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FDA USER FEE REAUTHORIZATION:

ENSURING SAFE AND EFFECTIVE MEDICAL DEVICES

WEDNESDAY, MARCH 30, 2022

House of Representatives,

Subcommittee on Health,

Committee on Energy and Commerce,

Washington, D.C.

The subcommittee met, pursuant to call, at 9:01 a.m. in the John D. Dingell Room, 2123 of the Rayburn House Office Building, Hon. Anna Eshoo [chairwoman of the subcommittee], presiding.

Present: Representatives Eshoo, Matsui, Castor, Sarbanes, Welch, Schrader, Cardenas, Ruiz, Dingell, Kuster, Kelly, Barragan, Craig, Schrier, Trahan, Fletcher, Pallone (ex officio); Guthrie, Upton, Burgess, Griffith, Bilirakis, Long, Bucshon, Hudson, Carter, Dunn, Curtis, Crenshaw, Joyce, and Rodgers (ex officio).

Staff Present: Vincent Amatrudo, FDA Detailee; Jacquelyn Bolen, Health Counsel; Waverly Gordon, Deputy Staff

Director and General Counsel; Tiffany Guarascio, Staff Director; Stephen Holland, Senior Health Counsel; Zach Kahan, Deputy Director Outreach and Member Service; Mackenzie Kuhl, Press Assistant; Una Lee, Chief Health Counsel; Aisling McDonough, Policy Coordinator; Meghan Mullon, Policy Analyst; Kaitlyn Peel, Digital Director; Caroline Rinker, Press Assistant; Chloe Rodriguez, Clerk; Kylea Rogers, Staff Assistant; Andrew Souvall, Director of Communications, Outreach, and Member Services; Charlton Wilson, Fellow; Caroline Wood, Staff Assistant; Hilary Carruthers, Minority Fellow; Alec Aramanda, Minority Professional Staff Member, Health; Grace Graham, Minority Chief Counsel, Health; Nate Hodson, Minority Staff Director; Peter Kielty, Minority General Counsel; Emily King, Minority Member Services Director; Clare Paoletta, Minority Policy Analyst, Health; Kristin Seum, Minority Counsel, Health; Kristen Shatynski, Minority Professional Staff Member, Health; and Olivia Shields, Minority Communications Director.

*Ms. Eshoo. The subcommittee on Health will now come to order.

Due to COVID-19, today's hearing is being held remotely, as well as in person.

For members and witnesses taking part remotely, microphones will be set on mute to eliminate background noise. Members and witnesses, you will need to unmute your microphone when you wish to speak. Since we will have some witnesses that appear virtually from our next panel, I ask my colleagues in the hearing room to mute themselves whenever they are not speaking, so we can clearly hear the witnesses' response.

Since members are participating from different locations at today's hearing, recognition of members for questions will be in the order of subcommittee seniority.

Documents for the record should be sent to Meghan Mullon at the email address we have provided to your staff, and all -- excuse me, all documents will be entered into the record at the conclusion of the hearing.

The Chair now recognizes herself for five minutes for an opening statement.

Every day, Americans rely on safe and effective medical devices. From the joy of an ultrasound during pregnancy to the distress of a cancer diagnosis via an MRI, medical devices treat, diagnosis (sic), and monitor the health of

patients.

When I was working on the original legislation that created the Medical Device User Fee Agreement process in 2002, we could not have imagined the innovative devices that are on the market today. And without the user fees supplementing the FDA for the past 20 years, many of these innovations would be stuck in a backlog, instead of helping patients.

A few months ago I visited a hospital in my district, El Camino Hospital, which is using radiation technology with AI to individually target tumors. This is just one example of the hundreds of devices that the FDA has approved or authorized since MDUFA was last authorized in 2017.

With this impressive innovation comes an increasingly complex FDA review process. Over the past 20 years, the user fee agreements have evolved to make sure that the FDA has the resources necessary so that its reviews are timely, transparent, and predictable. MDUFA V is the latest evolution. The recently-announced draft agreement will provide FDA $1.78 billion over 5 years in user fees. This is about 10 times the amount provided in the original 2002 user fee agreement. But it -- when you compare it with pharmaceutical drugs, they are very different.

With this funding, the FDA's Center for Devices and Radiological Health will be able to hire 387 new, full-time

employees, and also meet rising payroll costs. The user fees will also fund successful FDA policies, such as the use of Real-World Evidence, the harmonization of international medical device regulatory activities, and patient engagement to inform the evaluation of products.

While MDUFA V is a significant increase in user fees from medical device makers, it is important to keep in mind that user fees cannot and should not relieve Congress from its responsibility to fund the FDA in a robust way. That is why I was pleased to see President Biden's budget included a $95 million increase for FDA's medical product safety work.

Today we will hear from representatives from the FDA, private industry, and public health about the negotiated Medical Device User Fee Agreement. As the proud mother of MDUFA, I look forward to shepherding the agreement through reauthorization before the program expires on September 30th.

[The prepared statement of Ms. Eshoo follows:]

**********COMMITTEE INSERT**********

*Ms. Eshoo. The chair is now pleased to recognize the distinguished ranking member of our subcommittee, Mr. Guthrie, for his five minutes for an opening statement.

*Mr. Guthrie. Thank you, Madam Chair. Thank you for holding this important hearing.

And today we are building off the work we have done over the past several weeks to find additional opportunities to foster American biopharmaceutical innovation. The focus of today's hearing is to discuss the recently-announced Medical Device User Fee Agreements, MDUFA. This will be critical to continuing to enhance our medical device ecosystem here in the United States.

Like the prescription drug industry, innovators working to develop new and innovative medical technologies experience significant delays in getting their products reviewed by the Food and Drug Administration experts. That is why Congress, regulators, and industry all came together to develop a solution in the Medical -- or MDUFA, Modernization Act of 2002, that would streamline the review process and help get these devices to patients more quickly. This agreement has been authorized by Congress every five years.

The original MDUFA gave the FDA the necessary tools to hire more clinical experts to review device applications. It also offered industry the same assurance of being able to hold the FDA to higher performance standards. The successes

of this partnership are clear at the FDA's Center for Devices and Radiological Health. CDRH has granted novel technologies four times -- as many approvals marketing authorization as clearances over the past decade, largely resulting from policies made possible by past MDUFA authorizations.

The agreement before us today represents an ambitious agenda set by industry and CDRH experts. The goal is to ensure FDA is doing everything it can to protect patient safety, while also supporting the development of medical device technologies. Highlights include authorizing the FDA to collect 1.78 billion from industry, and potentially up to 1.9 billion over the next 5 years to bolster CDRH's workforce, and to help get products reviewed and approved as quickly and as safely as possible.

Of note is the creation of the new Total Life Cycle Advisory Program, which CDRH states will help promote the long-term sustainability of the Breakthrough Devices Program. I was proud to support the creation of the Breakthrough Devices Program that was created as part of the bipartisan 21st Century Cures Act. In 2021 CDRH granted breakthrough designation to 213 devices, and there have been over 600 designations made since the program's inception. This includes a device that harnesses machine learning to help health care providers diagnose autism spectrum disorder.

However, I am still frustrated by the Biden

Administration's actions to undermine the bipartisan-supported Trump-era medical coverage of innovation technologies rule that would have helped to get breakthrough devices to seniors once the breakthrough device is approved by the FDA. This directly conflicts with the earnest efforts made by Congress, CDRH, and the medical device industry to encourage investments in these emerging technologies.

I encourage CMS to work to reverse this decision, and work with the industry as well as their FDA partners to address outstanding concerns.

To that end, I am also continuing to push for the codification of the 2018 FDA guidance that permits pre-approval information exchanges between product sponsors and payers. These information exchanges help get products covered more quickly once they are approved by the FDA. My bill, the Pre-Approval Information Exchange Act, would do just this, and help public and private payers to make coverage determinations earlier based off real-time health care, economic information exchanged between entities.

Additionally, offering needed clarity around the FDA's 2016 guidance on emerging signals is another important priority of mine in the device policy space, and I am working on a solution to offer needed regulatory certainty on this issue. Outlining a process that affords companies the chance to work with regulators on addressing reported adverse health

events associated with their devices will not only protect patients, but will also create regulatory predictability that will protect against gaps in care for patients who rely on these devices.

I look forward to working with my colleagues over the next several months to re-authorize this important user fee agreement that will promote even greater innovation for decades to come.

Thank you, and I appreciate Dr. Shuren for being here, and I look forward to having questions, and I will yield back.

[The prepared statement of Mr. Guthrie follows:]

**********COMMITTEE INSERT**********

*Ms. Eshoo. The gentleman yields back.

Colleagues, we are going to break at 9:45 so that members can attend Dear Don's funeral, and then we will resume at 1:00 with the second panel today.

So we want to hear from Dr. Shuren and get as many questions in as possible. But before we go to that, we will go to the chairman of the full committee, Mr. Pallone, for his opening statement.

*The Chairman. Thank you, Chairwoman Eshoo. Today we are continuing our work to re-authorize the FDA user fees, which provide critical resources for the agency's medical product review programs. All of the other user fees expire on September 30th of this year. Or -- I said all of them do. And Congress must pass these re-authorizations well ahead of that deadline to ensure FDA can continue to operate without interruption.

At today's hearing we will review the Medical Device User Fee Program, also known as MDUFA. And throughout the COVID-19 pandemic, the FDA's Center for Devices and Radiological Health, or CDRH, has been at the forefront of regulating and adapting guidance to help develop and authorize diagnostic tests. It has also managed the supply chain for critical items like gloves, masks, respirators, swabs, and ventilators.

And the staff at CDRH have been working day and night to

stay ahead of the virus, and they deserve our recognition and appreciation. Their work over the last two years has underscored the importance of ensuring that FDA resources are in place to make sure we have a safe and effective medical device supply chain.

The draft agreement that we are discussing today between FDA and industry will substantially increase funds for CDRH, which will lead to a significant increase in staff capacity at the agency, as the chairwoman mentioned.

The performance goals included in the draft agreement will also allow for innovation through the creation of the Total Product Life Cycle Advisory Program pilot, or the TAP Pilot. And this pilot program will allow for earlier interaction between FDA and developers, and will facilitate regular engagement throughout the medical device review cycle. And this will hopefully lead to a sustainable program that builds safety and efficacy discussions into the front end of development to speed innovation in a responsible way.

Now, the draft also lays out new transparency measures that will ensure funds are being spent efficiently and going to the programs authorized by the agreement in the legislation we passed. And when I mention transparency, I want to also note the importance of the process we are undertaking here in the committee today, and the process Congress has laid out for FDA and industry to reach the

agreement we are now reviewing.

By statute, as part of the MDUFA reauthorization, FDA is mandated to consult with regulated industry, patient, and consumer representatives and health care professionals, receive public comment, and submit recommendations to Congress no later than January 15th of this year. This deadline is not a mere suggestion. It is actually the law. And the process is important, because it allows for FDA, industry, and members of the public to examine what has worked well and where review programs can be improved through the reauthorization process. It also provides Congress with sufficient time to thoroughly review these recommendations, and re-authorize the program ahead of the funding deadline.

Now, you know FDA just released this draft commitment letter to the committee last Tuesday, which is more than two months after the January 15th deadline. FDA has not received public comment on the draft, and this is troubling, considering there are serious questions about numerous issues, including how the agency and industry contemplated the extensions of programs due to the sunset in their agreement. And there is still a lot to review and more work to be done, and we must act quickly. So failure to re-authorize the program on time would be catastrophic for patients relying on safe and effective medical devices.

I am just trying to say -- I am not trying to beat you

up, Dr. Shuren, but, I mean, the bottom line is, you know, we get this two months later -- we are going to meet our deadline because we don't want to have the pink slips. But I remember a few years ago, when the pink slips went out, and everybody was saying, "Well, Congress, you know, why didn't you do this quicker?'' Well, in this case, it is your fault. I mean, I don't know how else to put it.

So we are not going to miss the deadline, though. And I appreciate FDA and industry being here today to help us understand their proposal. And I also think it is important for us to discuss how we can improve the process so this does not happen again in the future.

And we will also review two other common-sense proposals: one bill from Representative Schrier would create a new advisory panel at FDA to bring an independent public health focus to regulatory decisions, evolving diagnostic tests, the importance of which are still being seen during the COVID-19 pandemic; and we have another bill from Dr. Burgess that would incorporate cybersecurity into medical device applications, which is also critical as medical devices become more interconnected and technologically advanced.

So look forward to the discussion today. And I yield back, Madam Chair.

