

Mary: Hello, everyone. Thank you for joining us on this Friday. We're just going to give it a few minutes as people come into the webinar.

Well, good morning, everyone, and happy Friday. I'm Mary Dwight, the Senior Vice President and Chief Policy and Advocacy Officer at the Cystic Fibrosis Foundation. I have the privilege of being the President of the Alliance for a Stronger FDA. I'm joined today by Steve Grossman, the Alliance's Executive Director. This is our fifth webinar in the Alliance's series on the FY '23 Budget Priorities for the FDA. We're grateful for the senior FDA leaders who have participated already, Doctors Cavazzoni, McMeekin, Mayne, and Solomon. Transcripts from those webinars are available from the Alliance on our website.

We're so pleased today that Dr. Jeff Shuren is joining us to discuss CDRH's budget priorities. Our last program in the series, Dr. Peter Marks will be speaking about CBER's priorities on May 10. We hope you will join us for that, as well.

Serving us for co-moderators in today's discussions are two of my fellow board members, Wayne Pines, a senior counselor at APCO Worldwide, who is also a former FDA Associate Commissioner for Public Affairs and chief spokesman for the agency, and Nancy Myers, President of Catalyst Consulting. Earlier in her career, she served as Senior Policy Counsel and then as Senior Strategic Advisor, serving the FDA's Acting Deputy Commissioner for Operations. Both Wayne and Nancy are co-founders of the Alliance, known for their innovative leadership in the FDA stakeholder community. Of course, we'd also like to welcome Alliance members, the media, and our guests to our webinar today with Dr. Shuren.

First, a quick word about the Alliance for a Stronger FDA. We're a multi-stakeholder coalition that advocates for increased appropriation resources for the FDA. We've been an important force in doubling FDA's budget authority, funding from \$1.6 billion to \$3.3 billion since our inception. Our other mission is to educate policy makers, the American people, and the media about the FDA's growing mission and its large responsibilities. We're also the only advocacy organization focused on resources for both food safety and medical products, as well as other components of the FDA's mission.

Our members are vast, including consumer and patient groups, research advocates, health professional societies, trade groups, and industry. We have about 150 members and we always welcome new

members to further strengthen our advocacy efforts and education efforts.

For today's webinar, Dr. Shuren has agreed to respond to questions submitted by the Alliance and to be followed by ample time for moderator and audience questions. You can submit such questions by clicking on the Q&A box at the bottom of your screen. Important to note, it's not the chat box. It's the Q&A box.

Now, before introducing Dr. Shuren, I do want to make a specific thank you to Lindsay Lloyd of his staff. She has collaborated closely with us in preparing this webinar. Thank you, so much, Lindsay.

I now have the privilege of introducing our esteemed speaker for today's webinar. Dr. Jeffrey Shuren, Director of FDA's Center for Devices and Radiologic Health. Dr. Shuren became Director of CDRH in January 2010. He previously served as Acting Center Director, beginning in September 2009. The Center is responsible for ensuring the safety, efficacy, and quality of medical devices and ensuring the safety of radiation emitting products such as cellphones and microwave ovens and fostering device innovation.

He received his BS and MD from Northwestern University under its honors program, completed his medical internship at Beth Israel Hospital in Boston, his neurologic residency in Boston, as well, and fellowships at the University of Florida. He also has a JD from the University of Michigan. He's had a variety of policy and planning positions within the FDA since 1998, including Acting Deputy Commissioner of Policy, Associate Commissioner for Policy and Planning, Special Counselor, Assistant Commissioner, and Medical Officer. Dr. Shuren, we're delighted to have you with us this Friday, and the floor is yours.

Dr. Shuren: Thank you very much. Pleasure to have the chance to talk to everyone. I'll just start with, if anyone is interested in a little bit of CDRH swag, just email me separately, happy to let you in on the deal.

So, I thought for my time when I'm talking before questions, I'd cover a little bit about some of the things we did in 2021, and then really talk about 2022 and fold into that our budget needs that are in play right now with the 2023 budget proposal. So, for starters, just a little bit of reminder for us, we're about 1900 people. We're responsible for over 230,000 different kinds of medical devices on the US marketplace. We oversee about 25,000 manufacturing

facilities worldwide. Actually, the number is a little bit higher right now. For us, we wind up getting a large amount of work coming in the door that was upwards of about 19,000 submissions coming in pre-market for a variety of different things.

