History

of the

U.S. Food and Drug Administration

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JS: This is John Swann from the History Office. The date is November 7th, 2023. I'm here at the FDA White Oak Campus in Silver Spring, with Dr. Paul Seligman, who's here to participate in an oral history, one in a series on the pioneers in the FDA's international offices. Paul, thanks very much for joining me. I really do appreciate it, and you were obviously the first director of the Latin America office. I certainly want to hear much more about that.

However, I think we'll start with the beginning. If you wouldn't mind just sharing a little bit about your background, where you were born, your education, and then we'll pick it up with some of your first positions in the Peace Corps if you don't mind sharing that part with us.

PS: Sure. I was born in New York City in 1951. Shortly after my birth, my entire family moved out to Southern California, in mid-1951. Both sets of grandparents, and my parents, so I basically grew up as a Californian, in the Los Angeles area. And went to high school there, and then after graduating high school, I was an undergraduate at Yale University in New Haven. When I finished Yale I joined the Peace Corps, where I was a chemistry and math teacher in western Kenya, as a Peace Corps volunteer from 1974 to 76.

JS: That must have been a fascinating experience. And you clearly were interested in the sciences, right?

PS: Yes.

JS: From an early stage. Were either of your parents in a scientific field?

PS: No, neither of them were. My father was a stockbroker. My mother was a jewelry designer. And my grandparents owned a jewelry shop in Beverly Hills. My mom designed jewelry for them.

JS: But that was a big move from New York to L.A. Where did that come from?

PS: That's a long story. It actually goes back to, probably, to about 1912 when my grandfather as a teenager in Budapest ran away from home. His desire was to go, actually for reasons I never quite understood, to California. He ran away from home, ended up in Trieste, Italy, got on a boat headed for America, and ended up in Sao Paulo, Brazil, where he changed his Hungarian last name to a Portuguese one. After World War One, he emigrated to the United States ending up in New York City. After World War Two he left New York to make the move to California. But for some reason that was a 30- to 40-year goal with my grandfather. He really wanted to go out to California. And I guess somehow or another convinced the entire family, in 1951 or 1950, to make the move.

JS: That's a good story.

PS: Yeah.

JS: So, you graduated from Yale?

PS: As a chemistry major.

JS: As a chemistry major. And that was a big step, to devote two years to being a volunteer in the Peace Corps.

PS: I was, at the time, not clear about what I wanted to do, and I was still kind of part of the John Kennedy generation. And it seemed like an exciting opportunity. And frankly, to be honest, I went through the Yale Station post office one morning, and there was a Peace Corps recruiter handing out applications, and he stuck one in my hand, and I took it back to my room and looked at it. It was two pages. So I said, I can do this. So I filled it out and I sent it in, and didn't give it much thought until towards the end of my senior year, at which time I hadn't really made many plans for my next steps, and lo and behold I got an offer from the Peace Corps. So it's an opportune moment, at a time for a graduating senior who didn't quite have a clear direction as to what he wanted to do next. It worked out well for me, and frankly was a life changer for me in many ways. It really got me interested not only in international work, but got me interested in health and public health in general. And it was really the stimulus for me during my time as a Peace Corps volunteer to apply to medical school.

JS: So, what did you observe when you were in Kenya—and it wasn't clear if you were in a rural or an urban setting?

PS: Quite rural.

JS: Okay. The public health experience you had or you observed there was one that seemed to have quite an impact on you.

PS: It certainly did. Although there was a large group of us who were teachers, there were also a lot of folks in the Peace Corps group that I was in that were engineers, water engineers, doing sanitation projects, helping dig wells, and it just stimulated my sort of interest in the overall field of health. And so I guess that's what sort of pushed me in that direction to apply to medical school.

JS: Right. And indeed for the next few years, that's what you were doing, right?

PS: Yeah. I spent four years at the University of California Davis, and then I did a three-year residency in internal medicine back on the east coast in Cambridge, Massachusetts. And it was toward the completion of my residency that the director of my residency. who actually served as a yellow beret in the Public Health Service during the 1960s, said you seem like the kind of guy who's really interested in public health and the bigger picture. There's a great two-year fellowship program at the CDC called the Epidemic Intelligence Service. You should sign up for that, and do it. And I did. The two years at the CDC and the EIS launched my career in public health.

JS: It really registered with you.

PS: Yeah. So, I ended up making basically a career of public health based on my initial two years at the CDC.

JS: Wow. And was this before you were at NIOSH ?

PS: That's when I joined NIOSH. So one of the institutes that I was assigned to as part of the Epidemic Intelligence Service was to NIOSH. And NIOSH is one of the centers, it's the Center for Occupational Health. They have a center for infectious diseases and for chronic diseases, and for vaccinations, in a variety of centers. And one of the CDC Centers was for occupational health.

JS: And what were some of the things you did during your years there, which I gather was from about 1983 to 93?

PS: Yes, when I started there I began in the Hazard Evaluation and Technical Assistance Branch (HETAB). There is a program where workers as well as employers can request, of NIOSH, assistance in evaluating a health hazard in the workplace. Whether it's repetitive injury, whether it's asthma, whether it's a skin condition, whether it's an ocular condition, there are a whole host of potential work-related injuries and illnesses. When NIOSH was established in the early 1970s, as part of the Occupational Safety and Health Act, which also created OSHA at the time, one of the programs that was authorized was this assistance program for employees and employers. So I basically did field investigations in HETAB for about three or four five years. And there were all sorts of things, from exposure to ocular hazards to ethylene oxide and the

formation of premature cataracts, and workers who were doing gas sterilization for medical supplies in a company in Augusta, Georgia, to a skin outbreak from exposure to celery amongst grocery workers. It was just a whole wide range of things and it really depended on who filed the request and how they were assigned.

JS: And were you doing these at a national level?

PS: Yeah, all across the country. So from Georgia to Alabama, out to California, to Wisconsin, yeah, so it's a national program.

JS: Oh, okay.

PS: We're headquartered in Cincinnati.

JS: You eventually assumed an administrative position, primarily an administrative position, while you were still in NIOSH, though, right?

