HISTORY OF THE

U. S. FOOD AND DRUG ADMINISTRATION

Interview between:

Theodore C. Maraviglia, Retired
Director Region III

Philip Brodsky, Retired Investigator
(Drug Specialist)

and

Fred L. Lofsvold

Cherry Hill, New Jersey

September 11, 1981

INTRODUCTION

This is a transcription of a taped interview, one of a series conducted by Robert G. Porter and Fred L. Lofsvold, retired employees of the U. S. Food and Drug Administration. The interviews were held with retired F.D.A. employees 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.

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

DATE: Sept. 11, 1981 PLACE: Cherry Hill, N.J. LENGTH: 130 Min.

INTERVIEWEES

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INTERVIEWER

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FDA SERVICE DATES: FROM 1935 TO: 1976 RETIRED? YES

TITLE: DIRECTOR, REGION III
(If retired, title of last FDA position)

and

NAME: Philip Brodsky

ADDRESS: [redacted]

FDA SERVICE DATES: FROM 1951 TO: 1977 RETIRED? YES

TITLE: INVESTIGATOR, DRUG SPECIALIST
(If retired, title of last FDA position)

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This is a recording in the FDA oral history series. The recording today is with Theodore C. Maraviglia, a retired Regional Food and Drug Director from Philadelphia region, and with Mr. Philip Brodsky, a retired Drug Investigation Specialist. The recording is being made at Mr. Maraviglia's home in Cherry Hill, New Jersey. Interviewer is Fred Lofsvold.

Lofsvold: Mr. Maraviglia would you briefly sketch your career with FDA.

Maraviglia: I'd be glad to, Fred. I started with FDA in 1935 as a Food and Drug Inspector. I came on board at the same time as Fred Delmore, and Gilbert Goldhammer. The three of us were appointed and reported for duty on the same day. I started work at New York as did Delmore, and then Goldhammer started at Baltimore District. The Districts were called "Stations" then. At that time, there were three regional Districts you recall, the central, eastern and western districts. Previous to my appointment, I had been interviewed by Bill Wharton, the Chief of the Eastern District and his deputy, if you want to call it that, Charlie Herrmann. Mr. Wharton had quite a reputation as a disciplinarian, and he ran that district with an iron hand, as did the other two district directors. Well, anyway, I stayed in New York for most of my probationary

period which was a year, and just before the year was up I was transferred to the Atlanta station. I stayed there almost a year. The chief of that station at the time was John J. McManus, a real gentleman, and a transplanted Rhode Islander. He had been down in Atlanta, and in Savannah before that when Savannah was the headquarters, for years. Anyway, there were five inspectors in Atlanta at that time and we covered the entire states of North Carolina, South Carolina, Georgia and Florida out of the Atlanta headquarters. There was one resident inspector out of the whole station and he was in Jacksonville. He was, you remember him I think, Monte Rentz. Monte worked out of Jacksonville, but there was so much work that a lot of us took trips into Florida to help Monte and all over that territory. I recall very distinctly, spending maybe five or six weeks on the road out of Atlanta. I was single at the time so I didn't mind it at all. I had a room in the YMCA in Atlanta which I practically just used to store my clothes and personal belongings. So I was on the road quite a bit at six dollar per day, per diem. Do you remember that early? No I guess not.

Lofsvold: You got six dollars?

Maraviglia: When we first started it was six dollars, I seem to recall. They went up to nine dollars, I think, a couple of years later. Anyway, during the year in Atlanta I also helped out with the seafood inspection, do you recall? They had several big seafood plants in Thunderbolt, Georgia, in Savannah and up along the coast and near Jacksonville. As Food and Drug Inspectors we were also trained to do seafood inspection work to help out. I remember working with Allan Rayfield in Thunderbolt, Georgia on seafood inspections. Also, part of our job then was to train some of these seafood inspectors in food and drug work and I recall that I was out with Rayfield trying to train him. Can you imagine that? In food and drug inspection work.

Lofsvold: Who later was our boss.

Maraviglia: Who later was our boss and what a boss! There could of been worse bosses, he was all right if you knew him.

Lofsvold: He did the job.

Maraviglia: Yes, he got the job done. He was dedicated, let's say that. That was his best quality. Anyway, I remember one time, is this taking too much time, Fred?

About a year in Atlanta, then I was re-transferred back to New York station. Then when I got back to New York

the resident inspector, so called, at Newark, New Jersey, which was a part of the New York station, died in a skiing accident. His name was Hugh Smyser and not many people remember him probably. Anyway, they sent me to Newark in his place and I spent a couple years in Newark as the resident inspector, just one man in that station.

Then I came back to New York and worked in the eastern district with George Meeks and Allan Rayfield, under Bill Wharton, Olson and Charlie Herrmann. And, let's see, in the interim, between those moves I had been drafted into the army and I spent about three and a half years in the army. When I came back, I went back to work in the eastern district and spent a couple years there before I was asked to go to Philadelphia as chief inspector, and that was in 1951.

I came down to Philadelphia in '51 and spent about nine years there and when they opened a new district in Detroit, in 1959 and asked me to go there as chief inspector, which I did, and from 1959 till 1961 I was in Detroit. In 1961, when Sam Alfend left Cincinnati, I was asked to go to Cincinnati district as the Director. I spent 1961 to 1970 in Cincinnati district, and then I came to Philadelphia as the Regional food and drug director for Region three. I retired from Philadelphia in 1976, after

41 years of service with FDA. That's a brief capsule of my career service.

Lofsvold: Mr. Brodsky, would you give us a similar recap on your FDA career?

Brodsky: Surely. I started with the FDA, the day after New Year's in 1951. I was interviewed for the job shortly before I started, I think sometime in October, by Dick Williams who was then the chief inspector in Philadelphia.

I came to work January the 2nd, 1951, and I remember very vividly that they gave me a manual to read and a little pamphlet that was the food and drug law. I sat off in the corner and I started to read that, and after I'd been reading for about an hour one of the inspectors came over and introduced himself, it was Charlie Dickinson and he told me that he was going to train me. We went out to collect some samples, and I went with him that first afternoon. After about a week of familiarizing me with the forms that they had, they sent me out to collect samples and make an inspection of a, what we wouldn't consider an inspection today, just sort of an interview, to find out what the people were doing.

I stayed in Philadelphia up till January of '59 I think when I was transferred to Cincinnati, to replace a drug inspector, Weissenberg that had been out

there who had been transferred to Washington. In Cincinnati, by that time I had learned quite a bit about drug work. Prior to joining the Food and Drug I had gone to medical school for a while and I think that was the reason they put me into drugs, I was familiar with the names. During my stay in Cincinnati I did most of the drug inspectional work, which covered the area of eastern Ohio, all of Ohio I guess, part of Indiana, Kentucky, and eastern Tennessee. All the drug work in that area I practically handled at that time. There was only one senior drug inspector, and I did most of the training then.

I stayed in Cincinnati until 1971, then was transferred back to Philadelphia, where I started. I had an office in Philadelphia but was attached to a new group in Washington called EDRO, and spent most of my time working out of Philadelphia for the EDRO group in Washington.

While in Cincinnati, back around 1963, I was asked to aid or assist headquarters group in Washington to make some foreign inspections in England. Intermittently during that time I was called on to travel abroad for short inspection trips. I think, resulting from that the EDRO group was formed in Washington to coordinate them into a foreign type inspectional group that was tapped from various areas

within the country. It had two or three people mainly from New York, like Charlie Wayne and Cyril Osbrack, and Irv Feldman were doing, and myself in Cincinnati were the only ones that I knew of that were making foreign inspections out of the inspectional force. Later on, after I was transferred back to Philadelphia, they started a, this EDRO group. They recruited a man from Chicago, Bumiller, Charlie Wayne from New York, myself from Philadelphia, and occasionally they started to train with the three of us, people from other areas of the country. They would select somebody from San Francisco and L.A. and Atlanta and so forth, to go out with each of us at different times and finally by the time I retired in 1977 they had a fairly good sized group of trained investigators to do foreign drug inspections. I retired in August of 1977 after 33 years of government service, but seven of those years were with the military. One interesting side light, is that during my whole career almost my entire career, Ted Maraviglia was my boss. He followed me or I followed him from one place to the other.

