

History
of the
U.S. Food and Drug Administration

Interviewee: Harry P. Lynch

Interviewer: Fred L. Lofsvold

Date: April 2, 1984

Place: San Juan, Puerto Rico

INTRODUCTION

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



CASSETTE NUMBERS: 1 & 2

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

DATE: April 2, 1984

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INTERVIEWEE:

INTERVIEWER(S):

NAME: Harry P. Lynch

NAME: Fred L. Lofsvold

FDA SERVICE DATES:

FROM: 1955

TO: Present

RETIRED: No

LAST FDA POSITION HELD: Director of Investigations, San Juan District

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This is a recording in the series of FDA oral history recordings. We are interviewing today Harry P. Lynch, Director of Investigations, San Juan District, Food and Drug Administration, in his office in San Juan, Puerto Rico. The date is April 12, 1984. The interviewer is Fred Lofsvold.

FL: Mr. Lynch would you start this interview by giving us a little background of when and where you were born, where you were educated and the various positions that you have held during your service with FDA.

HL: I was born in Elizabeth, New Jersey and was one of those individuals that was drafted out of high school during World War II. So, when I returned from the service I had to go back to high school for a couple of years in the evening to get into college.

I finished high school and went to New York University in Manhattan and graduated in biology. I worked for private industry for about two years and then came with FDA in 1955. I started in Philadelphia as an Inspector. After about a year, I was transferred to Atlanta, the same position, for about a year. Then I was fortunate enough to be transferred to New York. That was when Fred Lofsvold was my Chief Inspector.

I found that when I got to New York I had pretty much of a free hand, which I hadn't had at the other districts. Finally in 1960 I had an opportunity to take a job in San Juan, Puerto Rico as a Resident Inspector. I stayed there about three years and I got transferred back to New York and worked as a Food and Drug Officer for a couple of years. Finally I was able to move out of that job and was reassigned as a Supervisory Investigator. I worked in that job maybe about two years.

An opportunity presented itself at the FDA headquarters. The foreign drug inspection program responsibility was transferred to New York. The District combined that job with import operations and I was selected to run what we called the International Section. I worked as the Chief for about a year and a half and then got another unexpected opportunity. I kind of grabbed

the opportunity. I was transferred laterally to San Juan P.R. as the Chief of the San Juan Section, which was part of the New York District. I think I made the right move because the job in New York was a little shaky. About three or four months after I left, Headquarters took back the foreign inspection program and the job was downgraded.

When I was transferred to Puerto Rico for the second time in 1969 there were about ten people in the office. About three years later we became a District and Dr. Max Crandall, a veterinarian out of the Chicago Region, came down as the Director.

I had been the Section Chief so they invented some new title for me. I was called the Assistant Deputy Regional Director. I was the only one in FDA with that title; I was the Chief Inspector and the Compliance Officer combined. That lasted about three years and, they finally got around to bringing a Compliance Officer in 1976. My title changed to Director, Investigations Branch (DIB), and that is what I am today. Now we have about 57 people in the District and the Investigation Branch has about thirty.

FL: When you first came here, you came as the only representative of FDA on the island?

HL: Yes, I came here the first time in the summer of 1960 with very little assistance from FDA. I pride myself in the little money that it cost the government to transfer me. I still have my original travel voucher. The total cost was \$25.00, in addition to the plane ticket.

Before I came to Puerto Rico in 1960, the FDA office had been closed for 28 years. However, one of the officials in the Health Department was commissioned by FDA to do work. As a result FDA work was done in Puerto Rico even though we very rarely visited from New York. Samples were collected and seizures were made. Imports were handled by Customs, who analyzed samples or shipped them to the New York District. It just so happened, coincidental to my transfer here, the person in charge of the U.S. Customs Lab, Mr. Sparkman, was transferred back to New York Customs which was in the same building at 201 Varick Street, as FDA. I got

to talk to him before I left New York, and he told me a lot of horror stories. I found them not to be true when I got here.

Sparkman had been a chemist in the New Orleans District and then went to Customs to get a better paying job. Although FDA had no one in Puerto Rico, Sparkman really was the FDA representative. He had a lot of ideas and Customs was quite a different organization in those days.

The second day that I got there I had a list of people in U.S. Customs I had to go see. I had an address where the FDA resident post was going to be and Customs had all the furniture in storage.

FL: That office space had been arranged by the Washington headquarters, I believe.

HL: Office space was arranged by Washington headquarters, sight unseen. Apparently they had corresponded by mail. Unfortunately at that time, there was no General Services Administration (GSA) in Puerto Rico. The resident post office was located on the third floor of a commercial building, on one of the very narrow streets in Old San Juan. The bottom floor was a ladies department store. There was no way to park the car in the narrow street in front of the building. There were vendors in front of the store all the time and they had the parking spots blocked off. There was no way to park the government car. It was a poor location for an FDA office.

I went to Customs, which was about four – five blocks away. When I got to Puerto Rico everything was quite foreign to me and I didn't seem to see any friendly faces, nor hear any friendly sounds. I arrived at U.S. Customs and it was like a new world. The Deputy Collector was the man that ran the operation, was Bill McLaughlin. The Chief Customs agent that we worked with many times subsequent to that was Ben Murphy. The Chief Inspector, I can't recall his first name, but his name was Martin.

