

HISTORY OF THE  
U. S. FOOD AND DRUG ADMINISTRATION

Interview between:

Clifford G. Shane, Director

Region VII, FDA

and

Fred L. Lofsvold  
Robert G. Porter

Denver, Colorado

April 23, 1980

## 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.

## STATEMENT OF GIFT

I, Clifford G. Shane, hereby give to the United States of America for inclusion in the collections of the National Library of Medicine and for administration therein by the authorities thereof, the magnetic tape recording of the interview held on April 23, 1980, between Robert G. Porter and Fred L. Lofsvold and myself, together with the final edited transcript made from this recording. It is my understanding that a copy of the final edited transcript is to be deposited in the library of the Emory University as well as in the National Library of Medicine.

I hereby dedicate to the public my literary rights to this recording and its transcript, so that they may be freely examined, listened to, cited, quoted, or reproduced in whole or in part, subject to such restrictions as the Library may impose to insure their proper protection and preservation and subject to the following restrictions of the donor. The recording is to be sequestered for a period of fifteen years from the date of the recording until April 23, 1995. The transcript may be freely examined, cited, quoted, or reproduced in whole or in part, with the following restrictions which are to be sequestered for a period of fifteen years until April 23, 1995.

Page 12, line 4, beginning with the fourth word through the first word of line 6.

Page 20, line 14, beginning with the sixth word through the first word of line 17.

Page 29, line 12, the proper name.

STATEMENT OF GIFT

Clifford G. Shane

Page 2 of 2

Page 31, line 5, the proper name.

Page 31, line 6, the proper name.

Page 61, lines 8 through 25, starting with the statement, "In fact \*\*\*" and ending with the statement "\*\*\* details that he could."

Page 69, lines 6 through 12, starting with the statement "I think \*\*\*" and concluding with the statement, "\*\*\* one day."

Page 70, lines 10 through 15, starting with the statement, "Bob, I'm positive that at \*\*\*" and ending with the statement "\*\*\* convinced of it in my own mind."

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National Library of Medicine  
Bethesda, Maryland

## INTRODUCTION

This is a transcription of a taped interview, one of a series conducted by Robert G. Porter, who retired from the U. S. Food and Drug Administration in 1977.

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.

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TAPE INDEX SHEETCASSETTE NUMBER(S): 1 - 2 - 3GENERAL TOPIC OF INTERVIEW: History of the Food and Drug AdministrationDATE: April 23, '80 PLACE: Denver, Colorado LENGTH: 135 Min.INTERVIEWEEINTERVIEWERNAME: Clifford G. ShaneNAME: Robert G. Porter & Fred L. LofsvoldADDRESS: [REDACTED]  
Overland Park, Kansas 66210ADDRESS: U.S. Food & Drug Admin.  
Denver, ColoradoFDA SERVICE DATES: FROM 1955 TO: Present RETIRED? No.TITLE: Director, Region VII, U. S. Food and Drug Administration  
(If retired, title of last FDA position)

CASS. NO.	SIDE NO.	EST. MIN. ON TAPE	PAGE NO.
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Porter: \*This recording is being made on April 23, 1980 at the Food and Drug Administration District Office in Denver, Colorado. Present are: Clifford Shane, Regional Director at Kansas City, Missouri; Fred Lofsvold, retired Regional Director from Denver, Colorado; and Bob Porter. This recording is made in an effort largely to get Mr. Shane's views on a number of important things that have happened during his career in the Food and Drug Administration. I'd like to start the tape, Mr. Shane, if you would just give us a little sketch of your career in the Food and Drug Administration.

Shane: All right. To give you a thumbnail sketch of my career, I started in Kansas City in June of 1955 as a GS-5 Inspector. I was in Kansas City for about 4 years and then, in 1959, I was promoted as the Resident Inspector in Portland, Oregon. I was in Portland, Oregon about a year and a half. I was on a road trip, and Ken Monfore, who was then the District Director or District Chief, as they were called at that time, called me and told me I'd been transferred to Washington. I spent a year and a half in Washington in the old Bureau of Field Administration. It was at that time headed by Alan Rayfield. The Administrative Chief Inspector was Ken Lennington, and the fellow who was our Supervisor was Doug Hansen.

\* Portions of this transcription have been deleted upon instructions of the Donor. A full transcription as well as the magnetic tape of the interview will be released on April 23, 1995.

Porter:

That's when they were in the old tempo R.

Shane:

The offices were in the old temporary R building out in the mall right across from north HEW. These were old World War I barracks converted into offices. The assignment was considered the executive development program of that time. You were on a two-year assignment with the understanding that, if you made good, you had the chance to progress further in the organization. I was there a year and a half and was then sent to Los Angeles as the Assistant Chief Inspector. It was a newly created position because of the expansion program that had taken place in F.D.A. I think L.A., at that time, had something like 55 investigators. I was in Los Angeles one year to the day when I got a call and was advised that I had been transferred to Chicago as the Chief Inspector. Now it's called the Director of Investigations Branch. The District Director at that time was John Guill. I spent 5 years in Chicago as the Chief Inspector. I then was transferred to Detroit in 1968 as the Chief Inspector. I was in Detroit two and a half years and then I was transferred to Cincinnati as the District Director. During my tenure in Cincinnati, I'd only been on board about a year when I was detailed back into headquarters to head up a project called, "Project Hire". That consisted of being responsible for the recruitment, equipping, training, and housing of 750 new investigators. They were supposed



to be brought on board, trained, and out in the field performing sanitation inspections within a two-month period. I was the Director of that project under Paul Hile, who was then the Executive Director of Regional Operations. At the conclusion of the detail which took about 8 months, mainly in headquarters, I was promoted to the Regional Director of New York in 1972. I went with an understanding that this would be a 2 to 3 year assignment, which lasted until 1979. I applied for and got transferred to Kansas City as the Regional Director. So that is a thumbnail sketch of my career, transferring around in the Agency.

Porter: Well, Cliff, why don't you tell us, since we know you were involved in some interesting OTC work early in your career, unless you have something else in mind, why don't you just tell us something about that.

Shane: I got an early introduction into the OTC work. I had been on the job about one week when I was assigned to go to one of the local bars called "Bradley's Bar" south of the downtown Kansas City area and observe a buy of amphetamines that was going to be made by Weems Clevenger, and Jim Green. About all the instruction I received was to sit there and see if I could observe what was going on. I went into the bar and sat down, had a beer and struck up a conversation with the bartender, or rather he started up a conversation with me. He asked me what I was doing, since he obviously hadn't seen me in the bar before. I

told him that I was a school teacher. School was just out and that I had come into Kansas City for a holiday and was going to spend the week living it up and asked him where the hot spots were in town. He told me that evening to come back to the bar because usually there was a lot of action in the bar. I sat there and sipped on a beer and, about a half hour later, I noticed the bartender open up one of the cabinets underneath the bar where they stored beer and liquor. He reached in and pulled out a bottle, which later was found to be a bottle containing about a thousand amphetamines. He commenced to count out a number of them into a napkin, wadded up the napkin, and stuck it back into the cabinet. A short time later, Jim Green and Weems Clevenger came into the bar, went to the back and met a fellow who was later identified as Junior Bradley. Junior Bradley then came out and got the napkin with the drugs in it and walked to the back of the room where I observed him eventually hand the napkin to Green and to Clevenger after he had received a little money from them. The thing that we did not realize at this time was that Junior Bradley was also under investigation by the FBI for bank robbery. It was not too long after that that he was arrested for bank robbery, possession of firearms, and I can't remember all of the charges. The thing that was involved was that we also wanted to charge him with illegal sales of drugs.

The FBI was very reluctant to charge him, and it took a little persuasion from the Justice Department to get the job done. But they finally agreed to tack on a misdemeanor for illegal sale of drugs to all the felony charges.

Porter: They didn't want that . . .

Shane: They had no use for it at all. Most of our cases at that time were still drugstore cases. We used to get a lot of complaints about druggists. Doctors would phone in and find out that patients had been getting prescriptions refilled illegally all the time. It was very easy to make a drugstore case, especially if it was a prescription refill. If you could get a cooperating physician, you could probably go in most any drugstore at that time and get illegal refills. To give you an example, we had gotten a complaint that the drugstores in Junction City were illegally refilling prescriptions. I went to Junction City, Kansas and was able to get prescriptions from one of the local doctors. There were 5 drugstores in town, and I started in and walked down the street, entering the prescriptions, and periodically I would go back and get illegal refills and then start getting other sales of drugs that were associated with prescription drugs. I usually bought a little penicillin because I told them I'd been out with a girl and looked like I was in trouble. Usually they would dispense penicillin very freely. I

would tell them I was having problems with the amphetamines and that they were keeping me awake and I had this girlfriend who I was having trouble keeping up with and asked for Metandren, which was a male hormone. Usually I was fairly successful. Most of them were wanting to get a little bit of an inside track upon the activity that was taking place and, with a little bit of an explanation of this hot chick that I had in the motel, they sold me very readily. Again, about this time, the truckstops started selling a lot of amphetamines. When I first came to work with FDA, the Agency had sent a group to learn how to drive trucks so that they could go out on the highways and try and make buys of amphetamines at the truckstops. One of the problems that they encountered early on was that it became very apparent that they were not hauling a load and those trucks were empty. Anybody in a service station could see by looking at the springs that the trucks were empty, and they had a very difficult time making buys. What they did then was loaded the trucks with junk and also found out that the greatest thing was to sprinkle a little sugar on the tailgate. If anybody asked what you were hauling, you could always tell them sugar, because that would be contraband, especially down in the south. It was understood that you were probably going to make a delivery to a moonshiner. Buys were then very easy to make and we made a series of truckstop cases.

Lofsvold: Our interest in the sale of drugs in the drugstores as I remember, was chiefly the public health aspect. And, most of the time, if I remember correctly, we only went to those drugstores where we had at least some kind of a complaint. Preferably an injury, but at least some complaint, that they were illegally dispensing. Was that the case in Kansas City at that time?

