History

of the

U.S. Food and Drug Administration

Interviewee: Bruce Ross

Interviewer: John Swann, Ph. D.

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JS: My name is John Swann and I'm with the FDA History Office. The date is October 17th, 2023. I'm here in Silver Spring, Maryland, with Mr. Bruce Ross, the International Relations Specialist for the Latin America office and situated in Santiago, Chile. This is part of an ongoing series to document the pioneers in FDA's international offices.

So, Bruce, thank you very much for sitting down and sharing your experiences. I really do appreciate that. I can't imagine having a project like this and not having a long conversation with you. I do appreciate that.

The focus here, of course, is going to be, first of all, your role as the first Director of the India office, notwithstanding the brief period that Dr. Bev Corey was acting for you. And we also want to touch on your experiences at the other offices you've served in. But, before we get into that, I think it's important for context to recognize you had a long history in health-related foreign service prior to your arrival at the India office.

We don't, unfortunately, have time to do all of those positions you've held before then, to do those justice. However, I wanted to see if you could summarize where you served, what the periods were, and the core responsibilities you had in those posts.

BR: Sure. And John, let me also say thank you. It's a pleasure to be here with you and to help create some of the stories on record for FDA history. As you said, I have a long international career. My current post in Santiago, Chile, is my eighth post, and I've spent about 22 or 23 years based internationally, working for both CDC and HHS at the departmental level, as well as FDA.

My first international assignment from CDC was a detail into Kazakhstan, in the former Soviet Union, where I was on detail to USAID. There, the concept was to work on strengthening

and improving public health surveillance systems. We were trying to create an analog to CDC's MMWR, the Morbidity and Mortality Weekly Review, in essence reporting on various health events around the Central Asia region.

I was in Central Asia from late 1994 through 199 . I went from there to work in Kenya, again on a detail to the Carter Center, working on Guinea worm eradication in the South Sudan region as part of what was called Operation Lifeline Sudan, a UN-based operation that a variety of NGOs were providing services to the communities of South Sudan, which were in extreme refugee scenario. And at that time, Guinea worm in Sudan was the world's leading country of cases, with well over 60,000 cases a year. And we were doing outreach through those Operation Lifeline NGOs, providing technical assistance. That was from 1998 to 2000, at which point I moved most specifically into a CDC role in Uganda. At that time, Uganda was an HIV/AIDS research station, and I was assigned there for a two-year tour (… brief network interruption).

So, in Uganda, the transition from a research station into programming was something that was required because the US government formally recognized, in the late years of the Clinton administration, that HIV/AIDS was indeed a national security issue, which allowed us to use USG funding in the international arena to address the HIV/AIDS epidemic.

In 2002, I then transitioned to Thailand. With the same mandate, Thailand was an Asia-based research station for HIV, but it was rapidly expanding and providing outreach and technical support to the Thai government, and we were adding additional programs from CDC. So, we set up staffing in Thailand for tuberculosis and the international border screening for new immigrants and refugees coming into the United States.

So, both Uganda and Thailand were rapidly expanding CDC's established research facilities, and both focusing on HIV/AIDS first in its initial stages of the late Clinton years into

the beginning stages of PEPFAR (President's Emergency Plan for AIDS Relief), which rapidly expanded CDC's overseas presence.

In 2006, I was selected as the HHS Health Attaché and assigned to Beijing, China, and this actually was the beginning of the entrance of my career with FDA. I arrived in Beijing with an infectious disease portfolio covering the activities of NIH and CDC, both of whom had large presences in Beijing, China, but within the first month of my arrival, the FDA issued a countrywide import alert for five different seafood products; FDA's action meant. And there was a bunch of panic from the government of China and industry about what the import alerts meant. And shortly after that event was the melamine contamination in pet food. Which is a funny story that, hopefully I'll be able to expand on later.

But, just to continue with the summary, clearly FDA needed some representation in China. And during the two years I was there, I helped support a variety of commissioner-led and/or secretary-led, and large delegations coming from FDA. There were probably three secretarial visits, two commissioner visits, and three large FDA delegations, sometimes combined. But a great deal of my time in 2006–2008 (when I was in Beijing) was spent on FDA issues. And that was the transition into FDA, where FDA had seen what I've been doing for them to help them coordinate, inform, and learn about processes, the government, the oversight that China had of their commodities being exported to the US and asked me if I'd be interested in joining FDA and helping them open the foreign offices using my experience to provide advice and consult in that process as well as go be the director of the inaugural India office, with FDA setting up four or five offices worldwide. So, that was 2008 when I came home to work at FDA headquarters for a year to be the director of the India office.

JS: OK. Great. That's really helpful. That's an incredibly succinct summary of a lot of experience there, but I appreciate that. Just before we pick up, and I actually want to pick up on something that was going on in Beijing during that period before the office opened. But before we do that, I was just curious: in your previous posts, I guess particularly at the ones where you were working on behalf of CDC, did you have much engagement at all with FDA?

BR: No, I knew about FDA and its role and its functions within the department and its roles in the food and medical product regulatory spheres, but I had no contact nor engagement with FDA. While working at CDC. There, I was what they called a public health advisor (HR term), and my responsibilities were all on the operations side. I dealt with (responsible for) contracts, personnel, budgeting, and travel sorts of issues, supporting CDC implement programs that were led technically by medical epidemiologists in the CDC world.

And so that (operations and management) was the background that I had at CDC, and it actually was the experience and skill set that FDA was particularly interested in because they didn't understand yet how to function and operate within an embassy world. Nor how to support (staff, finance) programs internationally.

Fundamentally, for FDA, it was a decision. Hey, there's too much going on in these countries like China and India. FDA recognized that it could no longer stand at our borders and maintain the regulatory roles and functions of protecting the health of American citizens by understanding the quality and the manufacturing and or dissemination of the products that were flooding into the United States from those countries.

JS: And I know there was obviously a big push going on back here in the States, in the agency, in the department, and elsewhere to start responding to these problems, some of which you mentioned already. I know at the time and probably after you had arrived in Beijing, I believe you got involved in some of these discussions between the Chinese and the department and FDA on finding some kind of resolution to these problems. Resolutions that I guess concluded in an MOU, a Memorandum of Understanding that the department signed with the Chinese SFDA, State Food and Drug Administration, and the AQSIQ, the General Administration of Quality. I wonder if you could talk a little bit about that.

BR: There were two issues that I just highlighted. One is the import alert on seafood. The other on the contamination of pet food. So, first the seafood import alerts. The Chinese government was particularly upset. FDA's actions had a huge impact on their dollar volume of exports, and they wanted help in responding to, in effect, getting off of the import alert. And so, in those discussions that I helped to broker, in the sense that I made introductions between FDA technical folks from CFSAN, in particular with the part of the Chinese government responsible for overseeing seafood exports, what would they need to do in order to get off of import alert?

The Chinese were upset, and FDA was striving to get them to recognize some degree of responsibility and a assume an increased role in improving the quality and safety of the products that were manufactured within China destined for the United States. And so, we sent a bunch of CFSAN experts in the seafood arena to go look and see exactly what was going on and to collaborate with the Chinese.

So, the biggest concern from FDA's side and the reason for the import alert, was unapproved vet drugs, colors, and additives in the shrimp, eel, and these three kinds of basa or

tilapia. And so, we began a detailed look at the aquaculture processes and practices in China, which was such a high-value export for China to the US. There was an interest by the Chinese government to accept FDA help. And so that was one of the avenues that occurred during the time I was attaché, and when the FDA technical experts arrived in-country I helped support them, traveled with them, and communicated about China's actions or further questions when FDA staff were out of the country regarding issues that needed to be shared.

That contrasts dramatically with the process that happened with pet food contamination. The irony there is that at first China didn't know that they had any responsibility over the exported contaminated pet food and didn't know (were unsure) what to do. Pet food and who was responsible for pet food in the US government wasn't clear to them. They tried to come to the embassy and talk to the agriculture USDA people, thinking that it involved animals, and USDA representatives turned away and said, nope, not my problem, not my issue. And then the media and things in the US got louder and bigger and we needed a response.

Finally, they found me, and I recognized FDA, who'd now been reaching out to me, saying who do we talk to in the China government? And ultimately, what FDA wanted to do was send their inspectors to go see where this contamination had happened. Where did they get the melamine, which is actually a scrap material from the plastics industry that had been ground up into an incredibly fine powder and added as a result of specific specifications that a customer in the US asked for a very high level of protein to be in this pet food, somewhere in the 40 percent range? Normally, we don't test for protein. We test for nitrogen, and plastic melamine has a high nitrogen content. And so, chemically, when you test for it, you see a lot of it and you say, OK, looks like high protein content.

It wasn't the case. And, of course, melamine caused a great deal of kidney damage and death in pets. So, when FDA sent their people to come and investigate where this pet food originate from, I supported a team from ORA, and at that time what was called the OIP under Mel Plaisier, to come to China to look. We were traveling probably an hour and a half outside of Shanghai to find this actual manufacturing facility (the source). The Chinese government, first, was very difficult in issuing visas and claiming it was the May holiday time period for them, with the long holidays everything was closed, and we had to push back hard to say no, it's mandatory, it's essential that FDA comes; and ultimately they issued the needed visas for FDA staff.

But the bottom line in this short story, when we ultimately got there: the week before we arrived at the rural facility, somebody had bulldozed, literally flattened, the buildings on the lot! And so, when FDA arrived, we found it was behind a high fence with a locked gate, with no evidence of manufacturing.

I stood on top of a five-gallon white plastic bucket, like those that pickles are provided to in the restaurant industry, and looked over the fence, and you could see a little Bobcat bulldozer, and just rubble everywhere. That was what was left of the facility that the Chinese claimed had been the source of the production of this melamine that had found its way into US pet food.

And so, I tell the longer story because it represented a push on the Chinese government for assistance that contrasted with the Chinese asking for help on the seafood side, where we did provide that assistance. So, you can see two kinds of who had the interest and who was willing to be responsive.

But you're right, John, in indicating this ultimately led to the signing of two agreements. The Chinese government at that time was engaged with multiple parts of the US government in

what was called high-level economic dialogues, where three or four cabinet officials (Treasury, Commerce, Agriculture, Health,) would travel to China maybe twice a year to have various discussions on as variety of issues, whether they were about trade or currency or whatnot. Food safety and medical product safety were included in those dialogues, and in late 2007, that led to the signing by then Secretary Leavitt of the food safety agreement with AQSIQ. Since the signing, AQSIQ has been disbanded, renamed, and reorganized. But at that time, they had responsibility for issuing export certificates. They were also in charge of the border products going in and going out of China, as well as what happened at the airports. So, more akin to our Homeland Security and border and protection parts of the US government, but that's who was responsible for exported food safety at the time.

The medical products agreement was signed with what was then called SFDA, the State Food and Drug Administration, is now morphed into the NMPA, the National Medical Product Agency. So, that represents FDA's initial engagements with FDA in China, 2006-2008, albeit with differences in response from the Chinese government, but ultimately leading to the signing of the agreements and MOUs, there were languages that both sides could establish a presence within the embassy and the respective countries enabling FDA to proceed in late August of 2008, to when we actually opened the China office in Beijing.

JS: And I know those provisions included, to some extent, medical products; maybe the final details still awaited some of those to some extent, but I know it called for registering and certifying products and even verifying them. But it was in place in advance of the opening of the office in Beijing. Is that right?

BR: That's right. They were enabling for FDA to establish an office in China. They gave permission, and they highlighted broad stroke areas in which FDA would be working with the Chinese authorities on food safety or medical product safety issues and characterized the future engagements that have evolved over the last 15 or so years.

JS: Right. That's a great background on the development of those. I appreciate that. As you said, after your post in Beijing expired, that was in 2008. So, you went back to headquarters. I want to get to that as background because the India office awaits. Much as you related in the case of the situation in China, there were issues of concern to the agency with products coming from India as well, particularly drug products and generic drug products. I wonder if you could just point to what some of those problems might have been in advance of the opening of the office of in India.

BR: Yeah. India is a major producer and source of generic drugs, as you just indicated, for the US market. I think it produces more than 10 percent of our drug supply, and of that volume, more than 40 percent are represented in the generic sphere.

And there was a great deal of inconsistency in the quality. There were products being stopped. There were incomplete, insufficient, or concerning findings in our inspections of those facilities, and it just raised the question in the medical product—particularly the pharmaceutical arena: who is in charge? What was their level of oversight, of control? And who could we communicate with? There were some food issues that were occurring too. There were vet drug problems in seafood, particularly in shrimp. There were concerns about additives in foods, particularly in spices. We were seeing lead in various spices and colors that were being provided

to the US. India, and China, were early recognized by the agency as sources of large volumes of products. We had little information at headquarters about who is in charge, what were the regulatory structures and rules, what their regulatory process really was, It would be in our interest to get a deeper dive and better understanding and help us protect the health and safety of the American people from those products that had irregular, inconsistent quality that were being caught at the border or subject to recalls or market withdrawals as a result of substandard or contaminated products circulating in the US.

JS: OK, great. Something also, in advance of the opening of the office there. I know there was some discussion between FDA and officials in India on their development of laws and, I guess, institutions to carry out regulation of medical products. And there was the 2006 Food Safety and Standards Act there, correct? I'm curious, though. My understanding is that there were discussions between the agency and the Indian government about these new Indian laws. What was the FDA's role in that? Advisory, or connecting those to what FDA requirements were?

BR: The Indian government was going through a reorganization—a not uncommon experience in India. They're always modifying their bureaucracy and moving responsibilities across, around, and in between ministries. And so, within the Ministry of Health and Family Welfare where food was supposed to be regulated, but it didn't really have the attention, and it didn't have a robust set of regulations. The Indian government had indicated this to us during travels by the secretary and other FDA people that had been visiting India in the same 2006–2008 time frame as described for China earlier. They established the Food Safety and Standards

Authority of India--FSSAI is the acronym, and they were creating new rules and regulations for oversight for the production, manufacturing, or modifications of food within the country of India. FDA did offer to look over their shoulders, if you will, to provide technical assistance, advice, and share our regulatory regimes and guidance and laws in case that would help them in writing their own.

We encouraged them towards harmonization to look towards established international standards rather than create their own *de novo*. And we thought that engagement would be helpful and help strengthen their process.

JS: And did they take up any of this?

BR: It was a mixed relationship and reception. They expressed interest, and we shared a whole lot of FDA regulations and documents with them. But our concern really was obviously about the food and the products that were leaving India that were being exported into the United States. And the Food Safety and Standards Authority said, frankly, our concern is about the products that are staying here in India. Those exported ones, that's over there in this other part of the Indian government, over in the Ministry of Commerce with what's called the Export Inspection Council, EIC, which has the mandate/responsibility to validate or ensure that a product going to another country is indeed meeting the requirements of those other countries.

And so, when we said to FSSAI, we have problems or concerns about this food or that commodity, they said, not my problem. It's exported. We don't pay attention to that. You have to go talk to EIC. And EIC said we're only responsible as it's leaving, not as it's being manufactured. And so, we fell into this catch-22 because it was being exported and it wasn't so

clear who was ultimately responsible in the Indian government. And there were some facilities in India that were manufacturing only for export and not for domestic use. We found this was particularly true in the medical pharmaceutical arena; some facilities literally would have two or three lines, and one was definitely for export, where the quality and the oversight was much more rigorous than those for domestic consumption/usage.

But there was also, in the same building, perhaps right alongside, another line that was producing products for the domestic market. It was different on the medical product or pharma side, but again, there was that separation; not (FSSAI) my responsibility because it's being exported, or some of the firms particularly recognize that because the pharmaceutical product was being exported, they needed to upgrade, to have higher standards, cleaner, and more attention to quality testing and quality functions throughout.

The irony in both food and medical products at that time, was that the Indian government had no regulations for medical devices. In order to regulate a device, they had to call it a drug. And they could regulate it under the pharmaceutical regime, which, as we know, it is not appropriate. But again, if you fast forward a decade, they're writing and establishing medical device regulations for the last two or three years, and indeed, in that approach, they are looking to the international arena and harmonizing. So, one could say, perhaps our efforts in 2006 on food safety standards authority, where we provided guidance and suggested they look at the international regimes, took a little while in a different commodity, but they're now doing that in the medical device arena.

JS: The story that you tell there speaks, I suppose, to the importance of having feet on the ground to understand who has responsibilities. The idea that you have similar commodities but are overseen by different ministries, even though they might be the same thing going on side by side, could be very confusing.

BR: The issue of who we should be talking to when we find a problem, and wanting to work to find a solution or resolve it, that's the reason why FDA needed to understand how the host government is organized and which agency or, department, or ministry has the responsibility.

And, of course, it's always better to have relationships, knowing where to go and whom to talk with when you have a problem that needs a solution quickly when it's not a crisis, particularly when the health and safety of people or taking a contaminated product off of the market are part of the solution.

JS: Absolutely, and we're also proceeding here on the assumption that it's always a centralized authority, and that's not the case. I do want to get into that, especially with your tenure. But before I do, before you assumed the position on-site in India, you were back in headquarters. You mentioned the position, but could you say just a little bit more about what you were doing in headquarters before you made the trek to Delhi?

BR: So, just a bit of background. At that time when I was leaving China, my HHS supervisor said I had exceeded the time limits that HHS had for people to be continuously overseas, which at that time was established at six years. I thought I'd reset my clock, if you will, between my

tours in Uganda and Kenya, where I spent a few months back at CDC, and I thought the clock reset during those 5 months.

HHS said no. And at that time, coming back to FDA was resetting my clock to a mandatory year at headquarters before being able to go back out. Colloquially, in my world, I call that my year in the penalty box because I couldn't continue the international career based overseas. However, while I was learning about FDA in that period, I was working in the international part of FDA.

So, I focused on international things, still part of my international career, just not based overseas. That's a bit of a background to the reason why I came back to the United States. Today, those rules have changed. There is no limit to how long you can be overseas within the HHS world. The only limit that exists now is, no more than six years in any one country. And it's one and done. So, if you spend six years in China, that's it. You can't live and work in China for HHS anymore. You have to go to another country, but you can now spend your entire career working for the department, (e.g., CDC, FDA, NIH, or HRSA) internationally if you can string those different assignments together collectively, either within FDA, i.e., post-China to India, to Latin America, Mexico to Costa Rica, like that or as I did from FDA to CDC and from CDC to FDA, etc.

