HISTORY OF THE

U. S. FOOD AND DRUG ADMINISTRATION

Interview between:

Arthur A. Checchi

Former Assistant to Deputy Commissioner

and

Fred L. Lofsvold

U. S. Food and Drug Administration

Washington, D. C.

July 24, 1984

INTRODUCTION

This is a transcription of a taped interview, one of a series conducted by Robert G. Porter, Fred L. Lofsvold, and Ronald T. Ottes, retired employees of the U. S. Food and Drug Administration. The interviews are being held with F.D.A. employees, both active and retired, whose recollections may serve to enrich the written record. It is hoped that these narratives of things past will serve as source material for present and future researchers; that the stories of important accomplishments, interesting events, and distinguished leaders will find a place in training and orientation of new employees, and may be useful to enhance the morale of the organization; and finally, that they will be of value to Dr. James Harvey Young in the writing of the history of the Food and Drug Administration. The tapes and transcriptions will become a part of the collection of the National Library of Medicine, and copies of the transcriptions will be placed in the Library of Emory University.

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

DATE: July 24, 1984 PLACE: Washington, D. C. LENGTH: 114 Min.

INTERVIEWEE	INTERVIEWER
NAME: Arthur A. Checchi	NAME: Fred L. Lofsvold
ADDRESS: [redacted]	U. S. Food & Drug Admin.
[redacted]	Denver, Colorado

FDA SERVICE DATES: FROM 1945 TO: 1959 RETIRED? Resigned

TITLE: Assistant to the Deputy Commissioner
(If retired, title of last FDA position)

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Arthur A. Checchi Interview

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This is a recording in the series of FDA oral history recordings. Today we are interviewing Mr. Arthur A. Checchi, at his office in downtown Washington, D. C. The date is July 24, 1984. The interviewer is Fred Lofsvold.

FL: Mr. Checchi, would you give me an oral curriculum vitae of when and where you were born, where you went to school, how you happened to come with FDA, and then a list of the various positions you held with the Agency.

AC: I was born in Calais, Maine, in 1922. I was educated in the local schools, and then went on to the University of Maine as a member of the Class of 1944. However, due to the wartime speed-up programs, I finished in late 1943. I then attended Harvard University where I did some post-graduate study. In early 1945 I was at home trying to make a decision as to whether to get off my father's payroll and get a job, or go on to further graduate study. An old junior high school teacher, Hank Hamilton, came into my father's store and asked me what I was going to do. I told him I was trying to decide, and he asked me if I would consider working for the Food and Drug Administration. My question was, "What is the Food and Drug Administration?" Quite frankly, I'd never heard of it at that point. He told me about it and it sounded interesting. So, to make a long story short, I applied for the job and was put on with a temporary appointment (as they all were in those days).

I started as an Inspector in the Boston District in late June or early July, 1945. After the war we all took exams, and I was lucky enough to pass and get a permanent appointment. I was an Inspector until 1949, when Shelbey Grey was Director of the District. He appointed me to the post of what was then called Assistant to the Chief [of the District]. My primary responsibilities were doing whatever the Chief wanted me to do: holding hearings, writing summaries and recommendations, etc.

I stayed in Boston until late 1952, at which time I was transferred to Kansas City, again in the post as Assistant to the Chief. In late 1954, I was transferred to Washington. I worked for Allan Rayfield in the old Division of Field Operations. I actually worked as assistant to Frank Clark, who was the Chief Inspector of the Food and Drug Administration at the time. I was writing Inspectors' Manuals and helping Frank decide which Inspectors should be transferred, promoted, and doing the general work of the Division. In mid-1956, I was transferred to the Denver District as Chief Inspector. Six months later, on January 1, 1957, I was transferred back to Washington and made Assistant to the Deputy Commissioner of FDA. At that time, the Commissioner's office consisted of a Commissioner, a Deputy Commissioner, two assistants to the Commissioner, and one assistant to the Deputy Commissioner. I

stayed there until I left in November, 1959.

FL: The Deputy Commissioner at that time was Jack Harvey?

AC: Right.

FL: What was your degree in, Tillie?

AC: Zoology.

FL: When you reported in Boston as a new Inspector, what happened?

AC: Winton Rankin was the Chief Inspector at that time. They had a stable of very competent, experienced Inspectors. Winton used to have a training program, and two of us started at the time, myself and a fellow named Stan Petroski, who left shortly after. A couple of months later, Fred Cassidy and Lou Buckley joined FDA. Winton had what I regarded as a first class training program. We would have morning sessions with him twice a week to review the Food and Drug Act. We explained to him what we thought it meant, and he told us whether he agreed or disagreed. We went through the entire law, section by section. In those days, the regulations of concern to Inspectors were all, as you may recall, Fred, in a single little book. When we reviewed the law, we had to understand and be able to explain what those regulations meant and how they applied to our work. We also spent virtually all of our time, the first two months at least, working with the Senior Inspectors. The first assignments we got independently were the

mundane things like picking up official samples and what not. I think the training program we had, while not structured in the sense that it came out of any particular manual, was excellent and did a first class job of showing and telling us what we were and what we were to become.

The type of work we did in Boston at that time was rather heavy in the fish industry. Between Boston, New Bedford, and Gloucester, Massachusetts, there was a very substantial tonnage of fish. There was probably more fish for human consumption coming into those three ports than the rest of the United States.

FL: This was sold as fresh and frozen fish?

AC: Yes, both fresh and frozen. That was an active project. We also had a good confectionery industry, a very small drug industry, and in season, a good dairy industry in Vermont.

FL: Were you active in maple syrup in those years, with the problem of lead, or had that pretty well been solved?

AC: No, it was quite active, but most of it was syrup coming in from Canada. All maple syrup that came in and was offered for entry was automatically detained, deleaded, and then released. I don't remember that much was done with the maple syrup produced in Vermont. Maple syrup from Vermont was only a small fraction of the total amount. I think most of it came from Quebec.

I worked mostly on confectionery and bakery inspections. Then for over a year, I did almost nothing but inspect fish. In those days, we'd go down to the docks for the auction at 6:00 a.m. and visit every fish house twice a day. The reports were nice, you just had a little blank to be checked off that I was there and saw no problems. You didn't have to do an IDIP inspection. The main activity I was involved in as an Inspector was on the fish project. It was interesting work; there were good people in the industry, and also some scoundrels.

There is one anecdote I thought was rather humorous. It didn't involve the FDA particularly, but those fellows used to put fish in the freezer and borrow money against it in a bonded warehouse. One fellow put the fish in during the day (he was in collusion with the night foreman), and at night he'd take out the fish, put empty boxes in the corner and full boxes on the top so it would look like the same lot. They'd sell the fish and "have their cake and eat it", too. I don't know if he ended up in jail, but he disappeared and ended up out of the country for a while. There was a lot of skullduggery of that sort.

The interesting part of that project was that both my predecessor on the project, Charlie Dickinson and I, and the Food and Drug Administration gained the respect of all of

those fellows. They knew we were not "on the take" and could be trusted. We used to get quite a significant number of tips from industry. One weekend I got a call from an unidentified caller whose voice I immediately recognized, but we both agreed that I didn't know who it was. He told me about a company that was unloading a batch of fish that had been held out of the regular auction because they didn't want the Inspectors to know about it. So I went down, walked in and said, "Hey, whatcha doin', fellas?"

