

HISTORY OF THE
U. S. FOOD AND DRUG ADMINISTRATION

Interview between:

Allan E. Rayfield,

Retired Director,

Bureau of Regulatory Compliance

and

Robert G. Porter

Sarasota, Florida

May 1, 1979

INTRODUCTION

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

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

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, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

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

DATE: _____ PLACE: _____ LENGTH: _____

INTERVIEWEE

INTERVIEWER

NAME: Allan E. Rayfield NAME: Robert G. Porter

ADDRESS: _____ ADDRESS: U.S. Food & Drug Administration
Denver, Colorado

FDA SERVICE DATES: FROM _____ TO _____ RETIRED? _____

TITLE: _____
(If retired, title of last FDA position)

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DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

TAPE INDEX SHEET

CASSETTE NUMBER(S) 1, 2, & 3

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

DATE: May 1, 1979 PLACE: Sarasota, Florida LENGTH: 175 Min.

INTERVIEWEE

INTERVIEWER

NAME: Allan E. Rayfield

NAME: Robert G. Porter

ADDRESS: [REDACTED]

ADDRESS: U.S. Food & Drug Administration

Denver, Colorado

FDA SERVICE DATES: FROM 1935 TO 1965 RETIRED? Yes

TITLE: Director, Bureau of Regulatory Compliance
(If retired, title of last FDA position)

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P. - This is an interview with Allan E. Rayfield. The date is May 1, 1979. The interview is taking place at his home in Sarasota, Florida. Allan, you correct me if I'm wrong, but I believe you were appointed to the Food and Drug Administration in 1935 as a seafood Inspector, and you retired in December of 1965. Your last tour of duty was as Director of the Bureau of Regulatory Compliance. My name is Bob Porter. Allan, if you would start us out by giving us a little thumbnail sketch of your career, I'd appreciate it.

R. - Fine, Bob, I reported to a small shrimp cannery at Cedar Point, Georgia. The cannery was located on the Albemarle Sound. It was a very small community consisting of the cannery and four residences. One residence was occupied by a retired, blind minister and his secretary. One by the two brothers, who owned the plant, and their wives. The third was by a retired, Atlanta dentist and his wife. The fourth was a small one room and bath cottage which my wife and I occupied with our three month old son. The manpower at the cannery was local, negro women, wives of farmers in the area, with a few of the wives of negro fishermen. We operated the cannery from about 4:00 in the morning to 2:00 or 3:00 in the afternoon, 5 and 6 days a week.

That was my introduction into Food and Drug work.

From Cedar Point I got transferred first to one cannery and then another, as was the custom in those days. My tours of duty included Thunderbolt, outside of Savannah, Darien, Georgia, then back to Cedar Point, Fernandina, Florida, St. Augustine, Florida, and finally I was elevated to the position of seafood Supervisor and stationed in Jacksonville, Florida. There were about ten canneries at that time on the East coast. For a period of for about eighteen months I operated out of Jacksonville, either as Seafood Supervisor, or as the second Resident Inspector. It was practiced at that time for Seafood Supervisors to be transferred into regulatory work as vacancies developed in various parts of the country. I would pinch-hit as Seafood Supervisor during such interim periods. Then in the early part of 1938, I was transferred to Philadelphia as a regulatory Food and Drug Inspector full-time, free of any seafood obligations. I reported to Mr. C. S. Britton, and J. Kenneth Kirk was at that time Chief Inspector. In 1940 I was transferred to New York as an Assistant to the Chief of the Eastern District, then Mr. William R.M. Wharton and operated there for about eighteen months,

really under the supervision of Oley Olsen, Chief Inspector of the Eastern District. This was a training position and many people who later became District Directors or Assistant Commissioners occupied that position. McKinnon and Kirk for instance had been on that job before me. Rankin, John Guill and Ted Maraviglia occupied that position after I did.

In '41 McKinnon was elevated to the position of Chief of Baltimore by virtue of Frank Wollard's death, and I was transferred to Baltimore as Chief Inspector under McKinnon. From '41 to '47, I was in Baltimore in that role, and then in late '47 Oley Olsen retired as Chief Inspector of the Eastern District. I was offered the position of Chief Inspector of the old Eastern District and did move back to New York. Eight months later, the Food and Drug Administration went through what I considered at that time, and still do, the first major reorganization since I had been in the service. This is when the three regional Districts were abolished and there was the establishment of direction from Washington offices on a functional basis, rather than regional. John L. Harvey, who was Chief of the Western District at that time, was moved into Washington as Director of the Division of Regulatory

Management. J. O. Clarke, who was Chief of the Central District was moved into Washington as Director of the Division of Program Planning.

P. - Why was that done?

R. - Heretofore, before reorganization, all of the activities of the individual, then stations; Atlanta, New Orleans, Baltimore, Minneapolis, San Francisco, flowed through the District Offices for review, approval and for controlling and managing its rate or acceleration, or even if it was the type activity worthy of being handled at that time. There were those of us, and primarily Charlie Crawford, thought the District control was an extra layer of control that was unnecessary.

P. - Was he Commissioner at that time?

R. - No, he was at that time Deputy Commissioner. Now being in Baltimore with Washington a resident inspection post and with two resident Inspectors, Baltimore Station Chief McKinnon, and later Retzlaff and I were frequently in Washington. If Baltimore Station had a regulatory proposal (i.e. seizure, injunction or seizure) that they thought warranted rather prompt action, we would phone New York, discuss it with them and obtain the Eastern District's approval to forward to

the administration with a copy to ED. At this moment, I don't remember any cases in which Eastern District said "no", we're not willing to go along, you send it up here and let us take another look at it. Then we would take the proposal, usually hand carried, over to Washington to the headquarters. If any discussion, amplification or additional work was needed, direct action was started. Regulatory action moved a heck of a lot faster than otherwise would be possible. In fact we had made inspections in the morning and gotten injunctions that afternoon.

P. - And this was peculiar to Baltimore because Washington--

R. - This was peculiar to Baltimore because of its physical location, but it was not peculiar to any other part of the country because Denver need not have sent it to San Francisco and then San Francisco sent it to Washington. There was no reason in the world, if Denver had prepared the thing right, why it couldn't have gone straight to Washington. And that thinking is what led to the establishment of the planning deal in Washington so that the planning all over the country would be uniform. They'd been planning before, but each District had its own individual plans. The overall plan was from Washington and each District adopted the gen-

eral plan to conform to its peculiar problems and its industry. If there was any need for coordinating the activities, Field Operations would do that rather than have the three Districts do it together.

P. - If anybody reads this who's used to today's planning, they might not understand that planning, it was infinitely less detailed than it is now. What kind of planning was it?

R. - Well, I don't know how detailed the planning is today.

P. - Well, it's too detailed, in my opinion.

R. - The planning at that time was a broad brush approach, detailed only to the degree of the amount of resources, manpower that would be desired to be spent on the project.

P. - And the project was relatively broad in itself.

R. - And the project was relatively broad in itself. The individual Districts, and Stations became Districts then, took these broad plans and turned them into detailed operational plans for their particular Districts. Now, D.F.O. and Program Planning would get together before plans and manpower allocations were issued to see that there was a realistic appraisal by everyone of the amount of effort that needed to be put in individual Districts on projects, because D.F.O. had

a little more knowledge, because of its day-to-day activities with the District, as to the size of industry and the complexities of industry there. When the work came back in and the District plans came back in, D.F.O. and Planning would review the District plans to be sure that they stayed within in the broad outline they had. Now, the Division of Regulatory Management, at that time audited all court actions but initially involved itself in only 2 types of cases those that were specially designed to test out a section of the law that needed to be tested, or in which there was a complicated court action requiring expertise outside of the District's competence. Regulatory Management assumed prime responsibility for obtaining the Supreme Courts interpretation of 3011k), the Hoxey and Ghadiali-Dinshaw case. As of today any legal action on Laetrile would be under Regulatory Management's control.

P. - Routine cases they didn't?

R. - Routine cases they just wanted to be kept apprised of it, and were kept apprised of it, and quite frequently would give some advise and counsel as to what they thought about the way it ought to go. But the responsibility for the cases still rested with

Districts. The responsibility for detailed planning rested with the Districts. The responsibility for carrying out those plans according to their idea rested with the Districts. The resources available to them had to be used in accordance to their overall objectives. So the reorganization of '48 was brought about in order to cut out a layer between the actual work being accomplished, and where the final decision was being made. That was the main reason for that reorganization.

P. - And if I interpret what you also said, to more or less make planning, or the priorities, or whatever you want to call it, uniform across the country.

R. - Yes, Kenny Milstead was in the Central District office in Chicago during the same period that I was in the Eastern District office in New York, and both of us had essentially the same type of an assignment. All three of the District Directors had that kind of assignment. The three district chiefs, they would select people they believed had potential to grow in the organization; they would bring them in for training and experience provide a broader look at the District's activities. Each man selected for these assignments considered himself as fortunate and faced with

a challenge. Milstead developed the plans for the Central District and sent them to the Central District's Stations. His plans were more detailed than the old Eastern District plans were. I tried to get Mr. Wharton to let us adopt some of Kenny Milstead's plans for our Eastern District because to me they were good, and with a little adaptation; changing here and there, we could make them work in the Eastern District. Mr. Wharton did not agree, he wanted everything from scratch. This was a type of competition existing at that time. I don't think it was bad competition, but nevertheless it was not necessarily the best. Incidentally, back in those days, many of us, and I was one of them, were fearful of ever being transferred out of our District.