The FDA furniture was created, cabinets, desks, file cabinets, storage cabinets, two desks. Customs assigned a couple of men to me immediately. They moved and assembled the furniture. It took about two days to get everything completed.

My first experience in Puerto Rico, other than meeting Customs officials was getting to meet the Health Department people. The individual who FDA commissioned had retired. I believe his name was Mejias. His two principal assistants are still my good friends to this day. One was Dr. Eduardo Toro and the other Mr. Brigman Diaz. Toro being in charge of the food operation and Brigman Diaz being in charge of the drug operation. The Secretary of Health was Dr. Guillermo Arbona, FDA had the whole-hearted cooperation from the Health Department, and so we got off to a very good start. The island of Puerto Rico is only 100 miles long and 35 miles wide. Most all the roads were mountain donkey trails that were black topped. The first city was San Juan and the second was Ponce. Ponce was 75 miles away, but it took about four hours to drive there because of the mountainous roads.

That is another story. Would you believe that the FDA car sent down with me was a big 1960 4-door Plymouth with huge tail fins? To make matters worse, it was a stick shift and used to stall going up the mountains.

I was in Puerto Rico about a week and we had a hurricane. I can't recall the name of it. FDA people thrive on hurricanes and natural disasters. Humacao, a little town about fifty miles from San Juan reported fifty people killed. The hurricane resulted in a deluge of water coming down from the mountain, causing the river to overflow. I never had any experience in preparing for a hurricane. Everything got boarded up in town. Everybody put metal sheets and wooden boards over all the windows. Fortunately it didn't really hit San Juan. It came down on the other end of the island. The second day I rented a car and drove over to the town. It was a mess. The town was littered with dead cows, dead pigs, and some human bodies floating. I am there with the FDA attitude of trying to get rid of the possibly contaminated food. It really didn't fit in this situation. We were dealing with a little more primitive type of operation that we usually deal

with. The Health Department did see that all the food that was under water was destroyed. So, it worked out all right.

The FDA car arrived about a week later. The first thing I did was go on a week-long road trip. I drove to every principal city on the island and met all the principal Health Officials. I visited all of the U.S. Customs ports. I probably accomplished more in meeting people in that one week than I've ever done again. I think it was about a 300 mile trip around the island.

I came back to the office and said, "OK, now what am I going to do?" I had direct orders from the District Director, Charlie Herrmann. He was a smart man. Before I came to Puerto Rico, he said, "Harry, I am going to give you some orders. I don't want you making any inspections for six months." I didn't really understand what he meant by that. So, after a couple of weeks I said, "I've got to make inspections, that is what I get paid for". So I didn't make inspections, I made factory visits.

Almost every factory or warehouse that I went to had serious problems. I wrote them up as visits and sent the reports to New York. I recall about three months later it hit the fan. Some people in headquarters found out about the sorry conditions, so I was ordered to go around and make inspections. I visited the same places and fortunately or unfortunately, I don't know, but we had plenty of seizures. More work than we could do. The flour at that time was shipped from the states. In the hot climate it was always hard to find any flour that wasn't insect infested. So, every place I went to I got the Health Department to come in, we put the embargo and we made a seizure.

One of the problems was getting the samples packed and shipped to New York. The transportation wasn't that good and it took a long time for the samples to arrive. We raised quite a stir down here with all this federal activity. It probably seemed like there might have been about a dozen of us and it was only me. I had the orders then to report all violations and take normal action. I just followed the orders and submitted the reports and samples. It went on like that for a couple of years.

The drug industry was new at that time. We had two major drug companies. Before I opened the office, one of the New York District inspectors, Irving Feldman, had been to Puerto Rico. He inspected the Parke-Davis antibiotic operation. That was the first drug company I visited here. Also, there were many local drug companies. They were in a sorry state. Most of them made oral liquid preparations, but some made injectables. There might have been about twenty such drug firms. All but three are out of business now. They just couldn't comply with the requirements of the Act.

Now I am going back to the Health Department. So, here I became very good friends with the Chief Inspector in the drug area. If I had to get anything done in a hurry, they supplied the assistance. It is a pretty well organized system. In Puerto Rico, there is only the State Health Department. There is no city, county or local health authorities. When I arrived there were about 500 food inspectors and ten drug inspectors in the Health Department. They are strategically placed in 78 towns. Each town has a little health unit, where the sanitary inspectors are located. The food (sanitary) inspectors were not professional. The drug inspectors were in a little different category, they were all pharmacists and for the most part their work was licensing and illegal sales of drugs, rather than control of good manufacturing practices (GMP) type over the drug manufacturers.

In Puerto Rico some innovative things had to be done if you wanted to accomplish anything. When I arrived, the resident post office had been arranged for, out of headquarters. It was definitely no place for an FDA office.

I scouted around and I found another place. Old San Juan is a city that was surrounded by a wall. The wall is still up except for about one-quarter of the area. There is limited access. The streets are very narrow and congested. Now, we have a parking garage in Old San Juan. When I arrived there was none. I searched another area which was about 4-5 miles away which was the commercial center of the city of San Juan. I found an excellent location. I can't recall how I found it. It was in a building, where the Social Security Administration and the

Immigration Service were located. It was a private building. There was excellent office space available on the second floor. The lease costs were less than FDA's Old San Juan location. I got this data, forwarded it to New York, and you can imagine what happened. I received a nasty memo from the Chief Inspector at Headquarters, Ken Lennington. He told me to mind my own business. Space location wasn't my responsibility. He said GSA would find us a new place if we needed it. About ten months later we broke the lease and moved to the new location. Everything worked fine there. Social Security was helpful. They provided some clerical support.

