Fred L. Lofsvola

HISTORY OF THE
U. S. FOOD AND DRUG ADMINISTRATION

Interview between:

Fred L. Lofsvold

Retired Regional Food and Drug Director

and

Robert G. Porter

U. S. Food & Drug Administration

Denver, Colorado

August 25, 1981

INTRODUCTION

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

The tapes and transcriptions will become a part of the collection of the National Library of Medicine and copies of the transcriptions will be placed in the Library of Emory University.

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Fred L. Lofsvold

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DATE: August 25, 1981 PLACE: Denver, Colorado LENGTH: 410 minutes

INTERVIEWEE	INTERVIEWER
NAME: Fred L. Lofsvold	NAME: Robert G. Porter
ADDRESS: [redacted]	ADDRESS: U. S. Food & Drug Admin.
[redacted]	Denver, Colorado

FDA SERVICE DATES: FROM 1939 TO: 1980 RETIRED? Yes

TITLE: Regional Food and Drug Director
(If retired, title of last FDA position)

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This recording is a part of the FDA oral history project. The person being interviewed is Fred L. Lofsvold, retired Director of Region 8. The record is being made at the FDA office in Denver, Colorado, the date is August 25, 1981, and my name is Bob Porter.

Porter: Fred, why don't you start by giving us some biographical information about your career in FDA.

Lofsvold: I was appointed as junior chemist in 1939, but I never worked in the laboratory to any extent. At the time of my appointment and in my pre-appointment interviews, I indicated that I would prefer the outside work of an inspector, so I started right off as an inspector. I was an operating inspector from 1939 to 1946, stationed in Seattle, Portland and Spokane, Washington. In 1946, I took a job as assistant to the Chief of the Seattle station. This was a newly created administrative position intended to relieve the director of the office of some of the administrative duties. The job has gradually evolved over the years into what we now call a compliance officer. In 1948 I was promoted to Assistant Chief of the office, took on some additional duties in managing of the Seattle office until 1953, when the Food and Drug Administration suffered a cut in appropriations. That year the agency underwent

its only reduction in force and that included abolishing my position and most of the similar positions in the field at that time. I reverted back to being an inspector then for two years, and in 1955 I transferred to New York District in the position of Assistant Chief. That job entailed essentially running the compliance operations at New York. In 1956, the job of Chief Inspector of New York became vacant and I was transferred laterally into that position. In 1961, I became the Director of the Philadelphia District Office and in 1965 came to Denver as the District Director.

When the Regional Food and Drug Director positions were established about 1970 or '71, I assumed that position and retired from it in February of 1980. Since that time, I have been employed as a re-employed annuitant working part time for FDA, doing some work in the history project and in the presentation of Food and Drug law training courses for our own people from the various parts of the country.

Porter: Fred, how did you take a job in FDA in the first place?

Lofsvold: Mostly by accident. I graduated from college in 1937 with a degree of Bachelor of Science in chemistry and was employed by a small mining company in central Idaho.

We were located about nine miles from the nearest town and got to town very seldom. One day I got a letter from some of my friends who advised me that the government was going to conduct a Civil Service examination for junior chemist, the first such examination that had been given in several years during the Great Depression. They sent me the necessary application forms. I filled them out, and on the last day before the thing closed, I took them into town and got them notarized. This was a requirement for applications for government employment at that time.

The examination was held about six months later in August of 1938. It was an all day affair, a three-hour examination in general chemistry with two-hour exams in various specialties. I took the exams in analytical chemistry and organic chemistry. It was a very difficult examination and I promptly forgot about it until the following December when I was notified of my grades. The grades, I believe, were 82% in organic chemistry and 87% in analytical. I thought that those were so low that I would never stand a chance of any appointment, so I forgot about it again and was very surprised in July of 1939 to receive a letter from FDA advising me that my name was on a certificate and that I should contact the resident inspector in Spokane for an interview. I had some difficulty locating

the inspector, Kenny Monfore, because he was traveling a good part of the time, but we finally got together for the interview.

About a month later, John L. Harvey, the Chief of the Western District, came to Spokane to interview me again and on that occasion he interviewed both J. William Cook--who subsequently became a authority in pesticide chemistry--and me simultaneously in a very hot hotel room in the Davenport Hotel in Spokane. I thought it a little odd that Mr. Harvey would interview two people at the same time, but an interview with Harvey was something different than the usual interview--he did most of the talking and it was quite easy for him to do that with two of us present.

Porter: It was kind of a listenview, wasn't it?

Lofsvold: Yes. Actually, I surmised afterwards that Harvey's interview was simply his way of confirming what he had heard from Monfore and to have a look at us before he signed the final recommendations for appointments. Bill and I were duly hired and got our instructions to report to Seattle. My reporting date was September 18, 1939.

At the time that I got the letter from FDA until I talked to Monfore, I had only the vaguest of an idea of what the duties of the Food and Drug Administration were. I knew that there were some kind of so-called pure food

laws, but I had no idea what agency enforced them or what procedures or what authorities they employed in that enforcement process. I suspect that I was as green as anyone could be in my first contacts with the agency. I accepted the offer of appointment because in 1939 jobs still were scarce and the pay at the entrance grade of P-1, $2,000.00 a year was an impressive salary for someone who was just starting out in his career. I took the job with the idea that I would learn what it was all about and that I could always quit if I didn't think it was a job I could enjoy. But, here forty-two years later, I'm still associated with the agency and very happy that I originally came aboard.

Porter: Well, Fred, what did you learn about the organization of FDA at that time?

Lofsvold: Well, in 1939 FDA was a very small government agency. It was located in the U.S. Department of Agriculture and had been in business since 1906 when the original Food and Drugs Act of 1906 was passed. There were about 900 people in the agency, including those of us who were appointed that year. Because the Food, Drug and Cosmetic Act of 1938 became effective on June 30 of 1939, there was an effort to increase the staff of the agency. This resulted in the appointment of perhaps 100 or 150 inspectors and laboratory people across the United States.

The agency consisted of a headquarters group and a field staff. More than half of the employees of the agency were located in the field. The field was organized into three geographic districts: Eastern, Central and Western Districts; with their headquarters at New York, Chicago and San Francisco, respectively. Within each district, there were local offices called stations. In the Western District there were stations at San Francisco, Los Angeles, Denver and Seattle. Each of the stations had a designated geographical area or territory. These areas were established to conform with the flow of the regulated products; foods, drugs, and so on rather than on state lines. For example, in the Seattle station territory there were the states of Washington, Oregon, the northern and southwestern portions of Idaho and the most western part of Montana, as well as the territory of Alaska. This configuration conformed with the commerce in products, particularly foods where western Montana, northern Idaho, eastern Washington, and Alaska received much of their food from the Seattle area; and the southwestern part of Idaho and the eastern part of Oregon were satellite to Portland, Oregon. The other part of Montana and the southeastern portions of Idaho, did most of their business with Denver and Salt Lake City and consequently were in the Denver stations territory.

At the time I reported to Seattle, the staff consisted of 25 people. There were five inspectors, two of them stationed at Seattle, two at Portland and one at Spokane, and six chemists. Management of the office was in the hands of the Station Chief, Bob Roe; the Chief Inspector, Ken Monfore, who had been promoted from the Spokane resident post; and the Chief Chemist, Jim Palmer. The addition of us neophytes raised the number of inspectors to eight and the number of chemists to nine. Clerical staff consisted of four people, and there were two persons who assisted in the laboratory, two import inspectors, and a tea examiner. This staff remained fairly constant until 1956 when the expansion of the agency really began. The present staff is about 125.

The staff at a station such as Seattle carried out investigations, inspections and analyses of samples and recommended legal actions when they thought it necessary to the District Office in San Francisco. The recommendations were reviewed at that level and if approved were then forwarded to Washington headquarters. The headquarter's staff consisted of the immediate Office of the Commissioner, who before 1940 was called the Chief of the Food and Drug Administration, and a group called the Interstate Division who handled all regulatory matters. Supporting them were

the technical people organized in divisions according to products such as the Food Division, Drug Division, Vitamin Division, et cetera. Regulatory actions coming in from the District Offices were reviewed there and if approved were then forwarded to the appropriate United States Attorney for filing. The Department of Justice had given the agency authority in most cases, to deal directly with the United States Attorneys through the agency's general counsel rather than sending the proposed actions through the Department of Justice in Washington. This facilitated the handling of cases and speeded up the regulatory process. Although all of this communication was carried on by mail, the process was reasonably quick. Mail service was excellent and the various people involved were very aware of the need for speed in developing and filing a legal action. I think that this attitude prevailed because most of the people at the District and Headquarters level who were involved in this process had served time in the field organization and were aware of problems that existed in controlling illicit products, and consequently were anxious to further the process. Of course, when the novel case or one that presented some kind of evidentiary problems came up, there were considerable delays getting these filed. But by and large, cases moved rapidly from the investiga-

tional stage to a filing in court, either to seize goods to remove them from market or to bring some sort of regulatory action against responsible firms and individuals.

Porter: Fred, what kind of training did you get when you came in this outfit, did they just throw you out on the street, tell you to start operating?

Lofsvold: Because there were about 20 people appointed at the same time in the Western District, they took advantage of that opportunity to put on a centralized orientation and preliminary training course. I reported at Seattle on the morning of September 18, 1939 and that night I was on the train en route to San Francisco, formally transferred to the San Francisco station for training purposes. This was a money saving dodge that was employed by the agency which in those days was very frugal--

Porter: That meant you didn't get any per diem in San Francisco during that period?

Lofsvold: That's right.

Porter: You lived there?

Lofsvold: We were paid per diem while we were en route, but once we arrived in San Francisco, we had to support ourselves on our salaries and then at the conclusion of the training course we were formally transferred back to our

assigned post of duty. When I arrived in San Francisco, I found that several of my colleagues had already been there for up to two and three weeks, but had not been involved in any real training awaiting the arrival of the rest of us. The training started a day or two after I arrived when we had most of our group assembled. Initially it consisted of lectures every morning from 9 until noon conducted by Mr. Harvey, the Chief of the District, or his deputy Mr. J. Edward Kimlel. They talked principally about the laws that the agency enforced with the major emphasis, of course, on the brand new Food, Drug and Cosmetic Act of 1938 which had become effective only a few months before. They talked to some extent about broad policy matters, but there was no real effort to define a regulatory philosophy for the agency.

The instructors clearly implied and we students quickly understood that FDA was a law enforcement agency and that these various laws were the tools which we were to use for bringing about compliance with the statutes. The role of the inspector was defined as being one who gathers information, but who does not draw conclusions as to whether or not violations exist.

Although we were instructed to discuss our observations with managers of factories, warehouses, and other

establishments when we thought we saw a violation of the statute, we were warned to be very careful about making clear cut, hard and fast statements about the legality of any labeling or any particular practice. In other words we were encouraged to bring questionable things to the attention of industry, but to carefully refrain from suggesting to them what they should do to correct them.

All of our training was directed toward explaining to us the requirements of the statute and illustrating various sections with real or hypothetical instances of violation. Where appropriate methods of gathering evidence to support actions based on such violations were included in the lectures.

At the same time the Chief of the Food and Drug Administration and other high officials were engaged in making public statements regarding requirements of the new law and were setting up and participating in training courses sponsored by trade organizations, such as the National Canners Association, the Confectioners Association to promote compliance with the new law.

As individual inspectors and chemists we clearly understood that our job was to obtain and report evidence which would support legal actions when our superiors thought such actions were necessary.

Porter: Can I just say, see if you wouldn't agree with this, that in addition to gathering evidence we were encouraged to sort of be ever alert for anything that we thought might be a violation of the law, gather the evidence and submit the facts to our superiors even though it wasn't something that we had been told to do ahead of time.

Lofsvold: That is exactly right. Inspectors were expected to develop sufficient facts when they observed something they thought might be a violation so that a case could be presented with little or no additional work. This was particularly true when inspectors were operating in travel status away from headquarters where they had no opportunity to confer with their supervisors or others about the situation that they found. The communications from an inspector to his headquarters when he was in the field were limited to mail reports and an occasional telegram. It was not exactly forbidden but certainly discouraged to use the long distance telephone which was another example of the economy practiced by the agency. An inspector in the field operated with a great deal of independence. He had certain assignments through rather rudimentary work plans or special assignments that had been sent to him. But otherwise he was expected to develop leads of his own through check-

ing warehouse stocks and goods in transit at rail, truck and steamship docks and when he found something that he thought needed correction, he was expected to develop the evidence necessary to support such corrective action.

The lecture sessions while devoted mostly to the Food, Drug and Cosmetic Act, also covered the other laws enforced by FDA at that time, including the Insecticide and Fungicide Act, the Caustic Poison Act, the Naval Stores Act, and the Import Milk and Filled Milk laws. Soon after I came in, in 1940 to be exact, the Insecticide and Fungicide Act and the Naval Stores Act, were transferred out of the FDA. This occurred at the time of the reorganization of the federal governemnt under Reorganization Plan number No. 4 in which FDA was separated from the Department of Agriculture and placed in a new entity called the Federal Security Agency. The insecticide and fungicide enforcement and the naval stores work were left in USDA when we departed.

During our first few days, we all were assigned to the laboratory in the afternoons. San Francisco district was conducting a survey to determine whether there should be a change in the tolerance of defective nuts in almonds. They had collected hundreds of samples from various almond growing and packing establishments in California, and we neophytes set about examining these samples by cracking the

almonds with a hammer and visually examining the kernels. We had the advice and instruction of two experienced micro-analysits who showed us which nuts were considered bad and helped us to classify our findings. As a result of all of these hundreds of samples that we examined, the tolerance was lowered for the next year's production. Tolerances were set informally in those days on this kind of basis, that is, what the industry could reasonably be expected to do when they handled their products properly.

We received on the job training by accompanying experienced inspectors in a wide variety of tasks. One of the earliest inspections I participated in was an inspection of a very large tomato processing plant in Hayward, California. Gordon Wood, who was a very experienced inspector, took several of us neophytes by prearrangement, to this factory and took us through the plant explaining the process and demonstrating the kinds of examinations that an inspector should make in such a factory. Attention was given, principally, to the quality of raw material and the adequacy of the sorting to remove unfit tomatoes. Subsequently, each of us made inspections of similar plants with other inspectors until we understood not only how to inspect a tomato plant, but had some indoctrination in general principles of inspection of a factory.

Because the 1938 act contained a number of sections which gave new authorities to the Food and Drug Administration, there was a great deal of attention given to surveys of industry to get information on what violations existed so that follow up work could be planned. I recall that in this connection, I accompanied a San Francisco inspector in visiting flavoring establishments and a candy factory or two, in order to check on their labeling and packaging practices. We were interested in whether their labels bore all of the information required in new sections of the new act and also whether any of the packages were so formed or filled as to be deceptive to consumers. My first independent inspection was made for this purpose, an inspection of a macaroni manufacturer in south San Francisco, and subsequently I made independent inspections of eight or nine more macaroni factories and some candy and bakery plants as well.

Another feature of our training was dock surveillance work. At that time in FDA, a considerable amount of an inspector's time was spent on steamship, railroad and truck docks making field examinations of outgoing shipments. In some cases, the products could be actually examined on the dock. For example, an inspector could crack out nuts to look for defective kernels or could examine dried fruit

being shipped for evidence of decomposition or insect damage. Other things that an inspector could see were the labeling, the deceptive packaging, and similar fairly obvious violations. Dock surveillance also was an opportunity to learn about new firms. If you encountered a shipment from some firm that was new to you, you made notes about the product and checked at the office whether we had a file on this firm and when we had most recently inspected them. If you were in travel status and were not likely to be back at this point for some time, you might take a sample without checking to see whether we had previous history. In the seaport districts, it was also quite common to look for specific products or specific code lots of products from certain manufacturers which had been inspected and found to be packing defective material. Inspectors generally carried a list of such products and codes and when they encountered them on the dock, they collected samples for laboratory examination. Through experience, inspectors also learned to know what products were likely to be defective and would frequently sample any lot of such products that they encountered. For example canned huckleberries, being canned from berries collected in the wild very often contained either insect larvae or were moldy before they were canned and if an inspector encountered a shipment of

huckleberries on the dock, he probably would sample them on speculation.

The training also included surveillance of warehouses, drug warehouses particularly, for label claims on proprietary drugs, and observations of stored foods similar to the ones made on the dock.

I also had the opportunity to participate in an import reconditioning supervision of some Philippine peanuts, I remember, and like all neophytes was initiated into the sampling of bulk butter for butterfat content. In those days, butter was shipped from many, many small creameries to processors in the city. Butter was shipped in 64 pound cubes which were then cut into one pound prints by the receiving firm for retail sale. Great emphasis was placed on the compliance with the standard for butter which required 80% butterfat and we collected many samples and made many seizures of butter which failed to meet that standard. Seized goods normally were brought into compliance by reworking in the churn to remove some of the moisture and subsequently released for sale.

I returned to Seattle on December 1, 1939 and my training was continued there. I remember that the first inspection that I made there was one with Chief Inspector Monfore, when we inspected a candy factory located right

across the street from the Seattle office. Everything seemed to be going well in the candy factory, until we got down in to the depths of their basement, where we found a lot of corn flakes in burlap bags which had been attacked by rats. The new law forbade the storage of food under conditions whereby it may become contaminated with filth. This was a brand new section intended to control insanitary conditions, but nobody was quite clear as to what kind of evidence would be required to support such a charge in the event of a contest in a court case. In this instance, we used our own judgment, or rather Monfore's best judgement, and collected samples of the contaminated product from the holes gnawed in the bag, collected some of the rat droppings that were in and around the product and tried to write up a description of the lot to the best of our ability. We did not have, at that time, any equipment for photographing the conditions which we observed. That did not come around until about a year later. Evidently, our efforts were considered adequate, because the charge in the seizure included the charge of the insanitary conditions. Of course, the actual contamination of products which we observed, which was apparent from the samples we had collected, would have been a sufficient charge to condemn the goods in any event.