P. - Me, I was.

R. - Crawford and Dunbar were Commissioners when I got to Washington, and those are the two I really knew. I never really got to know Mr. Campbell too well, even though I saw Campbell many times. When I was in Baltimore he was still Commissioner. They made a real effort to prevent competition between Districts, in fact I happened to be privileged at a meeting before the reorganization at which I heard Campbell tell the

three Regional District Chiefs: J. O. Clarke, Bill Wharton, and John L. Harvey, "I want each of you to go home and you do some exchanging. I do not want this ingrowing deal that we've got going. I want the country a little more diversified than that." I don't know who got transferred out of that. This was something I shouldn't have been involved in, shouldn't have heard, so I skedaddled. And I've forgotten now why I was able to overhear Mr. Campbell's remarks, but I trembled in my boots for a little bit. I know for a fact that early in the week John L. Harvey had talked to me about whether I would like a transfer to the Western District. I wasn't interested. I was well off where I was. Now when this came up I thought just sure as hell--

P. --he would go ahead with that.

R. - No, I was hoping that Bill Wharton would act strong enough, resistance against it so I wouldn't go. And I don't know what others have said, maybe nothing, but this gives you a background into some of the philosophy I had when I got to Washington about people staying in the same area. But I soon saw that people too long in one location lost initiative and became too provincial. I had seen it and I think Campbell was right. We had

too many people that didn't know damn thing about Food and Drug work except what was going on in New York, or what was going on in Chicago, or what was going on in New Orleans. The rest of the country was a foreign country and they wanted no part of it. I am hopeful that in the pretty close to twenty years I was in Washington we got rid of some of that.

P. - You know a lot of it is beginning to grow back, because now you don't get transferred unless you apply for a job.

R. - That's right.

P. - And we have people who will not apply. They don't maybe get promoted as well as they would otherwise, but just the same, they stay right where they are. I think that's too bad. I think that philosophy is right.

R. - Well, that brings me up to Washington. I moved into Washington in '48 as the Director of the Division of Field Operations. There were about three different reorganizations after I moved to Washington.

I moved to Washington on October 3, 1948 as the Director of the Division of Field Operations. And then there was a reorganization in 1958, when the Division became a Bureau. The reorganization in '48 did not change the Washington organizations. There was the

Commissioner, Deputy Commissioner, Assistant Commissioner, and Associate Commissioner. Under the Associate Commissioner, there were offices for considering food matters, offices for considering drug matters both human and veterinarian and an office for considering special dietary food. Ralph Kneeland was in that group, if you remember Ralph.

P. - Yes.

R. - And cosmetics pretty much fell into the drug area.

Well, in 1958 the office of the Commissioner essentially got reorganized in that there was a Commissioner, Deputy Commissioner, and Assistant Commissioner, and that was it. And Bureaus were set up. Responsibilities of the Associate Commissioner were transferred to the three Divisions created in 1948, plus the establishment of the Bureau of Medicine for both human and animal drugs. The Washington Technical Divisions, such as Food, Nutrition, and Pharmacology, continued to report to the office of the Commissioner. In 1964 that was further refined to the point that they set up, then, a Bureau for the Washington laboratories. Each of them up until that time had been reporting individually to the Commissioner. There was no central control over the Washington technical divisions. There was also a

Bureau of Medicine. And then they had the Bureau of Compliance in which case management, as well as field activities, all came into one. There was a Bureau of Planning and this Bureau of Planning was expanded to not only be concerned with field activities, but also Washington activities, to be sure that Washington didn't go running off on a methodology which the field never could use, or which would be of no value to anybody but a limited number of people. So that was in early 1964, my last reorganization as I retired at the end of '65, so I don't know what's happened since then.

P. - You know it's been reorganized over and over again.

R. - Yes, so I have heard that it's been reorganized over and over again. Some of the changes appeared to me to be for the objective of forcing out some senior officers. From the time I entered and even before I entered, the Food and Drug Administration, every person whether he was a Chemist or an Inspector, was told and saw the possibility that through developing his own skills, effort, and native ability, to maybe one day achieving a fairly high role in the Food and Drug Administration. There was a ladder, and it was a fairly clear ladder up to--really up to a Station Chief, the ladder was quite clear, beyond that it became a little

less defined. I would guess that some of the competition I talked about earlier may have been as a result of this individual competition going on.

P. - But only in part. There was a morale that didn't have to do exactly with that kind of promotion.

R. - Well no, the morale of the Food and Drug Administration then I don't think was exceeded by any other governmental organization. It was a way of life. You either liked it, you joined in, or you got out. There was no in between. Oh, there was some in between, but there was really no group that thought, well--it's a job, long as they pay me, I'm going to stay." Everybody thought that what they were doing was something worthwhile, were glad to do it, achieved a high degree of job satisfaction. 1964 was when we had the last reorganization in which they established as Bureau over the several Washington Laboratory Divisions. Bob Roe was made the Bureau Director. Then there was a Bureau of Medicine and Dr. Holland headed that--there was another guy followed Holland--I can't think of his name now. And then there was Planning which was under Rankin by that time. And then the Bureau of Regulatory Compliance which took over Regulatory Management and Field Operations.

You raised a question about the philosophy at the time Food and Drug was moved out of Agriculture into Federal Security Agency, which later became HEW. At that time I was really no more than an operating Inspector so I really was not close enough to the heirarchy of the Food and Drug Administration to give an intelligent reply. I do know, though, that there were divergent objectives of Food and Drug and Agriculture. Agriculture looked on Food and Drug as somebody hurting Agriculture. That buggy grain, sub standard peas, sub standard tomatoes and violations that sort of hurt the farmer in the eyes of Agriculture. It didn't help farmers, and therefore, we were at cross purposes with them. Whether that was actually true then, I don't know, but from the position I occupied at that time, that seemed to be the case. Now, in the light of Roosevelt's reason for organizing F.S.A, all you have to do is take a look at his reason and it makes logic to put--to move us into F.S.A, if you're going to move us anyplace other than as an independent agency. We had several Federal Security Agency Administrators before F.S.A became D.H.E.W. The only administrator that I got acquainted with and had any dealings with, was Captain Miller. I think he was an old

Army captain. I was in Baltimore. Food and Drug had seized three carloads of butter that had been consigned to the Army. This was during the war. The military had asked us to sample it before they accepted it. We did. We found that it was not legal butter in terms of manufacturing conditions and the quality of the butter. The Army rejected it and we seized it. The Bowser Trading and Sales Corp. was the manufacturer and was located at Sisterville, West Virginia. Mr. Bowser proceeded to exert some political pressure as well as contest the seizures. I was Chief Inspector and was going to handle the court case in West Virginia. One day I was invited to the Administrator's office to talk about the seizure. I think now he must have come from that part of the country, because I remember he had on the mantle of his office, a big piece of coal that had been mined with a leaf frame very distinctly outlined, that had been given to him. I sat down with Miller and explained to him the case; what had brought it about. He wasn't interested in all of the detailed findings. He wanted a broad brush of it. I did. And with that--I think it was Dr. Dunbar who took me up there he said, "Oh, I think Allan and I can take care of things." "Come on Allan, let's go." And with that we

marched out, and got into his car and went over to the Senate office building, and saw one of the Senators from West Virginia. On the way over he said, "Now, you just sit tight and I'll tell you when to talk." He proceeded to expound on the soundness of Food and Drug Case, and to my amazement was able to retain a heck of a lot of the information that I had given him. And he says, "Now", and he calls the Senator by name, "you see, Food and Drug Administration and I can't properly do a thing about this, but let it go through the courts." And with that we got up and left.

P. - Well, he was a good politician.

R. - He was a good politician. He knew how to handle it. Nelson Rockefeller, when he was in as HEW Under-secretary, was the guy that I got to know and deal with not Oveda Culp Hobby. Nelson Rockefeller was the moving force that really ran the department and Mrs. Oveda Culp Hobby was the head, of course.

P. - I was trying to think what I've heard about her, but it seems like she was a difficult person.

R. - Well, she never could forget that at one time she was the head of the Womens Army Corps. She established an officer-of-the-day for the weekend. Every constiuent agency had to have an officer-of-the-day. Larrick was

then Commissioner. A number of us had to take the role of officer-of-the-day and I had my turn. And that meant on Saturdays I had to go to the office and spend the day there. Fortunately I had a secretary who was most agreeable. She came down on Saturday. That Saturday I was there, I was able to catch up on my work with no interruptions, no phone calls. I usually got a phone call in the morning, the department operator, to be sure I was there. When we would go out to lunch. I'd phone to the operator that Ms. Burns and I were leaving for lunch. At the end of the day I would phone that I was going home, and what my plans were for the weekend. Whether anybody else ever had any business, I don't know, but I never did. It was not all in vain as much as I thought then it was ridiculous, because--who is it in Detroit--the drug firm in Detroit?--Parke Davis. Parke Davis was doing some research work on live polio virus. They shipped a couple of five gallon carboys of live polio virus in solution by air from Detroit to Baltimore, by way of Washington. Somewhere along the route, and this was on a Friday night, one of those carboys got broken in the airplane. The carboys were shipped on Capitol Airlines. Dr. Ludwig G. Lederer, who was Chief Medical Officer for the Capitol

Airlines, who had one time had been a Food and Drug medical officer, and my equivalent in Public Health Service in charge of field activities and I, through the telephone set up by the department, stayed in constant telephone contact with each other and put into practice the program designed by Mrs. Hobby in her "office of the day" concept. Before Saturday was over with we had rounded up every piece of personal or express baggage, every passenger, every person who had been in contact with that plane, either as passenger, crewman or plane service man. And I'm telling you the plane on leaving Washington had flown to a number of cities carrying a lot of people. I took responsibility with respect to goods. The carboy broke in a section of a plane housing the air intake of the air conditioning of the plane. So there was a *distinct possibility* that this virus had gotten airborne throughout the plane, and every passenger, and crew member exposed, as well as all cargo. We located all the cargo, which besides luggage included flowers, sacks of IBM punch cards, cannisters of movie film, and boxes of dresses. The plane had turned around and had gone to two or three other places before we learned of the accident. Every passenger was immunized. Public Health Service

took care of that. The whole crew and the plane itself was thoroughly cleansed, sanitized and disinfected. The airline took care of that. The flowers, movie film, IBM punch cards, boxes of dresses and the food stuff, everything--even if we didn't have any responsibility for saying, "destroy this", were burned. We found some items were actually wet from the spilled carboy contents. Destruction was at the end of the runways and not moved from the airport land. So what they did was to load the questionable cargo on one of the airport luggage carts and haul it out to the runway, pour gasoline on it, and set the cart and everything afire. Not a soul came down with polio. But all day long my phone was hooked up to the telephone exchange at the office. How the telephone operators did it, I don't know. Whenever I picked up my phone, it was a Department telephone operator answering it. I asked to talk to Dr. Lederer or to the PHS Officer, or to talk to Denver, Detroit or Los Angeles. All day long I stayed at the house on the phone. Mrs. Hobby's officer-of-the-day concept helped get the emergency organized and operating, and I'll have to give her credit for that.

