HISTORY OF THE

U. S. FOOD AND DRUG ADMINISTRATION

Interview between:

Robert S. Roe

Retired FDA Bureau Director and

Associate Commissioner

and

James Harvey Young

Emory University

Fred L. Lofsvold

U. S. Food and Drug Administration

Washington, D. C.

February 7, 1982

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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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DATE: Feb. 7, 1982 PLACE: Washington, D. C. LENGTH: 155 Min.

INTERVIEWEE	INTERVIEWER
NAME: Robert S. Roe	NAME: Fred L. Lofsvold & James Harvey Young
ADDRESS: [redacted]	ADDRESS: U. S. Food & Drug Admin.
[redacted]	Denver, Colorado

FDA SERVICE DATES: FROM 1925 TO: 1967 RETIRED? Yes

TITLE: Director, Bureau of Scientific Standards and Evaluation
(If retired, title of last FDA position)

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Memorandum of April 22, 1966 by James L. Goddard about Reorganization of the Science Bureaus in FDA.

Letter of June 27, 1958 to Mr. Roe from H. A. Toulmin.

Reprint from Food Drug Cosmetic Law Journal of article written by Mr. Roe entitled: "Evolution of the Field Organization".

This is a recording in the series of the FDA Oral History interviews. We are interviewing today Mr. Robert S. Roe, a retired scientist from the Food and Drug Administration who held several high-level positions with the agency. The date is February 7, 1982. The interviewers are Dr. James Harvey Young, Professor of American Social History, Emory University, and Fred L. Lofsvold, Food and Drug Administration. The interview is being conducted at the Cosmos Club in Washington, D.C.

Lofsvold: Mr. Roe would you please briefly sketch your background as to education and experience in FDA?

Roe: Yes, I'll be glad to. I am a native of Denver, Colorado where I was born in March, 1902. Went through the public schools of Denver and graduated from the University of Denver in 1924. Worked for a year, as I had worked part time during my last year in college, as a chemist for a paint factory in Denver.

I entered the federal service in September 1925. I was appointed to fill a vacancy in the Minneapolis laboratory of the then Bureau of Chemistry of the Department of Agriculture, which was the enforcing agency for the then Federal Food and Drugs Act of 1906.

I was told to report for duty in Chicago at the District Headquarters for several months training before going to the assignment in Minneapolis. They worked on me for five years in Chicago and never did get me in shape to go to Minneapolis. I spent my first five years as a chemist in the laboratories in Chicago; a couple of years in the food laboratory, and about two years in the drug laboratory, and then almost a year as acting bacteriologist for the Central District.

I was transferred to Washington in July of 1930 and assigned to the office of Import Supervision as Assistant to the Chief of that office, Dr. A. E. Taylor. At that time the Headquarter's organization was in two groups, the Interstate Supervision, which at that time was headed by Charlie Crawford, and the Import Supervision headed by Dr. Taylor. I spent four years in that assignment in Washington. It was interesting. The work of that office had gotten way behind so they had put me in as a third officer to help get out the back-log. After four years there we were pretty well up-to-date. There really wasn't enough work at that time to keep three of us busy, so I went to the Commissioner who was W. G. Campbell, Walter Campbell. I told him we were up-to-date there in the Import Office and there really wasn't enough to keep three

of us busy and I was the number three guy, didn't he want to re-assign me. I assumed that I would be re-assigned to the laboratories in Washington, but within a week I was on the way to San Francisco. He promptly acted on my suggestion and I was sent to San Francisco to be the Assistant to the Chief of the San Francisco Station.

Just a month before Frank Vorhes, a chemist in the Washington laboratories, had also been sent to San Francisco to be the Chief Chemist of the laboratory. No that isn't quite right. He was sent there to be Assistant to the Chief of the District, as I recall. He later was made Chief of the laboratory at San Francisco Station. Well, it turned out that the San Francisco Station was a bit behind in some of their work. There were hearing records piled up all over the Chief's office that had not been written up, and the reason for my assignment there was to help the Chief dig out the hearing records. Well, I'd never held a hearing before, but I soon became an expert as a hearing examiner.

It was a fact that the records of hearings were way behind schedule so I went to work on them with the Chief of the Station. But I was designated the hearing officer and from then on conducted all of the hearings at the Station. I worked out as best I could the past hearing records as we had time to do it.

These hearings involved situations where violations had been disclosed and it was a question of whether or not there should be any prosecution or follow-up of that kind, of the offending party. This did give me a good education on many of the problems of the District and the Station area because it involved the violative cases that had been encountered in the operations of the office.

The holding of hearings was not my only function there. I did participate with the Chief of the Station in the other administrative matters of the Station, such as the supervision of the Inspection office and the laboratory operations, generally.

I did have opportunity to go out in the field with some of the inspectors to get acquainted with the problems of the area. I remember one time making tomato cannery inspections. This was a big area of tomato production and on the East Bay across from San Francisco, there were a number of tomato canneries and manufacturers of tomato ketchup, and tomato puree and various tomato products. This was the first year when there had been noted in California a heavy corn-ear worm infestation in the tomato crop. In one of the canneries there I was shocked to see the condition of the tomatoes with the respect to worms; going through the packing line and being ground up for the tomato juice and

the puree and so forth. I remonstrated to the superintendent of the plant and the laboratory superintendent, and the answer was, "To hell with the worms, you can't find them when they're all ground up. We're getting out the mold and the bad tomatoes." And this of course, was a challenge which resulted in activity by our laboratory and other laboratories. I think the Microanalytical Laboratory in Washington already was working on the problem because the infestation had been present in other areas of the country before then.

There was developed before that season was over, the "worm fragment count", which enabled laboratory detection of worm or insect contamination in comminuted products. A good portion of that particular cannery's pack of that year was tied up before the year was over, because we were able to detect that contamination that we had seen going into the packs of that particular plant.

Another active project in that area involved fish canneries in Monterey particularly, and of course other fruit products production. At that time we were having problems with bad cream and milk going into butter manufacture. There was a regulatory program sent out by Washington, to check on milk and cream, particularly cream going to creameries for butter manufacture, for possible contamination

by rats. The program called for the tasting as well as the smelling of such cream. The Chief of the Station designated me to supervise the handling of that project. I looked into the problem rather carefully. I was concerned about this tasting business. I found out that at that time, California herds of cattle were likely to be infected with brucellosis. As a matter of fact, the data that I got indicated that brucellosis infected herds were being moved into California from neighboring states. So I told my inspection staff not to taste the cream, that we can find the worst bad cream here on the odor. We had so many seizures actually, that the United States Marshal pled with me not to seize any more, that they didn't have any place to store the seized shipments. Now I suspect that some of our people did taste it anyway, but I actually gave out the order to the inspectors they were not to taste it. This raised the hackles of one of the assistants in the district office because he said the program calls for tasting. I said, "Well, we got enough seizures, all we can handle on examination by odor."

That fall there was a Western District conference at San Francisco and Dr. Dunbar came out from Washington to attend the conference. The project of cream came up in the course of the program discussions. I was asked to make

a report on it from the Station, and I did report. I reported that I had instructed the inspection staff of the San Francisco station not to taste the cream in spite of the orders in the project, because of the fact that I was afraid of brucellosis and that there was no need to taste it. The Assistant from the District office then roundly laid it on to me that I hadn't followed the instructions. So Dr. Dunbar cut in at that time and said as I recall, "I haven't got a very good stomach and I couldn't taste the cream, but I'm not afraid of it." And I replied, "Well my stomach's all right, but I'm afraid of it." And I thought, "oh boy some of the group looked pretty shocked...Roe's in for it now."

But that passed, and later an order came out from Washington not to taste the cream. I was told that Dunbar had gone back to Washington and discussed this with Dr. Hunter. Dr. Hunter said, "No that shouldn't be done." It turned out that the program procedure was initiated by somebody else and Hunter was aghast at it too.

Lofsvold: That was Dr. Al Hunter the Microbiologist?

Roe: Yes the bacteriologist, Albert Hunter, yes. Well that was an interesting incident there.

At any rate after three or four years in San Francisco, during that time I became Assistant Chief of Station, there

were changes in assignments. Vincent was relieved of duty as Chief of District and sent to Denver as Chief of Station. Kimlel, then Chief of Denver was sent to San Francisco as Assistant Chief of District. Harvey who had been Chief at Seattle was brought in as Chief of the District and I succeeded Harvey in Seattle as Chief of Station. That was in May, 1937.

This was one of the most interesting and exciting periods of my career, the six years I had at Seattle. There were several important and sometimes difficult projects in that area. It was a large and extensive fruit producing area, apples and pears particularly, and at that time was one of the heaviest spray districts in the country. Eight or nine arsenical sprays were common on the apple crops in the northwest at that time.

The program as established by Mr. Harvey, my predecessor, in cooperation with the State officials of Washington and Oregon, contemplated testing the fruit for spray residues before it was shipped. My instructions from Commissioner Campbell indicated that I was expected to see that the 25,000 cars of apples and pears rolling out of the northwest were clean so that there wasn't any problem at destination. The arrangement, in the State of Washington, for instance, the State of Washington had a law that

required the state inspection and certification release, as I recall, of apples and pears before they could go out into interstate commerce. This was a law to insure the maintenance of the quality of the fruit,- a marketing arrangement. Harvey had arranged with the state to include in their release certification requirements, the requirement that the fruit be tested and shown within the residue tolerances.

The state didn't much favor the federal tolerances, but they were willing to do that with the cooperation of the industry in order to insure that their fruit wouldn't be sampled and seized in commerce at destination. So there had been a number of private laboratories set up to do the analytical work. We had arranged with those laboratories for our chief chemist to visit with them and check with them and we checked samples with them to be sure they understood the methods and were using the same procedures. We made checks with them from time to time to see that everything was going all right.

One year I recall at one of the larger laboratories in Wenatchee, we found that things weren't going right. I had the inspectors draw samples repeatedly from stuff released by that laboratory. We found a number of high ones so something was wrong. I just took the bull by the horns and issued an order that from now on we wouldn't recognize

release by that laboratory. I probably should've given them a hearing and at least looked into it further, but I didn't. I was young in those days and we went after it, and it really blew things up and shook things up pretty bady, but improved the operations.....

A week or two later a State Senator from eastern Washington came in to see me. He was one of a trio that controlled the legislature at that time and it seems that his connection in eastern Washington also had a laboratory that was operating in the spray residue program. He was very familiar with the whole program and he told me then, that the head of the laboratory that I had brought action against had come to see him immediately. In fact, he said that he and the Head of the Horticultural Department of the state had raced across the state to see this Senator for advice as to what to do about Roe in the Food and Drug Administration. The Senator told me, that he told them that "if Roe was wrong, sue him. If he isn't, do nothing." He said, "They haven't done anything so I guess you weren't wrong." Well, I did a bit of sweating at that when I realized the situation.

Another incident occurred in the spray residue area, as we called it at that time. Idaho was in my territory, and part of Montana, and Oregon. The situation in Oregon was a

little different. The laboratories there were actually operated by the state and they were doing a good job on checking the fruit going out. Idaho, I forget just what the laboratory set-up was, but we'd had a problem with somebody over there. Senator Borah, a powerful member of the Senate at that time, represented Idaho and I learned later (I didn't know it at the time), that Borah had demanded my scalp because of some problem with one of his constituents involved in spray residue. I don't remember who it was or what it was. I learned later that Borah had requested the then Secretary of Agriculture to do something about it, but the Secretary hadn't done anything.

Lofsvold: That was Mr. Wallace probably.

Roe: Yes, Henry Wallace. Henry Wallace didn't take my scalp.

A big project in the Seattle area was canned salmon. Salmon was canned in canneries along the Washington coast, the Oregon coast, and of course extensively in Alaska. There were three areas in Alaska; southeastern Alaska, central Alaska, including Kodiak Island, and Bristol Bay.

It took an inspector, almost two weeks to get around the Aleution Peninsula, into Bristol Bay. He would go by boat from Seattle to Seward and then transfer to a little boat that took about ten days to go up around the Peninsula

and then into Bristol Bay. There was no town there, no hotels or anything. You literally had to thumb rides on cannery tenders, between canneries and put up at canneries over night and so on, for about a month, the season in there. It was a rough assignment. In southeastern Alaska the coverage was made by a Forest Service boat that was provided to us. Southeastern Alaska is a series of mountainous, heavily wooded islands, and mostly under the Forest Service. The arrangements were for them to provide a boat and to take our inspector around the area. It would take about three weeks to get around. There were about fifty canneries in the area.