[The prepared statement of The Chairman follows:]

**********COMMITTEE INSERT**********

*Ms. Eshoo. The gentleman yields back.

The chair is pleased to recognize the ranking member of our committee, Representative Cathy McMorris Rodgers, for your five minutes for an opening statement.

*Mrs. Rodgers. Thank you, Madam Chair. Today this subcommittee will hold its third hearing to consider the reauthorization of the FDA user fee programs.

Congress has acted to authorize the Medical Device User Fee Amendments, or MDUFA, four times before, and we remain committed to reviewing this authority on time and through regular order.

I would like to thank our witnesses for testifying today, and would also like to welcome back Dr. Shuren. Dr. Shuren came before this subcommittee when we last re-authorized these programs in 2017.

Before we discuss the proposed amendments and the two bills for today's hearing, I would like to join in expressing my disappointment with the failure of FDA and the regulated industry to deliver their proposed agreement to Congress by the January 15th statutory deadline. MDUFA negotiations have been going on for over a year, and we have had just one week to review the proposed amendment language and commitment letter before this hearing. This delay hinders Congress's oversight responsibilities. Re-authorizing these programs on time is a goal shared by all of us on this committee, and

failure to do so will result in delayed patient access to needed medical technologies.

Further, I have raised serious concerns about the lack of transparency throughout this process. In November I wrote to then-acting Commissioner Woodcock about the delay in posting minutes, meeting minutes from FDA industry negotiations. To ensure transparency and progress, documentation of meeting outcomes and action items are supposed to be made part of the official record, and made publicly available. While this posting minutes publicly takes no more than two to three weeks, during MDUFA V negotiations we saw delays of more than six months. Even today, there are no meeting minutes posted for any meetings that took place after June 30th, 2021.

I know that my colleagues and I are looking forward to getting answers today on what took so long for the proposed agreement to be delivered to our committee, and how we improve this process going forward.

Now, regarding the proposed MDUFA V agreement, as well as two pieces of legislation introduced by Representatives Burgess and Schrier, Dr. Burgess's bill ensures the cybersecurity of devices is approved or cleared by FDA. Dr. Schrier's advances on the real world impact of medical device diagnostics (sic).

We want to make sure FDA has the resources to keep up

with cutting-edge medical technology, such as artificial intelligence, robotic prosthetics, and facilitate innovation and production of the more routine devices we rely on: syringes, gloves, gowns. We need to make sure these resources are used wisely and improve people's quality of life.

The promise of American innovation will allow medical technology to help keep patients healthier, enable treatment at or close to home, and improve timely diagnostic -- diagnosis and treatment. This reauthorization requires FDA to leverage digital health technologies and Real-World Evidence in the review and clearance or approval of medical devices where appropriate.

The proposed enhancements also direct significant investment in hiring and retaining world-class scientific and technical staff. There is no question that the COVID-19 pandemic severely disrupted business for the FDA to review applications and make timely decisions. The Center for Devices and Radiological Health has especially had a daunting task. FDA has fallen behind on the accountability part of the deal, missing three review goals during fiscal year 2020 and six during fiscal year 2021. I hope that FDA will improve going forward, and that the hiring commitments and performance goals agreed to under MDUFA V will get us back on track.

I am also encouraged that the commitment letter contains enhancements to improve performance, accountability, and financial transparency. FDA is committed to publishing an annual five-year financial plan which will include hiring targets and a full accounting of where user fee funds are being spent.

MDUFA V also continues enhancing its Patient Science and Enhancement Program, which -- excuse me, which will prioritize including the voice of patients in the review process.

The goal of these improvements will improve pre-submission communications with innovators, make sure patients are heard, and improve overall efficiency, integrity, and effectiveness of medical device reviews.

Re-authorizing MDUFA before September's deadline will allow agency operations to continue, and will also enhance patients benefit for medical innovation and advancements. This is the goal that I know is shared by all of our colleagues.

I look forward to today's discussion. I yield back.

[The prepared statement of Mrs. Rodgers follows:]

**********COMMITTEE INSERT**********

*Ms. Eshoo. The gentlewoman yields back.

Pursuant to committee rules, all members' glorious written opening statements will be made part of the record.

I now would like to -- well, he really doesn't need to be introduced, but I am going to introduce him anyway. Our witness for our first panel, we all know Dr. Jeff Shuren. He is the able director of the Center for Devices and Radiological Health at the FDA.

Welcome back to the hearing room, Doctor Shuren. It is really wonderful to see you again in person back to the subcommittee. We are very happy to have you with us today, and we look forward to your testimony.

You are familiar with the lights, so I don't have to walk you through that. But a warm welcome. You have five minutes for your testimony.

STATEMENT OF JEFF SHUREN, M.D., DIRECTOR, CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, FOOD AND DRUG ADMINISTRATION

*Dr. Shuren. It is nice to be back. Chair Eshoo, Ranking Member Guthrie, and members of the subcommittee, thank you for the opportunity to testify today about the fifth reauthorization of MDUFA.

The investments made in previous MDUFA re-authorizations have paid off dividends, with an increasing number of innovators bringing their devices to the U.S. first, and a more robust pipeline of innovative new devices, which ultimately has led to more timely patient access.

I want you to know that I personally regret that we missed the statutory deadline to deliver our recommendations to Congress. I and the entire agency take this obligation very seriously. I am pleased to report, however, that the long deliberations have ultimately produced a strong, thoughtful agreement on recommendations to Congress that, if enacted, will continue to advance medical device innovation, while maintaining the FDA's standards to protect patients.

CDRH continued to meet and exceed most performance goals through the first half of MDUFA IV. However, we missed some goals later on. During this time we saw a rise in our workload for which we were not fully funded. For example, so far, during MDUFA IV, FDA received over 3,000 more pre-

submissions than we were resourced to review, including more than 1,000 in fiscal year 2020 alone. And since fiscal year 2018, FDA has granted more than 600 breakthrough device designations, more than 200 in the last fiscal year alone. Medical devices have and continue to be increasingly more complex, and the review of their pre-market submissions more resource intensive, while the number of submissions we receive annually has increased, as well. And we expect these trends to continue.

Then COVID hit. It pushed us into a continuous all-hands-on-deck operations in order to facilitate the development and availability of pandemic-related medical devices. We have received approximately 8,000 emergency use authorization and pre-EUA requests, and we are still receiving about 130 of these submissions a month. We have granted emergency use of full marketing authorization to over 2,200 medical devices for COVID-19, including 15 times more EUAs than all other previous public health emergencies combined. This has truly been a perfect storm, and my center has been battling against it for two years.

Moreover, our efforts to grant emergency use authorizations are not covered within the scope of MDUFA, so they don't count towards our performance.

On the other hand, the magnitude of the emergency response inevitably led to a backlog, and delayed review

times, and we fell short on some of our MDUFA goals. I and my center take these commitments seriously. We know this has had a great impact on companies across the country. This is why we have been transparent, communicating about impacts publicly and regularly, and we have worked hard to address delays for COVID and non-COVID devices through hiring more staff and contractors, reallocation of staff, and changes in policy, procedure, and practice, with many of my staff burning the midnight oil and burning out in the process.

We greatly appreciate the support from Congress, particularly in the form of supplemental funding, and we have now turned the corner. CDRH has reduced the backlog of non-COVID device submissions by 44 percent, and we are targeting to have most of the center back to normal operations later this year.

Despite these challenges, during MDUFA IV we authorized record numbers of novel devices, over 100 a year during the pandemic. The MDUFA V proposal takes important steps to address resource gaps that began to show before COVID-19, and to support improved performance.

It also features a new accountability mechanism for add-on payments under which FDA would receive additional user fees if it meets specified goals. These additional funds come with even more ambitious goals for the later years of MDUFA V.

The agreement includes a new voluntary pilot to provide earlier, more frequent, and more strategic engagement with sponsors of breakthrough devices, and those included in the Safer Technologies Program, incorporating lessons learned from the pandemic, where we saw how engaging with sponsors through the pre-EUA process to problem-solve and answer their questions in real or near real-time was critical for facilitating important technologies coming to market quickly and safely.

The MDUFA V proposal would also support advancement of the patient perspective in regulatory decisions, continuation -- expansion of the use of national and international consensus standards, leveraging of Real-World Evidence for regulatory decision-making, and enhanced coordination with international regulators to advance global harmonization, among other priorities.

We appreciate Congress's patience and support. Thank you again for the opportunity to testify today. I am happy to answer your questions.

[The prepared statement of Dr. Shuren follows:]

**********COMMITTEE INSERT**********

*Ms. Eshoo. Thank you, Dr. Shuren. We will now move to member questions, and the chair recognizes herself for five minutes to do just that.

Dr. Shuren, in your testimony you said you have received approximately -- did you say 80,000 or 8,000?

*Dr. Shuren. Eight thousand.

*Ms. Eshoo. Eight thousand EUA requests during the pandemic. This has, obviously, strained your center's capacity, especially since EUAs do not generate user fees.

Are you still receiving a heavy volume of EUA requests in 2022, so far?

*Dr. Shuren. Yes, for EUAs, pre-EUAs, it is still about 130 a month.

*Ms. Eshoo. A hundred and thirty a month. What is your long-term plan to balance COVID-19, EUA requests, with your center's -- I guess what I would call your regular workload?

And how does MDUFA V help address the center's capacity gaps? Because they are -- it is really jaw dropping, these numbers.

*Dr. Shuren. Yes, the numbers are phenomenal, and really, a credit to my team for all the hard work. And I appreciate the support of Congress in doing so.

So some of the steps we have taken is to sort of narrow the focus on where we put our resources. We are in such a different place today as a country than we were at the

beginning of the pandemic. And I think, over the coming months, really, the goal is to start to turn off the spigot on EUAs, that, you know, there is enough product out there, and it is now turn and use more of our resources on the non-COVID products that are there.

*Ms. Eshoo. In January you issued final guidance to engage patients in the design and the conduct of medical device clinical studies. Since publishing the guidance, have you seen medical device clinical studies include more diverse patients?

It is an area, on a bipartisan basis here, at our subcommittee, a commitment to really reform clinical trials so that they are diverse, because they are not today. Tell us how you are doing with that.

*Dr. Shuren. Well, too early to tell with the new guidance.

That said, I want you to know that one of our strategic priorities for the center for 2022 to 2025 is advancing health equity. At the top of that is increasing the representation of diverse populations in clinical trials for devices.

At the same time, we want to do this responsibly. So one of the actions we will take is putting out a framework about when that is absolutely critical, and what circumstances, what devices, and where that will be helpful

to have.

*Ms. Eshoo. You don't have any legally binding standards, though, do you?

*Dr. Shuren. We don't.

*Ms. Eshoo. You don't.

*Dr. Shuren. We do need the evidence to support the use in intended populations. And quite frankly, if we are going to provide high-quality health care, then no patient should be left behind.

*Ms. Eshoo. In 2021, June of 2021, FDA issued draft guidance that included what FDA sees as the distinction between servicing and re-manufacturing medical devices. Has that draft guidance helped clarify the apparent confusion between servicing and re-manufacturing, at least amongst the entities that perform these activities?

And does the term "re-manufacturing'' need further clarification in statute, which is, obviously, where we come in?

*Dr. Shuren. Well, at this point, because it is draft guidance, it is still -- we are getting feedback. It is not finalized as official policy.

That said, there is value for providing greater clarity, and maybe even doing so through statute with further expansion than through guidance.

When we saw reports come in that there are allegations

about problems with servicing, most of those turned out to be re-manufacturing. And so clarity about what constitutes and doesn't constitute re-manufacturing is critically important.

*Ms. Eshoo. Okay. The chair now recognizes the ranking member of our subcommittee for his five minutes of questions.

Mr. Guthrie?

*Mr. Guthrie. Thank you, and thank you, Dr. Shuren, for being here.

I will tell you, watching over what happened over the last couple of years, I know it has to be absolutely exhausting for you, but it also has to be exhilarating. I mean, you are -- the FDA, in the whole Operation Warp Speed effort, I think, rose to the occasion. We have things we have to look at and questions we need to ask as we move forward, but absolutely, ensuring that we had products out -- I know you are on the device side, but just the vaccines, having the products and the testing that you -- out as quickly as it did, I mean, it just -- any time you have a mission that brings you together like that, exhausting as it is, has to be fulfilling, as well. And helping American people get through the pandemic that we are still getting over, hopefully, or getting -- figuring out how to live with it, moving forward.

But -- so just a couple of questions on the agreement as you were looking -- I know a big part of it is the hiring

goals, and some more money for hiring goals moving forward. And so my question is, how does CDRH plan to meet your hiring goals set forth in the agreement?

