.S. Food and Drug Admin.
[redacted]	Rockville, MD

FDA SERVICE DATES: FROM 1938 TO 1967 RETIRED? Yes

TITLE: Acting Director, Division of Microbiology
(If retired, title of last FDA position)

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DEED OF GIFT

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Dr. M.T. Bartram

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Chief, History of Medicine Division
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RO: This is another in a series of FDA oral history recordings. Today we are interviewing Dr. M. T. Bartram, retired FDA official, in his home in [redacted]. The date is August 6, 1987. I am Ronald Ottes.

Tom, or Bart--whichever you prefer to be called--would you please briefly sketch your background, when and where you were born, where you were educated, when and why you joined the Food and Drug Administration, and the various positions which you held with FDA during your career?

MB: To go into my life history is a very easy thing. I was born here in Chester County, Pennsylvania, not more than fifteen miles away from where I am now living, on a farm. We remained on the farm until after I was twelve years old. During World War I, it was impossible to get help, so we moved down to a 10-acre farm from a 150-one. We remained, with me as chief farmer on that 10-acre farm, until I went away, first to prep school and then to college.

I got my bachelor of science degree in Agriculture and Biological Chemistry at Penn State University in 1929. From there I went to the University of Maryland on an assistantship for two years, getting a master's degree in bacteriology. Let me interject here that in those days the science dealing with microorganisms was called bacteriology, and it was only a few people in the Public Health Service who coined the phrase "microbiology"; and they were regarded with some scorn, because of the fact that they tended to set themselves apart by "microbiology." But actually they were right, because in bacteriology you're dealing only with bacteria, whereas microbiology would cover mold, yeast, virus, and the other microorganisms that should be covered, and were being covered in the field of bacteriology.

So I got my master's degree in bacteriology at the University of Maryland and stayed on, supposedly full time, to work for a doctorate degree, teaching and doing research work in the experiment station. They were kind enough to give me a quarter of my time to take graduate work toward that degree, and I managed to get a Ph.D. in the same department in 1936. I stayed on for two more years, but during the time that I was a graduate student, I had come to know some of the people in Food and Drug Administration, in the bacteriological branches, particularly Dr. A. C. Hunter and also Glenn Slocum. Glenn was working toward his doctor's degree, and I had the privilege of meeting him both as a scientist and also because he took some of the courses that I was teaching at the University of Maryland. We both, I think, put that behind us; he learned something in addition to what I taught him! At any rate, my reason, really, for applying for a job with the Food and Drug Administration was because of my high regard for Dr. A. C. Hunter.

RO: What was Dr. Hunter then?

MB: When I went into the Food and Drug Administration in April--actually April Fool's Day, in 1938--the unit, whatever its title was, was a branch of the Food Section, I believe was the title, under Dr. Ben White. But at that time the plans had already been made and approved to transfer the unit as a separate section. I don't think they were called divisions in those days; it was a section.

Dr. Hunter, I think, had come directly from Brown--it's where he'd graduated--into Food and Drug in about 1918. He was an outstanding individual; there were no two ways about it. He was not given full credit for his accomplishments

outside of Food and Drug, nor, do I feel, inside Food and Drug. They really didn't recognize him because he was a quiet man and retiring, and didn't push himself. But I never will forget my first attempt to write a letter for him after I got there. I had written a two-page letter. I was very proud of it. I've forgotten to whom it was written, but it was to somebody out to the field. I took it in for Dr. Hunter's signature. The next day I got back a three-quarter-page letter that he had signed for my initials. And I learned right quick that was the way he did business.

But in any event, I think there were six in the organization when I came in. I made number seven. After we changed over to become a separate unit, being removed from Food, we added a deputy. First, Bill Hale was in for a couple of years when he resigned to become head of the Bacteriology Department at Iowa University. Then Henry Welch came in as deputy in the department. Now, I can't give you the years that all of this occurred, but the department remained about stationary in numbers through this period until the war years, when we got into the job of examining all of the surgical dressings, and injectible preparations, and the hypodermic needles that were supplied to the armed services.

RO: Just for sterility?

MB: Just for sterility, as far as we were concerned, but they were being examined by the Drug Division, and also by Pharmacology. They had an input into these things, but not as much as we did. Also, we were testing the germicides for the navy; that was part of our game. So it was necessary to add some people during that particular period of time.

Also, as is probably well known, during that period antibiotics began to be prevalent. Dr. Fleming came over to this country and was taken under the wing of Dr. Charles Thom. Dr. Thom was, in my mind, an outstanding mycologist, probably the outstanding mycologist in this country, certainly, and probably in the world. He had been in the Department of Agriculture for a number of years; I don't know how many. But when the split was made and Food and Drug was taken away from the Bureau of Chemistry, Dr. Thom was left in the Bureau of Chemistry. It was a very sore issue for him; it really spoiled things for him. I think it was a grave injustice, because he would have added a great deal. But I suspect there was play between Dr. Howard, who was head of Microanalytical Division, or whatever it was called, and therefore they didn't have room for both Thom and Howard.

RO: This is the Dr. Howard.

MB: I can't tell you his first name.

RO: Of the Howard mold.

MB: Yes, the Howard mold count man. At any rate, Thom took Fleming out to NIH, to the Biological Control Division, and they turned him down out there. They wouldn't have any part of him, for what reason I never did know. But Thom, at that point, brought him into Food and Drug and Food and Drug, as is well known, took on the responsibility for testing and developing the antibiotics. NIH deeply regretted that move, and I'm telling you, except for a few indivi-

duals in the lower ranks, they weren't very cordial to any of us from then on in the Biological Division, although we got along together down at the lower echelons.

What was happening then as far as Food and Drug was concerned was that Henry Welch had gone from the bacteriological group up to the microanalytical group as head. The antibiotics were put into the Bacteriological Branch for the time being. But because Dr. Welch had had so much experience in the medical field--though he didn't have any medical degree, but his undergraduate work and graduate work had been associated with the medical areas--he was brought in as a consultant. Later the decision was made to pull antibiotics out of bacteriology, set up a separate division, and transfer the Microanalytical Branch into what was to become the Microbiological Division. At that time, John Wildman was the branch chief for the microanalytical group, and after his resignation, there was a little feuding that went on between Eisenberg and Harris as to who was really running the Microanalytical Branch. That was a little unpleasant, I'm sure, for a while.

In the meantime, Dr. Hunter had died very suddenly in the mid-forties; Glenn Slocum then moved up into his spot as chief, or director, or whatever the title was at that time. I took Glenn's place. Now we really didn't have, at that juncture, any title, but we did have somebody that ran the particular group and also served as the deputy for the division. I fell heir to that job.

That was in the mid-forties, and along about that time also--and I think it was less than a year later--we also lost a man who had been with the Food and Drug for more years than had Dr. Hunter. While he had no degree--he did not at that stage even have a high school degree--nonetheless, he served as laboratory

chief and did everything else that needed doing around the department. We lost him, and his death, and that of Dr. Hunter, was really a blow. I'm telling you, it was a tough time for Glenn Slocum and myself to pick up some of the history and carry it on.

I've always felt that one of the beauties--and I might interject it right here--of working for the Food and Drug Administration was the fact that there were so many old-timers there that knew it from the ground up, had grown up in the organization. And this was true not only down in the ranks, but it was also true clear up to the Commissioner's office. I had the pleasure of serving there with Campbell and Dunbar. I guess Charlie Crawford came next, then George Larrick. And each one of them had grown up in the organization and understood it fully from top to bottom.

As a little aside here, I never will forget one day that I attended a conference with the Public Health Service people, and the Surgeon General came in. Everybody jumped up on their feet and stood practically at attention till he found a seat. I had lunch that day with Charlie Crawford, and I said, "Charlie, what would happen if you walked into a room of, supposedly, Food and Drug people, and everybody stood up?" He said, "Hell, Bart, I'd know I was in the wrong place and get out" (laughter).

