History

of the

U. S. Food and Drug Administration

Interviewee: Jerry A. Burke

Interviewer: Ronald T. Ottes

Date: July 22, 1993

Place: Washington, D.C.

INTRODUCTION

This is a transcript of a taped oral history interview, one of a series conducted by the Food and Drug Administrations History Office. 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.

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

DATE: July 22, 1993 PLACE: Washington, D.C. LENGTH: 90 minutes

INTERVIEWEE	INTERVIEWER
NAME: Jerry A. Burke	NAME: Ronald T. Ottes
ADDRESS: [redacted]	ADDRESS: Food and Drug Adm.
[redacted]	

FDA SERVICE DATES: FROM 1959 TO: 1992 RETIRED? Yes

TITLE: Deputy Director for Systems and Support, CFSAN
(If retired, title of last FDA position)

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DEED OF GIFT

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Jerry Burke

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Chief, History of Medicine Division
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RO: This interview is one of a series of oral interviews on the history of the Food and Drug Administration. Today we are interviewing Mr. Jerry Burke, a retired FDA scientist, in the Federal Office Building 8 in Washington, D.C. The date is July 22, 1993. I am Ronald Ottes. This interview will be placed in the National Library of Medicine and become a part of the Food and Drug Administration's Oral History program.

Jerry, to start this oral interview, would you briefly sketch your education, when and where you were born, the background of what brought you to FDA and the various positions that you held in FDA, and then some of the interesting projects that you worked on during your career in FDA?

JB: I was born in Elkins, West Virginia, in June 1937. In 1959 I graduated from West Virginia Wesleyan College, with a bachelor of science degree in chemistry. Sometime toward the end of my college years I came across information about the federal government as an employer and in fact took the Federal Service Entrance Exam, which was given in those days, on campus. And as it turned out there were only two of those on campus who took the exam that made a sufficiently high grade to draw some interest--both of us chemistry majors. Information began flowing to me from the federal government and within a short time I received ten inquiries for job availability. I soon learned that the Federal Service Entrance Exam wasn't the best route to get a job in chemistry and then made appropriate application to different civil service regions including the civil service office in Washington.

Immediately after graduation I went to work for Marbon Chemical in Parkersburg, West Virginia. They recruited me pretty hard and offered me an attractive salary compared to the federal GS5/7 that was being offered in inquiries I was getting from the federal government. After I had been at Marbon for a couple of months I realized I really didn't like the place, and coincidentally I heard from FDA. I got a call from the resident inspector in Charleston, West Virginia. (I don't remember his name.) We arranged a dinner meeting and an interview. He told me

he would recommend that I would be hired, and shortly thereafter I heard from FDA Bureau of Foods in Washington. I started work with the Bureau of Food, Division of Foods, on August 3, 1959.

RO: What did this Marbon Chemicals do? What were they involved with?

JB: Marbon was Borg Warner's chemical division. I don't recall their range of activities, but they had a major effort in the development of plastic resins and applications for them. One of the plastics that they had pioneered was called ABS Acrylonitrile Butadiene Styrene, a high-impact resistant material. Things like TV cabinets, football helmets, telephones, and that sort of thing were made from the ABS polymer. It probably would have been a good company to be with from what I heard later. But I simply didn't like it, didn't like the work, and to be honest, I didn't like the atmosphere of the group I was with, even the larger group there. It was entirely different when I got to the Bureau of Foods, which had just a wonderful human environment to be a part of.

RO: It was a pretty small unit when you joined it in '59.

JB: Henry Fischbach was the director of the Division of Foods, and I would estimate that the division size was between forty and fifty.

RO: Had Frank Vorhes gone?

JB: Frank Vorhes had gone. Henry had been there, as best I can recall, no more than a year.

RO: And Lowrie was the deputy . . .

JB: Lowrie Beacham was Henry's deputy. Lowrie was the first professional that I met when I came in. I, of course, met Fischbach's secretary, Louise Walstrom, as my entree into the division. And I can remember yet sitting there with Beacham in his office on the third floor of the South Agriculture Building and in that conversation he said to me, "There are people out there from grade 5 to grade 15. Where you get is up to you."

RO: That sounds like Lowrie.

JB: I was assigned to work initially in the pesticides area with George Yip, sort of a technician assistant to George, who was looking at some biochemical means of measuring residues of organophosphorus insecticides. That was a breaking-in period I would say. I'd been there a relatively short time--six weeks perhaps--when I was assigned to work with one of the old-timers, Fred Hillig, who was collecting data on the chemical indices of decomposition of fish. I could see early on that that was going to be a lot of, just churn out the data, and I sensed that I probably wouldn't want to spend too much time doing that. But I didn't have long to think about that, because one of the milestone episodes in government's dealing with pesticide residues happened.

In November 1959 we had the so-called 3 A-T cranberry issue. Three A-T is 3-aminotriazole, a herbicide. The Food Additives Amendment, which included the Delaney clause, had come along in '58, and 3 A-T had been found to be a carcinogen, and its presence in processed berries (i.e., it was by definition a food additive) was an issue. The secretary of HHS, or HEW as it was in those days, had decided to act against it based on the zero carcinogen residue concept of the Delaney Clause. And this was just before Thanksgiving.

RO: Who was the commissioner at that time?

JB: (George) Larrick. That brought our group a lot of work necessary on the analytical chemistry for 3-AT residues, which had not been well-developed. There was a two-prong attack here in Washington: one, working out the details of an analytical method, and two, actually analyzing selected samples in concert with the field. There was sampling and analyses being done by the field resulting in recommendations for regulatory action. So it was a very intense time for the first month or so.

RO: Who headed up that group, that was working on 3-aminotriazole?

JB: I don't think it was a group per se. Henry Fischbach got the division staff together when this broke and set up several two-person teams, initially to deal with samples coming in and the analytical method issues. Danny Banes was the deputy bureau chief, and Banes, an excellent organic chemist, actually went into the laboratory to look into some of the methodology. As this wound down a bit, Bob Storhrer and I were the principal people working on the analytical methods, reviewing the analytical data that supported the field recommendations for regulatory action, and analyzing occasional critical samples. I don't remember exactly how long this went on, but over the next year 3-AT was a major project, at least from my perspective, in the Division of Food chemistry laboratory relating our work to recommendations for regulatory actions, and coming up with a credible analytical method that could be pointed to as the method that FDA would use to enforce the regulation. We did develop an analytical method that met FDA regulatory needs for 3-AT residues in cranberries and a few other products.

RO: Was that a colorometric method you used?

JB: Yes, it was a colorometric method and there was--you know, it's been a long time--but as I recall one of the principal concerns was the inconsistency of results

between laboratories, probably largely because of an unstable colored product being measured.

RO: That was before gas chromatography.