Lofsvold: That, the specialized group that you speak of that was intended, not only for foreign inspections, but also for more the most difficult domestic inspections also wasn't it?

Brodsky: As well as special investigations.

Lofsvold: Phil described his first few days on the job and the early training that he got, Ted, how was yours?

Maraviglia: Well when I reported in 1935, there was no formal training as you would understand, formal training course, all right. The training consisted entirely of going out with older inspectors, or more experienced inspectors for a week or two at a time and kind of rotating from one inspector to the other. I recall going out with Charlie Greenlee, you remember Charlie. I learned by observing and listening to Greenlee, I went out with him for a couple a weeks at a time. Then after Greenlee, Leo Lusby who was chief inspector would assign me to somebody like Ed Palmer who took me out in his special kind of work. After Ed Palmer, Leo Lusby might send me out with Fred Gray for a couple of weeks. And so it went, a couple of weeks at a time with each of the other inspectors who had more experience and so you really picked up the knowledge by observing the older guy, listening to him, asking questions and with references of course to procedure, instructions in the so called inspectors manual that we had. That was, there was no class room type of training, we had at the time that I can recall in those very early days.

Lofsvold: Was there any systematic discussion and requirements of the law?

Maraviglia: Not that I recall.

Lofsvold: Only as it applied....

Maraviglia: Only as it applied to the particular job that we were doing at the time. There was no, later on, oh this must have been after the war I recall that in places like Philadelphia, we used to have regular inspectors meetings, you know, where we would discuss anything and everything that pertained to inspection work, particularly sections of the law, you know, legal cases and investigations, type of evidence that was required to build a case and that kind of thing. And that kind of training was, I think, excellent because inspectors were able to participate and contribute, and learn at the same time from the experiences of others. And occasionally we would have people come in who were expert in a certain field and talk to the inspectors, out of our own shop you know. But in the early days, that I say, the on the job training was literally on the job. That's the way I learned it in the first couple of years.

As I mentioned earlier this is the way that we trained other inspectors because when I went to Atlanta as I told you I was trying to train Rayfield by accompanying me on various work. I don't know if I was a very good trainer or

not because I remember clearly one incident when we were supposed to take a sample of I think it was dried milk, in a barrel, and you know, we were supposed to take it in a sterile manner. We had these little alcohol lamps and you had a trier that you stick into the barrel to remove the dried milk and place in a jar for sample. I was trying to --I lit the alcohol lamp in trying to sterilize the trier and the damn thing, I started a conflagration. I remember Rayfield, "What the hell are you doing, you're supposed to be showing me how to sterilize it." Anyway, the alcohol spilled and I started a little fire, but that was the kind of thing, the way we learned, but doing it on the job. But as I say, that was in the early years, in the middle thirties and so on. My recollection is that the training consisted of going out with these other people. Later on, as I said, this was after the war, I remember that our training became a little more formal but it was more instituted in house, you might say. At the district we would get the inspectors together and have regular meetings with them every month or week or once a month at least. This is the way it developed after the war.

Brodsky: I recall Ted, you were alluding to the in house type of conferences we had. I remember, I'm not sure whether it started when you came as chief inspector to Phily or when Williams was still there.

Essentially, when I started in 1951, the training was similar to what you just recounted. Although, I might add that it depended on different inspectors you would go out with would treat you differently. Some would tell you as a trainee, don't you say a word, you just watch and listen. Others would tell you, take the lead and do the inspection and if you get in any trouble, I'll recognize it and I'll jump in. There were all degrees of this, from say nothing to do everything. And otherwise things were as Ted described up, with the exception that I remember we had these Monday morning meetings where we were assigned certain sections of the law and the food and drug officer had an office with references of food and drug law. And we could go in there, they would, the chief would guide us and tell us here's where you can get some information and there were pamphlets put out by the Food and Drug and Law Review, was it? What was the name of that little magazine that we used to get? Food, Drug and Cosmetic Law Journal, yes. And there would be specific cases in there that, if you went around to some of the more experienced people they'd tell you where you could find it, usually the food and drug officer would tell you. So there were again, all degrees of cooperation there, some guys would really read this stuff and learn it. Other guys could get by without doing

anything, but on Monday mornings we had this meeting. I think this is where I learned most about the law and as far as any formal training, by this time there was, in the manual a section with respect to the drug inspection. I don't know who had written it or when it was written, but it was there when I came, and it had captions and some detail on drug inspections. It wasn't very, I mean it was very good for that time, for the types of inspectional work that we did. I don't think the inspectional jobs in the drug industry were nearly as thorough as they turned out to be later in the '60's and '70's.

Maraviglia: In the early days too, Fred, as I recall, a lot of our drug work consisted of collecting so-called quota samples, you may remember that yourself. We had quota samples for pyrogens, we had quota samples for hormones, like pituatary extract, and that kind of thing. These were simply collection duties that we did for some of the bureaus, special drug bureaus in Washington that had to analyze these special products. This is the way they kept an eye on the condition of these types of drugs on the market. Do you remember that?

Lofsvold: Yes I remember that very clearly.

Maraviglia: A lot of our time was spent in collecting those quota samples. I recall, in connection with quotas,

this is an interesting incident, to me it was, back during the war, World War II, that is. I guess it was right after the war, I was a resident in Newark. One of my assignments was to collect a quota sample, of quinine sulfate. Around that time there was a real shortage of quinine you know, because of the war. So I went to McKesson and Robbins in Newark. They had a branch warehouse there and I collected this quota sample, routine sample, and sent it in. After a while we heard that this sample, contained no quinine. It was not quinine, and this led to a great scandal of that era. If you recall, they were supposed to have warehouses up in Montreal in Canada somewhere of quinine and there was nothing there. There were no stocks of it, it was just an empty, you know, empty warehouse. As a result, I remember the names of these guys they were Coster brothers, do you recall that name?

Lofsvold: Oh yes, F. Donald Coster.

Maraviglia: And when they uncovered this, Goldhammer followed that investigation up, and as usual he made a tremendous investigation. As a result of this investigation, they uncovered this scandal where the Costers were just, you know, deceiving everybody with nonexistent stocks of quinine as collateral, or what have you. In fact there was some kind of indictment, a grand jury indictment,

wasn't there? When the marshals were on their way to the Costers, I think they lived in Connecticut, well McKesson had its headquarters in Connecticut, in Bridgeport I think. They were on their way to arrest the Costers, the marshals were, when one of the Costers, at least committed suicide. He shot himself in the head. He knew the jig was up and it was all over. It all started from a simple collection of a quota sample.

Lofsvold: And then this drug company which was nationwide, was forced into receivership and operated under receivership for many many years.

Maraviglia: They were also in the liquor business at that time. I think the drug business almost expired, but I think their liquor business kept them afloat.

Lofsvold: They maintained their wholesale drug business throughout the country, but ultimately they became Foremost-McKesson.

Maraviglia: As I say, going back, a lot of our work was in collection of these so called quota samples.

Lofsvold: I think then we depended more on laboratory analysis to determine the integrity of drugs rather than our inspection of manufacturing processes.

Maraviglia: Yes, of key important drugs, which could be tested or analyzed pharmacologically or pyrogenically.....

Lofsvold: We still use the technique as an adjunct to inspection, but I believe over the years we are now more interested in the process.....

Maraviglia: The emphasis is on inspection, you know, pre-marketing rather than in post-marketing of these drugs.

Brodsky: Your story reminds me of a similar thing that evolved from a quota sample when you were chief in Philadelphia. I remember Detroit had examined a vial of posterior pituitary on a quota sample for posterior pit, from Pittenger Labs, Harvey Pittenger, in Philadelphia. As a result you had sent me out to Lustgarten Labs who had shipped it. While I was out there, I was supposed to try to find out why this was low, there was no potency at all in this stuff. I remember, I was out there making an inspection and wanted to get a sample, a reserve sample, so that we could analyze this stuff. And they had none of the stuff, it was all shipped out. At that time they used to filter through these candles for sterility. And having inspected this firm a number of times previously, I remembered that this posterior pit is pretty expensive and usually leaves about 50 cc's in the candle, and they usually save it. And so I asked them how about what was left in the candle, do you have that. And they said yes they had it. So I got a sample of that and I called Ted, I

remember I went outside got to a public phone and called Ted, and suggested that maybe he could get Luther Johnke to go over to Harvey Pittenger while I'm still here, because right now we knew that they had a sample and do you remember this at all Ted?

