

# History

of the

## U. S. Food and Drug Administration

Interviewee: Jerome Bressler

Interviewer: Robert A. Tucker

Date: April 23, 1999

Place: Chicago, IL

## INTRODUCTION

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

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

# INTERVIEW INDEX

General Topic of Interview: History of the Food & Drug Adm.

Date: April 23, 1999

Place: Chicago, IL  
FDA District Office

Interviewee(s): Jerome Bressler

Address:

Last FDA Position: Director of Compliance Branch,  
Chicago District

FDA Service Dates: November, 1942 - December, 1984

Interviewer(s): Robert A. Tucker

Number of Tapes: 2 Length: 90 minutes

---

Tape	Page No.	Subject
1-A	1	Personal history
	3	Early FDA employment information
	5	Food regulatory enforcement work
	7	Drug enforcement work
	8	Abbott Laboratories recalls
	9	Fountain Committee hearing re Abbott Labs.
	13	1964 aborted FDA Abbott Labs. inspection
1-B	15	Kefauver-Harris GMP drug inspections
	16	Small drug firm recalls
	17	Tylenol recall
	18	HACCP fishery product inspections/recalls
	19	Krebiozen investigation
	22	Compliance Branch Director experiences
	24	Factors relating to unique tenure in one District

Tape	Page No.	Subject
1-B	25	Traditional agency criteria for promotion
	27	CEPHS (Consumer Protection for Enviromental Health Services
2-A	29	G. D. Searle animal study data problem
	31	Abbott Coumadin product contamination problem
	32	Aminotriazole cranberry contamination, (investigation & recall)
	34	Industrial Biotest (IBT) Naprosyn, ("graphited" animal test data)
	37	Nutra-Sweet investigation Personal impressions re FDA
	38	Voluntary Compliance
	39	Military service; Bronze Star & Closing remarks

DEED OF GIFT

Agreement Pertaining to the Oral History Interview of  
Jerome (Jerry) Bressler

As a conditional gift under section 2301 of the Public Health Service Act (42 U.S.C. § 300 cc), and subject to the terms, conditions, and restrictions set forth in this agreement, I, Jerome (Jerry) Bressler

~~do hereby give, donate and convey to the National Library of Medicine, acting for and on behalf of the United States of America, all of my rights and title to, and interest in, the information and responses provided during the interview conducted at FDA's Chicago District Office, Chicago, IL on April 23, 1999 and prepared for deposit with the National Library of Medicine in the form of recording tape and transcript. This donation includes, but is not limited to, all copyright interests I now possess in the tapes and transcripts.~~

Title to the tapes and transcripts shall pass to the National Library of Medicine upon their delivery and the acceptance of this Deed of Gift by the Chief, History of Medicine Division, National Library of Medicine. The Chief, History of Medicine Division shall accept by signing below.

I place no restrictions upon the use of these tapes and transcripts by the National Library of Medicine.

The National Library of Medicine may, subject only to restrictions placed upon it by law or regulation, provide for the preservation, arrangement, repair and rehabilitation, duplication, reproduction, publication, description, exhibition, display and servicing of the tapes and transcripts as may be needful and appropriate.

Copies of the tapes and transcripts may be deposited in or loaned to institutions other than the National Library of Medicine including the U. S. Food and Drug Administration. Use of these copies shall be subject to the same terms, conditions, and restrictions set forth in this agreement.

The National Library of Medicine may dispose of the tapes and transcripts at any time after title passes to the Library.

Date: 8/21/99 Signed: Jerome Bressler

I accept this gift on behalf of the United States of America, subject to the terms, conditions and restrictions set forth above.

Date: \_\_\_\_\_ Signed: \_\_\_\_\_  
Chief, History of Medicine Division  
National Library of Medicine

RT: This is another in the series of taped interviews for the FDA History Program. Today, Jerome Bressler, retired Director of Compliance, Chicago District, FDA, is being interviewed at the Chicago District Office. The date is April 23, 1999, and Robert Tucker is with Mr. Bressler doing the interview.

Jerry, as we begin these interviews, we like to have a brief autobiography, where you were born, raised, educated, and any significant experience you might have had prior to joining FDA.

JB: Well, I was born March 19, 1922, in Chicago, Illinois. I attended the usual, the grammar school, the high school, and then after high school I went into the military. I became a sergeant in the Radio Section of the 1st Battalion of the 414th Regiment of the 104th Infantry Division. We were on the "line," if you want to call it that, for 198 days in combat.

RT: What years?

JB: Nineteen forty-four through nineteen forty-five.

My service entry date was November 24, 1942; I got discharged December 9, 1945. Shortly after my discharge, I enrolled at the University of Illinois in Urbana, Illinois. I got my B.S. degree in nutrition chemistry in June 1950.

RT: OK. Did you . . . ?

JB: I worked . . . What?

RT: Go ahead. I'm sorry.

JB: After getting my degree, I worked for Armour & Company located at the Union Stockyards in Chicago, Illinois. I was doing research involving byproducts from the meat industry.

I was then transferred to a laboratory outside of Chicago, in Cook, Illinois, doing chemistry analysis on soaps and other byproducts from the meat industry. I was there till around sometime in 1956, when I heard a speech from Dr. Durbin. He was at that time in the Bureau of Veterinary Medicine.

RT: Dr. Charles Durbin?

JB: Was it Charles Durbin?

RT: I believe so.

JB: I know he's dead.

RT: Yes.

JB: I was impressed with his speech, and I talked to him. He suggested I take the Civil Service Exam and join the FDA. I took the Civil Service Exam, it's the FSEE (Federal Service Entrance Exam), to become an inspector. I passed the exam. I became an inspector July 1956 at Chicago District.

RT: You entered at what grade level?

JB: GS-5. We all entered at that time GS-5. I believe because I was a veteran, I received a five-point--I can't remember whether it was a five-point or ten-point advantage

on the test. I know I made very high on that exam, plus I was given an oral exam, which I passed also. I was interviewed in June or July 1956.

RT: Who was the interviewer?

JB: The interviewers were the regional representatives of the HEW, FBI, and the U.S. Attorney. Then I was interviewed by Mr. George Daughters. He was the director of the FDA district. I believe he's deceased.

RT: I believe he is.

JB: And George Daughters hired me as an inspector. In those days, we were all inspectors or chemists.

