

Ron: Okay. So, good morning everybody. I'm Ron Bartek, President of the Alliance for a Stronger FDA, and I'm joined this morning by Stephen Grossman, the Alliance's Executive Director, and two of our Alliance board members. The first is Nancy Myers, Founder, and CEO of Catalyst Healthcare Consulting, and leading expert in regulatory affairs. Nancy also served in a number of roles at the FDA, including that of Special Assistant, and Senior Strategic Advisor in the Office of the Commissioner. She's also a founding board member, and past President of the Alliance for a Stronger FDA.

The other board member is Emily Holubowich, who is currently the Vice President for Federal Advocacy at the American Heart Association. Emily has more than 20 years of experience in public health, fiscal policy, and government relations, and is a highly sought-after lecturer, and advisor in these arenas. We also would like to welcome Alliance members, the media, and a number of our guests to today's Alliance webinar with Dr. Shuren. First, a very quick word about the Alliance for a Stronger FDA. We are a multistakeholder coalition that advocates for increased appropriated resources for the FDA.

We've 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 the other components of the FDA mission. Our members include consumer, and patient groups, research advocates, health professional societies, trade groups, and industry partners.

We have about 150 members, and we would welcome more to further strengthen our advocacy, and educational efforts. In regard to admin, and logistics for this webinar, Dr. Shuren has agreed to give an opening presentation, followed by ample time for some of your questions. You may submit your questions at any time during the webinar by clicking the Q&A button at the bottom of your screen.

Before introducing Dr. Shuren, we'd like to acknowledge the tremendous help we received in arranging this webinar with – from Lindsay Lloyd, of the CDRH staff. I now have the privilege, and honor of introducing Dr. Jeffrey E. Shuren, the Director of the FDA Center for devices, and radiological health since January 2010. Dr. Shuren has deep, and broad leadership experience in the health policy, and regulatory community.

Beginning in 1998, he has held various policy, and planning positions within FDA, including acting Deputy Commissioner for Policy Planning, and Budget, Associate Commissioner for Policy Planning, Special Counsel to the Principal Deputy Commissioner, Assistance Commissioner for Policy, and Medical Officer in the Office of Policy. From 1999 to 2000, Dr. Shuren served as a detailee on Senator Edward Kennedy's staff, on the Senate Health, Education, Labor, and Pensions Committee.

For five years, he was a staff volunteer in the NIH's cognitive neuroscience section where he supervised, and designed clinical studies on human reasoning. Dr. Shuren also served at the Centers for Medicare, and Medicaid Services, as Director of the Division of Items, and Devices, Coverage, and Analysis Group where he oversaw the development of Medicare National Coverage determinations for drugs, biologics, and non-implantable devices. Dr. Shuren, thank you very much, indeed, for all of your service, and leadership to date, and for agreeing to speak with us today. The floor is yours.

Dr. Jeff Shuren:

Thank you, Ron. It's always a pleasure to be talking to this group, so thank you for the opportunity. So, I got asked if I would answer a series of questions that the Alliance put together. So, I was given 11 questions, and asked if I would go through the questions, and then the answers. So, I appreciate that resources are tough for everyone. They're tough for the FDA. They're tough for the Alliance. I appreciate the fact there are limited resources for moderators now. Now, you have your invited guests doing the moderating, too. So, I love the creativity. So, I'm gonna ask myself a bunch of questions. Let's do it.

So, the first question – There are 11 questions that were sent to me. The first question is the following: “Jeff, the last 18 months have been a tale of two missions CDRH. Can you provide a brief overview of CDRH's successes, and challenges in each work stream?” So, “Thank you, Jeff.” So, the two missions – we're really talking about COVID work, and non-COVID work. You know, for COVID, big successes, I'd say, are that we have authorized, either through emergency use authorization, or our traditional pathways, over 1,500 medical devices for COVID. Just a phenomenal number.

And, we've responded to – or, prevented, now – over two dozen device, or device component shortages. And, we've provided an unprecedented level of engagement with developers, and other stakeholders. For, example, we offer something called a Pre-

Emergency Use Authorization – Pre-EUA – and this allows a developer to work with our technical experts in real time, answering their questions, proactively problem-solving, even submitting data on a rolling basis. We started a weekly townhall for test developers in the first week of March 2020. We’ve held that pretty much every week to give them updates, answer questions.

We have a 1-800 hotline that we staff 24/7 for many weeks, to answer anybody’s questions around COVID, and medical devices. On the big challenges side, though, it’s a massive workload. So, during this time, we have received over 7,000 EUA requests, and Pre-EUA requests. Just a massive number. And, this is on top of roughly about 25,000 over the whole course for the pandemic. About 25,000 traditional pre-market submissions on top of it. So, a massive, massive workload. No great surprise with that, and really insufficient resources, it put tremendous strain on the system. And, it’s really shown the limitations in the system.