P. - Was Nelson Rockefeller--was Food and Drug one of his--

was he greatly interested in Food and Drug or--

R. - He was interested in Food and Drug. He was interested in all department activities. How accurate I am on this, I'm not sure, but I was given to understand that Nelson Rockefeller brought with him a personal staff. The Department didn't pay for it. He paid for it. They worked for Nelson Rockefeller. That resulted in the period in which we had to make charts for everything. Shelbey Grey was involved in developing FDA's charts. There were many and some quite immense charts; charts to show this, that, and the other thing. But Nelson was a dynamic person, to my mind a top executive. He was of course wealthy, but he never let that be shown. He never let that make a difference in his way of doing things. And he made it a point to become intimately acquainted with programs and people and would come down and sit down with you like you and I are doing now--"what's going on right now".

P. - Well I know Shelbey told me one time, we were just talking and he had lunch with Nelson Rockefeller a time or two, so that was what really I thought that it seemed like maybe he was taking an especially great interest in Food and Drug.

R. - Well, he may have taken more interest in Food and Drug

than in some of the other offices in the department. I'm not sure of that, but he did take a real interest in Food and Drug and was responsible in trying to help Food and Drug get across the story better than what it had been doing. We had some periods of very difficult times in getting financial support, appropriations. Obviously since 1965 Food and Drug hasn't really had that problem.

P. - Why did we have a problem then?

R. - Why? I have only the slightest idea. I think maybe we were quite proud of the fact that what we were doing was costing the taxpayer less than a nickel a person. Made no bones about that. We grew up--and many of us then young Food and Drug people--you take Shelbey Grey, Chet Hubble, Walter Moses, Winton Rankin, Nevis Cook and myself, we all were depression babies. We finished college--I've just been to my fiftieth class reunion. In 1929 - the 30's, jobs were hard to get. If you had one, you didn't keep it too damn long. Things shut down. I worked as a chemist before I came to Food and Drug at twenty-five cents an hour, twelve hours a day, seven days a week. So these jobs probably had a little more meaning to us than a job today. My eldest son told me just last week, "Dad we're hiring

college graduates in engineering with nothing more than B.S. degrees for \$17,000, \$18,000 a year." I made \$1,800 a year and thought I was doing pretty good, right after graduation. There wasn't overtime. FDA made do. It stretched and perhaps didn't ask for enough, wasn't strong enough in its approach. I don't know. One reason why FDA got cut the half a million dollars one year was because the Food and Drug Administration made a seizure of canned so called baby beets. The firm shredded down very big beets to make beet salad or some such item, and they'd taken the little heart center, canned them, and called them baby beets. They weren't baby beets, so FDA seized them. They were from New York state. The guy had persuasion with Congressman Tabor. Tabor wanted the seizure action negated, and there was a couple of other things like that Tabor was interested in. Charlie Crawford said, "No, they violated the law. The law says so and so." And he stuck with it. Tabor was personally responsible for cutting the appropriation ten percent.

P. - That really seems incredible, doesn't it?

R. - There was nothing grey with Charlie Crawford. It was either white or black. Charlie was not one of these that hobnobbed with people on the Hill. Charlie hob-

nobbed with you and me. I'd go over to Washington when I was Chief Inspector in Baltimore, and often had something to take up with somebody in the Administration, as well as with the Resident Inspectors. This was when FDA was in Agriculture South Building and all were jammed pretty close together. The Resident Inspector's office was down the hall from the Commissioner's office. Maybe a half a dozen doors down the hall. To go and leave the Resident Inspection's office you had to pass the Commissioner's office to catch the elevator. I know one time I was there, I was getting ready to go, it was getting around noon time Charlie said, "What you doing around here?" "Oh, I got some things to do. I'm doing this, that, and the other thing." Well he said, "This is Friday afternoon". If you get through around three o'clock, why don't you drop in?" It was an invitation. To me it was a command. At 3:00 I went in, and Charlie had nothing in particular to tell me except he wanted to talk to me about how we (Baltimore Station) were doing. What were the things that were happening? What were the interesting things? What were the problems we were running into? What were the problems we foresaw? When Larrick became Commissioner, Larrick made a point to get acquainted with the people on the

Hill. You seldom saw a Larrick at lunch time. Larrick was at the Press Club or some other place having a nice meal. To me Larrick got away from the Food and Drug Administration. Charlie had lunch in the Liars Club, which was one of the laboratory rooms in Agriculture where the Commissioners and the many FDA'ers would brown bag it, so to speak. They made tea or coffee and everybody would sit around and talk of interesting personal and official activities, while eating lunch.

P. - Still he didn't quite accomplish the other either did he?

R. - No.

P. - You know the political sort of end of it.

R. - No, I'm afraid not.

P. - Because if he had, things would have turned out a little differently, I would think, if he had this kind of support that I presume he was looking for--

R. - Well, the support he had was stong--Dingle--from Michigan, Senator Hill from Alabama and 1 or 2 others whose names escape me at the moment. Another Congressman later became Secretary of Defense. He had the support of the Democrat from Rhode Island who was Chairman of our Appropriation Committee.

P. - Now that one I should know.

R. - Fogerty.

P. - Fogerty.

R. - We had the support of John Fogerty. No question about it. John had his own ideas. He wanted to be damn sure that--and John Fogerty was the first one to start giving Food and Drug some increase of appropriations. We began to get some increases about then. Not great big ones like they are today, but he's the one that made funds available for FOB-8. He is the one that made funds available for equipment; laboratory equipment and supplies for the District offices. But those people didn't stay of course.

But we had esprit de corps. Sure, we disagreed with each other. We didn't agree on everything. We didn't have the same approach to things, but we were all members of the Food and Drug Administration.

Henry Welsh's deal. I was really not very knowledgeable about that. Charlie was Commissioner. Larrick was Deputy Commissioner. J. O. had already retired and John L. Harvey was sort of the next in line, as everybody saw it. I think perhaps there were others who were a little more familiar with that than I am.

P. - How did that affect Larrick? Could you see. I mean

just from--

R. - I think Larrick and Crawford and I'm sure Campbell and the rest of them before him accepted any explanation that any of us gave them as an honest, forthright answer. And if we weren't doing anything that we shouldn't be doing, and if something appeared to be out of line, we'd tell him what we were actually doing and they accepted that.

P. - There was no reason for them to do differently.

R. - No. Henry Welsh started out in Bacteriology then under Dr. Hunter, he was the number two man under Dr. Hunter and when certification of antibiotics came in, Welsh was put in charge of that. He was pretty much a natural for that position. And he took hold and he ran the division.

P. - We're back on the air.

R. - I'm not sure that the Welsh matter really disturbed people outside of Washington, a great deal. It may have. I'm not aware of it. In Washington, yes. Because everybody involved in the Welsh matter were Washington people. It was Henry Welsh. Charlie Crawford was Commissioner and therefore in command. Henry wrote a book with Charlie Lewis, Dr. Lewis. In my judgment it broke Charlie Lewis. But the other

people in the Division with Welsh, Jester, Joe Di Lorenzo, and Don Grove--sure they were under the guns. They didn't know what was going to happen next. There was a pending court case and several were expected to be subpoenaed, but outside of Washington I don't think the Henry Welsh Affair really had an impact.

P. - But the committee that was more or less set up by the Secretary, I guess caused us to fill out questionnaires and that part of it affected each of us. I've had people tell me that they thought that was--that there was a loss of morale from that that never--that we never recovered from. What you agree with that?

R. - I really had momentarily forgotten about this. There was a committee set up; chaired by the head of the New York FBI office. We had to fill out a questionnaire, and each of the Bureau Directors were called over to an office in the Federal Office Building next to the White House for an interrogation about our contacts, our personal affairs including each member of our family. Out of that came some rules about which stocks and bonds you could own and which you couldn't. I didn't own any then, so it didn't affect me. I know I got the job, delegated by Larrick, concerning certain financial interests. I had the responsibility for deciding

whether or not field personnel could retain certain stocks, or whether they could buy certain stocks. If they inherited some (considered as a possible conflict of interest), we gave them a reasonable length of time to dispose of it. I don't remember anybody having already bought some stock in say Abbott Laboratories or Upjohn or Parke Davis. It could have had a strong anti-morale factor in this business of having to disclose his personal financial status.

P. - Course the fact of the matter is most of us didn't have enough money to own anything.

R. - That's right. Those that owned anything were usually from an inheritance. Oh, there were a few exceptions. There were a few guys that had been pretty skillful with handling their affairs. Beyond this immediate inquiry, and it was handled, I must admit, in a rather high-handed fashion. I don't think there was a long lasting deal. I may be wrong.

P. - I would almost agree with you in the sense that I was outraged at the time, but somehow it became routine after awhile.

R. - I'd forgotten about the damned affair until you mentioned it. Now off the record--

P. - One question I wanted to ask you Allan, over I don't

know how many years, but let's say twenty years or so, there's been a shift from handling regulation almost entirely by case law, to such things as recalls and other administrative actions. I wonder what you might want to say about the philosophy or your recollection of that.

