

Mary: Good afternoon, everyone. I'm Mary Dwight, Senior Vice President and Chief Policy and Advocacy Officer at the Cystic Fibrosis Foundation, and I'm also the President of the Alliance for a Stronger FDA. Today, I'm joined by Steve Grossman, the Alliance's Executive Director, and our moderators for today's discussion, two of my fellow board members, Wayne Pines, Senior Counsel at APCO Worldwide, and Tom Kraus, Vice President for Government Affairs at the American Society for Health Systems Pharmacists.

I would add that Wayne is a former FDA Associate Commissioner for Public Affairs and was Chief Spokesperson for the agency, while Tom is also a former FDA Associate Commissioner for Legislative Affairs and subsequently was Chief of Staff for the agency. We're delighted to have them as today's moderators.

First, a quick word about the Alliance for a Stronger FDA. We're delighted to have you here today with us. We're a multi-stakeholder coalition that advocates for increased appropriated resources for the Food and Drug Administration (FDA) and educates about the agency's mission and responsibilities, like today's webinar. We're strongly committed to strengthening the resource base needed to advance FDA's regulatory and public health mission.

As an advocate for the FDA, we've been an important force in doubling the FDA's budget authority appropriations from \$1.6 billion to more than \$3.2 billion. We're the only advocacy organization focused on resources for both food safety and medical products, as well as many other components of the FDA's mission. Our members include consumer and patient groups, research advocates, health professional societies, trade groups, and industry. We're about 150 members strong, and for guests of today's event, we welcome new organizations to further strengthen our advocacy and educational efforts. We're glad to have you.

Regarding procedures for today's conversation, Dr. O'Shaughnessy will begin by interviewing herself using some questions that the Alliance has provided, and that will be followed by questions from our moderators and you, our audience. You can submit questions at any point during the webinar by clicking on the Q&A button at the bottom of your screen, and I just want to point out – please do use the Q&A button, not the chat function.

Now, it's my privilege to introduce our fabulous speaker for

today's webinar, Dr. Jacqueline O'Shaughnessy, the FDA's Acting Chief Scientist. As you will hear, her office is a hub for scientific programs that support the Centers, as well as the overall mission of the FDA. The Chief Scientist oversees the National Center for Toxicological Research and initiatives involving regulatory science, technology transfer, scientific professional development, and scientific integrity. She also oversees the FDA's Medical Countermeasures Initiative.

Dr. O'Shaughnessy began her career at the FDA in 1996 as a pharmacologist in the Center for Drug Evaluation and Research (CDER), providing scientific and technical expertise and regulatory policy and complex data analysis. In 2011, she joined CDER's Office of Medical Policy as Health Scientist Policy Analyst, where she led the development and drafting of rulemaking and guidance related to medical policy issues, including human subject protection and good clinical practice. She subsequently advanced several times to become Deputy Director of the Office of Medical Policy Initiatives.

In 2017, Dr. O'Shaughnessy joined the Office of the Chief Scientist as a senior advisor, focused on developing and implementing the office's regulatory science guidelines and initiatives. She's received her Ph.D. in pharmacology and toxicology from the University of Medicine and Dentistry of New Jersey Graduate School of Biomedical Services, and completed postdoc training at Rutgers University's Environmental and Occupational Health Science Institute.

Dr. O'Shaughnessy, we're delighted to have you today. Thank you so much for your longstanding commitment to the FDA and for joining us to speak about the Office of the Chief Scientist. I'm certainly looking forward to your remarks. So, with that, Dr. O'Shaughnessy, the floor is yours.

Dr. O'Shaughnessy: Thank you very much, Mary. I really appreciate that introduction, and of course, good afternoon, everyone. I appreciate the invitation to speak with this important group. The strength of this organization stems in part from the fact that you bring together so many different segments of our society, from consumers to patients, industry, healthcare groups, and others, in support of the goal of ensuring a stronger FDA.

We appreciate your recognition of our agency's critical responsibilities and the importance of ensuring that the FDA has

the resources to support its mission to protect consumers and advance public health. Your leadership provides a roadmap for policymakers and others in support of that mission.

So, you've already heard a little bit about my background. Through my varied work at FDA, I've, of course, been able to experience and appreciate the vast range of FDA's responsibilities. The positions I've held, both individually and collectively, have underscored the importance that high-quality, rigorous science plays in the FDA's development of effective regulatory policy.