That's the reason why I came back. But while I was at headquarters, I was assigned to the Office of International Programs. And one of the main things that we did during that period was an active recruitment program. FDA had obviously selected the director of the China office. Again, the irony there was he was my direct supervisor at HHS when I was the attaché; he was the former director of the Office of Asia and Pacific, Chris Hickey. And so he came to FDA and Beijing just after the Olympics ended. I left the day after the Olympics started in 2008. But while

I was in OIP at FDA, we were organizing and recruiting and trying to staff up all of FDA's foreign offices, So the directors all got together: Chris Hickey, Paul Seligman for Latin America, Linda Tollefson for Europe, and me from India, and Bev Corey for Africa (after her stint in India). Collectively, we went around to the different FDA centers to learn and inform ourselves. We focused on what were the issues that those centers might have had in the countries or regions to which we were going to be assigned? At that time, this was modeled on what was called the CDER Forum. CBER had a similar forum, a week-long set of activities where the Centers' different offices and programs came and talked to us and presented: this is our mission, this is what we do, these are the important products that come from the international arena, these are the problems that we see for those programs.

So, it was like a fast university seminar series focused on the different centers to learn about their issues. I was also helping FDA establish those operational management systems to support and work through the embassy to be able to support staff and educate and inform. Basically, I helped ensure that relevant OIP staff were communicating with CDC, which at that time had a very established headquarter-based support unit, and enabled the folks at FDA who are going to provide that kind of service to the foreign offices to go down to Atlanta and meet with CDC, to get the reference books and guidance and operation manuals to help set up an FDA supporting process.

It was a big job to staff the offices, and the staffing decisions had already been made by FDA leadership. The India office was going to have 11 staff; the China office, 13; Latin America, seven; Europe, 2. We needed to find and identify those kinds of people who were going to staff up those offices. And so, recruiting/hiring was a big proportion of our time.

JS: I was just going to say the first step that you alluded to earlier was the identification of the directors in each of the offices. I recall seeing notices that went out for staff. Certainly, for the China office and others. I do remember running across the notice for the position that Paul Seligman eventually took, but when were the directors selected for this? And this was at some point in 2008, I gather, right?

BR: Yeah. All but the Middle East director had been selected by the time I arrived in August 2008. So, I don't have good insight into how the identification of the directors worked. Some of it may have been reassignment. There were some obviously relevant candidates. Chris Hickey was reassigned from HHS to FDA. I was reassigned from HHS to FDA India. Linda was reassigned from CDER to the Europe office. The only candidacy that I recall was the Middle East Office because that was the last of the directors to be selected. And then, I think once directors were selected, then we went through the HR process to write PDs for deputies, and I don't know that we called them international relations specialists, which is the HR term we use now. I think we might have called them policy advisors or program advisors, and they had a pharma or device or food label.

And then, of course, for China and India, a large percentage of those staffing numbers were expected to be CSO inspectors living and working in country, which remains actually one of the greatest values of having our presence in a country. The ability of that staff to get familiar with the manufacturing and various procedures that exist or are unique to China pharmaceutical or Indian food production to just give two examples. More importantly, though it doesn't happen very regularly, but to be able to drop and run if and when there's a recall, or there's an outbreak, or there's a reason to get to a facility quickly. They don't need to wait for a visa and

plane and travel arrangements. They can get there within days as opposed to what happened before the foreign offices when literally it had taken months in order to organize and get all the travel support. So, that certainly is a value that's proved itself over and over in the last 15 years and was a big part of the reason for having large staffs in India and China; it was part of that recruitment process.

JS: Yeah. Speaking of that process, there was obviously something that had to be worked out because of your situation, needing to spend your year back in the States until you could take the position. You said this was a policy that after six years you had to step away from international service. What was the reasoning behind that old policy?

BR: I don't know that there's a written reason or policy. I know functionally, there was a perception that if you spent too much time overseas or in any one country, either the department or the agency wasn't getting the value of your experience. In other words, you weren't sharing or bringing experience back to the agency as in a learning mode.

But through your assignment in a country, you'd become so experienced or so comfortable that you weren't sharing those lessons learned with other people. And some people characterize that in colloquial way: going native. You forget that you work for CDC because you're working in Kenya, and you think you're working for Kenya because you're focused on improving health services or access to information or regulatory regimes.

Now, they realize there is an exchange in that organizationally and programmatically, those can and do become institutionalized. So, I think it took a long time to overturn that regulation. And part of it was driven by the large numbers of people that CDC had overseas in

their PEPFAR responses. There was no place for them back at CDC headquarters to continue in the same (HIV/AIDS prevention) programmatic area. Just to clarify that, the director in of CDC in Thailand was managing a bigger program with more dollars than the individual at CDC Atlanta had running its domestic HIV/AIDS programs. And they weren't moving. Yet, somebody had to leave Thailand, and where were they going to go?

And where was their expertise going to go? Unlike the foreign service agencies like State, Commerce, Agriculture or AID. We in HHS don't have staff in domestic positions that also must rotate. And so, there wasn't that sort of rotating circle of expertise coming from the field and going to headquarters and moving back to the field.

We still don't have it. It still would be a good idea. I'm again another example—having come back from my Mexico post to headquarters for five years and now back to Chile—of how that could work. But it wasn't designated. This is a position for somebody who's been overseas. It was my experience or the recruiting of other people who said, I want those skills or sets of experiences that Bruce has in this domestic position. That may not be the case.

So, that's still something the department could work on in recruiting. But that's the reality in the background. Where do these people go when you call them back? And how do you capitalize on the skill set and experiences that are unique in a foreign setting and are not necessarily as valued domestically within the agency? What do you do with (e.g., How to retain) that individual after they leave a country post?

JS: I know with other members of the staff, there's an assurance that there will be a position back at headquarters when their deployment is done, but it won't necessarily be the same position. And I guess that's a segue to another question I wanted to ask in the formation of your

office in India. We were we're putting a number of people in each office, certainly more in China and India. Was there a great deal of interest from technical experts and CSOs for the India office? Did you have a lot of people to choose from?

BR: That's a great question, and it actually highlights the response that I experienced. I think it's important to establish that the agency, by some process, had already decided on the number of people for each office by the time I came back from China. And somehow they characterized allocation of those numbers by commodity area across devices, foods, pharma inspectors, and policy staff.

And so, we were given a dance card, if you will; in my case in India, I needed to hire a deputy, I needed to have three policy people and six CSOs that were characterized as four pharma and two foods. So, I had some holes that I had to fill with pegs. The commodity-specific staff specialized either in the policy arena or in the inspection arena to meet that mandate.

And one of my first reactions coming off of 14 years of being overseas was, why is this so hard? Why are there not a huge number of people at FDA clamoring for these international positions? And it took me a while, I think, to understand. I don't know if this is the ultimate reason. But India's not an easy place to live. They, drive on the wrong side of the road compared to the US; in the British way, driving on the left instead of the right. The food's very different. The levels of sanitation and plumbing are very different. Travel is very difficult in India. And particularly for inspectors. As I was interviewing inspectors, I had to overcome what I later labeled as the urban legend of how difficult it was to live and travel in India.

And so, the idea that somebody might pick up their family, wife, and children and move to the other side of the world, 11,000 miles away, 11 time zones, and live in a place that they'd

had a not very positive three-week travel experience, was just something that I had to keep overcoming. And even in the four years that I served as the India office director, I never, until two months before my tour ended, had a full complement of 11 people. I spent the four years in a constant recruitment mode trying to get a full complement. Now, they weren't all in country because once you get selected, there's a whole pre-departure set of prerequisites and so forth that have to be completed first. But literally two months before I left in 2013, I hired the 11th person for the India office. Now, some people came and went, but I never had a full complement of CSO investigators in the India office. Sometimes, it was easy to get a pharma, but not so easy to get food, or it didn't fit the parameters.

When I first started, I was supposed to have two devices, but again, as I intimated earlier, India didn't have device regulations, and they weren't exactly ready. But I had some very interested people who wanted to come live and work in India that had BIMO experience. And so, I talked to CDRH and ORA and said, I got somebody who really wants to be here, but he's BIMO, he's not devices. Can we recategorize that characterization and that expertise? And they agreed, and now we have three BIMO people in India, and it's a huge support for the volume and level of clinical trials that are part of the pre-approval process for the pharma industry but was not the original concept. And it was driven because I had somebody who, once, when Peace Corps returned, was working in the BIMO arena and said, I want to come live and work in India. And we were able to negotiate it with the FDA leadership and a program was born from it.

JS: India is technically classified a hardship post—is that correct?

BR: The State Department has a variety of ways to characterize and provide some incentives or allowances; they're called in the State Department language to overcome the degree of difficulty of living in a country. And there are two that are important. It's not India that's called the hardship country. Actually, China has that label, not India. So, these two modes of addressing those challenges, one's called the cost-of-living allowance, and that's a direct comparison of a basket of goods purchased in India or Delhi or various cities where there might be a consulate compared to the cost of those very same goods in Washington, DC. And so your pay can be adjusted in 5 percent increments. It's not exactly your pay; it's your disposable income. So, it's maybe 60 percent of your pay might get a percentage bump based on the difference in the cost of those things.

The second way they do it is called post differential. And that addresses the hardship issues that you alluded to. Is there a library? Is there Internet? Are there places to go on holiday? What's the quality of the plumbing? And that's an annual review, and that can also move in 5 percent increments, and that's a direct increase to your pay based on those percentages. The State Department evaluates those conditions on an annual basis, and a post differential can move up or down depending on conditions changing. So, India has both a post differential and a COLA cost of living allowance as an increment to your pay. China also, because of the conditions during COVID, had some escalations both in those two allowances, as well as a specific hardship because entry into and exit from China was incredibly difficult during COVID. I wasn't assigned to China at the time, but I was the director of the Office of Global Operations during COVID and had to manage the withdrawal. Because of COVID, for the first time, we extracted all of our staff from China for a period of six to nine months and then put them back in. But there were no commercial airline flights, and they had to go in by charter and subjugate themselves to a high

degree of testing, repeatedly, in isolation by the Chinese government before they were released as part of what China was doing to control COVID. And so, China had a hardship pay associated with that.

JS: So, there were some financial incentives.

BR: There's also two non-financial incentives that are provided when you're overseas. So, the first and probably the biggest one is the government provides you with furnished housing at no cost and no tax implication based on family size and grade. So, you get put into a house that's furnished, and the embassy takes care of all the maintenance, fixes the plumbing, and so on because they want you to be working and not worrying about your house. The second is they provide some airplane tickets and travel support. So, one is what's called home leave after a period of two years with an onward assignment of a minimum of 12 months. Now it's used when there's two years completed at a post and with at least a two-year extension following the Home Leave taken. You get home leave, which is accrued based on the number of months you spend in country; it is different from annual leave. It is a plane ticket for you and your family back to your home, as well as the time off. And depending on what the post differential is, you can earn anywhere from 5 to 15 calendar days of home leave annually.

So, at the end of two years, you have 30 work days of leave that's in addition to your annual leave. So, those of you with finger counting can see that's four weeks of leave and a plane ticket home if you have another onward assignment. The other one is designed to be in the middle of your tour and around the world; State selects an R&R location. So, when you're in India, I'm blanking on the name now; it'll come to me as I talk. But the location of travel is

London. When I was in Thailand, the location was in Australia. So, you get a plane ticket for you and each of your family. You have to take annual leave when you go there. But you get a plane ticket to travel to those R&R—rest and recuperation—sites and locations. Or you can cost-reconstruct that ticket and return to the United States. And many people do that so they can visit with family and renew relationships with cousins and grandparents, etc., that are hard to do when you're living on the other side of the world.

R&R travel, home leave travel, are part of the compensation. The two COLA and post differential are allowances. We also have a retention bonus--"Compensatory Recruitment Incentive Pay", or CRIP-- which after approval of the program appropriation by the Agency, is offered (on an annual basis to help recognize that serving overseas comes at a cost. And the reality is not everybody understands how to move their bank account and live overseas and go shopping in a different way. Of course, many countries have Uber food deliveries, and shopping and supermarkets look just like they do in the US. That's the way it is for me here in Chile. As an example, it looks very much like living in the United States, and I don't have a post differential. Our COLA is minimal, and it goes up and down depending on the dollar exchange with the Chilean peso. But I could be living in Cleveland save for the fact that the language on the street is Spanish and that the architecture looks a little different. But access to libraries and Internet and vacation spots and such are quite comparable in Latin America to the United States and maybe not so in India, where plumbing and roads are not always paved, and toilets in India sometimes are still squat, the Asian style toilet, as opposed to a sit flush toilet like we have in the US. But that's all improving in India. And development in that country is accelerating dramatically.

JS: These incentives that you characterize, these apply to anyone in the federal government working overseas, right?

BR: Correct.

JS: We haven't talked about the local nationals, the Indian nationals that were brought on for the office. When I talked to Chris Hickey …

BR: They are gold to FDA. They go by LES, locally engaged staff, or FSN, Foreign Service Nationals. These are people who are citizens of the country where the office is who are contracted employees through the embassy, and they provide the continuity to FDA. As we come in on 2-, 3-, or 4-year tours, they're still there. So, not only do they provide that sort of living history and the ability to explain why something is the way it is, but they are also the interlocutors to make the introductions and help keep the relationships and, in a pinch, serve as translators. That's not their job function, but they obviously do that regularly when needed.

We, as an agency, would be lost without our locally engaged staff. And they're so critical in those countries where English is not the native language. They're absolutely essential in China. Chinese is an incredibly difficult language to learn for a Westerner, particularly an adult, to adapt to those tones that are found in Mandarin. But even in India, which has more than 20 nationally recognized languages, having local staff who can speak the language, can interact with the government, and with industry, and can help serve as translators if and when needed are absolutely critical. And, of course, you have to be in country to hire them. You have to have an

office, and just as at FDA, you have to have position descriptions, PDs, that are classified and go through a similar hiring process.

And we have both administrative types who help move the travel and the budgets and keep the office functional with the embassy services, but we also have technical experts who maybe once worked for the regulator or came out of industry. But collectively they bring local experience knowledge to the FDA staff assigned in country and help us do our work. And they're a critical support function. I cannot speak highly enough about their role and their importance and their value to the agency.

JS: And who is responsible?

BR: We have some who've been with us for 15 years. Someone hired in China, as Chris may have mentioned, is the most senior FSN in the China office. The previous attaché, hired her in the month before he left, just before my arrival in China So, she worked for me as the HHS attaché LES. And when FDA opened the office I said to Chris, you need to hire her. She needs to be your senior person. And Wang Lixia indeed moved over to FDA, and she remains with FDA. She started in 2006 working for HHS and moved to FDA in 2008 and has been with us ever since. And then I forget, maybe it was like 2014, was named HHS' LES of the year against all the other local staff of CDC and FDA, NIH, etc.. And her award for that honor was she got a round trip ticket and living expenses for a week in Washington DC, so she could visit/work with FDA and HHS. She came and shook hands with the Secretary of HHS and had meetings at HHS and spent a whole lot of time at FDA meeting the people with whom she'd been corresponding. So, to put names and faces to the emails is incredibly important and useful.

JS: Chris did, by the way, mention her and in equally glowing terms that you just referred to. But I wanted to ask, who was responsible for bringing on the LES? Does the country director make the decision or the embassy?

BR: No, the country director does. The agency office is responsible for the selection. The embassy provides the HR structure in the system to classify the PD and do the time and attendance and the payroll associations, but the desired qualifications and identification of a suitably qualified, experienced individual is based on the agency who wants that help. And that information is what makes up the embassy's PD As to who's chosen, sometimes, it's the director; sometimes, it's the policy people; more often, it's a group of those people who are interviewing the candidates and engaged to make the selection.

JS: OK, great. Thank you for clearing that up. So, I wanted to jump into some areas of operational concern to the office and to you as India
office's first year or two unfolded, looking at relationships, how information was gathered, inspections, outreach, that sort of thing. What I would like to ask is now, here you are, with all of the experience you've had in foreign service. And, recognizing that the initial months were under Bev Corey's acting position, when you started your tenure as an office director, what was your first order of business?

BR: You have to recognize that you're building from the ground up, and there's no infrastructure, no physical space, no staff. The operation of the foreign system, the State

Department bureaucracy, as opposed to FDA bureaucracy, both for hiring, managing money, traveling, all is different.

So, that was a role I played from headquarters to advise Beverly, as well as the other office directors; this is what you can expect because none of them had that prior exposure and experience, and I had 12 or 14 years of it. So, I was a contact point of information for many people. I fed documents, examples of position descriptions. I described budget requests and accounting procedures that State would use. I indicated that what we needed to do in terms of hiring staff clearly. One of the first things was to hire an administrative person who could interface with the embassy so that if you needed to travel or you needed to spend money you could operate and function in that bureaucracy.

Secondly, we advised to identify some policy people to help make appointments with the host government. Sometimes, we can rely on other US Government agencies. Agriculture is a great example of that. Their Foreign Agricultural Service, or FAS, often carries the FDA buckets in a country where FDA has no presence because they're there representing US Agriculture. They obviously understand and know a lot about what FDA does. And so, if we needed to meet with the Ministry of Agriculture or Ministry of Health to talk about the regulation of food products, USDA often knew about it because they were responsible for the export of grain or soy or dairy US AG products into a country. So, they often were the first point of contact to know who's doing what, who I should meet with, and how do I get up to speed and organize myself. There's also the simple fact that you need an office, you need a computer, you need to know where you can go sit and have a functional telephone and begin your work.

So, those are all the main areas that, from day one through maybe month three, you're focused on. But keep in mind, the embassy's got great support for you, the employee; but you've

got a family. In many cases, they have kids who have to enroll in school. There's some decisions: do you go to the American school, the British school, which school? How do I pick a school? You have to pay for it; that's coming out of the US government funds. It's another benefit that the tuition at international schools for any school-age children are covered by the US government. The wife is trying to organize a house that's been provided by the US Government but, maybe doesn't understand how the air conditioner works or the refrigerator blew a fuse and what to do. And how to interface with the support mechanisms coming from the embassy. It's called the General Services Office GSO. They have mechanics and plumbers and painters and so forth. And organizing to get service if and when.

And then there's another office in the embassy. It's called CLO, the Community Liaison Officer. That's the single first point of contact for any question that a spouse or family or even an assignee may have. Where can I get peanut butter? Is there a library? Does anybody have used ski jackets to buy? How do I find this or that? And the CLO helps in the settling and the organization of the family and the household.

Maybe the family wants to hire a nanny, or a cook, or a driver to move around. And the embassy has people and offices that can help identify or contract hire someone for that desired service need. So, familiarizing yourself with that support; that's literally what the first week in post is about. You need new credentials, new badges, check-in, fill-out list, and account for USG-issued property; how many couches and lamps are in my house? Did I get a desk? Do I have a State Department computer in addition to what FDA gave you? But now they're 9,000 miles away, and, you know, it better be functional. But you still have to make the State Department service systems function and provide support And that's where, in the beginning,

it's important to learn the differences and get them to work for you, instead of fighting all the problems by yourself.

JS: It's wonderful that they have such a structure built up. And I suppose FDA isn't the only agency situated there, right? CDC had a presence, right?