There’s not a lot of give, but the way we got so much done is because our folks gave all they had, and more to get the job done. But, they have been burned out as a result, and there have been other ripple effects I’ll talk about in a minute. The other thing is the limitations in authorities, particularly around shortages. I’d say the insufficient resources in the authorities. If we don’t address these going forward, then history is going to repeat itself. And, that is something we are working with congress on.

The other mission, non-COVID. So, frankly, the big success is just the very fact that we kept the ship afloat, and we kept the team together. We’ve been continuing to take steps to meet our MDUFA commitments as best as we can, and we’re anticipating we’ll probably fall off some of those goals, but we’ve continued to put out deliverables under that program. We’ve continued to advance our digital health, patient-engagement, real world evidence missions. We’ve dealt with important device safety quality issues. Big challenge is, though, I mentioned the tremendous workload from COVID.

The amount of effort we put into this, it’s the equivalent of over 330 people working fulltime for an entire year just on COVID. And, this is in a center that has about 1,900 people. So, that’s a big impact. And, as a result, that’s lead to backlogs, in some cases for COVID-related submissions – as the numbers just bloomed. But, also on non-COVID submissions, as we had to shift our resources to make the pandemic the top priority. And, we are currently

digging out of that, and getting things back on track. But, again, big ripple effects.

And the other big challenge has been the tremendous stress on my CDRH colleagues from the workload, from the loss of work-related social support, and the kinds of homelife stress that everyone has had to deal with.

Second question: “So, what lessons did you learn from COVID-19 that will influence CDRH in the future?” Well, there have been a lot of them, and ultimately what sticks, we will have to see. But, let me mention, too, with the caveat that, to me, a great tragedy out of this tragedy would be if we did not learn from the lessons that came across our way. So, let me flag two that I think were critically important. They are regulatory flexibility, and engagement. And these two together were really the drivers for our ability to facilitate the authorization of those over 1,500 medical devices for COVID. They were the secret sauce.

So, by regulatory flexibility, after the public health emergency was declared, we were able to leverage our emergency use authorization abilities. It gives us tremendous flexibility, and better tailoring our evidentiary, and other expectations to the technology, and then quickly adapt as circumstances change. That allowed us to facilitate, for example, tests being developed, validated, authorized, even deployed, within a few weeks rather than traditional months, or a year, or longer. I think that kind of flexibility is something that we need all the time. Not just in the setting of a public health emergency.

I’m not talking about changing the US standard of reasonable assurance of safety, and effectiveness. That stays. What I am talking about is how you meet that standard that we should have more flexibility in crafting those regulatory pathways to meet that standard. The reason being, we deal with a device regulatory framework that is now essentially 45 years old. It was designed for literally my grandmother’s technology. It doesn’t fit for many of the technologies today, like digital health. The stage gate approach that we have doesn’t work for those technologies, and quite frankly, they even put patients at risk.

We need a modern framework for modern technologies. And the hallmark is this idea of flexibility – regulatory flexibility. The second was engagement. You know, in COVID, I mentioned Pre-E ways, and all the other things we did to work with developers, like I said, essentially in real, or near-real time. Now, we are not

resourced to do that routinely. It's unsustainable. But, the impact has been enormous. And, when I talk to companies who are able to engage with us that way, they all say the same thing. "We would like to never have to go back to the old way." So, we could do that if we had the resources to make it happen.

I think it's a gamechanger, and it's why we put a proposal on the table in our MDUFA authorization negotiations. That would address this very issue in structure in a way that would help advance ultimately what has to be high-quality safe, and effective devices getting to the marketplace in a far more effective, and efficient manner. We call that "TPLC" – T-P-L-C – The Total Product Life Cycle advisory program. Those are the two big lessons learned that I'd love to see moving forward.

Third question: "So, when you last spoke to the alliance in December 2020, you predicted that 2021 would involve a reset in the center. What did you mean, and how is it going?" So, what I was referring to is, again, this tsunami that hit us on COVID, and caused us to really change our focus, and lead to backlog, as I mentioned, with a number of submissions, and also a lot of other priority activities. For example, the lawmaking we were gonna put out on over-the-counter hearing aids, of course, got delayed because of the resources we put into COVID.

So, we kind of view 2021 as our getting back to normal, if you will. Resetting things, moving forward on the non-COVID submissions that we had to put on hold, moving forward on other priority areas to kind of get the ship back to where we were beforehand. And, I think we'll have most of that accomplished in 2021. There are some pockets that it's gonna bleed into 2022. The other is that we always have strategic priorities for the center. We laid out three for 2018-2020 with the goal of, at that point, they really be incorporated into the DNA of the center, and we would now build on that with new strategic priorities.

