History

of the

U.S. Food and Drug Administration

Interviewee:	Christopher Hickey, Ph. D.
Interviewer:	John Swann, Ph. D.
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JS: My name is John Swann from the FDA History Office. I'm here with Dr. Christopher Hickey, and this is one of our ongoing series of Oral History interviews on the pioneers in the FDA's foreign office development. The date is August 29th, 2023, and we're here at the FDA headquarters campus in Silver Spring, Maryland.

So, Chris, thanks so much for joining me to participate in this oral history. This is a particularly important one, given your role as the first director of one of our foreign offices. I'd like to start with a bit of history about you up to 2002 — where you came from and early interests as well as setting us up for the future of your career after 2002?

CH: Sure. The cliff note version is that I grew up in Northwest Indiana, not far from Chicago. I studied as a normal small town American kid. As a college student I double majored in American Studies and Spanish at Franklin College — a small college in Indiana. Towards the end of college, I decided I was going to do a PhD. So... I ended up doing my master's at the University of Illinois and I did my PhD at University of Virginia in sociology. What I ended up doing my dissertation research on was really the rise of alternative medicine in the U.S. It was a little bit less of history and more of almost anthropological study of patients. Well, “patients” was not the term I used, but people who used different forms of alternative medicine; I ended up calling it health seeking behavior. I didn't want to just look at the things that were medicine, but things that included yoga and those types of health seeking behaviors. So fast forward, when I was in college in 1992, I took my time and finally finished the PhD by 2002.

JS: Well, it takes a while, considering funding needs and everything that graduate students do.

CH: Well, yeah, I think I was a little bit naive when I switched schools. I mean, you really ended up doing the coursework all over again. But it was in Charlottesville, there were a lot of other things going on. Also, in those later years of being done with my coursework at UVA and getting a dissertation proposal together and all that stuff, I did a few other things on the side. I worked with the American Sociological Association with some summer internships, and also as a part-time employee for them through the school year, continuing to do public affairs for them. That was mainly media and supporting writing for the public that they needed done.

So, by the end I was doing a full-time teaching position at Mary Washington College, which is now University of Mary Washington, for a year with a full load—a small liberal arts college, right? So, there were plenty of things that slowed down the process. The saving grace was that my wife was starting her career, wherever she was. By 2000 she was five years into a career working for a USAID contractor and she was the lead for a project in Ukraine or part of a project in Ukraine. We moved there, and I just put my nose to the grindstone and wrote at home — me and the cat. I'd done everything I needed to do in 2000 to make sure I had all the resources I needed boxed up and with me. I wrote my dissertation there over the course of 15 months or so. Halfway through, I got stir crazy and decided that I needed at least three or four hours a day to do something outside the apartment.

So, that was important only in that, what I ended up doing was a little bit of consulting for some of the different USAID contractors, including the same company my wife worked for, that had things going on in Kiev. What they really needed was an American on the ground who could interview Ukrainians who were potentially going to be included on a proposal for a USAID project. I could sit across the table from them to see how good their English was. If they

became somebody that the company was interested in, I would edit their CV to make it native English. The only importance of that is that it was my first time really getting my toe in the water on international work. I mean, it was HR work, really. So that takes me up to finishing my PhD. And then I started job searching.

JS: I hear two developments in your career already that were preparing you for what you would eventually do — obviously international work, but also this interest in alternative medicines. What better way to get ready for a gig in FDA, right?! What interested you in that?

CH: Well, it went back to the beginning of my graduate career where I was interested in sociology of religion. The thing I found very quickly when I jumped in the deep end on sociology of religion was that a lot of it was just boring stuff that I didn't want to do. So, there would be statistical measurements, weekly attendance of church services or synagogue, cross tabulation against somebody's income, education. It was that type of thing, and I just had no interest in doing that type of research. But I continued to be interested in how people make meaning of their lives. So, I was trying to find some other way to do a sociology of religion dissertation, without doing religion per se. So, I took a little side trip into whether I could do a historical study on things like the Black Death or the plague and how people understood cataclysmic events in the middle ages and that ended up being a little bit difficult.

So, what I finally landed on was behaviors that people were using to seek health, but also to seek broader meaning. I think I ended up interviewing 200 people or so. I used 40 different people for each of five different modes of health seeking behavior or medicine. And I just went deep into, how did they land here? Why was Reiki meaningful to them? There's either someone

who's non-religious or someone who's extremely religious and conservative, so how did yoga make sense to them? That's how I got into it.

JS: It's fascinating. It really is.

CH: You can still find it on the UVA website if you dig deep enough.

JS: I can find it in University Microfilms International, right?

CH: Yeah. Right.

JS: That's terrific. So, this was 2002, how did a sociologist end up in the office of Global Health Affairs in HHS?

CH: Well, I'd left Ukraine, and the question was would I be able to make this leap to international work? There wasn't that much else about my resume other than that last six months of HR consulting and living in Kiev that showed I was an international guy. So, I did a job search in early 2002 where I landed at an NGO — the Institute for Global Engagement. I was there for about two and a half years. It was Philadelphia based and it was founded by the guy who was the first-ever Ambassador at Large for International Religious Freedom at the State Department. It's a position that still exists to this day and they have these ambassadors at large in the State Department that advocate for issues as opposed to being assigned to a country or a UN agency.

So, there was a guy named Bob Seiple who headed World Vision for ten years before he was appointed by the Clinton Administration to this position as Ambassador at Large for International Religious Freedom. When he finished that work, he founded an NGO called Institute for Global Engagement (IGE) to continue doing that work in selected countries like Laos, Vietnam, Uzbekistan, with the contacts that he had made in his two and a half years or so in the Clinton Administration.

So, it did somehow serendipitously bring together a bunch of things that related to what I had done. So, I ended up being the lead for Education and Research for that small NGO. There were maybe just seven or so full-time employees. I didn't know exactly what I was looking for when I started that job search, but I knew that this would give me credibility in terms of doing international work. I'd be doing it from the U.S. primarily, but it was related to foreign policy. It was related to operations and programs in the country. So, I saw it as an opportunity to give myself more substantial international experience.

From there I made the move to Health and Human Services in the summer of 2004. There was a personal side to this in that my telecommuting wasn't nearly so common at the time and my wife was continuing to telecommute, such as it was, to her company in Bethesda from Philadelphia. It meant a lot of time on the Amtrak which was trying and challenging. And we were looking to get a Washington-based role for me so that we could move to Washington. Again, it was a lengthy job search. I hadn't really done much in that NGO on health-related stuff, but they had a journal that mainly dealt with international religious freedom issues and human rights issues, but also more broadly touched on the intersection between religion and foreign policy. So, I did write a piece towards the end, knowing that I was interested in the topic, but also that I wanted to transition to health.

At the time the Bush Administration's policy on AIDS prevention was beginning to develop under the President's Emergency Plan for AIDS relief. So, it was really aimed at a more conservative faith-based audience, and it related to condom use basically. So, I was interested in the topic, because I knew that the audience for that journal was primarily on the conservative evangelical side of things, which was a large part of the Bush Administration's political base. But I also had interest in giving myself some kind of publications, public credibility on these issues of health that I hadn't really been doing that much in the last few years.

So that helped and I made this transition, again, through connections that I had from that job with the Office of faith-based Community Initiatives at the White House. But then there are also these Centers for faith Based and Community Initiatives in many of the executive branch agencies.

And through those connections, I got linked up with the Office of Global Health Affairs at Health and Human Services. So, it was like a lot of job search things. There was somebody I met at a conference who was at the USAID, faith-based office, and he ended up at the White House office. He connected me with the HHS lead for faith-based initiatives. And when I talked to him, he said: " Listen, we don't have a role, but OGHA is an office that we do a lot of collaboration with. Obviously, you've got international experience." So that's how I ended up at the at OGHA. Very quickly I ended up doing a lot of other things that had nothing to do with the faith-based Community Initiatives, but that's how I got in the door.