Now, of course, in 2021 and even now, COVID still occupies a lot of our attention. Since the start of the pandemic, we've, in fact, received over 8,000 Emergency Use Authorization and Pre-EUA requests. We have authorized, either with EUA or full marketing authorization, almost 2,300 medical devices for COVID. So, just a massive number of work coming in the door and lots of products getting onto the marketplace. That includes over 460 tests and self-collection kits.

In addition to that work, there has been a lot of effort around engagement and transparency. I mentioned these Pre-EUAs, that's working with developers, really hand in glove, to answer questions, problem solve. When the numbers were smaller, we were able to do that real time. That made a big difference. Obviously, as the volume got bigger, it made things a little bit more challenging. But that's the level of engagement that we don't, otherwise, do to that extent, outside of this public health emergency. But it has informed some of the things we're going to be doing in the future.

In addition, we provide information through a lot of different ways. We had over 350 frequently asked questions. We updated those over 550 times. We have 28 guidances for COVID. They've been modified about 21 times. We've received over 420,000 inquiries from patients and providers and companies and others that we've responded to. We've been holding tons of webinars and townhalls, in fact 107. Many of them, over 80, have been for techs, for developers and other interested parties. In fact, from March 2020 until the fall last year, we held those every single week. Now we do them every other week. So, lots of efforts on engagement and transparency, trying to be clear about our work.

Also, some very unique partnerships with other parts of governments and other groups. For example, with NIH, we were engaged from the ground level in their RADx program, kind of a Shark Tank approach, to facilitate the development of tests that were going to be point of care or at home. Already, we've authorized 39 tests coming through that program. And also, for the very first time, setting up the capability for the US Government to conduct independent evaluations of tests. We've started that with the National Cancer Institute, for antibody tests for COVID, and then

we did it with NIBIB with members of RADx for over-the-counter antigen tests. It really has given us an expanded capability we didn't have beforehand.

But you know, throughout the pandemic, we also continued to authorize record numbers of novel devices, most of those not for COVID, on average, over 100 a year. This has really been record highs for the 45-year history of the device program. So, things kind of going strong.

As we look ahead to 2022, first want to say one of the things I've been amazed by, I have been so appreciative, before the pandemic, of my staff. I work with some of the most amazing people, I've had the pleasure to be colleagues with. They are just truly lean forward people. But during the pandemic, I have to say, I have to say I've been just blown away. They so stepped up to the plate, so many of them just working long hours. About 75% of the Center, constantly engaged in overtime. Over 50% of the Center was involved in the COVID efforts. And the rest of the folks trying to pick up the slack.

Truly awe inspiring. Just want to take a moment to acknowledge them because now there are ramifications, too, for them and for us. I told you about all that COVID work coming in the door. Well, we face challenges with that in terms of both COVID work and our non-COVID work. In fact, prior to COVID hitting, we started to see challenges in our program. Here's really a big one. Every time we engage in reauthorization of the MDUFA program, we sort of estimate what the resource needs are going to be to meet the goals and the service that we're committed to provide. And we don't agree to anything that we don't think is to do or that we can do. It's a guesstimate on the resources. If we're wrong, though, and we underestimate, we take the hit.

Unlike in the drug program, there isn't an adjustor for workload. It used to be in MDUFA. Got taken out by Congress. It's been a contentious point with industry. It's not in there, but we kind of run those risks. In MDUFA IV, we saw a big increase in work load we hadn't anticipated. Roughly 3,000 more pre-submission meetings than we were resourced for. Device complexity continuing to go up, submissions getting bigger as a result. The size of 510(k)s almost around doubled during the course of MDUFA 4. And just a lot more work with even the number of submissions increased.

In fact, last year, was the highest number of 510(k)s over the past 15 years. And then of course, COVID hit, and it was just a perfect

storm. So, there's been a backlog in our work. We had to reallocate staff. We hired more staff with dollars that Congress gave us with COVID supplementals. Those are kind of term appointments. They are going to help out temporarily. We have temporary help with contractors. We made changes with policies and procedures and practice. Now, we've really turned the corner. In fact, we've reduced that backlog by about 45%.

Another thing we had to do was first put on hold and then start back up, we're a bit delayed in our pre-submission meetings. The exception was IVD's where we've only been holding them for certain kinds of submissions, certain situations. I do want to say, starting fairly soon, we're going to make an announcement about this, but relatively soon, we're going to open up the door for all pre-subs. They may be delayed a bit, but we're going to open the door for everything. Our goal is to get most of the Center back to normal operations by the end of this year. Still recognizing that we receive almost 120 EUAs and pre-EUAs for COVID every month, still. So, still a lot of COVID work coming in the door.