We made a conscience decision, in the light of the pandemic, "Let's not put new things on our staff. Instead, let's stay the course, and keep those priorities." So, they'll continue into 2021, and then take the advantage of leveraging what we learn out of the pandemic as lessons learned, as well as the fact that we're in the midst of MDUFA negotiations, and depending upon where we end up, we may want to incorporate that – lessons learned out of COVID – into a new set of strategic priorities for the center that we would roll out in the beginning of 2022. So, again, reset on a variety of levels, and we are moving forward on that course.

All right, Question No. 4: “Has CDRH’s budget kept up with the demands placed on it? What new demands is CDRH facing in 2021, and 2022?” So, the real answer on the budget, as it kept up with demands, the simple answer is, “No.” We still have great needs, and they are much worse with the pandemic, which again showed that we really have very little give in our capacity. Now, for roughly a decade, we hadn’t seen any kind of meaningful increases in our appropriations at CDRH. And, when you combine that with the fact that the cost of things continues to go up, just from inflation alone, the purchasing power of every dollar we have goes down. So, a flat budget, in reality, means a continuing budget cut.

And, we finally – starting in 2019 – began to get some targeted increases in our funding from congress, and I have to say a very big thank you to congress, and particularly our appropriators. Those dollars have been critically important, and they are making a difference. So, again, we are in areas like post-market safety, and surveillance. But, we are a resource-strapped center. When you think of our portfolio that we’re responsible for roughly over 230,000 different types of medical devices, you know? And, over 20,000 different manufacturers, and over that, for manufacturing facilities worldwide, it is a huge responsibility.

The devices, you know, they’re not cookie cutter. They are so varied and can be so complex. We need a variety of expertise. And, for us, too, we get – mostly, we depend upon appropriated dollars. Only about 35% of our program is supported by user fees, and the scope of those user fees that we can spend it on in MDUFA are much more narrow than you see on the drugs side in PDUFA. For example, really excluding post-market safety. And, at the same time, you know, compare us to the user fees we get, which for the drug program is something like, I think, eight times, or more the amount that we were seeing.

Compare CDER to us. CDER is about three times the number of people we have, but I would not say that they have any more work than we do, and again the things we deal with are so different, and complex. So, when you put that together, again, the resources are still tough. As far as new demands go, they include being able to address the pandemic, and try to get back to the new normal. Quite frankly, we’re not well-positioned to meet the current needs that we see today, let alone well-positioned to address the technologies that we know will be coming to us soon, or even the distance future.

And, of course, quite frankly, many in the public, some in industry, some elsewhere – are just used to us being underfunded, and somehow always pulling off a miracle, if you will. I will tell you that after having gone through the pandemic, and where we are, there are essentially no more rabbit to pull from our hat. That's the bottom line.

Question 5: “So, building on that, what are CDRH’s long-term budget priorities? How do these priorities align with where you think the med/tech field will be in five years?” So, here are our priorities: First off, we have to be at the leading edge of science, and medicine. If we are not best in class, US patients, and consumers will not have first in class healthcare. Now, this may not be exciting, like some big initiative, but it is foundational. We have to have the people. We’ve gotta have the experts. We have to have a deep enough bench, and they have to have the ability to continue to stay on the leading edge.

We have to have enough resources to truly get the job done and be prepared for what’s coming to us next. Often, when things are challenging with the program, and it’s hard for us to get there because resources, the kneejerk reaction is to move to remove our oversight, and authorities, rather than to add to them, and those resources as would typically occur if I might deal with a drug-related issue. And, from a public health perspective, that is troubling.

Issue No. 2 with the budget: We need to establish a permanent device shortages program. Believe it or not, we have never received dedicated funds for a device shortages program. That has obviously important ramifications as we found in the context for the pandemic. So, as a result, when we hit the pandemic in the beginning, we had to pull people to do work on shortages. We essentially had to reassign fulltime, or parttime, roughly 130 people to do that. So, that is No. 2. No. 3: Cybersecurity, and Digital Health. And, these are really national security issues, and for digital health, it is at the forefront of healthcare.

You know that healthcare is increasingly moving to the home setting. COVID put that on steroids, and the lynchpin to care at home – and, by “home” means at home, at work, at play – is digital health technologies. Without them, you don’t have care in the home setting. We’re not just simply talking about telemedicine. That simple platform isn’t a device, but all the things that then, for diagnosis, and treatment, and prevention – those are medical

technology.

And, quite frankly, that move to that homebased care, and using digital health technologies is gonna also be essential if we are gonna provide equitable care in this country, particularly to disadvantaged populations, including rural communities who don't have the same access to the healthcare system, or healthcare facilities. Of course, too, the great things that we are seeing as we move forward in med/tech field – we have artificial intelligence, and increasingly, just about every technology is gonna have AI build into it. Even moving to the world of cyberonics, and increasingly where technology, and people are gonna be involved in a symbiotic relationship. And, we have to be prepared for that.