Shane: That was the case, Fred. We only followed up drugstores on complaints. I think at one time, from my discussions with people early on, they used to be able to just walk down the street and walk in a drugstore and make buys. The cases were very rampant. I think, in order to get some limitation to that activity and put it in its proper perspective, they decided that we would only go in on a complaint, a complaint of an illegitimate practice of some kind.

Porter: Really much earlier, the way we did it, we would just shop stores. We weren't building cases. It was an educational effort, and we got out what was called a PL-5 letter, which was a Policy Letter #5, which, in effect, told the guy we'd bought this in his store and told him it was illegal and not to do it again.

Shane: I suppose, Bob, the reason for us requiring a complaint, was to lay the basis for taking legal action and at least give some probable cause to go in there and buy illegally.

Lofsvold: Yes. The initial one you're talking about, Bob, I believe was, there were two purposes: first of all to determine what the extent of the problem was or whether there was a problem, and then, secondly, to publicize to the pharmacists that this was illegal under the Federal Statute, and then progress from there to actually bringing a legal action on the basis of a complaint. Now I think then we progressed into the truck-driving aspect because of some rather spectacular accidents that were highly publicized throughout the country where people were killed and there was indication that the drivers were driving too long and depending on amphetamines to keep awake.

Shane: Yes. One of the classic examples of that, Fred, was a situation involving a truck driver who was involved in an accident. He'd rammed into the rear end of a car, killing the occupants. His excuse when they started talking to him was that he was trying to evade a snake that was in the cab of his truck. Obviously he was high, and later, blood samples determined that he was high on amphetamines. He'd been driving something like two days without sleep. The major problem seemed to be focused on produce haulers coming from Florida or that area of the country, hauling produce up into the eastern seaboard, up into New York nonstop, dead head back and pick up another load and turn around and come back. They just deadheaded up and back without any sleep, and they would become a real hazard to the road.

Porter: Do you know how we made arrangements for this truckdrivers school? Who conducted it?

Shane: No, I don't know all of the particulars on it. I do know that it was made through one of the regular truck driving schools.

Porter: Was it in Pennsylvania?

Shane: It was in Pennsylvania, Bob, and I think it was also sponsored by some of the major trucking companies who were concerned about their own drivers using amphetamines.

Porter: We had two fellows from Chicago, Bob Case and Bill Chaffey, who went to that school.

Shane: It became very common usage among truckdrivers. I think just the boredom of going down the highway. I remember talking to some truckdrivers, and they claim that just the monotony of sitting behind the wheel would put you to sleep. This was their excuse for breaking that monotony. If amphetamines were taken properly, they didn't get sleepy; they were more alert; they were better drivers. In other words, that's what they felt in their own minds, and that was their excuse. A number of doctors prescribed amphetamines for the truck drivers.

Porter: They didn't have their two-way radios, their CB's . . .

Shane: No, CB's were not an in-thing at that time.

Porter: They can keep interested in something now.

Shane: In dealing with the illegal sale of drugs problem, I had done some OTC work when I was in Portland, not too much, mainly there it was dealing with longshoremen. I

also had the job of approving all the ship's stores, involving purchases of drugs. I noticed a number of the ships were ordering large quantities of amphetamines, well above and beyond what they would normally need for a voyage. They would get very irate when I would disapprove those purchases. I did successfully make a case against a longshoreman who was peddling pills. He was one of the major peddlers in that area.

When I was in Washington, the other job that I had was to assist Lou Lasher, who then was the coordinator for the illegal sale of drug work in the Old Bureau of Field Administration. This office was in charge of the field operations. I helped him coordinate the cases on a national basis. It became apparent even at that time that not only were we dealing with the amphetamines and the barbiturates, but that then the hallucinogenic drugs were starting to come into vogue. When I went to California, I really became cognizant of the use of LSD, peyote, and other types of hallucinogenic substances. Those were probably the two most commonly used at that time in the early '60s. It was very difficult to make cases. For some reason or other, the illegal sale was done through an individual who was at that time considered the early hippie. There wasn't so much of a sale at that time for profit and gain; it was more of a cult deal that was involved.



You were always expected to be a participant and, or course, we were not about to find ourselves as a participant in that type of a situation.

Lofsvold: Don't you think one of the problems too might have been that those particular drugs came from clandestine sources rather than being diverted from the normal channels of trade and being manufactured by established companies?

Shane: Yes, they were made in small clandestine laboratories. Anybody with a good chemistry background or even some chemistry background could probably compound LSD. That was what you were dealing with, and it was a different sort of distribution pattern than we were normally used to. I suppose, at that time, I had probably one of my most harrowing experiences in that area. Two fellows from Kansas City came into Los Angeles and had made contact with an individual who was supposed to be a major drug distributor in the L.A. area, a fellow by the name of Siples. He professed to have a large supply of drugs available to him that he could get out of Mexico or anywhere else that he desired. I was at that time assigned the responsibility to run cover for these two individuals. One was an informant, and the other one was Harold Leap. Harold was an investigator out of Kansas City, primarily doing OTC work. We checked into a motel in the Long Beach area, since Siples lived in that area of L.A. and commenced to try and make arrangements for a buy. He would sell

small quantities, maybe a dozen pills or two, but he would never come up with the quantity that we were asking for. We were asking to buy about a million pills. He was a very unstable person.

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I don't know the truth of his statements, but he seemed to be a fairly irrational type of individual from what I could tell in the dealings with him. He also had another fellow, a Hawaiian, who was part of his gang, as he called them. The Hawaiian indicated that Siples probably couldn't deliver the drugs, but he could. After about a week of trying to buy drugs from Siples, we decided to approach the Hawaiian and to find out if he could actually deliver the drugs. So we made arrangements to meet him in a motel in downtown L.A. As far as we were concerned, we were trying to cut Siples out, and it was with the blessing of one of his gang members. We rented the motel room; we got adjoining rooms. We had the new Kell unit at that time which had a receiver and a little transmitter radio unit about the size of a package of cigarettes. We set it up in the room, and I was in the room next door recording the buy. The receiver also had a tape recorder attached. The one thing that I was concerned about, and everybody else was a double-cross. I brought my shotgun along, which was an illegal act, since we could not carry fire arms. I figured that I was going to go bird hunting

or skeet shooting and that it was appropriate that I have it with me. We had a prearranged signal that, if anything went wrong, that all they had to do was to say my name and drop to the floor. I would spray the interior of the room with shotgun pellets. We had the door latches taped so that I could get into their room without any trouble. We were ready to make the buy; it was all set up. I'd even bought a fifth of scotch because, about this same time, I'd been told I'd been promoted to Chief Inspector, so we figured after the buy, we'd do a little celebrating. Everything was all set to go and, at the appointed time, there was a knock at the door. I ran over and turned on the recorder. All of a sudden I heard Siples voice. He came into the room, and I could hear him clearly over the transmitter. His first words were, "You S.O.B., I'm going to kill you. I'm going to blow your brains out." I can remember the words clearly. You may have to edit that. You could hear the click of the gun. He had the gun pointed at Leap's head. About that time, I grabbed the shotgun and threw open my end of the door, and I had my foot ready to kick open the other door. I was waiting for him to say, "Shane". Siples commenced to talk and talk and nothing was happening. I was standing there all ready, but I was afraid to go in because I would shoot both of our people. Finally the conversation kept going on and on, and Siples kept talking and talking. The

more he talked, the more apparent it became that he wouldn't pull the trigger. They went on and on for about 4 hours. They finally decided that they would rob Leap and Junior Gates, the informant. They marched them out of the room, And I was afraid that they were going to try and take them away. I'd made up my mind that I wouldn't allow them to be removed from the motel room. Well, he had three other fellows with him. They were searching the room trying to find the money that was going to be used for making the buy. I opened the hall door, and I could see Siples with his back to me. I tried to get Gates and Leap to get out of the way, but they refused to move. I figured I could hit him in the legs without any problem and at least wound him and disable him. As for the rest of them, I wasn't worried. He was the only one I could determine that was armed. They wouldn't move, and probably to their benefit. Finally they turned the place up and down and couldn't find the money. Junior Gates had a gun with him that they found when they were ransacking the baggage; they took Gates's gun. Leap had also rented a car; they took the keys to the car and took off with the car. After they had gone, Gates and Leap wanted to try and continue the buy, but I figured that we'd had enough. I called and got in touch with Les McMillin, who was the Chief Inspector, and advised him that I was calling in the local PD because the situation had gotten out of hand, as far

as I was concerned. We then called in the local police and advised them what had happened. It was surprising; about the same time the police were there, Siples called the motel room and told Leap and Gates don't try and go anywhere or do anything funny because he had the car and had had no problems with killing them if they tried to leave town. He did promise delivery of the pills. The local police then went over to where Siples was staying and kicked in the door and arrested him and the other people. Later we went to trial under State charges of false imprisonment, burglary, and grand theft. Four individuals were indicted and all four were convicted. That was a close call for me. I have often thought what would have happened if I had shot Siples.

Porter: That was a very interesting case, Cliff. Why don't you tell us about some of the cases in Chicago while you were there?

Shane: I suppose Chicago was a completely different situation. When I went to Chicago, there was not a great deal being done with OTC cases. Primarily, it was an internal problem within the district. You couldn't get the district director to really approve of illegal sale of drug cases. I don't know what the reluctance was on his part. You couldn't get the compliance officer to write up the cases. His understanding was the Assistant U.S. Attorney handling our cases did not want those types of cases.

Porter: Well, you know, I was there just before you, and we had this problem, but I don't think it was really a matter of policy as much as just lethargy or something like that. You just couldn't, the cases would end up in his office and there they would sit. By the time you could get your hands on them, the evidence was so old you were reluctant to use it.