One of the other things we've kind of turned to is that transition for if you're under emergency use authorization or one of our enforcement discretion policies for policies that may be on the setting for COVID, that there'll be a transition to full-marketing authorization. So, we put out two guidances on this several weeks ago. Got comments on it. Comment period closed about a month ago. We're going through those. It kind of lays out our expectations that if you want to stay on the marketplace, here is what you need to do and when you need to do it. We're reviewing the comments. Our goal is to get those final guidances out later this year so there's a bit more predictability.

As we look to this new year and beyond, we put out our strategic priorities for 2022 to 2025. And they are three of them. Sort of that biblical three that we've been using for the past several years. So, one is to promote a modern and diverse workforce. The second, to enhance organizational agility and resilience. And the third is to advance health equity. Our come back to these in a moment. But they are all focused on further advancing our ability to achieve our vision, which is our North Star, that patients in the US have access to high quality, safe, and effective medical devices of public health importance, first in the world. Again, first in the world is not about beating other countries. It's just a good metric for timely patient access.

So, we want great technology. It's got to be high quality, safe, and effective. And really focus on those with the biggest bang for the buck for public health. But patients get the greatest value if they have timely access.

Now, in our last set of priorities, we felt we were getting closer to our goal. We always put out publicly goals we're going to try to achieve. And we start with overarching goals. So, previously, we had a goal that by the end of 2020, over 50% of manufacturers of novel technologies for the US market intend to bring their device to the US first or in parallel with other major markets. So, the idea was changing hearts and minds, understanding the next stage would be do the devices in fact come here first. By the end of 2020, over 60% of those makers of novel technologies did intend to come to the US first.

Well, now for these new set of priorities, we've set a goal that over 50% of those manufacturers in fact do bring their devices to the US first or in parallel with other major markets. That's our goal by the end of 2025. So, really get at that point where we are achieving our vision.

We also have a complimentary goal on safety that over 75% of the time, FDA identifies and acts on significant safety signals related to medical devices marketed in the US and other major markets first or in coordination with regulatory agencies of other major markets. In fact, we've already set up a mechanism starting in the context of COVID to meet with regulators from other countries, pretty much on a monthly basis, to share information on what we're seeing on the safety side with technology. Our intent is to meet that goal, again, by the end of 2025.

So, the priorities we have, two of them are very heavily focused on our workforce and on our organization. Much like I recognize in medicine, if someone has a cardiac arrest, you always get taught you're going to give CPR. Check airway breathing circulation. In reality, what they miss is the first step, which is check your own pulse. If you're not in a good position, you can't provide the care that you need to that person who is in need. It's very much the same with us. We have an obligation to make sure that we as CDRH are optimally set to be successful in our public health mission.

So, really focused on assuring that we, to truly serve the American public, we have to reflect the diversity of the American public. We need to be more agile in our ability to shift and adapt. We certainly

learned that with COVID and we're taking those lessons learned as we are making changes in our organization. And recognizing that we're in a new world when it comes to employees. It's not the old days of my generation where you stay somewhere forever. People, they come, and they go. So, we have to make our place a destination where people want to come because they're going to get the training they need to be successful in the job they have today, but also to be successful in the job they have in the future, even if that's not at CDRH.

An advanced health equity is a recognition that no patient should be left behind. We have to make sure that we have technology out there that's ultimately fit for purpose for all people in the United States. Part of that, too, is that people have access to healthcare. We know that technology can play a critical role because if you want to get out to unrepresented populations who may not have access to healthcare because of who they are or where they live, technology can be a bridge, like many of the digital health technologies.

So, our priority focuses on how we are assuring technology, when it's developed, is more fit for purpose for the intended populations and that the evidence collected reflects those populations. So, a lot of things around clinical studies. But also, what we are doing for having technology that gives people greater access to healthcare, including the availability of technology in the home, such as at-home tests.

One of the underpinnings for our success, of course, is our IT systems. I've spoken with folks before about our big digital transformation effort as we moved to agile platforms and data in the cloud. We've already launched that effort. Coming up is some improvements that we're going to see around adverse event reporting. We've done a lot of changes to facilitate our use within the Center. We're doing more in terms of ultimately what will be available out for the public. We are now streamlining our workflow and leveraging new platform for our work in the Center.

As we move into later this year and next year, the submission tracker we created for 510(k)s is going to get expanded for other submission types. And with, also, a greater ability for accepting more smart regulator templates for submissions, beyond 510(k)s that we created last year.