JB: Yes. Gas chromatography came along soon after the 3-AT problem. Three-AT got me into the pesticide work in the Division of Food, and my next assignment was an application of gas chromatography to the measurement of pesticide residues. I stayed in the pesticide area, and that brought me a good bit of contact back then with Bill Cook and with Henry Fischbach, two men, I'd add right quick, that I admire greatly.

RO: Bill was more into looking at the submissions, wasn't he, from the pesticide manufacturers?

JB: Yes, in 1960 FDA reviewed the petitions for pesticide residue tolerances, working with USDA that reviewed the use aspects of the chemical. This continued until about '71 when EPA was formed. Bill Cook was the chief of the branch that did the chemical review of pesticide residue petitions.

RO: And you just continued to work then on pesticide analytical methods?

JB: After the 3-AT emergency, if you will, wound down, I was assigned to work on analytical methodology for pesticide residues. I had a lot of contact with Paul Mills--another man I have an awful lot of respect for. Then we focused principally on the organochlorine compounds, which were the pesticides in widespread use and of principal concern because of their stability and propensity to biomagnify in the environment and in the food chain. Milk and dairy products were principal food

items of concern. I had a good bit of contact with representatives of the milk industry and some states, especially Wisconsin, on analytical methodology.

I'd have to say I was influenced heavily by Paul Mills in pursuit of what we would call a multi-residue analytical method. Paul had adapted paper chromatography, some of the techniques of Lloyd Mitchell, to the detection and semi-quantitative estimation of organochlorine pesticide residues. Paul did ground-breaking work in this area. He presented at an ACS meeting (in 1959, as I recall), and then published one of the landmark papers in pesticide residue analysis. He outlined a scheme to couple the paper chromatography determination with techniques for extraction and cleanup which would allow the paper chromatographic determinative step to detect and semi-quantitate any of about a dozen organochlorine pesticide residues--a multi-residue analytical method.

RO: This was Paul Mills or Lloyd Mitchell?

JB: Paul Mills put together the analytical scheme, adapting Mitchell's paper chromatography to the overall analyses for multiple pesticide residues. When I say pesticides here, it's the organochlorine type principally.

RO: That didn't involve the phosphates then.

JB: At that time, no. This was the foundation of multi-residue analyses that has grown, still growing today, bringing in as many chemicals as practical to the analytical scheme that operates on a single sample.

RO: Do you recall offhand how many chlorinated pesticides that the Mills procedure could detect?

JB: Well, I won't hit the number on the head, but it was, in those days, between six and twelve. Today an analytical scheme derived from that beginning can demonstrate the absence at known quantitation limits of 150 or so residues and provide quantitative measurements of residues found. There are now several different multi-residue schemes that can be operated independently, usually for different chemical types, to expand considerably the total number of pesticide residues which can be analyzed for.

RO: Well now when you say six to twelve on those, how did you quantitate that?

JB: Paper chromatographic quantitation was by the visual estimation procedure. You put a standard amount of the pesticide in question on the paper chromatogram alongside the sample, carried out the procedural steps through color development, and used the eye to compare intensity of the spots from sample and standard. There were people who could estimate quantities reasonably well, and there were people who couldn't. And that was one of the problems with paper chromatography. But in its time, it allowed sorting of samples for residues either above or below tolerance levels with reasonable effectiveness.

RO: So this was really a separation method, and then you did a semi-quantitation with paper chromatography. How did you separate that? With a column or extractions or . . . ?

JB: The separation prior to paper chromatography (or any determinative step) is to remove the gunk that you extract from a biological sample, whether it's milk or vegetable, leaving a solution that is reasonably free of that material but which contains the pesticides. Paul Mills used a column chromatographic step on a material called Florisil to accomplish some of this separation of the sample material. This technique also separated the pesticides into two distinct groupings which were

dealt with separately by the paper chromatography. For example, DDT would be in one of the fractions from the Florisil, and dieldrin would be in another. Paper chromatography will separate, within limits, chemicals according to how they migrate up the paper with the chosen solvent system.

RO: Well now the organic phosphates like parathion, for example, you had to take another sample to extract and quantitate.

JB: Yes, in those early days of research on multiple residue methods, the organophosphorus compounds were dealt with as a separate group, and Bob Storhrer led the work with the OP compounds.

RO: Did it ever get to be a multiple detection scheme on organic phosphates, like on the chlorinated?

JB: Yes, but at that point in time gas chromatography had made the scene. There was some early work with paper and, more particularly, thin layer chromatography of the OPs. But those techniques were pretty rapidly passed over as gas chromatography made the scene in the early sixties--'61. I think that I probably had in the laboratory the first gas chromatograph that we had here in Washington for work with pesticides. There were gas chromatographs in the Division of Food before that time with Bill Horwitz's fats and oils group. The gas chromatograph purchased for pesticide work had the so-called microcoulometric detector. This detector's ability to specifically, or at least selectively, respond to halogens opened up the door for gas chromatography in the pesticides. Dale Coulson at Standard Research Institute was largely responsible for developing this detector which was commercialized along with a gas chromatograph by the Dohrmann Company.

That was followed shortly by other detection techniques, the electron capture system, which was responsive principally to the organochlorine compounds, which

included a few of the OP pesticides. Then the so-called thermionic detector, an alkali doped flame detector very sensitive to OP compounds, which was pioneered by Laura Giuffrida in the Division of Food, really opened the door for dealing with the organophosphorus compounds as a class. The developments in gas chromatography separation and detection, and practical refinements in that technique, opened the door for the development of practical, large-scale analysis for organic residues--in this case pesticides--of quite low residue or, I should say, concentration levels.

Our field laboratories were in this, too. Electron capture gas chromatography was in the field labs before it was in Washington. There was really a tremendous amount of interchange between field labs and with Washington. Many young energetic people were hired throughout FDA in the early sixties, and they wanted to apply themselves and to discuss their work and FDA needs among their colleagues. That was the most fun I had in the nearly thirty-four years I was at FDA.

RO: You were in the laboratory primarily then. All of your career in Food and Drug was not strictly devoted to the laboratory, was it? You were associated with it, but you weren't really getting your hands wet on the bench all the time.

JB: I worked at the laboratory bench until '65. Those were the days before we had merit promotion procedures for selecting supervisors. One day Bill Cook came to see me and told me I was going to be a supervisor. And over my objections I became the supervisor of the halogenated compounds section, which meant that I was responsible for a small group that dealt with the organohalogen pesticides, principally organochlorine. Then we get into PCBs which, although they're not a pesticide, was a group of chemicals of much interest to us.

RO: That was polychlorinated biphenyls, PCBs?

JB: Yes.

RO: Where in the environment did we run into problems with them?

JB: From my experience, FDA first began encountering PCBs in fish in certain locations. We initially looked at them as a problem (an interference) in carrying out analyses for the organochlorine pesticides. It wasn't too long, though, until we had to be interested in PCBs as a chemical contaminant in its own right. I emphasize chemical contaminant here, because I don't consider pesticide residues a chemical contaminant. Pesticide residues may be present on foods via their approved use in most instances.