The drinking water was pretty bad in the building, so everybody used bottled water. You had to arrange everything through New York, so I wrote a little memo saying I needed to get the bottled water. I think it cost about a \$1.00 a week. A few months later I got a memo back from our fiscal clerk that said the District Director decided I didn't need any bottled water. He said to forget about the visitors. It's kind of a classic thing. I put the bottled water in and paid for it myself, so that was the end of that.

FL: When Lennington wrote the letter to you about not needing to change offices, was that after he had come down here and seen where you were? Or was it before?

HL: It was before. He hadn't seen the location.

FL: I was supposed to come down with him and visit you after you got settled but unfortunately I got transferred to Philadelphia before we ever came, so I missed that trip.

HL: He came down in the summer with Clevenger and we had just moved into the new quarters. Since there was no GSA here and we had the government vehicle, and there was no parking garage, there was no place I could keep that car. But where I lived there was a garage and the people that owned the house consented to rent us the garage. Lennington didn't like that

at all – keeping a government car at home. I remember when he came down; he stayed at Condado Beach Hotel. I lived about a block or two from the hotel. The first day I went to pick them up – he and the Chief Inspector Clevenger – to do what we had to do and at that point he told me, “Now let me see, where was that government car parked and how far did you have to drive? Hmm, that’s dangerous, I don’t want you driving that government car to pick me up in the morning because you might have an accident and we would have a hard time explaining it. I’m going to walk over to your house and we’ll start our work out from that point.” Lennington had been down here maybe five years before. He had been down here on an over-the-counter drug (OTC) survey, I think in 1956, and he brought with him Danny Rodriguez, who was one of our clerks in New York district who was formally a clerk with the San Juan office before it closed down. Naturally, they found complete disregard for the OTC requirements of the Food and Drug Act in those days, I mean the selling of drugs without a prescription.

After I was there about a year and a half, the head of our Federal State Relations office, Jim Pearson, who used to be my District Director out of Atlanta, and Fred Killingsworth, who was the Assistant District Director at New York at the time, came down to make a visit.

They stayed about a week and it was more of a Federal-State type visit. The very first meeting was with Dr. Arbona, Secretary of Health. Dr. Arbona insisted on taking us to lunch. Dr. Arbona had a glass of wine and he asked Mr. Killingsworth and Mr. Pearson, and they said no, no, no, just like it was a sin. I had a glass of wine with Dr. Arbona at lunch. That night we went back to the hotel and Jim had some bourbon. But during working hours he didn’t touch the stuff.

I took them to all the major cities to meet the officials. They both wouldn’t drink tap water. They were drinking soda out of bottles, with their restaurant meals. We didn’t have any Burger Kings or any of those types of restaurants there. However Pearson and Killingsworth ate local hamburgers. They wouldn’t drink the water “because it was contaminated,” but they had a hamburger.

That went on for a week. The final day of the tour I took them to the local slaughter house to show them how that hamburger was made. Both were farm boys from down south. Their eyes were opened. The operation was primitive. There was no United States Department of Agriculture (USDA), or local control.

Anyway, they got the point. I don't think they probably ever ate hamburgers after that. When Lenning saw the slaughter house, he was completely unimpressed, as if he'd seen nothing. That wasn't an FDA responsibility. It made no difference to him. So it didn't work with him.

Things generally were primitive and I think FDA was a little too sophisticated at that time.

I remember getting complaints about cereal being added to Vienna sausages. Even though it came from an inspected plant in the states. USDA had no real control here, so they referred these things to me. I was getting meat cases that FDA in those days took with USDA concurrence.

One of the most serious ones involved jerked beef called "tasajo" in Spanish. I followed up a complaint and found a warehouse full of insect-infested dried beef. Some kind of strange bugs. I'd never seen them before, green and red. I collected a sample and sent it up to New York and they analyzed it and sure enough – USDA said great, take it off the market. We seized it and about that time that was the same time that Lennington visited Puerto Rico. We went to see the U.S. Attorney and I think Lennington mentioned the case to the U.S. Attorney who was Mr. Francisco Gil. Mr. Gil said it was a good case and he would handle it personally. He said he planned to dispose the seized meat by feeding it to his farm animals. Mr. Lennington told him he couldn't do that. We were going to burn it, destroy it somehow. It was burned. I remember helping the Marshals by throwing old tires on the fire.

I remember another time. About 500 bags of flour were insect infested. We seized it. The Marshal and the U.S. Attorney released it to a pig farm without denaturing. So Mr. Killingsworth got on the phone to me and he did some chewing. I got my tail out there, about a

hundred miles away, and supervised the denaturing of those 500 bags at the farm. Everything wasn't handled as efficiently as it could have been handled back in New York and New Jersey at the time.

FL: That meat seizure I suppose was in the time when the Meat Inspection Act did not apply to goods after they had left the inspected premises and we had to make the seizures under our statute that nowadays would be made by the Meat Inspection Authorities. Is that correct?

HL: That's correct. That was before. The local USDA representatives here were happy to have somebody to something. It wasn't like I was stealing their thunder. Today, we could not do that.

