

History

of the

U. S. Food and Drug Administration

Interviewee: Samuel Hart

Interviewer: Ronald T. Ottens

Date: January 9, 1992

Place: Homestead, Florida

DEED OF GIFT

Agreement Pertaining to the Oral History Interview of

Samuel M. Hart

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INTRODUCTION

This is a transcript of a taped oral history interview, one of a series conducted by Robert G. Porter, Fred L. Lofsvold and Ronald T. Ottens, retired employees of the U.S. Food and Drug Administration. The interviews are with persons, whose recollections may serve to augment the written record.

It is hoped that these narratives of things past will serve as one source along with written and pictorial source materials, for present and future researchers. The tapes and transcripts will become a part of the collection of the National Library of Medicine.



Food and Drug Administration
Rockville MD 20857

TAPE INDEX SHEET

CASSETTE NUMBER(S) 1 & 2

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

DATE: January 9, 1992 PLACE: Homestead, Fl LENGTH: 65 minutes

INTERVIEWEE

INTERVIEWER

NAME: Samuel Hart

NAME: Ronald T. Ottes

ADDRESS: [REDACTED]

ADDRESS: U.S. Food & Drug Adm.

FDA SERVICE DATES: FROM 1956 TO 1973 RETIRED? Yes

TITLE: Deputy Director, Bureau of Product Safety
(If retired, title of last FDA position)

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RO: This is one of a series of oral interviews on the history of the Food and Drug Administration. Today we're interviewing Mr. Samuel Hart, a retired FDA and Consumer Product Safety Commission (CPSC) official [REDACTED]. The date is January 9, 1992. I am Ronald Ottes. This interview will be placed in the Library of Medicine and become a part of the Food and Drug Administration's oral history program.

Sam, to start this interview, would you kindly sketch your education, when and where you were born, the background of how you came to FDA, and some of the various jobs you held in FDA. And then when you had left the Food and Drug Administration and the Consumer Product Safety Commission was formed, I'd like to cover some of the experiences you had with them and whether it was easier to work with one commissioner like in the Food and Drug Administration or the five commissioners in the Consumer Product Safety Commission.

SH: All right, Ron. It's good to see you again. I was born in Missouri, and then my folks moved to Colorado when I was a young man about three or four years old. We had to move there because my father had asthma and he had gotten to where he couldn't breathe in Iowa during the wintertime--Iowa and Missouri--so we went to Colorado. So I was really raised in Colorado. I went through high school in Loveland, Colorado, and then went on to Colorado State University at Fort Collins, Colorado.

Of course, back in those days it was very difficult to go to school, even though the tuition wasn't what it is today to go to school. But I had to work in order to pay my way through college. So I worked eight hours a day and went to school four hours a day, and it took five years to get through college doing that. While I was doing the work, I worked at the sugar company as an analyst in their laboratory, so I got a lot of sugar analysis type experience while I was going through college. And that comes up I'll mention this experience a little later. So then I graduated from Colorado State University with a bachelor of science degree in chemistry in 1941.

And at the same time I had been active in the reserve officer training corps, and I got a commission as a second lieutenant in the field artillery upon graduation.

So in June of '41, I was called to active duty as a reserve officer, because they said every reserve officer had to serve one year's active duty. I was called to active duty at Fort Sill, Oklahoma. I went down there and went through the basic battery officer's course at field artillery school. When I completed that, I was initially transferred to the Tenth Field Artillery in San Antonio.

When I got ready to move there, my wife and I were going to get married in October after I finished this school. And this other lieutenant in my class came in, and he said, "Sam, I'll trade orders with you." And I said, "Well, where are you going?" "Well," he says, "I'm going to stay right here at Fort Sill in the replacement center, and you're going to my unit that I want to go to in San Antonio." And I said, "Well, I don't know whether I want to trade with you or not, but why?" "Well," he said, "I just want to go there, and I'll give you \$25 if you'll trade orders with me." So just getting married and all, I thought, well, \$25 is a pretty good tip; I'll take it. So we went in and the General agreed to reassign us so I'd go to the replacement center and he'd go to the field artillery at San Antonio.

RO: I didn't think that the military would really do any swapping that way.

SH: There was about a hundred of us in the class, and they had to assign so many to so many places, so I guess it didn't make that much difference. But I found out later the reason he wanted to go, his father commanded that unit and he wanted to serve with him.

RO: Oh.

SH: Well then, of course, war broke out in December. So instead of being in active duty for one year, I was in for the duration plus. Well, I never did get my \$25

from this young man. So I was transferred around several places in the artillery, and finally in '43 I was sent back to Fort Sill as an instructor in gunnery and survey in the Department of Gunnery. When I went into class one morning, who was sitting in the back of the room but Second Lieutenant Robinson who had offered me the \$25 to trade with him. And he was a second lieutenant at the time, and I was a major. And so I walked up to the front of the room, and I said, "Lieutenant, before you go to lunch I want to see you in my office."

He came in and I said, "Lieutenant, you owe me \$25 that you promised to pay over two years ago, and you haven't paid." He gave me a stiff salute, and he said, "Major, if you think with gold leaves on your shoulders when I still have gold bars on mine I'm going to give you \$25, you're crazy." Well, I found out he wanted to go to that unit because his father commanded it, and then they were transferred to the Trinidad Isles. And of course, there was no vacancy in his unit, so he was not able to get a promotion. So I was fortunate that I took the reassignment.

So anyway, things went along that way. And I served at Sill, and then I went down to Fort Bragg and helped organize a new 240 millimeter howitzer battalion which we took to Germany during World War II. I was in combat over there. I was promoted finally to the *commanding officer of that unit*. Then came back to the States after the war was over, and I decided that I'd go into business. So I was looking around for various businesses to go into in my hometown in Colorado and still remained active in the reserve and kept going to summer camp and training periods every week with the artillery. I was hoping to get into some kind of retail business which I could own.

So one thing led to another, and the first thing you know . . . I couldn't seem to find the business that I wanted to get into, and I heard in 1956 that they had a vacancy for some chemists at the Food and Drug Administration in the Denver office. Loveland's about 50 miles north of Denver. I drove down to Denver. I went in and talked with Sam Fine who was the chief chemist. That was about 15 years after I had graduated from college, of course, and I hadn't been active in chemistry

that whole time. So he says, "Well, Sam, since your degree is in chemistry and since you are a veteran, I've got to give you an opportunity to show you can still be a chemist. But I'm going to tell you one thing. I'll give you ninety days, and if you can't prove you can be a chemist in ninety days, that's it, you're out." I said, "That's fine, Sam. I'll take that opportunity."

So I drove back and forth to Denver every day during this period. Along about, oh, I guess, it was about forty, thirty-five, forty days, maybe forty-five days into the training period--maybe a little longer than that--of the ninety days that Sam said he'd give me, he gave me a honey sample to analyze. And he said, "I want you to really tell me what's wrong with this sample if there is anything, and I want you to do it from A to Z." I said, "Okay, fine."

Well, I went back and did the analysis. And at that time in the Denver office, there were six chemists in the lab. And Sam's desk was over at one end of the lab. And when you turned in your report, you gave it to Sam, and if he had any questions, he'd sound off your name--"Sam, get over here." So I did my honey sample and turned it in to him, and all of a sudden there was . . . I knew there must be a problem, because he hollered, "Sam Hart, get over here!" I thought, well, that's it; I'm through. And he hadn't any more than gotten me over there, and he turned and he said, "I want all the rest of you chemists over here, too--right now!"

So we all went over there, and he held up my report. He said, "I want to tell you something. This is the first chemist I've ever assigned a honey sample to that has got it correct from A to Z. And I'd like to know how after being out of chemistry for fifteen years you can do that." And I said, "Well, Sam, the fortunate thing was I was a sugar analyst at the sugar company for five years while I was going through school. That was the easiest assignment you could have given me. If you had given me anything else, I would have probably flunked." (Laughter) So he said, "Well, you've got a job."

So I stayed there in Denver and worked up. And finally Fred Garfield, the chief chemist in Washington called me, and he said, "You know, Sam, we're

considering giving you a promotion, but you're going to have to take a transfer. Do you have any particular place you'd like to go?" And I said, "Well, anywhere west of the Mississippi, Fred. I don't want to go east of the Mississippi. I don't like that country back there." "Okay, fine."

RO: Who was director then when you joined Denver?

SH: Rayfield. Oh, the director in Denver?

RO: Denver, yes.

SH: Ralph Horst was the district director in Denver then. Anyway, Fred said, "Well, we'll work it out, and I'll call you." So about two weeks later he calls me, and he says, "Sam, I'm transferring you to New Orleans." And I said, "Fred, I said, 'Anywhere west of the Mississippi.'" He said, "You can live on the west bank of the Mississippi in New Orleans. What are you hollering about?" So it was interesting. So I went down to New Orleans and . . .

RO: What year was that then?

SH: Let's see, that was 1960, I believe. And we went down there in the fall, and my son was a junior in high school. So we got organized down there, and then about a year later they called me up and they said, "Sam, we're transferring you to Cincinnati." And I said, "Well, how come?" "Well, we need a supervisory chemist in Cincinnati, and we want you to go up there and be a supervisory chemist." So I said, "Okay, fine." So we moved up to Cincinnati. I believe it was in '61. And when we got up there I was a supervisory chemist and Schartzman, George Schartzman was the chief chemist. And we worked together very well. And I was in Cincinnati all told I think about six years. I think it was '67. Yes, about six years.

RO: Well, Sam, before we leave New Orleans, who was the chief chemist and who was their . . . Was Boudreaux the . . .

SH: Edwin C. Boudreaux was the director and . . . Now, again, what was his name? Dick, no.

RO: Dick Heuerman?

SH: I believe Dick Heuerman was the chief chemist. So anyway, in Cincinnati I worked as supervisory chemist, and then the Food and Drug Administration sent me to Washington to attend the Executive Development Course. And then they sent me back to Cincinnati. First I was chief chemist and then deputy director of the district there.

RO: And who was the director then?