Maraviglia: Vaguely, yes.

Brodsky: And Luther went out to Harvey Pittenger Labs and started quizzing them about where they got their glands to make the posterior pit and he started to get funny answers. In the meantime, I got the sample from the candle, we sent that out, I think we used to have to send that out to a division in Washington. In the meantime we got the results, it had no potency so then Luther and I together, started out at this Pittenger Lab. Well, Luther and I were then sent out by Ted to make an investigation at the supplier of the posterior pit which was Harvey Pittenger Laboratories. This is where I learned a great deal about some of the investigatory methods in drug inspection. First, Luther wanted to know where he got the glands and the fellow told him he got them from some abbatoir in Camden, New Jersey, so he asked him for the invoices. He didn't have any invoices. He asked him where he got the standards to check the potency of the material, the posterior pit, he knew you had to have USP standards to test

it against. And they couldn't show him that, he asked them for the pigeon boards where they used to run the test on pigeons at that time, they had no pigeon boards. They had no cages for pigeons, they couldn't show us anything. I remember just listening being fascinated, and by this time I'd been in, I don't know what year this was, maybe four years or five years at this time, and never had been exposed to anything like this. Yet, I knew enough about the drug end of it, but the investigatory end I don't think I would've known what to do. And I just stood there fascinated and as he start asking these specific questions, other things started to come to my mind and when we'd get out I'd ask him how 'bout this, how 'bout that and he's just tell me, you just listen and boy he was a real education. It finally wound up that these people, these were two brothers, I think their name were Cohen. Eugene Cohen was the main person, and they were both graduates from Philadelphia College of Pharmacy and we made an investigation of their background at school and they were both Ph.D's, at least one of them was a Ph.D. And they were terrific students while they were there, had great marks and everything and so they knew enough to do the job right. But it turned out that, at least my impression of what they were doing was this. At that time a lot of manufacturers

were shipping what we called inert glandular preparations, and this laboratory, Lustgarten Laboratories shipped a lot of those. And at that time we were making some seizures on those, but not too many because the companies that were shipping this material used to tell us that as long as doctors wrote prescriptions for those they could ship them, and that's what they were doing. It was my, or our conclusion that the reason that this firm was shipping this inert material to Lustgarten was that they thought that they were putting this into the inert glandular preparations, when in fact, once a year only, this firm would put out posterior pituitary preparation. That's a straight posterior pituitary, I think it was 20 unit stuff, which was really therapeutic injectible preparation. And figuring that nobody would ever catch them with the inert material, I think that's why they shipped it. And as a result, this firm was put out of business, there was a trial, they were told by the judge to get out of the drug business, and never get into the drug business at all in the future.

Maraviglia: On the subject of training. I don't think any real formal training of a centralized nature started until the three original Districts were broken up and a division of field operations was formed in Washington headquarters.

Then is when Rayfield and his group started controlling the operations of the field, including the training aspects, a large part of it anyway. This was under a generalist philosophy, i.e., that each inspector should be a generalist and should be able to do any type of inspection. So they set up requirements that before an inspector could be promoted, he had to do a certain amount of work in each "project", that's what we used to call them, remember that, "project". And this caused a few difficulties because as chief inspector I had good men that I knew deserved a promotion but they wouldn't approve them in Washington because they lacked a little experience in a certain "project" or field of work. I remember, Charlie Pyatt, who's still with FDA, when he was in Philadelphia with Phil and me and Charlie was anxious to get a GS-9, and I wanted to get him a GS-9, but we couldn't. It couldn't be approved by Washington because he had not done any of what we called OTC work, that is, over the counter work, which meant buying prescription drugs without a prescription. So finally Charlie, as distasteful as it was to him, managed to make a couple of "buys" as we called them at a drug store, of some sulfa drug or other, and with that we were able to get him a GS-9. And I think the same thing happened with Phil, and maybe Phil can tell you what his experience was.

Brodsky: Your story, or your reference to Charlie reminds me of a similar thing that happened with me. Charlie and I were recommended for 9's around the same time, I think it was exactly the same day. What happened, is I had a lot of work in OTC and the drug field but in order for me to get a GS-9 I had to get work in bakery inspections and candy inspections. Having spent a lot of time, most of my time in the drug field, very meticulous type stuff, when I went out to do the bakery inspections, I did those the same way. I start finding bugs all over the place and almost every inspection that I made on these ones that I knew nothing about turned out to be, to hit pay dirt. I was very appreciative of the thoroughness. Also, I wanted to mention that I had mentioned in the, at the beginning at the tape about my experiences with Ted, I followed Ted almost every place I went, or he followed me.

I remember Ted calling me in one time before he recommended me for the 9, the GS-9. He had asked me why I didn't come in and bitch, he said everybody else is bitching about these 9's. He said don't you think you're worth it, and I said well, not yet, there's alot of stuff that I had to do. But I remember saying to him when I feel that I know it, I expect you'll know it by that time. And he said no, I was kind of shy. He told me, you get out there and

you're doing a good job and he gave me a lot of confidence, and told me, he said, you're just as good as everyone else, and don't forget it. And I never did forget that.

Lofsvold: In these instructions that we got from headquarters on training, they also included an outline for beginning inspectors as to things that they ought to learn over a six month period, as I remember, is that correct Ted?

Maraviglia: Yes, there were time limits.

Lofsvold: And they also told us certain time was required to be spent on explaining the sections of the law to the new inspectors.

Maraviglia: Yes, and this really was a start of some really formal training, whereas previously to that we had to rely on our own, you know.

Lofsvold: Don't you think that was probably because we were such a small agency and we didn't acquire very many people at any one time. A formal training program probably wasn't necessary, or as necessary then as it was later.

Maraviglia: I think that's probably true. As you recall I've mentioned that we only had five inspectors in the Atlanta, which covered the whole southeast portion of the United States. As you can see in the earlier days they had even less than that. But yes, you're right, I don't think a quite formal training, was really necessary.

Lofsvold: Of course one of the other things a young inspector had to watch out for when he went out with a trainer was to make sure the trainer was doing it right. I believe that with some of my early trainers I learned more by deciding I would not do what they were doing and I would come out better.

Maraviglia: Well you have to give those young inspectors in those days a lot of credit for common sense.

Lofsvold: Ted, what is your earliest recollection of cases that we developed against companies, or individuals, involved in the development of new drugs.

Maraviglia: Well my first prominent recollection of an outstanding incident, was that involving the drug MER-29, so called. This was a so called anti-cholesteral drug, supposed to reduce the amount of cholesteral in the blood. But it caused serious side effects, including cataracts in the eye. As I recall, the company and various investigators associated with the company, falsified data, the clinical data on this drug and also failed to report the serious side effects caused by the drug, as reported to them by various physicians. The company involved was the William S. Merrell Co. in Cincinnati and I think they later became Richardson-Merrell and are now part of Dow Chemical Co. Anyhow, the drug was manufactured and distributed from

Cincinnati and that was the earliest, outstanding incident of clinical investigators falsifying data and/or failing to report data. The ultimate disposition of the case was that the company was prosecuted and fined and several of the people were put on probation. Also a number of civil suits were brought over the years against the company which were settled out of court and in court. I don't know, they may still be going on some of these suits every once in a while I hear something. And then the other prominent case involved...

Lofsvold: What year was, about....

Maraviglia: It was in the early 1960's. It was, it might have been '61 or '62 because the firm was finally prosecuted and fined in 1964, so it was in the early 1960's.

Lofsvold: The fines were substantial?