RO: That was before Food and Drug was really in the Public Health Service, wasn't it?

MB: Yes. We never were, as far as I was concerned, in the Public Health Service during the time I was there up until I left, in 1967. But we both were in the HEW or whatever the titles were prior to that time.

RO: For a while we were in the Federal Security Agency, and then it got to be HEW.

MB: So our contacts were not too direct. But I think we did have good liaison. For example, there were two agencies in the Public Health Service that were operating generally in the same field as we. One of them was the CDC in Atlanta, and the other was the Robert Taft Sanitary Engineering Center--which we termed "RATSEC," just to make them mad—in Cincinnati. I can't remember which was which, but Glenn was the liaison with one of them, and I was the liaison with the other.

We had a policy where we would visit those laboratories, and they would us, a couple of times a year, including, of course, the scientific meetings that we jointly attended. Thus, officially we would be in contact several times during the year. So I never felt that, while there was duplication in our efforts, perhaps, and in some of the work we were doing, certainly we were aware of what was going on, and there wasn't, really, duplication without knowing about it. I can't say the same thing doesn't occur today. I'm sure it occurs within, must I say, Food and Drug. I've been back and asked some of the divisions how they correlated with another division, and they say, "Huh? What are they doing?"

RO: Maybe that's some of the problem of growing pains.

MB: It is, and I wish I knew what the answer is to these things, because, as I remarked to you earlier here, before we started taping, one of the delightful things was that we were so small that I hadn't been there very long before I not only knew all the people that were in Washington, I knew the lab helpers and I could tell you exactly what each individual was doing in his project. And part of that, if I can put this in, also, was the coffee club that met every lunch period. I don't know whether anybody has mentioned that here before.

RO: You mean the Liars Club?

MB: The Liars Club, yes. Has somebody covered that?

RO: No.

MB: That was occasioned by Mr. Leper, generally known as Heinie Leper, who was the chief coffee taster for the government purchase of coffee for . . . I don't know what it was, GAO, I suppose, the General Services, for the Veterans Administration, and so on. He was getting in samples of the coffee to test for specifications for purchase. And he, of course, had surplus, and it fell to one of the lab helpers to brew pots of coffee at lunchtime. A number of people--I guess there were twenty, twenty-five individuals at a time--would get up there for lunch with brown bags. And this would include the Commissioner. During this period there was a free discussion of what was going on, including the Commis-

sioner. He didn't hesitate for a minute to tell us what his problems were and give us all the input that went into his thinking. I always felt that, because of the fact that we knew exactly what he faced and we knew what his evaluation was of it and how he was deciding something, and because we had a chance to tell him when we felt he was wrong at those meetings freely and fully, there was a better feeling throughout the whole place.

I can well remember that, whereas in my day, when I wanted to see the Commissioner, I had no problem. I'd simply call his secretary and say, "Hey, when the boss has a minute, I want to talk to him about so-and-so." And she'd call back and say, "Well, he's free now, come on up." The fellow that took my place told me later that he was lucky if he saw the Commissioner twice a year. To me, that's no way to run a railroad. But that, as you say, may be the problem that goes with business.

RO: I remember those Liars Club meetings. I can remember even beforehand, when you didn't mention that it was green coffee beans that came in, and they'd roast them right in the laboratory.

MB: Oh, yes. Of course, that's what Heinie had to do was roast them. Unfortunately, that, along with some other things, was killed just because of petty jealousy. Somebody felt they were excluded, and therefore it was a waste of time and government property to roast the coffee, and the whole thing had to grind to a halt.

And we ran into the same thing in Micro Division because the surplus foods that we would have, opening cans of even spinach, people would gather around

to get some. There was no preference; first come, first served. That, again, had to be stopped, because there were protests that it was not right. It was stopped, and it didn't benefit anybody, because even such agencies as Goodwill and some of the other groups weren't very anxious to take this food, and we'd practically have to beg them to come take it to save it from being thrown in the garbage.

In the early days, when I went with Food and Drug, I would say that about 90 percent of our time was spent in the problems of foods, and very little was devoted to drugs and drug products. In fact, we didn't know that we had a problem in the drug field, really, up until 1948. But preceding that, somebody had discovered that the cotton and the gauze bandages used in the hospitals were not sterile. There was no provision under the Act to take any action against those sort of things, although everybody, including the doctors all around the country, recognized that cotton should have been sterile. But Dr. A.G. Murray, who was then head of the Regulatory Drug Program in the Commissioner's office, was ingenious, to say the least. He hit upon the scheme of charging that the cotton was misbranded, because the package only said cotton, and it contained cotton and bacteria, and the bacteria weren't declared. And you know, he got away with it, I suspect largely because nobody dared to admit that they had what we would now call contaminated cotton. But this was probably in the late thirties and early forties that this had occurred.

RO: Was it labeled then as sterile cotton or just cotton?

MB: No, it was not labeled as sterile cotton, and it was not recognized as needful. But about this time, the U. S. Pharmacopeia began to pick up the need for having sterility requirements and set up a committee. For quite a while either Glenn Slocum or I were members of the revision committees of the Pharmacopeia, dealing with sterile products. Of course, one of the first things we had to do was develop test procedures which were satisfactory, much along the same lines as test methods are now being conducted within the AOAC. In fact, there was some spillover into AOAC. In later years these tests were going into AOAC as well as USP.

We worked in that connection with the Biological Control Branch of the Public Health Service and had very good relationships with them in developing methods, media, and test procedures for the biological products, even though, as I have said previously, they were a little bit miffed because they had lost out on the antibiotics--through their own neglect, not ours.

The drug problem really came to a head with Cutter Laboratories out on the West Coast, that had, as I recall it--and my memory's not too good; this was in 1948--a problem with mold in the large-volume transfusion flasks. I remember all too well that within a few weeks we had one of our vacant laboratories, which were 10 x 10 or something, literally full of cartons of Cutter transfusion products. Glenn Slocum and I came to the realization at that point that we really didn't know what was going on in the pharmaceutical field and the sterile products field. We had, in the field districts, men who were specializing in the area of inspecting drug plants; we'd never gotten together with them. They really knew nothing about the testing procedures that should be employed, and we didn't know exactly what they were concentrating on.

So I can remember that we took the problem to Dr. Dunbar, told him that we really needed to get out and find out something. I remember he told me, "All right, I want you to get out and do some inspecting, cover everything you think to need it, come back and write me an article on what you find that's being done properly in the field." I saw him two days later and he said, "What in the devil are you doing here? I told you to get going." This was in the days before we could use the telephone, so it was a little problem to set up your dates and get out to the field.

Anyway, I think it was late '48--I looked at some of my travel diaries to verify it--I got out to Chicago, Detroit, Buffalo, Philadelphia, and New York, and--I think there was possibly another district, either Cincinnati or Cleveland involved there--covered major pharmaceutical and surgical dressing manufacturers. I'm telling you, it was a revelation, because I think out of the whole group that I covered there was only one that I really couldn't find any flaws with. So I came back and told Dunbar, "If you want me to put down the good things, give me a postage stamp. If you want what's bad, it'll take me a few weeks, but I can write that up in a long article."

That was the start, really, of what became the GMP for drug products. Right after, I came back I sat down and wrote out a rough draft of what I envisioned should be in such a thing as a GMP. I didn't have in mind that that's what it was, because I wrote it up with the idea that it would be a training program for inspectors. We got in the experts from the field, that is, our people in the field who had been doing the inspection work, and we had, I think it was probably a week-long conference in going over the things we'd found wrong, the

things that should be right. Of course, the other divisions, such as Pharmacology and the Drug Division, also participated, along with Micro.