Shane: Well, the excuse that I have heard, Bob, was that the Assistant U.S. Attorneys were reluctant to file cases and so it became a rather frustrating situation. You could go out and develop a case and not get it filed and prosecuted because of what was happening in the district, whatever his thought were. I talked to John Guill a few times about it and really couldn't get any satisfaction. I was told, well, make the cases and present them, but that's all that happened to them. A situation occurred in Chicago which changed the whole perspective of the OTC work in the district. Evidentially, two young kids had got high on pills. An elderly man was walking down the street and they encountered him. They assaulted him. They knocked him down and then commenced to kick him to death. After that hit the newspaper, I was called into the U.S. Attorney's office, and he wanted to know where our illegal sale of drug cases were. He advised me in no uncertain terms that if we could buy one pill illegally he would prosecute anybody that sold them. So, with this type of an attitude coming

from the U.S. Attorney's office, the district, I think, at that time, really had no option but to get busy and start developing some illegal sale of drug cases. We had received a lot of information that the illegal sale of drugs had progressed into organized crime in Chicago and was being handled in that fashion. We decided that the only way we could really be able to do anything with this was to try and put a couple of agents on the street and let them just work the street for a long period of time without bringing any cases. Not necessarily making cases, but bringing any cases to trial. I had a couple of young fellows by the name of Tim Hadden and Jim Braseth, both just young fellows right out of college with no experience or knowledge in undercover work. We decided that, with my background, I would give them close personal supervision in developing illegal drug cases. Working with them and arranging for cover as much as possible for them to try and keep them out of danger. It so happened that they were both good pool players. They would visit the bars in the evening and begin to play pool. We had a restriction that we wouldn't reimburse anybody for more than two beers. I guess the Agency figured if somebody drank more than two beers he'd get drunk. You were at a disadvantage to place somebody on the street and expect him to run the streets at night with two beers in hand. Since they were both excellent pool players, I think they made enough

profit off of their pool to cover their losses. They became acquainted with a fellow by the name of Lester Halfacre who owned a bar in South Chicago. For some reason or other he took an intense liking to them. They tried to encourage him to buy pills for them, and he tried to encourage them to get out of the pill business and go to school and make something of themselves. However, since he took such a liking to them, he agreed to make some arrangements for making some buys for them. We'd made a number of small pill buys as we went along from people on the streets, but again, these were all small peddlers. We'd also been in the process of picking up some counterfeit money which we turned over to the Secret Service. We picked up stolen money orders and a few other things which we turned over to the Postal authorities, and we were able to wire one of the Secret Service agents in to make them a "funny money" case, as it was called by them. So we had a fairly good working relationship with the other Federal agencies in the area. Getting back to Lester Halfacre, Lester arranged to set up a buy from a fellow by the name of Cross-eyed Whitey, who owned a bar in Cicero. Whitey supposedly was associated with the mob. When Lester and our two inspectors went over to make the buy, they found out that Whitey didn't have the pills, and Lester flew into a rage and was going to do bodily harm to Whitey. Of course, the guy was named Cross-eyed Whitey because his



eyes were so crossed it was unbelievable. I don't know how he ever saw where he was going. Lester commenced to chase him. Whitey lived over the bar and Lester chased him up to the rooms. He locked himself in the apartment and, of course, Lester was right after him. He was going to kick down the door, and so Whitey finally said that he would go get the pills. He'd promised them, and he'd go get them. He opened up the door and the two of them came down back into the bar. Whitey went over and opened up the door and fired a gun into the ceiling and told everybody to clear out of the bar. The bar emptied very quickly except for about 4 or 5 thugs that were sitting in there. All the patrons just vanished. He commenced to call all the guys over there and opened up another door and started handing out firearms. Lester asked him what he was gonna do, and he said, "Well, we're going out and get your pills for you." He called both Braseth and Hadden over and . . .

Lofsvold: They were still in the bar?

Shane: They were still in the bar. And he started to hand them a gun. They were wired, and I was sitting outside, and you could monitor all the conversation that was taking place in the bar. They had the Kell unit on them. They were sort of at a loss for words. Lester finally said, "The hell with you, if we're gonna pay for 'em we're not gonna go help you steal 'em." And he told both Braseth and Hadden to, "Just sit down, we'll wait for you," he told Whitey

They took off, and they came back a couple of hours later with the pills that had been promised for sale. We never knew which one of the drug warehouses or where they'd gone to get the pills. I was afraid to ask. This is, in essence, what we were dealing with, and our relationship with the Secret Service finally really paid off. They had picked a fellow up in Cincinnati who originally had served time for counterfeiting. They called me and said they'd caught this guy on a second offense and that they had him working for them, and he'd worked everything they could get out of him. They understood he was in the pill business. And when they told me his name, I couldn't believe it. He was considered the major distributor for all the truck-stops down the southeastern seaboard.

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So they offered to drop him off as an informant. They told me that they'd left him with our Cincinnati District Office. I called down to Cincinnati, and they said, "Oh yeah, we've got him here, and we're gonna make a whole bunch of truckstop cases." And I told them, no they weren't, that he was my informant, and he was coming into Chicago because we had better things in store for him. There was a little bit of argument that took place, but they finally concurred that our use for him in Chicago was better than having him run up and down making a bunch

of truckstop cases. So we brought him into Chicago and we checked him into a hotel west of town which was supposedly owned and operated by the Mafia and set him up to make a series of buys for us. He started out and we monitored his activity. He walked into wholesale drug distributors in Chicago and made purchases. Just walked in and picked up the bottles off the shelf. It was by mutual agreement that we would pay so much for a bottle of a thousand. At that time, we'd been fairly active and had driven up the price to where I think we made it profitable for the Mafia to move in. When I started out in Kansas City, you could buy a bottle of a thousand amphetamines for \$10.00. At that time, the price in Chicago was up to \$100.00 a bottle, on the street, \$150.00. So the price for the illegal sale had gone up considerably, and I think that's the thing that got the Mafia involved. He then began to give us the name of distributors and made calls for us introducing our agents to illegal distributors. He made a call to Wisconsin to a drug warehouse. We went up and picked up three or four cases at \$14.50 a bottle out of the warehouse in Wisconsin. He also gave us the names and made introductions to three or four other drug distributors in the Chicago area who supposedly were operating under the Mafia. He also set us up to make buys from a known Mafia member. We later consummated a buy from him. Most of these cases were developed about the time that the Bureau

of Drug Abuse Control came into being. So that most of those cases were handed over to that group after they were formed. They commenced to reap the harvest of the hard work that we'd put into it. However, Brathes and Hadden fared well. They went with that bureau when it was formed and ended up doing quite well for themselves. I understand Brathes is in charge of the office in Minneapolis for the Drug Enforcement Agency now. The Bureau of Drug Abuse Control was combined with the Bureau of Narcotics of the Treasury Department, and they later became the Drug Enforcement Agency.

Porter: How long had he been in? That name sounded, I wonder if he's the guy, could he be . . .

Shane: He was only in for about a year or two when we put him on the street.

Porter: I hired him. I think I hired him.

Shane: You probably did.

Porter: See, I was, I didn't leave Chicago more than a few months before you went there.

Shane: You probably hired him because he was relatively new. He showed a real great aptitude for the work. It was unbelievable, his ability to make buys. He'd worked on a mink ranch, and he developed the name of Mink. He was known throughout the street trade as Mink.

Lofsvold: Let's see, B.D.A.C. was formed about 1967?

Shane: About 1967, yes, Fred. At that time, I had a decision to

make in my career. They had offered me the position as the director of that group, and I agonized over it for a long period of time as to whether or not I wanted to spend all of my time and efforts in dealing with the illegal sale of drug work. I finally came to the conclusion that I was really more interested in Food and Drug work per se. The other was stimulating and exciting, but I didn't think that I wanted a full dose of it because I'd had too many sleepless nights the way it was. Anytime those two kids were on the street, I don't think I had any night's sleep until they got off the street. And I just felt too responsible for somebody's life and welfare. I suppose that was one of my overriding decisions, that while it was enjoyably and it was fun, I was still sort of a true Food and Druggery and true to the philosophies of the Agency.

Porter: Boy, I used to feel that way in Chicago. I can remember yet walking down 47th Street in Chicago and kinda thinking, "What am I doing here?"

Lofsvold: It is quite remarkable that we did not have people killed or seriously injured because we had very limited training, and mostly we were learning as we went along and many times were in situations that we didn't realize just how dangerous they were.

Shane: No, I think our ignorance was our blessing, Fred. I think, number one, since we couldn't carry firearms, we realized

that there was no way we could protect ourselves and probably this was to our benefit. Had we been allowed to carry a gun, I think it would have been to our detriment. The other aspect of it is that being so damned naive, I think worked to our benefit in that our people found themselves in a situation that they found that they had to talk themselves out of and, if necessary, that they had to rely on their wits. They knew this, I think that the blunders that they committed, had anybody thought that they were a cop, they would have never done such stupid things. That's my own personal feeling.

Lofsvold: I think you're correct there, that the ignorance was probably one of our strong protections because we did not have the kind of background that law enforcement people generally have and, consequently, didn't act like law enforcement people.

Shane: No, I don't think anybody would ever have picked our people up as law enforcement agents. I remember a case, a classic example. I'd taken a 6-week training course in New Orleans on surveillance. It was run by the Bureau of Narcotics to give us a little bit of training on it. That was when I was in L.A. It was a six week course.

Lofsvold: That was quite late in the game. We had been doing this work for several years before we had that kind of training.

Shane: But the training was really not much in the way of training. They taught us how to post surveillance on somebody and how

to interrogate. There was really not much or anything that was taught on self-defense or anything else in that course. It was strictly interrogation and surveillance type of activity. A thing happened in one of the cases in Chicago. Working with the Post Office, we were very fortunate. They would give us one of their mail trucks if we wanted to run surveillance, and they had it set up so you could operate a camera out of it. You could film the buys from the rear with the camera. The nice thing about the mail truck, it could be anywhere and it was not suspicious. We were supposed to make a buy on one of the street corners in the south side of Chicago and, due to my own ignorance, the limited schooling I had, one of the fellows was standing on the corner and we couldn't get him turned around to get a good picture of him, for some reason or other. So I said, "I'll show you how we can photograph his face." I got out of the truck, circled around the block, walked up to him, tapped him on the shoulder and asked him for a match and struck the whole book and it flared up; it was a little dark so we thought we'd get a little light on him. You know, dumb things like this that anybody in their right mind wouldn't do. But, you know, like I say, I was happy in some ways to see it go because I just think in my own personal point of view that the job of the Agency, the true mission, was really being distracted from by the amount of time and effort that we were putting into this

activity. And it became a great drain on manpower and time. However, when we first started, of course they expected you to do your 8 hours of work a day and then in the evening you were expected to go out and do the illegal sale work so that, at a minimum, you were expected to put in about 12 hours a day. All overtime was gratis, of course. And the kids even at that time in Chicago put in a lot of time. They never got paid for any overtime. We tried to adjust the work hours, but we even sent them out at that time to make inspections in addition to the drug work they were doing.