SH: Ted Maraviglia was the director. And then they sent me back to Washington on a special assignment in this training. Then following that, after I was back in Cincinnati only a couple of months as deputy director, they transferred me to Chicago as director of the district office in Chicago.

Winton Rankin was FDA deputy commissioner at the time. Jim Goddard was the commissioner. Well, one day I get a call, and Winton Rankin says, "I'm out at the airport at O'Hare, Sam. Can you come out and pick me up?" Now I had no idea he was coming, so I went out and picked him up. And he said, "I want to talk to you a little bit." He said, "Would you consider a transfer to Washington, D.C.?" And I said, "Well, a little bit depends on what you want me to do, Winton." And he said, "Well, I want you to go in as deputy director of the Office of Product Safety under Howard Weinstein. He's the office director right now." And I said, "Yes, I'd consider that assignment." So I went in and talked with him. And he said, "Well, I

should have just called you over the phone and save me a trip out here, but I was afraid you'd say no, and I wanted to be here to convince you to say yes." So I said, "All right, fine, I'll take the assignment."

RO: Well that wasn't a bureau then, was it?

SH: No, it was an office.

RO: Yes, office in where?

SH: It was just a separate office established for product safety, but then later it became the Bureau of Product . . .

RO: Yes, I was wondering was it attached to a bureau? Was it in the old Bureau of Foods?

SH: No.

RO: Or was it in Medical Devices?

SH: I think it was in Medical Devices, but I'm not positive of that, Ron. Because as I remember it, we served under the Bureau of Medicine or something--I mean, somewhere or other--Medical Devices or something.

RO: Yes.

SH: But Howard was the director of the office, because he'd been in the Bureau of Medicine, and they had put him in as director and took me in as deputy director. So anyway, I was transferred to Washington, and then eventually, as we've

mentioned. it became the Bureau of Product Safety within the Food and the Drug Administration.

But before it became the bureau, I have to tell you a little incident about what happened. After Charlie Edwards was the commissioner, I got a call one day from a Congressman. And he said, "Mr. Hart, I want you in my office in fifteen minutes." And I said, "Sir, I can't get from my office to your office in fifteen minutes." He said, "I didn't ask you, Hart, I told you. Now get up here." "Yes, sir." So I went down to Charlie's office, and I told Charlie Edwards that I'd got a call from this Congressman. He wanted me in his office in fifteen minutes. Would I be there? And I said, "Charlie, you know we have the Congressional liaison officer that deals with Congress. Shouldn't he go?" "Well, Sam, if he called you, you better go, but be careful what you say." He said, "You know, he's a Congressman." I said, "Yes, but," I said, "If he gets upset with me, I'll get upset with him, because he puts his pants on one leg at a time the same as I do." And he said, "Well, just be careful, Sam."

So I went up to the office. I knocked on the Congressman's door, and his secretary says, "Come in, are you Mr. Hart?" I said, "Yes." He says, "He's in his private office there. He's waiting for you. Go on in." So I went in. He introduced himself. He says, "Hart, you've got a case pending against one of my firms." He named the firm. I said, "Yes, sir, that's right. They have been in violation of the Federal Hazardous Substances Act for about four years. I've had the president of their firm in my office two times, and he has agreed to correct the violation, and he hasn't done it. So I filed a law suit against him, as I am entitled to do." Well he said, "I want you to drop that suit."

And I said, "Sir, I'm going to ask you three questions, and then I'll tell you what I'm going to do." First of all, did you vote for the law that I am now in charge to enforce?" "Well, of course. Do you think I want my consumers to think I'm not in favor of protecting them?"

"All right, sir. The second question: What will be your reply when I issue a press release? If I agree to drop the charges, I will issue a press release when I leave

this office today. And that first copy of the press release will go to your hometown newspaper. And it will state all of the violations this firm has had in violation of federal law for how many years. And it will state that you as Congressman from that district, who believe in protecting consumers, ordered me to drop the charges because they pay by money and vote to get you elected every year, which you told me." "Hart, you wouldn't dare do that." I said, "You don't know me, sir. And I'm not going to be the goat in this situation. If anybody's the goat, you will be the goat."

He said, "Hart, I don't believe it's necessary to ask the third question. I believe you'd do just exactly what you said you'd do." "Yes, sir, I will." He said, "Just go ahead and forget that I ever talked to you. I don't want any mention of my meeting with you or anything. Do your job as you have to do it."

So I went back and told Charlie Edwards. Well he said, "Sam, I appreciate the way you stood up to him, but you better look out. Next year, he'll cut our budget. You wait, he'll be at the appropriations hearing and cut our budget." I said, "Charlie, I'll be there. When the hearing is held, I'll be right there." So the next year I went up. Here was that Congressman sitting up there at the table. And when they asked any comments on the FDA budget, he got up and started to say something. And I stood up and waved my hand. And I said, "Mr. Congressman, I'd like to just say a few words in favor of our budget." "Well, Mr. Hart, it's good to see you. I just wanted to say I'm totally in agreement with the budget. You don't have a thing to worry about." And that was the end of that situation. But it just proved to me, Ron, that you have to be willing to stand up and face those people and not let them tell you everything to do.

So then about that time they were considering forming the Bureau of Product Safety in FDA. Well, Mac (Malcolm) Jensen came over to head up the bureau, and he brought in some of his staff from the (National) Bureau of Standards (NBS) because we took in a lot of other products.

RO: Sam, let me ask you this, because there has always been a rumor around that when Mac Jensen came in to head up the bureau . . . You remember Charlie Edwards always had a Monday morning staff meeting, where the bureau directors and everybody attended.

SH: Yes.

RO: And that at that Monday morning staff meeting, who should appear but Mac Jensen. And reportedly that was the first that Charlie Edwards knew that Mac Jensen was coming as the director. What do you know about that?

SH: That's the way I heard it. And that's the first I heard about it was that he was at that Monday morning staff meeting and was said to be the new director of the Bureau of Product Safety of the Food and Drug Administration. And he brought several people along with him from his old office.

RO: What was that? Wasn't he from another government agency?

SH: Yes, he was with the National Bureau of Standards. I believe that's what it was. Anyway, it was over in the Department of Commerce, and I believe it was the National Bureau of Standards. And they had done a lot of development of standards for various products, you know. And so since we would be determining the safety of those products under those standards, I guess they thought that his experience there would be helpful to us in the Bureau of Product Safety.

RO: What happened to Dr. Weinstein?

SH: He got ill and went to the hospital while we were . . . Well, I've forgotten now whether we'd become . . . No, we were still the Office of Product Safety. And

he got ill and went to the hospital. And he was in the hospital two or three or four weeks, and I didn't hear anything from him. And I finally went over to the hospital, and unfortunately he'd had a mental collapse, he had just totally deteriorated. I don't know what caused it. But I went to see him two or three or four times in about a month and a half, two months period. He never came back to service. And finally I was notified by the hospital he had passed away.

And that's when, I guess, then Charlie Edwards said, "Well, you'll be the director of the Office of Product Safety." But when they made it a bureau, they brought some of the people from the Bureau of Standards I'm sure it was, but I'm not positive. Anyway, they brought a bunch of those people over to the Food and Drug Administration in the Bureau of Product Safety, and that's when they brought Mac Jensen over as director of the bureau. Now he was a GS18 at the time, and when they transferred him there, there wasn't much choice for them but to make him the director.

RO: The director, yes.

SH: And Charles Boehne came over as one of the . . . He was the administrative . . . What did they call him?

RO: Administrative officer?

SH: Yes, administrative officer. And he was, of the bunch that came over, he was the best. He was top notch. You could talk to Chuck Boehne, and you could get reasonable answers. You could understand him. And if you had problems, you could go to him and he'd help you solve them.

RO: Well we always thought that Mac didn't really appreciate having you as the deputy, that that was kind of a shotgun wedding.

SH: That was true. He wanted his man, John Locke as his deputy. And, of course, he couldn't make him his deputy, because I already held the position. So there was no choice. If somebody called me, I'd answer the question. But when Mac had a meeting, he'd very seldom include me in the meeting. He'd take John Locke. I think he appointed him as his special assistant or something that way until he could get things worked out.

RO: Well that was in 1970 that the bureau was formed.

SH: Yes, I believe it was about 1970. So one thing led to another, and finally Mac did call me in, and he said, "Well, Sam, there's no need in you just sitting here. I'm going to assign you certain responsibilities, but they're mainly administrative responsibilities to me." And he let John and, of course, Chuck Boehne being the administrative officer had the most of those. But if there was something like reviewing a proposal for a contract to do a certain study, he'd let me review it and then pass it on to John to get his final approval on it. But that's all . . . I learned to live with it. That was what you had to do.

RO: When CPSC was formed there were a number of FDA personnel that were transferred to the commission.

SH: Right. And then, of course, they started holding hearings on the bill to create the Consumer Product Safety Commission as a separate agency from FDA. And I did what I could to say, no, that it would be better to keep them as part of FDA. But they didn't want that. The Congress wanted a separate agency, and I don't know what politics was behind it, because I wasn't involved in politics, of course. But they finally passed a law establishing the Consumer Product Safety Commission. Then the whole Bureau of Product Safety was transferred to the commission; plus each district office or regional office had to transfer so many people over to the commission; plus

I believe there was still some people in the Department of Commerce under the Flammable Fabrics Act or something, and they had to be moved into the new commission. And so it was a combination of several different agencies that formed the Consumer Product Safety Commission.

RO: It was always rumored that Mac Jensen never wanted to be in FDA anyway. So when he came in to head up the Bureau of Product Safety, when there was a movement for establishing a separate commission, was he actively involved in promoting it?

SH: That's what I heard. I was in an office here, and he was in his office there, and there was the administrative offices between our two offices. So I really didn't know a whole lot that went on in his office, but I do know he had different people in from . . . And whether they were from Congressional staff or whether they were from somebody else or what, I don't know. But I know he and John Locke pushed hard to get a separate commission and take us out of FDA.

RO: And that was in 1972 about.

