History

Of the

U.S. Food and Drug Administration

Interviewee: Joseph L. McCallion

Interviewer: John P. Swann
Robert A. Tucker

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Interview with Joseph L. McCallion

July 16, 2007

TAPE 1, SIDE A

RT: This is another in the series of FDA taped oral history interviews. Today, July 16, 2007, we're interviewing Joseph L. McCallion, who retired July 3, 2007, as a Special Assistant in the Office of Regional Operations. His current work was regarding bioterrorism, which we'll cover later. Participating in the interview are Dr. John Swann and Robert Tucker of the FDA History Office.

Joe, as we begin our interview with you, we'd appreciate a brief overview of your personal history, where you were born, educated, and any previous employment you may have had as it may relate to FDA or as to how it may relate to how you joined FDA.

JLM: Okay. Thanks, Bob.

I was born on July 20, 1947, in New York City. I had two brothers. I'm the oldest of three. I attended Catholic parochial schools, both elementary school and high school, in New York City. I attended The Catholic University of America here in Washington as a chemistry major, and I graduated with a B.A. in chemistry in January 1971.

JS: Can I just interject one question quickly? What got you interested in science?

JLM: A couple of great high school instructors. Actually, a physics instructor was very upset that I didn't study physics. Just anecdotal, and I'll make it brief.

My father had gotten to the sixth grade. He emigrated from Ireland in his twenties -- and there's a whole story there that I'm not going to go into -- and in picking out high school courses, my father suggested that maybe, in addition to the academic courses, I might want to take a course in accounting or typing for a job prospect. And this physics instructor, he was a Christian Brother, he looked at my father and he said, "You don't have to worry about his job prospects, and it would be a waste of time for him to take typing and accounting." So that sort of pointed me toward an academic career right there.

As I said, I graduated with a B.A. in chemistry with, at that time, the astounding total of 160 undergraduate credits. You needed 120 to graduate, but the way the tuition worked, it was all you could eat for 160, and I managed to convince the dean to let me take 20 credits a semester regularly. It didn't seem to hurt me.

After graduation, I held several short-term jobs interspersed by periods of unemployment. I worked for a while as a research assistant at Mt. Sinai Hospital in the early '70s doing peptide and protein synthesis. I then had a job at an industrial chemical company in New York City that basically did water treatments for boiler systems and for industrial air conditioners. At that point, I'd been putting in applications for various jobs, mostly large companies, several New York City, New York State jobs, and several federal jobs.

When I was growing up in New York City, the joke about job prospects was that the Irish Nobel Prize was a civil service job, and I guess I got the Nobel Prize because

everybody in my group, an awful lot of people went to work either for the civil service or for the big utilities. Ma Bell was one, Con Ed was the other, and both of them have seen hard days, so I guess pursuing a civil service career was the right choice.

Anyhow, in June of 1974, I was hired by the Department of the Treasury, Bureau of the Mint, at the New York City Assay Office, which no longer exists. The property was sold off in the middle ‘80s and there’s a skyscraper there now. But it was a very distinctive building. It was a five-story building that had a seven-story smokestack, and the smokestack was there to settle out all the fine powders and dust that had precious metals to keep it from going out the window. So when they tore the building down, they actually chipped out the concrete, tore out the rugs, burned the furniture, and recovered thousands of ounces of metal that had accumulated over 60 years.

The New York Assay Office’s main job was to refine gold. It was the last surviving government gold refinery and operated one block south of Wall Street in New York City, on the East River. When I got there in ’74, they were still working with the gold that President Franklin Roosevelt called in, I believe, in ’32. Gold in coinage, in the U.S. eagles, the double eagles, was not pure gold, because pure gold, literally, you can put your thumbprint in. I did it many times. Gold for coins is 90 percent gold -- in the U.S., it was 90 percent gold and 10 percent copper, so-called 90-proof fine.

Gold for international settlement that countries used to settle accounts and to trade on the markets had to be at least 99.9 percent, so it had to be purer than the gold in coins, so we’re still refining the gold. When they brought the coins back in in ’32, as they were collected, they were melted down to form base ingots, and then over the ensuing 40 years, those were all electrolytically refined, basically dissolved the gold in an acid bath,

pass a current through it, pure gold plates out of one side. So we were still refining gold, and as the gold was refined, we had to assay it to mark it for purity, and we would assay it and then stamp the bars and show the fineness of the gold. And, again, the minimum quantity was 99.9 percent, or so called 999 fine. That was the minimum. The target was 999 and three-quarters, and why they had a quarter at the end is beyond me, but it would be 999 and three-quarters.

The way we did the gold, analyzed the gold, was a method called fire assay, which was so modern that our most recent reference at that time was a textbook published in 1906 by the Denver School of Mines. There were many ways to refine gold, depending whether it was metal, whether it was ash, whether it was ore, whether it was scrap, but in general, in a fire assay, you take a certain amount of the test material, wrap it in a sheet of lead, put it in a cup or a cupel, c-u-p-e-l was the word -- I don't think it's common these days -- made of bone ash, preferably bone ash ground up from the upper femur of a sheep. Believe it or not, these were the specifications.

The reason is this cup was very porous. It was basically a powder that you put under pressure and you make a die in the cup, and when you heat the lead and the precious metal to about 1800 Fahrenheit, the lead melts and oxidizes to lead oxide, which is something called litharge. And only impurities in the gold dissolve in the litharge, but the gold and the other precious metals don't. The litharge being melted is sucked into the cupel, and it leaves a little button of the precious metal. After you cool it -- very important to cool it; I saw what happened when you didn't let it cool -- you would take the button out, put it in a little press, roll it out to make it as thin as possible. Then you dissolve it in nitric acid, which would dissolve out the silver and leave the gold, platinum,

palladium, ruthenium, osmium, iridium behind, and then you would separate them out, weigh it all together.

Now, this was all done without instrumentation. It was a pure fire and gravimetric process. The only instrument we had was a balance with the little pans. You've seen the big analytical balances where the pans are about that big around, maybe three inches at most. These pans were half an inch apart, and it was like a miniature balance, and we could use this to get down, on a good day, to a quarter of a part to 10,000 with no instrumentation at all. And even when I left -- and I don't know if it's, I haven't kept up on it, but when I left in '77, even though a lot of companies had developed electronic methods, atomic absorption spectroscopy, x-ray spectroscopy, the referee method, if two labs disagreed, was still the fire assay. It was the absolute standard.

Beside the gold, we also did a lot of the recovery of precious metals for the government. At that time, before gold was re-legalized, the government could not sell gold. So if the government had gold scrap, it could not sell the scrap. It had to contract out to a commercial outfit who would refine the gold out of the scrap, and then the commercial company had to return the gold to the government and then be paid for whatever the cost of the refining process was.

We had submarine batteries, we had torpedo batteries. Once we got a live torpedo and didn't know it was a live torpedo. The torpedo came in on a flatbed parked in the yard behind the building, and the superintendent called up Colts Neck Armory down in New Jersey and said, "By the way, you did disarm that, didn't you?" and they weren't sure, so we sent it back. I never found out if it was live or not. We weren't sure.

Aircraft wings. Certain aircraft had silver coatings on the interior of the wings. I found that was very hard to dissolve, titanium. It took a week and a half to dissolve a titanium wing. Ash from x-ray films.

Once we had some plates, metal plates that looked like printed circuit boards but had nothing but metal on it, and it came from some outfit I'd never heard of before called NSA. At the time I thought it meant No Such Agency. I later learned that NSA meant National Security Agency. And when we were working on it, there was a visitor from NSA coming through to see what we were doing with the material. He saw the plates and had an apoplectic -- he got very upset. He said, "You're not supposed to have that. That's classified!" He grabbed all the plates off the bench and left with them.

They showed up again about two weeks later in drums ground to a fine powder, and then we assayed the powder and there was platinum in it. Apparently, according to the scuttlebutt, it was some sort of coding or decoding equipment that wasn't supposed to have left NSA intact, and somebody screwed up big-time.

Anyhow, after three and a half years of working at the Assay Office, there was an announcement at FDA. I was sort of unhappy at the time. I'd been hired, because of my grades, as a GS-7. At that time you could be hired either at a 5 or a 7 for entry. I had the grades to get me in as a GS-7. And I had got one promotion to a 9 after a year, and then there was a freeze, for fiscal reasons, in Treasury. And there was a freeze on promotions, sort of. It turned out that all the accountants and business managers were promoted, and all the chemists and the technical people weren't, and it became pretty obvious that if you worked for Treasury, you were an accountant or you were not much of anything.

So I and a few other people over the years, there were about four or five people that I know of -- I think I'm the last now -- who all transferred from the Assay Office to New York FDA, I think for the same reasons. But I know Bob Reuss was another. He retired from New York a few years ago. He was a chemist. The other names I can't think of offhand.

JS: But these chemists had transferred, like you, to FDA from that?

JLM: The same building, yes. We were the assay group, and everybody knew who had done that.

Oh, Bob Mackelroy, I believe, was another. He was an investigator. He had been a chemist, but he transferred over. He retired many, many years ago. He committed suicide shortly after retirement. He had family issues which I wasn't privy to.

But anyhow, in September -- actually, the announcement hit the papers in August, I believe, July or August of '77. I put in a response to it and then immediately got a call from the head of the Treasury laboratories, who I met once, saying, "We understand you want to transfer. We understand your promotion's been held up, but we think we can get you your 11 in a couple of weeks if you just hold on and trust us," and I said, "I'm sorry. I put the application in, so the application's in."

I was selected. FDA wasn't that particularly nice to me even though I was a 9 at the time and expected to be at least brought over as a 9. They had their own rules, so they brought me over as a 7, but they brought me over at the top step of the 7, so it was a

GS-7, step 10. It was only a few bucks less, and I had felt fairly sure I'd be promoted in a year, so I took it.

I had one requirement when I was interviewed.

Oh, the interview process was very interesting. This was FDA in its regulatory stance. Ed Rennard was the guy who interviewed me . . .

JS: Who is that?

JLM: Rennard, retired since.

RT: Was Charlie Hermann head of the lab at that time?

JLM: No. It was George Boone when I was there.

But Ed Rennard's interview was pretty brief. He'd known I'd worked at the Assay Office, and one of the things we did there was batched a lot of samples. We did like 50 samples at a shot. And Ed was running a survey lab and he was very interested in people who could do more than one or two analyses at one time. You know, he liked production to go through. So we talked about the lab and about my background.

And he said, "One of the last things to ask you, what do you know about FDA?" and I said, "Well, you protect the safety of food and drugs."

"Our job is to put people in jail, Joe. Do you have a problem with that?"

And I said, "Hey, I'm your man." That was it, and I was hired.

I had gotten engaged about six months before, and the wedding was set for two weeks after, so my anniversary is the eighth of October, and I was hired the first of October, so I said, "Well, I'm going to be taking some time off real soon." That caused a little bit of consternation because it would have been right at the beginning of the six-month training period. But they thought about it and decided to hire me anyhow.