R. - I believe that the first recall of any significance, nationwide recall, involved a salt substitute that had pretty wide use. And it was recognized to be literally impossible to get everything off the market through normal regulatory activities, seizures; small lots, wide distribution. That led to calling in the firm, laying before them the facts, and relying upon the provisions of the law that allowed the Food and Drug Administration to give public notice of danger to health; and therefore saying the material ought to be returned, or recalled. Now, the stuff just poured in and the product left the market. Then there were smaller recalls that occurred about that time. A small firm in West Virginia re-labeling, bulk castor oil, bulk spirits of turpentine. They put castor oil labels on the turpentine and turpentine labels on castor oil. This was recalled because it went out, six bottles here and two bottles there to a lot of

grocery stores and small shops around. To get the stuff seized it would incur prohibitive costs. Also you didn't know whether or not you could reach everybody and particularly the stuff in the hands of people who had it in their homes. So this was a case for putting out a recall, focusing the public notice to those areas where the stuff was located. Now, throughout the time I was there, I always tried to get a seizure action started and underway by the time the firm was asked to, or we told the firm their particular product ought to be recalled. I took the position that at least thru seizure action, the firm would have a mechanism, a means, of going into court and challenging what we--our action. When you went out on press, the only thing they could do was disclaim it in the press. But the government's word was stronger and louder than the firm's words. But if we had a seizure, there, they had a chance to have their day in court. This was the idea that I always put forward and always started a seizure. When I'd go to Lar-rick, to Harvey and propose a recall, I said, "We have approved a seizure of this material" -- wherever it is located. It may not have been more than a half a dozen bottles, but it was at least a chance for the firm to

challenge it. I don't know. Some seizures were accomplished and went by default. A couple of cases I know we told the firm, we thought a recall was required. We advised them of our notice to our Districts to alert the press and the public in their areas. Also that we're going to put out a public release, and here it is, and we've got a seizure request in. And I'd tell them where the lot was that was to be seized. More than likely they went out and grabbed that before the Marshall could ever get there. But they had a chance. All they had to do was leave it alone. The Marshall would seize it. They didn't have to do anything, but just let it go. But if they wanted to contest the government's action-- There were those who figured, and it is true, that seizures, multiple seizures of dangerous thing could really take up your resources, time and energy. A recall would get all illegal stocks back faster.

P. - Did those of you in charge at that time--did you sit around the table and say look, you know that's a better way of going. Let's start going that way.

R. - Before we ever started a recall a conference would be held. Attending would be Morris Yakowitz who was--and I'm thinking about at the time that I retired--in

charge of what used to be Regulatory Management; Fred Garfield, who was the Deputy Bureau Director; Reo Duggan, who was Chief Chemist; Ken Lennington, who was the Chief Inspector. We would also have in the appropriate Washington units from the Bureau of Biological Science, Bureau of Pharmaceutical Control, and the Bureau of Medicine. Methodology, assay results, assay reliability and reproducibility would be resolved to everyone's satisfaction. Then does the violative item present a sufficient threat to the public health to warrant a recall? Is this of that importance to warrant a recall? Medical judgement always was involved--all you've got to do is go back to the files and you will find in every case memorandums indicating that these meetings were held and there was a unanimity of opinion. Then we would go to Larrick, or Harvey for approval and authorization. There was a recognized procedure to follow.

P. - Okay now, that would be on a specific item, but at some previous time did you and Harvey and Larrick and some of you sit around and say--is the general philosophy let's see if we can't correct this by recall, rather than by seizure. It would be cheaper.

R. - As a general policy? I don't recall any.

P. - It was something that well--to say it just grewed maybe isn't quite fair, but did something develop over--

R. - It was something that developed in the light of the specific individual facts. I don't know of a single recall that didn't involve a real threat if not an actual danger to health. Maybe it was mislabeling castor oil and turpentine as an illustration.

P. - Just as dangerous as--labeling can be just as dangerous--

R. - That's right.

P. --as composition.

R. - Right. And there was a--oh heavens above--it developed and grew by weight of its--I guess effectiveness.

P. - How about warning letters and that kind of thing. Did you start--

R. - Warning letters, no. The warning letters came after. Remember this, the first injunctions that were ever imposed under the 1939 Law involved danger to health. They did not involve economic violations. Mr. Walter G. Campbell had the idea that an injunction was one of the worst things that could befall a firm. It was a course of action of the last resort. Now I was a proponent for injunctions and got one hell of a lot of injunctions in my time in Baltimore. I thought

injunctions could put an end to repeated violations quicker than anything else, if you handle them right. If you handle them properly. Campbell didn't believe in that. There was a firm on the eastern shore of Maryland who had in the early 1940's--this is during the war--a warehouse full of canned peas. There was a set-aside order for the military. The military took less than its quota because the rest of the pack was substandard. In short the firm had not been able to meet their quota, and the pack awaiting shipment to the civilian market was substandard peas. And they were shipping right and left. We had already made a number of--several seizures. On economic violations you could only make one seizure until that one was adjudicated, then and only then was multiple seizures permitted under the FD&C Act. I went in and proposed to the Administration that--here's all of these early June peas hard as rocks, dry, mealy peas; substandard. Why waste our time and have the people cheated on buying these as early June peas? Mr. Campbell wouldn't go for it. It was too drastic an action. Later on that view changed. By the same token it got changed to a point where injunctions would be approved by the Administrator, G. C., and Department of Justice in a

days' time. In fact, in the state of Maryland that was the only course of action FDA had. The District Court Judges in Maryland would not entertain a criminal prosecution. Injunction was the only action we could get. We did get seizures, but we could not get prosecutions. McKinnon had the unhappy experience of having something like a dozen criminal cases on watered oysters thrown out by Judge Coleman in one day. I wasn't there, but I understand he tongue-lashed McKinnon no end and threatened to jail him. So in Maryland if we had a case that normally would go, and should go, by federal prosecution, we went by injunction. Incidentally the court insisted we get the state and city to do something about violations FDA uncovered. They did as they saw fit. The court tried to get the state and city people up before it, and one time they responded to the court's invitation. The Judge blasted them--gave them a tongue-lashing. They refused to go up anymore. It was a trying time in federal-state relations. We'd tell Ferdinand Coff, "look we got a dirty plant down here. It's in the city limits." "I'll take care of it." And he would to the extent that he could, but it wasn't totally effective, then we had to go in for an injunction.

The recall grew because of the incidence of danger to health and that was the fastest most effective way to remove widely scattered stocks from the market. And it paid, I don't know what they are enjoying now. After all its been over fifteen years since I've been around.

P. - I think there's somewhat of a trend toward injunctions again, but the overall trend, of course, towards prosecutions and seizures has just been down and down and down. I would say I don't know what the figures show, but it definitely is a downward trend.

R. - I've noticed that. This thing here (The Consumer) says that. This is a thing that has bothered me especially as I read and study the N.J.'s.

I haven't done any consulting work now in five years--I ran my own consulting business. I didn't advertise. I didn't even go out. I just got called in. One of the last times I got called involved a drug firm in the Los Angeles area. I got a long distance call from the outfit and I'm not sure how they got my name, but it was on a Friday or Saturday and they wanted me to catch the plane Sunday and be out there--be at the plant Monday morning. Well I couldn't make it that week, but I agreed to come out the next

week. Well, the company president called back, this was on Friday, (about an hour or so later) and said, "Fine, do that, because we just had a delay in some proceedings out here." Well I never could get out of him just what the proceedings were, but I realized he was in trouble with the Food and Drug Administration. And I said, "All right, send me copies of whatever you've got--that had been filed with the court, so I have some knowledge when I get out there what we're dealing with. And you indicated you have some other help--they made some reports to you, let me have them." This was in March. The government was filing a request for an injunction, based on factory inspections, started two and a half years before. The last inspection was in September of the preceding year. Now, when I got there, they had a copy of the factory inspection reports. Apparently Food and Drug sends out a copy of the inspection report now.

P. - They can get it under the--

R. - They had copies of several inspection reports. I don't know how they got them. I was surprised. I read them. So I knew everything that the Inspectors had found, and many of the things that the Inspector had

seen initially were critical to good manufacturing practices. I paid more attention to the last report than to the earlier ones. Many conditions were found to no longer exist. Some things I grant you did exist then. So I found on arrival in Los Angeles there was a request for an injunction filed. So, I asked if the FDA were going to enjoin you, why didn't they enjoin you in September? They had found about four times repeated poor manufacturing practices. I told the firm, "Look if I was still with Food and Drug, I'd have shut you up a long time ago." This is ridiculous. I'm out here. I'm prepared to give you a hand--under this condition. You are willing and have somebody go around with me and institute things to change these conditions. I mean change them now, not next week. Well they did. The injunction case got put off. The hearing got put off for about two or three weeks. Now why the government was willing to put it off--I do not know, but they did. Well, I made a written report of my findings and observations. Then when the hearing came up, the court took a look at the government's last report (now some months old) and they looked at mine, only a week old. The court held there was no use enjoining in the light of the most recent inspection

and asked FDA to reinspect. So then FDA sent in a team of 5 Inspectors. The FDA team started out on a Thursday. When they arrived, I said, "Ok, let's have five people in the company, one to go with each man." So the leader of the group, who knew me and I didn't remember him, I said, "What areas you want?" "Well we want to look in the laboratory." "We want to look at--and he named off the areas." "All right, Mr. so and so will go with your man to the warehouse." "Mr. so and so will go with your man to sterilization area." "Mr. so and so will go with your man in labeling." "Mr. so and so will go with your man in raw materials." And I will go with the FDA man to the laboratory. I knew the laboratory people were highly nervous and they got upset pretty quickly. The inspection went to the close of business on Friday or for two days. Whenever FDA asked a question, or took a sample, I took a sample, the firm took a duplicate sample and recorded the question and answer. When they came back on Saturday, the plant was closed down as it never operated on Saturday. The FDA team wanted to continue inspection on Saturday and were told, "No, we're not operating. What we're doing is housecleaning. This is normal maintenance shut down. We

aren't operating." The firm's lawyer quoted the law to them. So the FDA team to a man sat outside all day long to be damned sure that production didn't start. Now I thought that was particularly, utterly, ridiculous. They did come back on Monday and finished up in a half a day. The judge ruled, "You don't have a basis for injunction." FDA had made some seizures and I watched the reports of the seizures. They have all gone by default, small lots. And as far as I know, FDA decided not to prosecute. And why they didn't prosecute, I don't know. An injunction filed in March from a factory inspection the preceding September with a documented history over a period of two years of repeated inspections showing poor GMP does not suggest good enforcement of the FD&C Act. Somebody is not on the ball.