BR: Not in every country, but in they're in both China and India. There's no CDC in Santiago, as an example, and there's no CDC in the Brussels Europe office, for example. But many times, yes, there is or was a CDC presence. But in some of these embassies there are 40 other US government agencies, law enforcement, the military agencies that we have no exposure or experience dealing with. And now, suddenly, when you're assigned overseas, you're subject to what's called Chief of Mission authority. You're part of one US government. So, yes, you may wear an FDA hat. But the ambassador can still tell you I need this, or I want that to happen. He's setting priorities in country for what the US government needs and wants, and you need to bring the FDA issues to the floor or line them up in concert with what the ambassador is indicating. And the other agencies and posts are doing the same. And so, in our presence in both Beijing and Mexico City and even in Delhi, those are among the largest ten embassies in the world. And we're one of perhaps 40 or so agencies at post, many of whom we've never worked with.

When I was in Mexico, there's a Federal Agency that's responsible for maintaining cemeteries: US cemeteries that are in Mexico. I'd never experienced that. I had no idea that the US Government had such a thing. Others are more common. There's Customs and Border Protection, and Homeland Security, Legal attaché, which is the FBI, Agriculture, and Commerce

are all present. And those are more obvious and they sometimes form the hierarchy in the embassy, too. But it's an eye-opening experience, and it makes one proud to be part of that kind of a team. It's very different than the kind of team that you have in FDA when you have a domestic assignment. You're obviously knee-deep in regulatory issues and enforcement issues or meeting the code, the US Public Health Service Act, etc.

Nobody overseas knows anything about those things. And you wear a label on your forehead. You represent FDA. You may be an inch thick across some of those wide ranges of issues from food to medical devices and pharma. Or maybe you have a couple inches thick in a particular center. That's what the policy people are targeted and hopefully bring to their assignment representations of, say, CFSAN or CDER. But the director needs to know all about FDA. And that was the hardest thing for me. I guess I had a year at headquarters. I went through the range of forums and other opportunities in the different centers.

But when I got to India, I quickly realized I needed to know how to call a friend or someone who could give me the details that I needed, because the association or the industry or the government thought I knew it all. And, of course, I didn't. I'd only had six to 18 months of FDA exposure and experience. And so understanding that, I needed my deputy to represent the pharma knowledge that I couldn't acquire rapidly, where I didn't need my deputy to do the administrative, operational issues because I could do that in my sleep after 12 years of doing that at CDC. Whereas other offices had a different mix of what their needs were. That was the first recognition of the office director. What did they know? And how could they assemble knowledge and experiences in the staff to be hired that would make a rounder, deeper representation of the agency in country?

JS: Did the headquarters desk officer have a role in this at all?

BR: That's the way other agencies, particularly State and Agriculture are set up. We did that originally in the early days of OIP. There was a Europe desk and a Latin America and some people were, quote, left behind. They stayed at headquarters but represented those issues. But as time has gone on, there really isn't a desk at headquarters that represents Latin America or represents India. And you're going on your own. Through the international part, each of the centers has some kind of international affairs staff that deals with international issues, and that's the entry point into the center. But it's not centralized in OGPS in the way that State would have an Asia Near East desk and a whole cohort of five or seven people that uniquely deal with India.

That goes back to the concept of having a set of rotating staff; those are domestic positions that people in the field could come back to or could rotate from headquarters to the field. But FDA doesn't have the priority or the staffing depth to have that kind of a model currently. Even CDC does it by function. So, they have management and operations support people at headquarters. And they have technical people, experts in monitoring and evaluation, or in the field. FDA has it in CDER, CBER, CFSAN, CVM, and CDRH; all having international groups. And that's how we deal with it as an agency.

I also, John, need to recognize we've got about five minutes remaining because I've got to scoot to my next meeting at the half hour.

JS: Rather than jump into the next big category that I want to explore in these theme areas, maybe what we can do is take this up in our next session with issues surrounding building and

maintaining relationships because that's an important one I know for all of the offices. And rather than get started with that now and have to cut you off, we can start off with that next time.

BR: I'll pick that up on Friday.

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JS: This is John Swann from the FDA History Office. It is October 23, and we're resuming the oral history interview with Bruce Ross. Bruce, we had started with your arrival and first orders of business as Director of the India office, and what I was hoping we might be able to do next is explore some of the areas that were of a particular consequence and importance to you. And I'm wondering if we could possibly do this by the general areas of building and maintaining relationships. Also, the importance of the function of gathering intelligence and information about the country and outreach, training, and then finally, the importance of inspections and everything that entails.

Let me begin by asking about cultivating ties with regulatory counterparts in India. I assume in some nations this can be done principally at a national level, but I'm wondering if India presented any sort of differences to that approach? That is, were regional entities important to be aligned with as well? Also, how did you go about pursuing and building these relationships, give how that's an important part of all of our foreign offices, right?

BR: As I suggested previously, there was some degree of history of engagement, if you will, with the Indian government prior to the actual opening. There was the publicization by both the

Indian government and the American government that we, FDA, were going to open up offices. The initial plan called for us to open two offices: one in Mumbai and one within the embassy in New Delhi. Mumbai was selected because it was closer to where some of the manufacturing facilities that were shipping drug products to the United States. But in the run up, in that same period while I was in China, say 2007–2008, Secretary Leavitt had also made visits to India along with some representation of FDA's leadership at the center level. They traveled around in India and made their first foray, asking questions about policy oversight and, in the end, indicating that we expected to open up our foreign office in India in the 2008 timeframe. And that actually happened midway in the fall, October-November time of 2008, when Beverly Corey went to country.

As I described a little bit before, the first things that people do with a brand new office—in addition to what is required in the embassy, include setting up operations and management and going through the process that fundamentally allows you to receive appropriated money, from FDA so that you can operate in India, pay local staff, travel, purchase pens and pencils, and whatnot.

And once that's taken care of, then obviously, eyes all turned to engagements with the government. In most cases, as you stated in your lead-up conversation question here, it begins at the national level. One needs to make acquaintances and introductions with the leadership. And in particular, we approached the Ministry of Health, where we knew that the Drugs Controller General of India, DCGI, is located. We went to visit with the minister and discover if you will, the Indian bureaucracy and what the titles and layers and oversight are within the ministry. And there's permanent secretaries and different levels of responsibility for both policy and answering to parliament and the government and different operational levels. What was made very clear to

us as we opened up the office and Beverly started this and fed information back to headquarters, is that it certainly was repeated again when I got to country in late June of 2009.

Because of the transition, people changed in the FDA India office with Beverly departing to go open the office in South Africa and my coming in to take over the reins after my period at headquarters. So, we discovered and met with the Drugs Controller General and asked about regulatory oversight—anywhere from approvals to the conduct of inspections—to better appreciate and understand how it works. And one of the first things staff in India did was begin to investigate that process in the three main areas for which we had policy individuals: for pharma, for medical devices, and for foods. And in each of those areas staff wrote a paper—which remain on FDA's webpages to date—that described the process: who was in charge, who the players were, and the relationship between the center and the periphery through the states and provinces. Also, for the local level, oversight and what regulations existed.

And those documents were meant to create a fundamental understanding for any interested party. Obviously, the folks in country needed to become "expert" in their level of understanding and the familiarization of differences of who the players were and who to interact with should there be a problem. Also, to be responsive to the government who, as we sought to learn the process, often was informing them. Oh, gee, that's different from what we do. We do it this way. And so that prompted a variety of kinds of questions from the government. Why? How? Not that it created reforms or changes, but it again reflected the evolution of the understandings on both sides of what the other systems brought. So, if I take pharma as just an example and DCGI, one of the things we were particularly interested in was approvals of drugs and that process in country; more particularly, the oversight of facilities that may be shipping products to the United States. As I talked about in our first session, India was selected as a site

for one of the FDA foreign offices particularly because of the importance and the large volume of pharmaceutical products, generics in particular, that originated in India.

India, like China, is also a source of APIs, active pharmaceutical ingredients, and so their import to the pharmaceutical products that are sold or used in the United States is truly important and a significant percentage, but we discovered that the DCI had a very small staff, numbering in between 20 and 50 people, certainly nothing like the 1,000 or so people in CDER on the FDA side that conduct our drug review and approval processes and compliance represented by ORA staff inspectors plus compliance in CDER. It was a log scale of differences.

And so that kind of raised questions in our own mind. How could they possibly go through the same level of rigor or review with such a difference in the number of staff? So that was an "aha" experience. It made us wonder. We found the answer. But the bottom line is it seemed if anybody else—any other regulatory authority—had approved the product . . . India required at that time, and may still—I don't know if they've changed this, but they required a small clinical study to prove the same sort of safety and efficacy in Indian citizens if the initial approval had not been conducted in India prior to approval.

But in other words, outside of the clinical trial data, they relied heavily on another stringent or more significant regulatory authority—the US, the Europeans, the Japanese, the Australians, the UK. They look to others to see and maybe rely on their investigative and review process before approving a product in the United States.

JS: Bruce, can I ask a quick question? I guess a clarifying question before you move on. You referenced in our earlier talk the issue of there being a recommendation for, to the extent possible, harmonization of requirements as the country was developing its own regulatory

scheme, right? With ours and perhaps others. So as we're here, as you're talking, I'm wondering how far apart the systems were in terms of requirements and in terms of how we were trying to communicate those requirements that Indian products would have to meet that were going to be exported to the US vis-a-vis what the recently developed system in India had required of medical products? For example, with drugs.

BR: Yeah. That's a great question and the response comes in two parts as we tease out the difference both in the status of where we were at the time of the existing process or whether the process was under review, experiencing possible modification, or being developed. We discovered the pharmaceutical process to be fairly established in the Indian structure and not currently within their parliament or within their regulatory oversight undergoing any particular change; quite different from what was happening on the food side. As we discussed briefly last time, the Food Safety and Standards Authority of India, FSSAI, was just being stood up within the Ministry of Health with respective regulatory oversight responsibilities.

That presented an opportunity because it was "being birthed," and they were writing regulations to push a little harder to provide more information to hopefully engage and receive reciprocity from the India side to look more carefully at what we had, or if not us, the British system or the European system, thinking along the colonial connection that India used to have with Britain. There are a lot of similarities between their bureaucracy and their procedures. It served as their starting point, obviously, and back at independence.

But in pharma, we didn't have that same opportunity, but in foods we definitely did, and we did in medical devices, but that took a whole lot more time, a number of years—more than five—until the Indian government was ready to directly involve in medical device change. So,

our efforts in pharma and harmonization were to strongly encourage them to participate in the ICH meetings. They had been sometimes on again, off again, if you will, visitors to those sessions. And as you may know and our audience knows, the efforts at ICH were exactly looking to create some harmonization where a number of the leading drug regulators and other parties would come together and talk about particular areas and segments, and they all receive numbers in the ICH world, so they might focus on inspections or they might focus on laboratory testing for quality or different areas like those two just as examples.

What we tried to do was first to create the understanding, hoping that the Indians would not only recognize the value and purpose, but then become regular participants. Now, we want them to move past observing and just casually sitting on the back bench and watching and listening to actively discussing and sharing the details about their own processing systems so they could begin to see for themselves where there was a difference and/or an opportunity to make a change to tighten things up. These harmonization bodies, whether they're for pharma like ICH or in the food's codex or in medical devices later, IMDRF, have different levels of engagement. You can be committee chairs, you can be part of steering committees, you can be a formally accepted member, you can be a formally designated observer.

So, if you think about it as concentric circles, there are different ways to start to get towards the center of the steering committee, decision-making role-playing involvement. And we tried as a generalized approach to push India from the periphery as a comparatively passive observer and sometimes attendee into a more regular attendee and a more active participant and perhaps later in time to take on oversight or leadership of a committee that was working on a particular area across different regulatory authorities and meetings in time to reach the endpoint. For example the issuance of ICH 6 or 9 that focused on, say, inspections or laboratories. So the

drive on the harmonization front was to get India--because they also represented such a significant source for the rest of the world—to take a place that reflected that role and volume of manufacturing generic products that went to the rest of the world.

JS: You've been speaking principally to the relationship-building with the national authorities, I gather. But to what extent are regional authorities somewhat independent and have to be dealt with directly by the office?

BR: That was part of FDA's discovery by having boots on the ground and beginning to travel outside of Delhi. And that travel centered around talking through and to different pharmaceutical associations in country to learn that there was a difference in role and responsibility as well as quality between what happened at the provincial or state levels in India. Maharashtra is the largest state with the largest number of facilities shipping pharmaceutical products to the United States. The paper policy backgrounder I previously mentioned that still lives on OGPS' webpages and gets modified, has a map that shows where all the facilities shipping to the United States are physically located. You can see large collections around Hyderabad, Mumbai, and the states of Maharashtra and Gujarat. We started to meet with those state-level drugs authorities, the Gujarat FDA or the Maharashtra FDA or the Hyderabad FDA to introduce ourselves to find out who they were, what they were doing, what kind of oversight, what kind of staff, what training, because what we discovered is the more regular and consistent instructions for licensing purposes for the ability to produce product in any facility rested at that local state level, provincial level.

That cohort of regulatory authorities and inspectors was really important, but the center level could be involved if it was a serious issue or had crossed provincial borders. So if we take a large company in India that manufactures drugs, whether it's Ranbaxy or whether it's any other company, they may have two or three or five or seven facilities all in different states. And each state would have responsibility for the facility in their province, but it controlled the product only within that province.

So much like the FDA has the concept of interstate commerce, when a facility in Hyderabad ships a product, say, to Mumbai or Maharashtra, crossing state lines, then the national authorities have some responsibility. But they usually rely on the states for that. But if there's a problem, then the Federal System, the National System at DCGI, would partner up with the state officials to go investigate what was going on. And that was particularly also apparent when, in the early days of the FDA office, some of the facilities were only producing for export and not for use in the particular state, nor in India. DCGI had that responsibility.

So we had to discover these anomalies or differences, and that led us to engagements with the different state levels. And, of course, just because we wanted to meet with them, that wasn't always met with receptivity or availability or willingness to engage. One of the early adopters—and we discovered in time the strongest of these provincial FDAs—is Gujarat. They were most willing to receive FDA to have our experts from CDER come and conduct training about changing guidance or responsibilities for safety and quality that was going on to inform and respond to industry. And we found that working alongside the DIA India—the subgroup of the Drug Information Association in India—was a great forum because they could deal with the organizational side to bring industry to a meeting to a venue where we could bring the experts who could deliver the technical piece. But we, FDA, were not burdened or tied down with

operational and financial issues of organizing at a hotel and planning an agenda other than what the topics were and who the speakers were going to be; we left that operational piece to DIA.

And so even beginning in 2009 and continuing through to this year, CDER, traditionally, every year goes to India and conducts usually over a two-week period in three or four different locations a series of two-day or three-day trainings at each place around relevant issues that are important in drug regulation and drug quality and safety—oversight kinds of issues for Indian industry to participate.

That's been a tremendous opportunity and benefit from those early days of making contact and introducing ourselves. Frequently today, 10 to 15 years later, they are always meeting in those sessions in Gujarat or Mumbai, which are about an hour and a half away from one another; also down in Hyderabad, which is on the southern east coast of India, where Maharashtra and Gujarat are on the northwest coast of India. That allowed FDA experts and pharma, and CDER in particular, to join with ORA to talk about compliance, about quality issues, about different laboratory testing, or whatever the issue of that particular year might have been. But the key was the discovery of the roles and responsibilities at the provincial level differing from or being limited to the geography and how or when the Federal System came into the process.

JS: How many different state systems did you have to deal with? And also, you made a reference to not all of them being quite ready to engage. Could give an example of how that might be manifested when we face that sort of thing?

BR: I don't have the exact number of provinces in India in my head, but it's in the 20s, and they're not all equally important to us. There's probably a handful, maybe four to six or seven, that have a large volume of manufacturers who send products to the United States or where research and clinical trials might be ongoing that would be subject to FDA oversight because of the role in the development of a product coming to market or seeking marketing approvals in the US.

JS: How did it manifest?

BR: As you might expect, obviously, everything is done with permission. India is a huge country. It geographically spans four or five time zones; east to west and north to south is, I guess, about 2,000 miles. Land mass, it's kind of comparable, I believe, to the United States, but it's got a population five times the United States's population.

A little over a billion. And at that time, we were just crossing 300 million. Now we're probably 330 or 340 and India is probably 1.3 or so billion. When you move as a diplomat in country, first to arrive, you have to have what's called country clearance permission from the US government to be in country and mostly to create awareness. Why are you here? What are you doing? To deconflict any other in-country policies that may be going on within the embassy, but also because literally the ambassador takes responsibility for your health and safety while you're in country. But India also has a number of consulates. I think the number might be five consulates.

And so when you travel from one consular district to another, you also have to receive permission. So the same, it's akin to boarding a ship in the Navy. You can't step on the deck

until you receive permission from the captain to board his ship. The consular authority permissions are like that.

So, say we wanted to go to Hyderabad or to Mumbai. We would submit our request to the consulate. We want to come April 1 to 15, and we intend to meet with a variety of Sun Pharma, or Ranbaxy or Ideal Pharmaceutical Company and the local government and they would say yes. At the same time, we either, because we had the contacts and that might have come from our locally engaged staff, and that was one of the points I made in our earlier conversation, the importance that they represent to us, often they have and maintain as part of their responsibility once they're hired, the register roster of who to go to for what issues. Who's sitting in the chair of the state drugs authority or, who's the chief inspector, or where are they located?

So, we would indicate we were coming down and request a meeting. And sometimes they would say: yeah, sure, that's great. We're available on Wednesday as you proposed. Or sometimes it was: we're really busy, and it's not a good time. So you had to read between the lines in the response, whether they were or weren't, being receptive. And if they were busy, obviously, we tried to change dates or ask for what would be more convenient. And if we arrived at a mutually acceptable date, then we would judge receptivity from that early meeting. Who are you? This is who we are. What do you do? How do you do it? This is what we do.

And we would start asking questions. Again, to develop our local knowledge of the Indian system so that we could reflect back to headquarters if and when there was an issue or a problem, where to go, and who had the responsibility to address or fix that kind of a problem. So it was really through these introductory meetings that we identified that Hyderabad, Gujarat, and Maharashtra were the three most important states for us in terms of production and number of facilities. Hyderabad politically, in the early days of the India office, was going through some

issues. The state, it's called Andar Pradesh, actually was separating into two reflecting ethnic differences. And so it was really awkward because nobody wanted to make promises or engage too much with the foreigners until they had that, if you will, constitutional reform when state separation occurs. And they, you know, they went through a proposal: should we be three parts, two parts, or one part? And that took a really long time to sort out. Today, later, there's two now, Telangana and Andhra Pradesh, which is headquartered around Hyderabad. But then we had to deal with a whole new set of authorities as they stood up that new province.