RO: In most instances?

JB: There are certainly cases of residues resulting from misuse, environmental contamination, etc., but pesticides are permitted to be used on foods, and the law provides for the presence of certain levels of residues in certain foods.

RO: You said you had to distinguish the difference between PCBs and some of your chlorinated pesticides. Could you have mistaken PCBs for a chlorinated pesticide in the analytical scheme?

JB: Certainly, and it probably was done in some laboratories. When I say some laboratories I don't mean FDA laboratories. But during those years I recall a good bit of discussion amongst laboratories reviewing technical reports and so forth to make sure that when we said it was DDT, it was in fact DDT and not PCBs, and we did much research on means of separating DDT and its analogs from PCBs to ensure accurate analysis. In fact, that was an issue in one of the few court cases that we had on pesticides where there was a trial involved. The City Smoked Fish case in Detroit resulted in a major trial. We were trying to enjoin City Smoked Fish from selling smoked Lake Michigan chubs interstate because of DDT exceeding five parts per

million, which had been decided to be the level at which FDA would take action. There were other such cases in Chicago. I don't remember the companies involved.

RO: But with the City Smoked Fish then, actually there was PCBs in addition to DDT, or wasn't there any DDT at all?

JB: DDT and PCBs were present in the chubs, and we were able to show that we could successfully separate the two, thereby making an accurate assessment of DDT level. I recall the defense there also threw out the issue of chlorinated napthalenes. I don't remember the remote industrial use chlorinated napthalenes may have had, but the defense certainly wanted to use these chemicals as a possible reason that we weren't accurately measuring or accurately identifying DDT. We were prepared, because we had tried our analytical procedure with chlorinated napthalenes and had demonstrated before the trial that they can and would be separated from DDT in FDA analyses.

RO: Where were the napthalenes coming into the environment?

JB: I don't believe there was any chlorinated napthalenes involved here. It was a smoke screen by the defense in this trail. PCBs were coming in from numerous, possibly, industrial uses, principal among which was various electrical applications where PCBs were insulators in transformers. That is not the only place PCBs were coming from, but that was a principal one for the Great Lakes.

We later got involved with PCBs getting into grayboard, which was used in food containers. PCBs were an ingredient in the carbonless copy paper which was recycled after use to make cardboard, the so-called grayboard, that went into boxes like cereal containers. Our folks in Kansas City carrying out the Total Diet Study discovered PCBs in certain dry breakfast cereal and showed the grayboard container as the source. This touched off a rather long effort which led to the elimination of

PCBs in carbonless copy paper. The problem was eliminated by a lot of interaction between FDA and industry, not only the food industry but Monsanto, who made PCBs, and the boxboard manufacturers.

RO: You mentioned the Total Diet. Briefly, what was that?

JB: The Total Diet--we now call it the Total Diet Studies--was initiated about 1960 to measure radionuclides in foods. That was back in the days of atomic weapons testing. I think Dr. Laug in the Bureau of Foods--I don't remember the name of the division--was a principal in initiating the study. The sample was a collection of food that would represent the diet of a teenage boy--a rather large diet.

I give the credit to Henry Fischbach for conceiving the idea of the Total Diet Study for pesticide residues. The study has been expanded to include toxic elements, PCBs, and a few other potential chemical contaminants and several chemicals of nutritional interest. Henry Fischbach (who, as an aside, I think is probably the best scientific manager I've seen in FDA) was very interested in measuring exogenous toxic chemicals in foods at levels much lower than the permitted levels for these chemicals. Henry saw the value of looking beyond pesticide residue tolerance levels of residues actually present, thereby with the food consumption data on which the Total Diet Study was based, estimating actual human intake of pesticides from food. This idea was coupled with the fact that analytical techniques, i.e., gas chromatography, were coming of age and could function at these lower levels and do so reasonably well.

The first samples of the Total Diet I worked with was to demonstrate applicability of some of the gas chromatographic techniques and to measure low levels that were found. There was a period of this experimental work around 1962-63 as the approach to the Total Diet Study was taking shape. I think you may have been in Baltimore when some of that was going on, because Baltimore did some of the early work perhaps before it became a formal study.

RO: Yes, I was.

JB: Now the Total Diet Study is a permanent fixture in the FDA's program, in the nation's program. There ain't no other game in town like it. The sample itself has been refined considerably and updated as new food consumption information has been collected through the years, and it's been updated with analytical chemistry techniques as those came along. And over the years it has been moved from being carried out in four or six district laboratories to just one laboratory at Kansas City. Kansas City now has a super program going with much interaction concerning pesticides, toxic elements, and nutrients with the Center for Food Safety and Applied Nutrition. And our data, the FDA data, are looked at worldwide.

RO: There's been some recent publicity on maybe our diet isn't as safe as the Food and Drug Administration has always said that it was. What do you think?

JB: When you "safe" do you mean in regard to pesticides?

RO: Pesticides, yes. I'm sorry.

JB: I would say first that FDA is really not in the pesticide safety business per se. That's the EPA. Given that the EPA established tolerances, or permitted uses and so forth, provide safety to the food consumer, FDA data show quite clearly and have for many years that residue levels are well below those tolerances. These data show that the organochlorine compounds which were eliminated from use in the early seventies, have almost but not entirely disappeared from the diet, because we can still find DDT and dieldrin because of their longevity. But their levels have gone down tremendously. These data show that PCBs, although not a pesticide, have virtually disappeared from foods where it was found several years ago.

FDA cannot explicitly speak to the safety regarding pesticides, because we don't have the toxicological responsibility or the expertise in that area, but we have a long-running monitoring program that shows consistently from year to year and from five years to five years that these residues are within the established safe limits and they've tended to go down. Personally I believe the food supply is safe regarding pesticide residues. Again, personally I think with pesticides, the areas to be concerned about first are environmental insults and the folks, the applicators and the farm workers, who are very close to large quantities of pesticide chemicals. However, the question of potential human insults from pesticide residues on food will continue--long term. And it's FDA's business to gather the data to address the question--which and what amount of pesticide residue are people--adults and kids consuming? That's the reason for the Total Diet Study and for continuing to improve it wherever practical.

(Interruption)

RO: At one time, FDA had the responsibility for setting the tolerances, after consulting with USDA as far as the use necessity. Is that right?

JB: That's correct. Bill Cook, Jerry Alpert, and Howard Jones were involved in that for a number of years.

RO: And then in the late '69s or somewhere in the early seventies that that responsibility was split, and the EPA then was . . .

JB: I think that the executive order which established EPA was in December 1970. In 1971 EPA came into being, and the responsibility for establishing the safe use of pesticides concerning man and the environment became EPA's. FDA retained

responsibility for enforcing tolerances for residues on food and animal feed established by the EPA.