Well, Harvey and Dr. Dunbar had arranged to try out airplane coverage, the first...well the second year I was in Seattle. Harvey had used airplanes up there, as it was quite common transportation in Alaska at that time. There was not much, there was practically no commercial air travel in the lower 48 at that time or it was very rare. They had arranged a contract with a little airplane company in Ketchikan to try it out in southeastern Alaska. So when word got around the station that the Alaska inspectors were going to use air travel, I heard that some of the wives of the inspectors were going to call on me to protest this dangerous operation. I called in the Chief Inspector and

told him what I had heard. He said, "That's right, they're going to descend on you." I said, "Well, I like to see the girls and all that, but not on a mission of this kind, and I'll tell you what I'm going to do. I'm going to make the southeastern inspection assignment right now. You're going to cover southeastern Alaska this year and I'm going with you."

Young: Who was this?

Roe: The Chief Inspector, Eric Gray.

Lofsvold: Who was a qualified fish examiner.

Roe: And I said, "You can let that leak out and I'll deal with your wife and mine." So that's what we did. Eric and I set off for southeastern Alaska and neither of us had ever been in an airplane before. Eric told me on the way up there on the boat, he said, "There's one place I'm a little concerned with, that's a place called Hidden Inlet. You go in by boat in a narrow channel between great walls of mountains on each side, that's going to be...." "Well," I said, "We'll leave that till the last. We'll try the airplane first somewhere else."

We arrived at Ketchikan late in the morning about noon of that day. As we got into the hotel we met...a name I can't recall...he was the President of the Nakat Packing Company, which was the Atlantic and Pacific Tea Company's

salmon operation. He said, "I'm going over to the cannery this afternoon, you boys want to come along?" And I said, "Yes, we'll go", not knowing where this cannery was or anything. It turned out, it was Hidden inlet. So we got on the plane with him, a little five passenger job. Eric and I climbed on. We watched what the other fellows did and we tried to act nonchalant, our first time on an airplane, it was a hydroplane that took off from the bay there. Went up over the mountain and came down on the bay at the proper point to taxi up to the cannery dock. Everything went fine it was very interesting. I said, "Eric, where were all those cliffs you told me about?" "Hell", he said, "They looked different from up above!" So our first airplane ride was to Hidden Inlet. It used to take at least a week for the boat to get from one end of that area to the other. If they happened to be up around Juneau and Sitka when the weather was hot and there was a heavy fish run down Ketchikan-way, by the time they got down there, it'd be all over. By the airplane we could get to any cannery in the area within about an hour or two.

One trip I recall, we had called for a plane for about seven o'clock in the morning to go from Ketchikan up to Juneau. We wanted to inspect some canneries up there. We landed on the Bay at Juneau and taxied up to the dock.

Somebody had to get out on the wing to throw a rope up to the dock. Eric got out there. The wing was wet and he slipped and dropped right off the wing into the water, and I managed to crawl out enough to get his hand and we got him back on the plane. He sat by the stove at the cannery dock all day and I went out and inspected the factories. When we got back to Ketchikan that evening, I spoke with Mr. Munter, who was the head of the airplane company. He was the chief pilot, he was one of the old-time barnstorming pilots, a good one. I told Munter about this incident, I said, "Eric slipped off the wing and went in the bay." And Munter looked at me and said, "Did his hat float?" I said, "His hat would've floated if he'd had a hat on." In other words, did he go clear in, and he did.

We used to fly when the fog was high enough, right across the islands up the valleys and over. But often the fog was pretty low so we didn't dare go above it because you couldn't tell where to come down, it was all mountainous. So then we'd skim around the islands just a few hundred feet above the water.

I recall one day when we were coming back from a trip we had started up a valley to cross an island and the fog started rolling down on us. The valley split into three valleys. The fog was rolling down in front, we turned to

the right but the fog came into the right also, so we tried the left (it was coming in behind us by then) and we just got out on the left valley. I was sitting up next to the pilot and I had a big forest service map in front of me. I liked to watch where we were going to see if I could spot the places. After we'd been going for a while the pilot said, "Let me have a look at the map." I thought, "oh my god, he doesn't know where we are." I gave him the map and he said, "Oh yes, that's it." He knew where we were all right, but he couldn't remember the name of that peak there. He wanted to radio in his position. Well, those are two or three of the interesting items we encountered in Seattle.

Lofsvold: Was that 1938?

Roe: I was in Seattle from May 1937 to June '43, and that probably was in 1938 when this happened. That was the start of the airplane coverage.

Lofsvold: Did you have any further problems in the next year, of people not wanting to go? Or wives not wanting husbands to go?

Roe: No, I don't recall any protests or complaints. I remember one inspector, Bob Silver, who went up quite willingly, but when he came back he told me of one incident that he'd had, that at the moment was very disturbing to him.

He was flying out of Anchorage to cover Bristol Bay. Instead of 10 days by boat around the Peninsula, you could fly over there in a couple of hours from Anchorage. He took off one day with a pilot who was not feeling very well, obviously disturbed about something. It turned out as they flew along that the pilot said he had just received divorce papers from his wife. He was greatly disturbed and he made the remark, "That he didn't give a hoot whether he got back or not." Well, Silver did, but he was in the hands of the pilot.

Young: Can I just ask a question? I'd read about the situation with respect to canned salmon in the early '20's and so on. Before we go on, could you just characterize the status of salmon canning. Was it pretty clean generally by this time, or were there still bad situations you ran across every so often?

Roe: Well, there were still problems and we still had occasional shipments that contained bad material. But it certainly was a vast improvement over what it had been earlier.

I was told that canned salmon first came into commerce extensively during World War One. Lots of it was provided the troops in that war and there was a lot of bad stuff in it, so that canned salmon had a very bad name among

consumers who were familiar with it as a result of the situation during the war. Well, by the time we were up there in the 1930' and '40's, it was under pretty good control. Now there are a lot of problems, there were and I suppose still are, in the preparation of canned salmon. For one thing there are tremendous tides in Alaska, twenty foot tides and that means that many of the cannery docks can't be reached except at high tide. At low tide they are way out of reach of the fishing boats. Often, if they didn't get a good catch, the fishing boats would stay out for the next tide until they got a good catch. Some of the fish in the hold was pretty old by the time they got in to the cannery, on the tide. So the rules were established to require the fishing boats were to come in on the tide regardless of the size of the catch. That was one thing.

Cannery superintendents weren't always too careful. They were rated, in part, on the number of cases they made per ton of fish delivered. So they were getting everything they could into the cans. There were other problems involved in the delivery, the sorting and butchering of the fish, and the canning and processing that added to the difficulty of avoiding the inclusion of spoiled or partially spoiled fish.

In the World War I period, I was told that it was not uncommon to find 20 or 25% of the cans in a shipment containing bad fish. By the 1930's the whole operation had been greatly inproved and generally was under good control so that not many shipments were encountered that contained significant spoiled or stale fish. I might add another comment on canned salmon...

The year I took over in Seattle was the first year in operation of the "Better Salmon Control Plan". When I was told what the plan was, I frankly was a bit shocked. It was such a departure from the usual enforcement procedures, involving direct participation by the industry. But it worked very well. Commissioner Campbell told me it's your job to make the plan work. The plan briefly was that, those canneries whose operators chose to operate under the plan, were to provide us with a complete list of their packs and their code marks and everything. They were to have their packs tested by the National Canners Association lab in Seattle and any lots that the Canners Association lab found bad they were to withhold from the market and notify me that they were withholding it, and it would be reconditioned under proper supervision. That any lots that we sampled and found to contain bad fish that they had not reported, they were to hold for seizure.

Most of the canners, I think all of them, I don't recall any now that were not on the plan, participated. I was concerned because this was something new and it was the NCA laboratory boys who had appeared in court against us on cases that went to trial, and of course they gave the best picture they could from the standpoint of the organoleptic tests that were used then as opposed to ours. I said, "Gosh, that's just going to be pretty risky." But you know, it worked out very well.

I remember that first year or second year there were, I recall three instances where canners came in to me and said that the NCA had knocked over a lot that they knew we had sampled and we hadn't said anything, so we must've found it all right. If so, couldn't the lot be released without reconditioning? I would say to them, "Are you on the plan or aren't you? You don't have to be on it, but if you are on it then you must follow the rule and dispose of it." Three times that happened, three different canneries and I told them all the same and so they went back and reconditioned their lots.

There used to be a meeting of the Salmon Packers every year at the end of the salmon season, I think it was late in the Spring sometime. I was always invited to make a speech, in fact they put me the last on the program because

they liked to have a lot of questions and harrasment and if I was last on the program that kept the guys in attendance. They wouldn't be sneaking out. So, I was on the program that year and I ad libbed a little bit in the course of my prepared speech and referred to these instances of where three of them had asked to be relieved of having to follow the condemnation by their laboratory. I told them that before we took action against a lot we had to be sure that we were right. In other words, we had to allow a margin of error, that we had to find a little bit more than would be enough to call it bad to be sure. I said, "Your examiners have to use that same margin of error but in the opposite direction because their job is to prevent you from shipping anything that we might find bad on our sampling. So they have to be a little more careful on that same margin of error but in the opposite direction so that anything they release is going to go right through." And I said, "I'm not surprised that there are occasional lots in which your examiners find something that my examiners don't. If that were not the case, I would think something was wrong." I said, "This satisfies me that you're getting a competent and an honest job from your laboratory and you ought to be darn glad of it." That took care of that situation. I didn't have anymore requests.

I don't know what the situation is now up there, that was back in 1938 to '43 but the first years of that operation worked out quite well. It was possible in that area because the great bulk of the packs from Alaska was brought down for warehousing at the Seattle docks and that's where it was labelled out and sold and distributed. Oh, there were some packs that went direct through Canada from Alaska by rail but most of it was warehoused in Seattle. The canneries within the state, who operated on the plan of course were there with their packs and there was no problem.

Lofsvold: That Better Salmon Control plan was one then that had been negotiated before you got to Seattle?

Roe: Yes.

Lofsvold: Was it just the year before that it had been agreed to?

Roe: Apparently yes, because my take-over up there was the first year of its operation and it had been negotiated with the Commissioner in Washington.

Lofsvold: I think Harvey had a hand in it too.

Roe: Harvey was involved in it yes, I'm sure. Well, I've stopped too long at Seattle, perhaps.

It was in July 1943 I was transferred to Los Angeles and I spent nine years there at the Los Angeles office as Chief of Station and later they called it Director of the

District. They changed the organization as you know. The problems in California, some of them similar to those in Seattle but many of them different. There were fisheries there, canned tuna principally in that area as to the canned products and, mackerel and sardines. And of course, a big citrus fruit industry and also a big drug industry or pharmaceutical industry, lots of quack remedies and various types of vitamin products and that kind of thing there. It was an interesting territory, a difficult one in some ways.

We had a lot of court work in Los Angeles. It was a big U.S. Attorney's office there. I think there were some twenty-five or twenty-six assistant United States Attorneys. There were six or eight judges, I've forgotten just how many but it was a large set-up. A sub-office in San Diego where there was one judge stationed and an Assistant U.S. Attorney. The U.S. Attorney's in Los Angeles was organized into a Civil Division and a Criminal Division. Our seizure cases, of course, went through the Civil Division. The criminal cases, the prosecutions went through the Criminal Division. It was the practice there at that U.S. Attorney's office, when cases came in for the filing of an information or the development of an indictment they would go to a certain Assistant U.S. Attorney who would decide whether to file the cases or not. So, every once in

a while they would raise questions and hesitate to file the case, but after discussion they would usually file it.

