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Lynn L. Bergeson (LLB): Hello everyone, and welcome to *All Things Chemical*, a podcast produced by Bergeson & Campbell (B&C®), a Washington, D.C., law firm focusing on chemical law, business, and litigation matters. I'm Lynn Bergeson.

This week, I had the distinct pleasure of speaking with U.S. Food and Drug Administration (FDA) Deputy Commissioner (DC) for Human Foods Jim Jones. We spoke about all the amazing initiatives Jim is overseeing as the agency's first Deputy Commissioner for Human Foods. Many of us know Jim pretty well, given his extraordinary career at EPA [U.S. Environmental Protection Agency] leading both the pesticides and toxics programs. Jim's role at EPA culminated as Assistant Administrator for Toxics in the Obama Administration. Jim, of course, was Technical Advisor to Lautenberg [Frank R. Lautenberg Chemical Safety for the 21st Century Act] and is intimately familiar with that law. In addition, Jim's understanding of the administrative process, chemical prioritization, risk evaluation, and risk management principles make him, in my view, anyway, uniquely well-suited to lead the Human Foods Office at FDA. We discussed his priorities, the recently released systematic, postmarket review process, and how Jim intends to tackle the many challenges FDA faces with regard to chemicals, chemical contaminants, food additives, and human foods in general. Now, here is my conversation with Deputy Commissioner Jones.

Jim, thank you so much for being with us. Many of us in the TSCA [Toxic Substances Control Act] and FIFRA [Federal Insecticide, Fungicide, and Rodenticide Act] community know your storied career from EPA pretty well. But some of our listeners may be less familiar with who you are and your many contributions to government service and chemical regulation. So maybe you can just give a little background on your extraordinary career with the government here in the United States.

Jim Jones (JJ): Thanks, Lynn. Sure, I'd be happy to. Probably the first really major activity I had in my time at EPA involved -- I was working for the Assistant Administrator in the early '90s, Lynn Goldman who is well known in the community, and I was her staff person, sort of held the pen as the administration drafted what became the Food Quality Protection Act (FQPA). Unlike the last three or four administrations, the Clinton Administration actually

developed legislative proposals and then looked for members of Congress to introduce them. EPA, working with, actually interestingly, colleagues at FDA and USDA [U.S. Department of Agriculture], drafted a bill to modernize pesticide law in the United States. That bill, although it didn't go anywhere for a couple of years, it ultimately got passed in 1996 as the Food Quality Protection Act. I then had the somewhat unusual and unique experience of then moving into the program, the pesticides program, and worked for the next ten years implementing the law that I had helped to write. I was not the policymaker in the writing of the law, but I certainly had a front row seat to it.

Then I spent a good ten years in the implementation of FQPA, which was an incredibly formative part of my career. I then moved over into the air program for a little bit and ultimately came back into chemicals as the Assistant Administrator for Chemicals Safety and Pollution Prevention, where I had an interesting. This time I *was* in the policy seats in the development of what ultimately became the Lautenberg Chemical Safety Act as my time as the Assistant Administrator. I've had a fair amount of experience both in developing legislation and then implementing the legislation I helped to develop.

LLB: I'm going to circle back to that in a bit, Jim, because I think you're very modest. You have an extraordinary background in developing two of the most consequential chemical regulatory programs in the United States, under FIFRA and TSCA. But let's focus on your new position. You've been there about a year. In September 2023, you joined FDA as the agency's first Deputy Commissioner for Human Foods. Before we discuss what that position entails and some of the really important initiatives that you have articulated very recently, I think our listeners would welcome learning a little bit about the expert panel in which you participated in connection with the Reagan-Udall Foundation's 2022 evaluation of FDA's Human Foods Program. In preparing for this podcast, I will admit to not being as familiar with that report as I wish I had been earlier. But how did you get connected with the report? And what are your observations regarding its findings and how it has ultimately led to the position you now lead?

