Ron: Good morning everybody. I'm Ron Bartek, President of the Alliance for a Stronger FDA and I'm joined today by Steven Grossman, the Alliance's Executive Director and two former FDA Chiefs of Staff, who will be co-moderators.

The first is Tom Kraus who is currently Vice President for Government Affairs of the American Society of Health System Pharmacists.

The second is Susan Winckler who is CEO of the Reagan-Udall Foundation for the FDA. While Chief of Staff, Susan also served simultaneously as the head of the FDA's office of legislation, external relations, public affairs and the executive secretariat.

We'd also like to welcome Alliance members, the media and a number of guests to the Alliance's webinar with Associate Commissioner for Regulatory Affairs, Dr. Judith A. McMeekin.

First, a very quick word about the Alliance for a Stronger FDA. We are a multi-stakeholder coalition that advocates for increased appropriated resources for the FDA. We have been an important force in the doubling of the available annual budget authority resources from $1.6 billion to more than $3.2 billion. And we are the only advocacy organization focused on resources for both food safety and medical products, as well as all the other components of the FDA mission.

Our members include consumer and patient groups, research advocates, health professional societies, trade groups and industry. We have about 150 members and we'd welcome more to further strengthen our advocacy and educational efforts. In regard to admin and logistics for this webinar, Dr. McMeekin has agreed to respond to a dozen questions submitted by the Alliance, 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.

And now before introducing Dr. McMeekin, we would, as the Alliance, like to acknowledge the tremendous help we had in arranging this webinar from the ACRA Communications Director, Sarah Clark-Lynn.

I now have the privilege and honor of introducing Dr. Judith A. McMeekin, Associate Commissioner for Regulatory Affairs within

the FDA's Office of Regulatory Affairs. With the responsibility for over 5,000 staff and all the operations of the office which constitutes the FDA's field force, supporting the FDA's product centers via responsibilities that encompass inspections and investigations including criminal investigations, compliance, and enforcement, import operations, regulatory science and field laboratory operations.

The office also 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 speak with our membership today. The floor is yours. And you're muted Dr. McMeekin.

Dr. McMeekin: Okay.

Ron: There you go.

Dr. McMeekin: There we go. Let's start that over. Well, first of all, thank you, Ron, for inviting me to speak and for the Alliance for a Stronger FDA. I'm really excited to be here. I'm glad to have this opportunity. I believe it's the first time that an ACRA has actually spoken with this group or it's the first time in a long time. So, we all have a common goal which is really to make certain patients and consumers have access to quality medical products and our food supply is safe.

First. I'd like to explain a little bit about how ORA is organized

and how we're funded. So, I'm very proud to lead over 5,000 dedicated staff who work in over 230 offices in 49 states, the United States, Virgin Islands, Puerto Rico and foreign posts around the world. I've been in the ACRA role for about one and a half years, just as the pandemic started. So, it's been quite the experience.

The Office of Regulatory Affairs or ORA is FDA's lead office for regulatory field activity. So, we are the eyes and the ears of the FDA. We are the boots on the ground interacting with all of our regulated industry and stakeholders to provide access to quality food and medical products. ORA has investigators conducting inspections globally, domestic and foreign. We have 13 accredited laboratories that perform analysis of domestic and imported products to aid in the enforcement activities. We also cover ports of entry and have staff in nine international mail facilities.

In addition to executing its mission through its federal workforce, ORA also works with federal, state, local, territorial and foreign regulatory and public health counterparts. And this is to further the agency's mission. ORA manages a large portfolio of contracts and cooperative agreements with the state. They are our credentialed state regulatory partners. They help conduct domestic food inspections, a number of device inspections and tobacco retail compliance checks.

ORA's inspectional staff and laboratorians are aligned and specialized by commodity. So, when an investigator starts with ORA, they are aligned either in the drugs program, the devices program, biologic, clinical research, bioresearch monitoring or the human and animal foods. This structure really optimizes field investigations to deal with focused public health issues. And we do this with each of the centers being either CBER, CDER, CDRH, CFSAN, CTP or CVM.

ORA also, as was mentioned, we have an Office of Criminal Investigations that's associated with FDA regulated products. ORA's budget request is about $1.3 billion. 90 percent of our budget comes from budget authority while 10 percent comes from user fees. However, most of that budget authority is non-discretionary. So, many people know FDA and the Centers but I'm also often asked, "How do I relate to the center directors?" And if I am part of their decision-making process or if they're part of ORA's.

Well, I'm in a very unique situation. I have the advantage of a 20,000-foot level seat as ORA interacts with all of FDA's regulated commodities. So, this position really allows me to see the need for an enterprise or FDA-wide approach. As earlier noted, our investigators are the sharp end of the spear that directly interacts with regulated industry where they operate.