That's one complicated example of when they were reluctant at first. We even entertained for a period of maybe in 2012, late 2011 through 2013, of opening up a third FDA office in Hyderabad. So during that period around 2010 or 2011, Congress gave us authorization, or maybe told us—I don't know the best way to phrase that—to increase the number of in-country drug inspectors in both China and India.

So, as we talk about India, we started off with an FTE count, full-time equivalent, count of 13. And later Congress indicated and gave us money to increase up to 19. They added six, and they wanted more pharma investigators in India to address what had been a series of more significant findings from increased inspections that were occurring in India because we had people on the ground, and that increase led us to consider maybe we should have staff in Hyderabad.

And we went through the process just as we had to do in opening up the India office of getting relevant permissions and acceptances from the Indian government at the national level, as well as the local Hyderabad level, as well as the US consulate in Hyderabad. Ultimately, later in time, the State Department reflected on inspectors in a consulate, and this really arose because of issues in China. Fundamentally, consulates are designed to do consular work, respond to lost

passports, and issue visas. Having investigators is definitely not consular work. And so they wanted to change the diplomatic status of the FDA people in China, that were based in Shanghai and Guangzhou at that time. And say, if they're not issuing visas, they can't be in those locations.

FDA extrapolated that in India and said, oh, if that's the case, our CSOs in the consulates are definitely not issuing visas; they're there because of the proximity reduction in travel time to get to a drug pharmaceutical producing plant; we better recentralize all of our staff. And so, the idea of being in Mumbai and Hyderabad changed in late 2013 and now focused on everybody in New Delhi.

But so there's two examples of some receptivity issues that started back in 2009, 2010 where they weren't outright refusing to meet with us; they were just polite but they didn't actively throw their arms open for an engagement in Hyderabad. They were formal and disclosed and responded to what we asked, but it was not the same welcome we got in Gujarat.

And like water will find its path of least resistance and go there, our engagements with Gujarat blossomed first because they were such eager partners, and that translated itself into a particular engagement with the Gujarat regulatory—It's called the Gujarat FDA—with more invitations to their training sessions. Their intent was to have our staff either in Delhi or the investigators—who were at that time still based in Mumbai—come and talk. We often gave talks about our findings and summarized without getting firm-name specific. We keep finding this problem in your facility. You are not ever checking your SOP and validating that these results are meeting the expected standards. It's one sort of thing, or you keep repeating tests until you get the standard rather than looking for the root cause as to why it didn't meet the standard the first time.

Having FDA investigators come and talk to both industry and to the regulators about our findings was one of the central informational exchanges that we did locally, in-country. That is to say, staff based in India supplemented later more codified and regularized travel from CDER and ORA to India to present training opportunities.

JS: I just want to go back and make sure I understood, did you say that the staff was centralized to Delhi from Mumbai as of about 2013. That we no longer had staff in Mumbai at that point?

BR: We closed that office in the consulate in Mumbai and moved the staff from Mumbai to New Delhi, expanding our footprint, if you will, such that so when we first opened, we were supposed to be, I think it was six in Delhi and seven in Mumbai, but it could have been the other way around. I don't remember exactly. We never had a full complement in either place in the four years I was there. So we were recruiting CSOs, particularly in the food side, where we were deficient in the early days of the India office. We were supposed to have two food inspectors, and we didn't get two food inspectors in country until maybe 2012.

We were supposed to have three or four pharma inspectors, and those were easier to get; medical device inspectors, we were never able to get, more than one and I spoke before about that transition. We did get a BIMO inspector and then later created the medical device inspector. We initially were supposed to recruit two medical device inspectors, three pharma, and two food; I think that was the initial complement.

So, seven would have been in Delhi. And we got one medical device and one BIMO and kept them after trying to get the two foods. Now, we've changed that dynamic. I think there's

two BIMOs. I don't know that there's a medical device inspector, but three foods and five or six pharma inspectors is what the cohort is.

And I believe Sarah (McMullen), the current Director, indicated just at the beginning of 2000 or the end of 2022, having selected a full complement for the first time in the office ever, but tthey weren't all in country. As I said before, there's quite a long process of pre-departure prerequisites that have to happen. And that can often last a year or more as they acquire those different things, clearances, and training both in their profession as well as security to meet the position description requirements. That's a constant in both India and China offices when recruiting staff.

JS: Are there other US agencies that have a presence in India?

BR: It's a two-sided story. India is a pretty large embassy and there probably are upwards of 30 different federal department and agency representatives across what I use the term Mission India. That would be the embassy plus all the consulates as opposed to Embassy New Delhi just the embassy. And there are two natural partners within the embassy in particular: The Department of Agriculture has two agencies traditionally overseas, at least within the embassy. One is the Foreign Agricultural Service, or FAS, who fundamentally has a mission or responsibility to market US agricultural products in that particular country, whether it's beef or soy or cheese or dairy. But they're there to help sell US agricultural products in the host country.

The other part of the Department, USDA, that is more akin in the sense that they are indeed a regulatory authority, goes by the acronym APHIS, the Animal Plant Health Inspection Service. And their function in a country is much like ours: to prevent a substandard or, in this

case, a commodity infected with a pest or with a bug that could harm US agriculture. So they have inspection facilities in country. I think mangoes going from India to the United States have to go through some process before they can arrive in the US and be sold. We also have a responsibility, but it's not about the pest. When it reaches our border, FDA's responsibility is, first, to be sure that it's registered and it meets various quality and regulatory preparation requirements, and then we would let it in. So our most natural partnership in an embassy is APHIS and FDA. But not every country has APHIS. China doesn't have APHIS. I have APHIS here in Chile, that has regional responsibilities. Similarly, FDA is not in every office. And in that case, it's usually Agriculture, and nominally the Foreign Agriculture Service that has awareness and understanding of FDA issues.

And so the colloquial phrase is that FAS carries FDA's buckets when and if needed. So USDA is one of the most important partners in an embassy. The other one is the Department of Commerce. They have what's called the Foreign Commercial Service. And again, their issues are to help US businesses enter into the market, help the United States find investments and partner up as needed or to help Indians invest in the United States. And because of that relationship with industry, there are often identifying challenges or limits in the trade sphere that are what we now call technical barriers to trade. And we have a whole part in the Office of Global Policy and Strategy that deals with these sorts of trade issues that may be limiting to US products in the United States, US products entering India in this case.

So, truly FDA has no responsibility for that. We would be neutral, not have anything to say; India's regulations are India's regulations. We wouldn't want another country to fight with us about our regulatory issues, but we are often brought by the Department of Commerce to the table when they have a problem to explain the difference or to indicate how FDA in the US

approaches that issue. Again, looking towards harmonization and hoping they might see it our way, if you will, and adapt or modify the constraining regulation the same way that the Foreign Agriculture Service might bring us to the table if India stopped the shipment of soy because there was contamination or a pest present. Foreign Agriculture Service would be hoping that we could convince the Indian authorities to respond to allow that shipment of soy in.

Again, we wouldn't want anybody to tell us that we had to allow a shipment, say, of mangoes that didn't meet standards into the US, but our role in either of those host government meetings with Foreign Commercial Service or with FAS is again to explain the FDA process and procedures. But we're not going to fight with the regulator or the regulation because it's truly outside of FDA's mission. But we have awareness, and we have expertise about the why on our regulatory stand or process that we can explain to the host government. Again, the hope is through that explanation they might change, mitigate, or pivot. But that's their decision, not ours. We just provide information in support of agriculture and commerce.

Now, those are the two principal agencies. Obviously, when your US government agency is within a country's mission, it's all one US government. And we're all subject to what's called Chief of Mission Control, which fundamentally means if the ambassador says do it, we do it, because the ambassador is the president's representative. And so we're meant to follow that guidance and not stray too far away from it. Now, usually, there's respect and understanding for where our mission starts and stops. We're not often asked to cross those lines, but we may be asked to help out in a secretary of state visit or a presidential visit or if the government says we want to work with a host government, India in this case, to change a policy, we might reflect what FDA stance or position is that may influence. So issuing certificates of free sale is FDA's

response to India's requirement that some countries put a certificate of export that guarantees that the product arriving in a country will meet the standard. FDA can't or doesn't do that.

As a regular process, we would indicate that the last time we were in the facility, we didn't see any problems, and it was meeting FDA's, the US standard. But whether it met another country's standard, FDA doesn't have the expertise to make that statement. And so we often contract or engage with the Department of Agriculture, say the AMS, the Agricultural Marketing Service, to set up a system where industry in the US seeking to export to India can go through a process that has been approved by the Indians where AMS actually issues the certificate. So again, that's just stressing the importance of the role and engagement with USDA. But I've never experienced it in the eight posts that I've been in where AMS has issued a certificate. The embassy has a structure of itself and there's a political section, an econ section, and they're also looking at issues and changes and reporting on what's happening in the government. And they may come to FDA: Hey, India is creating new medical device laws. Can you watch and advise us as we come and get our understanding up to speed and maybe review cabling? Cables are the way the US government talks to itself. It creates a record; the understanding is that if it's not in cable, it didn't happen. So political and econ sections are reporting on what's happening. In this case, India's parliament, new laws, new guidance, etc., might be reported by cable and FDA as part of the embassy would have a role to contribute to those cables.

So those are some examples of some of the other agencies. And that's part of the initial arrival in country, whether you're new or replacing somebody or whether we're establishing a brand new office. You have to become familiar not only with the operational and admin side of the embassy, which enables and makes your life functional and provides how you move around for work and such. But you also have to become familiar with the roles and responsibilities of

the other sections or agencies that might be at post so that you understand the US government position, something about their position, and maybe recognize there's opportunity for collaboration.

And in India, we also have…

JS: Bruce, we lost you for a moment. Can't hear anything right now. I don't know if you can hear me. Bruce.

BR: OK. So USAID, the US Agency for International Development, also has a very large presence in India. Not only in development, but in Agriculture and food security issues, but more particularly in HIV/AIDS and PEPFAR. CDC is also very active in India. And so those two agencies, and they're not everywhere—here there's more AID than there is CDC—but they also represent opportunities for engagement and separation or understanding of where the lines of mission and where the lines of operation either stopped and started or overlapped and clarified.

So, starting first with CDC, again, they had sort of two main responsibilities. They had a very large HIV/AIDS PEPFAR program that they shared with AID. That was around drug safety and quality, in particular antiretrovirals, ARVs, that were being purchased with US government money and distributed in Africa and Asian countries that couldn't afford necessarily to buy their own. But the AID dollars were PEPFAR dollars that were looking at that program to be sure there was appropriate quality management, and obviously, that's our area of expertise. But since these particular facilities and these ARVs were not destined for the US market, they didn't fall under our authority. There was a separate program that exists out of CDER at headquarters that reviews the application of these facilities that want to participate in that program, and then we

provide oversight and what's called tentative approval. That is to say, we would approve, but it's (that ARV) still licensed or under some kind of intellectual property limitations, and so it's not available to be sold in the United States.

But because we've reviewed and approved it, you can use US government-appropriated funds to buy the product as long as it doesn't come into the United States. And so it fits within PEPFAR and is and was distributed widely in Africa or elsewhere and is the source of much of the very positive numbers of millions of people that today are still alive because of these provisions of antiretroviral program products that come out of India.

So we needed to work with CDC and AID to understand how that worked in the field to be sure if they or their teams were going from headquarters, they often had contractors come to inspect a facility. We wouldn't be in the way, we wouldn't overlap, and we could add some insight if asked about that facility in their program.

The CDC has a variety of other programs associated with training about surveillance kinds of programs for respiratory illness or diarrheal disease or response to particular illnesses like tuberculosis. Again, not a particular role for FDA, but sometimes they would ask us about therapies or treatments that had been under FDA oversight or approval.

Same thing with AID having programs in food safety—sorry, food security. People often get those terms—food security and food safety—mixed up. Food security is about having enough food to feed people, and food safety being about the quality of the food without contamination or in a good state for consumption by humans.

And through AID's connections with some of the agricultural authorities at the state level helped us address with industry food safety issues as FSMA came on board in 2011. So again, this was a couple of years after we opened the office in 2009; suddenly, FSMA became a very

important aspect with the beginnings of that new law —the Food Safety Modernization Act— representing a large endeavor of outreach activities to explain the first seven rules and what industry needed to do. And by that time, there were some parameters of the evolving new food safety standards authority that were visible, and we could see that our outreach around FSMA and their development of a national regulatory system—again, on top of what was happening at the state, provincial level—would have an opportunity for future engagement. Maybe that's a topic for another conversation: how we went about doing that. But, again, AID and CDC were present in India, and that was part of the embassy community with whom we needed to engage.

They also had interactions with some of the same people in the Ministry of Health. The Ministry of Agriculture was the place that was issuing certificates for the export of products going to the US, and that wasn't necessarily our requirement at FDA. We don't require certificates. We assume that a facility understands and knows, and we use trust but verify so that we check or inspect at the border rather than look at a certificate. Under the FSMA process and implementation, we also then discovered another part of the regulatory authority in India, the Export Inspection Council, EIC, that is the entity actually within their Ministry of Commerce and Industry, and they have the responsibility for any exported product, not just the ones that FDA exports. But if or when a country has standards or requirements, it's EIC in India that certifies that this product or that facility will meet the receiving country's requirements. We hadn't dealt with them before; that was new to us.

JS: So these were certifications of the commodity meeting the standards, in our case, the US standards for products that are aimed at export to the US. Is that correct?

BR: That's their general responsibility, synthesized simply.

JS: And that certification was based on what? How did they determine that these products met those standards?

BR: First, familiarity with the country's rules and regulatory standards that might exist. And they occasionally would inspect a facility, but more frequently they would conduct some sort of laboratory testing. Think about MRLs, minimum residue levels. A product has to have no more than some number of some chemical or less than some number of some additive; the EIC would have the laboratory responsibility to produce the test that showed that the product met that standard. Things like aflatoxin or some sort of chemical additive would be subject to that sort of thing, and EIC would do testing.

Other food commodities would have the absence of a pathogen. There's no salmonella here, there's no listeria here, therefore, it should proceed. So, they would conduct and produce evidence of that laboratory testing that would lead to a certificate. But we had too much experience with fake or adulterated or non-real certificates to rely on a piece of paper. That's one of the main reasons FDA doesn't require it. We will accept all comers under the assumption that they can/have/will meet our standards. They're registered with us. And in that process, there's some kind of indication that they've read or understand our rules and laws and regulations.

And then, we'll validate; verify through random checks, which are developed because we use a risk-based and sampling process to determine what should be sampled and what's risky or is complicated to make or a facility has a history of poor performance. Those kinds of variables would lead us to look at a firm or a facility more carefully in time.

But at first, we don't want the paper because we don't trust it. But we're going to verify, FDA's going to verify for itself. And that's a mantra that FDA has. We trust, but we verify to be sure that it is true or meets expected standards of quality or safety.

JS: That, that makes sense. This is all very helpful, and I appreciate the detail that you've gone into all of the relationships that the agency faced and relied on in India. I want to move on to our role—again, a very important role—of providing information back to the agency about the commodities and country and what we might possibly expect.

And I'm curious about how this sort of intelligence or information is gathered, and if that's done on a regular basis, but I guess especially what the communication is between the office and the Agency. And I'm not sure if that's principally through the Office of Globasl Policy and Strategy or with the centers directly, or ORA for that matter.

I wonder if you could speak a little bit to that because I think it's something that perhaps people would like to know a little bit more about, and the agency always talked about how investigators/inspectors are the eyes and ears of FDA traditionally? Here, I think the people on the ground in the countries, you're really the eyes and ears of the agency in terms of what's going on. And so I wondered if you could just say a few words about that, Bruce?

BR: Yeah, sure. Just to expand on that metaphor about being the eyes and ears. The centers are like the brain of the organization, and ORA is like the hands and feet. They go off and do what the brain tells them to do, and they bring back the information. So, our inspections conducted by ORA produce the evidence, and they write their reports. First, they issue, if needed, what's called in FDA parlance a 483, which is a list of the observations deemed at that point in time to be in violation of our rules, regulations, and legislation.

And then, after that observation is documented on the 483, the investigator writes a report about what they saw and why they said that this was out of line or not meeting the expectation. So it amplifies the information in the 483, describes the specifics behind it, maybe provides some photos or diagrams or elaborates on the issue, what they looked at, and what evidence was also seen. So that's a very formal mode of transference of information about a particular facility at a particular time back to the center. And that document goes through ORA and their supervision. It's reviewed, but more particularly because it's a foreign facility, it goes to the center's compliance office. So that's a little bit different than the domestic system, where the action and responsibility all stays in the district within ORA. With inspections done in consultation with the center in the international arena in India or China, where we have foreign offices, the reports are all directed back to the center.

So, that relationship with the centers is incredibly important, and the investigations are the major paper documentation of conditions on the ground found at specific or identified facilities. So, the agency indicates its interest in these sorts of things. Every year, they produce what's called a work plan on those facilities that they would like to be inspected in a given year. And each of the centers, the commodity centers, has their own unique risk-based model that contains a whole range of variables, some of which I just described: the history of performance, the last inspection, the complication of producing the product in question, etc., etc. goes into that model. And it generates and spits out, if you will, a list of firms that ideally would like to be inspected. That list is transferred to ORA, and since we opened up the foreign offices, those that are in India and those that are in China would be shared and looked at, and determined whether it's feasible to inspect those facilities.

So, part of it is a resource allocation. Part of it is the address or location provided sufficient enough that we know exactly where we're supposed to go. Some stay on the list, and others do not. So that's repeated every year. That's how we know where to go and produce a report. So that's the investigation part of the inspection part.

So we typically call them investigations rather than inspections, and investigations in the FDA world are conducted by Consumer Safety Officers—CSOs, that's the HR title—and they are experts in their commodity area since the program alignment in 2017. There was that focus on commodity and usually that's one person, but sometimes an inspection is complicated or very large, and sometimes another CSO, a laboratory person or an expert in, say, sterile processing or in aseptic processing, would join with a CSO. So it could be a team of individuals to produce the report. So I'm going to leave that aside. That's the center …

JS: Bruce, I'm sorry, but just very quickly. Are these carried out primarily by in-country inspectors, or are they supplemented by inspectors or investigators that are based in the US that come over for the purpose of doing specific inspections?

BR: That hinges on the word primary. So, the inspectors based in India are expected to conduct individual inspections by themselves. But the volume of inspections in India is greater than the number that could be conducted by those that are on the ground and, therefore, supplemented by the agency staff-based at headquarters.

JS: OK, great. Thank you.