I continued to work both independently and with other inspectors, for the next few months, and in March of 1940, went on my first of many road trips, this again in the company of the chief inspector. We went down the coast to Aberdeen, Washington inspecting oyster packers and food warehouses and the crude drug industry. I found the latter most interesting. Digitalis, Cascara Bark; and certain other crude drugs were collected in the woods in that part of the country by children, and men and women, in their spare time. They sold these products to individuals who collected them at feed stores and similar establishments. Other individuals located in larger cities, periodically visited these collection points and purchased the materials for assembling shipments to drug factories in the midwest and eastern part of the United States. As you might imagine, the goods were stored under very primitive conditions. Frequently they were not properly cared for and became moldy and they presented a considerable problem to FDA to make certain that these products, particulary digitalis reached the ultimate drug manufacturer in the best shape possible.

My first independent travel in field inspection, came in May of that year. I had accompanied Larry Warden to Yakima, Washington to assist him and state authorities in

supervising the salvage of fire damaged materials resulting from a fire in a very large grocery warehouse. When we arrived in Yakima, Washington, where the fire damaged goods were located, we found some assignments awaiting us, instructing me to take the car and go to Walla Walla and Spokane, Washington. I remember that at Walla Walla, I had to visit the state penitentiary to collect some samples of red sour pitted canned cherries which were suspected of containing mold. It was an interesting experience to go into the prison in order to collect the samples. At Spokane, my assignment was to inspect a flour mill to obtain information which could be used to set food standards for cracked wheat and crushed wheat. Having never been in a flour mill before, and understanding very little of the process, I admitted my ignorance, explained what information I needed and obtained excellent cooperation from the miller who explained his process and furnished samples of the product to me. At that particular time, we were doing a great deal of food standards work. The new law had authorized the establishment of standards of identity or definitions for various staple food products and a good deal of work was being done by the agency along this line. The purpose of the standards, of course, was to protect the consumer by limiting and defining the kind of article that

could be sold under a particular name. In order to set the standards, the agency needed information on what was being prepared and sold under such designation. The inspectors visited factories, such as this flour mill, to obtain samples and to get details of processing and the opinion of knowledgeable industry people as to what specifications, if any, should be established for this product when the hearings were held to establish the standards. I returned from this field trip on the 22nd of May, a Saturday, and the next Monday when I arrived at the office, I was told to get ready for an extended trip to Portland. I spent three days cleaning up such assignments as I had pending, and on Thursday, the 27th of May, left for Portland and did not return until the following July 20th, a period of eight or nine weeks. This was not unusual for that time in any of the western offices of FDA. Because there were so few inspectors, it was necessary to deploy them wherever there was work to be done. In the summer months, in western Oregon, there were a great deal of fruit and vegetable packing operations in progress. The two inspectors regularly stationed at Portland could not handle the volume of work, so it was necessary to send help from station headquarters. I reported to the Portland office the following morning and was briefed on what things were pending by

George Downard, who was the junior inspector at the resident post. He was about to depart to supervise preparation of an authentic pack of canned gooseberries in a Salem cannery, again for food standard purposes, and suggested that I accompany him. We went to Salem in the afternoon and worked all night on this gooseberry pack. I soon found that this was a regular pattern of work at the Portland office during the fruit and vegetable packing season. The various fruits were gathered during the day, delivered to the processing plants in the afternoon and were processed during the night. If we were to observe their operations, it was necessary for us to be there when they were packing. Our regular pattern of operation was to leave the office sometime in the late afternoon and work until sometime past midnight making our inspections and spend the following morning writing up the reports of the places that we had visited . At this time the freezing of fruits and vegetables was just beginning. No retail sized packages were yet being prepared, but strawberries, raspberries, and other fruits were being frozen in either wooden barrels or thirty pound tin cans for commercial users such as jam and jelly manufacturers, bakeries, and so forth. One of the tasks we had was to supervise and observe the packing of barrels of strawberries which we would then seal and

identify so that after they had been shipped to a preserver in the eastern part of the country they could be used in an authenticated pack of jam prepared under the observation of another inspector. In this way the Administration could obtain analytical data on the chemical constituents of the fruit from the time that it was packed at the plant until it was made into final jam. The inspector's presence insured that neither sugar nor water, nor other materials were added which would change the constituents of the fruit. The analytical data derived from these studies were then used in the enforcement of the jam standard established a few years later.

Porter: I was interested in what you said about your long trip to Portland. That sort of parallels my experiences as an inspector in Denver too, and I just wondered if maybe this might be a good time for you to talk a little bit about inspector's travel in those days at least in the western district.

Lofsvold: Some of the trips that we took were of reasonable duration. It depended on what area you were visiting and what work there was to do, for example a trip from Seattle to Yakima or Wenatchee, a distance of 150 miles, would last for perhaps a week or maybe two weeks, but when we went to some place where there was a lot of work or when

we ventured into the farther reaches of the territory in southern Idaho or western Montana, trips were characteristically long. This particular trip, my first long one to Portland, was not just to Portland, but the entire western half of the state of Oregon up and down Willamette Valley and as far south as Medford. We traveled by car and we were paid a per diem rate which was to cover our cost of food, lodging and laundry. At that time the rate was $4.50 per day. By current standards that sounds woefully low, but as a matter of fact considering the prices that prevailed then, it was adequate. We stayed in hotels principally, because there were not yet the motels that we currently have, and the leading hotels in these smaller towns, and in fact in the larger towns, rarely ran more than $2.00 a night. The costs of food were similarily low so that an inspector could do quite well on the $4.50 per diem rate.

While you were on an extended trip, particularly one that took you into the far points away from the office, you were required to check daily with the Western Union office in towns where you were working, so that the office could send you additional assignments or instructions if necessary. You also received mail which generally was delivered to general delivery or perhaps to your hotel if your itin-

erary was sufficiently fixed in advance so as to permit delivery to the place where you were going to stay. Largely, however, while you were in travel status, you were an independent operator and were expected to use your own judgment to handle things that came up. If you found a new product or saw what you thought was a new manufacturing establishment or warehouse you were expected to immediately determine the status of the article or the establishment, in other words to collect a sample if necessary and to make an inspection of the premises. Occasionally, when a new inspector went to a different area that he had not visited before, he would unnecessarily duplicate something that had been done before but this was expected, and the inspector was not criticized for this. He would be criticized if he had observed something new and different and had not fully explored and reported on it.

Porter: Now this meant, too, that we were constantly changing our own itinerary. We had full authority to change our itinerary as the circumstances dictated as long as we informed the office. Certainly that was true in Denver and I'm sure it was in your case.

Lofsvold: Yes, I think that was the general practice perhaps across the country, but certainly in the western district. The only requirement was that you inform your

office of changes by telegram so that they would know where they could reach you.

Porter: There's always the story of the inspector who traveled and always when he changed his itinerary he would always say "leaving Spokane," or "leaving Walla Walla" or wherever it might be but he didn't ever tell where he was going.

Lofsvold: That was definitely frowned on. You were expected to be on duty at all times and it was also expected and you were indoctrinated by the people that trained you with the idea that you did not waste daytime hours in writing reports unless there were some emergency that required you to get the material in to the mail quickly for delivery. The usual pattern was to do your inspection work during the day and then to prepare your report after dinner. The reports could be either typed if the inspector were a sufficiently skillful typist or in my case either written in longhand or dictated. Dictating equipment was quite primitive. It consisted of a wax cylinder Ediphone dictating machine which weighed about 35 or 40 pounds and was quite a handful to carry into the hotel. They suffered from another hazard also, because the wax cylinders were quite fragile. We mailed them to the office using a franked label in a cardboard carton which held one cylin-

der. I had the unfortunate experience a few times of mailing perhaps three cylinders in to the office covering a lengthy inspection report and on arrival the middle cylinder would be broken. The clerks would transcribe what they could of the report from the surviving cylinders and then I would be required to reconstruct from my notes which were generally a bit sketchy what I had said some weeks before in that part that perished in the mail. So there were hazards in the use of dictating equipment. But it was a lot quicker then either typing or longhand.

Porter: That was terrible equipment in terms of the kinds of the things we are used to today. You can hardly believe how primitive it was. I didn't use it myself. I tried it but I was a good typist and I could just sit down and type.

Lofsvold: In my case it was really highly useful and I used it regularly.

The inspector traveling by government car was required to put the car in a storage garage under lock and key every night. This sometimes was a little difficult in some of the very small towns where we worked. In that kind of instance you would hunt up a filling station operator who would lock your car on his grease rack during the nighttime hours. The cars were actually property of FDA and they were purchased on competitive bid so that the manufacturers

consequently stripped them down to the bare essentials to meet the specifications and they were purchased on a fleet basis. Some of them were found to be not fully comparable to cars that manufacturers sold commercially, and we had some problems with them which probably were the result of this matter of selling them for a price. My recollection is that the 1940 Plymouth that was brand new when it was assigned to me in early 1940 was purchased by the government at a price of less than $500.00.

Porter: The first car assigned me was a '39 Chevy that only had one windshield wiper, for instance. We ought to mention that there wasn't such a thing as a GSA in those days.

Lofsvold: No, it made life somewhat simpler.

Porter: As I recall, it was at about this time that you got transferred to Portland, if I'm right. Would you tell us a little something about your experiences then?

Lofsvold: Yes, that long two month assignment at Portland in travel status ended on July 20 and on August 7 I was officially transferred to the Portland resident post. It already was a two man post, Russ White and George Downard were there, and the management of the station had concluded that there was enough work there to justify the addition of a third inspector on a permanent basis. It was a very good

assignment and I was there until January of 1943. The first year there were just the three inspectors. We operated as residents. Russ White was the senior inspector. He had been in FDA for a total of about three years when I got there. George Downard had been in the seafood service of FDA and been an inspector for about a year and a half and I had less than a year's experience when I got there. So you can see that the post was manned by a group of people with very limited experience. We tried to make up in hard work what we lacked in knowledge and by and large things worked out quite well. I got there in August and in September just after I had completed a year of service, I again took to the road on an extended trip. I left on September 23 for what was supposed to be a two or three week trip to Yakima, Washington working on the spray residue problem. At that time to control the coddling moth, which was a very serious pest in apples, the growers utilized lead arsenate sprays and sometimes added to it some calcium fluoride. These sprays were applied with a dispersing agent to make sure they got a good cover on the apples and also with chemicals which they referred to as stickers which made the spray material adhere firmly to the apple. Over the years that they had used the sprays, the coddling moth had gradually become more or less immune to

them with the result that they had to spray the apples as many as ten or twelve times during the summer. When the apples were ready to harvest, they were hardly recognizible as apples because of this thick coating of spray which totally obscured the color of the fruit. In order to reduce the amount of lead, arsenic, and fluorine that was present on the apples to levels that toxicologists considered safe and which the Food and Drug Administration had established as informal tolerances, it was necessary to wash these apples first in a solution of dilute hydrochloric acid followed by a wash in dilute sodium hyroxide and finally a clear water rinse. Even these heroic measures sometimes were insufficient to bring the level of the toxic chemicals down to the tolerance. To monitor the situation we would visit the various apple packing houses at least once, and sometimes twice a day in a particular area where we were working, collect four pound samples of apples after they had passed through the washing procedure and ship them by railway express in the evening to the laboratory in Seattle. From Yakima the apples arrived in Seattle the next morning. The laboratory would promptly analyze them and if there were any samples showing over tolerance, I would be notified either late that afternoon or the following morning that there was a lot of apples

that was in excess of spray residue tolerance. When I got that kind of report, then I had to determine what had become of those apples, whether they were still in storage or whether they had been shipped in carloads going to some market outside the state. When the cars were consigned, ordinarily there was no destination established at that point. The railroad referred to them as "rollers". A refrigerated car loaded with apples would be headed somewhere in the midwest or the east and would be sold by the packing company or broker en route and the car then would be ordered diverted to the ultimate consignee. When the cars had been shipped, I reported that to Seattle by telegram and they or I would trace the movements of the cars to it ultimate destination. The results of the analyses were forwarded to headquarters and the car was seized at wherever the destination was. This was a kind of work that brought us inspectors into contact with people who did not like us very much. Most of the growers and packers at various times had suffered a loss of shipments and consequently they were not kindly disposed toward the Food and Drug Administration. I never had the problem of being threatened with physical violence but such incidents had occurred in the past and did occur to some of my colleagues on rather rare occasions, but it was a tense

situation especially when an extra heavy infestation had required the use of extra heavy sprays during the growing season. About the time I was due to return to Portland from Yakima, the chief inspector, Ken Monfore, came over by train and we left for southern Idaho where he introduced me to the practices of the southern Idaho apple packers which were a little bit different from those in the big packing houses in Yakima, and then left me to continue for another month in the southern Idaho apple area. I continued the work on spray residue plus other work as time permitted, and did not get back to Portland until the 20th of November almost two months to the day from the time I had left on the original trip. One incident, of personal interest to me in that period, was that while I was in Yakima the date arrived when all young men had to register for the draft in World War II, and I had registered in Yakima giving the address of the office in Portland as my legal address. At that time, because I traveled so much, I did not have really a permanent residence. I was not married at the time. I lived in hotels or rented furnished apartments and when I left on a long field trip I would give up the apartments, store my few belongings and then rent a new place when I returned to town.

Porter: One thing, this is about the second time you have mentioned something that brings to mind the fact that in at least the smaller stations out west the chief inspector was not somebody who sat at the office and was totally a manager but he was sort of a cross between a working inspector and a supervisor and was not only out in the field training his men but on occasion went out independently to do regular inspection work.

Lofsvold: At Seattle, during those early years, when Monfore went out, he was generally with someone else for training purposes but occasionally when we had a special kind of an assignment where the station chief wanted his very best man, normally he would send the chief inspector. In this spray residue connection, I recall that when the Food and Drug Adnministration was in trouble with the Appropriations Committee of the House regarding its spray residue activities and needed an investigation at Wenatchee to check on possible injuries from spray residue that Monfore personally made that investigation.

During the summer of 1941, it was concluded that a laboratory should be established at the Portland office. The principal impetus toward this decision by the commissioner, came from the importers at Portland who complained about the delay in receiving their shipments because

customs submitted samples of imported goods to the Seattle laboratory and held the goods until they had the results of the tests. At the same time it was also decided to establish branch laboratories in Houston, Texas, principally to handle imports, and at Pittsburgh, Pennsylvania because of the large volume of work that was done in that particular resident post. In the case of Portland, the substation as it was called, was established using the three inspectors who were already at that location, and transferring in three chemists and a clerk and hiring a young man as storekeeper. Richard Edge came in from San Francisco as the senior chemist. He had about twelve years experience with the agency at that time and had done considerable administrative work particularly on imports in the San Francisco office. He was considered to be in charge of the laboratory and also did the administrative work on imports issuing notices of sampling, releases and detentions and generally carrying on the liaison with customs. The other two chemists were Theron Strange, an experienced chemist and Bill Cook, my contemporary, who were transferred from Seattle. Our clerk was Dorothy Koegler, from the San Francisco office, who later was secretary to the deputy commissioner in Washington. It was an interesting arrangement. No one person was in charge of the entire office.

In theory, the chemists reported to the chief chemist in Seattle and we inspectors reported to the chief inspector in Seattle, but in practice, we worked out most of our problems among ourselves. The arrangement was highly successful and pleased the local importers who had originally complained. Unfortunately, the economy measures that were necessary when our appropriation was cut in 1953, brought about the closing of not only Portland but also the Pittsburgh and Houston substations.

During the three years that I was at Portland, our program emphasis was mostly on sanitation and economic violations. While we gave attention to any health hazards that arose, we did not have a formal program to try to find health hazards. For example, in the canning of low acid vegetables, we gave little attention to the times and temperatures of the cooks that were used in the canneries. It was rather assumed that the efforts of FDA and the National Canners Association in the 1920's and early 30's had pretty well educated all the canners on the hazards of botulism. While it was routine to report the times and temperatures used for various size cans of products being packed at the time of inspection, we did not minutely examine the records of the canneries looking for discrepancies. Each year there were a few botulism cases to be investigated, but invariably they turned out to

be caused by home canned products, rather than commercial ones. So far as I can recall, in those years in the 1940's, we had only one authenticated case of botulism from a commercial product, a death, I believe in the Los Angeles district, from the consumption of Liederkranz cheese. So far as I'm aware despite extensive investigation, no other jars of the product contaminated with botulinus toxin were located. We did look into all reported food poisonings although our sources of information were limited generally to the news media, radio and newspapers. I recall one serious incident that occurred in November of 1942. While I was shaving, preparatory to going to work, I was listening to the news on the radio and heard a report of a serious poisoning at the state mental hospital, in Salem, Oregon that had occurred during the previous night. I hastily got dressed and went to the office, told the people there to let Seattle know that I was already on my way when their inevitable call would come and drove hurriedly to Salem. I should say that at this particular time, I was the senior inspector there, George Downard having been transferred to Spokane and Russ White having recently been called to active duty in the army. Arriving at the hospital, I found a total state of confusion. The staff of the hospital, both physicians and others, were very reluc-

tant to furnish me with any information. Several other investigations were under way, including the State Departments of Agriculture and Health and the state police. I was able to learn that the first symptoms had appeared immediately after the evening meal. The principal dish served at this meal was scrambled eggs made from USDA surplus frozen eggs and USDA surplus dried milk. After some time I persuaded a physician to give me a portion of the suspected food, scrambled eggs, which he had collected and took it immediately to the state Department of Agriculture's laboratory. The symptoms had suggested the presence of fluoride and there was on the premises a large drum of sodium fluoride used for the control of roaches. The cooks and others in authority steadfastly denied that this product could have contaminated the food. Nevertheless the state chemist soon found that fluorides in massive amounts were present in the cooked food. I returned to the hospital just in time to hear the state police announce that their laboratory had also made this finding. The state police pressed the investigation as the lead agency because it appeared that contamination had occurred locally and finally a patient who was assisting in the kitchen admitted to having inadvertently brought a large container of the sodium fluoride powder to the kitchen mistaking it for the

dried milk which was in a similar drum in another room on the opposite side of the corridor in the pantry.