PS: Yeah, so I got very interested, after my first three years doing hazard evaluations and in surveillance. And I got interests in the way that state and local health departments collected data, on the incidence of occupational injuries and illnesses, and particularly on lead poisoning. There was at the time, and I think there still is, health objectives for the nation. At the time, there was a health objective for the nation to eliminate occupational lead poisoning. And I said that's a fascinating one. It seems like a condition that could certainly be eliminated. What data do we

have to show how much lead poisoning there was out there? There were no data. And, interestingly, employers who work with lead, primarily in, for instance, battery manufacturing, is a good example. They are required to perform regular blood monitoring for their employees to see how much lead they're exposed to. And if it's above a certain level, they need to remove them from exposure and take steps to limit the amount of lead fumes that are in the working environment. And all of these data came through OSHA certified laboratories. So it was actually a source for learning who was getting exposed to lead and at what levels. And there were a limited number of OSHA-certified laboratories that did this kind of laboratory work. So I got very interested in ways in which we could gather these data from not only the certified laboratories, but also get state health departments engaged in this effort, since many of them were already involved in lead remediation efforts for children, who were primarily exposed to lead in indoor lead paint. So we developed a very good working relationship with the lead folks down at CDC and figured out ways in which we could collaborate, to not only bolster the systems for lead reporting in children, but also to create systems for lead reporting in adults. And it was a very exciting time. At that time, we developed surveillance systems for occupational asthma, for occupational skin diseases, for work-related carpal tunnel syndrome. So I got engaged in a whole host of projects, to both develop case definitions and then develop mechanisms for gathering these cases and then figuring out ways in which resources could be utilized to mitigate and/or prevent these kinds of cases from occurring. So surveillance was a fun time for me.

JS: You obviously kept up the interest in occupational health, although with a very different focus, though, when you moved in 1993 to the Department of Energy, right?

PS: That's correct.

JS: Say a little bit about that, if you wouldn't mind.

PS: Sure. Just prior to moving to energy, I was given a wonderful opportunity to spend a year on Capitol Hill. At the time, the American Political Science Association, the APSA, ran a program for folks who had somewhere in the neighborhood of 10 years in federal service, to give them an opportunity to work on either a personal staff or a committee staff, in either the Senate or the House. And they'd selected two people per department, from Defense, and Labor, and Transportation, and Health and Human Services, and I applied for and was selected to be one of the HHS fellows for 93 and 94. I had a great year of basically working for Senator Paul Wellstone from Minnesota, on what was then the early days of the Clinton administration's efforts to pass a Health Care Reform Bill. And it was while I was in Washington at that time, in 93-94, one of my former colleagues was Dr. Steven Galson, whose career I've followed in many places, both at the Department of Energy and subsequently at the FDA. He had been detailed to the Department of Energy to be their Chief Medical Officer. And they were looking for someone to head their Occupational Health and Health Studies program, and he introduced me to the Assistant Secretary for Health at the Department of Energy. Lo and behold, I ended up getting that position. So I moved from my political science fellowship to be a Deputy Assistant Secretary for Health Studies at the Department of Energy on basically a reimbursable two-year detail from the CDC.

JS: I see. But this went beyond that, though.

PS: Yeah, the two years turned into seven years. It was renewed after two years, and it was renewed subsequently, and it was renewed for a fourth time, actually.

JS: Okay. Technically, you were still on CDC's roster, even though you were detailed to –

PS: Yes. I was still at CDC, although the Department of Energy was reimbursing the CDC for my position.

JS: Okay. But for all intents and purposes, you were in the Department of Energy.

PS: And I was still a PHS officer.

JS: Ah, okay.

PS: Yeah, so I was still a Commissioned Officer.

JS: Okay. So your focus there was more on occupational health, involving the nuclear weapons industry?

PS: Yes, right. At the federal level. Basically, there were two prongs. The first was occupational health at all of our weapons manufacturing facilities, and testing labs and

developmental labs; so, Los Alamos, Brookhaven, Rocky Flats, Oak Ridge, Hanford. And I was basically charged with helping to develop health monitoring programs, primarily for people who'd been exposed and were now retired.

Not only who'd been exposed to radiation, but also to other potential toxins, in particular to the metal beryllium. Beryllium is a metal that's used in the core of a nuclear weapon and it's a metal that is basically lathed and refined in the course of manufacturing, the sort of inner workings of a hydrogen bomb. But it does cause a chronic, permanent fibrotic lung disease, very similar to asbestos and silicosis. And so I was working to help establish these programs as well as develop a program to help compensate workers who develop these kinds of illnesses.

Historically, workers' compensation has been and continues to be at the state level, but states didn't do a very good job of compensating workers who have a disease with long latency. In other words, that occurred 10, 15, 20 years post-exposure. And so, we worked closely with Congress and with the Department of Labor and HHS to develop and to pass a law that created an occupational illness compensation program for Department of Energy veterans. Similar to what veterans in the military were offered, who had been exposed to atomic testing in Nevada and in the Pacific during the 1940s, 50s, and I guess early 60s. So that was an exciting time. It took a number of years to develop all of the background information that was necessary to essentially establish that, and get that legislation passed. And it's still a very active, vibrant program. The act was called the Energy Employees Occupational Illness Compensation Act, of 2001, I think.

JS: Did you ever have any opportunity, at this time in your career, to go and take part in legislative sessions or hearings or testimony?

PS: Oh, absolutely. Yeah, oh yeah. I did a lot of testifying on the Hill, on behalf of this bill, and in meetings with Senators and their staff. It was a great, it was a wonderful opportunity and a great challenge. And of course the most wonderful thing about it was that it actually resulted in a piece of legislation that's really provided meaningful compensation to the Cold War veterans who'd devoted their lives and careers to protecting the nation, but who unfortunately have suffered with health issues as a consequence of that. And then the second prong of my job at the Department of Energy was on the epidemiology side. We were supporting a series of long-term epidemiologic studies, primarily of communities in and around our weapons sites, who'd been exposed to either contaminated soil or runoff or other kinds of toxins that had leaked out of our weapons sites. As well as an international program.

So we were the locus for the ongoing support of the A-bomb survivor studies in Hiroshima and Nagasaki. We were the locus of support for the studies of the Marshall Islanders who were exposed, in particular, to one test in 1954, Castle Bravo. And also in support of the environmental remediation work that was going on in the Marshall Islands, primarily at Bikini Atoll, where they were trying to remediate the Atoll to make it habitable again for the Bikini Islanders who were moved in the late 1940s, and their desire is to get back to their Atoll. We also supported a study through the National Cancer Institute, of the downwinders from the Chernobyl accident. We helped to establish a program, at that time with the Russian government. This was after the dissolution of the USSR. I think it was called the Federated States, but we worked with and ultimately hired on our staff many Russian scientists to do the same kinds of health-related studies that we were doing in and around our weapon sites. As well as in the environment around their production facilities. So, anyway, I could go on all day.

JS: That's really quite fascinating; particularly with getting the Russian counterparts involved too. And was there actual collaboration there, in securing their role in doing this, on the same or similar that that we were doing here?

PS: Yeah, absolutely—we had no issues with that. They were very excited to be able to do this work. This was at a time following the nuclear test ban treaty and with the dissolution of the USSR, there was a lot of concern about the Russian scientists leaving and going to North Korea or to Libya or to other countries, and so this offered an opportunity to keep them employed doing work that they were very interested in and excited about—whole projects related to the preservation of both their dosimetry records as well as the preservation of their medical records. And we spent a lot of time working with them and helping them with the conduct of many of these kinds of studies. And then there were, of course, universities and environmental institutes in the former Soviet Union that were also interested in doing these studies of downwinders.