JJ: It was interesting. I actually got the call out of the blue from the Commissioner's office asking me if I'd be interested in participating in this panel, and it was a surprise to me. I -- you'd have to ask them how they got my name. But I was really intrigued by the idea. I'd been out of government for about five years at the time, and the opportunity to sit on a panel with a number of other individuals who are very highly regarded was really appealing to me. So I accepted and was really excited to participate in it. I worked with this panel for about four months to develop the report that ultimately was given to the Commissioner. I would say that Commissioner Califf, who is still the Commissioner, really accepted many of -- certainly the key recommendation of this group, as well as many of the other recommendations. It was pretty gratifying -- as someone who has received reports like that before -- to have been on the other end of writing one and to see it come to fruition the way that it did was really very gratifying.

LLB: That did not escape my attention in both reading the report and learning a little bit about the Reagan-Udall Foundation. To me, it's just pure kismet that they landed upon you, given your skill set and your deep, deep administrative experience in risk assessment, risk management, and chemicals in general. I note a key finding of the expert panel is that the FDA Human Foods Program's quote, unquote "current culture," at least according to the authors of the expert report, inhibits its ability to accomplish the goal of protecting public health. Factors contributing to the culture deficits include -- and this is a quote -- "lack of a clear vision and mission; a disparate structure and a consensus government model;

competing priorities; and the lack of a strong, supportive leader and … ultimate decision-maker, who is responsible for the Human Foods Program."

With that short excerpt as background, maybe you can share a little bit about how you came to be that strong, supportive leader and decision-maker who now leads this new Human Foods Program at FDA. And a couple of follow-on questions, a review panel from the outside can provide insights, as you did. What now do things look like from the inside? Because you are kind of in the epicenter now of this program (a very important one)? And finally, what have you learned now that in a perfect world, you would have liked to know more about FDA's work as a panel member? Your perspective probably has changed a little bit. And what can you share with our listeners, given your experience as an expert panel participant and now, as leader of the pack over there in Human Foods?

JJ: A little bit of background on those observations that the panel made, and one of the reasons why this panel was convened. The FDA structure is basically built around centers. There is a center for the various types of drugs, Center for Drug Evaluation [and Research], Center for Biologics [Evaluation and Research], Center for Tobacco Products, Center for Veterinary Medicine. And there was a Center for Food Safety and Applied Nutrition. Over time, within the Commissioner's office, there was, there were created an -- it evolved over time with multiple different names. But it was an office; it wasn't a center, it was an office that the last iteration was referred to as the Office of Food Policy and Response that actually had a Deputy Commissioner in that position. When you read the position descriptions for the Deputy Commissioner for the Office of Food Policy Response and the position description for the Center Director for Food Safety and Applied Nutrition, they read very similarly. That thought, that organizational structure is really what led to this finding that the panel made about a lack of clear decision-making. It was unclear as to who had decision rights on any food-related issue. That lack of clarity can really permeate an organization. Where do you take an issue to get resolved? How does it get resolved? Who makes the call?

That structure, which formed the basis of really our fundamental recommendation, which is you need one individual who has these responsibilities, and that's the creation of what is now referred to as the Human Foods Program, was bringing this Office of Food Policy and Response, the Center for Food Safety and Applied Nutrition, and some parts of what was known as the Office of Regulatory Affairs into one cohesive structure, with one individual with the ultimate decision- making. That is the Deputy Commissioner for Human Foods. So in many ways, the cultural issues that were identified in that report really go back to the organizational structure. I think we are well on our way to addressing many of those cultural characteristics that were described, not because I'm here, but because we have now a structure that is much more amenable to clarity of vision, clarity of mission, clarity of decision rights.

Within a month of being here, my executive team and I, we pulled together a vision and a mission statement. It is very clear from the organizational chart who sits on top. I don't have to talk to a peer of mine to come to consensus on any individual issue. Of course, I need to be in the framework of the Commissioner, but that's true in all organizations. I really think there was a fundamental structural challenge that needed to be addressed, and I think we've addressed that.