In this work, ORA represents the agency and I want to be clear that I fully understand regulated industry sees us as FDA, not as CDER, not as CBER, not as ORA. We are one FDA and so with our stakeholders simply seeing us as FDA, it is important that we be consistent in our operations across the programs in the work that we do. As such, I routinely meet with the Center Director and my Center Director counterparts.

We collaborate regularly. I meet with them one-on-one and also as a group. It's important that we collectively have relationships and have inclusive discussions about decision. As the ACRA, I am included with the center directors regarding some of the discussions about their organizational decisions and vice versa as appropriate. And we collaborate with agency level decisions also. Some of the things that I've discussed with them or where I've needed their input is talking about resuming prioritized inspection.

What does success look like that for us as an agency? What things do I need to take into consideration when they're subject matter experts join us on inspections? So, I include them in these discussions but I also needed to include our information technology leaders. What did we need for them and how could we work together to improve the work that we do? We've also had discussions about identifying vaccination distribution for our staff. What does that look like? How can we get vaccinations to our staff? How did we do that?

And then more recently, what does post-COVID workplace issues look like? So, we continue to have discussions about commonalities and strategies for protecting public health. Our combined ultimate priority is to promote and protect public health as one FDA. In fact, we will soon stand up an agency-wide decision-making body, it's called the FDA Inspectional Affairs Council. This is focused on optimizing inspections as part of the agency's regulatory oversight. This council consists of top leadership from each of the centers and ORA and will really

present and provide insight on strategies and initiatives.

What type of new technology can we use? How do we optimize our inspection process? And because inspections cross all the commodities, it's really important that we have these discussions on policy issues surrounding inspections as a cross agency, as an enterprise. So, that we can ensure optimal agency resources across the agency and really navigate the regulatory landscape for many years ahead.

So, over the past decade, FDA has expanded its global operations. I want to go through a little bit of the history and key elements that we're working to further develop. Our food and medical supply chains are obviously very global. For many years, we've worked to protect the safety of the supply chain in all of our regulated commodities in an increasingly global marketplace.

Some of you might actually be surprised to learn that our international inspection program began back in 1955. And this is with the inspection and certification of certain antibiotic manufacturers in Europe. And then over the past few decades, the program has increasingly expanded. In the mid 70s to late 70s, we conducted our first international medical device inspection and in '78 we conducted about 50 foreign inspections. By fiscal year 1993 our foreign drug inspections had increased to nearly 268.

It was in 2008 that FDA opened its first global office in Beijing. So, obviously our foreign inspection work really has increased as our authorities have changed. And two critical ones were one being in 2011 with the Food Safety Modernization Act and then another being in 2012 with the Food and Drug Administration Safety and Innovation Act or FDASIA. So, FDA has been really steadfast in identifying the need to expand its global offices and increasing our global presence.

We've also increased our partnerships with international regulators and also law enforcement partners. So, mutual recognition agreements or MRAs between FDA and foreign regulatory authorities really allow drug inspectors to rely upon information from drug inspections conducted within each other's borders. MRAs allow FDA to recognize drug inspections conducted by foreign regulatory authorities if FDA determined that those authorities are capable of conducting inspections that actually meet U.S. requirements.

And currently, we have 28 countries that we rely upon through this mutual recognition to help meet our public health need. The MRAs really yield greater efficiencies for not only for the U.S. but also for foreign regulatory systems by avoiding duplication of inspections. And it also enables allocation of resources towards inspection of drug manufacturing facilities with potentially higher public health risks across the globe.

Having the MRAs during COVID has been extremely helpful as non-mission critical travel was suspended in March of 2020. This information from the MRAs provides us with additional information regarding a facilities conformance with regulatory requirements, which has also been used to help inform our decisions on drug approvals and drug shortages. And it can also be used in lieu of an FDA inspection. In the human and animal foods program, the system's recognition agreements with several countries have really allowed FDA to greatly reduce the number of foreign inspections in these countries and target inspection resources to really countries of greater concern.

In addition to the transnational nature of the crimes being committed related to FDA regulated products, our Office of Criminal Investigations has expanded its presence overseas. And continues to seek optimal locations for additional OCI criminal investigators. Our Office of Criminal Investigations or OCI collaborates frequently with our foreign law enforcement partners. Targeting elicit FDA regulated product coming into the United States and also through our international mail facilities, express courier hubs and seaport.

So, I'd like to pivot a little bit now and talk about balancing between competing domestic and global demands. And it is challenging but my ultimate goal is to move the organization into working with the operating view that we are regulating products that are developed and manufactured in a global interconnected economy. And that we need to deploy our resources irrespective of the borders to be very successful.