Then, fourth and last, I'll flag post-market safety, and quality of medical devices. Again, an area we have gotten some dollars for, but there's so much more we need to really serve the American public. All right, Question 6: "Is CDRH staffed at a level that allows you to carry out your critical public health mission? What types of staff are you currently hiring, and your priority, and what do you need to accelerate your hiring process?" So, first off, are we staffed at the level we need? No. And, I don't think we're really close to the staffing we truly need to carry out our critical public health mission.

As to hiring, we've hired almost all of our new folks that we've committed to do so under MDUFA. And, we really don't have a lot of other money to be hiring other kinds of folks, although we are looking at using, if you will, certain dollars – carryover dollars – in user fees, for some of that. And, in terms of the type of staff, it's, for the most part, been the type of staff we have today, and mostly then for backfills, or to fill out our hiring commitments. However, we do have some proposals in play for MDUFA reauthorization, and if they come to pass, like in the case of TAP, we are gonna be talking about some new kinds of people at this center.

To accelerate hiring, quite frankly, the big thing is we need to be able to pay more. We have to be competitive with the marketplace. We continue to lose good people to the private sector. We even lose people within the agency to those who might be able to pay more and offer better opportunities. So, we'd like to see the chance to make better use of CURES pay, and an expanded scope of CURES, quite frankly. Personally, it should be the pay scale for all positions across the FDA, and of course, we would need the funding to be able to pay people at those levels. I think we have to offer remote work, and lots of telework.

Increasingly, folks might work at the FDA, but are not gonna be in the DC area. And, we lose good people. And, then, we have to have the capacity that people have to take the time for professional development. That is important for public health, so our folks stay on the leading edge of science, and quite frankly, that investment in them – in the opportunities for professional development – makes the job more attractive. But, too often, because we don't have the capacity, our people feel that they are chained to the desk. They don't have the time to take advantage of the professional development opportunities we already offer to them.

So, the job has to be attractive. It has to be fulfilling, and it's gotta provide, too, a good work/life balance. If we continue to treat people as if they're in a sweatshop, quite frankly, it will continue to be difficult to get the best, and brightest. And, then we also need to invest more in the basic infrastructure to recruit, and to hire people. That includes a build out more of that capability within in CDRH.

All right, Question 7: "What's your vision for the digital health center of excellence? What are the emerging issues, and some of the long-term challenges?" Well, the vision is the following: That we advance, and accelerate the responsible development, and availability of innovative, high-quality safe, and effective digital health medical technologies. And, the role of this center of excellence is to collaborate, communicate, and innovate.

To build out of collaborations with external stakeholders, but also internally in FDA, to serve as a resource on digital health, digital health technologies, again, from the outside, and internally for our own folks that we start having, if you will, the black belts in digital health technologies – and really these medical technologies – for working with our other staff, and overseeing the training, and advancement of policies, but also be available as a resource within the FDA for other components.

And, then, innovate. That these are the folks who are really taking the leap looking at more modern regulatory frameworks, better tailored to digital health technology, that regulatory flexibility I talked about that ultimately would require congress to make it happen. For emerging issues, I mentioned artificial intelligence in everything. And, there are lots of issues, and challenges around AI, and how you assure that technology is safe, and effective.

Typically, when you have machine learning built into it, and that

technology is continuing to adapt, and evolve as it continues to learn, how do we do that in a way that is responsible, that assures it's still a safe, and effective device, and you have appropriate patient safeguards at the same time that you also have timely patient access. Because, otherwise, we could become a barrier to ultimately where healthcare is going, and where it needs to go – that delivery of care in the home.

Other emerging issues: Interoperability – the interconnectedness in the world. Of course, related to it, cybersecurity. The more that technologies talk to one another, and are connected in networks, the greater the risk for, and the impact of cybersecurity threats. Long-term challenges, go to cybersecurity. They go to the outdated regulatory framework, and lastly, what I call “Cognitive Human Impactors.” You know, often you design a technology, and you think about that human to machine interface from a physical standpoint. The button is in the right place, so I don’t turn the machine off, if you will, when instead I’m trying to program it for something.

And, that’s why your phone is designed the way it is. But, we don’t often think about the impact on people cognitively. And, as technology increasingly is influencing how we think, how we behave, and ultimately how we live, then we have to think about, and we have to assess how it changes us, and assure that when it does, it changes us for the better, and not for the worse. And, there’s a whole science behind that.

No. 8: “How does CDRH work to address supply chain shortages.” Well, for starters, you want to be able to identify potential shortages, and head them off at the pass. And, critical to that, is you have to have good intelligence on an ongoing basis of what is going on in the marketplace, in the supply chain. Unfortunately, today, we do not have that capability. So, what we have to do for shortages has done great difficulty. I mentioned before we never had dedicated funding for a permanent by shortages program. So, we had pull people.