LLB: Being one of your huge fans, Jim, I think if anyone listening to this podcast cast their eye at the Reagan-Udall Foundation report, I think it does a fabulous job of articulating some of the redundancies, lack of clarity, and inability to have a clear linear decision-making process in the Human Foods Program, which to me provided a really good blueprint for your

office's reorganization and the new organizational structure that became effective October 1 of this year, about a week ago. The speed with which you have moved is, to me, just kind of breathtaking. You've been in the federal government for a long time. I think you probably share my awe at being able to move from where you were at as an expert panel member to being Deputy Commissioner for Human Foods and having a new organizational structure. That's a very short period of time. And I, for one, am very impressed with your work and your team.

JJ: I have a -- it is a great team here. I have been impressed. I was always impressed when I worked with FDA in my life at EPA, which we did a fair amount of in the pesticides program because FDA is the enforcer of pesticide tolerances. There was a lot of coordination. I've always been impressed with the team here, and getting here, arriving here, and the year I've been here, I'm even more impressed. It is really top-notch staff here, top-notch leaders here. Actually, that was one of the interesting things being on the expert panel, that was the perception of literally every panelist. You know that there's an organizational structural problem if everybody has nothing but good things to say about the quality, the commitment, integrity of the staff, but then observe -- but why aren't things working quite right? And then you look at that structure, like, "Oh, I think I know why. The structure is not correct." But no, it's really, really a remarkable group of professionals here at FDA.

LLB: Organizationally, how many folks do you have working in the area that you now lead? And with regard to funding and resourcing, I know your former colleague at EPA, Dr. Michal Freedhoff, is always expressing the need for more resources. I'm confident, given your recent testimony last month before Congress, you also expressed interest in getting additional congressional funds. But is that something that you continue to press for? Where are your areas of chief concern in carrying out the very, very ambitious agenda you've set out for yourself?

JJ: In the Human Foods Program -- now post-reorganization, so as of last Tuesday, October 1 -- there are 2,300 staff in the Human Foods Program. The resource challenges here are -- they were noted in the Reagan-Udall reports. I've made reference to them in testimony. Commissioner Califf has spoken extensively about them there. We are a seriously underresourced organization, and I think the area where it is most challenging is actually in the chemical safety space, where historically, FDA is -- it sort of reminds me in many ways of TSCA, where you've got a premarket program. But old TSCA did not have a mandatory postmarket program. And what happens in the government, when you have no mandate, if you have authority but no mandate, as you find over time, you don't get much of a robust program. Similarly, we have a premarket requirement here. We have postmarket authorization, but no mandate, so there was not a very robust postmarket program. Also -- the parallels to TSCA are quite remarkable; feels like it's 12 years ago. You have an emerging consensus in civil society that there needs to be a more ambitious postmarket review program here in the food chemicals program. Because the public interest community is not satisfied with that, they're going to states. Sound familiar, Lynn?

LLB: Oh yes. It's remarkable the parallels here.

JJ: I know. It is remarkable. We're seeing all these state restrictions coming along related to food chemicals, which has incentivized the industry to say, "Hey, FDA, we need a more robust postmarket chemicals program." You've got this now consensus evolving within civil society, public interest groups, industry saying the same thing. That does create an opportunity. But, but the challenge is going to be funding. You need money to do postmarket review work. What we are telling Congress, we're telling the stakeholder

community is, with the money we have, this is how many chemicals we're going to be able to look at in a year. If we need to do more than that to satisfy civil society's interest in this area, we will need more resources. We will see how that plays out. But I don't see the states slowing down, unless we're able to be more active in the space, which we're working to do. But again, it will be resource dependent.

LLB: My colleague, Jim Aidala, your former colleague at EPA -- we mused in preparing for this podcast on whether you're experiencing some degree of post-traumatic stress disorder (PTSD). Given all of these parallels -- having a beautifully crafted TSCA statute but lacking a mandate to actually implement the provisions and aspirational goals of the law. This -- it just seems so eerily familiar with what's going on in your interest in monitoring postmarket food issues. Again, I can't emphasize enough, Jim, how your skill set and the mandate you have before you as the first DC of Human Foods. You're just tailor-made for the job.

JJ: It's funny that you say PTSD. I think that my experience actually has given me a fair amount of comfort because it feels like I've been here before. I think I have a sense of where to go.