We need to be agile and nimble and constantly thinking of how we can optimize our inspectional efforts. Throughout our inspection process, we really use a wide of oversight tools across the different segments of the international supply chain. In ways that are decreasing public health risks while maintaining a level playing

field for the domestic and foreign firms. It's important to know that we apply the same requirements to all regulated products, regardless of where they are made.

To best protect public health, our priorities are focused on products that present the highest risk to patients and consumers. We are able to maximize our public health impact by allocating resources based on risk level. On the drugs side, we utilize risk-based site selection models and these are used to determine where we should focus our inspectional resources for surveillance inspection. This helps us assess the risk of the facility and the products that they make.

On the food side, we do a very similar thing in the fact that we apply the full range of oversight tools to ensure that imported food is as safe as food produced domestically. So, although the tools may differ in the foreign and domestic arenas, they ultimately create a multi-layer safety net strengthened by areas of overlap.

So, let's talk a little bit about budgets. ORA has a few important long-term budget priorities. One priority is to increase our budget for medical products and medical product safety to better meet the need for oversight due to the advancements in areas such as stem cells, vaccines, medical counter measures. ORA is also working to enhance our workforce for biologics and devices, but we currently must rely on our budget authority.

It's critical that our compliance and enforcement tools and authorities keep pace with the increases in our biologics and device inventory as well as the medical product technology advances. So, stem cells, 3D printers, advanced manufacturing. We also need to be certain that we have the most skilled and well-trained workforce to keep up with the advanced technology. We are working to enhance our IT platform to more efficiently and effectively support our oversight work across all commodities.

Data is at the heart of FDA's work as a science-based agency, and we anticipate ongoing rapid increases in the amount and the complexity of the data that informs FDA's regulatory decision-making and public health mission. The amount and variety of data that FDA generates, and needs, and uses is rapidly increasing at exponential rates. However, the agency utilizes some antiquated methods including large volumes of PDF often by hand, in order to identify critical safety signals such as human and animal drug and device safety concerns or emerging foodborne outbreaks. And so

this is an area that we can improve in.

We recognize the need to provide a better foundation for developing a more fluid, agile and efficient FDA that is scaled to respond to novel technologies and a rapidly increasing workload. Therefore, our funding and FY22 has been requested to for data modernization and to help build an FDA wide platform. Again, looking at that balcony level and looking to see how things can be done as an enterprise. We are seeking new authorities around medical device and clinical research or biomedical monitoring inspections.

In those commodities. We currently have limited authority to request records and other information in advance of or in lieu of a physical facility inspection. For drug and biologic facilities, we have the authority to request records in advance of or in lieu of an inspection. And this has been proven to be very effective during the pandemic. The lack of this authority and other commodities has limited our ability to make broader use of remote regulatory assessments during the pandemic.

In regard to the new era of smarter food safety, without new resources for the new era of a smarter food safety, our ability to maintain the safeguards needed to help keep food safe will significantly lag behind. Sweeping changes are happening in the marketplace, potentially putting consumers at risk. The pandemic has definitely accelerated the need for enhanced traceability to better understand the supply chain vulnerabilities to explore the use of remote and virtual food assessments.

We have addressed safety vulnerabilities for foods increasingly ordered online. We have all ordered more food online and from takeouts during the pandemic. We are also supporting a strong food safety culture on farms and in facilities is important. As mentioned in our recent Resiliency Roadmap for FDA Inspectional Oversight, the FDA is ready to work with Congress on changes that would allow the agency to conduct inspections of human and animal food facilities.

For food in general, we are focused on a data driven, analytical approach to deploying resources. Ultimately, with this approach, the number of inspections of high-risk facilities could likely increase. The additional requested resources will also strengthen the animal food inspection system. Domestic mutual reliance is a

critical component of the new era of smarter food safety. As it strengthens partnerships with states to ensure optimal use of resources and maximizes the food safety reach.

Historically, the agency user fees and as I mentioned before, about 10 percent of our budget is user fee generated and these are user fees for PDUFA, GDUFA, BsUFA, MDUFA, ADUFA, and AGDUFA. They've all been targeted and prioritized to the centers for activities that are focused now on application reviews. ORA seeks to work with our stakeholders to increase our funding that supports the inspectional components of the programs. ORA is currently implementing time reporting to create the data that will help us illustrate how our work supporting access to new and long-standing products and how user fee spending should continue to facilitate this critical work on application and license approvals and supplements.

In regard to ORA's budget, keeping up with the demands that's placed on it. Unfortunately, our budget authority has been stagnant on the medical products side for the past several years. With technological advancements in medical products, this has created some challenges for us. It also prevents us from having the funds to modernize our IT infrastructure and other core functions that are necessary. We've received significant budget increases from Congress over the past five years. About 75 percent of our budget authority supports human and animal food safety.