I remember one case that we thought was an important one because we had developed it with a certain situation in mind. It involved a vitamin product that was deficient in one or more vitamins. It had been manufactured in San Diego, and shipped to Los Angeles. We sampled it in Los Angeles, and found it deficient and on the theory that this was part of a lot that this dealer ships in to interstate commerce and we had evidence that shipments were made in to interstate commerce. Our theory was that instead of waiting to sample a shipment in interstate commerce, which would be only part of the lot involved and if we find that bad then go through the procedure with respect to that interstate shipment, why not act on the main lot here before it is shipped. Since some of it is going to be shipped, and the manufacturer had guaranteed it on his invoice as in compliance with the Food and Drug Act we thought we had jurisdiction. The person who bought it, the distributor, was shipping in commerce so we sampled it there and found it low, and filed a request for prosecution of the San Diego manufacturer. The Assistant United States Attorney said, "Oh, no, you are stretching the law." So, we argued for some time and then he agreed to go to the

U.S. Attorney, who then was Mr. Tolin. So he and I went to Tolin, he explained his position and Tolin said, "What did I have to say" and I told him our view of the matter. I am not stretching the law, I am trying to apply the law. We have the court here to tell us if we have gone beyond the law. Why should we decide that we should narrow the law to this point. We think this is important that it's a basis for control of this product that ought to be up to potency in the claims that they make. Tolin said, "That's a reasonable argument, go ahead and file." So Mr. Komins filed the case.

The case was against the San Diego firm so it was set for trial in San Diego. The Assistant United States Attorney there protested. "On the facts here, we shouldn't proceed on this." Tolin told her to proceed with the case. Well, the judge ruled against us and frankly we expected him to because of a ruling the Ninth Circuit Court of Appeals had made on some other case. We thought that the trial court might feel bound by that ruling. Our theory was, that's all right. The situation here is one that we can appeal direct to the Supreme Court. The district court judge as I recall, was one that we felt wouldn't be too unsympathetic with our view, but he would adhere to the law as he interpreted it and he did. But he gave us a record

that did enable direct appeal to the Supreme Court and the Supreme Court ruled with us. We did get an interpretation of law on that point that we thought was very important, I don't know how it's worked out.

Young: Do you remember the name of the company or the case?

Lofsvold: Michael Walsh trading as Kelp Laboratories.

Roe: That was the one.

Lofsvold: We still use it in the basic law course that I've been helping teach. We don't use the guaranty section now as much as we did in those days. Since then we have other court decisions that give us jurisdiction over goods before they are shipped, on the basis of one of the ingredients was received in interstate commerce. That made the guaranty provision less important for controlling goods before they are actually distributed to the public as you were trying to do in this case. The guaranty section is still there and can be used but it isn't needed nearly as often as it used to be.

Roe: That was one interesting situation we had with the...

Young: It was about the same time as the Sullivan case, wasn't it? Roughly speaking.

Lofsvold: Late '40's, yes.

Young: A little later. But they were all involved in the question of jurisdiction.

Lofsvold: Yes, this was another aspect of interstate jurisdiction. It was 1947.

Roe: Well, after nine years in Los Angeles I was transferred to Washington. In the mean time, there'd been a reorganization of the field service. When we started out there were the three field districts with headquarters in New York, Chicago and San Francisco. Now those districts were done away with and all of the former stations became Districts and there was set up in Washington the Division of Field Operations, the Division of Litigation, and a Planning Division. The three former District Chiefs came in to head up these three new divisions except Wharton didn't come in, he retired.

Young: Were you consulted at all prior to this change of administration, about it? Did you have anything at all in the way of input to make as this decision was brewing?

Roe: No, I do not recall we did.

Lofsvold: Do you know whether the District Chiefs consulted? Obviously they would have been?

Roe: I think they probably were but I do not know.

Lofsvold: I cannot recall, I wasn't a Station Chief but I don't believe Monfore was consulted either. He was your

successor as Station Chief at Seattle, and I was his assistant at that time, but I don't think he knew anything about it either until it happened, even though he was transferred to Washington as Harvey's deputy.

Young: In your being informed of the change, do you remember the key reasons given for the advantages of the new system over the old system? Did they tell you reasons for the change?

Roe: I don't recall whether they did or not. Incidently I wrote an article on the organization for Food and Drug Law Journal once. "Evolution of the Field Organization", that's right, Charlie Crawford asked me to do that.

Lofsvold: Shall we make just append a copy to the transcript of this interview?

Young: Right. December 1952 issue of the Food Drug Cosmetic Law Journal.

Roe: When the Districts were done away with and the new organizations put into effect, J. O. Clarke, the Chief of the Central District went to Washington to head up what became termed the Division of Program Research, which was, really, the Planning office. He retired a few years after that and I succeeded him in that assignment. That was in the middle of 1952, in fact about August '52. I was in that assignment for two years and then Charlie Crawford

retired as Commissioner. Crawford was Chief when I went in there and he retired and Larrick became Commissioner and Harvey, who had been an Associate Commissioner became Deputy and I became the new Associate Commissioner for a couple of years.

Then there was another reorganization of the set up and this reorganization did away with the Associate Commissioner positions and set up a bureau organization. Previously, the assignment I had as Associate Commissioner was the coordinator of the headquarters Divisions, - the Division of Operations, the Division of Program Planning and the Scientific Divisions.

My assignment as Associate Commissioner was to be coordinator of the Headquarters Divisions, including the Scientific Divisions. But on the reorganization there was set up a Bureau of Field Operations, a Bureau of Medicine, and a Scientific Bureau, the Bureau of Biological and Physical Sciences we termed it. I was assigned to head that Bureau and to organize and develop that Bureau. It was bringing together the then seven Scientific Divisions. This was perhaps my most interesting and challenging assignment in the Food and Drug Administration, to get these Scientfic Divisions coordinated into a good operating scientific team.

There had grown up some walls between the Divisions, where there wasn't always the degree of cooperation that there should be. We felt by setting up a Bureau of Science that we could better administer that and get a good hard-hitting scientific team. I did not pretend to be the chief scientist of the administration which I was not because the people in the Scientific Divisions, the Division Chiefs and many others were far greater, better scientists than I was. I was the administrative director of the Bureau. The scientific expertise resided in the Division Directors of each Division who were experts in their fields.

I think this organization developed very well, at least from my stand point I feel we set up a good scientific organization. We had participation by several different Divisions at a time on a certain project or problem, where before they had independently dealt with it if they dealt with it at all. We could call on the different types of scientific expertise that they had there to apply on these problems in a better, coordinated way. It worked out very well in the years that I was there, which was seven or eight, from '56 to January '65, Director of the Bureau of Biological and Physical Sciences.

At the time I took it over I think there were seven Divisions; Antibiotics, Cosmetics, the Division of Food,

the Division of Pharmaceutical Chemistry, the Division of Pharmacology, the Division of Microbiology, and Division of Nutrition.

There were perhaps four hundred or four hundred and fifty people in the group. We were enlarging it and had plans to bring it up to about a thousand people in the Bureau. At the time that it was reorganized again we had about seven hundred, as I recall. I would say about 67% were in professional scientific categories. There was a fairly large group of technicians and animal caretakers and laboratory helpers and then of course the clerical and secretarial staff. We had a good organization.

During those years; the early years - we were in trouble financially, that is with depleted resources. That was the time when the Eisenhower Administration came in and the ranking Republican, Mr. Tabor, became Chairman of the Appropriations Committee.

Tabor of New York, had his day. He saw to it that Food and Drug appropriations were cut. We actually had to run a RIF at that time and it was devastating. So we were in pretty low straits for a few years.

I recall that it appeared to many of us that the new Eisenhower Administration appointees believed their

campaign rhetoric, that government bureaucrats generally were incompetent or worse. It always takes some time for a new administration to get acquainted with the Department staffs and programs and establish mutual confidence with the permanent personnel, etc. This seemed particularly the case in this change - it was evident, I thought, in several Departments - and particularly so with us, emphasized by the "Taber appropriation cuts", which necessitated a R.I.F. in FDA. Some industry groups took advantage of this atmosphere and complained to the Department about certain regulatory programs or procedures. Our "Clean Grain Program" is a prime example. This program had been developed by the Division of Program Research after several years of thorough field studies. (The sanitation clauses of the Act of 1938 had enabled programs to clean up insanitary conditions in manufacturing plants such as rodent and insect infestations. Now, in the case of cereal products we were inaugurating a program to improve the handling and storage of food grains to prevent rodent contamination).

I became Director of Program Research in 1952 - the Clean Grain Program was one of our major activities at that time. At the start of such a program we sought to take action against the worst contaminations, so our program at the start called for condemnation of corn, for instance, that contained more than one rat pellet per pound.

Early in the new Administration, Mrs. Hobby, Secretary of H.E.W. stopped the program. A few years later after Mr. Mintener had become Assistant Secretary of the Department, the program was reactivated with his help, and I believe perhaps with some assistance from Under Secretary Rockefeller, but at an action level of two pellets per pound.

(The Department of Agriculture had not been happy with our program - we, of course, had sought their cooperation because of their interests and responsibilities in grain products.) In the revival of the program, Assistant Secretary Mintener designated me to represent the Department in meetings and contacts with the Department of Agriculture to secure their cooperation and we did get their acquiescence and cooperation.

It was during the early Eisenhower years that a National Cancer Program came into being, which we did participate in, as I mentioned at lunch; accepting funds from the Cancer Institute to set up and enlarge our Pharmacology laboratory so that we could do some of the toxicity testing on compounds that they wanted to study in this cancer program. That did enable us to enlarge our laboratory and maintain our staff there and get some training which came in well a few years later when we dropped out of the program, or the program changed.

By then we did have more appropriations and we did have more responsibilities in the Pesticide Amendment and the Food Additive Amendment and the Color Additive Amendments and all of that, which made for a tremendously important and tremendously difficult scientific operation in some respects. I think that we had there a first class Scientific Bureau that the boys in their fields, in the Pesticide field, and Pharmacology and in Microbiology were just tops in their areas anywhere.

Young: Prior to the budget cuts that you mentioned, did you feel that you had enough money adequately to staff for the tasks that you had and to get good scientists? There was shortly to come, a good deal of criticism about FDA for not being able to secure and hold as many and as competent scientists as it ought to have had, as in the Citizen Committee reports. Was this criticism based solely because of the cuts of the Tabor period? Or had you really had trouble with your budgets getting people? You've mentioned that these are as skilled people in their field, and very appropriately skilled to their tasks. Would you talk about the quantity and the caliber of the scientists in light of this background of criticism that was to come.

Roe: Well, I think even before the Tabor period, we did not have adequate funds to do what we should have been

doing and could have been doing. This period of course, just enhanced the problem when we were cut back. I think, yes, I think perhaps we did have diffculty in getting and maintaining scientists of the caliber we wanted. Although those that did stay with us, I do not want to depreciate, I think we had high caliber talent but many scientists of that quality were not interested. They wanted to do strictly research and basic research. After all, we weren't basically a research organization. We were a law enforcement organization or a law administering organization. The basis for our being there was to supply the underlying science and methods of analysis and procedure and so on to enable enforcement of the law.

We had to direct all of our operations toward that end and many scientists just weren't interested in that phase of it, as I see it. They would leave to go to Public Health Service or universities, or places where they had more control over what they could do and what they could study, as basic research people. I think it's amazing that we had and retained as good quality scientists as we did.

Young: That was part of your job to keep working at that problem of staffing with the best scientific personnel that you could.

Roe: That's right. I did have, frankly some problem within the organization. Our business office, when we were setting up our budgets and asking for facilities for this project and that which involved some research for study and development of methods, or research to study the composition of certain foods and so on. They would say, why you're not a research organization, you're supposed to be enforcing the law and you shouldn't have that kind of work going on. I had, from time to time to repeatedly argue that this is basic to our ability to do what is required for enforcement of the law.

There was this continual criticism within the organization. Why even from the General Counsel's office one time, as I recall, a memorandum was sent to the Commissioner, saying that the Scientific Bureau should not be working on development of methods, or improving methods,- that they were just making trouble for us as they get more sensitive methods and then everything's blown up and they shouldn't be doing that. I had to argue, of course, we should be doing that. If we should stop doing it it isn't going to stop development of methods, that's going on all over the world, but we should be the leaders in this field.

Young: Otherwise you'd be the laughing stock in court.

Roe: Yes.

Young: You were, in many ways, the leaders in the world, weren't you?

Roe: I think we were.

Young: Can you remember examples that you would point to of things that show the Food and Drug Administration leading the state of the art?

Roe: Yes. I think in chemistry, in the methodology of pesticide chemistry, some of the work reported by our people certainly was in the lead. And certainly in pharmacology, I think most of the toxicity testing work that was followed, not only by our laboratory but laboratories everywhere working on this had been developed by our pharmacologists, or came from that pretty much.