Many, many years later, I found out there was another obstacle to my being hired. It turns out that at that point I had three years, three months' federal service, so I had passed my probationary and I passed my career conditional. They were bringing me on as career, which would have made it extremely difficult to get rid of me if they didn't like my work, and this was a major issue. In fact, apparently, besides the issue of time off for my honeymoon, they wondered, "do we want to hire somebody we can't get rid of," and they took a chance. What can I say?

RT: When you went to FDA, did you get into a different type of analytical field?

JLM: Much different. It was almost like I was back in college again. I mean, they ran us through the beginning. We had to show we could use balances; we had to be able to do titrations, I mean, things that I had done in analytical chemistry in my freshman or sophomore year; had to keep notebooks. Heaven help you if you were found writing in pencil or writing on a scrap of paper. Everything had to be in ink; everything had to be in a bound notebook. I think things have gotten a little laxer in the intervening 30 years. But if you failed to do these things right, you could be written up. If they saw you doing a hand calculation or doing something on a scrap of paper before recording it in your

diary or your notebook, you'd be written up for that. That was a major, major faux pas. So we did several weeks of really basic exercises.

Maybe six weeks after training or so, during the time of the fixed workday, we started at eight and went to four-thirty.

Oh. Let me go back a bit. I got into training before talking about my first day on the job.

We all went down to Federal Plaza. There's a group of seven of us, and there was another group, I'm guessing, of about 20 investigators hired at the same time. This was what was called Project Extend, which was a follow-up hiring to Project Hire, which occurred in '74. Project Extend was meant to continue the build-up of staff.

So we all go down to Federal Plaza, and, oh, there must have been 200 or 300 there from various agencies. It was the beginning of the fiscal year, and I guess a lot of agencies were hiring. In a big auditorium, they explained to us the basic federal workplace rules, the conflict-of-interest rules, what our general benefits, health, pension, etc., etc., were.

Then it came time to take the oath, so they said, "Everybody stand up, raise your right hand, and repeat the oath of office. FDA, you sit down. We can't swear you in." So we sat down. Everybody else got sworn in.

The reason for that was that the head of New York District wanted to do his own initiation of the FDA new hires. The New York Laboratory at that point was part of New York District; later, it split out. The District Director was an interesting individual known as George Gerstenberg, and I'm sure that he's been reported about before.

His appearance was striking, and I am not making this up, an uncanny resemblance to Saddam Hussein. In fact, if you put the pictures of the two of them side by side, you'd swear they were related, and some people used to refer to George Gerstenberg as Saddam's evil twin.

He lined us up in his office, the District Director's office, in a line, single file, and he marched back and forth in front of us. It was sort of like a scene out of "Full Metal Jacket," ranting, raving, telling us he didn't expect much of us, but we'd do what he wanted us to do, that he didn't allow for slackers and you'd better not cross him because you'd regret it, and he ended with the line, "This is my ship and you'd better shape up or ship out, and there ain't no ships leaving." And I remember turning to whoever was next to me at the time and saying, "You know, this might not have been the best career move we could have made."

Anyhow, that was the last time the investigators and the analysts were together, during the swearing-in, and then they had the front half of the office, we had the back. They did not encourage analysts and investigators to talk to each other.

George Boone was the head of the laboratory. Ted Hopes was the head of the chemistry section. And my supervisor was Ed Rennard, and my trainer was Fred Gretch. Fred is still in New York. He is a laboratory director doing pesticides. He's still on board.

JS: I just want to go back to one thing you mentioned, the issue of analysts and investigators communicating with each other. Walk us through a little bit. What was that all about?

JLM: Well, at the time, I wasn't sure. It might have been a certain animosity. Both George Gerstenberg and George Boone didn't like each other very much, and I know George Boone said that an investigator could not enter the laboratory without going to his office first and getting permission to go to the laboratory. There was the feeling on the investigations side -- and I'll get into this a ways later when I transfer to investigations -- that the analysts were a little too free-spirited for the investigators.

I mean, the laboratory was, you know, I won't use the word hippie directly, but it was, you know, jeans, tie-dyed shirts, pony tails. You know, we sort of looked like a college laboratory. And the investigators, primarily because of their management but also because they had to go out and meet the public, were more suit-and-tie type people. The feeling was that the two groups didn't mix well. We weren't given a reason for it; we were just told it wasn't popular to be seen on the other side.

JS: Right. I think what I was getting at here, just aside from the two personalities you mentioned, this kind of issue of having people not necessarily communicate so well to each other, might not be quite all that unusual to be going on.

JLM: Well, and the other thing that was, and I learned this only when I went to investigations years later, the big feeling at the time was that they wanted the investigators to report what they saw in the field; the analysts to report what they saw as a result of the analysis of the samples, and that information was then to go in to the compliance officer, who was to meld it together. A logical reason could have been, I

mean, at some point, if an investigator said that he saw a rodent infestation and collected samples, and then the analyst went through and didn't find any evidence of rodent filth but was told that the investigator had seen, there might be a little prejudgment. But I think it was more just personalities. There was a theory that it was best to keep the two sides separate until the information came in to the compliance officer, but I don't know for sure, it's anyone's guess.

Anyhow, jumping back to where I left from, after we'd done our first six or seven weeks of training, we all started cleaning our desk out at 4:25, and at 4:30 we'd get up and start heading for the door, and Ed Rennard looked over at us and said, "One moment, gentlemen. Please sit. Gentlemen, I just reviewed your training worksheets for the first six weeks of analysis, and, quite frankly, looking at these worksheets, I can seriously say you are all worthless as shit. I'm not sure that we will ever be able to get any evidence out of your work that we could present in a court of law. And he went on and on and on.

RT: Was that the director of training?

JLM: This was the training supervisor. He was a lab supervisor. Ed was not a bad guy. He tended to resort to hyperbole at times.

But he met me later in the elevator going down, and I don't know if he met anyone else at other times. But he turned to me and says, "Joe, you know what I said back there about the work. You know I wasn't talking about you, right?" Now, I don't know if he said that to everybody or what, but Ed was an interesting character. He was

very conscientious but very paranoid. He hated the thought of anybody putting a personnel action against him, which was unfortunate.

We got hired in September, and I have always made it a point of privilege to take St. Patrick's Day off because I usually march in the parade. I didn't march this year for reasons I won't get into, but I've marched for, like, 30 years. I and my family march, my cousins, several of us.

Anyhow, so the week before St. Patrick's Day -- and this is six months after being hired, and we just finished training and were starting to work on real samples. So I put my leave slip in. I had plenty of leave, as I came in with plenty of leave. Ed looked at me and said, "Joe, I know you have the leave, but, you know, we just spent six months training you, and we'd like to get some productive work before you take some leave. I don't think I can approve the leave."

I said, "Ed, you're right. I apologize. Can I have the leave slip back?" He gave it back to me.

In the comment period, where I had left blank before, I wrote down in big letters, "Religious Observance," and turned it back in.

He turned beet red, glared at me like he'd like to strangle me, signed off "approved," and said, "McCallion, don't you ever, ever, ever do that to me again!"

I said, "Eddie, sure, no problem."

The following year -- it was just a joke -- I turned in a "Religious Observance" leave slip, and every year he was my supervisor, I turned one in. It got to be a running joke after a while. But that was it.

Chernobyl. Not Chernobyl, the other one, Three Mile Island, and that would have been -- I started in ’77 -- it must have been ’79, I’m thinking.

JS: Seventy-eight, ’79.

JLM: Seventy-eight, ’79. It wasn’t long after because I was still in his lab. Ed was the radiation officer for the district, and all the radiation officers were told to be ready to supervise evacuation camps – but they never actually evacuated. But if they had to set up camps, they would have been set up. The radiation officers were all told to go home, pack a bag, and be ready to move out. Eddie was not a happy camper. He went around for days muttering under his breath, “I don’t care, they can’t make me go, I’m not going to go, they can’t make me go.” Everybody could hear him muttering, and one of his other nicknames became Three Mile Eddie. He was known for years and years afterwards, long after people forgot about Three Mile Island, he was Three Mile Eddie.

I started out as a drug chemist. I had Evelyn Sarnoff as a supervisor. She was an old, old-timer. She’s still alive, I believe. She’s famous and should be in the annals somewhere. She retired after like 35, 36 years of service, a wonderful person, never married, and very dedicated to FDA, and a real pain in the ass.

JS: No relation, to your knowledge, to David Sarnoff.

JLM: Apparently, she was a distant relative, as she used to talk about the NBC Sarnoff.

She was my second supervisor, and I came up for the worksheet review. I think this has gone out of practice now. But, again, one of the things that was pressed into us working in the laboratory was that we were there to provide evidence suitable for use in a court of law; that everything we did had to be justified, everything we did had to be accurate, and beyond reproach. Since people didn't get to testify all that often, they came up with a "worksheet review."

Basically, your supervisor would select one, two or three, depending on the complexity of your worksheets, and then would convene a mock court consisting of your supervisor, who was there to defend your work; another lab supervisor to attack your work; and then a compliance officer, who would be the judge. In my case, the compliance officer was Bob Applebaum. He retired many -- all these people retired years ago.

So we sat down, and Evelyn, being my supervisor, presented the situation, and the documents were passed around, and Marty Finkelson, who just retired last year, he was the opposing supervisor. He was my devil's advocate. He was attacking me.

He asked a few questions. Marty was a hard-ass. He basically said, this seems like a reasonably good job considering he's been on board for a year. I don't see any major deficiencies here.

Then Evelyn started saying, "But you didn't look at this and this. He should have done this and he should have done that." It got so bad that Applebaum, the compliance officer, had to interfere and said, "Miss Sarnoff, your job is to defend Mr. McCallion, not to attack him."

JS: She was getting treated as a hostile witness.

JLM: Exactly. But she was that sort of a person. She was a very nice woman, but very intense. I mean, she lived, breathed, and, well, she didn't smoke, but lived and breathed FDA.

Anyhow, I went through there. I did drug chemistry, then I went over to food chemistry and did pesticides. I met old-man Weber, the original nose, Al Weber, who was the fish smeller who retired. He must have retired around '77, early '78.

JS: This was out of the New York District?

JLM: Yes, New York District, and his replacement was another Weber, no relation, Tom Weber, who's still there; and Mr. Bob Dick, who was the tea taster, who passed away several years ago. I tried out for fish smelling. I did the two-week training, but I couldn't tell the difference between putrid or decomposed. I could smell the putrid. That was easy, a retailer's dream. But decomposed, in between, sometimes I hit it, sometimes I didn't, so I didn't make the nose.

I never tried tea tasting. I don't particularly care for tea, so I guess I wouldn't have been a good tea taster.

I was just basically on track doing general analytical chemistry and did a lot of pesticide work as well as a lot of chromatography work.

Then in '82, I did import samples, mostly pesticides. Most of the pesticide samples back then were imports. Most of our drug samples were not. I don't think I ever

did an imported drug sample. I can't recall it anyhow. But most of our food samples were imports, and I did a lot of pesticides. Did some filth, but mostly pesticides.

Oh, I have a funny story about imported foods.