JS: Well, that's probably not unusual for this to happen that way. But you were there for four years, right? From 2004 to 2008. And I know were here primarily to address the work in FDA and in the China Office. But can you talk a little bit about what you were involved in?

CH: Yeah sure. So, for maybe the first year or so, I continued to do some work on the President's Emergency Plan for AIDS Relief. And there was a decent component of that that was focused on the role of faith-based Community Organizations in supporting that work for AIDS prevention/treatment. So, I was a liaison between the Office of Global Health Affairs and the faith-based Office. But what very quickly took up most of my time was the International Health Regulations.

At the time, the WHO was updating the International Health Regulations. The IHRs, as they came to be known, hadn't really been updated for a generation. This was late 2004 with SARS. There were concerns about the next flu pandemic. And we just were not ready for that. So, WHO was negotiating and initiating a process for member states to negotiate an update on the International Health Regulations. And it was an enormous task. It was led by an FDA alum — one of the senior people most involved in the nitty gritty of the day-to-day was Stuart Nightingale, and he was honestly just great to work for.

There were several FDA connections here. I mentioned to you before we started that Mark Abdoo and I worked together in OGHA. He and I were sharing an office. In that time frame in fall 2004, regardless of who won the election, there was going to need to be a transition process from the then HHS Secretary, which was Tommy Thompson, to whoever the next one was going to be. Initially I had been put on that project, and Mark had been put on the IHRs. That lasted for about an hour, and Lou Valdez, another person who landed in FDA, came in and said: “Well I talked to Bill Steiger, the head of OGHA at that time, and we're going to switch this. Chris, you're going to work on the IHRs. And Mark, you're going to work on this transition package.”

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And that became my main work for the next nine months. It was an intensive negotiation process at the WHO. Three rounds of negotiation with the guidance document for the delegation, which included at least six or seven agencies represented in Geneva. But then there were six or seven back in Washington that had been involved in the interagency process and had equities in what in essence was a treaty. So, it was a 300-page guidance document for the delegation, and the guidance document that Patrick Marchum, another colleague under Stuart's leadership, and I developed leading up to the first set of negotiations in late October, continued to be updated as negotiations went on.

And then eventually I joined the last two rounds of negotiation. That was formative for me. I went into details on that because for me, it was a baptism by fire on at least a significant element of international public health policy. I was working with people at the White House and people from all the different agencies that had equities and they were usually people at a GS-15 level at least, if not an SES level. So, that was vital for me.

After that negotiation process was done, in subsequent years, I worked on an interagency foreign policy planning project known as Project Horizon. It was a long-term planning project that looked out 25 years at the four or five scenarios and trajectories that the world could take, and at the competencies that the U.S. government needs to be developing today to be ready for whatever emerges. So that was fascinating.

Again, there is another inter-agency process where we got to interview some of the top experts in the U.S. government including many of the top people at FDA, NIH — I remember sitting in an interview with (Anthony) Fauci. A number of them also participated in the scenario

planning workshops that we did the next spring. Mac Lumpkin and Ellen Morrison might have been in it, many senior people at FDA were in that as well.

One other to call out is that I worked on the UN treaty on the Convention on the Rights of Persons with Disabilities, CRPD. It was another fascinating process with the interagency. State had much more of a prominent role in that than they did with the IHRs. HHS was a supporting agency, but there were significant equities in that treaty related to health. And we all negotiated in New York over two or three rounds in 2005, 2006 and early 2007, in that timeframe. So, that was incredible. The bridge over to China was that in May of 2007, the director of the Asia Pacific Office left on short notice. They asked me if I would move over and take a full-time promotion over to direct the office of Asia Pacific.

It's somewhat funny — I remember Lou saying to me that she thought the challenges and the shape of the job would be at least in the first six months or so, and that this was seemingly true since we just had a big round of negotiations with the Chinese—at the time it was the SED (strategic economic dialogue). So, things would be a little quiet on China for a few months until the next round of those negotiations in December, and this was May. So really, the focus will be elsewhere, right? And what she couldn't have known and didn't know at the time was that all these issues that were bubbling up, you probably remember the biggest one being the pet food.

JS: Right, there was a lot going on involving China in this period.

CH: You're right. If you look at the timeline, it may have already boiled over. But what she didn't know was that Mike Levitt was the HHS Secretary at the time, and he used the side lines of the SED to talk with Chinese authorities about this as a bigger issue, not just the specific issue

of pet food, but the broader issue of the China brand. What I understand — I think I heard it from Secretary Levitt himself, was that the pet food issue was so significant and so prominent in the leadup to this SED in May of 2007. Hank Paulson, the Treasury Secretary at the time, came to Levitt and said, “Listen, health is an important part of this dialogue, you're a key partner. However, I'm asking you to keep this off the table during the SED itself because if it's on the table during the SED, it'll take over the whole thing. So could we work together to figure out a way to have a conversation about this while the Chinese senior officials are in town, but on the sidelines.”

So, what ended up happening was that on the U.S. side, at HHS in the Secretary's conference room, was Secretary Leavitt, Commissioner (Andy) von Eschenbach, and the USDA Secretary at the time. And on the Chinese side were the Minister of Health and one other Minister — I don't remember which one it was because the agencies that we ended up negotiating with were not actually part of that round of the SED.

There were one or two ministers on the other side who were related to our issues. And there was this lengthy discussion about what we could do. The way that Leavitt framed it was, “The China brand is in danger, the Made-in-China brand is in danger. And we want to work with you to address those issues.” It set the framework for the agreement — there would be a more in-depth discussion with the relevant ministers by teleconference in a few weeks after that, and it happened. It was maybe two or three weeks after the discussion in Washington.

My recollection is that the conference call went on for two or three hours with consecutive translation — all the painful things of international negotiations at a secretarial or ministerial level, and it was in that discussion where the idea was conceived. I wasn't in the discussion beforehand, but I'm sure Levitt knew what he wanted to propose going in. The

proposal was the agreements that we began negotiating later that summer. So, suddenly this thing with China that was supposed to be on the back burner for the first chunk of my time in the job ended up becoming the main thing that I worked on, from June to December of that year. That was how the thing initiated at least.

JS: Right. There are lots of things going on in 2007 as you alluded to in these very high-level discussions that you mentioned, all these problems coming out, whether it's pet food, heparin or what have you. There are clearly problems and obviously a perception that there should be an FDA presence to help deal with this. We're getting to a point of transition for you, though, from HHS to FDA. And obviously you're building up this incredible understanding of what the situation is there, right?

CH: Right.

JS: So, how did that transition come about? There's a decision on what FDA is going to do and that involves China. Can you walk us through that part?

CH: So, I was experiencing these things in 2007 through the fall, from the OGHA side of things. So, I had more insight into what was going on in the Secretary's office. Obviously, at the same time, there's all kinds of things going on at FDA. My recollection of 2007 into 2008 was that it wasn't just pet food from China. There were a lot of other things from China, and some of these came to the U.S, some were elsewhere. But things like cough syrup — I think it was

diethylene glycol, cough syrup, toothpaste — were not FDA regulated products. But problems with tires and toys from China.

JS: Seafood?

CH: Yes, and then, as we began the negotiations, this import alert on five or six forms of Chinese seafood that contain cancer causing residues. The political dynamic we had was, that the Democrats have won back both the House and Senate in 2006, right? So, we have the opposition party with the Bush administration. Of course, we're going to have hearings, and from my recollection, I wasn't handling it day to day, but it just felt like (Andy) von Eschenbach was up on Capitol Hill every other week. They just were not pretty hearings. I mean, (Bart) Stupak and (John) Dingell headed the House Energy and Commerce Committee, I believe, and it was not pretty. It was the kind of thing that you often get in the government, which is, "All right. Mr. Commissioner, please characterize the problems that are coming out of China. What do you need to deal with the problems that are coming out of China? So, Mr. Commissioner, will you testify that you need more budget resources?" And of course, the Commissioner can't say that. Right? So, it was a lose-lose proposition in terms of the perception from those hearings on Capitol Hill.