*Dr. Shuren. Well, MDUFA V also provides us with additional funding to take advantage of the Cures Authority for hiring that was in 21st Century Cures, and I really thank Congressman Upton for his leadership in moving that bill forward.

So that, and I think the greater flexibility that we are now offering, in terms of work circumstances with telework and remote work, is going to help us recruit. And we have seen better recruiting in the past few years than we saw previously.

But I will put on the table something, if Congress is interested to help us, is the ability to have direct hire authority, regardless of whether or not someone is on under 21st Century Cures. So if we find the right person, let's bring him in as quickly as possible. And that will help us be successful on implementation of, I think, MDUFA, but all of the UFAs.

*Mr. Guthrie. Yes, thank you. I think that is the -- throughout our -- and we have to figure out how to have hiring that is correct and right. I know we put a lot of these in place, little things that, in the way past, were political.

But I can tell you, from my VA, local VA clinics, this was -- when hospitals are lining up for nurses graduating from nursing school, and we have to go through the process we have to go through, then it makes it difficult to get people to -- I am sure you are competing with the same kind of groups. We need to look at that, or the proper committee needs to look at that, as well.

So I mentioned earlier about the signaling, merging signal. Could you explain how CDRH's emerging signals process works?

And will you commit to working with me and other members of the Committee on ways to address concerns about the manufacturer input during this process?

*Dr. Shuren. So we have not only policy that has been issued, we have an entire program that is focused on what we call signal management.

So if we get an indication there may be a problem with a device -- it could be through an adverse event report, a study that is published out in the literature -- we will then go ahead and do an assessment on that. We have a whole process for how we do that review, and then make decisions around, if this requires more data, is this sort of a real signal or not. And then if so, what is the appropriate action to take?

Part of that includes, in certain circumstances, putting

information out on what we call an emerging signal, because this is really important to get this information out to the public. As a part of that process, we generally engage with the manufacturers in that signal evaluation process. And then, if we are going out with the communication, we give advance notice to the manufacturers, and we tell them about the general content of the communication, unless there is -- it is not feasible. There are so many manufacturers -- like we did with warnings about using masks with metal if you are having an MRI scan.

But those communications do need to be FDA communications. They need to be -- we need to be independent. If we are back sharing it, and then we are going to end up in negotiations with companies, and we need to avoid delaying tactics, where companies that try to, if you will, preempt us, and put their own spin on the science, that will undermine public health. It is absolutely critical we have our independence to get important information out to doctors and patients so they can take appropriate steps.

*Mr. Guthrie. Thank you. I appreciate that. That is something -- absolutely.

Also, could you explain the differences between pre-submission program and the Total Life Cycle Advisory Program, and how you ensure the TAP program doesn't divert resources from other important programs? You have about 30 seconds for

that.

*Dr. Shuren. Yes, so pre-submission is very popular, very important. And over half of them are requested by small companies, start-ups. Here, important questions that really take more time to answer or provide to us. And then we review if it is appropriate. Then, you know, within 70 days we are going to provide -- or at least 5 days before meeting -- written feedback. It is this stage gate approach.

If you really want to engage in problem solving, what TAP does, it says, rather than the stage -- questions takes time, more questions come back. We work with that developer of innovative technology in a fluid manner, trying to answer questions as close to real or near real-time as possible, and have the capacity to engage in strategizing with the company on how to get to yes. Obviously, the data has got to support that it is safe and effective.

But this is to address the challenges with that valley of death. We really go from concept to market, go beyond what we have in the MDUFA today, which is just focused on pre-market review. If we can solve the challenges before you send us a submission, we are not talking about saving days, we are talking about saving months and years --

*Ms. Eshoo. Years.

*Dr. Shuren. -- and getting to yes more efficiently. TAP can be a game changer, and this is what we learned from

COVID that really works. It is part of the secret sauce that got those 2,200 devices out onto the marketplace so quickly.

*Mr. Guthrie. Thank you. I appreciate your work.

I yield back --

*Ms. Eshoo. The gentleman yields back. The chair now recognizes the chairman of the full committee, Mr. Pallone, for his five minutes of questions.

*The Chairman. Thank you, Chairwoman Eshoo.

Dr. Shuren, you know -- you could tell from my opening statement that I don't want to be -- you to send out pink slips again. And, you know, my concern, obviously, is, you know, people start looking for other jobs, and the process of approving medical devices gets delayed. So can you describe what would happen to your center at FDA and to the medical device supply chain if we enter August or September and Congress has not acted? What would this mean for patients, if you will?

*Dr. Shuren. And again, my apologies for our being late. I know it puts Congress in a very tough bind. But if it is not authorized in time, then we have to move forward to issue those pink slips, and we start letting people go, and we wind down the program.

The program is absolutely essential for assuring that we get safe and effective technology to patients. If we are under-resourced, it is going to take more time. There will

be delays. We will start losing the edge we have got now in medical device innovation here in the U.S. with more important technologies coming here first. We will lose all of that, and we will not be well positioned to also protect patients from unsafe products.

*The Chairman. Thank you. And, you know, I don't want to keep dwelling on the delay here, but, you know, maybe what we should talk about is how we can improve this process going forward.

So you, obviously, were one of the participants in these negotiations with industry. Can you help us understand what caused the delay this time, and provide any ideas on how to improve the process when it is time to re-authorize again, you know, five years from now?

*Dr. Shuren. I have been involved in MDUFA re-authorizations since 2005. So, you know, we got a late start, too. And this was us and industry both said, "We are getting hammered with COVID. We need more time.''

One thing Congress could do is maybe, rather than just have the date about when you have to come to Congress, have the date when we have to sit down and get this started. You know, so we have got enough lead time, you know, to get it done. And maybe then, you know, think about -- we could be a bit more accountable publicly if we are going to be late.

And I appreciate, too, our delay on the meeting minutes.

That puts you in a tough bind, as well, to make well-informed decisions.

*The Chairman. All right, thanks. I wanted to note that, as I think has already been discussed by you and the chairwoman, that the proposed MDUFA V significantly increases funding above what was laid out on MDUFA IV. So could you explain why this increase in resources is necessary, how it will help with product reviews, and how FDA determined what resources were needed this time to ensure the agency is funded over the next five years?

*Dr. Shuren. Well, one of the challenges was, you know, as I mentioned in my opening statement, is under-resourced in MDUFA IV. Look, we make our best estimates on what the costs are going to be, but there is no way to really adjust that as we move along. And some things are just, you know, out of control.

But at the same time -- so what MDUFA V is going to do, deal with those gaps, but give us the ability to further improve our performance, which is important. It is going to create that pilot. We are going to test drive TAP, and that, to me, is a major game changer. But I think we are doing it responsibly. Do a pilot. Learn from it. See if it is worth keeping, and go from there. And then greater investments to do more work on bringing the voice of patients into the picture, we will continue to have funding for Real-World

Evidence, and then better leverage that moving forward, better use of national and international consensus standards, and drive towards greater international harmonization.

This is really -- I view it as, like, the next frontier, where we need to go for a program.

*The Chairman. All right. Thank you.

And I know we are running out of time, Madam Chair, so I will yield back.

*Ms. Eshoo. The gentleman yields back. The chair recognizes the ranking member of the full committee for her five minutes of questions.

*Mrs. Rodgers. Thank you, Madam Chair.

In December, FDA published two draft guidance documents to provide the agency's policy for device manufacturers planning to transition products granted emergency use authorization during the pandemic to regular marketing submissions. These guidance state that products currently marketed under an EUA would need to submit a pre-market application and change their product labeling within 180 days of the end of the public health emergency.

Manufacturers have expressed that this is not sufficient time to submit applications, particularly for those that are still gathering clinical data. Others raised concerns about the burden that updating the label twice is going to raise, once during the application review, and then again during the

approval decision. This is going to be a burden on manufacturers.

I wanted to ask, is FDA taking these concerns into account, so as not to make supply chain challenges worse and hurt patient access to devices that will continue to be needed, even once the public health emergency has ended?

And then, can FDA even process an influx of applications within 180 days, and meet MDUFA goals?

*Dr. Shuren. So we are taking all the feedback we are receiving into account.

And I will mention, you know, during the pandemic we issued 28 guidances, but most of those guidances were immediately in effect because, as a public health emergency, we wanted to move quickly. We made the decision that, for transition, it was absolutely critical we get public input before we finalize. We made an exception in this case, because we wanted to hear from manufacturers and others, and we do want to get this right.

I will say I also encourage manufacturers, don't wait for us to tell you at some point in the future you need to come in with a pre-market submission. You are out there in the marketplace. If you want to stay on the marketplace in the long term, get your data, come in the door, and we will -- of course, if you submit a data for an EUA, we are going to be leveraging that in our final decision-making, too.

Also, if you come in the door, remember the product is on the market. So it doesn't matter if it takes a little bit longer to review a pre-market submission. We are more focused right now getting new product on the market. The transition devices will be second, but we are not going to disenfranchize anyone. No product would come off if something is in the door.

*Mrs. Rodgers. Okay, okay. Thank you.

As I mentioned in my opening statement, I have expressed concerns about the lack of transparency throughout the cycle of MDUFA and the negotiations. The requirement for FDA to publish meeting minutes is a -- is in place so that policymakers and the public can monitor the status of the user fee negotiations in near real-time, not months later, and stay informed about the key issues. They aren't optional, and we expect them to be published quickly.

FDA has not published meeting minutes since June. How many negotiation meetings have been held since June 30th, 2021?

*Dr. Shuren. I will get back to you with the number. But I have to say a lot. So --

*Mrs. Rodgers. Can you estimate how many?

*Dr. Shuren. I am going to say over a dozen.

*Mrs. Rodgers. Okay. Would you speak to why the meeting minutes were not published on time?

*Dr. Shuren. First of all, I will again apologize for that, because we should.

I have to tell you, negotiations on MDUFA, it is more like an international treaty: lots of parties, lots of perspectives. And the same happens with the meeting minutes. There is a lot of back and forth on them. I don't mean that by way of an excuse, but everyone wants to be comfortable with what is in there. Folks were so focused on let's get the deal wrapped up. And as you know, we went late, and we were all pushing, and we wanted to get accord. We felt it was important to get consensus, and that meant more discussions to do it. So we put the priority with our limited, you know, bandwidth on getting the deal done in the meeting minutes. But again, my apologies because that does put you all at a disadvantage.

*Mrs. Rodgers. Okay. Well, we are missing a lot of information because of that. And we -- and Congress has made multiple requests. Can you speak to how many times FDA and industry met in December and January leading up to the January 15th statutory deadline?

*Dr. Shuren. Somewhere in January -- there were offline discussions, not a lot of in-person meetings while other information was being gathered and other issues were being dealt with. I don't have the exact number, but I will -- I can get back to you with all of those details.

*Mrs. Rodgers. Thank you. I just want to conclude by expressing concerns about a proposal in the President's budget that would significantly expand the scope of mandatory device supply chain reporting requirements that were just put in place for the first time during the pandemic.

With less than two years since FDA was first given this authority, I am unaware of any study or review that has been conducted to understand the benefits and the burdens of this data collection. I am open to understanding how FDA can better utilize its current flexibility authorities to efficiently review changes to components or sourcing. But imposing sweeping government mandates and more paperwork requirements on businesses is only going to disincentivize innovation and reduce competition.

I yield back.

*Ms. Eshoo. The gentlewoman yields back.

*Dr. Shuren. Could I respond to that? Because I -- if it is possible?

*Ms. Eshoo. Sure.

*Dr. Shuren. Just to say I appreciate that.

First off, the authority, that broader authority, as you say, already applies for drugs. We are asking for parity on that. We have used -- and I want to say thank you for the authorities in the Cares Act, because we used that during the pandemic. Those notifications helped us prevent or mitigate

shortages with test supplies, and ventilators, surgical masks, respirators, dialysis systems, defibrillators, even needles and syringes being used for vaccines.

The problem is shortages occur outside of a public health emergency. In fact, for a public health emergency -- in COVID it started before the public health emergency was declared. So we were behind the eight ball because of that. And that hurts our frontline workers. It hurts patients. And even during the pandemic, we had a shortage of resin because of a winter storm. The only reason we got notified is because it happened in a pandemic, which helped us prevent large-scale shortages of tests. If this was not in the setting of a public health emergency, no obligation to tell us, and patients will get hurt.

We know -- we have dealt with shortages for years, but we have not -- we need this authority. We were flying blind without it. When the pandemic hit, without that authority, and before public health emergency, we had to reach out to about 1,000 manufacturing facilities over 12 countries, cold calling them. And we got maybe responses in about a third, and often incomplete responses. And that put people's lives at risk.