RO: Were you involved in establishing the working relationships with EPA? Did USDA still have to establish that there was a use necessity, and then EPA set the tolerance?

JB: No. EPA got the full responsibility. To your first question, I wasn't much involved in the early days of EPA. I had not been much involved in reviewing petitions. I frequently commented on analytical methods and frequently had some interaction with the people that did laboratory trials of those analytical methods. Later I had ongoing interaction with people in EPA's pesticide chemistry section regarding analytical methods, analytical standards, Pesticide Analytical Manual Volume II, etc. I co-chaired a committee with an EPA representative which served as a forum for dealing with matters of mutual concern and for maintaining ongoing communication. USDA, FSIS, was asked to join the committee and did so. I believe the committee continues to meet.

RO: Did EPA do any validation of the methods?

JB: Yes, over the years they have done that. They've never been able to really keep pace with submissions from industry. It's a very onerous task. They're generally a little bit behind, and once in a while there is an issue about a certain method. We have quite a bit of interaction with them about how a particular method functions especially when it is a method for a widely used chemical or a chemical for which there is a particular safety question. Underlying all of that, we work with EPA to take the methods for the individual pesticides as they approve them and put them into the Pesticide Analytical Manual Volume II. That is one of those jobs that is very difficult to keep up, because it is difficult for it to compete

with other work for people.. But FDA has done pretty well over the long term in maintaining that manual, but it runs behind. It's not up to date with the latest pesticide use EPA has approved.

RO: They talk about the weathering of pesticides, and doesn't that involve more than just the disappearance of the parent compound? Isn't it possible that some of the parent compound could metabolize into something that is more potent?

JB: It's not only possible; it happens. The residue that is left is often different than the chemical that's put on, and the toxicity of the metabolite may be different than the original chemical. I think that Bill Cook's involvement with parathion and some of those organophosphorus compounds illustrates how that could happen. In those days when he was working in the lab, back in the fifties, there wasn't much known about that kind of thing. It's pretty well recognized now that the residue may be different than the chemical that was put on, and EPA's requirements of the chemical's sponsor cover looking at what the actual residue will be and what its toxicity will be.

There continues to be some question about what's the most practical way to monitor the residue if it is metabolized into one or more chemicals. Should they just pick a marker compound and establish a tolerance in terms of that marker? Should they include all the components of the residue, all the metabolite components? EPA has not gone to the marker compound concept for pesticides. I think that this is done with animal drugs.

RO: Does Food and Drug look for some of these metabolites in their analytical procedures?

JB: Oh yes. Our development of multi-residue methods has been geared towards designing a method to measure the residue of interest, which may be a metabolite.

RO: I see.

JB: I should add one other thing. EPA maintains--it's done under contract for EPA--a repository of analytical standards of those chemicals, be it the parent compound or the metabolite that is important as part of the residue. Availability of analytical standards is important to organizations, state, federal, or private that do analyses for residues.

RO: Do you think that with the government's ability to detect pesticides at lower levels has anything at all to do with the way that EPA establishes tolerances?

JB: Well, yes. I don't think you can separate analytical capability from establishing tolerances. If you go back in time long enough you get to those years when zero tolerances were established for certain chemicals. As analytical chemistry progressed, labs could detect and effectively measure a lesser amount; consequently, the value of "zero" changed. I think this is an example of the connection between analytical chemistry and pesticide residue tolerances. Where the chemical is sufficiently toxic to be of concern at a very small amount, the analytical chemistry of today can generally measure it, and the tolerance can be set at a quite low level.

RO: What do you think of the Delaney Amendment?

JB: I shouldn't try to answer that question. I've never been as uptight about it as those who think that it's a major thorn in the side of government administrators. It probably has outlived its usefulness. It probably has cost an awful lot of effort in trying to deal with it, and we could deal with it more effectively--"it" being the chemical of interest--we could deal with it more effectively if the Delaney Amendment weren't there and we scientifically established what the uses and what the

residual amounts, etc., of the chemical may be, based on modern safety testing and so forth.

RO: Do you think that Congress will ever abolish it?

JB: If it were a horse race, I would not bet on it. I don't think they will. There's an awful loud consumer advocacy out there.

RO: Jerry, you were in charge of this methods group for a while, and then you moved on to other assignments within FDA. Do you want to mention some of the other assignments that you had.

JB: I was, I suppose you would say pretty fortunate in that I happened to be around when jobs were open in the early seventies. I became branch chief of a group that had pesticide residue and toxic elements analytical method and related responsibilities. That was a few years after the bureau had reestablished our toxic element capability, which I've often used as an example of how easy it is to get rid of something and how difficult it is to bring it back within an organization such as the government. Let me digress a minute. Long before my time, toxic elements, principally lead and arsenic, were major concerns at FDA, with folks both in the field and in Washington working on analytical methods and sample analysis. In the mid-sixties the Division of Food or its successors had no capability whatsoever for the toxic elements. And along came methyl mercury to be followed by concerns about lead and cadmium. I wasn't principally involved in that, but from the sidelines I could see how difficult it was to resurrect capabilities. When I became chief of a branch that had chemistry responsibilities for toxic elements, the metals group came under my management, and I was quite pleased at some of the capable young people there, some of whom are still here. So we have a top-notch toxic elements group now, and there's some top-notch toxic elements capabilities in the field. Someplace

in that period of time the analyses for lead, cadmium, and a few other toxic elements--was put into the Total Diet Studies.

Then in the mid-seventies I became an associate director for the Division of Chemistry and Physics. John Howard was the director. That went along for a couple of years and we were up through 1980. There was a retirement in the Division of Chemical Technology, and I was asked to take that division on a one-year assignment, and I eventually became the director.

The Division of Chemical Technology was established '72, about the same time EPA was formed, with the intent here in the foods organization of focusing on the so-called industrial chemicals, those chemicals that have no reason for being in food. PCB is an example. That division was formed from out of what was the pesticide analytical methods unit. In fact, bureau management eliminated for all practical purposes the pesticide unit in what is now the Center for Foods. Looking back over my career, that's one of the things I objected to the most. I thought it was a mistake then, and I continue to think it was a mistake as we look at the situation today with the National Academy and others saying, and all the years in between, that we need to pay attention to pesticide residues in food. Even though I believe that pesticide residues in food do not present a safety problem relative to EPA tolerances, pesticides more than anything else I believe has shown FDA that consumer confidence in food safety is a significant issue, an issue we have to deal with. And it can only be dealt with by data; we can't deal with it by rhetoric. I believe the bureau leadership that abandoned pesticides, for all practical purposes, in those days made a mistake.

RO: Who was the bureau director at that time?

JB: Virgil Wodicka. I stayed with a small group that did some pesticide analytical methods and related work and tried to maintain support to the field, but it was very difficult. The pesticide laboratory in the center gradually was brought back, but it

was a slow, painful process. In my Monday morning quarterbacking on this issue, I have always believed that the center could have done both the chemical technology and the pesticides without throwing the baby out with the bath water, so to speak.