Porter: We did it partly to protect them, because we didn't know that was going to become a specialty and, if they got too ingrained in that, it might even reduce their chances of promotion.

Shane: Oh yes, it probably would have hampered their career. However, it, I think, was apparent that some of the people who were successful in this area seemed to have a decided advantage in getting promoted within the Agency.

Porter: Oh, I agree with that.

Shane: And I think that was one of the things, Bob, that sort of stimulated the people. The people were more than willing to get involved because it was advantageous to their advancement.

Porter: It was dramatic, and it called attention to them as individuals.



Lofsvold: The people in headquarters became aware of individuals by name, seeing their names on reports of the cases that they had developed, the spectacular sorts of cases.

Porter: Doug Hansen admitted to me once that he did a good OTC case in Seattle, and it got worked for about 3 promotions before it wore out.

Shane: Well, I think you're right, Fred, you've got the high visibility in headquarters. If you were an investigator out there plodding along doing your job, nobody heard of you. And this gives you the visibility.

Porter: Have you got any other good drug cases?

Shane: I suppose one of the ones that had an unexpected ending was when I was in L.A. We had received word from the Attorney General who was then Bobby Kennedy that he had a complaint from a mother whose daughter had been given LSD, and it caused her to suffer a breakdown and become neurotic. I was given the assignment to go over and interview the girl to find out if we could determine where she got the drugs. Her mother was a very determined type of woman. I talked to the girl's psychiatrist or psychologist, who was treating her at that time, and he said that it would be very detrimental to interview the girl. He said that it could put her into a relapse and possibly hamper her recovery. I reported this back to the District, and a short time later we got another telephone call from the Justice Department demanding that we interview the girl. I made

arrangements to go over and interview the girl and find out a little bit about her. I found out that she had started out as a dancer in Las Vegas and eventually had gone to the Latin Quarter in New York and from there was picked up by a modeling agency, and became one of the top fashion models in New York. When I went to interview her, I made arrangements to interview her at the clinic, so that I would have somebody close by to give me some help in case I needed it. Her psychologist or psychiatrist was out of town and the Director of the Clinic said that he would be nearby. He warned me to watch that, if her eyes began to flutter and roll back in her head and she got a little incoherent, that she was probably in the process of flipping out on me and to call him immediately. When I first started interviewing the girl, she was a very attractive girl, needless to say, being a high fashion model. I waved the flag in front of her for a long period of time and talked to her about everything but illegal sale of drugs. She became very talkative, and then I explained to her why I was there and that my purpose was to find out if I could find out where she got her drugs and that we didn't want to involve her. All we wanted to do was to find out the source and the names of the people that were involved. She told me a rather harrowing experience of being involved with drugs. She had been on a yacht trip with a famous New York millionaire and found herself the next morning

in bed with a movie star. She had attended parties by New York socialites and had been involved in all types of drug parties and orgies. Finally, I think I really won her confidence because the second day that she came back for the interview she had a little black book which contained the names of all the sources of suppliers of drugs that she had in New York. She gave me all the names of the people who were involved, places where you could buy drugs. I remember one place in particular, in the Village, it was called the Big Fat Black Pussycat. It sort of stuck in my mind. Her crowning touch was when she said that she was at the home of [redacted] and that she was lying in bed and she received a drug from him which later she found was LSD. She said as she lay on the bed that the bed became smaller and smaller and she was shrinking into nothing. And the next thing she remembers was being in a mental institution where she was undergoing treatment. Later she was released and came back to Tucson under the care of her mother. I had gotten all the information, supplied it to New York, and forgotten the incident. When I was in Chicago, we got a phone call in the district, and a man was asking the operator for LSD 25. The clerk went down the register of people that we had and said that she couldn't see anybody there by that name and initials or number that we used for record-keeping purposes, and told the fellow there was nobody there by that name.

He called back later and asked to speak with somebody about LSD 50, and she again told him that we didn't have anybody there by that name. He finally called back and asked for the Director of Investigations, and I got him on the phone. He told me that his son was spaced out on LSD, and he found a whole shoebox full of sugar cubes which he assumed were treated with LSD. I sent two investigators over to interview him and to try and get hold of the drugs and to talk to the kid. He was a fairly young kid. He had been sent to Chicago as a major distributor of LSD for a fellow in New York. Either fortunately or unfortunately, but fortunately for us, unfortunately for the kid, about the time this whole thing took place his girlfriend almost died from the use of drugs. She was in New York, and he found out about it. I think he began to realize how serious and how dangerous these drugs were, then he agreed to work for us. We therefore arranged to make some buys. We made a mail order buy from his connection in New York. We then got in touch with him and arranged to send an agent to New York to get a direct buy from him. We had the agent stay in New Jersey and then had the guy cross the river from New York to establish the interstate movement of the drugs. New York District set up surveillance and then followed him across the river to the motel. Since he did not stop after crossing the river until he reached the motel, we could prove the drugs crossed a state line.

Later, New York District was able to have him arrested. They got a search warrant and searched his premises and found some LSD. The irony of the whole case is that this individual turned out to be the individual who was supplying with his LSD. He was probably the one who had furnished with the LSD that he had given to the girl in Tucson that had the bad experience with it.

Porter: Why don't you tell us about some of the other kinds of activities that Food and Drug was engaged in when you came in.

Shane: I suppose the main activity that we were engaged in was filth work. We called ourselves pellet counters. One of the primary jobs in Kansas City in the spring of that year was to follow the wheat harvest. We would start in front of the harvest and inspect grain elevators. It was part of our Clean Grain program that was in effect.

Porter: This was like 1955 or shortly thereafter?

Shane: That's right, in 1955. When I first came to work, one of my first road trips was to go on a two-week trip to inspect grain elevators and make certain that these grain elevators weren't filthy when they were putting grain into them, and that they were in good condition to protect the grain. There were still a lot of old country elevators around. We didn't have the big concrete terminals, they were just in the process of being built. Most of them were rickety old buildings you could throw a brick through. They were

overrun by rodents and rats, birds, everything else under the sun. Our policy at that time was an educational program. You were expected to go in and make a complete investigation and gather all the evidence to support a legal action. However, we also had an educational program; you left them a checklist, in addition to the FD 483. It became very apparent that there were no legal actions going to take place with these elevators. The Agency just had committed itself to try and clean up the grain industry through education. So we went for a number of years, I think it was almost 3 or 4 years, before we brought an action against one of those elevators. After we brought the prosecution action and the seizure of a bunch of grain, it cleaned up the grain industry immeasurably. I think that was probably the best education they ever had. Again, the other was general, basic filth work, warehouses, manufacturers. The other industry we had was the old sour cream industry. It is all gone now. That basically was in Kansas and Nebraska. You had to be qualified as a cream taster, which meant you tasted sour cream for decomposition, and then we used to do whole can filtering for filth. It was not uncommon to occasionally pick up a whole mouse or a bunch of rodent pellets where a mouse had got in a cream can and died. You would go in the summertime into those creameries and the cream would come in and you had to be very cautious when you opened the cream

cans because you'd tap them and they'd explode and put big dents in the ceiling from the can lids. You could tell about the creamery when you went in because of all the dents in the ceiling. You knew dang well they were getting bad cream.

Lofsvold: This was cream from milk that was separated on the farm and the cream accumulated over several days and then shipped once a week to a creamery.

Shane: This was when farmers came to town twice a week. Wednesday they brought in the cream and Saturday they brought in the eggs. There was no refrigeration on the farm. Therefore, the cream soured by the time it got to the creamery.

Porter: From those areas, a lot of it came right into Denver.

Shane: It was called the old sour cream industry out there. Especially in the summertime, it was an assignment that you hated because it was no fun dipping that plastic rod in those cream cans and slurping the cream. I'm not fond of sour cream anyway, Bob. The other activity that we had was frozen eggs put up in 30 pound tins for commercial pack. Again, these were eggs that were raised on the farm and collected once a week or twice a week and brought into the egg breaking operations. When we were involved in the egg business our primary means of detecting bad eggs was drilling a hole in the frozen eggs and sniffing the eggs for decomposition.

Porter: That was the cans of frozen eggs.

Shane: That was the 30 pound cans of frozen eggs. Smelling was really the only way of detecting decomposition. We didn't have a chemical means of determining decomposition at that time. That was my claim to fame and my only formal training in FDA. In 1957, they had an organoleptic school for determining decomposition of frozen eggs. I was selected to attend, to represent Kansas City. Larry Warden came out from headquarters and headed up the training program. Horowitz was there. Dunnigen, who was a bacteriologist, and Fred Hillig, who was a chemist, were also there. Hillig was, at that time, working on a method to determine decomposition in eggs by chemical analyses. Harold Post and Pete Calluccio were two fellows from New York that were brought into the school as experts. They were considered experts out of New York. I remember we started at night and had to break out the eggs and had to measure out each egg. We took good eggs and subjected them to time/temperature abuse. They would hold them at room temperature for six hours, 12 hours, 24 hours, 48 hours, and then they would go into the freezer. Others, we would measure out portions of bad eggs that were black rots or green rots or molds. They had all types of classifications of bad eggs. Then we would mix a portion of bad egg in with the good egg. They were then frozen. After the official packs had been prepared, you went through them



once as knowns. You would drill a hole in the middle of the can with a drill and bit and smell the odor given off. by the eggs heated with the drill. After that, you had to go through the packs twice as unknowns. You would examine them and make a record of your results as to acceptable, decomposed or abnormal, or passable results. The school was so structured that, if you failed one good can of eggs, you automatically flunked. I was designated as the number one smeller in that class and therefore endearingly called myself "One Smart Egg Smeller". A lot of my time then was spent in the summer doing egg breakers throughout Kansas, Missouri, Oklahoma and Nebraska.

