

HISTORY OF THE U. S. FOOD AND DRUG ADMINISTRATION

Interview between:
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Retired Assistant to Director
Bureau of Foods
and
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U. S. Food & Drug Administration
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TAPE INDEX SHEETCASSETTE NUMBER(S) 1 - 4GENERAL TOPIC OF INTERVIEW: History of the Food and Drug AdministrationDATE: 8/28/85 PLACE: Alexandria, Virginia LENGTH: 190 Min.INTERVIEWEEINTERVIEWERNAME: Lowrie M. BeachamNAME: Fred L. LofsvoldADDRESS: [REDACTED]ADDRESS: U. S. Food & Drug Admin.[REDACTED] [REDACTED] Denver, ColoradoFDA SERVICE DATES: FROM 1934 TO: 1974 RETIRED? YesTITLE: Assistant to Director, Bureau of Foods
(If retired, title of last FDA position)

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INTRODUCTION

This is a transcription of a taped interview, one of a series conducted by Robert G. Porter, Fred L. Lofsvold, and Ronald T. Ottes, retired employees of the U. S. Food and Drug Administration. The interviews are being held with F.D.A. employees, both active and retired, whose recollections may serve to enrich the written record.

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

FL: This is an oral history interview on the History of the Food and Drug Administration. The interview is with Mr. Lowrie M. Beacham at his residence in [REDACTED]. The date is August 28, 1985. Interviewer is Fred Lofsvold.

Lowrie could you start this by putting on the record sort of an oral curriculum vitae of where and when you were born, where you were educated and when you came to the Food and Drug Administration. And then, with approximate dates, the various jobs you held with FDA.

LB: I was born in Atlanta, Georgia on October 27, 1911 but very shortly my parents moved back to their home area which was the State of South Carolina. So, I was educated in South Carolina and received a B.S. degree in Chemistry from the University of South Carolina in 1931. There followed several years during the depression, when jobs were difficult to find, and I found them also difficult. In October 1934, I received a communication from the Food and Drug Administration from L. M. Clarke who was then the Chief Clerk asking whether I would accept temporary employment as a seafood inspector at New Orleans not to exceed six weeks. I replied by telegraph that I would accept such employment and the next day I received a second telegram directing me to report to the Customs House in New Orleans on the morning of October 22, 1934. I did and became a seafood inspector, a position I held until January 1936.

In January 1936, I was transferred to the Food Division in Washington because at that time the Division was actively engaged in preparing standards under the old McNary-Mapes Amendment to the Food and Drugs Act of 1906. I remained in the Division of Food, and its successors, for the remainder of my career, starting from the position of junior chemist which I received when I came to Washington in 1936 and moving up slowly through the career ladder. I became assistant to the chief of the Food Division in 1941 and in 1949 I became chief of the Fruit and Vegetable Branch of FDA.

In 1957 I became Deputy Director of the Division of Food and, following a reorganization in 1963, I became Director of the Division of Food Standards and Additives. I kept that job until 1968 when there was a second reorganization and a Division of Food Chemistry and Technology was established. I was appointed Deputy Director of that Division in 1968 and became Director of the Division in 1970.

In the meantime, the Food and Drug Administration had become involved in the Codex Alimentarius program, which is a program sponsored by WHO and FAO to formulate international food standards. I was asked to head a number of delegations to the meetings of the Codex Alimentarius Commission and its program. This began to occupy more and more of my time and in 1972 I was made Assistant to the Director of the Bureau of Foods for International Standards and for the last three years

of my career, I devoted almost all my entire time to the International program.

I retired from FDA in December 1974, having served 40 years, 2 months and 5 days.

FL: Like so many other FDA people of your era, and mine, you started with the seafood services. Could you talk a little bit about some of your experiences there, what training you had and what happened when you got out into the plants.

LB: That was a very interesting experience. When I became a seafood inspector, I do not believe I had ever seen a live shrimp or even an uncooked shrimp. So, when I arrived in New Orleans and reported to the Customs House, E. C. Boudreaux was the chief of the station and Malcolm Stephens was the chief inspector. Larry W. Strasburger, a bacteriologist, had recently been transferred from the Washington office to New Orleans to become the immediate supervisor in the seafood service.

So, under Malcolm Stephens and Larry Strasburger's direction, about six or eight of us who had appeared in New Orleans at the same time were given about a week or 10 days training. We were taken into the plants, we were shown the plant operations, the fishing operations, the unloading. We were shown what good shrimp looked like and what deteriorating shrimp looked like. Then we were given an intense training or study of the new seafood regulations which had just been drafted and

a cursory study of the Food and Drugs Act of 1906. After this brief period of training, each one of the new inspectors was taken and assigned to a plant somewhere along the Gulf Coast. At that time the program had perhaps a dozen or 15 plants operating and they extended all the way from Bayou LaBatre in Alabama to Golden Meadows in Louisiana and shortly thereafter all around the Texas coast, Aransas Pass and Palacios. I was assigned to a plant in Biloxi, the Seafood Packing Company, and I worked there with another inspector who had about three weeks more experience than I'd had, one Kenneth McClure.

I remember well the first morning that I went on duty. We were called at about 1:30 in the morning and went down to the plant at 2:00. One of the characteristics of the gulf seafood industry or the shrimp industry was that they usually began operations about 2:00 or 2:30 in the morning which often meant that by the time the sun came up they were finished with the day's operations. I never was able to understand the rationale of that but I was never able to change it either. FL: Did they catch the shrimp earlier in that same night and bring them in or ...?

LB: Well, if the inspector was lucky, they had caught them the previous night or the previous day. But often times that was not the case and sometimes at least some of the shrimp in a load might have been caught several days or a week earlier and so one had to always be on the lookout for these pockets

of old shrimp that would be carefully hidden and concealed and mixed in with the good ones.

FL: Your job then was to see that they properly sorted these shrimp to remove the bad ones.

LB: That is correct. The procedure was that all of the shrimp, when they were unloaded, had to be passed over an inspection belt and the plant, of course, furnished the sorters who were to pick out the unfit material. The inspector had to be in the plant at all times when the plant operated but he had other responsibilities for watching operations in the plant other than the belt. But the inspection belt was the critical point in the plant because a few moments' absence from the inspection belt and the unfit material could readily find its way into the packing room. And so the inspector had always to be on the alert to see that this didn't happen because, as I said, the loads might well be mixed and what appeared to be a very excellent load of shrimp when the boat was first opened could very readily change in character in the next few minutes.

Shrimp in those days were measured by the barrel but they were not packed in barrels. They were packed in the hold of the boat, with ice, and unloaded by being first shoveled into wire baskets. There were three baskets to a barrel and a barrel weighed 210 lbs of shrimp. The price that was received for the shrimp at the plant in those days was \$4.50 a barrel;

\$4.50 for 210 lbs of green shrimp.

FL: Were there other problems in the plants besides the quality of the shrimp.

LB: The quality of the shrimp was the principal problem. There were many other regulations that had to be observed. The plant had to be screened, the operator had to keep flies down, keep the flies out if he possibly could. There had to be the usual cleanup all of the time. The pickers - the women who shelled and deheaded the shrimp were called pickers - they were supposed to wear head coverings and there were numerous other regulations. And then another very important one dealt with the proper processing of the canned shrimp.

Food and Drug Administration had received from the National Canners Association recommended heat processes for the several sizes of cans in which shrimp were packed. And the retorts in which the cans were sterilized were equipped with recording thermometers. So each cook had to be identified on the chart and the inspector had to make certain that each retort load had received the full cook and initial the chart.

Then, on the finished product the inspector had to certify each lot of shrimp that was shipped out. In other words, if the packer had an order for 75 cases of shrimp labeled in a certain way, the inspector had to write a certificate for the lot which stated that the goods had been packed under the supervision of the Food and Drug Administration. And, also,

each label used had to be approved in Washington and a file copy of it should be in the plant's file. That was a procedure that was taken from the Department of Agriculture's meat inspection program. Because, you see, FDA was a part of Agriculture at that time.

One, I wouldn't say humorous but memorable, morning in November 1934, I was called down to the plant about the usual time and they had a very large load of shrimp. It was pouring down rain, a miserable morning, and very shortly after the boat began to unload it became apparent that the boatload was simply unfit and was going to have to be condemned. The inspector had the authority and the duty to do that. Well, I insisted on more sorters being put on the belt and protested with the management that we were not getting out all the bad shrimp, the bad shrimp were getting into the packing room. That brought on an argument, of course, as to which shrimp were bad, which were not, and the situation deteriorated until finally I condemned the load. I told them, "you can't unload it, it's going to have to be destroyed."

Well, that was quite a financial blow to the packer, more importantly to the fishermen because if the shrimp were not unloaded, they wouldn't get paid. And, of course, they had an investment in it because they had paid for diesel oil and for ice and they had spent that time (they spent more time on those shrimp than they should have) getting them in. And so

that precipitated a near riot because, not only the fishermen who were directly involved but all their kith and kin, male, female, all, they began to protest and to gather around and to make threatening gestures and so forth. And I was, frankly, a little frightened for my own safety. But the condemnation did stick but one feature of that particular episode that impressed itself on me, and that influenced my behavior with the press the rest of my career, was this.

In the middle of all this hassle, a young man came up, well dressed, necktie and coat on, and introduced himself as the editor of the local Biloxi newspaper and inquired, "What's this all about?" I explained to him what it was, and something of the program. He asked some very intelligent questions, very searching questions, and finally he got down to the bottom line. He said, "Mr. Beacham, what can be done with these shrimp?" I said the regulations required that they must be destroyed and that meant that they must be taken out here in the harbor and dumped. See, we didn't have an EPA in those days. He said, "couldn't they be used for some other purpose." I replied, "Well they can be used perhaps for some purpose, but they cannot be used for human food." He asked, "Could they be used for hog feed?" And I said, "Yes, they could if it can be certain that they are used for hog feed."

Well, he went his way. The shrimp were not used for hog feed. Ultimately, the fishermen took the boat-out into the

bay there in Biloxi and shoveled the shrimp overboard. When I got back to the hotel that night where I was staying, the Riviera Hotel, the evening edition of the Biloxi paper was in the lobby and there across the front of the paper in big headlines: "Biloxi Shrimp Fit Only for Hogs, Says U.S. Inspector". So, I never really trusted a newspaper reporter from that day to this.

FL: Were there any repercussions from this episode?

LB: No. I received complete support from the FDA.

FL: Good.