This is something simple to fix. We don't want to be over-burdensome, but at least parity with the drug program.

*Mrs. Rodgers. Well, this merits a longer discussion.

Medical devices are different than drugs, and I think we need to consider that.

Thank you. I yield back.

*Ms. Eshoo. Before the reforms, the approval by -- the approvals by FDA were based on the yardstick by which pharmaceutical drugs were measured. So, you know, we really have made progress.

Colleagues, we are now going to recess for Congressman Don Young's memorial, and we are going to resume at 1:00 this afternoon when members, of course, will continue to question Dr. Shuren, and to host our second panel. So, Dr. Shuren, you have time for breakfast and lunch. How's that? And we will see you back at 1:00.

*Dr. Shuren. All right, thank you.

*Ms. Eshoo. We will be in recess until then. Thank you, everyone.

[Recess.]

*Ms. Eshoo. The Health Subcommittee will come back to order.

Thank you again for your patience, Dr. Shuren. And I believe -- who is next? The chair recognizes the former chairman of the full committee, a great member of this subcommittee, the gentleman from Michigan, Mr. Upton.

*Mr. Upton. Well, thank you again, Madam Chair, for holding this hearing. And we all regret the loss of our good

friend and colleague, Don Young, which is why we broke for his private service, with many of us there attending.

Dr. Shuren, I really appreciate your leadership, particularly over the last couple of years. You were -- for those that don't know, you were a major help as we got 21st Century Cures done. Not only did you travel around the country, but you helped us in a number of roundtables to make sure that we did it right. And the proof is in the pudding. And we are very pleased with a good number of the results since President Obama signed that bill into law.

I guess I have got, really, two questions. I hope I can get through both of them while we are here. I have heard from a number of the medical device manufacturers and, as you might know -- I am sure you are aware -- they are very concerned about the potential on these new regulations that may be coming out as it relates to the surveillance once they are done. They are very afraid that, in return for the faster approvals -- and they did this with the EUA -- that it would shorten the time to get some of those out. But they are concerned that the hammer may be out there for a long time, perhaps afterwards. And I just want to get maybe a couple of quick comments from you, and maybe just have the opportunity down the road.

I don't have language, or -- but I just wonder if you could work with us as we relate it to those potential

changes. I know that there would always be a comment period, et cetera, but I just wonder if you might be able to look at some constructive ideas that would alleviate some of the fears that the device industry might have as it relates to these. I don't even know if there are proposed regs yet. I don't know if it is -- if they are actually out or not. But if you could just sort of walk us through that process, that would be helpful to

*Dr. Shuren. And just to clarify on surveillance, is this in terms of the -- you had mentioned with EUAs, is this on the transition to EUAs?

*Mr. Upton. Yes, the mandatory reporting -- the manufacturers are experiencing increased demand or having issues with components that are life-supporting, life-sustaining, or intended for emergency medical care during surgery. These would be targeted towards the devices in terms of the reporting of issues that they might have after they were approved.

*Dr. Shuren. Yes. So that pertains to, you know, proposed legislation that is really in Congress's court that goes back to supply chain shortages.

*Mr. Upton. Right.

*Dr. Shuren. And in shortages, we are always talking about is there permanent discontinuance of the device, or is there a meaningful disruption in the supply, and we are just

clarifying. One of those circumstances is where the demand really goes up, and the manufacturer cannot make, you know, sufficient -- and there is going to be a real shortage with meaningful, meaningful impact.

We saw that in COVID. You remember, with personal protective equipment, the needs for health care workers skyrocketed, and we had massive shortages of those products. And it made a big difference. In fact, the question came up, you know, devices are different than drugs.

I would kind of put to you, ask our health care workers how important it was to them that they have, like, N95 respirators.

*Mr. Upton. Great.

*Dr. Shuren. Our doctors and nurses. And they didn't have it in the beginning of this pandemic. And some of those issues, in fact, started before even a public health emergency. So here is a case where one of the causes is demand goes up way above supply. And it is another example of issues that start before a public health emergency and why, too, we don't want to limit it to just those circumstances.

*Mr. Upton. But are there some regulations, then, that are pending as it relates to the reporting of issues or not?

*Dr. Shuren. I think this is in reference to what we put out for our -- in legislation. But we always are

continuing to provide greater clarity on reporting that is in the CARES Act. But here we have talked about making sure that, if we are doing something in supply chain, let's be clear on the circumstances that are important, that are leading to it.

*Mr. Upton. Great. So I may come back with maybe a letter, and try to --

*Dr. Shuren. We are happy to have -- talk about this, because we want to get to the right place. This is a major problem for the United States --

*Mr. Upton. Okay, so --

*Dr. Shuren. -- and for health care.

*Mr. Upton. The last question I want to ask quickly is that a common refrain that we are hearing from patient groups is that CMS is taking a long time to make payment decisions on new drugs once they make it through the approval process at FDA. While I know that FDA is part of the payment process decision, are there ways that FDA and CMS can better communicate so that, once a drug or device is approved, it can make it through the payment process more quickly?

*Dr. Shuren. To date, you know, we have a very good working relationship with CMS, and there are a number of opportunities. For example, we have our parallel review program, the chance for a manufacturer to ask to meet with CMS and us in advance to kind of get our expectations for

what it takes for FDA approval and for CMS, you know, coverage determination.

We are also working through the Medical Device Innovation Consortium, and CMS is a part of that. And there is already a workstream regarding to reimbursement and things, too, to facilitate. And we stand ready to work with our CMS colleagues on whatever is helpful to them to sort of streamline that pathway from FDA approval to Medicare coverage.

We know in the U.S. one of the big drivers, either to help or to harm innovation, is to have, you know, predictable pathways for reimbursement. Certainly, that is a broad challenge here in the U.S. and, again, something we are very happy to --

*Mr. Upton. We are looking to try and help with the Cures 2.0 as part of that.

With that, Madam Chair, I yield back my time.

*Dr. Shuren. Thank you --

*Ms. Eshoo. The gentleman yields back. That is a -- it is a huge issue. And I am glad that you are attempting to align and have cooperation between the agencies. I don't know what it is producing, but it is a constant complaint, and it is a legitimate complaint. So thank you for what you are doing, and anything that you can -- you think that we can get into the legislation which would advance this case, I

know that you will work with us.

The chair now has the pleasure of recognizing the gentleman from Maryland, Mr. Sarbanes, for five minutes of questions.

*Mr. Sarbanes. Thanks very much, Madam Chair.

Dr. Shuren, thank you for being here today. I appreciate your testimony. Obviously, it is very important as we are considering the MDUFA performance goals letter, and Re-authorizing the Medical Device User Fee Agreement.

While we have you here, I was interested in your perspective on the importance of increasing clinical trial diversity, and ensuring that trials for medical devices better reflect the patient population that might utilize the device in the future. We sometimes don't think about that in this context as much as we do in other contexts.

Can you talk about the importance of enrolling trial participants that reflect the intended patient population of a device?

*Dr. Shuren. Now, we consider this a critically important area. If you want to know if the device works, it is intended for a particular population, you have got to go ahead and, you know, assess it in that population. We have put this as one of our strategic priorities over the next years as part of our advancing health equity.

It is also reflected in the MDUFA V agreement, where

there are commitments around increasing, for example, participation of patients, you know, across broad populations in device trials. And that includes leveraging technology as a way to get more patients enrolled in clinical studies. If they don't have to come out of, for example, their home setting, it will make it easier for data collection, and that will make it easier across populations who otherwise have been feeling more disenfranchized from the ability to participate in clinical studies.

*Mr. Sarbanes. Has FDA had the opportunity to kind of pilot that in any significant way, and see what the benefits of the technology are? Could you describe some of that in a little more detail?

*Dr. Shuren. There is already work underway, and we have tried to facilitate the use of such technology in the setting of COVID, because we knew that it would be more challenging for people who otherwise would be enrolled in a clinical study to get to a clinical trial site, and so have really -- have put out guidance on this.

And there is more that we, as an agency, will be doing in this space to, again, facilitate these sort of remote clinical trials. And a linchpin for it is technology.

*Mr. Sarbanes. It is another example -- we have been seeing this across, it seems, every arena, that the pandemic [inaudible] us to new opportunities that we can then seize

upon and deploy in a more permanent way going forward.

Talk to me a little bit about the relative responsibility with respect to inclusive and representative trials between the FDA, on the one hand, and industry on the other.

*Dr. Shuren. Well, industry will come to us -- for clinical trials that pose a significant risk. We get a submission to be able to review in advance, and also companies come to us through the pre-submission process to seek our advice.

One of the things that we think could be helpful here is to provide clarity on a framework for those circumstances for technology where it is important that a diverse population is included in the clinical trial. That could help facilitate manufacturers assuring that, if you will, their clinical trial is fit for purpose, for the intended use for the technology that they wish to get authorized.

*Mr. Sarbanes. Are there things that you think we can be doing in Congress to incentivize and encourage greater diversity when it comes to the clinical trial side of things?

*Dr. Shuren. I think this is something I really would like to take back to the agency. This certainly goes beyond medical devices, and I want to make sure that we are speaking with one agency voice, since this affects lots of different products.

*Mr. Sarbanes. Well, I appreciate it. I want to thank you for your testimony. Obviously, as you can tell, I am interested in how we increase the use of digital health technology to spur greater trial participation. You have alluded to that being one of the goals in MDUFA V, and I certainly appreciate that.

So we will [inaudible] it. And if you generate some interesting data in -- as you begin to pilot this, and invite industry to bring a perspective to it as well, [inaudible] with us, because it may inform our ability to do some things here on the policy side.

Thanks very much, Madam Chair.

*Ms. Eshoo. The gentleman yields back. The chair is pleased to recognize the gentleman from Virginia, Mr. Griffith, for your five minutes of questions.

*Mr. Griffith. Thank you very much, Madam Chair.

Doctor, at the beginning of the COVID-19 pandemic the CDC tests for COVID were not accurate. What role did the FDA play in the approval of these faulty tests?

*Dr. Shuren. Well, the test itself, the design of the test, was fine. And so we authorized that test. But, you know, from our review there was an issue around the manufacturer. We believe that there may have been contamination that occurred in later batches of the test that was produced.

*Mr. Griffith. And will you provide this committee with the FDA's after-action analysis and report on the various causes, whether it was manufacture or otherwise, of this significant failure?

*Dr. Shuren. I am happy to provide you what information we can. We did not have an official report of -- coming from the agency. But I did have the director of our in vitro diagnostics office we had sent over to the CDC to facilitate looking into this matter. He has many years' history of developing tests, both in the laboratory and at commercial manufacturers. And --

*Mr. Griffith. If you could share that with us, I would appreciate it.

*Dr. Shuren. I would be happy to.

*Mr. Griffith. Switching gears a little bit, how many emergency use authorizations were granted in the last two years vis a vis the two years prior to that?

I don't expect you to have that answer here today, but could you provide that to the committee, as well?

*Dr. Shuren. Yes. I think, if you are talking about all medical devices, I think we are somewhere over 870 EUAs granted.

*Mr. Griffith. During the last two years?

*Dr. Shuren. In the last two years.

*Mr. Griffith. Okay. If we could just get that --

*Dr. Shuren. We will double --

*Mr. Griffith. -- comparison of pre-COVID and post-COVID, what the use of that was. All right.

[The information follows:]

**********COMMITTEE INSERT**********

*Mr. Griffith. Digital health is an important component of MDUFA, and in the MDUFA commitment letter I am glad the agency will put such a strong focus on this important area. But I wonder whether device, drug, and biologic centers will operate in silos which could hurt digital health innovation because of inconsistent regulations.

What specific actions will the agency take to ensure that this does not occur?

*Dr. Shuren. One of the steps we took is to create a digital health center of excellence out of the Center for Devices, which serves as also a resource and a convener for the rest of the agency. And we have already an intra-agency group that serves to advise the center and to facilitate coordination between the different parts of the agency on cross-cutting matters relevant on some of these aspects for digital health.

*Mr. Griffith. All right, I appreciate that.

It has also -- a little bit different, but in the same area, it has come to my attention that a significant challenge associated with incorporating digital technologies in health care is distinguishing between a medical device which requires FDA approval and a consumer product which falls under the FTC's jurisdiction.

Do you agree that there should be more cooperation between these two agencies, as we determine how best to

regulate devices that can be helpful in our health care?