The Human and Animal Food Safety Funding has increased by 21 percent since 2014. ORA does not have the flexibility to respond to medical product related activities. For example, without the COVID funding enacted by Congress, which we're very grateful for, ORA would have had to reprogram funding from foods to medical products to meet the needs with public health during this public health emergency. As I mentioned, our priority is to increase our budget for medical product safety.

So, what does this mean? ORA's biologic funding has been steady since 2014 without any increases. ORA's medical device funding has only increased 5 percent since 2014. Over the past five years, ORA did receive an increase for medical products about $35 million in support of the opioid epidemic in FY20. Which was a great effort and again, very grateful. In addition to medical products, we did receive critical funding to modernize the international mail facilities. And when I say modernize, I mean

make internet available to our staff that was in the IMF monitoring our import.

In addition to expanding, we received money to expand our laboratory capacity at these facilities along with being able to hire more staff to support the increase in imported FDA regulated products. So, the FY22 request that we have put in has $18.8 million set aside for inspection with 75 percent of that funding being medical product related. We also requested $10 million for opioids to increase our staffing at the courier hubs and ports of entry. This would allow us to conduct more comprehensive examination of packages at the IMFs and at these courier hubs that are suspected of containing drugs to determine if those drugs should be refused delivery to the U.S. consumer.

I'd like to touch now a little bit about hiring and recruitment and our staffing levels. First of all, ORA staffing levels are key to our success in carrying out our critical public health mission. ORA has identified areas where we would like to expand our staff in order to be able to keep up with the demands of industry. Especially in the device and biologics areas I've mentioned. Also, we would like to expand our foreign cadre. ORA will hire medical product investigators including investigators for pharmacy compounders and outsourcing facilities.

And in our FY22 budget request, it would also fund permanent scientist staffing at the international male facilities and this is to expand our examination of opioid shipments as well as unapproved foreign drugs or counterfeit drugs and health fraud related shipment. Developing a skilled workforce is also key to carrying out our public health mission. A few years ago, FDA's program alignment initiative, we transitioned our organizational structure from a geographic to a programmatic structure. Thus, our investigative staff now are specialized high commodity.

This has been a huge asset with the expansion and growth in complexity due to advances in food and medical product technology, the globalization of our supply chain, increasingly complex and diverse data sources and emerging scientific approaches. In ORA, we've placed a lot of emphasis on hiring, especially since 2020. ORA hired over 200 Consumer Safety Officers or Investigators in FY20 and we have the most overall hires of 290 so far in FY21 in comparison to other centers in the agency.

We also have the highest net gains of 92 full-time employees. I believe that our direct hire mechanisms to speed the hiring process, along with this year, we rolled out a student loan repayment program in FY20. We effectively targeted key positions for recruitment and retention bonuses as well as utilizing title 21 for key leadership positions. These have all contributed to improving recruitment and retention within ORA. Currently, ORAs attrition rate has decreased from 8 percent in FY18 to 4 percent which is slightly below the FDA average of 4.16 percent.

So, now let's transition a little bit to talk about program initiatives, data modernization and inspections. ORA's partners are also extremely critical to helping us carry out our public health mission. Our partners include federal, state, local, tribal, territorial, international and regulatory public health agencies. There are multiple vehicles that have been used to create or facilitate and advance these partnerships. And we utilize grants or cooperative agreements, contracts, partnership agreements, information, sharing agreements and memoranda of understanding.

It's through these collaborative relationships that we'd level each other's inspectional resources. We share training opportunities, we improve the exchange of data, information, enforcement strategies and enforcement actions. We are working to expand our partnerships to include industry trade associations, academia, non-traditional partners to increase our capability and capacity to protect the health of the American people. Our international regulatory partners collaborate in the oversight of FDA regulated products.

We facilitate regulatory collaboration by sharing public and non-public information with our international regulatory partners, consistent with the agency's various confidentiality commitments. We also conduct and coordinate audits and inspection notifications of our foreign regulatory counterparts. Additionally, we support internal and external partners to implement programs and initiatives to advance international mutual recognition for drug inspections and systems recognition as I mentioned before for our food inspections.

We also promote collaboration with our territorial regulatory and public health partners through facilitation of non-public information sharing consistent with formal information disclosure

agreements. As I mentioned earlier, modernizing our IT infrastructure is a top priority. We are in the process of updating and optimizing business systems to gain operational efficiencies. To address technology constraints, meet customer experience expectations and support adoption and integration with other systems based on newer technology platforms.