Lofsvold: Then too, the antibiotics people were responsible for.....

Roe: The Antibiotics Division, of course, was in the fore on antibiotic testing and antibiotic standards and I think that's pretty much the case in pharmaceutical chemistry. That many of the USP methods derive from work at least participated in, and some of it initiated by our people.

Young: In vitamins?

Roe: Yes. Now in vitamins, and the Division of Nutrition, which was formerly called the Vitamin Division, they did develop some of the methods on vitamin assays that have

wide recognition. Dr. Oral Lee Kline who participated in one of your meetings, is very familiar with the vitamin work and the nutrition work of the Bureau.

I take great pride in the scientific competence of our people. Oh, they weren't the greatest scientists in the world all of them, and some of them had their foibles and we had problems. But I think by and large they would match up with and in fact, lead most laboratories that I know, in competence and integrity. (See attached letter June 27, 1958 from H.A. Toulman, Jr. to R.S. Roe).

Lofsvold: I think one of the shining examples, especially of the interplay between Divisions that you spoke of under your supervision, was the mycotoxin problem when chemists and the microbiologists worked together on that, and also the pharmacologists in the early days of the aflatoxin problem.

Roe: That's right I recall what I used to do when a matter would come in like one of the cancer problems, such as the Hoxsey cancer case or some other that was giving us much trouble. The Division of Field Operations wanted to get some scientific work done to back up a case they were developing. As had been their habit before, they went directly to one of the Divisions where they thought some work should be done. I heard about it, so I asked them to bring all

matters like that to the Bureau office. What I did when I got a request like that was to decide which Division should do the work. In many cases several Divisions might be involved.

What I did then was call a conference of the Divisions that I thought might be involved and have the Field Operation present their case as to what the problem was and what they wanted done. Then I would designate somebody to head up the investigation and indicate the Divisions that would be in on it. This worked out very well. I remember Dr. E. M. Nelson, - Elmer Nelson was head of the Division of Nutrition at that time, - he told the Commissioner that this development of inter-Division teams on specific projects was one of the best things that had happened. They were all a bit skeptical when I came over to be Bureau Chief, the Administrative Chief. I got Elmer and other Division Directors in on one of those conferences one day to select a project Director and determine which Divisions should participate on a certain problem. It was then that Elmer told the Commissioner that one of the best things that's happened here was getting the group together to work on a coordinated basis.

Young: It just was an inter-disciplinary seminar on the particular practical problem you confronted?

Roe: That's right. So we had a very interesting and, I think, worth while time there in that Bureau. Then reorganization again. Our Bureau was cut down the middle.

Young: When was this?

Roe: This was about January 1965. Now what brought that about...some reorganization within the department.

Young: Still this was the last year of Commissioner Larrick's term.

Roe: No...

Young: I think he retired in December 1965 if I remember right.

Roe: Well, I'm not sure of that date but I am pretty sure of the date that January 1965 when they set up the Bureau of Scientic Standards and Evaluation and the Bureau of Scientific Research.

I was designated as Director of the Evaluation Bureau and Dr. Banes, who was my Assistant Director in the Bureau of BPS was designated Acting Director of the Bureau of Scientific Research. (Dr. Summerson was brought in as Director of the Bureau). In my view they should have named Dr. Banes Director and left him there, he was really good, and very capable and knowledgeable. However, that's the way it started. He was Acting Director there and I got the other Bureau. And as set up by our business office in the

administration the Bureau of Scientific Standards and Evaluation was to have practically no laboratories at all. We were to review petitions and set up tolerances as before, and food standards work and anything involving standards and evaluation. We had the Certification Divisions also.

Well, I protested that loudly. I said, we just cannot adequately do the job without laboratories. These are scientific matters, we have to have scientists who know all the angles to evaluate these petitions. They said, well you can call on the Science Bureau for that. I said, no, we've got to have it here and I protested that strongly so finally they agreed yes, we could have some laboratories and scientists and so on. Well, in one of the laboratories I had to have pharmacology expertise. So when we first set things up I had one of the Divisions designated Pharmacology. The business office said no, you can't have Pharmacology we've got a Pharmacology Division in the other Bureau. We can't have two of them. I said okay we won't have pharmacology then, but we will set up a Division of Toxicology. They accepted that and that's the way we took care of that one, at least temporarily. Well, this new Bureau organization I felt was a mistake, but...

Young: That is to say, splitting the Bureau was a mistake in principle, right from the start?

Roe: Yes. There had been, as I recall, before this Division was made, this reorganization...and there was some other reorganization within the Food and Drug Administration at that time. I do not recall what it involved but our Division Directors and some of the other scientists, and I had met with the Commissioner and the Deputy Commissioner, some months before when it was obvious that there was to be a reorganization. They discussed it with us and asked for our input and indicated that there would be further discussions with us, but there weren't further discussions. Suddenly I was called in one day by Larrick and handed the program. No explanations. I don't blame Larrick or Harvey, I know they had pressure from the department and just what it was I never did know. I discussed it with Larrick and at the time he presented it to me I wasn't prepared to evaluate it. I said, "we'll see what we can do to line it up." Then after I thought about it for a while it just seemed to me, this is bad, I don't think it's right. I wrote a memorandum to Mr. Larrick about it. I didn't handle it very well, I wish I could do it over again. I worked on it at home and had my wife type it and we made several drafts and I finally had it worked out very well. I left it with Larrick. He was hard to see in those days, he wasn't too well, you know and he just

wasn't available. So I left it with his secretary to give to him with a copy to Harvey. I outlined I thought it was very very bad, that after all, this was an extremely important thing that the development of standards and the setting of tolerances...and we must maintain the leadership in this field. We couldn't do it without having the review scientists backed up with a laboratory of their own and participating in the work of the laboratory. I protested real strongly and I wound up by saying I realized that eventually this Scientific Bureau has got to be headed by a recognized scientist of stature, that I don't qualify for that status, and you may want to replace me, but I think its important that the splitting of the Bureau not be done.

Well, I'm afraid I didn't hit Larrick just right on it and I don't know how much of this should go in the record, but Mr. Harvey called me and was quite disturbed. He said, "If this gets out to the Congressional Committee its going to blow up the works." I said, "Well nothing's going to get out Harvey." He said, "Well its on the record, your secretary..." And I said, "My secretary in this case was my wife. Nobody else knows anything about this." So that relieved him. I said, "I'm certainly not going to any Congressional Committee, but I feel its my duty as Chief of

your Bureau to give you my views on the meaning of this and that's what I've tried to do." That's the way it was set up and we worked then, oh about two years, on that. Yes, I guess that must have been about the time that Larrick went out, Dr. Young. It was shortly after that that Goddard came in.

I remember my first meeting with Goddard. He'd called in the Bureau Chiefs and how he ridiculed the nomenclature of the Bureaus, the Bureau of Scientific Standards and Evaluation. So I didn't last long after that, that's right. January '65 that started, July '67 I retired. So I had a year and a half as Director of the Bureau of Scientific Standards and Evaluation.

Young: And it was during that time you worked hard to build up its own laboratory competence for its mission?

Roe: Yes, of course when we split up, we did get part of the existing laboratories. I protested anything else. We did build them up some.

Early when Goddard came in, he ridiculed the whole business. I remember one conference he called me in to discuss that and challenged me to show why we should have this Bureau. I said, "Well Dr. Goddard I really didn't think we should have had in the first place this set up." and I told him, in fact I may have showed him the letter

I'd written to Mr. Larrick. In fact, Goddard was saying that he was going to consolidate those Bureaus and he did consolidate them. Actually the two Scientific Bureaus lasted less than a year under Goddard. I said to July '67 but it was in May '66 that Goddard re-combined the Bureaus into the Bureau of Science or whatever he called it. He designated Dr. Summerson as the Chief of the new, combined Bureau and Danny Banes as Deputy and designated me as Associate Director. I thought this was sensible to re-combine those two Bureaus into one Scientific Bureau. (See attached Goddard/All FDA Employees Memo, April 22, 1966).

I never did understand just why the old Bureau of Biological and Physical Sciences was broken into two Bureaus in the first place. Except that, it was becoming a large unit then. We had around seven hundred people and expected to enlarge it more. From the size it may have been felt that there should be some change and perhaps there should, but I felt that the way it was divided, just in half didn't make good organizational structure. I'm sure that the Commissioners office was under some pressure from the Secretary's office for that type of change and I never did understand just what was involved there or what the problem was. I'm sure that the Commissioner had intended to talk with the scientists more on that to get their input but had

not been able to do so because of some pressures or problems on him.

Lofsvold: Wasn't it about that time that the Humphrey Committee and others were pressing that we needed to bring in outside, recognized scientists? And that that might have had some bearing on the fact that they went out and recruited Summerson from the military?

Roe: I think it may well have been, there was that feeling there. I also got the impression from some of the comments I'd heard from Congressional Committees, that the Congressmen involved seemed to think that only MD's were scientists. Whereas those in my Bureau weren't quite so sure that MD's were.

Young: You said at lunch that you once had met Dr. Wiley and you entered the agency when Mr. Campbell was head of the Food and Drug Administration. Therefore, you served under every Commissioner from Mr. Campbell to Dr. Goddard. Though, obviously agency policy and the total nature of an agency are a lot more than a Commissioner, none the less the Commissioner is an important ingredient. I'd appreciate it if you'd tell briefly your impression of Dr. Wiley as a person from that one occasion when you saw him at a convention, then perhaps talk a little bit about each of the Commissioners along the line, their style, their

personality, with perhaps an incident or an anecdote if one comes to your mind, which helps make their mode of operation vivid.

Roe: Yes I'll try. Some things have kind of faded from memory of course as to specific incidents and so on.

My first five years was in the laboratory in Chicago and it was during that period that I was sent to one of the A.O.A.C. meetings in Washington. Maybe about 1928 or '29 I'm not sure which year. Dr. Wiley was the speaker at the A.O.A.C. banquet that year. It was a rather small group then, nothing like the huge groups they have now at A.O.A.C. meetings. It was a small group at the dinner, and I, of course, was very impressed as a young chemist from the Chicago lab to see and hear Dr. Wiley and actually to meet him and speak briefly with him. That was my sole contact with Dr. Wiley and so I didn't know him but I did meet him on that occasion.

Young: What kind of a person was he as you walked up to him now, and you remember him in memory and you heard him in action? How would you describe him in his mode there in retirement but still interested in the problems of the agency?

Roe: Well, he certainly was interested in the activities and the organization of the A.O.A.C., and was very cordial

to us young fellows who were there to meet him. I was quite impressed with him. His speech I don't remember much of it, except one or two anecdotes that he told that showed a great deal of humor and general understanding and it was a very outstanding occasion to me.

I think it was on that trip that also I was to meet Mr. Campbell. Dr. Paul, the Chief at the Chicago Station had suggested I call at Mr. Campbell's office to meet him. So I had set up and arranged an appointment to see him at ten o'clock on a certain morning as I recall. As I started to go to his office I noticed my shoes looked very bad so I thought, I can't go to the Commissioner like this. I stopped to get a shoe shine and I got to his office about two minutes after ten. At that time his title was Director of Regulatory Operations of the Department of Agriculture. I presented myself to his secretary and she said the Secretary of Agriculture just sent for Mr. Campbell to be over in his office at ten o'clock so he had to leave. He's left his apologies, he wanted to meet you and all, and I thought, oh I've done it after all. So I didn't meet Mr. Campbell on that occasion because of that damn shoe shine. But I found I wasn't blacklisted after all. But I did have to report back to Dr. Paul that I'd tried to see Mr. Campbell but the Secretary of Agriculture had sent for him just before I got there.

Young: Was he a comfortable man to be with when you finally did meet him and have business with him?

Roe: Yes, quite so. I found him easy to meet and very cordial and yes, we all thought highly of Campbell and the other Commissioners so far as that goes.

Dr. Dunbar, at the time I was Assistant to the Chief of the Import Office in Washington the three years, or four that I was here was the Assistant Chief of the Administration. Mr. Campbell was nominally Chief but he still was pretty much involved with some of the other affairs of the department. So that I had an opportunity to work with Dr. Dunbar and notice his operations and I certainly found him very competent and effective operator.

Lofsvold: During that period that you were here in the Import Office, was that the time of the Ambruster Hearings?