Porter: You say that was in '57?

Shane: That was around '57.

Porter: I remember how, in Chicago, we decided who went to that school. They had a smelling contest, and they created several different kinds of smells, and everybody would smell them and put down what they thought it was with the idea that the ones that had the most accute noses would go to the school. I knew enough about that kind of buisness to know I didn't want to do it, so I made sure I didn't smell very good.

Shane: It was a rather motley crew that was involved in the training. That was the only formal training course that I attended until after I became a Chief Inspector in Chicago. Then I went to a basic supervisory course. There was

not much in the way of formal training at that time by the Agency. Our training was on the job. The only training was if you needed a specialization like this to qualify as an expert to support legal actions.

Lofsvold: Most of the time when the Agency was small, I believe the theory was that you learned on a one on one basis from a person who was an expert in a particular field. And it probably was a sound way to do it as long as your numbers of new people coming into the Agency were relatively small.

Porter: Warden was one of the teachers, you mentioned?

Shane: Larry Warden was in charge of the school at that time.

Porter: I can tell you a story about him right here in Denver when he was Chief Inspector. He took me out to smell eggs one day shortly after he got here, and I hadn't any experience yet. We came back all excited we'd found bad eggs and went in to tell Wendell Vincent about it, who was the Chief here. He didn't like Warden very well anyway, and he looked up at him and said, "Larry, it seems to me that when you went to that egg school and learned to be an egg smeller, you had one of the poorest records of anybody in your class." The fact is that Warden had been one of the best, and boy did he get mad. They had a big argument there. I stood by, just enjoying it immensely.

Lofsvold: That was unfair, because Warden was at Seattle when I started in 1939, and he was already an expert on frozen eggs and did a great deal of frozen egg work up there

for 4 or 5 years before he came to Denver.

Porter: I don't think Wendell did that out of ignorance; he did it out of meanness.

Shane: Larry was, at that time, in the Bureau of Field Administration in headquarters. The egg school was one of my first exposures to New York people, Calluccio and Post. They were sort of a different breed of individual. Later I had the occasion to become involved with them in an egg case in Portland, Oregon. There was a fellow by the name or Tom Dicillo who owned the Portland Egg Company. I went to make an inspection of his place and, at that time, I had another fellow with me for training named Harry Butts. We went in to make the inspection and found the place was loaded with turkey incubator reject eggs. He had everything in there but good eggs. Most of them were checks, cracks and leakers. A check is where you have a crack in the shell, but the membrane is not exposed, and a crack means it has exposed the membrane. A leaker means there is some of the eggwhite oozing out. That seemed to be his main supply of eggs. As soon as we got there, he instantly stopped breaking eggs. We went to examine some of the eggs he had in the freezer. As we started to drill the eggs, the first thing he did was light up a cigar and come over where we were and started blowing cigar smoke in our faces, so it was obvious we couldn't smell the eggs. Harry and I then started an

investigation on all the hatcheries around Portland, Oregon and documented a series of shipments, probably 200 to 300 cases of eggs that he had received during the hatchery season time.

Lofsvold: These were eggs that had been incubated that never hatched?

Shane: They failed to hatch because they were sterile eggs.

Lofsvold: Sterile eggs?

Shane: Sterile eggs, they were in the incubators until the chicks had hatched and these were the ones that didn't hatch. So their quality was somewhat in dispute.

Lofsvold: They were not only sterile, but kind of ripe.

Shane: They were more than a little bit ripe after being in the hatchery for a period of time. We then tried to get shipments from him, and he refused to give us shipments. So we started checking around with a number of trucking companies and found out he had made a large shipment of eggs to New York. We got in touch with New York and asked them to sample the eggs. They examined and found them bad, and New York seized them. Dicillo was a rather unsavory character. He had threatened a number of our investigators. One of the investigators that was in Portland with me at that time, about 1960, was a fellow by the name of Tom Takioka. Tom had gone to the Portland Egg Company to do an inspection and to get some information. Dicillo had threatened to see him floating in the river face down. After he found out about the seizure in New York, he called me. Let me back-

track. I received a bomb threat at home after the seizure of Dicillo eggs. I got a call and somebody said, "There's a bomb outside your door, and it's gonna go off." Of course, I ran to the door to see if there was a bomb. I couldn't find anything. As a matter of precaution, I got the family out of the house and went back and called the police. I had them come in, and they went over the premises with me. We found nothing. Later I was at the office when I got a phone call threatening my children, and I happened to recognize the voice as being Tom Dicillo. I flew into a rage, and I told Dicillo that he had better hope that none of the kids on the way home from school stumbled and scratched themselves, because I'd come over and blow his brains out. He then let me know who he was, and complained I was picking on him, and we were treating him unfairly and all these other things and was crying over the phone. We later prosecuted him, got him to trial. We were having trouble because we couldn't get the evidence in on the quality of the eggs. We did not actually see him breaking the eggs, the incubator rejects. Every time you'd go over there he'd stop breaking. And again, you couldn't examine anything on his premises because he'd blow the cigar smoke in your face. So, we just charged him with the one shipment of adulterated eggs in interstate commerce. We only had the one count against him. During the course of the trial, we presented the evidence that the product was decomposed and shipped in

interstate commerce. That's about where we were until Dicillo got up and testified that he had produced all those eggs out of triple grade A (AAA) eggs. This opened Pandora's box. It allowed me to get on the stand and testify as to the quality of eggs he had in his premises and the quality of the number of shipments of incubator reject eggs that he had received. The judge became very incensed. He wanted to know what an incubator reject egg was, and we explained it to him. He wanted to know what happened to these eggs. We told him they were sold to bakeries and macaroni and spaghetti manufacturers, anybody that made any type of a bakery product that contained eggs. At the conclusion of the trial, it was a jury trial, the jury found him guilty. The judge handed down one of the stiffest sentences we've had in a long time. He made him pay full court costs which came to around \$6,000 because we had to fly the people in from New York who had made the examination and the people who had received the shipment. He then fined him the \$1,000 maximum fine and sent him to prison for one year and imposed that he must serve 6 months of the term. After the trial, we all went back to one of the hotel rooms and were sitting there drinking to our good fortune of getting this S.O.B. convicted. The telephone rang and damned if it wasn't Tom Dicillo on the telephone. He told me that if he was going to go, everybody else was going to go. He commenced to give me the names of all the people who were involved at that

time in the illegal sale of incubator reject eggs. When I was in BFA, I was given the opportunity to conduct an egg school for the investigators throughout the country which was held at St. Louis in about 1960.

Porter: Cliff, while you were in Chicago, you worked on the Krebiozen case. Why don't you tell us something about that.

Shane: Of course, when I went to Chicago the Krebiozen case was at that time probably about mid-way through its development period. A lot of work had already been done prior to my arriving there. But, because of the significance of that case, I personally took control over directing the investigation. One of the things that we had to do was to try and locate individuals coming from out of state to receive Krebiozen. We would stake out Ivy's place where he sold it and copy down license numbers of out-of-town patients.

Porter: Excuse me, for the record, would you tell us what was Krebiozen and what was it supposed to do?

Shane: OK. Krebiozen was an unproven cancer cure. It followed the Hoxey's cancer treatment. Hoxey's cure was very simple. He wrote a book, You Don't Have To Die. He told how he had found the cure because his uncle or his grandfather had a horse that had cancer of the leg and the horse stood in a corner of the pasture and rubbed his leg in these weeds, and it cured the cancer of the horse's leg. He harvested the weeds and promoted them as a cancer cure. I've been quite involved in that investigation and the

interview of patients. So, when I went into Chicago, here again was Krebiozen which was another quack cancer cure. Our analysis of the product showed that it was nothing but mineral oil. The Durovics, Marco and Stephen, came to this country and claimed that when they entered the country that they had a substance that was of value worth millions of dollars because it was a cancer cure. Come to find out that the Customs Agents laughed it off and never really found out anything about it. Customs allowed them to bring the product into the country. They expounded that this was a great cancer cure and began promoting it. They then got Dr. Ivy involved who was a renowned physician from the University of Illinois, and he had also come to the conclusion that this was a cancer cure. After our analysis showed there was nothing but mineral oil, the Durovics contended that Krebiozen was there in such small quantities that we couldn't detect it. They then started adding a substance called Creatin to the mineral oil. Creatin is a common muscle chemical that is found in the muscles of all humans. That seemed to be the total substance of it. However, the sales significantly increased by the word of mouth rumors which spread about this being a cancer cure. They offered it as a cure, so a number of cancer patients were coming to Chicago and buying Krebiozen. It was being used by a number of physicians. One doctor in Chicago treated a number of patients. In order to establish the interstate jurisdiction



and to try and get records of interstate shipments or offers for sale, we were trying to get the license plates of people who were coming in from out of state and being given the drug to transport back home. We were not very successful because it was difficult to determine those people who had out of state plates because they were in downtown busy Chicago. Most of those people either parked at parking lots, commercial lots, or they were from hotels. They came in and stayed in the hotel; they came in taxis and went back to the hotel. Others came in by public transportation. One of the investigators who was involved in that case was Jerry Breßler. Jerry came up with the great idea of raiding the garbage. We pondered for a while as to what the legality would be of taking these people's garbage, but we figured once that the garbagemen picked it up and put it on the truck, then it belonged to the public so that there was no problem with trespassing to take the guy's garbage. We made arrangements with the Sanitation Department whenever they picked up the Durovic's garbage from the clinic and from this doctor, Dr. Phillips, and from Ivy so that we had an investigator on the truck with a plastic bag. When they dumped the garbage, we had them dump it into the plastic bag. By going through that garbage, we gained a great deal of information on patients' names. Also, we got quite a bit of information on the sales between the doctor and the Durovics from the clinic and were able