Just as important is how they have highlighted the ways that FDA applies this science through collaboration and multidisciplinary teamwork. My experiences in the Center for Drug Evaluation and Research, where I started my career at FDA, provided those initial opportunities to work with a wide array of subject matter experts and taught me the critical importance of active and thoughtful engagement in gathering valuable feedback, viewpoints, and perspectives.

Nowhere have these takeaways been more relevant than in my current role as Acting Chief Scientist. The Office of the Chief Scientist, or OCS, is unique in that our work relies on and encourages scientific engagement across the agency and outside the agency. Its sometimes discrete but overlapping efforts create a cohesive, stronger whole, built on the application of the best available science.

Some of your leaders suggested a few topics that might be of particular interest, so I'll begin with those, and then I hope we can open up to additional questions. I'll start by providing a high-level overview about the Office of the Chief Scientist – and again, OCS. I'm sure that some people, when they hear the job title "Chief Scientist," may conjure an image of someone in a lab coat working in a laboratory. I'd like to share with you that OCS has a far broader range of responsibilities and reach than what our title indicates.

At its most basic, our work supports the research, science, and innovation that advances FDA's regulatory mission. We do this through a broad framework that encompasses scientific collaborations, laboratory safety, the transfer of FDA inventions to the private sector, scientific integrity in FDA policy and decision making, and the professional development of regulatory scientists. This diverse array of offices within OCS help to support all of

these efforts.

So, I'd like to walk through each of those offices and areas. The Office of Regulatory Science and Innovation (ORSI) for instance, spearheads external and internal scientific collaborations that advance the development of new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of FDA-regulated products. ORSI manages our Senior Science Council that provides advice and guidance to agency and Center leadership on cross-cutting regulatory science issues. ORSI also manages several innovative programs to support the Centers and Offices, including the Intramural Grants Program.

Our Office of Counterterrorism and Emerging Threats (OCET) leads, coordinates, and provides oversight for FDA's national and global health security, counterterrorism, and emerging threats activities. This includes the FDA-wide Medical Countermeasures Initiative, which is an FDA-wide initiative to coordinate medical countermeasure development, preparedness, and response.

The Office of Laboratory Safety (OLS), ensures that the research labs and workplaces that FDA scientists work in are operated in a safe and secure manner. OLS leads, coordinates, and implements the policies, procedures, and centralized training to facilitate safe and effective laboratory science and security, environmental management, and occupational safety at FDA facilities. Lab safety and modernization has been an area of particular importance in recent years to ensure that we are able to keep up with the science, to ensure that our staff has the resources to do so, and as a means of attracting the best scientists into our ranks.

Our Office of Scientific Integrity (OSI) works with the FDA Centers and the Office of Regulatory Affairs to preserve and promote integrity in scientific decision-making and consistency on such issues across the FDA.

Our Office of Scientific Professional Development (OSPD) collaborates with FDA Centers and Offices to strengthen FDA's workforce by supporting a range of innovative programs and activities for FDA scientists and all of our stakeholder community. OSPD provides professional training and continuing education collaborations to strengthen FDA's scientific staff as well as recognize their achievements. Among other educational events, OSPD manages the biennial FDA Science Forum and our monthly FDA Grand Rounds.

And the Advisory Committee Oversight and Management Staff helps to ensure the smooth conduct of FDA advisory committees, which provide independent advice and recommendations to FDA on scientific and technical matters concerning the development and evaluation of FDA-regulated products.

OCS also has oversight for FDA's National Center for Toxicological Research (NCTR). I know you heard at the end of last year from NCTR's distinguished director, Dr. William Slikker, so you probably already appreciate the important role this Center plays in generating vital data the FDA uses for our regulatory decision-making and development of sound regulatory policy. It's also the only Center situated within OCS, underscoring how toxicological research is critical to everything FDA does in advancing regulatory science.

What each of these offices within OCS share is that they all work to encourage, support, and advance scientific efforts and collaboration across the agency. This is indeed a key focus of our work, as we are involved in leading and coordinating the agency's cross-cutting scientific and public health efforts, providing strategic leadership on evolving science, and helping ensure implementation of high-quality, collaborative activities that meet our extraordinary public health responsibilities and advance regulatory science.

So, I'd like to give you a few examples of the various work that we help to support. We provide oversight for human subject research conducted or supported by FDA to ensure protections, compliance, and administrative support are all in place. We co-lead the cross-agency's important One Health Initiative to support the FDA's focus on the interconnection among people, animals, plants, and their shared environment to achieve optimal health outcomes.