Roe: The Ambruster Hearings were just concluding at the time I reported for duty in the Import Office. It was about July 1 1930, I think, or maybe I got there a little before then. My orders were to report to the Import Office in Washington on a certain date then go up to New York for a week to work on the docks there and observe the import operations at New York, the big station and then come back. I was to report to Dr. Taylor, the Chief of the office.

I recall I arrived there at the appointed time. Dr. Taylor was not there, but Mr. Stengel, the Assistant to the office was, so I reported to him. Stengel said, "Dr. Taylor's up on the Hill at the Ambruster Hearing, they're just winding up today. Maybe you'd like to go up and hear it." I said, "Yes I would." So I hied up on the Hill and found out where the hearing was and went in and listened to the wind up of that hearing and it was the wind up.

It is my recollection that this matter involved hearings held by a Congressional Committee on charges brought by Mr. Ambruster against the Food and Drug Administration, the Commissioner and others with respect to shipments of Ergot offered for entry into this country. Ergot is a drug elaborated in the growth of a fungus on grain, particularly rice.

The activity of the drug is due to several ergot alkaloids. It was an important drug at that time for use in controlling hemorrhaging following child birth. It was a U.S.P. item; there were established standards for the alkaloidal content or alkaloidal activity. It was important that the drug be up to the expected potency. (I do now know whether Ergot is still widely used).

Most of the ergot in commerce was imported from Spain; Mr. Ambrusher was in the business of importing ergot and

tried to corner the market in Spanish ergot. His competitors sought new sources of ergot, principally in Russia. Ambruster claimed this ergot did not meet the U.S.P. specifications and FDA should not have allowed its importation. He made serious charges against FDA procedures, tests, and methods of assay, the details of which I do not recall. It is my recollection that Ambruster's charges did not stand up and that FDA got good marks from the Congressional Committee.

Young: Did you see Ambruster there?

Roe: Yes.

Young: Can you describe him as a man?

Roe: No I can't. He was there but I really have no recollection of him.

Then I saw Dr. Taylor in the hall at the conclusion of the meeting, and you may want to erase this later but, I went up to Dr. Taylor, reported myself to him and said I'm here. He said, "I don't want to talk to you now, I don't want to talk to you," and turned away. I thought well, there's something I don't understand here. So I went back to the office and told Stengel that I had seen Dr. Taylor, but that he didn't want to talk to me then. I asked what is the program; Stengel said he didn't know. I said, "My orders were to go to New York tonight, be up there for the

week and then come back. Dr. Taylor didn't want to talk now...." Well Stengel said he didn't know and I said, "All right I'm going to New York tonight, I'll be back next week." So I did. When I came back Dr. Taylor was not there. Stengel was and Stengel said well Dr. Taylor's off for a few days, he's resting. I said okay, what should I do. He said Dr. Taylor wanted me to use the other half of his desk and and he pointed to the files stacked around the desk that I could start working on. So that was my start in the import office.

Young: He was just so upset by the hearing?

Roe: He was upset by the hearing. Dr. Taylor was a very fine man, very knowledgeable on his work but, he would have nervous problems every once in a while. I found out later that he was out at the Seventh Day Adventist Sanitarium. He was there for a few days to rest.

Young: That would've been a very arduous time for the...

Roe: It was a very difficult time for him and for the whole agency and Dr. Taylor as head of the Import office, of course, was right in the middle of that Ambruster stuff, so he was pretty upset.

Young: In the long run, the fact that Senator Copeland was present during that hearing and came away with a very good impression of the Food and Drug Administration as a result

of the hearing, was to be of decisive importance in the 1930's when the effort to get the new law was underway. Did you have anything to do with Copeland at all?

Roe: No, I never did. But one thing about that new law was of interest.

I remember when the Roosevelt Administration came in and Rexford Tugwell was appointed Under-Secretary of Agriculture, we were still in Agriculture then. We in Food and Drug were quite concerned because Tugwell was, I think, a professor up at Columbia or somewhere and had made some critical comments on the Spray Residue program for instance, of the Food and Drug, that they were too lax in enforcement and so on. We were concerned that maybe we're in for some problems here. I remember one day sitting in the office, Dr. Taylor and I were there and Dr. Dunbar came in all kind of excited. He'd just come back from Campbell's office and he said, "Campbell's been in to see Tugwell." The reason for it was Campbell was asked to prepare a letter for the Secretary's signature to some farmer I think, or farm organization, discussing the residue problem and problems of fruit production in answer to the correspondents complaint, I guess. I don't remember the details of it. Campbell had prepared a letter and it went to Tugwell to sign and Tugwell sent for Campbell, so

Dr. Dunbar told us. Tugwell's comments on the letter indicated he thought that Campbell had been pretty lax in his discussion of the spray residue business in this letter. Campbell had pointed out to Dr. Tugwell, that this letter was issuing from the Secretary of Agriculture and the Department of Agriculture had other interests and responsibilities for the farm community and the agriculturalists besides administration of the Food and Drug's Act. What he had tried to set out here in this letter was the overall interest of the Department. I don't remember all the details. He said Tugwell accepted that and concluded it was a proper letter and signed it. Then Tugwell sat back and said, "Campbell, you have some problems on this haven't you?" Campbell said, "Yes." Tugwell said, "Aren't there some defects or limits in the law?" Campbell said, "Yes, there certainly are." So they talked some more and Tugwell said, "Well, I think we ought to do something about that. I'm going to take it up with the President." Campbell gave him some ideas. So Dunbar came in that day all excited to tell us this. Tugwell was going to take it up with the President, or maybe it was after Tugwell had taken it to the President that Dunbar came in. Yes it was, and then he told us about how it developed and that Tugwell had seen the President and the President had said write a new law.

Young: That was the start of it. It was Mr. Crawford who was really the pivotal person in the Food and Drug Administration at the time in the drafting of the law.

Roe: Oh, I think so.

Young: Were you involved at all in that aspect?

Roe: No I really wasn't.

Lofsvold: I remember some story that Crawford was very ill, and while he was recuperating at home that he drafted a good part of the new law. Do you remember any circumstance like that, Bob?

Roe: Yes just this. I remember Crawford telling me that he had been ill and he'd gone out west out in Texas or somewhere in the country to recuperate. He was working on the thing out there on some aspects because they made some arrangements for him to be out there to recuperate but at the same time to continue on the payroll. He was really working. I don't remember all the details of it but I do remember he told me that he was out there and that they brought stuff to him and he did a lot of work on it, but the details of it I don't know or don't recall.

Young: From reading a lot of the letters during the period, it's clear that Tugwell really was deeply interested in this. It was, I think, Tugwell who got a couple of young lawyers of whom Cavers was one.

Roe: I think that's right.

Young: The other man's name was Handler, from Columbia. They helped Crawford. Crawford would make assignments to them and they would draft certain sections. There was a lot of correspondence back and forth while they were working drafting this first bill to introduce in 1933. I had never heard this about Mr. Crawford being sick though and working on the draft while he was away from the office recuperating.

Roe: I don't know much about it but when you mention it I recall that Crawford told me something about it.

Lofsvold: That might even have occurred before the conversations with Tugwell because I think that Campbell had been thinking about a revision of the statute for some time before the opportunity arose in the Roosevelt Administration.

Roe: I think he had, I don't know whether that occurred before then or not. Campbell had told Tugwell at that conversation that there were some revisions that should be made and then they wound up saying, write a whole new law.

Young: I know that the ten year annual report, the tenth year after the law had been begun to be enforced, maybe it was a 1917 report then, contains a critique of the law and an indication of things that needed to be done to change it which obviously must have been written by Mr. Campbell. Of

course, the chances during the '20's were so remote, -- in fact, it was preventing ripper bills getting through that would do things like knock out the multiple seizure provision, that they had to pay attention to in the '20's,-- there was no chance really of getting a new law. Not until the New Deal did that become anything more than a kind of study, a quiet study project on Mr. Campbell's part.

Roe: I think that's right, yes.

Young: You talked about the spray residue situation when you were out in the west. Do you remember anything about the big fight in connection with the spray residue and the experiments that were going on in the Food and Drug Administration? The point of view between the Food and Drug Administration and the Public Health Service was distinctly different and there was a sort of bureaucratic wrangle. Finally the Food and Drug Administration was told it shouldn't do anymore experimentation on spray residues. This would've been right before you came to Washington.

Roe: Yes, that was before I came into Washington.

Young: You served under all the Commissions from Campbell to Goddard. Do you have any stories about them that illustrate their styles as Commissioners?

Roe: Well, I find it kind of hard to recollect specific instances now that would be meaningful...

Young: It's the color of it as well as the substance, the way it reflects upon the style of a man as administrator, that sometimes makes an incident or an anecdote important.

Roe: I'm sure it is important. The several Commissioners that I served under were different, did have different styles. I don't know just how to describe them.

Mr. Campbell, of course, was the one that sort of set the standard that we gauged them all by. He was the first Commissioner and he, after all had been the first chief Food and Drug inspector under Wiley. He was a very good administrator I thought, at least he had the administrative appearance and very, very smooth, a good talker, could explain things very well.

I remember sitting in on one meeting when I was stationed in Washington with the import supervision, sitting in on one meeting where Campbell was addressing a group from the industry. Men from the canning industry as I recall, who had made some loud protest about the application of the McNary-Mapes Amendment, that is the canned food standards. How Campbell just brought them around. Campbell explained that he wasn't proud of the standards that we had set. They were very minimum standards but we had to start somewhere and he brought this out. You know, those fellows just were eating out of his hand before that

meeting was over. He didn't put anything over on them but he explained it so well, in a convincing way that they understood why he had set up the regulations as he had, and how it wasn't to their disadvantage after all. Campbell was very artful in that way and could handle it very well.

Now Dr. Dunbar, style somewhat different. I would say he wasn't quite as smooth as Campbell was and he perhaps gave the impression of more being a "bureaucrat" than Campbell did, that is he adhered more to the rules. Really, he was very good too. I think most all of us had a high for all of our Commissioners in those days, but they were different.

Then Crawford came along and Crawford's style was still a little different. We used to meet informally in Crawford's office every morning. More or less as we wanted to, all of the Associate Commissioners and some of the Division Directors would just drop in and sit around for fifteen or twenty minutes just talking. I think this was helpful to us and to the Commissioner because he'd bring up things kind of informally. We were talking about some aspects of the work or what was developing and this and that. But in a very informal way.

Then Larrick came and well Larrick also held meetings of that sort but not quite with the same informality that Crawford had.

Larrick was a little more nervous type and he was, as compared with Crawford I would say that Larrick was more interested in well, the publicity aspect of things. Of getting the story across and did not want to unnecessarily upset industry. He wasn't going to kowtow to them but he was more careful in his approach and contacts. Crawford was a little more direct and a little rougher I thought on some of his handling. I certainly think that all of those Commissioners were very competent and men of integrity on the job.

Lofsvold: Earlier Bob we were talking about the recent problem of insufficient resources for science. Actually it was, perhaps insufficient resources for the whole agency during those years that you were in charge of the Bureau of Biological and Physical Sciences. Was there anything here that reflected a conservative attitude on the part of Campbell and Dunbar towards asking for more money and more people.

Roe: I don't know, really, Campbell and Dunbar on that, I'm not sure. I don't know.

Lofsvold: It seemed to me that Crawford took the first steps in that direction when he asked for the Citizens Committee.

Young: Yes he did.

Lofsvold: With the idea that they were going to recommend an expansion, which they duly did.

Roe: Yes, I think that was Crawford's idea...a defensive move. I think it was, well you might say, a defensive move because of the cut backs that we had received. Severe cut backs in the beginning of the Eisenhower administration. I think it was Crawford. I never talked with him about this that I recall, but I think it was generally understood that Crawford had come up with the idea of a Citizens Advisory Committee, in an effort to do something to get some support for the agency under the fire we were under. He was so sure that we were an outfit that ought to be supported and needed further support, that he was willing to take a chance on an outside committee of citizens to review the whole thing and see if they wouldn't come up with some recommendations that would be helpful.

Young: It was Mr. Mintener in the Secretary's office. He was an Assistant, or Associate Secretary, was he not, at the time?

Roe: That I don't know. Mintener was an Assistant Secretary.

Young: You said that you had talked to him last week. Did you know him all that well at this time?