BR: I guess one amplification of when that happens, and that's true in China and India. Maybe there's enough people to complete all the pharmaceutical inspections. But in another example, in China, all the food inspections that have been given to China are conducted on the ground, unless there's some kind of high risk or something else. If there is an injury or outbreak involved, then maybe they would send additional food inspectors to China. But in pharmaceutical area, there are too many that come out of the work plan requests to be conducted only by those that are based in India. And so they're supplemented usually in a volunteer mode. ORA would say we need to conduct an inspection in April with these kinds of pharmaceuticals; maybe it is with sterile, or it's about finished goods facility and who's available and has the expertise, and they would raise their hand in a volunteer mode. I'm available. And they would be matched, approved, and then sent on the trip. These are typically three-week trips in the pharma world. They would conduct two to four inspections in that period, and then they would come home. And that volume of inspections supplements the volume that is conducted by the CSOs based in country.

The other source of information, as I said at the beginning of this session today, are OGPS/OIP staff and country-produced reports. So, what's the structure of the medical device industry? How is it regulated? Who are the big players? Who are the responsible people in government and the foreign offices? Do they remain responsible for updating if and when there are changes in the regulatory process and updating the contact lists?

The paper covering things like that is posted originally on OIP but is now on OGPS's website, and anybody in the agency can look at that document. So that serves as the foundation for how does the system work: who is responsible, name, phone number, email, and contact. That's then supplemented by what has evolved—again, depending on the commodity and the

interest from headquarters—into regular phone calls. Usually they're monthly, but they could be every other week if it's a great deal of interest or something is wrong that needs more close attention. But regular phone calls and teleconferences occur now between interested parties at the center. So that would usually involve the compliance office and various parts of CDER, occasionally ORA. And include those in country with that commodity. And they'd be talking about what they found or upcoming trainings or indicating that the government of India has asked for help in this area and what should be our response. Sometimes, the foreign offices are included in compliance conversations about the inspectional findings, particularly when it was an in-country CSO. So that's the more regularized, up-to-date level of communication that occurs between the field and headquarters; it's very similar to what might happen between Kansas and headquarters about a facility in Kansas with communication between the district and the center. And that's pretty regularized.

There were no longer people in OIP headquarters that had a country-specific engagement. In the early days, Latin America had one or two people at headquarters supporting the region, and the India office had one. That kind of evolved away by, I don't know exactly, 2010, but definitely by 2011. So there's not a lot of engagement with OIP headquarters people in these conversations between the foreign offices and the commodity center about what's going on. So, that relationship with the Center or ORA is incredibly important. Sometimes it's hard, but it has to be developed such that the flow—the give and take—we want to know more about; here's the answer, if you will, and it's dependent on the engagement and the relationships of the individuals.

Each of the commodity centers has an international group; there's the International Affairs Staff and CFSAN. CDER's has a name that barely even has international in it. I don't

remember exactly what it's named, but there's a cohort of individuals in each of the centers who have responsibility for things international. Sometimes, they're involved in these office communications (…) with the field, and generally when it involves regulatory policy, broad regulatory issues, changes in international harmonization, or changes in our own guidance. Rarely are they involved when it's the technical issues; that's generally just the center subject matter experts and the foreign office commodity policy staff and/or CSOs alongside the leadership director and deputy director of the foreign office.

JS: Regarding the importance of the kind of information that's conveyed from the foreign office back here to headquarters, it was maybe around 2009 or 2010, there were import alerts issued based on the reports from India on food that had been exposed to pesticide-contaminated water. I wonder if you could speak to that or perhaps any other examples of where the information came from and how that information was derived? For example, if it was based on an investigation of a particular plant that was producing these commodities?

BR: I don't remember the specific example you're talking about, but I can give you two other sorts of pieces that line up under that. Another part of the responsibility of the policy people in country is to recognize if and when there are conditions that occur on the ground. Whether it's flooding or hurricanes or earthquakes or things that would disrupt the natural flow, and then to look and identify what the impact of that was. I don't remember the specifics of the case of pesticides spread through flooding, but if there had been a flood in a particular region where there were facilities that were shipping product to the United States, the first alert of that might come from the foreign office, which then would be working with headquarters to identify

whether or if there were any facilities that were subjected to or impacted by that particular event, natural disaster, or environmental impact as the case you raised. One could fast forward and think about what happened with the earthquake and tsunami in Fukushima as a real-time kind of example where there would be very careful engagement with the host country government, looking at what land or products may have been impacted.

So that happened also in China with the explosions in Tianjin back in 2016 or 2017, but it could have been later. An explosion at the port of Tianjin had an impact on facility shipping to the United States. The purpose of an import alert is we don't have to have test results to detain or prevent a commodity or product or something that originated from either a region or a particular plant from coming into the United States. This kind of information about the explosion or contamination in Fukushima or pesticide flooding example would prompt us to say, wait a minute: That product can't come in until you prove to us through laboratory testing that it's not contaminated.

And so that's how an import alert about potentially pesticide-infected flooding of a facility would have an impact. The firm shipping their product would have to prove at the border with independent testing that there was no pesticide contamination of that product that may have been subjected earlier to an environmental disaster or unexpected environmental event that might cause harm. So that's how that works, but I don't remember the exact example you offered. But hopefully, with those three examples, that clarifies your question.

JS: Thank you. We've been talking about what the centers are interested in and the guidance that they provide in terms of the request about whom to go out to inspect, for example. I'm wondering, if given the fact that here we have staff on the ground that are very observant, is there

much in the way of inquiries from headquarters to the offices about what do you all think? Do you have a role in identifying which firm should be inspected?

BR: We have the opportunity to express opinions. We have the opportunity to indicate we're seeing trends in this, and we're unsure about it. In the foreign offices, in India in particular, in the early days of the foreign office, there were a lot of questions about their ability to maintain sterile processing, which is pretty complicated. And there were a number of large Indian pharmaceutical companies with multiple facilities in India; Sun Pharma and Ranbaxy, to just give two examples.

And so often, the CSOs would select those firms or that kind of a problem to follow across several inspections, such that the same individual would be developing more in-depth knowledge. If we only carried this out with the volunteer CSO inspection process that I described, where somebody was available in April and a different person available in November, that institutional knowledge would only exist on paper in the reports that had been, therefore, read and stored by those people who might have access to the reports.

But in the foreign offices, say, I see that there are three facilities in India where Ranbaxy is producing product destined for the US, and I want to do all three of those Ranbaxy inspections. That brings a degree of familiarity and focus to the three inspections because they're conducted by the same person so they can see what are the firm's continuing processes. So one of the things that is looked at is what's the firm's adherence to quality management and how is it implemented equally at all three facilities or differently at each of those facilities. That might be lost if it was done by three separate individuals, but perhaps it's captured in a more detailed and

deeper mode when it's done by the same person. That's one kind of example, another one from China's information about concerns about falsification of records that…

JS: Bruce, you dropped off again. We lost you after "falsification of records."

BR: OK. So, China had indicated something that their inspectors were seeing. They thought that there might be some regular falsification of records going on in various food facilities where paper seemed to be preprinted with laboratory results but then dated, as the inspector showed up. So they shared that information with headquarters, and headquarters then decided that they were going to conduct a number of unannounced inspections so that they couldn't follow that process.

And together, the China Office, CFSAN Compliance, and ORA developed a process, and they looked at, I think, 12 firms over a six or eight-week time frame, and a number of those findings resulted in import alerts and significant regulatory actions associated with the documentation of problem records. That's a great example, though it took place not in India, but in China. John, I've got to get another appointment on the hour, so we need to wind this session up and schedule another if you want to go farther.

JS: Let's finish off in our next session the beginning of the years of your time in India and then pick up with your next assignment. I appreciate your willingness to do that. So let's go ahead and stop it here, Bruce and again, thank you so much for taking the time out, and I'll be I'll reach out to find out a good time for our next one, OK?

BW: Wonderful. Thank you. It's fun to reminisce with you, and I appreciate the time and the questions that you were using to prompt me to help create the document.

JS: You don't need much prompting but thank you! You've been great. Thank you, Bruce.

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JS: This is John Swann from the FDA History Office. It's October 30, 2023, and I'm here again for part three of my conversation with Bruce Ross. We're talking right now about the early years of the India office, the FDA India office. And Bruce, thanks for coming back here. I really appreciate it. I wanted to just briefly pick up because we are nearing the end of the conversation, I think, about the early years of the India office, but I did want to return to the inspections and their role in the office.

From about 2010 to 2013 or so I know there were some issues we had with vaccine production in 2010 from sediments in dosage forms that Shanta Bionics had produced the same year. There were some issues with parenteral drug products from Claris Life Sciences. And then, of course, we had ongoing issues with Ranbaxy and some of their facilities, some of which were banned from exporting. In fact, one source I ran across said that from about early 2013 to mid-2014 or so, FDA had added about almost two dozen drug-manufacturing plants in India to a list of those banned from exporting drugs to the US. I want to add, of course, there were some remarkable success stories. It was in 2012 that there was an issue with Salmonella in tuna products, and it was the in-country investigators in India that had traced that, I believe, back to

facilities in India, which I think led to an import alert, but do you have any recollection of those events?

BR: I do. I don't have much of a recollection about the first two vaccine firms, but certainly a lot of recollection about Ranbaxy and about the food one. But let's start about with the food one just because we've been talking about others. That one still proves today to be an example that the agency talks about in terms of being able to identify a source and how the changing technology that was used by the agency to identify food product contaminated with some sort of a pathogen that was causing illness associated with an outbreak.

When human illness occurs, CDC's usually the first agency that gets involved in identifying that there's a cluster of illnesses, and through their epidemiological surveillance tools, usually questionnaires, they begin to narrow down the food source, and then they identify a food source. In this case, it was tuna coming from India. Then they engage with FDA. And, with the suspect being tuna, then FDA engages, through its process, to identify how that product appeared in the location where the people consumed it and, therefore, got ill. So, in this case, it was restaurants. They use a traceback methodology to go through invoices, identify who the suppliers were, check their import records, etc. They work their way backwards through this traceback to identify the source. In this case it was in a city on the western, southwestern side of India, way down towards the point of the country, and they were struggling.

It takes a long time to get permission clearance for an FDA traveler to go to India. They need visas, and they need to organize schedules, and it's an incredibly long flight. We in India, had not only a foods inspector but a foods policy person who had once been an inspector and had changed their portfolio when they were assigned to India to policy, and the two of them

volunteered to go down to the location of the facility that had been identified as the source of this tuna product. And they went down and inspected and looked at conditions and tried to take samples of swabs in the processing plant. They were actually in the harbor where the boats came in that offloaded the tuna.

One of the challenges that FDA still faces with these international food inspections is our inability to get the sampling of swabs in a facility to an approved laboratory within the required 24 hours before the sample is no longer viable. We didn't have such an approved facility in India, but it prompted the conversation: Wouldn't it be nice if you'd have to be shipping through DHL or FedEx or one of the international shippers to do that. At that time was the best you could do was a 15-hour direct flight from Delhi to Newark. It was an incredibly long journey, and sending cold chain samples that were maintained in a cold chain to an approved laboratory just wasn't feasible. But it was through that inspection that we were able to collect sufficient evidence to identify that the processing facility was way out of alignment with guidelines and requirements for following seafood HACCP. They hadn't identified appropriate hazards, nor did they have relevant control points.

So it was that combination of having staff in country, being able to respond in a quick, short time frame to a request from headquarters: Hey, can you go down, travel down to the far Southern point of India from New Delhi, have a look-see, and report back to us. The inspection probably took about a week with multiple phone calls in the evening in India time with, crossing 11 and a half or 10 and a half hours of time difference. Not exactly the most convenient for folks at headquarters late in the evening or very early in the evening on one side or another to make that information exchange viable and real for the folks at CFSAN who are overseeing the

outbreak and determining what kind of information would be suitable to take that enforcement action.

So that's how the identity of what the product, which I think was called tuna scrape was made. It is used in sushi, a hot, spicy tuna scrape that used ground-up tuna that was sent to the United States and used in various outlets at the retail level to create those spicy tuna rolls that you see in a supermarket or in a restaurant; frozen packaged tuna scrape that had products added to it. Anyway, that's my recollection of that particular episode.

JS: In terms of the drug cases, Ranbaxy, in particular, we had some ongoing problems with them. Did those precede your arrival?

BR: No, they were all happening. While I was in country, there were, as you said, several different facilities in Ranbaxy that were having challenges with their overall quality systems. Within the different manufacturing plants a variety of FDA inspectors had, through their inspections, identified those concerns or problems through our system of collecting the evidence and, noting it down in a 483, and writing it in an EIR, and that led to being put on import alert. Or having various meetings with Ranbaxy senior officials going and traveling to Washington to meet with FDA and talk about those concerns.

I think earlier in my commentary with you, John, I've talked about how the work plan of firms to be inspected often came to country, to India, and our CSOs, the Consumer Safety Officers, would look at it. I recall that as a result of one or two facilities having had what I would call poor outcomes in their inspections, that led to potential enforcement actions. There was a period—probably 2010 or 2011—when one of the CSOs said, there are a whole bunch of

Ranbaxy facilities on this year's work plan. I'd like to take all of them so that we can develop the expertise and familiarity of the Ranbaxy facilities across India and report back on that. And that was one of the occasions, I think, where there were probably four or five different facilities for different kinds of products. There could have been a sterile one as well as a regular GMP inspection.

So, they might not all have been unique facilities. I think one of the challenges that I also recognized with Ranbaxy is that I was often reading in the newspaper about the agency taking action and felt I ought to have a heads up, but would get surprised with a lot of questions from the embassy when it happened. And, of course, I may have been at an industry meeting when FDA announced it and then suddenly put in the awkward position of not having enough information and certainly not being cleared by the agency to be the spokesperson.

So, I had to scramble and work hard to engage with folks both in ORA and in CDER to find channels of communication where they could share with me slightly in advance of a public announcement of an enforcement action. That way I could be aware of key things in the embassy and then later follow up with the drugs controller general when those actions occurred.

JS: How unusual is that for that to happen—had that happened previously? There are plenty of actions that the agency takes involving Indian firms. Is it more typical that there'd be more communication between the office and headquarters?

BR: We had to, if you will, fight our way to have a seat at the table. Not necessarily throughout the entire back and forth conversation about how significant a violation or how strong or how complete was the evidence presented. Not all of the back and forth, but as they were

nearing potential for action, I was successful in communicating both with CDER compliance and folks in ORA who were conducting the inspections that there was a utility to keep me informed of things pending as they were near close to being done. That was a challenge. We were concerned about the sharing of nonpublic information. Did I have a need to know? How secure were the communication channels? But in the background of this, I also, during the four years I was the director of the India office, I was pretty much on serial recruitment mode trying to get the full complement of staff, as I've discussed earlier. And so I was traveling back and forth between India and FDA headquarters probably three or four times a year to do interviewing and staff recruitment. And during those times, I would go physically meet, sit in the office of senior folks in CDER compliance, and hear the story. They didn't want to talk about it on the phone or certainly didn't want to put it in an email. And that perhaps helped aid in the trust and the desire to include me in some of those actions.

One of the problems we had with Ranbaxy, was the identification that later turned out to be pieces of blue plastic in vials of medicine that were presented in a powder form, to be reconstituted. The prescription or the medicine was presented in two different vials with a diluent and then a solid powder. There were unknowns—later identified as pieces of plastic—that had broken off in the bottling process that had not been picked up by the firm's quality control.

So that was one of the big concerns that pointed out that maybe, as a company, the sense of quality across all their worldwide facilities was highly variable in that they had not been successful in identifying this contaminant. But for me, one of the highlights was that we actually organized, between India and headquarters, to have near close to simultaneous entry into three different Ranbaxy facilities with no notice or as minimal notice as possible. They entered two facilities in India and one in the United States had roles in the production and distribution of this

particular pharmaceutical product within 30 minutes, even though those in India were separated by a couple of hours of time and distance. Two hours later they entered the same Ranbaxy facility in the United States, such that there couldn't be communication between the firms. Here comes somebody, hide or prepare or do things differently. But this unannounced simultaneous inspection truly allowed FDA an insight into the range of quality that might exist across the company in its different facilities, so it was a huge coordination of staffing. We had four people in India, two in each, going to the facility. And a team, I don't know what it was, they were ORA district staff; I think it was a New Jersey facility. But that really identified significant quality issues for Ranbaxy, and put them into import alert for a pretty long time until they were able to address those issues. I think that's one of the highlights that OIP, now OGPS, uses to demonstrate that, by having staff and country who are qualified and capable, they can coordinate and collaborate with headquarters to have a more significant outcome by being present in country.

JS: You've mentioned a few times how permissions are always necessary when moving about the country. And I'm wondering, does that have an impact if our intention is to do an unannounced inspection? Can you still do that and still secure the kinds of permissions that may be needed?

BR: It's not the same as the authority we have in the United States where the US FDA can show up at the facility, present their credentials, and say, here, I am ready to conduct an inspection. Internationally, there are a couple of hurdles that can be overcome. So first is permission to be in the country that, usually, is overcome by having a visa, and often FDA gets

their visas by having the facility to be inspected write a letter of support that is submitted with the visa application. We can overcome that by going through the embassy, having the embassy writers at DipNote invite John Doe, an inspector from FDA, to conduct inspections without being very specific as to exactly where and which firms on what dates are going to be inspected. Sometimes that works perfectly and we don't have to get specific. So, that would be the first hurdle, getting into the country.

The second is, as a US government employee—and I described this before—having country clearance. Country clearance also has to be given when there are different consulates in a country. They have what are called consular districts. They're responsible for what happens to Americans in that area. And I spoke before about Mumbai and Hyderabad as examples. So when an American is going to a facility that's outside of the Delhi consular district, we need permission from the consulate.

But traditionally, FDA informs the regulator. We intend to come to these facilities on these dates, and we actually invite the regulator to join us, to accompany us, in the sense of observing what we're doing or being there. We do not engage with the firm to get permission for the regulator to be there, but the regulator, like FDA in the United States, should have the relevant authority to be there to conduct inspections to assure safety. All we're doing is saying we're going to be there on Thursday at 10 o'clock, and if you want to show up and do your own thing at Thursday at 10 o'clock while we're there, we're happy to have you join us or observe what we're doing.

So that's another in-country hurdle we traditionally face. And sometimes, after we've signed nonpublic confidentiality agreements, which enable us to share nonpublic information, we

can say, under the terms of our confidentiality agreement, we're telling you we're going to go on Thursday, but we don't want you to tell the firm that we're going to come.