Maraviglia: Yes, an $80,000.00 fine as I recall, plus probation for several of the responsible people involved, and that's one of the first incidents of this nature.

Brodsky: The only thing I would have to add would be my recollection of the investigation after Ted and Tom had begun this, Tom Rice, who is now retired, living down in Florida. We had a lot of follow up interviews to make from people who had had cataracts, or doctors who had prescribed the drug who had given them drugs, so called drug

investigatory patients. And we had to try to determine through these interviews whether the doctors were commercializing or these people were actually investigational patients. I know we travelled in all the states of our territory interviewing people and I think that was the reason that Ted wasn't able to go. He couldn't run around the states and still run a district. And that's how I got in on it. We wrote up the reports of these interviews and these were coordinated by the food and drug officer and Ted and other administrative personnel.

Maraviglia: I'd like to add something here if I could. The case was so important that Jack Harvey you remember, who was running the division of regulatory management at the time, sent up Gilbert Goldhammer who was his deputy at the time, to personally take over the investigation and make sure all the loose ends were tied up. I recall, I don't know if you remember that Phil, but Gil Goldhammer came up and spent quite a time, quite a bit of time up there tying up all of the loose ends of the investigation. He really wound it up--so Gil, I'm sure, remembers a lot of personal touches that we can't recall.

On the subject of clinical investigators, the other outstanding case that comes to mind is the thalidomide case. Again, a drug in which William S. Merrell was

involved. There were a lot of Congressional hearings there I remember about thalidomide later on, in which again Tom Rice was the principal contributor. But the one fact that isn't too well publicized, is the fact of the prosecution recommendation of William S. Merrell and Co., based on thalidomide, that we submitted when I was in Cincinnati. Our investigation in Cincinnati disclosed that for all intents and purposes William S. Merrell was marketing thalidomide as a commercial product under the guise of so called experimental use. In other words at that time, a firm was permitted to distribute a so-called investigational drug solely for investigation or experimental use. The regulations prohibited it from being marketed for any commercial use while it was still you know, being investigated. But it developed in our investigation of Merrell that their whole marketing strategy was to promote this and to sell this drug, really, using the same techniques that they were using for any commercial drug, and this is what they were doing. There were cases, some of the doctors weren't even using it for experimental use, where they were not reporting back any findings, you know. The doctors were supposed to, by law, report their findings of these clinical tests and trials, but in many cases, many cases they weren't even doing that. So to all intents and

purposes and for all practical purposes the firm was marketing this damn drug as a commercial drug. On the basis of that evidence we held a hearing of the firm and its officers at which the firm was represented by a Mr. Lawrence Walsh who was a one-time federal judge, and at one time was also president of the American Bar Association. He came in with another legal counsel Mr. Brad Mintener, you know Brad, and along with representatives of William S. Merrell. We held a hearing in Cincinnati. George Meeks and I, as Director of Cincinnati District, held a hearing with these gentlemen present where they presented their case, and their response to our charges which we took down. Eventually after the hearing we in Cincinnati recommended that the firm be prosecuted for shipping an unapproved new drug, really, in interstate commerce because it had never been approved for commercial use. Then, this prosecution recommendation went to our headquarters in Washington and it lay there for months, and a year, and a couple years. I kept inquiring about it and wasn't getting anywhere and finally I was told that the recommendation had been sent to the Department of Justice by the FDA headquarters and there it apparently died a quiet death and we never heard anymore about it. But we in Cincinnati felt that we had enough evidence of the commercialization of this drug, of this

so-called experimental drug which was being deliberately marketed commercially. And apparently, I don't know I guess our headquarters felt the same way because they bumped it up to the Justice Department according to the information I got over the phone from somebody in Washington but nothing happened after that. But I don't know whether this fact ever came out in the Congressional hearings or not but I don't know, Tom Rice, he might of mentioned it. There'd been volumes of Congressional hearings on thalidomide after that, I don't know what committee that was, was Kefauver still alive then?

Brodsky: At the beginning, the last thing I heard about the disposition was they didn't prosecute because they had been done so much harm, you know, that old excuse.

Maraviglia: They'd already been "hurt" enough.

Brodsky: Yea, they....

Maraviglia: But at the same time that I understand it Fred, there were a lot of civil suits brought against the firm based on deformed babies who had used thalidomide or that had been exposed, you know, their mothers had used thalidomide. And there were many cases where I expect that the use even if it had been for experimental investigational uses, it was never reported back, the results were never reported back to the company.

Lofsvold: Well at that time our regulations were less specific than they are now I think .....

Maraviglia: They were specific enough, I think 505(i) was the section of the law which pertained to the use of investigational drugs. It was specific enough to show that that's all they could be used for, i.e., clinical investigational purposes. They did rewrite the regulations later to make them, you know, tighter.

Brodsky: At that time when we went out to try to get an investigator, the only ammunition we had under the law was the distributor or the manufacturer had to do three things when he sent a thing out for investigational use. He had to label that thing, Federal Law For Investigational Use Only. He had to send the investigator a slip and a thing to sign that he's a bona fide investigator and he had to have that on file. That was two things. There was a third thing and that was the shipper was required to have the investigators statement on file before he could ship the drug and this usually was just the reverse.

Maraviglia: While we're on the subject of clinical investigations, a more recent one real outstanding one involved the G. D. Searle & Co. in Chicago in which Phil was directly involved, in fact Phil headed up the investigation group that worked on that case. I'd like to know whatever

happened to that, which leads me to express a personal opinion here that I wonder what the enforcement philosophy of the agency is at this time. Is it directed toward real health violations or, to me it seems there for the past few years we have been concentrating our criminal activities against really, non-health matters such as, sanitary violations. And if you look at the record you'll see that a lot of our criminal cases have been against people who are guilty of sanitary violations and very few, if any, against people who are really, had the life and health of the American public in their hands, namely drug manufacturers and others. So this is why I'm asking what happened to that Searle investigation again, involving falsification of clinical data and all the rest of it. Maybe Phil can expand on that a little bit.

Brodsky: I am also wondering what happened to the case. I haven't heard anything more. I've been in touch with some of the people that worked on this and the information I have is that nothing seems to be going to come of this anymore. And I've read recently that Aspartame, one of the products that we investigated and turned down is about ready to be released shortly. Another thing that puzzles me is after investing all of this time, effort and money, a three month investigation with six investigation teams

housed in Chicago in a hotel over three months, and all the documents submitted, what is the disposition. Why don't we hear something? That really puzzles me. Everything quieted down.

Maraviglia: We don't want to sound like disgruntled muck-rakers but at the same time it makes you wonder what of all this effort and taxpayers money? Where has it gone and to what avail, I don't know. One thing about the field people. I think they've always been dedicated and hard-working, you know, and I guess you might say an idealistic feeling that they were working towards some kind of a goal. Whether it was a seizure or some other kind of action they felt like they were protecting the consumer. I guess when you get up higher-politics start influencing...

Lofsvold: Earlier we were talking about training of our investigators. What is your recollection of the earliest formal training in drug inspections that we had?

Maraviglia: Well, my earliest recollection of any kind of drug training was a conference in 1948 which was spear-headed by Winton Rankin who was in Washington at the time. At this conference one or two so-called "drug" inspectors were brought in from all over the country, from each district or station in the country at the time. And the training actually consisted of presentations by people in

the administration, various bureau people and by the participants themselves. In other words, I was given assignments to present a couple of papers involving certain sections of the law based on specific adjudicated cases. I remember one of my assignments was to present a paper on res adjudicata which of course means, it's a legal term applied in seizure cases where you can only bring one seizure on a misbranding charge and no more afterwards once that issue has been adjudicated. So in other words each participant, each inspector that attended the conference was to come prepared to deliver a couple of papers on specific subjects, a lot of them having to do with legal matters or sections of the law pertaining to drugs. One section of the law I remember that we discussed thoroughly at the time was that involving new drugs. Remember, this was before the 1962 amendments but there was a section of the Act that involved new drugs and we spent time on it, I remember, I think Goldhammer was involved in that discussion. Anyway, a lot of us presented papers, and as a result of the papers there would be a discussion following. And this was the kind of--this was the way the program format for that conference was.

