

Nancy Myers: Good afternoon. My name is Nancy Myers, a proud Alliance board member, and a former FDA-er. I am fortunate to be co-moderating this webinar with Rachel Sher, who is a new addition to the Alliance board and also former FDA staffer.

I am the CEO and Founder of Catalyst Healthcare Consulting, an FDA regulatory policy and strategy firm, a co-founder of the Alliance, and former Chair of the FDA Alumni Association. While at FDA, I worked in the Office of the Commissioner and served as Senior Policy Counsel and then as a Senior Strategic Advisor, serving the Acting Deputy Commissioner for Operations (aka JW).

My colleague, Rachel Sher is a partner in Manatt Health. Previously, she worked for the National Organization of Rare Diseases and the Association for Accessible Medicines (AAM) as well as the House Energy and Commerce Committee. While at FDA, she was a Senior Policy Analyst in the Office of the Commissioner.

Rachel and I would like to take a second and welcome our Alliance members, the media, and Alliance guests to our webinar with Associate Commissioner for Regulatory Affairs, Dr. Judith A. McMeekin. We have a great turn out today.

First, a quick word about the Alliance for a Stronger FDA. We are a multi-stakeholder coalition that advocates for increased appropriated resources for the FDA and have been an important force in the doubling of the FDA's budget authority funding from \$1.6 billion to \$3.3 billion.

Our mission also includes educating policymakers, the American people, and the media about the FDA's growing mission and responsibilities. We are the only advocacy organization focused on resources for all that FDA regulates-- including food safety and medical products.

Our members include consumer and patient groups, research advocates, health professional societies, trade groups and industry. We have about 150 members but as a shameless plug -- we would welcome any new members to further strengthen our advocacy and educational efforts.

For this webinar, Dr. McMeekin has agreed to conduct a "self-interview" and then respond to questions submitted by the Alliance,

to be followed by ample time for moderator and audience questions. You may submit such questions by clicking the Q&A button at the bottom of your screen, not the chat box.

And now before introducing Dr. McMeekin, we would like to thank ACRA's Communications Director, Sarah Clark-Lynn, who has collaborated closely with us in preparing this webinar.

It's my privilege and honor to introduce Dr. Judith A. McMeekin, Associate Commissioner for Regulatory Affairs within the FDA's Office of Regulatory Affairs. She oversees more than 5,000 FDA employees who have responsibility for FDA's field activities. ORA supports the FDA's product centers with responsibilities that encompass inspections and investigations (including criminal investigations), compliance, and enforcement, import operations, regulatory science and field laboratory operations.

The office works closely with global, federal, state, local, tribal, and territorial partners and administers contracts, grants, and cooperative agreements to advance an integrated system and ensure an effective public health safety net. Prior to becoming Associate Commissioner for Regulatory Affairs, Dr. McMeekin served as the Deputy Associate Commissioner, acting Director of ORA's Office of Strategic Planning and Operational Policy and as the Director of the Division of Operational Policy.

Dr. McMeekin began her FDA career in the Center for Drug Evaluation and Research in the office of compliance, eventually serving as the Director of the Division of Prescription Drugs. Before joining FDA, she worked for the United States Pharmacopeia and several health systems as a clinical pharmacist. Dr. McMeekin received her Bachelor of Science Degree in Pharmacy and her Doctor of Pharmacy Degree from Northeastern University in Boston.

Dr. McMeekin, thank you so much for all the service indicated above and for agreeing to "interview yourself" and share your thoughts with our membership today.

Dr. McMeekin: Great. Well, thank you, Nancy, very much, and I want to thank the Alliance for a Stronger FDA for inviting me to speak. I'm happy to have this opportunity to highlight ORA's work.

We all have a common goal, which is to ensure patients and consumers have access to quality medical products and our food supply is safe, and the Office of Regulatory Affairs, or ORA, plays a critical role in this goal.

ORA has a staff of roughly 5,000 employees, which is nearly one-third of FDA's workforce. We have an annual budget of \$1.2 billion. We are the lead office for regulatory field activity, the boots on the ground, as I like to say, serving on the front line to ensure products are safe and of a high quality.

I'm often asked, what does ORA do? And I'd like to give you a little bit of a preview, as we have a wide array of professionals dedicated to public service.

Our investigators conduct inspections globally for all commodities that FDA regulates, whether they are based in-country or our investigators travel from the U.S. to conduct inspections around the world. We can have investigators on any given day in China, in India for a drug inspection, or in Germany for a device inspection, in Australia for a biologics inspection. They could be at a produce farm in California, ensuring they are adhering to produce safety regulations. They could be at a tobacco facility in Virginia because they want to bring a new product to market, reviewing vaccine clinical trial data at a hospital in Maryland, and so on.