Porter: Did a number of people die?

Lofsvold: I believe that the total number of deaths was something like thirty five. It was quite a shocking sight. They converted the gymnasium into a temporary morgue, and had all of the bodies there. It was the kind of experience you do not soon forget.

In the drug area, we did not have much opportunity to get involved with dangers to health. Drug production in the Seattle territory at that time, was limited to some of the crude drugs and to very small manufacturing operations at Seattle and Portland. Our principal thrust in the drug area, probably nationwide, was the problem of unwarranted therapeutic claims on the labels or labeling of products. We had a few such manufacturers in our area, one of them the Research Laboratories of Oregon, which put out a product called Nue Ovo a proprietary remedy for arthritis. They distributed nationwide. They had been in business since the early 1920's and were violating the law by making claims that their article was useful in the treatment of arthritis and rheumatism. The product was a mixture of herbs in a liquid base and was generally considered by experts to have no value in the treatment of those dis-

eases. Under the 1906 act, we had been loath to take action because we would have to prove that the claims were not only false but also fraudulent, that is that the company knew they were false at the time that they made them. But with the passage of the 1938 act, the burden of proof became less in that we needed only to prove that the claims were false or misleading. Since we expected a serious contest in any action that we developed, we began to very carefully lay the ground and while I was at Portland, one of my duties was to deliver to a physician at the University of Oregon a quantity of the product rebottled into plain, unlabeled bottles with similar bottles of a placebo prepared by our San Francisco drug laboratory so that he could use these two products in a controlled experiment with arthritis sufferers whom he was treating. At the same time similar tests were being run by other physicians in other parts of the country. There was much other investigational work done. Inspectors from Seattle and Portland developed a pattern of questionable activity in the preparation and publishing of testimonials which the firm used extensively in its advertising. Long after I left Portland, a consolidated multiple seizure case came to trial in Tacoma, Washington. It was a very hard fought trial, which resulted in victory for the government and

ultimately put the firm out of business. These kinds of ...

Porter: Excuse me, was there any precedent set in that case?

Lofsvold: Yes, the case went on appeal to the circuit court of appeals and the Supreme Court refused certiorari so that the appellate court decision stood. That decision was very useful to us because it established the legal principle that expert testimony by persons who have training and experience in a particular field is admissible not only to their actual experiments which these physicians had done using the product, but also to their expert testimony based on their knowledge of the ingredients of the suspect drug, and also their general opinion based on their knowledge of the practice of medicine. It broadened the scope of expert testimony in these kinds of cases that involve false and misleading claims, and was very useful to us subsequently.

Our food work, as I noted, did not often get into the area of danger to health other than the spray residue and the food poisoning reports. The big emphasis at this particular time was sanitation violations and economic violations. The economic violations involved such long standing things as short weight, but also involved the new require-

ments contained in the 1938 act. For example, packaging made or formed in such fashion as to be misleading was a very common sort of violation during these particular years. Prior to the passage of the act, it was a common practice in the packaging of certain products, notably tubes of toothpaste and bottles of flavoring extract, to make the outside carton vastly larger than the immediate container of the article. We had examples of toothpaste tubes which occupied 25% or less of the outer carton. Similarly, extract bottles were enclosed in bottles which were taller, wider, and deeper than necessary to enclose the bottles. The bottles themselves were frequently formed so as to be misleading by indenting panels on both front and back of the rectangular bottles so that the volume of the container was much less than would appear from the outside dimensions of the bottle. We had some actions of this kind against local manufacturers who put out products of this sort and shipped them in interstate commerce. Ultimately, this section of the law became impossible to enforce because of some later court decisions that favored the manufacturer's argument in some of the cases that we brought, that the kinds of excess packaging which was used was necessary to protect the product. But in the early years without ever going to court, other than a few seizures, we revolution-

ized most of the industry and brought packaging down to a point where it was more reasonably representative of the contents of the package.

In the area of sanitation, the law outlawed any food which had been prepared, packed, or held under conditions whereby it may become contaminated with filth or injurious to health. This section of the statute was aimed at a problem which had existed for many years. While the FDA was operating under the 1906 act, many inspections showed that food products were made under very reprehensible conditions. But the 1906 act required us to demonstrate the presence of the filth in the food before we could take action. Sometimes this was impossible to do because of the limitations on the methods of analysis. With the new section it was intended that FDA do something about all foods were prepared under conditions where contamination was at least possible or probable.

Initially we did not thoroughly understand what kind of evidence the courts would require to support this kind of charge. So by mostly trial and error various inspectors started out to establish methods of evidence development. I recall being told by Jim Pearson, who was at one time my boss, that when this law was passed he was the resident inspector in Norfolk, Virginia. He and his chief inspec-

tor, McKay McKinnon, immediately started work to develop a case under this section of the law. They picked out a candy manufacturer that both of them knew from previous visits was very insanitary. Arriving at the place, they started to collect exhibits of anything that they thought might be helpful and as Jim said, they left there with almost a car full of various exhibits that illustrated insanitary conditions. When they turned all this amount of exhibits in to their laboratory, the laboratory had no good methods of analyzing most of it, so they simply took measures to preserve it for later presentation in court. Ultimately, the case came to trial in the court and they presented their testimony as to their observations and displayed some of the more graphic exhibits they had, with the result that they won the case. It was from this kind of experimentation that people developed ways of doing things. The laboratory, with leadership from headquarters and a lot of innovations in the field, developed methods for recovering small amounts of insect parts or rodent hairs, which would demonstrate to the court that in all probability a mouse or rat excreta pellet had been dissolved in the product at some stage of the manufacturing. Various inspectors experimented with photographs with some rather striking results. And gradually over four or five

years more or less standardized procedures for handling these cases came about.

My first experience with it was a case in Portland about 1941 when another inspector and I visited a place called Sweetarts, Incorporated, a manufacturer of candied fruits. We had just received our first camera with an attached flash gun, so we were out to experiment with our picture taking abilities. We found this place to be an excellent one for such experimentation, because it was literally overrun with rodents. They had left their excreta adhering to trays of candied fruits which were in various stages of manufacture. And we had no difficulty in getting some striking black and white photographs of the conditions that prevailed. While our efforts, in hind-sight, were not nearly as good as they would have abeen four or five years later when we had more experience, they still were sufficient to support a criminal prosecution of the manufacturer who pleaded guilty to the charges. Our purpose in these kinds of cases was to demonstrate that the manufacturer was operating under conditions which would be abhorrent to any ordinary consumer if they became aware of them. At that time, sanitary conditions in food factories were, generally speaking, much worse than they are today. It was not uncommon to find evidence of gross contamina-

tion by rodents or by insects or by insanitary personal practices on the part of the employee. Today, the kinds of insanitation that we find are more subtle and usually much less gross than they were in those days. On the other hand, people have become accustomed to expect better sanitation and the conditions that we take action on today are the ones that the general run of people under today's standards would find inadequate.

Porter: Don't you think that some of that occurred by education, but the very people involved in these manufacturing operations have different personal standards which have affected conditions.

Losvold: I think that's true, certainly in the early times our efforts gave great impetus to training programs put on by the industry, particularly in the candy and bakery industries to improve their operating procedures and their sanitation. I believe that the net result has been over the years a good one from the standpoint of consuming public.

Porter; What did you do in the way of drug work in those days Fred?

Lofsvold: Our drug work in Portland and also in Seattle was very limited. We had no real manufactures of prescription drugs, but as I mentioned earlier we did have some

manufacturers of proprietary preparations. In those products our interests was principally the claims that manufacturers made for the products. In addition to our manufacturing firms we collected samples requested by other FDA offices so that they could bring legal actions against their drug firms which were violating the law.

Our interest in products that were labeled with a false or misleading claim was not only to protect the public from being cheated monetarily because they had bought something that wouldn't work, but also to prevent their being injured by depending on a worthless product in lieu of adequate medical treatment. I remember two cases that illustrate this aspect of misleading claims. One of them was a manufacturer in Portland who prepared a product, an escharotic, he recommended for the treatment of cancer. Most of his business was local, but he did ship some in interstate commerce which gave us jurisdiction. This man was in the regular business of manufacturing radiator cleaning compounds and similar industrial chemicals, but he operated his medicinal venture from the same shop. We brought a criminal action against him charging him with shipping a product in interstate commerce which was misbranded by false and misleading claims for the treatment of cancer. At the time that the case was being tried in

Portland Federal Court, the newspaper carried a story about a woman who had purchased his product to treat breast cancer after refusing to undergo surgery. At the time of trial she was dying of cancer in a local hospital.

The other instance involved a preparation from the Denver station area called Diaplex. This was a supposed treatment for diabetes prepared from a common weed that grows in that area. The manufacturer distributed it throughout the western part of the United States and may have been nationwide. One of his customers was a man named Henry Legler in Boise, Idaho. In 1941 while I was on a field trip to Idaho, I was asked to collect a sample from a shipment made to Mr. Legler. I found him at his job of an elevator operator in the State Capitol. Henry had suffered from diabetes for many years. One leg had developed gangrene and had been amputated above the knee. Despite this advanced stage of his disease, he refused to use the insulin his doctor had prescribed and relied on Diaplex. I was unable to collect the sample because he was so convinced that Diaplex was a valuable drug that he would not allow a government agent to in any way interfere with its distribution. A year later I returned to Boise and, visiting the State House on other business, I asked about Henry Legler. I was informed that he had died six months before from complications brought on by his diabetes.

Porter: Fred, you were down in Portland and you were a long way from headquarters in Washington and, for that matter, from San Francisco. Did you have contact with technical people from Washington and people who had important jobs in administration and that type of thing?

Losfvold: To a limited extent. I remember that in 1940 when I was first transferred to Portland, the Western States Association of Food and Drug Officials held their annual meeting in Portland. Dr. Paul Dunbar, who was the Deputy Commissioner, and Mr. Walter Frisbie, who was head of federal-state relations for FDA, both attended the meeting. This was the first contact I had with anyone from Washington and I was greatly impressed, especially by Dr. Dunbar who, at that time, was a very dynamic individual. I didn't see Dr. Dunbar again until 1946 and was struck at that time by how much he had changed, he had aged considerably in that ensuing period.

We regularly saw Mr. Harvey from the District Office in San Francisco. He stopped in usually three or four times a year when he was traveling throughout the district visiting the stations. It was, I believe, an advantage for us at the substation to meet these dignitaries because in the less formal atmosphere of a very small office they were much more relaxed and had an opportunity to talk with the

operating inspectors and chemists to an extent that would not have been possible in a larger office.

Porter: You know, my experience paralleled that in being in Salt Lake City, the same thing happened. They would stop en route from Denver to San Francisco. In the station they would obviously or naturally spend most of their time with the station chief, but in a place like Salt Lake and I'm sure in Portland, those of us who were just inspectors were the people that they spent their time with.

Lofsvold: And in addition to seeing them at the office, we often would go out and drink beer with them and have dinner and meet them on a social basis which was, I think, very useful to us younger people in learning about not only the individuals who were running the outfit, but also in picking up information about problems as they saw them.

Porter: In Salt Lake, J. Edward Kimlel who was the Deputy Director of the district came out, for instance, and made some inspections because he wanted to sort of refresh his feeling for the plants. And I remember him telling us in Salt Lake, you must have a tremendous bakery here in town because I see these great big trucks with PIE on them and he apparently wasn't aware that PIE stood for Pacific Intermountain Express which was a general trucking company and not a pie outfit in Salt Lake.

Lofsvold: You know, what you said there about refreshing their experience was true about our technical people in headquarters, too. In the summer months at Portland, we got visitors from the Washington laboratories who came out to go with us on inspections of all kinds of establishments, but principally the fruit and vegetable establishments. For instance, Victor Bonney was in charge of the canned foods laboratory in the headquarter's division of foods. Mr. Bonney spent a month or more on two different occasions going with us on inspections of canneries and talking to the managers and superintendents of the canneries about about new developments in that industry. Similarly, Bob Osborn, whose specialty was beverages including fruit-type drinks and flavoring materials, visited factories with us at least one year in order to bring his knowledge up to date.

These people were the agency experts in their particular field and conscientiously made the effort to keep abreast of what was current in manufacturing processes and other innovations that might be taking place in that industry. Of course, those of us in the field who were assigned to act as their chauffeurs and to take them around to these various plants often wondered whether the weather in Washington in the days before air conditioning had some bearing on the way they timed their trips to the field.

Porter: Did you have a lot of microanalytical people come out?

Lofsvold: We had some of that, but I was not personally involved in it. I remember that one year John Wildman from the microanayltical laboratory, came out on a survey of tomato products and spent considerable time preparing authentic packs of tomato products containing varying amounts of rotten tomatoes to correlate his microscopic findings on the finished article with the materials that went into it.

Porter: That was when they were developing the rot fragment count, I think?

Lofsvold: I believe so. I think it was perhaps 1944 or thereabouts.

Porter: I worked with him in Western Colorado that same summer.

Lofsvold: When he came to the Seattle area, Charlie Cooley, another inspector, conducted him throughout the region.

Of all the visitors we had, I think that I was most impressed with Jack Harvey. From the time that I met him as a new trainee in San Francisco I recognized him as a man of superior abilities. He was a very personable man and had a tremendous command of the language. He was an

inspiring kind of leader, but at the same time retained a common touch so that anyone of his subordinates, no matter what their job could approach him and talk about any subject. He was extremely interested in enforcement proceedings and almost always turned up whenever there was an interesting case being contested anywhere in the Western District. His interest in the law and its enforcement ultimately led him to become an attorney and a member of the Bar in Virginia about the time that he retired from FDA as Deputy Commissioner.

During his visits to Portland, we had many sessions with him, both in the office and outside, in which we discussed any subject that anyone wanted to bring up. In those particular years, I believe that he was the most effective leader that I ever worked for.

Porter: Of course, I worked for him out here as you did for many years, but then when he became the Deputy Commissioner years later, I went to Washington on a personal trip and I had never been to see the Food and Drug offices in Washington. So I went in and I thought well, I'll just see if Mr. Harvey has time to say hello and shake hands. He was Deputy Commissioner and I realized he probably would be too busy. But when his secretary told him that I was there, I was invited in and I sat down in his office and I

think we talked for an hour just in the most friendly fashion. You know, not only is that really kind of an informative experience for somebody, but you're inspired by a man who will treat you that way and who is an important man.

Lofsvold: Correct. Now this opportunity to meet with the leaders of the agency came to a stop for me, however, in January of 1943 when I was transferred to the resident post at Spokane, Washington. At that time, Spokane was the most remote resident post from the most remote station, Seattle, from headquarters, so you were rather isolated. I was there for a little over three years. During that time I believe that I saw the Chief Inspector five times at Spokane, went into the Seattle headquarters only twice, and talked to the Seattle office only once by telephone.

Being in such an isolated position, however, was not all bad because it gave me opportunities of independent action that I would not otherwise have had. The Spokane assignment required considerable travel because the inspector there was responsible for northern Idaho and western Montana and also was required to make occasional trips to southwestern Idaho. The southwestern part of Idaho also was covered by Portland inspectors, so the trips to that area were usually alternated.

During the three years that I was there, the work included a continuation of the emphasis on sanitation in bakeries and candy plants and during that time we began getting interested in sanitary conditions in flour mills. Another industry that required much attention was the manufacture of dairy products, particularly cheese. As part of the effort to increase food production during World War II. the federal government encouraged the establishment of new cheese factories. Much of their output was purchased by the government, not only for feeding the military, but also for shipment to allied nations abroad. In western Montana, for example, there were about eight or nine cheese factories where none had existed before the war. The farmers who supplied milk to these plants formerly had separated their milk on the farm and sold the cream to local creameries for the manufacture of butter. This was a sideline with these farmers and they did not fully understand the need for sanitation in the production of milk or the manufacture of cheese. As a result, the milk being delivered to the cheese plant was often contaminated with manure and other extraneous material.

Our work in the cheese factory covered the examination of incoming milk for sediment and the inspection of sanitary conditions in the manufacturing and cheese storage

area. The condition of the milk in many instances was deplorable and we tried to bring pressure either directly on the plant or through state dairy agencies to force the plants to improve their milk supply by educating the farmers and rejecting unfit milk. These efforts were not wholly successful, but I believe that we did correct the most gross conditions during these years that we worked in the area. After the war, most of these cheese plants went out of business.

Porter: I think our efforts were very good for Johnson & Johnson who sold milk filtering equipment and the farmers learned to filter their milk so that the obvious sediment was no longer there and only the soluble part of the manure that didn't show was still there. And you know, Fred, I expect it was like this in Montana, but in those days I was working in Utah and parts of Idaho and it was not uncommon to see the farmer go out into the field with his buckets and cans and just milk the cows wherever they were, you know, with no effort to clean them off or to be operating in a place where you could keep things clean.

Lofsvold: That's right. I think they had always done that but when they separated their milk, the separator removed that sediment from the cream that was sold for butter and they used the skim milk to feed the pigs. So they were not

used to the idea that you should clean up the cows and take other precautions to protect the milk before you shipped it off to market.

Porter: That kind of business doesn't exist any more now, I don't think, or at least practically --

Lofsvold: I believe that even the farm separation of cream is extinct, that nowadays butter is made from properly prepared whole milk delivered to the factories from large dairies.

Porter: Milk that would probably meet Grade A standards.

Lofsvold: Yes, I would think so. In southern Idaho, the emphasis was on preparation of butter and dried skim milk at large centralized plants. These were in considerably better condition because they had been this business for some years, but again the war time pressures got more people in the dairy business delivering milk and so they had their problems also in keeping the milk supply clean. In general, however, those plants were better managed, had better educational procedures and did a better job than the brand new cheese plants that had just started up in business.