Lofsvold: Did it cover the technical part of drug manufacture, how you make drugs and so on?

Maraviglia: As I recall, Fred, there was very little of that. The way Winton had prepared the format it dealt a lot with the legal aspects of our inspection work, you know what I mean. In fact as I mentioned before, my specific assignments dealt with "res adjudicata" which is a legal matter involving seizures where you could only bring seizure based on this charge one seizure at a time. And the other one had to do with an old case called Lee's Save The Baby which really went back and was another consummated seizure legal action involving the principle of res adjudicata and we had to discuss the legal ramifications of that case.

So a lot of discussion centered around the new drug portion of the law which was relatively new at the time. And so there was very little about inspection techniques if that's what you mean, at that particular time as I remember. There's a program somewhere in the files I'm sure you can dig up if Winton Rankin doesn't have a copy himself. Anyway we talked, and that was the general tenor of the program with very little inspection techniques and you know, "how to do it" kind of thing. But more abstract legal discussions as I remember it. So that was the first formal drug inspectors conference I recall, in 1948. I believe there was another one a year or so later maybe in

1950 but I'm not sure. My memory isn't too good on that but Phil maybe could pick it up from there as to his recollections of his earliest drug inspection schools.

Brodsky: Well what I'll try to do, Fred, is tell you from my memory the schools that I know about or that I attended, and tell you, try to classify them as to the type of school they were and what they tried to teach you.

The first one that I'm familiar with was, I was still a recruit. Ted sent me to this school and I often wondered why. It was to an antibiotic conference in Washington and that was considered a school. What it was was Welch, who was the head of the division of antibiotcs and some outside people talked about antibiotics, the discovery of them and so forth and filled you into the background of antibiotics. They told you what they projected for the future, how important they would be and so forth. And that's about what that amounted to and if you took notes, nobody told you to take notes, there was no individual instruction on how to make an inspection, they just gave you the history of antibiotics. It was very interesting and informative. That was the first one that I knew of.

The next one was about 1960. And that was similar to the type of school that Ted mentioned, where you were given assignments with reference to the law, the legal aspects of

the food and drug, and you had to discuss cases. And they picked inspectors from various sections of the country to attend this school, it was called a conference.

The next one that I recall was a true drug school. It was called a basic drug school. The basic drug school consisted of attendees from the various drug districts in the country. There were lectures from some of the division in Washington. I remember, Les Baukin, talked on his section, what he knew about drug inspections. We had Earl Meyers, we had Charlie Wayne and several other people, some of the regulation writers, some of the people from the lower echelons of the divisions in Washington talked to us. And it was sort of a friendly atmosphere and there was a five day course as I remember.

Now the next drug school that I recall was the advanced drug school that was handled on a similar basis to the basic drug school as far as representation went. Except the only ones eligible to attend that were ones that had attended the basic drug school. Now these were, by this time people that had made a lot of drug inspections, depending on the districts that they were in. But it included the guys who had made most of the detailed investigations around the country and so forth. Now during this course, this one lasted at least a week, it may have been

more than that I'm not sure, it may have been a two week course. But this is where the heads of divisions, the MD's and the dental service and the pharmacy people and the laboratory people had well prepared lectures. Larrick attended almost every session and at the end of the session the thing that I remember was that he dwelt on making investigations.

This advanced drug school took place sometime in the middle sixties, probably '65 to '67, sometime in there, and this was well structured with well prepared lectures by people that really knew the stuff, the professional people, MD's, the dentists, the pharmacists, the heads of pharmacology and so forth. And the Commissioner gave a welcoming speech and indicated that this was, you know, for training for advanced inspectors. And one of the very, very impressive teaching techniques was a set up situation where the inspectors were left in the dark until they set up the situation, but the instructors were well prepared for this situation. The situation was such that the inspector would have to meet a plant manager or enter a firm and get into that firm when the situation was such that they were not going to let you in or not going to let you look at records. It was very instructive and you could see from this that those inspectors from districts that had

already done some investigations had techniques which eventually got them in, they always confronted the plant manager, their antagonist, with a question in which they had to let them in or else almost admit that they're trying to break the law. And those that didn't have much experience were non-plussed, so it was a good learning technique.

The next formal training sessions I think started around 1966 or '67 where a basic training school situation was set up with the University of Rhode Island Pharmacy School in which inspectors from the drug districts were selected to attend this school and here they learned how drugs were made, mostly tablets. They learned how tablets and capsules were made, how to coat them, they learned the techniques and the shortfalls involved in manufacturing them--

Maraviglia: Could I interject something here?

Brodsky: Sure.

Maraviglia: This coincided with the start of the Intensified Drug Inspection Program, it was just about that time that the Rhode Island schools were instituted too.

Brodsky: And since you say that, it was probable that the school started a little before '65 or '66 because the Intensified Drug Inspection Program came out in 1967 and I

think that was the basis of starting these schools, to get us really trained because of the Kefauver-Harris Amendment. One of the stipulations in that amendment during the Congressional discussions was that you had to have inspectors--the trade indicated that we had to have inspectors that were trained to make drug inspections and I remember there were some documents that circulated within the districts indicating that we needed this training. And the school was set up with pilot plant equipment and personnel to train the inspectors as well as experienced inspectors from the field as lecturers.

Maraviglia: Are they still running these Rhode Island schools?

Brodsky: No, these Rhode Island schools ran from that starting date sometime in the early or middle sixties all the way up through, to my knowledge, through 197?--the fall of 197?. After that--I'm just referring to the basic drug schools--in 1978 I understand from my contacts with the FDA that the districts were responsible for training their own drug inspectors and I know that I did a consulting job for New York District--I ran a school up there as a lecturer--they had some of their men go out to--St. John's, is it?

Maraviglia: Yes.

Brodsky: St. John's has a pilot plant and the lecturing--I delivered a lecture or a couple of lectures there. And then the next year, I think '79, I did it for Newark District out at Rutgers and since that time I don't know whether they still run schools or not.

Losfvold: I believe schools are being run in various parts of the country now, usually in connection with schools of pharmacy at nearby universities.

Maraviglia: Fred, Phil could give you a good slant on foreign inspections because he was one of the first--you'll probably get into that a little later on.

Lofsvold: I would like to get into that.

Maraviglia: He was one of the first to get involved in that.

Brodsky: I'll continue with the basic--that ends the basic I mean that's the history as I know of it of the basic drug schools. And that one advanced drug school that I talked about was out of Washington and subsequent to the first or second or third basic drug school, they started a formal advanced drug school, set up--I think by Harold Post. The educational end of the administration in Washington contacted universities around the country and settled on the University of Pittsburgh to start an advanced drug inspector's course. And that ran almost every year as we got

new inspectors in and as inspectors finished the basic drug school and as the IDIP progressed--that's the Intensified Drug Inspection Program progressed--we needed more and more experienced inspectors and so this became a yearly school that was highly thought of and well run. I personally never attended it because I had attended the one in Washington that they called the advanced drug school then. Then we started to have a number of problems with large volume parenteral preparations with a number of the drug firms. There were a number of recalls and an advanced drug school for parenteral preparations, which is the only drug school that they had for parenterals, was established in Tennessee at the University of Tennessee, I believe. And I don't know if that's still going on, but there were three types of formal drug training schools that evolved after the early 1960's from the conference type and in-house type of trainings for drug inspectors.

And finally, there was another school established for pre-clinical investigations or biomedical investigations which was held down in Arkansas at the Pine Bluff Installation, which was sort of a close relation--it was part of FDA, but seemed like not many people were aware of it. There, following a very intensive biomedical investigation of the G. D. Searle Company, it was decided that the

investigators that participated in the investigation at G. D. Searle would go down as the first class to inspect our own facilities at Pine Bluff, Arkansas.

Losfvold: That's the pharmacology research facility?

Brodsky: That's pharmacological research facility of the Food and Drug Administration which was composed of the so called experts. And when this group of investigators, I think there were thirteen of them, hit that place after making a three month investigation at Searle, they tore that place apart and found everything that you could think of wrong with the place. Really, it was so dramatic that the people down there just were nonplused. They couldn't refute what we found and I mean it was obvious. We found so many things that were....