During training, one of our training experiences was to check for adulterated olive oil. Back then, a common way to adulterate olive oil was to take pure olive oil and add 90 percent corn oil and sell it as pure olive oil. Some samples were brought in that we used as a training exercise. Sure enough -- I can't remember the brand name; it was a fairly well-known brand name -- and it was 10 percent, by analysis, 10, 11 percent olive oil, the rest was corn oil. So we wrote it up.

I go home that day, and my wife, who's half Italian, half Irish, says, "I just went to this new odd-lot market, and I got this wonderful bargain. I got a gallon of pure olive oil for $18!"

I said, "By any chance, was it such-and-such?"

She said, "Yeah, how'd you know?"

I said, "It's not pure olive oil."

My wife's father was a meat inspector for New York State, so she learned early on what it was like to butcher meat, so it was hard to gross her out, but on occasion she would get annoyed.

In '82, they formed the New York Import District. This was the one of the early attempts to start focusing more on imports. Imports, historically, were the stepchild of the '80s. Imports, on the investigation side – and I know this anecdotally because I was in investigations. I was not an investigator at the time, but it was where they sent people as punishment. In fact, I heard a story of two guys that were sent out. They did

something that the boss didn't like, and he sent them down to the docks for three months, import duty on a rotation, as punishment. And after six weeks, the boss had a change of heart, or he needed some bodies to do something, so he said, "Okay, you've suffered enough; you can come back." They said, "No, we like it here. We want to stay." It drove him absolutely nuts, absolutely nuts.

JS: What was it about import work that people would find so objectionable?

JLM: Well, there were a couple of things. At the time, most of the people doing imports were CSI's [consumer safety inspectors], inspectors as opposed to investigators, and there was a great difference. Inspectors, at that point, rarely went above a 7, or never went above a 7. Investigators went up to 11.

When they hired people, they pretty much picked the better-qualified people to be investigators. Everybody would apply at the same announcement, and then they, you know, during training they say, "Okay, he's okay, he's okay, nah, send him to imports." It was considered lesser work because you didn't testify in court, because you didn't do inspections, you didn't go and look at GMPs. It was considered sort of lesser work. And there were a couple of cases where investigators who came in and were thought to be worthy of being investigators didn't work out. They would be trashed down to imports. And if you had an import inspector who was really sharp and got people's attention, he'd be moved out of imports and moved up to investigations, investigations being domestic and imports being imports.

RT: The work itself, in imports, would that entail going in shipholds and more undesirable places?

JLM: Well, it was dirtier to a certain extent, and you were out in a dock area. This was still, back then, I mean, I actually worked the docks. I worked containers. That doesn't happen anymore. I mean, it's all been mechanized now.

But, again, it was just basically, you know, pejoratively, called sample grabbers. They went out, they grabbed a sample, dropped it, and, you know. How many samples? Oh, you got 20 samples today? Okay, that's okay. You only got 15? Not good. It wasn't a question of doing in-depth investigations.

I wasn't privy to the reasoning behind the formation of the Import District. I'm not aware that we had hearings or that there was any hue and cry or any public outcry, but somebody somewhere started that idea, you know, maybe we need to look at imports a different way. The New York Import District, I think, to the best of my knowledge, was the first attempt the agency made to set up a dedicated unit to deal with imports.

Joe Faline, who had been a, I believe he had been the DIB [Director, Investigation Branch] in New York District. The Director of Investigations was made head of the Import District, and that immediately set up a rivalry between him and Gerstenberg. Before, he used to work for Gerstenberg, and now he was co-equal with Gerstenberg. They didn't always get along.

Ed Rennard, who had trained me, became the head of the Laboratory Branch for imports. Charles Cardile, who is currently a consultant, and who had worked in the laboratory, was selected as the head of the Investigation Branch, because imports was set

up as a whole district. We had an Investigations Branch -- that was Cardile; the Laboratory Branch was Rennard; Kenny Klein, who retired recently, was head of the Compliance Branch, so we had all three branches. Willis Ward was the Administrative Officer.

I don't know what the feeling was on the New York District investigation side about the Import District, but I know on the laboratory side, George Boone, who was head of the laboratory, was very upset that he was losing about a third of his staff and facilities, because they actually dedicated certain rooms just for the import laboratory. It was the same laboratory complex, but certain labs were set off. He was heard to say that he didn't think it was going to work out because people were going to have to be drafted into doing imports and they wouldn't like it, and maybe their grade wouldn't be supported. Maybe if you were only doing import samples, you couldn't support a GS-11 grade, and he gloomed-and-doomed, nobody's going to want this, blah-blah.

They needed 30 people to voluntarily transfer from the laboratory. They got 31 applicants, mostly to get away from George Boone. The nickname for the laboratory was Boone's Farm, and he ran it like a plantation.

I was on temporary detail as Administrative Officer to him because he was, as part of the Import District being set up, the New York Regional Office being spun off out of the District, the New York District was originally the lab, domestic and imports, and after reorganization, the laboratory became the New York Regional Lab as a separate structure, and imports became another separate district: one became three, and he was trying to set up an administrative type operation, which he'd never had before, so he detailed; I served as the second administrative officer on detail. Halfway through my

detail, he called me in and said, “Well, we just got the word. We’re going to have our own administrative officer, but it’s going to take 60 days to get an announcement out. Would you extend your detail?” I said, “Well, George, I’d consider doing that, but you should know I applied to go to the Import District.” There was like dead silence for like 10 seconds. Then he just looked down and started shuffling things, “Okay, okay.” Afterwards, I was told I had flunked the loyalty test.

I am not going not into personal stories, but George and I had a rotten personal relationship. I won’t go into personal stories in detail, but I will tell one actual story about George Boone. This is not a personal because I wasn’t personally involved.

Bob Dick was the tea taster, as I said, and it was just two days after I became Administrative Officer when I got a work requisition completion notice from GSA advising that they had come in to fix the dishwasher, because the day before, there had been the annual tea-tasting session. They’d gone through hundreds of cups of tea. The dishwasher had broken down, and Bob Dick had called for an emergency repair. I went back to talk to Bob and find out what the details were, and he told me, “GSA saved my butt. This tea-tasting session would have collapsed if I didn’t get it fixed right away.” I said, “Okay, no problem.”

So I go ahead with the day’s stack of administrative work to George, and he’s going through them one by one. “Joe, what’s this?”

I said, “Well, Bob Dick had to have an emergency repair on the dishwasher done late yesterday afternoon. You weren’t in, but GSA came up and they fixed it in time for the tea tasting.”

He said, “Oh, okay, okay. So, is the work done?”

I said, “Oh, yeah, yeah.” I said, “Bob Dick says it’s fine, it’s fine. He says he’s very happy he got it done.”

He says, “Joe, you know, on this 393 requisition order, I don’t see my signature on it anywhere. I’m not paying for it.”

I said, “George, it’s not like the GSA is going to do another emergency repair without authorization.”

He says, “I don’t care. I didn’t authorize it. It’s not coming out of my budget.”

True story.

Anyhow, you can excise that if you want, but you should know it was a true experience.

Anyhow, beside the Import District, then, after I told George I was doing Import District paperwork too -- and I’d only put my name in at that point because it had to go up to Personnel and they could theoretically say, “You couldn’t go.” But everybody went.

About two weeks later, George is out. John Hardy, a very nice guy, was head of the Micro Lab. He had hope for the two people directly under him. To put it in context, John is a black man, just so you understand it, basically the context. He comes around with a personnel notice and I see it’s New York Regional Office, and I open it up. It says, “Your request to transfer to the New York Import District has been granted. As of such-and-such a date, you will be assigned there.”

So I looked at John and said, “Thanks, John. I guess this is my Emancipation Proclamation.” I expected him to make some comment. It just went right over his head.

But that's exactly the way we felt, going from George's unit to Imports, because most of us, I mean, a good third of the lab happily left. He was a very difficult person.

Many, many, many years later, I had gone to a meeting, and Burton Love was there. Burton Love had just been asked to gather some people's thoughts about the direction we should go on imports. This was after 9/11, after we did all the bioterrorism hires. He said, "You mind talking about your experience in imports and ways we can change the program?"

I said, "Sure, why not?"

So we had a couple drinks. And at the end, he took his book and he put it away.

"Joe, there's something I've always been wanting to ask you," because when I came to headquarters, Burton was just leaving to go to Chicago as the Regional Director. He had been the head of DFI, Division of Field Investigations. And I came in to work in Imports, which was a branch. He actually signed off on it. But I came in, and two weeks later he left, so we never had a chance to really have a discussion. This is like 10 years later, you know, we finally had a chance to have a talk.

He says, "I have one question. Did you people in New York think George Boone was as a big an ass as we thought he was here at headquarters?"

I said, "Boy, could I tell you stories."

All the time in New York, we thought Boone did things that he had to have backing from headquarters, and apparently he was one of these guys that was in a position, they couldn't do anything about him. He was just put there and they tried to ignore him.

Anyhow, enough George Boone stories.

Well, there'll be one more, very short, when I get out of this.

The New York Import District was my first real introduction to imports. I was still a chemist; I worked in the laboratory. But they were perennially short-staffed, and because most of the investigational staff was CSI's, they didn't have CSO's [consumer safety officers]. They didn't have some of the analytical skills that the CSO's would have, so a lot of people from the lab got drafted out to do details either in investigations or in compliance.

So I managed to get one and that's when I first went out on the docks. I first took samples and went out there and opened containers. I did details in Compliance. This was when I first really got involved in imports.

The big case at the time was the Amex Chem case. At the time, there was an ongoing problem with unapproved veterinary drugs. People were bringing veterinary drugs into the country in bulk and then distributing them out. In other words, it wouldn't get sold to the end user because the shipment might be too big for the end user, so middlemen were set up to bring in the product to warehouse and then to sell portions off to various firms that actually used the product. Because these things could not go to non-holders of approved applications, New York set up a mechanism whereby every time a portion of the shipment was sold, the middleman, the guy who imported it, had to send a copy of the purchase order of the firm it was going to, and then we would check that firm and make sure it had an approval to use the product.

Well, what happened was this one character, Heinz Dall, decided he could make more money selling it to the unapproved users, and to get around this checking, he started Xeroxing purchase orders. In other words, he would take a legitimate purchase order that

he had submitted for going to an approved holder and show they received the product, and then he would photocopy the top of it and then type in more information and sell it. And this went on probably for about two years, I'm guessing.

Then a really sharp guy, Jim Nelson, who, like me, was a chemist, would come over to the Import District while doing one of the periodic details. We all did periodic details in Compliance. He noticed that the typefaces didn't look quite right. He happened to be going through a file, and saw documents that just didn't look quite the same. There were discrepancies in the typeface, etc. So we started doing some digging and we uncovered the plot. That was the first big criminal prosecution in Imports that I am aware of.

It involved the company Amex Chem. There was an outfit out in Kansas City. There were several seizures made. This was before the formation of OCI [Office of Criminal Investigation] by quite a while. But a number of the field investigators who worked on it ended up moving to OCI when OCI was formed. So that was my first time I testified. It wasn't for the prosecution per se, because I had come on a little later, but in a subsequent seizure of the product, I went out to Chicago and had to testify in the seizure action. During the testimony, it was funny, but the judge who was presiding over our seizaure action was also handling a big Sears discrimination case going on at the same time. He was hearing the Sears case during the day and the FDA seizure case at night, doing double duty. The judge was a little frazzled at that point.