LB: Absolute support. And, no, there were no other repercussions and, as a matter of fact, I expect that in the long run that incident aided me in my career because I was the first of the seafood inspectors who were transferred from the seafood inspection over into the regulatory service. And, you see, I'd gone down there for an appointment not to exceed six weeks, then they had extended it another six weeks. Then it became apparent that the seafood program was going to be a long range program and so they stopped issuing temporary appointments and I then received a probational appointment as a seafood inspector. But, then when that was changed into a probational appointment as a junior chemist, I was then on a sound rung in the career ladder.

FL: Were you one of the very first group of seafood inspectors?

LB: I was in the second group. The amendment to the Food and Drugs Act authorizing the seafood inspection services was passed June 22, 1934 because FDA had been very active in its program against decomposed, canned shrimp. The shrimp industry at that time along the Gulf Coast, and to some extent along the Atlantic Coast, was in the hands of people who really had no scientific training. It was a cookbook operation, handed down from father to son. Canning in Biloxi had begun in 1876 in a plant doing business as "Dunbar Dukate" and that was the first shrimp canned along the Gulf Coast so far as I have been able to learn.

Along the Gulf Coast, Mississippi and Alabama, it was in the hands of people who had come from what is now Yugoslavia, along the Adriatic Coast and they were hard working people but were uneducated. And they were doing things in the way that they had always done them and they were packing up shrimp that were sometimes decomposed to an extended degree, and often times were not being properly processed so they were getting spoilage problems and, on top of that, FDA was seizing them because of unfit raw material.

Therefore, the industry, those in Mississippi and those in Louisiana, who were principally Cajuns of French extraction, got the Congressional delegations from Mississippi, Alabama, and Louisiana to press for this amendment to the Food and Drugs Act. Thus, on June 22, FDA was confronted with the

problem of furnishing seafood inspection because the amendment said that any packer of any seafood might petition the Food and Drug Administration, or the Secretary of Agriculture I believe it said, to furnish him seafood inspection. And it went on to say how it should operate and that this would be at the cost of the packer.

Also, the shrimp season started about the middle of August and FDA had only about two months in which to establish a service. Well, they got the service underway some time in September and drew in about five or six youngsters, taking all of them off the Civil Service rolls, as chemists. And then I went in in the second group, about a month later.

FL: So you were in really at the start of it.

LB: Really.

FL: Did you spend all of your time at that one plant?

LB: No. No, I was stationed at two plants in Biloxi and then at a plant in Pascagoula and then at a little plant at Myrtle Grove, Louisiana. Myrtle Grove was about 25 miles down the river from New Orleans, right out in the swamps. I was there until June of '35 and then the shrimp season closed and, it was understood, that was a part of the conditions of employment, that we would all be furloughed until the next season started. So I was furloughed on the 6th of June, 1935 and reported back for duty on the 10th of August of the same year. Thus, I was out about six weeks, so I got a nice vacation,

got a chance to go back home to visit my people in South Carolina. Fortunately, I was single in those days.

FL: It was a simple matter.

LB: Yes, it was no job for a married man, although a few of the inspectors were married and the living conditions in most of the places were very primitive. In Biloxi, as I say, I and several of the other inspectors who were stationed in Biloxi stayed at the old Riviera Hotel which was a large frame hotel right on the beach front. For a room, equipped with an electric fan, and bath, we paid \$15 a month. Then when I went to Pascagoula, I lived at a private boarding house, run by a Mrs. Kell, which was not too bad. When I got to Myrtle Grove, that was pretty well back in the boondocks.

Yes, I remember one morning hearing a great commotion in the kitchen of the house where I was staying and I stuck my head in the kitchen door to see what was going on. The cook had a black snake behind the stove and she was trying either to kill it or chase it out. The snake would slither around one side of the stove and she'd come around with a piece of stove wood and bang it. In the meantime, the snake would go back the other way. I don't think she ever killed the snake and I'm not sure what ever happened to it and I was always a little apprehensive.

FL: Well then, you were in the seafood service just a little over a year.

LB: That's right. I was there from October of '34 to January of '36 and I reported for duty here in Washington on January 19, 1936 in the middle of a big snow storm.' I didn't quite realize what the situation was. I had driven in from New Orleans and had arrived in Washington the night before, Sunday night. I'd driven in snow all the way from Fredricksburg to Washington. I'd gone to the YMCA which was located on G Street at that time, G and 18th, and early the next morning I set out to report, because I certainly did not want to be late on my first day of a new appointment.

There was about 20 inches of snow on the ground and the streets were only partially cleared and I worked my way from 18th and G down to 14th and Independence Avenue. I knew my office was in the new South Building of Agriculture but the South Building was not entirely completed at that time. Construction was still going on and many of the entrances and corridors were still blocked off. I made two or three false starts before I could get through to my office which turned out to be on the southeast corner of the building, and I came in on the northwest corner and there were no diagonals across. Well, I finally got into the office about five minutes of nine and, sure enough, I was on time. However, there was no one there to receive me. Office was entirely empty.

In about 10 minutes the secretary to the chief of the division, Mary Grayson, showed up. Mary was a motherly

character who immediately took me under her wing and showed me the ropes. She introduced me around to other personnel when they arrived and in particular to Dr. Ward Benjamin White who was the chief of the division. Dr. White was a great character. I worked with him and for him until he died in 1951 and I never had a supervisor that I felt closer to, who was more admirable, had any greater effect on my way of operating and thinking. I have a great admiration for Dr. White and my experience working with him was something to be remembered with a great deal of pleasure.

FL: I knew Dr. White. I met him only once or twice but one of the things that I appreciated, although I was out in the field and didn't have personal contact with him, was reading the things that he wrote. He was a master of the English language.

LB: That was one of the personal effects he had upon me. Any writing ability that I may have, I can attribute it to him because he insisted that written documents should be letter perfect, not only in regard to spelling but also as to syntax and vocabulary. That was one of his hobbies and I have made it one of mine.

FL: I think that next to Mr. Campbell he probably was the most respected and admired man in the whole organization when I started.

LB: I think that is true. He certainly was as far as I was

concerned. He had integrity.

FL: What kind of duties did you undertake when you first came in.

LB: Well, as I mentioned, we were primarily engaged at the time in developing food standards for canned foods because the McNary-Mapes Amendment authorized standards of quality, condition, and fill of container for all canned foods except for canned meats and canned milk. So, at the time, we were principally concerned with fruits and vegetables; peaches, pears, apricots, cherries, peas (particularly peas), and later tomatoes and green beans. Our objective was to develop laboratory methods for evaluating quality and that is not an easy task because quality often is very subjective and the usual system, even today in the Department of Agriculture, is to write grade standards in terms of subjective attributes that have to be determined by the skilled observer and tester. But, since ours was a criminal statute and our actions had to be supported in court, we felt that we had to have reproducible laboratory methods and so much of our work was given to first developing a method and then testing the method on authentic samples. So I was put to work in the laboratory on developing methods; one of those which is still used today was the test for the alcohol insoluble solids in canned peas. There were other tests such as penetration tests to determine the hardness of peaches or pears or other fruits. There was a test employing the

Munsell color disk for determining the color of canned tomatoes and of tomato products, such as puree and paste, and similar tests. And then during the packing season, I and several others who were also engaged in the same work would go out into the field and visit the canneries where a typical operation would be to arrange with a canner to allow a small portion of a field to go through several stages of maturity, even beyond that at which he would normally harvest the field. He would reserve that portion for us and then we would make a series of experimental packs using that material, usually to pack 48 cans or maybe more at a given stage of maturity. Then we would send those back to the laboratory and during the remainder of the year we would apply our tests to those to evaluate them and to obtain parameters that could be written into a standard. So that was the type of work. That continued until 1938 when the present Food, Drug and Cosmetic Act was passed which gave the FDA even broader authority for establishing food standards because in addition to standards for quality, condition, and fill of container, it provided also for standards of identity, and it expanded the number of foods to include practically all foods. It eliminated fresh or dried fruits and vegetables, melons, and one or two other items, but it gave FDA much greater authority for establishing standards. And so from 1938 until the U.S. entered the Second World War in, you might say, 1942, about four years, FDA was very, very

actively engaged in establishing standards not only for canned products but for flour, bread, alimentary paste, and many other food products.

FL: The alcohol insoluble solids test for peas that you mentioned, that was to determine the maturity...

LB: Maturity, that's correct.

FL: The problem was the packing of peas that were too hard.

LB: That's right. At that time a great many peas were packed on the eastern shore of Maryland, in Virginia, and in Delaware and they were the smooth-skinned, so-called, Alaska peas.

Alaska peas did not originate in Alaska. The variety was developed back in the late 1800's when the Atlantic crossing record was held by a steamship called the Alaska. So this new variety of peas was called the Alaska peas and it became the common or usual name for virtually all smooth-skinned peas. When I say smooth-skinned, that refers to the condition of the dried pea. The common sweet pea is a wrinkled skin in the dry state.

And, well, I was saying that the Alaska peas were grown principally in the Tri-state area and there were lots of them. But, the weather and the climate in this part of the country is not very favorable for growing peas. Peas do better in a cool climate while in this area, we go from spring into summer in a period of about 5-6 days and so it was very difficult for the canners to harvest all of the peas they had contracted for

and get them in the cans before they grew too mature. But that was the purpose of the standard and it was a very difficult standard for canners in this area to meet. The upshot of it has been - I don't think it's Food and Drugs action so much, as just the pressure of the marketplace - that peas in the Tri-state area are no longer canned in anything like the volume that they were back in the thirties and early forties. FL: Was there any problem of using soaked dried peas at that time too?

LB: Yes, there was and, of course, the alcohol insoluble solids test would fail those uniformly. So much so that there was a packer, Morgan Packing Company, at Austin, Indiana, I believe who took us to court. Morgan Packing Company packed nothing but soaked dried peas and none of those met the standard, so he contested the standard in court and won. He won an exemption for soaked dried peas because the court held that because all soaked dried peas would be substandard, the standard as it applied to soaked dried peas was unreasonable and so soaked dried peas do not come under the standard for canned peas today, although I believe that FDA has since established a separate standard for soaked dried peas.

FL: At least the ones that are so labeled.

LB: Right.

FL: When did the McNary-Mapes Amendment become effective?

LB: July 8, 1930.

FL: It had been in effect then for some years before you came.

LB: About four years before I came on board. That's right. And so a good deal of preliminary work had already been done and one or two standards had already been promulgated by the time I came to Washington.

FL: And from FDA's standpoint, those standards were desirable because then we had a standard with the force and effect of law...

LB: That's correct.

FL: ... that we didn't have to prove each time we went to court.

LB: That's right. Prior to that in the absence of a standard, it was necessary for FDA to bring in trade experts to testify that the product did not meet whatever commercial standards there might be and those victories that FDA won were without precedent value because FDA had to do the same thing the next time the issue arose.