JS: Chernobyl had a huge impact, right?

PS: Yeah, exactly.

JS: I know you were at Energy through 2001. And then you made a change to FDA. Can you tell me about that, and how that came about?

PS: Yeah. Primarily as a result of Steve Galson. He'd taken a job as a deputy director of CDER, working for Janet Woodcock. And he gave me a call one day and said would you be interested in applying for a potential position in what was then the sort of post-marketing safety group in CDER. And that's how I ended up here.

JS: And, certainly, the time you spent in FDA before moving on to international service was spent in the general area of drug safety, right? And it was an interesting time to be in a position like that because there were a number of events—drug safety events—almost like clockwork from 2000 on. Issues that we had with drug withdrawals, whether it's Rezulin in 2000 or others—Vioxx, Bextra, Palladone. So, it's very much on the minds of the agency, and certainly the public and Congress. Part of that led to a study by the Institutes of Medicine on drug safety. To what extent were you involved in dealing with all of these things that were going on? This was a very busy time, in this area, in the agency.

PS: So the answer is yes. Clearly there was a lot of interest and focus on how we were collecting data, how we were utilizing data, how we were making decisions. And, although the ultimate responsibility for making decisions about the availability of a product lies within the review divisions and those who are responsible for approving drugs, they were clearly leaning heavily on many of us who are collecting data, doing studies, and weighing the relative merits of whether a product should continue to be marketed and/or under what conditions it should be marketed in terms of boxed warnings or labeling changes and things of that nature.

This was also a time when there was a lot of interest in risk management. And in fact, when I came on in 2001, that was really the charge that Janet Woodcock gave me and others in

our group: to come up with an approach to how these drugs' risks should be appropriately managed. Because we know that all drugs have side effects, of some form or another. And we know that some of them have serious side effects. And the question is not only at what point do the risks exceed the benefits, but also, how to effectively ensure that the appropriate individuals are getting the medication, that they're being used and being prescribed appropriately, that the necessary information is provided to prescribers and to patients. So risk management became a big focus of my work, in terms of providing guidance documents, in terms of developing risk evaluation and mitigation sort of strategies, or REMS, to figure out, again, what was the appropriate context in which a medication should be used, in order to ensure that indeed the benefits continued to outweigh the risks. I would say that a large focus of our group during that time was just on that, on thinking about what the appropriate way or ways to do it. And clearly, every drug is different. The indications are different, the safety and benefits profile are different, so you have to think carefully about how you want to tailor a system that's appropriate for the product.

And one of the first ones that we dealt with was with the Accutane, isotretinoin, which is a known teratogen, but an extraordinarily effective drug for a very disabling dermatologic condition. It was at a time when Accutane's patent was expiring and it was going to become a generic drug. So we had to think through what the best way is to work not only with the originator, but also the potential generic companies, to establish a system that would be friendly and usable for dermatologists, that wasn't onerous, but at the same time ensured that no young woman got pregnant while she was taking the drug, right? Or, that she was not given the drug while she was pregnant. There was Accutane, and then of course there was a series of other

strategies for, again, different kinds of pharmaceutical products that we were working with. So, I would say that was probably the largest focus of my time in that group.

JS: So this emphasis on risk management and safety overall—that was baked into the organization, in bits and pieces, right? Into the CDER organization. Safety seemed to be a more important part in the center organization.

PS: It certainly did. Part of it resulted in the hiring of a deputy director for safety inside the review divisions. So there were a variety of personnel changes that occurred, and as a result that helped institutionalize this view. And, the other thing, of course, we spent a lot of time focusing on how to best utilize the million or so adverse event reports we were getting every year. How do we analyze these data, and were there effective electronic data mining tools that we could use, that would help us to not only discern signals that we should be paying attention to, but also more rapidly help us discern these signals. And then, during my tenure, we completed a system which allowed sponsors to electronically report their data, instead of sending us reports. One of my earliest trips, since I was new to the drug development world, was out to Eli Lilly in Indianapolis, to look at how they initially collected the reports, since the vast majority of the reports that we received came via the pharmaceutical companies. At that time only about 5 percent of them came directly to the FDA, from mostly physicians, or on occasion patients.

JS: Was this outside of the MedWatch system?

PS: No. MedWatch is primarily for physicians and patients, but the vast majority just came from pharmaceutical companies, who would get those reports directly from either physicians or patients. And if you open up your package insert you'll see a number, actually there's an 800 number now for the FDA, but in the old days it was just a number for Pfizer, or how to call Lilly, to report any problems. And then, depending on the seriousness of the condition, they were reported on to us. Either within 15 days or in the course of a periodic report. But, what I had learned when I was out at Eli Lilly was that their reports were all computerized. Then, they would print them out and send them to us, and we would type them back into our computer system. We had contractors doing this and it was expensive. As a result of that and the recognition by myself as well as others in the group, we ultimately developed an electronic reporting system that allowed sending these reports directly to us to populate our own databases.

JS: In the course of things, there was a new position that was created and that you were appointed to, right? Can you tell me a little bit about that, and when that happened?

PS: Sure. When I arrived, they created this office called the Office of Pharmacoepidemiology and Statistical Sciences. They took Robert O'Neill's group in statistics and mashed it up with the group that Peter Honig headed at the time, of post-marketing drugs, I'm forgetting its name now. But anyway, it mashed up those two groups into one, into what they called a super office. I think it was an interesting experiment, but I think most of us realized at the end of the day it was probably not the best match up, because the statistical folks actually really needed to be much closer to their review division folks, which is basically where they did the vast majority of their work. And we decided to disaggregate that, then again, and developed the office of what would

essentially become of Office Drug Safety and Epidemiology, which Gerald Dal Pan became the head of. He is still the head of it to this day. I was moved to a position that basically reported directly to the deputy director, to Steve Galson, as the Associate Director for Drug Safety. We were responsible for ensuring that we were coordinating safety issues center wide.

JS: Okay. That was a flurry of activity in the center in just a short amount of time, really.

PS: It was a busy few years.

JS: Yeah, it was. Obviously, this was a period that the agency was in the news a lot.

PS: Although it's always in the news for lots of reasons.

JS: That's true. The next stage, and what certainly I'm also anxious to hear about, is the move within the agency but to a very new type of position. And this seems like a really major change for you, to move to become the first director of the Latin America office. Certainly this was one of the earliest offices, the international offices, but there were others in India and China, that had preceded the Latin America office. Could you tell me a little bit about how this all came about? This was a huge change for you, right?

