History

of the

U. S. Food and Drug Administration

Interviewee: Arthur James Beebe, Jr.

Interviewer: Robert A. Tucker

Date: August 6, 1997

Place: Wakefield, Massachusetts

DEED OF GIFT

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Arthur J. Beebe, Jr.

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INTRODUCTION

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

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

CASSETTE NUMBER(S) 2

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

DATE: August 6, 1997 PLACE: Wakefield, MA LENGTH: 85 Minutes

INTERVIEWEE	INTERVIEWER
NAME: Arthur J. Beebe, Jr.	NAME: Robert A. Tucker
ADDRESS: [redacted]	ADDRESS: FDA Headquarters Office
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FDA SERVICE DATES: FROM: July 3, 1956 TO: July, 1996

TITLE: Regional Food & Drug Director, Northeast Region, FDA
(Last FDA position)

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RT: This is another in the series of FDA oral history interviews. This morning, August 6, 1997, the interview is with Arthur James Beebe, Jr., former Regional Food & Drug Director, Northeast Region, Food and Drug Administration. The interview is being held at Mr. Beebe's residence in [redacted] Robert Tucker is doing the interview with Mr. Beebe.

Jim, when we start these interviews, we like to begin with a brief personal history, such as where you were born, educated, and any early work experience you might have had prior to joining the Food and Drug Administration.

AB: Bob, I was born March 10, 1930, in New London, Connecticut. I went to the University of Vermont for my first year of college, and then transferred to the University of Connecticut where I graduated with a bachelor of science degree in the spring of 1952. I was immediately contacted by my draft board, classified 1A, and inducted into the army at Fort Devins, Massachusetts, November of 1952.

Prior to reporting to Fort Devins, I drove the school bus for the elementary school for about six weeks. Because of this, I came in contact with some children who had the mumps, and I came down with mumps while I was in camp at Fort Devins. The people that I got inducted with went to Indiantown Gap, Pennsylvania, and eventually to Korea. Because of my illness, I was separated from that group and sent to Camp Pickett in Blackstone, Virginia.

After taking basic training, I was sent to Chicago to receive training in auditing food contracts for the military. After graduating from the training center, I worked in the Chicago stockyards for six months, and then was shipped to Bellingham, Washington. I worked there in fish processing plants filling contracts for the military. This was at a time just following a major scandal involving the seafood industry. A number of military inspectors had approved purchases of salmon of lower value and passed it off as salmon

of better quality and higher cost. Several people, as a result, were prosecuted and sent to prison at Fort Leavenworth, Kansas.

While in the Army Veterinary Corps, I became aware of the FDA because all of the contracts specified that products had to meet the requirements of the Food, Drug, and Cosmetic Act. I also was motivated to look into FDA later because of Les Baukin, an FDA inspector whom I met while he was making an inspection at a Bernstein's seafood plant. He later worked at headquarters in the Bureau of Drugs.

When I got out of the army in November of 1954, I obtained a position with the Department of Agriculture and worked for the Bureau of Disease Eradication. It involved inspecting hogs for a disease that was similar to hoof and mouth disease. I did this while waiting for an opportunity to get a job with FDA.

RT: What really prompted your interest about FDA in particular, Jim?

AB: Well, like I said, it was because of the inspectional work that I did while in the military. I had to go to Philadelphia to take a written examination, and as you know, today a written examination is no longer required.

I was selected and brought on board at the Boston District Office on July 3, 1956. I came on duty with eight other employees, and we doubled the staff of the inspection branch. I thought it was pretty neat working one day and then getting a paid holiday on the second day I was on the job.

Harris Kenyon was the chief inspector, and the district director was Les Hart, a former chemist. He stayed on for about eight months and then retired. Ken Kirk, who later became the number three man in the agency, took his place as director. FDA at that time was really a very small agency, people and moneywise in 1956. The agency had only about a thousand employees, and as I recall I think the budget for the agency was only $5-

6 million. Boston District had a staff of forty-five people. All the investigators at that time were GS-9s, except for one person who was a GS-11.

Do you care about any of the names of the people who were there at that time?

RT: Perhaps some of the ones that affected your career or were involved in important agency activities of the time.

AB: Well, two or three of the people who started with me eventually rose to positions of considerable responsibility in the agency. Don Sherry retired as a compliance branch director in Baltimore; Nat Geary was at headquarters and very much involved in the voluntary compliance program; and Charles Karademos left the agency to go with the Bureau of Drug Enforcement and became a district director with that agency before he retired. Claire O'Keefe was a GS-3 clerk, I guess is what they were called at that time in the office, and she later became an administrative officer at the Winchester Engineering & Analytical Center (WEAC) and also in Boston District. After that she worked in headquarters and was very much involved in visiting districts and implementing administrative programs for the field.

RT: At headquarters, would she have been in the Regional Operations Office?