Actually, those were free-wheeling days and people tried to get away with a lot, but we did have the respect of the industry.

FL: Wasn't the problem mostly decomposition?

AC: Yes. A boat would leave Gloucester, start to fish, break down, and then instead of coming back to port and dumping, they'd throw ice on the old fish, and once repaired they would fish on the way home. So we had decomposition. That was the principal thing. On the rosefish, or the so-called redfish there, it used to be a problem of copepods but those can be detected by "candeling" and removed.

FL: I was on the West Coast at that time, and our problem there was largely with fish intended for canning. We didn't really have a filleting or freezing industry, except for whole halibut or similar fish.

AC: We had some canning industry, of course. The Maine sardine industry was totally canning. I don't think there were any sales of fresh or frozen sardines. In Gloucester, they canned mackerel and fish cakes. Other than that, most of it was frozen fish. Fresh fish would only be shipped as far a Philadelphia, the distance a truck could travel overnight.

The frozen fish business was interesting. As you know, Fred, the quality of fish depends on how long it's been between catching, processing and freezing. We used to have a kind of grading system. I've forgotton what most of the numbers meant, but one number, presumably zero, meant "very good", and four meant "decomposed". Perhaps it was in reverse order, I've forgotten. At any rate, there were the borderline fish, which would be rather stale and quite offensive to an old New Englander like me. But it was not decomposed. I used to note that they would sort that stuff...the very good fish would go into one lot and on down the line. The poor quality but passable fish would always be reserved for sale in the St. Louis/Kansas City area. I asked the fellow why and said, "Why in the hell don't you teach those people what good fish is all about and increase your market?" He told me I was rather naive, because if they did that, they wouldn't have a market for their lousy fish! I didn't think that was funny when I was transferred to Kansas City a couple years later.

FL: That's an interesting comment, because I did a recording with Weems Clevenger, who was talking about the creamery business in Kansas City, where they reserved tha very worst butter to sell within the state, rather than run the risk of losing it in a seizure, and sent the good butter east. So the people of Kansas City lost on both fish and butter.

AC: I learned a lot of interesting things. I had never heard of sour cream for use in butter until I got to Kansas City and Denver. My experience in the dairy business was in Vermont, where all butter was made from sweet cream. When I first got into a dairy, I was stationed in Denver. When I saw sour cream for the first time, I couldn't believe it.

I'll tell you something very funny that happened. When I got to Denver (I didn't know I'd only be there six months), I thought I should spend the first two months traveling with the Inspectors, to meet them personally and get to know them and to learn something about the regulated Dairy Industries operating in the territory. One of the things we had at that time was the whole can motor pump for examining sediment in cream. Ralph Davidson was very proud of that pump. He was going to show me how it worked. He got the empty can and set it up. They brought the full can of cream and he hooked up the intake valve. Everything was all set. I was standing there along with the plant people, watching this new remarkable operation.

Ralph threw the switch and a 2 1/2 inch jet of stinking cream hit me right in the belly!

FL: Oh, No!

AC: It knocked me right across the floor. He obviously hadn't connected it up right. The management thought that was so funny that they didn't even charge us for the cream! I think they took great delight in seeing the Food and Drug Inspector nearly drowned in sour cream. I wanted to kill Ralph...I smelled so bad, I think I had to burn my clothes.

One of the advantages the Food and Drug Administration had in those days was moving what I regarded as pretty good people (I say that immodestly, of course) around the country. What I learned in Boston as an Inspector about the inspectional techniques per se, are applicable anywhere. But in order to have the necessary understanding of how foods are produced, and what raw materials are used in different parts of the country (there's no way you can learn it from reading a book), you can only learn by getting out in the field. Everyone used to say that Alan Rayfield was a tyrant, and in some respects he was, but I think his basic policy of moving people into different geographical areas for training purposes, among other things, was excellent. It paid dividends.

FL: In my own case, I didn't like the idea of moving from Seattle to New York, but in the six years I spent in New York

I learned things I couldn't have learned anywhere else.

AC: I worked in three districts, as I mentioned earlier: Boston, Kansas City, Denver (for a short time), and Washington headquarters. I learned a hell of a lot in all four places.

FL: I would agree. Even though it was traumatic at the time, especially since previously we had not been subject to that kind of risk. You moved around within your own geographical region, like the east, west, or central part of the country. Generally you only went from one of those big, old districts to another if you were doing either very well or very badly.

AC: I think there was another trauma in those days. That is, unlike today, where your moving allowance is at least adequate. In our day when you moved, you got a fixed allowance that didn't really cover the cost of the move. I remember when I was transferred to Denver, my last duty day in Washington was on Friday and my first duty day in Denver was on the following Monday. When I got there I was not on per diem. I had to live in a motel until I could find a place for my family. The trauma was both emotional and financial; I think somewhat more financial.

FL: Right. Especially if you had a family. When I started, I wasn't married, so transferring was a fairly simple matter. When were you in Boston? About the time we started work on the over-the-counter sale of prescription drugs, wasn't it?

AC: Yes. It was in Boston in about 1950 that the Administration decided that over-the-counter sale of prescription drugs was becoming a national problem, and decided something should be done about it. They set up a pilot program in Boston and started to develop the types of techniques and background the Administration would need throughout the country to deal with the problem. They sent a number of Senior Inspectors to Boston from around the country. I'm not sure I can remember them all...there was Charlie Armstrong from Cincinnati, Stan Gilmore from San Francisco, Charlie Wayne from New York, and Joe Milunas. There might have been one or two more, plus one or two men from the Boston Distict. They formed a team and started covering the Boston/New England area drug stores to determine if they were selling drugs illegaly. In those days, we weren't necessarily following up on specific complaints. The purpose of this particular team was to take a sampling of what might happen. I don't remember the numbers, but it did show that in the New England area, a significant number of pharmacies were selling barbiturates and amphetamines without prescription. Those were the two major abuse drugs at the time. This team was a temporary thing, and when it disbanded, each of these fellows returned to his district, headed up groups, and the FDA's over-the-counter drug project got under way. I think the FDA Enforcement Reports will show that

during the 1950s, probably half the prosecution actions brought by the Food and Drug Administration were against pharmacies and pharmacists for the illegal sale of drugs.