As IT receives funding piecemeal and frequently requires the development of enhancements to enable implementation of new regulation, ORA follows a very evolutionary path to modernization. We're really trying to embrace looking at our current IT systems to be able to see what can we support and then what do we need to really be able to work with other centers to be able to have that enterprise approach. That's why data modernization was really a major part of our recent budget request.

We have utilized funds over the past years to support our legacy import system and we're working on fixes to our platform recall system also. ORA is also working to improve IT and analytical capabilities to assist in import screening systems. We're strong partners with our U.S. Customs and Border Protection. We are working to align with CBP on the 21st century framework to examine how the two agencies can enhance on our targeting and screening. Also, along with FDA's Office of Food Policy and Response and the Center for Foods, we have conducted the first ever artificial intelligence or machine learning pilot to evaluate targeting capability at imports for seafood which will be completed in August.

Additionally, ORA is working with the U.S. Postal Service and Customs and Border Protection to develop additional methods of ingesting additional data to improve targeting of products before they're admitted into the U.S. market for sale. Lastly, I will highlight ORA's inspectional plans the coming months. On May 5th, 2021, FDA released the Resiliency Roadmap for FDA Inspectional Oversight. This is a report that outlines the agency's inspectional activities during COVID.

It details a plan and key priority areas to ensure a consistent state of operations that will enable the agency to provide the American public with timely access to safe, quality FDA regulated products. Throughout the pandemic, we continued to conduct domestic and foreign mission critical inspections and effectively implemented a risk-based approach to inspection. Going forward, we will

prioritize domestic and foreign inspections that we were unable to perform during the pandemic by using a risk-based approach to help ensure that the continued safety of our nation's food and medical supplies supply.

Just this past July 1st, we activated the base case scenario which is a gradual transition to standard operation that's detailed in the resiliency road map. What does this mean? So, it really means that we transitioned to standard operations for domestic inspections and other operational work. The FDA will continue to prioritize mission critical work. This transition will help us address inspections that were postponed earlier in the pandemic. ORA and our center colleagues collaborated by reviewing data, showing the pandemic impact on inspectional work and develop a prioritization scheme or approach for inspectional operations for all of our regulated commodities.

So, this was a moment in time where we met with our center colleagues to identify what's the prioritization approach and inspections considered mission critical will obviously remain the focus. So, we also have and will continue to successfully leverage the use of alternative tools and approaches that help us in addition to our onsite inspection. We've used alternative tools and approaches throughout the pandemic where inspections were or not currently feasible. And this includes remote interactive evaluations which are remote live streaming video of operations or teleconferences or screen-sharing. We also utilized record requests and leveraged information from our trusted regulatory partners.

We were able to review records and information requested from facilities in advance of or in lieu of certain drug and biological inspections to support regulatory decisions and actions that were authorized under 704(a)(4) of the Food, Drug and Cosmetic Act. Use of this authority has really supported application approval decisions. It's helped FDA identify areas of focus for future inspections. And it's also supported the placement of certain products on import alert based upon violations discovered during this process.

So, we are closely monitoring also travel advisories for foreign inspections, but we will continue conducting mission critical inspection. So, that was a lot to absorb. Hopefully, I have given you a bird's-eye view of ORA and the critical work we do, the unique view and seat that I have at the table at the agency and that

ORA has. And the importance of collaboration in our work and mission to protect and promote public health. As I said, at the beginning, I am extremely fortunate to lead an incredible workforce that is resilient, passionate about the work they do in protecting the American public and is our biggest asset.

So, I'm going to go ahead and turn it back over to Tom and Susan. So, thank you.

Susan: So, Judy, that was just great. You actually reminded me when I was at the agency one of my favorite things to do was to sit next to the ACRA because then I'd know exactly what was going on. And then I'll admit, I occasionally, if I saw whoever was serving as the ACRA come down the hallway with a look of concern on their face, I knew it was going to be a long evening. So, thanks for taking me back to that and reminding us of the significant scope.

We've got a number of questions here. So, I'm just going to go ahead and jump in with one and this one is speaking to that kind of knowing all that's happening. It's because you have a field force in so many different places. So, let's ask a pandemic specific question. For most of FDA, the work-life impact of COVID-19 was shifting from going into the office to working from home but for the field force, did they have that opportunity? I mean, did your team on a day-to-day basis shift from boots on the ground to boots at a desk? What happened to those boots?

Dr. McMeekin: Well, the boots remained on the ground and some remained at it – were transitioned to a desk throughout the pandemic, Susan we've remained steadfast in our real commitment to protecting public health. Our ORA investigators, they work to support COVID-19 pandemic efforts and the regulatory mission of the agency in a multitude of mission critical inspections domestically. We have successfully conducted about 30 foreign inspections that were mission critical. Going and conducting these foreign inspections during the pandemic, it hasn't been without tremendous efforts to mitigate risk to our investigators.