PS: Yeah. Like most things in life, one day you see a job announcement and you look at it and say, ooh this looks like an interesting and fun challenge and something that's new and different. And having been a Peace Corps volunteer, having spent a lot of time doing

international work when I was in the Department of Energy, and actually doing a fair amount of international work even when I was doing drug safety work within CDER, with the International Conference on Harmonization—ICH, which involved working with our Japanese colleagues as well as with our European colleagues. I enjoyed working internationally, and this just seemed like a real interesting opportunity.

JS: It's interesting you mention that, because I saw the job announcement for this position, and I also saw them for the positions for the first China office director and India office director. And interestingly about this one that you applied for, the announcement indicated that a basic requirement was either an MD or a DO along with a residency. And I'm wondering, I don't remember seeing that in the other directors' announcements, but were they particularly interested in medical products, or that this director would be involved in medical products in that region?

PS: I have no idea why the announcement had that as a requirement, because, frankly, based on my experience down there, it didn't really make much difference, unless they somehow felt that someone with that level of degree or certification might help in terms of their being respected or accepted by colleagues in Latin America.

JS: Right.

PS: But, in terms of a requirement in order to be able to conduct the work of the job, I don't remember of course seeing it. But I'm also glad to hear that in subsequent announcements it was not part of the requirement.

JS: I imagine that certainly one thing that was in your favor, you had a pretty strong background in Spanish, at the time, right?

PS: Yes.

JS: Okay.

PS: I would say, conversationally I understand about, 90, 95 percent of Spanish. I can read it almost fluently. My speaking abilities are, I would say, probably at the sort of middle school to high school level, but not much beyond that. But with thought and preparation, I can certainly make myself understood and carry on a conversation, and even conduct a news interview.

JS: Even better, since I'm sure you did a little bit of that.

PS: I did, yes.

JS: So, as background to this, on the eve of your moving down to take the position, can you convey a rough sense of the situation with imports from these nearly four dozen nations that the US obviously depends on. Particularly food imports, of course. In other international offices, these were set up often in the wake of problems. Whether it was generic drugs in India, or a variety of human and animal foods and drugs in China, and so on. So, were there some issues, some high visibility issues, that were going on with the imports that are coming in from the Latin

America area to here that preceded an interest or desire to have an FDA office or offices set up there?

PS: I would say that there were ongoing issues. Not just for me, there were cantaloupes from Mexico, and cilantro from Guatemala, and grapes from Chile. So every year, or every other year, there was always some other potential source of an outbreak from an imported food. But, I think part of it was, finally the recognition that as good as our FDA inspectors are at the borders, with the quantity of imports coming across our borders we'd never be able to inspect our way to safety. And we really needed to, for lack of a better term, push the border back, right? And Latin America presented a real challenge. And foods in particular presented a real challenge. Unlike pharmaceuticals, which have a more limited number of large industrial facilities that you could identify, foods were grown by small farmers and cooperatives and groups all over Latin America, all eager to import to the United States, because the US was a big market. And Latin America is so close, geographically. So it wasn't like China or India, which are halfway around the world. But part of it was, can we do something to work with local governments, local trade associations, local growers? Something to make them better at what they do, so that what they end up exporting won't encounter problems on our side of the border. There had been a number of Frontline or other news articles about how overwhelmed our border patrols were, in terms of intercepting counterfeit drugs or counterfeit materials, or all sorts of problem materials that were coming from all over the world, and not just Latin America. So I think that was, in large measure, the impetus. And we, of course, have a strong, long-term and ongoing relationship with the Mexican government, which is a huge source of our imports. And part of it was to really build a more cooperative and shared responsibility for ensuring primarily food safety.

JS: We did certainly have an office established in Mexico City. But first, obviously, the Latin America regional office, the Latin America office, was in San Jose, Costa Rica. And that opened January 7th, 2009.

PS: Correct.

JS: So, at that time were you there and did you have a staff there?

PS: Yes, I was there for the opening with Secretary Leavitt, Commissioner von Eschenbach. Who else came? Mac Lumpkin was there. And we basically had an opening ceremony at the US Embassy in San Jose, at which time we had lots of local dignitaries invited, and I did a press interview with a local television station, and then we packed up and we went home. I didn't come down officially to staff the office until April of 2009. It created a little bit of a problem because, as a result of my broadcast in the news, lots of Costa Ricans started calling the FDA office. And the embassy switchboard was instructed, please take a message.

JS: So, I have to ask, were we under a deadline to open the office by this date?

PS: I think the desire was because there was going to be a change of administration on January 20th. And I think the secretary and commissioner wanted to do something before the next administration took the oath –

JS: Of course.

PS: Three, two weeks later. So I think that was primarily the impetus. But I was not physically down there doing the job until April. When I arrived, they put me in a storage closet that was used by the Embassy store. They cleaned out all the candy bars and liquor and whatever and put a desk and a telephone and a chair in there, and a stack about three inches high of little yellow slips to make phone calls. So I started working my way through all those return phone calls. But also, part of it was, one of the reasons for coming back was to hire staff. And it's between January and April where I interviewed and hired our FDA staff.

JS: Okay.

PS: So that's at the time that I hired Moises O'Neill and Lisa Lopez and Edmundo Garcia.

JS: In the other offices, when they did the hiring, they were looking at a combination of technical experts and inspectors, and of course the locally engaged individuals, which I know other offices they were quite dependent on them. Very important hires there, too. What about you? What sort of positions were you filling, or what were you looking for?

PS: It was the same kind of thing. I was really interested in the people who, of course, were Spanish speaking—that was important. But also folks who knew the FDA and came from a series of different kinds of backgrounds. Moises O'Neill was a laboratorian, and I thought that was a fabulous hire. Having somebody with laboratory expertise was extremely important.

Edmundo came from the Office of Regulatory Affairs. He'd had a lot of food experience. And then Lisa Lopez had a lot of device experience.

JS: CSOs--Consumer Safety Officers?

PS: Exactly. And then I came from the drug world. So we had, I think, pretty good coverage in that regard.

JS: So you had a staff of four US-based staff.

PS: Right.

JS: Now, how about the locally engaged staff?

PS: And then we hired a locally engaged person who basically put out an announcement in San Jose and got a large number of incredible folks. We ended up hiring a woman, Gisella Kooper, who had a lengthy history working both in academia and in industry, again on the food side, and who actually had a lot of contacts inside the Costa Rican government as well. She was fantastic. And then Marcia Miller was our office administrator. She actually was working inside the Embassy in another office, and we hired her to basically help us manage our lives, both inside the Embassy –

JS: Was she in the US federal government or was she local?

PS: She was a local hire; she was Costa Rican.

JS: Okay.

PS: So that was our staff of six.

JS: Okay. Now I want to get into the everyday activities and so on, but just to get the chronology straight, there were eventually two additional offices in Latin America, and Mexico City obviously being one of them, as you mentioned before…

PS: Right.

JS: That came later in the year, like December or so.

PS: Yeah, but I was also beginning to interview and hire for folks as well. I don't remember the precise chronology, but it was in 2009 that we ended up opening an office both in Santiago, Chile, and in Mexico City.