We provide overarching support and guidance to the Animal Welfare Council, which helps enhance the quality of FDA's animal programs and promotes harmonization of FDA's animal research-related activities, and we perform and support a great deal of intramural research and scientific activities in collaboration with scientists and others across the FDA, as well as extramural research with stakeholders and external partners in the broader scientific community.

For example, we operate the Centers of Excellence in Regulatory

Science and Innovation, or the CERSI program. This successful endeavor supports collaboration to leverage expertise and resources not available in-house. The CERSIs, as you may well know, are important joint efforts between FDA and four prestigious academic institutions aimed at working collaboratively on projects that promote regulatory science, including cutting-edge research, education, and scientific exchange.

I mentioned that our work supports the advancement of regulatory science. That's an important phrase, and we use it a lot, but for many, regulatory science may remain a discipline that's not fully understood. In brief, regulatory science is the science of developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of FDA-regulated products.

This is at the core of FDA's work. It involves ensuring that breakthroughs in technology and medical science are translated and applied in ways that allow for their development into safe and effective products. That connection is really what the FDA is all about: helping facilitate and support scientific innovation in a way that gets new products and treatments into the hands of consumers and patients to help make their lives better. At OCS, we strive to ensure the robust scientific foundation necessary to advance the FDA's support of this kind of research and innovation.

That's a big lift in this age of nonstop scientific advances, so you might ask: how have our responsibilities evolved in recent years? The answer, in a word, is: significantly. The Office of the Chief Scientist was established by Congress over a decade ago, prompted in large part by the rapid transformations taking place across 21st-century regulatory landscape and the understanding that science is inherently about change. OCS was created to provide the necessary oversight, coordination, assurance of quality, and regulatory focus of FDA's intramural research programs.

At the same time, the 2007 Science Board report titled "FDA Science and Mission at Risk" advised that a position of Chief Scientist and a central science infrastructure be established to enable regulatory science to appropriately inform the regulatory process. Since then, we've been able to adapt and stay ahead of the technological and scientific advances, and our responsibilities have also continued to expand to include new challenges and initiatives.

This leads to a topic that I know is of primary importance to this

audience. How do we pay for these new initiatives, and for ensuring we have the resources to meet the growing challenges? On this point, I can assure you that we are very appreciative that the Alliance is so focused on the adequacy of our budget. I suppose I should begin this portion with a basic question: Just how large is the office's budget, and how is this determined?

Not including NCTR, as I know you already heard from Dr. Slikker, the OCS budget is approximately \$37.5 million before contributions to central funds. This has been consistent for the last two years. We've also received approximately \$4 million in supplemental funding in FY22. An additional \$6.6 million was requested for the Office of Laboratory Safety in the FY22 President's budget, which Congress is still considering.

In thinking about these numbers, it's important to keep in mind that the OCS budget not only includes OCS-specific activities, but also supports the wide-ranging work we do across FDA in partnership with the Centers, the Office of Regulatory Affairs, and offices within the Office of the Commissioner, as well as supporting research grants and both international and external collaborations, but we do have both immediate and long-term program and budget priorities. We start with the understanding that our budget is relatively modest, so it's important that we leverage it wherever we can to fund as many promising scientific research projects as possible, both internally and externally.

To some degree, our work is shaped by developments in the world of science and public health. Regulatory science is a rapidly advancing space, so we will need to continue to invest in emerging technologies and areas that will help our scientists make the best regulatory decisions possible. Certainly, one example of this is our continuing response to COVID-19. Our Office of Counterterrorism and Emerging Threats, as I mentioned – OCET – works closely with the Medical Product Centers to help facilitate the availability of vaccines, therapeutics, and tests used in the robust U.S. response efforts, and we also help coordinate and sign Emergency Use Authorizations (EUAs).

As many of you may know, the EUA is a regulatory tool created by Congress after the 9/11 attacks. It's designed to enable rapid availability and use of medical countermeasures and lifesaving products during public health emergencies, and it's been extraordinarily important in responding to the pandemic. During this emergency, we've issued more than 400 EUAs, covering more

than 800 medical products, including diagnostic tests, PPEs, and of course, the authorization of several vaccines.