We did – and thank you to congress – get some dollars in supplementals in the American rescue plan that at least we can get a foundation going, but we would need money in our base to really build out and maintain that effort. And, as a result, and secondly, we didn’t have authority. There was no requirement for folks to report information to us about potential shortages, let alone for the volume of their production. And, so, back in January, we had to start reaching out to manufacturing facilities. We had to contact

over 1,000 manufacturing facilities across 12 countries in literally weeks. And, our response rate was, on average, about a third because there was no requirement.

And, often, our responses were incomplete. Now, during COVID, congress did give us some authority under the CARES act, and thank you for that, that required some reporting, but it's only after the public health emergency is declared. So, it's limited in what we get, it's too little, and it starts too late. We really can't do this stuff after the fact, and again, we're working with congress on that. And, so, what we did in the case of COVID – we've done in other cases – first of all, can we find alternatives to what's in short supply? Can we authorize new products?

So, in the case of respirators in the beginning, massive shortages as world demand for them came on – in China, nationalize many of our facilities over there, and kind of took the supply. To great need, we had to deal with CDC, and putting out conservation strategies. What do you use as an alternative? We were then authorizing through EUA more product, working with the Department of Defense, and HHS, and expanding the industrial base. Similar things with tests, as we looked, also for alternative, like on testing supplies. We even served as a clearing house for laboratories.

We basically said, “Look, if you try an alternative – an alternative reagent, or platform for a test beyond what it's authorized for – because we don't know if this will work – if you look at it, you validate it looks good – if you're willing to share the data with us, and we think it looks good, we're just gonna go out, and tell the lab community, put it on our website. We'll talk about it in those weekly townhalls. You know, “This alternative looks good. You can start using it. Let's not hold up. Let's get it going.” All those things we've done, we even helped facilitate with other partners inner lifts, and swabs out of Europe, and pipettes for the use of tests.

Question 9: “What is the cybersecurity threat to medical devices, and how is CDRH addressing it?” Well, first off, cybersecurity is crucial for medical device safety, and effectiveness. And, you think about it, though, a little bit differently than you think about safety. So, it is a somewhat different approach, but you gotta bake it in. I'd say the need for effective cybersecurity, and cybersecurity hygiene has become increasingly more important as we see more, and more wireless internet network connected devices out there in the marketplace, portable media, and of course, the frequent use of

electronic exchange of medical device related health information. So, the need is great.

Real threats there. Often, it's from bad actors. So, ransomware. We've all seen a number of attacks. Often times, it may be to a healthcare facility, or healthcare system, and even if it's not to the device, the device is networked. So, it can impact the technology. Sometimes it's on components, or operating systems that are used in medical devices. And, it may not be an attack. It may be a vulnerability that's identified, but if you don't address it, then you have a backdoor way for bad actors to take advantage. So, it's critically important that device developers really build in cybersecurity into the design. You can't patch it on later.

So it is important folks are following the policies out there that are in guidance on pre-market, and on post-market. In fact, we are working on an update to the pre-market as we continue to learn things. Other big challenge: Legacy technology, legacy software that are many years old, when developers were not thinking about cybersecurity. You can think about those technologies that hang around for many years, big capital investments may have legacy software. We work with developers, "If you can't patch, can you swap it out?" And, of course, encouraging to move to more modern technologies.

Along in our work, a lot of it is done collaboratively with Department of Homeland Security, and others. We regularly partner with Department of Homeland Security's cybersecurity, and infrastructure security agencies – CISA. They work with us hand in glove. We work with them hand in glove. We coordinate disclosures when we learn about a new vulnerability that can affect the safety, and effectiveness of medical devices. We also partner with NIST in responding to the President's executive order on how to lean forward to proactively improve the nation's cybersecurity.

And then, we are seeking new authorities for things like a Software Bill of Material. If you make a medical device, often times, if you have software, you're not making all the software yourself. You're actually using software from other vendors. So, if there's a problem with another vendor's software, that can impact your device. But, if your users don't know that, then when they learn a problem with another software, and they don't know it's in yours, they can't take appropriate step to assure that their system is cybersecure safe. And, so, it's putting out there, as a developer, "Here's the software that we use in our technology."

Question 10: “How has CDRH utilized new regulatory science tools, like real world evidence, AI, and blockchain?” Well, you can think about we’re a user in two ways. So, one, those kind of regulatory science tools, again, used in the support of decision-making that we do as a center. So, those tools that may be used by product developers, or by others. And, we’re engaged in a lot of efforts to both develop new tools, as well as to qualify them. We have a whole program for essentially assessing, and how you assess these tools to assure that they are regulatory, that the results that come out of them we can rely on.