Porter: Now, these were just little tiny producers. It would take maybe a hundred producers to get the milk for one plant.

Lofsvold: Yes, the farmers were not full time dairymen. They had a few cows in conjunction with whatever other kind of farming that they did and so the dairy part of the operation got less off their attention than the other part that represented the bulk of their cash income.

Another war time problem was the use of mineral oil as a substitute for edible vegetable or animal fats. It was a problem to which we gave considerable attention because the agency recognized that if we permitted this kind of substitution it would be damaging to the nutritional value of the country's food supply. Mineral oil not only was useless in human nutrition, but it also had an adverse effect in that fat-soluble vitamins would dissolve in the mineral oil and be carried out of the body without being absorbed. We found mineral oil at various times being used in salad dressings, as a grease for bread pans in bakeries and introduced into various kinds of foods. In Spokane, one manufacturer of popped popcorn for the theater trade was substituting mineral oil for vegetable oil in his product. We brought a seizure action at Coeur D' Alene, Idaho which was contested in Federal Court there. The government lost the case, the judge finding that the amount of mineral oil present was too insignificant for his attention. We chose not to appeal the matter.

Another case, however, involving filth in peanut butter was more successful. During an inspection of a Commercial Creamery Company in Spokane in 1944, I found that there were a large number of mice in the factory. They had chewed holes in bags of shelled peanuts before roasting and left evidence of having been in and on the equipment used for holding the roasted peanuts and packaging the finished peanut butter. I collected samples of the peanut butter from outgoing shipments on the auto freight docks within a few days after the inspection. Analysis at the Seattle laboratory recovered rodent hair fragments from the finished product confirming my observations that the mice had an opportunty to contaminate the finished product. We brought criminal action against the company. They pleaded guilty to charges of shipping four different shipments of peanut butter which we charged was adulterated because it contained a filthy substance and also because it was prepared under insanitary conditions.

Our general counsel prepared the criminal information for the U.S. Attorney charging four counts based on the four shipments, each of which was adulterated in two different ways. The United States Attorney decided that it should be eight counts charging one count for each kind of adulteration rather than one count per shipment. He

notified the general counsel that he intended to rewrite the criminal information. The general counsel, Pat Cronin, wrote to the U.S. Attorney, Ed Connelly, advising him that this was improper, but Connelly persisted and charged eight counts.

The case came up for sentence on a guilty plea before Judge Schwellenbach, a former U.S. Senator. Judge Schwellenbach had the reputation of being anti-government in almost any case brought before him. I was therefore astonished when he sentenced the company to the maximum fine of $1,000 on each of the eight counts. Some time later, I asked the Chief Assistant U.S. Attorney why this had happened. He said that he, too, had been surprised but on careful inquiry had found out that the judge had been placed on a rather restricted diet by his physician a few months before this case came up. The diet required him to eat large quantities of peanut butter as a substitute for meat and he had been using the Commercial Creamery product.

Another interesting investigation involved the use of hair lacquer pads manufactured by a Chicago firm. I got involved in September of 1943 when I was on one of my rare visits to the Seattle office. Just before I was ready to return to Spokane, we received an assignment to investigate several reported injuries caused by this product. The product consisted of cotton pads saturated with a lacquer

solution. Women dabbed their hair with these pads to make it stay in place. The pad served the purpose that aerosol hair sprays serve today. Unfortunately, there had been a change in the formula because the war caused a shortage of certain lacquer ingredients, with the result that the new ingredients caused severe reactions in many young women who used the product. Two of the reported injuries were in Boise, Idaho, so I took the night train back to Spokane, picked up my government car and drove to Boise at thirty-five miles an hour, the World War II speed limit. I arrived there very late at night. The next morning I was able to find the two injured women, got statements from them and obtained samples of the product.

My samples were not involved in the subsequent legal actions that were brought against the shipper, but the case ultimately resulted in a very useful appellate court decision. The court held that even though the firm that shipped the goods had not manufactured the article and had not known that the actual manufacturer had substituted ingredients which caused the action, the shipping firm still could be held criminally liable since it was their responsibility to insure that the product they shipped met the requirements of the law. The case involved the Parfait Powder Puff Company in Chicago, Illinois, and was decided in the Circuit Court in Chicago about 1948.

Porter: How serious were the reactions, were they --

Lofsvold: They were very painful but not permanent. The product caused swelling in the area of the ears and behind the ears. The skin would break open, bleed and it would take several days or weeks to heal up. So it was not a trivial reaction, it was quite painful to the people involved.

Porter: As I recall, Fred, then in 1946 you were transferred to Seattle and promoted to the position of Assistant to the Station Chief.

Lofsvold: That's right. In March of 1946 I was offered the newly created job of Assistant to the Station Chief, but it was not a promotion. In fact, it was the common practice in those days to transfer people without giving them a promotion. When I went from Portland to Spokane, the grade for a resident inspector in a one-man post was P-3, but I was not promoted to that grade until I had demonstrated that I could handle the job. I believe the promotion came about eight or nine months after the transfer.

Similarly, I was offered the job in Seattle but moved there without a promotion and received it about five or six months after I had made the move. I think this was generally true of all jobs in the Food and Drug Administration.

If you did not for some reason demonstrate that you could handle the new job they then could move you into another job at your old grade without any problems of demotion.
Porter: I never had a transfer and change of job and a promotion simultaneously in my whole career.
Lofsvold: Well, I think the only one I had where I got a promotion when I moved was -- no, I was going to say when I went to Philadelphia, but even there I moved without a promotion and it didn't come for several months. I believe that's true of me also.

At any rate, I went to Seattle in this job which had been set up around the country in almost all stations to relieve the station management of some administrative tasks. Prior to that time, the chief of the station, the chief chemist and the chief inspector had handled all of such tasks as holding hearings, corresponding with consumers and firms, reviewing all of the reports from the inspection force and the laboratory and preparing recommendations on legal actions. It was concluded that the volume of such work now justified additional help in these areas and the newly established jobs were ended to provide this relief. Unfortunately, no clear guidelines were laid down as to what these individuals appointed to the new positions should do. As a result, they functioned in

different ways at different stations, according to the ideas of the station chief. I was fortunate in that my boss concluded that I should try my hand at almost all of the tasks that he was involved in, and as a result I got a very broad education in the management of the office. At some other stations, particularly in the eastern district, the assistant actually performed as an assistant to the Chief Inspector, and thereby was limited in the kinds of things he was permitted to do.

Porter: This was Monfore?

Lofsvold: Yes, by this time, Ken Monfore had become the Station Chief in 1944 when Bob Roe had been transferred to Los Angeles as chief of that office. Monfore's idea was to delegate to me a wide variety of duties and I was able to try my hand at almost anything there was to be done. Because of this opportunity the job became more important and the title was changed to Assistant Chief with another promotion. Actually, it involved operating as a deputy to the Chief who after the 1948 reorganization became known as the District Director.

At first when I started this job, I had some difficulty figuring out how to get things done. I had begun my FDA career at the Seattle office, but after six months or so I had gone out to the resident post first at Portland

and then at Spokane, so I had only the foggiest idea of office procedures. Generally, I knew what I wanted to do, but I sometimes did not know how to do it. Fortunately, I had a lot of assistance from the chief clerk, Laurel Liddle, who used to laughingly say that she had trained five station chiefs in her time. She undertook my training in FDA internal procedures and I soon was able to handle that part of the job. The experience that I gained in this particular job was very valuable to me later in my career. It was the first time that I had been involved at all in management, so I had a great to learn. In those days management, at least in FDA, was not a well-defined science or art as it is today, and people learned mostly by on the job training from their supervisors who had learned in a similar fashion. I don't know whether formal management training was yet available anywhere but certainly in the FDA, the theoretical side of management was something no one ever talked about. It was not until about 1966 when Jim Goddard became commissioner that any form of management training was introduced for FDA people.

After I had been on the job two years the agency underwent a nationwide, fundamental kind of reorganization. The three geographical district offices were abolished and each of the stations was elevated to the status of dis-

trict. Each district reported directly to Washington headquarters which was also reorganized along functional lines. Mr. Harvey went to Washington to head the new division of litigation which was charged with managing all regulatory actions in the field. Monfore went with him as his deputy. The other new divisions were the division of program planning, which was headed by the former chief of the central district, Jimmy Clarke and the division of field operations headed by the former chief inspector of the eastern district, Mr. Allan Rayfield. When Monfore left, Jim Pearson, chief inspector at Atlanta, came to Seattle as the district director. Because he had operated in the eastern district throughout his entire career, some of the procedures which he introduced were different than those we were used to, but we soon learned to appreciate Mr. Pearson's ability and I found him an excellent man to work for. He was unfailingly patient in teaching me those things that I needed to know. The reorganization had a rather marked effect on the field offices. We no longer had the advantage of the district office in San Francisco as a source of information and advice. We were given additional responsibilities in responding to correspondence with people outside FDA and in a very short time were given additional duties in the preparation of cases submitted for legal action. The district

offices were required to prepare drafts of the pleadings in seizure, criminal, and injunction cases, to expedite consideration of the case and conserve the scarce manpower in the office of the general counsel. This job fell to me and at first I was very perturbed at the prospect of drawing up these legal documents. With a little practice, however, it became quite easy to do and most of the time the pleadings which we prepared locally following instructions and models sent to us were accepted by our attorneys and sent as is to United States attorneys for filing.

On the negative side, the reorganization curbed some of the informal free wheeling we had followed for years in the western district. Because Mr. Rayfield had come from the eastern district, where things were done on a more formal basis, we were now required to prepare more detailed work plans and to file reports with headquarters that previously we had not been required to do. Another negative effect, at least as we at Seattle perceived it, was the thought that FDA now was a national organization and employees were subject to transfer anywhere in the United States. Prior to that transfers ordinarily were only within a large geographical district so that anyone appointed to one of the western district stations could usually look forward to a career in the West. Now it soon

became very obvious that people were going to be transferred to anywhere in the country, a prospect that did not appeal to us dyed in the wool westerners.

Porter: It became a fact for me in three years. I was transferred from Salt Lake to Chicago and that was a fate worse than death. I turned out to like Chicago work pretty well but I didn't know that ahead of time.

Lofsvold: In my own case, it came somewhat later, but was from Seattle to New York which was something of a cultural shock but after I got acquainted with the place, I found that it was a fascinating place to work.

One of my duties was the administrative handling of import goods. All foods and drugs and other articles subject to the laws FDA enforces are subject to examination when offered for entry through customs into the country. My job was to review the customs papers filed each day and to decide which of the shipments, if any, should be examined in the laboratory to check its compliance with the law. The decisions on which shipments to sample were based partly on experience with the particular commodity or the particular shipper involved and partly on information which we received weekly from other districts in the country as to violations they were encountering. I found this work extremely interesting, especially because at the time I

went there in 1946, the import trade was just being revived after World War II. During the war many of the countries that normally shipped goods to the United States were unable to do because of lack of shipping, occupation by enemy forces, and so on. This was particularly true of the East Indies and other places which normally supply spices. Many of these places had been cut off for four or five years and spices that had accumulated in warehouses there had become moldy, insect infested, or otherwise unfit for use. For a year or more after importations were resumed, we had a great deal of difficulty with such products and detained many shipments and required them to be re-exported. Also about that time, certain other countries, particularly France, began shipping alcoholic beverages to the United States in bottles which were of inferior quality. This condition probably was also the result of wartime shortages and disruptions of manufacturing in Europe. The bottles contained bubbles in the glass which broke and released sharp splinters and flakes of glass into the contents. For several years, almost every shipment that came in had to be candled by inverting the bottles in front of a bright light to see whether there were splinters of glass floating in the contents. This resulted in many detentions and re-exportations also. Gradually, these kinds of problems

caused by World War II cleared up and we resumed more normal import surveillance.

At various times certain products gave us problems. For example, one year during the late 1940's, the Alaska pink salmon run was almost a complete failure. To get pink salmon for the market, canned salmon was imported from British Columbia, a very unusual kind of commerce, since Canadian salmon generally was shipped to England and other parts of the Commonwealth. Examinations of some of the early shipments showed a relatively high percentage of decomposition in the canned article with the result that we made several detentions. Both the importers and the Canadian authorities were quite disturbed by these actions and intimated that we were being unreasonable. We had meetings with the importers and the Canadians both in Seattle and in Vancouver, B.C. and finally convinced them of the accuracy of our findings. As someone described it at the time, it appeared that the Canadian salmon canning industry was about twenty or thirty years behind the American industry in the matter of making certain that their canned salmon was not decomposed at the time it was canned.

Another problem with the Canadians was the shipment of apples containing excessive spray residue. These originated in the interior part of British Columbia and were

consigned to manufacturers of apple sauce and similar products in the San Francisco bay area. The rail cars were almost impossible to sample at the time that they entered the United States and consequently when the reached the destination and were sampled and detained there the importers were insistent that they be allowed to clean the apples at that point. The volume of this traffic put an excessive burden on our San Francisco office which was required to draw the samples, examine them, do the paper work of detaining, and to supervise the cleaning of the apples. In order to discourage this practice and force the Canadians to clean the apples on their side of the border, we took the then unusual action of detaining the apples and refusing to permit the reconditioning forcing them to spend the extra freight to haul the apples from San Fransico back to Canada. This quickly put a stop to their previous practice and apples began to come across the border already cleaned below the tolerance for lead and aresnic.

Another campaign which we began and then wished that we had not, was a coast wide program to shut off the importation of Chinese herb remedies labeled with false and misleading therapeutic claims. At that time almost every city in the coastal states had a Chinese herb doctor who practiced a traditional Chinese kind of medicine treating

his patients with mostly infusions and teas made from various kinds of vegetable materials. This had been a practice of long standing in the west dating back to the gold rush days and the patients included not only people of Chinese descent, but also many Caucasians. Someone in San Francisco decided that we should impose the requirements of the Food Drug and Cosmetic Act on these products on the basis that they were worthless for the conditions for which they were being used. The medicinal claims were made for the products on their labels generally in Chinese, sometimes in English, and also in collateral printed material prepared by the Chinese practitioners who used them. In a coordinated effort, Los Angeles, San Francisco and Seattle began detaining these products and were soon joined by the other coastal districts throughout the country. We shut off fairly effectively the legal flow of these goods but soon found that the importers were using ingenuity in bringing the goods in both legally and illegally to avoid our surveillance. We never did completely solve this problem but the question became moot when the Chinese Communists took over the mainland and all importations from China were banned.

My primary duty however, was the handling of regulatory matters for the district. I reviewed factory inspec-

tion reports and drew the district conclusions as to follow up. I also reviewed reports from the laboratory to decide whether legal action should be instituted. In either case, I prepared the district's recommendation for action and sent it forward to Washington headquarters. In many of these cases our policy although not specifically set down in writing, was well understood by everyone, and I could make the decisions entirely on my own. In any other kind of case, where there was any doubt or in situations which were novel, I consulted with Chief Inspector, Chief Chemist and the District Director, to make certain that we all agreed on the proposed action. Once the actions were approved and returned to the United States Attorney for filing, it was my duty to maintain the records to insure that the cases proceeded promptly.

In Seattle I maintained close contact with the United State's Attorneys office, but in Portland, Spokane and the other resident posts which were opened later the resident inspectors performed this function. In places like Montana or Idaho where we did not have residents, I carried on the liaison by mail or by telephone, or traveling inspectors checked the status of cases as they passed through the area.

At that time the district had a good deal more responsiblity for this kind of work than at present. The General Counsel's office did not have enough attorneys to maintain contact with the United States Attorneys directly. On certain difficult and important cases, they did correspond with the United States Attorneys and in the western area one general counsel's attorney, Mr. Arthur Dickerman was stationed at Los Angeles and was available for consultation. On the more routine cases, however, the district carried on the contacts and provided the assistance attorneys needed either from district resources or if the question was one the district could not handle, by passing the question along to the general counsel.

When cases came to trial, the district always had a representative on hand to assist the United States Attorney. If it were an especially difficult case, an attorney from the general counsel and other expert advisors would be present, but in many of the actions, the district personnel handled the matter themselves.

I recall the first case in which I had the responsibility of representing FDA during trial. It was a prosecution of a frozen berry packing plant in Kalama, Washington and was tried in Federal District Court in Tacoma. The company, when they were packing strawberries, had sorted

out the partially rotten strawberries from the sound ones, and had tried to save them for the preparation of strawberry juice. They put these unfit strawberries into barrels and shipped them to a cold storage house in Portland, Oregon thereby placing them in interstate commerce and subjecting them to the provisions of the Food, Drug, and Cosmetic Act. We sampled the goods, found them partly rotten and brought seizure action against the article. Because the firm had a history of doing this sort of thing, we brought a criminal action against the firm and the responsible management.

The trial was interesting in several respects. The judge was a visiting jurist from Honolulu who on the first day issued pads and pencils to the jury and urged them to take notes on the testimony just as he was doing. It was the only time that I ever saw this done and I believe it was almost a unique practice to permit the jurors to make notes. Most judges will not permit any note taking at all during the trial by the jury. The case was tried by a very experienced Assistant U.S. Attorney, Harry Sager, who presented our case very well. The defendants introduced testimony from a commercial laboratory and from USDA grade inspectors refuting the charge that they had ever packed moldy berries and the case went to the jury.

At the time the jury was being selected, there was one individual among the jurors who appeared from his answers to questions to be anti-government. Mr. Sager and I discussed whether we should peremptorily challenge him to get him off the jury, but decided not to. I was very surprised late in the evening after the trial had closed, to get a call from Harry in which he reported to me that the jury had found for us on all counts. And he also reported that the juror that we had been so concerned about had been elected foreman of the jury and was for the government from the very first ballot. It was a lesson that I didn't forget, not to trust appearances when you're trying to decide whether a juror should be challenged.