In 1981, when I became director of that Division of Chemical Technology, its work on the industrial chemicals was beginning to wane. It wasn't too long before the division was reorganized to include work on pesticides, toxic elements, industrial chemicals, and the division also had responsibilities related to field programs in those areas.

RO: Typical of the government, every time you got a new bureau director did the bureau reorganize?

JB: I don't think so. I'm a little bit vague on recalling all that happened over those many years. Bob Roe was the bureau director when I came in, and there was a reorganization not long after that to set up a Bureau of Scientific Research and a Bureau of Scientific Standards and Evaluations, and you can see what was happening there, sort of separating research from the premarket approval process. The reorganization under Wodicka in the early seventies was to set up product technology organizations; there were chemical, cosmetics, color, and food technology. There were a number of people brought in with industry backgrounds. Charlie Jelinick and Bob Schaffner were two that I principally remember. I worked for both of them. Jelinick was the initial director of the Division of Chemical Technology and did a great job with it.

RO: I thought Schaffner was more involved in . . . rather than chemical technology, wasn't he . . .

JB: He was trained as an engineer with an industrial career as a food technologist.

RO: Food technology, that's right.

JB: And Schaffner and Jelinick were on board at the time that the interest in lead intake mushroomed. They were much involved in the initial work with the trade associations and the canning industry to turn industry heads toward paying attention to reducing the lead levels in food. I think Schaffner's industrial background positioned him quite well for doing that. That was the start of a long program that was still going on when I left here four months ago--working with the industry to eliminate or minimize the lead that their product may contribute to food, developing some additional regulations, improving monitoring for lead in food, and providing information to help the consumer avoid dietary lead.

RO: As a division director or a branch director, did you have any input into the center's program priorities?

JB: When you say program, I'd ask for a little clarification on what you mean.

RO: I guess I'm thinking more in terms of the field programs, because the agency gets a chunk of manpower that's supposed to be spent on foods and drugs and things, and a certain amount of it is going to be spent in the field.

JB: Yes, when you put program in terms of the center's influence on the field sampling and analyses programs, I felt that I had a good bit of involvement with the pesticides, industrial chemicals, and toxic elements. I got my two cents worth in, so to speak. With analytical methodology the question often arises, Is the method there to support a program? I'm happy to say that from that standpoint we had a good bit of involvement ranging from the research that was conducted to specific input on whether a method was suitable, the methods capabilities, and limitations, etc. There was also the involvement on selected chemicals, like PCBs. What can we do? What

are our limits of quantitation? I think the center and its predecessors the bureaus have always paid a lot of attention to the analytical capability (or lack of it), in addressing regulatory sampling and analyses. They don't go ahead and do something until they find out about the analytical chemistry involved; where do we stand on the analytical method? The management here turns very quickly to the folks in the laboratory.

There has been in the past, and it should continue in the future, a good network of people here and people in the field, principally at the chemist or the first-line supervisor level where you pick up the phone and call somebody in some district and say, "How's this working?" You also know some field labs that are good at some things. Different field labs do different things well or not so well. I would say we had . . . I had a good bit of opportunity to be influential that way. And I had ongoing opportunity to contribute to the overall content of monitoring programs for pesticide residues, e.g., food/residue combinations to focus on.

For example, FDA did a PCB Atlantic Coast Bluefish Monitoring Project several years ago. Buffalo district got that work. Well, obviously we couldn't decide what district would do it, because that's too complicated and wasn't our management prerogative anyway. But we had good feelings about where the capabilities were, and we had some informal conversations with the people there and some informal conversations with the people in the field headquarters organization so it could be planned smoothly and get a good product assured. I believe the groups I worked with had a good reputation for responsiveness and what I'll call product integrity. This good reputation allowed us to have continuing influence in a very general way.

RO: I can remember when I was in the field and you'd submit a recommendation for seizure on a pesticide residue, for example. And the analytical worksheets and all the documentation came into the bureau, and somebody with their eagle eye would go over it and decide whether or not the analytical work was sufficient to support a seizure. Did you continue to do that?

JB: I personally didn't continue such technical reviews, but the people in the group did. Someplace along the line--I think Tony Celeste was still here then--it was decided to formalize the process for pesticides in terms of the communication between the field organization and the Center for Foods. This involved principally the center's former Division of Regulatory Guidance, which received these recommendations and sent the analytical report to the chemistry group, which I was in charge of at one point, for review. I insisted on those things being a high priority. For example, if they came on Friday afternoon, they got looked at. I think that principle still holds with the people there now doing this work. The field's Division of Field Science had a specific role to play and a knowledge of what the technical review covered. Division of Field Science had a role; the center had a role; and they worked together in communicating with the respective field office. I think that has worked pretty well. There is always a problem, though, if you overdo the technical review, either on any one item or too many items or taking too much time to turn around a recommendation from the field. Technical review of field recommendations for regulatory actions was being looked at when I retired to determine if certain types of analyses and situations would not require center technical review.

RO: I remember one of the fellows that used to be in the bureau. You probably remember him--Sid Williams. And Sid used to look at the analytical work with a jaundiced eye. I think he had a warm feeling about the work coming out of some districts and not such a warm feeling coming out of other districts. And I'm sure that that happened a lot of times.

JB: Well, there's certainly a lot of tension there when someone is reviewing someone else's work, and also there's the time factor--the field feels put upon that they've got to wait too long for somebody in Washington to give the go-ahead. The procedure that we set up when Tony Celeste was here I think helped to separate the review of the particular recommendation for that particular situation from additional,

more general comments about how this type analysis was carried out. We set up the review so that there were two parts to it, and you could clearly separate them. If there was quality control comment for the respective analyst and managers to deal with, it was set down totally separate from, "Yes, this work will support action" or "No, it won't." Of course, if it's "No, it won't," then some details must be given. Sometimes with a "Yes, this work will support action," it is important to add, "However, next time it might be useful to consider improving some aspect of this type analysis."

RO: There used to be a criticism in the field that the bureau was working on methodology, but they weren't in the real world. They weren't confronted with the problems that the analyst on the bench in the field was. How did you try to overcome that so that there was more of close feeling between the field and the headquarters' chemists?

JB: Well before I say how it was tried to overcome this, I will say that I think that there's always going to be a certain field/headquarters tension in any organization that has a field unit and a headquarters unit.

I think the pesticide workshop for field and center chemists that was begun in 1963 with people like Reo Duggan and Paul Mills and Bill Cook involved was the principal thing that was done, probably not specifically to overcome this attitude but to get at problems and define the analytical methods. But it had the bonus factor: people got to know each other, and they got to talk shop, and it made it easy to do what I had mentioned earlier, pick up the phone and call somebody whether you were calling from the field or to the field. And those workshops still continue, not at an annual rate any more, but every other year. And then there are some spinoff meetings such as with the Total Diet Studies chemists and center people. So I think that getting together face to face to work on real problems helps to overcome the organization tensions. When people know each other they can be more effective.