Before Congress, we have sought funding. I have gone back year after year. Last year, we had our last request in the door. We got part

of it. The final ask, which is about \$2.5 million is on the table for 2023. It's essential dollars for us because we need to be able to not only have those systems, but to be able to upgrade and modify those over time. They really are a critical engine for all the work that we do at the center.

Another important effort we have on the way, of course, I mentioned digital health and the role that it plays in health equity. Of course, last year, we launched our Digital Health Center of Excellence to kind of bring together all the pieces within our Center on digital health. But also, serve as a resource for the rest of the agency and for the public.

Coming up in 2022, we're going to put a bit of a spotlight on some of the regulatory science research opportunities that are out there. We're going to put out a final report on the pre-certification pilot that we've been running, just our lessons learned and where we go from here. We've got an upcoming meeting of our Patient Engagement Advisory Committee to talk about considerations in augmented reality and virtual reality, including in special populations.

We're looking to put out our final guidance on clinical decisions towards software later this year. We're building something called a Digital Health Policy Navigator. So, you can kind of try to figure out if your product is something that's regulated as a medical device or not by the Center and what are the applicable policies.

And then also, putting out a draft guidance on the use of a change control plans for technologies that are enabled with artificial intelligence machine learning, kind of laying out here's what you need to do if you want to have a plan for making changes and how you validate them that we would then review. If we accept it, you can go ahead and make those changes without coming back to the FDA because we know the ability for that machine to occur more quickly and closer to real-time, in some cases, real-time, is important for improving performance and maintaining the safety of the product.

You know, part of this work is also on cybersecurity. In the past, we'd only received about \$500,000 to support medical device cybersecurity. So, just a little bit of a down payment for the work we do. However, we have seen cybersecurity incidents increasing over time. We've already issued about 11 safety communications on device cybersecurity. We're seeing the numbers grow and we're tracking more and more of these. We've put out policy in the past.

Recently, we issued a new updated draft guidance on quality system considerations and content of pre-market submissions that's now out for comment. It's based on our latest learnings in the field.

But we now have, in the 2023 budget, a request for \$5 million, so at least we can have a serviceable program on device cybersecurity because the White House, National Security Council, Department of Homeland Security, **LCCSA**, Department of Justice, FBI, the states, they all look to us for helping to identify and solve cybersecurity problems with medical devices. Of course, we've got to work with developers to make sure that devices are designed to be cybersafe. And then engage in constant monitoring and development solutions. And working with companies and others to roll those out.

So, we've got to have a core capability. If not, these are not just threats to the devices themselves, it's to national security. These are network devices, and your network is only safe as your weakest link.

Along with that, too, we have requests for authorities in cybersecurity. Those are contained, actually, in the PATCH Act, that's been introduced on the House side by Burgess and Craig, and on the Senate by Cassidy and Baldwin. These are absolutely critical authorities, if we're able to ensure that devices are cybersafe. You can never make it absolute. But we can really try to protect against attacks.

Along with this, is our work on supply chain. You know, COVID, we had no base funding for a supply chain program, and we had no authorities. So, we had to cold call over a thousand manufacturing facilities. It made the US fly blind. Now, Congress gave us authorities in the CARES Act to require reporting for what we call critical devices, really those life-sustaining, life-supporting, absolutely essential devices. But it is limited to the pandemic.

So, we do have there, also, a request for expansion of authorities that we should be getting that kind of information outside the pandemic because we deal with device shortages all the time. Doctors and patients don't care what the cause of the shortage is. They just care that they don't have critical medical devices that they need to assure the health and quality of life of patients.

We also need the funding to have a program that is not just reactive to problems, but is proactive and, even better, predictive. That we have the capabilities, the platform, and the ability, the funding to get the data to be able to have that kind of predictive capability and

prevent problems in the first place. Congress gave \$5 million in 2022 out of a \$21.6 million request. So, the rest of that money, the \$16.6 is a budget request for 2023. It is a top priority for the Center. If we don't have those dollars, because we got COVID dollars to start to build the program, but if we don't have the money in our base, we won't be able to maintain it and the US will be right back where it started pre-COVID days.

We're very thankful with the money Congress has given us. It really is a great shot in the arm. But we want to make sure those investments stay.

Along with that is our work for quality, our case for quality and advanced manufacturing. We already have been doing a pilot on something we call the Voluntary Improvement Program. This is leveraging a maturity model approach by independent third parties conducting appraisal to look for companies who are compliant with quality systems on their ability to proactively identify and address safety and quality issues. It's really also to be helpful to companies to help them up their game.