Maraviglia: Well did that cast some questions on their own work?

Brodsky: Well it cast some questions on some of the animal studies especially some of the work they're doing on coal tar colors and what not, but they made a quick revision and correction of some of the controls. Mostly it was the controls. You couldn't say that what they did was not valid, but the controls, there was no way of telling whether the controls that were enforced retrospectively were any good. But what was going on now at the time that we were there we found all kinds of possibilities.

Maraviglia: Are they inspected regularly now....

Brodsky: Well we had we conducted nine I was involved with all of the inspections that were held there during 1975 or 1976 or '77. We had nine different classes there and this thing was set up by Post.

Maraviglia: Whose idea was it originally to make that investigation and inspection in house inspection?

Brodsky: Well I think the idea was were generated from Washington from the group from Searle, when we found out-- I think it was D'Aguanno may have had something to do with it. He was on the steering committee of this Searle thing and we made an inspection of our own facilities in Washington too, and found things a little hazy there. Some of the guys on the, well you know, we did what the hell. That's what we found and the bosses there, the guys who were in charge, we gave them our report. They told us to do it as if we were doing it outside and so we did it. And we found some.....

Maraviglia: We harp on firms, drug firms making self inspections and maybe we should.....

Brodsky: Now you must remember when you have you know twenty six pair twenty six eyes looking, what I miss Joe Doe gets, and what both of us miss, the third guy gets. So there wasn't much that was missed and the same thing, just

to refer back to the basic drug schools, as part of their training we used to go to a big drug firm, during each of these and make an inspection of that firm. Twice a year we would inspect that firm until that firm you couldn't find hardly anything wrong with it after twelve years, twice a year, twenty four, twenty five inspections.

Lofsvold: Best operated firm in the country. I trust that the people in charge of our own laboratories made corrections of what you found.

Brodsky: Oh yes they made corrections. As a result of the biomedical inspections or preclinical inspections that were made, there was one made every month for nine months at this same installation down in Pine Bluff, Arkansas. So that.....

Maraviglia: Oh yes?

Brodsky: So that, yes and I attended each one of them a week. We had people from pharmacology giving lectures on their aspects, on foods and also drugs you know, and food additives. As a result of that emanating from that were the regulations on preclinical inspections. D'Aguanno and I first wrote up the first copies, rough drafts of these in Washington and they were sent out through the regular course and they were added to by people down in Pine Bluff and various areas of the food and drug that had some expertise.

Lofsvold: In Phil's discussion of the training he mentioned, part of it was prompted by the Intensified Drug Inspection Program. Ted, do you want to talk a little about that?

Maraviglia: The Intensified Drug Inspection Program was a concept that was developed by Jim Goddard when he was Commissioner of food and drugs. It actually started in 1967 and this was a kind of a joint effort on the part of FDA and the drug industry to improve the quality of the drugs being marketed. What it involved was a an agreed-upon inspection which might take months on the part of a food and drug inspector who actually made the inspection. Well, what happened was that the FDA people of the district would get together with the management of the drug firm beforehand and discuss the purpose and all the other ramifications of the inspection to be made at this firm. They were told that an inspector might be at the plant for weeks, if not months; that we were asking for their complete and open cooperation and that the purpose was to help them improve their operations and our purpose was not necessarily to develop any evidence for criminal actions or other legal actions but to primarily help them in their own operations so that the final result would be a better product that they could put on the market. In other words it

would be to their benefit and also to ours in working together. So most of the firms when we had these pre-planning conferences would agree to it after they understood what the ultimate objective was and there was really no objection on their part. They saw it for what it was--that it was to their benefit for us to be in their plant for weeks and months at a time if necessary. This is what happened then and the program seemed to me to be working pretty well and it went on for at least two or three years. As I recall there was some improvement in the quality of the drugs being marketed to the American people as a result of this program. Because our inspectors were instructed to be as thorough as possible and cover every aspect of the operation. In fact, during this program we would maybe inspect only one part of the operation at a time. In other words, with a firm making tablets we would spend weeks and if necessary months on their tablet operation and then come back and spend another period of time on their parenteral preparations. In a large firm we had to break it up into those departmental-type inspections, because otherwise it would be unmanageable. So even though it was a time consuming project on our part, I think the ultimate objective, mainly to have better drugs on the market seemed to work. That in essence, was the Intensified Drug Inspection Program.

Brodsky: I would just like to add that in addition to providing better production and control procedures, there also was produced, at least in the area where I was at the time, a lot more trust between the firms and the districts. As a matter of fact in Cincinnati district at the time, we broke these inspections up for the large firms into segments. And at the end of a segment we would tell the firm what our objectionable what their objectionable conditions were and often they would agree to most of them, and some they would disagree vehemently. And when it came to an impasse we invited them into the district to discuss it. At these meetings would be the investigational team that was running that segment, probably the firm's lawyer and their plant manager or their interested parties and our district director and our food and drug officer and the inspectors who were involved in the inspection. Now I think every time we came to a cordial reckoning here.

Maraviglia: It was like having an inspector in residence at the plant, that's what it amounted to, you know like a USDA meat inspector or somebody. Even though we said that our primary purpose was to be helpful and to improve their operating procedures and not necessarily for anything aimed at legal actions, there were occasions when you couldn't escape finding some products that had to be seized

i.e., taken off the market or recalled. And if there was any evidence of deliberate criminal intent, naturally we wouldn't want to turn our backs on that. But the primary purpose as I said was to help them improve their operating procedures.

As a matter of fact many firms, even after the Intensified Program was over, quite a few firms would come to us voluntarily and tell us about recalls that were imminent or about things they had found wrong. I remember Lilly coming to us once in Cincinnati and they, what was his name, the quality controller, Dr. Hilty and told me about how they had found their ipecac syrup something was wrong with it. They had found something the matter with their ipecac raw material and their analysis indicated that the alkaloid content somehow was not strictly up to par. Investigations developed later that the source of their ipecac, a crude drug supplier up there in the Newark area somewhere, had been supplying them with contaminated or some kind of substituted alkaloids that were cheaper, a type of alkaloid that didn't have the USP content.

Lofsvold: I believe that during the 1960's we were also doing some other things to improve the quality of drugs. I recall that we had an educational program for the manufacturers. Do you remember that?

Maraviglia: You must be referring to the so called Zero Defects Program.

Lofsvold: That's right.

Maraviglis: Yes. This was another concept aimed at, as you say improving, not only the quality of drugs, but any manufacturing operation that came under our jurisdiction really.

Brodsky: This was sort of a spin off Ted from the aerospace industry.

Maraviglias: Yes, right. General Delmore, Fred Delmore, when he came in back to FDA somewhere in the middle '60's, he brought this concept with him from the Army where he had been using it, and as an educational thing he tried to introduce it all over the country to the various FDA districts. In fact, he headed up, as you may recall, the Bureau of Education and Voluntary Compliance. Frank Clark, our good friend Frank Clark, was his deputy. And I remember them going around to all the districts and issuing educational material to the districts and urging them to give talks to firms, manufacturers, on this whole Zero Defects concept. The Zero Defects Program is I think, self-explanatory, you know. Whether it was a practical thing or not the fact that we tried to approach a Zero Defect basis was worth it in itself. I remember giving a

couple of talks myself to various firms on this whole concept and encouraging them to install some kind of a Zero Defect Program in their own operation. And on the whole a lot of them were very receptive to it and of course some of them had heard about it through the Aerospace Program, or the military, but that was another strictly educational effort aimed at voluntary compliance. At that time we were stressing voluntary compliance quite a bit to get the industries to cooperate and come in line.

Brodsky: At each of those seminars that we mentioned previously, the Wisconsin seminar and the Hershey seminar, General Delmore presented talks on Zero Defects at each of these and other members of the pharmaceutical industry, both the proprietary and the prescription drug industry had their, had instituted their own Zero Defects Programs under other names. Like Pride, I don't remember specifically the names of them but, Pride in the Product I think, something similar to that was one with Merck. And the various companies had a different name for them but most of the big companies had a program of their own after the first year of General Delmore's talks. He encouraged that and the firms went along with it.