Then, following that, we all went out to the various districts and went around with the inspectors. I went to New York, I believe, and accompanied several different inspectors there, going around and making inspections to give them a little understanding of how I viewed these particular problems.

(Interruption in tape.)

MB: One of the things that happened during that inspection, I never will forget. I can't tell you the name of the drug firm, but they were sending their injectible preparations out for testing in a consulting laboratory. So I told the inspector, "Hey, we've got to get out and see what goes on in this lab." He said, "No, we can't do it." I don't remember whether he called back to the district or not, or whether it came out later; he just said, "No, I can't possibly do that. It's not part of our inspection to go to the consulting laboratory." I said, "Okay, that's all right with me. You take me down the street and you stop a block away, if that's what you want, and I'll go on in and make an inspection." But I think he did condescend then to go on in with me, and we found that the things absolutely weren't being done correctly. But the man that was running the laboratory was very cordial about it all. He grumbled about some of my suggestions, but he didn't say no. And the curious thing is that he later became a very staunch supporter of Food and Drug. He got into the Pharmacology Institute, I think it was called, on the East Coast, and also he got into AOAC and became very active in the field.

RO: That was before they considered that these consulting laboratories really fell under our jurisdiction, as they were an extension of the manufacturer.

MB: As a matter of fact, when I got back to the district office, I called the Commissioner. And I said, "I did it. If you want to fire me, go ahead, but I feel that this is part of the game, so I've gone ahead and made this inspection." And told him the things that we'd found wrong. I guess it must have been Dunbar who was Commissioner at that particular time. I get sort of amused now when I see the fact that consulting labs are definitely included in the work.

There's another one that I might add here. When we were developing the test procedures for drug products, we realized that there was a deficiency in the prepared media that some of these firms like Difco, particularly, were turning out, and, to some degree, perhaps, BBL [Baltimore Biological Laboratories], although we never felt they were quite as bad. I argued strenuously that these things did come under our Act, because they were used in the diagnosis of disease, which was, of course, part of the Act, and because the media was used for the isolation of the organisms. This is where the greatest deficiency lay, in those media that were used for identifying the organisms. But I got turned down on that quite promptly. I get very much amused these days when I see that about half of the green sheets are taken up with work with drug products and with some of the newer diagnostic equipment that are being used, the machines.

But I wasn't satisfied with that, and along with Dr. L. A. Black, who had been my major professor at the University of Maryland, and whom I had con-

vinced to go out to Cincinnati to head up the inspection program of the milk laboratories around the country . . . He was very much concerned with the media that was used in these laboratories. So we dreamed up an idea of setting up a corporation. I think we actually did get it incorporated to certify media, and we got pretty good cooperation from everybody except Difco. Difco would never cooperate, but BBL and, I believe it was Oxoid, the British firm, cooperated. We set up a test procedure. This involved, now, just the media for total counts in milk products, but that also involved total counts in other products as well. But we were concentrating on the milk aspects of it.

We set up a test procedure and of course there had to be a little collection of funds; so we were selling little stickers that were to be put on the bottles of media. Well, Difco didn't like it, and they eventually raised such a stink and went to the secretary of HEW, who held that we were out of bounds as government employees to engage in such activities. Again, I have to go back and say to anybody that is familiar with microbiology that nowadays you will get, any time you buy a bottle of dehydrated media, a certification that it's been tested against such-and-such organisms, following exactly the same general scheme that we had dreamed up. So I guess all wasn't lost, even though we got squelched on that deal pretty promptly.

RP: But this was apart from your official duties. You were certifying this?

MB: All we did was set up the program. We did not engage in the testing procedure. We set up the method. Black arranged with some laboratory to do the testing procedure, following the general scheme of testing as would be done by

AOAC in setting up a test program and testing a method. As I say, it didn't come to naught, and I see nowadays that dehydrated media is included in one of the gamuts of the Food and Drug Administration.

RO: You were just ahead of your time.

MB: Yes, we were too far ahead, I guess. We lost on that particular one.

It might be of interest that, in the early days, we had no bacteriological work out in the field laboratories. So when I came in, there were any number of big boxes in which you'd pack up big sterilizers, stills, and all that sort of thing to take out to the field to do your bacteriological work. This was generally set up in the health departments or in some university or school, wherever they could find space. Of course, it was a heck of a job to pack all this stuff up, together with your media, cart it out by truck or ship it out on the railroad, mostly, to these places. It handicapped a great deal the work that actually had to be done in developing a program and in developing criteria that could be used in setting up a bacteriological program.

But very shortly, in the early forties, we got a trailer laboratory, and it was pretty good. It was a new house trailer that had been equipped with all the necessities for bacteriology. There was only one problem with it: you could not run the still and the autoclave or something simultaneously, so you had to flip a switch from one to the other. And whoever had wired it had not grounded it properly, so when it was on one leg, it was all right; but when it was on the other leg, anybody that touched that trailer and stood on the ground was going to get a shock. So when we'd see an inspector coming, we would very often

make sure which leg it was on so he'd have to jump to get in the trailer without getting a shock.

That worked fine, except that the trailer was too heavy. Our tow cars weren't good enough and it caused problems. But that permitted the division to get out and do some of the investigational work, particularly in crab meat and nut meats and that sort of thing, where we didn't have any background to know what levels could or should be expected.

RO: My gosh, you must have almost needed an auxiliary trailer to handle all your supplies and things, because I never saw a microbiologist that needed as much . . .

MB: That trailer was very, very self-containing, and you had very little problem with it once you got it equipped. Eventually, we had enough glassware that we could stock it. Of course, this is in the days before we had all these plastic throwaways, so you had to carry your glass Petri dishes, and your glass test tubes, and pipettes, and all that sort of thing, which made a tremendous weight that you had to carry around.

RO: Let me ask this, Bart. Why was it so essential to have this laboratory on site? Couldn't you transport the samples back to a laboratory?

MB: Not too well, because you have to remember that we didn't have airlines for flying from any distance, so it was necessary to have the lab on site. For example, I went out several times working on crab meat projects, and since they

start picking crabs at, say, four o'clock in the morning, you had to be in there. Then you had to get your samples after they got on the noon train, or the two o'clock train, or whatever it was. The inspector would get on the train with the shipment and ride till it crossed the state line, and then grab his sample and jump off, and come on back to the laboratory, or to the trailer laboratory, in this case. So it wasn't at all unusual for the bacteriologist to be putting in a twenty-hour day actually working in these fields.

This is in the days when we had but the one laboratory, and that was in Washington. We didn't have the field labs. I can't remember exactly when they were first established, but my guess is it was in the early fifties that we established four field laboratories in New Orleans, Chicago, Philadelphia, and San Francisco. Paul Elliott was on the West Coast and Norm Kramer in Philadelphia. These people, in those days, were under the technical direction of the division, but administratively they were in the district, for their payroll and that sort of thing. That was a great boon. Then we didn't have to have these trailer labs, and actually, by that time, the trailer lab had gone, I think, down to Texas, and was being used largely for import control on the Mexican border.

In addition to that, at one time--and this was shortly after the war--we borrowed or leased some mammoth laboratory from the army, and we used that on the West Coast, mostly in crab meat control out there. I don't think it was used for any other purposes, although it may have been for chemical and not for bacteriological work. But it was a mammoth setup.

RO: I guess you had retired by the time Dr. Wodicka came in as head of . . .

MB: Oh, no. Wodicka had been involved in the botulism in canned tuna on the West Coast. He was connected with a firm that made the lids, I think, that were put on the tuna cans. I had forgotten when he came in that he and I had met over the examination in Detroit of some of those cans of tuna that had been involved in the botulism episode. I said something about, "I'm glad to meet you; I don't think we've met." He said, "Oh, yes, we did." I got off on a bad foot with him right away, quick.