*Dr. Shuren. Well, we do have a good working relationship with them, and there have been a number of cases with just medical -- with products more generally, where there has been an issue on, you know, which side of the line it sort of falls. And we have coordinated with them, such as on cribs, risk of strangulation on cribs. And we will continue to do so, because that is an important relationship.

I do think the committee was very helpful in 21st Century Cures, for example, on clarifying certain circumstances where the software is not a medical device, and so falls on the other line. And that clarity then helps, you know, for these jurisdictional issues.

*Mr. Griffith. All right, I appreciate that.

The MDUFA commitment letter also describes several activities the FDA plans to undertake to support better harmonization among medical technology regulators across the globe. What international harmonization efforts are currently underway?

*Dr. Shuren. Right now this is all through the International Medical Device Regulators Forum. And there is a particular focus right now on harmonization pertaining to artificial intelligence -- biggest focus on machine learning.

*Mr. Griffith. And how do you see this work evolving in the future, specifically referencing artificial intelligence

and the support of that in decision-making and in clinical work?

*Dr. Shuren. It has become increasingly more important in the work that we do. We have already authorized, you know, over 300 devices with AI ML capabilities -- just 50, I think, you know, in the last year.

So we have a whole action plan that goes through a number of steps we are taking to sort of facilitate the development of AI technologies, and to ensure they are safe and effective.

*Mr. Griffith. And one of the things we have to work on as we work on AI is to make sure that we are using that, and helping to bring down health care costs, because there are a lot of things, if it is not something serious, that we could actually use AI, as opposed to actually using one of our health care providers, who -- on site. So if you combine AI and telemedicine, we could do an awful lot to bring down costs and bring service to people who may not otherwise have access to the medical care that they deserve.

*Dr. Shuren. No, we agree. I will say one of the challenges we face is that, you know, the device frameworks, you know, that are in place, they are about 45 years old. So they were really designed for, literally, my grandmother's technology. You know, it is hardware-based, and we are talking about software. And it is just not lined up, you

know, with the innovation cycles that you see.

And I would personally say I wish I had the flexibility that we have in COVID on tailoring the pathway to the technology in the least burdensome way, and have that ability to do it in peacetime. Not change the U.S. standard of market, but have the flexibility to offer it voluntarily, you know, and then you pick the traditional route, pick the new route. And, you know, if we don't do that in this software area, like with artificial intelligence, we are going to kill important technology that will make a big difference to patients. That I do worry about.

*Mr. Griffith. Let us know what we can do on that.

I yield back, Madam Chair.

*Ms. Eshoo. The gentleman yields back. The chair recognizes the gentlewoman from Michigan, Mrs. Dingell, for your five minutes of questions.

*Mrs. Dingell. Thank you, Chairwoman Eshoo and Ranking Member Guthrie, for having this really important hearing today.

Since 2002, user fees have supplemented funds appropriated to FDA to support timely review of medical device pre-market applications, facility registrations, and other activities. These funds enable FDA to hire more staff that have the necessary subject matter expertise to review the complex data that, as a result, applications may be

reviewed in a shorter period, shorter amount of time, while FDA standards for safety and effectiveness -- and that matters -- are still met.

For the first time, MDUFA V, FDA, and the industry have agreed to an increase in fees for the last 3 years of the new cycle if the goals are met in the first 3 years, beginning in 2023. If FDA meets the initial goals and fees increase, the corresponding review goals for FDA in fiscal year 2025 through 2027 will also escalate.

Additionally, if FDA doesn't meet its hiring goals, registration fees would be reduced. This should create additional incentives for FDA's Center for Devices to review pre-market submissions by the agreed-upon goal dates. But Dr. Shuren, I do have some questions.

Since user fees were first considered decades ago, there have always been questions about whether payments by regulated industry to the regulating agency create a potential conflict of interest. How does the CDRH assure that the fees and the goals agreed upon in the MDUFA only impact review times, and not review outcomes?

*Dr. Shuren. Well, we do assure, you know, that is baked into the agreement. We are making no commitments regarding policy decisions. We make no commitments on decisions regarding individual products. This is basically the fee for service.

The other is -- you mentioned the add-on payments. And they will only kick in for more money. At least we are not talking about cutting funds if we have a net performance.

But the other thing that is sort of assured is that, with additional funds that may lead to faster review times, it doesn't undermine the quality of the decisions that we make because this is a bit of a queuing issue. And so, if we have more people, we are able to do things, we have more people to spread it out, we can reduce the overall time on a review.

The other added advantage is that it allows us to bring on board more experts, and we have a deeper bench on expertise like around digital health -- assures that we make, you know, well-informed decisions.

*Mrs. Dingell. So do the new performance incentives present any risk that speed may sometimes have a negative impact on the quality of the pre-market review?

For example, is it more difficult to identify and explain submission deficiencies for a greater number of submissions in a shorter period of time?

*Dr. Shuren. Well, I do think, if we are identifying deficiencies, then -- and we do have enough time to identify them if we have the added people for doing the work. Like I said, it is a bit of a -- it is a queuing issue. And the reason why there is a certain timeframe isn't because you

take a file and you spend 100 percent of your time reviewing it. Our reviewers have a stack of files sitting there, and they are looking at one, they are moving to the other, and that is why it takes a certain amount of time.

Some of this, if you have more people, they have fewer files on their desk, they can spend more time on the file, and it takes less time. That is not taking away from their ability to identify deficiencies and communicate those.

*Mrs. Dingell. Thank you, because I worry about it.

Also, can you discuss how the new performance improvement adjustment can come about, and is there evidence supporting this incentive structure?

*Dr. Shuren. Well, this was discussed as an accountability measure for the FDA. In fact, there are a number of things baked into MDUFA V to increase the level of accountability on the agency, the add-on payments being one of them. This is the first time we are doing it in any of the user fee agreements. And I do think, you know, we will get experience from this.

But we felt that this would be a reasonable thing to try in MDUFA. And we worked with industry to design it in a way that we think can support our being successful.

*Mrs. Dingell. Thank you. Thanks for your response. I look forward to discussing these issues further, as well as ways to improve post-market surveillance, as my colleagues

have mentioned, in the weeks and months ahead.

I yield back, Madam Chair.

*Ms. Eshoo. The gentlewoman yields back. It is a pleasure to recognize the gentleman from Florida, Mr. Bilirakis, for five minutes.

*Mr. Bilirakis. Thank you, Madam Speaker, I appreciate it very much.

Dr. Shuren, your testimony mentions the popularity of Breakthrough Devices Program with significant growth in pre-submissions for breakthrough-related devices. Can you tell me about how this MDUFA agreement expands upon the successes of that program, and how the new product Life Cycle pilot will help innovators earlier in the development?

*Dr. Shuren. So the funding that we are going to get from industry is going to allow us to hold more pre-submission meetings within the specified timeframes. And that is an advantage to anybody who takes advantage of that program. And it is very popular, and that is why we have seen, you know, the number of requests continue to go up, because manufacturers find it very helpful to have those meetings.

TAP moves away from that sort of stage gate approach and longer time for meetings, trying to make this a much more fluid interaction with the innovators of very important technologies like breakthrough devices, to try to -- and also

give us the capacity to not just give feedback, but --

*Mr. Bilirakis. [Inaudible] asking questions --

[Pause.]

*Dr. Shuren. To also problem-solve with the developers. So the goal here is let's deal with not just the issues around pre-market review, shorten that timeframe, but focus on what is even more impactful, what leads up to the pre-market submission. And if we can work with developers in more real time there and problem-solve, we shorten that time from, really, concept to pre-market submission. And if all things look good in a pre-market submission, we are actually in a position to maybe even review it more quickly because there aren't issues, we have dealt with them beforehand.

*Mr. Bilirakis. Thank you, Doctor. I appreciate it. Another question for you. I want to ask you about the use of both unique device identification, UDI, numbers and the national drug codes on certain over-the-counter medical devices for reimbursement purposes.

This impacts, like, again, the items like the test strips, needles, and syringes, which are critically important to be -- again, to help patients manage chronic conditions, so very important.

For years, FDA has exercised enforcement discretion to allow both numbers on the label -- both numbers on the label. Since the UDI number cannot currently be used for

reimbursement purposes, I think it is time to find a permanent solution. I believe you probably agree with me. For example, FDA could allow both numbers to remain on the label permanently, or until such time that the reimbursement systems support using the UDI number.

Will you work with the committee to find a permanent solution?

If not, are you planning to at least retain enforcement discretion to reduce uncertainty in the industry, and keep patient access to these OTC devices?

So if you could answer that for me, I would appreciate it, Doctor.

*Dr. Shuren. We have had outreach regarding UDI and the NDC code. Of course, there has been some talk about changes in the NDC code, and the implications there. And so we are looking at, you know, opportunities to assure we do not disrupt the marketplace, as you have raised, you know, one of them being continued enforcement discretion.

That said, we would be very happy to have conversations on, you know, what is the -- what really is the right solution at the end of the day.

*Mr. Bilirakis. Please, please. Let's follow up on that. Thank you, Doctor.

Thank you, Madam Chair. I will yield.

*Ms. Eshoo. Good to see you, Gus, real close to the

camera. Nice glasses.

[Laughter.]

*Ms. Eshoo. The chair now recognizes the gentlewoman from California, Ms. Matsui, for your five minutes of questions.

*Ms. Matsui. Thank you very much, Madam Chair, and thank you, Dr. Shuren, and, ultimately, the industrial witnesses, for being here today, as well.

When the COVID-19 pandemic began, FDA was able to utilize and fine-tune the emergency use authorization process to authorize over 100 different diagnostic tests by the summer of 2020. I commend the agency for their work in this area. However, I understand these tests with different technologies or platforms have been validated in a variety of ways and varying levels of accuracy.

Of course, hindsight is 2020, but it seems that in the future there may be a more effective and efficient way to develop and utilize accurate diagnostic tests against a highly infectious virus. To that end, along with MDUFA, the MDUFA agreement, today we are discussing the Diagnostic Device Advisory Committee Act, legislation that will establish a panel of experts on diagnostic devices at FDA.

Dr. Shuren, what lessons has FDA learned from COVID-19, in terms of development, validation, and use of diagnostic testing as part of the coordinated public health response to

a pandemic? Dr. Shuren?

*Dr. Shuren. Well, thank you for the question. Let me mention maybe three things, because, quite frankly, to date we have issued about -- a little over, I think, 450 authorizations for tests and self-collection kits. And we should never be in that position again.

If you want to solve it, pre-position manufacturers of tests in advance of the public health emergency. Have contracts with them, so that when they are asked, they are set to do it. And you do it with manufacturers who make these kind of technologies, and they can make a lot of it very quickly. That is what South Korea did. They even had two companies who started to make tests before they even got asked.

Second, de-risk the enterprise. You know, we did this for vaccines. We pumped all this money in to take the risk off of production. You knew you weren't going to get reimbursed. That didn't happen, you know, with diagnostics. And so you had manufacturers who are, "I don't know if there is a marketplace,'' and they were skittish about going into it. We had to convince some of them to even make tests. So what you do is you have guaranteed minimum purchasing agreements if you get authorized, and guaranteed reimbursement. South Korea did that, as well.

Third, I would say, we found that, rather than having

the companies validate their tests or do all of it, have it done independent of them. You know, because, in the beginning, conserve your resources for the material you need to validate. And you can assure it is done right and it is done quickly. We wound up doing that for antibody tests, and now for over-the-counter antigen tests. South Korea had that set up with their CDC. And so, if there is funding to go do that, the country could be able to make these decisions also a lot faster.

*Ms. Matsui. Could I ask you --

*Dr. Shuren. So a few developers, large numbers [inaudible] decisions.

*Ms. Matsui. Well, could I ask you, could the agency utilize a panel of experts on diagnostic devices to assist in future public health crises?

*Dr. Shuren. Well, expert -- outside expert, you know, input is, you know, always helpful, and we look for those opportunities to bring them involved. And so this is something we would be very happy to have conversations about regarding the proposal, and work with all of you.

*Ms. Matsui. Okay. The CARES Act of 2020 sought to prevent shortages by requiring device manufacturers to notify FDA about any discontinuances and interruptions in the production of devices critical to public health emergency.

Dr. Shuren, has this notification from device

manufacturer has been useful to the FDA during the COVID-19 emergency?

*Dr. Shuren. It has been exceptionally helpful. And again, thank you to Congress for those authorities.

We have been able to prevent or minimize a variety of different shortages from -- you mentioned test supplies -- a number of personal protective equipment, defibrillators, dialysis systems, really, across the board. And again, those situations can arise both just before the public health emergency is declared, as we found with COVID, and from other causes. And if we are not well positioned to deal with that, we are going to have important shortages that aren't resolved.