RT: What was your early involvement with the agency? What kind of work were you assigned to?

JB: For a while I was working in the lab, if I remember. We're talking forty-two years ago. I was working in the lab for a very short while, and then I became an inspector. Because most of the people who had any chemistry background were working either in the lab or became inspectors, and I became an inspector. At that time, I remember my salary was \$3,640 a year.

RT: It's changed a lot, of course, since then.

JB: And quite a number of the inspectors were married and had children and had extra jobs to keep them going. And at that time, I was a generalist. A generalist is one who



makes inspections covering all commodities. Primarily at that time it was food sanitation, pesticides, and health fraud.

RT: I think when I first knew you, Jerry, you were working with Charles Curry . . .

JB: And Frank Thompson.

RT: And Frank Thompson, yes.

JB: And they took me out for training in Indiana, because northern Indiana was part of the district. Chicago District was a large district. It had the northern half of Indiana, all of Michigan, including the Upper Peninsula, half of the eastern portion of Wisconsin, and northern Illinois.

RT: Yes, it was a large territory at that time.

JB: We did a lot of traveling. Sometimes we'd be away from the district for as much as a month.

RT: That was a problem, of course, for some of the people, as you mentioned, who had families, being gone that much.

JB: That's true. It was difficult. And also those inspections covered primarily sanitation; although we did cover labels/labeling, short weight of labeled food products. As inspectors we sampled a wide variety of food stuffs for filth and the presence of pesticides. We also were concerned with health fraud.

RT: Now who was the chief inspector at that time? Do you recall?

JB: Bill Cavett. He's long dead. He was the chief inspector. We made many road trips. We might be in the district maybe a week to write up our reports. Most of the time we're out in the field. We had very few inspectors; we were a large territory; we had to cover quite a bit of territory. I believe, at that time the agency may have had a total of 120 inspectors to protect its citizens. We were a very poor agency, budget wise.

RT: Now, in those early days, were you involved in any particular investigations that led to regulatory actions?

JB: Well, I can't recall specifically, but most of the cases at that time were seizures and prosecutions.

RT: And these were for the adulteration of foods?

JB: That's right, adulteration. Surveillance for adulteration was necessary at that time because the food storage industry, especially food warehouses, were filthy.

RT: And perhaps misbranding?

JB: Short weight based on false weight declaration on the label. In some cases false medical claims on the label of certain drugs.

After I had been in the district seven months, I received by GS-7 rating. In those days, you had to have two prosecutions during the fiscal year to receive a promotion to a GS-9.

We concentrated "on cleaning up" the food industry, covering wheat in railroad box cars, food processors, food storage facilities involving interstate commerce.

RT: So the . . .

JB: Because of our lack of inspectors, I believe Chicago District had about twenty to twenty-five inspectors, we avoided enjoining a violative firm. The district had to monitor the injunction which was personnel intensive.

RT: So the measure of success at that time was more or less on a basis of the number of regulatory actions.

JB: That's correct.

RT: Voluntary compliance concepts were not being pursued much then?

JB: We were concerned with voluntary compliance, and at that time we tried to measure voluntary compliance. We would suggest management "clean up" of their facility. If there was correction, it was reported in your inspection report.

RT: Would that have counted on the promotion?

JB: I don't remember.

RT: Now as you were promoted . . .

JB: It probably did. I know I had quite a number of violative cases. I know at one time I made over a hundred inspections in one fiscal year, and a majority were violative.

RT: Those were mostly in the food area?

JB: Yes. We did some inspections in the drug area, but at that time we did not have the GMPs (Good Manufacturing Practice regulations). Prior to the passage of the Kefauver-Harris Amendment that resulted in the GMPs, our inspections were limited to those drugs that had a New Drug Application (NDA). Our inspections determined whether a firm was meeting the requirements of the NDA.

RT: So these would have been drug manufacturers primarily.

JB: In 1962, the regulations covering--the Kefauver-Harris Amendment came into effect.

RT: Right. And that required, of course, proof of efficacy?

JB: That's correct. A drug firm, at that time, based on the Amendment, had to show not only that the drug was safe, but had to show that the drug was effective. But that was not too much of a problem at the district level. Our inspections determined if a firm was meeting the current Good Manufacturing Practices (GMPs), under Section 402(a)(B) of the Act.

RT: All right. Now how long did you serve as a field inspector? Later, you got into compliance activities. Is that farther down line?

JB: Oh, yes, much further. At that time, Owen Lamb became the chief inspector, and I don't remember all the facts. But at one time, he decided to become, I don't know if you call it the chief or director of compliance, and Owen Lamb asked me to leave supervision and become a compliance officer. I don't recall the year.

RT: Now, before you really moved from the field inspection level, were you . . . ?

JB: I became a drug inspector or investigator.

RT: Were you involved in the investigations of some significant cases? There were a number of them in this district. Were you involved as an investigator in some of those?

JB: As an investigator inspecting Abbott Laboratories.

RT: What's the story with that firm? What's the situation with the laboratory? What kind of a problem was that?

JB: Well, they had a series of recalls because of label and product mixup involving large volume parenterals, and I was in charge or team leader at that inspection. Mr. Ray Mlecko was part of my team, and Al Woodson, a chemist.

RT: Mr. Mlecko, who you mentioned, is currently the district director here in Chicago.

JB: That's correct. I was in charge of the team. Our inspections of Abbott Laboratories took about a week or more. We found evidence that Abbott was not meeting the GMP regulations. I think this might have been in 1964 or '63. I am guessing. This was more than thirty years ago.

Based on our findings of the violative nature of their operations in manufacturing large volume parenterals, Abbott had the largest recall of any drug firm at that time. In effect, Abbott was shut down for about one or two months because of the nature of the recalls. We collected samples of their large volume parenterals. In some cases we found mold; in some cases the label on the bottle did not agree with the product that was inside the bottle nor with the label that was on the cap. This recall was covered by virtually all of the investigation staff across the country who were engaged in collecting samples of a wide variety of Abbott's large volume parenterals.

RT: Now these large volume parenterals recalled were causing septicemia?

JB: Yes, septicemia and bacteremia. Well, you can say just septicemia.

This was the second recall. Let us not get this recall mixed up with the recall covering the inspection with Ray and Al just mentioned.

RT: OK. Now . . .