We have a robust multi-pronged oversight program to help ensure the foods we eat and the medical products that we use every day are safe and of high quality. So, any given day, we also could have laboratorians in one of our 13 accredited laboratories testing product samples for hidden drug ingredients or conducting an analysis on a cosmetic. We could have consumer complaint coordinators following up on an adverse event, where patients may have been injured, or a criminal investigator making an arrest at a city because this persona allegedly violated the Food, Drug, and Cosmetic Act. We have import investigators at all nine international mail facilities, screening packages containing FDA-regulated products being offered for import. We have investigators across various aligned program commodities who are reviewing records that a facility may have submitted following our request. And we have investigators reviewing inspection reports from our international regulatory counterparts that have been deemed capable, following their

inspection in a third country.

I thought it would be important for you to understand or for me to describe the three different types of inspections that we conduct. One is for-cause inspections, and these are triggered at any time when there is a reason to believe that a facility has a serious manufacturing problem, or to investigate a specific problem or product complaint that has come to FDA's attention.

Another type of inspections would be grouped to the pre-approval, pre-market, or pre-license inspections that are conducted when necessary as part of the review of an application to market a new product. And generally, approximately 20% of applications require an inspection before a product can be approved. This is often because the facility has already had an established inspectional history and has been found to have acceptable compliance during those previous inspections.

And then lastly, our surveillance inspections of regulated facilities. These are used to monitor ongoing compliance with current good manufacturing practice and other requirements of the federal Food, Drug, and Cosmetic Act.

The vast number of surveillance inspections result in a classification of "no action indicated," which means no objectionable conditions or practices were found during the inspection, or "voluntary action is indicated," which means objectionable conditions or practices were found, but the agency is not prepared to take any or recommend any administrative or regulatory actions, versus the third type, which could be an official action indicated, which means that regulatory and/or administrative actions will be recommended.

Companies have a responsibility to ensure the quality of their products, and most companies comply with FDA requirements and follow the law. We base our surveillance inspections on risk to better use our resources to protect public health.

If a manufacturer previously had a classification of OAI, or official action indicated, we would rank that facility higher on our priority list to conduct a surveillance inspection. We also would be less likely in that situation to use an alternative tool, such as a remote regulatory assessment or records request to evaluate that facility. We would likely go inspect.

We have continued to conduct domestic and foreign inspections throughout the pandemic, traveling to 30 countries over the past two years, effectively implementing a risk-based approach to inspection.

Through our inspections, coupled with our alternative tools, we've maintained oversight of our regulated industry throughout this unprecedented pandemic.

When I last spoke to the Alliance members last July, we had recently issued a resiliency roadmap for an FDA inspectional oversight. We provided an update to that report in November with information on the state of FDA inspectional oversight and plans to address postponed inspectional work using a risk-based approach. I'm happy to say that by the end of FY21, we exceeded our goals for completing domestic surveillance inspections as outlined in the resiliency roadmap, completing more than twice as many domestic surveillance oversight activities than we had predicted earlier in the year.

We also were able to make significant progress on the postponed application-based inspections by the end of FY21, where travel was safe and the product was deemed mission critical.

For those that remain postponed, we are working to inspect these facilities based on the public health need and user fee commitments.

We also exceeded our goal related to following up on previous inspections that were classified as official action indicated.

At the beginning of the pandemic, we developed new oversight approaches and expanded use of a variety of surveillance tools which significantly contributed to our ability to exceed these goals. It also enabled us to provide oversight to as many facilities as possible, where utilizing our resources to ensure safety of the foods we eat and the medical products we use every day.

In addition to executing our mission through our workforce, we also work with federal, state, local, tribal, territorial, and foreign regulatory and public health partners to further the agency's mission. We manage a large portfolio of contracts and cooperative agreements with the statement for credentialed state regulatory partners, and help conduct domestic human and animal food

inspections, some device inspections, including nomography and quality surveillance, and tobacco compliance checks.

In fact, the states conduct 80% of the animal food inspections through these contracts and agreements, which allows us to prioritize resources for other priorities, high risk or mission critical work.

A mutual recognition agreement with the EU member states and the UK allow us to rely on information from drug inspections conducted within their borders and has proven extremely valuable during the pandemic and our oversight of foreign firms. And in September 2021, our mutual recognition agreement with the UK was expanded to officially bring veterinary medicine under the umbrella, so this has been very beneficial.