A quick example, outside of a public health emergency, we had facilities using ethylene oxide to sterilize medical devices. In fact, a little over 50 percent of devices that require sterilization use ETO. When those facilities were closed, we had no window as to whether shortages were going to be caused. A few companies told us, many did not. We had to manually go back in our systems, try to identify which products were being sterilized there, and see if there was going to be a shortage. In fact, we got complaints, once a shortage happened, from the users because we never heard from a company. And this is all because there was no requirement for a notification. It puts -- it really puts people at

risk.

And what does it matter, the cause on the shortage? Because, at the end of the day, patients don't care the cause of the shortage. They just care they didn't get the medical device they needed that may be saving their life. And the doctors, nurses, other health care workers care that they could not provide the necessary treatment to patients. And as a doctor, I find that --

*Ms. Matsui. Absolutely, Dr. Shuren.

*Dr. Shuren. -- you know, difficult to swallow.

*Ms. Matsui. I have run out of time. I really can't -- so I yield back. Thank you.

*Ms. Eshoo. The gentlewoman yields back. It is a pleasure to recognize the gentleman from Utah, Mr. Curtis, for your five minutes of questions.

*Mr. Curtis. Thank you, Madam Chair. It is great to be here with you, Mr. Ranking Member. It is a great --

*Ms. Eshoo. Great to be with you. Thank you.

*Mr. Curtis. Dr. Shuren, clearly, many of my colleagues are familiar with you. This is my first hearing with you, and it is a delight to be here.

I am really excited to talk about this portion, because Utah really excels. As a matter of fact, we have the fastest-growing life sciences community in the nation, BioHive, and I love to brag about these companies. The first

artificial kidney came from Utah, and perhaps many in this room remember the Jarvik heart that came from Utah. Merit Medical is a Utah born and bred company. It was founded on the design of a polycarbonate coronary control syringe designed to replace dangerous glass syringes. Merit Medical was once a small company, and really the heart blood of my district are these small and medium-sized companies.

But I also feel like -- that sometimes we are the hardest on these small and medium-sized companies. And I think my first question to you, Doctor, is it appears that they are disadvantaged, compared to some of these larger corporations who can weather longer time approvals, and they tend to have far less capital and lack the established relationships that the bigger companies have.

What can be done to level this playing field, and help these startup companies who are so critical later on, right, as they grow and become more important? Any ideas on leveling this playing field?

*Dr. Shuren. Well, I have to tell you, and so much innovation comes from these, you know, small companies. And they do not have the resources also for the help of what they need to do to figure out -- to actually get to the marketplace.

That is one of the reasons we had proposed this TAP pilot, is to help. And the big focus is because most of

these innovative technologies coming through with the breakthrough device designation are these small companies, and let's be there to help them. If you will address the questions that they are finding challenges with, and they don't have the outside -- you know, the big companies have so many experts, maybe it is less helpful to them. But the small companies, in particular, need that.

And in fact, the person who heads this up, I hired a year ago, is my deputy center director for science. He was a venture capitalist for three decades. He started a bunch of small companies. He gets it. And he came to the FDA specifically to do just what you are asking for. How do we help, you know, these companies deal with these issues and get through that valley of death, if you will, and safe and effective to the marketplace.

*Mr. Curtis. Yes, and I just really need to emphasize how much more difficult the process is the smaller you are. So thank you for addressing that.

We have been discussing for months the importance of FDA keeping pace with industry and the role of these agreements and the FDA working effectively and efficiently. It has been brought up a number of times today, these negotiations are running two months behind PDUFA, GDUFA, and BsUFA, which were submitted to Congress in January. It is troubling to me that this agreement was delivered to Congress well past the

statutory deadline, impacting our ability to ensure that they are authorized on time.

We have also discussed at length the many instances we are finding that COVID-19 created problems and concerns that we are seeing and experiencing in our health care system. Over many of these are things that were there before the pandemic. COVID-19 highlighted these existing problems, making them things we cannot and should not ignore. I don't think that we should be using COVID-19 as an excuse, a shield the hide behind, instead of addressing root causes. It was a factor, and we recognized the initial delay it created. Yet you spoke earlier about concern over pink slips going out, and I share those same concerns.

It is my understanding that MDUFA initially -- meeting was delayed by COVID from March 2020 until October 2020, but PDUFA and GDUFA and the initial public meetings in July of 2020. Why did it take MDUFA -- why didn't it move forward as promptly as the others?

*Dr. Shuren. Well, COVID hit the medical device industry, and it hit us very, very hard. And so we mutually felt we needed more time to get started.

And then there were a lot of issues, you know, ultimately to work through. And there is -- the medical device industry is very heterogeneous, and it has very diverse opinions, and that can take time to work through.

Regardless, we should have had that to you on time. And that is our fault, ours collectively, and we take responsibility for that.

*Mr. Curtis. You have been very good in taking responsibility. But I want to point out that BsUFA had an initial meeting in November after MDUFA, and they still made their deadline on time.

Dr. Shuren, there are many Utah medical device industry stakeholders that have vocalized concerns to me over communication breakdowns between them and FDA. What measures can the FDA put in place to ensure this communication is better?

Often when I hear from the complaints, it is communication more than anything. What can my office do in working with you in facilitating this? We hesitate, right, to step in to the middle of this when we hear from them, but we would just love your advice on, like, how we help these companies in a way that helps you and is not counterproductive.

*Dr. Shuren. Well, if they feel that they are not getting, you know, the interactions are supposed to, they are not getting the answers they are supposed to, they are identifying issues with our program, talk to us. And quite frankly, you can send them directly to me.

*Mr. Curtis. And Doctor -- I didn't realize we are out

of time, Madam Chair -- I would love to continue that dialogue with you to figure out how to better coordinate with them.

And I yield my time.

*Ms. Eshoo. You know, there is something that hasn't been mentioned in this relative to timing, and meeting deadlines, and all of that. And it is one aspect. It is understandable, but I think it should be stated, that there was a -- you know, some real schisms between the very large advocacy or -- you know, for large medical device companies and the small companies. And they did not see eye to eye. It is not a surprise, because each one has its own -- you know, its own self interest. But that took time, as well.

So everything is not -- doesn't rest with the agency. They have to negotiate with people. And if they are not coming to an agreement within the industry itself, that slows things down, as well. So I think it is fair just to put it out there. We are all thrilled. I was thrilled when I found out that they, you know, came to an agreement so that everything could move along, but that was a part of this.

And as you pointed out, the smaller companies have -- they may be small, but they want their voices heard. So bravo to them.

Okay, it is a pleasure to recognize the gentlewoman from Illinois, Ms. Kelly, for your five minutes of questions.

*Ms. Kelly. Thank you, Madam Chair and Ranking Member Guthrie, for holding this hearing on the FDA user fee authorizations for medical devices.

According to the newly-released MDUFA performance goals and procedures, the FDA is committed to hiring 200 new employees in the coming 5 years. The FDA Diversity and Inclusion Workforce Strategic Plan of 2018 through 2021 outlines FDA's commitment to, and I quote, "cultivate and promote a diverse, inclusive culture'' in their workplace to reflect the diverse backgrounds of those served by the agency's work.

Doctor, what metrics will FDA use to ensure that there is adequate representation of racially and ethnically diverse employees across all levels of positions in these FDA new hires?

*Dr. Shuren. So we collect that information already as to what the representation looks like.

But I will tell you, we have already just issued for our center our diversity, equity, inclusion, and belonging roadmap on steps we are taking that includes hiring, addressing that, and it is part of the strategic priorities. I mentioned one: advancing health equity. The second is on, you know, a modern, diverse workforce that, if we are going to represent a diverse country, we need to reflect that diversity in our center. And that is a commitment from us,

and there are already workstreams.

And so that includes our outreach for hiring in the first place in different places, so that, again, we can bring that sort of talent, diverse talent, into the center.

*Ms. Kelly. Thank you so much, and great to hear.

You discussed the importance of patient voices in the development of medical devices. How can patient preference information, PPI, and patient-reported outcomes, PROs, and patient-generated health data be leveraged to ensure clinical care is culturally relevant for racially and ethnically diverse individuals?

*Dr. Shuren. Well, for example, for patient-generated, you know, health information, here is a great opportunity where using technology -- you know, technology is much easier to push out into settings where people are living their life. And so those who may have a hard time getting to a clinical trial site or, you know what, they have some discomfort of doing that, any number of reasons, if instead they can provide that information in the comfort of their home, at work can make it easier for individuals who don't have that same access. So we think that is a very important route.

You deal with patient preference information -- I will just mention if you have intended populations, you want to make sure that is represented too in the patients in whom you conduct that study. Because we see the preferences of

patients are not uniform at all. They kind of stratify on a variety of factors.

*Ms. Kelly. Okay. The MDUFA agreement outlines the use of patient input to inform clinical study design to increase recruitment and retention of a diverse clinical sample. From a clinical and device efficacy perspective, why is it important for clinical trials to have racially and ethnically diverse participants?

*Dr. Shuren. Well, it is important that, if you are going to use a device in an intended population, that you know it is going to work in that population. And we have seen, you know, plenty of instances where there may be a difference in how that technology works. That may be due to a variety -- it may be race, it may be gender, or any number of things. And so you want to make sure you have looked at it in those appropriate circumstances so you know it works in the intended population.

The other is, even if your intended population is small, we have got to be thinking about, if that technology could add value in other populations, we should be looking at that so that we don't have devices simply made for certain segments of the U.S. population. We ultimately have high-quality health care for all.

*Ms. Kelly. Thank you. And that is why I have been working with my colleagues on the DEPICT Act and the NIH

Clinical Trial Diversity Act that would ensure diversity in clinical trials.

Thank you so much for your patience, and thank you for being here.

I yield back.

*Ms. Eshoo. The gentlewoman yields back. The chair is pleased to recognize one of the wonderful doctors we have on our subcommittee, Dr. Bucshon from Indiana, for your five minutes of questions.

*Mr. Bucshon. Thanks, Dr. Shuren. I would like to talk to you today about a topic that isn't included in today's hearing, but that I thought maybe ought to be, and that is diagnostic testing reform, and specifically the VALID Act, which I have been working on, which -- you have also been working on this issue, I know, for many years.

I was driven to start working on diagnostic testing reform based on my experience as a doctor before coming to Congress. Health care providers and patients routinely use and increasingly rely on diagnostic tests to make difficult decisions about the best course of care and treatment. Unfortunately, we continue to see examples of some tests that don't meet the level of analytical and clinical accuracy that are needed to make reliable medical decisions, causing some patients to go through with life-changing procedures that may not have been necessary.

This is why I believe Congress must provide certainty, and that is why we are trying to accomplish what we are trying to accomplish through the bipartisan and bicameral VALID Act, which I have been working on with my friend, Representative Diana DeGette, in the House for about five years. We are working to provide certainty for patients that the results of their tests are clinically accurate, and provide certainty for doctors that the tests they are administering and making health care decisions based on are accurate.

And lastly, we want to provide certainty for test developers and labs that the regulatory framework won't suddenly change, and that they will have a clear understanding of what is expected from them within the risk-based framework.

I would also like to note that the sponsors have been mindful throughout this process to make sure we are balancing patient safety while promoting innovation. For example, VALID provides certain flexibilities to help facilitate development and support innovation for diagnostic tests for rare patient populations, all while keeping in place high standards for patient safety. This is instrumental as we continue to move towards the future of --

[Audio malfunction.]

*Mr. Bucshon. -- will enable physicians to provide more

individualized patient care to discover a cure and treat diseases that were previously unknown and untreatable, which is why I am somewhat concerned that the committee is seemingly ignoring the issue and the legislation all together. I have repeatedly called for hearings on VALID so, as a committee, we can better understand the issue and the legislation needed to promote innovation and provide clinical and analytical certainty.

Therefore, I would ask the chair of the -- Eshoo and Chairman Pallone to work with me in the coming weeks, and with Congresswoman DeGette, to have a hearing on VALID, the VALID Act, so that Congress can help better serve patients, as I truly believe the time for Congress to clarify the rules of the road for diagnostic testing is now.

So, Dr. Shuren, it is my understanding that the FDA currently does not have a process tailored specifically to diagnostic test review. And rather, the FDA uses the existing medical device process for diagnostic testing review, even though the two are quite uniquely different. Is that true? Is that accurate?

*Dr. Shuren. Well, the pathway we have for in vitro diagnostics is different for other devices. I mean, the law is very clear that IVDs, regardless of who makes them, are called medical devices, but how we regulate them is different, and we really tailor that to that kind of

technology.