JB: At that time--gosh, it's thirty years ago--I was . . . I can't remember whether it was John Guill was the district director or Bill Clark? If I remember, this was the second recall. Let us not get confused with the recall that was initiated by a label mix-up. This second recall was based on our finding septicemia and bacteremia.

RT: It was Guill at that time. Clark was later, wasn't he?

JB: I don't know.

RT: Anyway, those two men both served as directors of Chicago District.

JB: Anyway, I was sent down to represent the district to the Center for Disease Control (CDC) down in Emory, Georgia. There was a question of what was causing this septicemia or blood poisoning found in patients that received Abbott's large volume parenterals.

RT: And your purpose in going to CDC was . . . ?

JB: As a representative of the district.

RT: To provide investigational input?

JB: Well, oh, oh, oh. Let me backtrack. I'm getting two issues with Abbott mixed up.

The first recall was based on the inspection that we made and found label and product mix-ups. Then later on there was another recall. Abbott had three recalls that I was involved in. One was the one because of the label mixup. The second or third recall involved the presence of septicemia in patients. That's a separate inspection. And that's when I went down to CDC, because CDC did the analysis of the drug, and at that time we thought it might be contamination of tubing coming from the IV solutions to the patient. CDC learned that it was not the IV tubes. The contamination was caused by Abbott changing the lining in the caps of the IV bottles. Their research found contaminated water in the lining of the caps used on the large volume parenterals.

RT: Yes, then what additional information was obtained?

JB: Abbott Laboratories at that time decided to change the inner lining in the cap. They had a screw-type cap, and they changed the lining. Previously they had a lining under the screw-type cap that had paper with several layers, maybe six or seven layers of paper, that was in the screw cap. What Abbott did is they decided to change the inner lining to a plastic type. I can't remember the name of the plastic type liner. It was learned that the smooth plastic liner in the cap of the IV large volume bottle did not fit tight under the cap. The plastic liner in the cap did not fit into ridges that might be on top of the glass. So when in the processing of large volume parenterals they were heated to sterilization temperature, and the bottles were then cooled in water causing a vacuum which sucks in the cooling water. This water was drawn into the bottle. The water got under the cap. That's what was causing the septicemia in patients. This water got into the product itself. It had nothing to do with the tubes, as CDC learned.

Why Abbott decided to change the other inner lining, which was a paper layered lining, I do not know. The paper would fit into all the ridges tight--the plastic did not. The paper lining fit tight and sealed the cap to the bottle. The use of the hard plastic did not. These ridges were quite small--not quite microscopic. Thus, the cooling water was under the plastic rigid liner. When the bottle was opened, the cooling water was able to get into the actual solution.

RT: I see.

JB: And that's the inspection we made. Abbott changed from the screw cap to a bung, so today there is no problem. The firm no longer uses a cap for their solution. In other words, the theory is when a nurse or therapist prepares to use the IV bottle that had the screw cap, he or she would turn the screw cap in such a way that if there are any pathogenic organisms under the cap, the microorganisms would get into the solution. This was the reason for the recall of all of the solutions that had, I believe, the "Mylar" plastic liner.

Then the third recall; I can't recall whether it was before Abbott decided to use a bung or not. I think that was prior to using the bung. The first was the recall because of label mixups. This is the second recall when Abbott decided because of a strike at the manufacturing plant to use Class I bottles, which would be obtained from Mexico. These bottles were not very good; they were not Class I bottles that should be used for parenterals. We received a telephone call from Seattle District. A good friend of mine, Inspector Goldsworthy. I don't know if he's still alive.

RT: Bob Goldsworthy.

JB: Yes, do you know him?



RT: Yes.

JB: He called me. We got to know each other. He said he was at this public warehouse. He was a fellow inspector like myself, and he called me. He says, "Guess what? Abbott is pulling these bottles out, and there's something wrong." Abbott did not inform us that they were pulling the product, withdrawing it, or recalling it. We learned that the bottles that they were getting from Mexico were creating what was referred to as split finishes in the bottles. The bottles containing the IV solutions split at the top edge of the bottle.

RT: The firm really wasn't under an obligation to report to the Food and Drug Administration this change, were they?

JB: I'm not sure, but they didn't call FDA about this problem. I believe they should have, because these products are life-saving drugs. They should have, but they didn't. That is how we learned of their recall. We went to Abbott Labs and confronted them with the facts. This resulted in another large recall that the agency had to monitor. All of these recalls nationwide involved quite a large number of investigators and chemists. I have no idea of the man hours used.

RT: So after that recall, presumably they reverted back to an American bottle manufacturer?

JB: Yes. Abbott was shut down until it got Class I bottles from an American firm after the strike. I don't know which one. Class I bottles had to be used for large volume parenterals.

RT: All right.

JB: There was something . . . You asked me a question, and I lost my thought.

RT: Well, let me stop and we'll go back and see what the question was.

(Interruption)

JB: In 1964, I was subpoenaed by the Fountain Committee, the Oversight Fountain Committee, concerning Abbott Laboratories and the first recall described earlier. This is after that first inspection. I represented the district, but prior to my testimony, John Guill, he was the district director, testified before the Fountain Committee, as well as Cliff Shane, who was the chief inspector at that time, and I was the inspector. This was before the Fountain Committee. This was after that first inspection we referred to where Abbott had these recalls and so on.

I know there were some changes made based on our inspection. My supervisor was Frederick Carlson, and I don't recall whether he wrote the transmittal to the inspection report or whether Cliff Shane did. Anyway, I believe there were some changes made in the transmittal to the inspection report. I know that during that inspection of '64 (I believe) I received a call from Mr. Frederick Carlson, who was my supervisor, for me to leave the firm. We aborted the inspection. I remember we were to get out before noon; we left at 11:56. Abbott questioned why we weren't finishing the inspection, and we told them we've got orders to leave. I think that was part of the questioning by the Fountain Committee why we left and did not complete the inspection. I said we were told to leave early.

RT: Is there a reason?

JB: I don't know all the details because I can't remember all of it because it's over thirty years ago. But I know I testified. I did testify before Congress, as well as a number of people in headquarters. I know Jim Nakada also testified.

RT: Jim Nakada.

JB: He testified. At that time he was working for (Allan) Rayfield, and I believe the message came from Mr. Rayfield, who was in charge of the field, possibly through John Guill or to Cliff Shane. But I know my supervisor, Fred Carlson, told me as the team leader to leave and we did.