It was a different ball game and later on when the Meat Act went into effect. I can't recall the year; Puerto Rico very wisely opted not to have anything to do with it so the federal government controls all meat in Puerto Rico. They inspect all slaughtering houses and as a result many of the smaller slaughtering houses are closed down and they have some newer modern ones. We don't have that type of problem anymore.

I remember one contact with the number one Federal Health Official, Dr. Marvin Cashion, head of the Public Health Service Outpatient Clinic. At that time we weren't part of PHS. He was very helpful to me, but he sand-bagged me one day. Got food poisoning on one of these freighters coming from Europe. The crew all but mutinied. There were all kind of complaints. We went on board the boat – they had me make an inspection. At that point I knew I was sand-bagged, because I could see it was sabotage. It was nothing, but it was a political-type issue. It was a Norwegian freighter. So did I get the riot act read to me by FDA? PHS has responsibility for the vessels, not FDA. It took me quite a while to get out from under that.

It was people like that you had to deal with to effectively operate. You had to have the assistance. Being a one-man agency was almost an impossible job. You just sit down and look at

it and all of these hundreds of violative plants. How do you start and how do you get the samples packed up and shipped them to the states and then how do you get the cases through the court? There were many more cases then we have now, and we still can't get them through. But the relationship . . . I know definitely with the court system and the U.S. Marshal's office, was a lot different than today. It was a lot friendlier and more understating towards FDA. Overall, I was treated extremely well in Puerto Rico.

When I transferred to Puerto Rico in 1960, I had just purchased a new Chevy. It was the first new car I'd ever bought in my life. I couldn't bring it with me because the local taxes would have been exorbitant. Of course, the government didn't pay for shipping cars in those days. I would have paid to ship it. I did have an old clunker but I had this new car sitting back in New Jersey and my sister was using it and I had to be content with almost nothing in Puerto Rico.

So after about 2 ½ years, I was pretty happy that I was being transferred back to New York. While the work was satisfying, and I liked Puerto Rico, I was unable to accomplish what had to be done.

For the most part I was pretty happy although I don't ever recall complaining. If I had problems, I didn't let the New York office know about them.

To get back to my transfer – I was given about six month's prior notice. I had a decision to make. I was going out with a young lady at the time, for about two years, so I had to decide whether to get married or not get married. I was transferring out. I chose to get married. We have a 17 year old son, today.

FL: She came back with you then.

HL: She came back with me and we are still together. Her name is Fernanda Cruz Lopez, a delightful person.

So, we both left. We got married here and went back to New York to start a new life and a new operation. Concurrent with me working in Puerto Rico, we had the Virgin Islands to worry about. Now, if you think Puerto Rico was bad, the Virgin Islands were a disaster. We had a lot of competent people in Puerto Rico, but in the Virgin Islands we just didn't have that type of set up. The government was not constructed in such a way to operate efficiently. Since the place was so small we had very few manufacturing facilities that would qualify as an FDA obligation. We did have a number of cases and we put bakeries out of business and ice cream companies.

As I recall from the very beginning, again, luck had it. Dr. Melvin Evans was the Commissioner of Health. A real gentleman and a backer of FDA programs and policies. His Chief Assistant was Pedrito Francois and he was in charge of the inspection program. Dr. Evans later on became Governor and ultimately the Virgin Islands Resident Commissioner in Washington. Mr. Francois left the Health Department about ten years ago and went to head up another agency in the Virgin Island Government, more allied to the Environmental Protection Agency (EPA) problems. So those two individuals from the very beginning, again, gave us all the help we needed. We didn't have that many legal actions, other than some seizures and maybe an injunction.

Puerto Rico was kind of self-sufficient to an extent, but not the Virgin Islands. Everything had to be imported. The problems were almost insurmountable. However, I found out that when I first got there Customs was doing some FDA work. They collected samples, especially of drugs, and sent them to New York.

FL: What happened after you left and you went up to New York?

HL: I was replaced by Dennis Miracky and within about a year Adam Trujillo and Ramon Longoria were sent down to help. The agency figured that those two individuals being fluent in Spanish would fit better into the operations. Both Adam and Ramon stayed about two years and

went on to better things and better jobs. Other individuals from the states were sent down to replace them. Dennis stayed here a total of six years and had about eight or nine people in the office, it was still a resident post.

FL: All investigators?

HL: We had a problem shipping frozen samples to the states, so FDA decided sometime in '68 that we would build a laboratory in Puerto Rico. A small laboratory. In the meantime an analyst was sent from New York. He operated for a period of time in the Custom's lab. Under Miracky there were two clerks, about six inspectors, an analyst and a microbiologist from Denver. By the time I returned in 1969, we had built the laboratory which was a general purpose lab. The microbiologist, David Stephens, was operating full time. We had two clerks and six inspectors. I think there were actually four investigators and two inspectors at that time. The two inspectors were local hires and all the investigators were from the states. The place was growing and work was getting more complex. The drug companies by this time had really moved in. When I arrived, the investigators were Ed Fry, Terry Musson, John Harris and Ira Coltan. The inspectors were Richard Dent and Jose Rodriquez.

FL: Most of those people went on, then, to bigger things?

HL: Yes, including Adam Trujillo, and Ramon Longoria. Everyone seemed to go on to bigger things. We had a good staff of investigators.

FL: When you first came here, Harry, did you speak Spanish?