Another case that occurred during this period was one that went on to make food and drug history. It was a case brought against Ira D. Cardiff who operated an apple drying establishment near Yakima, Washington. Dr. Cardiff was a Ph.D. agricultural economist who had formerly worked for the U.S. Department of Agriculture, but about the time that World War II started he had left government service and opened this drying plant. Because the military purchased very large amounts of dried fruits and vegetables, his company had been highly successful. Dr. Cardiff was completely opposed to the idea of government inspection. From

the first time that an FDA inspector had visited his plant, he had consistently refused inspection. This was unusual, but not wholly unprecedented. We had occasional refusals of inspection and all of the inspectors, of course, were always advocating that we bring an action under that section of the statute which required manufacturers to permit inspection.

This was a new section in the 1938 Act, and FDA headquarters and the general counsel were not eager to test it until they felt sure they had a very strong case. With the Cardiff case, we thought we had such a situation. We had just concluded a prosecution of a competitor firm which dried apples and was located across the street from Cardiff. The charge had been infestation with mice which had contaminated some of the apple products.

I prepared a memorandum to headquarters pointing out that we had just completed this case, that we had no knowledge of whether the Cardiff plant was in the same condition but thought that it might well be since it was in the same location and environment. I pointed out the record of consistent refusals to permit inspection and suggested that this was a situation we could very well use to test that section of the statute, particularly since we had a friendly judge in the Eastern District of Washington and

had received favorable decisions from the Ninth Circuit Court of Appeals.

After some period of time, this proposal was approved and the Chief Inspector, Russ White, and one of the other inspectors, Horace Allen, went to the Cardiff plant and were refused permission to inspect. We issued a notice of hearing. At the hearing Dr. Cardiff and his attorney argued that the section of the law was unconstitutional. We brought the case in the the District Court and in 1951 I attended the trial of the case. All of the facts in the case had been stipulated to by both parties. Judge Sam Driver, in his remarks from the bench, acknowledged that there was some question in his mind about the constitutionality of the law, but held that it was constitutional and levied a fine against Dr. Cardiff. Cardiff appealed to the Ninth Circuit Court of Appeals which reversed Judge Driver, finding that the section was unconstitutional. The government appealed to the Supreme Court which about a year later agreed that the section was unconstitutional in that it was too vague to define a criminal act.

As a result, FDA was without authority to make inspections. We continued to make inspections, however, and were refused no more often than we had been in the past. The statute ultimately was amended with the language that now

appears in it. In amending the law, Congress wrote in a number of requirements which had not been there previously including the requirement of written notice to the owner, agent, or person in charge of an establishment, written receipts for samples collected and written observations by the inspector of any conditions he saw which might contribute to filth or insanitation.

At the time that revised statute was passed, the field inspectors and others of us in the field felt that we were being held to requirements which would make it impossible to do our job, but in following those procedures over the years I don't believe that it really hampered our enforcement activities to any appreciable extent.

Porter: I would agree it was strange and I still find it difficult to understand why more firms didn't refuse with the publicity of a Supreme Court decision saying we did not have the authority, but in fact I was in Chicago at that time where we had some pretty sophisticated operators and I don't recall a refusal during that time and it was quite a long time, a couple years, wasn't it?

Lofsvold: I think about that, yes, I think from '51 to '53. And of course our timing was not very good. By the time that we got the Supreme Court decision and brought the bill to Congress hoping to get amended authority, I think

it was the first time in maybe thirty years that the Republicans controlled both houses of Congress and Congress had a very conservative bent and as a result these requirements were imposed on the agency as well as on the manufacturer.

Another interesting piece of litigation I was involved in was a criminal action against Golden Grain Macaroni Company of Seattle. It was a second offense case against the firm for operating under insanitary conditions and it was somewhat noteworthy because it was the only time that I have ever heard of where the judge tried a contested seizure action and a criminal action at the same time. This came about because of some peculiar circumstances. As I mentioned earlier in the Pacific Coast districts, it was common practice to sample shipments of goods on the docks in the hands of the steamship companies before they were loaded aboard ship. Legally, they were already in interstate commerce just as much as if they had been delivered to destination.

When we inspected the Golden Grain Macaroni Company and found their conditions in violation, our inspectors immediately went to the steamship docks to look for outgoing shipments of articles prepared under the conditions they had observed. They found such shipments consigned to

Hawaii and Alaska and collected samples for the laboratory examination. While the laboratory was examining the goods, the stevedores went on strike so that no ships were loaded or unloaded for several weeks in the Port of Seattle. We completed our analysis, and made our seizure recommendations to headquarters. The instructions to seize came back to the United States Attorney and the Marshal attached the goods right there on the dock rather than in the ordinary course of events having to attach them at destination in either Hawaii or Alaska.

Porter: Did you get any static from the U.S. Attorney's Office about whether or not that was proper?

Losfvold: No, they went right along with the idea. There was lots of precedent by then as to where interstate commerce started that covered that kind of point. So the seized goods were in the jurisdiction of the court.

Losfvold: We had gone forward with our prosecution case also and it soon came to the United States Attorney. Both cases were filed. And in an unusual kind of request, the defense counsel, who was a former United States Attorney who had handled Food and Drug cases, proposed to the court that he try the criminal case without a jury and try both cases at the same time.

Porter: Even though one was a criminal and one was a civil action?

Losfvold: Yes, the criminal case required proof of guilt beyond a reasonable doubt, while the seizure cases required proof to the lesser standard of a preponderance of evidence, but the judge assured counsel that he could make that distinction in his own mind and we proceeded to trial. It was a lengthly trial, spiritedly contested but ultimately the judge found for the government in both kinds of case, ordered the goods condemned and destroyed, and sentenced the defendants to a monetary fine despite the fact it was a second offense case.

About three or four years later after I had left Seattle, they brought a third criminal case against the company and at that time one of the owners received a jail sentence.

Another unusual case that happened while I was doing this kind of work involved frozen salmon steaks purchased by the Army Quartermaster in San Francisco for shipment overseas and for distribution to troops in the area. The Army had called for bids for steaks of silver salmon, but the contractor purchased another species, chum salmon, in Canada, trucked them to Half Moon Bay, California and cut them into steaks and delivered them as silver salmon. Chum

salmon is a less desirable species. The flesh of the fish is a bright pink before cooking but after cooking it turns a chocolate color and is not as flavorable as the higher grade silver salmon. It was an economic cheat which was making considerable amounts of money for the contractor.

We were tipped off to this practice by a Quartermaster sergeant who had the information about it and after an excellent piece of investigational work by Doug Hansen, one of the Seattle inspectors, we brought a seizure against the goods. The Army officials responsible for the contract were very disturbed by our action. One day while I was acting director in the absence of Ken Monfore I had a call from the Assistant United States Attorney, John Dore, to come immediately to his office. Arriving there, I found him confronting three full colonels, two from Quartermaster and one from Veterinary Corps. The Quartermaster Corps colonels, particularly, were insistent that we dismiss the libel. Both John and I took the position that this was an important violation and we would not dismiss it even if we had authority to do so, which we did not. We were overtly threatened that they would see that we were dismissed from our jobs, but we maintained our position and they left. The seizure proceeded in the normal fashion to a conclusion.

Afterwards, I learned that the military people were so insistent because one of them was slated to become the next Quartermaster General of the Army and perhaps because of this action he was passed over for this position.

During this period of the late forties and early fifties, we were beginning to bring cases against pharmacists and other people for selling drugs without prescription. Most of the cases in the Seattle area involved pharmacies which were diverting the products, either to non-drug use or for persons who wanted to treat themselves with these potent drugs.

Normally these cases were brought only when we had a complaint or other information indicating that there was potential or actual injury involved. One such situation arose in Anchorage, Alaska in 1952. At that time there was a heavy concentration of military in the area and a lot of civilian activity in mining, construction, and other fields. The town was booming. The health officer reported traffic in amphetamines and other dangerous drugs at some of the bars in Anchorage. Doug Hansen, who was in Alaska on a salmon cannery inspection trip, undertook an investigation in the area. He sought assistance from the local health authorities and somehow information about his investigation became common knowledge in the town and thwarted any attempt to pursue that particular lead.

The next year we had a further complaint from the health officer that there was widespread sale of antibiotics for self-treatment of venereal diseases. He was concerned at the health risk involved and asked our assistance. This time, we decided to make the investigation by not informing any local authorites. Les Baukin and I traveled to Alaska visiting fish canneries and doing other work in southeastern Alaska and gradually worked our way through to Anchorage. As soon as we arrived in Anchorage, we started visiting the local drug stores requesting penicillin and other antibiotics. We were careful in our requests to be nonspecific as to why we wanted them and to make no pretense that we had visited a doctor.

Each drug store we visited freely sold any kind of antibiotic we requested. First we started with tablets, but then to our surprise, we found that they would sell injectable syringes containing up to a 1,500,000 units of penicillin. Since the practice seemed to be so common, we requested assistance and two other inspectors joined us. Before we were finished, we had developed criminal cases against eight of the nine drug stores in town. The only reason we did not include the ninth drug store was because it was not listed in the phone book and was located in one of the suburbs and we were not aware of its existence until

we had identified ourselves and started making our close-out inspections.

Because the daylight hours are so long in that part of Alaska in the summertime places of business were open almost twenty-four hours a day. It was an interesting experience to finish a close-out inspection at one drug store at 11:30 p.m. and start another such inspection at another store at that hour and still complete it before the drug store closed.

The criminal cases were brought against each of the stores, including one operated by the president of the territorial Board of Pharmacy and another operated by the Board's secretary. Our examination of hospital records after we had finished developing the cases showed at least one death from the promiscuous use of chloramphenicol. A woman who had taken that antibiotic to treat a cold had developed aplastic anemia.

The cases ultimately were settled by guilty pleas and the pharmacists were fined.

Porter: I was interested in your working your way up through Alaska to Anchorage, Fred. How did you travel at that time? We had reports of earlier travel up in Alaska and some of the difficulties and by the time you're talking about which was, when, in the early fifties?

Lofsvold: In 1953. By that time commercial aviation was well developed in Alaska, particularly in the parts where we were working. We flew from Seattle to Ketchikan with Pan American in, I think, a DC-4 at that time. Then through Southeastern, we rode the Grumman Goose which was a twin engine propeller driven amphibian plane built for the Navy during World War II and used by the small local airline to go between cities. It operated much like an inter city bus would in the continental United States, about as equally informal. They carried no co-pilot, just a single pilot who not only flew the airplane, but also took the tickets and stowed the baggage. It was an interesting way to travel. From Juneau then, traveling into Cordova and on out to Anchorage, we flew again with commercial airlines in a DC-4. Some of the more remote canneries at that time, we would visit by float plane. On this particular trip we didn't cover any of those but in the usual cannery inspection operation they would charter a small float plane to take them to those places.

Porter: I see.

Lofsvold: This was a vast improvement over what had prevailed before World War II and during the war when our inspectors caught rides on cannery tenders and other small vessels that were going between canneries, and found their

way across Alaska any way that they could. I believe that by now things have improved to a greater extent and there are more of the small commuter lines so that there is scheduled travel to most places although there are still some remote spots where we have to charter a small float plane to get in.

Another project that came into prominence about this time in that area was our program on cleaning up the wheat supply. Having started with bakeries, then proceeding to flour mills, the next logical target for the sanitation campaign was the wheat itself, from harvest to storage and shipment to the mills. In order to get data on this subject, there was a national survey made in which we sampled carloads of wheat at the mill, followed the wheat through the milling process, and determined what the process would do in the way of removing such things as insect damaged kernels, insect and rodent exceta pellets from the wheat. Once we knew how much filth the normal process would remove, a tolerance was set on the amount of excreta pellets or insect damage above which we would take action against in wheat. Such actions were brought against carloads of wheat sampled at the mills. This work held some risk to our inspectors, particularly inspection of some old dilapidated storage elevators. But it was very

successful in improving the quality of the wheat and improving the conditions under which it was stored. We got into some political difficulties with this program in its early stages. The agency had established a limit of one rodent excreta pellet per pint of wheat sampled in a specified method in a rail car. In 1953, soon after the Department of Health, Education and Welfare came into being, and FDA was transferred from Federal Security Agency into that department, representatives of the grain industry complained to the brand new secretary, Mrs. Hobby, about this tolerance, with the result that we were directed by the Department to increase the tolerance to two pellets per pint, at which point it stayed for many years before we were able to bring it down to the one pellet per pint tolerance. Despite this higher tolerance, the campaign was a very successful one.

Another problem resulting from World War II, and occupying our time for several years thereafter, was the problem of supervising the disposition of ships' stores. The thousands of Liberty and Victory freighters built during the war were not needed once the war was over and gradually they were withdrawn from service and laid up at various ports along the coastline. All of the food stuffs and drugs on board intended for use by the crew were unloaded at the time these ships were decommissioned and had

to be inspected by FDA before they could be disposed of as surplus on the civilian market. This became quite burdensome because much of the food materials were unfit by the time they were unloaded. Ships that had sailed in the tropics were invariably heavily infested with insects. Flour which was unloaded was buggy and rat damaged and required denaturing before it could be used for animal feed. The various drugs, some of which were quite potent, had to be examined and the Maritime Commission advised as to which lots could be released and which were required to be destroyed. It took considerable manpower at the various districts located at port cities.

Porter: Well, Fred, are there any more things about your Seattle tour of duty you would like to talk about before we go to your transfer to New York and the things that happened there?

Lofsvold: Well, the time that I was in Seattle, particularly the last few years, the late 40's and early 50's, was the time of the Cold War. That brought about in this country, an air of general suspicion and there was an executive order issued by President Truman about loyalty of public employees, I think it was the aftermath of the Alger Hiss case, and things were sort of leading into what came to be known later as the McCarthy era. During that period, under

that kind of situation, there were allegations made about the loyalty of federal employees in various departments. None of them involved any of the FDA people at Seattle. There was at least one case involving an inspector at New York, Kenneth Cole, that I learned about later. Cole was accused of being a member of some kind of group that was on the Attorney General's list as being subversive. There was an investigation and as a result, Cole was fired, but he sued and the case went all the way to the Supreme Court, where it was decided in his favor. He came back to work, while I was at New York and was restored to duty as inspector and paid for the several years that he had been off the roll. But I didn't know of any other FDA people that got involved. Actually, we did get a little inkling of the kinds of things that were going on, however. An employee of another agency in the Federal Security Agency where FDA was located at that time was accused of holding meetings with other people in some kind of a subversive situation. The information was turned over to the Federal Security Agency which had a policy of appointing an attorney from the General Counsel's office to make a separate investigation of behalf of the employee. Joe McGuire, a trial attorney from the General Consul's office in Washington, was assigned to this particular case in Seattle and when he

came out there, since he knew all of us because of his representation of FDA in his regular line of work, he came around and sought assistance. We let him have one of the government cars and a few days later he came around and asked for help in the investigation. We assigned one of the most experience inspectors we had to work with Joe for several days on this matter. They were able to identify the informants who had given the original information to the FBI, identified in the FBI reports only by initials. When they interviewed these informants, they found that the charges were based on very nebulous grounds and one neighbor who had complained that the government employee had clandestine meetings at his house, was unable to identify the accused employee when shown photographs of several individuals. As a result of this work, this employee was cleared of any suspicion of wrongdoing. The case, I think, was probably typical of many of the cases that were brought as charges against government employees during that particular period.

Porter: Fred, it seems like then you got transferred to New York and kind of to a new world, why don't you bring that up now?

Losfvold: In April of 1955, I reported to New York as Assistant Director, as the job was called. Virtually all

of my time was spent on compliance work; holding hearings, preparing summaries and recommendations, maintaining the contacts with the United States Attorneys, representing the District at the trial of contested cases, and so on. I had no regularly assigned staff except for the legal processing clerk, but the volume of complaince work was such that other people were occasionally drafted to help me out. Most of their help consisted of holding the hearings and preparing summaries and recommendations to headquarters on proposed actions.

It was quite a cultural shock to go from a small city on the west coast into the largest city in the country. And from a work standpoint, there also was a great adjustment that had to be made. Because of the population, and the concentration of industry at New York, the volume of work possible for FDA was staggering. Although the staff there was the largest in any field district being about one hundred to one hundred ten people, it was woefully inadequate to provide the depth of enforcement activities I was familiar with in Seattle. At that time the Seattle staff was about thirty-five people and we had a pretty good idea of all the food and drug industry in our area. I found that at New York, however, there were firms that no one had ever visited and, in fact, some that we didn't know about

at all. They would come to our attention by accident or happenstance and we would learn that they had been in business for fifty years and had never been visited by a Food and Drug inspector.

Porter: Wouldn't you, now just as a kind of a rough guess, I would think that the work load in New York was at a minimum ten times what it was in Seattle, you know, the real work load.

Losfvold: I would think so, I'm sure that to do the kind of job in New York that we did in Seattle, and I'm sure this was being done at most of the other field districts New York would have needed a staff of probably three or four hundred people. I'm sure you're right. Chicago, I think, would be the only one that compared with it in volume and I think their problem was about the same as New York.

As a result of this, I soon learned that the kinds of factual situations which would have been enthusiastically pursued with a view towards legal action at Seattle were disregarded as being not worth the time and effort to develop the evidence and present it to the court. It was a firm rule that in any kind of sanitation violation, no criminal action would be taken on the first inspection. Warnings would be issued and action would follow if those

warnings were disregarded, but even in serious infestations we did not go to court without having given the firm an opportunity to make some kind of correction.

Because it is the leading port in the United States, the import work load was very large. We had a staff of fifteen or twenty import inspectors whose job was limited to examination of goods on the dock and collection of samples for the laboratory. The import operation was run almost as an autonomous part of the district. Although the import inspectors theoretically were under the supervision of the chief inspector, they operated as a unit under their own supervisor and much of their direction came from the Food and Drug officer in charge of the import operation, at that time Fred Killingsworth.