AB: Yes. Yes, she was. The chief clerk in a district office back in the fifties was a very powerful position. As I remember, if you wanted to get a new pen at that time--you know, things were very tight moneywise; the agency was very frugal--you had to turn in your pen to get a new one. Old batteries you turned in to get some new batteries, and the supply room was certainly kept locked.

FDA also at that time owned its own automobiles, and kept them for a good number of years. When I started in 1956, they had old 1948 Pontiacs. The back seats

were removed to make room to carry the necessary inspectional equipment and samples collected by inspectors.

I only stayed at Boston District for three years.

Well, let me say, the agency was very regulatory oriented at that time, but the focus was on sanitation rather than drug or device work, which is given priority attention today. In the limited time I was in Boston, I developed three prosecution cases and collected a good number of samples that resulted in seizure of adulterated and misbranded products. Today there's not a district or even a region that has three prosecutions a year. It shows how the pendulum has changed over the years from the emphasis on regulatory action to voluntary correction and education.

RT: Well, at that time, persons who were more proficient in bringing matters like that to prosecution, were recognized and moved ahead.

AB: Definitely. If you weren't skilled enough to develop a case when violations were present, you didn't get ahead in the agency. Today it's not that there aren't violations, it's just that they are handled in an different manner. Firms are given an opportunity to correct before action is taken. They're given one bite of the apple, and too often in my opinion, two or three bites of the apple before regulatory action is taken.

RT: We'll talk about your management experiences later, but as a retired manager at the highest level in the field, do you believe that the current way of operating leads to as much success for compliance as the former days of court cases?

AB: Well, it may be cost effective, that's a difficult question to answer. Let me just say I believe it's unfair to the majority of the industry that complies with the law that those

who don't comply are able to have an unfair advantage before correction is made and not be penalized.

RT: That was kind of an observation I thought you would make.

AB: Back then, every time you got promoted, it went along with a transfer. So in 1959, I was transferred to Detroit, where a new district was opened at that time. It was quite exciting and interesting, because all of the people there except for three or four who had been residents, came from other districts all over the country. We all had a new beginning together.

RT: Now, the director there was . . .

AB: George Daughters was the director, and he was quite a character. He had been at Chicago before being selected to lead the new district.

I remember one time that I had made a good inspection and collected a lot of evidence that could be used in developing a case. At the end of the day, he invited me into his office and we had a shot of whiskey together, and that doesn't happen today.

While I was at Detroit, there were two cases that I was involved in that are of some interest. One involved Lelord Kordell, who was a spieler promoting special dietary foods and dietary supplements to cure or prevent all illnesses including cancer. He gave lectures at a hotel in downtown Detroit. Another investigator and I wired the auditorium, and then from a hotel room recorded his lectures. He promoted various supplements that he claimed were needed to overcome all of the harmful chemicals that are in our food supply. Using the transcripts and relating them to products he was promoting, we were able to develop a prosecution case. He was eventually successfully prosecuted and served some time in jail.

RT: Well, this is an aside--when I worked in the state of Indiana, this "you are what you eat" health faddist--at the moment my recollection doesn't recall his name. Anyway, we sent a couple of our lead secretaries down to tape record him. What was kind of interesting is when they came back they were almost convinced of some claims made in his speech.

AB: I think the person that you're talking about was on the radio, had a radio program, too.

RT: Yes. Right now I just have a mental block on that name; I believe it was Carlton Fredericks.

AB: Another case while I was at Detroit involved salmon in Lake Michigan. We found the roe was contaminated with DDT, and it resulted in a number of seizures, and eventually it was exported to Germany, because it was acceptable to the German government and the purchaser in Germany.

I didn't stay in Detroit very long. Just a little over a year. In 1960 or '61, I was transferred to Atlanta, Georgia, where a new district office was being occupied. There had been a district there, but this was a new facility. The district director was John Sanders, and he certainly had a reputation of being enforcement minded. At that time, there were a lot of insanitary warehouses in the southeast. If you went on a two-week trip and you didn't come back with one or two seizures, you were looked at with a little suspicion about what you'd been doing. There were a lot of trips to Florida, three-week trips. We'd fly down and then pick up a government car in Miami.

While I was in Atlanta, I did a lot of work as a Food and Drug officer. I remember John one day came in, and he put ten files on my desk. They were all crab meat firms.

He said, "Pick out the worst two and write them up for prosecution." I did, and the responsible individuals and firms eventually were successfully prosecuted.

RT: Now, for those that might read this transcript, the Food and Drug officers' responsibilities were what?

AB: Well, you got all of the evidence that was developed by the investigators and the analytical work from the laboratory that went along with the case, and you put it all together, and you wrote up what was called an S&R, Summary and Recommendation. It was reviewed at the district level by the director, and if he approved it, it went into headquarters to the Office of Enforcement, and if approved there, then to the General Counsel's Office for approval and referral to the Justice Department.