At some point, I forgot what the exact question was, but the defense attorney, the guy for Heinz who was contesting the seizure, asked me a question that I, for some reason at the time, didn't think was a valid question, but the U.S. attorney wasn't

objecting to it. So, having heard this before, the testimony, I started to question the question. I said, "Well . . ." I forget what it really was. I mean, it's been a long time.

It was something along, "Well, when you detain a product, does that mean that it's stopped?"

And I replied, "Well, it all depends what you mean by detained. If you mean this or this . . ."

And the attorney turned to the judge and said, "Your Honor, will you admonish the witness not to quibble?"

And the judge looked at me over his glasses and said, "Mr. McCallion, I won't admonish you, but you could be more direct in your answers."

By that time, the U.S. attorney woke up to what was going on and objected, and the whole line of questioning went out.

RT: How much product or value was involved?

JLM: Oh, gee, I have no exact recollection.

JS: You said over two years, so it must have been an enormous . . .

JLM: It was, yes. I couldn't give you a dollar amount. Let me see, the case broke, the case must have broke about '84. This did not occur until two or three years later, by the time the seizure ends, way out. It might have been half a million. I really can't say.

RT: So the seizure was in New York District?

JLM: No. It was in Chicago because that's where the goods were. The goods were out in the Midwest someplace, so that's where the seizure was filed.

RT: I see.

JLM: That was my first court testimony.

JS: How did things end up?

JLM: Oh, we won. We got the seizure. The seizure was upheld, and the goods were destroyed. I think Heinz put in two years in jail. But, again, that was the prosecution, which was a separate case.

JS: Heinz Dall.

JLM: Dall, yeah.

And things went on pretty much in Imports after that.

That's when I first started looking at automation of imports. We tried to do some local computerization of import data, but, of course, it was too big to do. This was when imports was strictly a paper record basis. Well, let me talk about the paper process in a second when I get to the automated system.

Just talking about New York, back in, let me see, about ’86, the great experiment ended, and it folded us back into the District. And myself and one other guy, Neil Bisciello, who’s also retired since, both went to Joe Faline and pointed out that we busted our butts for him for four years, and we really didn’t want to go back to work for Boone, and he owed us something, and we wanted to transfer, at that time, to Investigations, because he became District Director.

When they folded the Import District back in, Faline, who had been head of the Import District, became the Director of New York District. Gerstenberg, who had been the Director of New York District, was transferred out to Los Angeles and became head of Los Angeles District. So we figured, by Faline going back, as the DD, he could do something for us.

JS: Just one quick second.

JLM: Sure.

JS: Why did they fold the Import District back in?

JLM: Don’t know. The decision was made here at headquarters.

Part of the problem was, I think there was a general realignment. There were several district directors. I think that there might have been several reasons. There might have been personnel issues. I think the driving force could have been the fact that they wanted to get Gerstenberg out of New York. If they moved him to L.A., that left the

whole of New York and they had to find someone to fill it. Faline was in place, and there wasn't anybody really ready to take over imports. That might have been part of it.

The other part was, well, it was interesting, but why should New York be different than anyplace else? Every place else doesn't have a separate Import District.

JS: But New York probably handled as many imports as any site.

JLM: It did. Well, as big as L.A. It was always back and forth between New York and L.A. as to which was the biggest. And various places had little, they had branches within the division, district, but they never had a complete breakout center.

So, again, as to the actual reason why, I can surmise it was a combination of things, but I don't have any inside information on that.

Again, I was still down in the ranks; I wasn't even a manager at this point. I was pretty far down the totem pole, so that information didn't come in to me.

The only thing Faline said to us was that the word came out of Caesar Roy, who was the RFDD [Regional Food and Drug Director] at the time: had decided that everyone who left the laboratory would go back to the laboratory, no exceptions. That's why we referred to it as repatriation, like after a war. You all go back. But Faline said if there were any openings in the District, they would consider it.

So I was back into the lab about a year, and I was working at my bench doing a titration of something or other, and I hear this noise like someone is standing behind me in the lab. It was Faline. How he got by Boone, I don't know, but he was standing back behind me.

He said, “You still want to be an investigator?”

I said, “Yes.”

He says, “Well, we have an opening, but you’ve got to go talk to Jerry Woryshner,” who was then the DIB. Faline was the DD, and Woryshner, who later became the DD, was a DIB at the time. “You’ve got to go back. He’s got to hire you.”

So I said, “[unclear].”

Worsyshner, you know, he knew me as a wiseass lab type, and I knew him as an old-fart investigator.

So I go to see him in my jeans and my sweatshirt, with a beard, and I say, “I understand there’s an investigation job. I’d like to put in for it.”

“Put your papers in – but you’re a lab person.” This is Woryshner.

I said, “What do you mean by that?”

He says, “You lab guys, you go out, you do your work, and you turn it in. You’re too independent. I mean, I like someone who keeps checking with the supervisor, doesn’t work independently.”

I said, “Look, Jerry, I’ll do whatever I have to. Want me to shave? I’ll shave the beard. I’ll do anything you want.”

He then said, “Well, all right, if you cut the mustard.”

One of the problems was, at that point, that I had gotten my GS-12 in the lab as a drug specialist, and they would have brought me back as a GS-12, and no one had ever gone back, departed from the laboratories to investigations, as a GS-12, because as a GS-12, you’re already a specialist. You’re supposed to compete for that.

The person I was working for, Regina Feuchbaum, who was my supervisor at the District, Investigations, had also come out of the laboratory, but she came out as a GS-11, so it was great. There was a little hard feeling. You know, some of the investigators weren't happy about seeing them take someone out of the lab and giving a GS-12 as a lateral instead of promoting an investigator into that position. But they got over it; I got over it; we all got over it.

So I went back to Investigations. I had to go through training again, though I ended up shepherding the other trainees around. They put me in charge of the other trainees because they couldn't be bothered, if for no other reason than I'd been around for 10 years at that point.

I finally got to take the law course, which at that point they wouldn't give to the laboratory staff. You had to be an investigator. So I got signed up.

I remember hoping to go out to Bandero, Texas, one of the nice places. I was out on leave. My second daughter was born, and while I was out on two weeks paternity leave, they signed me up for the law course in Buffalo, in July. Thanks a lot!

Anyhow, I go up to the law course. Mundis was giving the law course at the time. I forget who the other two were.

JS: Fred Lofsvold

JLM: Yes. Who was the little guy? There was Fred, and who was his buddy? That's the name I couldn't remember. He was a stamp collector. He worked in the OE [Office of Enforcement]. He was short.

JS: Oh, yes, I know who you mean, Howard Schloss.

JLM: Those were the two. It was Lofsvold and Schloss.

JS: Yes. He was in FOI [Freedom of Information].

JLM: No, not FOI, but in the Office of Enforcement.

But, so we go out for law training. Marge Hoban, who I'd never met before, ran the course, and she took a whole group, mostly investigators, one or two other people, like me. Well, I was an investigator then, but, you know, long term, in the course, she took this totally disparate group and united us, because we all hated her after the first 20 minutes. That's when I first came to know Marge the Sarge. She read us the riot act at the first nightly meeting, what we could do, what we couldn't do, and how fast she would ship us back to our district if we screwed up. So that was interesting.

I really enjoyed the law course. It was probably the best course I ever have taken at FDA. I got a perfect score on the exam. I am told that there was only one other perfect score a couple years later, and that perfect score was after an answer was changed to allow the two answers because the question was poorly worded. They gave credit for two answers, and that's how the other perfect came about.

They sent a letter to [Arthur] Beebe, which I still have -- actually, it's in my personnel file -- congratulating me. Woryshner, who didn't want to hire me six months before, grabs me, walks me around to all the compliance officers in New York District,

saying, “This is Joe McCallion. He came out of the laboratory six months ago. He got a perfect score on the law exam. He’s going to have your job someday.” Needless to say, all the compliance officers loved me after that.

I did about a year in inspections, a couple of drug inspections, GMPs [good manufacturing practices], a couple of, worked on one seizure, which fell through because the guy voluntarily destroyed it before we could seize it, which I thought was fine, but Regina Feuchbaum was very upset that we didn’t get the seizure because the owner had gone ahead and voluntarily destroyed it. I thought, what’s the difference, but at that point you were counting marks.

I got my big break, probably the biggest break I ever got, in the fall of ’87 -- let’s see, I’m trying to think. There’s a mistake on that date because I started at JFK in March ’88, and the thing I sent you said March ’87.

JS: It said ’87.

JLM: Yes, because there’s two ‘87’s, and there was a typo there. Yes, that should be ’88.

Rich Peccora, who was the closest thing to Joe Faline’s son, although he had daughters, he had no sons -- but Joe doted on him, and Rich was set up to take over when they were setting up a resident post at JFK Airport, the first import-designated resident post. Peccora had some financial issues that had to deal with, he was buying a house at a bad time and got screwed by the builder. He needed money in a hurry, and resigned to

go work for Chuck Cardile, who had left years ago, as a consultant. He went to work for Cardile after leaving FDA.

TAPE 1, SIDE B

JLM: Joe tried to get him to stay with the others, but there was no way he could boost his salary enough to make up for what he needed.

So Peccora left, and Faline was looking around for somebody to take over the Import resident post, and everybody who's doing imports, just about, everybody from Imports at that point was a CSI. I had been a year or so in Investigations, and seemed to be doing a decent job as an investigator, and as they wanted a CSO to run it, bingo! I became the resident-in-charge. I mean, I don't fly. I think there were three applicants. I don't think they read the other two. With all due respect, I don't think they read the other two applications, because if you look back at what I had done in imports during the Import District, I forget, I had the grade because I was a GS-12, the job was a GS-13, you know, grade counts. So I got to run it. That was an interesting experience.

It started about three o'clock in the morning in April, on a Saturday -- no, two o'clock in the morning, a Saturday morning in April. The phone rings. I'm half asleep. I pick up the phone. It's Faline. "They're dropping off the office at JFK in 15 minutes. Be there," click, because we didn't have an office. They had rented one of these mobile trailer type things as an office.

So we had to get there. Of course, it was too wide to get through the gate, and then we had to call somebody from airport security. They had to pull the gate posts up. Then they had to turn it.

Actually, it was a trailer parked inside a hangar, because that's the only place they had the utility outlets. So it was this huge vacant aircraft hangar, Hangar 77. I still remember it. We had a trailer parked in it, and it was perpetual night because there were no lights. The only light came from the doors.

RT: That was an office rather than a mobile lab?

JLM: It was an office, yes. There was no lab. We had no lab. It was exactly like you see at a construction site. We had a toilet you couldn't use because it wasn't hooked up, so we'd use it to store supplies there.