LLB: *Déjà vu* all over again, right? Let's pivot to talk about the, I think, very interesting systematic process you and your colleagues rolled out last month. The August 12 *Federal Register* notice announced the availability of a very well-written discussion paper that provides a great deal of information on your vision for a postmarket assessment of chemicals in food, including food additives, color additives, generally recognized as safe (GRAS) substances, and substances used in contact with food and environmental contaminants. I want to remind our listeners that comments on this, I think, very, very important consequential discussion draft are due December 6, and people are urged to read the document and comment on it, because I think your office would appreciate feedback from the regulated community, Jim. But maybe you can generally describe what you regard as key elements of the process and what you hope to learn, and what would be most important for stakeholders to share with you on or before the comment period ends.

JJ: Yes. The first thing we need to do is come up with an approach for how we're going to select which chemicals to work on first. We've got a very familiar territory. There are more chemicals that are potentially subject to reevaluation than resources allow you to do, so it's really important to pick those that are potentially more risky than those that are not. We have identified the criteria that one would consider in selecting which chemicals to look at first. The parallels to TSCA are very similar to the prioritization process we did there in 2013.

Has there been some change in hazard that would make you more concerned? Some change in exposure? Are there characteristics that one would be worried about? Carcinogenicity, reproductive toxicity, chronic effects, acute effects: the kinds of characteristics of a chemical that we may have knowledge of now that we did not know when they were originally authorized that would give you concern. What should we be thinking about when we prioritize, when we select the chemicals to work on? And then, what should the process look like in terms of when we do an assessment, opportunities for the public to give us comment? Ultimately, if we come to risk management, the law will govern that. EPA provides a fair amount of guidance about how to do risk management. But before you get to risk management, what are the steps that we should be taking that will allow the public broadly to make sure that they have an opportunity to comment? Where should we be plugging peer review into the process? It's laying out sort of how do we select chemicals and then what should the process look like as we assess a chemical?

LLB: Drilling down a bit, the discussion draft goes into some very helpful detail of differences between what is called a focused assessment -- a shorter term, not necessarily public review of chemicals that have been prioritized based on the criteria that your office is using, and a comprehensive assessment -- which strikes me as being much more akin to a TSCA Section 6 risk evaluation, spanning perhaps multiple years. Maybe you can just summarize for our listeners a little bit about both assessment processes.

JJ: Yes, and we're looking for comments on this as well. It is not unusual in the food chemical space where there may have been an assessment done seven or eight years ago, let's say, and *a* new piece of information comes in, *a* new study. In that context, it may be appropriate to do what we refer to as a focused assessment, where you say, "Does this study inform this assessment in any way that would lead to a different conclusion?" You're not starting from scratch. You're not starting with, "Okay, let's line up all the data. Let's then take a chemical that's not been assessed in many, many years, and we're going to look at all of the data and systematically evaluate that data and assessment." It's really -- we've got one new piece of information. How does that new piece of information inform a previous assessment?

The new piece of information can be as complicated as a new study, or it can be just some signal we're picking up: There are suddenly consumer reports coming in related to this chemical that are different. That's, I think, in lay terms, how we're trying to think through what a focused assessment would be versus a more comprehensive assessment.

LLB: We've already touched a little bit upon this, Jim, but I wanted to see if you had anything further you wish to add, because I think your background in chemical evaluation, risk evaluation, hazard assessment, prioritization, risk management all seem to be very important skill sets to deploy in your current job. There are notable exceptions between and among the Federal Food, Drug, and Cosmetic Act (FFDCA) and its legislative underpinnings and TSCA and FIFRA, the two statutes that you're most familiar with. But as you noted earlier, you also worked extensively with FDA on food issues in your job as top FIFRA officer.

One topic that I know intrigues me, and I see a lot of it, a lot of questioning now about what might be considered generally recognized as safe. The regulatory structure for food ingredients and food packaging materials was established way back in 1958. And unless people choose to disagree, I think it is really premised on a recognition that many natural and human-made materials have what was regarded then as a long history of safe use in foods and are otherwise considered GRAS (generally recognized as safe). That premise seems to be called into question a fair bit these days, both at the federal level by stakeholders in the FFDCA community, and of course, as you noted earlier, by many states. What is GRAS anyway, and are there evolving standards of safety? How is that principle enduring over its many, many years of existence? My bottom-line question is how will you and your office go about kind of modernizing this deeply embedded GRAS concept in the policies, and practices, and procedures that you are contemplating and initiating now?