When I look at this (news report)--they're talking about needing a new law. Yes, I really think they need a new law; some amendments such as, the Delaney clause needs to be changed. You need to update it purely in terms of the language rather than the authority. They've got all the authority they need now. What are they doing? The same types of projects that were occurring thirty years ago, rats, bugs, spray

residues--I don't know what about the new drugs. There is no indication of interest in excessive preservatives, food additives, standards, unfit raw materials. Enforcement apparently is largely through administrative rather than judicial action. Now the sulfanilamide episode, everybody denied it, but I am convinced the sulfanilamide episode was a reason for the new drug provisions in the law. The law was about ready to be passed after five years when the elixir of sulphanylamine episode occurred, and then all of sudden the new drug provision. And I think it's a good one. Administering, it is something else. Thalidamide episode--the government doesn't really deserve any credit for the thalidamide episode--taking it off the market. It's just a matter of chance, that the thalidamide NDA hadn't been approved. A doctor outside of the Food and Drug Administration perused reports and journals, called the attention of some colleagues, who in turn called the attention of the Food and Drug Administration to these reports.

P. - Oh, I guess they--as long as the opportunity existed why they acted like they--

R. - Of course, Kefauver is the one that gave Dr. Kelsey all

of the credit and the publicity. A lot of people in Food and Drug disagreed with that, and it wasn't because of jealousy. It was just I guess--didn't think it was fair recognition.

P. - What about the Kefauver hearings. Is there anything you want to say about that?

R. - No, the Kefauver hearings--were--preceded my position in Washington, so I really wasn't in the place to really have any intimate knowledge of it. Of the Delaney hearings that was also true. I was there then, but at that time I was in with DFO. Those Delaney hearings had an impact only to the extent that we were called upon from time to time to get certain illustrations, certain facts from, either a memory of the Washington files, or go back to the Districts and get some things from the District files. About my only trips to the Hill were in appropriation hearings, except the last one which was the Abbott hearings, by the Fountain Committee, the Interstate and Foreign Commerce Committee. Somewhere along the line they got the idea, quite frankly, that because John L. Harvey had a brother that was a vice president for Abbott that the Food and Drug Administration had given Abbott special treatment. They were convinced of that.

P. - Before they started?

R. - Before they started. The whole object was to confirm that view. If there ever was a kangaroo court, that was one. For five days I appeared before that committee in executive session. Nobody else from Food and Drug, no member of the General Counsel's office, and nobody else from my staff, just I alone went up there before the damned committee for five days.

P. - How did they keep it going that long?

R. - How could they?--repeating the same questions over and over again, inquiring into my own personal life; what my kids were doing, who they were working for, how did they get their jobs. They had a list of every telephone call that I had made from my own home phone. They knew what long distance calls. Which calls I had made which calls that had come into my home phone; which calls I had made from the office. They had talked to people in Food and Drug. They had talked to a doctor who had been the man that the Bureau of Medicine had assigned to work with us on the Abbott recall. He was participating in every meeting we'd had among ourselves and with Abbott. He had initialed every memorandum we had made of such meetings, and then all of a sudden he prepared a memorandum in draft form on a

yellow sheet of paper. He got it put in the file and the only copy in one hands of the committee. Nobody else saw it. The first time I saw the damned thing was when I was shown a copy by the committee. That memorandum took a position entirely opposite from one that we'd had in a conference in the office. My only answer was, you have to ask him about that view. I've never seen this memorandum. I am not aware of this view--the view he's supposed to be concurring with is in the memorandum, the other memorandum. But that thing went on. They went through the files, and they've been going through the files since then. Gil Goldhammer, I think is still working for that committee. He was.

P. - I think he is because I saw him a year ago and he was--

R. - --he was working for the--

P. - He was working for the committee a year ago.

R. - Yes the committee has a lot of authority in that respect.

P. - A Congressional Committee--I guess there's no one to really judge what they're doing. No one will.

R. - Well, the Committee themselves have staffs, and some of them have been there for years and years, and there's a trust that this position may lead them to the possibi-

lity of a better job in some more important Committee. So they're out to make a name for themselves. Heavens above, I've been to appropriations hearings, Senate appropriations hearings. One man, Mr. Hill, would be the only Senator there. And the guy who was a Chief of the Staff--and we'd make our case, put in our budget request, it would last an hour, hour and a half. Nobody would listen to you. You know darn well that's the reason why back in those days appropriations were hard to come by. Nobody had any interest. Now, how much interest do they have now? I don't know. They must have a lot more.

P. - Well, I hear tell that the Commissioner spends half his time on the Hill for this, that, or the other thing now.

R. - Well, Larrick used to spend a good bit of his time on the Hill too. Of course Food and Drug is a different organization than what it was when I was there. Of course they got the Virus, Serum and Toxin Act and other responsibilities. I am personally convinced in some of the conversations I've had with--and there's been not too many I must admit--Food and Drug people that they are not getting the personal satisfaction from the job that you and I did, when we were operating

Inspectors or otherwise.

P. - I think that's absolutely true that we thought we were part of the Food and Drug Administration and they think they work for the Food and Drug Administration and it's a different feeling entirely. We felt that even working there even at a low level, you still felt that way.

R. - That you were part of Food and Drug. Oh sure.

P. - And of course you were, in a way. You were treated that way. You were expected that that made a much higher expectation of you too. I remember when I was Resident in Albuquerque. I wasn't very old. It was about 1946 and I'd go into Denver very, very seldom. You didn't run back and forth all of the time.

R. - You didn't need to.

P. - When I did go into Denver, old man Vincent--

R. - Wendell Vincent--

P. - Wendell would say, "Now, Bob, I want you to remember in that whole state of New Mexico, you are the Food and Drug Administration." He would make you feel pretty important the way he said it. You know Vincent had his faults, but he had a way of making--when you worked for him he had a way of making you feel like what you were doing was worthwhile. He could treat you pretty bad in a sense, and yet you somehow liked him for it. He had

quite a knack at that.

R. - Well, Vincent got his nose out of the joint and I don't know on what basis, but I guess he was not faultless in it. That virtue was not limited to Vincent, but J. J. McManus, Bill Wharton, Olie Olsen, Frank Wallard, all could make you feel you were a part of the Food and Drug Administration.

I got sent out as a P-1 Inspector, out of Philadelphia, I hadn't been in any length of time, and Mr. Britton got a call from the--I guess it was the State Health Department saying that several people around the state had been rushed to hospitals, it was not in just one city, but several cities, because all had the symptoms of appendicitis. When these various individuals reached hospital and almost ready to have their appendix removed, the surgeons found these people had already had their appendix taken out. Then they found out by inquiring that the patients had taken a type of a home remedy called "Bad X Salts", or effervescent salts--made out in Carlisle, PA.

P. - What was it called?

R. - Bad X Salts. It was a sort of a effervescent salts sort of like a Alka Seltzer. This was on the 23rd of December. Carlisle, PA was just beyond Harrisburg. I

was the most readily available candidate, so they sent me out to find out about Bad X Salts. I stopped in Harrisburg, saw the guy who enforced the food law. There really wasn't any drug law in Pennsylvania then. The food law was by the Department of Agriculture. The drug law was by the State Health Department. I found out all they knew about the firm and where it was located. This was late in the afternoon and early evening. So I got up early the next morning, and high-tailed it to Carlisle, and went to the freight office--went over their books and got records of all of the shipments this firm had made. I got a whole list of them. And then I went by the post office and got the address of the firm. The Postmaster told me the owner, a retired doctor, and his wife made the stuff, shipped it out of their home. Then I went--this was about to about 9:30 a.m., 10:00 a.m., to the Doctor's house. Sitting in the living room was a guy twiddling his thumbs, he was from the State Health Department. He was waiting to be seen. Somebody had let him in and then I was there. I've forgotten now who let me in. I knocked on the door and I just said, "You know the matter that we are here about is a serious matter and one that we just can't take all

day to get around to." I have to talk to somebody now about this. Well, the Doctor came out about that time. I showed him my credentials. The State Inspector showed him his. The old Doctor just sorta ignored the state man. But I found that they made it down in the basement. The doctor had run a proprietary drug firm and had gone out of business. His wife was making Bad X Salts for pin money. The doctor contended the formula was secret. I insisted that it could no longer be a secret as it was creating a problem." So he got out the formula book and he gave me the formula. There really wasn't anything to it. The laboratory could have found out in no time. We went downstairs where it was made, and there among the ingredients was tartaric acid, sodium bicarbonate, sodium sulphate, and a little milk of sugar. There was also the expected stock of bottles, caps, labels, cartons, and quite a few dozen full bottles of the Bad X Salt. A round cannister about 30 inches around was pointed out as the container of tartaric acid. I picked it up and there was a label reading "tartaric acid". I turned the cannister around and stenciled about so big, "tartar emetic 25LBS". I said, "Here's the culprit." "Now, let's stop fooling around." "You have not been adding tartaric acid.

You've been adding tartar emetic." I thought the old doctor was going to have a heart attack. Where are your shipping records? Well, he didn't know. His girl that took care of that wasn't there. I said, "Well, you get her." Well his wife was upstairs at the head of the steps, and she recognized the roof was about to fall in. When we got upstairs, she had a ledger, and here were all the shipments they'd made. Well from the date of the cannister, I knew how far back the questionable shipments were involved. So I listed every shipment they had made, and I had already listed most of them because they had gone out by express. I went back down and took some samples. I hung onto this tartar emetic drum like dear life. I took samples of the other ingredients. All of the tartar emetic was taken as the sample. Then I got to a telephone, and called Philadelphia, and told them that the "Bad X Salt" contained tartar emetic, and listed all of the shipments that had gone out. See this now was Christmas Eve. This was on the 24th and many of them went in to the Baltimore area. And Baltimore never did forgive me for phoning them in because a lot of those--

P. ---worked Christmas.

R. - Christmas was upset by it. Now, if we had believed in

recalls, then as recalls later developed, we would have had an immediate announcement on the air, and on the radio, and every other news media. Distribution was through wholesale and retail drug outlets so a dozen bottles here, and a dozen bottles there, and six here, and two other bottles somewhere else.