And, for many years, we have focused on, “How do we have regulatory science tools that meet unmet needs?” We don’t have them out there to begin with, or better tools. Those are more robust. They’re more efficient. That was one of the underpinnings for the development of a public/private partnership called The Medical Device Innovation Consortium, which was the first public/private partnership devoted to advancing medical device regulatory science, and developing out those tools. We have our own laboratories – our Office of Science and Engineering laboratories.

We engage in a variety of regulatory science tool development. We recently put out a catalog of many of these tools that can be used, and then, of course, there are many others that are really fit for purpose if they’ve already been qualified. We have, of course, at the center, our Office of Clinical Evidence and Analysis. So, CEA is engaged in methods development for use of real-world evidence. And, we have our Digital Health Center of Excellence, also focused on tools to be used in assessing for AI. And, then we’re also – our patient engagement program has been facilitating the development of tools like patient reported outcomes, and patient preference information studies.

But, we’re also a user of some of these – you can think about tools from advancing our own work. So, we, for example, have been developing AI tools as part of our digital transformation initiative for evaluating, better identifying safety signals that maybe contain information that we have, like our medical device reports, our recall information will continue to build out those capabilities.

Last question that I was given here is: “When FDA and the Alliance say the proposed investment technology, and data monetization will be transformative, we find that a lot of people have trouble visualizing what that means. Can you provide some examples of specific data, and technology investments that you

would consider transformative? How would consumers, and patients benefit?”

And, first, let me say how folks would benefit is patients, consumers, then, by having a more effective, and efficient FDA, including in the detection, and resolution of new safety signals – and, by that I mean access to better, and more useful information like medical device adverse event, and malfunction data, then that is tremendous benefit to patients, and consumers who have a more effective FDA protecting them, and assuring them we get important technologies to the marketplace in a timely manner, that they have better information to make better informed decisions.

In terms of what we’re talking about, let me see if I can share with you these two slides. Oh, “Host has disabled participant screen sharing.” Is there any way I could share something? If not, I will just talk to it. But, you know a picture is worth a thousand words. All right. Well, let’s assume not for the moment. So, what I was going to show you is the world we’re kind of dealing with on our IT side. It essentially looks like it threw spaghetti at the wall. We have a little over 30 different IT systems. Many of them are proprietary. They’re siloed, and they’re old. They’re legacy. And, so they’re clunkers to use. They’re not connected.

Think about our pre-market reviewers. They go out over eight, or more different systems over the course of day to do their work. Very inefficient to do that. Hard to connect the data so we can’t make optimal use of it, and to keep systems going – again, they’re dying – you not only have to do basic maintenance, but you also have to do upgrades, and then we have to keep making modifications, so it has the capabilities we need to get our work done. And, several years ago – really, starting in 2015, we recognized we had to make a change.

We started something we called Digital Transformation Issue, which we got contractors in, and a lot of support to plot this out. To make the transition to more modern, agile platforms, interconnected, flexible that we can make modifications great. Thank you. Let me show you this. So, this is what I was talking about – that spaghetti. This is a diagram of really what the systems look like at CDRH. And, the problem is, too, we were throwing money at having to upgrade, and make modifications, and wouldn’t get great return on investment. It would take too long. Not money well-spent.

We said we really should take some of this money that we already

have, and are receiving dedicated to IT, but spend it at a later date when we need it to make this transition because we're talking about bigger capital investments. And, so, we took steps to do that. We also went to congress, and said, "Uncle. We need help." And, to congress' credit, they have given us dollars. We went back in 2019, they gave us some of our ask. But, I told them, "This is my top ask," at the time. So, I went back in 2020. They gave us some more. Not enough. We went back in 2021, got some more. Not enough. So, I went back in 2022, and we'll see what happens if we get the rest of it.

But, this is what we're then going from the spaghetti diagram to. This would essentially be the new world. So, this is what it would look like, and you can really see we've narrowed this down to just a handful of platforms. This is using very common platforms out there. Off-the-shelf systems, and then just doing appropriate customization for our needs. So, we have much more agility now to also adapt them to our needs, and quickly, and really great value proposition. But, along here, I want to highlight this customer collaboration portal. But, we now move to, ultimately, a virtual workspace with us, and our customers, or stakeholders.

Already, we've built out like a FedEx tracker for premarket submissions so sponsors can see where their 510k is in the review cycle. We're gonna build that out for other kinds of submissions. We're gonna bring in, also, our E-store. This Electronic Submission portal, but there are so many other things we're doing. I mentioned already some of the work on modern analytics, but this is really the world of the future. And, if we took this further, our vision for our reviewers, and our other staff is a little like Iron Man. You know, Iron Man has kind of had their AI – the had their computer in front of them, and they had AI capabilities.

You had Jarvis. Jarvis would help do analysis and bring information to Iron Man, and that is really what we would like to build out for our folks. That makes the best use of the data we have. It gives us ability to use data we don't have today, as we have data standards, and be able to get the most out of it so we can best serve all of our customers from patients, and consumers at the top, to industry, to providers, and others. So, I will stop there, and I will open her up for other questions.