JS: Okay. Did you have in mind a different portfolio of skills for each of those offices? Did they have particular commodities that you were looking to cover, whether inspectionally or technically, or was it just…

PS: I was less interested in that, and frankly more interested in people who had, relatively, 10 or more years of experience working either in the FDA, or particularly in the FDA, who knew the ins and outs, knew the organization, knew where to find things, but also had the right kind of language and diplomatic skills.

Part of what we were trying to achieve was not only to provide some technical expertise, but more importantly, was to provide the right connections. And to make sure that we were able to connect people back to expertise inside the FDA or inside one of our regional offices, where they could get the advice that they needed. We couldn't be the sort of Jack and Jane's of all circumstances. But having somebody who knew the ropes.

Also, because of the nature of this office, we needed to make contacts in lots of other countries as well. Even though we were headquartered in Costa Rica, and had offices in Mexico and in Chile, we needed to reach out to Brazil and to Argentina and to Panama and Guatemala and El Salvador. So, we needed folks who felt comfortable in those kinds of environments and had the right kinds of personality and people skills. So, that to me was extremely important. In fact, even beyond just technical expertise, which is important in and of itself, being able to take that and translate it into those kinds of relationships was very important.

JS: That makes a lot of sense, because as you said, you can't be an expert in all of these things. You need to know how to find answers, certainly.

PS: Exactly.

JS: And how to cultivate those.

PS: And that's what folks in Latin America were looking for. They were looking for information, they were looking for answers. They were looking for ways to do things better, to help comply. One of the earliest phone calls I got while in Costa Rica, was from the vice president of Latin American operations for the largest supermarket chain in the United States, Walmart. I remember this conversation, and she said, I'm so delighted that the FDA has opened this office in Latin America. We have an issue. And I said, what's the problem? She said, our Walmart business model is, something comes off the shelf and we replace it, okay? Big food company. When something gets hung up at the border, or something doesn't show up when we anticipate it because FDA is looking at it or put a hold on it or it's a potential for pesticide residue or whatever, it creates a problem for us. And specifically labeling is a big issue for us. Can you do a seminar for our Mexican clients who are importing into the United States--on 'etiqueta', which is the Spanish word for labeling? And folks at Walmart said, we'll hire the ballroom, we'll get everybody in there, you take as much time as you need. We want all of our suppliers in Mexico to understand what they need to do to properly label all of their exports to the United States. And I said, be happy to. We'll invite speakers down. We'll have experts. But my only request to you is that we open it up to anybody in Mexico, whether they are a supplier of Walmart or not, to be able to attend, okay? And we make it widely available. And she said, great. Just tell me how many rooms you need. Okay? We ended up doing this great five-day seminar in Mexico City on labeling. And we had speakers come down from the FDA and we took the FDA labeling guidance and translated it into Spanish, so that everyone would have access to the Spanish version of the guide. And we believe there has been ultimately a great success in terms of ensuring that everybody knew how to label a product.

JS: And this came out of one of the first calls you received when you started? That's amazing.

PS: Exactly. It was in the first few months, and as soon as Edmundo, Moises and Lisa got down there, we said let's get to work on doing this in Mexico City. The other thing about San Jose, Costa Rica was, why San Jose? San Jose was the headquarters for the Inter-American Institute for Cooperation on Agriculture (IICA). It's an agency of the Pan American Health Organization, PAHO, and they do work on all of Latin America, on training courses, and they're like, almost for lack of a better term, like a US extension service. And they were just a great ally and a great colleague, and I was happy to see, subsequent to the time I was there, that one of my subsequent directors formally developed a memorandum and a formal working relationship with the IICA to conduct training and exercises, throughout Latin America. Even though Costa Rica was not logistically the best place to be, because the best airport in Latin America was in Panama City. Or in Central America, it was in Panama City.

JS: Just to go back briefly to hiring, how much interest did you receive in these positions, between all three offices in San Jose, Mexico City, and Santiago, from the FDA end of it? Because I've heard of different experiences in different offices.

PS: Interestingly, I would say we had maybe 25, 30 applicants for our Costa Rican and Chilean positions. We had a hard time recruiting for Mexico, primarily because of Mexico City and the perception that it was not a safe place to live. And because we were primarily recruiting

folks who were mid-career, they had spouses, they had children, and so we were asking a lot of folks to basically uproot their families and move to a foreign city. And Mexico City was just not very attractive to a lot of folks. That was the one position that we just had a very hard time filling. Costa Rica was not a problem. And it turned out that Santiago, even though it was much further away, was also not difficult. But so it turned out to be site-specific inside our office.

JS: Okay. I'm sure much easier when it came to bringing on locally engaged people.

PS: Locally engaged people were not, and there were lots of qualified folks, as you might imagine, both from government, from academia, from the private sector. I remember as we were interviewing in Costa Rica, all of us, Moises and Lisa, and we were looking at each other and saying how are we going to make a decision? Because they were just some really, wonderfully qualified folks. Local hires.

JS: A good problem to have, though.

PS: Yeah, it was a great problem to have.

JS: And you already started talking about some of these areas, though, but I do want to jump into broader activities that the office was involved in, from the standpoint of engaging relationships and training, as you mentioned, inspections, and so on. But before that, I have one general question to paint this position and this responsibility a little bit differently than the others. So, this was an office that was in charge of a terribly large region, one that constituted

more than 40 countries. Now I know not every nation in Latin America exports equally to the United States, but we're still talking about nearly four dozen principalities that have their own constitutions, perhaps their own regulated industries. I'm just curious how you wrap your head around such a responsibility? Because you're obviously representing the US for all of these countries that are dealing with FDA regulated commodities, right?

PS: Very simply, we actually started with the data. We just said, where are things coming from? We looked at the FDA data in terms of, where were the foods coming from, where were devices coming from, and focused our attention, not only the high volume, but also where there had been problems in the past. Whether they're either particular commodities or particular sectors that we needed to focus on. Just looking at the data was very helpful in terms of knowing, for example, having our eyes opened to devices being a large import area out of Central America in particular. And actually, even out of places like Costa Rica.

Turns out that a lot of device components are produced in Latin America, and then the final and finished assembly happens in the United States. So it was just interesting to see where these component manufacturers were, and also, again, looking at some of our own data on where problems were occurring. I think following the data and the experience was more important. And there's some countries that, you know, had very little. But, yeah, as you might imagine, Mexico is a big actor. Brazil is huge. Chile is big. And then you have these small Latin American countries, which in Central America have lots of interesting seafood, and lots of small garden vegetables, from cilantro to raspberries to all sorts, like mangoes and other things that come to the United States seasonally. But again, that's the way we wrapped our heads around this region.

JS: That makes sense, certainly from a standpoint of risk, right?

PS: Yeah.