SH: Seventy-two, yes. And then in '73 the new commission was formed, and then we were all transferred to it. Dick Simpson became the chairman. He interviewed all of us in the old Bureau of Product Safety and decided what he would do with us and where we wanted to be. And he asked me if I had any particular job, and I said, "No, I'll serve where you want me to." Well he said, "Would you serve as secretary of the new commission?" And I said, "Yes, I'd be glad to." So I went to work, and my initial duty in the new commission was secretary of the commission. And I had a staff of about eight or ten people working under me. And we would prepare and publish the regulations and proposals and handle the correspondence and so forth.

There were five commissioners at the time: Dick Simpson, Connie Neuman, Barbara Franklin, I've forgotten the man from the Bureau of Standards that was brought over, and then there was a black man, and I can't remember his name. He was a preacher, pastor there in Washington, D.C. But he was brought in, and that was the five initial commissioners. It's funny I can't think of his name. But the man from the Bureau of Standards had a lot of experience and was a deputy director or director of one of the major offices in that bureau and had a lot of experience of establishing product standards, and that's why they brought him in, I understood, as one of the new commissioners.

RO: Well what was the hierarchy then on that commission? You were the secretary of the commission. There was . . .

SH: There was a . . . Well, the five commissioners, and they each had their own staff. And Dick Simpson was, as I remember, the chairman. And then underneath the commissioners there was a secretary's office, there was an office of regulatory affairs I believe it was--something that way anyway--and then there was a director of field offices. I've forgotten what they called it. But it wasn't like the old Food and Drug. But they had a Standards Office; a Bureau of Regulatory Affairs like office; they had a Bureau of Field Office; they had an investigative; and then they had a contract office, I believe it was. They had five or six offices or bureaus under the commission. And the various heads of those offices reported to the chairman who ran the commission.

(Interruption)

SH: The five commissioners had to have a meeting any time any major thing was discussed. And as secretary I would sit in on that meeting and make the records of it and then record it. Then I'd issue the federal regulation or the publication in what

they call the *Federal Register*. I'd issue the publication for that and whatever decisions they had made.

RO: Well, the commission then established their own field offices.

SH: Right.

RO: But you didn't have as many as the Food and Drug Administration.

SH: We had more initially.

RO: More.

SH: We had thirteen field offices to begin with. Every place there had been a FDA resident inspector and he had been transferred to the Product Safety Commission, they established that as a field office initially. So I think they had thirteen initially. They had one in Cleveland, one in Detroit, one in Atlanta, one in Miami, you know. And then finally they asked for a reorganization proposal, and they came up with it seems to me it was about ten field offices. They still had a couple more than Food and Drug. They had eight, didn't they, in Food and Drug?

RO: Well, ten regional offices.

SH: Regional offices, yes. And I think they came up with ten. Well then when John Byington . . .

Well, before I get to that, finally Dick Simpson called me in and he said, "Sam, what would you like to do if you weren't secretary?" And I said, "Well, Dick, I have been in Washington long enough." Well he said, "I need a director of the

Chicago regional office of the Product Safety Commission. Would you take that assignment?" And I said, "Yes," so I was transferred back to Chicago.

RO: I see. When the commission was formed, of course, and separated from FDA, did you have an opportunity to stay with FDA?

SH: No. Everybody in the--as I understood it, at least--everybody in the Bureau of Product Safety was transferred automatically to the new commission.

RO: I know I was involved in transferring people to the commission from FDA.

SH: Yes, right.

RO: Especially, you know, the field people. And we felt that anybody that had been working at least a majority of their time--the investigators and also the laboratory people--on product safety should go. And so I was just wondering, though, at the office level, headquarters level, if you had had an opportunity to stay with FDA or you had no choice.

SH: No, I did not. No. All that I knew was that Mac Jensen called us all together and said the whole bureau is being transferred to the new commission, and that's all I ever heard. I don't know what opportunity I'd had other than that, so I said, "Okay, I'll just go and help work the new commission."

RO: Well, now, when the commission was formed then there was no need for Mac Jensen. Is that right?

SH: Well he thought that he would get to be the chairman of the new commission. That's what he personally thought. But, of course, he wasn't politically . . .

RO: Attuned, I guess.

SH: . . . attuned, right. And so Dick Simpson, as I understand it, was assistant secretary of Commerce or something that way, and so the president appointed him as chairman of the new commission.

RO: Well, before we lose this, Sam, you then transferred out to Chicago in their regional office or whatever they called it.

SH: Yes.

RO: What year was that? Do you remember? The commission was formed in '72.

SH: Seventy-three, yes. It was the fall of '73.

RO: And then you retired in '75. Is that right?

SH: No, I retired in 1978. I was in Chicago five years. I'll tell you this afterwards, but I was . . .

(Interruption)

RO: Sam, one of the things I'd like to discuss while you were still with FDA, and that was when you were in Chicago, and I believe it was one of the first major recalls that we had, and that was with Abbott Laboratories. And if I'm not mistaken it was one of the parenterals that . . .

SH: Coumadin.

RO: Would you care to talk about that?

SH: All right. Well, in the course of our normal inspections of various drug companies, food companies, etc., we had inspected Abbott Laboratories. One of my inspectors collected several samples of Coumadin tablets from the finished product as it came from the mixer. And he brought them in for analysis. We ran them in the lab and found that they ran about 72 percent of the declared amount of the Coumadin. And as I recall--now, it's been quite a few years ago--but as I recall, I think the USP allowed 95 to 105 percent or something like that of the labeled amount. We also checked several samples that had been collected from various locations in the mixer and found quite a variation in the percent of Coumadin in the mixture from the various locations, showing mixing was not being done adequately before the finished tablets were processed.

And so when we found 72 percent, I told the chief chemist, I said, "I want you to have a different chemist run this drug and not let the first chemist know that we have any question before we take any action." And the second chemist ran it, and by golly, we got a surprising thing. We found that it had 142 percent of the declared amount. And I said, "It can't be." I said, "Somebody goofed in our laboratory." So I said, "Now I want you to take a third chemist, and instead of running a sample of twenty tablets . . ." I think it called for twenty tablets to be ground up together and then take your analysis portion out of that twenty. I said, "What I want you to do this time is run twenty, maybe even fifty individual tablets so it's one by one by one." And so we did that, and we found anywhere from 72 to 140 percent on individual tablets. It didn't make any difference. Some of them were 99 percent; some of them were 97 percent; some of them were 101 percent; some of them 110 percent. But the lowest was 72 and the highest was 140. Now how those samples initially had to get all the low ones or all the high ones, I don't know, but it did.

So I said, "We've got a problem." And I called Washington and told them what we'd found, and they said, "Well, we'll have to get a recall," because Coumadin,

you know, is a very sensitive drug. The doctor prescribes it according to what your blood clotting figure is, and if he gives you too much you'll bleed to death if you have a cut; if he doesn't give you enough you'll get a blood clot. So he has to be very careful. Well if it varies this much, he can't prescribe it, because it's not going to be an accurate prescription, because he may this time be prescribing for the 72 percent and next time the 140 percent, and he's not going to be able to take care of you.

So after talking it over with Washington, they said, "Well, see if you can get the company to come in and talk to you about it." So I called the Abbott Laboratories head office, and they said, "Yes," they'd come in; what did I want to talk about? And I said, "Your Coumadin, this blood clot drug." And he said, "All right."

So the president of the company along with his chief of his laboratory came in. And I said, "I think you're going to have to recall this." And he said, "No, Mr. Hart. I don't think so. I think you're being a little bit overzealous on your work here." He said, "We have run two samples of this drug. We ran one when we manufactured it, and we ran another one yesterday when you told me you had a problem with it." And he said, "I don't think you'd be that hard-nosed about this, really. We found 94.8 percent, and the USP allows us to have a minimum of 95. Now surely you're not going to be hard-nosed over 2/10 of a percent."

I said, "Sir, you know me better than that. I wouldn't even have you in here if that was the case. Well let me give you the results of our analysis. We had 72 percent on the first sample, 140 percent on the next sample, and I couldn't believe it and I said, 'My chemist made a mistake.'" So I said, "I had them run I think it was fifty tablets. And look, there are some that read 94.8; there are some 97; some are 101; some are 110. Every tablet was different. The lowest one was 72; the highest one 140. So you know what happened sir. You did not get the drug mixed good before you tabletted it."

"Ooooh," he said. "I see what you're saying." He said, "Will you let me use your telephone a minute?" I said, "Yes, sir, you can." And he went over to my telephone, and he called his home office up north Chicago. He said, "I want you to

issue a notice immediately nationwide to recall every bottle of Coumadin on the shelf--right now! Not five minutes from now. Do it now. We don't want any problem with this drug." So I said, "Fine." He said, "Will you accept that?" I said, "Yes, sir, if you'll give me a letter, now, and tell me who you notified so that we have it on record." He said, "As soon as I get back to the office I'll get you all that information." So they did the recall, and it was effective. We checked, and it was effective.

Then I said, "Now, I'm going to send my inspector out when you manufacture this next batch. I want him to see how you make it." And we did. Well what they had done before, as I recall, Ron, and I can't be absolutely positive now, but it seems to me that in the vat that they made this drug, they made several hundred pounds at a time in a big mixing powder vat, you know. And when they sampled it, they either sampled the top or the bottom. And if the top was all right, then they said, "Well, it's mixed good." Or if the bottom was all right, it was mixed good.

But I told them they ought to sample about every so many inches down from the top and so many inches up from the bottom, because they could never tell whether it was mixed good unless they had sampled various sections of that mixing vat. And so he said, "Okay." And when they did that, they found that, yes, it wasn't mixed good. They found they had to mix it, I think he said, three to four to five times as much as they used to mix it in order to get it equal from top to bottom in the vat. But they did that from then on, at least while I knew about it. They did that from then on before they ever made tablets out of that drug.

RO: Now is there a difference in the granulation of, you know, that material than there was . . . What about some of their other tablets then?

SH: We never found that much variation in the other tableting. Now why, I don't know. It may be because the Coumadin, as I remember, was a strong dose in a small concentration in the final tablet. It took very little dose to be effective.

RO: I see. So that the amount they put in there was actually small compared to the excipient material.

SH: Yes, that's right.

RO: A lot of times when they have that problem, they'll mix the active ingredient with a portion of the excipient material, mix that real good, and then add that to the rest of the batch.