So, all of that was going on. We began negotiations with the Chinese authorities, and we were in the process of forming the drafts of these agreements. But what I remember before that was, we had the first ever formal bilateral meeting between FDA and the then SFDA (State Food and Drug Administration) of China, in a hotel somewhere in DuPont Circle. Mac Lumpkin was sitting across from his counterpart in the Chinese government, at least for drugs and medical

devices, food safety, and another agency. And it was literally the day that the former SFDA commissioner had been executed in Beijing — a few hours before we started our meeting. Obviously, that was left unsaid in the context of our meeting, but it drove home the stakes of this meeting. Now, he wasn't executed for the problems that happened in 2007 and 2008. It was for corruption issues back five years or so. Nonetheless, it set a certain tone for the meeting.

As we went through the fall of 2007 and negotiated those agreements with SFDA for medical products and then AQSIQ — which is a mouthful and no longer exists as a separate entity. But at the time, AQSIQ stood for the General Administration for Quality Supervision Inspection, and Quarantine. So, they had responsibility for food safety. The first thing was identifying who we were negotiating with. Once that was clear, it was time to get some drafts in place. This is where Mel Plasier was deputized by Mac to run point on all this stuff. So, Mel and I were joined at the hip. We were also joined at the hip with Rich McKeown, who was the Chief of Staff for Mike Levitt and had been his Chief of Staff in Utah when he was Governor as well as his Chief of Staff at EPA. So he knew Leavitt very well and was honestly great to work for and had a deep background in conflict resolution and negotiation. He was just masterful. So, Leavitt had designated Rich to make this happen by December, which is when the next meeting of the SED, the Strategic Economic Dialogue, would be. And we had to have the substance. So Mel took the lead on drafting those agreements while we were putting together working groups to support the negotiation. So, the working group on food safety was led by David Acheson, who was often called the food safety tsar at the time, right? The deputy commissioner position, that was later created by FSMA, technically didn't exist. But he was the top food safety guy for Andy. And then the medical products negotiation was led by Susan Winkler, who was Andy's Chief of Staff, but could coordinate between CDER and CDRH.

Rounds of negotiation with the Chinese went through the fall of 2007. The only thing I remember distinctively about the negotiations, was that we had a draft that we were ready to give the Chinese maybe by middle of August. We had done the first trip to China in late July. And it was more of getting to know our counterparts. There wasn't any text or negotiation on the table. It was also shortly after the import alert that had been issued on aquaculture. They really wanted to lobby us on the food safety side of things — why we should quickly lift that import alert. So they took us on site visits to different places and Southern China to see some of their best facilities for aquaculture.

But what ended up happening was, we said, "Okay, we'll have new drafts in a couple of weeks." What we underestimated was the interagency process and USTR. They were tough in terms of — if they had their druthers, we probably would not have done the agreement, because they were concerned that we were going to come to terms that were inconsistent with the U.S. trade policy or were too easy on China. Whatever the rationale was, we would send a draft through the interagency and on a 20-page document, we would get 300 or 400 comments and edits. Fortunately, Mel Plasier was like a force of nature and would turn those things around extremely quickly, not just by dealing with it herself, but from her years and years of FDA experience — knowing what the red lines were, knowing where she was going to have to talk to CDER, ORA, or CDRH. She just handled that stuff masterfully.

So finally, by late September we were able to get a draft agreement to the Chinese. And they hated the drafts. They were none too pleased because the drafts looked a lot more like trade agreements than they had expected. They were public health agreements. But we did have to make sure that we had a one-administration approach to this so, it had to be consistent with the

trade policy. Throughout that entire time there was the discussion to get to what I know you really want to focus on — the overseas offices.

JS: Before we jump into that. The agreements that you've been talking about address the core issues that were affecting us.

CH: Right.

JS: So, are there provisions for registration, certification and even verification that come out of these agreements?

CH: Yeah. They ended up being much more detailed. It's been a few years, so I'm sure I'll get a few details on this wrong. On the food safety side of things, what we wanted to do was to have the Chinese government certify shipments that were coming from China to the U.S., but we also wanted to have other processes for certification so that there could be third party certifiers. And what we really wanted was a system in which third party certifiers who were not Chinese government certifiers could help to, in essence, raise the quality level and the rigorousness of the Chinese system. And so, they agreed to those terms.

On the drug safety side of things, it was somewhat similar, it wasn't quite as detailed in terms of the certifications, but the primary thing that we were trying to deal with China in that agreement was active pharmaceutical ingredients because we weren't getting a lot of finished drugs from China. We were getting a lot of active pharmaceutical ingredients, but they really were not—they were very lightly regulated. The key loophole, I remember, was that chemicals

and active pharmaceutical ingredients were regulated very differently. On the books in China, active pharmaceutical ingredients were pretty robustly regulated. But if you simply labeled your API as a chemical instead of an API, it was much more lightly regulated. So, these were huge things that we needed to deal with.

JS: Right. I know the issue with foods got settled easier but the issue with the drugs though, those had to be dealt with more to FDA satisfaction and they came a little bit later, if I'm right.

CH: Right. So, we decided early on that we were not going to deal with the issue of overseas offices in the agreements themselves. That was kind of set aside, but at the same time as we're negotiating these agreements and eventually they're signed in whatever, December 2007 under the Strategic Economic Dialogue, as all these things are going on back in Washington there is pressure from Capitol Hill to put boots on the ground or whatever analogy we want to use. They have a much more robust FDA presence in some of these key, especially high-risk countries, including China. So that was going on as we were negotiating. So really that process, it really was going on in parallel and, you'd have to look to verify, but my recollection was that there was basically, by the end of 2007, around the time that we signed these agreements, political endorsements for FDA to open overseas offices, and I think the funding then followed shortly thereafter in early 2008. I know that FDA was recruiting by January or February for those directors of overseas offices, because that's when I heard about it. So, it was at that point in January of 2008—these roles in the Secretary's office are demanding and there can be a lot of burnout and it certainly was incredible to staff this—that I traveled with Secretary Levitt all around the world, especially that last year when I was running the Asia Pacific office.

JS: And he took a lot of trips?

CH: Yeah, right. I think he visited China six times in a year. And that's just China. There was also India, Indonesia, Vietnam, other places. But you don't really have much of a personal life. So, I was kind of feeling like, all right, I am definitely open to other possibilities, and at a personal level, our family, my wife and I had been looking for a chance to get overseas again, but this time on my job. And so when FDA began the process of recruiting for those overseas offices I had some conversations with Mac Lumpkin about what the process would look like, and I didn't assume necessarily that I was going to be the leading candidate. I thought it might be possible that FDA was going to look for somebody who had had 25 years of experience at the agency but as it turned out I was a pretty strong candidate.

So it was, I guess by March of 2008, around then, that I made an offer and I didn't actually move over from the Secretary's office for a couple months after that, I think May of 2008. But there was a conversation with Mac at one point about which countries are there going to be overseas offices because that was still being determined. And I pretty quickly concluded that the one that made most sense, given the six months of experience I had with those negotiations and just in terms of the upside and the potential, was China. And so, I said to Mac, "I think China is the one I'm interested in." And, by federal government hiring standards or even the process of moving from one job to another, it moved pretty quickly. So, yeah, that's how I at least started in the job.

JS: Right. So, you come to FDA 2008, early springtime.

CH: May 2008, yeah.

JS: And I assume you land in the Office of International Programs?

CH: Yep, yep. Over at Parklawn at the time.

JS: So OIP is developing what these offices are going to be; this is obviously something entirely novel to FDA.

CH: Right.

JS: We've had people serving, doing inspections abroad for decades, but nothing like this.

CH: Right.

JS: And I'm sure there's a mixed bag of sentiments within the agency about the idea of creating an international office.

CH: For sure, yeah.