Five of us were there, with a window. The brokers would come up, they would drop their papers, people would go out and do their assignments. We couldn't get away with driving in because the back of it was parked right on the tarmac, and you would have to drive right out on the tarmac. In fact, I had one investigator who wanted me to get PONY [Port Authority of New York] plates for the government cars so we could drive on the tarmac, and I said, "Yes, I'll get a call about you racing a 747 one day. No, I'm not buying, getting the PONY plates."

It was cold in the winter and hot in the summer. The air conditioners never worked.

But, again, it was the first full post we had there.

We were in the trailer for about a year. Then we moved to an office when they got offices, an office site just on the airport proper but just off the cargo area. That first Christmas would have been the Christmas of ’88.

I got a call from Faline saying, “I’ve decided to give everybody the day before Christmas, give everybody half a day off, so tell everybody they can go home.”

I said, “Thanks, Joe.” I said, “I guess I should call the brokers around, tell them not to bring any papers in.”

He said, “I didn’t say I was closing the office.”

I said, “But you said send everybody home.”

He said, “Yes.”

I said, “You mean I get to stay?”

He said, “Yes. Merry Christmas, Joe.” Click.

So I was there till the end of the day pulling papers.

I’m still going to hold off on the import data process till we talk very specifically about it.

But the next step, there were openings -- and I’ve always wanted to work at headquarters. My kids were getting older. My oldest was in first grade, and we were in a very small house. It was time to look around, and there was an opening here at headquarters. Jim Lyda was the head of Import Operations, and there was one opening there, and I put in for it. Virginia Mahady, who was Commissioned Corps and a Compliance Officer in New York, also put in for it. They liked us so much, they took both of us, and we both came down to Imports.

I arrived in October ’89.

JS: This is the Import Branch?

JLM: It was the Import Branch of the Division of Field Science.

JS: Import Operations Branch.

JLM: Right. It later became a division on its own, but not then. That was down the road a bit.

When I got down here, the first thing they were just starting was to set up the automated import process. Well, some people wanted to do it. There was a very small group, like three, who thought we've got to get away from paper. We were getting, at that point, on the order of a million entries a year across the country. It was all on paper. And what districts would do is they'd get the brokers to either mail or carry the invoices in along with the forms. There were various multipart run-off forms that were used for various operations. They'd be looked at one by one, and if something caught your eye, you might go look at another reference to see if we should be doing something, or there'd be lists or cheat sheets. You know, if you see cashews from India, take a sample or something, but it was very ad hoc. And people started to think, well, maybe we should be looking at some sort of an automated system. But, again, we were starting from scratch. We were still using punch cards at that time for PODS [Program Oriented Data System].

Customs had started an automated system back in the mid-‘80s, the Automated Commercial System [ACS], which was supposed to have been retired in the mid-‘90s, but the replacements were a little slow coming, so they’re still running it. They hope to have it retired by the end of the decade.

Now, the real driving force was a Customs commissioner, Von Raab. What was his first name? I think it was Charles Von Raab, two A’s, who apparently -- I never met the man -- talking to people in Customs, was a real son-of-a-bitch. He was so upset that someone in Customs might harm him that he disarmed all the Customs offices at headquarters. Before he was Commissioner, Customs officers would actually carry their sidearms at headquarters. When he was Commissioner, he took them away. To this date, Customs officials don’t carry sidearms (at CBP HQs).

Once Customs, during the reorganization of DHS, when Border Patrol became part of Customs and Border Protection as one agency, they’re still carrying their sidearms. In fact, at Customs headquarters, the guys, the really heavy-duty uniforms with the sidearms are the Border Patrol people, so they carry them even at headquarters.

But anyhow, Von Raab was a very irritating and annoying person, apparently, never having met him. He decided that one of the holdups on . . .

You know, Customs has gotten to the point where 70 percent of their entries are automated, which is really great. And the 30 percent that weren’t automated were all FDA entries. And he wrote a famous “Automate or Perish” memo to FDA in, I believe it was the end of 1988, basically saying, since FDA has shown no interest in automating their import system, as of January 30, ’89, Customs will no longer collect entry

documents for FDA nor will they forward entry documents to FDA, that we were totally on our own.

RT: Who was the FDA Commissioner at that point?

JLM: It was before [David] Kessler.

JS: Probably Frank Young.

JLM: Yes, it might have been Young.

JS: Nineteen eighty-eight.

JLM: Yes, I think it was Young.

RT: Because that decision would have been at the highest level.

JLM: It wasn't discussed. Customs didn't invite conversation. It was an ultimatum. It was an ultimatum.

Now, entreaties were made to Congress. Some congressional folks called on Von Raab. It was postponed under the assumption that FDA would start working on an automated system.

Originally, it was the FDA-Customs interface, because we were actually going to have two sets of terminals. We were going to have a Customs ACS terminal, and we were going to have an FDA terminal, and the data would come in on the Customs terminal, and we would stand over here and type it into the FDA, and back and forth, back and forth. The interface would have been the individual.

That pretty much, once they figured out the logistics, didn't work. Then it was renamed the EEPS, the Electronic Entry Processing System, which would take the electronic data that Customs received from the brokers or from the trade. Based on something called a tariff code, it would determine which products were FDA regulated, and then it would split off that stream of data to the FDA system. So FDA would not have to look at the Customs system. It would all be internal. It would just come off.

It was a very rudimentary system. It only screened on a few elements, and it didn't have any internal tracking. It was basically just a one-way mailbox. And that's what we set up in -- I'm trying to think of the year -- '91, I believe. We piloted that in Seattle in October of '91. It was a three-month pilot.

JS: On the resume you sent us, you mentioned March of '90 that you were assigned to work on an electronic input system.

JLM: Right, right. It had already been started before. I didn't initiate it. I came. There were Dennis Linsley, Steve Kromburg, Howard Kawazoe. Who was the big guy from California? Lloyd Lehr had been working on this for about a year and a half when I came on.

I came on basically, they were working on the internal part that FDA would be processing. My job was to deal with Customs. Prior to me dealing with Customs, Mary Ayling was really the first Customs Liaison, but she had dealt more on operational matters and not the electronic process. She did issues for the current reports, coordinating activities, but not so much the electronic process.

I started off on the interface project as dealing with Customs and getting them to get their system to give us what we wanted. It was basically negotiating, we ended up negotiating an MOU [memo of understanding] that was signed by Commissioner David Kessler in '92, I guess, by Kessler and whoever the Customs -- I think it was Hallett, in Customs, Carol Hallett was the Customs Commissioner at the time.

Then, once the interface project came into fruition in the mid-'90s, I took on general customs liaison. It wasn't just electronic interface that I sort of grew into, because Mary was stepping out of it at that point because she had gone out to L.A. as the Director of Imports for Los Angeles District.

But back to the interface project.

We started up. Gary Dykstra was the lead person on the FDA side. He was Chesemore's deputy at the time. The guy on the Customs side was a guy named Bob Ehinger, who was really the father of their electronic system. And we set up a pilot program.

The first pilot was in Seattle. Again, it was the fall. I'm thinking October of '91; it could have been '92, '91 or '92. It was a three-month project when we started out. The brokers were moaning and groaning because they were having to type in all the data they

used to give us before on Xeroxes. They would just Xerox an invoice. But now we wanted details.

The Customs descriptions were not as detailed as ours. Customs would quite often take foodstuff or fresh vegetables. We wanted more than that. We needed an FDA product code, we needed quantities, we needed manufacturer information, so they were having to input all this in. So the brokers were moaning and groaning about how terrible it was and how they wouldn't do it. It was voluntary at first; they didn't have to do it. And we got a couple of brokers on, then a couple more came on, a couple more came on.

The advantage to the brokers for the effort in doing the input is they were getting turnaround in 15 minutes. Well, when the system started working right -- it took a while to get the system to work right -- but when the system finally started processing, anything we were not interested in, they'd get a response back in 15 minutes. In the old days, it would take them three to four days because they'd either have to mail or hand-carry it into an office. That would go from one office to another. Somebody would review it. They'd bundle it, they'd put it back. The broker would have to pick it up. So, three- or four-day turnaround was normal.

JS: Just a second. Let's turn this off. I know it's going to stop soon.

RECORDER TURNED OFF

TAPE 2, SIDE A

JLM: So, after we explained to the brokers what they had to do for the electronic processing, they complained that this was a lot of effort on their behalf, they'd have to hire extra staff, and this was not a good use of their resources.

At the end of three months, we had the data needed to go on to the next stage, and the idea was we were going to shut the system down and then expand it and bring it up in two years nationwide, and the brokers went ballistic. They refused to let us shut it down. They went to Congress and said it would kill their business. Even though no one else in the country had it, they were saying it would be a hardship on them to shut down the system, and they basically . . .

And I believe, again, my memory is a little soft here, but I think I actually went to Representative John Dingell, and I think Dingell, at the time, was still in power. I think that was the end of the Democratic run, or maybe not. There was still a couple years ahead.

JS: Around '95.

JLM: Yes. Dingell managed to convince us to leave the Seattle pilot up and running while we developed the rest of the system. It caused us a little bit of difficulty because at one point we had to maintain a system that we had been planning to shut down while we were developing the next stage.

Again, this was a real simple system. It was a one-way mailbox into us to get the results, to get the modus of entry and minimal messaging back. Basically, if the broker didn't get a "we're not interested" message, he had to wait for paper, so it was a very

limited system. It was literally the two tin cans and a string between, but it was still something that they didn't have before.

JS: But it was on the way to becoming a paperless . . .

JLM: It was, and it was paperless to the point that as long as we were not interested in sampling the product, it became a paperless system. But anytime we decided we wanted to sample it, then they had to submit paper. And that was EEPS, the Electronic Entry Processing System.

What we were moving towards was ISIS, the Import Support Information System, and that was a much more robust system. One thing, it would support all FDA actions. In other words, it was paperless for 99.9 percent of the entries. The only time that we required any paper was when there would be a certificate or something that might have to be submitted separately. But irrespective of whether FDA was going to sample it or release it, it still put low paper burden on the brokers. And it was more than that. It was a full tracking system for FDA because it allowed us to interface with our other databases so that the information we got in didn't just sit in the system, but actually transferred to LMS, the Laboratory system, and to the Compliance system.

There were several ups and downs. We were using a small contractor whose name escapes me at the moment, but it was a small, six- or seven-person shop. They were perennially late in making deadlines.

After the pilot was over, Gary Dykstra sort of handed the whole project over to Frank Flaherty for the full state. Frank Flaherty had worked in medical quality, MQSA,

whatever that acronym was, and that was, I think, being handed over to OE or phased out or something. Frank did a good job.

Frank was an excellent manager.

JS: Also from New York, right?

JLM: Yes. Newark, actually. I think he was from Newark.

An effective manager, a very effective manager.

If you remember the Ninth Beatitude, "Blessed are the slave drivers, for they get results," that was Frank. He got things done, but he ruffled some people.

I personally got along with him except for one occasion, which I tried to get over, but a lot of people had difficulties with Frank. But I think he did a good job; he got things done.