SH: Right.

RO: I was under the impression that that recall had to do with one of their parenterals, but I guess the parenteral was later.

SH: I think it was later, yes.

RO: Because it seemed to me, that recall was one of the first times that the agency started to pay overtime for some of the work that the investigators were doing on that.

SH: Yes.

RO: Were there any other major regulatory issues that you remember while you were with FDA that you would like to mention? Because I would like to get into some of the regulatory aspects of the Product Safety Commission such as standard setting for consumer products and enforcement actions under the Toy Safety Act.

SH: There was . . . Let's see, I think I already told you about the case of the Congressman that wanted me to . . . Yes, I told you that. There were several other

toys. I've forgotten just which one it was. But when they got the new Toy Safety Act, while we were still in Food and Drug, there were a couple, three toys that I had to get the company to make some major changes in. And very frankly, Ron, I can't remember what it was.

RO: Do you remember anything about the Consumer Deputy Program?

SH: Hmm. I hadn't thought about that. Hmm. Now that was the person that worked with the industry, wasn't it, or something?

RO: Well, this was almost like a consumer representative that was going to help on, I understood it, to do market surveys on hazardous toys and other consumer products.

SH: Oh, yes.

RO: If I remember right, that program didn't last very long.

SH: No, I don't remember that much about it really. Right.

RO: What about the NEISS (National Electronic Injury Surveillance System)? Now this was with product safety. That was with your, what, National Electronic Intelligence Surveillance System.

SH: Yes.

RO: That was supposed to be for hospitals primarily to be able to report injuries and things of that kind. And if I remember right, that was one of the first really major systems that Product Safety would have as far as receiving reports on injuries.

SH: Yes, they . . . I can't recall now, again, whether that was initially reported to Atlanta to the . . .

RO: Poison Control Center?

SH: . . . Poison Control Center, or whether it was a new thing that we started or what. I can't . . . I remember, yes, that we tried that for a while, and we did, in Product Safety, we did get some reports, and we would follow up on injuries that we got from that.

RO: You worked in FDA for a number of different commissioners, and of course, while you were in the districts a number of different district directors. Were there any differences in their personalities, in the way they managed things, the way, how aggressive they were as far as enforcing the Food, Drug and Cosmetic Act?

SH: Yes, I think there were some differences. If the company would come in and talk to them and present a problem solution, they would listen to them. And if the solution was agreeable and would accomplish what they were after, fine. Most of them were very reasonable and very concerned about . . . But the main thing was that the people that I worked with generally had one thing in mind--let's protect the consumer; let's see that if the law says they'll do this that that's what's done. And then if they don't, we'll get hard-nosed with them.

I'll have to tell you a little example of one of those while I was a chemist at New Orleans. We had a problem where an orange juice manufacturer supposedly was selling orange juice that was not pure orange juice. It was orange juice that he had diluted with water and sugar to make it go further. And so they asked me to, as I was a chemist there, to run samples of orange juice. And we sent inspectors. It was Texas orange juice, and at that time the Texas area was under the New Orleans office.

So we sent inspectors into the orange groves in Texas when the oranges started maturing until they were completed. About a five month period of time there. Every week I would get a sample of oranges, a different variety from different areas of Texas. And I'd run it for natural ingredients--sugar, acid, everything, you know, that makes up orange juice--so that I could say that basically if this was a naval orange or a Valencia orange or whatever kind of orange, this is what the ingredients would be at this time of year and as it progressed up to the full ripeness.

Then we collected samples of this manufacturers orange juice that he was selling. Now he had his . . . I believe his main plant was in Houston, but I may be wrong on that. Anyway. But apparently what he was doing was diluting the orange juice with water and sugar so that you couldn't tell it, but it made it go further because it made more orange juice. Then he was selling it not as a concentrate but as that liquid, and you didn't have to dilute it when you bought it. It was pure orange juice, supposedly. So then we collected samples of his orange juice as he was selling it. Some of it was shipped in tank trucks, big semi-tank trucks, like oil. And they'd ship it up north and then bottle it up there to sell it. So we even sent inspectors from those offices where it was sent to go to the bottling plant and pick up the samples and send them in to me.

Well I worked on this case for about five months in New Orleans and developed data for what pure orange juice from Texas would be versus what his orange juice was. And it came out to be that we proved that he was diluting his orange juice. And the thing which proved that was when we found that his orange juice contained more fluoride than in any natural juice. And when I found that I said, "Well, why?" So we sent an inspector to the Houston area and had them collect water from that place where he was juicing the oranges. The water naturally contained the fluoride. So it was his dilution of the juice with the water that put the fluoride in it.

So we took him to court and we won the suit. I've forgotten what penalty--he got a pretty good penalty. But it proved that you can detect adulteration. You can detect falseness in claims and everything if you do the analysis properly.

RO: What prompted you to look for fluorides?

SH: I guess when I ran it I ran it for everything that was possible to run it. And I had no idea that there would be fluorides in it, but I found . . . What do they call the chloride? I can't even remember now. The chlorides and the fluorides and the bromides. What's that chemical term for those, that class?

RO: Halogens.

SH: Halogens. I found a halogen. That's what it was. And I couldn't detect which halogen. See I'm getting too old. (Laughter) I can't remember all my chemistry. And I found that it had a halogen. And I thought, Well, it's chlorine. And then I ran it down and found it was fluorine. And I think it was a precipitation or something when I did something that showed there was a slight halogen there, and that's the reason that I got led to it. So anyway, we got a pretty good fine against a man. And he said in court that what he had done, that he had to wash his equipment and that he did know that he concentrated the juice slightly in the way that he was handling it so he did dilute it with water to make it back to the original strength. Well, that was just his statement to get by.

Well about--a little more to that story--about two years later when I was in Cincinnati I went to a meeting in Chicago. And I've forgotten what kind of a meeting--some kind of a special meeting for food industry people. And I got on the elevator to go up to the meeting in the hotel at the room where they were holding the meeting, and this man and his wife got on the elevator. And he turned to me as the door closed, and he said, "I know you." And I said, "I'm sorry, sir. I don't believe

I know you." Well he says, "You ought to." And I said, "Oh?" He said, "Yes, you're the darn chemist that was in New Orleans that cost me a \$50,000 fine, because I'm the president of that company in Texas that got fined for falsifying orange juice." (Laughter) So it was kind of interesting.

RO: Yes. Well the reason I asked about looking for fluorides, because back in those days looking for fluorides was not an easy task in a laboratory compared to what it is now.

SH: That's right.

RO: You know, I was thinking about that Abbott recall. Dr. Goddard was commissioner about that time, wasn't he?

SH: Yes, yes.

RO: And, of course, with Goddard, he brought an entirely different focus to things.

SH: That's right.

RO: He suggested that when you find a violation, the first thing you do is to let the firm know about it and say, "Hey, what are you going to do about it?" Before that, the administration usually felt that we'll see them in court or something.

SH: Yes, yes, right.

RO: So at least that was quite a drastic change.

SH: And I think it was much more effective in a lot of cases. In Product Safety you had to send everything to Washington for review and then they'd study it, and then they'd maybe call you back and say, "Do this." And then maybe it would be three, four, or five months after you've found the problem before you'd take any action. In Product Safety the general counsel's office would sometimes delay taking any action for six months to a year after you found a violation. And to me this was ridiculous.

And while I'm on that, I wanted to say this other thing that's not on Food and Drug now, but it's on Product Safety. I met with the five commissioners one time in Washington. And this was when I had been taken in by John Byington to do some study on how we could improve the field operations. And I went down there every week for about, oh, I guess about six months I was on temporary duty in Washington. And I suggested to the commission that they do one thing: that they establish general guidelines for action by the district director or regional director so that, like if you found by analysis on a hazardous substance that this was the thing that was causing the hazardous problem and the label did not declare that, as it should by law, that the district director had the right to pick up the phone and call the firm's president and say, "Either correct it or we're going to have you recall it." And that we'd get immediate attention to correct a problem that could be a real hazard to the consumer, which I thought was our job. And I said, "This is what I had said in Food and Drug several times while I was in the Chicago office--that they ought to give the area director that kind of authority." And they did in some cases.

RO: Yes, there was a direct reference seizure.

SH: But the Product Safety Commission didn't do that. They wanted to make all decisions. Well, one of the commissioners when I made this proposition said, "But Sam, you've got to stop and think. We're the people that Congress is going to call on the carpet if something isn't done to protect the consumer in that problem." I

said, "That's right. But do you want to go up there and say, 'Oh, my goodness, and that's been a problem for a year?' And the Congressman says, 'Yes, and you haven't done anything about it.' 'Oh!' Wouldn't it be much simpler, Commissioner, if you could say, 'We gave Sam Hart, as director of the Chicago office, authority to take action in that type of case. And it's been a year and he hasn't done anything? He's the guy we're going to call on the carpet, Mr. Congressman, not me the commissioner. And believe me, when I leave your office today, he will hear from me.' But the other way you can say, 'I didn't do anything,' because you were the one that was making the decision." And this commissioner says, "Sam, that's a good suggestion. We ought to do it."

So then we got a little delegation of authority--not as much as I wanted--to the area directors to make certain decisions in certain cases. And I think to enforce the law that's what you need, Ron. I think that you give the guidelines, but you don't let somebody sit in Washington and make every final decision.

RO: Well, if you remember, Sam, when Dr. Goddard came in as commissioner, they did away with the interim headquarters level of field reporting. The district directors reported directly to the commissioner. Some of those district directors, later the RFDDs, but some of the district directors took advantage of that. They were really happy, because finally they were going to be able to make some of those decisions themselves. But some of the others were lost.

SH: Never.

RO: They were so used to being spoon fed, they never did anything.

SH: That's right. That's right.

RO: So it was kind of interesting as far as the difference between Goddard and some of the other commissioners. Were you in headquarters when we were under CPEHS (Consumer Protection and Environmental Health Service)?

SH: I believe I was. I'm not sure now. I don't remember when you went under CPEHS. Do you remember, Ron? Gosh, I can't remember now. I went to headquarters, Food and Drug, in 1969.