That one's a little tricky and is not always assured that they will honor that, but that's the intent sometimes under the confidentiality agreement and one way that we could say that we're going to go. But a firm in a foreign country has the right to refuse an FDA inspection, and it's taken a while, but the agency now has the ability when a firm does that to put them on import alert under the guise or the interpretation, and this is my interpretation, not necessarily the legal one. But if they don't allow us to come in and see what's going on, then they have to prove to us, when their product appears at our border, that it's adhering to and has no safety concerns. So, that import alert took a long time to come. I don't think it came into being until 2017 or 18, perhaps. I don't know the exact date, but there are very stringent requirements about how you document the refusal in order to put a firm on that specific import alert for refusing an inspection. And over time, in the last couple of years, that also has expanded a little bit; if they refuse to share specific requested records of something of a process or the laboratory testing, then that would also qualify as a refusal of inspection, and give us the ability to put them on import alert. So that's the far extreme in terms of what could happen if we're not able to conduct an unannounced inspection.

So now we're to the art of the term unannounced. And sometimes it's not much notice. A few hours or maybe at most, we're coming tomorrow so that they still can't do a whole lot of change or make a lot of repairs knowing that we're coming, which is something that we're well aware exists when we give a firm, say, three months' notice that we plan to come. They could make all sorts of changes in the facility before we show up. Again, the concept of inspection is one view on that particular day about what happens. And through that, through record review,

we're looking at procedures and processes, and we can identify trends. But an inspection is only what we see or experience on that particular day. It doesn't say anything about what happened in the past or what will happen in the future, although we do try to draw inferences or conclusions from the evidence that's collected by documents, etc.

JS: How effective is just the mere threat of going on an import alert to gaining actual access to a particular establishment or their records? And you mentioned also that if they are subject to an import alert, then they have to show to FDA when their product comes to the port that they meet the requirements. Without going into detail, but how do they do that? How do they show that they met those requirements?

BR: It's a barrier, for sure. It's an administrative process. It's based on the appearance. We are not required to test and show that a problem exists but it's reversed. The firm has to show us that whatever the import concern is about—it could be a pathogen contaminant, it could be about quality—they have to show us, present administrative evidence, that their product is safe or is not contaminated or is not subject to those conditions.

So, the most common is independent laboratory testing to show that a product doesn't have that contaminant or that pathogen, and then it may be released. So the harm or the concern that the firm has about being on import alert is the delay at the border, at their cost, of the shipment that they've sent that they hope to get into US commerce. Often when a foreign firm foreign firm sells a product to the US, they own it until it's taken possession by the distributor in the US. They're out a lot of money, if you will, waiting for a payment. And if they're subject to import alert, then it has to sit at the border, which is then subjected to additional storage costs.

And the laboratory testing is relatively minor in comparison, but it's still an additional cost and time while the laboratory samples and analyzes for whatever the issue is.

So, it impedes the ability of the firm to send their product into US commerce for an indefinite amount of time. The evidence has to be collected from the laboratory, presented and considered by FDA, and then released. And those delays can be substantial. It could take a couple of weeks; perhaps it's just 7 to 10 days, but it could go on for several weeks if the testing or the evidence required is sufficient. Of course, then when a firm's on import alert, they come running to FDA, you've got to get me off, you've got to help me. There were occasions when we had problems with rice. Basmati rice, for example, was on an import alert for various pesticides and chemicals that were not meeting the US standards. And the industry was outraged. They were complaining that the stocks on the shelves in the US-based stores—the Walmarts or the Targets or the diaspora-focused stores—didn't have basmati rice.

And we said that's not our problem. Basmati is one of the multiple variables, jasmine or white or brown, and we produce rice in the US. There's rice available. That's not the issue. Maybe not basmati. And we had to explain to them what the process of getting off an import alert is and we still do that.

And the foreign offices spend a lot of time with that issue. Now they have to petition us to ask us please consider taking us off of import alert. They have to present five clean and sequential shipments of their product that have been presented at the border and met the test and entered into commerce. Sometimes, some imports require an actual on-site inspection if it has to do with quality rather than a contaminant, which has to be scheduled. All that information goes through the Office of Compliance for whatever the commodity, a medical product or a food and takes months.

In the meantime, every shipment that they send to the US is held up, slowed down, required for testing. So, it increases the cost of selling their product in the US. That's why they want off. And there is no guarantee that after that administrative review by FDA, they will get off. Sometimes, they mess around with five clean shipments. It's not one, two, three, whoops that one didn't clear, and then I start again, four, five. No, if you have a bad shipment, then you start again counting five clean shipments. So again, the intent of this review is to assure the firm truly has made changes and that contaminant or that poor quality to put them on your import list truly has improved by seeing five regular sequential shipments that don't have whatever the problem that put them on import alert was. So it's a big deal. It's the most stringent enforcement action that we can take against a foreign firm because we don't have the ability to take them to court in the same way that we could if it was a US-based firm.

JS: Before we move on, and looking back at the Ranbaxy situation, when we ban shipments from particular facilities, do you recall there being an impact on supply chains associated with some of those products? Obviously, they were a huge supplier of drugs.

BR: Ranbaxy is a huge producer of generic drugs, and it's pretty rare that there's only one supplier of a generic product. Often, there are three or four or five, but sometimes, the import alert is against a facility that manufactures multiple products.

And so there's a whole part of CDER that would be involved in looking at shortages and the impact of those things and who else can supply product and if or when. There might be a shortage, so tCDER takes extra steps. Maybe they will look more closely when that product is sent to the border and perhaps use some enforcement discretion because they're meeting the

shortage, and that's the only place producing this product in shortage. I don't have a specific recollection of Ranbaxy. Across their firm and their products, in terms of presenting shortage of a specific medicine to the United States, that could have been the case but that's not in my memory.

JS: OK. I appreciate that. The FDA Safety and Innovation Act in 2012 had, of course, introduced generic drug user fees. And one of the things that these user fees aimed to do was increase inspections at generic drug facilities. I'm wondering if you saw much of an impact? Since this was toward the end of your tenure there, perhaps not. But was there much of an impact from funds deriving from those fees under this law that you witnessed in India and your ability to increase inspections there?

BR: Yeah, so I have a funny anecdote. That's actually a great memory of how sometimes getting things done occurs. But first, in general, the point of user fees when they were first introduced was to provide additional resources to the agency whether it was for approvals or the conduct of inspections; we would have additional funding. The agency was agreeing to certain timelines of completing various actions that allowed its generic products to be sold in the United States by the payment of these fees. When it was first proposed there was huge outrage, obviously, in India, notorious for low-cost products, and now suddenly they would be subject to literally hundreds of thousands of dollars under these user fees. And at first, they were like, no way, we can't pay that. We can't afford to do that. That'll hurt our margins too much. We would have to raise prices to recover. Even if it got our products to market faster and we could earn

more money because we have new entry more quickly, and the return on investment was happening more consistently and regularly under user fees.

So, in the initial days of those proposals, we had to spend time to describe what the real impact and outcome was and how there was benefit on both sides, that they would benefit as well as we would in having funds now for specific resources to be able to hire more reviewers or carry out more inspections. So, that took a little while, but they understood that pretty quickly. They're pretty sharp, astute businessmen in India producing products for the United States.

But the anecdote I truly want to share, at the same time that user fees were being discussed, Congress was noting the challenges and the number of adverse findings that were occurring. As a result of our inspections, Congress was encouraging us to increase the number of pharma inspections in India and China in particular. And so they gave us additional money to add staff to the India and to the China offices. So that was, in India's case, to expand beyond the initial 13, to add another six drug inspectors to boost our total staffing up to 19.

So when that happened, there was a proposal. We were going to add six more Americans in country. And approvals had to be reached both from the State Department under the Chief of Mission Authority to accept having six more people within the embassy, but also the government of India had a say about how many people were stationed as part of an embassy and what their jobs and duties were. And so we went through that process, and the State Department didn't have much of a concern. They looked at it from their ability to administer, administratively support us, including the increase in the number of travel or houses in the housing pool or vouchers or procurement that might occur as a result of these additional staff. The agency was able to provide sufficient background information that allowed State to approve that pretty quickly.

The government of India was a totally other story in terms of how fast they wanted to approve because they were concerned more inspectors in countries were going to create more problems. If we look historically, once FDA opened its office in India in 2009 the number of violations identified in facilities in India showed a change, an increase because we were there inspecting more facilities. We had more attention on India, whether it was the direct result of being in country or more volunteer inspectors. That's for other data analysts to look at, but still, you can see an increase. And so the government and industry were probably concerned that there were going to be more people in country. I kept episodically going back to the Ministry of Health saying, we're still waiting for you to approve this request to increase six CSOs in country. And they would say yeah, it's being considered, it's at this permanent secretary level, or it's at the DCGI, or point to some bureaucratic place where it was under consideration.

But it was probably near close to a year when I suddenly had a brainstorm. I was engaged in an industry association conference and meeting with the head of one of the associations that is responsible for about 80 percent of the generic drug products that go to the United States. It represents about 12 or 14 very large Indian pharmaceutical companies. We were discussing, hi, how are you? What's going on in your issue? And I was lamenting about how long it was taking to get the additional inspectors in country. And at the end of that meeting, he came to the point and he said to me, you mean to say that I'm paying hundreds of thousands of dollars to be inspected more rapidly, and the government won't allow you to have the inspections in countries so that I can be inspected?

And I said, yes, that's right. We can't add the staff to the office until the government of India approves our request to add six people to the embassy. He said, oh, that's outrageous. I'm going to go talk to the ministry; that's preventing me from selling my products in the United

States. I'm going to go fix that. And within two weeks of that meeting, we had approval from the government for the six. Now, I like to think it's as a result of that conversation and that intervention by the India Pharmaceutical Association. I can't prove causation there, but I think, for me, it was a new way to approach the issue to raise that problem with industry and their recognition that there was an advantage of having the user fees not only get them faster timeframes but seeking their own government's permission to hire the staff.

And I think it was maybe in 2021 when the FDA in the office finally hired the last of that additional six cohorts of drug inspectors from the approval that I think was granted in late 2014. To identify those people and get them willing to move took us still another five years to increase the number of staff.

JS: I know this was the story in China as well—having to work through channels even when the funds were available. So, before we move on to you know your next assignment, I wondered if you could look back to your time in India as the first full time director and reflect on what you think were the most important actions you took to put the office on a solid foundation and also integrate it into the network of food and drug production and regulation in India?

BR: So I think you're asking me to tick off a couple of what I think to be the most memorable or considerable significant achievements. So obviously just the creation of the office, standing it up within the embassy, identifying and hiring staff who could enable the work to occur, and creating systems within the embassy to support those staff.

Also later, it started during the tail end of my departure, but concluded after I left. First, the effort to expand into Hyderabad and then later the decision to close both Hyderabad and

Mumbai and move all our staff to Delhi. So, the ability to be responsive and resilient to the need of first creating an office within the embassy of Delhi and then to be responsive to the needs as it grew from the original seven based in Delhi to now 19, and finding space and creating offices and all the support that goes along with that—travel, etc. It's a huge achievement to create that infrastructure that still continues and has been tweaked and expanded, and there's actually going to be a physical move. The embassy has outgrown their physical buildings, and a new building is soon to be completed, I think, in the next year and ready for occupancy. During my tenure, we planned for that building to occur, and now, in 2024, staff will move into that bigger facility, and more directly, FDA will be all on the same floor instead of in little pockets where we could identify space.

Second, the integration of FDA within the mission's priorities and other agency engagements I described earlier with CDC and their efforts to create surveillance and programming around both communicable and infectious diseases as well as PEPFAR in the HIV/AIDS world that served us well during COVID. Also, the interaction with AID and the health attaché alongside HHS' so-called operating divisions (OpDivs) NIH, CDC, and FDA; establishing that functionality within the embassy and awareness of one another's programs.

Similarly, creating and building on the relationships established with the Indian government. Discovering, in the initial days when we arrived, the challenge that they had with regulating medical devices; they had to call them a drug in order to regulate them. So, going from not much oversight to now creating new laws associated with medical device regulation.

As we were setting up the office, India was setting up their own food safety and standards authority that would be the centralized regulatory authority. We interacted with them as our own FSMA regulations were being released, overcoming or dealing with the issues that they weren't

very focused on—products that were being exported. But they were very focused on the domestic market. Our work in traveling in country across provincial and state lines was part of an evolution and change in a relationship that was built on how things are controlled, both within the Ministry of Health and at the state level. But there were also engagements of the Ministry of Commerce, where a lot of the industry associations and some of the export promotion boards that we deal with today are located: the Export Inspection Council, which certifies that a product meets the US standards, and the Marine Products Export Development Association, with whom today we're engaged in the shrimp pilot activity, as two key examples.

Another achievement, I think, is just the recognition for FDA headquarters that the India office, albeit on the other side of the world, 11 plus thousand miles away, is really part of the agency. It may be a special corridor, so to speak, metaphorically, that you have to walk down in different time zones and have a smaller number of people to engage, but there's a benefit to the agency. We have people in country. We have people who not only have specialized expertise in different commodities, but also specialized knowledge about Indian things and what goes on there, who to talk to, who to engage with, and when and if there are issues or the desire to train.

And noteworthy, too, is the establishment, particularly in the medical product arena, between ORA, CDER, and occasionally CDRH, of regular travel to India to deliver training about our changing guidelines or requirements or our new rules, whether it's track and trace or whether it's FSMA related, etc. This provided information exchanges to industry and through the associations, whether it was DIA or the India Pharmaceutical Alliance or the India Pharmaceutical Association. Those training sessions have become, as I said earlier, institutionalized, regularized, and happen frequently, such that the purpose and value of the India office to the agency has been established.

And so, during those first four or five years with Beverly and my leadership, we helped set the base, the foundation upon which others who followed us have built and expanded. And now we have a pretty solid house if you will. And this metaphor that can encompass this and enable ongoing work to happen on the other side of the world, that's truly important. It has led to improving the oversight and assuring the safety of the products that are manufactured in India and destined for US commerce.

JS: That's very helpful. It's a terrific reflection back on the impact that your office made and that you made. I believe you stepped down from that position around September of 2013. Is that correct?

BR: It would have been I think July 2013, when I moved to Mexico as the new Latin America Regional Director based in Mexico.

JS: Could you say a little bit about that transition? For example, if you had any interim appointments in headquarters. I don't know if any limitations on one's stay in country came into play here, but did you have any interim positions, and just how did it work out that you moved from the director of the India office to the deputy director of the Latin America office?

BR: It is indeed a new chapter. To answer briefly, it was a direct transfer where I moved with my family directly from India to Mexico. I actually had to wait in India before I could take up the new post. So, it was through a vacancy announcement application that was posted about the vacancy of the Deputy Director in the Latin America office.

I applied and was accepted, but because I was the director, I was not allowed by headquarters to move because there wasn't a replacement identified, and it would have left the India office short-staffed in their leadership positions. There was a deputy, but they wanted to have both a director and a deputy and didn't want me to leave until they could have a new incumbent.

So I was probably an extra nine months knowing that I was going to be moving to the deputy director position before they identified and that individual cleared their prerequisites in order to be able to move. So the vacancy was maybe six, eight weeks between my departure and the next incumbent being able to sit down in Delhi.

But there was an interesting component. When I applied for the job as deputy director, it was based in Costa Rica, and by the time I was moving, they came back to me and said there's so much going on in Mexico, and so much travel between the director and the deputy from the regional headquarters in Costa Rica to Mexico. We think it makes more sense to have the deputy based in Mexico. Is that OK? And so I was presented with a change of what I thought was going to be a posting in San Jose, Costa Rica, as the deputy, to now being presented with wanting the deputy to be based in Mexico City, Mexico. So I had to think about that for a little while and talk it over with my wife because I had not had a lot of exposure to the country of Mexico. So, I wasn't aware of a whole lot other than my own personal tourist travel when I used to live in California, into Baja, California. And I needed to think a little bit before I could say yes, but ultimately, that wasn't a problem. I said yes. It was actually a fantastic assignment. I think Mexico is one of the best-kept secrets. It's a wonderful place to live in Mexico City, and concerns that people hear about violence associated with the drug trade, etc., that may be real in

other cities, but it's not so in Mexico City. It's a very genteel and polite, with wonderful weather and a great place to live. In looking back, I had a wonderful time in Mexico City.

But the reason the agency made the change of the deputy was there were a lot of issues associated with foodborne outbreaks with commodities coming out of Mexico. The attention was on what are we going to do about this and how do we get a better handle on who oversees what in Mexico. Working with the regulatory authorities was deemed by the agency to be better served if they had more direct leadership in Mexico. And that ultimately played itself out. At the time, it was called the Produce Safety Partnership, a signed agreement that Commissioner Hamburg and Deputy Mike Taylor traveled down to sign with the regulatory authorities and SENASICA, which is on the agricultural raw herbs, raw commodity side, and COFEPRIS, which is on the minimally processed Ministry of Health side. Those two regulatory agencies in Mexico form the comparability to FDA's oversight. COFEPRIS is closest to FDA, but COFEPRIS doesn't deal with products like carrots or tomatoes or avocados that just come straight out of the field and aren't processed but just packed and shipped.

So we had to work with both of them, and that would be one of the major highlights of my Mexico time. I walked into an established office. There were a couple of what we call today international relations specialists: one in foods, one in medical products. And then we had a director to that cohort of staffing in Mexico. And then later, during my tenure, we also added the foods-based inspector in country. Again, the need was similar to the same sort of thing that I described about India: to be able to go quickly to a place that were of concern or of interest to the agency. But they were readily based in Mexico and didn't need to organize other domestic demands that would prevent them from traveling quickly. So it changed. The agency went through some sort of iteration prior to my arrival in 2013 that said the staffing needed to change

in Mexico. I believe it was in response to issues that were going on in the food sphere. And then, during my tenure, staffing changed a little bit and it subsequently changed after I left as well. So that's the introduction to Mexico. It was a surprise move. I thought I was going to San Jose; I went to Mexico City and had a wonderful two years there.

JS: The formal statement of intent or that agreement that you referred to, which I think was around 2014, not long after you arrived there, is also reminiscent of what happened when you were in China. That is, what eventually turned out to be, I think, an MOU between the agency and the Chinese government.

BR: You learn from different places. In China that was definitely led by the agency and the government. I just helped carry the pails and made sure people were talking to each other. The one in Mexico was still the gleam in the eye. That came from headquarters and the leadership from the agency out of Washington or College Park in this case. But, I had a much more substantive role in assuring engagements and delivering messaging, and ultimately assuring that all three parties were communicating and moving in the same common direction.

JS: All right. So, as the deputy director of the Latin America office operating out of Mexico City, was your focus strictly on Mexico or was it broader, because obviously the Latin America office has jurisdiction over almost four dozen countries, right?