I'll provide more insight into ORA's roles in a few minutes, but I first wanted to highlight how ORA works with each of the FDA Centers. I have the unique vantage point across the agency that really helps me see the need for an enterprise- or FDA-wide approach. It is important that regulated industry sees FDA as applying consistent regulatory approaches to our oversight, and we are cognizant that they see us as one FDA and not the individual Centers that comprise the agency.

I routinely work with my Center director counterparts. We collaborate regularly, meeting one-on-one and as a group, and we collaborate on agency-level decisions. Our ultimate priority is to promote and protect public health as one FDA. In fact, last August, we set up the agency-wide decision-making body, the FDA Inspectional Affairs Council, or FIAC, and this focuses on optimizing inspections as part of the agency's regulatory oversight.

The Council is comprised of top leadership from each Center and ORA, and provides insight on strategies, policies, and initiatives, such as the use of new technology that might have significant influence or impact on the inspection process.

Ultimately, our goal is to ensure the optimal agency response for navigating the regulatory landscape for the years ahead. I believe it is critical the agency keep an enterprise inspectional approach to our inspectional work. We need to think as the industry re-regulates, as there are companies or facilities that produce more than one

commodity. So, consistency and open communication is critical with industry.

This multi-year effort to further modernize inspections, along with the agency's efforts to transform our data enterprise platforms and cross-program interoperability infrastructure – and I'll touch on that briefly in a few minutes – but this will better support modernization and optimization of our regulatory oversight.

In regard to budget, ORA's FY23 budget request is about \$1.36 billion, which is broken down by 91% of that being budget authority (BA) and about 9% being user fee funded. One of the key areas in our FY23 budget request focuses on our need to optimize inspectional activities and enhance our inspectional capacity across the enterprise, which is the focus of the FDA Inspectional Affairs Council.

We requested funds to increase support for the recruitment and training for new investigators to improve the efficiency of the agency's human and animal food and medical product inspectional operations.

With additional personnel, as well as expanding the use of new and existing inspectional tools, the agency will enhance its inspectional capacity and build on the efforts to keep pace with rapidly expanding industry, including medical countermeasures and advanced manufacturing.

The agency also has requested additional funding to further investments in data modernization and enhanced technology. The agency has begun a multi-year modernization effort to further transform our data enterprise platform and cross-program interoperability infrastructure to better support innovation related to our regulatory oversight role.

This is critically important to ORA's operation and our work to protect public health.

As we look at ways to optimize our inspectional approaches, it's crucial that we have IT systems that talk to one another, especially those that impact the inspection process. In ORA, we are working to optimize our business systems to better align with the agency's modernization effort, which will hopefully gain operational

efficiencies, address technology constraints, meet customer experience expectations, and support adoption and integration with other systems based on the newer technology platforms.

However, it is critical that while we maintain legacy systems, we also develop new systems with enterprise-wide systems with an enterprise-level vision, and that is exactly what we are doing as an agency. ORA received funds in FY22 to help address the opioid crisis and the rise in volume of fraudulent and counterfeit COVID-19 related medical products. We are utilizing those funds to streamline and gain efficiencies in newer technologies to enable our import investigators to better detect and destroy unapproved fraudulent drugs. This also includes fraudulent and counterfeit medical devices, including COVID-19 kits and personal protective equipment.

Over the last several years, we have seen the rise of e-commerce mail, and the pandemic caused a rise in medical product commercial shipment. Additionally, we've been able to establish a mobile laboratory at the Chicago International Mail Facility to provide sample analysis on site. This increased efficiency by having labs and analytical chemists next to our import investigators to help make decisions to hold or not hold potentially hazardous non-approved drugs faster.

As our mobile laboratory program matures, additional resources will be required to meet the increased volume and complexity of the samples.

Additional resources also are needed to manage and support new or existing and political tools deployed for field use, and develop new analytical methods or strategies to meet accreditation and proficiency requirements and to expand the safety program for the geographically diverse locations.

We also have initiated a national opioids operation with U.S. Customs and Border Protection at all nine international mail facilities, at the courier hubs and some ports of entry. This has expanded our efforts to increase interdiction work aimed at stopping the illegal flow of counterfeit and unapproved prescription drugs, which in numerous cases includes opioids, and has led to increased destruction of illicit and unapproved opioids and other unapproved drugs before these products are accessible to Americans.



Also, in our efforts to address the opioid crisis, we are conducting added investigational assessments of compounders who are producing opioids. These expanded assessments have involved tracking and tracing supply chains along with production activity at the compounding facilities.

Additional resources are needed at the outsourcing facility as the outsourcing facility inventory has grown, and the product produced in supply chains have become more complex. These same resources could assist in label review to ensure the proper information is provided to patients and healthcare professionals and subject matter assistance at the international mail facilities on things like supply chain of bulk drug substances.