FL: Was there opposition by the industry to such standards?

LB: No. Actually the McNary-Mapes Amendment had been passed at the instance of the National Cannery Association because there was so much substandard merchandise and distress merchandise on the market that they felt it was depressing the price for better quality merchandise. So the initiative, as I say, came from NCA, and FDA, being a bureaucracy, like all

bureaucracies was perfectly willing to take on more authority.

FL: Of course getting the standard was an advantage to us too.

LB: That's right.

FL: Do you have any feel at all for how much input FDA had in formulating that amendment. Was Mr. Campbell involved in that?

LB: I'm sure that Campbell and Charlie Crawford also were involved. I'm sure it didn't happen without their knowledge nor probably without their cooperation but I don't know the exact extent. I have a feeling that they were not nearly as involved in that as they were later in the 1938 Act.

FL: In those early years Mr. Campbell, of course, was chief of the agency and Dr. White of the Division. Who worked with you in that section on standards?

LB: Yes. In the Division at that time we had several branches although I believe they were called sections at that particular time. One of the section chiefs was J. Walter Sale and working with him was Robert Osborn and John Wilson.

Another section was headed by...

FL: They worked mostly on juices...

LB: Beverages and juices, that's right.

FL: ...and flavors.

LB: Jams, jellies, preserves, fruit juices and that type of food. Then Henry A. Lepper was in charge of the dairy

products section. That dealt with butter, of course, and with other dairy products - cheese, dried milk, evaporated milk, similar products. In my own section, the canned food section, it was under the direction of Victor B. Bonney. And I had working with me Julian Palmore and Sumner Rowe. There were other members in the Division but they were not as closely related to the foods standard work as were those people I have just named.

FL: But all the activity as far as standards were concerned then was in the canned foods area since that was where we had the legal authority.

LB: That is correct. We, of course, took regulatory action against other foods but we did not have food standards for them. I had mentioned butter, for example, now. There was no Food and Drug standard for butter and there is not today; but there was a legislative standard for butter which had been passed in 1923 by Congress which states that butter is the product commonly known as butter and has not less than 80% fat, all tolerances being allowed for. So, FDA did a lot of enforcement work against low fat butter and later against low fat margarine, although the problem was never as acute with margarine as it was with butter. The dairyman would sharpshoot trying to get as close to 80% as he could without falling below it. So, we would seize a lot of butter at 78, 78 1/2, 79%. Although the law stated that all tolerances had

been allowed for, we allowed .15%. We never took action against anything above 79.85.

FL: During those years, that was about the time that efforts started to replace the 1906 Act with a new food and drug law. Were you involved at all in that.

LB: To a limited extent. Charlie Crawford, who today would be called Deputy Commissioner but that was not the title at that time, was Campbell's right-hand man. He was the one who did most of that work with Congress and with Senator Copeland on that bill. Charlie and I were quite close to one another. As a matter of fact, Charlie Crawford was the first member of the Food and Drug Administration that I ever met because I was aware that this Amendment, authorizing seafood inspection service, had been passed and I also knew that I was on the Civil Service Junior Chemist Register and there was a possibility that my name might be reached. It happened that in September, about the first of September 1934, I was living at Spartanburg, South Carolina at home with my people and employed in a filling station, pumping gasoline. But oddly enough I received a communication from a boys' school over at Massanutton, Virginia asking if I would come there for an interview with the view of becoming an instructor in the boys' school. Well, to get to Massanutton, one had to come by train to Washington and then take a bus over to the Shenandoah Valley. So I took the train to Washington and knowing that FDA was hiring, I

went down to the old FDA building on 13th Street, went in and went up to Mr. Crawford's office. The receptionist asked me what I wanted and I said, "I'd like to see Mr. Crawford." And she said, "Do you have an appointment" and I said, "No, but tell him that I am a friend of Sherman Jeffords in Spartanburg, South Carolina." He and Jeffords had been in the same class at Oklahoma State. In fact, Jeffords had been the one who told me that FDA had this program going and that I should pursue it.

She walked in for a moment and came right back out and said "Come on in and see Mr. Crawford." So, I went in and I immediately liked him. Almost everybody liked Charlie, he was very cordial. He asked, of course, about his old friend and he asked me about what I was interested in and I said I understood that they were setting up this program. He said, "Yes, we are" and told me all about it. And he asked me, "Are you on this Civil Service Register?" I said, "Yes, I am." He pushed his button, the secretary came in, and he said, "Ask Clarke to come in, please." And, L. M. Clarke, Head of Personnel, came in and he said to him, "Find out where Mr. Beacham is on the Civil Service Register would you?" Clarke came back in a few moments and said, "Well, he's there near the top. He should be reached very shortly." So, although I went on down to Massanutton and had my interview, I didn't pursue that very vigorously. Sure enough, within a few days

after I'd gotten back to Spartanburg I got this telegram from FDA. That was my first contact with Charlie Crawford.

Then when I came back to Washington a year and a half later, why, we were all in the same building for by that time FDA had moved over into the new South Building. I was on the third floor and Charlie Crawford's office was on the fourth floor. So, I saw Charlie almost every day. In those days we had a little luncheon group which was called the Liar's Club. Many of us, virtually all of us, brought our own bag lunch and we would meet in one of the laboratories there where we had table space and we would have coffee because FDA, among its other responsibilities, had an agreement with the Veteran's Administration that it would test all of the coffee that the Veteran's Administration bought. We would get first the bid samples and then whoever got the successful bid would make a delivery and then we would get samples from the delivery for comparison. So FDA always had a generous supply of green coffee on hand and every day one of the laboratory helpers would roast a supply of the green coffee and would prepare one or two big Erlenmeyer flasks of coffee.

Charlie Crawford and L. D. Elliott, who was also in the Front Office, and Paul Dunbar and many others would come down -- this was almost a daily occasion -- and then with a number of us from the Division of Food and other divisions usually we would have 15 or 20 people sitting around in the laboratory

eating our lunches and drinking coffee and all of us listening then to what those from the Front Office had to say. And we had wonderful communication because the various cases that were being developed and tried, the developments over on Capitol Hill, just about anything else of real interest would come out in the Liars Club. It was a very informal affair - questions and answers and everybody on a first name basis. It really was a wonderful experience for a young chemist in an organization like that to be that closely associated with top management and to see the inside workings. And, so, yes, I followed the development of the 1938 Act quite closely because every few days Charlie would tell of hearings that had been held, committee actions, language that had been substituted, and that sort of thing.

I remember well when he came in one day and recited the verbiage that now resides in Section 201(n) of the Act about the revealing of material facts. He was very instrumental in drafting that language and the real purpose of it at that time was directed at patent medicines, but it's been used, and I would say abused, since then. But it was really intended to apply largely to patent medicines. Its been expanded now to where FDA tends to contend that anything that it wants on the label is a material fact, but that was not the purpose of the original legislation.

FL: That process went on for years with one bill and then

another that the Congress changed...

LB: Oh, yes. The first serious attempt to either amend the Food and Drugs Act or to rewrite it began in 1933 following the publication of "100,000,000 Guinea Pigs" and that excited the public interest in the food and drug situation. So, Guy Rex Tugwell introduced the first proposed bill in 1933.

And every session of Congress after that either continued work on that bill or introduced a new bill. Some of them would pass the House, some would pass the Senate, some would die in committee; but the issue remained alive all the way from '33 to '38 when finally ...

FL: During those times they were forced into compromises in language and other things that did not get into the final act. Do you have any recollection of what Crawford or Dunbar felt about some of those? For example, the opposition that the Federal Trade Commission had to including some of the drug language, especially the advertising part.

LB: The original bills, and even the one that finally passed I believe, had at one time provided for advertising to be covered in the same way as labeling. It was only late in the legislative history that Senator Wheeler, who was never a friend of FDA, and, of course, others were successful in separating out the advertising and assigning it to the Federal Trade Commission and, yes, Charlie Crawford and Campbell were greatly disappointed at that because they felt, and indeed it

did, that it diminished FDA's authority quite a bit and complicated the problem of truthful labeling.

FL: Were there any other similar compromises that were made that you recall.

LB: I'm sure there must have been but I don't recall the details of them. But in general I felt, and I think Crawford felt, that FDA had been pretty successful in attaining the provisions that it wanted. Of course, as regards drugs, the original FD&C Act did not go nearly as broadly as it does today following the later amendments to it. But, even so, it was a tremendous step forward and, of course, the new bill provided for the regulation of cosmetics which prior to that time had no regulation whatever. So, yes, I think, at the time that the 1938 Act was passed that FDA and those who had worked in getting its passage were quite pleased with what they had attained.

FL: In this whole problem of standards for foods, one of the old landmark cases, of course, was the Bred Spred case under the 1906 Act. Were you involved in that?

LB: I was not. As I recall the Bred Spred case had already taken place by the time I came to Food and Drug, or at least by the time I came to Washington, but it was still a matter of conversation and of interest because, as you will recall, FDA had attempted to take action against Bred Spred on the grounds that it was an imitation preserve. It was low in fruit, high

in sugar, but because it was being sold under its own distinctive name, Bred Spred, the court held that we could not require it to comply with the FDA's informal specifications for jam. Bred Spred case was one of the cases that FDA cited as justifying a new law.

The other was the Lash Lure case. Lash Lure was an eyebrow and eyelash dye that had produced severe eye injuries and in one or two cases blindness. And, yet, FDA was totally powerless to deal with Lash Lure because it was a cosmetic, it was not a drug, and FDA had no authority. Even in the famous Elixir Sulfanilamide case, although FDA probably would have found some other grounds for taking action against Sulfanilamide, the charge that it brought to get the stuff off the market was that it was labeled "Elixir of Sulfanilamide" and elixirs consist of alcoholic solutions but Sulfanilamide had no alcohol. As a matter of fact, that was the problem. It had diethylene glycol in it. In that connection I was amazed to see recently the news item that the Austrian wines have diethylene glycol in them. I just wondered isn't there anybody in Vienna who ever heard of sulfanilamide.

FL: That was about my reaction too when that news broke here a few weeks or months ago.

LB: Yeah.

FL: And I understand that they used it as a sweetening agent of all things.

LB: Well, I suppose it does have a sweet taste, but...

FL: You'd think there would be another sweetening agent they might have used.

LB: I could suggest several others.

FL: At that time we had all of our laboratories pretty much in one place and there was the opportunity for people to know one another. Was there any formal or informal cross pollination you might say between the various divisions in the scientific side.