RT: So the primary regulatory experience you had there was in food warehousing and so on?

AB: Yes, you know, peanuts, oil, cottonseed oil mills, and it was mostly food work in the southeast. Again, they had health food and medical device spielers there too. They were pretty prevalent in the fifties.

RT: OK. Then after your tenure in Atlanta, you next . . . ?

AB: I was transferred to headquarters, to BFA, Bureau of Field Administration. At that time, the office was headed by Allan Rayfield. There are a few names right on the tip of my tongue.

RT: Let's see. Was Malcom Stephens . . . ?

AB: No, he was head of the Bureau of Enforcement. Ken Lennington was the chief inspector for the country. Maybe they'll come to me later.

RT: Well, let's see. How about Fred Garfield?

AB: Fred Garfield was the chief chemist for the country, and Reo Duggan was his assistant. Ken Hansen was in charge of the operating people in BFA, which consisted of myself and four or five other people.

RT: Was that Ken Hansen or Doug Hansen?

AB: Doug Hansen. Doug Hansen. There was very close oversight of field operations at that time. Every promotion, even from GS-5 to GS-7, came into headquarters and had to be approved by Lennington and Rayfield. Every inspection report that came into BFA was reviewed to make certain that appropriate action had been taken, that the inspection was NAI, No Action Indicated, and to make sure that no violations had been overlooked.

RT: Well, even at headquarters the influence of Mr. Rayfield and that unit were pervasive. I came into the Division of Federal-State Relations and had been there a short time, and made the error of directly calling someone in the field. I think it was George Schwartzman who was the chief chemist at Cincinnati. So my boss, Jim Pearson, and I were called over to Mr. Rayfield's office, and it was made rather clear that people like me shouldn't talk directly to the field. They should come through Mr. Rayfield's staff. Even though it was a relatively minor manner.

AB: The chain of command was pretty solid in those days.

RT: It was.

AB: Let's see. Turn that thing off for a minute while I think of it.

Oh, I got it. Mr. Rayfield wouldn't allow anybody from the field to be selected to come into the Bureau of Enforcement. So Malcom Stephens, who was the director of the bureau, had to hire and train people from outside of FDA to fill Food and Drug officer slots in the bureau. That wasn't a healthy situation. People in the field who had the knowledge and skill required lost an opportunity for promotion.

RT: Yes, I was just going to ask you if that didn't require quite a lot of additional attention to training of these people if they weren't already familiar with the agency's operations?

AB: Yes, it did. We had people reviewing the work of people who had more knowledge than they did.

RT: Apparently that may have contributed to a turnaround time factor for actions to be taken. Is that plausible?

AB: Well, they were slow then in reviewing cases, and the situation didn't improve much over the years either.

RT: In BFA you got primarily involved with what kind of activities?

AB: Well, initially it was reviewing the inspection reports that came in from the field to see that they had been properly classified.

One thing I might say, you know, Allan Rayfield had a reputation of being very stern or a strict person. I didn't find him that way myself working for him. In fact, when I was transferred, when I got to Washington, he invited me to his house, introduced me to his wife, and we had a drink. He told me that if I needed any help in finding someplace to live to let him know, and he'd do anything possible to help me. But he did have rules that he went by.

He had a very strict dress code. One day there was a snowstorm, about a foot of snow. Lou Lasher, a co-worker in BFA, came in about 11:00 A.M. through the snowstorm, and he didn't have a suit on. Rayfield called him in his office and told him not to come to work that way anytime in the future--if you can imagine that.

RT: Yes, Lasher lived way up in Rockville, and it was quite a challenge to get downtown in the snow from there.

AB: Yes, he did it.

The other job I had at headquarters is they established an audit group that went out to the districts to review various operations, and I was involved in that for about three years. Paul Hile was in charge of the group.

RT: That was a quality control activity.

AB: Yes.

RT: So what did you primarily look for?

AB: Well, we reviewed collection reports, inspection reports, analytical worksheets to see that they were all handled in the appropriate approved manner.

RT: When you completed that review, did you turn your recommendations over to somebody in headquarters, or did you make them directly . . . ?

AB: We had a verbal exit review with the district director, and then we turned in a written report that was reviewed at headquarters and recommendations were developed and sent back to the district.

RT: Was that about the first time in your experience the agency had gone into that kind of audit operation?

AB: I think so, yes. It hadn't been done prior to that time. This was the first, like you say, quality control program.

RT: Was that inspired by a decision at headquarters or through a field committee?

AB: Well, we didn't have field committees at that time. It was something that was developed at headquarters.

RT: Beyond that, are there any particular things you recall about being in BFA?

AB: Only the conflict between BFA and the Bureau of Enforcement, which was pretty open and recognized throughout the agency.

RT: Was that ever managed at the commissioner level to straighten it out?