I believe there is some history, because I believe Cliff Shane was interviewed and others were interviewed, as well as Nakada and Guill way back when, regarding the Abbott issue.

RT: I think they have spoken to that in . . .

JB: What?

RT: I think these gentlemen have touched on that in oral interviews that were done with them.

JB: Bob Porter was the one that interviewed--no, no . . . Yes, he interviewed me, and I, at that time, gave him what information we had. At that time, I was an employee of FDA. You must understand this was over thirty years ago.

RT: OK. That was certainly a big case, an important one. Are there some others . . . ?

JB: This was the first time Congress was concerned about whether we were making inspections involving the Kefauver-Harris Amendment which had to do with Good Manufacturing Practice regulations which was the field's responsibility.

I remember when I testified before Congress, that was in Executive session. I can't remember which congressman asked me the question, whether because of the problems with drugs itself, whether we should have an inspector there at all times, such as in the meat industry, and I told him emphatically, "No, because of the nature of the drug industry, the inspector could be in one portion of the firm and something else could be going wrong at the other, and the inspector should not share responsibility with industry for putting out a proper product. The industry should be solely responsible; we should make inspections to check if they're meeting the regulations at all times."

(Interruption)

JB: . . . more later on, probably at home.

But, anyway, shortly after that I became a supervisor primarily supervising drug inspectors, drug investigators.

RT: You were promoted to what?

JB: Supervisor. It was a GS-12/13 at that time, twelve.

RT: When you went to the GS-11 level, had you become a specialist in drug work?

JB: Yes, yes. I became that. And I had made inspections mostly in a drug area to fulfill our obligation under the Good Manufacturing Practice regulations, because the law read that we had to make an inspection of each drug firm every two years, which put a tremendous load on the districts to get people trained. So there were all kinds of courses

given by the agency on Good Manufacturing Practice regulations to train the people doing this kind of work. This work is very different than collecting rodent pellets or insects. Now you're collecting, reviewing mostly records and the procedures that the drug firms are following. The agency had to be prepared to make a different type of inspection in the area of drugs. At that time, devices was classed essentially as a drug. The amendments covering devices had not been written, approved, whatever.

So primarily I was a manager now. Although as a manager I would go out on occasion with our inspectors. Our investigators--they were now investigators.

RT: What year was it that you became a supervisor? Do you recall?

JB: Oh, this was probably 1965 or '66. Maybe '66.

We had other drug firms that I had inspected. We had a large increase in recalls, because the agency increased its inspections of drug firms. We were finding all kinds of violations of the Good Manufacturing Practice regulations which covered the manufacturing of drugs, whether it's large volume parenterals, small volume injectables, tablets, capsules, and suppositories. Abbott at that time might have been maybe a \$2 or \$3 billion corporation. The firm was not only manufacturing large and small volume parenterals, it was also manufacturing all kinds of tablets, suppositories, and capsules, as well as some products of an agricultural nature. We were spending a lot of time at Abbott, as well as Baxter Labs.

RT: Was there any regulatory action that came about then?

JB: The district covered some of the smaller drug firms, like Medical Chemicals, Hallmark Labs, Evvon, etc. These firms had all kinds of recalls. I don't know if these firms are still in business.

Until we got a recall coordinator, the investigator also had the problems of monitoring recalls. The administration decided because of the amount of recalls, we had

to have a recall coordinator, a special position. Today, there is a recall coordinator in every district.

RT: I don't know whether this fits at this point in the chronology of your experience, but I would like somewhere along the line to touch on such recalls as Tylenol and others that were important events.

JB: Oh, you remember the Tylenol. Someone laced the capsules of Tylenol with cyanide.

RT: At the retail pharmacy level.

JB: Yes. The laced Tylenol was found in some retail pharmacy where an individual or individuals placed cyanide in the Tylenol capsules. At that time we were working with the State of Illinois covering the investigation. We were collecting samples. Everybody was working. Primarily all we did was collect samples and analyze them for the presence of cyanide.

RT: Was that . . . ?

JB: And that also occurred within the district, but I was not totally involved at that time, except having our people and collect samples.

RT: The laboratory examinations were done in Chicago?

JB: That's correct.

RT: Did you become involved in some of the fishery or fish for food contamination problems in the Great Lakes that occurred somewhere along the line? I think we had some PCBs or maybe PBBs in ale fish and in chubs.

JB: No. I got involved later on as a director of compliance or as a compliance officer with the inspection that was done of a firm called Impex. And we made seizures, and the case eventually was given to OCI (Office of Criminal Investigation), which prosecuted the firm. That's maybe five years ago. We're jumping.

RT: Yes, I understand. Well, I'm trying to shuffle the chronology.

(Interruption)

RT: You mentioned the Tylenol recall. Do others come to mind in that category?

JB: There was a recall, some of their fish which was decomposed, and that might have been the precursor to the seafood program that we have today, that is the HACCP (Hazard Analysis of Critical Control Points) program. I'm not sure, but I know we had a lot of problems with the kind of fish distributed by this company.

RT: Well, there was quite a problem with smoked chubs.

JB: That's right. There was a firm located in Grand Haven, Michigan, that packed their fish in a sealed container which created an anaerobic condition, whereby the fish became contaminated with botulism. The fish had the spores of botulism. Botulism is deadly. Several people died after eating the fish. I was on the peripheral end; I was not involved with that case except sometime later collected samples to analyze for botulism.

RT: Now another important issue that was dealt with in this district was the problem with Krebiozen. Do you recall anything about that in your experience?

JB: We made an inspection, Ray Mlecko, myself, and Carl Sharp, of a Dr. Phillips. He was a doctor who was giving Krebiozen for cancer. I know one night we stayed till about 1:00 or 1:30 (a.m.). We collected his records, his patient records, and then had to go back to the district, make photocopies, and bring it back to him the next morning. And at that time we were able to obtain, because of Krebiozen, a Xerox copy machine. We were the first district to have a Xerox machine. It was a Xerox Model 911, and we had a lot of copying to do. Investigators went to all the hospitals, patients, and so on. My goodness! I forgot all about the number of records involving the use of Krebiozen. We worked on that for weeks or months collecting slides, x-rays, patient records, etc. We conducted an inspection of Dr. Phillips, who was promoting and giving patients the Krebiozon, an injectable (ampules).