The feedback we've gotten and the results we've seen in our pilot have really been stupendous. Companies cutting the number of defects, reducing adverse event reports, reducing recalls, and increasing productivity. We've built a collaborative community around this. We're also building a new platform for voluntary sharing of information based on a model that's used in the airline industry and really creates a safe space for sharing data that, otherwise, FDA doesn't have access to. And using that for learnings that we can then provide out to industry and others.

And then we'll work on advanced manufacturing. You know, devices are so varied, there's no one-size-fits-all approach. So, one of the activities that we are moving forward towards, and this is also related to supply chain, if you shore up the manufacturing capability, you do have a more resilient supply chain. We will, sort of later this year into next year, be launching a clearing house for advanced manufacturing where we're working with other groups, in public-private partnerships, in identifying potential technologies to use, either from other industries or in Med-tech now, vetting them, identifying pros and cons and putting that information out there. And then working with companies on adopting them.

You'll also see, over the coming year, policy on draft guidance that lays out how we will leverage information from the voluntary

improvement program into our work and ultimately stand that up as a full-fledged program. When we piloted this, for example, with over 600 30-day notices, we found our review times dropped dramatically from about 24.5 days to, I think, a little under 10 days, too. So, lots of value coming out there. More to come this year.

Just some other quick policies to flag for the coming year, the over-the-counter hearing aid rules, statutory deadline, July 17, our goal is to meet it. And then, of course, our new quality system regulation amendments where we would adopt the ISO 13485 standard, really to harmonize with much of the rest of the world. That was out as a proposal in February. Comment period closes in May. And then we're going to move forward expeditiously to finalize that regulation. That's an important one for us.

Finally, let me just touch on MDUFA. Of course, we have taken public comments. We are looking to wrap up and send the final package to Congress by the end of next week. This is a big source of funding for the Center. It will have improved performance goals, if Congress enacts the recommendations. There will be improved performance goals. There's a lot more accountability mechanisms and a lot more reporting. The funding had the base amount of about \$1.784 billion. It has something called add-on payments. If we meet certain goals, we actually will qualify to get additional funding to support even stronger goals. That can go up to about a total of \$1.9 billion over five years.

Sounds like a lot, and it is, but keep in mind if you add up all the funding for the drug user fee programs, it's five times the number for drugs than for devices. So, big increase in user fees for us, but still a big difference between the programs. In that, it will include additional funding for patient engagement work because we continue to push on better ways to include the voices of patients in our work. One of the focuses in MDUFA will be around a greater engagement and clinical studies, more about using technology to be able to expand patient access into studies.

Finally, it will support a pilot for what we call the Total Product Lifecycle, TPLC, Advisory Program or Pilot or TAP. And TAP is really an exciting opportunity. It comes out of our lessons with COVID. I told you about the Pre-EUAs, and are working hand in glove with developers in real or near real time, and how important that was for expediting important technologies coming to market. That's what TAP is about. It really is to spur more rapid development, as well as more rapid and widespread patient access

to safe and effective technology.

So, under this, we are expanding our review capacities so our review teams have the ability to not do the typical stage-gate involvement and pre-submission meetings, but really try to engage, literally, within a day or two, sometimes getting answers that day for more complex things, during a shorter period of time, and adding on a new position, something called the TAP Advisor, who really is the liaison with the company in ways to think strategically of what it really takes to get from that point in earlier development out to the marketplace and to offer it to companies interested. Engagement with interest patient groups, healthcare professionals groups, and payers. So, TAP, very, very exciting opportunity coming out of COVID.

So, with that, I'm going to stop and open it up for your questions.

Wayne: Thank you, Jeff. That was very, very impressive in terms of what you've done and what you're doing, especially in the face of COVID. I think that anybody who listens to that kind of presentation would be very, very impressed by what you and the Center are doing, except for Sen. Burr. You appeared before him this week and he had a number of criticisms. How do you respond after giving – you gave all the numbers and all the challenges. And then you hear from a Senator saying that you're unresponsive and not meeting deadlines, and need to do still more?

Dr. Shuren: I sort of view it more – I've known Sen. Burr for many years. I also dealt with him when he was a Congressman. I really view it more as tough love. He is a fan of the FDA. I think he wants us to be successful. If he sees things not going right, he's going to call us on it. Power to him for that. I, myself, and you heard me in the hearing if folks tuned in, we take accountability if we don't hit the mark. So, that is the case.

Now, I did try to explain, for not meeting some of the MDUFA goals, there are extenuating circumstances here. So, you've got to put it in perspective. I'm good with that. It's basically Congress doing its job.