AB: Well, I think that when Dr. Goddard came in as commissioner, he was the first commissioner who didn't come up through the ranks in the agency, and he encouraged

quite a few people to retire shortly after he got there. Rayfield left, and Stephens left, and Kirk wasn't too long after that. BFA and Bureau of Enforcement were merged while Goddard was commissioner. I think it was called the Bureau of Regulatory Affairs.

RT: Well, Goddard, of course, wasn't bound by any allegiances to either people or organizational history.

AB: That's right. Yes, he cleaned house.

RT: Then after your time in BFA, what was your next career assignment?

AB: I went back to Detroit District as the chief inspector.

RT: And that was what year?

AB: That was in January of 1966.

RT: So you had been in headquarters four or five years?

AB: Four or five years, yes.

RT: When you went back was Ted Maraviglia the director then at Detroit?

AB: No, he had been the chief inspector when I was in Detroit the first time, and then he had moved on to Philadelphia as the district director. Hayward Mayfield had filled the position after Maraviglia, and then I took Hayward's place.

RT: I see. The management of the district was then by . . .

AB: George Daughters was still the district director.

RT: During the time you were chief inspector, I guess you got into some different kinds of activities and perhaps cooperative roles with the states in that area.

AB: Yes, we worked quite closely with the state people in Michigan and Indiana. Used to go on retreats together for three or four days up in northern Michigan with the Michigan State Food and Drug staff.

RT: A planning conference type thing?

AB: Planning and training conference, yes.

RT: I think one of the first sort of intergovernmental FDA-state planning efforts probably originated in Indiana with regard to the tomato canning industry, where the federal and state people would get together and decide which agency would take the lead in particular firms.

AB: What was the fellow's name in charge in Indiana? Frank . . .

RT: Well, Frank Fisher was there.

AB: Frank Fisher, that's the fellow I remember.

RT: And Tim Sullivan was his predecessor.

AB: Yes. Fisher's the fellow that I knew.

It's kind of interesting. When I was the chief inspector in Detroit, two of the three supervisors that I had in the beginning had started work with me in Boston, Don Sherry and Nat Geary.

RT: Is that right?

AB: Yes.

RT: In Detroit, you had experience with some drug firms, didn't you?

AB: Well, there were a lot of large drug firms: Eli Lilly, Upjohn, Mead Johnson. Those are the three that come to mind right away.

RT: And then you had more regulatory concerns with . . .

(Interruption)

RT: I think I was about to ask you, in that part of the country, the medicated feed industry was rather extensive. Were there any particular problems encountered in that field?

AB: What I remember was a meeting down at Purdue, where Bob Wetherell, who was in Federal-State Relations, came out, and I went down from Detroit, and we put on a three-day training session for state inspectors. Neither one of us were what you'd call experts in the medicated feed program, but we were able to keep one chapter ahead of the group.

RT: Was that about the time the agency was getting into state contracts? When that occurred, one of the first programs that we got into was contracting with states for medicated feed inspections.

AB: Yes, it might have been part of that program effort, starting to get something going.

RT: Now, regarding human drug pharmaceutical firms, were there any particular regulatory problems encountered? Some of those firms that you named are prominent in the field.

AB: They had occasional problems with labeling and sometimes with potency, cross contamination and sterility, but the big drug problems came much later on after GMPs were promulgated.

RT: Anything else noteworthy at Detroit? If not, I know you moved on from there again to a more responsible position.

AB: In November of 1970, I moved back to Boston as the regional director for Region I, which at that time consisted of the six New England states. In 1987, Region I and Region II were combined and renamed the Northeast Region. Region II had consisted of New York, New Jersey, and Puerto Rico. I retired as Northeast Regional Director in July of 1996 with forty years of service, twenty-six years as regional director.

RT: Now, for the record, what was the basis of the decision to combine these two separate regions into one?

AB: Well, there had been ten regions, and in keeping with the downsizing of government, the regions were reduced to six.

RT: So this was just a part of that.

AB: Part of that.

RT: Now, when you first came to Boston, you were regional director. Who was the district director in Boston when you first came over?

AB: Tony Celeste.

RT: When the combination of the two regions occurred, who was the director in New York prior to that time?

AB: Well, when the combination occurred, Joe Faline was the district director in New York. Caesar Roy was regional director before me. While I was in Boston as the regional director, there were several district directors. Tony Celeste, Dick Davis, and others.

RT: Davis was . . .

AB: Later was the regional director of Philadelphia.

RT: Davis, what was his role then in Boston?

AB: He was the district director after Celeste in Boston.

RT: In Boston. OK.

AB: John . . . John . . . John . . . You know.

RT: Who are you thinking of?

AB: Who took Davis's place. It was John Taylor who later became the associate commissioner for Regulatory Affairs. And after John Taylor came Fred Carlson, and then Ed McDonnell, and finally Jim Rahto.

RT: All in Boston.

AB: All at Boston District.