RO: Well, in 1969 we were separated from CPEHS. So we were only under CPEHS about a year, I think.

SH: I went to Chicago in '67, stayed till '69; and then '69, August, I went to Washington and stayed till '73.

RO: You were out in the field then when we were under CPEHS.

SH: Yes, that's right.

RO: It must have been about the time that Goddard left, then, that you came into headquarters. Did you say that Charlie Edwards had asked you to come in?

SH: No, Winton Rankin, Dr. Goddard's deputy.

RO: Because as soon as Charlie Edwards came in, he didn't want Winton Rankin on his management team.

SH: That's right.

RO: So Winton ended up down in the department.

SH: Right. No, Goddard was commissioner when I went in, and I worked with him on a lot of things in the product safety area. Yes.

RO: Well, did you notice much difference in the approach that Goddard took to things as compared to Charlie Edwards?

SH: There was a difference, yes. I can't touch anything specific now. I do know that it seemed like I could approach Dr. Goddard with a problem in product safety while we were part of Food and Drug and I'd get an answer a little sooner than I did from Dr. Edwards. I mean, I'm not saying that Dr. Edwards didn't ever answer, but I think he would consult more with his staff, and Goddard would be more inclined to do it himself.

RO: When Dr. Edwards came in, then Sam Fine went up to be the associate commissioner for compliance.

(Interruption)

RO: I guess we were discussing, Sam, if there was any difference between the approach to managing the Food and Drug Administration between Dr. Goddard and Dr. Edwards. And I think you mentioned that Dr. Edwards probably consulted and used his staff more than Dr. Goddard did. Of course, when Dr. Goddard left the agency, there were some rumors the reason that he did leave is that he wanted to head up that combined group, the CPEHS, and he didn't get that. So some of that was at least one of the speculations as to why he left. Well, Sam, if there's anything else you'd like to cover while we're talking about this, your career or some of the people that you worked with, the differences in their approach to things . . .

Tape
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SH: Well, I guess not a whole lot. I think it was a tremendous experience for me, as I stated early. I started late, really. I was fifteen years out of college before I started, and I wasn't sure what I was getting into or whether I'd like it. But the people that I worked with from the very beginning right through to the end, so many of them were top-notch, helpful, considerate people. They had different ways of doing things, but everybody does. But they were willing to listen to you. Like in Denver when I started with Sam Fine as chief chemist, he was willing to listen to me. He was willing, if I had a problem, he was willing to help me solve the problem. When I went to New Orleans I had people there.

And I liked the way that the laboratory staff, the enforcement staff, and the inspectors worked together to solve a problem rather than, "Well, I'm this, and you don't know anything about what I'm doing." Sure you had a few of those--"Well, I'm it, and you don't know anything"--but generally they worked together as a team. And I think that's one reason I enjoyed working so much with the Food and Drug people.

It was a little different when we got over to Consumer Product Safety. Again partly because the people that made up that new agency were not people who had worked together for years and had a kind of established routine. And you had people from the Bureau of Standards, people from Food and Drug, people from industry, people from politics that came in to make a new agency, and there hadn't been any pattern established. There hadn't been any real understanding of how to do the job. He had his idea, I had mine, you had yours, and so forth. But I think that, again, I enjoyed the experience I had of working with everybody.

I enjoyed the experience I had in Washington. In fact, I've said that everybody, every citizen of the United States, ought to have to some way or other serve one year in Washington, D.C., to find out how their government works.

RO: Well, in CPSC you had kind of a conglomeration of employees from other agencies, so a lot of the people had their own agendas rather than having come from within a single agency. And of course that was one of the things they always

criticized the Food and Drug Administration for--it was so inbred. And, of course, since Dr. Goddard, there hasn't been a commissioner that has come up through the ranks.

SH: That's right.

RO: They've all been from the outside. And you know there were some that felt that with Goddard coming in and coming from the outside, that was going to kind of be the demise of the old Food and Drug Administration. Well, it's hard to say. I remember with the Bureau of Product Safety there was always that feeling that your director, Mac Jensen, felt that he should have his own field force. And I'm sure you remember that was some of the things that you and I were trying to resolve so that we could keep our bosses, Mac Jensen and Paul Hile, from getting at each others' throats. And it was no different when the Bureau of Biologics and Radiological Health became a part of FDA. They had been used to having their own inspectional force and their own field force, and it was the same thing there. So it's been interesting times.

But I didn't realize, or at least I had forgotten, that the role you had when the commission was formed was a little different than before. You were kind of the executive secretary to the commission. Rather than trying to get standards through and things of that kind, you had to resort to whatever they were doing.

SH: Right, right.

RO: I was wondering what your reaction was as far as the problems you might have had, of setting standards for the toys and other consumer products. Well, Sam, I've really enjoyed this, and we want to thank you for giving of your time for FDA's oral history program.

SH: Very good. I enjoyed having you visit with me, Ron. And it's good to see you again.

(Interruption)

HISTORY OF THE
U. S. FOOD AND DRUG ADMINISTRATION

Interview between:

William K. Hays, Retired Director,
Compliance Branch, New Orleans District
and

Robert G. Porter

New Orleans, Louisiana

April 3, 1977

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

TAPE INDEX SHEET

CASSETTE NUMBER(S) 1 & 2

GENERAL TOPIC OF INTERVIEW: Food and Drug Administration History

DATE: 4/3/77 PLACE: New Orleans, La. LENGTH: 80 Min.

<u>INTERVIEWEE</u>		<u>INTERVIEWER</u>	
NAME	<u>William K. Hays</u>	NAME	<u>Robert G. Porter</u>
ADDRESS	<u>2639 Ramsey Drive</u> <u>New Orleans, La. 70114</u>	ADDRESS	<u>U.S. Food & Drug Admin.</u> <u>Room 500 New Custom House</u> <u>Denver, Colorado</u>
TELEPHONE	<u></u>	TELEPHONE	<u>837-4915</u>
FDA SERVICE DATES: FROM <u>1935</u>		TO <u>1969</u>	
RETIRED: <u>X</u> YES <u>NO</u>			
TITLE: <u>Director, Compliance Branch, New Orleans, District</u> (If retired, title of last FDA position)			

CASSETT NO.	SIDE NO.	ESTIMATED TIME ON TAPE	SUBJECT	PAGE NO.
1	1	0 Min.	Seafood Inspection Service	1
	2	0	Seafood Inspection Service	
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	2	23	Career, transfers, etc.	22
	2	27	Cases of interest in New Orleans	25
2	3	0	Cases of interest in New Orleans including U.S. vs. Leon Rayburn (OTC Case)	
	3	20	End of interview	31

INTERVIEW WITH WILLIAM K. HAYS
NEW ORLEANS, LOUISIANA

APRIL 3, 1977

PORTER: This recording is being made in New Orleans, Louisiana, on April 3, 1977, and I am going to ask William K. Hays to tell us something of his experiences as an employee of the Food and Drug Administration. Bill retired as a Food and Drug Officer, now known as a Compliance Officer, at New Orleans District in 1969. So, Bill, I believe you started with the Seafood Service in 1936, and won't you tell us something about it.

HAYS: Well, I actually started in March of 1935, and the Seafood Inspection Service had its beginning in the fall of 1934, so I was not one of the first ones but while the first man who reported for duty came in the fall of 1934, I came in the spring of the following year. Now, when I came here, it had not been solidly set in all of its methods, but it was working fine. It had been set up as the result of an amendment to the old Food & Drugs Act that provided for an Inspection Service in the seafood industry and to be paid for by fees charged to the canners on the basis of a basic charge for a certain number of cases each year, with a few cents added on for any cases over that basic amount. It had the purpose of giving the shrimp canning industry security that it did not have at the time. The whole industry was in a mess because the canners had been canning unfit shrimp that had partially spoiled and had not been kept

properly refrigerated, and then they were not using proper sanitary conditions in the plant, nor were they processing the stuff as long as it should be processed in the retorts. So there was just a general overhauling of the whole set-up and the whole canning methods by requiring that they conform to the regulations that were made up by the Food and Drug Administration.

In the beginning, I believe the first nominal head of the Seafood Inspection Service was Malcolm Stephens, but he was more interested in switching back to his original Food and Drug Administration regulatory work, so, after a relatively short time in the job, he became Chief Inspector at New Orleans and Lawrence W. Strassburger, a bacteriologist, became the head of the Seafood Inspection Service. At the beginning he had two supervisors and then came the regular Seafood Inspectors. I don't recall exactly how many were already working at the time that I arrived with two other new men, but I would guess there were probably 15 to 20, plus the three that I mentioned being new men. Two other new men who came in at the same time I did were James Herring and Delmas Barber. We had a period of about two weeks training at an old hotel down at Biloxi, Mississippi, on the beach front there, and then we were assigned to canneries in that area.

PORTER: How much did you make, Bill?

HAYS: Well, I made the annual salary of \$2,000.00, which there in the Depression was considered very good, and to back up that statement there were maybe five or six men there with doctorates, generally, in chemistry, and, of course, those men hoped just to have a job for the time being, and they hoped to work into the Food and Drug Administration Laboratories, and I think that all of them that stayed with Food and Drug did that. A few of them got other jobs later and went out into industry.

Now, in the beginning of the work, and through at least the fall of 1935, the hours that a Seafood Inspector worked in the height of the season were almost incredible. So many of the canneries wanted to start about 2:30 in the morning and run until almost dark in the afternoon, and then the next day get up again at 2:30. You almost met yourself going back and forth. One really necessary piece of your clothing was rubber overshoes to keep the shrimp juice, that sort of got on the floors and around, from soaking into your shoes, and then it would dry and it would smell so that it was very impracticable to try to work without those overshoes.

PORTER: You would smell like a dead shrimp!

HAYS: Oh, yes, and then sometimes in the morning you would wake up and the clothes that you had worn the previous day smelled like dead fish or something when you got up in the

morning, and a lot of jokes were made about it, but it was a serious matter to try to keep from being a real stinker as a Seafood Inspector.