*Mr. Bucshon. Okay. Does this -- so you wouldn't say this process limits your ability to validate that all diagnostic tests out there today are analytically and clinically accurate?

*Dr. Shuren. Well, the answer is no. We have had this policy of enforcement discretion for -- since the start of the program for tests made by laboratories. And at the time that made sense. They are low risk --

*Mr. Bucshon. Right.

*Dr. Shuren. -- locally, but they are far more complex, riskier. And we have seen, over the years, you know, problematic tests from laboratories to market.

At the same time, though, those LDTs play a critically important role in health care. And, as you note, increasingly, they and tests made by commercial manufacturers are important for making clinical decisions. And we have to assure, ultimately, that they work. Those assurances are in place if it is made by a commercial manufacturer, then not in place if they are made by a laboratory.

And so having a legislative framework that clarifies an overarching approach to assure that all developers, whether they are commercial manufacturers or laboratories, are working with FDA and all of us acting consistently under a modern framework -- you know, I mentioned the frameworks are

years old. It is time for an upgrade. This is a time, really, to do it. And that could have a big impact on public health, but done in a way that is protecting patients, but driving -- you know, supporting that innovation.

And I, you know, thank you and Representative DeGette on your leadership on trying to push this forward. We do think the time is right. We have publicly stated for years we would -- we were holding off on administrative action because we thought a legislative solution was really the best way to go.

*Mr. Bucshon. Thank you for that response. I couldn't agree more.

I yield back.

*Ms. Eshoo. The gentleman yields back. The chair recognizes the gentleman from Vermont, Mr. Welch, for your five minutes of questions.

*Voice. Oh, sorry, let's go to Cardenas.

*Ms. Eshoo. Oh, I am sorry. Who is it?

*Voice. Mr. Cardenas.

*Ms. Eshoo. Oh, okay. The gentleman from California, Mr. Cardenas, is recognized for your five minutes of questions.

*Mr. Cardenas. Thank you very much. I appreciate this opportunity for us to discuss this important issue, Madam Chairwoman, and also Ranking Member Guthrie.

I appreciate you, Dr. Shuren, for joining us to discuss what we should be doing, and continue to do for the American people. Dr. Shuren, once again, thank you. And obviously, it is critical that the devices we bring to market are safe, effective, and work for everyone.

It is one of my top priorities to ensure that our approval process at the Federal level includes diverse perspectives, and that medical therapies and devices are tested in trials that include demographics that mirror the nation as broad as we are as a nation. How will FDA incorporate the perspectives of patients and stakeholders from diverse backgrounds?

*Dr. Shuren. One of the commitments I will highlight under MDUFA V is to expand exactly that: patient perspectives in the design, conduct of clinical trials, as well as to facilitate participation.

So one of those approaches is really using technology as a way for patients to participate in clinical studies without having to keep going to clinical trial sites could facilitate more patients participating, particularly those who have less access to the health care system.

*Mr. Cardenas. Well, less access to the health care system, sometimes that comes from a lack of access to transportation, a lack of access to technology, et cetera. So what you are saying is, by removing some of those daily

barriers, we are hopefully going to be looking at more diverse input, which means a better output.

*Dr. Shuren. That is correct.

I mean, another step is, in designing studies and looking for patients, work directly with those centers that are in the communities where you are trying to recruit. It is very important to have that kind of partnership.

Also, it can drive a greater participation from diverse populations. You have got to go to where people are --

*Mr. Cardenas. Okay.

*Dr. Shuren. -- and meet them --

*Mr. Cardenas. Thank you, and I think that --

*Dr. Shuren. -- as opposed to asking them to meet ours.

*Mr. Cardenas. And I think what you just described not only is diversity in more ways than one, it is also rural, as well. So thank you.

I also recognize that it is critical to ensure that we are expediting the time it takes to approve devices without sacrificing a review that will determine safety and efficacy. What steps will FDA take to ensure patients will not be harmed by devices that have been approved using more expedited processes?

And how do you, you know, work with and -- with these concerns?

*Dr. Shuren. So any of the times we reach an accord

with industry, we are never doing it where we believe it would ever sacrifice the quality of our decisions, and then put at risk our authorizing an otherwise unsafe device because of it.

And we believe the extra resources -- will it allow us to meet the commitments that we have laid out in the commitment letter in a responsible way? We have more people. It means that we have more folks with fewer files on their desk. They can move through it more quickly. But it does not compromise the quality of that review. If anything, by expanding our expertise in the center, we may have more experts to help out, particularly things like in digital health, bringing -- and that is one of our commitments. Bringing on more expertise into the center can be helpful so we have better-informed decisions, but we can do it in a more timely manner.

*Mr. Cardenas. With higher user fee collection, how may that affect diversity in clinical trials?

And you just mentioned having more experts. I am sure with more and better funding, we can actually have higher and have better and more experts to do the job. So how does the funding and allocation affect that?

*Dr. Shuren. The funding also expands our patient engagement program, the people who are working directly with patient groups and working with communities. And part of

that mandate under MDUFA V is we will be using some of those additional resources to facilitate a greater participation by diverse populations in clinical studies.

*Mr. Cardenas. Okay, thank you. I appreciate you sharing your insights and thoughts. And once again, thank you for the work that you do.

It is imperative that we ensure timely access to innovative devices, while still confirming that they are going to work as intended, without undue risk to the users.

And once again, if the information coming in is more diverse, then we stand a greater chance that efficacy will work in all communities --

*Voice. That is fine.

*Mr. Cardenas. -- not just some.

And with that, my time looks to be expiring. I yield back. Thank you, Madam Chairwoman.

*Ms. Eshoo. I thank the gentleman, and he yields back. It is a pleasure to recognize the gentleman from Pennsylvania, another one of our doctors on the committee, distinguished physicians, Dr. Joyce.

*Mr. Joyce. Thank you, Madam Chair Eshoo, for yielding, and for convening this hearing.

The approval of new, cutting-edge medical devices and safely getting innovation into the hands of patients and physicians is critical to improving health outcomes in the

United States.

To that end, Dr. Shuren, how can the FDA and CMS work together better and earlier to ensure that beneficiaries of Medicare do not face additional barriers to coverage once that -- the FDA approves or clears an innovative and lifesaving medical device?

*Dr. Shuren. Currently, both FDA and CMS are members of the Medical Device Innovation Consortium. And about a year ago a workstream was started that is focused on health economics and value that really is on the reimbursement side of the house, and what steps might be able to responsibly streamline that pathway, like including the voice of patients in decision-making.

We also were engaged in discussions with them on MCIT, and certainly stand ready to facilitate discussions too on whatever is helpful to them on establishing predictable pathways for reimbursement. I mean, we are not insurers. We can't stand in their place, but we all -- have always been there to facilitate as best we can.

*Mr. Joyce. Would it be helpful for CMS to communicate with the FDA at early stages of development the important issues that might be addressed in clinical trials to help facilitate timely Medicare coverage upon market entry?

*Dr. Shuren. We do think the voice from CMS early on can be very helpful. We offer that in the parallel review

pathway, which is voluntary, you know, for companies who may qualify.

I will say a challenge for CMS -- so I am going to tin cup for my sister agency -- they don't have enough people. You know, if we really want to do something there, like for coverage, national coverage determinations, they need more people. And I, by the way, used to work over there many moons ago, so I know exactly what it is like. And they can -- they could use some help.

*Mr. Joyce. Thank you, Dr. Shuren. I would like to touch on an area that Chair Eshoo mentioned before the recess regarding the distinction between servicing and re-manufacturing of medical devices.

Just to be clear, is it your opinion that it will be helpful for Congress to further clarify what constitutes re-manufacturing in statute?

*Dr. Shuren. We do think that that can be helpful. Again, the devil is in the details as to what it always looks like. But we know that, even though we have got guidance that is going through, there is a lot more comfort sometimes -- it is guidance, that there is more comfort if certain things are baked into the statute.

So again, we think this could be helpful, again, depending upon what that provision looks like, and we would be -- if there is interest, we would be happy to work with

the committee on it.

*Mr. Joyce. Thank you. And I would like to conclude by thanking my colleague, Representative Peters, for working with me on the introduction of Clarifying Re-manufacturing to Protect Patient Safety Act, which I believe would provide the necessary clarity on what constitutes a significant change to a medical device, as well as what constitutes re-manufacturing.

Thank you. I see my time has expired. Again, thank you, Madam Chair Eshoo, for convening such an important hearing.

*Ms. Eshoo. The gentleman yields back. Thank you for your kind comments. The chair is pleased to recognize the gentlewoman from California, Ms. Barragan, for five minutes.

*Ms. Barragan. Thank you, Madam Chair.

Dr. Shuren, several non-profit consumer advocate groups and public health organizations have raised concerns over the lack of transparency regarding the FDA's non-public negotiations for the Medical Device User Fee Amendments program. How involved were patients and consumer advocate groups during the negotiations?

*Dr. Shuren. We had held, I think it was, monthly stakeholder meetings to provide updates and to seek comments on the MDUFA V negotiations.

*Ms. Barragan. So my understanding is that there are --

no public stakeholder calls were held this year, and only one public stakeholder call was held in 2021. Do you know if that is accurate?

*Dr. Shuren. No, I don't believe that that is accurate. We can get you the details.

*Ms. Barragan. Great, I appreciate that. Thank you.

Dr. Shuren, according to a January 2022 report by the GAO, the FDA lacks an agency-wide strategic workforce plan, and has no process in place to measure agency performance. The report emphasized that creating a centralized workforce strategy is vital for the FDA. Does the FDA plan to adopt an agency-wide strategic workforce plan?

*Dr. Shuren. I would like to take that back, since it is the agency speaking. But I have to tell you that those recommendations were taken seriously, account -- and there have been a lot of efforts to facilitate our ability to hire and bring on board the people that we need in the agency to get our mission accomplished.

*Ms. Barragan. Great. Well, you know, for the first time in MDUFA's history, the FDA will publish the five-year financial plan with hiring targets for the MDUFA program. So I would like to know how the FDA is going to build and retain a diverse FDA workforce that accurately reflects, you know, our country when trying to meet these new hiring performance goals. Is that something you can comment on today?

*Dr. Shuren. Yes. So we are -- already issued a roadmap on diversity, equity, inclusion, and belonging, where this is one of our actions. It is part of our strategic priorities on a modern, diverse workforce.

Moving forward, such activities include recruiting from targeted areas so that we are more reflective of the diversity in the country. I mean, there is a lot of diversity in CDRH to begin with, but there is a better job that we can be doing that that is reflected across all layers in the organization.

*Ms. Barragan. Well, thank you. This is of great importance to me. The -- you know, the Hispanic Caucus, and making sure that we have diversity and inclusion, and the perspectives of those. So I just wanted to thank you for that, and I look forward to following up with you, and seeing anything more you have on this.

With that, Madam Chairman, I yield back.

*Ms. Eshoo. The gentlewoman yields back. The chair is pleased to recognize the gentleman from Georgia, Mr. Carter, for your five minutes of questions.

*Mr. Carter. Thank you, Madam Chair, and thank you, Dr. Shuren, for being here. I appreciate it.

Dr. Shuren, way back in 2017, I -- since that time I have really appreciated your engagement on legislation that that myself and others on this committee have authored to

establish over-the-counter hearing aids. I am a pharmacist by profession, and I see firsthand, and have seen throughout my professional career, the need for this. And I want to tell you that I appreciate your engagement in this.

The agency proposed a rule on October 19th, as I understand it, of last year that got a lot of things right. And I want to thank you for that, as well. Any idea when -- or any indication that you can give us when the FDA might finalize this proposed rule?

*Dr. Shuren. Well, sir -- and first of all, thank you for that provision. We couldn't agree more. This is -- these technologies are very, very important for public health.

We are supposed to, you know, issue that 180 days from the end of the comment period. So that turns out to be about July 15th. And our goal is to do that. We know this is important to the Administration.

I can't -- you know, some of it is out of our control, but that is our goal, to try to meet that statutory deadline.

*Mr. Carter. And you said it would be, what, June?

*Dr. Shuren. July 15th.

*Mr. Carter. July 15th? Okay.

*Dr. Shuren. Yes.

*Mr. Carter. We will look forward to that. I hope it will be before then. I will tell you there -- again, my --

and my experience has led me to believe and to offer to you that this is needed. I mean, you know, we got reading glasses. I mean, we ought to have over-the-counter hearing aids. I get it if there is a need for more severe cases. But for most people -- like myself, who are getting on up there a little bit -- you know, you do need a little bit of help, and there is no reason why we shouldn't be able to do this. So I look forward to that, and thank you again for your work on that.