Roe: I don't think Mintener was the Assistant Secretary at that time. I don't think so for this reason, that it's my recollection that when Crawford retired, Mintener has told me this, if I recall right, that he was approached to be Commissioner to replace Crawford. Now don't take this too definitely because its just my recollection that this is what he said to me at one time. He said no, that the Commissioner should come up from the ranks, this was a career job, and they should not go outside the agency. He said they wound up by offering him Assistant Secretary of the department, and that's when he came in. They did lift Larrick up to the Commissionership. Now don't take that without checking it somewhere but that is my recollection.

Another thing that may have saved a "career' appointment to the Commissionership at that time was this:

Early in the Eisenhower Administration, the first year I think -- the new Assistant Secretary of Commerce overruled a decision of Dr. Astin, Director of the Bureau of Standards in the "Battery Addition Case". A California manufacture had marketed a "battery additive" which he claimed would prolong the life of a storage battery, such as an automobile battery. He had supporting "testimonials" from satisfied users. The product had been submitted to the Bureau of Standards for testing. The scientific tests

of the Bureau showed the product of no value for the purpose intended and the Bureau so reported.

The new Assistant Secretary urged Dr. Astin to change or withdraw the report, indicating he believed the worth of the product should be determined by the "play of the market place". Dr. Astin refused and he was relieved as Chief of the Bureau. This caused a public furore. Scientists throughout the country united in support of Dr. Astin. Astin was reinstated and the Assistant Secretary resigned.

It was shortly after this episode that Crawford retired, so the job of Food and Drug Commissioner was open for appointment. I was told later that the Secretary had intended to seek an outsider for appointment but that somebody in the Republican hierarchy asked if this was a scientific position and when told that, it was urged second thoughts on any political appointment.

I have always felt that Dr. Astin had, in effect, "run interference" for all scientists in government.

Lofsvold: I believe that the request for the Citizens Committee may have antedated the Eisenhower Administration.

Young: It may have. But then Mintener had something to do...

Lofsvold: Oh, he was always interested in FDA before he came as part of the Eisenhower Administration.

Young: But he had something to do with the Citizens Committee I think.

Roe: I think maybe so, and I think you may be right that *the Citizens Committee started before then but I'm not sure* of that. Because it started with Crawford, well, that's right, Crawford was in when I came in in '52, Crawford was the Commissioner then, so I'm not sure of the timing on that. But I am sure that, it is my recollection at any rate, that Crawford was the instigator for the idea of that Citizens Committee.

Mintener was acquainted with Food and Drug, well acquainted with the Commissioners and others in the organization, and had been helpful in one way or another. I first met him when I was Chief at L.A. Mintener and Charlie Dunn came out there in connection in setting up of the law course at the University of Southern California. I was Chief of Station so they called at the Station and that's when I met them. I went with them out to the law school that night to hear the discussion and the development of that law course out there. So Mintener was acquainted with the organization. He'd been a lawyer for one of the flour companies up in Minneapolis.

Lofsvold: Pillsbury.

Roe: One of the unusual lawyers who didn't undertake to fight Food and Drug on the points of the law, but undertook to get his clients to comply with the law. Gave them I thought much better service than some who acted in a different way.

Lofsvold: The story I remember was that, as a young lawyer Pillsbury sent him to defend some seizures of Pillsbury flour down at New Orleans, where the charge was insect infestation. When they went down there for trial, B. J. Howard was there and he was quite impressed with talking to Mr. Howard about the microscopic examination of food. That aroused his interest in this area, and he pursued it the rest of the time.

Roe: That's very interesting. I wasn't aware of that or had forgotten.

Young: I hadn't heard that either.

Roe: Your mention of B. J. Howard recalls something though, about Mr. Howard. When I was Assistant Chief at San Francisco, Mr. Howard was scheduled to come out there to do some field work one summer. I sent one of the inspectors, Hamill I think, any way, one of the inspectors to meet Howard. The inspector told me later he had gone to the station, -- he was to meet him in Sacramento I think as

that's where he was going to start his work, out there in the field in Sacramento. So, the inspector was at the station and he said he posted himself back where the Pullman cars would stop and gosh, Mr. Howard didn't get off. Hamill thought he must have missed the train or there had been some change in schedule. But as he walked down the platform here was Howard. He'd ridden the coach from Washington because the appropriations in his Division were getting kind of low and he'd had to save money. And that was Howard. He rode the coach from Washington to keep within his appropriation. Not many of them do that these days, or even then.

Lofsvold: When you were at Chicago, as a bench chemist Bob, did the chemists stay pretty much in the laboratory or did you have opportunities to do field work with the inspectors at that time?

Roe: We stayed pretty much in the laboratory. There was an occasional field work. The only time I remember going out was when I went out with Inspector Simmons once to sample some frozen cherries. We had quite a time trying to sample that barrel of cherries and get a proper proportion of juice and cherries. I don't think we ever solved that very adequately until later, when I was in Seattle when we developed a boring tool to get into the frozen pack. After it is thawed its pretty hard to get a sample.

I remember Les Hart, was in the lab in Chicago part of the time I was. I recall that he went out on a trip on pesticide or spray residue work of some kind once. I remember that because he wired me he was out of money and would I send him ten dollars, which I did.

Lofsvold: Well, I asked the question because by the time I came in '39, there at Seattle, a number of people in the laboratory were regularly making inspections, particularly in our rush season, during canning time. Mills, and Strange and some of those fellows were regularly leaving the bench, Risley on fish, and would sort of double as inspectors.

Roe: That is right. But I think there was some difference in programs, that there in the Seattle area much of the work on fruits does involve some appraisal that the laboratory people can handle very well in the field. Same with fish, its coordinated with the examinations as well as the packing and other things. So there was more opportunity and more point to the laboratory personnel getting out in the field in the Seattle area, than there would be in the Chicago area, in my opinion that is. There's a little difference in the operation. But even then there were times when it would've been well for the chemist to get a picture of what was going on in the inspection areas.

We had a lot of work in the drug laboratory in Chicago. I think it would've been helpful if they had sent us out to see the factories and see what was involved on the manufacture of pills and various pharamaceutical preparations. But we didn't have that concept then. So yes, I think its always well for the laboratory personnel to see what some of the problems are in the manufacturing field, in the production end.

Young: After you came to Washington, you told us at lunch, you were designated as Food and Drug's representative on some interagency committees. Would you mind, for the record, repeating the gist of those stories, the one in connection with cancer and the one in connection with radiation and food.

Roe: Oh yes. There was a cancer chemotherapy program set up under the National Cancer Institute, which involved the study of various chemicals that were thought to be of some value as anticancer agents of one sort or another. The reason I got involved on that was because the Cancer Institute assigned to Food and Drug Administration, certain funds appropriated for that cancer program to enable us to set up and do some of the pharmacological work on some of the compounds they wanted to study. Since this involved the Pharmacology Division in my Bureau, I was designated to

represent Food and Drug on what was then termed the Cancer Chemotherapy National Committee, as I recall it. It had representatives on it from the Cancer Society and from various medical institutions and various persons like Mary Lasker, who were interested in programs of that sort, and represented foundations that gave some support to such activities.

This Committee was set up to spread information about the program for one thing, to the agencies that they represented. But for another thing, as sort of an advisory group to the Cancer Institute. Really we were sort of a kind of a window dressing group in connection with the development of the program. It was helpful to me to understand what my agency's part in the program should be. I think it was perhaps helpful in some ways to the administrators of the program. I participated in that perhaps for two or three years in the early part of that program.

The other interagency group that I was involved in was the Interdepartmental Committee on Radiation Applications to Food. That, I don't believe was the real name of the Committee, I just can't recall the terminology. Principally, as I recall the meetings I attended, we were concerned with the various applications of radiation to food products or materials that might come in contact with food.

The agencies that I recall being represented on the Committee were the HEW, the Atomic Energy Commission, the Department of the Army, Commerce Department, Agricultural Department, and perhaps others. I think Interior was on it on some of their fishery products.

The designated representatives of the HEW were, the Assistant Secretary for Medical Affairs and the Commissioner of Food and Drugs, but each of them had designated an alternate. I was the alternate for the Commissioner and a fellow named Miller, from the Public Health Service, was the alternate for the Assistant Secretary. It turned out that we alternates were the ones who attended the meetings during the period at least that I was on that designation. We didn't have regular meetings but we had fairly frequent meetings for a while during the period when there was a great deal of interest in possible applications of radiation to the preservation of food.

This was of particular interest to the Army because they felt that this application might enable the holding of food products without the need of refrigeration. It was a very sound idea to examine that and go into the problem. Also, it was during the period when the Joint Committee of the Congress was pushing hard for peaceful applications of the atom. They were pushing the Atomic Energy Commission

and all of the other departments to get applications going. Our concern, of course, in HEW was to present the need for proper testing and experimentation to insure the safety of any such applications. So Miller and I were quite often "bad boys" on the Committee from the standpoint of the Army and the Atomic Energy Commission. Because we did raise problems and stumbling blocks where we didn't think there was adequate testing available.

Examples of some of the problems involved in the evaluation of the safety of pesticides include the situation involving well, EPN and malathion. Malathion is one of the organophosphate pesticides. Among that group it seems to be of lesser toxicity than most of the others, although it is pretty toxic. We, at one time had tolerances for malathion for a number of crops. We also had tolerances for EPN, the particular type of EPN pesticide I'm not sure of right at the moment.

But at any rate, I do recall that one of the young pharmacologists came down to my office one day, when I was in charge of the Bureau of BPS. He casually remarked to me that he had been doing some experimentation and he noticed when he fed the rats a mixture of EPN and malathion, or when he fed EPN some time after malathion had been fed, that the toxicity was bumped up about 100-fold. Well, this

startled me very much and I called a conference of the Division Dirctor and some of the other pharmacologists and said, "Look, we have tolerances for these two things and suppose they get mixed up and our tolerances are not safe?" Some discussion was had and one of the fellows said, "Well, don't worry Chief, they never use those together, they use them separately." I said, "Suppose I make a fruit salad here in Washington from apples in New York that have EPN on them, and pears from somewhere else with malathion on them?" And then everybody got excited and I said, "We've got to do something about this quick. There's a problem here of possible potentiation, that our tests don't provide for. And we have two or three other organophosphates in petitions before us right now. Before we pass on them we've got to know what are the possibilities of potentiation. This opens up a whole new can of worms." So we did immediately start some further experiments and we did tell the two or three petitioners who had petitions before us, that they were going to have to do some further work to test their product against some of these others to see if there was potentiation. This caused quite a storm of protest, as I recall, we had inquiries from the Hill as to what's going on and protests that they are changing the rules. We did do further work and we did find that there

was an increase in toxicity under certain conditions where they were mixed or one used before the other. We undertook some other work to determine if we could discover why because if it is a matter of potentiation we've got to set up tests that will anticipate this on any other products. Well, the up-shot of it was that we did find what we think was the answer to this particular problem, that malathion is detoxified by the liver up to a certain level and that is why it seems to be less toxic than some of the other organophosphates in very small dosages. If you go beyond that point, it gets pretty toxic. EPN the other chemical involved destroys that capacity of the liver to detoxify malathion. So, we said that the liver contains an enzyme, malathionase, which is destroyed by EPN and so that the body has no protection against the full potency of the malathion. Well, that didn't give us an answer as to what to do about the new situations because it involved a specific biological factor on the malathion, but it did answer that question and did enable us, as I recall, to clarify the tolerances if they needed any changes as to EPN and malathion. It turned out there was not the hazard that first appeared might be there.

Young: Can you just say a broad general word about the state of knowledge of potentiation at that point? You used the word, so the word was in....

Roe: Potentiation as I understand it was not a new thing. That phenomenon has been known, in fact has been used in the development of drug mixtures, I understand; where they want to increase an activity and find that certain chemicals or certain products will act to potentiate or increase the activity of certain other things. So, potentiation was not a new thing. Conversely, of course, in the situation such as we were dealing with we don't want to increase any toxicity and this would be a factor. If it is likely to occur on pesticide chemicals, then it is very important that we know that and know how to deal with it. So, that was what worried us at the time. It turned out, as I outlined, that we think we have the answer in that particular case, -- which was not an instance of potentiation and the situation is not applicable to others, at least so far as we know at this time.