JJ: Yes, that is one of the aspects of food chemical law that is very different from the other major chemical laws in this country: TSCA and FIFRA. Our approach has been to strongly encourage manufacturers to voluntarily submit their GRAS determinations for our review. We actually get about 70 of these notifications every year. But what we don't know is -- that's the numerator; we don't know what the denominator is. And that is a vulnerability for the food chemical safety system, that there are chemicals out there that are -- manufacturers take advantage of the GRAS provision under the statute, and they do not need to let FDA know about that. It's really tricky to talk with confidence about -- we know what chemicals are in food when they actually don't have to tell us.

When we don't know what that denominator is, we're going to continue to encourage manufacturers to voluntarily notice us. We then do a review of their finding, and they have to submit the basis for their finding. We periodically will send them back a letter saying, "That's not GRAS, and that, as a matter of law, is not GRAS." We are also looking at data systems we have because you do need to put ingredients of a food on the label of the food, so we are able to scan food labels to see if there are chemicals that we've never had an opportunity to review. We are doing that, and that will allow us to do some, again -- after the fact -- go to a manufacturer and say, "We'd like to see your GRAS substantiation."

Definitely it's a challenging part of the law, and we are definitely looking at how we can increase our oversight of GRAS to ensure that when a manufacturer makes this determination that a substance is GRAS, we have an opportunity to look at it. But under the law, they do not need to let us know they've made this determination. If they have and we find out, we can ask to see -- "We need to see your determination," and we can make an adjustment at that point. But it's definitely a challenging part of the statute.

LLB: You touched on, not by name, but a little bit, about whether or not additional authorities are needed to help you discharge your mandate in your current role in your testimony last month before the Subcommittee on Health, Committee on Energy and Commerce -- this is on September 10, both in your written testimony and in your oral remarks. You noted that we -- presumably FDA -- need Congress to grant us the authority to prevent food and dangerous levels of environmental contaminants from ever reaching store shelves. And we need to remove the limitations on sharing certain regulated commodity information in real time with our state partners. To my eye -- and again, I tend to practice mostly in TSCA and FIFRA, but I do a bit of FDA work -- it seems that FDA has limited opportunities to obtain information on premarket, in the pipeline, products, and given the somewhat squishy burden on food marketers to demonstrate safety, do you think there are opportunities for enhanced not necessarily oversight, but legislative authority to help modernize the FFDCA in ways that might make it more efficient for you to get the information you need to make important food safety determinations? Is that something FDA would consider seeking, or are others on the Hill moving in that direction?

JJ: First I'll start with what I was referring to in that testimony, which is actually somewhat narrower, but very important. It relates to the issue we had last year with an apple cinnamon pouch product that had excessively high levels of lead in it, that ultimately, we came to the conclusion was the result of economic adulteration, as opposed to -- there were small levels, low levels of lead in the cinnamon from naturally occurring uptake. But we had asked for -- prior to that incident happening -- FDA had asked Congress for authorization to mandate testing for heavy metals in foods primarily consumed by children.

Over the last 15 years, there's been a fair amount of data demonstrating that baby foods have had levels of either arsenic or lead in them, so we had asked for a mandatory testing authority for such products. The testing would be done by the manufacturers. That testing authority, had we had it granted then, would have definitely prevented the lead in the apple cinnamon pouches. That's specifically what I was referring to there. I did make reference in the testimony to the fact that one of the challenges in a postmarket program at FDA is that we *don't* have authority to mandate the generation of health and safety data, two things that *do* exist in the pesticide -- TSCA chemicals -- world that were significantly strengthened in the Lautenberg Chemical Safety Act: the ability for in this case -- in that case at EPA, to mandate testing for purposes of postmarket review. FDA does not have that authority, and I pointed that out as a challenge to doing a postmarket assessment. I think it's a significant challenge. We'll come across that as we start doing more and more postmarket assessments,

that there are data we would want to have that we cannot mandate the manufacturers to generate.