These workshops were held at a field location, hosted by the field, so that field staff would more or less be the leader. Oftentimes there were laboratory demonstrations. There were lab walk-throughs and highly detailed discussions so that you could get to understand the other person's problem.

RO: Of course, back in the days when (Allan) Rayfield ran the field, it was a no-no for the field to call directly into one of the scientific or technical divisions. The queries were supposed to go through BFA headquarters, and then someone there like a Hy Eiduson or somebody would contact someone in the bureau and get the answer and then go back to the field again. I never agreed with that, but that was kind of the relationship that he wanted.

JB: I think direct contacts are vital, but there are matters that must be handled through the organization, and then there's direct contacts. You don't make management and administrative decisions or assign work through these informal things, but if you prohibit scientist-to-scientist interaction you lose an awful lot in the process. So good judgment has to be invoked in deciding how you communicate.

RO: When the field established the research centers, a pesticide research center was established in Detroit. What was the headquarter's or the bureau's reaction to establishing strictly research unit in the field?

JB: I tried my damnedest to stop it. And then I tried even harder to get the functional statements to say that these centers would do certain types of monitoring or investigative sample analyses, in addition to methods development, etc. I worked harder on the functional statements--to no avail--than I did to stop the center idea. There was in my judgment, looking at it from down here, a very narrow-minded view in setting up the research centers to do research to develop analytical methods, where much of what this agency needed in the respective topic areas was informa-

tional--what (pesticide, contaminant, etc.) is out there and how much of it is there in the food supply, data that you couldn't easily get through the regular sampling/analyses programs, data and information that offered an opportunity for publication, studies that would build upon the field's capability to acquire samples and get information about those samples, but doing the sampling and analyses in an investigative type of way (i.e., research), perhaps using methodology, that couldn't be used in the regular program and in publishing the findings. But that wasn't well received at all.

RO: In the bureau.

JB: No, in the field. The field didn't like that idea. The field management's desire was, it seemed to me, not have these folks doing anything that involved sample analysis but doing "research," presumably on analytical methods.

RO: What you are saying, then, is to really have a surveillance sampling program to determine the residues that were out there. Is that right?

JB: I would permit investigative sampling and analyses focused to answer particular questions about specific chemical and/or food. This would have been a research center function, not to be totally what they would do, but have it as something that they do. Yes, if I had been God there wouldn't have been any research centers. I would have emphasized the Total Diet Studies and put a lot of support around it.

RO: Well wasn't the bureau involved, though, in what kinds of work the research centers would do?

JB: Oh yes. We had to be, because the research centers were going to happen. The part of the organization I was with, and with Charlie Jelinick as program manager for pesticides and chemical contaminants proposed research, reviewed work from the centers and had meetings, either face to face or by phone, to plan research center projects. When I retired, this type of communication was still occurring. Now there is an FDA Pesticide Analytical Methods Research Plan that includes all the methods research.

(Interruption)

RO: Jerry, during your career in the Food and Drug Administration, what do you think were some of your more noteworthy accomplishments--I mean, as far as projects were concerned?

JB: Well, when you say project . . .

RO: Or programs

JB: I think that I could reflect in a positive way on the transfer of analytical technology from headquarters to the field; something that was developed here, getting it into the field, and then working through improvements in its application. And that's not to suggest that one person or one organization does it all. But I think I've had some positive influence there.

I've mentioned earlier that Paul Mills had gotten FDA started with multi-residue methods. I think through my stubbornness and persistence we have maintained work here and in the field to increase the number of chemicals that can be monitored for with our analytical schemes. In other words, you get more bang for the buck every time you do one of those analyses if you know the analytical behavior of a large number of compounds. Gathering this data is not glamorous work, and

you don't finish it at one setting; you keep adding knowledge, little by little. I kept a little fire lit under that all along.

I think that I had some influence on defining and reasonably maintaining throughout the monitoring program specified limits of quantitation in our pesticide residue analysis. With this approach we could say, after the fact, that we had analyzed for a certain residue and showed it was not present above the specified limit of quantitation of FDA's analytical method, or we could readily state where the agency could take regulatory action in a no-residues allowed situation. This allowed the agency to state how low the methods would determine a certain pesticide residue. We had to draw a clear line somewhere, i.e., the lower limit of our analytical capability. The technique we came up with--I call it a convention--for defining a limit of quantitation, was very useful there. John Wessel was very helpful in working out and supportive of the limit of quantitation approach. You can never get it applied exactly in a large number of laboratories, but you always have a benchmark to come back to and say, "Here's a way to set up the method to meet a certain quantitation limit, and here's the quantitation limit we strive for, and we can calculate the quantitation limits for other compounds for which we have developed prior detection response data."

RO: In other words, the sensitivity of the method.

JB: Yes. I'm using the term "limit of quantitation" to be synonymous with the often-used term "sensitivity of the method."

RO: Was your group responsible for the pesticide analytical manuals?

JB: For many years, the responsibility for maintaining the Pesticide Analytical Manual (PAM) has been in the center. The PAM was initiated with an awful lot of effort by Reo Duggan and Helen Barry with support from a number of

other people--Loren Johnson, for example. From a management perspective, I fanned the flames under the PAM over the years, and I think that had not somebody done that the PAM would have died. We're very close to having a complete new edition. In fact, Bernadette McMahon, the co-editor, is having a party Monday evening so that folks who are in town for the AOAC meeting will have an opportunity to reflect on that a little--you know, some of the key people who have been players over the years, and that includes the field people. There's been a lot of input from the field on the PAM. This input is vital, even if it's nothing more than comments by key field chemists about how a method works and how we should construct the writing in this manual to reflect some of those practical things.

RO: The PAM is pretty well accepted internationally, isn't it?

JB: Yes, it's probably *the* most comprehensive source of complete instructions on how to analyze for pesticide residues in food products. The PAM lets FDA say--and I think this was the reason for its initiation--"Between these covers are the methods we use." We don't have to refer to a lot of places in the literature. We don't have to scramble around and equivocate about it. Here are FDA analytical methods for pesticide residues. It's not always up to date; we've usually got more material in preparation. But, with that qualification, FDA can say here are the methods used in this country to enforce the pesticide residue tolerances, as well as to collect data on residue incidence and levels in food. The major interest in FDA's pesticide work from the outside world is not in enforcement; it's in what's in food, residue incidence, and levels. I would guess that after the National Academy report on kids' exposure to pesticide residues there will be a greater interest in monitoring to gather data on residue incidence and levels; more federal spending to measure pesticide residues in food.