RT: Now, when you took these two regions as one--of course, you had different staffs--were there any particular differences in managing them?

AB: Well, one of the differences was that the department (Department of Health and Human Services?) has a regional office in Boston and they also have a regional office in New York. They didn't reduce from ten to six. So I had to work with two regional departmental offices. That took up quite a bit of time.

RT: Now, as far as the operating staffs of the two offices, was the operating staff in New York different in the requirement of management attention than Boston?

AB: Well, the import operation was much, much larger in New York. About 25 percent of all the entries in the country come in through the port of New York. So import

operations received a lot more emphasis than had been given to the program in Boston. Also, the drug workload in New York was much larger than in New England. While I was there is when we had the generic drug scandal. I would say about a dozen firms in New York District were involved in submitting false samples to get their generic drugs approved.

Also, there was a very significant case involving Barr Laboratories, where the firm was enjoined solely on the basis of poor GMPs without any analysis of products to show that they were adulterated.

RT: Yes . . . Would you just repeat that last thing? I missed what you said. What kind of a case was it again, did you say?

AB: Based solely on GMPs.

RT: "Based solely," I just missed those words. So was that a first again as far as that kind of a regulatory action?

AB: I believe it was. They made over 160 drugs that they had to stop distributing until they could go back and review all their batch records and show these products were being made in compliance with GMPs.

RT: Were they assessed any penalty other than a great deal more management oversight or regulatory oversight?

AB: Yes, this was an injunction.

RT: Now, this is kind of a more frivolous thing, but when you were at Boston, was there a flying bullet incident of some sort?

AB: Yes, my . . . The office was on Commercial Avenue, and the window looked out on the Charles River. One morning I came in, and there was a bullet hole in the window behind me, and, I guess, if I'd been sitting there, it could have been close.

RT: There were no personnel in the office at the time this occurred then?

AB: No, it happened during the night.

A couple cases in Boston that we might mention involved C. R. Bard. It involved the sale of a medical device used in angioplasty. It was an investigational device, but it was being sold. It resulted in a number of seizures, and prosecution, and a fine of $61 million. Three of the officers were given jail sentences. This was the first case in the Boston Eastern District Federal Court where everything was entered on personal computers. It was the first time a case like that was tried by FDA. Boston District staff set up all the equipment in the courtroom.

RT: Well, that's kind of a first, would you say?

AB: Another interesting case involved a New England shrimp company, where the firm was packing shrimp for the military, and they were supposed to be using domestic shrimp, but they used shrimp that was imported from India. In order to make it look like domestic shrimp that are pinker than the imported shrimp, they treated it with sodium hydroxide to burn it, and then to mask the taste, they used . . . What's that sweetener?

RT: Oh, saccharin?

AB: No, the other one.

RT: Cyclamate?

AB: Saccharin. They used saccharin. Yes, soaked it in saccharin to mask the taste. Then during the trial we had a chemist put on a demonstration on how the shrimp was treated. The jury was quite impressive. It resulted in the president of the firm getting a jail sentence.

The shrimp that was seized eventually was abandoned by the firm, and the government became the owner. On a political basis the shrimp was allowed to be reexported to China for use as animal feed, but I suspect that probably some humans in China ate some of that shrimp.

RT: They might have. Well, one of the people in our office of Federal-State Relations used to be the resident inspector at Honolulu. He said a lot of times rejected goods going back to the Orient would show up at Honolulu where an attempt to unload it would occur.

AB: Was that Ted Herman?

RT: I was thinking of Gary Beard.

AB: Gary Beard.

RT: Ted Herman was there prior to Beard, which seems like an exotic post. But I think these resident inspectors felt they were kind of out of the mainstream as far as moving ahead in the agency.

AB: They certainly were pretty much a self-directed group at that time, or individual.

(Interruption)

RT: To step back for a moment. While you were managing Boston before the consolidation of Regions I and II, the Winchester--the WEAC-- as well as . . .

AB: Well, it was just the Winchester Laboratory at that time, and it was under the direction of the Bureau of Radiological Health. In 1974, for reasons not clear to me, the Bureau turned the laboratory over to the Office of Field Operations. Apparently it was costing them money and people, and they weren't getting too much out of owning and operating the laboratory, so they gave it away.

RT: Now, when that came to the region wasn't it staffed primarily by Commissioned Corps?

AB: Yes, I'd say about half the people there were in the Commissioned Corps. There probably were forty people there, and half of them were given positions at headquarters and half remained at WEAC.

RT: They were primarily doing research and analytical work with regard to radiological health then?

AB: Right.

RT: So that was a new field for you to manage, wasn't it?

AB: Right. They had x-ray machines, and television sets, and microwave ovens, and, you know, they were looking for leakage of radiation on those products.

RT: In managing that at a separate location; what steps did you take to bring them into the fold of the region?