HL: No, I knew none whatsoever.

FL: How much did you learn the first trip here?

HL: Very little. In three years, I had enrolled in a Spanish course at the University, but it didn't work out too good. I couldn't attend the classes because of urgent work that had to be done. Then I married a Spanish speaking girl and my Spanish still isn't so good. So I admire the people that can float back and forth between Spanish and English. My son is like that. A number of our investigators operate like that. You find it very, very helpful because you can move into any society and right away they don't know that you're not a "Gringo" you're not an outsider or you're not. . . you speak either with any language, and it's (without an accent) a great advantage. In fact, most of the people that come down here from the states, there's only a handful – by handful, I mean two or three – they really learned how to speak Spanish. All the ones that have come in and gone out. . . many knew none at all after a couple of years here. You have to take this into account that all the drug companies which most of our business operate in English and all the major food companies do, at least there. . . The business. . . The language of commerce is English, so it didn't present a problem. Some of the smaller firms, it presents a problem. Most of them could operate effectively in the job we had to do without – because all of our counterparts in the Health Department or any of the other Federal governments operate in English continually in Puerto Rico. So, it wasn't a great hindrance. So, the people I have today two or three from the states cannot effectively communicate in Spanish. But it is much better if you can and some people I have working today cannot communicate that well in English, which does present a problem. It's always been a problem.

FL: What about the employees who grew up in Puerto Rico and English is the second language to them?

HL: English is the second language and could be accented. That's not bad. The problem lies with the ability to write in English, that's where there is the problem. Now how can we expect those people, who write highly sophisticated or technical or legal type reports, so we do have a kind of problem here. We try to correct it but it does create problems sometimes. It's readily understandable to me. The verb usage and other situations where the words are reversed in Spanish and English, so you have the translated. . . So that is a . . . it's been made an issue at a few times in the past, but not lately. I think more than it deserves, the fact that they can't. But it's just a fact of life. They improve, of course, but still and all your ability to write and communicate. . . Many people we have, or a good number, are truly bilingual, having maybe grown up in New York, Puerto Ricans. . . A number of them have never lived in the states, but their parents were military people and traveled around the world, you know, and then educated in an English-speaking school. That's one of the problems here. I call it a problem, but up until 1940, approximately, just about, everything was taught in English in Puerto Rico. It was all American school teachers down here and we came into the Island and we just pushed the English down people's throats. So, all the public school kids learned English. But then about 1940, it was changed and people who were educated after 1940 really didn't have an opportunity and today there's no real teaching of English in the public schools. They may call it that, but the teachers are not qualified and the students aren't able. . . So we don't have the vast majority of people that are not. . . don't have the opportunity to learn English. But in the days of Mario Brau, everybody that graduated from high school was competent in English, and he'll tell you that, how things have changed. When he came to the federal government, no problem, he moved right into it.

So that's a problem we have here, the public school system is not very good. FDA now has an emphasis on training. One of the advantages of working for the federal government in Puerto Rico is the availability of a Federal school for the children. They use a school run by the Navy. It's a Department of Defense (DOD) school run by the Department of Education and

English is the language of instruction. Of course, Spanish is taught as a foreign language. Federal employees, in certain categories, those who are transferable, qualify to send their children free of charge. A good private school in Puerto Rico would cost at least \$2,000.00 per year, maybe \$3,000.00. So here, we have the opportunity to send the children to the school at no cost to the parents. The best thing is that the kids become completely bilingual. I've seen kids who went to school in the first grade knowing no English at all; by the second grade they had no accent. Of course, as you get a little older, it's harder. They don't lose any accent. They learn the English, but if they get them in early, all those kids in that school . . . One sentence in English and one in Spanish. Bounce back and forth and they're completely at home and it's great in either language. There are no problems. So that's one of the advantages over here.

One thing I left out. When we located down here in 1960, we were on San Francisco Street in Old San Juan. After about ten months, we moved the Resident Office to Ponce De Leon Avenue in Santurce. Sometime in about . . . I'm not too sure of this . . . but maybe 1967 or 1968, the government decided down here that they didn't want any more leased space especially for FDA, so they put us in the Federal Building in Old San Juan, which was the Federal Building and Post Office.

When I came here we were in the Federal Building in Old San Juan. We occupied a couple of real tight rooms on the ground floor and one laboratory. It was on the ground floor in the basement.

About a month after I arrived, a chemist from New Orleans, Billy Miles, was transferred here to run the laboratory. A lab technician out of New York, Joaquin Palau, was sent down to help him. The microbiologist was Dave Stephens out of Denver. Billy Miles was kind of a jack-of-all-trades chemist, he could do anything, drugs, foods, what have you. Then we brought on a local technician, Rafael Rivera, who is still with us, he is now a microbiologist, to help Dave, so we had four people in the lab. We had two in micro and two and two in general chemistry. We started running drug and food samples. We didn't have to send too many things out unless they

were rather complicated or on special assignment. So things were running so good that after about a year or two, we decided to expand the lab and we built one. . . about three new labs adjacent to this old lab in the basement. The basement at that time was used by GSA to store all the old air conditioners from all over Puerto Rico. That was a horrible area. We convinced them that we could utilize that space. They took the air conditioners out. So some people from headquarters came down and designed a pesticide lab, micro lab, and an instrument room. Then the original micro lab and chemistry lab just became the chemistry lab. We wound up with four different labs.