With this kind of staff, we were able to cover perhaps five to ten percent of the importations subject to the Food, Drug and Cosmetic Act that came into the port. Because of the long background of experience on the part of Mr. Kellingsworth and the inspectors, they were able to channel their efforts toward products that historically were most needing attention, but sometimes new kinds of violations appeared and were undetected for some time because of the small staff.

On the domestic side, the staff was so small that much of the effort was directed toward taking care of emergencies. The industry in New York was located oftentimes in very old, run-down areas of the city. It was not too unusual to find food establishments operating in buildings which did not even have hot water facilities, and I recall one warehouse that did not have electric lights. Under these kinds of circumstances, sanitation violations were much more common than in the western part of the country where the cities were much newer and there were no such establishments operating.

At this time, although sanitation had improved considerably since 1939 there still were serious sanitation problems in bakeries, candy plants, and other kinds of food establishments. The incidence of plants having serious problem was much higher in New York than it was at Seattle. As a result, there was no lack of violations on which we might proceed if we so desired. Our objective was to bring those cases that were most serious from the standpoint of the consumer, because we could not prosecute every case that we encountered.

The kinds of problems that we encountered at New York were very interesting. We had some people there who were very ingenious in figuring out ways to make a quick dollar

and violate the statute in the process. Some of these schemes would work only in New York where there was a tremendous number of firms and people who were potential customers. For example, I believe the practice of repackaging physician sample drugs for sale to drug stores began in New York and was a very lucrative business there, because there were over five thousand retail drug stores in the five boroughs, the business was very competitive and some of them were willing to purchase drugs which were of questionable origin.

This business was developed by individuals who called on doctors and purchased from them at very low prices containers of popular drugs which the drug company salesmen had given them for trial use. Some of these containers would be the large ordinary container a drug store might have, but most of them were small packages which the physician was supposed to give to individual patients for their use. The volume of such free goods was so great that doctors soon accumulated drawers full of this material and when they were offered a price for them were willing to sell the quantity that was excessive to their own practice.

The purchasers would take this material to a central point, open the small patient size sample packages and repack them into larger containers which they would then

sell to retail pharmacies at a price sufficiently below the normal market wholesale value to make it an attractive buy for the pharmacists.

The hazards of this kind of business were that all the control numbers were lost in the process so that a particular lot could not be traced if injuries occurred. The required labeling was normally not present on the repacked material and most importantly, there was always the hazard that drugs would be mixed up in the repacking process and one potent drug be substituted for something quite different.

Porter: Was there really no control in these repacking operations?

Losfvold: No, they operated without any controls, it was a back room deal, usually a one or two person operation. But the volume of drugs that they handled was somewhat surprising. I cite this as a typical kind of operation that could be developed in an environment like New York City. Although it was known in other parts of the country, it was not to the volume that existed in New York. Economic violations lations were sometimes somewhat unusual. Periodically we would have someone substituting oleo for butter making up prints either quarter pound or one pound prints, labeled as butter which consisted of oleo. Since there

was a considerable price differential in the articles, money was to be made in that fashion.

Misrepresentation of proprietary drugs or health foods was another common violation. We tried one particular case in the northern part of New Jersey in which the entrepreneur had put very broad health claims on an herb preparation. At the time of the trial, he tried to claim to the court that he had received a letter from FDA approving the labeling he was using. The judge stopped proceedings, directed the United States Attorney and the defense counsel to go to the man's establishment and secure the copy of the letter which he said he had there. Our inspector accompanied the U.S. Attorney. The individual was unable to produce any letter such as he had described and when they returned to court the judge was greatly incensed at this false claim and attempt to mislead the court and sentenced the defendant to eighteen months in jail, on the kind of a violation which normally had resulted in a relatively small fine.

In one of the oleo substitution for butter cases, the judge again was quite incensed at this kind of a crime and also sentenced the defendant to serve a jail term. It always seemed interesting to me that judges often are much more impressed by economic violations than they are by the

ones that we think are very important because they have public health significance. Perhaps it's because judges normally deal with economic matters rather than with those involving health.

Porter: Don't you think too that economic violations are often something you can actually measure?

Lofsvold: It's something that everybody understands, there's nothing nebulous about it.

There were other strange and unusual matters. One of the kinds of cases that occupied a good part of our time during my six years at New York was the incubator reject business. This involved the use of eggs which failed to hatch in the preparation of frozen eggs which were sold to bakeries, macaroni factories and other industrial users of egg products. The people operating the business collected these reject eggs from hatcheries located as far away as Texas and Arkansas. They brought them by truck into New York or the northern part of New Jersey where they broke out the eggs, mixed them usually with sound eggs, sometimes treated the eggs with chemicals to disguise off odors and sold the resultant frozen product in the metropolitan area. Again, the racket flourished because they were many small and large bakeries and other establishments which were willing to buy eggs offered them at under the normal market

value, even though they had no clear idea of the history of the particular product.

Another difference that I found in working in New York as compared with the west coast, was the problem of inspector travel. At Seattle, it was not unusual for an inspector to leave the district headquarters and go fifty or a hundred miles out to do some work and come back in the same day. I soon learned that at New York, you could not expect to accomplish such work in a single day because of the congestion and the difficulty in travel.

For example, if an inspector was to leave the office in Manhattan and go out to Suffolk County on Long Island, a distance of fifty or sixty miles to collect samples of cauliflower for spray residue examination, it was an overnight trip. The traffic situation was such that he could not drive to the cauliflower field in less than three hours and consequently would not have time to collect the samples and return to the office within the normal work day.

Also because of transportation problems, it was almost impossible to have people work longer than their normal hours, because in some instances it would be impossible for them to get home until very late at night, especially if they rode commuter buses or commuter trains. Consequently, the work habits of the inspectors and chemists were much

more rigid than they had been on the coast where such problems of transportation did not exist.

In some of the kinds of cases that we had in New York it was necessary to work very irregular hours and when that kind of situation arose, the inspectors raised no problems at all; they were entirely willing to change their pattern of travel between home and office to get the job done. One of these situations was the incubator reject racket that I mentioned earlier, the practice of taking unhatched eggs and converting them to food use. This was a clandestine operation. The people who were in the business established their breaking rooms and cold storage facilities in all sorts of odd places. Our job was to ferret them out which sometimes took considerable detective work.

One of the places I remember that they operated was an old abandoned brewery in Elizabeth, New Jersey, and after we found them there and put an end to that operation, they moved it up into Westchester County to a place which had been a turkey farm where they had raised and slaughtered turkeys. It was ideal from their point of view since it was in an isolated area approachable only by a single road. It had a steam boiler for hot water and cold storage facilities for freezing the finished product. Pete Colucio and other inspectors spent considerable time locating this

place and finally got a lead because a repairman who serviced refrigeration equipment told them that he had had a call to work on the refrigeration at this old farm.

Pete drove to the place and came upon it more quickly than he had anticipated. When the government car drove up, all of the employees immediately fled the building, including managers and everyone else. Pete found himself the sole occupant of the manufacturing operation which had been in full blast. There were shell eggs, liquid eggs in process and 250 cans of frozen eggs in the freezer. Knowing that these eggs would disappear if we left the premises, we sent a number of inspectors to the plant and they maintained their vigil around the clock over a weekend until we could get the United States Attorney's Office to file the necessary papers to seize the frozen eggs that were in storage and move them to a place where the operators of the plant could not get them.

The case resulted ultimately in a criminal action and conviction of the responsible operators.

Similarly, we had to work odd and unusual hours in the attempt to control the manufacture and distribution counterfeit drugs. During this time that I was in New York, some unscrupulous drug manufacturers found that it was a very lucrative business to prepare exact duplicates of

trademarked drugs which were very popular, such things as steroids and other new drugs which were highly popular with physicians and were very expensive because only one firm held a new drug application and a patent to produce them.

By closely imitating these drugs, the counterfeiters could sell them to unscrupulous pharmacists who would substitute them in prescriptions. They would sell them at a lower price than the genuine article sold for at wholesale and still would clear a tidy profit. This kind of work also required detective-type investigations, hunting for the people who prepared the punches and dies that were used to manufacture the tablets, seeking out the print shops that prepared the labels and the cartons in which these counterfeits were packaged and so on.

Porter: You know, we had an interesting experience in Chicago along that line. During a period of several months I was acting chief inspector there and Joe North was in charge at that time of monitoring all this kind of work out of Washington. He had gotten it through his head that a certain counterfeit drug that was being sold all over country was made in Chicago and Charlie Curry who was our senior inspector in that kind of work had somehow got information and insisted that it came from a firm in the St. Louis territory.

St. Louis inspected that plant and couldn't find any dies that matched this counterfeit and this made Joe North in Washington all the surer that it was made in Chicago and we just -- he put a lot of pressure on us -- and we just searched literally day and night and we never could find them and Charlie Curry kept insisting they came from this plant in St. Louis or in their territory. And you know that we never did solve that, we never found them. Joe never forgave me for what he considered incompetence, I think, but actually in the end some years later St. Louis inspected that same firm again and that inspector was alert enough to find some old dies on a shelf and lo and behold they did match this counterfeit drug. Our man was right, but I really sweated through several months of criticism from Washington and we really worked hard and it was all because at the one inspection in St. Louis they just didn't happen to find them.

Lofsvold: These kinds of investigations were terribly time consuming, very frustrating, and generally we solved them only because we got lucky and found someone who was willing to tell us about the story, which I guess is about the way that crimes are solved anyway.

Porter: They were very important because many times over the counter sales cases all over the country hinged on being able to prove where that counterfeit was made.

Lofsvold: At this time we also were working more on the larger scale dealers involved in over the counter sales of prescription drugs. Some of them got rather complicated. Boston District got information that a drug salesman in York, Pennsylvania, was supplying distributors in the Boston and Buffalo District territories with amphetamines and other prescription drugs to be sold over the counter principally to truck drivers.

Charles Karadimos at Boston was able to contact this individual by telephone and gain his confidence. After making some smaller purchases, Karadimos arranged for a rather large purchase of these drugs to be delivered by the salesman at Stamford, Connecticut. The salesman delivered the goods in his personal car so we had the problem of making certain that we could prove interstate commerce. This was before we had developed the microanalytical ballistics method of analysis which later could be used to prove interstate commerce conclusively by examination of the product. In this instance, we felt the only way we could actually prove it was to follow the man across the state line and observe his delivery of the drugs to Karadimos.

Philadelphia District made elaborate plans to follow the salesman from his home in York across Pennsylvania and through New Jersey. The plans included that State Troopers

from the two states would accompany FDA personnel in this surveillance. When the salesman got to New York, he was to be kept in sight by New York inspectors who would follow him into Connecticut. As you might expect, this scheme was far too complicated for our limited experience in this kind of surveillance.

I was at New York awaiting a call from Philadelphia who would let us know that the chase was on. Hours went by and finally Philadelphia reported that despite their best precautions, the salesman had left his home without being detected by their investigator or the State police. He was somewhere en route at that time and nobody knew exactly where. In order to salvage something from the effort, I sent two inspectors immediately to the State line between New York and Connecticut and instructed them to park there and when this car appeared, to follow it into Stamford. I also alerted our people who were waiting in Stamford, accompanied by the Connecticut State police, and they dispatched a Connecticut police car to the border in an effort to intercept it.

The inspectors later reported that they saw the car across the border as planned, that it was traveling at about 80 miles an hour and the government car that they had could not keep him in sight. Fortunately, the State

Trooper was equipped with a surveillance car with a pursuit type engine and he was able to match the drug salesman's speed and keep him under observation to the motel where the delivery was made and photographed and the Marshal seized the lot of goods in the back of his car and took the salesman into custody. Everything worked out well, despite the fact that our elaborate plans did not function as they were supposed to.

Porter: That sort of points up something about that kind of work we were doing in those days, we weren't trained for that kind of criminal investigation, we were scientifically trained, we were trained in food technology and the manufacturing techniques and so on, and suddenly we were thrown into circumstances where we just had to kind of use our wits and I don't think we did so bad, but none of us, I don't think, signed up originally to ever do that kind of work.

Lofsvold: All of this was totally foreign to what we had done previously. It was very interesting, and as you say, we sort of made it up as we went along.

In retrospect, we did a lot of very foolish things. I think we were very fortunate that we did not have any of our people injured or killed when we were dealing with some people who were out and out criminals.

Porter: I think we did things that a really trained experienced criminal investigator wouldn't, or he would have protected himself.

Lofsvold: I think some of the things we did were successful perhaps because of our ignorance. We were willing to try to do things that somebody with experience would have rejected as too wild of an idea. Perhaps it was to our advantage, at least in part, not to have had police background.

Another program that required quite an investment of time at New York was the poultry sanitation program. At that time before the passage of the Poultry and Poultry Products Inspection Act which is enforced by the U.S. Department of Agriculture, FDA had the responsibility for controlling poultry. Part of the problem was the practice of selling diseased or very emaciated birds to low class restaurants. New York was a place where there was a considerable market for this type of poultry and much of the production in the United States gravitated in that direction.

We also had problems with sanitation, the contamination of the dressed birds with chicken manure. There were very few poultry slaughtering plants doing interstate business in New York. Most of the supplies were shipped in

from outside chiefly from Delaware and Maryland and Virginia area, but some from as far away as Arkansas. The slaughtering of these birds left something to be desired in that they contaminated the outside of the plucked fowl with fecal material from the birds. John Zaic was the inspector who did most of the work on this program. He was very experienced in the examination of poultry and had had considerable on the job training from veterinarians who had been employed at New York District at various times. At the time I was there, we did not have a veterinarian on the staff.

John also handled work on rabbits, which was a rather peculiar sort of business. In some of the sections of the city where there were large concentrations of very poor people, rabbits were sold under highly questionable conditions. Some of the rabbits came from the middle west and the far west where periodic drives to reduce the jack rabbit population resulted in the killing of large numbers of rabbits. Some of these were simply thrown into barrels without being skinned or eviscerated and frozen and shipped to the New York market, for sale as is. We made a number of seizures every year of rabbits of this kind on charges of decomposition, contamination with filth and the presence of bird shot. We also received rabbits from Australia

which were slightly, but not much better quality than the ones from the west. It was an ongoing project to try to improve the handling of the animals, but we did not make much progress until economic conditions had improved to the point where this was no longer a profitable business.

Porter: We tried to follow up some of New York's problems by investigating the source. I remember up in Idaho finding the name of the fellow who shipped the last batch of rabbits...but really what could you do? They had this drive where all the ranchers and the farmers would get out and form one great big circle, scare the rabbits, herd them, and shoot them. Then it was all over. They shipped them. There wasn't anything to inspect.

Lofsvold: With all of this business in the courts, we had very frequent and close contact with the United States Attorney's offices in the three jurisdictions included in the New York district. The relationships varied considerably from one district to another. In the southern district of New York, which is the largest single federal district court in the country, the U.S. attorney was a man named Lumbard, a partner in the prestigious Wall Street firm of corporation lawyers, Donovan and Leisure. The Donovan of the firm, was famous Wild Bill Donovan, who had been head of the Office of Strategic Services, the

forerunner of the CIA, during World War II. When Mr. Lumbard came to the U.S. attorney's office, he brought with him several of the brightest young attorneys in the firm. They were a remarkable collection of men, most of them graduates of Ivy League law schools and as a group, I believe the sharpest lot of attorneys that I've ever dealt with. One of them was George Leisure Jr., the son of the senior partner in the firm. I remember that we tried a case against Gnome Bakers, Inc., a sanitation case, with him, and that he did a fantastic job of preparing and presenting the case, which was his first FDA trial. These assistant U.S. attorneys were interested in their cases and confident of their own abilities. They did not seek, nor would they accept the assistance of our attorneys from the general counsel's office. They were very receptive to me and to other district personnel when we called on them with ideas and suggestions as to how the case might be presented. They felt that they were responsible for the case and they did not want any agency lawyers involved in it. An entirely opposite situation existed in the district of New Jersey, where the assistant U.S. attorney assigned to handle our legal matters, was almost incompetent. He was so interested in his political maneuvering that he had scant time to prepare any of our cases that went to trial,

and was only too glad to accept help from the general counsel's office. Alvin Gottlieb at that time, handled most of the trial work in the New York area for the general counsel and frequently was asked to present the cases in court rather than having the U.S. attorney present them in the usual fashion. We welcomed this kind of cooperation, of course, because we knew the limitations of the assistant and would much rather have a competent, experienced attorney from our general counsel's office present the matter. In the eastern district of New York, in Brooklyn, the situation was about half way between the other two extremes. Harry Fischer, the attorney assigned to our cases there, was a good lawyer and did well for us. He was much more receptive to advice from agency attorneys than his colleagues in the southern district of New York and in the most difficult cases asked for Mr. Gottlieb to come up and assist him. Mr. Fischer did insist on presenting cases in court himself, but he welcomed advice not only from the General Cousnel's office but also from representatives from the district. I think that this situation within these three jurisdictions was pretty typical of the range of our relationships nationwide with the United State Attorney. They ranged from those districts where our lawyers were able to do almost the entire job of representing

the government to those districts, such as the southern district of New York, where our lawyers were unwelcome.

Porter: You know, in my experience, I was resident in Albuquerque for a period of time and had the western part of Texas that I covered and there you dealt with the assistant U.S. attorney on a very, very, personal basis. You really had no need for those guys in Washington at all. I remember Cavett Binion was the assistant during the time I was there and he refused to file cases that the general counsel had sent out. But on an individual kind of personal basis, we could talk him into it, and I know we had one particular case that was set for arraignment and ... he and I both traveled , he traveled out of Fort Worth and I traveled out of Albuquerque and I called him in his hotel. I told him I would be in court the next day and he said, "No, you won't. I don't want you there." He said, "I didn't want to file that case and your people of Washington went to the Department of Justice and forced me to file," He said, "When they're arraigned, I'm just going to stand mute and let the judge do with it what he wants to. I said, "No, you're not. I'm coming over to see you with a bottle of whiskey." And so he and I sat around and drank whiskey and talked about it and the next morning he did a real good job for us. It was on a strictly personal basis.