P. - What in fact did we do? Did we go out--

R. - We went out, and we sampled it, and every bottle we could get a hold of it was too small for seizure--and we bought up all as samples. The firm was prosecuted, and the supplier of tartar emetic was prosecuted for shipping tartar emetic instead of tartaric acid. Now it was episodes like that that really I think evolved into the recall.

P. - This was part of your experience and other peoples' experience.

R. - Yes. To the time that I left, retired from Food and Drug, every Commissioner and every Bureau Director, with the exception of Dr. Summerson, who was a Bureau Director of Sciences the last year or two I was there, and the one or two medical Directors, were career people who had made Food and Drug their life work, who believed in it, and who aspired to make it worth something, not only to the public, but their associates and

themselves. The Medical Bureau people were short lived. They came in from medical schools research institutions, Military and what have you. So, with that background, we've got to say first, career people by and large were pretty much "wedded" to their job, so to speak; sometimes maybe more than they should be in terms of interest to their family. I've been accused a time or two by my wife of not spending as much time with my family at home as I should have, or my thoughts, as I was thinking more about my job somewhere else. They had their own standards. They had their own ideas of performance. Today, an expression that Wharton used, we all understood, but would be misunderstood today to no end. He made it a point "A sample a day, a factory inspection a day, a seizure a week, a prosecution a month." Now these were things when he would sit down with an Inspector, he wanted to know. He'd sit down with you and your field diary. Well, he wasn't like the guy out there making the score up on a wall for a policeman to make an arrest a month or giving a ticket a month, or going into court. It sorta sounded like that, but it was the idea that you were out making a selection, doing something to the end that the law expected you to do. I think many of us

I'm sure took pride in those kind of records. We did try to every day do something that was set out for us and the law to do. I never did know J. O. Clarke until after he moved to Washington. He was obviously just biding his time to retirement so I'm in no position at all to--but Bill Wharton and Harvey I got to know exceedingly well and considered both close personal friends. Harvey at times made statements that were misunderstood just like this statement that I mentioned of Wharton's, that I'm sure today would be misunderstood. Bill Wharton had lost an eye as a boy. He wore a glass eye. He used to give a lot of people the shivers when he would look them straight in the eye with this cold, glass eye you know. But he was a very personable guy. He had his own way of getting to know people. He taught me an awful lot of things about dealing with people as individuals. I worked under him for a year and a half there in New York. I know when he called me in to New York to offer me the job, I had seen him off and on. He had been to our house a time or two, first in Jacksonville and then in Baltimore. When I got to New York, I thought I was going to go up in the morning and come back that night. He decided that night I was to stay over. Well, I got to get a

hotel. "Oh", he said, "Let's not worry about a hotel. "I've got room for you at the house." I went home with him and Bill Wharton's first attempt right off the bat, he had an apartment down in Greenwich Village. He tried to load me up with more alcohol than I could tolerate, and what he was trying to do was to find out how I would react. Later on he admitted, he said, "I tried to get you drunk last night." I said, "Yes, I thought you were trying to." He said, "You realized in time." I said. "I hope it was in time." He said, "It was," "You'll have to be sure you always realize when it is time." Now, he had personal loyalties, and allegiances. He and Dr. Dunbar came into the Food and Drug Administration at the same time. I think they were one day apart. Dr. Dunbar came in one day ahead of him. Dr. Dunbar was a Chemist, Wharton an Inspector.

P. - He was one of the original Inspectors.

R. - He was one of the original Inspectors. Campbell was one of the first five. Dunbar had three daughters and Bill Wharton only had two daughters. Dunbar was always one ahead of Bill Wharton. And they had the biggest time in the world joking with each other about it. You never would say anything about Wharton that Dunbar

wouldn't challenge, and as far as Wharton was concerned, Dunbar had no peer.

R. - Wharton was a stimulator. He was always pushing, pushing, pushing. He was a stimulator and a driver. He set the pattern. He obviously was a good Inspector. Some of the early court cases were based upon some of the facts that he'd developed. Now, Campbell I never knew. I never got close enough to him to know him, and the few times that I met him, over a period of several years when I was in Baltimore, I was always boy to him. He knew my name, but it was just a sort of "hi boy." Now, Crawford was in a way a little bit my idol. Now there are some people who didn't feel that way about Charlie. There's some people who felt Charlie was not a good administrator. I thought the world of Charlie.

At one time Washington had the same sort of a deal that the Districts did. They were bringing in individuals for a period of eighteen months to two years assignment to work in Washington--a sort of training. Kirk went down under such a deal as that and stayed down there. Kneeland went in on such a deal and stayed down there, and others went in and went out. I think the good ones stayed and the others probably went out. In talking to Larrick one day, conversation included

the Washington training tour. I said, "That's just fine. There was only one of those training assignments down there I'd like to have, but I'd be scared to death of it if it was offered me." At that time Larrick was Chief Inspector. I said, "Well, this is in confidence, not to be broadcast around, but I think it would be a great experience and I'd learn one hell of a lot to work for Charlie. But I would be scared to death." "Oh, why?" "Well", I said, "I think he's too much of a perfectionist. I'm afraid I couldn't perform to the perfection that Charlie would expect of me." "Oh, I don't know, Okay." And that was the end of it. About a month later, I was over in Washington and Charlie saw me--motioned for me to come down to see him. He said, "I understand you think I'm a perfectionist." I said, "Larrick was not supposed to tell you that." He says, "Larrick didn't tell me." "I said, "Oh now Charlie, let's don't start talking that way. Larrick had to tell you." "Why do you say that?" "Well," I said, "I frankly think you are." He laughs and said, "Well, maybe one of these days we'll find out." And that was the end of it, but Charlie was a perfectionist. There's no question about it. His letters had to be professionally right, and if you ever get a chance to

read some of the responses he made to letters from the Hill or letters from industry, you will see perfect replies. The fewest possible words were used by Charlie. But he was as stubborn as a mule. He decided after the Tabor experience, the cut in appropriations, that we were going to stop all actions of any economic violations. We were only going to take care of important things, and the important things were those things dealing directly with health. And he stuck to that tooth and toenail. Some Districts would carry on projects and he'd find out about it and give me fits. I would go out to the field and--"Look, that is non project, stay off of it. We got enough health violations." "But Allan these are here" "The policy and the program is health, not economic." "The Commissioner has spoken and I'm right here to see that you follow the Commissioner's views." Some of them would come in anyway, and Crawford would find out about it, and Crawford would tell them. He had avowed that the program, and the purposes were to health and economic we weren't going to deal with, and we didn't. A number of people, and I'm quite sure when you talk to Kirk, Kirk's going to be one of those who thinks that Crawford was wrong. We had done all the work to prove the

violation, all we had to do was put the thing through--people were being cheated and we probably didn't help matters any by not filing them. We should have gone ahead and made the seizures.

P. - Right or wrong he was the Commissioner.

R. - He was the Commissioner. Larrick was an entirely different kind of individual. He was a lot easier to meet, easier to know. Larrick had some ideas that sort of surprised me in a way. One day Jim Pearson, who was an Inspector in Baltimore, had been up to Baltimore and was driving back to Norfolk, and something came up that I needed Jim--I was Chief Inspector --needed Jim to take care of a matter before he got to Norfolk. So I thought a minute, looked at the map, and heavens above, Jim was going to cross a toll bridge down halfway between Baltimore and Norfolk. So I got on the phone, and called the toll bridge tender, and told him who I was, and that a Food and Drug Inspector, James C. Pearson, should be crossing the bridge very shortly in a government car bearing license number so and so. If he saw him would he please ask Jim to call the office? So, he said, "Fine," and in a little bit, Jim Pearson calls. The toll collector had spotted him. Larrick learned of the incident and said, "Don't you ever put

the police out on the road looking for me." Well, I said, "I wasn't putting him out on the road, he was going to have to cross that bridge." "So why not use that chance. I got a hold of him. There's no reason for Jim to be upset about it." Well he said, "Don't ever do that with me."

When we were going to replace Cyril Sullivan at Boston, we needed to assure that a letter to Cyril, did reach him. Also we needed somebody to take over the office automobile, equipment, office files, everything right off. Shelbey was the logical person, he was Chief Inspector. Shelbey was selected. I called. Shelbey was on a trip. I talked to Lorraine, his wife. She thought he was going to be where he normally stayed at such and such a motel, but she wasn't sure. I called that motel and he wasn't registered there. They were filled, so if he had asked for a reservation, they couldn't satisfy him. So then I called the State Police to get a hold of Shelbey, and I described Shelbey, the car he was driving and everything. So I had the State Police out looking for Shelbey. Well, the State Police didn't find Shelbey. Lorraine found Shelbey instead. Shelbey called and was told what was happening, and to drop whatever he was doing, and ball the jack to

the office. There was, at the office, a letter putting him in charge. It had gone out the day before. Be sure to get back--lock things up. Well, Larrick found out later on, "Did you get a hold of him (Shelbey)?" "Yes, Shelbey's there, he's going to be there." "It took a little doing." He says, "What do you mean?" Well I explained to him what I'd done. Larrick was upset over putting State Police out after Shelbey. He said, "Don't you ever do that to me." I said, "I don't ever expect to look for you that way." Now why a thing like that was upsetting to Larrick, I don't know.

P. - I don't either.

R. - It was a natural thing to me. It was a natural thing to do.

P. - It wasn't unusual to try to locate an Inspector when he was out, because while we checked Western Union every day, if you needed him sooner than that--I remember once I was in Raton, New Mexico, in the back end of a grocery warehouse. I'd been there about an hour. I was getting several samples and the girl from the front office came back. She said, "You said your name was Porter." I said, "Yes." She says, "I don't know, I can't imagine how he did it, but your boss in Denver is looking for you on the telephone." It turned out that

what he did was--there was a trial coming up in Amarillo and he didn't want me to get off because I was heading back north.