ORA's budget has not kept up with demands placed on it, which is why we asked for additional funding in FY23 to help bridge this gap. Our focus will remain on how to best use our resources to protect public health.

I mentioned the pandemic and our commitment to inspecting regulated entities over the last two-plus years. Our approach to ensuring the safety and quality of products we regulate remains risk-based and deliberate. At the onset of the pandemic, we quickly pivoted and sped up our work to enhance our use of alternative assessment tools to help ensure continued safety of our nation's food and medical products supply.

We focused on identifying mission-critical inspectional work and prioritized inspections and inspectional efforts, along with being innovative and agile to protect public health. Factors determining mission-critical inspections include the following: whether the product received breakthrough therapy or regenerative medicine advanced therapy designation; whether the product is used to treat a serious disease or medical condition and there is no substitute; whether the product requires follow-up due to recall, or there is evidence of serious adverse events or outbreaks of a food-borne illness; or whether the product is related to FDA's COVID-19 response relative to drug shortages.

And we will continue to use all available tools to oversee the safety and quality of FDA-regulated products.

Our enhanced inspectional toolkit also helps us balance the competing demands of domestic and foreign inspectional work that can be a challenge. As we all know, consumers and patients expect and deserve high-quality, FDA-regulated products no matter who makes them or where they are made. We are regulating products for the U.S. market that are developed and manufactured in a global, interconnected landscape, so we need to deploy our resources irrespective of borders to be successful in our oversight.

We need to be agile and nimble and constantly think of how we can optimize our inspectional efforts. To best protect public health, our priorities are focused on products that present the highest risk to patients and consumers. This ensures that we maximize our public health impact by allocating resources based on risk level.

So, on the drug side, we utilize a risk-based site selection model to determine where we should focus our inspectional resources for surveillance inspections. This helps us assess the risk of the facility and the products that they produce.

On the food side, we apply the full range of oversight tools to ensure that imported food is as safe as food produced domestically. Although the tools may differ in a foreign and domestic arena, they ultimately create a multi-layered safety net, strengthened by areas of overlap.

There is no doubt that inspections are critical to FDA oversight, but they are one part of a robust, multi-pronged approach to overseeing the safety and quality of FDA-regulated products. We are fully utilizing other authorities and mimicking those authorities as a voluntary assessment of facilities where we do not have the explicit authority.

So, it's no surprise that moving forward, we will continue to successfully leverage the use of alternative tools and approaches to conduct inspectional work. As we move through and address these challenges and prioritize resources to carry out and fulfill the inspections, we also are employing maximum flexibility in using alternative inspectional tools to support regulatory decisions, including approving drug applications whenever possible.

We also will continue to prioritize domestic and foreign inspections that we were unable to perform during the pandemic by using risk-

based approaches to help ensure the continued safety of our nation's food and medical product supply.

FDA considers many factors as we carry out this approach to identify the work most essential to FDA's public health mission. Criteria include the public health need for the product, the product's complexity, whether the inspection is intended to follow up on an inspection previously classified as official action indicated, and other factors.

The approach is complex but flexible, allowing for recalibration and a consideration of risk decisions in the face of changing global public health conditions and agency priorities.

FDA continues to adapt to the challenges imposed by the COVID-19 pandemic, including enduring travel restrictions in China and other areas, and we are working as closely as possible to get back to a more normal state of conducting inspections.

I would like to highlight one key tool that we fully utilized during the pandemic, and that was our mutual recognition agreement that I mentioned earlier. Having these agreements in place gave us a reliable means for ensuring patient safety and drug manufacturing quality when travel restrictions and COVID outbreaks made it unfeasible or impractical to be conducting on-site evaluations.

This allows us to shift our precious inspectional resources to yield greater efficiencies for U.S. and foreign regulatory systems by avoiding duplication of inspections, and it enables re-allocation of resources toward inspection of drug manufacturing facilities with potentially higher public health risk across the globe.

At the beginning of the pandemic, we capitalized on a previously under-utilized existing provision in the mutual recognition agreement to leverage third country inspections, which is conducted outside the territory of either party. Most importantly, we can use information from third country inspections to support new drug application approvals and to prevent drug shortages.

As the pandemic continued, we expanded the use of third country inspection capability assessments and incorporated them into our annual work plan, allowing us to simultaneously provide regulatory oversight and to defer some surveillance inspections in high-risk

geographic areas where travel remained unsafe or severely restricted.