AB: Well, one thing we did is we took the laboratory out of Boston District and put it into WEAC and combined it with the people that were there. So that was the first laboratory actually that did analytical work on medical devices, and it continued to provide food and drug analytical support for Boston District.

RT: Does WEAC still do a lot of medical device work for the center at headquarters?

AB: Yes, it does a lot of research work for the center, and it does all the analytical work on devices for the field.

RT: Were there any particular regulatory issues or regulatory actions that occurred when you took over?

AB: Well, a couple of programs that you wouldn't ordinarily think of very much. One involved gloves.

RT: Rubber gloves?

AB: Rubber gloves, surgical. They were examined for leakage because of concern with AIDS. Analytical work on condoms also became a very heavy workload at WEAC, again concerned about leakage.

RT: Were the procedures for analysis similar, that is putting a certain amount of water and pressure to see if leaks occurred?

AB: Yes. It was done, you know, differently, but the concept was the same.

RT: Now, as you went along--if not then, certainly later--you became very active with the field advisory committee for this field, didn't you?

AB: I was the chairman of the Medical Device Field Committee for several years. And then at the time I retired, I was the chairman of the field committee that met with general counsel, and I was the first chairman of that committee. I think we did a lot to improve rapport between the districts and general counsel and helped to institute some procedures to speed up the approval of regulatory actions, particularly with respect to seizures.

RT: The field advisory committee system, of course, has been in place for some time. Were you involved in any other field advisory committees, or was this the primary one?

AB: Medical devices and the one with general counsel.

RT: When you had this enlarged territory, that required quite a bit of mobility, didn't it, for you between the two locations, Boston and New York?

AB: I maintained my home in Wakefield, Massachusetts, but I went to New York every week, took the shuttle back and forth, usually was there two or three days a week.

RT: Well, that's quite a commute schedule.

AB: And I did that for ten years.

RT: A rough routine, I'm sure, to keep up with.

AB: Leave the house at 5:15 A.M. in the morning. If I went down and back the same day, I'd get back about 8:30 at night.

RT: That's a long day. Do you have a sense of value about the field advisory system in general? In the field of rad health and medical devices, you said you thought it provided a little better liaison between general counsel and so on.

AB: I think the system had a very positive impact on relations, each of the field committees, between the field offices and the center. It brought the people together to know each other much better, and it did a lot to improve working relationships.

RT: In terms of working relationships, at various places in your career, you have worked with other agencies at the state level over a rather broad range of time. Do you recall any particular situations with state officials that were either positive or, on the other side, negative as far as FDA's programs are concerned?

AB: Well, I think generally all of the relationships were positive. Some states were more eager to work with FDA than others. I think New England probably, the northern states, were a little standoffish for a long time, particularly the state of Maine.

RT: Well, I assume that the fact that you are a New Englander might have been helpful in thawing that reluctance to cooperate?

AB: Yes, I think so.

RT: As you said, Jim, most of the state officials have been cooperative. I think there are some exceptions, and I think you had a rather unusual individual in the state of Massachusetts to relate to in regulatory matters. As I recall, he was the only state person that ever was able to convince his legislature to appoint him to his position for life, like a Supreme Court justice. Were there other unusual experiences with George Michael that come to mind?

AB: Well, I came to Boston, and my predecessor had signed several memorandums of agreement with Dr. Michael, whereby the state was given responsibility for inspecting a number of food manufacturers. When I had those firms audited, a number of them were violative, and a couple of firms were prosecuted because of operating under insanitary conditions.

George, on the surface, was always very cooperative, but he had a rather unusual close relationship with a number of industries, and from time to time, he slipped over the line, and it was obvious that he was accepting gratuities from some firms. Eventually this all caught up with him, and he was removed from his position. But it took a good number of years. I know at one time he was on TV, and he was filmed going into a retail grocery and coming out through a side door with his cart full of food, putting it into the trunk of his car.

RT: Well, that sort of activity, of course, is actionable at any level, federal or state.

AB: Then he had a son that was like his father. He ended up being prosecuted and going to federal prison because of providing false analytical data to the federal government. He received a two-year jail sentence.

RT: Having worked in the Division of Federal-State Relations for a number of years, I think that this example is certainly the exception, because as you earlier stated, most people are very committed to their work at the state level.

There is another area where the states have had a leading and large role, and that's in the shellfish sanitation program. That's been of particular concern in this part of the country because of several problems with shellfish.

AB: Paralytic shellfish poisoning, PSP. I think that's what you're referring to.

RT: Yes.

AB: The first time that I know that that was encountered was in 1972 when a number of people became ill from eating shellfish, and at that time it was thought that it was a one time occurrence, and we'd probably never see it again. But from that time on, it came back every year for a period of time, sometimes for a couple of weeks, sometimes for a month or longer, and we had to be very careful in closing areas to shellfish harvesting at that time.

RT: Now, as far as the Food and Drug Administration is concerned, if a state has not done an adequate job, what, if any, are the sanctions the agency can use to bring about corrections?