RO: I didn't want to get ahead of your story, but it was while Dr. Wodicka was head of the old Bureau of Foods that we got some more trailer labs. In the early seventies, Bart, we had a number of trailer labs, but one of them was going to be a big microbiological trailer lab. I remember that was when Charlie Edwards was the Commissioner.

MB: And this would travel where?

RO: We sent them around to various districts.

MB: Of course, those were the days when the microanalytical field work had left the Division of Microbiology and had been taken over by the Field Service under Rayfield.

RO: Yes. Well, it was in the sixties when we started building these new buildings that we started in to get field microbiology laboratories.

MB: But that really went on intensely, wasn't it, after . . . What's his name? The next Commissioner that came in?

RO: Dr. Young or before that?

MB: No, before that.

RO: Hayes?

MB: No, before that, even. The man came up from CDC.

RO: Goddard.

MB: Goddard, Jim Goddard. But on this concept of setting up field laboratories--I got in Dutch with Goddard because I was never a diplomat, I guess. He had the proposition that he wanted to set up all these big field laboratories in microbiology, and I said, "Wonderful, Dr. Goddard. That was something that the Division of Microbiology had looked forward to for years." That was the wrong thing; I should have given him credit for having thought of it. But, anyhow, he'd already said that I would never go any further than I had gone at that particular point (laughter).

RO: Going back a little bit to when you're doing this work as far as the large-volume parenterals or the transfusion flasks, one of the things later on, as far as the test procedures and things, they got so concerned about was the fact

that most of our laboratories did not have sterile rooms. I was wondering how you were thinking, then, when you set up these test procedures.

MB: Well, at that time they were all being done in Washington where we had a sterile room. And then it wasn't until after the microbiological work went over to the field service--what was the title of it that Allen Rayfield had?--that they began to say they could do it in the field. The way they solved the problem was to put in these so-called sterile hoods. The only trouble was that they didn't consult anybody and they put them in incorrectly. I can well remember getting a call in the middle of the night from J. K. Kirk, saying, "Bart, I want you up in New York. They have a problem with B. D. up there, Becton-Dickinson. A non-sterile component of some heart valves," or something of the sort. He said, "I think you better go up." I said, "No, J. K., there's no need of my going up there. I have a man, Carl Bruch"--who was then with the division--"up there, and he can take care of it." "No, I want you there at seven o'clock tomorrow morning." So I was there.

But what had happened in that particular case was they had put the sterile hood out in the middle of the room. It was "Grand Central Station" right behind it, and of course anything going on in there wasn't sterile. The man from B. D. had seen that setup. We had a little conference in the district office, and he came in and said, "Have you seen the hood setup?" I said, "Yes. I know what you're talking about." He said, "We're in agreement, I guess." I said, "Yes, we're in agreement."

But this is the kind of thing that, unfortunately, happened, because all the weight of determining what was good and what was bad was placed on the

shoulders of Paul Elliott, and Paul just didn't have the time and sometimes had not had the experience that some of the rest of us had had in seeing whether these things were handled properly. But there was nothing that we could do with it. We were really written out of the program, and were written out, unfortunately, of some of the places we should have been in such as handling the new drug applications in the medical field. I can remember when the Medical Bureau would call up sometimes when Dr. Hayes came back. Wasn't it Dr. Hayes that was head of medical branch for a while? No. Who was that?

RO: Ley.

MB: Ley, yes. He'd been in earlier and I knew him, and he called up and said, "Did you pass on this?" "No, I hadn't even seen it." He was madder than heck. But I don't think it did any good, because we still didn't get from the Medical Bureau the things that we should have had to review.

RO: Did you have any idea why you were cut out?

MB: Empire-building. It's the thing that happens. These people came in, they were new brooms, they were going to sweep clean. They didn't want anybody messing around in their bailiwick; so they took over. I can remember very clearly when Goddard came in, it was made very plain to those of us who'd been there for a while that we were finished. We were not going to go any further than we'd gone already, and there were going to be new people coming in to supersede us.

Dr. Summers, who was head of the Bureau of Foods, I guess it was called then, had much the same concept. In fact, he proposed that we should be abolished—that is, all the heads of the divisions should be abolished—and AOAC should be replaced. He thought AOAC was a waste. But he later came around and apologized individually to all of us that he hadn't realized the necessity of expertise from the past to conduct some of these things, to avoid getting into traps.

RO: Was Bob Roe still here then, or had Summers replaced Bob Roe?

MB: No, Roe was still there. But they had separate setups. I can't tell you the names. They were back and forth. They had a setup where Roe was in charge of research work or something of the sort, and Summers was in charge of the regulatory. We were being organized and reorganized. I remember calling Nevis Cook up in Boston one day and he said, "How do you like the reorganization? Oh, I forgot, you weren't organized. How can you be reorganized?" (laughter) It was true. We were in bad shape from changing horses all the time. But it didn't make too much difference.

RO: One of the things that you've been talking about is the bacteria and things that we commonly refer to as "common bacteria" for the non-microbiologists like myself. Now they seem to think that viruses are going to start to play more of a problem with us in food and drug products and things. Were you concerned back then about viruses?

MB: Yes, we were. But admittedly, we didn't know a whole lot about it. We did not have, to begin with, a proper setup for doing any studies in virology. It requires entirely different technique and a different expertise. But we did have two things. Let me say first that the concern became more apparent when we got so many frozen foods. And I think there's a concern even today that perhaps we aren't properly evaluating the potential danger of virus being carried over in frozen foods. Now, you've got to understand one thing: the process that you use to control bacteria is the very thing that stimulates the growth of virus. And if you hold back bacteria by your temperature requirements or chemical additions, you may enhance the growth of virus in a product; so that in order to conduct a virus identification, you have to get rid of the bacteria, because they will outgrow the virus.

We did get a man into the division who had some work in the field of virology, but we didn't use him in actually doing any experimental work. We only used him as an authority to give us some advice because of his previous work.

RO: Was that Dr. Casman?

MB: No. This was another. He'd been a student of mine at Maryland, and gone with the Public Health Service and then had had a nervous breakdown and had come back. We had to let him work very easily, so we couldn't put too much stress on him.

The other thing we did was set up a contract with the FRI [Food Research Institute] out at Madison. When it was down in Chicago, we'd begun to depend

on them for some advice in this particular area, and later, after they went to Madison, Wisconsin under Mike Foster, we had a contract with them to look into the potentials of virus, particularly in shellfish, seafoods, and that sort of thing, where we thought the danger was probably greatest. There really was nothing that came out of that as far as any continuing regulatory work was concerned, but it did lay the groundwork, I think, because it furnished some funds for these people to use out there to develop methods to see what the problems were. They would get samples from various and sundry production areas and examine them. I think the Public Health Service really got a greater handle and a greater benefit out of it than did Food and Drug.

I got myself in Dutch with the powers that be on that contract as well as on one involving botulism in dried fish, because I was naive. I just thought when you had some money for a contract, all you had to do was find the best expert in the country that you wanted and put him to work. I was visited by the GAO, I guess it was, that came down to tell me, no, that wasn't the way you had to do it. But then I had had a run-in with them before. They had tried to take away my files where I kept all my literature, and they said, "Why, shucks, they're all in the libraries. You can go to them." I said, "Yes, and I'll just sit and hold my hand because I can't do any work without my files" (laughter). We got along after a while.

Then they also bawled me out, I can remember one time, that I didn't require biweekly or bimonthly reports from the project leaders. I said, "No, I don't require that. I'm not going to have the men waste their time writing reports. It's my policy to drop into the laboratories at least once a week to see what they're doing, to sit down with them, to know firsthand how they're mak-

ing out. So I don't need them to waste time writing a report." I don't think I ever got agreement, but they didn't fire me because of it, anyhow.