JS: If, whatever, Ecuador, does not get so involved in devices, then why put your resources into devices there.

PS: One issue then, and frankly something that still pops up, is Listeria in unpasteurized cheese that comes from south of the border. And there were a lot of dairy associations in some of these smaller countries. They were interested in cheese and ways in which they could try to limit what is a problem that's difficult to limit, only because many of these unpasteurized cheeses are homemade and come into the United States in suitcases. Not necessarily because people are trying to – it's not like drugs or cash. But they're bringing unpasteurized cheese to their family in Los Angeles. And often they're contaminated, and have, and continue to result in, small outbreaks of listeria disease. So, again, we just looked at where the various problems were and what various associations were interested in working with us. Each one of these countries not only had a Ministry of Health. We went country by country and introduced ourselves, and went and talked to the Chambers of Commerce, and to the Agricultural Business Association. So we picked them off one by one, and went out the door and asked them what their issues were, what they felt are areas where we could be of assistance, or gave advice to them. Part of it was data, and then part of it was just outreach.

JS: Again, outreach and relationship building was important, I'm sure. So, I wonder to what extent it was important not just to engage the federal authorities in the country, but what about state and local authorities? Because I suppose not all countries are highly centralized, right?

PS: Yeah. We started at the highest level and then worked down to the trade associations. The one group that I haven't mentioned, which was a huge asset and really keystone to our success, was the US Department of Agriculture. Their own food inspection safety service, APHIS, had offices in all the US embassies. They were a godsend, both in terms of building a relationship with our US governmental counterpart, but also in ways in which we could be of value and assistance to them, and to make sure that we had a coordinated and joint approach to food safety issues. But in Costa Rica, since we happened to be local, we did get involved in working with some of the local governments and provincial governments. But, by and large we tended to stay at the national or the trade association level, and left it to them to communicate and to work with their local partners, either provincial or state. It's not like China, where they're big, their provinces are bigger than United States.

JS: You've mentioned a couple of times the trade associations. I would imagine that, in terms of reaching out to regulated industry—which clearly you've already talked about some of the ways you had engaged them—they must have been an important asset to help reach out as needed to the regulated industry.

PS: Absolutely. They were great. And they're the ones, if they're doing their job right, who have the pulse on their membership; they know what the issues and problems are with their

constituents. And so we found them to be very effective in terms of helping us and communicate issues to us. But again, in our initial forays to the various countries, part of it was just introducing ourselves, letting them know that we're here, letting them know what we potentially have to offer.

JS: In this series of GAO reports on the foreign offices, which I know you're very familiar with, one of the things they often talk about is the function of intelligence gathering, information gathering, by our international offices. In your office and was this a really important activity that a lot of time was spent on, and outreach done, to collect and communicate to headquarters from the Latin American office on what kind of information was needed, and so on?

PS: In the two years that I was there, I would say not. It was not. I don't think we ever got a request from either FDA headquarters or from other governmental agencies to look at a particular issue or to try to develop some information. So I think that, what information gathering we did, I would describe more as trying to help understand the landscape. That is, helping to understand the landscape in terms of what was being grown, what pesticides were being used, what were in people's sheds out in their field. This was valuable, but it was valuable only to the extent that it was helping to serve our ultimate goal of ensuring that people were doing things in a safe and helpful manner.

The only, one exception to that may be, shortly after our arrival, Moises O'Neill and I went to the National Laboratory in Costa Rica, where they test all of their incoming pharmaceuticals before they are allowed to go out in the market. Costa Rica is a national health system. The national government is there, it's a national pharmacy, so there's one large laboratory

filled with sophisticated equipment and lots of highly trained laboratorians who are doing the analysis, and they sat us around a room like this one, and showed us their horror stories of creams that, when you squeeze them out of the tube turned black, and intravenous solutions that had insects floating around in them. And any potential source of horrible contamination, they have seen it. And since a lot of their imports at the time were coming from India, they wanted to know whether the information that they had, about who was supplying drugs to them in Costa Rica, would be of use to our India office. So I contacted Bruce Ross, right? And I said, Bruce, here's the list of companies that are really, horrible, okay? And then I cited some of the examples. And Bruce basically wrote back and he said none of them export to the United States. He said, our menu is full. We'd love to help, but our primary focus is on those companies that are supplying the American market. So, we had the potential for gathering some useful information, but it turned out that these are not companies that were exporting directly to the United States. So, that was the only, apropos of the example that you just cited, that was the one.

JS: Okay.

PS: So I guess you could call that intelligence gathering, but that wasn't really our focus.

JS: No, I definitely gather that now.

PS: Yeah.

JS: So, what you shared about the Walmart, initiated a series of trainings. Did you engage the industries elsewhere during your time there, in these sorts of ways? And training them, and not so much in labeling, perhaps, but maybe in good manufacturing practices or things like that?

PS: Not while I was there. I know that subsequent to my term there was more of that was done. We did do a lot of local presentations and talks in various countries that Edmundo and Lisa and Gisella, our local hire, would do. So they did a lot of presentations, particularly in Central America, at the behest of local associations who basically brought together their membership…

JS: Presentations on a wide variety of topics and what FDA requirements were for this or that commodity?

PS: Exactly. There was a lot of interest in devices and device regulations, because the devices are a breed unto themselves in terms of how they are regulated. And helping people to navigate that was useful. And a part of what we started looking at, and I think it's more advanced now, is developing Memoranda of Understanding, just as it happened with the European Union. A lot of the Latin American governments and public health institutions were fairly sophisticated. And, the question is, could you rely on our inspections, or on our laboratory work, or on our data, to help ensure the safety of and purity and quality of a particular product. And so, there was a lot of interest in that. We began to pursue that during my term, and I don't know how much further that went, but clearly there was a lot of interest in this kind of mutual recognition.

JS: Just so I understand, when you say "rely on our", are you talking about the Brazilian government relying on something FDA does, or vice versa?

PS: Both.

JS: Okay. So this was just starting to develop.

PS: Well, we were percolating the idea.

JS: Okay. I want to talk a little bit about inspections, because here it was unlike some of the other places, which had their in-country inspectors, but often supplemented by US-based inspectors. Here, I think the concept was, from the very beginning, that the region would rely on inspections of consumer safety officers that are based in the US, but travel. And that was the case with the region, right?

PS: Yes. And it made sense. Because it was faster for me to fly from Washington, D.C. to San Jose than it was for me to fly from Washington, D.C. to Los Angeles. Mexico and Central America is fairly close by, and frankly most of South America is as well, unless you get further south towards Santiago, which is basically an all-day trip. So, it really didn't make sense, and we were all in the same time zone. So, it didn't matter; it didn't involve making long international trips, across eight or twelve time zones. I think the concept, initially, was that it made a lot of sense not to have CSOs stationed in Latin America, for logistic and personnel and expense reasons.