While we're on the subject of illegal sales, I was involved in another interesting project. When I was in the Division of Field Operations in 1953 and 1954, the Administration and the groups concerned with national highway safety had become aware that long-haul truck drivers were using amphetamines to try to stay awake, and quite a number of accidents had been attributed to hallucinating truckers. FDA had gotten together with the Teamsters Union and the National Trucking Association to discuss it. They decided they would, with the cooperation of these groups, put FDA Inspectors in the cabs of trucks as drivers to see what the magnitude of the problem was, and to start developing some regulatory actions in that area. I happened to come upon the scene at the right time. Al Barnard had done the spade work but before the project got under way was transferred to San Francisco as Chief Inspector. So when I came in they said, "Congratulations, you're in charge of our Truck Driver Program". I recruited a bunch of fellows from the various districts. These were people who had demonstrated the type of aplomb necessary to make a drug buy. I was never very good at it. When I went in and tried to buy a prescription drug, I would shake so much the pharmacist

would say, "You don't need a drug; you need a doctor". But some of these fellows could go in and asked for "bennies" or "redbirds", whatever they called them in those days, with the same nonchalance as when they ordered an ice cream soda. I don't remember all the fellows, but there was Bill Logan out of Baltimore; Weems Clevenger and Jimmy Green from the Kansas City District, Leonard Blanton out of Atlanta, and Bob Palmer out of the Philadelphia District. I think that's all. Those fellows had a lot of personal courage and deserve a great deal of credit. They were unarmed. There was no Drug Enforcement Administration in those days. In fact, the work they did led as much to the DEA (Drug Enforcement Agency) as that of anyone else. These fellows learned how to drive those big eighteen wheel trucks and they took off by themselves into this essentially hostile territory. They certainly couldn't rely upon other drivers for comfort. They tried to wheedle information from them, as to where the drugs were being sold, etc. They did a super job. They found not only truck stops that were peddling the stuff, but went beyond that and found a couple of doctors that were making these things available. It also led to spotting some drug manufacturers in the New York area that were making these drugs. The men in Microbiology, Al Tillson and others working under Glenn Slocum, developed a technique for identifying the manufacturer of drugs by ballistics meth-

ods. I remember they developed a technique for examining drug tablets microscopically. They could determine which dies were used to stamp them out, and by going through the market place and picking up other drugs, they identified the sources of these drugs. There were always a lot of humorous stories of wild rides experienced by the Inspectors, but I think the program was very significant and very important from the standpoint of law enforcement, in that it showed early on the abuse of drugs by a significant sector of the population, not just the truckers. All the work the districts were doing throughout the country in drug stores, and following up, showed that drug abuse even back in the 1950s was a developing and serious phenomenon. I also remember in Kansas City when we got involved in a case of some consequence - I've forgotton exactly how, whether it was someone who was arrested and found with drugs in his possession, or just what the circumstance was. I do remember there was a prostitute involved and that it was both significant and humorous. I think what happened, was the Kansas City police had picked up a prostitute with drugs in her possession, so they called us. Weems Clevenger and Jimmy Green went over to talk with her. She told him she had secured the drugs from an M.D. He didn't give her the drug directly, but according to her, if you wanted drugs you would go in and ask him and he would write you a prescription

for two dollars without an examination, and that was it. As you may recall, we used to work on regulatory programs, and there was nothing in that program about investigating M.D.'s. Sam Alfend, the District Chief, was away at the time, so I was in charge of the District. I decided if I asked Washington on the basis of what we had, they'd say no, so I decided to order a little investigation on my own, to see what this doctor was up to. So we put a recorder on the girl and also recorders on Weems or Green, I've forgotton exactly which. To make a long story short, we established that this man was writing prescriptions with no physical examination at all. He was writing them for two or three dollars. We wired our own people and a couple of outsiders, and the results were the same. So with that in hand, I wrote to Washington requesting authority to issue a Notice of Hearing, with a view to prosecuting that doctor. As we used to do in those days, I wrote this impassioned letter, citing the Constitution, the Bill of Rights, and a bunch of other splendid documents. I said that this man was causing a violation of the law. I don't recall what my legal argument was, but at any rate I sent the letter off.

In the meantime, Sam Alfend, the District Director returned, and as luck would have it, a letter came back from Washington giving us hell for doing what we had done, putting the Administration in an embarrassing position, and didn't we

think this was a problem for the local medical society? The Bureau of Drugs, at the time, was aghast that we would think of investigating a physician. So Sam called me in and, in his typical fashion, gave me hell. He said, "You didn't follow the Regulatory Program!" I pointed out to him that the Regulatory Program was silent; therefore, in the absence of a Regulatory Program, we thought it would be doing the public a service to give the Administration the type of facts they would need to decide whether they should have a Regulatory Program. Anyway, he blistered me and when he was all through I said, "Well Sam, maybe you're right, but what are you going to do about that s.o.b.? He is violating the law." Sam said, "By God, your right! We've gotta do something." So Sam picked up the cudgel and went back to Administration and told them that this man was as guilty as any cheap peddler on the street. And they did prosecute him. It was the first time, to my knowledge, that the Food and Drug Administration ever prosecuted a physician for illegally dispensing drugs.

They were exciting days. I think that the FDA's record of the 1950s in the over-the-counter illegal sale of prescription drugs had a tremendous effect. It led to the DEA. I've forgotton exactly when the Amendment to the law was passed. As you'll recall, it created within FDA, a unit designed to deal with the illegal sale of prescription drugs. It was

subsequently transferred to Justice and merged into the old Bureau of Narcotics and became the present day DEA.

FL: I think that law was passed in about 1964. I've been told Mr. Larrick decided to set the unit up as a free-standing unit, with the belief that it would probably be removed from FDA and taken elsewhere. I also have the impression that the Commissioner and other top officials in the Agency were never quite comfortable with our involvement in this kind of work.

AC: Well, it was alien to the kind of work the FDA was normally involved in. I don't know if the term is "white collar crime" or not, but generally the type of lawbreakers FDA deals with are inadvertent violators, people who think their quality control is better than in fact it is. It's not the people who are running around sticking guns in peoples' ribs and common thieves. If you're going to get to the root of the illegal drug business, you're dealing with hardened and intentional criminals.

FL: Certainly it developed that way. First you started with the drug store, then you had people whose sole business was the illegal sale of drugs.

AC: Exactly. It was a different element of society, and we were very concerned about it in the 1950s. The idea of our fellows having no legal right to carry arms (we certainly had no training in that area) made it more difficult. When I was

in Boston, if we thought we had a dangerous situation, we would ask the city police to have a plainclothes officer precede us into a store and order a coke or something, so in a sense we were covered.

FL: We used that same technique in New York. I used to be quite concerned about sending people out to do this. I was afraid someone was going to get hurt. We were just plain lucky that we never had anyone killed or seriously injured.

AC: I had an experience. As I told you earlier, I was not good at the buying of drugs. I went to this pharmacist that we eventually did prosecute, told him I was a student and needed some "bennies" to stay awake. He told me I'd better see a doctor. He said he would call a doctor right across the street (I've forgotten the doctor's name). He called and was told to send me over. I debated not going, but decided to go see what he had to say, and this doctor (in the tough south end of Boston) put me on the table and listened to my heartbeat...it must have been going 400 beats a minute, and my blood pressure must have been 900/700. I decided one thing I wouldn't let him do was give me an injection, but I'd let him do whatever else he wanted to, within reason. He made a partial examination, blood pressure and heartbeat, and as much as told me I shouldn't be taking these things because they weren't good for me, then wrote a prescription. He charged me

a couple of dollars, and I went back to the drug store where the guy filled the prescription and subsequently refilled it several times, even, as I recall, dispensing greater amounts than called for.

It was clearly something that needed to be regulated and I don't think, in retrospect, that FDA would have been the right agency to keep it. But what is important and significant here is that the Agency moved into a vacuum, a void, saw a need, and did something. I'm not trying to wave the flag for the old crew, but the work they did demonstrated that there was really a serious national problem. I think George Larrick was exactly right. Knocking on the door of a few druggists looking for illegal drugs is one thing, but that's not even the tip of the iceberg in the illegal drug business, as has obviously been demonstrated in subsequent years with the introduction and rapid growth of marijuana, cocaine, and other abused drugs. It really needs to be handled by people who are trained to deal with criminals; who have the investigative techniques, etc.