LLB: That's an interesting point, because I note EPA recently suggested prioritizing some metals under -- for risk evaluation -- under TSCA Section 6. Do you work with other federal agencies and state agencies in accessing information that would aid you in filling some of these data gaps, Jim? Or are there more structured memoranda of understanding between and among FDA, EPA, and other federal agencies -- and states, for that matter -- to help fill the data void? Because a lot of agencies and a lot of states are all mandating data development of one form or another, or data call-ins of one form or another. How are those opportunities optimized to give you and FDA what you need, if you don't have a clear or legislative authority to mandate chemical test data?

JJ: Yes, that's a great question, and that is going to be one of the ways in which we work to manage both our resource limitations as well as some of these authority limitations. The food chemical space is by and large a subset of the TSCA space, a rather small subset in the scheme of things. That means that most food chemicals have some authorized TSCA uses, which means that there is an opportunity to collaborate. Actually, we are working on phthalates; EPA is working on phthalates. Our teams are working together. We will be looking for opportunities to leverage data that were generated for purposes of TSCA, or REACH [the European Union's Registration, Evaluation, Authorisation and Restriction of Chemicals legislation], for that matter, or any other governmental entity that has looked at a chemical that happens to be in the food chemical space, so that we're not starting from scratch.

There are also some international authorities that we're going to be looking to leverage. There is a group under the WHO [World Health Organization] known as JECFA [Joint FAO (Food and Agriculture Organization of the United Nations)/WHO Expert Committee on Food Additives], that brings together a number of governments, and they do food chemical safety evaluations. Their safety evaluations -- our colleagues in EFSA [European Food Safety Authority] do food chemical safety evaluations. There is no reason to start from scratch if you've got a credible governmental entity that has evaluated -- every once in a while, that is often how EPA does a food chemical safety assessment, leveraging work that's being done by other governments, international, states if appropriate, our colleagues in the U.S. government in particular. I think EPA will be the most likely source of that information -- and collaborating when there is an issue that we're working on together. We did a lot of work with EPA on mercury, and we're doing a lot of work with EPA on the perfluorinated chemicals. I think there are lots of opportunities in both the chemical contaminants space, but also in the authorized chemical space for collaborating with federal, state, and international colleagues that can actually help us really significantly, particularly in this resource-constrained environment, as well, as you point out that we don't have certain authorities that are going to be challenging.

LLB: There's also just urging stakeholders to share information with you to the extent some of these data may not be publicly available. But if you have a focused assessment or looking at a more comprehensive assessment of a chemical or group of chemicals, so stakeholders are always -- don't need to be asked; share the information with FDA, which is always a helpful way of moving the needle.

Let me circle back on another aspect of your testimony last month. You had noted that your three strategic priorities in your office include preventing food-borne illness through advancements in microbiological food safety, strengthening the oversight of food chemical

safety, and decreasing diet-related chronic disease through improved nutrition. Is there a rough allocation of resources that you are addressing each of these priorities in equal shares, or do you prioritize within those? But how does your office allocate its resources to achieve each of these priorities?

JJ: Yes, our appropriations pretty much give us those. We have certain dollars for -- interestingly, the microbiological space is the best resourced part of the Human Foods Program. We also get a line item appropriation for nutrition, which is a distant second. And then food chemical safety being a third, but it's pretty much -- the resources that are coming into the organization, there's some -- there's a little bit of play, but not too much -- are dictated by our appropriations. They don't necessarily line up with risk. I think that the Commissioner and I have been very clear that nutrition-related risks are by far the largest risks that this portfolio presents, and yet it is resourced at a fraction of what we are resourced for microbiological food safety. That is by design by the appropriators. We've been pretty clear that those risks deserve far more resources than we are provided every year. That being said, we have some really remarkable things going on in that space that are very exciting.