In addition to supporting new drug approvals and preventing drug shortages, third country capability provided surveillance continuity and visibility across geographic areas, better assurance for continuity of the drug supply, robust inspections focused on critical assessments of high-risk operations with extensive reports written in English describing inspection scope, coverage, significance of the findings, and corrective and preventive actions, which informed us and expedited our decision making on certain applications. And a good size inventory of existing reports of on-site GMP surveillance inspections that we could leverage, which included sterile and non-sterile finished dosage forms, APIs, and laboratory inspections.

Having reports written in English saves us considerable resources in time since there was no need to wait for completion of resource-intensive translation.

There are some minor challenges as well. In many cases, the third country inspections of sites we were interested in averaged 18 months in age. Not all EU authorities conduct foreign inspections – to date, 22 of the 28 partners have third country inspection reports available, mainly because some authorities do not perform inspections outside their own borders or territories for human or vet medicine, and some reports were redacted, pertaining to details regarding product information pertinent to our assessment.

The good news is that we quickly realized that third country reports were equivalent to in-country reports and yielded the same level of assurance we needed for making sound classifications and application approval decisions.

This has been a very positive experience that we continue to pursue, expansion of the existing MRA to include vet medicine and third country explicitly.

So, I have provided a lot of information, and you see the critical works that ORA does, the unique view and seat that I have at the table at the agency, and the importance of collaboration in our work and in our mission to protect and promote public health. I am extremely fortunate to lead an incredible workforce that is resilient and passionate about the work they do in protecting the American

public.

So, I'd like to provide some opportunity for the Alliance to ask some questions. So, Nancy and Rachel, back to you.

Rachel Sher:

Great. Well, thank you so much, Dr. McMeekin. That was incredibly informative, and I'm just always struck by the breadth and scope of ORA's responsibilities. It's really quite amazing.

As Elisa just wrote in the chat, we seem to be having some epic WiFi/internet challenges today. Very bad timing, but hopefully it's working right now. Not to worry because we have others on the call who are ready to step in if I again get kicked off or if Nancy gets kicked off. So, apologies in advance if that happens. We will be talking to Verizon after this call.

And I also wanted to just remind people to use the Q&A function as we go through. We're going to start off with a few moderator questions, and we'll be checking out the Q&A box for when they come in for additional or different questions. So, thank you for everyone being here, and let me just start off with the first one.

Dr. McMeekin, I think your remarks were so compelling, again, for all of the details that you covered with the very wide range of responsibilities that ORA has. For you personally, what is the most demanding part of your job? I'm sure there are many, but what prepared you to take on this role?

Dr. McMeekin:

That is a great question, and you know, I think the most demanding part of my job is really just the variety of work and depth of work that we actually have. I mean, we hit every commodity that FDA regulates, and so it is a challenge just to be able to see that wide variety or that lens that we actually have.

So, I would say that's one of the fascinating aspects of my job, too. I started my position as ACRA at the onset of the pandemic, so the timing was quite the challenge. But perseverance, resiliency, and being creative has been a benefit. And I have a wonderful group of leaders, managers, supervisors, and workforce that are dedicated to serving the public.

As far as what prepared me to take on this role, I would say my career experience. Starting as a pharmacist, working in hospitals as

part of the patient care team, and really tapping into the variety of skill sets that people bring to a team. So, also strengthening and leveraging relationships. Being a good listener, being curious and asking questions, and using data to make decisions. Being a collaborative leader, putting patient and consumer health and needs first, was extremely helpful, I would say, to preparing me to lead ORA.

Rachel Sher: Great. Thanks for that. Nancy was going to take the next question if she is on.

Nancy Myers: I'm here.

Rachel Sher Myers: Okay.

Nancy Myers: So, you're just not going to see me. I'm going to act like Charlie in Charlie's Angels, where you never see my face. So, I love the "variety is the spice of life" answer.

So, one of the questions we had was: how does a new Commissioner impact ORA's priorities? Clearly, Dr. Woodcock was Acting Commissioner for a year, and now we have Dr. Califf coming in and taking over the reins. Have things shifted at all, and also how has the current global political dynamic affected what ORA is doing?

Dr. McMeekin: You know, I get asked this question a lot with a new Commissioner coming in, and I've had several Commissioners during my reign over the last two and a half years, and when I was a deputy. And you know, our mission, FDA's mission remains the same – to protect and promote public health. And so, some priorities may shift, depending upon the Commissioner. I've already met with the Commissioner on numerous occasions, and our priorities of really modernizing the inspectional process remain and will be consistently applied.

Nancy Myers: So, do you have any – I have heard people being interested in how FDA is going to deal with some of the – not only COVID as a global challenge with supply chain and all that, but also with some of the issues of the war in Ukraine and how those political ramifications will complicate what FDA does. Do you have any insights there?