Another illustration, the chlorinated compound known as heptachlor had been the subject of tolerances that had been set up for its use on a number of food crops, including I believe, certain forage crops such as alfalfa. We had been concerned as to this compound because many of the chlorinated compounds when consumed by cattle appear in the milk. So, before setting a tolerance for forage crops we had required that feeding tests on cows out at Beltsville,

with the cooperation with Agriculture, be conducted to determine if the petitioner was right in his claim that hepatchlor did not go through in the milk. Much to our surprise, it did not. So, tolerances had been set. Some time shortly thereafter one of the scientists read in one of the journals about some work done at the University of Illinois that indicated heptachlor in presence of sun light and air oxidized to form a heptachlor epoxide and that this formed the major part of the residues on fruit on which this product was used. This was brought to our attention and we discussed it and said "What do we know about heptachlor expoxide?", and it turned out we didn't know very much about it. We didn't know its toxicity, we didn't know whether it went through into milk if feed to cattle and so we hastily set up experiments to find out. We found out that it did appear in the milk very readily when the epoxide was fed. We found that it appeared to be somewhat more toxic that the heptachlor. So, that our tolerances as set up did not reflect the facts that occured when the product was used. We immediately took steps to withdraw the tolerances and the only way that you can do that, as I recall now, is to publish a proposal to revise them. At any rate we made known our intent and I recall that we got inquiries from the White House and from the Hill as to what was

going on. I may say that those inquiries that I got, when I explained what was going on and the why of it, there was no pressure put to change our intent. Here again, is an illustration of the serious problems that may develop. You think you have all the facts that are needed to make an appraisal of a compound and then you find that the compound you've appraised really isn't the compound that is in the residue that results from the use of the preparation. This is one of the reasons why I was so very insistent that our petition reviewers be people who were personally involved in the research and in the laboratory experimentation on these products, in order that they could at least anticipate and know what questions to ask and what the problems are likely to be.

Young: You know that is one of the problems that the agency...

Roe: One incident that I recall involved one of our chemists, who during the McCarthy era was accused of being a communist or one who had attended communist meetings. The chemist was to appear before a board of three people sent from Washington to hear testimony on the matter. I was Chief of the Station to which the person was assigned. I agreed to appear with her at the meeting. In fact, I had made some investigation of the case when she told me about

it and felt that she was entitled to some help in presenting her case. This did result in a rather lengthy hearing of several hours, at which we were able to present some evidence through acquaintances and friends of hers as to what activities she was interested in and her style of life, etc. during the period that she was accused of associating with communists. The up-shot of it was that she was acquitted of the charges. Later I was informed by the commissioner, Commissioner Crawford, that... Well, put it this way, later I received from Commissioner Crawford a note enclosing a memorandum from the security officer of the department, to the Commissioner. This memorandum commented on the investigation that I had made in this matter and my participation with the accused chemist at the hearing and in effect I thought clearly suggested to the Commissioner that I should be severely dealt with. As I recall, the Commissioner made no particularly comment in this transmittal memo other than indicating he thought I would be interested in the communication he got from the security officer. I, of course, was very grateful for the Commissioner's handling of the matter and replied to him indicating my appreciation of his note.

Young: Not very long afterwards, indeed you were promoted within the agency.

Roe: Yes, it was shortly after that that I went to Washington as head of the Program Office. I do not attribute that transfer to the activity just referred to!

Young: No, but it is an indication that this did not harm your record.

Roe: That is right.

Lofsvold: Apparently, he supported your position.

Roe: Possibly, but at least he did not "black list" me for it.

Another time, as I indicated, at a western district conference in San Francisco I was perhaps a bit sassy to Commission Dunbar, but that didn't hurt either. It got results.

Actually that program, if you remember, that Bad Cream Program was developed and conducted by a rather wild-eyed', impetuous member of the staff, who in my opinion should not have been designated to conduct it.

Lofsvold: It has been a long hard session this afternoon, Bob, and I think perhaps we can sign it off now, but before I do I want to express our appreciation for your taking the time to put all of these things on the record. I am sure that this is going to be very useful, not only to Harvey and his current activities but to people who may want to look into the history of the agency in years to come.

Young: Thank you indeed.

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UNITED STATES GOVERNMENT

Memorandum

TO : ALL FDA EMPLOYEES DATE: APR 22 1966

FROM : James L. Goddard, M.D.
Commissioner of Food and Drugs

SUBJECT: Reorganization of the Science Bureaus of FDA

The Secretary has approved the first major element of the Food and Drug Administration reorganization plan. Effective May 2, 1966, the Bureau of Scientific Standards and Evaluation and the Bureau of Scientific Research are abolished. In their stead, a Bureau of Science is established to carry out the interrelated scientific research and scientific standards functions of FDA. The ten divisions of the abolished bureaus are assigned, intact, to the Bureau of Science. In addition, the Laboratory Services Branch, ACA, is transferred to the Bureau of Science.

I have designated Dr. William H. Summerson as acting Director of the new Bureau. Dr. Daniel Banes is designated as acting Deputy Director of the Bureau and Mr. Robert S. Roe is designated as acting Associate Director.

It is my belief that this reorganization represents a logical regrouping of functions and will result in more efficient and effective FDA science operations. These changes should greatly aid FDA in attaining its goals and objectives through substantially improving the scientific support of our regulatory programs.

James L. Goddard

5010-106

H. A. Toulmin
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June 27, 1958

Mr. R. S. Roe, Director
Bureau of Biological and Physical Sciences
Room 4801
South Agricultural Building
Independence Avenue
Washington, D. C.

Dear Mr. Roe:

I want to thank you again and also Dr. Harris for the courtesy of both of you and also your laboratory staff in permitting Miss Bernthal and myself to see how you operate.

The tour was very helpful to us and gave us a number ~~of excellent~~ ideas for our new operation.

I want to make of record in this letter my congratulations to you and your associates for doing a job for the people of the United States and the United States Government which seems to me to be outstanding, particularly in view of the conditions under which you have had to operate. The Nation does not understand and does not appreciate the great service you are rendering and I am sure if members of the committees of the House and Senate took the same tour that I did, they would take steps to initiate plans for a more general allocation of funds for your operations. It is incredible that your top people, as well as your other employees, could function successfully under the conditions I saw.

Not only were you doing the work well, but I saw a great many ingenious managerial methods and great resourcefulness, which are certainly the

product of long and careful thought of able minds. It was the result of managerial experience that I have not seen for a long time, although I inspect many plants, laboratories, etc. in this country and abroad and many of them are the very greatest, but the way you are operating and the apparent skill in keeping track of the results was a joy to behold.

There is one thing more: it is the first United States Government department where I saw everyone working and tending strictly to business. Each of your departments were well-managed, skillfully directed and equipped with not only practical apparatus, but the improvisations were most ingenious and resourceful.

It makes a man proud to think that the Government of the United States is so loyally and skillfully served and is doing the job without sulking about the handicaps.

Sincerely yours,

H. A. Toulouse

P. S. - I am enclosing an extra copy of this letter for Dr. Harris.

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Food·Drug·Cosmetic Law Journal

THE FOOD AND DRUG ADMINISTRATION

Evolution of The Field Organization

By ROBERT S. ROE

Because of Inexperience, the Present Flexible Field Organization Had to Be Developed Mostly by the Trial-and-Error Method. As It Turns Out, However, This Flexibility Is a Decided Asset, Since It Permits Minor and Major Changes to Meet Changing Conditions

THE present organization of the field forces of the Food and Drug Administration is the result of many changes over the years. The enforcement of the Federal Food, Drug, and Cosmetic Act of 1938—as did that of the predecessor law, the Food and Drugs Act of 1906—depends upon the activity of the inspectors and chemists throughout the country in the inspection of factories, packing plants and distributors, the collection and analysis of samples, and various other field and laboratory investigations. The location of field laboratories and the deployment of inspectors are important factors in determining the effectiveness and efficiency of the Administration.

Investigations of the Bureau of Chemistry under Dr. Harvey W. Wiley over a period of many years prior to 1906 had disclosed widespread debasement and misrepresentation of foods and drugs. These disclosures had helped to crystallize the sentiment in Congress for the enactment of corrective federal legislation, resulting in the passage of

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the Act of 1906 and its assignment to the Bureau of Chemistry * for enforcement.

While the Bureau had had experience in the analysis of many foods and drugs, it had not had experience in the administration of a regulatory law of such scope as this and the conducting of investigations to gather evidence to support legal actions. The Bureau, then, was confronted with serious organizational and operational problems. Fortunately, no attempt was made to set up a permanent, rigidly defined filed organization. On a more or less trial-and-error basis, laboratories were established and inspectors assigned in various locations throughout the country. From time to time these locations were changed in an effort to improve operations, setting a pattern and policy which have been followed to the present time. Our concept of the appropriate organization of the field forces for the administration of federal regulatory statutes such as the Food, Drug, and Cosmetic Act is an organization that is flexible and can easily be altered as to territorial boundaries and personnel quotas as changes in production, manufacturing, transportation, population and other factors may dictate.

At the present time the field forces of the Food and Drug Administration are organized in districts with headquarters in 16 of the principal cities throughout the country. Each of the 16 districts is in charge of a chief, and the personnel includes chemists, inspectors and

* The Bureau of Chemistry of the United States Department of Agriculture. A reorganization within the Department of Agriculture in 1927 established the Food, Drug and Insecticide Administration (later termed the Food and Drug Administration) as the enforcement agency for the Food and Drugs Act and other regulatory laws, and the Bureau of Chemistry and Soils to which was assigned the research functions of the former Bureau of Chemistry.

In 1940, under the President's Reorganization Plan No. 4 issued under authority of the Reorganization Act of 1939, the Food and Drug Administration and most of its functions were transferred from the Department of Agriculture to the Federal Security Agency.

clerks. The districts are designated by the names of the headquarters cities. Well-equipped laboratories are maintained at district headquarters. In three of the districts—Buffalo, New Orleans and Seattle —"subdistrict" laboratories are also operated at Pittsburgh, Houston and Portland, Oregon, respectively. In all the districts, one or more resident inspection stations are established at other cities in the district territories.

At the time of the enactment of the Food and Drugs Act of 1906 there were already in operation six branch laboratories of the Bureau of Chemistry at the chief ports of entry (New York, Philadelphia, Chicago, New Orleans, Boston and San Francisco). These laboratories had been established several years before to handle examination of imports under the Act of March 1, 1899. After the enactment of the Act of 1906, additional branch laboratories were established. The annual report of the Bureau of Chemistry for 1909 shows 21 branch laboratories in operation: Boston, Buffalo, Chicago, Cincinnati, Denver, Detroit, Galveston, Honolulu, Kansas City, New Orleans, New York, Omaha, Philadelphia, Pittsburgh, Portland (Oregon), St. Louis, St. Paul, San Francisco, Savannah, Seattle and Nashville.

After a brief period of preliminary instruction and training in Washington, the newly appointed food and drug inspectors were assigned to various locations throughout the country. These inspectors operated under the instructions and supervision of the chief inspector in Washington. The branch laboratories as originally set up reported to the Division of Foods in the Bureau of Chemistry in Washington.

A reorganization occurred in 1914. The annual report of the Bureau for 1914 gives this explanation:

> To increase the efficiency of the enforcement of the food and drugs act the Bureau of Chemistry was reorganized during the year. The field service of the Bureau was set off from the central organization and divided into an Eastern, a Central, and a Western District, with headquarters, respectively, in Washington, Chicago and San Francisco. A single official was placed in charge of each District. He is directly responsible to the Bureau of Chemistry for all the work in his District, so that the food and drug inspectors and the laboratories are no longer separate or independent of each other. Incident to this division of the field service of the Bureau of Chemistry, the smaller laboratories at Detroit, Kansas City, Omaha, Nashville, Pittsburgh, and Portland, Oregon, were closed.

In 1917 this reorganization was extended to create "station districts" within each of the three principal inspection districts and to place one man in charge of both laboratory and inspection work in each "station district." In establishing the "station districts" or stations,

the boundaries of the laboratory territories were adopted as the boundaries of the new stations. This provided for stations with headquarters in the following locations:

Eastern District.—Boston, Buffalo, New York, Philadelphia, Savannah, Washington, Puerto Rico.

Central District.—Chicago, Cincinnati, Minneapolis, St. Louis, New Orleans, Kansas City. (At Kansas City there was no laboratory at that time but there was an inspection office, and the importance of the area required establishment of a station.)