There's another area that perhaps we haven't touched on that is one that comes up, and I think it's because of the lack of background knowledge that exists today, and that is the setting of food standards--that is, food standards in terms of the bacteriological content. Some of the people in the Public Health Service were always saying it was a failing that we weren't doing that, and the state health officers and the state Food and Drug people were always very much upset; and I can understand their problem. One time early on, both Dr. Slocum and I thought it would be a good idea--and I remember going to Dunbar and telling him we'd like to set up bacteriological standards in some foods, but we would probably admit to the presence of 500,000 bacteria. "No," said Dunbar, "we can't do that. We'd scare people to death if we told them something like that."

Then the thing swung around to the point where someone in the administration really wanted standards. I guess I was really the one that just was stubborn, and I wouldn't go along with it for the simple reason that I had seen too many cases where it had been abused. I can well remember going down to Florida in the early days of concentrated orange juice, and the state had set up specifications or standards. They were easily whipped, because all you had to do was put the lot back in the freezer for another two or three weeks, the counts would come down, and it was passable. Which, of course, was beating the devil around a bush. New York City did the same thing. They set up bacteriological requirements, and I know of one instance where crab cakes were found to exceed the standard. The firm merely put in a final-cook procedure. The crab

plant down in Florida was one of the filthiest that I'd ever been in, and it wasn't changed. Their procedure in the processing plant--and I believe it was here in Harrisburg, Pennsylvania--wasn't changed. All they did was cover up the insanitation by the use of a final cook. So it was that background on which I always opposed standards. Now I'm not opposed, never shall be opposed, to criteria, which is a general concept of what counts should be, or specifications, by which I mean that if I'm going to purchase something from you, I say what the bacteria levels should be. But that's what's going to occur right at your door and not what's going to occur in the supermarket, where there's all kinds of abuse that can occur to the product; and where, by simply keeping frozen foods, for example . . . If you want to get the bacterial count down in the frozen food, you raise the temperature to . . .

(Interruption in tape.)

MB: I don't know what I was saying.

RO: We were talking about food standards.

MB: What I was saying was that I never felt that the setting of a legal standard would control sanitation. And in fact, it wouldn't. This is what I was starting to say to you. By raising the temperature to just below the freezing point, you will decrease the bacteria in a product; but you'll increase the enzymatic activity. So you'll get a product that deteriorates quality-wise but will improve bacteriological-wise. So that's no way to do it. I know now where one of the firms--and

a big firm that is buying from us--had some bacterial counts in the mushroom products that were over the limits. They said, "Let's hold them for a while and see if they come down to meet our specs" (laughter). That was one of the things we knew and know can be done.

RO: I was thinking, Bart, we from the field participated with the Division of Microbiology trying to correlate the factory evidence with the bacterial load in the end product, and it seemed to me that for years we were going out on all of these projects, making inspections and collecting samples with the thought in mind that at some point in time we were going to be able to collect objective, finished samples and be able to take action without the inspectional evidence.

MB: Well, you can and you should, and there's no reason why they can't be doing it, provided they're taking the samples at the time of shipment and not taking them after they've been held for some time, and provided that they are correlated. Now the very thing you're talking about was the approach that we made with all the work that was done and the publications that were made primarily by Bernie Surkiewicz. I was very much disappointed when Bernie left us, but he saw the handwriting and he said, "No, the opportunities to continue in this field, we're losing them, and we won't be able to continue with it because there are other people with different concepts and we can't do it." So he went over to the Department of Agriculture and continued very much the same work in the meat and poultry industry that he was doing for us.

As I said earlier, the idea of bacteriological specifications is very prevalent. As you know, I'm working with a mushroom processor now, and I think

practically all of our major purchasers have bacteriological specifications. They're buying the mushrooms, they're going to put them into pot pies and what-not, and they want certain levels of bacteria. They are the specifications that are derived by our examination of the product as we are preparing it and as we have it ready for shipment. And the way we can control it is by controlling the sanitation. If we can't control it that way--and I'm up against a problem right now where we can't control it entirely by sanitation. We've got good sanitation; it's the problem of the raw product coming in, that there are too many bacteria on mushrooms. So we're going to have to go to a slight-heat process before they're frozen.

RO: You had left the agency before we got into the real problem with botulism.

MB: Yes and no. The smoked fish, I was there during that episode. We were very fortunate because we had hired a man from Dietrick who had worked with Type E at Dietrick. Now, he was not able to go back and get any of his information out of Dietrick, but he still could be helpful in advising us what the problems were and doing some of the research work on the smoked fish deal. See, this was an entirely different type, the botulism in smoked fish. Heretofore we had thought that E only occurred up in the northern parts of the country, and that we had no Type E and we <u>had</u> had no Type E below some parallel--I've forgotten which it was--that ran through Canada, except some import things that had come in from Alaska and from Canada. So we learned a lesson due to the fact that our methodology was not right.

This smoked fish deal was really the first time that we'd had an outside contract with Wisconsin and also with Oregon State to do research work on fish products from the Columbia River and from the Great Lakes. This is the one where I got my fingers slapped for going outside my authority in the way I handled the contract.

You say botulism. First thing was the viccychoise in New York. I am going to tell you very frankly, there was botulism in the viccychoise. But there was no botulism in all the other canned items that Food and Drug seized. Bon Vivant had called me in as a consultant, and Food and Drug very generously turned over all their records to me. The problem was nothing but inept examination in New York District--I'll be frank--because they had any number of cases, if anybody had bothered to look at it, where New York found positive results, not for botulism but for insterility. The same samples were examined by Cincinnati or Boston or somewhere else; they were found all right--the same code, the same lot, the same everything. And as I say, I was very critical and went to the Commissioner with the fact that this was FDA's own fault. Unfortunately, I didn't get a very satisfactory hearing, and the firm, against my recommendations, just threw in the sponge and gave it up.

Now the botulism scare that occurred in mushrooms was laughable because, in 1939 or 1940, I was examining some decomposed canned mushrooms, swollen cans--I think they'd come from Denver, one of the plants out there--and I found botulism in these swollen cans. And I went in to Dr. Hunter--I guess I was shaking--and I said, "Look, Doc, I found botulism in these cans." And he said, "Of course you did. That's garbage you're looking at; that's not food, that's garbage. It's to be thrown out. Nobody's going to eat that stuff." That was the

concept that we had about botulism in spoiled canned goods in those days. Now that didn't mean we wouldn't take action against the cans and get them off the market, and that we wouldn't look into the reason for them, and we wouldn't look into the problem as to whether there was going to be any continuation in spoilage; but we didn't put it in the newspapers and practically put an industry out of business, as occurred in 1973. There's never been a case of botulism in commercially canned mushrooms in this country. The nearest thing was some imported dried mushrooms that were put in a gravy out on the West Coast, and they did cause a problem. But that's the only commercial one. So this is again, to me, an example of where experience is not available to tell you how to proceed with some of these particular problems.

RO: Are you saying, Bart, that we really shouldn't have to worry about botulism in some of these canned foods, that by the time the toxin is formed, the food is going to be putrid and nobody's going to eat it?

MB: Except for the smoked fish, I have never seen a situation where the condition of the food was not so repulsive that it wouldn't be eaten. Now, in the case of Type E botulism in smoked fish, yes, that product was not repulsively spoiled because the conditions of growth of type E botulism are different.

There was one other similar type of botulism, and that is a non-putrifactive Type B botulism. There was a case of that in a liver paste. I believe it came out of Canada, and there was a death on Long Island that was traced back to non-putrifactive Type B botulism. But they are rare, and in general you're not going to find it. Now we ran across this problem way back, when somebody hit

upon the idea of putting frozen foods into cans. These were frozen; they were not heat processed, they were not commercially sterile, and there was a great fear, particularly among the California people, that this would cause problems. So we devoted a lot of time to inoculating cans of these products with botulism and seeing what their condition was after holding, and we never ran into an instance in which, just as you have said, the product spoiled beyond any useful purpose before the toxin developed. If we'd used this Type E, which we didn't frankly recognize then as being any problem, the results might have been different.