FL: Wasn't that pretty typical of the Agency at that time. If a problem arose that nobody else seemed to be able to handle, they would look for ways the Food, Drug and Cosmetic Act could be used to do something about it?

AC: Our General Counsel of the day, as you recall, was Bill

Goodrich. Bill used to say, "Don't ask me what the law says, tell me what you want to do, and I'll figure a way under the law that you can do it". When we first got started before the Durham- Humphrey Amendment of 1953, we did have to go a very tortuous way to to assert jurisdiction.

FL: Most courts never really understood it.

AC: But to answer your question, I think the FDA did, and probably still does. If there's a problem and it's not clearly someone else's responsibility, as long as the office can do it in a basic area where they have some jurisdiction, they innovate, and I think that's good.

FL: I think that's the proper thing to do if you're in this kind of business of protecting people from hazards.

AC: A few years ago, Peter Hutt said it was his view that the Food and Drug Administration could do anything that the Federal Food and Drug Cosmetic Act does not specifically prohibit them from doing. Everyone laughed and criticized him for saying it, but the simple fact is that's a philosophy the Agency has had all along: "Tell me what you want to do, and I'll tell you whether it can be justified under our law."

FL: Tillie, when you moved along to Kansas City from Boston, was there anything there that was of interest?

AC: Well, there were some amusing things, Fred, in terms of the difference in regulatory attitude among District Direc

tors. I remember when I arrived in Kansas City in January, 1953, my new boss, Sam Alfend, said he understood that in Boston I was experienced in holding hearings and writing summaries and recommendations. I told him it was one of my principal tasks. He said, "Fine, here is the hearing schedule we already have set up for you". There were 21 or 22 hearings scheduled for just about everything going on in the District. Some was over-the-counter work; some dairies that were selling or using dirty cream, etc. It was a potpourri of things. Sam said, "Now you hold these hearings, review the files, and if you're going to recommend prosecution, go ahead and write it up final and send it in. If you're not, see me first". Sam was a bear for prosecutions.

FL: That's the typical Sam Alfend. I followed him in Denver, as District Director. Ken Lennington came out and one of the first things we did there was review a bunch of cases. Both of us were sort of aghast, because we had been trained mostly under Charlie Herrmann of New York, who was very conservative, and Sam was bringing prosecution cases on evidence we would have regarded as inadequate.

AC: I'll tell you another story in that same vein. We held a hearing for a firm that made macaroni. When I reviewed their file, it didn't seem to me that we had enough to warrant prosecution, so hat in hand I went in to Sam and said, "Here's

one we're going to have to put in temporary abeyance". He looked at it, studied it, and came back and said, "Well, I think you're right, but let's not decide yet". I asked, "What are we going to do?" He told me to write letters to the St. Louis, Denver, and Los Angeles Districts. This company had factories in each of these cities. He said, "Ask them to send you their files, and let's see what kind of work they do in other areas". So I did, and in due course, in comes the material. Sure enough (I won't embarrass the other District Director by telling you the district), one of the district's file on it looked terrible...it should have been prosecuted. We took all that information, bundled it up, and I summarized all the other things, and we prosecuted the corporation in Kansas City, fundamentally for violations they had committed back in another district. We used all the material to simply show that this was not an isolated event in our district, but rather represented a pattern of the firm's practices in all their plants. This firm was just not spending the time and money on sanitation that it should. And the prosecution went through. It was a learning experience. If you're dealing with a corporation with facilities in other cities, consider the whole picture - what is their corporate policy? So, while Sam was a real "hanging judge", he was right.

I remember that probably half of our activities were

over-the-counter drug cases. In the two years I was in Kansas City, we terminated over 120 prosecution actions, 61 in one year and 63 in another year, as I recall. I don't know if Kenny Milstead knows it or not, but Sam always used to look at Kenny as his rival. Kenny, at that time, was Director of the Cincinnati District. It was interesting that Kansas and Cincinnati were two of the smaller districts in FDA, but they led the country in regulatory actions. As you say, Fred, you folks in New York were conservative, but as I see it, I think that Sam and Kenny were exactly right. If a given set of facts were prosecutable in courts in Kansas City and Cincinnati, they sure as hell should have been prosecutable in New York, Los Angeles, Chicago or anywhere else. I think the Administration needed more, not fewer people like Sam. He was an excellent teacher. He was not the world's greatest personnel director, but insofar as representing the Agency and carrying out its mission, Sam certainly did that. Of course I guess the issue then is what we regard as mission of the Agency. But in those days we were taught that the mission of the Agency was to bring regulatory action against violators of the Act.

FL: Nobody ever really expressed this to us, that I can remember, but it was something we learned, that it was the policy.

AC: Well, I don't think it was expressed quite in those terms but on the other hand, there was the implicit question, "What are you here for?" "We're not here to run an educational campaign. Industries ares supposed to educate themselves." As a matter of fact, I was not in the Agency during the days of Campbell. Paul Dunbar was the Commissioner when I joined the Agency. My understanding of the Campbell attitude was, "We don't have to tell industry anything...it's not our job to educate them; it's our job to police them".

FL: It's their responsibility if they're going to engage in this business to know what the law requires.

AC: Precisely. That was the Campbell attitude as I understood it. Certainly, the people who trained you and me were raised in the "Campbell mold". Kenny Milstead's and Sam Alfend's background was, "Look, we're not here to teach and we're not here to persecute - you guys are supposed to know". Some guys were tougher than others. In a sense it was unfortunate, because the obvious result was uneven enforcement, but I guess there is no perfect system.

FL: I think too, it was a conscious policy not only to punish the people who did wrong, but also to deter others. The idea of criminal prosecution as a deterrent was really the underlying enforcement philosophy.

AC: It was, and I think on balance the FDA did it very well.

Fred, we've been talking about the Agency doing things and doing them well. When I was in Boston we made a seizure of some horseradish. As I recall, it was in fact parsnip that had been spiked with vinegar or something. It was sort of a fun case. The interesting thing about it was that the claimant was represented by an old-time Boston lawyer in a dark blue suit, a red tie, with a nose to match, and gray hair; a very distinguished old fella. The judge was Judge Ford, who was a good, crusty old Boston Irishman. We started to present our case and as you'll remember, in those cases you talked about how you collected the sample, how you sealed it, how you did this and that, very meticulously going through to defend the integrity of the sample.

We were going through our act, and the analyst had told how he had broken the seal and gone on to the microscopic examination. I happened to be in the witness box when the claimant's counsel (his name was Fahey, as I recall) came over to the bench and said, "Frank", to the judge, "These people are nailing my client to the wall!" And the judge said, "Yes, Cal. And don't they do it well!" I thought that was funny as heck.

FL: Was that the case of a manufacturer in the Bronx? Jonas Carol arrived with his infrared spectrotometer studies he had done...the first time it had been used in court.

AC: Yes. We presented a novel case. As I recall, there was some question as to the sex of the claimant, but that was not an issue at trial and therefore left unresolved.