Now, at other times, perhaps the weather was too bad to fish--to get out with their boats--and then sometimes the catch for some reason would be light, and the cannery would not be operating for periods of time, and when it was not operating, of course, you didn't have to be at the cannery but you were on call at any time for a visit to the cannery to look over a certain lot, or various lots, of shrimp that had been canned under Government supervision and had to be checked out under a certification procedure. In other words, before they could make a shipment of any shrimp, they had to have a certificate for the goods, and the certificate showed what the codes were on the cans, how many cases there were, and it was all down to the individual can. They had to account for every can.

PORTER: And you issued that certificate?

HAYS: Yes, and that was the only duty you had during those periods when the cannery was not running. There were times within my service as a Seafood Inspector when I didn't have to go to the cannery for any purpose for a period sometimes of a couple of weeks, but it all balanced out quite well because of those very long hours that you worked at other times. Then, there was some employment of your time by use of a survey system that Food and Drug had to locate

misbranded drugs, etc. For instance, if you were in a town of any size, you would spend time surveying drugs and labelings in drug stores. You might say it had two purposes. You were being trained for the time you might be transferred into regulatory Food and Drug work, and the other purpose was for them to help the Food and Drug locate misbranded products in the drug line.

PORTER: Well, Bill, I seem to remember that this canned shrimp then, actually on the label, bore a statement that it had been certified. I don't remember the exact wording.

HAYS: Packed under the supervision of the U. S. Food and Drug Administration had to be on the label, and, of course, the packers wanted it on the label because this inspection service worked, from the beginning, very effectively in rescuing the canning industry from the bad economic situation they had had before the Inspection Service started--so many seizures by the Food and Drug Administration of unfit goods, canned either from unfit or spoiled raw material, or not processed properly, or whatever, and it had gotten to where the banks simply would not loan them any money on say 50,000 cs. of goods they had in their warehouse, and all of the canneries had to acquire money to operate in a very large volume that was necessary for success in the canning business. They had to sell a lot of shrimp because at that time the shrimp fishermen were being paid about \$4.50

a barrel for the shrimp they brought to the cannery, and a so-called barrel was a unit of 410 pounds, and then the--

PORTER: That is only about a penny a pound.

HAYS: That is about--pretty close to it, yes, and the sale price on a No. 1 can of shrimp, either what they called the dry pack, or the wet pack, was usually about 15¢ a can, but many stores ran regular special of two cans for 25¢. I don't know what the cost of that shrimp would be now, but it is very expensive. Hardly anyone buys canned shrimp any more, but you have to remember that at that time they had not yet developed the merchandising of frozen shrimp. There was no competition from that, and the only other two packs, or styles that they had were first, the so-called boiled, peeled shrimp, and that was shrimp that they cooked in a heavy brine, and then they packed it into large gallon friction-lid cans, such as used for syrup and things like that, and then they packed those cans in wooden--old wooden flour barrels with ice all around them, and then they would take a heavy piece of burlap and cover the lid and put a ring down tight around that, and it was shipped by express, generally to restaurants all around the country. Mostly up in the East.

PORTER: Didn't you just get out on the boats and look at the shrimp before it was unloaded?

HAYS: Oh, Yes.

PORTER: Or did you wait until they got into the plant?

HAYS: Well, that varied a lot. It depended on the quality of the shrimp that was coming in at the particular time. Usually, if you weren't tied up with some of your duties of checking on the recording charts and the thermometers on the retorts, or work of that nature, or checking the people as to how they were operating in the picking of shrimp to see that they were not doing anything insanitary, such as not washing their hands when they went out of the room before they came back, you would have time as the boats would have the hatches taken off to take a look at the shrimp in a general way on the top there. You are always interested in what you were going to be up against with this particular boat that was being unloaded, or was to be unloaded at that time. Generally, the shrimp was shoveled onto a conveyor that would reach the boat when it was let down to the boat and would go up to the inspection belt, which was a belt that was made of metal webbing and the shrimp would be spread out to one layer on the belt and you had employees who stood on both sides of the belt picking out the objectionable shrimp, and under ideal conditions from the time it went off the belt there was nothing in there in the way of shrimp, that is individual shrimp, that showed any signs of decomposition, and that was usually indicated by orange colors, or black colors, or things like that on them, and it would be free of small minnow like fish, and small squids, and

seahorses, and other kinds of extraneous material like that. Then you were talking about looking on the boat, sometimes as the shrimp was being run over the belt it might be getting more and more difficult to get all of the objectionable material out of there, and it might be getting down close to a point where you just had to say that they couldn't run any more of that shrimp--that it was too risky, you know, that the things would get by and that they just couldn't pick it out fast enough and that the quality of what was left was not satisfactory, and then you might go back and make more trips in there and maybe shovel off some of the shrimp off the top to see what it was going to look like further down, and things like that, and you could even find a spot in there where the ice had melted out of it too soon and then you would have them take that spot out of there and then go on with that which was below. Almost every day you had a variety of situations in that respect and it did not always follow a definite pattern. You had to use your judgment and ingenuity and at times, as I have already indicated, you would come to the conclusion that either the whole boat from the beginning, or portions of it that you got to down in there simply did not have enough shrimp in there that would be acceptable to justify running it, and then you would have to condemn the whole boat. Now, the regulations that they operated under required that anything that was condemned had to be destroyed, and they could

not take it to another cannery or anything like that, and sometimes you had to watch them very closely to see that what they were required to do was actually done. There were lots of duties peculiar to the thing. For instance, every time they unloaded the boat and got it unloaded, you had to inspect their cleaning operations on the boat before they could be allowed to leave the cannery, and all the boats had loose boards in the bilge that could be removed so that they could clean out underneath the boards. I remember that there was one cannery where practically all the--the most part of the fishermen who came in there with the shrimp, they spoke French--Louisiana Cajun French, and occasionally there were some of them that didn't--the people working on the boats, the deck hands, who did not understand English at all, so that in some instances we used French language terms to be sure they understood what we were talking about. Of course, for instance, I did not know how to speak French and I didn't even know how the French words were spelled, but I knew the sounds--it was a phonetic thing--for instance the instruction A/ was "Lift the planks and wash well underneath" in the bilge you know. Then the pickers on the belts, so many of them were people whom you told to be careful and look out for red shrimp and black shrimp, etc., while they might not react as well or they didn't react as well as if you just said something like B/, and warn them

A/ "Lever les planches et laver bien au-dessous."

B/ "Chevettes rouge, chevettes noir."

about it, so it was all in all a very interesting experience and it was so different to anything that I had ever done before, and then there was a certain amount of glamour, I thought, to being around boats and people who were boatmen and seamen who knew the sea and all, and I had come there from Western Texas--and it was dry land--and so I really enjoyed my time in Seafood. It was a wonderful experience and I made a lot of friends among the other inspectors there, many of whom I knew throughout all the other years.

PORTER: Who were some of the people from Food and Drug who started there?

HAYS: Well, one who comes to mind right away is Tom Bellis. He and I were very good friends, and John Schnabley, and Dr. Eugene H. Wells, whom I just visited with last Christmas up in Washington. Gene had a doctorate in chemistry and he was representative of that goodly number I mentioned earlier of men with that kind of formal education but who were glad to be Seafood Inspectors for a time. He enjoyed that work very much. He liked people, and he was an earthy sort of a character, and still is. When he quit, he did get transferred into Food and Drug laboratory and he was a chemist at Chicago and later at Washington for a number of years, and then he went out into private industry and became a Chief Control Chemist with one of the larger drug companies in the East--in Pennsylvania.

Now, I can name a lot of others, like Jim Herring and--

PORTER: Shelby Gray was one.

HAYS: And Shelby Gray. Shelby and I had known each other in school before we ever thought or ever heard of the Food and Drug Administration, and he became a supervisor in Seafood before he was transferred into the other work.

Another thing about the Seafood Inspection Service was that most of--or nearly all of the men who were in it were single-- a few married people. Those single people developed a lot of camaraderie, and there was a well recognized esprit de corps, and so many factors contributed to that. One was that it was the Depression and jobs were so hard to get and this was a good job for almost anybody, at least for the time being until things got better, and the people were from all over the country and came from--I don't think every State in the Union--but there were people from the midwest, I remember, in that respect, some of the fishermen--the people around the canneries that had just the very minimum of formal education--had lived in those areas where the canneries were for all their lives, and they found it very difficult at times to understand how these people could come in from the Hinterlands, or from the midwest where they did not know anything about shrimp.

PORTER: Yeah.

HAYS: And I remember we had a man there that was an excellent Seafood Inspector, Ken McClure was his name, and he was a supervisor rather early on in his work, and he made a decision one time to condemn a rather large lot of shrimp in one of those canneries down a bayou, and so a lot of people would get upset when you condemned a lot of it because sometimes it would even--even the people working there picking shrimp--their jobs would be cut off for a time because they would run out of shrimp because it all got condemned, and one of those persons one time--he was a little bit sharper than the rest of the people around him--was going to cross question McClure about what the hell did he know about shrimp anyhow. He said, "I understand you are from Kansas--what would you know about shrimp?", and McClure just popped his eyes open real wide in surprise and said, "Haven't you ever heard of the great shrimp invasion of Kansas?", and this man looked very surprised, to the great surprise of McClure, muttered a little bit, and then walked off, because he really didn't know what in the hell--what Kansas was or where it was--no, he didn't know anything about it. He probably had never been past the third or fourth grade in school.

PORTER: Bill, what happened to the Seafood Inspection?