He wouldn't have accepted help from a general counsel for anything. Maybe that's typical of Texans at least in those days anyhow.

Lofsvold: Well, I think it varied according to the personality of the individuals and the part of the country. Of course, when Arthur Dickerman from the general counsel's office was stationed at Los Angeles, and regularly travelled around the various federal courts in the western part of the country, he developed a personal rapport with the U.S. attornies and their assistants and I think was widely accepted in almost every one of the jurisdictions. Probably, that was part of it, personal familiarity. Of course, Dickerman's recognized competence in the area of food and drug law, was also a great asset.

During the years that I was at New York, that is, 1955 to 1961, some things were happening that changed the character of the Food and Drug Administration. George Larrick had become commissioner and had adopted a different philosophy from his predecessors. He encouraged a different kind of relationship with industry than had existed previously. Where we formerly had operated at arm's length, he fostered the idea of agency industry cooperation in matters where we could accomplish something desirable for the consumer. He did not back off from legal actions, but

he did try to create a different sort of atmosphere and to encourage industry representatives to come to FDA with problems and discuss them rather than to go ahead with some course of action that would inevitably lead to a confrontation in court. This change in philosophy, was not highly popular in the field, at least at New York, and I suspect that the reaction there was fairly typical of the rest of the country. Mr. Charles Herrmann, who was the director, was particularly critical of this approach. It was so different from what we had been doing in the past, that I believe it was resisted probably as a normal reaction, a resistance to change. But Larrick's philosophy did prevail and little by little the agency began to move in the direction of fostering voluntary compliance. Of course, this was considerably accelerated when in 1964, Mr. Larrick in a reorganization established a Bureau of Education and Voluntary Compliance whose business it was to foster this sort of thing. I suspect that part of the impetus for this change came from the report of the First Citizen's Advisory Committee that looked at FDA and recommended this kind of step along with a recommendation for increased staff and money for the agency and several other changes.

Porter: Don't you think that this was reflected not just in industry's approach to administration officials to dis-

cuss problems but inspectors were encouraged more and more to discuss their findings right there and then with the plant, and it seems to me in my training, when I first came in, they didn't do much of that. You were sort of viewed as a law enforcer and didn't feel an obligation to have much very helpful conversation, maybe not quite that bad, but that's sort of the way it was characterized. Then very quickly after I came in, in the forties, I would say, late forties, we began to, our instructions were to try to be more helpful in many ways. I don't know of a directive like that, but that philosophy did soak down through the organization and various inspectors were doing that in their factory inspections.

Lofsvold: Some of the other things that happened took place in Washington. Senator Kefauver's hearings on drug pricing began early in my stay at New York and continued for several years and were succeeded by the hearings conducted by Senator Humphrey. We in the field were not directly involved in much of this, but we did read about in the trade press and in the general newspapers. We recognized that FDA was more in the public spotlight, but we really did not react very much to some of the accusations that came out of those hearings. One matter that the

hearings uncovered which did have a wide affect in the field, was the revelation that Henry Welch was involved in some questionable financial dealings in his outside work in publishing. This Welch case sent a shock wave throughout FDA, including the field, and had a serious effect on the morale of the agency. Prior to that time, the agency had been almost completely free of any sort of scandal and the revelations that one its top officials was involved in matters of this kind was almost unbelievable. When the Welch matter was followed up by an investigation into the financial status of virtually every employee, there was a reaction of disbelief, disillusion, and anger from everybody I knew in the field.

All in all, my six years in New York were some of the most interesting I have spent with the agency. The work load was unbelievable because at that time the top management of the agency, particularly Allan Rayfield, the director of Bureau of Field Administration, did not believe that staff positions should be established to assist managers in the field. It was not until 1959 that any supervisory inspectors were appointed to assist the chief inspector in the management of that part of the operation. The chief inspectors, in order to get the work done, used some of their operating people as part time assistants.

This was a practice that had to be concealed from the headquarters because it was not considered proper management.

Porter: You had to be sure and get them out on a few inspections so that their names would turn up, something you could point to.

Lofsvold: The New York job, as chief inspector, was at the time, considered the last step in management training for people who were expected to become district directors. My three predecessors in the job and my successor also went this route. For several years the job as chief inspector was referred to as Charlie Herrmmann's finishing school for district directors. I learned a great deal in that job but I was not at all unhappy when it came to an end with a promotion to the job of district director at Philadelphia.

Porter: Okay Fred now that we've got you to Philadelphia as district director, what were some of the important programs that you worked on during that period.

Lofsvold: Philadelphia and western Pennsylvania and southern New Jersey, which were the territory at that time, have a large number, of large manufacturers of prescription drugs. Our emphasis during my four years there was principally on these drugs. At that time, FDA was working a great deal more on this kind of problem, because the drug

revolution of the late '40's and 1950's had brought to the market a wide variety of new, highly potent drugs with, in some cases, hazardous side effects. The agency recognized that we had to do a better job of controlling the quality of prescription drugs that were being offered on the market. And we began to train our people in the pharmaceutical manufacturing and the techniques of inspecting such operations to evaluate how well they were doing their job.

Porter: Was it during that period that we started having a series of drug schools.

Lofsvold: I believe so, I believe that we had some inhouse training courses at first, and then began the formal academic courses at University of Rhode Island where we sent some of our people to a special course designed to teach our inspectors what they needed to know to properly inspect a drug factory. At the same time our analysts were receiving training in the use of new types of instruments which were just coming to market, which made the analytical control of drug products much better than it had been in the past.

I think around this time the steroid drugs and the various tranquilizers were just coming to market and becoming very important in the treatment of a wide variety of diseases. All in all we worked very hard on all aspects of

the drug problem and I would guess that Philadelphia spent a high percentage of its time in those days, in this area rather than in foods and some of the other things that had been emphasized more in the past.

Porter: You developed some real good, inspectors who were known as drug experts that were really quite highly qualified in Philadelphia.

Lofsvold: Oh yes. Some of those were there before I got there. Luther Johnke was one of the pioneer inspectors in developing techniques for evaluating drug manufacturing processes. He trained a number of younger people who went on to become nationally recognized experts in inspection, at Philadelphia and other places where they were sent.

As an offshot of this we also had a problem with the over the counter drugs. Because we had so many drug manufacturers some of the plants there were sources of the tablets and capsules that were being illicitly used by truck drivers and others. So consequently we had a number of investigations in progress there at all times trying to determine whether the suppliers who were manufacturing these articles were actually connected with the illicit distribution, or whether they were simply sources of drugs which were being diverted by other people. We never were able to prove that any of our manufacturers was knowingly

involved in the illicit drug traffic though, we had strong suspicions of a few of them.

Porter: Don't you think that quite a few of them might have been, they were aware simply because of, among other things the very volume of those things that they were selling, that they were aware they were a source even though not being a party to the diversion.

Lofsvold: I'm sure that they were, especially when we would go to a firm and start going through their invoices of sales to somebody like Tex Palmer, the notorious distributor in Houston who did a wholesale business.

While I was there we also got involved in some of the first cases of investigating the investigators of new drugs. Many of the firms in the area had new drug applications and were in the process developing additional ones. They made arrangements with scientists in academic institutions and other places, to test these drugs on human beings as required by the new drug sections of the Act. Initially, the requirement was that a drug be tested by the manufacturer and approved by FDA when it had been demonstrated to be safe under the normal conditions of use. Later the law was amended to require, in 1962, that the drugs be demonstrated to be not only safe, but also effective.

One of the earliest investigations of a scientist who was testing a new drugs was conducted by Luther Johnke. The physician was a faculty member at a Philadelphia medical school and was highly regarded in his profession. Luther found that he was conducting clinical studies using various drugs on inmate volunteers at a local penitentiary. The prisoners volunteered to take part in this investigation and were paid a small sum for their effort. The problem arose when we found that the physician was testing as many as three drugs simultaneously on the same groups of prisoners, making it impossible for anyone to judge which drug was causing what effects, when those effects were observed. We brought this situation to the attention of the Bureau of Medicine in Washington. They disqualified the investigator and disqualified his work which had been submitted in support of NDAS. He was not prosecuted although we in the district urged that this step be taken.

The 1962 drug amendments also caused some changes in our inspection techniques. They formally introduced the concept of good manufacturing practices and authorized FDA to set regulations describing such practices. One of the first efforts in this direction occurred in Philadelphia when a group of experienced drug inspectors were gathered together to draft the initial regulations under that new

authority. These were submitted to headquarters and were ultimately used with submissions by many other people to develop current, good manufacturing practices regulations.

In 1965 I was transferred to Denver as district director, a move that was very welcome to me since it was an opportunity to get back to the western part of the United States.

Porter: I'd like to ask you a question there, Fred. What was the policy in regard to people moving at that time. Did you request this and get it or you know, just what was the way it came about.

Lofsvold: The policy was that people would be offered transfers to jobs for which they were considered qualified, for the good of the organization.

The needs and desires of the individual were of only secondary consideration. In my own case, I had made it no secret that I would prefer to live in the western part of the country and that I would welcome a transfer anywhere in that area. I frankly did not have any hope that this would be accomplished so I was very pleasantly surprised when Allan Rayfield, who was in charge of the bureau of field administration, told me that he wanted me to go to Denver to replace Sam Alfend who was retiring. On this subject of transfers, I might mention another situation or two that

illustrate how the policy worked. While I was in Seattle as the assistant director, I had some personal obligations that made it impossible for me to transfer. I communicated these to Rayfield who understood the situation and did not press me to transfer but I clearly understood that any advancement in the organization would depend on my availability for transfer. When the circumstances changed, and I was able to accept transfer, I inquired whether any such transfer was likely, and was told that there was nothing currently in the wind. On the basis of this, I started looking for a house to buy and one day found one and put down a deposit on it. That very evening I received a call from Frank Clark, who was one of Rayfield's chief assistants, advising me that he was pretty sure that I was going to be transferred although he could not yet tell me my destination. When I explained my predicament on the house deposit, he urged me to try to get the money back and fortunately, the owner refused my offer. I found myself very soon thereafter transferred to New York as I have previously related. At the time, my wife was seven months pregnant so we decided that it would be preferable for her to remain in Seattle with my brother's family until the baby was born, and I went on to New York without her. When the transfer to Philadelphia came up, again it was an

awkward time, the middle of the winter, in January, fifteen inches of snow on the ground and house sales moving very slowly. By this time, my two older children were in school so we concluded that my wife and family should remain in New York until school was out and I went to Philadelphia without them. Similarily, the offer to move to Denver, came in January, and I had to again leave the family behind until school was finished, at which time I was able to return and bring them here.

Porter: I had kind of similar experiences. I don't think they were vindictive in doing it this way. They just considered only the interest of the organization and didn't really consider personal inconvenience.

Lofsvold: I believe that's the case and it apparently was a practice of very long standing in the FDA, because in some of the things I've read about the very earliest inspectors that we had they were subject to frequent and abrupt transfer and it was an accepted part of the business.

Porter: I know my transfer from Denver to Salt Lake early in my career occurred with two days notice. I was single, the boss knew that and he just expected me to pack my car and go and I did. I was transferred later from Salt Lake to Chicago, literally kicking and screaming. In effect, I was

just told that's where my job was now. I was involved in a real estate transaction then, much like you did. I had just bought a house and was moving into it the day I got the notice, and had to go and leave my wife to sell the house and come several months later. The practice was of course, a lot more efficient than the present, advertisement, applications, and so on but it was sometimes pretty hard on the employees.

Lofsvold: In many ways the transfer policy was like that of the military when people were sent anywhere that their services were needed.

Porter: On the other hand, it wasn't all a black sort of story, I recall I had a young inspector working for me in Chicago who had come from Boston and shortly after they got there his wife had twins and she had some physical problems and they just weren't going to be able to make it without help. They knew if they went back to Boston they both had parents there who could help and they could do the job. I called Kenny Lennington and explained it to him and he had only one question to me and that was does this young inspector have a potential to be, you know, worth doing something for. I said yes he did in my opinion. He said I'll be back with you later in the day and later in the day he called me and said his transfer orders to Boston were in

the mail. So they were certainly capable of doing that kind of thing, too.

Lofsvold: Oh, yes, I don't think we would want to give anybody the impression it was totally inhumane. I think that in a situation such as you've described or in serious illnesses and matters of that kind, very often compassionate transfers were arranged. But lacking that kind of circumstance, there was no hesitation about directing someone to go somewhere where he might or might not like to live if in their management judgment that was the place he was needed.

In one way it had the advantage to the agency of placing the best people in the critical jobs. Under the current system, where the employee must request or apply for advertised vacancies, sometimes some of our very best qualified people will not apply to some place that they don't want to live.

Porter: And don't you think the former practice resulted in the people who moved up into the organization having much broader experience than if they just had their druthers?

Lofsvold: I would agree. I think that in the ten years I spent on the east coast I learned many things I could not have learned had I spent all my time in the western part of the country.

Porter: It wasn't all bad. I hated to go to Chicago but once I got there and got settled the work was really much more interesting than it had been in Denver and I got much broader experience, and was really never sorry once the move was made.

Lofsvold: Of course another part of the situation is that, comparing those times with the present, it was financially much easier to move then, I believe, than it is now, looking at the problem of buying and selling houses and the kind of market conditions that have prevailed in the last five or six years. At that time, houses could be sold fairly readily, sometimes there were problems, such as I encountered at Philadelphia when I left there when it took about six months before we found a buyer. But it was not the traumatic experience a person being transferred finds today when he sells a house with a reasonably low interest mortgage and buys one with a very high interest rate. The attitude of the people probably is the most striking difference. In these times that we were talking about, the people involved were willing to take this kind of treatment to further their career, whereas some of the younger people today do not put the value on a career to that extent. They're more interested in quality of life and are willing to stay at a lower level position in order to enjoy some

of the advantages of the place where they are currently located.

I arrived in Denver on February 8, 1965, a date I find easy to remember because it was my birthday. Less than a year later, FDA underwent a very marked reorganization when Dr. James Goddard was named commissioner. Goddard apparently came in with a mandate to make sweeping changes in the agency which had been criticized during the Humphrey hearings. One of his first acts was to announce a change in regulatory philosophy. He sought to deemphasize the reliance on court actions to bring about compliance with the law and to substitute for it educational means. His announced objective was to work toward the day when no legal actions at all would need to be brought and compliance would result from the voluntary efforts of the industry. He also announced a complete decentralization of many authorities formerly held in Washington to the field districts. In effect, the districts were made almost autonomous with the district directors reporting directly to the commissioner.

In making this sweeping change, he destroyed the existing systems for transmitting headquarter's policy to the field and did not replace them with any adequate system for providing this kind of information to field managers.

The reaction of the field managers, I believe, was rather mixed. All of us welcomed the opportunity to pursue some avenues of investigation that we could not have done under the supervision of headquarters. But some of us, and I was one, had some misgivings about the lack of policy direction fearing that it would result in a lack of uniformity in the way the law was applied across the country.

Some of my colleagues sprang boldly on the opportunity of doing some new and different things and within a relatively short time there was a great diversity in the regulatory philosophy and the regulatory actions that were being taken across the country. At the same time it also became apparent that it was not practical for eighteen field managers to report directly to the Commissioner and to consult with him personally on all the questions where consultation was needed. Several of the district directors got together informally and recommended that the Commissioner establish a staff position where day to day matters could be brought to headquarter's attention without having to personally take the Commissioner's time. Such a job was established with the title of Field Liaison Officer and Harris Kenyon, the director of the Minneapolis District, was selected to fill it.

In establishing this position, the Commissioner emphasized that the field directors still reported directly to him and that the field liaison officer had no line authority over the districts.

At the same time that this was going on, Dr. Goddard was making changes at headquarters. It seemed to me that he came in with the objective of building a new broom image. Within a matter of a few weeks he not only had made these changes in philosophy and in headquarters field-relationships, but also made a number of changes in the headquarter's structure. He abolished the Bureau of Field Administration since there no longer was to be a supervisory unit in headquarters which had responsibility over the field.

Many of the experienced managers in the headquarters organization were replaced. Several of them resigned; others were literally forced from office. In their place, he brought in a number of managers from outside, none of whom had had any experience in regulatory work.

As these changes became known to the field, many of the people in the field questioned in their own minds the wisdom of tearing down the structure, especially when they saw that no well thought out substitutes for previous systems were being installed.

Also simultaneously Dr. Goddard rapidly made decisions on several important problems which had been thoroughly studied before his arrival, but had not been decided by Mr. Larrick or Mr. Harvey. All of this activity was duly reported to the press by his new public affairs officer, Theodore Cron, who displayed considerable genius in getting Dr. Goddard's picture in all of the newspapers and news magazines.

It was said at about this time, that in his first six months in office, Dr. Goddard was the best known public official in Washington, not excluding the President of the United States. I'm inclined to agree with that statement.

I saw firsthand the emphasis placed on publicity. Dr. Goddard visited Denver about four months after he took office, principally to visit the local office of FDA's Bureau of Drug Abuse Control which had been recently established. He was accompanied by a reporter and a photographer from Time magazine who were with him constantly. They sat in on all his meetings with District and BDAC managers and staff, accompanied him on an inspection of a feed mill, and literally never let him out of their sight. A few months later there was a story with pictures in the magazine describing his activities.

He also used publicity as an enforcement tool, issuing press releases to bring pressure on industry to do things he wanted done. This was a departure from previous FDA practice. We had been quite conservative, not issuing press statements until we had solid evidence to support our position and usually not until we were prepared to go to court.

Ultimately, the publicity effort may have overreached, because it appeared that Dr. Goddard's departure from office was at least in part due to some public statements which were widely publicized and were widely criticized as being indiscreet.