LLB: There is no doubt, Jim, that you've got an awful lot going on. You've been extraordinarily busy: There have been lots of webinars that FDA has sponsored, your recent congressional testimony, the discussion draft, the opportunity to comment on that. Given all that's going on, I want to make sure that I didn't ask a question you had hoped I would ask. Please feel free to address any such issue now, and also ask you what are the two or three key messages that you would like listeners to take away from this conversation?

JJ: I would like to talk a little bit about what this reorganization is attempting to do, so if you don't mind, I'll --

LLB: Sure.

JJ: A number of things we've worked to address in this reorganization. One is the consolidation of what I refer to as programmatic activities. Over years, a number of functions developed in what I would call -- I call -- the inspectorates. It was called the Office of Regulatory Affairs. They have renamed themselves -- I think appropriately -- the Office of Inspections and Investigations. What I would say were programmatic activities had grown up in the inspectorate. We have consolidated them into the program, the Human Foods Program. The laboratories that actually measure whether there is a contaminant or a microbe in a food have now moved into the program. That's fundamentally a programmatic activity. It fundamentally informs whether or not -- it informs our surveillance, it informs whether we're going to take enforcement action. Those laboratories are now in the Human Foods Program, which I think are going to generate a lot of opportunities, efficiencies, and ability to expand our surveillance.

We also -- our states relationship was managed out of the inspectorate. That I think had happened over time because much of the resources that FDA provides to states was directed toward states doing inspections on our behalf. The fact that that's how we chose to have the states spend that money, though, is fundamentally a programmatic choice. It's not an inspectorate choice. It's a programmatic choice. Now the states relationship, the state resourcing is now in the Human Foods Program. We've brought together what I consider to be programmatic activities into the program, and then, a number within what had been the sort of Food Safety and Applied Nutrition. Over time, we saw that similar activities were happening in multiple parts of the organization. They've now been consolidated in a more

rational -- that's going to happen in any large organization. Over time, duplication begins to occur. We've done a bunch of consolidation around that, which similarly I think will give us an opportunity to reap some efficiencies.

And then, one of the most interesting -- for me -- aspects of what we have done in this reorganization is that we have created an office called the Office of Surveillance Strategy and Risk Prioritization, which is going to develop our surveillance strategy -- new surveillance strategy, so it will be purposeful and not *ad hoc*. And that will inform risk prioritization. The risk prioritization will largely occur within our priority areas. As I said, appropriators decide what goes in each bucket, but how you spend the money in the bucket should be informed by risk. It'll help inform which chemicals to work on first. It will help inform what combination of microbe and food is where we should be putting the next dollar, where the next resources go. What problem do we need to be solving in the microbiological food safety space? And similarly, in nutrition, what aspect of nutrition has the potential to generate the greatest public health benefit? This risk prioritization office is going to help the rest of our program make smart choices about where to deploy our resources. And that actually, I think is one of the most innovative and interesting aspects of this organization. That's basically what we've achieved in this reorganization and we're attempting to achieve, and very exciting.

LLB: Given the fact that the reorg is actually like one week old now, right (as of October 1), everything you say, Jim, makes perfect sense and just seems to be a very smart realignment of functions to help inform the agency's identification of true risks. What does it mean in your view? What can industry, and the regulated community, and listeners of this program expect to see more of? More surveillance, more inspections? Is there anything that you can shed some light on in helping our listeners be prepared?

One thing I can suggest people do is read the documents that are available on your website, not just the report that we spoke of earlier, that kind of identified some of the deficiencies and inefficiencies that led to the reorganization. But how you have -- you and the FDA -- have responded to those deficiencies also kind of portend where your resources are going to be deployed and what that might mean for stakeholders in the food chemical community. Might there be more inspections? Or just smarter alignment of resources in a way that prioritizes true chemical risks? What can you tell us in that regard?

JJ: I think that the things that the stakeholder community -- whether you're in the public interest community, the industry -- and hopefully they've begun to see it, because I've been here for a year, and I have been actively working toward these ends, even before we reorganized --

LLB: Sure.