LB: Yes, I'm sure there was because, as you said, we were all housed together there in the southeast corner of Agriculture. We had all six floors and there was close communication and I've already alluded to the Liars Club and so the chemists and the pharmacologists would be there. Yes, I remember H. O. Calvery who was head of the Division of Pharmacology was a regular attendant at the Liars Club and, yes, there was a lot of cross fertilization. Then, of course, there was and there still is the Journal of A.O.A.C. A number of the members in Food Division were associate referees so there was a close fertilization and communication not only within the divisions there in the headquarters office but a lot of communication back and forth to the field on the development of methods and items of scientific interest.

FL: At that time, too, in the canned foods area we were very active in the problem of decomposition in canned salmon.

LB: Right.

FL: Was that one of the problems that you got involved in?

LB: We never got very deeply involved in canned salmon.

There was some attempt to extend the seafood inspection service to canned salmon but it never got off the ground. Since it was a voluntary service which had to be paid for by the packers, the Alaskan salmon canners never felt that they wanted that type of service and so it was not extended. The problem of decomposed salmon, unfit raw material, was largely solved by the cooperative arrangement between FDA (particularly its Seattle office) and the National Canners Association and the Alaskan packers when they set up what is called the Better Salmon Control Plan. That was established, I think, about 1936 between John Harvey and perhaps Bob Roe and the National Canners Association and the Alaskan packers. It operated and continues to operate and I think it has operated reasonably successfully. So much so that it is my impression that FDA did not feel that it had a real acute problem in the matter of unfit canned salmon although once in awhile a case would arise. And I believe that Seattle usually sent one or two inspectors up into the Alaskan territory during the packing season to make observations and inspections.

FL: Was there any work done at all at that time on chemical methods of detecting decomposition?

LB: Yes. That, of course, was a very active area of investi-

gation in the Division of Food. We explored actively the possibility of using indole as an index of decomposition and to a limited extent we did use it in shrimp and oysters and FDA continues to use it today. They have developed better methods of determining indole and somewhat better correlation, but yes, I myself put up several experimental packs of canned shrimp, canned oysters, and canned clams attempting to evaluate decomposition by use of indole.

On the dairy side, and also on the fish, we developed methods for volatile amines, volatile acids, trimethylamine, and other indices of decomposition. Yes, that was an active program and still is.

FL: As a supplement to our organoleptic work.

LB: Yes. Because it was more impressive in court if you could show that you had a background and, particularly a published background to correlate some particular index with decomposition, that this had been given an opportunity for peer review and that sort of thing and that it was in the published literature. That carries a great deal more weight in court than qualifying yourself on the stand as an expert and which the jury may or may not believe.

FL: An expert smeller.

LB: That's right.

FL: When the '38 Act then became effective, as you noted a while ago, we really started a full bore campaign to set food

standards.

LB: That's right. It was a very active campaign there for about four or five years and a great many food standards were developed and promulgated during that time.

FL: That was about the time I came to work up in Seattle so I was on the other end of it. The authentic packs that came in here or went East for manufacture of authentic preserves and that sort of thing. That effort, I guess, was a casualty of World War II.

LB: That's right. The food standards program never regained its momentum after the War. It continued and continues to a very limited extent even today, but after the War there were other problems. FDA became more involved in other areas of activity and the economic circumstances that had made the industry support the development and the enforcement of food standards were now changed. There was more prosperity, more affluence. The small food manufacturers who had the greatest difficulty in packing high quality merchandise had largely gone out of business, or had passed into the hands of new management.

A case in point would be the seafood industry. I have mentioned that when I went there the industry was being operated by uneducated people who had no concept of food technology or food sanitation or bacteriology or the rest of it. One plant that I worked in in Biloxi was operated by an old gen-

tleman by the name of John Mavar. John was barely able to read and write. He was a man probably 50 years old at the time that I knew him. In the course of the next 10 or 15 years, the management of the plant passed into the hands of his son. His son had a degree in food technology from Mississippi State, and that was typical. The second and third generations as they came along were much better educated and so the conditions improved of their own volition. And, so the urge for food standards diminished. FDA lost much of its enthusiasm for food standards. As a matter of fact, FDA has lost much of its enthusiasm for all types of enforcement against economic violations, feeling that they have more acute problems to deal with and that the money is better spent on items involving health and nutrition than in economic violations. And so all of that has mitigated against food standards.

FL: Was that also affected too after World War II by the change in the kinds of foods that became available, the prepared foods and so on that hadn't existed in the 1930s.

LB: Yes, you're exactly right and also it brought into focus a new problem that FDA had not previously had to deal with to any great extent. That was the matter of food additives because the new prepared foods and the foods of that type quite frequently required ingredients that had not previously been used, or had not been used in any great extent. So that cre-

ated the problem of food additives which, of course, was finally dealt with in the Food Additives Amendment of 1958. That gave FDA a vast area of responsibility that it had not previously had which required resources as well. So, a number of situations like that have served to take the emphasis away from food standards.

Also food standards lost much of their industry support for this reason. FDA would write food standards but FDA did not enforce food standards. Their program of enforcement diminished markedly and so that left the conscientious food processor with the responsibility to comply with the food standard while the borderline processor didn't feel any such responsibility and he would cut corners. And, although the legitimate food processor would protest to FDA, it usually had little or no effect. I can recall any number of interviews that I had with members of the fruit preserve industry who were complaining that they were suffering from competition from products that were represented as jam, jellies, or preserves and did not meet the requirements of the standard and would beseech FDA to take more vigorous action. But FDA never did very much about it and consequently after awhile, again I recall, that Bob Kellen who was Secretary of the Jam, Jelly, and Preserve Association came in one day and said, "If you're not going to enforce the standard, let's rescind it." Well, FDA has not rescinded it and it hasn't enforced it.

FL: The philosophy on food standards seems to have changed from what we did there in the early years of the '38 Act in that they write the standards in broader language now than formerly. Is my impression correct?

LB: You are correct. The original standards, written in 1938, '39-'40, were very specific. They were recipe standards and they prescribed precisely what would go into the product and often times the quantitative aspects as well. Gradually that has changed now and one reason it has changed was the passage of the food additives amendment, because FDA used the foods standards authority to control such additives as were being used at that time. In other words, the safety of the additive had to be approved in connection with the promulgation of the standard. Whereas, now, the safety of the additive has to be shown independently of the food standard and if that has been shown then FDA can simply designate as one of the ingredients, a safe and suitable emulsifying agent, or use some of the broad terminology rather than specifying the exact emulsifying agent that might be used.

FL: And would still get the same amount of protection to the public.

LB: Actually more, because a probably more intense effort has been undertaken to demonstrate the safety of a particular additive under the Food Additives Amendment than would have been required under the food standards provisions.

FL: I have a hazy recollection that when FDA suffered a severe cut in appropriations along about 1953, that food standards work was suspended for some time. Is that correct?

LB: You are exactly correct. That arose out of a product known as Baby Beets. A packer in New York state had developed a technique for using large beets, reducing them to small spheres and packing them as Baby Beets. FDA took action against the product on the grounds that it was mislabeled in that the term baby beets was false and misleading and the company then besought the assistance of Congressman John Taber from their district. The outcome was that Taber was successful in cutting FDA's appropriations. As I recall, the original appropriation that year was to be five and a half million dollars and he cut it to five million dollars. And that loss of a half million dollars resulted in some RIFs, reductions in force, in the Food and Drug Administration and curtailment in the food standards activity. It didn't eliminate it but it certainly put a damper on it.

FL: Was there any other instance of congressional interference with food standards?

LB: None that I recall although there may have been but that was the most memorable one.

FL: But that one, at least, we were able to continue some but not at the rate we had been doing previously.

LB: That's correct.

FL: We had to shift resources to cover other things.

LB: And, of course, this was not primarily a food standards issue because there was not a standard for baby beets but it was an economic violation. And the upshot of it was that all economic activities were reduced and food standards was one of the principal ones.

FL: There was a legitimate product called baby beets made of small immature beets.

LB: Oh yes, and there still is.

FL: So then it was a real cheat as far as the public was concerned.

LB: Correct.

FL: You know, a little bit after that, we had some outbreaks of botulism in canned foods. I can remember as a young inspector it was sort of an article of faith that if the firm followed the NCA recommendations for time and temperature, we didn't worry much about it. And, then here all of a sudden, we were confronted with some actual cases in commercial products.

LB: You are exactly right, Fred. Oddly enough one of the first assignments that I received in New Orleans prior to being transferred to Washington was to chase down and sample a shipment of Italian antipasto that was suspected of having botulism. But botulism in those days was a rare occurrence as far as FDA was concerned. And, as you say, properly processed canned foods were supposed to be exempt from any hazard of

botulism. That had come about largely as a result of the work that the National Cannery Association had done. Russell Esty, who was in charge of NCA's San Francisco laboratory which later was moved over to Berkeley, and Karl F. Meyer had investigated botulism in canned, ripe olives in 1922 and 1923. As a result of that they had worked out the heat processes, what's known in the profession as the F sub zero values, which if those values were met with any particular food - and each food has a different F sub zero value - but if those were met, the product would be free from botulism and indeed it will be. Some of the values have had to be recalculated in recent times but the concept is quite valid and so I would say that from 1923 to 1963 there was no authenticated case of botulism resulting from consumption of U.S. commercially canned foods. Every year we would have instances of botulism from home canned foods that had not been properly processed and there would occasionally be a case from an imported meat product or something of that kind, but except for a rather uncertain case of botulism resulting from canned tomatoes in 1941, there was no botulism in canned foods until 1963, when we had the Washington Packing Company's tuna outbreak. That shook everybody's confidence until it was finally concluded that the botulism resulted from the can having been improperly sealed and that as it passed along the belts, after having been sealed and processed (even after it had been processed), that the organ-

isms managed to get in through a faulty seam attributable to probably the use of insufficient sealing material in the double seam. Well, anyway that was a case of botulism. But having explained it as a defect in the seam, everyone relaxed until 1978 when we had the canned salmon episode in Birmingham, England resulting from consumption of Alaskan canned salmon. No one knows definitely, even today, what happened to that one can, but it appears that the seam was injured probably by someone opening a case of canned salmon with a knife and cutting in the top of the seam. There was a very, very small cut in the seam. Almost microscopic. But no other cans were ever found that had a similar defect or any more botulism.