HAYS: Well, it finally developed that through--well what you just have to call the education that the canners got from operating under these regulations--that is, your raw

materials have got to be fit in the first place, and you have to operate your cannery in a sanitary way, and you have to make sure that your retorts are properly equipped with recording charts and with thermometers too as a check against that, and every retort had to have a bleeder at the top that was open, emitting steam in order to get all the air pockets out of the retort, because if you didn't the heat would not ever come up properly in that air pocket and the cans in that particular area would not get processed. You could not use absorbent materials for table tops and utensils because again that juice from the shrimp would soak in there and there was no way to get it out, and eventually it would harbor bacteria. Learning those things and having to operate that way over a number of years, they finally got so that they just realized that they could operate without the Inspection Service and without paying these fees that they had to pay, and they were rather expensive, and so it just began to taper off. Over a period of four or five years, they would--maybe two to three or four canner's a year would decide that they were going to go on their own, and it just got down finally to where there were only one or two canneries, and those last two were inclined to want to hold on because then they would remain as the only two in the industry that had on the label, "Packed under Government supervision", and they had had no trouble, you know, in borrowing money and things like that, and no trouble getting their buyers

or brokers to buy the stuff, and so they just hated to give it up, but they eventually, when it got down to two, naturally as the number decreased the ones that remained under the Service had to pay higher fees in order to keep enough men in the Food and Drug Administration in the Seafood Inspection Service, so it just cost them more per case as it went down and that was the reason why they finally dropped out, reluctantly. In looking back over it and summing it up, while I did not stay throughout the whole Seafood Inspection Service time, I had been transferred eventually back to New Orleans and was Food and Drug Officer, I believe, at the time that the last two dropped out, and I--anyone that knew anything about the service knows that it was, over all, a great success, a great benefit to the public, who ate the shrimp, and also to the canners that canned them. It paid for itself--it wasn't a Government hand-out like that--the fees had to be raised as expenses increased or as numbers of them dropped off, and things like that, to pay for whatever it cost--for the men, the few automobiles they had to use, and their per diem and everything was taken care of by those fees.

PORTER: Well, then, as the Seafood Service began to sort of drop off, were you all given appointments or jobs in the regular Food and Drug in regulatory?

HAYS: I don't recall that they lost any men as the result of the Seafood Inspection Service closing because, in the

first place, during the period that the Inspection Service was at its height, and at the time when it was going well, the hiring of Food and Drug Inspectors and Chemists directly for regulatory Food and Drug work was held down with the idea in mind that the people who proved themselves out in the Seafood Inspection Service would be taken into the Food and Drug Administration. They had a good opportunity to look people over at that time, and it would not be as much trauma if they did get ahold of somebody by mistake who didn't turn out very well in Seafood if they just let him go from Seafood, instead of taking him into Food and Drug directly and then having to let him go so it was a kind of a sorting place for people, and everyone they hired in that they had in mind that sometime they might need him in regulatory Food and Drug work.

PORTER: Where did you go?

HAYS: Well, I left New Orleans in November of 1937 and was transferred to Minneapolis, Minnesota, and there were two other men who left there with me on the same train, and one was the man I mentioned before, Tom Bellis, and the other, Dr. Gene Wells, and they went to Chicago. We all went to Chicago, they dropped off there, and I went on to Minneapolis, but Wells went into the Laboratory, as you might expect, and Tom Bellis became an inspector in Chicago.

PORTER: Who was the director at Minneapolis when you went there?

HAYS: A man, a very unusual man by the name of Channing Harrison, and he was a direct descendant of Benjamin Harrison, and he was from Virginia, and a rather unusual man. He was quite proper in his manner, and he looked like an old Southern plantation owner, or something. He was a real tall man, and there he was, in all places, in Minneapolis, but he had been there for a long time. We didn't have very many people there at that time. When I got there to work as an Inspector, there were three other inspectors there, and one of them was Chief Inspector. He was a veterinarian by training, and his name was Doc, they called him "Doc", Moberg, M-O-B-E-R-G. Doc Moberg was later in Chicago, I think, for a short time. I believe he died while he was there.

PORTER: Did you have any interesting cases, or did you have any interesting investigations while he was there?

HAYS: In Minneapolis?

PORTER: Yeah.

HAYS: Well, yes I did. In fact, I arrived there just in time to go to work in collecting some samples and making investigations related to the case that was just about to come up in court, and did come up there. It was a case against the Kraft Cheese Company for making what they called an Old English sort of cheese spread, and it was so labeled as to indicate that it was made from sharp and well-aged

cheese--it wasn't really cured very long--and it was cheaper and a lower grade of cheese, and they were putting oil from red peppers into it and that taste, very faintly hot taste simulated, to some extent, the sharp taste.

PORTER: I thought you were going to tell me they made an Old English Cheese, and you were after them because they didn't have any old Englishmen there.

HAYS: No, no, no. They didn't have any old cheese there, and not the higher quality, aged cheese. They denied that they had added this pepper at all but some of our chemists were able to get little vials of red pepper oil out of quantities of cheese, it took a lot of it--they had to get a lot of samples to extract much of it, but they did, and then their alibi at the last minute was, well, some of the employees were responsible for that and they didn't know it, you see. They never did admit that their officials knew anything about it, but we won that case all right. And, I don't know, when I first got there I started out on a trip immediately with one of the older inspectors there, Hugh Hennessey, and we just went off on this trip for my training, and that was going to be the extent of my training before we got back and I got started out on my own. I had already worked independently before I went on the trip, collecting those samples for the trial on the cheese, but on that trip we had some interesting experiences in that we had, of course,

the one car and we had a whole warehouseful of apples that we needed to sample very extensively in Amosinee, Wisconsin. They were in cold storage that was generally used for storing ferns and boughs of trees and things that were sold to florists, and it was refrigerated and these apples went right up to the ceiling. There must have been about eight or nine baskets high, and you had to find certain codes in there and take samples from them, and it took an awful lot of moving those around, and I was there sampling those apples for four or five days, while Hugh went off in the car, working on an investigation of rather imminent danger to public health. It was the sale of a reducing remedy containing dinitrophenol and it was done by advertising in small country newspapers and there seemed to be a lot of them in those days in Wisconsin--Polish papers and German papers, and things like that, you know, those ethnic group papers, and it got to be a very ticklish operation. As Hugh had told me when he first came back to pick me up from the apple deal, and as I witnessed in finishing up with him on his dinitrophenol remedy investigation. For example, we drove up in front of this house where he knew that a package of this goods had been shipped to a woman who lived at that address, and they had gotten these records, I think, from the manufacturer of the goods as to where it had been shipped, and so he told me that from his experience he thought it would be a mistake if two people went up to the door because every one of these women was very reluctant to talk about having received any such product and most insisted because other members of the family, and generally

their husbands, would raise a lot of hell about it if they knew they had been doing anything like that, and so he went up to the door and I waited in the car, and there was this fine, powdery snow over everything--just before Christmas--and this woman when he told her what he wanted, she first denied that she had received it at all, as they generally did, but then after he said he knew she had, then she got hysterical and said it was almost time for her husband to come home for luncheon, and if he came home he would probably shoot her first, and then any other bystanders who knew anything about it. Of course, that was exaggerated, but the woman was really seriously troubled by this possible leaking of the information to her husband, so he had to scoot back down to the car, he kind of trotted down--he was a little short-legged man--he trotted down to the car and we drove off with all this fine powdered snow swirling around. And, of course, he had made an agreement with her that what he would do would come back after lunch when her husband had gone back to work. We did and he got his sample and that settled the thing, but that dinitrophenol had actually caused a number of deaths of people who had taken it, and that was just the beginning of my education as a Food and Drug Inspector and not a Seafood Inspector. We got back into Minneapolis on Christmas Eve, just a little bit before dark, and during my time in Minneapolis, I was there for about 18 months, and I had two trips, each of which was three months. That's how much traveling we did.

PORTER: You mean you were gone three months without even coming back?

HAYS: That's right--three months without coming back, and on two different occasions out of the 18 month's time there. I spent the biggest part of that time in the Dakotas--in North and South Dakota--and parts of Iowa, and some in Minnesota and some in Minneapolis. I had a family at that time--my Mother and my kid brother--and I had left them in New Orleans--my Mother's health wasn't very good--it wasn't good at all really, and she did not want to go up to that cold climate, and so it did work out to my advantage, to a certain extent, in that I was traveling all the time up there and I did not have to maintain a place, you know, a room or anything like that, a living accommodation on a steady basis. I had an arrangement with the YMCA whereby when I left town I had a trunk in which I put my belongings, and I could put it in the attic--take it up on the elevator--and it was easy to do that, and then when I was gone, I was gone, and I wasn't paying for anything there, and when I would come back they always had a room for me, and I could get stuff out, if I needed it. If I didn't, I would just leave it up there. Per diem, at that time, was--I think it was \$3.00 and something a day, but you could rent a hotel room for about a dollar, most of the time, and you could certainly eat on \$2.00 easy enough, and the great depression was still on--we really didn't get over it until World War II, and so I had no

complaints, and I found that the climate up there in Minnesota, you know with very cold winters--several times it got down to 45 below while I was out traveling around. We just traveled all winter because in that country they always had regular equipment for breaking the roads open, you know, and cleaning the snow up so that anybody could move all winter long. Only one time that I got snowed in at a motel, a hotel, they didn't have any motels up there then. This was before the day of the motel, and couldn't leave town the next morning. It snowed so hard during the night that I just stayed there all day. I had so many reports to write, and when you go out on these three months trips and trips of even three or four weeks, you couldn't wait until you got through with the trip to write your reports when you got home. You had to keep writing on that all the time, and then you had to--some people might wonder how you would go out on a trip like that and stay so long. Would you take that much of assignments with you when you go? No, these were current assignments and, to a large extent, would originate in the District, or in some other District, and they would request some samples, or something, and then you had to keep in very close touch with your District, say Minneapolis, when you were out on the road for such long periods, and they had to know exactly where to send your mail all the time, and you used Western Union and Postal Telegraph to keep in touch with them lot of times, although many times when you were getting ready to leave a place you would have to send them

a wire that you were leaving there and where you were going, and you recall how that worked, of course, and so they could send you assignments, from heck to breakfast, on a three months trip I suppose that probably 75% of the assignments received on that trip were sent to me after I left Minneapolis. They would just keep you going all the time. Once they got you out there they would keep you going.

PORTER: You weren't the guy that always would send a wire saying, "Leaving Sioux Falls". Then after he had worked in Sioux Falls a few days, he would say--I mean, then when he had worked in the next town he would say, "Leaving--", but he never did tell them where he was going. He just told them where he had been, but they didn't know where he was going.