to document quite a bit of background information on the size and scope of this whole operation. When the investigation finally was over, we had almost the entire district tied up doing this job. For example, we got an assignment on one holiday weekend that we had to copy 100,000 records that they had secured from Ivy of his files of his 5,000 most prominent cases to support his contention that Krebiozen cured cancer. The problem of trying to get this whole job done and to copy those records was a monumental task. We finally went over to the Kodak Company and made arrangements to put them on microfilm. We had a situation going around the clock in which all the records had to be exactly in the same condition in which we received them. We had one fellow who would take them out of the box and one fellow who would feed them to the individual who would make the microfilm, and the other guy would put them directly back in the proper order and in the box so that there would be no records out of place. Again, we did a lot of patient follow-up. Probably, in my opinion, Bob, that is one of the worst investigations that you could make. It tears the heart out of an investigator more than anything I know of. From my own personal experience with the Hoxey case, I knew what these investigators were going through. Here you are sending somebody out to talk to a cancer victim who is probably terminal, has given up hope and he's grasping at a straw. This is what they were doing with Krebiozen. Talking to

this person with the understanding that he would probably die before he'd ever get to trial, to have him make out an affidavit and sign an affidavit of all experience that he had was a heart rending investigation. I remember one situation where one of the investigators came back. He was pretty shaken up when he got through. One of the things that we would do, if a wife would accompany the husband, we would ask her to sign the affidavit so, in case the husband died before we got to trial, then she would be able to testify to the facts. Of course, after the fellow had signed the affidavit, she asked why she should have to sign it and he, the husband, told her, "Well, I may not be around when the whole thing comes to trial." And, of course, she broke down. Those are really just heart rending things to get yourself exposed to. You know, here is someone dying, and you know they can't be helped, grasping at a straw, and they're being bled out of their money by somebody who is preying on them. You know, I consider these people worse than a bloodsucker. They'll suck blood out of a dying man. We were really tied up in this investigation. When the investigation was finally concluded, we prepared to go to trial. We wanted to go by injunction as we did in the Hoxey case and enjoin them from shipping the drug in interstate commerce or receiving it. We'd been successful in putting Hoxey out of business in this manner and figured that this was also

a good way to put the Durovics out of business with Krebiozen. The Justice Department got involved and decided that there was a felony here, and they wanted to bring felony charges. They decided that they would bring conspiracy charges, much to the Agency's consternation. We did not agree, but they insisted. The U.S. Attorney in Chicago insisted on going with felony charges. Gil Goldhammer came to Chicago from Washington as the Agency advisor to the U.S. Attorney on the case. Gil, at that time, was in the old Bureau of Enforcement in a special section called Regulatory Management, whose primary job was to coordinate major cases within the Agency. We assigned a young investigator by the name of Ray Mlecko to assist in the case. He was sort of the gofer. He'd go for this and go for that, probably got one of the greatest experiences of training in trial law of any of our investigators. The trial went on for 9 months and cost the Agency three million dollars. It was a trial by jury. The judge sitting was old Judge Hoffman, who also tried the Unholy Seven or whatever their name was. In Chicago, he brought them into the courtroom bound and gagged. A rather stern judge. When we started, the two defense attorneys at that time were Bass and Friend out of New York that represented the Durovics. Milton Bass was the lead trial attorney, and he was not very well liked by Judge Hoffman, for some reason or other. He would have a tendency, when the judge

was talking to turn his back and walk away from him, which infuriated Julius. Julius reprimanded him a number of times, telling him that, "You're not in New York. You're one of these New York attorneys." I remember one of his comments. Of course, you remember the name was Bass and Friend. The judge reminded them that they were practicing in Chicago, and they were to abide by Chicago rules and court decorum. He said, "If you, Mr. Brass and Fiend, can't understand that, we suggest that you learn how to practice law here." I don't know what happened, where the falling out came into being, but they later dismissed Bass and Friend and got a new set of attorneys. Both the Durovics each had his own attorney; Ivy had his own attorney, and there was a Dr. Phillips who had his own attorney. So there were 4 attorneys at trial after that. As a sidelight, a number of years later when I was in New York, I had a chance to be at a meeting with Milton Bass, and I asked him how come he had dropped out of the Krebiozen case. His comment to me was, "Well, whether you believe it or not, I do have some ethics, and I at least have to have some understanding that my client is not guilty." He said, "I did not have that after I had talked to the Durovics, and I thought it was best that I depart from that case." That was his version anyway. During the course of the trial, which, as I said, lasted for a long period of time, we got some information that the meat-cutters'

union had come out in support of Ivy and Krebiozen. We never could figure their connection into the case. The understanding that I got later on after the jury verdict came in, Julius Hoffman was infuriated over the verdict of not guilty, and he called us into his chambers. Who was the investigator? Bob -

Porter: Case? I don't know.

Shane: No, no, no. This was the guy that did the testifying for us out of headquarters.

Porter: Oh, that was Bob Palmer.

Shane: Bob Palmer and I went over to talk to Judge Hoffman. Bob did the original investigation of the Krebiozen Foundation and the Durovics. He told us that he had personally called J. Edgar Hoover and asked that he investigate, because he was certain that there was jury tampering. He said that Hoover had refused stating that he didn't have time to investigate the case. We agreed to start an investigation of the case and found out that, during the course of the investigation, the original verdict was acquittal of Ivy and a guilty finding on the Durovics, Both Marco and Stephen, and not guilty finding on the doctor that was involved. The original vote came out, I think, at that time was about 9 to 3. There was quite a bit of discussion going on in the jury. There was a woman juror in about her mid-thirties, and there was another male juror. From what we could find out during

the course of our interviews of people on the jury was that this male had paid quite a bit of attention to this middle-aged woman. He had flowers delivered to her room; he had candy delivered to her; he would manage to try and sit by her whenever they went to eat and paid her a lot of favors and compliments. He was a very strong advocate for not guilty for everybody. When the votes were taken, she would always vote "not guilty". She had originally voted for "guilty" on the first go 'round. She refused to talk to us and to explain. Evidentially she was married to a much older man we were able to determine and she was having an unsatisfactory marriage. We also determined that the fellow that was giving her all of these favors was associated with the meat-cutters' union. In fact, he had attended a meeting in Peoria, Illinois of that union and was present when the union had made the proposal to come out in favor of Krebiozen and Ivy. He was already an active supporter of Krebiozen. He was later convicted of tampering with the jury. One of the other sidelights that dealt with that issue on the jury was that we found when we investigated that there was a black woman on the jury. Shortly after the trial was over she, for some reason or other, came into possession of a whole household of new furniture which she wouldn't explain. It was a gift, she said. When we were talking to the other jury people, they said the deliberations boiled down that they agreed

that they would let Marco off, but that they would find Stephen guilty on all counts. They took the vote on Marco and agreed to a "not guilty" verdict, but with the understanding that, when they took the vote on Stephen, Stephen Durovic would be convicted. Of course, after they'd got the vote on nonconviction for Marco and took the vote on Stephen again, you had a split of about 3 people on that jury who voted "not guilty" and refused to budge. They were really a hung jury. The people had been there for so long at trial, 9 months, that they finally were just worn down and they finally came to the conclusion that it was a hung jury but, rather than have to go through this whole thing again, the simplest thing would be to find him "not guilty". And that's how the final jury decision was reached.

Porter: Wasn't this meat-cutter guy actually the foreman of the jury?

Shane: He was the foreman of the jury, yes.

Porter: His name was Buck, what was his name? It started with a B. B-U-, I've forgotten. But it ended up he was the only person . . .

Shane: He was the only guy that got convicted out of the whole thing. Everybody else got out scott free, and he's the one that got convicted. But I think he'd have probably even got off if it hadn't been that Judge Hoffman asked for the investigation. Judge Hoffman stated that that



was the best presented case that he had ever heard in all of his years on the bench. He also stated that the testimony of Bob Palmer and all of the FDA witnesses was the most outstanding presentation of evidence from a court case that he had ever heard in his judicial history. That was one of the greatest compliments that I thought could be paid to the Agency and the people that were involved in that case.

Porter: You know, we had an OTC case before him that I testified in where we got a conviction and when we got through, he wasn't quite that complimentary, but he complimented the Government's witness and said for the record that the fact of the matter was that here he had these 3 or 4 Government witnesses who had no interest in the matter other than to tell the truth and then he had the 2 defendants who denied what these men said, and he said, "Which should I believe?" He says, "I choose to believe the Government." I liked Hoffman too, very much, of course because I was one of those who testified. It's nice to have a judge say something nice about you.

Shane: Yes. Well, I had the opportunity to testify in that trial. I presented the micro-filming, all of the micro-filming that we had done. I had a very short, quick testimony, a little claim to fame in that trial from that point of view.

Porter: Were there any sidelights in that trial that wouldn't show

up in the record?

Shane:

Yes, there was a sidelight in that trial that dealt with Goldhammer. Goldhammer had retired before he came from Washington to Chicago, and my understanding is that he and Alan Rayfield had a falling out. There was some connection in South America as to the source of Krebiozen, and there were supposed to be some people that were well acquainted with the Durovics and all of their shenanigans. Goldhammer wanted to personally go down and talk to these people. Alan intervened and decided not to send Goldhammer, but to send Ken Lennington. And he also took away a lot of the authority that Goldhammer had over the investigation. When Goldhammer requested that we copy all those records because of the amount of time, effort and money that went to do that job, Rayfield became, I understand, fairly outraged over the whole thing. Therefore, he would not allow Goldhammer to make any money commitments that would involve large expenditures. The case cost FDA three million dollars. And so, Goldhammer chose to retire, and he actually came back as a paid consultant on the case. That was because of the falling out between the two over how that case was going to be managed and operated. So Lennington went off to South America, and nothing ever came out of it. It was a lead that they wanted to follow up on, but I don't think it produced anything of any significance in the trial.

Porter: Wasn't the first Krebiozen actually imported into the United States when they first brought the substance in with them. Supposedly a powder. The Durovics. They came into the United States from . . .

Lofsvold: Argentina.