The EUA process is a good example of how the FDA continually reevaluates the best available scientific evidence. Our review process is a meticulous and dynamic one in which we constantly are acquiring, reviewing, and evaluating data and expanding the evidence on which we base our decisions.

Even as we have responded to this public health emergency, we've continued to apply our science-based approach to our regular critical responsibilities to protect the public health, and we continue to make strides in other areas of science, such as artificial intelligence and alternative methods, to name some examples. As you understand, meeting the scientific demands of responding to public health emergencies, as well as meeting our normal responsibilities, requires extensive resources, both financial and personnel-wise.

I've already mentioned the budget but let me briefly note one other priority: ensuring that we have the personnel to address current and future challenges and to take on new initiatives. We continue to be focused at the FDA as a whole and in OCS specifically on recruiting, hiring, and retaining the best scientists and workforce we can to ensure that we continue to operate at world-class levels.

Currently, OCS staff has averaged 107 full-time equivalents over the past two years. We constantly examine whether our office is staffed at a level that allows us to efficiently and effectively fulfill our public health mission. It's always a challenge to recruit, develop, and maintain a workforce that has the necessary expertise and adaptability, particularly given the breadth of the FDA's responsibilities and continuing advances in science.

That's why we continue to be strategic and targeted in our efforts to identify the staff we need and to ensure they support and are aligned with HHS, FDA, and OCS priorities, and we do everything we can to ensure that new staff are multifaceted, multidisciplinary, and are able to evolve and adapt to meet the challenges of today and tomorrow.

One of the important aspects of recruitment and training involves the ability to be forward-looking, to think not just of current staff and current needs, but about nurturing, developing, training, and strengthening our commitment to the next generation of

researchers and scientists. We need our employees to be prepared for the scientific challenges that lay ahead, but we also need to provide opportunities for them to have rich and rewarding career experiences.

This is why we facilitate numerous continuing education efforts to develop and enhance the skills and knowledge of our scientific staff. It's also why, over the years, OCS has sponsored and supported a variety of training and fellowship programs designed specifically to attract and support scientists.

Let me give you one exciting current example of this. FDA is developing a new traineeship program to provide practical scientific training for pre- and post-doctoral scientists and physicians that have a background or interest in the natural sciences, the formal sciences, or any other field of science related to FDA mission programs. It also will provide practical training and project-specific FDA research and developmental activities derived through conduct and support of scientific projects performed at the FDA.

I was also asked to describe interactions that OCS may have with other federal agencies or with third parties. For example, OCS has numerous interactions with subject matter experts across HHS operating divisions as related to our various efforts. We also establish partnerships through Memoranda of Understanding (MOUs) with various government agencies and entities. These partnerships help us to effectively collaborate by leveraging resources and expertise to address critical public health needs.

Before I close and take some of your questions, I want to mention one critical area of focus for FDA and OCS. That's our response to the demands for new and more modern technology, and the importance of continuing to expand the sources and types of data we use. There's no better example of the importance of these new sources of data than how quickly we've been able to respond in our response to the SARS/COVID-19 virus.

Within OCS, we have the authority, through the FDA's Technology Transfer Program (TTP), which helps the FDA drive innovation and supports FDA collaborative research with external partners. The TTP is composed of experts in science and patent law and provides a framework and tools to support the effective transfer of FDA research results and FDA-created technologies to the market in support of public health.

More broadly, the FDA is taking important steps to modernize and innovate, to keep pace with evolving science and technology, as well as the agency's ever-increasing responsibilities. This includes our processes and digital systems to ensure that we are able to keep in step with the industries we regulate by having the ability to effectively and speedily review and evaluate the products they submit to us, often applying groundbreaking science.

These digital modernization efforts have already begun, thanks to our newly established Office of Digital Transformation's efforts to streamline and enhance the FDA's information technology, data, and cybersecurity abilities. We're certainly excited about its potential.

The essence of scientific inquiry is that it's always changing and advancing. The questions we're tasked with answering are increasingly complex, and the process of acquiring, reviewing, and evaluating data is a dynamic one. We must regularly refresh and expand the evidence on which we base our decisions.

The FDA's scientists are always looking forward, working to stay ahead of the curve by embracing the newest technologies and tools and incorporating the best possible data. At OCS, we do everything we can to support this work across the FDA, helping our agency continue to meet its commitment to protect and promote public health. Thank you for your attention, and I look forward to your questions.