BR: When I arrived, my director at the time in Costa Rica was Mike Rogers. And we agreed that it made the most sense for things in Mexico to be under my purview and that he would

manage everything else. So, one of the substantive changes in this transition from India to the Latin America office was that I was going from a single country office to a regional office. I was going from a country—India—that had primarily a pharma medical product focus with minimal food to a major food and minimal medical product focus out of Mexico. At that time, the multiple medical device facilities alongside the border, so-called maquiladoras, were within 50 to 100 miles of the US-Mexico border; FDA didn't inspect them because it was a security threat to have Americans in that zone. So the agency hadn't figured out yet its process in order to be able to do that. It didn't have a major focus, and Mexico is not a very big producer of generics. They produce a bunch of vitamins for us. But those were not necessarily controversial until later in time, and maybe we'll get to that. But it was, the change was really food, and Michael and I agreed in the role dissemination that things in Mexico would fall into my lane, and I would help him with the administrative things regionally.

He was relatively new, maybe a year in his role, and had been functioning without a deputy. There were a series of detailees, various people in different roles in the Latin America office assumed the role of deputy on detail for 60 or 90 days in a rotational way while I was still in India, destined to come to Mexico. so that's how he and I divided up the work. That's changed now today. The deputy deals with all of the administrative and functional things and has a food focus, while the director has a medical product focus, but she would regularly travel to Mexico when there were serious meetings or this Produce Safety Partnership that started but evolved over time into now what's called the Food Safety Partnership, which is a little bit broader yet became a more focused activity as administrations changed and governments in Mexico and leadership at FDA changed. So, that division that the deputy in Mexico only focused on Mexico is not the way it is today. But it was when I was there and it was mostly food and only Mexico.

JS: In this situation, comparing our approach to inspections in where you were before in India and now in Mexico, in Latin America we are dependent much more heavily on having inspectors, not in country so much, but dispatched from the states to our Latin America office. So I'm wondering if you could give us a sense of the advantages and disadvantages of this approach, whether it's an economic one or tactical or otherwise, between having your inspectors based largely in country as opposed to the way it's done in Latin America.

BS: I think it probably starts on two fronts. It's not clear to me which one necessarily takes the lead, but the ability to get to the country is certainly one of the considerations. And the second one is the cost differential of having somebody based in a country versus having somebody travel in and out for short periods of time. There is a huge additive cost that covers things like furnished housing and provision of office space in an embassy and the benefits that overseas assignees accrue differently. The allowances that I spoke of in our first meeting, for example, are huge cost impediments to the decision to add somebody to a foreign office.

It's not just the fully loaded salary of an individual of an FTE, a full-time equivalent, to be assigned, but it's these overhead kinds of expenses that add up pretty quickly. And the difference might be a quarter of a million dollars for a full FTE at the headquarters level to six or seven hundred thousand for a fully loaded overseas-based staff. So, economics is often in consideration. What do I get for that differential, and how many trips could I get if I didn't have to pay for that? And so Mexico, as well as all of Latin America, is fundamentally in the same time zones as the United States, it ranges from being two or three hours ahead of Washington to being in the same time zone as California. Quite different than the 11- or 12-hour time zone

difference between India and China. And, of course, it's not 15 hours of flying. Albeit north and south travel, and to fly from Washington to Chile, for example, is over nine hours. But it's essentially in the same time zone. So, the agency felt that they could easily get inspectors in and out of Mexico for far less cost than trying to base people in Mexico.

So that's how they started out. They have continued to have one foods inspector based in Mexico. And for a while when Michael and I were the director and deputy of Latin America. We had a hybrid position here, where I am now in Chile. This position during Michael's leadership was halftime of foods inspector and halftime of foods policy to take advantage of the physical location and the ability to easily go to Argentina or Colombia or Peru besides Chile—sources of food products destined for the United States. But that's changed again since we left. And now, my position is just the policy and not the hybrid situation. But let's go back to Mexico and continue your questions or thoughts there.

JS: I did want to ask about something you alluded to earlier. The food industry in Mexico is so dominant in terms of the greatest interest for the US, and not so much the medical products. But you did mention dietary supplements as a larger industry, and I wondered if you could speak to that: what were the US's concerns with dietary supplements that were being imported from Mexico.

BS: Yeah, I'll do so by describing an anecdote that really made our eyes pop open. The dietary supplements don't have a lot of oversight from FDA. They don't have to submit approvals and processing like pharmaceuticals or drug products would. But they do have a variety of good manufacturing processes that they're supposed to adhere to. Also, for the agency

they're not considered very high-risk products. And so we don't allocate a lot of our scarce resources to inspect or to look at products that don't have a lot of risk because it's just not deemed to be an efficient use of limited resources.

However, and I'm not quite sure why or how this came about, Michael had the idea that maybe we should look at what was really in these dietary supplements. You take one of these over-the-counter pills and, say, they claim to have 400 milligrams of that or 3 microunits of this, and they have various standards on the label that says what's in that pill. But nobody's ever done testing; nobody regularly. It was not part of the approval process. We just look at the manufacturing. How did they do it? But anyway, Michael worked with ORA, and they did a sampling and testing program of a number of dietary supplements coming into the United States from Latin America.

And I don't remember now exactly what the vitamin was or who was producing it, but they identified two different products that were coming to the United States that on their label said they had a specific level of ingredient that when we tested showed that there was none of that ingredient actually in the product. Or, in another case, it's a substantially reduced amount of that product. And suddenly, it was like people are paying for nothing. Just a pill. It was hearkening back to snake oil salesmen, so to speak, convincing a consumer to buy their product. But there was no vitamin D or no vitamin C actually in the product that said it had that vitamin at this level. And we only found that out from testing. So obviously, those firms were put on import alert, and they had to prove subsequently that their product did indeed have testing, but it opened up a new frontier, if you will, to look at dietary supplements in a different way that maybe occasionally we should verify that trust that we had, that the good manufacturing practices were

indeed assuring a level of quality of that we didn't find. So that's the anecdote about dietary supplements.

In time, we did meet with the generic industry, India being the leader. We didn't feel as comfortable having such a significant proportion reliant on India. And so we were looking to see because it's a relatively strong industry in Mexico, but their volume of production was mostly geared for themselves and maybe a little bit of exporting to Latin America, but not at a volume sufficient that could meet the US market.

That's how we found the industry. And so there were a lot of efforts to meet and describe as they considered. I don't think today that they've made the decision to expand production to include the US and get licensed as an approved generic for export but it was something that certainly got new insight as a result of the pandemic, and we considered how to address our supply chain concerns.

JS: Obviously, we have offices in India and China, the two largest countries in the world, but here we have an regional office that has charge of dozens of countries with multiple regulatory frameworks. How does one get one's hands around something like this when working with so many different entities that are interested in importing from or exporting goods to the United States? How do we even start approaching a problem like this? Or not a problem, but it's certainly a challenging situation like this.

BR: So it goes back to one of the fundamental bases the agency has, which is data-driven and science-based and addressing risks. So even though the Latin America office is regional and covers, as you said, over fthree or our dozen countries, islands, and territories that represent

everything south of the US border through the Caribbean, Mexico, Central America, and South America. Not all of those places are sending products to the US. Not all of those countries have a volume that raises our attention to concern for risks presented in the products that they export. And most of the region is exporting various food commodities that are either processed, canned, or frozen, or literally are just the fresh broccoli or tomatoes or avocados or nectarines or table grapes as the case might be that have not the same kind of risk to illness or threat of death or to human illness. Even though there could be a foodborne outbreak, in and of itself, that's mostly self-limiting. A week or ten days of whatever, vomiting or diarrhea, gets the bad thing out of your body, and we recover. Not a whole lot of death or maiming or concern, usually, as compared to the medical products.

We stratified which countries sent large volumes of goods to the United States, and that's how we, Michael and I, focused our leadership of the Latin America office. That kind of continues today. We were also driven at that time because of the release in 2011 of FSMA, the Food Safety Modernization Act, to be sure that all these food-producing countries had exposure to the new laws. And so, we developed workshops and worked through different modes to be sure that those high-volume producer countries had awareness or had the opportunity to hear directly from FDA about the changing requirements and regulatory issues under FSMA.

And so, staff in the Costa Rica office focused on the Caribbean and Central America, and Chile focused on South America to help divide up the regional responsibilities while I focused on Mexico with those issues. OK. I just want to call out, John, I've got about three or four minutes, and I've got to pop to my next meeting, so think about where your questions are and where the natural break might be.

JS: I think we might be at it, and I don't think we'll need another full session. So if you're amenable to it, and I know I risk straining your generosity of time again, but might you be able to sit down maybe for another hour?

BR: Yeah, certainly.

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This is John Swann from the FDA History Office. It is November 3rd, 2023, and I'm here with Bruce Ross for part four of our oral history on the early history and subsequent history of the FDA international offices. Bruce, thanks for joining me once again. And I would like to pick this up where we left off earlier in the week with your pending departure from the position in Mexico City. I know you subsequently served as the regulatory counsel in the Office of Partnerships in ORA from about 2015 to 2018, I think. And I know you had many responsibilities there. One among those I wanted to ask about was the role you had in coordinating on behalf of ORA, the audits of international regulatory counterparts of FDA, and the audits they carried out in the US to ensure safe food and drugs from their standpoint.

First of all, where were you during this period? Because I can't keep up with you! But could you say a bit about the authorities that the European Medicines Agency, the Taiwan FDA, and the others who carried out these audits and how FDA accommodated them?

BR: That's a pretty broad-based question, and I'll respond sort of to what I think is a sequential issue in terms of the transition away from a foreign-based assignment in Mexico City

to returning for the first time in an incredibly long time to a domestic assignment in the United States. So, when I first made that transition, I worked in ORA. In the ACRA office and functionally, the role was to be the international staff for ORA, and I reported to the DACRA. We've spoken before about how the foreign offices actually communicated and initiated activities, responded to requests with the various centers' international affairs staff, and that was what I was doing in ORA; I was trying to stand up that staff.

It had once existed in ORA, and for a variety of reasons, people had departed, and ORA hadn't replaced them. And so when I came back from Mexico in 2015 I had that position, working and reporting directly to Steve Solomon. And that position changed into the Office of Partnerships as a result of program alignment where ORA was reflecting on the need for commodity specialization, and there were changes in responsibility for the ACRA and DACRA. So it made more sense to locate the international engagements with the Office of Partnerships, which had the role to interface with all the different states and oversaw the various engagements, contract mechanisms, and cooperative agreements by which ORA worked with the states to receive a variety of different services, sample testing, inspections conducted, etc.

Organizationally in, I think it was in 2017—when program alignment impacted ORA—that the office bureaucratically changed its structure. Now the functions of the office, the interface, as you described in your question, included receiving queries from foreign regulators associated with requests for information: FDA, send us a copy of your last inspection, or send a copy of the various reports or results from the border import investigations or from the inspection sampling of a product coming into the country. Or, the conduct of audits of FDA in a variety of areas. So we were an information exchange clearinghouse and a coordinator across ORA and the many different district and sub-district offices across the country when a foreign

regulator needed or wanted something. And the most common of these was audits, so I'm going to skip the request for information reports, etc., for the moment and focus on audits because I think that's really what's behind your initial question. Frequently, we do this to other countries, and so it's not unusual that other countries would do it to FDA. We'd want them to understand FDA's span of control and ability to implement and oversee its regulatory responsibilities, whether it's for dairy products or food in general or some other sub-element of FDA's broad regulatory responsibilities. You spoke of two, Taiwan and the Europeans There were others, the Koreans, the Indonesians, etc., which may have come.

Usually, the process goes something like this. The regulator sends notification to FDA that they have intent or desire to come and audit and name the area, the food safety system, or the dairy registration, or your testing associated with toxic chemicals or with aflatoxins or things of that nature. And that query would go typically first to the center that had oversight. So, most frequently, that would be through CFSAN because most of those audits were food-related; although, associated with our activities under the mutual recognition work with the EU, there were some medical product investigations and audits that occurred and also associated with systems recognition work. The Europeans came in while we were doing similarly in New Zealand and Canada and various member states of Europe.

So the request comes into the center that says, let's pick a date: August 1st to the 15th. We want to come to the United States and we want to audit your system. Typically, that would then prompt planning and engagement. So obviously, it starts at headquarters where they get to understand and have briefings associated with our rules and regulations and laws, what gives us the authority to do what we do, and to hear about how we implement it. And then planning various places around the country; different districts to look at federal and decentralized

engagements with the different districts, as well as sometimes to observe an actual FDA inspection being conducted so they can understand how we implement our rules and regulations.

Traditionally, these audits have eight or ten different components: rules and regulations being one; training another; sampling and testing in a laboratory, a third; inspections, a fourth; etc. And a trip to various locations to meet those different requirements got planned. And my role in ORA was to help coordinate with the center where they were going to get relevant permissions from the different districts or just subdistrict offices where the team was going to travel, and identify if and when somebody from FDA would accompany this audit team. There was almost always somebody from the commodity center, CFSAN. Sometimes, it was a subject matter expert; sometimes, it was somebody from compliance or their current office of international engagement, or it was often one of the national experts for that commodity from ORA or people from the lab or district supervisor.

So, you know, that had a lot of moving parts, and we needed to settle both on the identification of the who and agree on the schedule and then the event would take place. As the event took place, at the end, there would be some kind of a closeout meeting. The foreign auditor would give first impressions about what they saw and ask questions to clarify or help improve their understanding before they went away to write their final report, which would then be returned or shared with FDA months later, typically four to six months later after they had reviewed and finalized the report.

And so I served in my position in ORA as one of the point people to help coordinate that with both the commodity leadership, particularly after program alignment—that might have been with OHAFO leadership or pharmaceutical leadership—and then the folks at the various districts to be visited so that the foreign regulator would have a good opportunity and experience to see

how this particular commodity or area that FDA regulated was actually managed by its rules and by its actual implementation.

And that took a lot of time. When an auditor said they were coming, there was a bunch of upfront time and typically that was a month or more in preparation. I never accompanied them on their field visits, but I often was part of the headquarter meetings to chime in and represent ORA if they weren't there and just the commodity center was. But that's the role; that's the function associated with foreign regulatory audits of the United States or of FDA.

JS: Do you recall any instances where, in the process of arranging for these audits, if there was ever a little discomfort on the part of FDA in terms of what our counterparts were interested in seeing or participating in or the kind of information they were looking for?

BR: I wouldn't say there was any sort of discomfort because we recognize the importance of this audit, and we often did it to them. So, it was a quid pro quo or a fair exchange. Where there were some challenges occasionally was, they would say we want to go to a particular state or district, and we would reflect that district would not be a good representation of what they were trying to look at, and we would suggest another location as being better: there were more facilities, or the travel time and support was easier on the agency. But they were always made as suggestions. And if the auditor said, no, I want to go to Laredo, Texas, and see this facility, then we would try to accommodate that request. But if the request seemed out of line, sometimes foreign regulators, when they say they're coming to the United States, don't necessarily appreciate the distances from an airport or how much time it might take to get from a particular location to another. And so that's one of the roles and functions that we would undertake, both

collaboratively with, say, CFSAN or the commodity center and ORA, providing relevant information.

Sometimes, we pushed back on the timing of the inspection because something was going on so that we couldn't move and that might put it first or last in a sequence. These audits typically last a couple of weeks. So that might provide relief for a change in location. But I never experienced the sense of, oh my gracious, we really don't want this regulator to come and dig around and look at our systems. I don't know the exactness of this, but I think the worst would have been, I'm sorry; that timeframe is not convenient for us. How about this one in a different month? But I don't have a specific example to share about where that might've happened.

JS: But in terms of the establishments that we and the regulatory counterpart were going out to in tandem, were there challenges, as you say, from the standpoint of our regulated establishments and in these arrangements?

BR: In order to answer that question, I want to take just a half step backwards. When we go to a foreign country, we inform the foreign regulator that we're coming to inspect a facility, and we invite them to join us. In that case, our understanding is we're not going to enable their entrance into the facility, but we assume, as a result of their regulatory authority, that they can enter the facility in the same way that FDA can under its authority. But when a foreign regulator comes to the United States, we say to them we won't enable your entry into the facility to conduct a regular surveillance inspection. We assume that you have the authority, and the facility can indicate whether they will, or they won't accept that inspection. So that's a normal conduct.

It's a little bit different in an audit because in an audit, they actually want to observe what FDA is doing, and traditionally, FDA doesn't inform a facility that we're coming on Thursday. We just show up. When there's an audit, and we expect to be observed by a foreign regulator, that does require advance notice to the facility for coordination purposes. Also in this case, because of the audit, we are enabling the entrance of the foreign regulator.

But we make it clear that the role of the foreign regulator is observing what FDA is doing. It's not a foreign regulatory inspection by that regulatory authority. So it's a little different in the sense that we inform the facility. FDA is being audited, say, by the Taiwanese to look at dairy products. And we're coming to your facility on Thursday with the Taiwanese who are going to observe what we do. Now, in some cases, dairy being one of them, state authorities are often involved in the oversight or the conduct of those inspections rather than FDA. We recognize the state work, but it's the state who actually performs. It's their staff who conducts the inspection, so that would be another wrinkle in terms of the coordination, and dairy is a good example of that case where particularly milk and cheese issues are more directly overseen by the state because of the distribution is more consistently not interstate; not entrusted, but it remains contained within the state. So in another dynamic, we might say our national expert is coming to observe what the state is doing, and we want Europeans or the Taiwanese to observe. I've only recollected one or two cases where the firm politely declined, and our response was; that's fine, we understand. And we picked another firm. It didn't interfere with the audit. It wasn't that the foreign regulator said, I want to go to that facility in Topeka, Kansas, just to name an example. But rather, we could identify a similar or comparable facility that would enable the foreign regulator to observe what they wanted to do, which is how FDA investigates or inspects a facility to assure and ensure that they're within compliance.

JS: OK, that's very helpful. Thanks for clarifying that. From late 2018 to early 2020, you were in the ORA's Office of Human and Animal Food Operations as a senior advisor. I was just curious—not to short shift this because I am anxious to move on to the global operations wsubsequent to this position. But were there international elements in that position and OHAFO operations?

BR: Yeah, I left the office for this position. The Office of International and Federal Engagement—as it was called—within the Office of Partnerships. So it was a small team of three or four of us ultimately. They maintained the functionality of that even as I transitioned into the senior advisor working for the Associate Commissioner for Human and Animal Foods Operations. The international component at that time still was a lot of work associated with Mexico and the transition of the broader safety partnership into the Food Safety Partnership. There were still outbreaks, with food identified as having originated in Mexico. And that was one of the areas of responsibility that Mike Rogers indicated that I should pay close attention to and keep him aware and informed of those activities by the agency. And if and when there were some events of more significance than others that he needed to pay attention to. But otherwise, he said, you follow for us participating in the CORE calls, engaging alongside ORA and CFSAN with the Mexican authorities. So there's a steering committee associated with that Food Safety Partnership activity, and then a sub-level of work groups and committees, and I was the point person for Michael and the OHAFO leadership for that activity in Mexico. If and when there was a foreign audit coming during that period in 2018 to 2020, I had a role, again, much akin to what I was because they didn't identify an incumbent when I departed. It was a series of actors who

filled that role. And so some of that coordinating responsibility for foreign audits during that 2018 to 2020 timeframe was my continued need to manage from the OHAFO position as a senior advisor.