HAYS: Well, in addition to that, of course, when you first started out you had to leave an itinerary of where you intended to go, and that itinerary really got changed much more in Minneapolis than in any other place I ever worked, and was a kind of a farce because of this system of sending your assignments after you got out there that you had no idea you were going to take care of.

PORTER: You got off your itinerary about the second day.

HAYS: Yeah. That's right, and

PORTER: Bill, did you go to the Division of Foods from that job, or did you--

HAYS: No, I left that job about--as I said, I got transferred to Chicago. And then I moved my family up there from New Orleans to Berwin, a suburb of Chicago. I guess I had been there about three months or so when--this was in 1939 and with the passage of what they called for years, "The New Food & Drugs Act of 1939", they had a tremendous amount of correspondence in Washington that they had to take care of, and so they brought in people on temporary assignments from various Districts at times, in rotation, and so I went up there--was sent up there for a month, in the beginning, to assist in that work, and then when the month was up they got it extended, and I think it was extended on the basis of one month at a time until I had been there nearly three months, and then Dr. White in the Food Division, with whom I had become quite well acquainted in that work and had consulted with him on this correspondence and all, offered me a job in the Canned Food Section. In the meantime I had met my wife, who was working as a Secretary with the Food and Drug Administration. She was there from Connecticut, and we had started going together, and we were very interested in each other, so I took the job, and then Dorothy and I were married in 1940--and then I moved my Mother and brother up there. We stayed in Washington for something over a year, but in that time, during that period, I felt that I was more interested in the work out in the field. The confinement of the laboratory, being in

the laboratory every day just wasn't as pleasant to me as it had been while I had been out in the field and had such a variety of things. I don't mean that I wanted to travel all the time, or anything like that, but at least you weren't in the office all day when you were a Food and Drug Inspector. If you were, then you just weren't doing your job, and so I thought that my skills, too, were better in that type of work, you know, in meeting people, personal contacts and things of that kind, and so I did ask to go back and several people, for instance, Mr. Larrick and Mr. Clark, of Chicago District, had both made promises to me several times before that they thought I really was wasting my time being in the laboratory--that I ought to be back in the field, so I had some reason to believe that any time I was ready to say I was ready to go they would say, "Okay, go", and that is exactly what happened. Clark was up there on a visit and he was in Larrick's office and I went in to see him and told him that I was ready to go, and that was all I had to say. They said, "Where do you want to go?"

PORTER: J. O. Clark was Chief of Central District?

HAYS: Yeah, we still had a Central District, and he said, "Where do you want to go?", and I said, "I came from Chicago--I'll go back to Chicago if it's all right with you", and they said, "Fine", and away I went. Then from there, after about a couple of years, I became a Resident Inspector

in Milwaukee and I stayed there seven years, back to Chicago again for about another two years, and then I came to New Orleans in 1955, back where I had started in Seafood. At first I was an Inspector, and then unofficially they did not have Supervisory Inspectors by name or title, but some people--they would always have one or two people who sort of work like that--you know how Walt Ernst used to work like that in Chicago, so I was doing that for a relatively short time and then the Food and Drug Officer job opened up and they gave me that. Then, I was Food and Drug Officer here for almost--what was it--from 1956 to the time I retired, 1969. 56 to 69.

PORTER: Did you have any --

HAYS: I was promoted up to different levels, different grades, to the top grade, and they changed that name to Compliance Section which I was in charge of before retiring, and they loosely referred to me as Compliance Officer but there was not any official title in the records at that time of Compliance Officer.

PORTER: Did you have any kind of special interesting cases or personalities in your New Orleans work during your period as Food and Drug Officer that would be interesting, or maybe significant in terms of precedence, or something like that?

HAYS: Well, yes, Bob, there were an awful lot of things occurring. It was a very long story of what happened during that number of years. Possibly, from the precedent standpoint, it wasn't the biggest case we ever had but it was one that was most unusual according to the statements of the Judge involved and the Assistant United States Attorney in Birmingham. I will try and make this short--I will over simplify the thing, but there was a pharmacist up there in Alabama, an older man, and he had this kind of old, rather run down drug store. It had been a fine drug store at one time I suppose but he was a very peculiar individual and he had been selling drugs over-the-counter, restricted drugs, or drugs that are restricted to prescription dispensing, over-the-counter on occasions without prescription, to people he knew, mostly. There had been a complaint on him so that a couple of inspectors made purchases from him over-the-counter, and as I recall, they weren't the worst--they weren't barbiturates and amphetamines but they were thyroid and drugs that were restricted to prescription but I am not sure at this late date whether there were any habit forming drugs in there or not. At any rate, a case was developed on him and he was cited to a hearing and he came in, and at that time he was a very peculiar man and he was very pleasant and all but he would just say, "Yep" and "Nope", and things like that, and so then the case was filed on him and then at the time of arraignment, he came in to enter his plea, as to

whether he was going to plead, "Guilty", or "Not Guilty", or the vague possibility of a "Nolo Contendere plea", which the Judge probably would not allowed him to have. The Judge asked him what his plea was and he said, "Well, I don't know Judge. I don't really know--but I will do whatever you say--I'll do just whatever you say. You tell me, Judge, whether I should plead 'Guilty' or 'Not Guilty'." When this man came in for arraignment he didn't have a lawyer with him, and the Judge asked him what his plea was, and he said, "Well, Judge, I'll do whatever you say. I'll plead whatever you say. I'll plead Guilty or Not Guilty or what." And the Judge told him that properly he could not make that decision for him, and he tried to get him to get a lawyer, and he didn't want to get one--he just wanted to do what the Judge said, which was very unusual, and so, to make a long story short, finally the Judge just reset the arraignment and told him to get a lawyer. He came back again and didn't have a lawyer, and went through the same procedure, and it was just a bottle neck. They couldn't do anything with the case, and so they got ahold of me and asked me to do something--to see the old man and try to explain it to him. He couldn't seem to get the point in Court or anything, and see if we can get it--that was a very troublesome thing and it was a small case anyway, you know, it wasn't any big deal, and so I went back up there and I had to go up there on a holiday to get it done before they

got through with their session of court in that area, and so I went up there to talk to him and I went to his drug store and he had his easy chair back in the little office there and he sat in his easy chair and smoked his pipe while I talked to him. To make a long story short, I had never heard of it before, but I worked out with him a Stipulation. I got Stipulations like attorneys would ordinarily get, wherein he stipulated as to his guilt to the whole thing, and it was a guilty plea, you know, in effect. We just came in and so then I called the United States Attorney the next day and told him what I had done and asked him if it could be used, and he said "Never before in all my time have I ever heard of anything like that."

PORTER: This was your idea --

HAYS: Yeah, and to stipulate a guilty plea. You know, a guilty plea and to stipulate the whole case. No witnesses required or anything like that, but he said its a desperate situation over a very small matter, and he says I think the Judge is going to be real glad to get this. So, sure enough, he was. He was just--he really was pleased, and the old man came in on the Stipulations and they pleaded him guilty and gave him probation--he was an old man--you know, and not in good health, and everything, and the violation hadn't been too bad, and he swore up and down that

he would never do that again. Then we made some follow-ups on him, and he wouldn't sell anything to anybody, and it was all settled and everybody was happy, and I got a letter from the U. S. Attorney's office, and expressing the Judge's thanks also for--I think I've still got that letter somewhere in that file. They said--they had written the letter to the District and I got a copy of it--they said that never before had there ever been anything like that, and here was this man who went up there on his holiday to get this thing off the track, and they were sure glad he did. So, you were asking for precedents, and that was a precedent. The Judge had never heard of anything like that he said, and they were both very experienced men--they had been--the Judge had been a judge for many years, and the U. S. Attorney was the Principal Assistant, and he had been working in the United States Attorney's office for many years, and, of course, I had been working at the Food and Drug for many years, but it was the only way I could see out of it, and the old man was very cooperative. I forgot to mention that the old man explained --

PORTER: What was his name? What case was this?

HAYS: We'll get back to this. Bob, I said a little while ago that I didn't remember the name of that case, but I find in the personal file I have here the name of the case. It was U. S. v. Leon Rayburn, an individual, trading as Rayburn

Pharmacy, Guntersville, Alabama. The one pertinent part of it is--and this is the last statement I will make about it--in this last conversation I had with the old gentlemen while I was getting all these Stipulations--he explained to me that what he had in mind was that he had met the Judge somewhere years before, when he was at some kind of a pharmacy convention, and the Judge spoke there, and he talked to him after he spoke, and he thought that eventually the Judge would remember him--would remember him as a friend--and that the Judge would tell him just what he should do--and he was very willing to do what the Judge would ask, but the Judge never did--he didn't know this old man--he didn't recognize him or anything--but that was what was in his mind as a reason for telling him that he would do whatever you say Judge--whatever you say, you see, he was regarding the Judge as a friend, but instead the Judge was being caused an awful lot of trouble. Of course, that was an unimportant case except for that technical difficulty.

We had all kinds of cases which were very important from the standpoint of the seriousness, the number of violations, the very lengthy investigation, tracking down bootleggers of amphetamines and barbiturates, and selling in quantities of thousands of pills at a time. Then we had a big orange juice case out in Dallas. Oh, it would take a long time to go through all the cases we had. I suppose that

at one time another man and I got our minds together and we estimated that I probably held more than 500 hearings in relation to cases, some of which were hearings more for warnings than anything else, and then for that reason they were not prosecuted, but out of that a very large proportion of them were actually prosecution cases. Then, of course, we had seizures going on all the time, and we had detentions of imports going on. We were very busy all the time. I never got to a point where I really was caught up, as you would say, in that work in the 13 years or so that I was Food & Drug Officer. At times they had to put other people in there to help out. There were men who knew the work to some extent, on a temporary detail, and then eventually they had another Food and Drug Officer, and now, I think, they have at least three Food and Drug Officers.

PORTER: I suspect so. Well, Bill, I don't want to keep pushing you, but if anything else comes to mind that you think might be interesting, well say it. Otherwise, we will just close off this tape.

HAYS: Well, let's close off right here, Bob. I think that by the time you interview all of these people you can't use too much from each one.

PORTER: No, but you know it's interesting. Well, thank you very much.

HAYS: Yes sir.