Nancy:

Great. Jeff, thanks so much. You were so comprehensive. That was wonderful. I guess the Alliance has now found a little bit of money to pay to moderators, so both Emily, and I will be asking you a couple questions. But, before we start, I would love to remind

people that there's a Q&A piece of this. So, if you go down to the Q&A box, we will – please add your questions in there. We'll try to get to them. We've only got about 12 more minutes, so we want to go very quickly. The first question we really wanted to ask is: For CDRH, people are so interested in COVID, and what's happening with the Delta Variant.

Do you have any – Can you give us some insight into how CDRH is gonna help deal with the variant, and also how will this affect the antibody testing that's coming up?

Dr. Jeff Shuren: Great question. And, we're clearly very concerned about the Delta Variant. And, you know, in addition to vaccinations, testing is gonna, of course, remain critically important. And, one of the things that we have been doing – and, this really started from back in March of last year – is to look at the databases out there for new mutations. And, then look at those mutations alone, and in combination with other mutations out on the US marketplace, and of course, a consolation of them would be a variant like the Delta Variant, to see if any of the tests could be adversely affected – their performance adversely affected.

And, then, if it looks like it could, we reach out to the developer for performing additional assessments. We put out guidance back in January on our expectations of what developers should do for that monitoring, for their evaluations, and for what they should do to design tests in the first place to make them maybe more resistant to adverse impacts. One of the things we've also done is work with NIH, and some of their RADEX partners to create a capability for us to do assessments on some of the tasks, particularly those, maybe, at risk – in particular antigen tests.

Those are a little bit more difficult to evaluate the impact of the variants because we are worried if we knock out some critical tests, then our testing capabilities go down. So, we're always vigilant on that score.

Nancy: I'm gonna ask one more question, and then turn it to Emily, who's going to ask some questions in the chat. But, one of the things CDRH has done yeoman's work during COVID. I mean, when you look at those statistics that you read about how many things you've reviewed already – it's amazing. But, there's a big group of sponsors, and stakeholders who are a little bit worried that they're getting responses from the center saying, "Hey we haven't given you a reviewer yet. We haven't assigned you a reviewer."

And, it's very late. Do you guys have any statistics on how many of the deadlines have been missed, or how – You said, going toward the end of 2021, and into 2022, you're gonna get your hands around it, but can you give us a better timeline on that?

Dr. Jeff Shuren:

Sure. Certainly. No, and obviously, this is of concern for us, too because COVID, obviously, top priority, but you know people get sick. People die from lots of other health conditions. And, we want to make sure that they have, again, if it's safe, and effective technology, the technologies they need to improve their health, and quality of life. So, of course, with the pandemic, we had to shift our resources. We had to have people working on non-COVID submissions start looking at COVID submissions. And, as a result, there were delays in other product reviews, particularly in those areas of the IVD product space.

Here's what's happened. For people who we had to move over to do the COVID work, from other parts of the center, we basically have, for the most part, sent everyone back. All of the submissions that were on hold, now have a lead reviewer, and they're moving forward, and anything new coming in the door will get a lead reviewer, and move forward. For most of the center, we're back on course. For – Now, let's put aside IVDs. For some of the other areas hard hit – personal protective equipment, think about ventilators, respiratory assist devices, general hospital – they're getting close to back on track for pre-market submissions.

There may be a few just on a case-by-case basis where it will take a little bit longer. For pre-submission meetings, though, there can be a delay, and we tell people, "Expect 120-day timeframe." But, we'll do the pre-sub mailings. In the case of IVDs, though, they were the hardest hit. You know, we only had 25 people with the virology expertise, and so we had to pull lots of people from our invitro diagnostics office, so HD7, to help out, and that put a lot of things behind the 8 ball. So, now we have all of the IVD submissions moving forward, but a number of those are gonna be delayed in meeting deadlines.

And, we're trying to manage expectations, and establish new deadlines. But, and I think we'll get back on course. We're looking to target most things back on course for submissions in 2021. For them, it might lead to 2022. But, in the case of pre-submission meetings, for IVDs, we're only holding those if the COVID-related, breakthrough devices-related, or companion diagnostics-related. Everything else, we're declining. We just don't have the resources. And, we think it's more important to focus on the

submissions we already have in house, and to talk about products yet to come before us. That's the tradeoff, but hopefully, some time in 2022, we'll get back on track.

Big unknown, how much more keeps coming in for COVID because we keep getting submissions? How many of those that we've authorized will come in the door for full marketing authorization?

Nancy: Great. Well, Jeff, we only have six minutes, so we're going to have a lightening round.