An investigator by the name of John Palmer from headquarters was at the district working with us. He was the one that testified in the Krebiozen trial. It was the longest trial in the Northern District. I think it was about nine months long.

That's the trial we lost.

RT: Was that John Palmer or Bob . . . ?

JB: Yes, John Palmer.

RT: John Palmer. Now Dr. Ivy was involved in this . . . Was he involved with Dr. Phillips?

JB: That's right.



RT: Dr. Ivy was a renowned, recognized doctor.

JB: He was the Chancellor at the University of Illinois School of Medicine. I only saw him once, and we would make tape recordings of some of the promotions. I went to Rockford and taped a promotion of the drug. He was promoting Krebiozen to patients that had cancer. We're talking about the early sixties.

RT: Now Krebiozen, that was a derivative using the urine of horses urine. Is that correct?

JB: They're looking for creatine from the horses' urine. It was a theory that was strictly, as far as I was concerned, a terrible scam.

RT: I believe that it involved the Durovic brothers?

JB: Yes, Durovic, and they were manufacturing the product right here in Chicago, putting it up in ampules above an abandoned fire station near the district. What street is it? Yes, we were watching what they were doing; we were at that time.

I'm sorry I'm a little vague because it's such a long time ago. We're talking about thirty years plus.

RT: Yes, I know.

JB: And the trial was I believe one of the longest trials the Northern District, the U.S. attorney ever had. It was nine months long.

RT: Apparently, Dr. Ivy for a time, didn't he get, or at least attempt to involve the medical community?

JB: I remember Ray, myself, and Carl Sharp were supposed to testify. Billy Goodrich, from our General Counsel Office, had dropped into the district. We went to the U.S. Attorney's office, and I remember waiting for a whole day--it was before Judge Hoffman--waiting the whole day because we thought we were going to be testifying. For some reason, Judge Hoffman decided the three of us did not have to testify. We had all of our diaries available if we had to testify. I remember Billy Goodrich--at that time, he was the head of General Counsel--took the diaries with him. We never saw them again. We didn't have to testify.

RT: I was about to ask you a moment ago, is it correct to recall that Dr. Ivy tried to get the support of the medical community at large behind Krebiozen?

JB: I don't know about that.

RT: I believe that was true.

JB: I was not involved.

RT: Yes. I understand.

JB: The districts would receive from the administration a list of patients that were supposed to have cancer, and we investigators would check on each of the listed patients. We would visit hospitals and get the patient's x-rays, their histological slides, whatever, and we would collect them and make copies of their records. If the patient had died, we would obtain the next of kin's permission to copy all the hospital records or at the physician's office. We'd get permission to copy all the records. These records were forwarded to headquarters for review.

RT: Did some of the supporters of Krebiozen demonstrate and make their presence known?

JB: Yes. I guess they did while the trial was going on. Not at the district, I recall, but probably at the U.S. Attorney. I wasn't involved in that part. I know there was some demonstration for Krebiozen. And all the studies show that Krebiozen was not effective.

RT: Were there any other classic cases, not necessarily in the order of occurrence, but in your experience that stand out?

JB: I can't remember any, you know, that stand out.

RT: OK. Well, when you were in the compliance unit here, what were some of your experiences there, either as a staff person or later when you became the manager of that office function?

JB: As a compliance officer of various cases, I would take over personally to the U.S. Attorney, such as seizures or maybe an injunction. I remember one big injunction that we had involved a defibrillator. I can't remember the name of the firm. We enjoined the firm through the U.S. Attorney. I got to be very close to the U.S. Attorney. Well, he's now in private practice. It was Fred Branding. At that time, he was chief of the Civil Division. Most of these cases were in the Civil Division.

RT: So did you, as you became manager of the Compliance Branch, undertake any particular reorganizations or ways of operating the branch that were new and different?

JB: Ray Mlecko appointed me as the director of the branch. Ray had, as you know, formerly been the director of a compliance branch in Seattle. The only big change that we

made was to decide that the compliance officers would be specialists in a given field, such as they have been in headquarters. An individual, based on his or her experience, knowledge and training, would be responsible for a given commodity such as: (1) food sanitation: labels/labeling, seafood (there is a special program covering seafood known as the Hazard Analysis Critical Control Point, HACCP); (2) drugs: GMPs, label/labeling, NDAs (New Drug Applications); (3) devices: GMPs, labels/labeling; (4) biologics: GMPs, blood; etc. This illustrates how we developed specialists in the compliance branch. In the past, a compliance officer was a generalist developing legal actions covering a wide range of violative investigatory inspections from the investigations branch.

RT: Did that specialization result in more rapid turnover of case load?

JB: Because of the complexity of cases today. It is better for an individual to become a specialist in handling these kinds of cases and the compliance officers have to be just as knowledgeable as the investigators.

RT: Yes, my point was . . .

JB: And, let's see. George Bailey handles biologics and drugs. Our drug compliance officer transferred.

RT: The point of my question is did that actually result in a more efficient operation?

JB: Oh, yes, of course, because they became more and more knowledgeable about the regulations covering that specific commodity. They become to know the investigators, who also were specialists. Oh, yes. The compliance officers became a specialist in a given area, who would meet with the investigator, who was also a specialist in a given area.

RT: You know, as an agency, we've always had concerns about long delays in the processing of things.

JB: Oh, I'm pretty sure this speeded up things, yes.

RT: I wondered if it speeded it up significantly?

JB: I would think so. I wasn't in a position to measure.

RT: I don't know where this happened in the chronology of things, but wasn't there a problem with Biotest, a Chicago firm? What was the nature of that situation? I think they were perhaps making fraudulent reports of some kind. Do you recall?

JB: No. I don't remember Biotest. I'm sorry. Sorry, maybe I'll recall it tonight. I don't recall it right now.

RT: All right. Well, you've worked under a number of different managers.

JB: That's true. There were quite a number. You're right, and I never left the district.

RT: In that respect, you're one of the relatively few persons that served entirely in one location. I think Mr. Boudreaux, who was director at New Orleans, is another example.

JB: Yes, he was in that district.

RT: He had started as a chemist and spent his entire career there, which is very unusual.

JB: Joe Phillips never transferred.

RT: Is that right? Has he been at Philadelphia all of the time?

JB: He's in Philadelphia District. He's still in this district.

RT: Which is rather unusual.