FL: That's the case! Later they were prosecuted for the same sort of shipments from New York. The first job I had when I arrived to do the compliance work in New York as assistant to Charlie, was to review the record on that case. There was about four inches of transcript because it was on appeal there. It was fascinating to read the record of the criminal matter. We got a conviction, but Judge Johnny Murphy was too helpful to us, so it was reversed by the Court of Appeals. Murphy, I don't think, was really happy as a judge. He finally resigned and went off to be Police Commissioner in the City of New York.

FL: After you returned to Washington to be Assistant to the Deputy Commissioner, what were some of the things that happened during that period?

AC: Let me talk a little bit about how things used to be run. Every morning, there would be a meeting in the Commissioner's office with the Commissioner, the Deputy, their assistants, and the senior managers of the Agency. Our office hours were 9:00 to 5:00 but we would get together about 8:00 o'clock. We'd spend the first hour of every day reviewing current events, planning, and deciding a variety of issues.

Shortly after I came back from Denver, one of the things that came up was an Attitude Survey that some government department had done. It was a general questionnaire to develop the attitude of government scientists and engineers. The print-outs of the study were sent to each agency, reflecting the views of their people. When it came in, Food and Drug looked very bad from the standpoint of employee morale. The results, if you believed them, would indicate that Inspectors and Chemists were not at all satisfied, in the main, with many important phases of their work. There were some, of course, that were facilities-oriented, such as adequate libraries. At the time, the Agency just didn't have money for lots of things. But more importantly there were some, what I regarded as serious undercurrents, as to the attitude of people toward their work.

At any rate, when the thing came out, it looked to me like it was heading to be swept under the table, and I commented that I thought it reflected some very serious possible shortcomings in our employee relationships. A couple fellows defended the Agency saying that the Study was not designed for Food and Drug people; therefore, it shouldn't be given all that much weight. I agreed, but argued that it nevertheless showed that we might be having a problem of employee attitudes at that time, and that while this study admittedly proved or

disproved nothing, it at least raised fundamental questions that the Agency should address. The Commissioner agreed with that position. Then a contract was drawn up with a professor from either George Washington or Georgetown University, to design and conduct a survey aimed very specifically at the needs of the people working for the Food and Drug Administration (chemists, scientists, etc.). I'm no judge of what's a good or bad survey, so I won't comment on that. The fellow spent a lot of time interviewing a lot of people in the Agency to determine, in his judgment, what important factors should be built into the questionnaire. He eventually completed his study, prepared a questionnaire, and sent it out. About that time I left the Agency, but was always curious as to what happened. The report apparently came back and, in a sense, confirmed what the first report suggested: that there was unrest among the troops, that they were unhappy with their jobs, and that their problems with the Agency were not entirely budget-oriented in the sense of better equipment and that sort of thing. Fred, you might one day want to talk to Mickey Moure about this particular survey, as to what happened to it. At that time he was working for Leo Miller. Mickey was the principal liaison man with the pollster. He can tell you better than I what eventually happened. I don't know that the results were ever distributed, but I do know that he raised a lot of concern. This was around 1960 or 1961.

What it reflected, Fred, and again you were in the field, is that a lot of new people had come into the Agency in the 1950s. Their attitudes might have been different than yours and mine; certainly their training was different. They weren't people raised and graduated from school during the depression or shortly thereafter; they were a different breed of cat. It showed a lack of understanding in a lot of things, I recall, such as transfers. It showed the Agency was not really communicating its personnel policies well to its people. I don't think anything was ever done about it, because along about that time all hell broke loose with the investigation of Henry Welch, which triggered a bunch of other questionnaires about how much money you owed, when did you stop beating your wife, etc., all of which contributed further to poor employee morale. Then there was the drug amendment and a lot of new things. I thought at that time it was a very important thing.

FL: Before you leave that subject, what was Rankin's position? What did he feel should be done about this?

AC: I don't remember that Winton had a strong position, one way or the other. Allan Rayfield and Bob Roe, who were the principal managers, (Rayfeld for the Field and Roe for the Science) I think felt betrayed by the survey. I don't think they believed it. Jack Harvey was neutral; he found it dis-

turbing; George Larrick agreed. It does raise questions. I don't remember whether Winton was pro or con. He certainly was not against the second study.

I went into the Commissioner's Office in January 1957. The first year and one-half my jobs were writing "Dear Mr. Chairman" letters on proposed legislation, or handling whatever came in and out of the Commissioner's office. Winton and I doubled in brass. When anything came in, one of us would get it. He spent more time on legislation than I did. I tended to be more concerned with helping the Commissioner settle some intramural disputes among his Division Directors. But the work was interesting and I guess the most significant assignment I had was to set up the Food Additives Program. Throughout the three years I worked there it was interesting; I did just about everything.

FL: I've been told by others that they felt in this period, or just a little before, that Mr. Larrick had set out deliberatley to build a constituency from the regulated industry, because FDA did not have any organized group that would take our part in dealings with Congress. Do you think that's really what happened?

AC: No, not really. I think what Larrick did was a continuation of Charlie Crawford's plan. Crawford recognized the need for help for the Agency, their budgeting, etc., and in

part, what was in Crawford's and in Larrick's minds, was a Citizens Advisory Committee. If you mean that was a part of the ploy to get industry to support the Agency, one could say yes, because the Committee was made up by members of the industry. But I don't think George's scheme was Machiavellian in the sense of getting the industry's support. George was an old pro and he recognized that he was in charge of this "chicken coop", and he wasn't about to let the foxes help guard it. So I think George's purpose in promoting and organizing both Citizens Advisory Committees was more to create public and Congressional awareness of the need of the Food and Drug Administration; I suppose he didn't want any negative reaction in the industry to a growing FDA. I wouldn't say he particularly courted industry.

Those were the days when other significant things were happening. My first year in the Commissioner's office, we had the first joint Food and Drug Administration/Food Law Institute Meeting (FDA-FLI). That was basically a creation of Charles Wesley Dunn, but he certainly wouldn't have been able to do it without the strong support and concurrence of George Larrick. As originally conceived, that was to be an annual meeting beween senior FDA personnel and senior corporate managers. Charles Wesley Dunn was a courtly old gentleman with somewhat grandiose ideas and a lot of nerve. His concept was

to bring in Chief Executive Officers and Chairmen of the Boards of these companies to meet with senior people in Washington. The first FDA-FLI meeting was held in a conference room (the "Snow Room") in north HEW. The room held only around 40 people (uncomfortably). That was where the first FDA-FLI meeting was held. It grew from that. The next year the Food Additives Amendment had been passed, and there was great interest, so we had to move the meeting to the HEW auditorium. It kept growing from there. While FDA-FLI is not now serving the purpose originally intended for it, it certainly does serve a marvelous function. I think that was quite a significant development during that period. Again, I don't think that George was looking for industry support with any deviousness.

FL: You mentioned the Food Additive Amendment a couple of times. You were deeply involved with that legislation, I believe.

AC: Yes. During the legislative stage I didn't do a lot. Winton Rankin and Jack Harvey were the principal point men for FDA in dealing with the Hill, the Secretary's office, and the various industry groups who were looking to get their points across. I was more of an observer than an active day-to-day participant during the hearings and passage of the legislation. When it was passed (signed into law) there was a bit of

a struggle within FDA, that is some competition as to which unit should be responsible for setting up and managing the program. The scientists wanted it over in the old Bureau of Biological and Physical Sciences, and Steve wanted it in his Bureau of Enforcement. So Larrick, I'm not sure of his motive, said there was no sense in debating it because it was going to the Commissioner's office and "Checchi's going to run it". So I suddenly found myself with the task of setting up the program, writing the regulations, and getting the thing in gear. That's how it happened. I came to work one day and was told, "Congratulations, you don't have a new job, you have an additional one".