Dr. McMeekin: You know, again, throughout the pandemic, we have had to be very versatile, agile, nimble, and have had to adjust accordingly, and

we'll do the same with the impacts of what is going on in Ukraine. I know we've had to look at clinical studies that have gone on. But we will continue to be flexible and attentive.

Nancy Myers: Great. Rachel?

Rachel Sher: Yes. You touched on this, Dr. McMeekin, in your initial remarks; basically, the uniqueness of ORA within the FDA as a whole in terms of really working across all product Centers at the agency. There's no one outside FDA who really does that. In achieving that work, who are ORA's partners, both sort of within FDA and then across the government, and even state agencies and the private sector?

And sort of teeing off of that, how do you coordinate even with global bodies to do the important work that ORA does?

Dr. McMeekin: Rachel, that's a great question, and because we touch every commodity, we have many stakeholders, including our counterparts in the FDA Centers. But I'll give you a couple examples. For instance, within our imported products, we sit on the Border Interagency Executive Council that was established by Executive Order to support completion and government-wide utilization of the international trade data system.

So, we, along with 40 other participating government agencies, work to really support a single window concept for the import and export of cargo.

For food, we partner with states to conduct inspections. They're critical partners in conducting inspections within their state. And other organization, such as the National Association of State Departments of Agriculture, or NASDA, and the Association of Food and Drug Officials, or AFDO, as well as organizations like the Consumer Brands Association. So, we work closely with them on the foods front.

We also have a domestic mutual reliance partnership between the FDA and the states with comparable regulatory public health systems that I had mentioned. As trusted partners that we rely on through these mutual reliance or mutual recognition agreements, we really leverage one another's work, the data, and the actions to really meet the public health goal of safe national food supplies.

The goal is to really improve industry compliance and avoid duplication of effort to really drive efficiencies and prevent or reduce human and animal food-borne outbreaks.

We also collaborate with the Centers for Disease Control and Prevention on outbreaks in foods and medical products, as well as other federal partnerships, like the U.S. Department of Agriculture.

I mentioned on the import side having some real-time interactions with U.S. Custom and Border Protection at ports of entry. In terms of international partners, we work with many of our foreign regulatory counterparts, and we have similar regulatory foreign counterparts under the Single Audit program for medical devices and systems recognition for food.

In addition, regulated industry is a critical stakeholder. They have the responsibility to ensure that they're adhering to GMP regulations and statutory regulations.

Nancy Myers: That's really helpful. So, just to build a little on that question, how does ORA get really involved in standardization and international harmonization of standards? Because I think that's one of the areas where when you're looking at inspections and kind of standardizing what you're expecting to see, how do you guys engage there?

Dr. McMeekin: So, international harmonization. Nancy, thank you for the question. It's extremely important, especially for regulated industry and for countries who share inspectional information so that we're all inspecting with the same approach.

And one example on the drug angle is our active collaboration with the Pharmaceutical Inspection Co-operation Scheme, or PIC/S. It's a worldwide membership of 54 participating medicines authorities which includes more than 2,000 inspectors. And so what we do is we work proactively with this group to identify where can we rely upon the work that each other does despite differences in laws and systems, and to use each other's work to make regulatory decisions and share the inspectional intelligence.

And these inspections or these interactions, actually, have resulted in many coalitions and productive tools and aid memoirs that have helped us work across the globe to preserve our respective finite



inspectional resources and to achieve efficiencies of scale in our regulatory approaches. So, in our global marketplace, this is extremely important and necessary for drug manufacturers to have one set of high standards.

ORA also supports bilateral information sharing with our foreign counterparts to gain a more universal understanding of activities and regulatory oversight.

Nancy Myers: Wow. That's a lot. But let me ask you just a couple –

Dr. McMeekin: I know.

Nancy Myers: Let me just ask you a couple of questions from the audience that have to do with foreign inspections. So, I have a couple here that the gist of them is: what is the status for the foreign inspections? You've talked about this study that you did, or how you guys laid out what the plan moving forward was, and that you were meeting and exceeding your domestic inspections. When do you think foreign inspections will be there, and when will FDA have boots on the ground internationally?

Dr. McMeekin: So, we have remained to have boots on the ground internationally. We continue to conduct foreign mission critical inspections. We never stop conducting foreign mission critical inspections. And we have expanded our foreign inspections to include certain prioritized inspections in all commodities, and this includes pre-approval inspections and compliance follow-up inspections that did not meet the criteria of mission critical.

So, while we initially were going and doing mission critical inspections, that left a pile or a subset of inspections that were not mission critical, and we have started to prioritize those non-mission critical inspections in the foreign front.