But, it was only a year or so later that we had another outbreak of botulism in canned salmon. This time in Belgium where a young college professor and his wife made up a salmon salad and he died, she got botulism but recovered. And there the cause of it was quite overt. There was a hole in the side, body, of the can. It had been partially sealed with salmon material and then the label had been placed on top of that so it was not detectable from the outside. But, when FDA began to investigate that, we found that that was not an isolated occurrence at all but that it was resulting from the use of the can reformers. As you know, the custom is to ship cans to Alaska knocked down with neither end having been attached

and the body flattened. Then before being used they have a can reformer that reshapes the can back into its cylindrical size. Then the bottom is placed on the can, it's filled, and then the top is sealed on. Well, this reformer, which was manufactured by American Can Company, (there were two models of reformers in use up there - one by Continental Can and another by American). The American Can reformer was the one that was creating this defect. It would only create it occasionally, once in a few thousand, perhaps in a few hundred thousand cans, but it would knock a small hole about - oh, I guess - 1/4 square inch - kind of a triangular opening - and FDA in the course of the next two years found quite a number of those but never found another can with botulinus toxin.

And then also when we began to investigate canned mushrooms we found a number of instances where canned mushrooms had viable botulism spores in them, but that was a matter of insufficient process. The insufficient process resulted from the fact that the cans had been - I won't say over-filled - but they had been filled to a greater degree than those cans on which the original processes had been developed. With the rise of the pizza industry - the pizza industry uses a great many mushrooms and they want finely sliced mushrooms and they are not particular about the quality of the mushrooms. They were pressing, and I suppose still do press, the mushroom industry to give them bargain rates on mushrooms. So, some

of the mushroom packers had gone on to develop shaking machines that would shake the cans as they were being filled and what with the shaking and the finely divided size, the mushroom pieces were packing down and making it a great deal more difficult to get adequate heat penetration to the center of the can and that was the cause of the mushroom episode.

But, you are exactly right, that for 40 years we had no instances of botulism in commercially canned foods, while particularly in the last seven or eight years we've had numerous instances. I just wonder if it was there all the time and that cases of botulism were never identified as such, or whether there really has been a change in circumstance.

FL: Maybe there is more awareness on the part of physicians, for example,...

LB: That's right.

FL: ...and the fact that people more often call a doctor now than they did 40 years ago?

LB: And many doctors were simply not aware of even the symptoms or the danger of botulism and they possibly would diagnosis it as something else.

FL: You said, I believe, in 1941 you became director of the section on canned foods. Was that right or did I remember incorrectly?

LB: No, I became - it was 1949. In 1941 I became Dr. White's assistant.

FL: Oh, that's right. And you worked then directly with him.

LB: I worked in the same office with him. We had a large office there, Room 3801, in the South Building and I had a desk in one corner of the office and he had a desk elsewhere and so for several years he and I were in daily contact with each other.

FL: That must have been a rather exhilarating experience for a young man.

LB: It was, it was, because in addition then to the information that was exchanged in the Liars Club, Dr. White, of course, was aware of a great many things that went on in the Food and Drug Administration - he rode to and from work with Dr. Dunbar - and he confided them to me, so I was pretty well informed as to what was going on in FDA at that time and it was great experience for a young, rising chemist.

FL: It was a tragic loss to us then when he died so suddenly.

LB: That is correct. I was devastated. He was in excellent health. Let's see, Dr. White was born in 1886 and his death occurred February 22, 1951. So he was 51 and 14 - he was 65 years old. But he was in excellent health. I don't recall that he'd been on sick leave or anything else to any extent in the previous year or so. His death took place at his home. He had invited Sumner Rowe and Bush Lochnane, who was finance officer at that time, and Bob Hollingshead out to his home in

Bethesda to play bridge. Might have been poker, but he was more of a bridge player than a poker player. Anyway, they played until about midnight and when they finished, Dr. White remarked, said - "Well, Frances, my wife, has made us some sandwiches and refreshments and they are in the refrigerator. I'll get them." And he stood up and fell dead. He had a massive aneurysm. His aorta broke and he was dead before he hit the floor.

FL: I knew it was sudden but I had never heard the details. It must have been a shock for Sumner and Lochnane and whoever else was there.

LB: That's right. And it was certainly a shock for me. I was in San Francisco at the time and the next morning my wife called me and told me and, as I said, I was devastated. I was as grieved as if I'd lost my father.

FL: Then he was succeeded by Frank Vorhes, wasn't he?

LB: Yes, that's right. Frank Vorhes came in then in 1951 and Frank stayed, I believe, until about '57. He was director of the Division of Food for about six years.

FL: Was there any appreciable change in the way that...

LB: Well, you see, Frank got there just about the time that the Taber cuts came into effect. Yes. Frank had a rather unhappy tenure at Food and Drug because we were on very reduced resources. So reduced, believe it or not, that at one time our chemists were borrowing filter paper from adjacent

laboratories in the Department of Agriculture because we didn't have funds to buy laboratory supplies. And, of course, we had difficulty if a vacancy occurred; it was almost impossible to fill it.

Frank was ambitious. He had hoped to inaugurate an active program in the Division. He had ideas. He came in from the field. He knew quite well what some of the problems were and he attempted to bring in some of the better chemists he had been associated with in the field, and he did bring some of them in. One notable one was Bill Cook. He brought J. William Cook in from San Francisco. He brought him in in 1952, and that was before the Taber cut went into effect. The Taber cut went into effect the next year and I would say from '53 on until Frank retired, he was operating on a shoestring. FL: Must have been terribly hard to, especially at that particular time when the technology in foods was expanding. LB: Expanding - that's correct. Such techniques as column chromatography and that, of course, was followed by gas-liquid chromatography, paper chromatography. Then, of course, we had the pesticide residues because the Pesticide Amendment had been passed in 1956. We were working on methods to detect pesticide residues in very small amounts - parts per million and that sort of thing - and so paper chromatography was widely used and one interesting bioassay was the fly bioassay using houseflies to evaluate or measure the pesticide residues.

There were so many opportunities for research and so little resources to even buy the laboratory supplies, not to mention the new equipment that was coming on the market, the chromatographs and all of the electronic equipment, that is just commonplace equipment in every laboratory nowadays.

FL: That was all brand new then.

LB: Brand new.

FL: I remember a story about Jonas Carol trying to get a spectograph, wasn't able to and had to go and borrow one someplace else.

LB: Like trying to get an infra-red spectograph. That's right he had to go to some other laboratory. I don't recall where he found one but he managed to do it, and we won an important case with his testimony.

FL: That was about the time of the famous cranberry crisis. Were you privy to what went on there as to the methods that were available and what we had to do to gear up for that?

LB: I approved the first cranberry seizure. It was just before Thanksgiving and the seizure recommendation had come in and someone over in Ken Kirk's office, and it may have been Ken Kirk himself, called me. He gave me the analysis and I asked if they had run a repeat sample and he said yes that they had run the repeat sample. I asked "What did they get?" Well, the two results were quite concordant and I said, "Well it looks to me like we've got an open and shut case. It's an

unpermitted residue and it's been detected and repeated. Go ahead and approve the seizure," and we did. Then it developed that a great many of the cranberries on the market that year had this residue. What was it, do you recall?

FL: Aminotriazole.

LB: Aminotriazole. That's right, 3-AT. And so we inaugurated a crash program there and we had chemists working around the clock there for about a week perfecting the method and simplifying it so that the field could use it and examine a large number of samples. The original method, I think, had been rather long and involved and we were attempting to shorten it and simplify it so that we could put it on a mass production basis and did so. I remember Danny Banes was one of those who worked on that.

I did not do any of the laboratory work. I had been out of the laboratory by that time by about five years and I certainly didn't feel competent to go back in at that time and had no particular desire to. But Bill Cook and others did, they worked around the clock to take care of that situation.

FL: Now, your mentioning Banes in connection with a food method I think is an interesting point because Dan ultimately became best known for his drug analytical work.

LB: That's correct and even at that time he was working more on drugs, but there was some feature of this method involving some instrument or something that he was expert in so he got

involved in that way.

FL: So there was no hesitation then to go across product lines.

LB: Not the least bit. They'd tap anybody on the shoulder who had a resource.

FL: I think that was also a characteristic, from what I've been told, of the problem with Aflatoxin that involved two or three different scientific divisions.

LB: That's right. And that's the way it should be. FDA attempts to use every resource it has without standing on order.

FL: Along about that time too there was a reorganization as the agency got a little bit bigger and there was an effort to sort of bring the scientific divisions into a single sort of organization, wasn't there?

LB: That is correct. The bureau system was set up and several bureaus were established and one of them was the Bureau of Scientific "something" and Evaluation. I remember the initials of it were BSSE and Bob Roe was the director and he had several divisions in the bureau. The Division of Food was one of them and so Bob and I worked quite closely together. I was either a deputy director of the Division or a Division Director at that time so I had daily contact with him.

FL: Was that a successful experiment. Did it improve liaison among the scientific divisions.

LB. I don't know that it did. The situation was complicated by the fact that about that same time we moved a portion of FDA out of the Department of Agriculture building. The organization as a whole had been out of the Department of Agriculture itself since 1940 but we had remained in the Agriculture building. But then about that time they moved about half of the organization over to North HEW and that meant almost a mile of geographical separation between the two. That cut down on communications. The Commissioner's office and one or two of the other bureaus were there. Also, they had established laboratories elsewhere in the city in rented quarters. We were getting pretty well dispersed geographically and setting up the bureau system, I guess, was an effort to compensate for that. But I'm not sure that it was successful. As a matter of fact, it tended to create rivalry between the bureaus and competition and there were certainly no great benefits that flowed from it.

FL: The Division of Food itself, after Vorhes left, who became the director then?

LB: For just a brief period, very brief period, a matter of days I think it was, Oral Kline, Dr. Kline, became the director. But, Elmer Nelson, Dr. Nelson, who was in charge of what was I think called the Vitamin Division in those days suddenly died. Lee Kline had been his deputy and so they transferred Lee back and made him the Director of the Vitamin Division and

they then brought in Dr. Fischbach as the director of the Division of Foods and named me his deputy, as I recall, at that time. So Henry and I worked together for several years with my being his deputy and then they once again reorganized. As I have commented on previous occasions, FDA periodically undergoes what I call a byzantine reorganization and this was one of them in which they took the division that Henry and I had been operating and split it and added some other functions and I became the director of what was left of the Division of Foods and Henry took another division and I believe it was simply called the Pesticide Division at that time. I remained head of the Division of Food Standards and Additives and then later the Division of Food Chemistry and Technology until Virgil Wodicka came in as head of what later became the Bureau of Foods but at that time was called the Bureau of Science. Virgil came in and after getting his feet on the ground, he decided that we needed, in addition to the bureau system, an Office level in the hierarchy and so he reorganized the bureau and established several Offices. He also brought in Bob Schaffner from Libby, MacNeil & Libby and made him one of the Office directors. Then Virgil took me and made me Bob Schaffner's deputy. So my job then became vacant and Dale Berneking came in and became the head of the Division of Food Chemistry and Technology and I became Deputy Director of the Office of - gosh, I've forgotten what the title of it was.