FL: Did you have much to do with the process at all, even tangentially, during the legislative period?

AC: Tangentially, in that as I think I commented earlier, the practice was for everyone to meet in the Commissioner's office every morning, so I had my input there as did everybody else. Bear in mind, the Commissioner's office only consisted of four people: Larrick, Harvey, Rankin, and myself. Wally Janssen was also an Assistant to the Commissioner, but he was in another part of the building and just handled press and public relations. The four of us would frequently meet; particularly Rankin, Harvey, and I because George was off sick quite a lot in those days. We'd sit and discuss strategy and other

things, so I was tangentially involved in that sense; therefore, I didn't have to start from "ground zero" when they told me to run the program, as I did when I was asked to join the Food and Drug Administration, and had asked, "What is it?" But I was not directly a negotiator for FDA in any meetings.

FL: One thing that always bothered me a little about that Amendment was that there were no provisions requiring the industry to inform us about the identity of additives which we might encounter in their factories. We had no authority to demand formulas of foods that might contain additives.

AC: I don't recall that it ever came up. I would say, with respect to what went into the Amendment, that Winton Rankin is the world's living authority. I don't remember any particular discussion to amend the factory inspection section of the law to enable FDA to get more information.

FL: As the law is now, if a recalcitrant firm denies using additives and refuses to give us the information, the only way we can get it is analytically, and considering the nature of most additives, it's a very difficult task.

AC: It never bothered you fellows in the past and I suspect it won't in the future. I think, however, there should be some broadening now of the factory inspection authority.

FL: You mentioned the early morning staff meetings of the people in the Commissioner's office. Did the General Counsel,

Bill Goodrich, participate in those sessions?

AC: He may have on occasion, but I don't remember Bill as a regular participant. Obviously, you should talk to Bill as to what his attitudes were, but as I perceived them, contrary to common opinion, Bill Goodrich did not to my knowledge, seek in my day to be a policy maker. He wasn't sitting there deciding what the policy of the Food and Drug Administration should be. His attitude was more one of saying to the Commissioner, "You fellows decide what policy you want, then I'll tell you how to do it or whether it can be done within the law". He regarded himself almost as outside counsel, rather than sitting in and discussing policy. Now clearly, during the legislative period on food additives, he was involved on a day-to-day basis; he had to be. Even on basic issues, Billy's attitude used to be, "Don't ask me what the law says; it says lots of things. You tell me what you want to do and I'll tell you whether your law will permit you to do it". Again, Fred, I think that's something you really should sit down and talk with Goodrich about, but I do see a significant difference (I could be wrong) between how Bill Goodrich approached his job and how his successors have.

FL: You were in on the very start of food additives control. What has been your observation of how the FDA has handled food additives in the years since you left the Agency and began dealing with them from the outside?

AC: I think there have been two major differences from where we started and where we are. One is packaging materials, and when does a packaging material become a food additive. The Act says it's something that might reasonably be expected to migrate. Then you get down to the question of what is reasonable expectation? Since then there have been court cases on this thing, the Monsanto acrylonitrile case being the most prominent one. Although the courts have ruled, we still don't know what the Agency is going do in terms of how much is enough. Our attitude was perhaps more cavalier, and toxicology obviously hadn't advanced quite as much in 1958-1959 as it has today. Our attitude then and it's also pretty much with respect to the other subject (when is a material generally recognized as safe?), was that the toxicologists know how toxic these things are, and if they decide that it was less than a certain amount, we used to regard that as zero, pretty much. We didn't try to regulate down to the part per billion, in fact there were no methods that sensitive. The most important difference, I think, is in determining how something is GRAS (generally recognized as safe). There's no requirement in the law that FDA issue a GRAS list or maintain a GRAS list in the first place. This came out about in two steps. During the Congressional Hearings, somebody asked the Commissioner to give a list of examples of the types of things that would be

exempted (not regarded as food additives), within the meaning of the law. Some of the things George had written down were baking soda, vinegar, sugar, and a few other things. He said these were the sort of things all scientists regard as safe and there was no reason to test them. When the law was passed, the question rose again: "Should there not be a list of substances which are not food additives"? We started getting lots of letters asking if a particular substance was a food additive. The Commissioner said, "Well, let's get out a list. So the first GRAS list was prepared in this way. I said to Staher, Kawanoto and Domras - remember them? They worked in Records. "Look, go through the records and your subject files and give me a list of all the chemical substances that we know anything about". They came in with a cartload of records. So I took these to Arnold Lehman's office. I sat down with Arnold, Garth Fitzhugh, Bert Vos, Arthur Nelson, and Les Ramsey and said, "O.K. let's go through this list from A to Z. What do you think the scientific community would generally regard as safe, and what is not?" If our people said they didn't know anything about a compound, we said it would be a food additive; if they said they knew about it and considered it safe - then we classified it tentatively as generally recognized as safe. In a half dozen such sessions, we went through the list. Finally we produced a list and said,

"O.K.", these were the substances the Food and Drug Administration would believe that the scientific community generally would recognize as safe. We presented it to the Commissioner who said it looked good to him and told us to put it out. I wrote the preamble and sent it to the General Counsel's office. We put a notice in the Federal Register to the effect that these were materials that the Commissioner of Food and Drug believed would be generally recognized as safe under the Federal Food, Drug and Cosmetic Act. We gave interested parties the opportunity to comment. In addition, Fitzhugh and some of the others picked out a number of scientists who had published in the field and were knowledgeable about the safety of food substances. We wrote them individual letters explaining to them what GRAS meant and said in effect, as we did in the preamble, that if these things were deemed as being generally recognized as safe, it was unlikely that much additional work would be done on them. We asked for their comments, pro or con.

Having done that, we sat back and waited for comments. The comments came back and Billy Goodrich sat down with that big stack of replies and started through them. We made a judgment as to whether or not they were valid objections. Where there was no objection it was easy. We got the objections down to a short list and sat down again with our scien-

tific group within the Agency. When they concluded the guy didn't know what the hell he was talking about, we rejected his comments; if on the other hand they thought he had a point, we said, "Fine". And off the list it came. That's the way the GRAS list was drawn up. It was not ever intended by us at the time, that there be a more formal procedure for doing it. Our attitude was if we thought it was GRAS we'd say it was, and not go through this procedure all the time, but would just make the judgment interally. If a firm disagreed with it, it could market the product and if we felt strongly enough, we'd sue them. This system worked well until 1969, when the Cyclamate episode came up. Richard Nixon was President at the time and as a consequence he ordered the Food and Drug Administration to review the GRAS list. It was at this point that FDA, I think, decided to fix something that wasn't broken, and made a mountain out of a molehill. They came up with this very elaborate GRAS Review Program. It's difficult for me to say what I would have done were I still there in 1969, when I had been out of the Agency for ten years, but I think that all they should have done was simply to repeat the procedure we'd used earlier, reissue the list and ask for comment. Instead, they undertook this elaborate review with FASEB and established a set of formal rules in the regulations as to what type of information has to be available before you

can determine if something is generally recognized as safe. What they required, to a significant degree, was the same type of information that would need to go into a Food Additive Petition in the first place.