JJ: -- a higher level of transparency, and a greater degree of stakeholder engagement. Transparency can influence all kinds of things, but including -- I want to be clear about what are we doing? I'm a long believer in doing work plans internally. I think it's also important to be telling the stakeholder community, here are the things we are doing. Obviously, if it's not on the lists, it's something we're *not* going to be doing. Being clear about what our plan is so that people understand what we're doing so they can prepare for it. They can participate in how we -- in giving us feedback related to it. They're not wondering, is this guidance ever going to come out? Are they even working on it? A greater level of transparency about our program -- and that means really all elements of our program -- and a greater degree of stakeholder engagement earlier in processes.

I talk about this internally a lot, that everywhere I've ever worked, there's a general reluctance to get too much input at the beginning of a process because people think it slows you down. The reality is, it speeds you up. It may take you a little more time at the beginning, but it's going to save you a boatload of time at the back end. That is because you have a much better understanding of what's important to people, where they may have opportunities to be more ambitious, areas where it's going to be harder to be more ambitious, areas they care about, areas they *don't* care about. You end up developing approaches by getting this feedback early that have a higher likelihood of succeeding, so you don't find yourself going back to the drawing board later in the process. With more stakeholder engagement early in the design phase, if we're thinking about approaching an issue, whether it be approaching it through guidance, or regulation, education- -- whatever tool we're thinking of using -- getting input across the board, all stakeholders, our state colleagues, industry, public interest community -- early in the process. You will ultimately end up delivering something that's more durable; it lasts longer. I'm not interested in putting something out on the street that then has to be redone two years later because there was no capacity to actually do it, there was no support for doing it, and you ultimately go back to the drawing board. I want things that that are durable, that achieve our objectives over time. That earlier involvement is something that I think that the stakeholder community can and *should* expect from us.

LLB: You are a man of your word, Jim. You have -- in my mind -- done an extraordinary job of communicating publicly. How many webinars have you participated in for your office over the past several months? Three? Four?

JJ: We have a whole stakeholder engagement team. The number of stakeholder engagements, whether they be webinars or otherwise, is in the hundreds.

LLB: Yes. No, but it's robust. That's one of the reasons I was interested in having this podcast, because I think members of the more traditional TSCA-FIFRA community need to appreciate the growing interest of chemicals in food and your extraordinary experience in identifying what priorities should be and how to build programs around prioritization, risk evaluation, risk management. And your commitment to transparency is all over these documents. The discussion paper is very well written. Your testimony on Capitol Hill was very clear. The all-day meeting that convened recently to talk about your interest in postmarket chemical review was very well received. There's a lot going on in this space.

Part of my goal is just to make sure that stakeholders in the more traditional industrial and pesticide communities appreciate that all this activity is going on *at FDA*. Some of these emerging programs are wonderful opportunities to participate, help guide the development of the program, and ensure that everyone's interests are fully reflected, and the resources that you *do* get from Congress are being deployed in a way that makes the most sense. I for one, Jim, appreciate your commitment to transparency and really, really acknowledge the hard work and extraordinary evolution of these programs in the very short time that you've been over at FDA.

JJ: Thanks, Lynn. I appreciate that.

LLB: I think I've already said where can listeners get more information? There's a ton of information on the FDA website pertinent to these activities, and I really, really urge listeners to comment. Yes, they've got plenty of time to do so, although there is a heck of a lot going on. But I think the comment period ends December 6 on the discussion paper that you and your colleagues prepared, and I think that would be a really good thing to take a

peek at. I'll put some of these documents when we post this podcast. I'll note your testimony, the discussion draft, and just remind people to comment and help build this program.

JJ: Very good. Thank you.

LLB: Jim, I've taken a lot of your time. Really enjoyed the conversation. Thank you for all that you're doing, and very much appreciate the time you spent with us today.

JJ: It's good talking to you, Lynn.

LLB: I hope you have enjoyed my conversation with Deputy Commissioner Jim Jones about all the consequential activities his office is pursuing. We can expect much more in the days ahead. Don't forget to comment on the postmarket review process. Comments are due December 6, 2024.

All Things Chemical is produced by Jackson Bierfeldt of Bierfeldt Audio LLC.