JB: Joe Phillips never transferred.

RT: Do you . . . ?

JB: I was very fortunate.

RT: Did you have a particular reason for how that occurred; that this opportunity occurred? It seems that most field people have had a lot of mobility.

JB: Well, when I joined the district, you were transferred whether you liked it or not under Mr. Rayfield. Fortunately, he never singled me out for transfer. So I was always promoted within the district. However, I never really put in for any position outside the district.

Today, when a position is available in another district, you have the chance to compete for that position. In the past, it was mandatory to transfer to that position if you are selected. It was rough, because many families were forced to transfer to a strange area.

Now, let me backtrack. It doesn't seem like too many people wanted to come to Chicago District.

RT: Well, there are several districts that are not as popular as others.

JB: When Chicago District had openings and placed a request for supervisors, as an example, Chicago received few responses from qualified people. Because of what other districts heard about the weather or the crime rate or whatever, people were reluctant to come to Chicago. Very few people wanted to come to the Chicago District. I know when I became a supervisor—I forget his name—came in for an interview. He was from Atlanta District. Can't remember the name. He came in, spent the day, he was interviewed, and he turned it down. He didn't like Chicago. He was from the south. He didn't like Chicago at all. Whether it was the weather or the big city, I do not know. There are two districts that very few people seem to want to transfer to: New York and Chicago.

RT: That's true.

JB: Most investigators preferred Denver, Seattle, Atlanta, Miami, etc. I do not blame them. The kind of work we do in Chicago—with its great variety and complexity—why go to Chicago? The pay is the same. Another reason may be the reputation of the district director.

RT: So your willingness to remain in Chicago didn't turn out to be a career disadvantage.

JB: No, the competition was from within the district.

RT: It's been my understanding that some folks have had the impression if they didn't transfer they were stymied and they weren't going to move any farther ahead in the agency.

JB: Well, yes, that was true when field personnel decisions were made at headquarters.

RT: Yes. I was thinking it might have been when Hile became the EDRO that vacancies were announced field-wide.

JB: I know Paul Hile very well. He was a friend of Owen Lamb's. He was my chief investigator and the director of the Compliance Branch. I worked for him in the Investigations Branch and the Compliance Branch.

RT: I think Paul had a more enlightened view of a person's personal preference and family needs than maybe the old-time management might have had.

JB: I remember we were under Johnson about that time, under another management level.

RT: Oh, President Johnson?

JB: No.

RT: Perhaps you're thinking about the Consumer Protection for Environmental Health Services?

JB: That's right.

RT: CPEHS.

JB: CPEHS. That's what I meant. Mr. Johnson, Director of CPEHS, visited Chicago District.



Anyway, someone challenged him and asked, "Why does a person in order to be promoted have to transfer?" He indicated that was not right and that he would look into this policy.

RT: Oh, I know who you mean. You mean C. C. Johnson.

JB: Yes.

RT: OK.

JB: I know his last name was Johnson. And he said, "That shouldn't have to be. People should have a choice. Nobody should be forced to transfer no matter how good they are, and if they don't want to go, they shouldn't be affected." All of sudden, if a district wanted a position filled, the district had to announce the position was available. People had a choice of whether they wanted to take the position or not.

I remember being considered for a promotion to a supervisor. I can't remember whether it was Owen Lamb; he was the chief of the investigations branch. Owen Lamb knew Sam Fine, because they were both from Dallas District. Sam Fine was the director of Field Operations. He was the Ron Chesemore of some time ago.

RT: Yes, I remember Chesemore.

JB: Sam Fine was a wonderful man. Owen Lamb told Mr. Fine he wanted me. The field was watching whether I would be promoted without a transfer. They figured if I got to be supervisor, any other person could be supervisor without being transferred. Mr. Fine approved of my promotion to supervisor. Owen Lamb went to Sam Fine and said that I know the area and I should have it and so on. That's why I owe a lot to Owen. I

believe I may have been the first supervisor to be promoted to this position and never transferred.

RT: Well, that was a precedent at that point, wasn't it?

JB: I was the first one. The first one that became a supervisor and never transferred. That's my precedent.

I remember having to go to Washington some time later. Who was the commissioner? What was his name?

RT: Well, what year was it that you're thinking of?

JB: If I knew the year I would tell you. At that time, I was with Carl Sharp. He was the chairman, and working with him and with Jerry Halperin. Alvin Gottlieb was in the session, and I represented the district. And, let's see, who else was there? Gottlieb. Dr. Daganno, he's dead. Dr. Frances Kelsey. That's when we were concerned about Searle, G. D. Searle, because of the lousy animal studies they did concerning investigating the safety of certain drugs and the food additive aspartame.

RT: Searle was producing what products?

(Interruption)

RT: We were talking about the Searle problem. Jerry, do you want to say something more about that group that you were discussing?

JB: I represented the district. Part of the task force was chaired by Carl Sharp. Frances Kelsey, Dr. Daganno-I can't recall the spelling-Alvin Gottlieb, Merv Shumate,

and Jerome Halperin were members of the task force. The task force wrote a report covering Searle's operations that went to the commissioner.

RT: The commissioner then was?

JB: Alexander Schmidt. I remember at the time that report was going to be given out, they were very concerned that it might affect Searle stock. It involved Searle's operations and that the stock would possibly drop, which I guess it did. At that time, they had a new chief executive, Mr. Donald Rumsfeld, who was formerly Secretary of Defense under Reagan.

RT: Now I'm not sure whether we touched on that. I think I might have raised the question of what class of products were involved?

JB: I'm not sure of the class of products, but I think it had to do with a variety of prescription drugs. I'm not sure exactly. I suggest that you interview Carl Sharp, because he was the chairman or obtain a copy of the task force report.

RT: Well, anyway, you were saying that Commissioner Schmidt was chairing the session.

JB: At the meeting with the commissioner, we discussed the task force report. Carl Sharp, with a team of investigators, inspected G. D. Searle. Remember this occurred thirty years ago. I represented the district, although I was not a member of the task force per se.

RT: Now the mission of the task force was what, to examine Searle's management quality control?

JB: Yes, their operations and procedures involving safety studies covering laboratory animals. I was not an actual member of the task force. I represented the district regarding the task force.

RT: All right.