JS: I wondered, are you aware of any analyses that might have been done comparing the overall benefit from doing it this way, as opposed to having your CSO's primarily in-country? And maybe looking at the success—and reducing the amount of risk involved, let's put it that way—from commodities that are being exported to the US from this region as opposed to –

PS: And that's a fabulous question. I think the folks in China or India, Bruce (Ross) or Chris (Hickey) or their successors are probably in a better position to address that question. I was primarily interested to see whether, as a result of things we did, like with labeling and with other kinds of assistance, whether we had an impact on reducing the number of products that were rejected because of labeling from Latin America. Or, whether certain pesticide residues, that were consistently bad actors, that showed up in foods that shouldn't be showing up in foods, disappeared as a result of our intervention. During my tenure, I don't think I was there long enough to really gauge that ultimate overall impact, but it certainly would have been worth looking at.

JS: I guess the way this is normally done is, the investigators are sent in with instructions from ORA and the centers with directions of where to go and which establishments to inspect. Were there ever times when the folks in the offices, in the in-country offices, were approached by those in headquarters about anything headquarters was not aware of that perhaps should be the focus of some inspectional activity, in-country? Because you were the folks with the eyes and ears on the ground there.

PS: That was not done while I was there.

JS: Okay. And I have no reason to believe it was done anywhere else. I'm just curious, though, because one thing we have the advantage of with the international offices is an outlook or a perspective on that perhaps others don't have.

PS: In Costa Rica, when we became aware that there were certain types of pesticides that continued to show up in products coming out of Costa Rica that were resulting in the products being rejected at the US, by the FDA, we worked closely with the Costa Rican government and the trade associations to figure out, not only a series of seminars, but ways in which we could identify where those farms were, and help farmers get that stuff out of their sheds. We were able to utilize information that we had, in cooperation with the local authorities, to help mitigate the issue. Because, ultimately, it was the benefit of the farmer and everybody else to get that material out of there.

JS: Yeah, of course. In the two years that you were there, did you see the level of staffing in your office, in San Jose, but also in Mexico City and Santiago change much? Was the level of staff pretty consistent? Did you have much turnover in that amount of time?

PS: We did in Mexico, because it was hard to attract a person there. Just building up and keeping staff was a problem in Mexico City. We only had one person in Santiago, and she was fabulous. And she stayed there the entire couple of years, through earthquakes and all. And we

didn't have any problems continuing to keep our staff together in San Jose. But Mexico City turned out to be problematic for a host of reasons.

JS: I was able to ask Bruce a few questions about that, too. He certainly seemed to enjoy the stay in Mexico City, but it wasn't for everyone, as you said.

PS: Yeah. In between the perceived threat of people being kidnapped, and the violence, and there was just a lot not to make it what I would call a family-friendly environment. At least they didn't have that reputation.

JS: Had you given any consideration to extending your tenure?

PS: I did, and I would have, but I went down by myself. My wife stayed here. She was employed at that time, elsewhere in the federal government. She didn't want to come down with me. She wanted to continue her job here. For me, it was just two years of being apart. It would have been like being a bi-coastal family, except that San Jose was a little closer than Los Angeles. And it was easy to get back and forth if it was a medical emergency or something that I needed to attend to up here, or if I needed to come back for graduation of a kid, or whatever, I could do that easily.

JS: So getting back as needed, as you said, since we're pretty much in similar time zones, wasn't a problem, if you really needed to?

PS: Exactly. Even if I wanted to come home for just a weekend. Flying up here on a Friday afternoon and coming back on a Sunday evening was not difficult, on a Monday morning, or for a three-day federal holiday, or whatever. And then of course, being in Costa Rica, my wife came down there fairly frequently, and so did my college-aged kids. Dad, we're coming to Costa Rica.

JS: I'm sure that was a treat for them. In closing this out, I might ask you to look back, when you were standing up an office in an incredibly large area that the country really depends on so much. For so much of the foods and other products that we consume here. That was a tall task. I'm wondering, as you look back, what do you think are the more memorable or significant things you were involved in your years as the first director of the Latin America office? Also,

from that standpoint of integrating the office into the network of counterpart regulatory authorities in the region. I just find that an incredibly tall task.

PS: To me, just as when I left the Peace Corps after being an undergraduate, I came to realize as a young man that people and families are the same around the world. They have the same aspirations and the same desires and the same needs. I came to realize that in Latin America, and this is probably true beyond Latin America as well. You've got regulators everywhere struggling with the same kinds of issues that the FDA is struggling with. There's a huge wealth of expertise out there, a huge wealth of goodwill, a huge wealth of desire, to engage and work cooperatively together. We tend in this world to read the news headlines and the headlines tend to cover things when things aren't going so well, and when there are conflicts and disagreements.

But what I came to learn from my experience in Latin America is that, in country after country, there were men and women of good will who had public health as their primary focus, who wanted to do well for their citizens and for the citizens of the world. And that to me was great; it was very gratifying. And to be able to be part of being able to allow FDA to engage on a personal level with those professionals was to me very exciting and very gratifying. It certainly made me appreciate, not only the degree to which FDA is regarded and well-respected worldwide for what it does, but also gave me the extraordinary opportunity of being able to reach out and embrace colleagues and counterparts in other countries who were eager for that kind of embracement. And for me that was just, it was really wonderful. You just often don't appreciate what is out there in terms of both expertise and goodwill.

JS: It sounds like this is something you'd recommend for others, regardless of what level of responsibility they were going to take on in an FDA foreign office, particularly, say, in Latin America.

PS: I would recommend it without hesitation. I think it's an extraordinary experience. Certainly in Latin America, particularly in Santiago and in Costa Rica, these were very family-friendly environments. Lisa Lopez came down with her three children. Edmundo Garcia came down with his three children. They were all enrolled in the international school in San Jose. Edmundo, of course, came down again for a second go-around. For both, on a professional and personal level, I think it was very rewarding for them. And I would, again, certainly recommend it to anyone who wanted to broaden their professional and personal experience.

JS: I appreciate that. And I also appreciate your sharing of your experiences, here, in this oral history. Thank you again. And I think this will be of great help to researchers and to non-researchers as well. Thank you, Paul.

PS: You're welcome. Thank you.

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JS: Paul, one other thing I should have asked you about and neglected to concerns not so much January of 2009, but April of 2009, when you and your staff started here—you were on the eve of standing up an office that would serve the entire region of Latin America. How did you do that? What was the first order of business and how did things unfold from there?

PS: The first order of business was to go meet the Ambassador. We were there at the good graces of the State Department and the US Embassy in Costa Rica, and they were basically being the landlord and the host for our office. And they had agreed, of course, to have us there and to provide space for us. So we had to find some space, to carve out inside that building, a place where there would be offices. That was one of the first orders of business, to meet the folks from the various agencies; not only the US Department of Agriculture and APHIS. There was a Foreign Commercial Service, there were lots of other agencies inside the embassy, as well as the Embassy staff who were responsible for housing, finding a place for people to live, getting them furniture, getting children enrolled in school, getting furniture and cars delivered. So there are all sorts of logistical kinds of issues.