We were actively planning certain prioritized foreign inspections to resume in February '22, but announced a temporary pause in those activities in December 2021 because of the spread of the highly contagious COVID-19 Omicron variant. So, we had to refocus. But now with the COVID-19 cases hopefully in a state of decline, FDA is able to adjust, and actually we've been able to resume conducting domestic surveillance inspections across all commodities, proceed with certain previously planned foreign surveillance inspections,

and we're working towards conducting additional prioritized foreign inspections. But that's where we are currently.

Nancy Myers: Great. And do you have any date or goal when you think you'll be totally caught up? I know nobody has a crystal ball, and we could have another variant come in, and I know there's so many things. But are you hoping by the end of the year to be back totally on track in foreign inspections, or do you think it's gonna take longer than that?

Dr. McMeekin: So, what we're doing with as far as – we will use all of the tools available that are capable for us to do, and I think one thing that we've learned through the pandemic is in addition to on-site inspections, we have tools that we have used and will continue to use to make sure that we meet those demands.

And then again, remember, I said that our surveillance inspections, we are prioritizing from a risk-based approach. We work with our Center colleagues to be able to decide what are the highest risk surveillance inspections that we need to get to, and those will be prioritized.

Nancy Myers: Got it. And this – I promise, this is my last inspection question until we get more – has FDA returned to performing unannounced surveillance inspections, like not for cause ones, of medical product facilities in the U.S.?

Dr. McMeekin: So, throughout the pandemic, we have been announcing domestically our inspections. And remember, we're still in a pandemic, and so we do announce that for a reason, for safety issues, so that we call in advance to make sure that there are no outbreaks at that facility and/or if there are any safety protocols, so that will continue to remain as we are in the pandemic.

Nancy Myers: Okay. Rachel, over to you.

Rachel Sher: Okay, I'm going to touch on one more question from the audience that is having to do with your food safety work, and specifically: how do the public health laboratories help assist ORA in all of the food safety work that you do? We have representation on the call from the public health labs here, so very relevant.

Dr. McMeekin: So, especially throughout any outbreaks, we have allowed flexible

funding to the area where we actually work with our state labs that are funded to be able to help move towards meeting our goals of conducting analysis. So, that's a program that we are continuing to strengthen.

Rachel Sher: Great. Go ahead, Nancy.

Nancy Myers: So, we also had a question. You mentioned in your self-interview that there is a lot of use of modernized technology in your IT systems and areas, different areas. How dependent is ORA on legacy hardware and software, and what are some of the issues that creates? And then following on, how can the IT and analytical capacity be improved to import screening systems, such as the system for entry review and import operations?

Dr. McMeekin: Sure. So, unfortunately, we are dependent on legacy systems. We are looking forward to Congress supporting FDA's request to support data modernization as it's critical to our mission. And while we need to maintain legacy systems for continuity of operations, we really need to develop new systems with that enterprise-wide system or enterprise-level vision. And that's what we're doing as an agency through our data modernization efforts that I spoke about earlier.

And I think you had mentioned something on the import screening, and what we're doing there is we're actually putting our toe in the water on artificial intelligence and machine learning and looking to see how we can use some of that import data to help streamline that information or those products offered for import.

Nancy Myers: Great.

Rachel Sher: A couple more questions here. So, how is it that people can follow exactly what it is that ORA is doing? Is there a strategic plan that we want to refer people to follow? And are there efforts afoot to make sure that ORA is sort of more transparent about all of the activities? I mean, sort of how does that links up with the resource needs and all of that?

Dr. McMeekin: Sure. It's a great question, Rachel, and ORA has a Twitter feed [@FDA\\_ORA](#). FDA has various news channels ([@US\\_FDA](#) and [www.fda.gov/news-events/fda-newsroom](http://www.fda.gov/news-events/fda-newsroom)) and documents like the resiliency roadmap (found on [FDA Efforts to Ensure Product Safety | FDA](#)), where we're trying to be extremely transparent with what

we are doing from an inspectional front.

Rachel Sher: Great. And we can maybe circulate some of that information to the attendees after the webinar so that folks can follow that.

Dr. McMeekin: Okay. Yes – happy to do that.

Rachel Sher: Okay, great. Is ORA staffed at a level that allows you to fulfill all of the mandates that you have on you? I mean, you definitely touched on the resource requests and the resource needs, but what does it look like from a staffing perspective?

Dr. McMeekin: So, another good question, one that is close to my heart, as it can be challenging to really maintain staffing levels necessary to meet our annual work plans. Our goal is to ensure that we have a diverse, highly capable, performing and adaptable workforce. We do continue to leverage all of the available hiring authorities that we have to meet those vacancies, including direct hire authority. Hopefully that will get renewed. Veterans recruitment, Schedule A. We're prioritizing hiring investigators that are able to complete foreign drug inspections, including bilingual investigators.