Physical Sciences I think it was. But, I only remained in that position for just a few months because, as I said, I was heavily involved in the Codex Alimentarius program. I was going to Europe about four times a year and Virgil then suggested that I ought to devote my full time to this international program and how would I like to become his Assistant for International Operations. And I said, Okay. So, I left Bob Schaffner and went up into Virgil's office, on the organizational chart, that is.

FL: What was your opinion of Dr. Wodicka as a manager of that operation?

LB: Virgil was indefatigable worker. He'd get up at 5 o'clock in the morning in order to be at the office or go out to Parklawn. He worked hard. Virgil had lots of good ideas, and some that I didn't think were so good, but I would say that Virgil did well. I was a little dismayed when I heard he was coming. I had known Virgil in the industry. He was with Hunt Foods. Hunt Foods had made the cans that the Washington Packing Company had used that had resulted in the first case of botulism in tuna. I had always thought that they shorted on the sealing compound that they put in those lids as just a matter of economics. I just did not have a very high opinion of Virgil when he came, but I grew to respect him and admire him a great deal, particularly for his hard work. He had ideas. He was articulate and certainly he had the interest of

FDA's programs at heart while he was there. I don't think he did before he got there and he may not have had them since then but while he was an FDA employee, he was loyal to FDA's programs.

FL: What was your general impression of that idea of establishing these several free-standing bureaus and moving things like the compliance activities to the bureau level rather than leaving it at the commissioner's office. Was that workable; was there a problem there between ...

LB: I would say that I never underwent a reorganization that I didn't dislike.

FL: That's probably true of all of us.

LB: That's true of everyone. We resist change and reorganization and it always appeared to me, and I'm sure this is a prejudiced view, that these reorganizations were largely designed to inflate the job structure and to facilitate empire building and that sort of thing. As I say, I'm sure that is a prejudiced view but that was my reaction to it in almost every instance, although sometimes I profited from the reorganizations.

FL: Of course, some of those reorganizations were brought about by our sheer increase in size that made some kind of change needed.

LB: You're exactly correct. One of the last things that Charlie Crawford did before he retired, and later died of

leukemia, was to arrange for a Citizens Committee to investigate FDA and to make recommendations as to FDA's future course. This first Citizens Committee came in with some very generous recommendations about increasing FDA's size. When I saw the committee's report, I said "This is a letter for Santa Claus" and never felt for a moment that those recommendations would ever be implemented. But, they were! And, so beginning around 1960, or perhaps a little earlier, FDA began to grow by leaps and bounds with increased appropriations every year and authorizations for more positions and so much so that when I came with FDA in 1934 we had 600 employees, foot, horse, and cannon. And, when I left in 1974, we had 9,000 employees. FDA does not have 9,000 now. I think FDA probably has no more than about 7,000 but we did reach 9,000 in 1974.

Well obviously the simple structure that had existed when I came in in 1934 could not handle an organization of that size and so it was necessary to make structural changes and I suppose these were in line with the best ideas current in management at that time or at this time.

FL: One of the other changes that seemed to me occurred with expansion - when the agency was small, it seemed to me that we had people in the scientific divisions who were nationally known experts in their particular area - where my impression is now that we don't really lead in technology to the extent we did then. Is that correct?

LB: You are exactly correct. Which is not to say that FDA does not have some very capable people and perhaps a few of them are leading in their area, but not to the extent that was the case in the thirties and forties. FDA had, as you said, recognized experts. They were people who were certainly nationally and to some extent internationally recognized. The reason for that, particularly in the area of food technology, was the in house training that FDA carried on in very limited fields such as the canned foods.

I mentioned that I went out in the field every year; not only I, but several other members of the Division, would go out to the various food processing plants, travel around the country and work with the FDA inspectors in the local areas, and would become thoroughly conversant with the technology as it was being exercised at that particular time. So, they knew what they were talking about and the industry recognized them and respected them. That's no longer the case now. There's virtually, so far as I can observe, no operations of that nature now. The people in Washington do not get out into the field. They do not get out - they are what I call "closet experts."

FL: You think it would be possible to do that at the present time.

LB: Yes. All it takes is money. Of course, in those days travel was very cheap. Per diem was \$4.50 a day. You could

get a hotel room for \$2. So it costs infinitely more now to keep a man in travel status.

FL: That fits with my recollection because I was at the other end, at the field, and we used to see Mr. Bonney or Dr. Osborn or Sumner Rowe almost every year.

LB: I think I went to the West Coast just about every packing season for five or six years and would start in with apricots and then the Royal Ann cherries, peaches, pears, right on through until sometimes I was on the coast from perhaps the 1st of May until the 1st of October. It was just one plant after another. So, I got pretty well acquainted with food operations and the industry personnel and some of the problem because, traveling all day with an inspector, I learned a great deal about the local problems there. The abuses that were taking place. And, yes, FDA does not have the recognized expertise that it used to have.

And, during my ten years with the National Canners Association (which during that time changed its name to National Food Processors Association), I was surprised by the number of complaints that we got from NCA members about the really outrageous behavior of some of FDA's inspectors. Well, they were obviously, absolutely uninformed on the operations and inclined to be pretty dictatorial, arbitrary, and officious and demand things that they didn't have the authority to demand. FDA inspectors are now, for the most part, held in fear and

contempt by the industry. And that is a very unfortunate situation.

FL: Speaking of the NCA, what was our relationship with that organization during your years with FDA?

LB: It was very close. Very close. Because, as I said, the NCA had been instrumental in getting the Canned Food Amendment to the first Act. They'd been equally instrumental in putting in Section 401 of the 1938 Act. So for a number of years we worked quite closely with the NCA in preparing experimental packs and in examining them. We would prepare the packs jointly with them and then divide the samples that had been prepared. FDA would examine ours, test them in our own laboratories and NCA would do the same and then we would compare results. And so in that way we could get pretty good agreement on just what the investigation did show.

FL: So that when you came to actually setting a standard or holding a hearing, there were some things that were agreed to.

LB: Certainly the basic data had been agreed to because it had been jointly developed. Yes, I worked with Howard Smith of NCA several seasons in preparing authentic samples.

FL: Were there other contacts then with them on problems as they arose, discussions in the division with representatives of NCA?

LB: Oh, yes, yes. There were and there still are. NCA and its present organization, NFPA, have deliberately maintained a

very close liaison with FDA. One of the features that they present to their members to encourage membership is that they do maintain a close working relationship with FDA. And that their personnel and their professionals are respected at FDA and their opinions are valued.

Now, FDA doesn't always agree with NFPA and while I was at NFPA I have on occasion told them that FDA is not going to agree with you and why FDA is not going to agree. But, nevertheless, there is a close working relationship and I think that is all to the good because it is one way in which the industry, at least to a limited extent, can be kept informed of FDA's mission and the way in which it attempts to carry it out.

FL: You know, some years ago we started that program on low acid canned products where we utilized the Section 404 as a vehicle for bringing about some changes in the way some plants processed things. How did that develop?

LB: That resulted from the vichyssoise incident where this vichyssoise had been improperly processed. The reason it had been improperly processed was that the manufacturer (a small manufacturer I believe in Newark, New Jersey) had two retort systems. He had one system piped to operate at 240° and he had an adjacent system piped to operate at 250°. The vichyssoise should have been processed for a certain period at 250°. Instead of that, one batch of it got in the 240° retort and

was processed the same length of time at 240° and, of course, that resulted in a death. That, and perhaps other circumstances, impelled NFPA (NCA at that time) to make the suggestion that Section 404 be used as the basis for a set of regulations that would ensure the adequate processing of low acid canned foods. So, based on that suggestion, that suggestion was made by H. Thomas Austern of Covington and Burling who was the counsel for NCA.

FL: So that novel application of 404 really came from the industry.

LB: That's right. FDA I think was feeling around for some authority to do essentially what it did do, but the suggestion and the support of that suggestion came from the National Canners Association and they worked closely with FDA and at that time I was quite active in the development of the regulations which are now 113 and 108, I believe, and 114.

FL: And I would think them quite beneficial to the consumer, not only with domestic canned goods but also with foreign canned goods.

LB: That is correct because you see once we establish that for domestic products, we are then in a position to require the same degree of compliance with the foreign processors and although we don't have the opportunity or the authority for plant inspection and that sort of thing, we have made those plants register their processes with us if they are going to

import their goods into the United States and on several occasions, at the invitation of the foreign country, we have sent FDA inspectors to those plants to see that they are properly equipped; that they do have in place the procedures required by Section 113. And so it has extended the protection of the Act widely to imports as well as to domestic products.

FL: For a good part of the time that you were first in Washington, 20 years or more, most of our scientific leadership, or much of it, came from within and especially in the Division of Foods. But, towards the end of the 1960s, or the mid-60s, we reversed that as I recall when Commissioner Larrick brought in Dr. Summerson to head the operation in science.

LB: Yes, that was true although not entirely true. Dr. Ward Benjamin White had been brought in from the New York Department of Agriculture in 1930 or '31 and then when Dr. Calvery, head of the Division of Pharmacology, died, they brought Arnold Lehman in from the State of North Carolina. But, then when the bureau system was set up, they set up parallel bureaus, one under Bob Roe and the other under William Summerson. They brought Summerson in, I believe he previously had been at Edgewood Arsenal working with the Department of Defense and he had no food and drug background whatever. White and Lehman had had food and drug background in the State services, but Summerson had never read the Food, Drug and Cosmetic Act, and I'm not sure ever has.

FL: Did he bring anything else over that was useful to us in terms of scientific knowledge or expertise?

LB: It's possible, although I'm not aware of it because I never worked for Summerson. I worked with Roe at the Parallel Bureau and there was a certain rivalry there between them and Summerson was not popular. He certainly was not popular in our Bureau and I don't think he was very popular in his Bureau. So, I wouldn't say that Summerson contributed a great deal to FDA while he was there.

FL: Then it was after he left that the two halves were put back together again.

LB: That's correct.

FL: Was that when Dr. Goddard came, or before?

LB: It was after Goddard came because Summerson was not popular with Goddard. I recall that there at 200 "C" Street in the basement, where they had the animal laboratories, Goddard would come in in the morning and he objected to the conditions down there, and rightly so I think, and he rode Dr. Summerson very hard about getting that area cleaned up. I think he had Summerson pretty distraught. That reminds me that the Bureaus were not joined until after Goddard had been there some time. Then Bob Roe retired and they put the Bureaus back together again in the Bureau of Science, I guess it was called. They were constantly changing the nomenclature of the organization.

FL: Then did Summerson leave about the same time?

LB: Summerson left about the same time. Yes. I don't recall just when it was but it would have been somewhere in the middle of the late sixties. Let's see, when did Goddard...