R. - I see.

P. - And probably staying in Trinidad that's most likely. And I had to be in Amarillo. So he calls up the operator. He knew I was working in--he knew I had--you know how we did, we check all of the warehouses when we got them and so on. He called the telephone operator in Raton and said, "I have this Inspector, this is his name." "He will be working in a warehouse, or possibly some kind of a food manufacturing plant, or he will be staying in a hotel." Didn't have many motels. "I want you to find him." The long distance operator called--

R. - Scouted around and found you. Yes.

P. - But the people at the warehouse were amazed.

R. - Well of course when I first came in, we had a regular report we had to make out at the beginning of the week, of every place we expected to be, and what assignments we thought we were going to cover that week. This was when I was at Jacksonville. I was a Resident, see. So if I was going to start off in Jacksonville and go to Lake City, and cover so and so, and then go on to Tallahassee. I had to say where I was going to stay

and what assignments I was going to cover; what plants, and do that for the full week, and mail that in on Friday so it would be in the office on Monday morning. So McManus would have--he was then Chief, would be able to follow me around. And if I changed my itinerary, then I had to wire him. He was a stickler for telegrams. He didn't want you to use the telephone, it was too expensive.

P. - That was typical, don't you think?

R. - --back in those days.

P. - That's the way I was taught.

R. - Yes, you wired, not telephoned. Of course the inspection staff then was considerably smaller; five or six to a Station was the size of the staff. I think in Atlanta there was--Monty Rentz was resident in Jacksonville and I was with him, Francis B. McAuliffe, Charlie O'Neal, George Meeks, and Wally Simms was Chief Inspector, and the guy who retired, his eyesight was so bad that he really had to be led around. There were six, and I was only really part-time. When I got to Philadelphia, Ken Kirk was Chief Inspector, Bob Stanfill, Marion Lee Gingell, John Y. Breckenridge, Clark T. Smith, the only man that started in Food and Drug as P1, and retired at P2, and he got to P2 just

before he retired. I was in Washington at the time and I just couldn't see Clark T. not getting P2. He was worth P2. This is one of these human frailties of people. He got in Bill Wharton's dutch and Bill Wharton never saw anything in him, and Clark T., by God, I must admit, got to be no more than a sampler, nothing but a sampler. So really wasn't too out of line.

P. - Lee--

R. - Lee Gingell;

P. - Never heard of him.

R. - Marion Lee Gingell.

P. - Most of those names are familiar, but that isn't at all.

R. - Well, Marion Lee retired oh, after I was in Washington.

Well, when we first bought cameras for Inspectors, back in '30, '38, and there weren't too many. The use of cameras by Inspectors came into vogue. I was assigned a camera, and there's a picture I've taken at Philadelphia. Now, that's Breckenridge, Lee Gingell, and Grigsby, he was the Chief Chemist. This was exploring how to use the darn camera. Here's another one of John Y. Breckenridge. Don't ask me why I've got these pictures in that drawer in there. This is at

a--I don't even have them dated so that's a bad help--this at a Washington conference. Some of those you ought to recognize: John Sanders, A.M. Henry, Jim Pearson.

P. - Sanders and Pearson I know.

R. - Now, this is where we were still with Federal Security Agency. This is Charlie Crawford to the back. This is Captain Miller, FSA Administrator. Here's Dr. Dunbar. Here's Ben White. Here's Bill Wharton right there. This is Leo Lusby, who was Chief Inspector at NY. I don't know who that one is. Here was a conference someplace. Here's Gordon Wood waving, and Bruce Locknane here, Glen Slocum, Kimlel, Litton.

P. - I went to see Kimlel last year.

R. - How is he?

P. - He's still fine.

R. - How about Mrs. Kimlel?

P. - She's dead.

R. - Oh, she died.

P. - Yes. She's been dead, I think he told me three years, three or four years. He's living alone.

R. - Here we are, this is Monty Rentz, George Daughters, Johnny Guill, John J. McManus, and the guy who was the Chief Chemist at Denver.

P. - Don Taylor.

R. - Don Taylor.

P. - And wild Bill Hesel.

R. - Yes. This is Dunbar at the dedication of the building in Cincinnati. Here's Stephens, Charlie Herrmann, Retzlaff, Weilerstein. Here's McKinnon and Wharton again. Do you know who that is?

P. - No.

R. - That's Malcolm Stephens. We had a drug Inspector's conference in Washington, and the last day we had a sort of a dinner deal and skits. You know any of those?

P. - Is that Lennington in the middle?

R. - This is Lennington. This is Milstead. This is Benjamin. See Stephens is standing up on along side of them. Milstead, Lennington, Benjamin, and at the moment I don't remember that one.

P. - I don't know who that is.

R. - This is Garrett, Chief of Kansas City, and died at the office.

P. Oh, his brother's name was Al Garrett and he was Chicago Chief Inspector. He retired about the time I went to Chicago. I know who that is, but his name won't come to me. Is that Bill Queen?

R. - That's Bill Queen. Bob Roe.

P. - Yep.

R. - Harvey and Davila. Litton, Dunbar, Larrick and Stephens. Charlie Herrmann, J. O. Clark, Jimmy Cribbet. Lewis L. Judge, one of the finest old gentlemen I've ever known, an Inspector at Baltimore. Now we go back to Philadelphia. That's Lee Gingell and Breckenridge. Ben White, Charlie Crawford, Retzlaff,

Harvey, Clark, and Welch. And this is J.O. after, he moved to Washington. I guess what I ought to do is identify them, because one of these days I'm going to even forget who some of them are. I think I'm doing pretty well remembering now who they are.

P. - You know a year or two ago Seattle District found an old briefcase full of pictures in a storeroom that Frank Clark had left, and everybody believes it was Larrick's collection of pictures that Frank got at the time he was working as Larrick's special assistant or something, but we don't know. They sent it to me. Of course I'm preserving it. It was a satchel-like briefcase and it's full of pictures.

R. - Frank worked as a special assistant to Harvey, not to Larrick.

P. - That's right he did. Well, they believe that's a

Larrick collection.

R. - Okay.

P. - That he got.

R. - Could still be.

P. - In any event nobody recognized it. It was in a closet that apparently hadn't been cleaned out for some time. It had been Frank's, and that's all they knew. Somebody had placed them in a series of envelopes. They didn't send me the satchel. They just sent me the pictures. I don't know whether Seattle placed them in envelopes, or whether they were that way, but the envelopes mean very little, they're not really sorted. Each envelope is kind of a mixture in itself.

R. - You will have to get somebody to go identify them, if you don't know them all.

P. - Well, Fred and I have done it, and we have taken some. We've done that with almost--I think all of the individual ones. There are a lot of individual pictures. That might have been Larrick--one way--well they were people Larrick would have known anyhow I think. The individual pictures I have mounted alphabetically. The idea that every individual picture I would get, that's in one of these plastic, you know, what they call them, magnetic sort of thing, as I get individual pictures,

I'll try to keep them in there more or less alphabetically. I can insert sheets. But that's nothing you have any knowledge of.

R. - No, I have no knowledge of those pictures.

P. - You'd know most of the people, but I meant the actual collection.

R. - Oh, I got another pile of these things in here; larger pictures, pictures taken at some of Welch's parties. And I have personal, autographed pictures of Larrick, Harvey, Dunbar, Crawford, and Campbell. Those were the four I worked under.

Campbell was Chief when I joined the Food and Drug Administration. He was one of the first five Inspectors as I understand it. When the 1906 Food and Drug law was passed the idea was that the work was going to be delegated to the states. That there would be no organization in Washington, perhaps other than the laboratory work under the old Bureau of --

P. - Bureau of Chemistry.

R. - -- Bureau of Chemistry. And there were five in that group; Campbell, Wharton, Wallard, the guy up at Boston, I can't remember his name now, but anyway Mr. Campbell became the Chief of that group and he always was chief or head of every unit thereafter. He went

to Kentucky Law School. Yes, he was a Kentucky Colonel. Well, what's the next thing you got there?

P. - I've about run out of questions. Are there any cases that you were involved in that you can tell some background that would be of interest?

R. - Oh, there are a couple, yes.

P. - Either in the way you investigated them, or something that happened, or you know, whatever.

R. - Well, I talked about the Bad X Salts. I made a list of a few of them here. I'm sure you've had all sorts of stories told about the elixir of sulphaniamide investigation.

P. - I've had quite a few--quite a bit from Rolland Sherman, who was in on it down in Louisiana in his inimitable style.

R. - Well, I was involved in it in the Elixir of Sulphanilamide investigation in Atlanta. The thing popped on us out of a perfectly blue sky. I got a telegram from Mr. McManus to phone the office. He told me what it was, who made it, and that there were several consignments in Jacksonville that he wanted me to investigate, and collect samples, and to report. He wanted me to do it that day, this was around noon time, and report back at the end of the day, even at home. Well, the first

place I went to, they contended they didn't get it, as I remember it. Another one they had a bottle and I collected it as a sample, and what happened to the rest of the bottle. Well, they had sold it to somebody. "Who?" Well, I finally got out of them the name of the individual. Looked up that individual, and by golly this was on a Thursday. The individual had died. He was colored, had died on a Sunday or Monday. He was still laid out in his coffin in his house and was to be buried the coming Sunday. They were waiting for the family to assemble. Well, it was quite common for Negroes to have placed in the coffin with them; all of the last things that they used, and have them placed in or on their grave. So I talked to the guy's widow and I explained to her that I was looking into some matters of medication, and her husband possibly could have taken it. Was there any medication in the house he'd been taking? Well, no everything he'd been taking either had been thrown out, or they'd put in his casket. So I went to the undertaker, and told him, and so we got everybody out of the room and looked in the casket. There was no elixir of sulphanimide in there. I don't know whatever happened to that, it probably got thrown away.