Wayne:

Thank you very much, Jackie, for an outstanding presentation. Tom and I are now going to pose a few questions, if we might, some from the listeners and some of our own. First question is: Emergency Use Authorizations are top of mind for everybody. I have to admit that two years ago, I could not tell you what an EUA was, and now, my children can tell you what an EUA is. So, what is your role in reviewing and approving all of these vaccines and other products under the EUA process of FDA? How does that really work? Where does the information come from, and how do they incorporate you? Because people might not know, but yours is the signature that actually lets the EUA move forward.

Dr. O'Shaughnessy: Right, thank you for that question. So, I guess with respect to the issuance of EUAs, maybe I can first start with the fact that the particular Product Review Center, with regulatory oversight of the candidate product for which the EUA is requested – they have the

responsibility for the scientific and technical review and regulatory management of the EUA submission.

The Product Center reviewers work closely with OCET –or our Office of Counterterrorism and Emerging Threats - within the Office of the Chief Scientist, who is responsible for overall coordination and implementation of policy as well as process-related aspects of the FDA's EUA activities. OCET works collaboratively, of course, with multidisciplinary teams of scientists, medical professionals, lawyers, as well as others on the development, review, clearance, and issuance of each EUA issuance, revision, and revocation.

Tom: Dr. O'Shaughnessy, can I follow up with another question? We have a question that was submitted by someone in the Q&A around appropriations. Can you just say a little bit more about the OCS budget and how it's derived? Does any of it come from user fees? How much comes from appropriations if you have a ballpark sense?

And then, you mentioned some requests that were made, including – I think it was \$6.6 million for the Office of Lab Safety; that's a relatively new office within OCS. Can you share a little bit more about what those dollars would allow the Office of Lab Safety to do? And obviously, if we're in a Continuing Resolution, we wouldn't have access to those dollars, so I think it would be helpful for folks to understand what you hope to do with those kinds of resources.

Dr. O'Shaughnessy: Thank you for that question. So, just a little bit about the work in the Office of Laboratory Safety. Of course, they have cross-cutting, comprehensive work to ensure that our research labs and workplaces are operated in a safe and secure manner. The considerations around the additional request really would enable additional opportunities for FDA to continue in its proactive program, really, to reduce risk from laboratory work, enhance our laboratory security and data quality, increase efficiencies across the Centers and ORA, and to further strengthen the culture and responsibility of safety.

I think that this will allow us also to sustain the development of new agency-wide standards and policies, the continued development of training and other tools and resources that are associated with implementing those standards and policies, as well as other activities that really, again, continue to emphasize benefits

of a safety-oriented culture. OLS really works very collaboratively in coordination with all of our Centers and Offices and all of the broad-based safety staff that exist across the agency.

Wayne: Can you give some examples of some of the cross-cutting efforts that have helped prepare for this environment of new science? What types of topics are being discussed at the monthly grand rounds? That kind of a discussion will help us understand the scope of the effort that FDA is making.

Dr. O'Shaughnessy: So, the Grand Rounds are really an opportunity to provide a platform for FDA scientists to share all of their different research activities and other initiatives that are going on across the agency. So, as an example, the different Centers have an opportunity to bring forward their various research efforts. NCTR has opportunities to present those efforts, and I do believe as well the information is posted up on the FDA webpages so that anyone could go back and, of course, take a look at the various opportunities that were provided in hearing about the agency's regulatory science considerations.

Tom: Thanks, Dr. O'Shaughnessy. One other area that folks may not realize OCS is involved in is oversight and management of the advisory committee staff. Can you just share a little bit about the role of your office in those advisory committees? Obviously, there's been a lot of attention on FDA advisory committees, and folks are probably more aware of them now than they used to be. Can you just share a little bit about that process?

Dr. O'Shaughnessy: Sure. I guess the starting point that I had mentioned is that they have responsibilities to help ensure the smooth conduct of the advisory committee meetings. I think that they have a main role, really, in ensuring that the advisory committee meetings comply with statutory and regulatory requirements, especially the Federal Advisory Committee Act, and that our Centers conduct the advisory committee meetings in a consistent and uniform manner.

Wayne: Sorry, one question, again, from the audience. There have been a lot of changes that have taken place in the way that FDA views regulation and science because of COVID over the last two years. Certainly, the staff has changed. What process does FDA have in place, and what role will your office play in assessing which changes are useful, which are not, which might negatively affect/impact public health or safety in the long term, and which ones will enhance? Which ones should remain, which ones should

not?