JS: I've certainly spoken to people, even in oral histories, who had some comments about this. But the thing is, it's something that we're going to do. So, OIP had been quite interested in

canvassing all the centers to find out what their interests were, and what their needs were. Is that something you were involved in? And do you recall what kind of feedback that OIP got from the centers in terms of these future international offices?

CH: I wasn't that involved in it early on, because I think a lot of what is it and sort of the existential questions were being addressed early on before I got there. So, I think it was really kind of that first half of 2008 before I arrived. I mean, I was at the Secretary's office, and I was well connected to Mac and Mel and others who were in these discussions. I think I learned as time went on what the views were. So, the issues that I remember being front and center in terms of both opportunities and challenges were, first off, this sort of question of just what would an overseas office be? Would it be kind of an ORA office? I think in some people's conception it was going to be basically an ORA office, an extension; it was just going to be in China.

JS: Like a regional office, but just happens to be—or a district office that happens to be in Beijing?

CH: Yeah. Just a district office that happens to be in China and is mainly about inspections. And honestly, this many years on, to some degree that's kind of what it became in the sense of just the numbers. I'll talk later about the expansion, but the numbers now are, if I remember correctly, I think 20 or 21 positions that are investigator positions and three or four that are other types of positions—international policy analyst or director or deputy director. The early life of the office, though, was much more of 50/50 proposition. And I think that came from (Andy) von Eschenbach's leadership. I think Mac clearly was of that view that we needed — yes, we needed

investigators and I think in HR terms or just in terms of people, we ended up with four investigator positions, and then we had four positions that were more focused, or at least let's say three or three and a half, that were more focused on relationship building and capacity building with the Chinese government.

Bear in mind though, the time that this was happening, which was 2008, the relationship with China was much different. As a government and as an administration at the time, it rolled right into the Obama administration, primarily about how do we collaborate to make China a better partner for us, trade partner, et cetera. So, the idea of capacity building and partnership was much more in the mainstream of the administration. And even on Capitol Hill there were some folks who might've wanted to see more of just a hardcore inspectional and investigational presence. But I think there was an understanding that it was important to also do collaboration and training. So, that was I think the fundamental question. I remember a year or a year and a half on a discussion where I was in the middle, but it was primarily, I could tell, a discussion that had gone on for a number of years between OIP and CDER. It happened to be this meeting, it was Mac and Janet (Woodcock). But it was one of these things where all of the international directors would come back and we would do engagements with the centers to get a sense of what we were doing in country, and get feedback from them. Certainly in China, there was somebody who was there with us. It was Brenda Uratani to start, and in later years it was Wong Gong. They weren't directly hired by CDER, but CDER was very much involved in choosing them as the International Policy Analyst who was going to focus on drugs, right?

So, CDER had somebody there that was advocating for the types of priorities that CDER had. The discussion that went on was “Well, why are we doing capacity building with China?” In 2023 that would be a very mainstream question, right? I don't know about in the halls of FDA

now, but certainly in Washington, I think there's a lot more questioning of that type of approach with China. In 2009, it was not in the mainstream of the view, but it was kind of what Janet was pushing us on. And I think her concern was China is going to get up to speed because China has shown its ability to get up to speed in many other realms. They're very likely to do it in the pharmaceutical realm. We don't need to help them to do that. Whereas I think the administration's view was, these are drugs that Americans are taking. The active pharmaceutical ingredients are coming from China, and it's in our interest to do everything that we can to ensure that those drugs are safe. So, I think that kind of tension wasn't unusual. And it wasn't only with CDER.

JS: Right, so, obviously the most important position in the office is settled. There's no issue there, but there's the staff and there's a decision to have, as you said, the makeup of the office of what, eight, nine positions —

CH: Right.

JS: Four consumer safety officers, right? And those would be split between medical products and food. Fairly evenly. The policy analyst—we're talking about the in-country staff, of course, and then there's the staff that are headquarters-based, but are not in country, but they're —

CH: Helping support.

JS: Right. So, again, you have a Deputy Director in country, but you also have a Deputy Director that's in headquarters. Let me just first ask about the headquarters staff. What was their role here?

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CH: Well, so, yeah, actually, you're stoking my memory here. So, what you had here at OIP were two folks who worked for Mel at the time who had been working on China for a number of years. So, if I'm remembering names, Julia Ho and then Astrid Sito were the China staff, and I think Julia had been working on China issues for FDA for a number of years from here. When the overseas offices were opened, the question was something like, "Okay, so what's their role now?" As it turned out there was plenty to do back at headquarters over the course of time. But in those early months it wasn't exactly clear. Do we now not need China people at headquarters? So, over time, I think what we saw was there was so much working of the bureaucracy needed back at headquarters that having those types of people here was really useful. I could talk a little bit later about how that kind of evolved.

But in terms of the in-country staff, we put together a panel of people. Each of the centers had somebody represented on the panel. ORA had somebody on the panel. And actually, at the time, Bruce Ross was just finishing his role as the HHS Health Attaché in Beijing. He wasn't yet formally on board with FDA or maybe had just come on board with FDA and was going to be the India director. But because of his role in those negotiations in 2007 and the fact that he knew all this stuff, I wanted him to be involved in the process as well. So, in that first round where we needed to find seven other people to join me in China, we also wanted to make sure that the centers and ORA were on board. So, we filled those positions.

The one that maybe I should just say one other thing about was Steve Solomon. He was one of the people who was just extraordinarily supportive of the overseas offices, but not in a naive way. He knew all the politics of the agency and would often come to me to say, “Listen, you're relatively new here. Let me help you understand what perspectives are coming in.” For example, you got to know that CDRH has this priority, or Janet has that priority at CDER or Mike Landa at CFSAN has another. You would be best positioned to do XYZ to help manage that. And he had been involved in those negotiations in the last half of 2007.

So, we got to know each other really well. He came to me before that process started and said, “Listen you're the boss. You get to decide. But I really think that you would do well to have somebody as a deputy who everybody sees and says, ‘Oh, that's an FDA person that knows the agency very well,’” and he wasn't saying hire one person or another, but he said leadership teams, especially when you're talking about a director and a deputy, you're often looking for somebody who complements the things that you don't have. And it's clear that I was coming from the Secretary's office. I had great connections through the agency because those working groups were mainly GS-15 and SES people. So, I had gotten to know the leadership. I had the political connections back at the department. But I didn't have the FDA stamp of approval. Like I said, Steve didn't say hire this person or that person, but it led me to hire Mike Kravchuk, who I think at that point had 30-plus years. He might have been 35-plus years with the agency, and had been at ORA but had done details to several different centers. And because he began as an investigator back in 1972 or whatever, he knew the whole thing. He knew how to do anything and everything. So anyway, we felt we had a good group and I think we did have a good group there in-country.

JS: Did you have a lot of interest in the positions? A lot of people applying for them?

CH: Yeah. I mean, especially because China was the first out of the gate and it was China. We had, I don't even remember, but I remember it was just an embarrassment, the number of people who were interested in the positions. That became less true in later years. But in that first round, the people who filled those positions, most of them had been with the agency at least 25 years. Mike had been 35 years. Dennis Doupnik, CSO, was 30 to 35 years. So, this first crew, with an exception or two, were kind of late career people who wanted kind of one last assignment for, I think, legacy. And they were all people who didn't require a lot of direct supervision.

I mean, in the federal government, or in any organization, but I found in the federal government people who have been there for 30 years aren't always the best people, but these really were the best people. They were just fantastic. So, that's kind of how we did that first round of hiring.

JS: Okay, good. November 2008 rolls around, November 20th in China, November 19th here, is when the office officially opened. What was that like? That must have been wild.

CH: It was, yeah. So, I had landed about 10 days before. Literally, I mean, it was really amazing. So, Obama was elected on a Tuesday. I got on a plane the Saturday after that and the administration, it was obviously still the Bush administration, and there was a huge push to get as much done as possible before the end of the administration, as always. So, Levitt came out, along with (Andy) von Eschenbach, and we did ribbon-cutting ceremonies in all three locations. In 2014-15 it was consolidated to Beijing.