We're also expanding the use of the Cures Act, hiring for scientific non-executive hirings. And while we're very grateful for the Cures Act hiring authority, it has created some challenges for ORA because Cures hiring authority is only for medical products. So, my investigators on the food side are not eligible to receive that, which lends to disparity among our staff within ORA. However, I know Dr. Woodcock has been working towards looking at different authorities.

Additionally, foreign travel for our inspectorate is rigorous, and really requires our workforce to endure long trips abroad, and are subject to restrictions that federal government employees are required to adhere to for travel status. I know I have traveled internationally for work, and these issues related to foreign travel do present retention challenges for the workforce who must travel to conduct inspections outside the U.S.

You know, so for each assignment, our foreign cadre staff conduct three-week-long inspections over consecutive weeks, sometimes traveling to multiple countries within the same trip. The staff may travel many hours in coach, and upgrades are typically covered by

the employee personally, so it's not like what happens in the corporate world outside of government.

So, in general, the foreign cadre are expected to conduct about 18 weeks of travel per year. So, those can be some of the challenges retaining staff.

Nancy Myers: So, Judy, one of the questions we also got, that I have to go back to the inspections again, kind of follows up on that conversation. What are the challenges for the inspectors in China specifically, and how do those challenges – are they the same or different than India? Are the challenges different country by country? And we've only got like two more minutes, so we've got to be quick – is your speaker on mute?

Dr. McMeekin: Yes, I'll try to be quick on this. You know, as different sovereign nations, the countries pose different challenges based upon the laws, structures, events, cultures, as well as the commodities that they produce. Inspectional approaches really need to be tailored to address these variances.

For example, initially with the Winter Olympics, travel was restricted in China. And right now, the challenge in China is travel restrictions due to the spread of COVID-19.

As you know, as requested by Congress, we recently initiated a foreign unannounced inspection pilot, and this really was hatched to initiate this in India and then expand it to China. But due to local lockdowns and travel restrictions in China, the inspections as part of the pilot are currently on hold.

In preparation for the pilot, we've worked to prepare and train our workforce to really implement the pilot consistently in India and to expand to China. I'm happy to announce that we have begun the short notice or unannounced inspections in India already.

But there are serious safety concerns in foreign countries that you need to be aware of, and the safety of our investigators is my top priority, in addition to protecting public health. A couple of examples. In India, if we conducted unannounced inspections of facilities in remote areas, in some cases we'll be likely forced to rely on local means of transportation or taxis that are generally less safe than when our investigators are in a major city and are able to use

safer and more reliable means of transportation.

And sometimes facilities can be in a special economic zone, and entry into these areas is not permitted unless escorted, and so conducting unannounced inspections on firms that are in these special economic zones really delay our investigators at the entry point of the zone until the firm is contacted, and then someone from the firm comes over to escort our investigators.

So, there's challenges in conducting the inspections, but something that we continue to deal with.

Nancy Myers: It's amazing, all the different components.

Dr. McMeekin: Yes.

Nancy Myers: But with that, I think, Rachel, we might – since right now it's 3:00, and so we are kind of at the end of our time. But we've gotten to most of the questions in the chat, in the Q&A, but hopefully we can just send you a couple if we get more.

Dr. McMeekin: Sure.

Nancy Myers: But Dr. McMeekin, thank you so much for taking the time. The Alliance really has made an effort in really reaching into the different parts of FDA and really understanding what the budgetary needs are, and ORA is really a very unique part of the FDA as an organization. So, we just appreciate you taking the time and talking to us because I think this helps us really understand the scope of your work, how many people are working very diligently through a complicated COVID world. And so thank you so much for your time and spending it with us.

Dr. McMeekin: Well, thank you, Nancy and Rachel, and ORA is the face of FDA to regulated industry, and my phenomenal workforce is passionate about the work they do and the difference they make in protecting consumers and patients and really enhancing public health by insuring timely access to safe, quality FDA-regulated products.

So, our workforce embodies FDA's mission, and I'm extremely proud of them. So, thank you for inviting me, and I look forward to continue discussions. So, thank you.

Nancy Myers: Great. Thank you very much.

Rachel Sher: Thank you.

Nancy Myers: Thank you for those who called in. Hopefully the video glitches are not so terrible, but we'll try to post some of the actual talking points and things like that. So, if you couldn't hear it or see it, you'll be able to read it. Thank you.

Dr. McMeekin: Thanks, all.

Rachel Sher Myers: Thank you.

**[End of audio]**

**Duration: 61 minutes**