Dr. O'Shaughnessy: I'm not sure I entirely am grasping the question. Are we thinking about particular regulatory science initiatives? Because I could speak a little bit about some of the efforts, for example, that stem from our Office of Regulatory Science and Innovation. So, I guess the Office of Regulatory Science and Innovation, or ORSI, operates a few programs that really leverage scientific engagement and coordination across FDA, and I had mentioned, of course, the Senior Science Council; the Senior Science Council really is an opportunity for providing advice and guidance to agency and Center leadership on cross-cutting regulatory science issues.

One of the accomplishments I can mention about the Senior Science Council is a report that was developed on the Focus Areas of Regulatory Science. We refer to that as the FARS report. It was released in 2021, and it outlines topics that FDA has identified as needing continued targeted investment in regulatory science research to facilitate development of innovative products, provide data and methodology to inform regulatory decision making, and improve guidance to sponsors, and you can find a copy of that report on our website.

The focus areas really aren't intended necessarily to be a comprehensive list of all of FDA's research needs, but they generally encompass research that affect more than one Center or Office, and the areas that have been identified are designed to be flexible so that they can be updated as needed when we're thinking about evolving regulatory needs.

Tom: Thank you, Dr. O'Shaughnessy. You mentioned during your initial presentation the Technology Transfer Initiative. Can you say a little bit more about that? What kinds of technologies or tools are developed within FDA that could be transferred to the private sector? And maybe say a little bit about how FDA engages with academia and industry around technology transfer.

Dr. O'Shaughnessy: Okay, thank you for the question. Sure. So, I guess I want to start out just by saying that FDA, like other federal agencies, carries out its federal tech transfer mandate under the Federal Technology Transfer Act. While there is no specific technology transfer initiative, I guess, at FDA, we are always looking for more efficient ways to license our technologies to maximize the use of our regulatory research efforts.

So, the technologies are made by FDA inventors, and FDA carries out its technology development mandate under that Federal Technology Transfer Act, so, of course, the inventions stem from our regulatory science work, and they can range from enhancements to mass spectrometers that make it possible to detect and differentiate between pathogen bacteria to devices for portable rapid screening for counterfeit drug detection. And I think you can get a look at the different technologies that are available for licensing and the collaboration opportunities on the FDA tech transfer website.

Tom: Great, thank you.

Wayne: The NCTR, the National Center for Toxicological Research, is one of the least known parts of the FDA. What role does your office play in integrating NCTR activities into the rest of the scientific framework of the FDA?

Dr. O'Shaughnessy: Thank you. We do have a lot of opportunities to interface and connect with NCTR, of course, and are supportive of the work of NCTR and its various collaborations across the agency. Many NCTR staff are, of course, supportive of our various efforts related to, for example, the Senior Science Council working groups and many other cross-agency activities that are focused on our regulatory science efforts.

We definitely have opportunities for engagement between OCS and NCTR and the Product Centers, and that really provides us with some additional opportunities for enhanced and greater exchanges between the Product Centers and NCTR.

Tom: Great. I think we maybe have time for just one more question, and I see in the Q&A there's a question. Can you share some examples of how EUAs are coordinated by OCS? You already mentioned the role of the Product Review Centers, but can you just share a little bit more about that and how OCS fits into the broader COVID-19 response of the agency?

Dr. O'Shaughnessy: Okay, sure. Well, I think that just reflecting back on just the overarching process considerations that our Office of Counterterrorism and Emerging Threats, with its responsibility for overall coordination and implementation of policy and process that's related to the FDA EUA activities, is a means of ensuring that there is this collaboration that is ongoing between our office and the Product Centers to enable the opportunities for issuing

EUAs.

So, I think it's a matter of thinking about how OCET is responsible for the overall coordination and implementation of those areas. They definitely have subject matter expertise in public health emergency and preparedness response, FDA emergency use authorities and in the scientific and technical aspects of EUA issuance.

Tom: Thank you, that's certainly a very timely topic, and I think that's all we probably have time for today, but Dr. O'Shaughnessy, I want to thank you for taking the time to speak to us and thank you for the work that you and your team are doing in the Office of the Chief Scientist. Thank you so much.

Dr. O'Shaughnessy: Thank you very much. I greatly appreciate the opportunity and thank you for allowing me to join and be here today.

Tom: Thanks.

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