Maraviglia: It really was a quality control program, you know, aimed at zero or minimum amount of violations.

Lofsvold: This was the same Fred Delmore that entered into service with FDA the same day that you did.

Maraviglia: The very same. We started in New York and at the start of World War II Fred was in the reserves and he went into the army as a commissioned officer. And after the war, he stayed in the army and got to be a Brigadier General. In fact he was the Commanding Officer of Edgewood Arsenal there at the time he was asked to come to FDA by George Larrick.

Lofsvold: I believe that he commanded the entire chemical warfare service of the...

Maraviglia: I don't know if he did that. I knew that he commanded the Edgewood Arsenal part of it. So he came back to FDA oh, around the mid '60's sometime or early '60's.

Lofsvold: He came I believe, just about the time that Commissioner Larrick established the Bureau of Education and Voluntary Compliance, in response to a recommendation from one of the Citizens Committee...

Maraviglia: Was that.....

Lofsvold: Phil, when you were sketching out your career, you mentioned that you had done a number of foreign inspections. Can you tell us a little bit about that program and how it came about and why we made inspections overseas?

Brodsky: Yes Fred. To the best of my knowledge, the reason that we started making foreign inspections was that during the Vietnamese War, our AID, that's the Administration for International Development I believe is the outfit that was supplying the drugs for the Vietnamese. And before they would accept drugs from anybody, they would have to, they wanted to be sure they met the standards of the United States. Now these contracts were let in all countries that wanted to manufacture them as far as I know even some of the Iron Curtain countries, as it developed later. I don't know whether that was during the Vietnamese War but, the Portuguese, the Spanish, the English, the French, the German, were supplying drugs both dosage forms and bulk, to AID originally. But mostly they were antibiotics, tetracycline, penicillin, streptomycin at the beginning, chloromycetin or chloramphenicol at that time. So in order to test these, headquarters from Washington sent some of the top men from the Division of Antibiotics to make these inspections, and they consisted usually of the division directors, or the chief bacteriologist. They were Dr. Di Lorenzo, Jester, and others.

These inspections were originally made by, at the begining by Dr. Welch and the heads of the antibiotics division, the people from Washington. Later on, as things

developed, more firms were submitting or sending drugs to AID. There were more inspections to be made as the inspectional procedures got more detailed and the good manufacturing practices were developed in the United States. The standard became a lot more stringent and inspections of the firms were involved and not only to determine whether the drug was safe and effective, they had to be manufactured under good manufacturing production and control procedures, which were part of our good manufacturing practices. In order to evaluate drugs from that point of view, as well as the laboratory analysis, etc., they needed some experienced inspectors. So I think it originally developed that the largest drug inspection areas in the country were, New York was the largest, and some of the best inspectors in the country of course were stationed there. So the first foreign inspections made by field inspectors were made by those inspectors in those districts and they consisted of originally, Charlie Wayne, Osbrack, and Feldman, all very very top notch drug inspectors. As things developed and more and more inspections had to be made a couple of the headquarters people from Washington that had originally made these inspections, were assigned to take field inspectors with them. So there were two or three people from Washington that would have a call maybe once or twice a

year to make an inspection and would take a field inspector with them. And I started this in 1963 with Dr. Di Lorenzo with an inspection of a couple of firms in England of antibiotics. Then the next year I made a couple of more inspections and then as time went on, there were just two or three of us from the field making inspections with one or two of the people from headquarters. Finally around 19.., or as time went on I don't know how it effected the other districts but by this time I'd been made a supervisor, and my chief inspector was a little miffed at my being away for six to eight weeks at a time two or three times a year and when I came back he raised hell with me, you know. Following, after several years of this type of work, up until about 1969, I came back from a trip around the world. Mr. Hile was in charge of EDRO, yes, by this time EDRO had been developed. That was a headquarters outfit that we alluded to earlier. He asked me how things were going and I explained to him I was having trouble back at the district because when I was away I had somebody else sitting on my desk and production wasn't as fast, of course when you have a substitute you don't get as much done. And I told him of an incident when I was being evaluated, I got evaluated as you know, just poor because of my productivity. And when I asked about it my supervisor says I'm

never here. So I explained to him that I go because I'm called and he approves it, and if I'm going to get low evaluations I'd just as soon not go. I figured I can stay, I can do either job, I'm available for any job that they ask me to do, I'll do it to the best of my ability. So Hile said well what's the solution. I said you either get in touch with the district and tell them what the problem is, or why don't you set up a thing here in in Washington, or transfer me to Washington or someplace where that's my job. So he said, well we're going to set up a thing, and this happened before EDRO was set up, and they set up the thing and then they finally transferred me. They asked me would I like to go to Washington or Philadelphia, I could go to either one. Ted, by this time had been transferred to Philadelphia and I had lived there before and had an idea of what it was like so I'd rather go to Philadelphia, my wife's family was around this area, so in '71 I was transferred to Philadelphia. But my boss was in Washington. I had a little office here in the Philadelphia district. I did some work for Philadelphia when I had time and they asked me well I would. A lot of the Philadelphia inspectors would come into my office when they had a problem and we would talk over some of their inspections and give them some ideas on investigation so I worked there both ends.

Lofsvold: As a technical expert and advising them.

Brodsky: Sort of, yes.

Lofsvold: One of the things that I'm interested in would be any opinions you have on the various commissioners that you served under. What kind of men they were, what there management style was, and any other thing you know about them, including any anecdotes of that show something about their character or personality.

Maraviglia: Well I guess the best way would be, to start from the beginning. The first commissioner I remember was W. G. Campbell but being a lowly inspector I had very little contact with him I recall. But my impression of him from far off was, of course you know he was a lawyer I believe and to me he seemed like a gentleman of the old school, kind of aloof but apparently a very capable administrator. I had never known him personally but there was the impression he left with the troops you might say.

Lofsvold: You saw him when he visited the districts where you were or....

Maraviglia: I don't even remember seeing him then. Maybe once or twice he might have visited the districts in Atlanta or New York somewhere. But he's very, he was very affable person but I didn't know him that well because I had very little personal contact with him.

The next, after Campbell I believe there was Charlie Crawford or Paul Dunbar. Now Paul, Mr. Dunbar was a very democratic type of individual as far as I recall. He would come into the district and talk with everybody you know, in the lab or inspectors or otherwise and might give us a little pep talk but he went around and made sure.....We were a small agency and everybody knew practically everybody else, you know Fred, you probably remember yourself how it was. And Mr. Dunbar impressed me as being a very approachable type of individual and a kind of a caring type of administrator, kind of a fatherly type, you know, that type.

Then after Dunbar there was Charlie Crawford for whom I personally had a lot of respect. To me he was a true southern gentleman if you can conceive of that image and again he was a very democratic type. He wasn't aloof, I remember, he used to come to the Philadelphia district when I was chief inspector and he sat in on a couple of meetings, inspectors' meetings that I had, just to observe, you know. And then we'd go out at night and go to one the inspector's houses, it might be John Breckenridge, you remember John Breckenridge? Well a couple of times we'd go over there or somebody else's place and play poker with Mr. Crawford. He was really one of the boys and yet he was a

very, I think, capable administrator and a real gentleman. He had some personal problems I understand family problems, which one would never know from the way he behaved towards other people, very courteous and polite to everybody, whatever his position was.