And since that, I could point out that there has been a Type F isolated. I ran into that in a case down in South America, when I was down there with AID, where there was a case in canned beans that was undoubtedly Type F. I tried to smuggle the culture back into this country, but by the time I got it back I lost it. I never got it identified for sure, but I'm sure that's what I was dealing with down there. I wasn't there for that particular purpose.

No, actually the problems, as I see it, in microbiology that are occurring today are not a whole lot different from what we had way back when. There's still the same old question of hands and time. In your canned goods, the greatest problem--and I saw it more and more after I came up here to work for the canning industry--is with defective cans. I came up here to Kennett Square to help the mushroom canners set up a certification program, and they actually formed a corporation, and I was hired as a consultant to them, an inspector. I would inspect these plants, certify that they were doing a correct job, following exactly in the certification program the program that Food and Drug later set

up for canned food products. But later the imports took over the market and all but two of the firms that I originally worked with have gone out of business.

RO: Was this after they'd had the big scare in the early seventies with the canned mushrooms?

MB: Yes, that was in '72, I believe, or '73, and I came up here in '74, after my arm was almost broken by some of the folks at National Canners. I promised I'd take the job for a while until Wally Bohrer had gotten free. While you're writing Wally Bohrer, write down B. A. Linden. That was the man in Food and Drug that I tried to remember earlier. B. A. Linden, who died shortly after Dr. Hunter did. But anyhow, as I say, the canning industry just went kaput, so this one firm that I'm with now asked me first if I'd establish a laboratory for them and then would I train their people. Then, gee whiz, since you're hanging around here, why don't you do the work for us? So I came up on a temporary, four-months agreement. That was seven years ago. I've been very fortunate, Ron, because since I retired twenty years ago this coming fall, there's never really been a time when I didn't have some project that I could undertake if I saw fit to do it.

RO: One of the things you didn't touch on, Bart, and if you don't mind, we can go back a little bit, and that is when Dr. Goddard came in as the Commissioner. There were some changes that you alluded to, at least, as far as what some of the old-line FDAers, their status, was concerned. He came from CDC, and one

of the programs he thought he could do, anyway, was to eradicate Salmonella from the food chain. Of course, you know the story of that.

MB: Well, to back up a little bit on that whole thing, I was going down to CDC very frequently to participate in their training program for the state people. So I'd be down there working with them a couple of times a year. They were working in the field of Salmonella. They had a very active program there, and earlier than this, Dr. P. R. Edwards, who headed up that program and who was and is, I guess, the expert in that field, although he's no longer living, was very critical of us in Food and Drug. I can remember sitting and squirming in my seat in a public meeting, because he was making remarks about this organization that was not living up to their duty in getting rid of Salmonella in food products.

So Dr. Goddard came in with a background of all this activity in Salmonella from CDC. Now whether he was really convinced that it could be done--to get rid of Salmonella in a food product--or whether it was something that he latched onto, I don't know. The boys down in CDC--and I'll be very frank about it--made no bones out of the fact that in their opinion Goddard was coming into Food and Drug to be close to headquarters and to make a name for himself with the idea that he would then become Surgeon General. I don't think there's much question that that was his motive and his idea. I think he made a stir in a lot of areas with the idea that that would be the thing that would get him attention in the public health field and he would have a chance to become Surgeon General. It didn't work out that way, I think very fortunately. But the boys down in CDC were very happy when Dr. Goddard left, and I criticized a few of my friends very profanely for not telling us about that beforehand.

But the whole Salmonella thing was a fiasco. Slocum and I were pretty well convinced, when we got into the field, that yes, we could make some headway in controlling Salmonella. It wasn't until we really got into it and began to look, after three or four years, at the record that we realized this was not the approach to do it. The approach to Salmonella had to be to go back to the source, and that means go back to the chicken farm and clean them up, to clean up the poultry, to clean up the hog farms, and get rid of the source. And once you could get rid of it at that particular point, then you're halfway there.

Now that isn't entirely true, because there were other cases. For example, the dried milk episode. I tell you, I had an uncomfortable half day down in CDC over that one, because they were convinced that they had very definite evidence that Carnation, I guess it was, was turning out the highest levels of contaminated dried milk. Not because they isolated it from the dried milk, but because the vast majority of people who had come down with salmonella had been drinking Carnation dried milk, which at the time was the most widely used brand. There were some people that I had on my side and we convinced them, "No, you can't publicize all of this until you get some evidence."

In the case of dried milk, there were several cases where the organism had come in from pigeons roosting outside the air ducts. In one plant they had oyster shells piled over in a corner, and the air was sweeping across them and into the dried milk. Because, you see, in every one of these cases, dried yeast, dried milk, dried eggs, where we had problems, they were products that were moist and were being subjected to drying, and it was contamination that was occurring in this particular drying process.

Borden had it. The bricks down in the parquet floor had gotten contaminated, and they had to sterilize the whole plant before they got rid of it. I hang my head in shame over that particular one, because we found Salmonella in inspection samples of their dried milk products. I advised Chicago, but by that time the firm had shut down for a two-months vacation. Chicago didn't follow up. I should have. I should have gotten in touch with some of the people I knew in Borden and said, "Hey, here's your product; don't ship any more, and get on the ball." But I didn't. I didn't have to, but it was something I should have done, really.

In all the work that Food and Drug did, and all the work the Public Health Service and CDC did, there's been no dent in the numbers of cases of Salmonella that are occurring. It's a very curious thing, because it involves mostly old people and infants that are more susceptible.

RO: You mentioned trying to control Salmonella at the source. We were going back to the imported fish meal. We thought there we could start with that feed ingredient and control Salmonella in the food chains. That was really an ambitious program.

I think it was in the early seventies, somebody we haven't mentioned--and before we end here, Bart--is some of the colleagues that you worked with, and one that I can remember, Dr. Angelotti. He came to FDA, I think, from the Public Health Service. But I remember in the early seventies that he was still trying to launch a program that was going to take Salmonella out of the food chain. We were finally able to convince him that we weren't going to be able to.

MB: Well, Bob needed a lot of convincing. I knew Bob. He was hired in Cincinnati by this man that I mentioned previously, L. A. Black. So I knew Bob through Dr. Black; Dr. Black would tell me about him. Bob is a very intelligent person, knew a lot of bacteriology, and I don't fault him for a minute for that. He was a gung-ho; he was always going to tear right in and do something. The only trouble was that Bob did not read the Food and Drug Law. And I can remember riding back from a conference with him when he was off on this standards idea. He'd set them up purely on the basis of store samples. So I said, "Bob, just wait until I get you in a witness chair to support those standards." He said, "Do I have to testify?" I said, "Why, of course you do. The Frozen Food Institute is going to take this to court to challenge you, and you're going to be the man in the hot seat." I found out later he went around to Slocum and several others and said, "Hey, is Bart right? Am I going to catch it?" They said, "Yes, Bart's right." Then, of course, it flopped.

But Bob did not know and did not understand the problems. He didn't understand the problems in the field, and this is another place where we were falling more and more and more behind, because we did not have the people who were going out into the field and seeing firsthand what the problems were and what could be done and couldn't be done in control. It was a policy, when Hunter and Glenn and I were running around the place, that we would get out a couple of times a year just to travel with the inspectors in different areas and to see what the problems were, not only to educate ourselves but to help to pass on to them some of the things that we could see with a different viewpoint and a little different training and expertise, perhaps, than they had.

One of the times I never will forget--and this was after we'd come back to Rayfield's day, when he was taking over in the programs--where I was out in Denver District. Something had come up out there, and I said we very much appreciated the fact that the inspector had passed on to us this thing that he had seen, because it allowed us to interpret the results that we were getting. Boy, he and I both got blistered for having done that. He had gone out of channels to let us know in Washington what this situation was. But we had to know this particular background.