But as a result, ISIS at some point had gotten a lot of baggage around it, so they did what happens all too often, they changed the name to OASIS. It was essentially the same system, but they just changed the name, the OASIS being the Operational and Support . . . No. OASIS, Operational and Administrative System for Import Support, which is what it is today. That expanded out nationwide by the mid-'90s, and went fully operational by '97. And so, to this date, when we get questions about import data before 1997, we only report the data back to '97. The data before '97 is spotty in some district, but not in all.

There's not much else I can really say about -- OASIS now is in the process of being remodeled into MARKS, which I'm not all that familiar with. It has to take into

account the new Customs system, ACE, the Automated Commercial Environment, which is replacing ACS. But these are really refinements. They're not like the original system, which was a total new system in comparison.

JS: Forgive me for asking you to repeat yourself here, but these transcripts are usually seen by people who know nothing about, or barely something, but not the details. Could you just summarize the type of data that we're seeing through this information system, what we're doing with it, and what's triggering us to respond in a more enforcement-minded way?

JLM: Right.

Again, the data that gets sent in – and this is going to change in a minute when I talk about the bioterrorism, which put another face on it.

But in OASIS, which applies to all products, not just food products but all FDA-regulated products, we get a copy of the data that goes to Customs for FDA-regulated products, with additional information such as the product code, the manufacturer, any information as to NDA [New Drug Application] numbers, the low-acid canned food, the FCE [Food Canning Establishment] numbers from the process filing information. All this information further identifies the manufacturer of the product to a greater depth than does the Customs data.

This information, again, gets transmitted by the Customs system to the FDA system, and then it hits against the FDA internal screening criteria. Those criteria come from multiple sources. It comes primarily from our import alerts, where we've identified

previous problems with products. It'll also hit against sampling criteria based on Center-derived programs, annual compliance programs, etc. It basically tells the entry reviewer on the screen what the compliance pattern of the product is, and will either identify something for examination or for release.

Post mid-'90s, I was, again, one of the two or three senior staff people in DIOP [Division of Import Operations and Policy]. I, at that point, under the tutelage of Marvin Bloomberg, who also retired a few years ago, I really got some in-depth instruction on personal importation.

Personal importation is one of those things that a lot of people know about it, but not a lot of people know the background of it.

If you look at the Food and Drug Act, Section 801, it's pretty cut-and-dry. If a drug product is unapproved or, in the words of 801, in violation of Section 505, it shall be refused admission. There are no exceptions. Obviously, people do travel with personal amounts of drugs. As far as we can tell -- and this is anecdotal -- the agency has never objected to travelers bringing in product for their use when they're in the United States. If you're visiting or you're a tourist or whatever, you may have a drug that's either not available in the U.S. or, if available in the U.S., you have a different version of it. So that's always been permitted, at least anecdotally.

JS: I just checked our precedent file when Bob was picking you up, and I saw a card from 1958. We put this policy in effect that, yes, unless there was a substantial problem, if somebody's carrying a drug product into the country, we didn't interfere with that.

JLM: The only exception would have been if somebody was bringing a quantity well in excess of normal use or it was something that was either a very dangerous or perhaps something like a narcotic that we might refer. But you're correct. I mean . . . But, again, this is lost in the mist of time somewhere.

The big change in personal importation occurred in the late '80s with the AIDS or the HIV epidemic. At that point, there were many drugs being tested around the world which showed some promise for treatment of AIDS which either had not been introduced in the U.S. for testing or were undergoing tests and the results weren't in yet. The AIDS activists, for lack of a better term, basically argued that they were under a death sentence and they needed a chance to try even the unapproved drugs because there was no effective treatment.

Frank Young, who was Commissioner at the time -- and I'm thinking this is probably around '89. There may be a file on it somewhere. Dr. Young had a meeting or he attended, I should say, a conference on HIV or an AIDS conference. He gave a speech in which he basically said that he wanted to give hope to the hopeless, or words to that effect, and that as long as there was no immediate and obvious risk to a product, that FDA would not object to people bringing in products for their own use. And this went through a couple of iterations, which were finalized around 1992.

It's interesting because some of the older ones are still on the Web. They're posted by various Internet drugstores because the older versions were more general and more lax. And in a couple of the cases where I've had to testify, they'll actually bring up the previous version and not the final version, and say, "Well, this is what it says back

then." We've actually had our people in IT [Information Technology - Computer System Folks] to go back, and there were websites that can tell you when certain articles were posted, and show the effective dates of various documents, so you can't get away with that anymore.

Anyhow, as the policy coalesced in the early to mid-'90s, it basically came out in two categories. First of all, drugs that are not for a serious condition. These were so-called -- it should have said over-the-counter drugs, that we would not take any action on. For some reason, the attorneys don't like that delineation, so the general term is drugs not for a serious condition. If there's no immediate evidence of harm, FDA will not take any action on importation for personal use.

If it's a drug for a serious condition, then there are several requirements. The first and foremost requirement is that the drug can't be available in the United States. This is really at the heart of all the Internet drug sales, because all the drugs you buy on the Internet are available here, except they cost more, and the personal importation policy never had an economic bias. It never said, nor was it ever designed to bring in cheaper drugs; it was designed to bring in drugs that you can't get here.

Then there are other conditions which are pretty general. You have to be under a doctor's care. You don't have to have a prescription. A lot of people think you need a prescription to bring in a personal importation. That's not true. A prescription would be evidence of being under a doctor's care, but you could have a letter from a doctor or some other statement that would serve as well. Quantity has to be for personal, commensurate with personal use, typically 90 days, but that's not a hard-and-fast rule. And there can't be any evidence that the product itself is harmful.

But, again, most of the time -- and I've testified at two or three Internet pharmacy cases, it all hinges around that first criterion, the drug can't be available here. And all of the products that are coming in are available here.

Ever since AIDS drugs generally became available, or better AIDS drugs became available, we see very little importation. During the last four or five years, I haven't seen a single case of a personal importation of an AIDS drug. Occasionally, you do see importation of some of the late-stage cancer treatment. When the doctor says nothing else is working, they'll import a European drug.

JS: So, regarding that policy on the existence of the drug here, it doesn't make any difference which formulation the active ingredient is in, as long as it's in some shape or form?

JLM: No. It's generally been interpreted based on the drug product itself. We had one case, oh, back in the mid-'90s -- and I forget what product – although the drug was available here, only in a hard capsule form. If the person couldn't tolerate the hard capsule, they can go to soft gel, which was permitted. We've had cases where certain drugs are in the U.S. formulation. It includes albumen derived from cattle. There was a religious group -- I'm thinking it was either a Jehovah's Witness or a Seventh Day Adventist – who said they couldn't use that.

Right now insulin is a big item. Insulin originally came from pigs' pancreases. Then it came from bovine sources. Then they started synthesizing it. Now, to the best of my knowledge, the only stuff approved for sale in the U.S. is the synthetic product, and

there were some people that can't tolerate that, who need either the bovine or the porcine insulin, and they can get that if they're under a doctor's care and the doctor ascertains they need it. So if a case can be made that the product that's approved for sale in the U.S. is not suitable for the patient, then a personal importation could . . .

Again, the big thing that doesn't work is a cost issue, to say that it's cheaper to buy it through the Internet. And we find, quite often, it's not cheaper. That's a separate issue.

There is a case that is still current as far as I know. It has to do with a vaccine, and I'm thinking it's a diphtheria vaccine, but a vaccine. Anyhow, and it's derived from fetal cells that, depending on which belief you hold, are from aborted fetuses or not, and there are religious groups that are asking for an alternate vaccine which is available in Japan from a different cell line which didn't come from aborted vaccine [sic]. The chief counsel's office is, as I understand, still tossing that around. It's been tossing it around for about a year now.

JS: But, of course, people are importing drugs that are already here.

JLM: Right. And the issue simply there is, when FDA finds it, we detain it, and if we don't find it, we don't detain it. The estimates on mail alone, parcels through the mail, are estimated to be between 10 million and 100 million parcels a year. That's a pretty big spread, but it's only one order of magnitude, so, depending on what the idea of big is. We can stop on the order of a couple thousand a year. So people do bring it in. If it's one of the pallets that we happen to examine and we find it, it will be detained.

There is one other part of personal importation that I didn't touch on besides travelers and drugs unavailable here.

Foreign nationals who are here on lengthy stays, for instance, diplomats, students; a lot of Canadians go down and spend -- if you were Canadian, you probably would too -- six months in Florida every winter. If you're a foreign national here on an extended stay and you can show evidence that you are a foreign national, then we won't object to your getting drugs from your home country.

In fact, that's probably the most common request we get now for personal importation, more so than drugs unavailable, in regard for individuals who are from another country and here on indefinite stay.

RT: Regarding the current issue concerning illegal immigration, is there a problem of bringing in drugs for either legitimate use or illegal distribution?

JLM: Yes. As a matter of fact -- and it's not just drugs. In fact, if you had said cheese, I would have given more examples.

Immigration and ease of transportation has changed the perspective on a lot of imports. One or two generations ago, if you emigrated, it was a one-way trip. I know my parents never went back. It was a one-way trip; they never went back. When people started visiting from Ireland back, you know, when travel got easy, people would try to bring in Irish bacon and blood pudding, whatever, and USDA would stop it. It wasn't permitted in the country. Then some enterprising guy got a USDA license, and to the best of my knowledge, there's still only one shop at Shannon Airport where you can buy

your Irish meat products and get a certificate, USDA inspected, and you can bring it in this country.

Right now, you have what I'm going to call casual immigration, where people come and go. They'll emigrate legally, although legally or illegally is not the whole issue. They'll come, they'll work, they'll go home, they'll come back again, and people in their immigrant communities here have a desire for their native products, whether it be a style of cheese, whether it be a type of fish, whether it be a drug product that you took as a kid and you still want to take. I'm told in lot of South and Central America, you don't get a prescription to get a drug. You just go to a pharmacy and the pharmacist prescribes for you, and I guess there's certainly that too.

But we've seen a real instance on so-called soft cheeses, unpasteurized cheeses, and there are periodic outbreaks. People who travel home and come back literally with 50 or 100 pounds of cheese, which is more than they could personally eat, but they'll either distribute it to their friends and neighbors or they'll sell it in the local ethnic store. And there are certain flights out of South America that literally, if you went through the baggage, you'd find hundreds and hundreds of pounds of cheeses. And when looking at cheeses, they found one guy had two valises packed with over-the-counter and prescription drugs. So this is all commercial, it's small-scale commercial importation masquerading as personal importation.

Back in the'80s and the '90s, in New York City, there was this fairly good-sized Jamaican community who would do anything to get some ackees, which is a fruit, the national fruit of Jamaica. If you remember the song "Jamaican Farewell," there's a line that goes, "And the ackees are fine every time of year." Well, the thing is, ackees are not

always fine. An ackee, if it's underripe -- I've probably got this reversed, but there are two toxins, one if it's overripe, one if it's underripe. It's hypoglyceme A and hypoglyceme B. Up until very recently, you couldn't analyze these. So if you picked ackees and handle them at the wrong time of the cycle, you had a poisonous fruit. And every year, people would die. You'd have a dozen or two dozen deaths in Jamaica. This doesn't make sense to me.