Then after Crawford of course, there was George Larrick. George, again, we were still a small agency more or less and he was, I remember going out with Mr. Larrick when he used to visit the districts regularly and he was an old inspector himself. He started out as an inspector you know and then became chief inspector of the whole FDA before he got to be commissioner. I remember I had some personal contact with Larrick on the job. He came down to Atlanta when I was down there. I think I was still on probation and he came out with me. We went out and made some inspections and he observed and was very helpful and understanding. George was very understanding, but he was a good inspector too. He showed me how to do a number of things.. I remember once we went into a pimento cannery that had had a fire. Canned pimentos were all around and there were a lot of open, I mean a lot of bulging swollen cans you know, suspect. I remember Mr. Larrick opening some and showing me how to examine them organoleptically you know, by smell. Just plain common sense inspection work and very edifying

as far as I'm concerned. I'd never have been able to do that. I would've taken a sample and brought it into the lab or something you know, but he made the examination right there on the spot and that kind of thing. He was very helpful. I was so nervous driving him around that after we left the district office and started out I had the car in second gear for about twenty miles and didn't realize it. He said, okay Ted relax lets have some fun you know, but he was that kind of guy, easy to get along with. I don't know what his personal life was like because we didn't talk about those things. As far as getting along with the inspection staff I thought George was O.K. You never met him did you?

Brodsky: Not personally.

Maraviglia: Anyway, that's my impression of Larrick. And then after he left, there was Goddard, Jim Goddard.

A lot of people didn't like Goddard but I did. He really gave us, the directors, authority in the field. I was district director in Cincinnati when Goddard came on. He changed the whole centralized form of control up to that time around, so that he gave a lot of leeway and responsibility to the field directors. Some of the things that I guess that a lot of us weren't used to, we didn't, maybe some of us couldn't handle all that responsibility having

not been used to it. We gradually learned how to accept it under Goddard's regime. In my opinion he encouraged us to run our own show in the districts. Whether that, maybe to a certain extent that was good, and maybe to another extent it wasn't so good, because you need some kind of central you know direction. Some of the guys really abused that privilege I suppose and...But it was a totally different kind of organization under Goddard. He what's the word that you use.....

Brodsky: Well he was too flexible with his troops.

Maraviglia: He's the kind, I remember one time he came to Cincinnati and he wanted to go out on an inspection with me. He encouraged the directors to do so, which was I think, a good idea to keep in touch with what's going on out there. Get out with your men, make inspections, get your hands dirty--you know. So he brought me out, we went on an inspection of a little drug repacker right there in Cincinnati and boy that place was a mess and we found more things wrong with it. He came back and said I want you to close that guy up. I said Dr. Goddard we can't close him up just like that. Goddard thought he was still back in the Public Health Service you know where you can quarantine somebody and shut the door on them. I said we'll build a case against them but it'll take a little while. So, every

time we had a directors meeting he'd say "Hey Ted have you closed that guy up yet?" But that's the kind of guy he was. Intelligent, brilliant, and ambitious I guess you'd say. But I liked working for him. If you could kind of keep him you know, under control you might say. That was my impression of Goddard, I liked him very much. Again, he was the kind that was one of the boys you know. We'd go out and have drinks with him and he wasn't aloof by any means. He wanted us to address him by his first name all the time. Well Goddard, as I say was the one who liked the decentralized type of organization.

After he left, there was Dr. Ley, remember Herb Ley who was an MD, came out of the bureau of drugs I believe. Ley was kind of a transition-type of commissioner I guess you'd call it. He didn't change things very much but he wasn't the charismatic type that Goddard was. It became apparent soon to everybody that there had been too much decentralization and in fact we needed some kind of central direction as far as policy at least was concerned. In fact, during the latter part of Goddard's regime some of us directors talked to him frankly about it--that we needed somebody in headquarters, a kind of contact with the field, which evolved into what they called a Field Liaison Officer (FLO), you remember? Goddard sounded me out on the job,

and I said no thanks I'd rather stay where I am and he got Harris Kenyon to become the first FLO, or Field Liaison Officer. Because even he realized and I think maybe Rankin talked to him a little about it, these people out there, you give them a lot of freedom and responsibility but they need some kind of guidance, at least as far as policy is concerned from headquarters. So that's when FLO started and that Field Liaison Officer gradually, over the years evolved into the present day Executive Director of Field Operations. Anyway that started even in Goddard's time, he realized that maybe they had gotten a little too far in decentralization, so after Goddard, Ley came along. He was just Commissioner for a couple of years, I think. He was another affable type. He'd visit the districts very friendly, but he didn't stay too long.

After Ley, we got our friend, Charlie Edwards, Dr. Edwards. He was one of the first to come out from a non-government source. All of the rest of these commissioners had been in government.

Lofsvold: I believe that Dr. Ley was in government for only a short time. He came to FDA, as director of the division of drugs, from Harvard Medical School.

Maraviglia: Oh, did he?

At least he was in the government when he was appointed Commissioner, whereas Charlie Edwards, I think, was the very first man to come in from outside the government as Commissioner, as a frankly political employee.

I liked Edwards, although he to might appear to be aloof but I think he tried to do the job which was kind of a strange one to him. Of course, his medical background, naturally, helped him a lot but it didn't seem to me like he wanted to make a career out of that position. I had some contacts with Edwards. He used to visit the districts occasionally.

Who came after Dr. Edwards? It was Schmidt, Mac Schmidt, another M.D. Schmidt visited the districts regularly. He came to Philadelphia a couple of times. Schmidt was the last commissioner I worked under and I retired on August of 1976 and he was still there. That's about all I can remember about all the commissioners.

We were talking about the formal and sophisticated planning that exist today in the agency and how centralized and detailed it is--which of course in the early days of my career in the late 30's and early 40's, there was no such thing as detailed planning that I recall. I was just an inspector, but I don't remember such details as they exist

today. I remember that we did seem to put a lot of emphasis, maybe wrongly or rightly, I don't know, on economic violations. For instance, many was the night that I've gone down to the, what used to be the Washington market in New York, in Manhattan, to take samples of fresh blueberries and bring them back to the lab where chemists would be waiting to examine them for maggots. Next morning, early in the morning, we'd be in the DA's office, drawing up a libel to seize the maggots and or having the city embargo the shipment if we had found the maggots that night. It seems to me like that was a violation that, I guess you might call it a sanitary violation, although it was economic too.

Another one that we used to do a lot of work with, things like watered oysters in Philadelphia. That used to be a big project in Philadelphia, real complex program for us, involving a lot of man hours. There again, you wonder about the priorities, sometimes, whether we spent too much manpower in that type of violation. Of course, as you know, after we lost the watered oyster case, we dropped that program pretty much.

Lofsvold: The courts declared our standard invalid.

Maraviglia. Yes.

It seemed that, at least in my early days in New York and places like that, a lot of our planning was based on the season. In other words, we knew that if it was harvest time in the Hudson Valley it was time to pick apples, and what have you for insecticides, for lead arsenate. Do you recall? And tomato picking and canning time in Georgia, or peach canning time; it was time to work on that project. And we knew instinctively that it was time to do that kind of work and maple syrup was another one.

And another thing, Fred that I'm sure you're familiar with, was the amount of voluntary overtime that we used to put in in those days. Men, of course would be out on the road for weeks at a time at least in a district where you had a big territory. Many's an evening we've spent mounting sediment pads from testing milk you may recall. All done on your own time and also you had to write up your reports while you were on the road and weekends too. If necessary you'd be out testing sediment in milk at dairies you know, and mounting those sediment pads all on your own time. I figured the government owes you and me, a hell of a lot of overtime. That was expected of us in those days. We were, at least I was, a depression baby, and I was thankful that I had a job and I was honored I could work and if I had work, I didn't know the meaning of overtime at that time.

Lofsvold: No coffee breaks either.

Maraviglia: Yes, that's right.

Lofsvold: I think coffee breaks became a national institution after World War II.

Maraviglia: Yes, that's a sacred cow now. But it was enjoyable.

Lofsvold: When you first started, FDA was operating under the 1906 act which did not authorize us to make factory inspections. Did you, during those three or four years, inspect factories?

Maraviglia: Oh, yes, we made inspections and of course we didnt' have the notice of inspection that we had later on. But it seemed to me that we assumed as inspectors that we had the authority, to go into a plant, and I don't recall any time that "my authority" was ever questioned by anybody. I don't remember ever being refused an inspection during that time. I suspect that most of the people that we did inspect had assumed also that we had the authority and were afraid to deny us entry. But that's my personal opinion. I never had any problems that I recall.

Lofsvold: I really appreciate your spending your time on this project and the materials that you have contributed, I think, are going to be very useful. Thank you very much.