JS: Right. But there was clearly a decision made in 2008 that there would be three sites,

CH: Right.

JS: Obviously Beijing would be the principal one, but was that something negotiated with the Chinese on which particular sites would be used?

CH: The only place you could put offices was where there was either an embassy or consulate, so, five options, the three we ended up with and then the other two were Chengdu which is more out west, in Sichuan, and then Shenyang, which is way up northeast. And so, I think given the options, those made sense. The way we characterized it was that Beijing was kind of the focus on engagement with the Chinese government and collaboration and training. Shanghai was going to be a focus on medical products, and I mean, Shanghai in many ways is kind of the New Jersey of China, in the sense of it's the center of where much of the pharmaceutical industry is in China. Not all, but many of them are there. And then Guangzhou, there's less of a center in terms of food producers in China because many of them are small operations in all kinds of places, but it was another spot that was a significant place where we also could expand our engagement with industry. It also gave us a geographic spread. You know, Beijing is like the same latitude as Philadelphia and Guangzhou is the same latitude as Havana, Cuba but it gave you a geographical spread also.

We did have to negotiate through the State Department with the Chinese government and they approved those positions. There’s probably not time to go into all of that, but I do know that

there was a lot of ongoing engagement between mainly Secretary Levitt and his counterpart at the Ministry of Health whom he had built a relationship with over time. Now, the Minister of Health doesn't necessarily have that much sway over the decision making of the Chinese government in terms of foreign policy issues and postings of diplomats in country. But Levitt had really leveraged those connections to make connections in the State Council, which is a more senior level of decision-making in the Chinese government. In fact, that was a good deal of the focus when we went to China in May 2008 and the Secretary and Andy, me, Bill Steiger, who was the head of OGHA, and a few other people went to Zhongnanhai, which is the equivalent of the White House of the Chinese government. It's where all of the leadership sits just next to the Forbidden City. We met with the state councilor who would be the top person in the Chinese government in decision-making on issues of diplomacy and foreign policy. We got to the top-level decision-makers, and we got that level of approval. And that staffing pattern stayed in place until almost my entire time there, until 2015, although there were permutations.

JS: Right. Well, you also brought on in country staff, too. I think maybe five or so?

CH: Yeah, that's about right.

JS: And these were all based in Beijing?

CH: No, for that chapter of the office's life, when we were Beijing, Shanghai, Guangzhou, we had two local staff—these would be Chinese nationals—in Beijing, we had two in Shanghai, and one in Guangzhou. So, in each of the locations, in Beijing, Shanghai, Guangzhou, there was a

different foreign service national scale. In Beijing, it was kind of like the equivalent of a GS 14 to 15. And Shanghai and Guangzhou each had someone who was kind of the equivalent of a GS 13 to 14. So, all very senior positions. And then Shanghai and Beijing each had basically an admin assistant who kind of helped to run things for the country. I will say that they were amazing, amazing people.

JS: Well, I can imagine they could have been helpful in many ways. I mean, language-wise, they must have been helpful, right? What was their role?

CH: So maybe let me just focus on two of them. Wang was eventually given the HHS Foreign Service National of the Year, which is HHS-wide. There are two or three thousand Foreign Service Nationals around the globe, and she got that award in 2014 or 15. When Bruce Ross was the Health Attaché in Beijing, she worked for him. She was in the middle of the negotiations in 2007 because there was no FDA office yet, right? The HHS Attaché's office supported that. She was in the middle of those negotiations. She was as vital to those negotiations as anyone like Mel Plasier or whoever, because she was the person who was talking most of the time on the phone to the Chinese government. In between those formal negotiations, she was the one who would be talking, and they'd say, "Hey, we hate this draft," or whatever the conversations were. But she had all of those connections.

She's a Chinese M.D., so it's a very senior position. And she had developed, over time, relationships with the Ministry of Health, with SFTA, with AQSIQ—with the people at the very top. And this is not unusual in MSCs and consulates around the world that a lot of the day-to-day work and tougher conversations behind the more formal engagements happened between the

locally engaged staff and the counterparts. So, she was in the middle of all of that. And she was also kind of my senior advisor, and not just me, but all the people in Beijing. You know, we'd say, "Listen we're trying to get X done. What would you advise in terms of the best way? How can we convince SFDA that it's in their interest to do this?" So that, that's kind of the role she played.

And then just to maybe describe one other, there was a guy named Evid Liu, who was down in Guangzhou. Because of the focus of that office on food inspections, he just began joining all of these inspections where he would be the translator, but over time he really got to know all the kind of tricks of the trade. He was really good at helping. I mean, obviously, the CSOs that are there that are U.S. citizens are the ones who are doing the investigation. But all the while, in many of these inspections, he's kind of seeing things from a Chinese perspective and picking up on things that they might not. There were many cases that the investigators who were in Guangzhou would tell me about where he noticed something that helped them to, for example, ask for a set of files that uncovered that there was inaccurate record-keeping and falsified documents and this sort of thing. So, he really was kind of hand in hand with the U.S. investigators in supporting those inspections. So, they really play a vital role.

JS: Was he there also to help translate, or the communication part?

CH: Yeah.

JS: He also obviously assisted with some aspects of this that weren't anticipated, but –

CH: Right, right. It wasn't unusual for a firm to provide a translator. They basically needed to under many circumstances, but what we ended up doing because we had two investigators, they were probably doing somewhere in the range of 20 to 30 investigations a year for food. He couldn't be with each of them on all of their inspections. So, they would try ahead of time to get a sense of which investigations might be more complex or difficult and he would join those. So, yeah, He was crucial.

JS: It sounds like the hiring decisions for the Chinese national staff was a pretty important thing, considering the role that the two that you just mentioned had in the operations.

CH: For sure. Also one that I didn't mention, Li Xia, who was in Beijing, and then there was also Helen, equally good, but just in the interest of time, I didn't talk about her, but the two of them we were able to hire, they had worked to support the State Department and in Li Xia's case, she worked for the Health Attaché, so she knew all this stuff. In fact, she was probably the most important hire I made because she really helped to kind of just seamlessly extend the institutional relationships that we had already developed. And then Helen, who was another senior foreign service national in Shanghai, had been working for the State Department to support what was the environment, science, technology, and health section of the embassy. That was the section of the embassy that focused on health-related issues, but had supported Andy and Mac Lumpkin on the visit to Shanghai. She had a background in pharmaceuticals, so she was also a really important hire that we were able to bring in that had institutional relationships already developed.

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JS: Well, I want to explore some of the areas that I know were crucial to the office being as successful as it was. In fact, you essentially have said this in the past yourself—the importance of the role in building relationships there. There were relationships that needed to be built with the regulatory stakeholders and with the regulated firms, right?

CH: Right.

JS: I don't know to what extent some of the other U.S. agencies were already there, but in some cases I believe other agencies carried out some of the responsibilities or assisted with those that the agency needed before FDA had a presence there. But now we had a staff in hand. So, when it came to, first and foremost, the regulatory stakeholders in China to what extent did these relationships have to be built on a local or regional level in addition to a national level? Because I know in other countries—India, for example—it's a very important thing to do. But in terms of China, I don't know if there's anything like an independent AFDO or state food control organizations in China or any similar organizations that would have been of assistance. Perhaps it wasn't as important as it might have been in other places.

CH: It was important. Both SFDA and AQSIQ in our early years there, but especially SFDA, made a priority of taking us to different provinces. So, the central regulators would travel with us, and I remember one of the first provinces was Shandong, right adjacent to Beijing and the northeast part of China. But then in subsequent years we also visited Yunan out in the West. We visited Zhejian province, a number of different places. And the theme of all of this was to help us better understand how the Chinese regulatory system works at various levels. It's interesting in

China because, in some ways you think of Chinese governance as being much more centrally administered, right? But let's say Shandong FDA, they have an administrative reporting line up to the central authorities, but their more operational, day-to-day reporting line is to the governor, or the head of the agency reports to the governor with a kind of dotted line to national FDA. That's very different than, say, a district office in South Bend, Indiana or wherever. And so, what was really important for us was to just understand.