So, in 1972 we took a couple more on, through Project Hire, and then the fatal day; on the first of January, 1972, we became a District. Nobody realized, nothing changed. Everything was the same. Everything we had at that time, maybe fifteen people, seventeen people, and we... You have to go back. We were a Resident Post. We were called the San Juan Section, because... The planning for the District had been going on about two years. We had planned it. It was all in the planning stage to make it a District, but even though we had a laboratory, we had an inspection staff, but that was it. Here, I functioned as the Section Chief and the Compliance Officer. I held hearings and I acted on imports. All of the domestic actions – the evaluations of the domestic samples – were done in New York. So we had very little authority. I had the authority to handle all the imports without interference, but everything else had to go to New York. Our official files were in New York – we had duplicates. So, all we had was a Resident Inspection Office, with a lab, no other capabilities. With that information, that's how we operated. So we became a District but nothing changed. We still...no responsibilities...A District Director was selected in the summer – that's maybe eight or nine months after we became a District and he didn't report until the following January, so one year later we had the District Director on board.

FL: That was Dr. Crandall.

HL: Dr. Max Crandall, the Veterinarian Officer out of Chicago Region, but he. . . Before he came down here we had a number of Acting District Directors sent down.

(End of Tape 1)

HL: So those thirty day details started out with George Gerstenberg followed by Felix Sabatino, followed by Darrell Brown and Pete Bolin and then Pitt Smith. The last one was John Weatherwax. There we had six, thirty-day details in a row with different District Directors, all having different ideas on how to do things. We're a new District and with Project Hire we expanded from 17 to 34 people. The most difficult part about the expansion was we hired a clerk. Those seventeen that we had originally included, only one experienced clerk. The second clerk had worked about a month. So we had one experienced clerk but the demands that were put on that one clerk were so great that she quit the job. We had eight brand new clerks and nobody knew anything about a clerical procedure. So, they sent some acting Administrative Officers (AO's) down from the States and needless to say, they didn't help, they made matters worse because we had a very good resident inspection post filing system, decimal-type filing system, which was just alphabetical. This individual that came down insisted that we put in a true decimal system, from that point on, nobody ever knew the filing and to date we do not have a subject matter file in San Juan. Unbelievable. They made us go by the book and nobody could figure it out, especially people we had. They decided we had these eight clerks in various jobs and they decided we didn't warrant an AO. So after about three or four months, they decided we had better re-evaluate this. So they made one of the clerks, who happened to be a military retiree, an officer, a retired Major took a job as a GS-3 clerk typist. One of the clerks, Pedro Mendez, who happened to be a military retiree, an officer, a retired Major, took the job as a GS3 clerk typist. They made him an administrative assistant and he ultimately became the AO before he retired.

Subsequent to this action we became a separate District and New York put all the cases, all the files in a big box and sent us everything. So, we resumed all the responsibility for compliance, for all the filings, for handling all the cases, we got the fiscal responsibilities, they dumped everything on us and it was a fiasco. To make matters worse, a different District Director every month. Now, some of those guys were very smart. They said, "Harry you run the office and I'll kind of do these other things, plan for the future." Others insisted on supervising every aspect of the office operation. My title was changed from Section Chief to Assistant Deputy Regional Director.

FL: At that time, what we now call District Directors were referred to as Deputy Regional Directors, I believe.

HL: That's right. Deputy Regional, so I was an Assistant Deputy. Can you imagine giving you a compliance responsibility and a Legal Processing Clerk that is a brand new hire and we lucked out though on all these female hires as clerks. We had an abundance of college graduates. There is a course here, a four year course, on Secretarial Science. So, we had a lot of those people that came to work for us that have four years in college learning on how to be a good secretary. So we had some top-notch secretaries. It was only a matter of time when we were able to handle our cases, but they sent legal processing clerks down to train us and people in the laboratory down. We also hired four or five new chemists through Project Hire; inspectors, analysts and clerks. The six months were quite trying.

By the time Dr. Crandell arrived in January things were not running smoothly. We had about 15 investigators. At that time I was the Chief Inspector, the Supervisor, and the Compliance Officer. The Regional Director, Cliff Shane, came down in about March – two months after Max. I said, "Cliff, I can do anything you want me to do, but this is ridiculous. How can I do all of these functions?" To make matters worse, Max Crandell had been a

Veterinary officer and he had no background in regular FDA type work – inspections, analysis – so, I asked Cliff for a supervisor to assist me. He did better, he gave me two. I didn't need two right at that point. The two supervisors, George Grubb and Del Porter, were old hands. They left after two years. Certain things in this environment here – now they're not unhappy with the Food and Drug Administration aspect of it, I've never seen that – it's the other things you have to cope with, the everyday living conditions.

I know George Grubb particularly, George came down here out of the Portland Resident Post. A nice person. We all liked him. But everything that could go wrong with anybody went wrong with George. It just happens with people. He thought he had a heart attack one night. Took him to the hospital and they couldn't find anything – it was kind of a ramshackle hospital – and it reoccurred later in the night and they took him to another hospital and they diagnosed it as a kidney stone but they wouldn't let him in. They had no room and here's George dying in the streets just about. He was accepted at a third hospital. It was something like out of the 19th century with the fans on the ceilings. They operated on him and he came through all right. George brought a trailer with him from Portland, Oregon thinking he would use it in Puerto Rico, not realizing how tiny the island was. That kind of discouraged him. He had this dog, some type of Yugoslavian sheep dog, it was like a kid to sun tan, and somebody poisoned the dog. You know all of these things kind of built up and poor George. . . and nothing seemed to go right. So in about a year and a half, George left.