P. - You looked high and low for it.

R. - I looked high and low. Another case was we found out that a taxi cab driver had bought 6 more over the counter from this druggist. I almost had to go to the State Police to get the druggist to tell me that he'd sold some to the cab driver. I found the taxi cab driver had died. The taxi cab had been turned back over to the automobile agency where it was bought. The brother, who ran a sawmill place, returned it over to the car company. I asked him what he had done with all the stuff in the car, since the contention at this man's home, was that the medicine he'd been taking, was kept in the glove compartment in the car. "Oh", he said, "I just took the stuff out here and threw it out here on the slab pile" Well, I hired a couple of men, and for about four hours we tore down this slab pile, took a pitchfork and sifted the sawdust. And where we didn't find the full bottle, we found the six ounce emblem--enough of the broken bottle, six ounces on the back side of it in roman letters and the "Rexall" imprint. It was a Rexall drugstore. So I went back to the drugstore, and got them to finally admit that they had sold it to him, and there were six ounces. In another place the guy denied having any. I went and

got the State Police, and there was no health department, but there was one doctor who sort of became a friend of mine, and between the two we went back to the drugstore and had the guy to confess that he had it. He brought the bottle out. The bottle was short about four to six inches. He did not remember what happened to it. So I took the gallon bottle as a sample; gave him a receipt. By this time it was eleven o'clock at night time. The next morning bright and early at breakfast, I got a phone call from this doctor. He wanted me to come to the hospital. When I got to the hospital here was a man in his late '30's, I would say. He was blind, was partially paralyzed, and actually while I was there, died from kidney failure. We were able from his family to get the remnants of the bottle. So there's stories on top of stories like that. One case, I wasn't involved, Monty Rentz was, he found the remnants of a bottle on the grave of a victim. Now, this elixir of sulphanilamide I'm satisfied was responsible for the new drug provisions in the law. I really don't think, and all the wisdom that was exercised at that time under the law, that anybody conceived of a new drug section until then. I may be mistaken on that score.

Talking about injunctions, we had some prosecution cases in West Virginia, Bluefield, three bakeries. Judge Moore was the presiding judge. Judge Moore had assessed a fine of \$1,000.00 per count (3 counts), collected part of it, and put them on probation until the next term of court, with the idea that if they cleaned up, they wouldn't pay the balance of it otherwise they would. He gave them six months to demonstrate that they could clean up and stay clean. We went back in six months, which was the next term of court in Bluefield. We made the inspection, and this was Johnny Guill and myself, the day before or two days before the up coming term of court. Two of the bakeries were okay and one wasn't. One had done practically nothing. The court closed the case against the two firms that had cleaned up. The third one that was still violative was required to pay the fine on all counts. Then Judge Moore turned and said, "Mr. Rayfield what else can we do about this thing?" And I said, "Your Honor you fined them, you put them on probation with the idea that they're going to pay more fines if they didn't clean up." "That hasn't stopped them." "The only course of action that I know of left to us is an injunction." He said, "I think that's right." "Bring me

in a bill of complaint this afternoon." The Assistant United States Attorney didn't know how to develop a bill of complaint under the FD&C Act. And, at that time I didn't carry around any typical forms with me. I hastened to tell the Court, "Well, your Honor, these things are handled as far as the Food and Drug Administration is concerned, by the Commissioner's office. "I ought to get in touch with them by phone." He said, "By all means." So I went back and called Charlie Crawford. And Charlie says, "Fine, go ahead and draw up a bill. Anybody says anything tell them I gave you permission." So we go back and draw up a bill of complaint. We draw up the bill of complaint in the name of the United States Attorney asking for it. Well, Billy Goodrich, over the years has argued that it was illegal as all daylights, that you don't draw it up in the name of the United States Attorney, you draw it up in the name of the United States Government. My reply has always been, "Well, be that as it may, the injunction went in, the judge signed it that afternoon, and the plant never opened up again." We didn't have to worry about them anymore. But when you're talking about injunctions, those are remedies that really ought to be brought when they are serious, and when you are

prepared to put them into effect right away. You don't let time get away from you.

F. - It should be timely, or it doesn't mean much.

R. - That's right. And time is not in order to give the United States, the District, the administrative review people, the General Counsel, the United States Attorney all the time enough to handle them and take them up in time. They've got to be pushed through very promptly. Oh, I could sit here and talk all afternoon about my own experiences, but that wouldn't give you anything. I was involved in--I don't know whether it still is or not--one time the largest seizure of flour in the country, a whole dockside warehouse down in Panama City. Now there had been a railroad strike of some sort, and so the flour instead of being shipped by rail, had been loaded on the ships, and gone through the canal from the West Coast, and had gone to Panama City, and had been unloaded and put in the warehouse. Well, by the time the flour got through that circuitous water route the railroad strike had sort of gotten over with and it began moving by rail. So here's this flour, surplus to what the bakeries in the area needed. They were trying to use it up over a period of time. Down in Panama City, in an ordinary freight warehouse,

on the dockside, normally handling paper, kraft paper, paper bags, and the things of that sort rather than flour and food items. That stock of 160 lb. jute or cotton bags had been sitting there for quite a few months. I went in and saw what this flour was buggy. I went in there one afternoon for the simple reason I had finished up the assignments that I had to do in Panama City that day. We never thought about traveling until after five o'clock, so I figured well I could find something else to do between then and between five o'clock, then I'll drive on back up to Tallahassee, my next port of call as far as my itinerary--to Marianna where I was to go. I saw this pile of buggy flour, and I looked in my manual, and there was absolutely no clue as to the sample size. So, I wired McManus, "How many bags should be sampled?" Well, he wired back, "Sample one percent of the bags." That meant a hundred and forty-four subdivisions. I didn't have a gross of pint jars. So I scouted Panama City, and buying here, and buying there, and the other place, I finally scrounged up a gross of pint mason jars. Wired McManus my itinerary was changed, I was staying there until I got this lot sampled. I hired myself two men. First time I had ever done that, and I was hopeful I'd get

paid back. I hired one to turn the bags up so I could get in with a trier and collect my samples. I hired another one to resew the seams, because the warehouse insisted that I leave the lot the way I found it. Of course this wasn't just going over the top bags, I had to move stuff around. I think I took two days in getting that sample. There was one seizure made out of it. There was something like two shiploads of flour involved. This was just because I was looking for something to do. I could have driven on up to Marianna, gotten up there the hours of the days' being over with, but that wasn't the philosophy then. I stayed, we did a worth while job as the flour was alive with insects. I tell you, you didn't have to go down to the and seam of the bag to get your sample. It was just crawling. Those sort of things are happening today, but I'm convinced from what I've seen in markets and stores and read that there is still much work to do. But I don't see any of it the reports of accomplishments in "The Consumer". I'd like to see is this changed.

P. - This is the "Consumer" magazine?

R. - Right. Incidentally, does Food and Drug ever put out an annual report?

P. - Oh, yes.

R. - How do you get a hold of it? Is the Food and Drug's Budget Request--

P. - A public document--I don't really know. I mean whether it's--I guess you buy them from the Superintendent of Documents, as far as I know. I know there is one.

R. - What about the Budget Request?

P. - I don't know. I don't know that's a--is that even--I don't know that that's a public document. I don't know. I honestly don't know.

R. - The budget hearings are open hearings.

P. - Freedom of Information Act might make that available too.

R. - It might.

P. - The annual report, of course, is published. You can get that. In fact any Food and Drug office would probably have an extra copy.

R. - Yeah, I guess so.

P. - In fact there has been a--there's a book that reprinted the last twenty-five, going through about 1972 or 3. I've used it for a reference.

R. - At one time the Food and Drug Administration was talking about having a reserve officer group in event of a national catastrophe. We had developed a roster just

before I left. I guess that's all gone by the wayside.

P. - I don't know anything about it at least. I don't know if it still exists, it's nothing I know about.

R. - Frankly, I don't see how Food and Drug today can possibly have any reasonably sound continuity when you stop and think of the number of changes in the Commissioner's office, and other changes that have occurred since January 1, 1966. P. - There is certainly not the kind of continuity we had before, obviously.

R. - Frankly, it's hard for me to understand how the Food and Drug Administration can prudently be spending \$320,000,000 and do no more than what they're doing. When they're talking about balancing the budget, I think I know where they could save a few million. I may be all wrong, all wrong. If I got back in there, God forbid, I'd be surprised. I think I've about answered all of your questions--except those that have a strictly personal aspect to it--personal experiences that I don't think you need to have. I think there are a lot of things. I know about the first seizure of large volume, I.V. solutions that was made--and I don't know why we were collecting the samples, what was our basis--maybe to find out whether the glucose content was as labeled. A firm in New York shipped some stuff

out down to Philadelphia. I got the assignment to sample several shipments. I went to three or four different hospitals. Every hospital I went to, when I asked for it, yes, they had some. Damned stuff is not any good. Each had some comment to make about it. I went to Temple University Hospital and there I found out that they had, because of pyrogenic reactions by hospital patients, set up a study. First, one intern gave for a period of time--gave all the I.V.'s. Second, they had started off with all new delivery equipment. Third, on one floor they used one manufacturer's; on another floor they used another; on another floor they used another. On another floor they used the Glucose Solution from this manufacturer. They had used about four or five different manufacturers output. They found out that on the floor where they used the solution from the manufacturer I was investigating--they had a very, very high incidence of pyrogenic reactions. On the other floors, nothing. So I came back with my samples, and this was over a period of days, and Dr. Ted Klump, who was then Chief of Division of Medicine, was there. We told Dr. Klump about it. Well there wasn't any test. Well, do you need any tests with this kind of experience with it.

He decided he would support a seizure recommendation if the hospital would testify in support." So I go trotting back out to the Temple University Hospital. The hospital administrator said well they wouldn't willingly testify, but they would always answer a subpoena. I knew who was the young doctor involved, so that was the first seizure of large volume of I.V.'s for pyrogens. It was just a matter of digging into it.

P. - Well, I'll tell you, we're getting near the end of the tape.

R. - Okay, I think I'm through with the story.

P. - Getting late in the day here, so I'll turn it off and thank you very much, Allan. I'll see that you a copy of this as soon as we get it transcribed.

R. - Oh, no big rush. I'll be gone in the month of June.

P. - Okay, well it will take a long time. Okay, well thank you.