And then inside the Embassy, we had to find some square footage, which we did, down in the basement of the of the Embassy. And basically to build out the space. When Edmundo and Moises and Lisa arrived in August of 2009, we hadn't finished the construction of that space. So, they got put in another larger closet up on the second floor, adjacent to the USDA's office space. I think they had a small conference room that I think they allowed our folks to camp out for a couple of months while construction was completed on our space.

JS: So you mentioned something there, I can't let it go by, so you were the only FDA representative there from April until August, when the others joined you?

PS: That's correct.

JS: That must have been fun.

PS: It was fun. But a lot of it was going out with the Embassy staff. Going to furniture stores, picking out furniture, touring some of the apartments and houses that they were going to be assigned to. So there are a lot of just household logistics related to that, in addition to going out and meeting folks in the Costa Rican Ministry of Health and doing some of the initial contact building inside of Costa Rica. Also, traveling down to Santiago to find an office space there. Going to Mexico to find an office space there. So while I was in the process between April and August of hiring somebody for Santiago and then hiring folks for Mexico, I had to start identifying locations and spaces for them in those offices while doing the same kinds of things. The embassies are great hosts. And they do this all the time, because they have foreign service

officers and families traveling through all the time. You've got to deal with all those things related to furnishings and locations and families and schools, and you name it. The US Embassy in Santiago was able to provide an office for Anna Maria Osorio. In Mexico City, we actually didn't have a space in the Embassy. We ended up going to the USDA APHIS facility, which was about, I'd say, five or six kilometers from the embassy, in a small inner city building. Quiet neighborhood. And they provided us some office space.

JS: What was their reason that...

PS: No room. That's what they say, no room in the inn.

JS: Okay. I'm glad you were able to find space with our colleagues from USDA.

PS: Exactly. But yeah, my wife would ask me what was I doing on any particular day, and it was, I was out looking at furniture today.

JS: Was that in the job description? Other duties?

PS: I don't recall it being in the job description. But when I got there, the embassy staff made it very clear to me, where's your furniture? We didn't want families moving their furniture from the United States, right? So we were going to basically furnish their apartments, okay? We did have folks bring their vehicles down, but the foreign service, basically, has a warehouse where they keep furniture that they use for all the foreign service officers that come through. And we

were going to just basically participate in the furniture pool. But in order to participate in the furniture pool, we had to buy some furniture. So we bought furniture for myself and for the other folks who were coming down. And then ultimately that becomes part of the furniture pool to be used by subsequent FDAers who move down, either into that house or into an apartment, depending on their situation.

JS: It's interesting, too, because you had mentioned when the office opened in January there was this interim. But in that interim there were people—regulatory counterparts, industry, whatever—already busy sending in questions for the FDA office in San Jose.

PS: Right.

JS: And so, when you go back of course you're attending to all of these issues of very practical issues of infrastructure. These questions and the requirements of the job are mounting as well, right?

PS: Yeah.

JS: How did you manage?

PS: I just managed. Clearly, it took me a few weeks to a month to return all the calls, but the Embassy switchboard was very nice. And they knew I was coming down in April, and they explained that to people who were calling and said we'll take your information and your message

and you can expect a call once they've arrived. So it wasn't like, leave your name and address and somebody will get back to you, and nobody gets back to you for three months. They explained that we would be coming out in April, and someone would be following up at that point. Yeah, and I just started picking them off from the top of the pile and calling folks. There are even just things like, it is in many ways not a whole lot different than dealing with bureaucracies in this country. You've gotta get insurance and register your car. Get emissions inspection, and all that kind of stuff. It's helping folks to accommodate to a new environment. My desire was, particularly on the housing side, to ensure that everybody, when they came down, had a place to live, and they had furniture, and things that you didn't have to buy. You didn't have to buy things for them.

JS: It's I'm sure not what you expected, but certainly something that had to be done, and there was no one else to do that.

PS: Right. And as part of the Embassy family, you actually first and foremost report to the Ambassador. You have a diplomatic title, and you're in their home. You are there to represent the US government, and you have a diplomatic title. And I would attend the weekly staff meetings of the Ambassador. And I had my own one-on-one, with a half an hour to an hour with the Ambassador once a week or once every other week to report to him or her about my activities. And we'd have functions specific to the Embassy, including night call. The Embassy is there to help support American citizens who are in Costa Rica in case somebody gets in a traffic accident, or has fatality, or gets arrested by the police, or has all their belongings stolen, all of which, by the way, happened while I was on watch. Those things sadly happened frequently in Costa Rica.

You were the night call person, and you carried a walkie talkie, and they call you, and you come down to the Embassy, and if it was a fatality, you'd work with the State Department in Washington, the desk officer there, to notify the family. You'd have to work with Embassy staff overnight to do whatever was needed to be done until the day crew came in and then took over. So, you did night call.

JS: How often was that requirement?

PS: I did it once a month. I think the Moises and Lisa and Edmundo also did it once a month as well. Because there were 30 days of the month, so there were 30 American officers that needed to cover those nights. You covered them, and you learned the ropes. Somebody shows up in San Jose and all of their belongings are stolen. What do you do with them? Where do you put them? It turns out there was a real process for putting them in a particular hotel and giving them a monetary stipend so they could have dinner and buy some fresh clothing or whatever. So we had –

JS: How much of this was learned on the job, as it happened?

PS: Part of it was, but there were actually well-defined processes. They would basically train you on what to do if such and such happened. And there were always backup folks for you in the Embassy if you needed to call somebody and you didn't know what to do. And there was always a desk officer in Washington, D.C., who was there 24/7. You could always call to get guidance and assistance. These were all the other duties as assigned. But, what people didn't appreciate

was that you were the American representative, and the ambassador would have various evening functions and social events where they would invite people from the government and from the business community and from the arts community, and all sorts of different groups. And of course you were expected, based on an invitation, to attend various evening events on behalf of the Ambassador. Sometimes you need to be part of welcoming parties for dignitaries who are flying down, from wherever they're coming.

JS: I've heard stories about those.

PS: Yes. Congressional delegations. And so there are responsibilities basically associated with being a member of the Embassy family.

JS: That's something that many people don't appreciate, I think. So I'm glad you shared that.

PS: It was, again, a great experience, and a surprise, and turned out to be great fun. Because, you met folks from drug enforcement and foreign commercial service, and agriculture, and all the other American agencies that were there on behalf of American interests. And they're ultimately on behalf of American citizens who were in Costa Rica, either for personal or professional reasons.

JS: Thanks for sharing that. I appreciate it.