From that point on, then, Dr. Crandell came in and then we got Goodman Everett down as a Compliance Officer. I lost the responsibility of having to do the compliance actions and things became somewhat easy.

I reflect and I talk to some of the people who are still around today, how I ever trained those fourteen people. I didn't. That was it. I just. . . I probably paid no attention, just did the paper work. I don't think I paid any attention to anybody, but they seemed to have gotten trained. Now the program is a little more normal.

But at that time, Region II was by far the leader in FDA, irrespective of what people might think. Bob Martin representing the Region II Director was sent to Puerto Rico in 1970 to reorganize the Health Department laboratory to give them some drug capability. He worked about a year in that job. He did a very good job and FDA worked very closely with the local laboratory people. We trained them and during that same period of time we developed a Memorandum of Understanding (MOU) with the Puerto Rican government regarding drug inspections. We split the drug inventory down the middle and the drug section of the Health Department had responsibility for certain firms and FDA for others. It was rather an historic occasion when FDA Commissioner Charles Edwards visited to sign the agreement with the Governor, Luis Ferre. The signing took place in the Fortaleza, which is a beautiful historic governor's mansion. It is the oldest executive mansion in existence on American soil. It goes back 450 years. There was a real good relationship from that point on, but later on the FDA decided that maybe we don't want to have all these credentials out, people doing our work for us. That was about 1974, so we kind of took them back, and then it started going downhill. We started having our own programs to worry about. Also there was a change in the administration down here. One party goes out and another party goes in, so it's a clean sweep. The Health Department had all new officials.

So when that new party got in, we weren't in the phase of becoming real chummy with the local government at that time but we're back now doing pretty good. Our regular contacts with the Chief Inspector and Chief Drug Inspector and all that, they persevered but we didn't work on a higher level anymore. Before that the Secretary of Health, of course was political here but before the new administration came in 1976 or '74 whenever it was, '76 I guess, so before that we were on extremely good personal terms with the Secretary of Health and that means a lot. The current Secretary of Health, Jaime Rivera Dueno was a former Health, Education and Welfare (HEW) and Health and Human Services (HHS) employee in New York. He was a good

man. He's got so many more problems today. We lost that intimacy we had with the Health Department. That's about eight or nine years now.

To reflect on Mr. Martin's assignment here, he was here about a year and it was to upgrade the capability of the Puerto Rico Health Department Drug Laboratory. The Health Department was somewhat splintered and the chain of command isn't like it is in the FDA. It's kind of like my problem that I have today with USDA. I can try to find somebody in USDA, a unit in USDA, and their sister units don't even know they exist and I can't find people. The Health Department is something like that. After Martin got the laboratory on its feet, to increase the drug capability, a supervisory investigator out of Newark, Alex Labonski, was sent down for a year to do about the same thing to the Puerto Rico drug inspectors.

Part of that initiative included sending a few of them to Basic Drug School in Rhode Island and then running those people through 30-day training details at the San Juan FDA office. In addition, he taught them how to write FDA reports and they wrote and made inspections of the complex drug firms. Now these people were all . . . they had good backgrounds, they were all pharmacists and they had good technical backgrounds and he got them training. This was that entire single system concept that we had and the Memorandum of Understanding (MOU). So he got them trained pretty well. In fact, up until about two years ago, I was still getting inspection reports from one inspector – he finally resigned and went elsewhere and I don't get them anymore. Every time they wrote an inspection, they would endorse them, they may not do a real great job but the information was there and we'd get a copy of the report written in our format on our forms from the Health Department. It was quite interesting.

In fact, one time, it hit the fan. Alex Labonski was a great one for sending out information letters. He didn't send them out. I guess they were called information letters years ago. Before we called them NAR. Our initial aspect of these adverse finding letters.

FL: Right.

HL: Right. So, he had them signed by the Assistant Secretary of Health who was in charge of that unit and he sent one to Eli Lilly. I think he sent it up to Indianapolis. That was the first time they had ever gotten such a letter in the FDA. I found that pretty interesting. Since then, we've given them a few, but at that time they came back and responded whatever the problem was. I don't remember it. That type letter was. . .

FL: That was before FDA generally was sending that kind of letter apprising firms of what we had found?

HL: Before this system was extensive as it is today, but in about 1970, 1971, we were doing it, and I find myself that it wasn't very . . . I'm looking at the food plants now...It wasn't very useful. Send them a no abnormal findings (NAF) letter, they wouldn't do anything about it and you couldn't take any legal action, you sent another one, they'd ignore it, so I got a little more meat in it now. We worded it a little differently. That was just citing and the same thing; tell us what you're going to do about it.

But interesting enough, that era was the time when FDA didn't do any food sanitation work. It was a dirty word. Probably one of the most horrible eras in FDA history. I reflect working here at that time and here I am with a lot of problems and you can't mention insects or rodents anywhere. You can't do any of that work. Some good came of it because we hit the island bacteriologically, microbiologically. We went up and down all the products. We never found any salmonella to date. Our work was all directed towards bacti and never found any serious problems with any foods. Now, that tells you something. So, today that information is. . .we don't do that much bacti work today but I feel pretty confident in certain areas where we don't do the bacti because we don't have any problems. If things are going like they did 10-12 years ago, we probably don't have to do any bacti work in that area. So, we did learn something.