You have to remember, there were many months before we had a vaccine and so our investigators were going out, traveling to foreign countries. And then entailed in a tremendous fortitude on behalf of our investigators, many had to quarantine upon arrival in a country for 10 to 14 days and military housing or in their hotel room. Some cases they were not able to really move around freely

and had to have meals brought to them. One example I like to share if I can, an example of the great work that my staff has done but there were numerous mission-critical inspections of clinical research facilities for the vaccine.

These are conducted onsite at healthcare facilities. Remember, these facilities were also treating COVID patients at the time of our inspections at the height of the pandemic. Our investigators conducted about 26 clinical research facility inspections before the advisory committee meetings and before we had authorized vaccines. So, in just four weeks, we completed all of those inspections with a team of more than 50 investigators. So, how did we do this? We collaborated with our centers. We collaborate with the centers for biologics, we planned out the inspections and the timelines in advance of the inspection assignments.

Our investigative team worked very diligently. We generally send in one investigator to the facility for clinical research inspections. In these cases, we send in two so that we could ensure the accuracy, reliability and the data in the shortest amount of time. So, we also implemented use of portable projectors to review the documents in a socially distant manner. We had to think outside the box in thought of how do we get these done for the public's best protection. We also did a couple of other things. While we were conducting mission critical inspections, ORA had the opportunity to also help the other FDA centers like our colleagues in the center for devices.

We detailed some of our investigators to assist our center colleagues to help with the plain chain, supply chain work that's associated with the COVID-19 response. We also transferred our training that was generally in person. And so our office of training and evaluation had to transfer all of our training to be able to be web-based so that our all the people that we hired could get trained so that they can conduct inspections when we get back to what the new normal will be like. So, everyone in every organization, ORA continues to adapt to the limitations. I think we've done a wonderful job of responding with diligence and effectiveness really over a very challenging year and our employees remain very focused on our mission. So, hopefully that helps.

Susan: That's great. Thanks, Judy, Tom?

Tom: Yeah. Well, thank you and Judy, I just want to thank you for

participating today in providing some additional detail on ORAs activities. Like Susan said, I think many folks outside the agency don't realize just the scale of the field force at FDA and the global footprint that it's responsible for. So, thank you for providing some of this insight. You shared some of the – really some of the incredible work that your team did in response to COVID-19. And you shared a little bit of background on kind of going forward, how you're going to be prioritizing some of the inspections that were that were not able to happen.

But I'm wondering, are there any kind of learnings or innovations that came out of the past year from COVID-19 that you're going to carry forward into the future work of the field course?

Dr. McMeekin: That's a great question, Tom and we understand how important inspections are to our oversight responsibilities and the public health mission. Inspections will always be an essential part of how we verify that manufacturers have systems and processes in place to quality products while maintaining our oversight work by fully utilizing other authorities and mimicking those authorities as a voluntary assessment. While we've expanded our approaches to assess the establishments we regulate, we do plan to continue to utilize these tools during the pandemic and beyond.

So, in the spirit of really learning from our experiences during the public health emergency, we're evaluating how we can optimize our operations to ensure that we're using our resources to the best optimal way. And as we learn more and decide how and when we might use these and other tools in the toolbox, we are committed to having a transparent dialogue with regulated industry as to how this may affect our procedures really in the future.

It was a time for us to really step back and say, "How can we do our work differently?" Because we were forced to really. But it was a great time for us to assess and think outside the box to be able to say, "Hey, we can do this, do it more efficiently, or we could use this tool or we could maximize this authority." So, I think that's been the silver lining if there's any in the pandemic is that we we've been able to look at the processes that we use and the tools that we use and even the way that our staff work as we've all had to adjust.

Susan: That's great, Judy. So, that was kind of a little bit of looking back. If we think and look forward, what do you see as growth areas for

ORA? If you were to have access to additional resources, where would you invest those dollars?

Dr. McMeekin: So, I mentioned our medical products budget has kept somewhat stagnant and so I would say we would probably utilize that in our medical products budget to really keep pace with the industries industry's growth and advances. We need to rely on our budget authority, but we need to expand that if we want to keep pace with it. It's really critical that our compliance and enforcement tools of authority keep pace with advanced manufacturing and medical countermeasures. But we also need to make sure that we have the most skilled and well-trained workforce to keep up with that advanced technology.

It's one thing for the technology but we've got to keep our workforce on the cutting edge to be able to understand what that technology is. That way they go and conduct these inspections, they're aware of that. So, that's critical for our successful oversight.