JB: The trouble is I didn't want to keep any documents, so I don't have anything at home regarding this task force. But you might talk to, when you get back to headquarters, you might want to get a hold of Carl Sharp. He lives in Bethesda. He can give you more information and he can fill you in. He is also retired.

RT: OK. We've really covered Abbott Labs earlier, but I just wanted to ask one thing further about Abbott. Did they have some problems with Coumadin tablets?

JB: Yes, it was called warfarin by its generic name. We made a seizure after my inspection. Abbott, in their processing of warfarin, which is really Coumadin. They were making another tableted drug that came through their tableting system, and I forget the drug. It was contaminated with warfarin. We analyzed it, and confirmed that it was contaminated with warfarin. When Abbott was informed, the contaminated drug was recalled. I forget what the drug was that the warfarin contaminated. Abbott did not separate their operations in such a manner as to prevent contamination. Coumadin was being manufactured on a line using the same equipment as for another drug. We collected official samples and, lo and behold, we found presence of the Coumadin or warfarin in the drug that had gone through the same lot. Abbott management was informed at the time of my inspection that their system was flawed. The sample or samples was collected in interstate commerce. Coumadin or warfarin causes blood to thin. This kind of contamination was very serious when found in the other drug.

RT: So it was a matter of poor cleaning?

JB: GMPs. Boy, you've done a little studying here.

RT: OK.

JB: That was a long time ago.

RT: Now were you involved during the . . .

JB: I was the inspector at that inspection.

RT: Were you involved at any time in the cranberry contamination with aminotriazole?

JB: Yes, I was with Ray Mlecko, present district director, and myself. We collected the samples of cranberries at the Chicago Cold Storage Warehouse. The first samples that we collected of the cranberries from Ocean Spray were analyzed, and the laboratory found aminotriazole.

RT: Was that the . . . ?

JB: These were now cranberries. You know, aminotriazole is a systemic type of weedicide, if you want to call it that, in a group of pesticides. The first sample that we collected at this cold storage warehouse was found contaminated with aminotriazole. There were a lot of recalls. In fact, as I remember, it was around Thanksgiving time. A systemic type weedicide is sucked up by the roots into the berry.

RT: That's correct.

JB: In fact, our management couldn't believe the first sample we collected and analyzed by our lab was contaminated with aminotriazole. The laboratory did a lot of analyses to verify their original results.

RT: Was the sampling by Chicago at the point of discovery of this problem? Were you the first district that identified that as a problem?

JB: Yes. We collected samples, but there might have been some indications of a problem earlier. I don't recall whether there was somebody that sent us out to the Chicago Cold Storage to collect the samples. There might have been some information that told us to go to Chicago Cold Storage. That's where the raw cranberries were stored, in paper bags in a freezer. This occurred in the late fifties, over forty years ago.

RT: That was a national problem.

JB: It was a big recall. It was national in scope, because the collected sample was contaminated with aminotriazole. This was the first one. Other samples were collected, analyzed, and aminotriazole was found.

RT: That's really what I was driving at.

JB: Of the aminotriazole.

RT: Very good. I just wanted . . .

JB: My goodness, where did you get all these cases? You've been doing all this studying. Bressler involvement, is that what you're studying?

RT: Looking at some of the other things that happened.

Now are there any other cases or problems that you'd like to cover before we cover other topics?

JB: Well, yes. One that you mentioned earlier is Industrial Biotest.

RT: Do we have any information to add on that now.

JB: The fact they were prosecuted. That was a seven-month trial. The three individuals that were involved, one got a year and a day and the two got six months apiece. Again I was working with Carl Sharp on that case. And there were follow-up animal studies. There were three individuals involved. Well, there were four individuals, but one individual did not go to trial because he had to have a triple bypass, and so the U.S. Attorney decided not to indict him because he had heart trouble. But the three individuals that were involved, this involved animals studies that were graphited (a regulatory term used to define substitution of records that are false). There were studies covering two pesticides and one other drug. One of the drugs was Naprosyn from Syntex, and I don't know what the other drug was. I can't remember what it was. The Naprosyn study was the worst one, and that study had to be repeated by Syntex, because this animal study was graphited.

In the one case, and I don't know whether it was the drug or a food additive. Anyway, in one instance, the animals were supposed to be posted. The animals were supposed to have been bled before being sacrificed. The blood was analyzed for the effect the test substance had on these animals. However, for some reason the animals were sacrificed by Industrial Biotest (IBT), but they then didn't do any analysis of the blood. If I recall-I can't remember his name-graphited (falsified) that the blood had been analyzed in the study, which was a lie. He put in false figures showing the blood was analyzed. A person that worked with me, Adrian Gross, unfortunately is dead. He was

the pathologist that worked with us. He worked with Francis Kelsey. The blood was analyzed to determine if the test substance caused any abnormalities in the blood of the rats on study.

RT: Were these animal studies relevant to a New Drug Application?

JB: That's right. Naprosyn was the drug. It was the most important. And there were two other food additives, but I think there was a second drug. The three responsible individuals involved were prosecuted. That was an important case involving animal studies to determine the safety of these drugs and pesticides, which if found in food would be food additives. That was a seven-month trial, and I remember Judge Norberg said something like this, after the jury gave its verdict of guilty for the three involved parties. He said that educated people should be covering safety studies of products consumed by the public. He did not want to see the guilty parties in his courtroom again. That was a very interesting case, and we only had three attorneys on our side, and the defense had nine attorneys.

At that time, the Center for Foods was very interested in the case. I would get calls on occasion. I remember John Taylor called me. At that time, he was in the Center for Foods, before he became the Ron Chesemore of today. He used to be the director of our labs here in Chicago. It was a very important case for Food and Drug, and we did a lot of work in obtaining witnesses and so on. I think there were possibly one hundred witnesses. It was a landmark case, because it was the first prosecution of this kind in which people were incarcerated. Two for six months and one for a year. Two of the individuals had Ph.D.s.

What's interesting is what our attorney told the jury, "Sometimes scientists do lie," and these scientists did lie. They wanted these studies to be approved, because the average animal study costs quite a bit of money, maybe \$200,000 or \$300,000. If I recall, Syntex, who manufactured Naprosyn, had to repeat the study. If I recall, the FDA would not



approve any of the NDAs or food additives that were submitted, based on our inspection and investigation findings.

RT: Were those products in question in this matter eventually approved?