Emily: I love it. Nancy, we have a lot of questions in the Q&A box. Dr. Shuren, thank you again for being with us. I'm gonna stay for a moment in the lane of COVID-19, and go to one of our questions there about the growing interest in inexpensive COVID tests that people can do at home. We might expect that interest to increase as kids are making their way back to school. But, today, the interest in this, or use of these has not really taken off, and so we're curious if you have any thoughts on why that is, and is CDRH working on any approvals of that type at this time?

Dr. Jeff Shuren: So, first of all, we continue to have sponsors we're dealing with who are making at home tests, and we continue to do so. Yes, we've seen that, too. The interest in these tests really didn't take off in the US. The NIH is actually performing some studies into it to better understand it. It just may have to do with the culture in the United States.

Also, I'll tell you from a provider's standpoint – and, we knew this dating back to H1N1, sometimes, not the same confidence because those tests may not be as sensitive as the lab-based tests, and it's one of the reasons why you also don't want a test out there that doesn't have at least reasonable performance, but keep in mind, we authorize those tests at lower sensitivity as a tradeoff between access, and effective diagnosis.

Emily: That's so helpful. Another, somewhat of a follow-up question. FDA officials have said that manufacturers of EUA COVID tests should begin submitting applications to convert those EUAs to full approval. Our audience member wants to know: Does that include laboratory diagnostic tests, and if not, what are FDA's plans to reassert its authority to authorize, and approve LDTs?

Dr. Jeff Shuren: I will certainly, for folks who have an authorize test – Emergency Use Authorized – If you want to keep it on the marketplace, we

encourage you to seek full marketing authorization as soon as possible, get your data, move it forward. LDTs – You know, the world of LDTs – there are always lots of discussions. We’re in discussions with HHS on it. Of course, we have folks in congress who are looking at maybe putting forward a more modern framework for IDD, and a more coherent consistent one across the test, regardless of who makes them. We’ll see what happens in the future.

For LDT developers, again, we’ll see for right now when it comes to COVID. Certainly, if you’re interested, and you would like full marketing authorization, regardless of what happens, we encourage you, if you’re interested, to certainly pursue it if you would like.

Emily: Thank you, Dr. Shuren. That’s so helpful.

Dr. Jeff Shuren: And, it’s “Jeff.” No one calls me “Dr. Shuren.”

Emily: Thank you, Jeff.

Nancy: All right, Dr. Shuren. Can you just tell us a little bit, with all the innovation that’s happening in digital health, and all the other areas you talked about – AI – how is CDRH working with the international community, and do you expect that there’s gonna be any significant change in the international regulations of these types of things led by FDA?

Dr. Jeff Shuren: Great question. To be seen. I think you know that we already led a workstream in the international medicalized regulators forum on what now became coined in international parlance, software as a medical device. There is workstream now that’s on AI starting with a focus on some of the terminology. So, these will – We anticipate we will be back at the table at some point in the future, thinking about going from where we are at 50,000-foot level, really down to – can we get down to 1,000 feet, maybe even grass. We’ll see, and but, quite frankly, if the US is gonna lead that, we gotta start with having a modern framework – regulatory framework – for these technologies that we can then leverage.

So, we really need congress to support, and we need others to work together in the community on that modern framework. You know, we’ve been piloting things like pre-cert, which would be Part 1 component of the modern framework. We need to have that in place. If we do, then we can leverage that to take that back to the international community.

Nancy: That's perfect. Jeff, we have like 30 seconds more, so why don't – I think we probably should wrap it up here. But, you have been so forthcoming. You have done CDRH, and FDA such a great service because just having people hear what you're thinking, and where you're going, and your great vision has been tremendously helpful. So, let me turn it over to Ron.

Ron: Thank you, Nancy. And, let me just reinforce that. Dr. Shuren, thank you so much for spending so much time with us this morning, and all of our members, and guests. You've really helped us very comprehensively, as Nancy just indicated, in understanding all the aspects of the very important CDRH mission, and all the miracles you've been able to perform in very trying times. All the rabbits you've been able to pull out of the hat. You know that the Alliance will continue to advocate, as we always do, for the number of appropriated resources you will need to continue pulling those rabbits out of the hat.

Maybe even add a few rabbits to the hat, and so because we know how important your mission is to all Americans. And, so, thank you very much for spending time with us today. Greatly appreciate it, and so do our members, and guests, and so does the rabbit that Nancy Meyers is helping pull out her hat for your benefit.

[Crosstalk]

Dr. Jeff Shuren: Well, thank you. I love it. Thank you, all. And, also, thank you for your support over the years. I can not tell you how important that has been for us to get our public health mission done, and quite frankly that support means so much to our folks, knowing that we have you in our corner. So, take care.

Ron: We are there. And, we'll be there. So, thank you very much, Dr. Shuren.

Dr. Jeff Shuren: Thank you.

Ron: Bye.

Nancy: Thanks.

Dr. Jeff Shuren: Bye.

[End of Audio]

Duration: 53 minutes