Susan: Makes perfect sense. Tom, I think we've got another question in the queue.

Tom: Right. So, going back to the pandemic a little bit, the pandemic really focused attention on foreign supply chains. What are the challenges that foreign inspections in particular post the field force and how does ORA kind of work to overcome some of those challenges of foreign inspections?

Susan: So, one of our biggest challenges, Tom, during the pandemic really has been that safe to other countries. There's been many travel restrictions placed, many quarantines. So, we continue to work closely and monitor travel advisories for foreign inspections but we – obviously kudos to our staff for stepping up and knowing – the commitment that our staff has is wonderful. They're very passionate about the work that they do, about how they protect public health. So, it's important to me to make sure that we're taking and monitoring the travel advisories from a safety perspective.

Moving forward post pandemic, we need to expand our dedicated foreign cadre. I would also like to see if there are ways that we can optimize travel for our investigators who conduct foreign inspection. The travel is very challenging. So, we need to have some more flexibility in how we travel and the clearances for

travel.

Susan: Hey, Judy, you just brought me back to your 14-day quarantine when you got to quarantine when folks got to a new country. That takes the international travel to a new level of commitment.

Dr. McMeekin: And Susan, from a workforce perspective, it's 14 days that they have to quarantine when they were there, then they can go do the inspection which could be 1, 2, 3 weeks and then when they come back, it was another 14 days. So, you're taking people out of the queue to be able to conduct the inspection. So, it was challenging but I'm very proud of the staff for being able to manage and be resilient.

Susan: Absolutely but it takes them out of the queue for work and takes them out of the queue for personal life too.

Dr. McMeekin: It does.

Susan: What an extraordinary commitment. Yeah. Here, so we've talked a bit about the field force and I've always been struck that for the ORA, the field force is part of your team but you also have such extensive coordination, as you mentioned, with domestic as well as foreign regulators. What role did ORA have in international harmonization of regulation?

Dr. McMeekin: So, we are actively engaged with the Pharmaceutical Inspection Co-operation Scheme or PIC/S. This is a worldwide membership of 54 participating medicine authorities which include over 2000 inspectors. This has really been very helpful and critical in having that relationship counting on our regulatory counterparts. And so PIC/S really allows us to work with the foreign regulators to be able to identify recognized or harmonized standards and inspector hit tools and procedures.

As well as interpretation of GMP standards which is most important to really help us strategically build collective trust and capacity with our counterparts but also with our state and local counterparts. So, extremely helpful. We're in this together to protect public health.

Tom: Judy, there's a related question that came in about higher risk countries. So, you mentioned kind of those where you can build collaborations with regulators. But if there are situations where

maybe there's a sort of weaker regulatory infrastructure in a country or maybe a one country that's not as open to collaborating, how does ORA manage that and think through those situations?

Dr. McMeekin: We're always trying to look to see how we can partner with folks So, it's about developing those relationships and leveraging those relationships. We are committed to protecting public health and having the best resources available and the best counterparts to be able to partner with to protect public health.

Susan: So, Judy another question the queue refers to something you mentioned in your remarks about the Inspection Affairs Council. And I couldn't actually see anyone in the audience perk up but I'm pretty sure I sensed that they did when you mentioned that. Now, I know you might not have the details tied down but do you have a timeline for when the Inspection Affairs Council will stand up? Anything else you can tell us about that?

Dr. McMeekin: Sure. We actually do. We're having a meeting next week. It involves each of the center directors and other agency leaders. We thought of this early in the pandemic and actually just through some of our experiences. For ORA and the inspection process, we touch each center, we work with each center, we conduct inspections with each commodity. We are always thinking of ways to optimize our inspection process and what better way to do that than to bring leaders to a table to be able to say, "How are we going to optimize our inspection process?" How are we going to do this across the enterprise as one FDA?

Our investigators are trained investigators and we utilize our subject matter experts in the field to augment the skills that we bring to the table but there's ways to optimize our inspection process. And so we need to do that collectively. Yes, ORA is the lead for the agency for inspections but it's important to bring that broad idea so that we do it consistently as an enterprise, as one FDA to be able to protect public health.

So, I'm really looking forward to it. Great insight we get from the centers and what they bring to the table and then we can collectively protect public health together. So, I'm really excited about it. And Dr. Woodcock Dr. Woodcock has been extremely supportive of it and giving some insight and so while she's not a voting member of it, she is the executive sponsor of it and has been really helpful in giving us some direction. So, I'm really looking

forward to it and again, it's an enterprise approach. It's one FDA.

Susan: Fabulous. Tom?