Now, recently, the Jamaican government has come up with a method to test for the fruit's wholesomeness, so now it's being allowed in after it's been tested and found to be okay.

But back in the '80s and the '90s, in New York, people would literally get off flights from Jamaica with two cases of canned ackees, one under each arm. A can of ackees that at the time would cost you 60 or 70 cents in Jamaica would cost you seven or eight dollars in Brooklyn, and they literally would pay for their flights with two cases of ackees.

That's what's happening to some extent now with certain ethnic foods and drugs that people are taking orders, flying home, seeing their relatives, having a vacation, and buying enough product in their home country to come back and sell to pay for their flights. It's a continuing problem.

CFSAN [Center for Food Safety and Nutrition], as I left, had been working on a program to do a survey just of the cheese, and get Customs to require a formal entry. I didn't get much into Customs rules here, but for commercial shipments, Customs requires what's known as a formal entry, which, among other things, means posting a bond to make sure the product is either admittable [sic] or destroyed if it's not admitted. They

don't require that for personal shipments, but they could, since Customs has to do so. What we're trying to do is gather data to give to Customs so that they can, should they encounter these shipments, tell the individual, "You have to file a formal entry," which is going to cost a certain amount of money, and hopefully this will discourage the shipments from coming in.

JS: Is there any penalty, beyond detaining the product, for importing a product that's not allowed to be imported?

JLM: Historically, detention has been the course of action. If you read 801, it doesn't say you can't take any other action, but historically . . . Assuming that you haven't done anything else, for instance, as to misdeclare the product. If you misdeclare a product, or if you lie about it, for example, if you say a product is A and it's really B, well, then you set yourself up for a criminal prosecution. But merely importing a product that's found to be adulterated, and FDA refuses it, and then you either destroy it or ship it out of the country, that has never been considered an offense per se. The action is taken against the product, not against the individual.

There has been periodic discussion that certain businesses, by their nature, are in the business to import adulterated product, and, at least in theory, those individuals could be prosecuted for introducing into interstate commerce an adulterated product. But it has not been something that General Counsel has been willing to entertain, and I think it's primarily because when you look at 801, Congress seemed to say, well, if you find an

adulterated product, you can refuse admission. It didn't say you can't take any other action, but it didn't do it, as well. So it's certainly an option.

Every case that I'm aware of, when we prosecuted on an imported product, it's not just for the fact the product was adulterated; you did something else. You either misdeclared it, you smuggled it, or some other action as well.

RT: Unless the foreign importing firm has business establishments in this country, it's pretty impractical to follow up on them anyway.

JLM: Well, that's why you would normally take action against the importer, not against the manufacturer. And generally, although there are exceptions, but generally, the importer does have a U.S. presence, either directly or through a subsidiary.

JS: Now, there were several criminal cases that you took part in that involved personal importation.

JLM: Yes.

JS: Are there any that stand out that you want to call attention to, or any way you want to characterize this?

JLM: They were all pretty much crimes of opportunity. I mean, people saw the, you know, the people ready to buy drugs off the Internet, they're all offsets of the Internet

basically. The Internet gives you the marketplace to sell stuff anonymously. You don't have to say where it's coming from. They pretty much all followed a pattern.

I guess the only thing that struck me on one of them -- and it was a case, although I don't remember the name of the case; it was a case out in Las Vegas -- but the guy, the defendant, was trying to make the case that he was selling these drugs to allow people to get drugs because they couldn't afford to get them otherwise. And then the attorney got a couple of customers to testify, because I assume they were guilty of something else, and said no, that they had insurance and they would have been cheaper to get the drugs through their insurance, but they just didn't want to get a doctor to sign off on what they were getting . . . These were all narcotics. So my personal experience is the argument of economic necessity for most cases is a lie.

JS: I also wanted to ask, in the whole issue of importing drugs into the country and how the agency is dealing with this issue, obviously Congress is dealing with it in its own way. To what extent have you personally gotten involved in how the agency is responding to Congress and others on what the agency's policies are?

JLM: Going back at least to the mid-'90s, I sat in on meetings with senior staff and with Acting Commissioner Bernie Schwetz and, before him, with Commissioner Henney, and to be honest and candid -- and I don't mean to cast any disrespect on any of those individuals -- the agency got itself in its own pickle. This was an issue that was repeatedly brought up and put on the table starting in the early '90s, before the Internet trade took up, and we started to see the people in the field and the people in the

operational offices came up and said, “This is a growing trend, and we really have to go out and make a public statement and, in no uncertain terms, let it be known that this not a legal practice, and the agency should take every effort to squash it early.” In more than one meeting the response was, “Well, technically it’s illegal, but we don’t have any evidence of any direct harm to public health. Let’s just wait and see how it develops.” It just kept getting bigger and bigger and bigger.

Then Congress started getting interested, I guess, heavily in the late ‘90s. I wonder if it was -- was it Bart Stupak’s son? Some congressman’s son got a drug on the Internet and died or maybe committed suicide or something. I’m not sure what the actual case was. That’s when the hearings really started to accelerate.

I still think that if before the Internet marketing had really exploded -- and that really didn’t take off till about ’94, ’95, ’96 -- if the agency had come out publicly and vociferously that this is not something people should be doing, we wouldn’t be in the state where we are now, the whole Internet pharmacy.

Then, when we did start taking action on the Internet pharmacy, we seemed to pay way too much attention on the domestic side and not on the foreign side. But it was, yes, I don’t think people figured it would get to where it was.

It was really sort of like a perfect storm. It’s the combination of Internet accessibility, increasing drug prices, people losing health insurance. I mean, everything sort of conspired just to bring it out.

RT: More recently, there have been some issues regarding terrorism in which you

have been involved that are of serious concern. Do you want to talk a little bit about them?

JLM: Well, after 9/11, Congress passed the Bioterrorism Act of 2002. I'm told it was unanimous. There was like one vote against it. There was like a tremendous surge of interest. There may be people in the agency who know better than I know -- we're not sure who, if anyone, was advising Congress in writing the provisions that had to do with the protection of food and drug safety. There were certain things included in that legislation which we would have either changed, or at least changed the wording.

The Prior Notice, which is what I was most involved with -- because I had a little to do with registration but mostly had to do with prior notice -- echoes something that we wanted for a while, which is more advance notice of the arrival. But we wouldn't have (a) limited it to food products, which the bioterrorism, they passed prior notice of food but not for drugs and devices or anything else; and we would have basically left the delineation of what information we wanted to regulation instead of putting certain specifics in the bill. As a result, when we wrote the regulation, we had to use some twisted logic to take what Congress said and determine, "Well, this is obviously what Congress meant."

RT: Did Congress define prior notice in terms of a time frame?

JLM: I'm trying to think. They basically said that FDA had 18 months to implement a regulation on how, what prior notice would be, time would be required. But if it didn't,

there were provisions in the bill as to how much prior notice would be required, and as I remember them, they were very stringent. I don't recall what they are, unfortunately, because we never got there. But they basically gave us an 18-month time frame to set the system up, or their provisions would take effect.

Now, prior to this, we never had any requirement that importers give any information to FDA on imports. There is nothing in the act, there is nothing in our regulations saying that you have to notify FDA of when you're importing product. We sidestepped that by using the language in 801 that said that it's actually Customs' job to notify us if a product is arriving, so it's a Customs' job to collect the sample. But there was an MOU signed years ago that said we would pick up our own samples. But if you read 801(a), basically it says Customs notifies FDA and Customs collects the sample if we request them to collect the sample. It doesn't work that way, but that's what it says.

So because importers were required to notify Customs, we basically told Customs -- and this goes back to the Von Raab days -- you give us the entry notification, and that's how we would get them. We'd get Customs to either give it to us directly or direct the importer to come and give it to us. As a result, we couldn't specify certain information.

One of the things we always want to know, who is the manufacturer of a food product, but because we were getting it from Customs and the Customs information was either the manufacturer or who would ship it, sometimes we got manufacturer, sometimes we got shipper, two totally different entities.

Now, for some food products, there were secondary regulations, like an FCE [food canning establishment] requirement is specific to a manufacturer. But for general food products, non-low-acid canned food products, before there was Prior Notice, we

didn't have to know; they didn't have to tell us who the manufacturer is. They could just say, "I'm shipping it. I don't know where it came from." Prior Notice said they had to give us the identity of the manufacturer. What it didn't say is that they had to give us the registration of the manufacturer. So we had to twist the congressional language of identity of the manufacturer to mean what we wanted it to mean.

RT: This Prior Notice, then, doesn't really take effect until the goods are at a dock. Is that correct?

JLM: No. Prior Notice requires that FDA, for a food product, receive Prior Notice either two, four, or eight, two hours if by air, four hours by land, and eight hours . . . No, I'm sorry. Two hours by land, four hours by air, eight hours by sea before it arrives, and it can be earlier than that, but it can't be any later than that.

If a product -- let's say you submit Prior Notice an hour before it crosses the land border. Well, FDA has made a commitment that if we manage to get it reviewed, we won't hold it up just because you were an hour late submitting it. But if we're still in process, you may sit at the border for an hour before we finish the review. So we've sort of bent over backwards and said that if we can get it done quicker, we will, but you don't have a safe harbor unless you give us the two, four, or the eight hours. The requirement is that the product remain either at the border or in a secure location until we do our review.

Prior Notice doesn't change admissibility. Admissibility's provisions still stay in 801(a), which basically say if a food is adulterated, misbranded, unapproved, etc., it shall

be refused admission. It doesn't change any of that. Prior Notice says if you don't give us certain information, then the food is refused. But even that's difficult because it's a different type of refusal. A refusal under 801(a) is the end of story. Goods must be destroyed or exported in 90 days, period.

A refusal under Prior Notice, under 801(m), or, for that matter, under registration, under 801(l), is a temporary refusal. It's refused until you give us the information. But Congress used the same word in both cases, so it's confusing.

The other big difficulty with Prior Notice when we started up was that we lost almost nine months out of the 18 months for implementation. I came on a few months after Prior Notice all started, but the original planning was for us to get all of the information through the Internet, not to use Customs' network, and to require enough Prior Notice so we could travel people out to the border locations.

Now, remember, we're in, on any given day, 80 or 90 locations. There are 320 ports of entry. Some of them are in rather remote parts of the northern or southern border. If we were going to be able to get someone out there to intercept a parcel because it raised a flag, we would have to build in enough Prior-Notice time to allow considerable travel time. So the initial rule, the proposed rule that went out in -- let's see, 2002, 2003, I guess it went out in fall of 2002 -- I think it was fall of 2002, the proposed rule called for 12 hours. No, not 12 hours, called for Prior Notice by midnight of the day prior to arrival, which could be as much as 24 hours, if you were coming in late in the day. It required a separate transmission apart from the Customs entry process.

We got many hundreds of comments, I'm thinking 500 to 600 comments, and the vast bulk of them were objecting (a) to the long arrival, long pre-arrival period,

particularly for somebody who's shipping from Canada or Mexico and they're three hours from the border. And you want it by midnight of the previous day? I mean, it's not going to happen. And the requirement that they would have to double-enter it. They would have to submit prior notice, and then when it got here, they'd have to do a Customs entry.