I can remember that one time we were in trouble with a firm out in Long Island who were using quats [quaternary ammonium compounds] to sterilize finger wraps. In order to test those, you have to use a neutralizer to get rid of the quat that's on the product. Because quats are a very good agent for inhibiting bacteria; they're bacteriastatic, but they're not bacteriacidal. So he was applying them to the finger wraps, and anybody testing with the usual procedure found that they were sterile when they weren't. Actually, the quats were just inhibiting, and continuing to inhibit, in the media the growth of the bacteria. Fortunately, the inspector in writing up his report called attention to what the firm was doing. We got that report and we'd already examined samples and said okay on some of the lots. So we had to backtrack real fast and say, no, they weren't sterile. The poor man up in New York never did believe this. He protested vehemently that his bacteriologist said they were sterile. We were just stupid.

RO: Rayfield guarded very jealously the relationship between the field and headquarters. He wanted everything to come through what was BFA at that time.

MB: I know that was the case, and it wasn't right and it isn't right, if it's ever done that way. I don't think we have to look any further than what's occurring in Washington today to see the hazards of that sort of thing. I can never tell you how many times I have gotten calls from one of the district chiefs in the middle of the night or early in the morning because he couldn't make the call from the office; so he had to call from home to pick my brains a little bit.

RO: You mentioned some of the changes that have taken place in the agency, and especially in the division that you were in, and one of the things that I often wondered about is, when Glenn Slocum left, and I think Dr. Olson came in, how did that really come about?

MB: The situation was, to go even further back than that, for a long time I wore two hats. I was chief of the Bacteriological Branch and Bill Eisenberg was chief of the Microanalytical Branch. Also I was the acting deputy director of the division, and then, of course, acting director in Glenn's absence. That was partially rectified by hiring Carl Bruch to come in as chief of the Bacteriological Branch. I still think Carl would have been a good person if he had settled down a little bit in there. Very interestingly, he came around later and apologized for some of the things that he did while I was still there.

But Glenn had a heart attack, which meant that he was out of circulation for quite a while in the hospital. Then when he came back, I guess we all conspired this "concept of deniability." We didn't let Glenn in on any of the hot issues that were going on around there; we kept him out of it for his own good, so we thought, and I think it was. Shortly thereafter, Slocum retired. But in any event, Bob Shelton* and I had to really carry the whole load of the division, and Bob, bless his heart, was really an outstanding individual. I remember he would come in to me and say, "Bart, we've got to get this report ready. Now, what would you like to say?" And I would tell him what my ideas were. He'd be back in in an hour; I knew darn well he hadn't written it; he'd had it written beforehand as to what our report should be.

But when Dr. Goddard came in, and Dr. Summers, it was very plain that I was not going to have the opportunity to go ahead, even though for virtually five years I had been really acting director of the division. It hurt a little bit, and it hurt in the pocketbook, too, at the time of retirement, because I didn't have that extra grade to count on. But in any event, it was absolutely necessary that we get somebody else in. There were several that had been recommended, but the only one who looked to be in any way available and who had been looked at by some of the others in Food and Drug--Dr. Summers, particularly--felt that he would be the candidate that we should get. Dr. Summers about that time was ill, so it fell to me to go out and interview my replacement

* Bob Shelton died September 23, 1987.

(laughter). I always got a good deal of kidding because of that. But Joe Olson, while he had a good knowledge of Food and Drug and the bacteriological problems, was not an administrator.

(Interruption in tape.)

MB: But he was quite interested in the international field, and, of course, got in FAO.

RO: Where did he come from?

MB: He'd come from Minnesota. He'd been at the University and been head of the department out there, and was very well liked and recognized there. As I say, I depended on some of the people who knew him from out in that area whose opinion I trusted in the field of microbiology to recommend him. So I know that I probably goofed up on that one in hiring my replacement (laughter). But it was necessary because I was wanting out. So he came in, and it was made very plain to him that I would be there for another few months, and then I was going to be retiring.

RO: You'd decided already.

MB: No one else knew it. I never told anyone except my secretary, Shelton, and Olson that I was leaving. I just, one night, put on my hat and didn't come back. But Olson did do one thing; he did keep in touch. He kept in touch with both

Slocum and me, asking us which way to go on things. And Glenn used to go in and see him. But I was involved with other things, and I was out in West Virginia a lot of the time at my summer home out there that I'd built; so I didn't come in to be with him. And then, of course, about that time, the combination was made with the Public Health Service. At that juncture, Angelotti came in. I don't think that was a very good move, but I don't think Joe had any choice. At least that's what he said, and I have no reason to question him.

RO: You mentioned Bob Shelton a couple of times. Before Bob retired, he was, I think, in international affairs, kind of the administrator of that office. I often wondered--he'd been in microbiology for all his career that I knew, and then all of a sudden he ended up over there. What really happened with his leaving microbiology?

MB: The reason was that there was no place for him to go. We couldn't get him promoted. Bob was brought in originally from New Orleans where he was in charge of the shrimp inspection service. When Dr. Hunter died, we were left in the division without any expert in fishery products; so we pulled Shelton out of down there. There were personal reasons satisfactory for him to leave the New Orleans area, so he came up. That was in the mid-forties. But, really, he wore no hat at any time except that he was what you might call an administrative assistant, both to Glenn Slocum and later to myself. He was excellent. Glenn also tried to get him promoted, but for some reason it didn't go over. One of the reasons later was that he didn't have a Ph.D. Well, Ph.D. be hanged, because B. A. Linden that I mentioned earlier didn't even have a B.S., and

Bernie Surkiewicz didn't, but we managed to get Bernie pretty well up the ladder in terms of his grades.

RO: I think later on that Ph.D.'s got to be more important in the agency than they were earlier.

MB: Yes, that's the point. You did have a little trouble early on in the case of Linden and, to a lesser extent, with Bernie Surkiewicz with the Civil Service to get them through. They didn't think that a man should have these responsibilities and this grade without a degree.

RO: What was Bob Shelton's training in, microbiology?

MB: Yes. He was a microbiologist, and he had his bachelor's and master's from Missouri. Then he had been in, as I said, the shrimp inspection; so he knew his bacteriology. He had a fantastic memory--still does--for memorizing what's happened in the past. I still call him up and say, "Hey, Bob, why was it we gave up on such-and-such a program?" I'm still picking his brains as I did then. He would have been excellent. He was a good administrator; he worked well with people, both in house and out in the field service. He was much more of a diplomat than I ever was in getting along.

RO: Getting back on something technical. You had mentioned crab meat earlier, and they were always trying to establish some kind of bacteriological standards--well, in fact there were some, as far as E. coli, but they were never

really enforceable. I believe it was in the late sixties that the industry started to pasteurize crab meat. I remember within the agency there was considerable discussion what FDA's position should be on pasteurized crab meat, whether or not it would be a wholesome product.

MB: I think it is. As a matter of fact, one of my neighbors here is still in the shellfish industry. He has a crab and oyster plant down in Crisfield, and he and I have a lot of discussion on it. The only trouble that I ever had was, and one of the things I think Food and Drug was negligent on, the fact that there was abuse. There was a tendency to put crab meat on the market as fresh. Then, if it didn't sell, pull it back, give it a pasteurization shot, put it back on the market. It probably was wholesome, but not very good quality-wise by the time it had been so treated. But they're doing it more and more, and I see nothing wrong with use of a slight pasteurization.

Now that process was developed by the Fish and Wildlife Service. As a matter of fact, the two men that did the work on it were people that I knew and worked with in the University of Maryland before they went over into Fish and Wildlife. One of them later came into Food and Drug in the Antibiotic Division, Bob Reedy. Then he went to Nutrition.