It wasn't so much like we needed to know the head of Shandong FDA for the relationship. I mean, really, the issues that we needed to deal with were ones we needed to deal with at the central level, but it really helped us to understand the limitations of some of the local regulators, just in that their success was more based on what the governor cared about than what the central regulatory authority cared about. And what the governor cared about was economic growth, right? So, you kind of understood the challenging situation that this relatively small agency in Beijing had in being a national authority because they did not have the command and control over these local FDA's that you thought they might.

That was also important because these local provincial FDAs could have as many as, I seem to remember Shandong FDA had 6000 staff, but the leaders of those provincial FDAs or the large municipality FDAs often would find their way and rotate to a job in Beijing. So, it was good to build relationships with people at the top because they were the roster of people that Beijing might call on in future years. There was a case or two where getting to know somebody, when he was down in Zhejian province, was really helpful because he became one of the top leaders at SFDA and you had established a relationship with him years before, right? So that was very helpful.

The other thing you asked about, well, I guess a couple things. So, one is the relationship that we had with other U.S. government agencies. I think I remember from when I first arrived in Beijing, the acting ambassador, the chargé—a guy named Dan Piccuta, the head of all the U. S. government agencies—said to me in my first country team meeting in the embassy, "Welcome, Chris, good to have you here. We've been answering your mail for a couple of years, so it's good to finally have FDA here at the table." But it was in fact true that they had been trying to manage these, especially the attaché's office. FDA issues were pretty, as you know, detailed, complicated, and technical, and they just were not set up to deal with them.

JS: Were these things like 'What are FDA requirements for such and such a product?' I'd like to export that to the U.S'?

CH: Right, and often it would land in USDA's hopper if it was food related or commerce's if it was pharmaceutical related. You know Bruce was just there for two years as the attaché, and about halfway through his tenure, these issues of melamine and pet food and stuff started percolating up. Bruce is a pretty smart guy, and he also had the benefit of having a very engaged secretary, right? So, he had been able to set up conference calls and so on with people at FDA headquarters to address some of these issues. But there's nothing like having somebody there on the ground who can explain it. So, that was important.

The other thing that was true, especially when we had presence in Beijing, Shanghai and Guangzhou was that while Shanghai and Guangzhou were CSO posts, they also played a secondary role of being the public face of FDA there in Shanghai or the region and Guangzhou or the region. And I tried to give them some relief in that I mainly wanted them to be out doing

inspections, but they would set things up where I would come down or one of the policy analysts would join me to address, in later years when FSMA was passed, what do we need to understand about FSMA? So, those were really useful engagements to be able to connect with people in two of the largest hubs on the Chinese seacoast. I think that was an important function that we were able to fill at that time.

JS: Clearly, making inroads with the regulated cohorts was important.

CH: Right.

JS: How did you go about doing that? I suppose the regulators themselves might have been helpful with that, right?

CH: You know, we got better at it as years went on. I think early on we didn't have a very good sense of how do we connect with Chinese industry. We obviously were inspecting them. So that's a connection. What we wanted to do is connect more broadly, whether it was training events or just information sharing or whatever. The reason I say we got better at it as the years passed is because our first instinct was to work closely with industry associations that we're familiar with. So, like with Am Cham or that sort of thing. And it turned out engaging with Am Cham or some of those industry associations was not so helpful because they tended to represent large multinational companies. And really, we weren't there primarily to be looking at Merck and Lilly and those folks. But what we and our policy analysts found over time as they worked with

their regulatory counterparts was that in China the regulators kind of have this quasi-parental role over industry.

The best way to get industry to the table was to work through our regulatory counterparts. And they would bring together a room of five hundred people, or a thousand people, or whatever, so that we could get the word out effectively. I think it was especially hard on the food side of things because there are just so, so, so many small producers. But I know it's kind of true on the pharmaceutical side of things, also, but we were able to make connections over time to the senior leadership of some of the top Chinese pharmaceutical firms. And by virtue of being able to get the word out through them, often it would spread. The other thing that we were able to do through about 2015 or 16 was partner with Peking University on the pharmaceutical side of things and a program that they had there. Both Brenda Uratani, who was the first policy analyst on the drug side of things, and then Wong Gong, who followed in her footsteps and was there until 2017 or 18, both worked very closely with this master's program in International Pharmaceutical Engineering Management.

JS: I think that program went back several years, starting out as a GMP, Good Manufacturing Practice, training, and then by 2007 or so, it kind of morphed into this sort of broader pharmaceutical science/regulatory science training. I was going to ask about that: once the office was established, to what extent were you all involved in that, but it sounds like you were quite closely involved with it.

CH: Yeah. And I don't even remember now. But you're right that it did have a history before the office was open. And a number of people at CDER were kind of involved in helping to

partner with that and create the program. The program lasted about 10 years. It phased out by 2017-18 for political reasons; political reasons that didn't have anything really directly to do with the program itself, but just had to do with kind of politics—Chinese Communist Party politics—within the university. And the benefit of the guy who ran the program was, he was China born but was a U.S. citizen who had returned to run that program. It was a guy named Jung Chang. What I understand is, when they reorganized, he did a broader reorganization of the university to be more directly under the supervision of the Ministry of Education. But he was just not politically connected enough for the program to survive, which is really too bad.

This was a great program, but during those years, you had—and I don't even remember what the number was—but you had basically the emerging leadership of Chinese pharma industry and the biotech industry who were part of this program. And so, if you could make an impact there, it could really duplicate over the years. So that type of program is where we really had the biggest impact. And not just the program, but people like Brenda and Gong who, by any normal measure of a federal servant, gave way above and beyond. I mean, they gave up their weekends for months on end. They probably had more weekends that they were working those workshops then weekends off in a year. And I did what I could as their supervisor to make sure that they got paid for that, but there's just no way to possibly do that.

JS: I think you mentioned earlier hundreds of people that were trained over the years. And, obviously in educating people, it's one thing to provide someone with what are FDA requirements, regulations, and so on. But they have to understand what they mean. So, this is quite crucial to success, it would seem.

CH: Yeah. And the thing I realized as the first director—and I lasted in the role for a long time, seven years, which probably is about as long as anybody has ever done one of these director roles—was that after a few years, people are regularly coming to you and citing you as sort of an expert and a leader. But what you realize is that the value for what these offices were set up to do, to me, was in in those engagements. I did some things that really helped, but it was Gong and Brenda and others who really knew these regulations well, could explain them, and in Gong's case, could explain them in Chinese. We built those relationships over years; otherwise, it would have been more of a symbolic presence, not as much of a substantive presence.

JS: Having the gift of picking the right people for the right job is not to be undersold here. It's pretty important as you just pointed out. There were a lot of things going on to assist in this education, training, whatever you want to call it. I know there were state regulators that were shadowing some of our inspectors on some inspections, right? I know CDRH experts were working with folks in-country as well, from time to time. And I guess OCI, the Office of Criminal Investigations, which was also providing some assistance on things like web-based products being sold and working with Chinese counterparts there, and everything that you've just narrated, too.

So, there was a lot going on to introduce our FDA requirements and what we expect, not only policy-wise, but on the ground, right? Did we see an outcome from this in terms of improvement in products exported? Everyone wants to look at performance measures, right? I don't know how to do that here. But maybe if the quality and integrity and reliability of the products is improved, that's one way. Is that the case?