FL: Goddard came in '66 and left in the middle of '68.

LB: Well then this would have been about '68 or '69.

FL: What about the changes that Goddard wrought when he became Commissioner? How did that affect the scientific side?

LB: Goddard came in fired with ambition to make FDA more active in a number of areas and he promised a great deal more than he was able to deliver. But, certainly it was Goddard's ambition to promote FDA's status to make it more of a recognized scientific organization and I think Goddard's aims and ambitions were creditable for FDA. The trouble was that he antagonized just about everybody that he dealt with. He was arbitrary. Dr. Goddard was just not liked in FDA. Everyone was relieved when he left.

FL: Part of that, I suppose, was due to some of the personnel changes that he made. Do you suppose?

LB: Yes. One of Goddard's plans was to reorganize FDA to integrate it with Public Health Service or integrate Public Health Service with it. I'm sure that with Goddard coming from PHS, he wanted the Public Health Service to be dominant organization. So, he - and this is speculation on my part now and I have nothing to document it - conceived the idea of a

super organization in the Department of Health, Education, and Welfare which ultimately became CPEHS. And I forget now what CPEHS stood for.

FL: Consumer Protection and Environmental Health Services.

LB: I think that's right. My speculation is that Goddard thought that he was going to be the Administrator of CPEHS and instead of that, they brought in a black public health officer from New York and, what was his name - Johnson?

FL: Yes, Charles C. Johnson.

LB: Charles C. Johnson. All right, when that took place, when CPEHS was set up and Charlie Johnson became the administrator, Goddard couldn't see himself working for a black man and he asked for either a transfer or retirement. I don't remember how he went out but he left FDA and left FDA in the clutches of CPEHS.

FL: Were there any personnel changes among our top scientists at that time that you found disturbing?

LB: Yes. The principal one was that, as far as I was concerned, Goddard's operations resulted in the retirement of Bob Roe and Bob had not wanted to retire. He was really not ready for retirement. But his relationship with Goddard became so unpleasant that he did retire. That is, so far as I can recall, that was the principal personnel change although I'm sure there were others that I didn't notice at the time or do not remember.

FL: What I remember was that Dr. Lee Kline left rather abruptly.

LB: You are right. I'd forgotten that, but he did. He was working in the Commissioner's office with Goddard and he was not happy. I do not remember any of the details of why he was unhappy, but I do know that he and Goddard were scheduled to go to Europe to some international meeting and Lee came into his office one afternoon, in the middle of the afternoon, and told his secretary that "I am taking the rest of the afternoon off and I will not be back." Then he applied for retirement. And that was because of personal difficulties he had with Goddard.

FL: But you have never talked to Lee about this.

LB: No. As far as I know, Lee never came back to FDA again. He may have come back to sign his retirement papers, but I've seen Lee only on one or two occasions since then but have had no opportunity to talk to him about it.

FL: Toward the last several years of your career with FDA you were in charge of the international standards operation. Could you tell me a little about that.

LB: In charge of FDA's participation in it. The Department of Agriculture plays an important part in that. Yes. About 1963 the World Health Organization (WHO) and the Food and Agriculture Organization (FAO) decided jointly to sponsor an international food program. The purpose of it would be to

harmonize international requirements for processed foods and to insure proper labeling. In order to do this, to implement this program, the Codex Alimentarius Commission was created. Any nation that is a member of either FAO or WHO may become a member of the Codex Alimentarius Commission simply by indicating its desire to do so. There are no dues or any other requirements. The Commission started off in '63 with a limited number of members, maybe 25 or 30 members. It now has 124 members - member nations. So it has been a growing organization.

The way in which the program operates is through a series of committees. There are five or six general subject committees such as one on labeling or food additives or pesticide residue. One on food hygiene and so forth and then there are about 15 subject matter committees such as fish and fishery products, processed fish and vegetables, quick frozen foods, chocolate and chocolate products, and so on.

With one or two exceptions each one of those committees is sponsored by a host country. A host country agrees to supply a chairman and a place to meet and the usual housekeeping and clerical facilities necessary to conduct the meetings. And the meetings of the committees originally were held annually, but more recently now, in the last 6-8 years, they've been further spaced so that the committees now meet every 18 months to two years. A few of the committees have actually

finished their work and have adjourned sine die.

The United States sponsors the Committee on Food Hygiene, a Committee on Processed Fruits and Vegetables, a Committee on Cereal and Cereal Products. Canada sponsors a Committee on Labeling and one on Vegetable Protein Products. Norway sponsors one on Fish and Fishery Products and Switzerland the one on Chocolate and Chocolate Products and so on.

As I said, I was designated as FDA's representative to the Codex Alimentarius Commission on those products where FDA has direct jurisdiction - like fish and fishery products, chocolate and cocoa products - whereas on the meat and poultry products, the Department of Agriculture has the primary jurisdiction. But on those committees, I would be the associate head of the delegation; working with someone from the Department of Agriculture.

So, the program was inaugurated. The first committee meetings were held, I think, in 1964. Certainly that's when I went to the first one which was a fruit juice meeting being held in Geneva, and then that was followed a week or so later by one on cocoa and chocolate products which was also held in Switzerland at Montreaux. I attended both of those meetings and got my inauguration into the Codex program.

Well, as the program developed and as more committees were created and the work expanded, I continued to represent FDA so that, as I said earlier, I was frequently going to

Europe for perhaps four times in a year to attend some of those committee meetings as well as those meetings that were being held here in the United States and in Ottawa. The Commission now has developed, I think, about 120 Codex Alimentarius standards and quite a number of Codes of Hygienic Practice which are very useful, particularly for undeveloped countries who don't have anything better to turn to. So they can use either the Codex standards or the Codes of Practice as guidelines for their own food processing.

When these standards are developed, there is time for full consideration by all parties. First an initial draft is prepared. That is sent out to member countries for comment and then that draft with the comments will be discussed at the subsequent meeting of the particular committee that is dealing with it. The draft will be revised then in the light of the comments received and more particularly in the light of the debate and the discussion that takes place in the Codex meeting, which lasts a week as they are always scheduled from Monday through Friday.

Then a second draft is sent to member nations for comment and discussion and that will come back to the following meeting which will be a year or 18 months later. Then in normal operations a third draft will be prepared, but sometimes even a fourth or fifth draft will have to be prepared and sent out before you get agreement. Then that draft is introduced into

a plenary session of the Commission which meets about every two years; the most recent one was in July of this year in Geneva. The Commission then will adopt the standard as a Recommended International Standard - a Codex Standard. That standard then will be sent back to member nations over the signature of the Director Generals of FAO and WHO with the request that the member nations consider the standard for acceptance.

Now in the case of the United States, and to a certain extent the case of any other country, but certainly in the case of the United States, if we are going to adopt a Codex Standard, then we have got to write the provisions of that standard into our own domestic regulations. That usually involves the drafting of an FDA standard or the revision of an existing FDA standard. A country may accept a Codex standard, give full acceptance, which means it adopts all the provisions of the standard and if it does, it agrees that it will apply the standard not only to its imports but also to its domestic productions so that there will be no discrimination between imported products and domestic production. Or, a country, and some of the developing countries do this, will adopt the standard with what is called target acceptance, saying that they will adopt this standard and enforce it, let us say, in five years time. In the meantime, products which comply with the standard may move freely in their own commerce but they are

not going to apply it to their own domestic production. Or the standard can be adopted with specified deviations, and most of the standards, I would say almost without exception, the standards that FDA have adopted have been adopted with specified deviations. Sometimes those specified deviations are quite trivial and sometimes they are fundamental. One deviation that always has to be taken is to require that the provisions of the regulations under the Fair Packaging and Labeling Act are applicable. No other country that I know of has requirements that are as detailed regarding the labeling as the Fair Packaging and Labeling regulation.

So that's the kind of boiler plate response that goes into every one of FDA's acceptances. But often times now FDA will decline to accept the standard even though we have participated actively in the development of it, but will say that although we will not apply it to our domestic commerce, products that comply with the Codex standard may move freely in interstate commerce. Occasionally there are places where the specific deviation is more applicable such as the use of food additives and particularly artificial colors because, you see, any artificial color that is used in a food in this country has to come from a certified batch. Not only has it to be an approved color but it has to come from a certified batch and that is always a stickler.

FL: Our laws are so much more stringent.

LB: That's correct. And many of the European countries and the Codex Commission itself permit artificial colors which we do not permit and ban a few that we do. ' .

FL: Well, how about the Codes of Practices. Are they adopted the same sort of way or are they just advisory.

LB: They are advisory. The Codes of Practice are advisory and so the countries are not asked to formally respond on those whether they will adopt or not adopt. But the Codes of Practice follow very closely those that we find in 110, 113, 114 but not 108 because 108 provides for registration, but 110 is the old umbrella.

FL: GMP.

LB: GMP.

FL: Current Good Manufacturing Practices regulations.

LB: Those Codes of Practice correspond very closely to the provisions of those because we've been instrumental in helping write them.

FL: Were other people in the bureau involved with you in this in their technical areas.

LB: To a limited extent. Bill Horwitz has always carried the ball on the methods of analysis. There is a Committee on Methods of Analysis and Sampling, and he has always attended that meeting which oddly enough is sponsored by Hungary. At one time, originally, it was sponsored by Germany, and Germany did a top flight job as you would expect because they've got

some darn good chemists in Germany and they know their methodology. But Germany gave up the sponsorship of that committee along about 1970. FDA would have liked very much to have had it. Bill Horwitz particularly wanted it, because he wanted to ensure that Codex methods reflected AOAC methods as closely as possible. He was successful in getting the FDA to agree to bear the expense, even to the point of creating a GS-14 position for someone to be the chairman of the committee and to do the necessary work. Although we got FDA's agreement, either the State Department or HEW, I'm not sure which, turned us down and so we missed a wonderful opportunity there to have had a real impact on Codex Alimentarius standards. We have had that through Bill Horwitz's efforts, but he has had to go to Budapest to do it, and I'm sure it has not been as effective as if the United States had had the sponsorship of it.

Then, as I approached retirement, FDA and Virgil Wodicka selected Bob Weik, Dr. Weik, to be my successor. So Bob worked with me for about a year previous to my retirement and upon my retirement he took over the role that I had as Assistant to the Bureau Director, and he still occupies that position and is very active and very effective in carrying on the program.

FL: So, we're still involved then with Codex Alimentarius.

LB: FDA is involved right up to its ears in Codex Alimentarius.

FL: Over the years that you served in FDA, obviously there were great changes in the chemical methods available for analytical problems. Would you comment on that?