RO: What about standards for the pesticides? Is there a source of standards that is considered, authentic standards, or do you have to go back to the manufacturers?

JB: The EPA maintains, as I mentioned earlier, through a contract, a repository of pesticide analytical reference standards. EPA maintained the standards repository in-house for years. From what I have heard from the people in the field and in the center a few months ago when I was still here, the standards program was handled better at EPA than it is under the contractor.

Over the years it has varied as to who could get those standards without cost. I believe that costs associated with getting the standards from a contractor is presenting difficulties to some organizations. Maintaining a standards repository is one of those unglamorous and costly things that this agency has to go to bat for periodically to say, "They're absolutely essential for us to do our job, and are also essential if the states and foreign countries are going to participate in pesticide residue monitoring, and it's essential that they do because we've got an awful lot of international trade in foods."

RO: Sure.

JB: Pesticide residues are a matter of concern beyond safety. You can quickly move out of the safety area into trade areas if things aren't done right.

RO: Earlier you mentioned Florisil. You were able to purchase a standardized Florisil that you knew was going to work. There were also redistilled solvents that were required. Are they still necessary, or are you to the point where you don't need that?

JB: The solvent question is probably the easiest to answer. FDA--it was someone in the field organization; I've heard it was Reo Duggan--said to a laboratory solvents

supplier, "We need a solvent that performs in a certain fashion." He pointed out the need for petroleum ether and possibly other solvents which do not contain electron-capturing substances which would interfere in gas chromatographic analysis for pesticide residues. Burdick & Jackson, a little company in Muskegon, Michigan, started meeting that need with its petroleum ether and perhaps a few other solvents. Some of the big manufacturers saw the market potential, but Burdick & Jackson met FDA's needs, the company grew and was a major supplier of FDA for a number of years. But it's gotten to the point now that solvents that meet these stringent requirements for pesticide and similar environmental contaminant analysis are available from a lot of suppliers.

Florisil I think--I'm not sure of this--but I think we still do pre-purchase batch testing in Minneapolis field lab to see if the material, which is made in Berkeley Springs, West Virginia, meets our requirements for separation of pesticides. It's a matter of trying to selectively purchase Florisil production lots that meet FDA performance needs. The manufacturing process was not that carefully controlled. Maybe it wasn't controllable. This was handled much better after we began pretesting of lots and supplying all field lab needs from a central supply maintained in Minneapolis. Florisil is not used as much anymore; because of the interest in different pesticides, there is different methodology than in the past.

The chlorinated pesticides are no longer the principal ones of interest. With the analytical approaches pioneered by Milt Luke and made better and used more over time, Florisil is not regularly used until some ancillary tests are needed on the extract.

RO: You were in the bureau under a number of different bureau directors. Did you see much difference in their emphasis from the scientific standpoint, their regulatory philosophy, going back to, well, you said Henry Fischbach was the first . . .

JB: Well, Henry wasn't a bureau chief.

RO: No, he was a division chief back then, but Bob Roe was there. I'm thinking more of when Dr. Summerson came in. I forget now whether he was a bureau director or whether he was . . .

JB: During my time I can recall Roe, Summerson, there was Keith Lewis for a little while, Virgil Wodicka, Howard Roberts, Sanford Miller, Dick Ronk, Fred Shank. Those earlier ones I never had a lot of direct interaction with. I've commented earlier that I thought Wodicka was mistaken in some of his organization changes which virtually eliminated research on analytical methods for pesticides. It was a personal feeling of mine that he was kind of aloof to the laboratory scientists, but when he wanted answers from the scientists, he called. The first time we ever met he said, "Do you know you've been charged with your laboratory getting a different result than Campbell Soup?" I was on the plane up to Campbell Soup in a couple of days. As it turned out our laboratory was correct, and we--Judy Armour, who was in my laboratory group--were able to effectively discuss this with Wendell Phillips and his folks at Campbell Soup.

RO: What was the pesticide?

JB: I don't remember. It may have been PCB. I think it was PCBs, because Judy Armour was along. Virgil Wodicka had met some exec from Campbell Soup at a meeting, and some little thing got blown out of proportion as top management often does, and Wodicka greeted me with those words. I never was and am not, I guess, a fan of Wodicka's. I had most of my interaction with Sandy Miller and Dick Ronk, and of course, Fred Shank.

RO: Well, Howie Roberts came in the interim. He was in the bureau's mathematics group, and then he was elevated as an acting bureau director, I believe . . .

JB: I don't recall too much about Howie's tenure other than I periodically was involved on some analytical method issue, usually to address the practical question, What can we do about thus-and-so? I worked closer to Miller, Ronk, and Shank. I think Fred is more effective than the other two.

RO: Sandy was another one that came from the outside.

JB: He was really a nice guy, but to me a little bit academic. And I guess I couldn't detect in him an organized direction of things. Most likely it was there and I couldn't see it, but I wasn't really sure where we were expected to be heading. Dick Ronk knew FDA inside and out, very intelligent guy, very intelligent guy, probably a little out of his element as a center director, a man that really cared for people when you got the time to talk with him. He could tell stories about you, and about me, and about people that have had difficulties. He's a very caring fellow when you get the chance to listen to him.

RO: What happened . . . Dick got in trouble, didn't he, as far as the center is concerned and ended up working for Mike Taylor now in the Office of Deputy Commissioner for Policy.

JB: Yes, he's with Mike Taylor now. Ron, I don't know what led to that. I think, though, that he and Young, Commissioner Young, did not . . . You know, they didn't make good chemistry together. And Dick was very quick to speak his mind.

RO: Oh yes. You never had to question that at all. He spoke what he thought.

JB: And by the same token I think that Fred Shank made a good impression on Young, because Fred kind of filled in a void as deputy to Dick and really hustled to organize the center director's office.

RO: Dick always impressed me as being a rather disorganized guy.

JB: Yes, his office spoke that to you if you looked at it.

RO: This last reorganization of the center . . . And that was shortly, I guess, before you retired, right?

JB: Yes. It was in November of last year.

RO: And your title then, when you retired, was deputy director for . . .

JB: . . . Systems and Support.

RO: And I'm uncertain how that fit in with what the rest of your FDA career . . . I guess I don't understand really what that deputy director's responsibilities were.

JB: As management looked at the way the center might be organized, it was decided not to organize along the traditional scientific discipline areas, instead, setting up offices that would have a broad, integrated responsibility ranging from research to regulatory. For example, the Office of Premarket Approval would have some laboratories, toxicological and chemical, which would support the premarket review responsibility. A large part of what the center has to do is in various administrative and internal management areas and ongoing work which cross out all of the program responsibilities. More visibility was needed for the center's field relationship, recognizing that the center and the field need to really be close. So a

two-deputy approach was taken--one center deputy for the center's programs (premarket approval, seafood, etc.) and another deputy for the range of things which provide continuous support to the center's programs. I believe that this elevated the visibility and recognized the importance of these vital support activities.