Wayne: There were also concerns about transparency. Can you address that and what you're doing to be still more transparent? Transparency is a buzzword that's being used throughout the government and in the private sector, as well.

Dr. Shuren: Oh, transparency?

Wayne: Yeah.

Dr. Shuren: Yeah, I can't talk about it [Laughter]. I mentioned a little bit about some of the things we did in COVID to put more information out there. One of the things we really learned from it is people gravitate to that. If we have the capability, we would probably hold these continuous townhall with folks because, particularly in an area where a lot is changing, the opportunity not to just get a piece of paper from them, but to look someone in the eye, hear the latest, and then pose a question and get an answer is a great experience for both of us, because we get to hear what's on people's mind, and people get to hear from us more in real time.

So, we are looking at, with the resources we have, what can we do more about being out there, being transparent in a human way. Then it comes down to information. We are looking at, for example, on our decisions, what additional information can we put out there that we can also do with resources we have? Folks should keep in mind, it's not as if there's a blue button you can hit. It does take time and effort. If we were optimally positioned, we'd put out everything we're allowed to put out. I'll put it that way. You know there are things we can't put out there.

But we are looking for better ways of doing it. In our strategic priorities, in part about health equity, for example, is how are we doing a better job of putting out information that people need, where they need it, in the format they need it, and conveyed in the way that's most useful to them. So, that is part of that strategic priority on advancing health equity. So, more to come. I'd say stay tuned.

Wayne: Nancy?

Nancy: Thanks, Wayne. So, Jeff, when I listen to all the activities that you guys are doing, it's just amazing. 107 townhall meetings, 400 test and collection kits approved. How is your staff responding to all this change and all this dynamics going on? I would think that from a leadership level, you can put things in place, but how are the review divisions responding to this and what's the feeling internally to CDRH?

Dr. Shuren: Well, first off, was just the response from the staff as we were rolling into this, people just kept putting their hands up, "What can I do? I'll take that." It wasn't the, "Oh, my God, we've got a lot more work."

It is, "We've got to do it and I want to do it." It was more of saying no to people than having to push anybody. I was just blown away by it. They were always lean forward, but they went above and beyond.

The toll, though, has been high. There are people who burned out along the way. We took a lot of effort to try to reduce that. As we're shifting people around, moving things around, we built up wellness programs, a lot of interventions from either other staff or from managers. Even set up a virtual wellness center, too, and we have lots of programs and a lot of interest in it. People keep signing up for the work that we do. Trying to, even at a local level, keep people connected and engage. It's a lot harder when we're in this virtual environment, particularly for people who have less of a support system around them. Just how we handle that.

I'm actually amazed that we're in the shape we're in because it's a lot better than I thought. But can't take eyes off the fact that there's still lots of work and we don't want people to burn out. We want them to continue on and have that good work/life balance. And that's what we're working towards.

Nancy:

That's great. I'm sure they appreciate all the extra work on that. Tell me a little bit, FDA's view of certain regulatory frameworks seems to be shifting around IBDs, around robotics, AI. Can you explain the process, is this because of COVID, things are shifting? Or that you're knowing more about the process? What's going on with regulatory frameworks?

Dr. Shuren:

This actually predates COVID. Because the regulatory frameworks that we deal with, the essence of them started back in 1976 with the medical device menus. And at that time, Congress was thinking about different kinds of technology than what we have on the marketplace today. The paradigms we have today don't necessarily fit well for a lot of technologies, particularly things that are software based. No one was thinking about software in 1976, I can tell you that much.

But that's the world of today. And there are just different innovation cycles, so you need different frameworks. In COVID, of course, we could take advantage of our Emergency Use Authorization authority. It gave us so much flexibility to adapt and adjust, tailored to the technology, and then make changes as appropriate, as circumstances change. We don't have that flexibility in peacetime. I've talked for a number of years beforehand, and even coming out

of COVID even stronger, we need to have agile regulation.

This isn't about changing the US standard to market. It's about greater flexibility about how you demonstrate you meet that standard. If we have that flexibility, we could build voluntary alternative pathways and let the companies choose. You can choose either one, you can choose both. You go down one, you don't like it, flip to the other. But if we can build something better, then people will come. It will better support assuring that devices are safe and effective, but facilitating the critical innovation that we need.

Nancy: But is that something that CDRH can do, or FDA can do on its own? Or is there some requirement that you have some Congressional authority to change this approach?

Dr. Shuren: It would require a change in the law.