LB: Yes. In 1934, or 1936, when I came with the Division of Food, the methodology in use was nothing more than a refinement of methods that had been developed many years earlier by such chemists as Liebig and Bunsen. And in the course of the next 40 years there were revolutionary changes that took place in methodology, moving from the old analytical methods employing wet chemistry and gravimetric. We moved on into chromatography; the first one being column chromatography which was developed originally by a Russian scientist named Tswett. That was a very primitive method but it was effective in separating constituents of a chemical mixture or a solution so that they could be isolated and examined from one another and then we began to get into instrumentation. Sophisticated instrumentation. Spectrometry and ion-capture and other types of electronic detection of ions and all of that was expanded and perfected, so much so that the analytical ability moved from the ability to, let us say, detect 1/10 of a percent of an ingredient to the ability to detect 1/10 of a part per million, and then ultimately a part per billion of some components of a food or of a drug or a mixture of any kind. The expansion of the scientists' ability to detect and to measure has just been astronomical in a 50 year period, 1935-1985. Yes.

FL: Could you cite some example of just how problems that plagued us in the past now can be solved by such methodology?

LB: Yes. One problem that FDA has struggled with over the years has been the adulteration of fruit products - products such as jams, jellies, preserves, or of fruit juices, and the analytical methods available to detect adulteration. The adulteration usually consists of using extenders of some kind in the product, that is, substituting refined sugar for the natural fruit sugars or of substituting synthetic acids for natural fruit acids. That type of thing.

It has been very difficult to detect with a degree of assurance that will stand up in court the addition of those adulterating substances. I recall about 1958 we had a problem with adulterated orange juice coming out of Houston, Texas. There was an organization there operating as the Cal-Tex Company which was flooding that part of the South with what purported to be reconstituted orange juice but which, as a matter of fact, consisted of about 50% orange juice with the addition of sugar and water and, if necessary, of citric acid to make it analyze quite similar to authentic orange juice. Our analytical methods were not sufficiently accurate to distinguish between the added sugar and the natural sugar or the other components that could be found in the juice to identify them and show that they were added and that the product was not in fact true orange juice. We solved that case and won it, but

we did it largely on the basis of inspectional evidence. That is, we had inspectors observing the plant, we had inspectors hidden in a house across the street where they could photograph the operations and show how few oranges were coming and how much product was going out and other circumstantial evidence. But on the analytical side we did have one stroke of good fortune. It occurred to us that possibly added fluoride might be helpful. So we ascertained that the City of Houston was indeed fluoridating its water and was adding one part per million of fluoride. We then examined the Cal-Tex product and we found that it uniformly had one-half a part per million of fluoride. We then examined extensive samples of oranges from Florida, Texas and California and found no detectable fluoride. We were then able to use that evidence in court as a substantiating, corroborating evidence that the Cal-Tex plant was adding about 50% Houston City water to its product which was exactly what we had charged. We convinced the jury and got a favorable verdict.

Since that time much more work has been done on the adulteration of fruit juices generally and is still being done and it is still a problem. But, we are much more able now to detect the adulteration of products such as apple juice, orange juice, cranberry juice than we were in those days. Although, as I said, the problem is still with us.

FL: Those techniques have also solved that long standing

problem of complaints about sugar being added to honey, I believe. Isn't that correct?

LB: That is correct. I understand, although this is a development that has taken place since my retirement, that chemists are now able to distinguish between cane sugar and beet sugar and certainly they can detect the difference between that and the natural sugars present in honey.

FL: One of the things we've done in these recordings is to talk to persons being interviewed about what they remembered of the various commissioners under whom they served. Stories that would illustrate that commissioner's style of management, problems that he faced, human interest anecdotes, and that sort of thing. You, I guess, started under Mr. Campbell.

LB: That is correct. In my career and since I have known ten FDA commissioners, I believe, beginning with Campbell. I knew Mr. Campbell personally. Had many opportunities to talk with him or to hear him talk, and also Dunbar and Crawford and Larrick. I was on a first name basis with each of them. They called me Lowrie. I called Mr. Crawford "Charlie" and George Larrick "George." I did not call Mr. Campbell "Walter" and nobody called Dr. Dunbar "Paul."

FL: I don't think anybody called Mr. Campbell "Walter" except possibly Dunbar.

LB: Or his wife.

It's hard to compare effectively those commissioners

because they served at different times, under different conditions, and were faced with different problems. Nevertheless I had a great deal of admiration for Mr. Campbell and certainly he was one of the ablest commissioners, if not the ablest, that FDA has ever had. Nevertheless, that must be said with the realization that the problems that FDA faced in those days were much simpler than those that have been faced by subsequent commissioners. Dr. Dunbar, I think, was just as effective as Mr. Campbell but in an entirely different way. Different approach but still a very efficient commissioner. My favorite commissioner was Mr. Crawford, but that was simply on the basis of personal predilection rather than in the belief that he was more effective or less effective than any of the others.

All of those, and then Mr. Larrick and Harvey his deputy, I knew those quite well and I thought they did an excellent job and faced some very difficult situations. Very frankly, I did not admire Dr. Goddard. I was never able to get close to him. I was always apprehensive of his reactions and I did not think that he was an effective Food and Drug commissioner. He was followed by Dr. Ley who was a very capable man but was, in my opinion, operating out of his element. He had been brought in as a medical doctor from Harvard Medical School to serve in a medical capacity within the Food and Drug Administration, and suddenly he found himself in charge of the whole opera-

tion. And I think he would acknowledge that he was not equipped for it and he was out of his depth. And although he tried diligently and, I think, in time probably would have become a very effective commissioner, he lost out in the cyclamate episode through no fault whatsoever of his own.

He then was followed by Charlie Edwards who came in from Booz, Allen, and Hamilton and he was an M.D. who had no previous FDA experience whatever and probably was a very competent administrator, but so far as I was aware never became closely involved with the operations down the line from his office. He seemed always to be preoccupied with relationships with the Department and with Capitol Hill. He was certainly not well known and not admired in the Divisions by the professional staff.

He was succeeded by Alexander Schmidt who, again, was an M.D. coming in from the University of Illinois. Personally, I liked Dr. Schmidt better than I did Dr. Edwards, but again that was just a personal predilection. I do not know whether Dr. Schmidt was a better administrator or a better commissioner than Dr. Edwards. I think certainly Dr. Schmidt was quite competent.

LB: It was during Dr. Schmidt's administration that I retired but even before that, commissioners had moved first to Crystal City and then later to Parklawn, and the geographical separation had its effect on the organization that remained down-

town, because we simply were not able to maintain the close communications, and certainly not the personal contacts, that we'd had when we were housed, first altogether in the Department of Agriculture building, and then later in the North HEW and then finally in 200 "C" Street. But when the commissioners moved to Crystal City and then to Parklawn, we lost something in the organization's esprit de corps.

Dr. Schmidt was followed by Dr. Kennedy and he was followed by Jere Goyan who then was succeeded by Dr. Hays and more recently by Dr. Young. Although I have had occasion to meet all of those individuals except the most recent one, Dr. Young, since I was no longer working in FDA I've only been able to observe them from the outside and so I really am not competent to make an opinion of any of those.

FL: After you retired, Lowrie, then went into a consulting business, you had a chance then to look at FDA from a different perspective. What were your impressions during that time?

LB: Fred, when I retired from FDA I was age 63 and I really was not ready to stop working at that time. My principal reason for retiring from FDA at the time that I did was the matter of economics. My salary at that time was frozen and had remained frozen for several years because I was up against the ceiling, and there seemed to be little or no prospect that the ceiling was going to be lifted. In the meantime, those

who had been retired were receiving periodic cost of living increments in their retirement and I observed that every year that I worked for the Food and Drug Administration, I was losing about \$1,000 in potential retirement income. So, I decided to retire and to become a self-employed consultant. It was in that capacity that I have worked the last 10 years and am continuing to do a little private consulting.

But very shortly after I retired, the National Canners Association asked me if I would be interested in working with them on a consultant basis, and that suited me fine because that enabled me to continue other business activities which I could not have continued if I had become an employee of the National Canners Association. I remained with the National Canners Association for ten years. My position with National Canners Association was as special advisor to the president. I was involved in all of the activities where NCA was dealing with Food and Drug Administration. So I had an excellent opportunity to see the other side of the coin, so to speak. As a matter of fact, I sometimes commented that it was very much like playing a game of duplicate bridge where I had been dealt and played one hand while I was with FDA and now several years later, I was dealt the opposite hand to play with NCA. And I found it intriguing. I also learned to appreciate some of the industry's problems while at the same time I was explaining to the trade association some of the reasons that

impelled FDA to take the actions that it took.

One thing that I learned to my distress was the, shall I say, trepidation with which the industry viewed FDA and particularly its inspectors. I'm sure that some of the stories that I heard at NCA were exaggerated, but even allowing for a certain amount of exaggeration, industry frequently had some real cause for complaint over the actions, and particularly the attitudes, of Food and Drug inspectors who came into their plants making inspections. That distressed me a great deal because as a former FDA career man, I had a love and a loyalty for FDA that I certainly will never get over. So, I often had the task of attempting to justify and to explain the actions of FDA inspectors which really were very difficult to justify or to explain. Many of our Food and Drug inspectors, I'm afraid, are intoxicated with the authority that they think they possess and they certainly do not present a good public image of FDA.

The next thing I observed was the difficulty that one has in getting in touch with someone in FDA, particularly in the Washington headquarters office. Even with my experience and my knowledge of who had responsibility for what subjects, I often had difficulty in reaching them. A telephone call to almost any Washington FDA office will result in your being told that the individual that you are trying to contact is "in a meeting" and if you are persuasive, you can get the secre-

tary to promise to have him call you. But frequently this is a promise that is not fulfilled and it may be days later, and maybe never, that the individual whom you called will call back. I do not think this is the individual's fault, but I think it is a breakdown of communication within the organization where the secretaries do not properly follow-up on a request. Again, this presents a very poor public image and to one like myself, calling from here - making local calls from the District - it is bad enough, but for an individual calling from Colorado or North Dakota or somewhere else, attempting to get in touch with some individual whom maybe he simply knows by name, because it has been given to him and he has a problem on his hands. Sometimes he has a very acute problem, and something demands an answer immediately; and to be put off that way does not improve FDA's image with the public. There is a great deal of room for improvement there.

FL: Well, Lowrie, we've had a long, rather exhausting session here and I'm sure you must be feeling the effects of the amount of talking you've done. Is there anything else that you can think of that you would like to say on the record?

LB: No, Fred, I believe I've said enough and perhaps too much already.

FL: Well, I think this has been one of our better recordings and I certainly do appreciate your taking the time to sit down here and talk about FDA during our times. Thank you very much.