AB: You mean under the voluntary cooperative shellfish program?

RT: Yes.

AB: It's very difficult to take regulatory action. But the states, they know that appropriate action has to be taken with respect to PSP. A longstanding problem has been harvesting of shellfish from closed areas and fraudulent tagging as to the source.

(Interruption)

AB: You asked what regulatory action could be taken if the state didn't take appropriate action. Well, if the shellfish is contaminated with the PSP and is shipped in interstate commerce, and we can show analytically that it's adulterated, seizure action can be taken.

RT: Jim, in recent years, there's been a strengthening of the National Shellfish Sanitation Program. It's become more active like the Interstate Milk Shippers Program, kind of patterned after that I guess. One of the problems, of course, that the states are trying to cope with is the bootlegging and improper tagging of shellfish.

AB: Well, the states have had great difficulty in complying with the more stringent requirements of the National Shellfish Sanitation Program, and I think it's because before the program became under the jurisdiction of FDA, it had been monitored on a buddy-buddy system by the Public Health Service with the states. So it took FDA a number of years to get the firms and states in reasonable compliance with the program. Bootlegging has always been a problem. That's taking shellfish from closed areas. And the tagging of shellfish, it hasn't been done properly to show the real source of shellfish. And there have been areas that should be closed that were not closed. But in recent times, situations have improved greatly, and most states have done quite a good job in policing the program.

RT: Yes, it's looking up in that regard I believe. In New York District, there was a program that was active for many years--I think it is no longer active--and that was the tea examiner's activities with regard to the Tea Import Act. Do you recall a little of that history?

AB: Well, the Act required that every entry be sampled and tested to meet the taste standards. The federal government for years tried to eliminate the program, starting with President Nixon. But it wasn't until two or three years ago under President Clinton that the Congress revoked the program.

RT: That was an organoleptic examination primarily wasn't it? Did you also have some examination of the product for filth?

AB: No. Filth in the early days had been a problem, but not in recent years. It was a tea-tasting program. We'd brew the tea, and taste it, and spit it out.

RT: So at the later part of the program it was primarily a quality or taste rather than a sanitation examination?

AB: That's correct. I believe, you know, a voluntary program has been established where industry collects the samples and has the work done so that the entries of tea are still being examined.

RT: When you were placed over New York and Buffalo as well as Boston, that included San Juan as part of the New York jurisdiction, did it not?

AB: San Juan and the Virgin Islands.

RT: In Puerto Rico, has there been some relocation of the pharmaceutical industry to that territory? And if that's the case, are there any particular problems, regulatorywise, in San Juan located pharmaceutical firms?

AB: There's over a hundred drug establishments on the island of San Juan, and their problems are no different than firms here on the continent.

RT: The reasons, then, for firms locating there is what, economic?

AB: Yes, they get a tax break by locating in Puerto Rico.

RT: Now, Jim, you've served the agency for quite a number of years. What was your tenure in terms of time?

AB: I started in July of 1956 and retired in July of 1996. So I worked for FDA for forty years.

(Interruption)

RT: Well, Jim, over this span of forty years, you have served under a number of different commissioners and top agency administrators. Do you have any impressions regarding what some have done or perhaps have failed to do for the agency as you see it?

AB: Well, I believe I worked for about a dozen FDA commissioners, the first being George Larrick, who was the last commissioner to come up through the ranks who had started as a GS-5.

The first commissioner to come from outside the agency was Dr. Goddard. He was brought in to shake up and change the methods of operation of FDA and to move out some people who had been in top positions for many, many years.

RT: One of the things I think that Dr. Goddard did was to place more decision-making at the field level. Is that correct?

AB: Yes, he did. He certainly did. He also intensified the inspection of the drug industry. I forget the term that was used, but there were intensified drug inspections (Intensified Drug Inspection Program--IDIP) where an inspector would go into a plant and sometimes stay there for two or three months monitoring the firm's operations, and that resulted in a number of regulatory actions.

Dr. Schmidt. What I recall about him was that . . .

RT: Dr. Alexander Schmidt?

AB: Dr. Alexander Schmidt. He took the criticism of Congress and others very personally, and it bothered him a great deal. I remember he had a rather large manuscript published that outlined the good things that the agency had done while he was commissioner.

Kennedy.

RT: Donald Kennedy.

AB: Donald Kennedy. He was rather flamboyant. He got a lot of positive publicity for himself and the agency.

Arthur Hull Hayes. I remember at one time we had a meeting at headquarters of all of the regional directors and district directors, and he invited us over to his home for cocktails in the evening. He's the only commissioner that did that while I was with the agency.