That was a significant change from the original concept, and I think it was unnecessary. If there is some scientific doubt, of course it should be expressed. That was the biggest difference I have seen. Another was in the issuance of regulations on packaging materials. There came out, in the early to mid-1960s, a lot of regulations on packaging materials, in which were listed all sorts of things, and said, in effect, you can use all of these things providing they don't get into food. As I understand it, if it doesn't get into food, it's not a food additive; therefore, you're not regulating anything. So I think there's a real mish-mash of regulations, with respect to indirect food additives, that are misleading. If you read the regulation carefully, it says you can use it if it doesn't get into food. I think the Administration has belabored the GRAS issue. They've made it unnecessarily complicated.

The other issue that has given everyone fits is the Delaney Clause. It was written into the original Amendment as a last minute compromise, "No Delaney Clause - No Amendment". In the early years the Delaney Clause didn't mean a thing. I

was only there two years after the passage of the Amendment. It didn't really start having that impact until later on when we got into the Cyclamate period.

FL: That is probably influenced to some extent by the advance in analytical methods of today.

AC: There are two factors. One, indeed is the chemical methodology which is now down to 10 to the minus 10 or some astronomical reverse figure, parts per trillion, whereas parts per million were pretty good methods earlier.

The other is that, in my days in FDA, we did not operate in the fishbowl that there is today. We could issue a GRAS list in the manner I have explained, and no one would think anything of it. We did not have the consumer activists and the methodology was different. Food and Drug was not a politically sensitive agency in those days. Today and for the past several years, obviously, the Agency is in more and more of a fishbowl; every decision gets examined by every Tom, Dick, and Harry; there are doubting Thomases all over the place, the types of people we used to ignore and get away with, but today they can't.

The Agency has made one move in the direction of realism with their constituents policy seeking to define a carcinogen. They're saying if it's an impurity and not intended to be there and as long as it's there in an inconsequential amount,

it's not a carcinogen. On the other hand, this is hard to rationalize. If the amount is small, what difference does it make whether you intend for it to be there or not? I think what has happened here is that whereas 25 years ago we could have made that decision without going through a lot of public announcements and getting a lot of comment, we could simply say the amount is not worth worrying about. We would have been able to deal with it administratively. They can't do that today.

Then there is the Freedom of Information Act. If you talk about events that have had a marked impact on FDA, you have got to put the Freedom of Information Act right up front. Here again, every time the FDA approves something, a thousand FOI requests come in and all the doubting Thomases sit and write letters. Look how they questioned Aspertame. Had Aspertame come along any time up until 1968, it would have been approved without any delay. It would have whipped through the approval process without any great hitches. But look what has happened to it. The Cyclamate Review or re-review or re-re-review is another matter. I'm not involved in it and, like Will Rogers, all I know is what I read in the papers, but it reads to me like all FDA scientists now agree that cyclamates should be approved. If they agree now that they should be approved, then obviously they never should have been revoked

in the first place. Having gone that far, how do you reverse that position? You can be sure that all the consumer activists will start screaming blue murder if the Agency does approve cyclamates again. I think a big thing that has happened in the food additive area is the impact of public scrutiny. You can argue that that's good, but it sure slows things down.

This is a self-serving statement, but look at the GRAS list that was prepared by Food and Drug Scientists, when I pulled them together - I was just the "note taker" - those were the men who made the initial judgments. So it can be said that the basic decisions on the original food additives GRAS list were made by FDA scientists relying on their own knowledge and experience - as, I believe, the food additives amendment contemplated. Some of the things have been taken off the original GRAS list as a result of the review and moved over into regulated food categories, but the substances on it are, in the vast majority, still permitted in food today. Two things have come off that I can think of, one is Cyclamate, and that was on the basis of new data, not facts available to anyone in our day; the other is brominated vegetable oil, which again, was barred on the basis of new data. All I'm saying is that the scientific review processes, in terms of their scientific validity, were darn good when you collected

the Agency's experts and asked them what they thought. These people read the literature and knew what was going on. The GRAS list they generated was as good a scientific document as what is being turned out today through elaborate, time consuming and expensive procedures, but it lacked the sophistication, the format, and the formalities. I doubt that the original GRAS list cost the FDA $20,000, in terms of personnel costs, and I suspect the Agency has spent at least $20,000,000 reviewing and finding nothing wrong with it.

As I said, Fred, it's the external factors as much as anything. This is not an argument for going back to the old system of FDA growing its own Commissioners, but it's important to note that in those days there was a strong common bond between FDA management and FDA senior scientists. They worked together, understood each other, and had a great deal of confidence in one another. Today, when a man comes in from the outside, he's not going to have the rapport with his new colleagues. It takes time to develop that relationship and understanding; therefore, the new senior manager is more inclined to question the judgment of the people below him, which may be good, but it takes time and creates additional reviews.

FL: One of the things we're doing in these recordings is asking the person being interviewed, about his opinions, im-

pressions, and observations of high-level officials of the Agency with whom he was associated - Commissioners and others, regarding their management style, their personalities, or any anecdotes about them that show what kind of people they were.

AC: There were three Commissioners during my tenure in FDA. They were Paul Dunbar, Charlie Crawford, and George Larrick. I worked in Larrick's office, so personally I knew him best. FDA was small, and I got to know the other two men, not equally as well, but I did get to know them. Dr. Dunbar retired in 1949 or 1950. I only met him once, when I was in Washington passing through, but the thing that impressed me a great deal about him was his knowledge of people, his deep concern about Food and Drug, and the people who were going to run it. When I announced that I was going to leave Food and Drug in 1959, Dr. Dunbar had been retired for about 10 years. He called me and wanted to talk. He couldn't understand why a fellow who had such good fortune as I'd had in Food and Drug would want to leave. He found it rather difficult to understand. He wasn't offended, but it was interesting that even though he was out of the Agency for 10 years, he was concerned about its leadership, and about people he thought had a good future.

I only met Mr. Crawford in the field. He was a very savvy, very quiet, scholarly type, with a driving ambition for

Food and Drug. Again, he impressed me with what he knew about what was going on. He happened to be in Boston, and it was he who told me I was transferred to Kansas City. This was an interesting story, in that my boss then, whom I shall not offend by naming him, had told me I would not be transferred. I guess he never bothered or forgot to check. At any rate, we had moved to a new apartment on the weekend and I came to work on Monday morning, Mr. Crawford was in the office and said, "I understand you just moved." I told him I had moved over the weekend and my wife was out buying curtains. He said, "Oh, Lord! Did you sign a lease? Can you get out of it?" I asked him why, and he said that just before he had left Washington, he had signed my transfer order to Kansas City. The landlord was very understanding, and fortunately I was able to cancel the lease.

When I arrived in Kansas City (I went ahead of my family to go and find a place to live), Mr. Crawford was there on a visit to the District. He kidded me about transferring me to Kansas City because I'd been "running" the Boston District long enough, and it was time for the District Director to do what he was supposed to do. The thing that impressed me about him was how much he knew about people in the field - about their personal problems and their philosophies. He talked all evening about the way he thought the Food and Drug Administra-

tion should be going. It's a shame the fellow was ill and had to retire when he did. Again, I was quite flattered. I was a young Assistant to the Director of the District and here he was the Commissioner, talking about his philosophies on law enforcement. He left me thinking this is the greatest outfit in the world to belong to.