Porter: He made a couple of statements that were particularly offensive to Hubert Humphrey who was then Vice-President, or who had become Vice-President, I think in the period, I don't know exactly how that goes together, and I had heard other people that we've interviewed that knew more than I did indicate that it was pressure from Humphrey that finally caused Goddard to resign.

Lofsvold: All together, it was my experience that the Goddard years were very difficult ones for people in the field. We tried to carry on our business as we thought it should be conducted, but it was very difficult to learn whether or not we were doing the things that were expected

of us under the new regime. Toward the end of Dr. Goddard's tenure, the probability of our being submerged in another government unit became very apparent. This occurred shortly after he departed when we became part of the Consumer Protection and Environmental Health Service, a part of the Public Health Service which included FDA and a number of environmental programs such as water pollution, air pollution and so forth, that ultimately became part of the Environmental Protection Agency when that organization was started in 1970.

I remember that at a district directors conference in New Orleans early in 1968, Dr. Goddard told us about the proposed new organization. At that time, he anticipated that he would be named to head it and that he would take Winton Rankin, the Deputy Commissioner in FDA, with him as Deputy Administrator. In the ensuing months, Goddard fell out of favor and departed from government service. So the new agency was started with a Public Health Service engineer, Mr. Charles Johnson, as its administrator.

In the year and a half or two years that CPEHS existed, it really never got off the ground. The regional administrators were named and tried to function, but found it very difficult to meld the various programs which had differing philosophies, differing histories, and differing

methods of operation. The other parts of the new agency mostly conducted their business by furnishing financial support to State agencies, while FDA, in general, carried out its programs directly using its own people. This made for considerable difficulty in trying to identify and develop common areas of interest and common field operational programs.

At Denver, we were able to do some worthwhile work with the air pollution people in a study of the effluent from the smoke stack of a smelter in East Helena, Montana. We investigated allegations made by private individuals that toxic quantities of various heavy metals and other substances were emanating from that stack and contaminating the nearby area. The results of the study were inconclusive, but it did have one valuable side effect. In the course of doing the laboratory work for this study, our Denver laboratory developed a very sensitive method for the analysis of mercury in various food and feed products. A few years later, when we were confronted with the serious problem of mercury in fish, we were ready with an analytical method that could be put into action immediately, rather than having to spend several months developing adequate methods of analysis.

In 1969, there was a general reorganization of the executive branch of government which required the establishment of new regional offices. Prior to that time, the Department of Health, Education and Welfare, and its predecessor, the Federal Security Agency, had a regional structure which involved nine regions. FDA had never conformed with those regional boundaries and had not been part of that field management system.

The '69 reorganization, however, mandated that several departments, including HEW, should conform their regional boundaries and their regional headquarters to a standard pattern, ostensibly for the reason that individuals or state governments seeking to deal with several different federal departments and programs would then have a single focal point in their area where they could meet with representatives of all of these departments and programs.

At this particular time, the Department insisted that FDA become a part of that structure and we established the position of regional director. I should have mentioned that at this time also the CPEHS organization was dissolved. FDA was made a separate agency again within the Public Health Service, and the environmental programs were shifted to the newly formed Environmental Protection Agency.

Also in the latter part of 1969, Dr. Charles Edwards came in as Commissioner. He came in simultaneously with a reorganization of the agency into the bureau structure that currently exists. This made considerable changes for the field. For one thing, Edwards became convinced that there needed to be more central direction of field activities and established an office for that purpose by converting the Field Liaison Officer to the Executive Director of Regional Operations (EDRO), an individual with line authority over the districts and regions. He assigned Paul Hile, who had been the Field Liaison Officer to this new position. Hile organized a small staff in headquarters and started to bring some uniformity to a rather chaotic situation.

Some of the field managers resisted this move to limit their local authority, while others welcomed it as a much needed reform to restore the idea that proper enforcements of the laws assigned to FDA required the agency to enforce them fairly and uniformly throughout the United States. I was one of those who thought some central authority was essential. Others resisted and for a period of a few years there was considerable turmoil in the field.

In the early days of the EDRO organization, I had several interesting assignments from Hile to assist him in organizing his headquarter staff and developing headquarter-field relationships.

Porter: As you know, Fred, I guess I was one of Paul's principal assistants during this time in charge of field management information systems and budgeting and planning--manpower planning--for the field, so I was kind of there when there were a lot of problems. And one thing that I recognized was that when the bureaus were established, apparently the Bureau Directors, for instance the Director of the Bureau of Foods, was told that he was in charge of the food programs of the Food and Drug Administration. Then when he came in and he got his feet on the ground and saw how it really was, it was apparent that here was an entire field organization which devoted at least half of its time to foods that he was not in charge of, at least not directly in charge of, although he did have the responsibility for developing their food programs.

And I think this laid the groundwork for considerable difficulties between the field organization and the bureaus and some of those difficulties still attain to this day. I don't think it was laid out as carefully as it might have been, and some of these problems never would have existed if it had been.

Lofsvold: As I recall the reorganization plan that resulted in establishment of the bureaus was done by a departmental task force, on which FDA had only limited

representation. Many of the decisions on how to organize the agency were made by people who were not that familiar with its functions. Do you remember anything like that?

Porter: Well, not specifically. I don't mean that that wasn't true, I just don't really know much about that. Fred, before we get to near the end of this tape, I wonder if you could talk to me just a little bit about your knowledge and your impression of the various Commissioners of the Food and Drug Administration that you have worked under.

Losfvold: Yes, I'd be glad to. I think I should first make the point, however, that never having had a permanent assignment in Washington, my personal contacts with the various Commissioners were necessarily limited. I did not have the advantage of having worked either directly under them or even in the same office where I would have had more opportunity to observe them, so the impressions that I have are largely those that I obtained from seeing them at various meetings, sometimes talking to them individually on a few occasions and such judgments that I would make from seeing the results of what they were doing. I think with this caveat, I can then talk about the Commissioners individually.

Walter G. Campbell was the Commissioner when I started with FDA, but I never met Mr. Campbell until after he had retired when I saw him at some meeting. I had no basis, from personal observation, to make any judgments, but the people who were my supervisors in my earlier years conveyed to me in the normal course of business their high regard for Mr. Campbell. He was a distant figure, so far as I was concerned, and in fact so far as most people in the field were concerned, but they had a great deal of trust in him and a tremendous respect for him as a leader.

His successor, Paul Dunbar, was the first Washington official of FDA that I ever met. I believe that earlier in this recording, I mentioned that he came to Portland, Oregon to a meeting of the Western States Association of Food and Drug officials in the fall of 1940, about the end of my first year in FDA. I was tremendously impressed with Dr. Dunbar, seeing him at that meeting, speaking to the State officials and responding to their questions. He was diplomatic, highly knowledgeable, able to answer any question that was thrown to him. He gave the appearance of great energy and I felt at the time that we were lucky to have him as one of our leaders.

The next time I saw Dr. Dunbar was in 1946 at a meeting in Washington. By that time he had been Commissioner

for two or three years and had had to deal with many difficult problems. He had aged markedly in that time, but still was obviously the man who was in charge of this organization and the large meeting that I was attending. Two years later I saw him for the last time. He had again aged markedly, his hearing had failed and he did not seem to have the aggressive take charge sort of attitude that he had previously.

Mr. Crawford, his successor, was a man who impressed me greatly. He was an extremely handsome man in a rugged sort of way, carried himself very erect, and looked the part of a distinguished public servant. Before I met him I had come to admire his writing style in memorandums and speeches which had been circulated to the field. He was widely known throughout the field organization as the principal author of the original bill which became the Food, Drug and Cosmetic Act of 1938. I met him on only two occasions, other than meetings where he did not take the leading part. These occurred during a 1953 temporary assignment in Washington. During the thirty days that I was there, I met Mr. Crawford twice. It was his practice to often eat lunch in the employees cafeteria, at which time he would bring his tray to a table where some of the junior employees were seated. During the meal he would

quiz us about what we were doing and talk to us about some of the problems facing the agency that he was dealing with at that particular time. Twice while I was there he happened to come to a table where I was sitting. On both occasions I was very impressed with his interest in his people and his encyclopedic knowledge of everything that the agency was engaged in.

His last years as Commissioner were, I think, a very frustrating time for him. He tried to resist some of the pressures from the new Department of Health, Education and Welfare, and as a result left office, I think, somewhat bitter and disillusioned.

Mr. Larrick, the last of our career FDA Commissioners, was a rather different personality than Mr. Crawford. I did not see as much of Mr. Larrick as I had even of Mr. Crawford, even though Larrick was in office for several years. The times when I saw him were in large meetings at which he was presiding, and I had very little opportunity to speak with him as an individual. I felt he was a man who was totally dedicated to the Food and Drug Administration, but I had some misgivings about some of the things that happened during his tenure. For several years, beginning before Mr. Larrick became Commissioner, we in the field heard reports of bitter rivalries among the top man-

agers of the agency, particularly at the division and bureau director level.

Three or four very strong personalities were involved, and we got the impression that sometimes they were so busy frustrating each other's efforts to enlarge their turf, that they lost sight of the fact that they all belonged to the same organization. I felt for a long time that this was a detrimental situation for the agency and wondered why Mr. Larrick or Mr. Harvey, who was his deputy, did not knock heads together and stop this kinds of bureaucratic infighting. I have no idea of what if any efforts were made to solve this problem, but it seems to me apparent from some of the recordings that we have made from the people who were in Washington during that time, that these rivalries had a definitely deleterious effect on management in the agency.

Other than that particular reservation, I think Mr. Larrick's period of management was very good considering the trying times during which he was Commissioner. These included the time of the very rapid expansion of the FDA staff, the Welch investigation, and the innumerable congressional hearings that he was forced to endure. I have speculated many times as to whether the history of FDA would have taken a different tack had Mr. Larrick and Mr.

Harvey retired three or four years earlier than they did and left the management of the agency to some of the younger career people who were there in Washington. It seems to me possible that had that happened, we might have forestalled, at least for a time, the trauma that was caused when we began getting Commissioners from outside the agency who did not really understand it or the regulatory process.

I've already commented to quite an extent on Dr. Goddard, and the things that happened there. Goddard was a very personable man, very impressive in appearance. He gave the appearance of a man totally in charge and totally confident of what he needed to do and ruthless enough to do it. At the time that he was making sweeping changes, many of which affected people that I knew, liked, and respected, I resented as much his manner of making these changes as the fact that he was making them. In fact, I guess I resented more his lack of sensitivity in dealing with people who had given their entire adult career to the agency than I did the fact that he was making the changes. I was not impressed with him as a manager although he did introduce FDA to many of the techniques and methods of modern management. He made available to the field for the first time management training, first the Grid Method and later

courses at the American Management Association. He was instrumental in procurring the first computer in FDA, but the uses to which he and the subordinates he brought with him put these new techniques, left something to be desired.

Porter: Can I jump in there just a second because actually we first made use of an RCA computer well before Goddard's time.

Lofsvold: That was a departmental computer, wasn't it?

Porter: It was a departmental computer, but actually it was justified and ordered for FDA.

Lofsvold: I wasn't aware of that.

Porter: And there was no room to install it, of course, except in the department building, and by the time it was installed, the department hierarchy decided that they wanted to be the primary users of this computer and they, in effect, took it over, and FDA was only allowed a certain amount of time on it. But actually, I think FDA should get the credit for acquiring that computer and that occurred, probably it was installed in '62 and '63, as I recall.

Lofsvold: Well before Goddard came. It seemed to me, though, that in his use of the computer and in the management system that he installed, he operated as he did in the personnel area without properly thinking through what the

total effect would be on other systems already in place. I guess the best way to sum up of my view of Goddard as a manager, was that he started many things which probably were desirable, but few of them were ever carried through to total fruition as well as they might have been.

Porter: That's right. One real good example, of course, of installing systems was one I was intimately involved in and that was the field management system that we called PODS, which was in a state of development and was presented to Goddard and he insisted, or at least he made the decision to implement it before we were really ready and we had all of the problems that you might imagine when you try to a install major information system before it's really worked out.

Lofsvold: When Goddard left, Herbert Ley, an MD from the Harvard School of Public Health, became commissioner. Dr. Ley had come to Washington to be director of the Bureau of Medicine under Goddard and succeeded to the commissioner's position. Ley was largely a caretaker because soon after he undertook the job, the Nixon administration replaced the Johnson administration and we had a total change in political climate in the executive branch. Ley was a fine gentleman, obviously an intelligent man, but so far as I was concerned, I never saw enough of the things he was

trying to do to make a any judgement as to his abilities to run the agency.

Dr. Charles Edwards was the new commissioner who came with the Nixon administration. He arrived simultaneously with the reorganization into the bureau system. Edwards had the reputation of being management oriented since he had worked for Booz, Allen and Hamilton, a management consulting firm. I saw Dr. Edwards several times at meetings with field managers but was not impressed. He obviously was ill at ease in talking to a large group of people from the agency. On one occasion I had the opportunity of being alone with him when I was called upon to brief him here in Denver at the end of a vacation in the Colorado mountains where had been out of touch with the office. He was a different individual under those circumstances, much less formal, much easier to talk to than he was in the other circumstances under which I met him. Considering that he came in with a tremendous reorganization and must have had all sorts of problems at headquarters to deal with, it is probably understandable why people like me in the field did not have much opportunity to have contact with him. His contribution to FDA that I was most familiar with was the establishment of the executive director for regional operations, a decision which I heartily applauded.

When he left to become assistant secretary for health, Dr. Schmidt from the University of Illinois Medical School, became commissioner. Mac Schmidt had the appearance of a good administrator and talked like one, but I had some problems with his style of management. He introduced into the FDA a collegial style of management which apparently he had used in his years as a university administrator. He sought to gain a consensus among his immediate top staff on a wide variety of problems, many of which should have been settled long before they reached that level. In this group which he designated as the Policy Board, some matters were argued which were not worthy of that kind of attention at that high level. He also gave the appearance of being indecisive and seemed to have difficulty in making up his mind, especially when some of the stronger subordinates were arguing on opposite sides. His tenure was clouded, too, by his preoccupation with accusations made during hearings before Senator Edward Kennedy's committee that the Bureau of Drugs was being grossly mismanaged. He spent a good deal of his personal time over a period of a year, in formulating a response to the charges and indeed the last half of his tenure seemed to be entirely colored by his preoccupation with this matter.

Dr. Donald Kennedy, a PhD biologist from Stanford who succeeded Dr. Schmidt was an entirely different personality. He was very outgoing and enjoyed nothing quite so much as being on a public platform before a group of people, many of whom disagreed with him. He seemed to enjoy the give and take of such impromptu arguments, and during his tenure, sought to promote this kind of interaction between the agency and the public, particularly that part of the public which was critical of the agency. He held public meetings with large industry groups on policy questions such as the use of chemicals in animal feeds and in general sought to involve outsiders in the policy making of the agency. I was fortunate enough to have a number of personal contacts with Dr. Kennedy because several of the public meetings that he attended and appeared in took place in the Denver region or in the Kansas City region where I served temporarily as regional director during a vacancy of that position. I found him to be a delightful person to be around in those circumstances, but I do not believe that he was a very effective manager of the agency. His entire previous career had been spent in universities and for a time as president of the faculty senate at Stanford. He had not been called upon to deal in an organized fashion with the large problems and the large numbers of subordi-

nates that he had in the FDA. Much of the management was delegated to Sherwin Gardner.

Mr. Gardner had come to FDA with Dr. Edwards as the director of planning for the agency and became deputy commissioner a few years later. He continued in that position under Dr. Schmidt and Dr. Kennedy which gave the agency some needed continuity when commissioners were coming and going every two or three years. His training was as an engineer and he developed orderly procedures for implementing the new reorganized structure of FDA. This was a great strength to the agency, but on the other hand, it seemed to me that his engineering background tended to make him treat the management of FDA as too much a mechanical matter and did not provide ways of dealing with the unplanned problems and emergencies that arise in the agency. Perhaps a less rigid system of management giving subordinate levels, particularly in the field, a little more opportunity to act on their own would have made the agency better able to respond to critical situations. It also would have encouraged people at those lower levels to develop and use their own initiative which under the management system that did evolve, was rather stifled.

Porter: Don't you think this, I guess you'd call it systems approach, probably is good where you have gen-

erally mediocre managers, but FDA had developed, certainly in the field, a corps of managers that had vast experience and whose judgement and leadership could have, we could have gotten more done with if it hadn't gotten stifled. Also, I liked Sherwin Gardner and I liked the things I saw from where I sat in Washington, but on the hand I often was concerned that we were getting, that these systems introduced an awful lot of paper work, and that we lost efficiency, that all of our people were involved in too much paper work and once paper work gets established in an organization it can never be less.

Lofsvold: It tends to become an end in itself. I believe that there could have been a happy medium using the systems approach for those problems we foresaw and decided to do something about, but there should have been some flexibility built in to seek out and identify new problems and to deal with those unplanned things that always occur in the course of our kind of business.

When Dr. Kennedy left, Dr. Jere Goyan, Dean of the School of Pharmacy, University of California in San Francisco, became commissioner. Dr. Goyan's tenure was somewhat like that of Dr. Ley's in that he did not have enough time in the position to establish initiatives of his own but acted more or less as a caretaker. Although he

came in a year before there was a presidential election, it is my understanding that he was held in check by the White House and the department who did not want any new regulatory initiatives undertaken during an election year.

Looking back at my career in FDA, I don't think that I would have changed anything. I came in totally ignorant of the agency, but very early found that it did some things that I thought were worth doing and that the subject matter with which it dealt was so varied and so interesting that I soon decided that I wanted to do this the rest of my working career. I have no reason at all to regret that decision because I enjoyed every minute of it. At times I have said that it was so much fun that I was ashamed to take the money although I always did. I do not think that I could have sat down and imagined for myself a more interesting, varied and rewarding kind of career had I been given the opportunity to do so.

Porter: Thank you very much, Fred, I think you said a lot of worthwhile things, things that will be of interest to people.