Why did they choose me?

RO: No, not, at all. That just seemed like it was not what your career had been associated with?

JB: Well, I frankly wasn't surprised when Fred Shank asked me to be the Deputy for Systems and Support (OPS). Although my career was associated with the technical aspects of pesticides and chemical contaminants that we've talked about most here, the last several years as director of the Office of Physical Sciences I got broadened a little bit. We had some premarket review in OPS. We had some other laboratory chemistry areas such as mycotoxins, food additives, color, and cosmetics. And during that time I had much more of an opportunity to participate at the center level on policy and administrative matters. I think that probably more than any of the other director-level people here, I recognized the value of the administrative side of the business and the importance of having a quality program there, as well as in areas generally considered to be support. Someone has to "carry water to the front-line troops," and, for example, that water may be the mass spec laboratory getting a particular sample completed so that the big research project can reach a conclusion. That mass spec, in that case, was the support. The mass spectrometry laboratory and other scientific/technical areas are organized on the support side.

RO: I see.

JB: I believe, Ron, I had a reputation for dependability in delivering a product--products that support a larger objective--and recognizing the value of support, and

I had a reputation for being reasonably responsive to the administrative things that an organization this size has to attend to: personnel, quality control, safety, you name it, the various management reports that the folks in those parts of the organization have to produce, under certain constraints of time, format and so forth, which many on the scientific side think are a waste of their time. They may be, but these things are still required to be done. The Office of Physical Sciences had a reputation of meeting its requirement on those kinds of things. So I think these are some of the reasons that I was asked to take that job.

RO: Systems, does that include your management information systems?

JB: Yes, the computer systems and so forth.

RO: You ended up with a master's degree?

JB: No. I have a bachelor's of science in chemistry, I had chemistry course work, at Georgetown and American University that would about amount to a master's degree, but I don't have a master's degree.

RO: For a bureau, like a lot of them, I can go back to when it was rumored--and this was back in the sixties, about the time you came in--that one of the reasons that Lowrie Beacham never got to be the director of the Division of Foods at that time was that he didn't have a Ph.D. You didn't have an advanced degree, but you got a bureau here in which most of your divisions and other offices had Ph.D.s. Did you ever feel intimidated by that?

JB: I didn't feel good about it. Not so much intimidated but, gee, it would be nice to have it, because you are either Dr. who or not Dr. Who; and not being a Ph.D.

stands out in a scientific organization, meeting with outside organizations, etc. It's an important prestige thing.

RO: Well, obviously you didn't need it.

JB: I believe the Ph.D. title reflects in a positive way on the organization you're leading or representing. I'd be quick to say that nobody ever used my lack of the Ph.D. as a reason for holding me back. And I'd also be quick to say that I had unbelievable support from my managers, my bosses so to say, as well as the people that I worked with and the people that called me their supervisor. Great cooperation. And what I didn't accomplish was nobody's fault but mine.

RO: I didn't want to leave you with the impression that I didn't think you were qualified for the jobs you had because you didn't have a Ph.D., but it's really a credit to your capability that you . . .

JB: You know, Ron, I think it's a credit to the people who were making the decisions. Not to say that giving me an opportunity was a good thing, but that I was here a long time, and I just didn't see discrimination. They were looking for--and part of the time I was amongst that "they" who were looking for--somebody that could do the job well and be relied upon.

RO: That happens. Are there any humorous stories about any of your colleagues that you would care to share with us.

JB: Oh, gee. I don't know. Probably if I thought long enough I could think of something, but probably never do it well within the time we have here.

RO: Well, Jerry, is there anything else you want to add?

JB: I would just like--and we've touched on it many times here--to add that I've always thought that I was a supporter of the role and the value of the field organization and the Center for Foods working together. I had the opportunity to attend the Field Food Committee meeting just before I retired. There was discussion, and pretty candid discussion, about things like research centers and the type of projects. One of the prominent field leaders made a remark. He didn't really mean anything derogatory by it, but I jumped in. He said, "Oh, you mean, you do it this way and then just let them do the scut work, the analyses." I took strong objection, and I did a little bit of it just for emphasis, to referring to chemical analytical work as scut work, saying, "These people, these analysts are well trained. Many of them are experts in their fields. That is not scut work. The result of any study is going to depend on how well the analytical work was done. Can it stand on its own merits? We ought not to be generating that kind of thought about the person that's there at the bench doing this work." I believe the message was received well, and I think they understood where I was coming from, that we've got to elevate the notion of the value of the chemical analytical work these people do. Being an analytical chemist or an analytical microbiologist is not like sweeping the floor--not that sweeping the floor is scut work either. The laboratory analytical work should be recognized for its enormous value to FDA food safety programs.

RO: Well, probably the reason that that comment came out was that so many times the field felt like surveillance work was "busy" work. You know, you go out and pick up a bunch of samples and analyze them for this. And after a period of time, if you're doing one analytical procedure on five hundred samples, that gets to be pretty routine, and you don't need to be an analytical chemist a lot of times to do that. I don't know who made the remark, but that's probably the reason they said it.

JB: Part of this kind of thing can be overcome by more interaction, and some of that's occurring. Doug Archer was up in Boston in exchange with Ed McDonnell, the

Boston director, for a month just before I retired. Carl Reynolds is in here from Detroit now. I understand that Tom Billy and Roger Lowell are going to switch seats for a little while. If you think there's glamour in the Center for Foods, I think you're mistaken. (Laughter) There's a lot of repetitious work here, too.

RO: Oh sure. That, at least, is the perception a lot of times in the field. They're expected to do a lot of the routine analysis and not have the fun of doing the research. And, of course, I know there's a lot of AOAC projects on which the field gets to do research work, and that's supposed to be the rewards.

Was there anything else, Jerry, you want to add?

JB: Probably some of the best times we had, Ron, were when you and Loren Johnson and I were in the old South Ag building . . .

RO: Fighting the cockroaches.

JB: About 1960, to give a date. Is Loren still . . .

RO: He's still district director in Philadelphia.

JB: I heard some mention that he might be retiring.

RO: I think the last I heard he was considering maybe next year for retirement. Well, those were good times. I think back. You mentioned Bob Storhrer and Paul Mills, and I think about that old South Ag and the Liar's Club where we had lunch every day. You haven't forgotten that surely. And there was a lot of fraternization there.

JB: Well I was pleased that Beacham and (Les) Ramsey came to my retirement party, and both of them had some words to say. Ramsey said he was eighty-four--looked good, spoke good.

RO: Well, Jerry, I want to thank you for participating in this interview.

JB: In closing, I'd like to say that as an employee of the federal government I always believed, and reminded myself, that I worked for the people out there throughout our country. As a supervisor, I always felt that I worked for those that I supervised and tried to be responsive to them. And I always answered my phone calls and mail promptly.