There is, of course, another thing that I'm very unhappy about that is not catching on and going further, and that is radiation. I think that it has a great potential, not in putting out a sterile product, but in putting out a product which is comparable, let us say, to pasteurization. I think if we could get radiation used on poultry products, we would go a long way to alleviating some of the problems with Salmonella, because that work has been done. It was done

up in Canada, and one of the last conferences that I attended was up in Canada, McGill University, I guess it was, dealt with the use of radiation on chickens. Not on the whole chicken, but on those that are cut up, and the cut-up parts, or the whole chicken which is protectively wrapped. It's no question but what it would eliminate some of those problems. It would also eliminate some of the insect problems and reduce the necessity of the use of chemicals.

I gave an hour-long talk on that here at Kendal one night. Every Monday night they have a current events thing, and I agreed to talk on radiation. When I would ask, they were, "Oh, we're against radiation." "Are you against chemicals?" "Oh, yes, yes." "Which would you rather have, radiation or chemicals?" I usually got no answer on that particular one. But I don't see it, and never have seen it, in terms of actually putting out a sterile product. I don't think it worked at all with the canned hams and the canned bacon.

(Interruption in tape.)

RO: Bart, before we close out this interview, we always ask the interviewees whether there was anything they'd like to add as far as some of the management styles, personalities of some of the Commissioners that they worked for, or some of their peers or colleagues. I'd like to ask you that, too.

MB: I feel that I was in Food and Drug at what was at least to me a very happy time. I came in just a matter of a few months before Campbell was going to retire, so I had very little experience in actually working with him. But my

impression was that he was inclined to be a little superior and standoffish and not as easy to get along with as some of the others that came later.

But from then on, my experience was with Dunbar, then I believe it was Crawford, Larrick. Jack Harvey was a deputy but never was a Commissioner. Of the three, Dunbar, Crawford, and Larrick, they were available to everybody, and they certainly knew what all the problems were. I mentioned here in passing about the Liars Club, the fact that the Commissioner ate with us. Dunbar didn't, perhaps, participate quite as much as some of the others--Crawford and Larrick--did. But he still was available to you, and he understood the problems that you had. In fact, with Paul Dunbar, one of the things that you had to be very careful about was in meeting him in the hall and not speaking to him. He was apt to yell at you. He made it very plain that he expected you to speak to him, and not because he was Commissioner, but just because he was a man that worked there and he wanted everybody to be friendly.

Jack Harvey was inclined to be a little less approachable than either Crawford or Larrick, and he was one that didn't come around as much. Now Dunbar, Crawford, and Larrick made it a practice, although it wasn't ever announced, to actually circulate through the laboratories, and it was not at all unexpected to look up and find them standing at your shoulder at the bench to see what you were doing. They were interested, really interested, in what you were doing, what the results were, where you were going. They knew what the problems were in the division, they knew who was involved in those problems, and they would make a point when they saw you to inquire as to how the research was going and what the outcome looked like to you.

That was something that was sorely missed after Goddard came in, because he definitely never came around. We never saw him, and it was very difficult to get to see him. Furthermore, after the change, he was first over at the HEW Building, and then later out at Rockville. He was completely unavailable, and you never had an opportunity to see him and to really discuss firsthand what was going on. With him a great many of the other people under him left, such as Dr. Elliott, who was here when I first came and who was largely in the food field and then the import field. Of course, J. K. Kirk, Rankin, all of those people were still available.

As to any of the personalities and the way they've handled their administration, I just couldn't comment because they all operated pretty much in the same way. Food and Drug had been organized in a certain way from way back when, and they--and in this case, I mean the trio of Crawford, Dunbar, Larrick--continued to operate in that fashion. So I have nothing much that I can say in criticism or in anything but praise for them in the way they handled it.

RO: One of the things that occurred to me when you were talking is that for a period of time the field offices or district offices didn't have microbiological capabilities until they started to build the new buildings in the sixties. One of the things that happened after that was the establishment of the Minneapolis Center for Microbiological Analysis. To begin with, it was my understanding that it was an extension of the Division of Microbiology, and then later it transferred over to the field.

MB: No, really not, because that was set up completely independent. We had no input into it. The people that went into it, except later years, were all from the field laboratories with, I think, about two exceptions.

RO: Harold Leninger really set that up, and he was in the division, wasn't he?

MB: He was in the division, but he didn't really get into it too much until after I left. He actually left the division, as I recall, before he went into the Minneapolis Center. That was supposed to be patterned after the drug center which was in St. Louis or Kansas City. It was not something that was set up under the Division of Microbiology at all.

RO: The drug was set up under the Bureau of Drugs and not the field, but Minneapolis was supposed to, I thought, do a lot of finished-food analysis, not necessarily for compliance, but at least survey work to determine what some of the standards might be.

MB: Well, that's what my understanding was. Of course, as I say, most of that transpired after I retired, so I can't really comment. The whole laboratory setup--I don't remember that any of that was functioning at the time I retired. I'm pretty sure it was not. It was more or less a gradual buildup and, as I said, pulling microbiologists from the other district laboratories, with the exception of Al Schwab and Hal Leninger, who got out there later. I think in both cases they went out--I know Al Schwab went out later, and I'm sure Harold Leninger left. But Harold had gotten involved in . . . Well, for example, we assigned him

especially to some work on the atomic energy problems, the fallouts, and he was involved in that for a couple of years. In so doing, he was pulled away from the Division of Microbiology. He didn't have a permanent assignment in the division; so it was somewhat natural, I guess, that he gravitated to Minneapolis. But I could never see the Minneapolis setup. But as you say, the understanding that I got from what they were planning was just that, that they were going to deal with the samples, both from regulatory and from investigational points of view, and leave the actual research in the isolation procedures and just what organisms meant under certain conditions to the Division of Microbiology in Washington.

RO: One of the microbiologists that comes to mind was Pete Dunnigan. What was Pete specifically working on? He was doing some research work, wasn't he, in Washington?

MB: Pete came in very shortly after World War I, and he was just doing general work in the division in the regulatory aspects. I don't know that he really specialized in a whole lot of things. He was perfectly capable. And so he had assignments such as preparing botulism toxin antisera, which we had to make for our own use because it was difficult to obtain it commercially. I tried to interest him in going out and looking at some of the commercial laboratories to evaluate some of the consulting laboratories around the country, but he was never very much interested in that. But I think at the end that is essentially what he was doing. After I left and Joe Olson had come in, they wanted somebody to go out and really look at some of these laboratories with the idea of possibly

certifying--not on paper, perhaps, but to see what laboratories could be depended upon to do research work or even to do the regulatory work for various companies, which still today is a need. I think that somebody ought to have available a list of capable laboratories around the country, because industry, very often . . . when I was with Food and Drug and later, I would get inquiries: "Where can I turn to get a laboratory in my area that I can depend on to do work for me?" And there is no list that I know of.

RO: I know, as you mentioned, that when a firm would get into some trouble and needed some outside analysis, they would seek FDA's advice on what commercial laboratories had the necessary capabilities. While I was still there, industry was attempting to get a list of laboratories that would be acceptable to FDA. I remember they were especially in pesticide analysis.

MB: I know that from time to time there was discussion of it. I'm glad to know that there still hasn't been anything done with it. But there are some competent labs. Down in your area, Strasburger and Siegel. They're still working. We have one of their men come into our plant once in a while to give us some outside advice.

RO: Well, Bart, is there anything you want to add for the record?

MB: No, I don't think so. I'm very glad to have had a chance to have a little input here. I won't call it a contribution, but it's given me a chance to think back over some of the things that happened. There are so many of them that

occurred, and I'm sure I'll always be thinking of something that should or could have been thrown in.

RO: If there isn't anything else, Bart, we'll close this session.

MB: Thanks very much, Ron.