Shane: Argentina. That was their source of entry, but they were originally from Yugoslavia. Now they passed themselves off as doctors. Marco claimed he was an attorney and Stephen said he had a doctor's degree. But we were never able to substantiate that they had degrees. We could never find records at anyplace they attended school. He explained that, conveniently, that the records were all destroyed during the war.

Porter: You know, it took us a long time really to get involved in that case after we knew quite a few of the facts because there was a difference of opinion in Washington as to whether, since it was really made from horses' blood, it was a serum type of thing, whether or not it was something the Public Health Service should handle or Food and Drug. I think there was considerable delay in doing anything because of that, until it was finally decided somewhere in HEW that the Food and Drug Administration would take it over.

Shane: Not only that, the case had some far-reaching ramifications on the Agency because of what it cost us in time and money. At the conclusion of that case, Goddard had become Commissioner. Since we had lost the case, he virtually killed

our Agency's fraud dealings. The administration just decided that it was not worth the time and effort to do any more fraud work. We just virtually turned our back and stopped doing any fraud work at that period of time, at the conclusion of the Krebiozen case.

Porter: You think that case had a lot to do with it?

Shane: Oh, yes, every time that you would get hold of something involving quackery, the first thing everybody would scream would be, "We don't want another Krebiozen on our hands." The attitude became that this too shall pass, that there was nothing we could do about it, we can't stop it, that as soon as we stop this one, something else will crop up and come along to take its place. People are going to search out something no matter what, so they virtually wouldn't do anything any more about quackery. I think that's evidenced by Laetrile. We let that totally get out of hand, and every time you talk laetrile, the first thing you start hearing is Krebiozen. And only until Laetrile became a national fraud of great magnitude did we step in and try and do something. But our great way of combatting that was to do nothing but publicity. We never really moved to institute investigations of any magnitude to stop that product from being marketed. To me it was a crying shame that people used that as an excuse to stop our fraud fighting. And that's what they virtually did.

Porter: You know, whether it was just the time had come or not, even though we lost the prosecution, the fact of the matter is that the Krebiozen business was done with.

Shane: It killed it. From there on, it went downhill and that was the end of it. I think the press had reported it quite widely, and I think the testimony reported in the press killed the people's faith in it and it died.

Lofsvold: Well Stephen Durovic left the country.

Shane: Stephen left the country with about three million dollars sitting over in Switzerland. Marco stayed, was brought up on tax evasion. I think he was able to evade that. Ivy ruined his career. I think, personally, Ivy thought that he had the cure. I think he wanted to think that he had it. That he was a man possessed with finding the cure for cancer as his great contribution to society. He was a fairly super egotist in my estimation in my dealings with him and my knowledge of him. He was grasping for a straw and he was vulnerable. They, the Durovics, convinced him that he had found the cure for cancer.

Porter: You know, Anthon J. Carlson, we heard the story that Dr. Young told in Washington. He was very old, he was, of course, very well known and a very reputable man and a great scientist. He had already had a heart attack about this time, that was towards the end of his life, and in a conversation with someone who we recorded in Washington a couple of years ago, he was said to have made the remark

when asked about Ivy and it was right after his own heart attack, he said, "I'm glad that my problem is here instead of here," and he pointed first to his heart and then to his head. So, there was a very eminent man who thought there was something wrong with Ivy's head.

Shane: I think that was the general consensus of the people that we talked to. One of the sidelights of that trial was being able to sit down and converse with some of the most eminent cancer specialists in the country and to get a little better knowledge and insight of the problem itself, so that you're not dealing with one thing, you're dealing with maybe 200 different things.

Porter: Cliff, while you were Chief Inspector in Chicago, we had the investigation in the Abbott recall case, the large volume parenteral case. That subject has come up on a number of our other interviews. I know you probably know things about it that no one we've talked to, no one else knows. Would you go through that case with us a little bit? Tell us some of the highlights and the sidelines and so on.

Shane: As you say, I was Chief Inspector in Chicago at that time. It was shortly after I'd assumed that job in 1963. We got a report of a label mixed up. We got a complaint from a hospital that the cap and the label on the bottle were different and that apparently there was a problem either in the cap or the label. We followed up on the complaint,

and we were able to get a sample. We found out, much to our chagrin, that the cap was right. The cap was coded. For example, if it was a 5% dextrose solution in water, the cap would be D-5-W, or if it was saline solution, it had a similar type of code. The label on the bottle was wrong. We then started an investigation and asked for stocks to be examined. As a result of that finding, Abbott also started examining stocks. We found a number of situations in which the label and the cap were in disagreement. In some instances, we found the product was as it stated on the cap. In others, as it was stated on the label. We immediately started an investigation at the firm, an inspection to try and determine the cause of the problem. What we found in general was that the capping operation in which the caps were formed was carried out in one room. Boxes were set around by the capping machine, and they would cap a set of boxes and set them on the shelf. During the capping operation, some of these caps would fly off of the capping machine, and they would light in other boxes so that they got mixed in where you would have a sugar solution, maybe an electrolytic solution cap would get in with that bunch. Nobody bothered to really get concerned about it. They were just sitting there banging out the caps and not being aware of the problem that was developing. We also found out that, during their labeling operation, at the end of the run, there

would be a bunch of labels stuck in the machine. They'd start the next run up, and they would put the new labels in, which would force the old labels out so that, when they changed the run, the first bottles through would have the wrong label on them. The other problem that we found at the plant was what we called the "Darling of the Pharmaceutical Elegance, or "the little old lady from Pasadena". Her job was, when there was a crooked label on a bottle, they would remove it from the line. She would soak the label off and walk over and set the bottle back on the line to be relabeled. One of the problems was that by that time she'd soaked the label off, they may have changed the type of drug that was being run. She would set that bottle on the changed line, and it would come through and get the wrong label on it. Of course, it took on national significance since Abbott, at that time, had a major portion of the market. There was no way you could recall all those drugs off the market without jeopardizing patients in the hospital. Of course, at that time, we had almost everybody in the Agency out trying to examine bottles and caps to see if they could find any evidence of mislabeling. It kept growing and growing until it reached astronomical proportions. We had over 100 lots that were mislabeled. It became apparent that there was a potential for mislabeling on almost everything they had out on the market. Abbott closed down their operation.



They changed the capping system, put barriers up; they set it up so that they would only cap one type of bottle cap at a time. They made certain the room was cleaned out and all the caps removed. Any stray caps were picked up. They also had a label inspection of the machine so that, when they got through with the run, they would make certain that the machine was clean, so when they started the new run, they wouldn't have the mislabeling problem. They abolished the practice of relabeling bottles that had a crooked label for pharmaceutical elegance. When they took them off of the line, they destroyed them after that. The FDA inspection had been going on for a number of weeks. As I said earlier, Abbott had closed down and, when they started up again, we wanted to be there at the start. My understanding is that the front office at Abbott, and I'm not certain of the names of the people involved, called Alan Rayfield and advised him that our investigators were making their people extremely nervous, and they were afraid that they would create errors. Alan Rayfield called me on the phone and asked me where we were with the inspection, and I advised him as to its status. Then he told me to terminate the inspection and get the investigators out of there as soon as possible. I told him that I didn't agree, and he told me that that's what he wanted done. Now, during the course of this whole investigation, there were daily telephone calls between myself and, pri-

marily, Jim Nakada, who was the Washington coordinator for all information involving the field findings as to mix-ups. We also advised him what we were finding during the course of our investigation. My understanding was that he briefed Rayfield daily on everything that was going on. After I got the call from Rayfield to terminate the inspection, I did not agree with that decision. Schurman, Doc Schurman, was the Deputy and Acting District Director, I went in and talked to him and told him that I'd received a call from Rayfield. I told him I didn't agree with it so he told me I better call John Guill, who was on vacation. John was the District Director. I called John Guill and told him of Alan Rayfield's call and told him I didn't agree with Alan and asked him if he would call Alan Rayfield back. He advised me that I should terminate the inspection or I'd be charged with insubordination. So I called Fred Carlson, who was a Supervisor at that time (the Lead Inspector at the plant was Jerry Bressler) and told him to get hold of Jerry Bressler and tell him to terminate the inspection at noon. We terminated the inspection at noon and brought Bressler back in and had him commence to immediately write up the results of the investigation that he had found and all of the records that we had to support the poor operations on the part of Abbott, poor controls. After the recall and the corrections out at the plant, the firm went back in operation. That

situation more or less just died down. Of course, it was a massive recall involving a tremendous amount of manpower and energy. The other thing that was involved, after Bressler wrote up the report, Carlson and I burned a lot of midnight oil helping Bressler. They demanded we get the inspection report in right away. Carlson and I then endorsed the report and we endorsed it with a recommendation for further regulatory action.

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Shortly thereafter, I was in Washington and was attending a Chief Inspector's meeting.

I came back to Chicago and received a phone call. That was on a Friday. I was returning Friday evening from Washington back to Chicago when I received the phone call. I was told that I was to be in my office on Saturday morning. I was to be interviewed by some individuals. One was a fellow by the name of Don Gray who worked for Representative Fountain. When I got back, I tried to call; it was rather late in the evening. I tried to call people without success; I tried to call John Guill and some other people to find out what it was all about. I tried to figure out what they wanted. When I got to the office that morning, again I tried to call people in headquarters to no avail. I couldn't get hold of anybody to find out what this investigation was all about, what it entailed. I arrived at the office at about 9:00 o'clock, and a fellow by the name of Don Gray introduced himself and some other fellow, I don't remember his name, were at the office building. I took them into the building and up to my office. They began to ask me for detailed information on Alan Rayfield's call to terminate the inspection. They also asked to see all my notes of telephone conversations and all reports that were involved in the situation. I refused to give the information to them on the basis that I was not aware of what their rights were to that information. Information at that time in our files was all considered privileged information and not to be made available. I, at that time,

refused to give them any information as far as the reports were concerned. I went through with them the whole incident involving the Abbott recall up to and including the call with Alan Rayfield and what happened after that. When Fred Carlson called Bressler, his comment to Bressler was to "bail out" and get out of there by noon and, of course, Bressler used that as the famous "bail out" situation.