At that point, after looking for comments, I, being Customs liaison, went back to Customs and tried to negotiate with them that (a) we would use their system to submit prior notice, and they weren't happy about that because using their system would be using the ACS system, which is the system they're trying to phase out, and they had made the decision they weren't spending any money on ACS because it was going away in four or five years, so they didn't want to do that. The second issue would be, for those locations where we were not co-located with them, for them to do the interception for us, to go out and sample and examine the product. They weren't happy about that either because they were -- this is still fairly shortly after 9/11, they were on their weapons-of-mass-destruction kick and they weren't interested in what we were asking. That's changed since, but it wasn't at the time. And it took several months of back-and-forth, and there was some, I suspect, departmental interaction that I'm not aware of.

But we ended up, in the interim final rule, with (a) brokers having the option of submitting the Prior Notice as part of the Customs entry, so they added a couple of data elements, really not very many. They had about eight extra data elements. And they do a single transmission. And (b) we trained and commissioned 9,000, I think, Customs officers, who would actually go out and act for us in those cases we couldn't get to.

Now, since Prior Notice has been adopted, we've never had to use the Customs officers. It turns out that, of the limited number of products we've interdicted, they've all occurred at ports where we were located, so went out and did it ourselves. I mean, we notify Customs; we typically do it jointly with them, but we're not depending on them.

I'm not sure of the current numbers, but we get on the order of 35,000 Prior Notices a day. They go on the screening system, and the first thing that's checked for, it's checked against any . . . The Prior Notice center is set up at a Customs location where they have access to Customs' databases as well as ours that look at terrorist connections, intel, foreign government information, etc.

Assuming there are no red flags raised, that this doesn't look like there's anything that would raise a significant and immediate threat to health, whether intentional, i.e., terrorist, or non-intentional, then it just goes into normal 801(a) screening and it's handled like any other report.

If it raises a red flag -- I shouldn't say . . . I'm one step ahead of myself.

Of the 35,000, all but 400 or 500 a day are screened by the computer. No obvious problem, they go right through the normal process. The 400 or 500 a day that have the potential for posing a terrorist threat or a significant and immediate health risk are routed to the prior-notice center that operates on a 24/7 basis, because these notices come in 24/7. The staff there then vets those 400 or 500 against the various Customs databases, the intel databases, whatever, and, assuming that they don't see the threat or nothing matches, they then release them, and they go on like the others for normal processing.

For the ones where the threat is perceived to be real, then the local FDA and the local Customs are notified that the shipment is arriving at X time, be there, sequester the area, examine the product.

We've only had in, coming up on three years, coming up on four years, three and a half years -- in three and a half years, we've only had on the order of 30 or 40 of those potential threats. Again, we screen 400 to 500 a day for those, but we've only had 32. And all of them, they've all been negative. There have been two cases where somebody passed in information that indicated it was a threat, but it wasn't. It was false information, and no actual positives.

But, again, the purpose of Prior Notice is not to determine whether a product is admissible or not. It is there to determine if all the information added together flags this as a high threat, and so far all the threats have turned out to be negative. I mean, a lot of the products have been found to be inadmissible, but on a high-threat basis.

JS: This is based on information submitted by the broker?

JLM: Well, both. The key information is submitted by the broker describing the shipment, where it's coming from. The information it's screened against, the criteria, are information that's culled from various Customs and other agency databases.

One of the things, the recognized weaknesses, is this is all self-reported information, and we noticed that when we started . . . Well, even before it was electronic, even on the paper basis, when we used to get paper invoices, that's all self-reported.

I use the analogy of the income tax. I mean, it's self-reported; income tax is self-reported. I'm pretty sure that IRS has ways of checking for discrepancies, and you want to be sure that if you're caught making them, having a discrepancy, the penalty is significant enough to encourage you not to have a discrepancy.

We do go out to brokers. We have broker evaluations. We go out and pull copies of their paper documents, their files, to compare it to whatever they sent us electronically. But that's assuming the paper document is accurate.

JS: What someone might wonder, of course, is you're getting 35,000 Prior Notices a day. That kind of gives you an insight into what kind of import activity we're getting. We couldn't possibly take a physical look, or Customs couldn't possibly take a physical look at any significant proportion.

JLM: Customs, I think, started a similar initiative, the Container Security Initiative, requiring that any cargo containers -- this is only shipboard cargo, the big, 40-foot shipboard containers -- that Customs get a copy of their manifests 24 hours before the container leaves the foreign port. And based on those manifests, they can order an examination. They can actually do an examination at sea. They've done that on occasion. And Customs, I think, is up, I'm guessing, up to 3 or 4 percent of the containers. They're examining 3 or 4 percent of the containers, and they'd love to get to 10 percent, but it's unlikely they're going to do it.

They've got x-ray machines.

Remember, they're looking for easier things than we're looking for. They're looking for hidden compartments, they're looking for some heavily clad metal objects inside a food container. They're not looking for salmonella in a food product or a chemical contaminant. And even they can't do 100 percent; they can't do 10 percent. They're lucky to do 2 or 3 percent.

On the face of it, 100 percent examination, no. Any significant percent examination is, unless you want to shut down trade, it's a spot check. But, again, that doesn't play well. You're not checking everything?

JS: Same with establishment inspections.

JLM: Yes.

RT: Are there any other phases of bioterrorism or surveillance than what we've been discussing?

JLM: Well, there are various . . .

CFSAN is continuously running threat . . . And, again, most of the bioterrorism to date is focused on food products, for one thing, the Bioterrorism Act. They put certain requirements into drugs and devices, but they're mostly for registration and listing. There's no prior notice or similar situation there.

I suspect, with the recent events in England with the medical professionals, people starting to look now maybe at products other than food, but at this point CFSAN purely

continuously runs threat assessments. They use a model which I don't understand called Carver-Shock analysis, where they basically look at the nature of the product, what products can be contaminated and not be apparent that they're contaminated, where the greatest impact would be. It's sort of an open secret that dairy products are very high on the list of products. Certainly any products that aren't processed, you know. I would expect things like fresh fruits and vegetables would have a high potential because you don't generally process to eat them, heat them or whatever. You just sort of eat them. In the past we've looked at bottled beverages.

They periodically target certain products and go out and do an extra level of screening on them just to see if there's anything there. But to a certain extent, in the absence of any triggering information, it's like a needle in a haystack. And it's pretty easy.

A perfect example, though it was not deliberate, was the melamine situation in the dog food. First of all, pet food is, if you're not a pet owner, it's a low priority. Secondly, this was a compound that we had no reason to look for in the first place. It was in a low-risk product and it was a contaminant we had no reason to look for, and there was no history of it. So what are the chances . . . I mean, in this case, the cats and dogs were the canaries in the mine, and it's fortunate they were cats and dogs and not people.

RT: Well, it's interesting, historically, that we had better nutritional labeling requirements for pet food than we did human food at one time.

JLM: But the lobby probably wasn't there for human food labeling then.

JS: We've covered a lot here.

JLM: Yes, we have.

JS: Now, if we left some things out, this is the chance to cover what we haven't covered. But this kind of takes you up through most of your time here. Is that fair to say?

JLM: Yes. We hit all the major points.

JS: There are certainly some highlights and maybe things that aren't quite so -- maybe lowlights -- that we've heard about. It sounds like it's been a pretty good experience for you.

JLM: It's been interesting. I certainly never expected to be where I was. I mean, when I was starting in New York, my goal in life was to be a GS-13 field compliance officer. I thought it was the best job in the agency. It's one of the few jobs I never had. I served on details.

I didn't mention it, but I did import course training. I didn't do too much new-hire training. I was a fill-in on new hires; I guess they didn't want to expose the new hires to me. Several of us for several years did an import training course for advanced import work, and I always used to preface my remarks by saying I started as a chemist

and I worked as an investigator, inspector, compliance officer. And if I ever found a job in the field I could do, I'd still be doing it, but, instead, I ended up at headquarters. But, yes, it's been interesting.

I got to travel more than I wanted. But I shouldn't say that. I really only traveled for like four or five years when we were setting up the system. But I saw just about every, I can't say every district, but I can't think of one I haven't been in.

JS: I guess one other thing I wanted to ask -- and I think we have a minute or two here -- is if there are any observations that you'd like to make on, particularly since you're the imports expert here, regarding where we're going import-wise in the agency, and if there are issues ahead that you see as particular problems?

JLM: Well, it's funny you should mention that, because the whole China thing -- and I'll just use China as an example of the developing world economies. Actually, in a way, I don't see the situation that's developed in China as much different from what I understand it was here in the 1880s, the 1890s, the early 1900s, when Upton Sinclair wrote "The Jungle" while he was out pushing for the first Food and Drug Act.

Basically, unfettered capitalism will do whatever it can do, and unless you have some sort of a regulatory scheme, you don't have much protection. I don't think it's feasible for us to examine every product that comes in. We basically need confidence in foreign countries' own internal regulatory schemes to be sure they're making products fit for export. And one of the things -- and this gets into trade and everything else -- but one of the requirements for any country exporting to the U.S. should be an adequate

regulatory scheme, and I think China belatedly is recognizing this. I mean, if you read the papers, they seem to be, you know, it's going to take them some years to get there, but I think they realize that it's in their own best interest to supply products that don't make their customers ill.

The question is, what do you do in the meantime? Until China can -- and I say China, but it's also India or it's Pakistan, it's Thailand. China is just the one that's in the papers right now. A lot of South American countries too.

I saw the joke that a couple of years ago, CFSAN came out with good agricultural practices, and they tried to get foreign agricultural producers to follow them. I read them and, I mean, they were good. They were great practices for an industrialized country. But one of the issues was to make sure you use potable water for irrigation and for processing the vegetables, cleaning the vegetables. I said to myself, these are countries that can't produce potable water for their populations. Where are they going to produce potable water to do crops with?

I think the real need on imports is to push it back to the point of production. And what happens in the interim? I mean, I have no doubt that in five, 10, 15 years, China will manage to have an adequate food-safety regime. Does that mean you don't import from them for four or five years? Or who's going to be testing the product?

One solution, which will go over like a ton of bricks, is put the onus on the food importers. Drugs have GMPs [Good Manufacturing Practices regulations]. Drug companies are required to make assurances that their raw materials meet their standards. There's no similar requirement on food products. So I think a combination of

encouraging countries to develop regulatory schemes and also, until those schemes are adequate, putting the onus on the importers.

I understand -- and this is only from reading the newspapers and the trade press and stuff -- that Walmart and other big importers are now hiring inspection firms to go out and check their suppliers. That's one option. The argument is it'll put the small guys out of business. I mean, the little guy on the street running a little personal import-export business is not going to be able to do what a Walmart does. But I don't know the answer otherwise.

JS: Anyhow, that helps.

RT: Well, if you don't have anything more to cover right now, we want to thank you, and we appreciate the breadth of coverage you've given regarding your career. Thank you very much.

JLM: Thank you.

END OF INTERVIEW