JB: Oh, yes, they were, but all of the studies, I believe, had to be repeated. Naprosyn was made by Syntex, a California firm. There might have been a fourth drug, but I can't recall. The two pesticides were classified as food additives because their presence in food would classify them as food additives. In the studies, these animals were consuming the two pesticides in animal feed at a control level, low level, mid level, and at a high level. The studies showed a "no effect" on the animals; that is, the pesticides at certain levels had no effect on their system-tissues, blood, etc.

There was another inspection we conducted, where we were at the firm for several months, from April till September. Four top investigators were selected to inspect G. D. Searle, Skokie, Illinois. They were Mike Erspomer, John Arnold, Carl Lorenzen, and another investigator. These investigators did not complete the inspection. One became very sick and the other had a family obligation.

Three scientists from the Center of Foods also accompanied us on the inspection. They were Dr. Dean Taylor, Toxicologist, Dr. Leonard Friedman, and Dr. Tom Xavier Collins, Teratologist. Dr. Collins reviewed the firm's animal study data.

RT: Who was in charge of the group?

JB: I was the team leader, and Tom Collins from the Center for Foods ran the animal study teratogenicity studies. Besides myself, Mike Erspomer, John Arnold, and two other fellows were involved as investigators. There were four of us. And also Dr. Jean Taylor--she's retired--and also Dr. Friedman. These are all from Foods. I know Jean Taylor is retired. Richard Ronk from Center of Foods selected the scientists, I think he's

retired too. Don Healton was at that time EDRO, and I had to report every two weeks to Bill Clark, district director, who reported to Don Healton, regarding the progress of our work. I know we were at Searle for some time--April 1977 to August 1977.

Our assignment was to determine the authenticity of their studies. There were three animal studies. One was a long-term study with rats and two were with mice. The studies covered the food additive aspartame, now known as Nutra Sweet.

Our task was to authenticate the submission to the agency of animal study data. We were to compare them with the raw data that was at the firm and to the submission to the FDA and to determine whether there was any fraud. We compared the available raw data at the firm with the submission to FDA. We discovered some major discrepancies in the rat study. This was a 115-week oral tumorigenicity study of the effect aspartame has on the rat.

RT: Well, Jerry I'm aware that your period of service to the agency spans more than forty-two years. I'm sure you have some impressions either about the agency or perhaps you would like to comment on why you elected to stay with the agency for such a long period beyond what many others have.

JB: There's no question, at least in my mind and based on the people with whom I associated, that FDA had a tremendous job to do in protecting the consumer. It was obvious to me that the consumer, based on our increase in population, could not do that much to protect themselves. I feel the key to our society is trust, and the only way the average person buying a product can have trust in that product is to have a regulatory agency that is there poking around and making sure that the products that the consumer is consuming or using are safe.

As an example, at one time we were sampling fruits and vegetables for pesticides, and we were making seizures all over in various areas because of the presence of pesticide(s) which should not be in anyone's diet because they are poisons. I figure based

on my career with Food and Drug progressing from a generalist concerned with sanitation, with poison in foods such as pesticides or different food additives, with the drugs that we're consuming, with the medical devices that are being used, and now with blood, I believe all these priorities illustrate the FDA's tremendous mission because the consumer can't do these things to protect themselves.

I know there are some economists who believe let the marketplace take care of itself. That's wrong when it comes to the products that the Food and Drug Administration regulates.

For instance, for example, someone buying a box of any kind of cereal does not expect it to have a pesticide in it, and there is one agency out there, a regulatory agency, that makes sure, that is the FDA. The agency recently monitored a recall involving a pesticide contaminated cereal.

For an example, I'll give you an analogy. There are those individuals, maybe five percent or whatever, who, when the highway sign says don't go over fifty-five miles an hour, will go sixty, seventy, or faster, and some people have died because of them wanting to take that chance. Food and Drug has the responsibility to maintain regulatory oversight over that percent of those firms in the covered industries to help assure the chance takers do not harm the consuming public by careless procedures.

I regard the forty-two years of my FDA career as an adventure and enjoyable. There were some times that were tough, but on balance they were a good forty-two years.

RT: What is your sense of the move in more modern times to a greater reliance on voluntary compliance or industry education? How does that square with your experience?

JB: No question about it, I believe in voluntary compliance. There are those, however, who, because of the almighty dollar and greed, are willing to take the chance, because it's costly in many cases to add controls, especially in the manufacture of drugs to make sure that the end product is what it's labeled to be and that it is effective. It costs a lot of

money for controls and there are those firms that are waiting to take a chance. And I saw that over the years. All you have to do is look at the history of the various prosecutions and seizures we've made, and you wonder why. This involves both small and large firms.

I strongly believe in voluntary compliance at those firms that you know are going to comply and make the necessary corrections, based on their established history of compliance.

The Good Manufacturing Practice regulations were passed in 1962. This is 1999, and we still see instances where there are seriously violative firms. We just made a seizure I understand in the Detroit District of millions of ampules that didn't meet the Good Manufacturing Practices regulations.

RT: Well, Jerry, if we've covered the bulk of your experience, then I guess we can close now. As I recall, you served in World War II and some time later received a special recognition for it. Would you care to comment about that?

JB: I was surprised when I got the bronze star. Our platoon leader, Lieutenant Stuart Popp, had written me up for the star. He had written me up and recommended me for a bronze star. When he died, his wife found the recommendation, and it was then cleared all the way up the Army. Our colonel okayed it, and I got the bronze star about forty-five years later.

At the time, I thought maybe for some of the dumb things I did while in combat, I would get court marshaled; instead I got an award. These were terrible times. We were on the line for 198 days. A lot of my friends were killed. It's hard to think back at that time because there was, you know, it was a terrible time. We were all so very young.

But the worst war experience I had was when we captured Nordhausen, which was a concentration camp where we saw five or ten thousand bodies laying in a plowed field and saw the ovens. That was the biggest shock, that humans would do this to other humans. That was the biggest shock that I had.

RT: Well, that was very appropriate that your recognition came, even though received late.

I want to thank you, Jerry, for participating in this oral history interview program; we appreciate your input.

JB: It's my pleasure, but it was hard for me to recall forty-two years.

RT: Well, that's recognizable, and I think you've done a great job considering that length of time for recollection. So we'll close now.

JB: OK. Thank you, thank you, thank you.

RT: Thank you, Jerry.