Then I worked for George Larrick. He wasn't too great as a manager, I didn't think, and since he was the only one I actually saw manage; maybe the other two weren't either. But George was a great delegator. He had such an obsession about getting a building put up that I sometimes wondered whether he thought more of the building than he did some of the things he should have been thinking about. He was a very compassionate man, and somewhat detached from day-to-day operations, but there again, we have to bear in mind his Deputy was Jack Harvey. Jack was a bear for work and the fellow that ran FDA, really, from the internal standpoint. Probably more than his predecessors, when he was Deputy George ran FDA internally, but when he became Commissioner, he just moved away from all that and concerned himself more with external developments. We didn't have much to do with the Secretary's office in those days. We attended the meetings and submitted the compulsory reports.

I worked for five District Directors and knew all of them well. I think Shelby Grey was probably the finest District Director the FDA ever had. He had a capacity for leadership,

and of inspiring people who worked for the Agency to believe in what they were doing. I think that the three men in the Agency I worked for that made the most profound impact on me were Shelby because of his sensitivity to people and his ability to lead them; Sam Alfend for his analytical skills and "damn the torpedos - full speed ahead" attitude; and Jack Harvey, who was a good manager and had an overall feel for the Agency. He had the capacity for not letting personal feelings about issues or people interfere too much with FDA activities. He would listen, and was also a great talker. I remember something very humorous with Jack. He and I were arguing over some issue about six o'clock in the evening, and he said, "I heard you and don't want to hear your views anymore! I'm in charge here and I've got the right to be wrong - if you think I am." I got mad and told him he had the right to be wrong, but, "Goddamn, don't abuse it, and that's what you're doing!" We really had a knock-down, drag-out. I stormed out and slammed the door. I was too mad to go home. A few minutes later, Jack stuck his head in and said, "Are you all right?" I told him I was, so we went home friends. Jack was a good leader.

There were many good people. Among them was Malcolm Stephens, a very solid man, Kenny Kirk and Allan Rayfield. Allan got a bum rap from people. Everybody used to think that

Rayfield didn't like people, and was heartless. Quite the contrary, when I was in Field Operations, working with Frank Clark, one of our jobs was to evaluate people and make recommendations as to who should be transferred, promoted, etc. When it came to transferring somebody, we'd say, "O.K., we think "Fred Lofsvold should be transferred from Seattle to New York." Rayfield would then sit down and tear us apart. He would question us as to why we made this decision, and we would have to justify that the transfer a) was not punitive b) that it was for that man's advantage as well as the Administration's and c) that it did not unduly inconvenience the man from a personal standpoint. He would grill us on this, and when he agreed, he'd go to Seattle and say to the man, "You're transferred to New York and you should be there tomorrow....you gotta go and no 'buts'!" He'd end up looking the "baddie" because he just did not know how to communicate outside the sphere of his own immediate staff.

This was the group of people who came into the Agency during the '30s. The Agency was blessed by the Depression, in the sense that in the 1930s, they acquired some absolutely superb people. People who might otherwise have gone into industry and higher paying jobs except there were no jobs at all in industry, higher paying or otherwise, and they were getting, with all due respect to the present breed of recruits, the

"cream of the crop". These fellows were superb people; intelligent, good managers, and just did a super job. Sure, we had some bad managers, but I won't name them because it serves no purpose. There were some people who were unfit for their jobs, to be sure, but in the main, the Agency had pretty good people.

FL: Did that do us a disservice when it came time for George Larrick and Jack Harvey to retire? Were there too many good candidates and do you think that had any influence on the fact that the Department went outside for the next Commissioner? In other words, was the rivalry among those people as successors damaging to the Agency?

AC: I don't think so. I don't see how it could be. If you don't have competitiveness, good people don't rise to the top. I wasn't there but I suspect the decision to go outside was made independently of any rivalries that might have existed. I think probably, in retrospect, that George Larrick should have retired a few years earlier. FDA had not bred a new Commissioner except for Jack Harvey, and while I've always been opposed to non-career Commissioners, I think the Agency probably had grown to the point where bringing in an outside manager might have been wise. I think it was time for a change.

FL: Did you ever think about coming back to FDA after you had left it?

AC: Yes. Let me preface this by saying the reason I left was not because of any unhappiness with the Agency. It was just that at the time, the salary structure was low, as you well recall, and with four children moving up to where I could see greater expenses than my income could support, I decided strictly for economic reasons to leave. If I'd had only one or two children, I would have stayed in the Agency. My leaving was purely an economic decision and not one based on any unhappiness with the FDA. It's quite interesting that at the time I had hoped to stay out 10 or 15 years and then perhaps seek to be rehired. It's like when you leave the old hometown; you would like to go out and make a fortune, then come back and live with the old folks. I had one probable opportunity, not a formal written offer to come back. In early 1970 I was told that I was a leading candidate for the Deputy Commissioner's job if I wanted it. I had a heart attack on a Friday in Milan, Italy, and was in bed when I got a call from home telling me that someone in Washington wanted to talk to me. I said I'd be glad to talk and he said, "This is what's going on; what do you think?" At this point, I was in the process of recovering from a heart attack, and wasn't in a position to do anyone any good for several months. I told him to let me think about it and write him a letter. I thought about it (this was January, 1970) and as I recall the job then paid

$37,500-38,000/year, but I had a significant equity stake in the company I was working with that could not be readily converted to cash. With three daughters in college and a son about to enter graduate school, and in addition being in the process of recovering from a heart attack, I just said thanks for the consideration, but unfortunately I was not prepared to go back. So I have considered going back. Would I go back today if I were asked? Probably not. One, I don't think they would want me back, and two, I'm winding down, not starting a career. But I think like a lot of old "Food and Druggers", if someone asked me to come back, there would be a lot of conditions and terms I would ask about. Working for the Food and Drug Administration was a very, very satisfying job. Certainly in 1959, if I had been asked if I would come back, my answer would have been, "Indeed, I will, but I do need to make some money first." I wish I could have afforded to stay. In the massacre of 1969, when Ken Kirk who took my job when I left, Winton Rankin and all our other friends got waylaid, I have no doubt I would have been among the casualties and transferred to some Social Security program in Alaska. I suppose I wouldn't have survived.

FL: As a personal matter, I regret that you didn't return to the FDA.

AC: Thank you. That's very kind of you.

FL: Is there anything else you would like to put on the record?

AC: No, not really, Fred. The Food and Drug Administration, you can't compare it to 25 years ago; that's apples and oranges. It's a different group. I don't think it has the objectives that I would like it to have. On the other hand, you've got so many more things to do than we used to have, so many different pressures, that the approaches of my day wouldn't work. But I would still like to see it more goal-oriented and more oriented within the context of what the Food and Drug Act requires, as opposed to what a lot of other people who come into the Agency think would be nice. I don't much care for this faddism.

FL: Thank you very much, Tillie, for your time. This is going to be a useful addition to the record we are accumulating.

AC: I hope so.