JS: You were about a year in that particular position, and then you moved on to direct the Office of Global Operations, I think, first on detail, then as the acting director or director, and that started at the interesting time of January of 2020.

BR: So here's the background. I spoke earlier about ORA going through program alignment in 2017. The Office of the Commissioner went through a reorganization, and what was once called OIP came up and changed its name and became a part of the Office of Policy Legislation and International Affairs, OPLIA, and the Office of Global Policy and Strategy came to be. And OGPS not only oversaw all of the foreign offices around the world, but it had two other components. It had a trade function and a third: supporting the commissioner's office with communications and strategic planning and things of that nature.

I believe that was stood up in the fall, the beginning of fiscal 2020, somewhere in October or November of 2019. It actually became this new entity. And at that time, Mark Abdoo, the Associate Commissioner for Global Policy and Strategy, was acting in three of the four office director positions. And he and I had conversations, and I asked him how is he managing and wouldn't he like some help. And maybe we could organize to have me be detailed as the acting director of the Office of Global Operations. So he and Mike Rogers had conversations and talked about it, and that's how it started.

The conversations and the planning were concluded in December of 2019 with a start date in early January of 2020, and then all chaos broke as the pandemic was occurring and, particularly in China, the agency experienced its first what's called ordered departure. The State Department has two levels when conditions on the ground get strange or unsafe or of concern. First, they have what's called authorized departure, where people voluntarily in that country or in that mission may leave due to the conditions on the ground, and then the next level would be ordered departure: a forced evacuation of people reflecting that the conditions on the ground had changed substantively and safety was being impacted.

So in January of 2020, as a result of COVID and the response of the Chinese government to shut down, contain, and prevent the movement of people, the embassy went through those two stages very quickly in a matter of weeks, maybe two or three at most. Our staff in China numbering about 13 to 15—I forget the exact number, but more than a dozen and less than 20—went through that authorized departure, which is when family members may leave voluntarily. Staff may stay, but they can also depart if they want. The agency had never, ever experienced either one of these conditions from its foreign offices.

JS: Had you?

BR: And I was in the hot seat when those tripwires occurred at Embassy Beijing and the State Department, who has ultimate authority, issued the authorized departure order. We had to engage with our staff and identify who wanted to leave and then start that operational support, finding plane tickets, and packing up family and children and spouses to come back to the United States

The other challenge of this under the State Department regulations, and this is reflective of the State Department being in charge, and also that FDA is not what is considered to be a foreign assistance agency, the implementation of an authorized or ordered departure says thou shalt come back to Washington, DC, State Department headquarters. That's not necessarily the case for FDA with all of our regional and district offices around the country. Many of the people who were in China had no support nor family ties in the Washington, DC area but did in Houston or Los Angeles or Topeka, Kansas.

And so we had to engage and receive permission from the State Department, reflecting FDA's multiple locations around the United States that our staff did not have to come to Washington, DC, but could with permission, and that permission was to just tell them where they were going to be stationed: To tell the State Department this family is going to be in Los Angeles and that family is going to be in Las Vegas and another family in Houston, etc., as these staff came out of China. It was also made chaotic because some staff didn't want to come out at first. They felt comfortable, safe, and recognized that there was work to be done in response to COVID and that there was value to continue their presence.

Also very complicating was the fact that we weren't the only ones who were trying to get out of China in a hurry, and so there were a limited number of planes and not everybody could get out as quickly as they wanted. That might have taken a week or ten days rather than tomorrow or within a week, as often these departures may occur. And in many cases, they had to leave their household, so they may have had people coming into the house, nannies, to take care of young children, people that had a job and would no longer have anybody to care for.

They may not have been able to get their pets, their dog, or their cats on a plane to bring them back to the United States. And so arrangements for those non-government supported

conditions—the pet, or the nanny, or the household help—was also a drag on the staff. There wasn't very much the agency and headquarters could do about it except understand that it was a drag or a pull that the staff person needed to organize. So a lot of January was spent moving through that authorized to ordered departure status and bringing home, I think ultimately, about 25 or 27 individuals: staff, plus family and children, back to the United States.

JS: Did any US-based staff remain? And also, regarding the in-country staff in China in particular—because I know we've heard you mention and Chris Hickey had mentioned how valuable they were—were they in a position to provide any sort of FDA work while they were there?

BR: There was a staggered departure, so not everybody left at once. And we ultimately got down to one person who stayed maybe a month later than the others. The embassy goes through a process that is not so different from what might happen in a shutdown, deeming people more essential or more critical to stay behind than others. And so the then director of the China office, who also was coming to the end of his tour, was designated as critical by the embassy. It was useful and convenient for us that he stayed because he was winding down his tour, and he could manage any requests that might come from the embassy in terms of what's happening in the interactions with the Chinese government along with our local staff. So, not everybody came out all at once, but there was that time lag, and it was the then director of the China office, Julio Salazar, who was the last to leave. Another concern was going on. There was a huge demand for personal protective equipment—PPE—and a lot of that was sourced in China. And so, I think our medical device policy person was also in the latter stage of departing from China, not in the

initial wave. So I think we had maybe two waves or perhaps three in how family and staff departed from China from the beginning of January through the end of February. At least, that's my recollection.

Now, the other part of your question was about locally engaged staff. That actually was also another kind of a challenge because they were subject to the Chinese rules about confinement or stay-at-home or testing. And so, in many cases, they could not even come to work in the embassy. Also, China has a great deal of constraint associated with the use and location of our IT equipment, and fundamentally, it's not allowed to be removed from the embassy. So, there wasn't the ability of staff to work from home because they didn't have approved secure IT equipment to do so. So, if you couldn't go to the embassy, it was hard to justify what kind of work could actually be accomplished. The other element was, if all of the Americans are gone, who's supervising the locally engaged staff?

Fortunately for us, in this case, HHS has a very large presence. In China, there was a health attaché, and we started our conversations about my role in that years ago. But so there's a health attaché, and there's a CDC staff, and there's an FDA staff, and as both CDC and FDA drew down . . .

JS: We lost you with the drawing down of the staff, but you were starting to talk about the HHS Health attaché.

BR: Oh, so HHS has a large presence in China with a health attaché in addition to CDC and FDA offices. As both CDC and FDA drew down their staff, their respective directors were amongst the last to leave, supporting the attaché. I'm sorry, the CDC director was also critically

important because of the relationships with the China CDC and information about the person and disease conditions occurring in China. So he, along with the attaché, were amongst the last to leave once they got to ordered departure. So, they shared that responsibility of the FDA staff. Before actually confining to home, the inability to move around actually occurred for a while. It was the attaché or CDC who supervised FDA's local staff.

But as long as the Chinese government allowed them to come to the embassy to work, the local staff continued to work. Our staff, even though they were involved in the US, had the ability to communicate with our staff in China. Our outreach and our engagements obviously changed, but we could provide some advice and request information to be gotten through the locally engaged staff who were still present in country. And even longer, a corridor or mode of communication existed; it just took longer to get information back, but it still functioned right.

JS: So some of the locally engaged staff in China actually were able to continue to come into the embassy?

BR: Until the government had forced shutdowns where people were confined. And so they had what was later referred to as a rolling shutdown. When COVID conditions on the ground became so significant, the government would increase the frequency of testing and require people to stay at home for a period of time. In those conditions, obviously the locally engaged staff did not come to the embassy. But when that was not in place the locally engaged staff did report on a day-to-day basis to the embassy. So the embassy didn't shut its doors and didn't cease functioning, but it contracted in such a way that we had minimal public engagement for consular visas, passport issues, and very little direct contact with the Chinese government,

mostly because the Americans were withdrawn to a bare minimum. That included the HHS attaché, but we continued, if you will, to limp along with what kinds of engagements were permitted, given the conditions on the ground.

JS: I know the Office of Global Operations has all foreign offices under its purview. How were the other foreign offices faring during the pandemic?

BR: None of them were as significantly impacted as China was. That was, if you will, on a continuum at one end of the spectrum, the worst, the most impacted with drawdowns. There were periods in India when they also went through authorized departure. You could if you wanted to, if you felt the conditions on the ground were unsafe; you or your family members could leave India, but it was never an ordered departure. And there were a few people who left under that authorized departure. That never happened in Latin America; although Chile experienced shutdowns and people were confined to their homes, which meant that they couldn't go to the embassy, they weren't as constrained by the security issues like China, but they could work from home, even though they were only allowed out. And of course, Europe didn't have any of those constraints. So that would be the other end from China in terms of the impact.

The other challenge that I think is worth noting when is you're in either authorized or ordered departure, your ability to return to post is now controlled by the State Department's—I think he's called the Deputy Secretary for Management, who reviews each case or conditions in a country to enable or allow somebody to go back. So it's not, hey, I'm sitting in Las Vegas, it looks OK, I want to go home, back to Beijing. No, the State Department says, and issues the "all clear", and then you can go back. And there's a pretty short window of less than two weeks

when you must go back once the State Department says things are all clear. For China, that was a number of months. I think folks didn't start to go back until June or July. Again, in a staggered way because, at that time, air traffic between China and the United States was severely constrained.

And the Chinese had really rigid quarantine requirements on arrival of all visitors in terms of having to be tested, prove negative, and to isolate in a particular place for seven or 10 days before you could go on or go to your home. And so this kind of got in the way of diplomatic conventions, the Vienna convention, and whether we could or should be subjecting ourselves to testing and quarantined by the Chinese government, and ultimately, the American government said, yes, we would be tested.

We would conduct charter airplanes and have tests before we went such that we wouldn't bring anybody who could be confined by the Chinese. And they negotiated that the hotels would be Western-style hotels with services, where people would have to spend their week or two-week confinement before they could really be released to go to their house. China said, not only will you be tested at the border, but you have to demonstrate in time that you have no further symptoms. They would test twice in that two-week period before you're released. So people literally had to stay in hotels when they first arrived back in China with their family members: they could not go out, had to have room services food, couldn't leave the hotel room, couldn't go downstairs to the restaurant, it was delivered to their room in isolation before ultimately, they could go to their residence. So it was those kinds of conditions that led people to want to come out and also that they had to experience upon going back. In that timeframe, from maybe late July through the end of September, all of our staff got back to China.

JS: Right. Once they were able or released to go to their homes, were they also at that point able to go into work at the embassy?

BR: Yeah. And the conditions in China were surreal because the rest of the world was subjected to incredibly high case counts, whereas China had pretty minimal case counts. Also, China insisted on regular and periodic testing. I don't remember if it was every two weeks or once a month. But people who were out and about in China had to stop by government run testing sites, get swabbed and tested, and if any adverse finding any positivity, then they'd be subject to quarantine.

We had one case in the return by charter flight, where one of the children of our staff was identified as positive on arrival in Beijing, and they were put right back on the charter plane after that 20-hour journey to come back to the United States where they were confined to isolation here in a hotel in Washington, DC before they were released. So the mom, who was the staff member, came back with the ill child while the father stayed with the other two children in the family. Again, reflecting the incredible hardship on staffing in the foreign offices during COVID that this represented.

JS: That's remarkable. We, of course, have to truncate a lot of your later service because of time constraints. I did want to ask, though, about your present position in Santiago, and as you are an international relations specialist, what brought you there? I gather your portfolio is mainly food-centric responsibilities, right?

BR: I spent near close to three years in the position in OGO, more than two and a half, but not quite three years in the position, and all through COVID, it was incredibly stressful and incredibly rewarding at the same time. And the purpose of this oral history is to capture my career. I'm in the sunsetting days of my career. I originally thought I was going to retire in September of 2022. And then I thought about it and, pining for one last assignment, when the vacancy in Santiago, Chile came about, our staff here had experienced some health condition. He had some health conditions and wanted to return to the United States. So I went to the Associate Commissioner for Global Policy and Strategy and said rather than retire, can I serve another two years there in Chile? Instead of retiring now from this position I presented how I could help maybe in the transition. Both at headquarters in the OGO position, as well as here in Chile. So that's how I came to Chile. And yes, you're right, the responsibilities are very different, much more relaxed. I have a regional position that looks out over things in South America.

Our office in Chile is here because of the large volume, particularly of salmon and fruit—frozen berries and fresh stone fruit and citrus—that goes to the United States from Chile. But there are not a lot of problems with that bilateral trade. Those products are well-controlled by the Chilean government, so there's not a need for great attention or problem-solving. And so, my regional portfolio involves the outreach of new ORA and food, FSMA implementation, Food Safety Modernization Act implementation. The Agriculture water rule and transparency traceability activities just got started in the last year or so as those rules were finalized. But we're also responding to a new activity that Congress mandated for FDA, to ensure the safety of imported aqua-cultured shrimp, and they identified that FDA should spend additive money that they made available looking at the quality of the products coming from the top three shrimp

importers. One of those, Ecuador, is number two in South America or within the Latin America purview. So, that's a part of my portfolio. We've been working over the last year to develop a regulatory partnership arrangement where we did an assessment of Ecuador's oversight and control over the aquaculture shrimp industry and deemed they have relevant control and oversight. They have various components that we would expect. And now we're in the process of developing a work plan, having signed the first of these regulatory partnership agreements with Ecuador in August of this year.

The intent is to mimic that in the other two countries—Indonesia and India—and they're in the process at various stages of the same process that Ecuador went through. So, the shrimp pilot with Ecuador is a major portion, but I also have a responsibility for whole genome sequencing across the region. Whole genome sequencing is, if you will, speaking metaphorically, the ability to fingerprint a commodity to know exactly where it came from and what's in it. And it is incredibly helpful in the response to foodborne pathogen outbreaks. So if Salmonella is, say, in mushrooms, we can identify the illness clinically in an individual and trace it back, match it up through whole genome sequencing with the same sequence found in mushrooms from a particular location, which allows us to identify how the contamination occurred in a particular place, be it in the field or in a processing plant to narrow the response.

It's not all mushrooms from Ecuador, so to speak, but mushrooms only from this particular area around Quito or that specific facility. So, it's a more surgical approach to foodborne outbreak response. And CFSAN has a project that they've been doing for a number of years, probably three or four years already, on surveillance of foodborne pathogens in surface water. And that project is being implemented in Chile, in Mexico, and in Brazil. And so data is being collected from various academic institutions for both Salmonella and Listeria that are

sequenced, and those sequences are uploaded into a public facing database that allows us to compare clinical and environmental samples to look at previous outbreaks.

And part of my portfolio is trying to expand that to see if the government would begin to test commodities to go along with the Ministry of Health testing human clinical samples for illness. We're not having a whole lot of success yet, other than raising awareness, but we don't have a lot of takers. Only Costa Rica so far. Their national lab uploaded some food commodity whole genome sequences back in December of 22. And we're trying to expand that same work in Mexico as part of the Food Safety Partnership. We should see those results, and we have commitments from the government to do that, but they haven't taken the action associated with that commission or commitment.

And we're in negotiations now with Argentina, looking to expand that. So the whole genome sequencing, it's the other significant part of my portfolio in Latin America. But it's dramatically different, smaller in function, less in pay and grade, and much more relaxed than being at headquarters and overseeing all of the foreign offices and those issues during COVID that I experienced when I was the director of the Office of Global Operations.

JS: But it's still a very exciting thing to be part of at the back end of your career with what you're doing right now.

BR: So this is my eighth post over a period of slightly more than 20 years. Four of those posts were with CDC, one with HHS, and this is my third FDA post. We spoke about India. We spoke about Mexico, and now I am here in Chile.

JS: I'm glad you brought that up, Bruce, because I guess I want to offer you a chance for a couple of closing thoughts, especially given your vast experience in foreign service but especially with those folks in FDA in mind who might be considering an assignment in an FDA foreign office. We talked a little bit about this before, but they might have concerns about what they could possibly face in such an assignment. So, it might be helpful, particularly to folks like that, if you could share what they might expect to take away from the experience of an assignment like that.

BR: Yeah. I spoke about how recruiting was a challenge, and I recognize in my own service that overseas assignments are not for everybody. It's difficult to pick up family, and that includes children and spouses that have family connections or school and friend associations or even work obligations for the spouse. But that said, it's an incredibly rewarding opportunity presented if or when you choose to select and take advantage of this opportunity. The ability to live and work in other cultures has learning experiences and life-changing experiences for everyone, regardless of the age.

But it's the ongoing interaction with different people and different cultures and different languages that make that so wonderful. So I would just encourage people and say, even if they have a thought they would like to do it, to reach out. I'm not the only one in OGPS that has experience or would be willing to talk to people. But if they have that interest, reach out and ask the questions. Get real answers. Don't just imagine and say it's not possible. It truly is. Some places are easier or harder than others. Sometimes, it works for everybody. One of the lessons in the FDA, when we first started the foreign offices back in 2008, was that FDA has to recognize that they're hiring an employee, but they get the family. And they don't have a lot to offer the

family. But if the family's not happy, it really doesn't matter how happy or how functioning the staff is; the staff's not going to stay because you have that work-life separation. And if the family's not happy, that's going to just wear out the staff.

So we need to not get in the way if or when that happens. I had a couple of assignments for me, where I thought I'm going to just do the two years that I committed to, and then I'm going on. And then there are others, wow, we're having a great time; let's extend, and we stayed four years in different locations. FDA has the ability with multiple offices to enable people to move from one office to another. The department, HHS, has opportunities itself with the attaché station world and also through CDC, which is located in about 60 countries. It's a little bit harder for FDA to move into the CDC world because we don't have EPI as part of our activity, but the management and the deputy roles are similar and comparable. Public health is public health. We may not have the same focus on infectious disease or HIV/AIDS or respiratory illnesses that CDC has, but we know how to support public health programming at FDA. And so those opportunities might exist. And I would just encourage people to think about the opportunity because it has such great rewards.

JS: That's, I think, a great place to end this, Bruce. I just want to thank you once again for helping us. And obviously this started out as an effort to document the pioneers and early history of our foreign offices. But you've given your experience. You've had so much light to shed on what goes on in the foreign offices and what have been some of the key issues, certainly in the ones that you've been involved in, and certainly the impact of the pandemic on our offices. This has all been truly helpful to help our understanding of what service like this is like. So, thank you so much for the time and insights you've offered. I appreciate it.

BR: Sure, it's been wonderful for me as well. And I appreciate the opportunity to give back to the agency. And I hope the oral history helps others decide, yes, that's for me. Or at least provide a better understanding of some of the pivot points that the agency took over time as they decided to open and continue staffing various foreign offices. It was a lot of fun and a pleasure for me too, as well, John. Thank you for the opportunity.