Then when it hit the fan with the project hire people we brought on board to start the sanitation work again, we had a field day again.

FL: But that was not on bacteriological work? That was on rodents and insects?

HL: We went back to rodents and insects again.

FL: Which are problems?

HL: Which are problems, right. So, we couldn't find the microbiological problem which is quite surprising, but we still have the problem. We probably have more problems in that area than almost any state in the union. We've got a 12 month rodent population and a 12 month insect population.

FL: And temperature and humidity that are conducive to growing insects at any time of year.

HL: You take the converse of that, in the drug, we probably have the best organized run drug industry in the United States, no doubt. It is first class, top notch, no money is spared.

FL: New plants.

HL: New plants, new designs, new equipment because of a tremendous tax advantage that the governments get here. In other words, money earned on non-U.S. soil is tax free if you don't bring into the U.S. If you want to build a drug plant in Puerto Rico, the Puerto Rican government will essentially exempt you from income tax maybe for 25 years, depending on where you build

it. So, you've got a period of time when you don't have to pay Federal tax providing you do certain things.

There is another 936 clause or regulation that does require taxes paid on money that goes back to the U.S. in a certain fashion. So, you've got this incentive, these drug companies that come here and we've got about a 100 major companies today. It is the state-of-the-art and the problem I see is not really worrying about them being in a state of control, but having my people trained enough to be smarter than the operators. You know, you've got an international drug firm and they have all kinds of scientific doctorates, Ph.D.'s, lawyers. So, to outsmart them and to get information from them that they are trained not to give us, and to find out if there is some defect because we don't find it in any analysis at a product, that's for sure. You've got to look at the systems approach of the manufacturing. We do find quite a few things. But to get an investigator trained, I've got quite a few trained to do that now. The newer ones, to get them up to that state-of-the-art, because we don't have any middle ground to train them. We've got so sophisticated and we've got so few tiny firms, 4-5, other than that. . . I kind of miss those New York and New Jersey firms that we used to have by the ton up there, that you go in and it is like shooting ducks in a shooting gallery. All kinds of GMP violations. Here we have to look for these esoteric type violations that might have some real significance in the world wide distribution of the drugs.

Many of the firms here manufacture products for world-wide distribution. These being the sole manufacturing point. That is how the tax exemption works. They bring 100% of the production, like Stelazine, Motrin, into Puerto Rico and it goes all over the world. So, we are talking about a problem that is developing and getting out of hand. Not in the United States but the world drug supply. So that takes the bulk of our work today. Fortunately it is a well-organized industry and well controlled and we have a similar type device industry, too. It is the same type of situation with national firms.

FL: Are your device manufacturing firms very large, too, or are they smaller?

HL: No, we don't have the small type device firm, they are all large and they are all this tax advantage and we have Medtronic here, the pacemakers. You take Travenol, Travenol has about seven firms. Seven different manufacturing plants. They make blood delivery systems, dialysis equipment. I think Johnson and Johnson may have nine different plants. Lilly's got about four. Travenol is located in all the mountainous towns. They are kind of scattered. The tax advantage is greater. You get ten years in San Juan with 25 years up in the mountains somewhere. So, Travenol, it is pretty hard to get to their places, it is a long ride, so they use a helicopter. A number of years back we did go with them from time to time. Then one crashed and then headquarters told us, no more helicopter rides.

FL: So, you had better drive to the mountains.

HL: Yes, I got to drive to the mountains. There are a lot of drafts in these mountains here and it is a little. . . The island is a 100 miles long and 35 miles wide. Other than the coastal areas, it is solid mountains. The whole island is one big peak of a mountain sticking out of the Atlantic Ocean.

I mentioned earlier that an advantage presented itself to my returning to Puerto Rico in '69. It wasn't planned, but I did come down. My job was essentially abolished in New York anyhow. At the time I came down that was not known. I know the Regional Director told me that it would never happen, but anyway.

What had happened in San Juan, Denny Miracky had been the Acting Section chief, for maybe two years, and he was a GS-12. The policy of FDA at that time was that nobody would become a 13 unless they were mobile. The word 'mobile' meant working in two districts. Miracky had worked in New York District and in the San Juan Resident office. Even though they were completely different and a complete set of circumstances, they would not listen. It went to the highest FDA authority, the Regional Director or the District Director tried to get the . . . they

would not approve it. So, finally Miracky, in utter contempt, he had been here six years, and in despair, he just took the job at San Francisco. A 13 was offered to him there, he applied for it.

To make matters worse, about six months after this had happened, the Civil Service Commission ruled that FDA's action was improper in restricting GS-13's to a mobility factor. So, it was discontinued.

I kind of slipped in that little void that they had there. They had nobody to put into the job and they wanted the place to grow. There were a couple of other political considerations, too, internal FDA politics. So Miracky went to San Francisco. He is still well known down here. He did a lot work and his name is. . . People, every day, in my operation ask me how Miracky is. Fifteen years ago he left. He retired two years ago.

FL: Thank you for taking the time to record this interviews.

(End of tape 2 – no closing statements)