Porter: It's interesting how just really a manner of speech put almost a different appearance on the thing.

Shane: That's right, and that became the key word in talking about the termination of the inspection. It wasn't too long after that I was advised to give the individuals any information that they requested, including my notes. My notes, which I supplied to them, were pretty sketchy as far as telephone conversations were concerned. I've always used steno pads and just make a few notes as a remembrance. I could recall fairly well from my notes. They wanted to take my notes, and I refused to give them to them. I told them they could get copies of them, but I wouldn't turn over my notes to them since it contained not only notes regarding that telephone call, but a number of other calls and other things that had nothing to do with the Abbott situation. They also asked for a copy of the file. After that investigation, John Guill received a call from Alan Rayfield, and he requested that John Guill

review the report and write his own endorsement on the report. I'm not certain what precipitated that; however, our recommendation for prosecution was not in line with basic endorsements on reports. Supervisors were told that they shouldn't put on recommendations. They should summarize the case, but not make recommendations, except if it was to be a followed up inspection or something, but not to make a recommendation for legal action. That's the only reason I can understand, Bob, as to why he asked Guill to review the report. Guill went over the report. His endorsement was fairly well in line with our endorsement; however, it did not contain the recommendation for prosecution. John Guill also advised me that Alan Rayfield had told him that it was up to him to make the decision as to whether or not to recommend prosecution of Abbott because of the label mix-up. He asked, and I advised him, my recommendation was to prosecute the firm. I recommend prosecution. I thought that the violation was of such significance that the firm deserved prosecution. It would be hard telling how many people actually died as a result of that mix-up. It would be the type where the operation was a success, but the patient died. Because here's somebody supposed to be getting an electrolytic solution and gets an injection of 5% saline solution or 10% saline solution, or you have a diabetic who may be on the operating table and gets a 5% dextrose solution.

Unfortunately, it would send him into a diabetic coma. Guill made the decision that he would not recommend prosecution. He said that he based his decision on the fact that he thought the firm had suffered enough monetary loss since Abbott had been required to recall virtually all of their parenterals off the market. I still don't agree with that decision. Not long after that I was subpoenaed to appear before Fountain's Congressional Committee investigating the Abbott situation. One of the things that was involved in this issue was that Harvey's brother worked at Abbott's. He was in the Abbott Corporation. I believe he was in the marketing operations.

Lofsvold: That was John L. Harvey, the Deputy Commissioner?

Shane: John L. Harvey at that time was the Deputy Commissioner. He was the acting Commissioner since Larrick was gone. I think Larrick was sick and in the hospital or on leave. The situation appeared that Harvey obviously had some influence as far as the action to be taken against Abbott. The reason for not taking further legal action against Abbott was based upon the fact that his brother worked for Abbott. Of course, Alan Rayfield denied that he'd had any conversation with Harvey and that he had made all the decisions. He had made the decision to terminate the inspection. In fact, initially, Rayfield did not even remember making the phone call, as I understand, and terminating the investigation. When I went to Washington

to testify, we were in a room, Bressler, myself, and Guill. The three of us were told that we had an appointment to be at the hearing at a certain time. We were given no consultation or advice by any of our people in General Counsel. In fact, there was no member of the General Counsel present. We were told, I was trying to remember who else was present, just to go and testify. We went over to the House, the Rayburn Building, where the hearings were being held, and were called in one at a time. Bressler was the first to testify. He testified primarily as to what he had found during the course of his inspection and testified that he had received the order to "bail out". He used the terminology rather than "terminate" as "bail out". I was the second to testify. I was told by the Congressmen that Mr. Bressler in his testimony had also testified that he did not concur with the termination of the inspection, that there were other potential serious health hazards there that he hadn't had a chance to uncover. By terminating the inspection, he was unable to determine whether we could find instances in which the cap and the bottle label were the same, but the solution was different. My own opinion is that we probably would have never been able to determine that during the course of the inspection. I think we had covered everything that we were going to find. But our concern was to make certain that when Abbott started up that



all of the appropriate control procedures were in place to prevent any further misbranding. They were highly complimentary of Bressler's testimony and read into the record what an outstanding civil servant he was. They then questioned me about the recall and the direction of it. They questioned me about Rayfield's telephone call. I told them the circumstances that had happened, that I'd received the call and I had contacted the Deputy Director. He had been advised to get hold of the District Director who told me that I should terminate the inspection or be charged with insubordination and that I had given the order to terminate the investigation. At the conclusion of my testimony, one of the Congressmen chastised me quite severely, since he thought that I should have continued the inspection contrary to orders received from a superior, and that I was not a good civil servant in that I did not carry out that duty and responsibility and act contrary to the Director's orders since it was in the public's interest. I told him that I did not concur with his evaluation, and we had a conversation about my assessment of the Agency and the dedication of the people. There were also questions regarding the Harveys' implication in the case. Rayfield claimed that he made all of the decisions. Jim Nakada was present in Washington as the coordinator. Nakada attended almost all the meetings involving the label mix-up about Abbott on the parenterals.

He told me that, during the course of those meetings, while Harvey never made a decision, Rayfield met with him and Rayfield would tell Harvey what course of action he was taking. Harvey would, more or less, agree. Harvey probably, at that time, also had the opportunity to disagree. I understand he did not disagree at any time with what Alan proposed to do. After my testimony, I went back to Rayfield's office. We were told to come back to that office because we didn't know when we were going to be dismissed. After the Congressional hearing, we were sworn to secrecy under penalty that we could not discuss our testimony with anybody. I was in Rayfield's office, and I decided in my own mind to go over what had taken place to recap orally to myself my testimony. Alan was at his desk, but he appeared to be totally mesmerized. He was on tranquilizers; he just sat there almost like a mummy, sort of rigid and . . .

Porter: Was this because of concern that he was going to have to testify?

Shane: I think so, yes. His concern over his testimony was having a serious impact on him. I'd never seen the man in that condition. He'd always been a very forceful, forthright man, fairly opinionated and probably, in some cases, justifiably so. But he was, you know, somebody that appeared to be heavily tranquilized. His one comment, after I had orally recalled to myself the testimony and

all the questions, was in essence "my friends are killing me". He had to be helped from the room. I'd been close to him, and there was no alcohol involved. I'd talked later to Ken Lennington, and Ken told me he was taking tranquilizers. Probably had overtranquilized himself and he had to be taken home.

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The testimony itself is a matter of record. I, myself, personally, think that Alan Rayfield acted out of his own sense of right and wrong. I don't think personally that there was any relationship between Harvey's brother and any decision Harvey made regarding prosecution or not prosecution of that firm. I think that John Guill had the opportunity and was given the responsibility for making the initial determination. He personally told me that was his free choice. He was not given any advice or anything else on the recommendation or received any pressure from anybody. He made the decision of his own free will.

Porter: By virtue of his position, he did have that right.

Shane: That's right. As the District Director, that was his prerogative to either recommend or not recommend. In

fact, I cannot really recall a situation in FDA where a District Director, to my knowledge, has ever been directed to recommend prosecution of a firm. So that he did exercise that right. I think, had he recommended prosecution, that it would have been given serious consideration in headquarters.

Porter: You think this "bail out" story precipitated the whole thing then?

Shane: Yes, I think that started the whole investigation, the Congressional investigation

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Porter: You know, I've discussed this with Rayfield since then, in fact, within the past year. Incidentally, he's very well and happy in retirement. He's bitter about what happened, but he did not name any names. He's mellowed about it to a great degree. It more or less terminated his career at that time, but it didn't destroy him as a man, he's well healed from whatever happened.

Shane: In my own mind, I think he was his own worst enemy in that investigation. I think of Alan Rayfield, as I knew him, as probably one of the most dedicated civil servants that I have met in my career who had the interest of the

Agency at heart and firmly believed in the principles of Food and Drug. Had he gone before that Committee and was himself as he was on the job, that it would have been a totally different picture than he presented. The other thing I understand is that, first of all, they sent him up there by himself. They sent nobody from our General Counsel's office. They did not provide him with any legal assistance or anything else.

Porter: He mentioned this, and it was obvious that he resented that. He also greatly resented the kind of questioning that he underwent from the Committee, that they didn't just cover this incident, but his entire professional duties, what he did all the time, but also his family life and even such things as what job did his son have and how did he get that job. You know, I think he resented this interference into what he considered was his personal life..

Shane: Well, I don't blame him. My experience with that incident probably has soured me more on Congress and Congressional Investigating Committees. I am a firm believer that the Committee has a goal in mind and the hell with the truth. That they set out to prove you guilty as to how they perceive you to be guilty. They're not interested in the truth, they're interested in publicity or else in proving their own preconceived notions.

Porter: In this case the Committee didn't actually do anything, did they?

Shane: No. There was no recommendation, no action, none of any kind, but it totally destroyed the man's career. You know, I survived my aspects of it with no wounds at all. I just don't agree with the way the Committee conducted itself, the line of questioning they took. I read the whole Congressional record, and I agree, they went into areas which they were trying to degrade the man. I think the incident initially had a very profound effect on Alan. I think, with all the pressures that were on him, I also think he was trying to protect Harvey. So that there would be no ill will on Harvey. I know that he liked him, respected John Harvey a lot, and that he wanted to cast no shadows upon Harvey. Nakada, of course, testified to the fact that those meetings did occur between him and Harvey. I think that, in Rayfield's mind, that he felt that he was doing no more than keeping the Acting Commissioner of the Food and Drug advised as to what was going on. Alan maintained he did not seek concurrence from Harvey. It was a matter of keeping him informed. I actually believe, knowing Alan Rayfield as I do, that that was probably his intent and purpose.

Porter: I think so too.

Shane: And it would be the same way if you were involved in personnel matters where you are a deciding official.

You need to know what is going on, even though you are not making judgments. That's the same way with anybody in a management position. He's got to have knowledge of what is happening. He can't divorce himself and become totally ignorant.

Porter: Thank you, Cliff. This has been an excellent session.  
This concludes the tape.