Western District.—Seattle, San Francisco, Denver, Honolulu.

Other Inspection Stations

At the time of the establishment of station territories, inspection stations were in operation in other cities as well as in the laboratory cities. Inspection stations were continued at Detroit, Nashville and Houston in Central District and at Los Angeles, Phoenix and Portland, Oregon, in Western District, and the chief of the Bureau commented that the scope of the territories and the nature of the inspection work might make it desirable to place additional inspectors in certain sections, with headquarters other than at station headquarters. Whether these inspectors, resident in cities other than station headquarters, should operate under direction of the station chiefs in whose territories they were located or report directly to the district chief was left to the discretion of the district chiefs.

Prior to the establishment of the stations in 1917, the boundaries of the inspection and laboratory territories were not always the same. For instance, in Western District the boundaries of the inspection territories evidently were determined primarily by railroad lines and were arranged in accordance with transportation facilities available to the inspectors stationed variously at Seattle, Portland, San Francisco, Denver, Los Angeles and Phoenix. The laboratory territories, on the other hand, followed state lines to take care of state cooperation and collaborative work, with special reference to assisting state inspectors and other officials in preparing and handling federal cases instituted by the states.

The Bureau of Chemistry orders establishing "station districts" stated that the territories of the stations were determined "primarily on the basis of hearings." This apparently contemplated that only at

the laboratories were there facilities for conducting hearings—office quarters and stenographic assistance—and that the laboratory locations were most convenient and accessible to the manufacturers and shippers in the station territories.

In 1917 the headquarters of Eastern District were transferred from Washington to New York City. Since 1917 there have been many changes in stations ("station districts") and districts.

Honolulu Station was discontinued in about 1918 and Puerto Rico Station in 1933. The work loads in these territories were relatively too low to justify continuing the stations, particularly since necessary coverage could be accomplished through cooperative arrangements with the territorial officials.

In about 1926 a laboratory was re-established at Kansas City Station to afford analytical facilities and to eliminate delays and costs involved in sending samples to other labortories. In 1931 the Los Angeles inspection office was converted to station status with the installation of a laboratory. This change was effected to enable more efficient and adequate handling of the increased work loads brought about through increasing population and manufacturing activity in that area.

In 1934 the laboratory and station headquarters located at Savannah, Georgia, were transferred to Atlanta. The station originally had been established at Savannah because of the extensive import trade at that port. A marked decrease in the importation of foodstuffs through the port of Savannah and the fact that Atlanta was a railroad center affording transportation lines to all areas in the station territory made Atlanta the preferable location.

District Boundary Lines and Transportation Lines

The reasons for some other changes are of interest. For instance, [illegible] 1929, transfer of a number of counties in Texas, Florida, West [illegible] and Ohio was effected in order "to make district boundary [illegible] conform more nearly to existing transportation lines." In July, [illegible] station boundaries affecting Kansas City, Minneapolis [illegible] Sections were based upon convenience of transportation.

[illegible] convenience of transportation was the reason for transferring a portion of West Virginia to Baltimore from Buffalo Station

In 1934 another reason appears as the basis for a change in station boundaries. This involved a change in the boundary between Chicago and Cincinnati Stations in Indiana in order to bring the boundary line in conformity with the judicial district line in Indiana. To have station boundaries coincide with judicial districts was the reason for adjusting St. Louis and Minneapolis Station boundaries in Iowa in 1936.

Reasons for Substantial Changes in 1945

In 1945 substantial changes were made in the boundary lines of Chicago, St. Louis and Minneapolis Stations, involving the transfer of southern Iowa from St. Louis to Minneapolis Station, and the transfer of a portion of Wisconsin and the upper peninsula of Michigan from Minneapolis to Chicago. Several reasons were given for these changes:

(1) The dairy industry in Iowa was more or less integrated with the same industry in Minnesota and western Wisconsin, and the dairy program of the Minneapolis Station was more suited to the work in that area than was the dairy program of St. Louis Station.

(2) The change in Wisconsin eliminated the division of the eastern judicial district in that state between the two stations.

(3) Products moving in and out of the Wisconsin area involved were predominantly from and to Chicago rather than Minneapolis.

(4) The upper peninsula of Michigan could be more easily reached for the occasional necessary trips there from the eastern area of Wisconsin than from Minneapolis, and the transfer of this area placed all of the State of Michigan in Chicago Station territory.

California, Montana and Idaho Boundary Lines Changed

In 1945 a change in the boundary line between San Francisco and Los Angeles Stations in California was effected in order to save Los Angeles Station a considerable amount of nonproductive travel through desert areas. Also in 1945 the eastern portion of Montana was transferred from Denver to Seattle Station and a change was made in the boundary line between these stations in Idaho. These changes were accomplished in order to relieve each station of traversing certain desert areas and to assign to each station most of the area in Idaho that

was directly tributary to the principal shipping centers in the respective station territories.

In 1948 a major reorganization of the field service was effected. This reorganization abolished the former three inspection districts which had been set up on a geographical basis and established in Washington three functional divisions made up largely of the staffs of the former field districts. This reorganization gave greater responsibility to the 16 field stations, converting them to district status, and established the present field organization. The abolishment of a number of administrative positions made possible the assignment of additional personnel to the field districts.

In 1949 a number of changes were made in the field-district boundary lines in Pennsylvania, North Carolina, Illinois, Florida and Tennessee in order to adjust the boundary lines to coincide with judicial districts. Similarly, changes were made in 1951 in boundary lines affecting Boston, Buffalo and New York Districts in the States of Connecticut, New Jersey, New York, Ohio and West Virginia. These changes eliminated divisions in Connecticut, West Virginia and Ohio and established the boundary line in New York State along judicial district lines. This change substantially reduced the area covered by the New York District, making it essentially a metropolitan district.

Influencing Factors in Locating Field-District Boundaries

It is apparent that many factors have influenced the location of the boundaries of the field districts. These factors include inspection travel requirements, availability of transportation and roads, population distribution, location of manufacturing and distributing establishments, geographical and topographical features. It is important that district headquarters (and resident inspection stations) be so located as to minimize the necessary "nonproductive travel" of inspectors, since travel costs constitute a large item in the operating budget. It is important that district headquarters have adequate transportation and communication facilities to the various parts of the territory to enable good contacts with the traveling inspectors and to allow prompt shipment of samples to the laboratory. It is also important that district headquarters be reasonably accessible to manufacturers and shippers throughout the territory to enable them to call at headquarters for information or to respond to citations. Transportation facilities also influence or reflect the mode or direction of distribution and hence

determine to some extent the proper deployment of inspectors. That population distribution and the location of food and drug producers and manufacturers have a bearing on the location of district boundaries is obvious.

The placing of district boundaries also has been influenced by the boundaries of existing federal judicial districts. It is desirable that food and drug districts coincide with, rather than overlap, judicial districts. This has become increasingly important because the growing complexity of cases brought under the Act makes it essential that the most efficient contacts exist with United States attorneys. This obviously is furthered when contacts with a particular judicial district are conducted by one field district. For the most part, district boundary lines now coincide with judicial district lines. There are a few exceptions, however.

Cooperation with State Officials

The same considerations apply—but to a considerably lesser extent—to cooperative contacts with state officials. It is desirable to avoid division of states between field districts, but this is by no means essential. Very frequently other factors are more important.

In arriving at the present districting of the country, an effort has been made to attain a reasonably uniform distribution of work loads and responsibility between the several districts. This is considered advantageous from the standpoint of general administration and classification of employees assigned to the field service. Greater accomplishment can be realized by districts of approximately the same size in personnel and similar work loads and responsibility than by districts of widely different work loads.

The table at the end of this article shows the number of employees in various categories assigned to the districts as presently organized. It will be noted that there is a heavy work load in New York District as reflected by the personnel assignments. The territory assigned to New York District is essentialy a metropolitan area. In that area there are heavy concentrations of population, drug manufacturing establishments and imports which enhance the work load. Except for New York, the work-load distribution among the districts is reasonably even.

Adjusted Personnel Quotas

In addition to the boundary changes, there have from time to time been changes in the personnel "quotas" allotted to the districts. Such

changes have been made to meet or adjust changing work loads. This is more or less a "continuing process," as the personnel requirements of the districts continually fluctuate to some extent. Exchange or transfer of personnel between districts, particularly in the inspection category, is deliberately practiced. This is necessary to maintain well-balanced staffs in the districts, and it serves also to broaden the experience and training of the individuals. Also, the occurrence of vacancies through retirements or resignations may lead to interdistrict transfer of personnel. The retirement of a senior officer of the Administration either in Washington or in the field often leads to a chain of transfers. The Food and Drug Administration as a "career service" endeavors to maintain a promotion system based upon merit. For instance, the selection of a chief chemist for a particular district is not limited to consideration of the chemists then on the staff of that district. Rather, selection is made from all qualified chemists throughout the Administration after careful appraisal of the needs of the position and the experience, training and aptitudes of the various eligibles.

In determining the relative work loads of the districts and, hence, the appropriate allotment of chemists, inspectors and other personnel, a number of factors are involved. Some of the same factors controlling the fixing of district boundaries are involved also in measuring work loads. Population, the number of food and drug manufacturers and producers—the distribution of population and manufacturing establishments within the territory—the volume of imports, the types of commodities and the types of violations likely to be encountered have some bearing on the manpower needed in a given district to enable enforcement coverage consistent with that of the other districts.

Flexibility of Field Organization an Asset for the Future

It can be expected that new developments in the future—population and industry shifts, new commodities, changes in production and manufacturing techniques and procedures, transportation changes—will dictate the advisability of further adjustments in the field organization involving district boundaries, the location of laboratories and inspection stations, and personnel quotas. The type of flexible field organization developed by the Food and Drug Administration readily permits minor or major changes to meet changing conditions. This type of field organization seems much more suitable as a vehicle for effective enforcement teams than would an organization rigidly defined by inflexible boundaries such as state lines.

Field Personnel by Districts Actual Staffing as of July 1, 1952

District	Administrative	Inspectors	Chemists	Wharf Examiners	Laboratory Helpers	Clerks	Total
Atlanta	1	10	6 -	..	2	5	24
Baltimore	2	14	7	1	2	6	32
Boston	2	12	8	1	2	6	31
Buffalo	1	10	9	1	3	5	29
Chicago	3	21	13	1	3	10	51
Cincinnati	2	14	11	..	2	8	37
Denver	1	9	6 -	..	2	4	22
Kansas City	1	12	6 -	..	2	4	25
Los Angeles	2	18	9	..	2	7	38
Minneapolis	2	13	6 -	..	2	5	28
New Orleans	2	10	9	..	3	7	31
New York	6	26	27	11	6	22	98
Philadelphia	2	15	11	1	2	6	37
St. Louis	2	14	11	..	2	7	36
San Francisco	2	13	13	1	3	5	37
Seattle	2	15	8	..	2	5	32
Total	33	226	160	17	40	112	588

[The End]

• FDA's MONTHLY REPORT OF SEIZURES •

A permanent injunction to stop further shipments of a cancer-diagnosis kit has been ordered by Federal Judge Philip L. Sullivan in Chicago, according to a report issued on November 25 by the Food and Drug Administration of the Federal Security Agency. The manufacturer did not contest the court order.

Dr. Gordon Granger, FDA medical officer, said that the government's charges that the kit is worthless were confirmed by tests of the product made by the M. D. Anderson Hospital of Houston. Tests were made on more than 100 known cancer patients and healthy medical students. Negative and positive results were obtained with both groups and, when the same individuals were retested, different results were obtained. A Houston physician did a series of tests on 30 patients, with results following the same pattern.

The FDA report also lists 24 criminal actions terminated in the federal courts on October, and the penalties levied for violation of the Federal Food, Drug, and Cosmetic Act.

Nearly 850,000 pounds of unfit foods were removed from the market in October in 88 seizure actions, FDA reported. Sixty other food seizures were based on short weight, failure to meet official standards, and debasement with cheaper ingredients. Predominant in the latter group were oysters with added water, which resulted in 27 seizures.

Fourteen drugs and devices were seized because they failed to meet labeled composition or were misbranded with misleading therapeutic claims. The remaining seizures involved a shampoo "plus egg" that would have furnished 1/180 egg for each shampoo, and a poisonous bowl cleaner that was not labeled with the warnings required by the Caustic Poison Act.