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CH: Yeah it's funny. When we walked in, I saw the track office there, and I had some recollection of that. I think that began to be stood up in my last year or two with the agency. What I remember is that was always a very difficult conversation just in terms of how do we quantify fewer products, or fewer shipments, offered for import that were rejected and those kinds of things. I think very honestly, and I know that at the time we came up with metrics and there was some indication that things were potentially improving. I go back to like my first day at Parklawn. I remember meeting with Mel Plasier and saying, let's talk about what does success look like at the end of year one? This is back in 2008, right? And I had some ideas about that, but Mel quickly jumped in and said, success at the end of year one is everybody is hired, everybody is in place, and we haven't had any big scandals. The last one she was kind of joking about because we didn't really have control over the scandals. But really, it had been a litany of, I think we talked about most of them, but dog food, toothpaste, cough syrup, blood thinner, and seafood, at least all of those. And it felt like for about a year and a half, it just was what's the next one going to be? What's the next one going to be? What's the next one going to be? I didn't at the time, and I would never take credit for the fact that there were no huge scandals after we opened the office, but I was grateful that there were not.

So, I don't know. Honestly, I don't have a really good answer for that one, partly because I'm so far separated. I know that we had some metrics at the time. And you probably have some ability to go back and access those. Maybe if you ask Mark or whoever because it's probably all in the system there. But to me, one of the tougher things was always how do we quantify? And I never had a great answer to that.

JS: And that's the sort of thing that Congress always wants to know about after bunch of time: "how you doing?" And this was when the GSA reports come out, that's what they want to look at.

CH: Right, right. And certainly, with the GSA we had two of those studies during our time there. And my recollection is when the reports came out, I was happy because of course they always are going to have suggestions about improvements, but they didn't make headlines and there weren't huge holes. So, now you're going make me want to go back and look at those reports to remind myself of what they said.

JS: I think your recollection is on the spot. I mean, of course, this is a GSA report and they will find issues that need addressing. But I think overall, both of those came out within a couple of years or so after the office began, maybe 2011 or so and then there's another one in 2015. But, there was a little bit of impatience about one of the other offices opening, but I don't think there was anything to be too concerned about.

I wanted to touch on one of the functions of the office that must have been quite important as well, and that's in the ability to have eyes and ears on the ground and the importance of gathering information about the regulated products and sharing that with the folks in headquarters and intelligence gathering. So, I'm kind of interested to learn how that was done. It's inconceivable that we have three offices in an enormous area of responsibility here, right? But any information would have been crucial.

So, number one, how is it collected? How is it shared with the folks back in headquarters and in the relevant centers, or directly with the OIP? And I'm also interested in the back and

forth. Was the office getting any kind of guidance from the centers or from other headquarters contacts on what they needed more information about that was going on in regulated industry in China?

CH: You know, I think this is another one of those where I'm probably going to give a response that's going to be less than satisfactory, in the sense that I do think that what Mel said about success in the first year was true. But then, once you've actually gotten people in place, and started to give a sense of this office is a real thing and we add real value, then the stakes go up, right? And there's an expectation, okay, you're there. You're doing inspections—we're probably doing more inspections in China. Although, I always reminded people that actually we've been sending people to China for years so, whether we were actually doing more inspections was really based on the assignments from the centers and ORA. But then there was this turn to how can we get the information in investigations that's about particular firms.

But how do we get actionable, helpful information that is in the other category? Not things we find in investigations, but the model that we always wanted to aim for: if we were on the ground in 2006, would there have been signals that we would have been able to detect that would have helped us to know ahead of time or at least very early on about the melamine and pet food stuff, right? So, I know that we spent a lot of time trying to develop a system for reporting back and there were a lot of stops and starts. There's all kinds of things that people could report back that were not all that helpful. The only recollection I have over time, and unfortunately, like I said, my memory of the details is really thin at this point. But I remember that towards the end of my time, maybe 2013, 14, 15, and this would be when Kelly Giannattasio was the deputy by that point. She's actually still in FDA. She and I worked on helping to refine the system. It was

not just a China office system. It was a thing that we worked on with headquarters to identify what types of information are most useful? How can we report it back through a system that you all back here at White Oak can access and then follow up with us with questions?

So, what I remember was, it was not just a China office thing. It was Lou, and I think Leslie Ball would have been the deputy at that point. You know, we were hearing this from the centers and from ORA. We need a more streamlined system, a system that makes more sense. In terms of the particulars of what got reported, I don't have real good memory on that. I know that was the goal though—not just have what I think in the early years probably felt like ad hoc communications; often just emails that were sent from the policy analyst that, "Oh, by the way, this, oh, by the way, this." Over time what we really were trying to do is have a more systematic process. But I'm sure the details would be a lot more interesting. I just don't remember.

JS: Well, I know they had kind of templates to report the information, analytical reports or something or other. And it was kind of curious to me if word ever got back to the offices, how it was used, or how much response it generated from headquarters?

CH: Again, I think this was initiated from the headquarters side of things, but I seem to remember that there was a contract that we had with some contractor that did AI-type stuff in terms of gleaning information from Chinese language reports, open source information that would, for example—and this is not like a state secret or anything—but if pork prices went up in China and pork is the most popular meat in China, right? If pork prices went up, what effect could that have on other sources of food and that sort of thing. So, it was more cross cutting, more forward looking. But that's all I remember about it.

JS: Yeah. I was kind of surprised to read somewhere, I can't remember where, but that for some offices this reporting was done pretty frequently. I mean, like every week.

CH: Yeah, I think that's about right. I think that's about right. It might be helpful to follow up with Kelly, who was probably front and center on that for us. The thing I remember early on was, and it's a little bit of a separate issue, but it's what eventually led to FDA-TRACK. I'm remembering that my last few years here, but wasn't that a Josh Sharfstein initiative? I think it may have started with him, so that would have been early in my time. But what I remember was there was a lot of challenge around quantifying, and it may have been for FDA-TRACK. But there was just all kinds of quantifying—what was useful, what was helpful? And how did we define that? That goes back more to the performance and how can we quantify what difference the activities at the office made, but it was always a very challenging conversation.

JS: Right. One of the things that these GSA reports that you mentioned tend to focus on are inspections.

CH: Right.

JS: Inspections, inspections, inspections. And I want to ask about those and getting people on the ground and everything. But one thing about the inspections, and I know the inspection decisions are from ORA, but one thing I wondered about is here we have an office in place, with inspectors in the country. And I'm wondering to what extent did headquarters look to the China

office for any recommendations when it came to inspection decisions? I mean, strategically where we might focus some of our inspection work?

CH: Definitely the assignments were coming from ORA. And what would happen is we would get the roster of whatever, fill in the number, but say here are 20 inspections that need to be done in China over the next number of months. Obviously, if you've got PDUFA drugs and stuff, that's a different category. It's a little bit different now because I think there's a supervisor for food, there's a supervisor for medical products, but at the time we didn't have that. So early in the office we would just kind of go directly to the CSOs and say, okay, we want you guys to pick the ones that are more challenging, right? And so that was the early version. I think on the food side of things, I mentioned the foreign service of the Chinese national, Evid Liu, who was supporting the food inspections. I think he was able to work with our food inspectors in Guangzhou to help. I don't think we were at any point really suggesting assignments. But when we saw patterns in one set of inspections or a certain set of issues here, we could help investigators who were coming on TDYs to understand better what to look for in these inspections in China. It was never the same as having somebody who was based in country and having a Chinese national supporting them. But I think it did help to improve the quality of inspections over the years.

Where, though, I think it probably made the biggest difference was on the drug side of things. I mean Peter Baker kind of became a bit of a legend, first in India and then in China because he really developed a technique for figuring out when a firm had been falsifying documents and really refined his process to kind of do that. Like I said, Peter did training for other investigators to help them understand the techniques that he used, and he even did training for Chinese investigators to help them understand how better to detect falsification of

information. So, I think it was more that type of wisdom that we gained through the years that we were able to pass on. I don't remember any specific time where we were suggesting assignments for ORA or CDER. I think it was more just how those investigations got done, where we really added value.

JS: I know having feet on the ground was important considering the level of industries in the country. The in-country inspectors—to what extent were those supplemented by some U S.-based inspectors working in China?