Nancy: Okay. Interesting. So, tell me, is it just a – kind of look into your crystal ball, I always love to know what the next technology that you guys are starting to prepare for, what that might be. You've mentioned it might be something like AI or it might be virtual reality. But what is that next technology that you think you're going to need additional resources to get out in front of it to know how to regulate it?

Dr. Shuren: Let me give you a laundry list of stuff. You hit some of them. Robotics, certainly there. You're seeing more on genomics, probiotics for detection of various pathological conditions, more of the closed loop organs coming out, more miniaturization, even greater non-invasive endoscopic surgery will be out.

But two things to flag is technology that really is fit for the home and that consumers can use. And simplicity, making technology that's simple enough is really hard to do. Even the stuff we have today is too complex for people. We've got to beat that. So, we're talking about very different kinds of technology. And for tests, we're going to be looking at breath tests. Blowing into the tube and know what's going on. Hopefully, we'll conquer light-based tests, too.

The second is I kind of think about symbiosis between humans and technology. We really think about that interface more physically, push buttons. But let's be honest, technology is interfacing with how we think. People don't realize how much has changed in the way they think, the way they have a tension or scan because of technology. Increasingly, technology is going to be an inherent part

of our life to understand what's going on in our bodies and helping to inform the decisions we make every day. If we don't do this the right way, we're going to mess ourselves up in really funky ways. That, to me, is really a very exciting area, but one if we're not well prepared for, really bad stuff is going to happen. And if we do it right, really good stuff is going to come our way.

Nancy: One thing that you had mentioned is that advancing equity is one of your three big pillar goals. When you think about some of the equity, it might be something in rural maternal health or something like that, are there any positive ways that CDRH can help move products like that through quicker just because it's meeting that equity requirement? Or is it more just something where someone's checking a box and making sure there's equitable access? You wouldn't want a new pathway but is there some prioritization that will be put on products that assist with the equity issue?

Dr. Shuren: Well certainly, when we think about technology, think about for breakthrough, if we now have technology that's going to either make it easier for patients to be able to leverage, get that access, or technology that's tailored to populations that you didn't have before, then those would be good candidates, potentially, for breakthrough or safer technologies programs. And those get their own sort of extra tender loving care, if you will. Technologies that are in those programs would also be candidates for the new TAP pilot.

Wayne: Let me shift gears a bit. Jeff, you've been, within the agency, a real pioneer in patient programs. I remember meeting with you, literally, 10 years ago and discussing patient outreach. And you jumped right on it and said, "Yes, we have to do more in that area." Are the present patient outreach programs and the input that you get from patients working the way you would like? And if not, how would you want to amend what the outside community is doing in dealing with the FDA from a patient standpoint?

Dr. Shuren: Yeah. I think we have a lot of stuff that's working. But I'm never satisfied. So, I always believe there's more we can do, there's better we can do. I think with the user fee funding that we're going to get, we're going to have more capability in that space. So, one of the things, it's newer, is around collaborative communities where you need representation from the key stakeholders groups. And the community are coming together to achieve shared outcomes, solve shared problems. And we don't run it. FDA doesn't run it. We just have a seat at the table, we're a member.

One of the requirements for us to participate in a community is that patients have a seat at the table. Not the you can opine on something developed from the community, it's no, you are part of the community, you get a say in this. To us, this is the way of doing business, if you will. We are looking to take learnings out of that to then see how we can then better pull in patients into the work that we do. Beyond what folks talk about greater access to participate in a clinical trial, for example. It's really weighing in other ways.

I think TAP is going to be part of that, too, because it is a chance where we're going to try to marry up with startups. Can we get you engaged with the patient communities early on in your development of the technology? So, it truly is fit for purpose. We're going to be creating forums with these different stakeholder communities, including patients, so that the voice of patients is part of designing, developing a technology from the very, very beginning. So, if it's then trying to be safe and effective, you know from patients and providers, thumbs up, we want to use this. Because it's already been made with us in mind.

Wayne:

Again, shifting gears a little bit. The Aduhelm situation in CDRH has obviously raised a lot of issues. One is the clinical information needed in order to approve a product, especially a long-term product. Secondly, the long-term studies that are needed, Phase 4 studies. And third, of course, the CMS decision to limit reimbursement. How does that affect you, those kinds of issues? Especially, CMS' intervention here to make a decision not to reimburse for all patients who receive an FDA approved product?

Dr. Shuren:

I can't comment, you know, on CMS' decision making. They have a different role, and they have a different standard that they have to apply. That said, we have a great working relationship with CMS. We engage with them all the time on technology, too. We've got a forum in the Medical Device and Innovation Consortium where we're working on things related to CMS.