Dr. Frank Young. He was the quintessential optimist. He could get battered around the ears and bloodied, and he would go away from a congressional hearing saying, "Boy, we really told them today, didn't we?" He came to New York right after the generic drug scandal broke and had a press conference at the regional office. It was really a very difficult press conference from the questions that he was getting from the news media, but it didn't bother Commissioner Young. He thought it was wonderful, but everybody else thought he was sitting on the deck of the Titanic while he was talking.

RT: Yes, he was a very personable guy, as far as relating to other officials and organizations.

AB: Yes, very pleasant.

And Dr. Kessler. I think he did a great deal for the morale of the agency because of the strong regulatory positions he took, particularly when he first came with the agency, and I'm sure that he'll go down in history as the commissioner who took on the tobacco industry and prevailed. Although the issue hasn't been settled yet.

RT: That's interesting in reflecting on past commissioners. Many would sidestep that issue and beg off on it, that it really wasn't a product that this agency should be interested in.

AB: Couldn't regulate it, right.

RT: There are, of course, divided opinions, as I've discovered. I still part-time work in the history office, and there are folks in the agency that are very annoyed that FDA's gotten into the tobacco issue; whereas others, of course, are very supportive of it as a public health protective measure.

AB: Well, there's no question that tobacco is detrimental to your health. So if action can be taken to prevent or encourage people not to begin smoking, then it should be very positive for the health of the American people and reduce the cost of treating illnesses caused by tobacco.

RT: Dr. Kessler, of course, also was commissioner at the time major changes were made in the labeling of foods. Some of that probably preceded his tenure.

AB: But nutritional labeling was accomplished while he was commissioner.

RT: And that's also something I think many commend him for.

AB: He probably would not be described by a number of people as a people person, but he was very focused. He would direct all his attention to one or two issues, and I think sometimes he would let other things go without giving them the attention that maybe he should have.

RT: Now, the commissioner, of course, is the head of the agency. There are obviously other folks on his staff who are very important decision makers or accomplishers. Are there any folks at that level in the agency that you recall working for that are exceptional in any particular way in your mind?

AB: Well, going back to Kessler just for a moment. He changed the structure of the agency. Prior to his coming, there had been a deputy commissioner, who was the number two person, and that was it. But he elevated the authority of the center directors who report to a deputy commissioner for operations. He also created a number of associate commissioner positions in the commissioner's office that weren't there before.

As far as the people that I worked for directly as the associate commissioner for regulatory affairs, there was Paul Hile, who I think had a significant role in the development of field activities.

John Taylor held the position for a short time. John was a very knowledgeable person, but he really wasn't comfortable in the job, I don't believe, because he didn't particularly like public speaking, and he could get very upset with sitting in meetings that didn't seem to be going anywhere, and as you know, working for the government, there are meetings held at headquarters that make you wonder why you're there and why some of the other people are present also. He retired after being in the position for a short time.

And the last person that held that job while I was with the agency is Ron . . .

RT: Chesemore.

AB: . . . Chesemore. I think Ron has done a very remarkable job, considering the responsibilities that go with the job and having to report to a commissioner. Not always directly to the commissioner, but through a deputy commissioner for operations who hasn't come up through the ranks, which makes it difficult sometimes to explain what's being done or why something is not being done by the field organization.

RT: Those folks have a disadvantage of not having institutional memory or institutional experience. Perhaps on the other side, they're not bound by it, so there's some balance

in the equation, I suppose. But certainly there has been noteworthy changes in the top echelon in these past few years with Dr. Kessler.

As to the agency, do you envision something different for it in the future than we've known? There have been proposals in the Congress now and then to divide the drug and the food functions and so on. Nobody knows what that will be, but do you have any thoughts about it?

AB: One of the things that we haven't mentioned is that FDA is a worldwide operation now; it's not just domestic. There are hundreds of trips made overseas now to inspect drug firms, and device manufacturers, and some food firms as well. So a lot of resources are devoted to international work. There's a European community of ten or twelve European countries that are banding together, and they're going to have a tremendous impact, I think, on activities in the future. We're trying to maintain our standards, and they're developing other standards that are different from ours. But there's going to have to be some compromises made eventually.

RT: Jim, we've covered quite a wide range of things. Is there anything else that comes to your mind that we ought to add before closing?

AB: Well, I would just hope that FDA continues to receive administrative and congressional support for its budget, and hopefully there will be enough positions made available to carry out the responsibilities of the agency, because it's an agency that's looked up to worldwide as the gold standard.

RT: Well, after forty years, it would be very understandable that maybe you've had enough. Was there any other consideration that led you to decide to retire at the time you did?

AB: (Laughter) Well, I think forty years is probably enough to work at one position, one agency, one type of job. Also, the role was changing considerably. The agency is moving more towards voluntary compliance rather than regulatory action, which was the kind of world that I really enjoyed.

RT: Well, you were always known as an enforcement-minded administrator and served very well in those capacities.

I want to thank you for this interview, Jim, and we'll close at this point then.

AB: Thank you. It's been a pleasure speaking with you.