Tom: Yeah, thanks. Thanks, Susan. So, Judy, a few years ago, ORA started an effort to align inspectors kind of against specific commodities in order to allow them to even their expertise and affiliation with other inspectors focusing on those products. I think we're pretty deep into that now. Can you share a little bit about how that has played out and how – are we seeing benefits from that approach?

Dr. McMeekin: I would say absolutely and you're referring to our program alignment. FDA went through a program alignment. ORA's reorganization into a framework that we currently are in where we align our investigators by commodity in our laboratory. And by commodity, I think it's been a huge asset in terms of our oversight of industries that are extremely complex. Also aligning with our center colleagues, our ORA staff gets to know their center staff. Learning from one another, working towards a common goal.

So, do we constantly look to be able to see how we can improve? Of course. I would say that's what we're doing with the Inspection Affairs Council but there's been some real benefit. Even doing some trainings together, strategizing about how are we going to prioritize like when we were developing the resiliency report. It was easy to be able to get the same people together to be better aligned with the programs, to be able to decide where's our biggest risk? What does mission critical mean to us in our commodity so that we have a consistent approach within that commodity.

It doesn't mean that everything has to be exact across the commodities. We just need to have the flexibility within the program but we shouldn't really be working with our regulated industry in a consistent manner.

Susan: Judy, we've had you on the hot seat for just over an hour now and we've got two more questions for you. So, I'm going to ask one more and Tom's going to ask one more and then we're going to let you out of the hot seat. So, thank you for investing your time with the Alliance and the webinar audience. I'm going to ask personnel and productivity question. For the ACRA, you have one of the most challenging personnel leadership challenges within the agency because your staff are all over the country and you send

them all over the world. How do you think about maintaining and improving morale and productivity within the field force?

Dr. McMeekin: So, it is a challenge to have a global workforce. I'm in Silver Spring, I'm in Maryland. My workforce is throughout the country and we have people that are doing details over in our foreign post. Our workforce is our best asset. So, it's really important for me to be able to connect. Normally, in a non-pandemic world, I'd be able to travel and go and meet the people, especially my first year and a half of being the ACRA. So, I've had to think outside the box and be able to say, "Okay, how can I meet people?"

So, we've done a lot of webinars and town halls and district meetings and one ORA meetings or conferences to really help them get through the pandemic and really think of different ways of doing things. I meet routinely with the district directors who have been amazing throughout all of this, the 19 district directors throughout the country who provide me feedback.

They have people, boots on the ground and provide me feedback as to what they need. The culture of ORA is extremely important to me. I'll continue to focus on maintaining and improving morale among our staff. They're hugely dedicated public servants and I'm so proud of and we'll continue. One thing I've recently started is working or having focus groups with the frontline supervisors, the first- and second-line supervisors. Because I think they're critical to the work that we do in influencing and molding our future leaders. And so I want to make sure that they have the tools that they need to be able to do their job and we're asking a lot of them with the pandemic and telework and juggling and being flexible. And it's a good way of communicating with the frontline staff and supervisors to see what they need and how I can help them overcome any barriers.

Susan: That's great. Tom, I'm going to toss it to you.

Tom: Great. Well, thank you, Judy. So, you've shared an incredible amount of information with us today and we're very appreciative. I guess sort of a closing question would be kind of going forward, can you just tell us a little bit about how ORA kind of will be sharing information to the public, to the regulated community about its activities and how we can provide some visibility into that – the great work that you're doing?

Dr. McMeekin: Sure. So, transparency is really key, Tom, I think, to public trust and it's extremely important to the agency. So, as I mentioned, the new tools in our plan to go forward during and following the pandemic, as we learn more and really decide when we might use these tools and other tools, we are committed. I'm committed to having a transparent dialogue with our regulated industry as to how this may affect our procedures in the future. So, it's just extremely critical to work together to protect public health. They have a responsibility and so do we.

Susan: Thank you.

Ron: And thank you Dr. McMeekin. This has been a terrific webinar. We appreciate all your time today. We even more deeply appreciate all the terrific work you do and you're terrific and completely devoted workforce around the country, around the world and helping protect the health of the American people. And you know how committed we are to helping build support for your mission and your workforce. And we know, especially from your wonderful presentation today, how you touch the lives of all of us. You touched the lives of all of our stakeholders, everybody on this call and many, many more. And so please help us help you and keep us posted on anything we can do in support of you and your workforce in your mission. So, thank you so much.

Dr. McMeekin: Well, thank you very much. It's been my pleasure. Thank you.

Ron: And we'll close there and thank you all for participating. Thank our two moderators Susan and Tom and thank you all –

Dr. McMeekin: Thank you, Susan.

Ron: Very much for being with us today.

Dr. McMeekin: Thank you. Bye.

[End of Audio]

Duration: 66 minutes