But that said, the broader issue around payers, too, how do you bridge some of these gaps in what we deal with on technology. TAP is one of those efforts. I mentioned the forums. One of the forums will be for payers. We've already been in discussions with folks. It starts with, can you build a better understanding of where we each come from? And the evidence is important in what we rely on. A lot of times, I found with payers, because it's very clinically focused and there's a lot of clinicians, the non-clinical data can get discounted. But for technology, that non-clinical data is so

informative that you can't do that. You're missing a key piece. So, part of this will be relationship building, for starters. If you get to that point in trust, and we've done this in so many other places, I think there's a chance to really build a much more streamlined pathway, if you will, from FDA approval to payer coverage and reimbursement. And it starts, ultimately then, with conversations with all the parties early on in development, not after something goes over the FDA wall out into the world for then payers to make decisions.

Wayne: Nancy?

Nancy: We only have a couple more minutes. I'll ask one last one, and then, Wayne, I'll let you do the wrap-up questions. So, Jeff, I don't want to put you too much on the spot. One of the things the Alliance is very opposed to is unfunded mandates. We don't weigh in on user fee agreements and that kind of thing. Are there any major unfunded mandate bills coming through that you guys are a little worried about? That might put on a lot of required activities that you guys wouldn't have resources to do?

Dr. Shuren: I'll sort of spin it around, where are the places where we need more money. I'd say there isn't any part of CDRH that doesn't need more money. I really don't mean it as tin cupping. I've kind of shown you where our workload is, how many people we have, and the kind of discrepancies in funding between us and – not a complaint, other programs in the agency. We've got to deal with all that.

But the place, because user fees are so focused on the pre-market side, what gets short shrift is, of course, post-market. That's the place where we'd love to – We've gotten some money from Congress, thank you Congress. We're never going to be upset if we score more money. Obviously, the priority right now is the supply chain, got to get the funding. Cybersecurity, and let's finish off having the additional dollars for digital transformation. I'll say this for Congress, really appreciate the money we've gotten. Also understand, they got a lot of hungry mouths to feed. So, hard choices for folks to make.

Nancy: Thanks. Wayne?

Wayne: One final question. That is the last two years have been difficult for everybody, except for the obvious changes that have occurred, such as the fact that you don't have to wear a tie anymore and you can wear your FDA shirt there. How has the COVID experience

changed the way that you think about your job and about the way that you run CDRH?

Dr. Shuren: First, I'll say, and I've said before, amazed for the folks stepping up to the plate and that lean forward mindset. But it has informed our strategic priorities for 2022 to 2025. A lot of that effort on enhancing the modern, diverse workforce, that resilient, agile organization comes out of a lot of the learnings from COVID. You'll see that in changes in how we run the Center.

I think, second, I know we all talk about we don't have to wear the tie in this now hybrid environment. I do think it's also sort of changed how we think about designing a workplace. In the past, the employer decides the workplace and then tells employees this is what you've got to do, here's what you've got to do. Today's world, the workplace is and should be designed by the employer and the employees. It's now a collaborative effort. It's just a different place. And you'll see this now, priorities, that a lot of this work, as we make changes in the workplace, are collaborative across the entire Center. It is not from leadership saying this is how things are going to be.

Lastly, you've got to trust your people. And you've got to trust them to do the right things and to do things well. I think COVID has shown, we know this, to be successful, particularly in a setting like that, you've got to constantly try new things. We were always doing something new. We had so many firsts during COVID. We learned from them, we adapted, and were not always right. So, I think the other part of it, you've got to learn to trust your people to be wrong. Because if they can't be, they can never be better. You'll see that in some of the things that are coming out now in our priorities and have even found their way into the user fee reauthorization.

Wayne: Let's wrap up here. On behalf of the Alliance, and I think the entire community, let me not only thank you for participating today and for so articulately presenting CDRH and your challenges, but generally for your leadership at CDRH for the last dozen years or so. It's been a transformation in terms of not only the marketplace but also in terms of the way that CDRH has to react. The world is changing so quickly and CDRH has kept up with it. I think a lot of that falls on your halo, so to speak, that you brought to CDRH. So, thank you for that leadership and thank you for participating today.

Let me sign off for the Alliance, remind you that Dr. Marks will do the next video. He'll be talking, I think, about vaccines, maybe not. We'll see what else he has in mind. Let me sign off now on behalf

of the Alliance. Thanks all for participating.

Nancy: Thank you, Jeff.

Dr. Shuren: Thank you, everyone.

[End of Audio]

Duration: 60 minutes