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CH: A lot. I don't even remember what the percentages were, but I know that in any given product area, the majority of inspections happening in China in any given year were still happening by people coming on TDY from the U.S. Which was just the reality. I mean if, for example, there were 200 food inspections that needed to happen in China in a given year and you had two food inspectors on the ground, they were going to get probably somewhere in the range of 20 to 30 done a piece. So that left 150 on the table for U.S.-based investigators. The reality is—again, this is just my opinion—that if you looked at posting investigators in China in terms of like bang for the buck, you are never going to get your biggest bang for the buck by having people on the ground in China in terms of numbers of inspections, because it costs. I'm sure the numbers have gone up over the years, but at the time, the rough number for posting a U.S. personnel overseas was about half a million dollars a year as a base.

So, you're spending an extra half a million dollars a year to have them there, as opposed to just the costs of a normal TDY from the U.S. So, the most efficient way to get the largest number of inspections done would always be to just have it be done from the U.S. on TDY, no

matter what country you're talking about. However, I think where we felt we added value, especially in China, were those areas of just getting a much more in-depth understanding of what kinds of things investigators who were coming from the U.S. might be missing, and that's where I felt like we really made a qualitative difference.

JS: But there clearly were advantages, as you just said, of having in-country investigators. And I know there was an attempt while you were there to bring on a number of them. As many as increasing the size of the staff by 10 or 12 or so. And that took a long time. I know some of the people that had been waiting to come eventually had to drop out. Why was that? Who was responsible for that?

CH: It was even more dramatic than what you described. It was that we were increasing the size of the office from eight Americans to 25. So, it was tripling the size of the office in terms of the slots, in terms of the FTE slots. So, it took a while. The genesis of this was, as I understand, a conversation between Peggy Hamburg and Michael Froman, I believe it was late 2011 going into 2012. And basically you had an election year. The administration at the time, the Obama administration, was looking to have a component of the budget that was, like, get tough on China. Or at least such as that would look like in 2012.

My recollection was, it was over the holiday break at Christmas and they got together; I think they lived in the same neighborhood in DC. They saw each other and Peggy said, well, we could be part of that if we increase our presence in China. So, from that conversation—and it was really improbable because normally, as you know, in the budget process you're blind by many months before you get brought into that process. But it was so high-level with extra

money, 10 million or whatever it was, added to that proposal, that was the genesis of expanding the size of the China office; to have it kind of part of the get-tough-on-China package that was rolled into the 2012 budget.

So, we basically began very soon after that to begin recruiting. When folks from the NSC asked me about this as they were putting together the proposal, I said, I'll be honest, it's going to be very challenging to go from eight Americans to twenty-five Americans in-country, because we are not a foreign service agency. You have to recruit these people, you have to convince people that they want to go move to China, because the length of assignment, at least initially, is only two years. Many of these people don't have security clearances. Just all these things that are going to be a real challenge. Regardless, we went forward. We began hiring people with the expectation that there might be a slight delay, but they would be in country within 8 to 10 months, which would be a normal time frame for those types of assignments.

What eventually happened was you needed the Chinese government's approval for an expansion of the number of diplomatic personnel in China, and that just got stuck at a certain point. I was spending a lot of time engaging with Chinese counterparts. I mean, you're engaging with SFDA and AQSIQ, when, in reality, you know that the powers that be are the Ministry of Foreign Affairs or the State Council. So, we're doing as much as we can to advocate with our counterparts, but there came a point at which it needed to move up. Biden visited—he of course was Vice President at the time—in December 2013. And so we worked with the NSC to make the approval of those visas or those slots deliverable for the Vice President's visit, which happened, and deliverables for that type of visit was approved. Here we are in early 2014 and some of these people had been hired probably late 2012, so already that's 15 months. And then it

really took another year in terms of it actually being approved and actually being able to post people to Beijing.

It was not until early 2015, and the story of us closing the Shanghai and Guangzhou offices is all related to that because one of the concerns. I never really fully understood the basis for it, but one of the concerns was that, if they were going to allow an increased number of American personnel, they did not want they did not want them spread across the country. They wanted them consolidated in Beijing, which was a concession that eventually we made. We would have rather had them in those locations around the country, but if it was one or the other, eventually we said okay.

So, finally, in December 2014 at the—what was it, the SAED at that point?—I think it was similar to the Paulson thing but had been rebranded in the Obama administration as the Strategic and Economic Dialogue, that was the last bit of final set of documents that had to be signed. Howard Sklamberg signed them on behalf of FDA, and we finally got the first person arriving in China in January 2015. The last thing to say about that, because I know we're running a little short on time, is in that interim period, which ended up being like two and a half years almost, we did a ton of TDYs and people would come for two or three or four months at a time. Some of the people we had hired, and actually others came without any intention of ever being part of the long-term office, but they said, "Oh, I can do a two-month or a three-month or a four-month assignment in China? That sounds like a great opportunity."

So, while it was not ideal, we got a lot of people a lot of exposure and opportunity to come out for a shorter period of time that they otherwise would not have. And some of those people then eventually did end up in the China office in later years after I left. Last thing to say, I guess is it was a little bit of a feeling like Moses in the promised land, because the expanded

office really was not done until say a few months after I left in 2015. There were all kinds of things related to how we dealt with office space and all of that in Beijing, but that was why it took so long.

JS: Perseverance pays, I guess.

CH: Honestly, it did make it somewhat easy for me in year five, six, and seven of doing the job — what are my top priorities, what's my top focus, and that was it.

JS: I have to ask this: You must have been the longest serving director.

CH: I guess so.

JS: What kept you there that long and why, in the end, why did you make the decision to step down then?

CH: Oh, so the decision to be there for almost seven years, was an incremental one. When my wife and I committed, and we had at that time in 2008 a four-year-old daughter, and we said, okay, we understand the HHS thing is two years. You know, my wife had done the international assignment before, and she did a two-year assignment for her USAID project, but we both felt like it's just not long enough to really feel like you've accomplished anything and really gotten to know anything about the country that you're living in. So, we went into it knowing that we would at least probably, as long as FDA was good with it, do a second two years. Probably we'd be

there at least four years. But then as things moved on, you kind of live life. I still say to this day that the FDA China Director job—it's the best job I ever had. I don't know. I've still probably another 10-12 years left in my career. So maybe I'll come up with some better job, but it was a fantastic job.

Then we also had a personal life. My wife had landed this job with the State Department where she had become an expert in China's investment in Africa. Our daughter obviously was growing up and she was this blonde hair, blue-eyed, fluent Chinese speaker because she was at a bilingual school in Beijing and was speaking Chinese in day-to-day life with people on the street, so we just more and more thought, okay, we have a kind of life here. And I knew that there was a kind of like six-year limitation. I was able to extend it a little bit because there's usually some grace for end of school year and that sort of thing. So, I got an extra half year, seven or eight months out of that. I think with all U.S. overseas posts, but definitely in China, there's a point at about five or six years where they want you to rotate out. And I think that's now formal HHS/FDA policy. That may be about the max you can be at any one place.

So, the only question for me was whether I was going to stay with FDA or move, you know, leave FDA. And ultimately it came down to we wanted to stay in Beijing, and the only way to make that happen was to leave FDA. And so, the good thing for those of us who do leave regulatory agencies looking for employment is that you're very marketable to regulated industry. I didn't necessarily start the job search looking to move to regulated industry. I actually did do some poking around to see about UN agencies or the Gates Foundation or those sorts of things. It was just a numbers game, honestly. The number of positions that made sense were a lot. There were a lot more of them in the private sector than there were in other places. So that's how I ended up with Pfizer. And then we spent seven more years in Beijing. So, I landed there in 2015

and my family came shortly thereafter. We left in July 2022, about 10 days after my daughter graduated from high school. So, we lived a large chunk of our life there.

JS: I know we've gone overtime here, but I just want to thank you so much for sharing all of this. This has been an incredible insight into our first foreign office. I really do appreciate your willingness to sit down and talk about this, and this transcript is going to be a really rich resource for research and for other purposes. So, I appreciate it.

CH: Great. Thanks.