*Dr. Shuren. We agree. I will mention we received about 1,000 comments. So there is just -- we want to make sure we get it right.

*Mr. Carter. You received 1,000?

*Dr. Shuren. Yes, about 1,000 comments.

*Mr. Carter. Pro, con, or can you indicate?

*Dr. Shuren. Mostly pro. Some had suggestions. You know, there are some differences of opinion, let's say, around where you set the output limits.

*Mr. Carter. Right.

*Dr. Shuren. For example.

*Mr. Carter. And I get that. And you are right, we want to get it right. We want -- you know, we don't want to do -- I mean, you know, the Hippocratic Oath, do no harm. So we don't want to do that. But at the same time, you know, we can help people, and we need to be doing that.

Let me ask you about the FACTS Act, if you are familiar with that, the FDA Advancing Collection of Transformative Science Act. That is legislation that Dr. Burgess on this committee and I have cosponsored. And it was considered at a hearing two weeks ago that we were in, and it has important ramifications about the medical device community, and Real-World Evidence, and a Clinical Laboratory Improvement Amendments, CLIA, waiver for EUA authorization, and for EUA-authorized diagnostic tests. And of course, again, this is very important. And I hope that the committee will continue to move this bill forward. It is a very important piece of legislation.

Will you commit to working and continuing to work, as you have, with this committee to improve and advance both the Real-World Evidence and Clinical Laboratory Improvement Amendments waiver provisions of this legislation?

*Dr. Shuren. We are happy to continue to, you know, talk with folks through that. We are looking -- I should tell you, in those transitions from an emergency use authorization to full marketing authorization, we are taking advantage of what has already, you know, been provided.

We will not -- like for a CLIA waiver, we are not planning to ask folks to go ahead and do usability studies. You know, there is no need. They have been out there. The biggest focus is really going to be on having enough data

just to make sure that they work --

*Mr. Carter. Right.

*Dr. Shuren. -- because we have relied on so little data to put them out on the marketplace.

*Mr. Carter. Right. Good, good. Well, again, thank you. These are important issues. And thank you and the agency for your attention to these.

And, Madam Chair, I will yield back.

*Ms. Eshoo. The gentleman yields back. The chair is pleased to recognize Dr. Schrier from Washington State for your five minutes of questions.

*Ms. Schrier. Thank you, Madam Chair. And thank you, Dr. Shuren, for coming today to discuss the medical device user fee agreements. Thank you for all you have done to help the American people get through the worst of the pandemic. And it is very nice to see you and talk with you again.

I would love to focus on what the FDA and industry can do together to get the right product to the right market at the right time and, frankly, even in the right quantity and the right price for a clearly defined purpose. And I have something clear in mind.

You and I have been in touch on and off for about a year and a half regarding the rolling out of rapid home COVID tests. And as you know, for most of that time I was feeling pretty frustrated, because the process just seemed so slow,

and seemed unnecessarily difficult to get these tests approved and into people's hands, even though the technology is pretty simple.

And I was hearing from universities and researchers and companies that had submitted applications but were still waiting for FDA emergency use authorization. And it seemed like at every stage there were barriers, but barriers that, with the right panel of public health experts and industry advisers all in a room together, could have really improved communication, and maybe been resolved quickly.

I am delighted that now we have 17 home antigen tests and a couple of molecular tests on the market for -- with emergency use authorization, although the price point is still too high for most people to use that for screening. But that means I was even happier when the Administration started sending free tests to every home in the country during the Omicron peak.

But still, reflecting on a year and a half, I felt like we were still lagging behind. And having an advisory panel to bring all of these specialists, public health, industry, consumers, and the FDA all together, could have defined that goal, set some standards that everybody agreed upon, figured out how you were going to test them, and even sped up that approval process.

My bill, the Diagnostic Device Advisory Committee Act to

create such a panel will do just that, and it will convene a group of experts meeting with FDA to discuss the real-world impact of diagnostics. And if passed, this will engage the diagnostics experts, consumers, public health, and you to talk about the risks, uses, needs, and the applications of these devices. And I think it will bring a lot of transparency and, hopefully, expediency.

So, Dr. Shuren, with the lens of lessons learned, I was just wondering if you could talk a bit about how such a panel might help future discussions, and how it might expedite getting things to market more quickly.

*Dr. Shuren. Well, certainly, input from the outside experts can be very informative. Certainly, things in advance, when we deal in a public health emergency, things moving quickly, just a -- sometimes a little bit more challenging. But this is something we would certainly welcome the opportunity to talk with you about, and work with you on.

I will say in the case -- I don't want to throw the baby out with the bathwater, you know -- for over-the counter antigen tests, which we put as a priority, actually, in the spring of 2020, and were one of the first countries to authorize, where we saw that you had lots of tests is where you invest in the marketplace.

It is not about having a lot of different tests. It is

about having a lot of tests made through high manufacturing capacity. And you have a country like the UK. When they put that money in through large government contracts that were going to then support large manufacturing volume, and they only did it with a handful of, you know, companies, and subsidizing so that your tests are low cost or free, massive increase in what was available. And many more developers came to their marketplace.

And I agree with what the Administration did. When they got money, you know, they invested in the marketplace. And we saw the same thing happen, a rapid increase, you know, of -- well, increase in production now over an order of magnitude. And that really makes a difference. And if that is not there, the numbers drop, you know, because the companies -- if there isn't that demand or guaranteed with contracts, they are going to cut production. We saw it happen in the U.S. There were more tests available in late spring than in late summer, because demand dropped, nothing propped up the marketplace. You know, a company closed a manufacturing facility.

*Ms. Schrier. And Dr. Shuren --

*Dr. Shuren. So that is a key piece that we need to have there.

*Ms. Schrier. I could not agree more.

*Dr. Shuren. And a last thing is independent review.

When we were able -- funding to support NIH with us to do the ITAP program, now we are able to make sure, without changing any standards, they were able to do the evaluations very quickly, just a few weeks, evaluate, and we authorize where the data was there. Our performance standards are really the same as we have seen, you know, that 80 percent sensitivity, as with other countries.

But the technology isn't as simple, though, actually getting those antibodies right on the strip. We have seen problems. In fact, the UK had the same experience. Most of the tests that came to them they never authorized, because of problems either with the test on validation -- we have had the exact same experience with the U.S. In fact, many of the folks we have seen are the same folks that made all those bad antibody tests, with the same technology that came onto the U.S. market.

So I 100 percent want to work with you. I also want to make sure, also, that we deal with some of these other issues, to assure that we, in the future, have the tests we need.

*Ms. Schrier. Thank you very much --

*Ms. Eshoo. The gentlewoman's time has expired.

*Ms. Schrier. I yield back.

*Ms. Eshoo. The chair now recognizes the gentleman from Texas, Mr. Crenshaw, for your five minutes of questions.

*Mr. Crenshaw. Thank you, Madam Chair. And thank you, Dr. Shuren, for being here with us today.

I certainly share my colleagues' concerns about how MDUFA V came together, and I hope you will work with us for a better process in the future.

We are excited to have you here to talk about the next frontier of medical devices. and how our phones and devices can deliver digital health. You know, we carry these things around, and they have tremendous possibility to improve patient health and well-being.

One that stands out to me in particular is the app connected to the continuous glucose monitor, which allows parents to track on their phones the glucose levels of their children with diabetes. A constituent of mine talks about this innovation as an absolute game changer. She used to wake up multiple times a night to check her son's glucose levels. Now, just as an app that notifies her when he drops to dangerous levels.

The FDA uses the framework of safe and effective to evaluate medical devices. I am always going to be a little skeptical of that mandate to regulate effectiveness, and whether the FDA is best suited for that. That is a conversation for another time. But giving us the framework we currently have, do you think FDA is suited to properly regulate things like artificial intelligence?

*Dr. Shuren. So, first off, we are the place for doing it. And, you know, we have authorized now over 300 devices with artificial intelligence, particularly machine learning -- I think just 50 in the past year.

But I do think that we need a regulatory flexibility that we don't currently have to better tailor the pathways to that kind of technology.

*Mr. Crenshaw. Okay.

*Dr. Shuren. The pathways in the law now are many years old. But I do think -- and I am happy to continue the conversation -- effectiveness matters. You know, as a physician, too, we want to know that benefits outweigh the risks. And that is really, at the end of the day, what we are saying: benefits outweigh the risk. We have got to know it helps patients and that, again, you know, the risks --

*Mr. Crenshaw. And the reason I ask about the artificial intelligence question is because three or four years ago FDA had a paper that said they might need different authority to regulate digital health. You are saying right now there might need to be some changes. And maybe -- and we don't have -- we have 2 minutes and 47 seconds, I don't think we are going to get through it right now. But if you would please follow up with us on what those changes need to be, that would be exceptionally helpful for this committee.

The other question I want to ask you in our time left

is, you know, one of the problems we often see with medical devices and other treatments is FDA approves something, then CMS has to evaluate it again, seemingly with the exact same set of tests and standards, just to determine if they will pay for it.

How do you think -- and maybe you weren't expecting a question like this -- but how do you think these agencies can work together to get patients what they need, once it has been approved by FDA?

*Dr. Shuren. Well, we do have different standards. You know, they are reasonable and necessary, you know, safety and effectiveness. And what they have, not different than other insurers.

But we believe it is very important that that pathway from an FDA marketing authorization to CMS -- or, by the way, any insurer's decision to coverage-reimburse, we have got to streamline that. Because, quite frankly, patients don't have real access to technology, particularly if it is expensive, if it is not covered and paid for, right, because people just can't afford some of these things out of their pocket, and they just won't get it.

And the U.S. is complicated. The reimbursement structure is much more complicated than some other countries. And providing predictability, however we do it -- I am not a payer, so, you know, I can't tell you, and it is not for me

to say what is the best thing from a CMS perspective. But I do think, as a nation, solving that problem to have more predictable reimbursement is absolutely essential for us to drive better technology for patients. And if we don't do it, we are at risk of losing our edge on innovation to other countries.

And I will tell you who is knocking at our door, is China.

*Mr. Crenshaw. Yes, and I couldn't agree with you more. I agree with the sentiment. I suppose we could delve into this a little deeper at a later time on whether CMS is duplicating the processes that occur at FDA already. I think that is what we are concerned about. You know, looking at cost effectiveness seems to be like something a payer would do. But do they really need to do extra safety tests when FDA has already done it? That would be our issue. And they are not here right now. So, you know, it is -- I am just curious what your thoughts were.

And with that, I yield back.

*Ms. Eshoo. The gentleman yields back. The issue was raised earlier in our hearing today, and I think that, working with FDA, with Dr. Shuren -- and Cures 2.0, I think, presents an opportunity for changes that we can work together on. But this is a concern on both sides of the aisle, very legitimate.

All right, all committee member -- staffers, members of the subcommittee, I will stay to finish out the questions if we only have three more. Congress members Kuster, Dunn, and Trahan. Do we have anyone else? Can you ping us? Otherwise, I am going to stop, and go and vote, and come back, and Dr. Shuren is going to have to wait again.

So why don't we go to the gentlewoman from New Hampshire? And I hope the offices respond.

*Ms. Kuster. Thank you very much, Madam Chair --

*Ms. Eshoo. The gentlewoman from New Hampshire is recognized.

*Ms. Kuster. Thank you, Madam Chair.

Thank you, Dr. Shuren, for being with us today. I want to jump right in, and ask you about the proposed pilot program at FDA known as the Total Product Life Cycle Advisory Program, also known as TAP.

This program is intended to foster earlier interaction between the FDA and industry to identify risks earlier in the development with input from outside stakeholders. While the pilot will begin in 2023 with only 15 products, importantly it will increase to 325 products by the end of the MDUFA in 2027. I am interested in learning about how this program will achieve its intended goals of improving patient outcomes, streamlining regulatory engagement, and increasing efficiency in the pre-market review process.

Dr. Shuren, can you elaborate on how TAP will achieve these goals?

*Dr. Shuren. One of the lessons learned from COVID is that, to facilitate technology coming to the marketplace, and safe and effective technology, developers sometimes are hitting, you know, roadblocks. Particularly if you are dealing with innovative technology, you may be dealing with new science.

And when we had the ability, as we did in COVID, to engage with those developers in near or real time to answer their questions, to work with them hand-in-glove to problem-solve, we could expedite product coming to market, because we solve problems more quickly. They were more efficient. You can be more efficient in how you spend your money -- you, as the developer -- and you can reduce that time, ultimately, on the development evaluation cycle and then, ultimately, for FDA authorization.

So TAP is just taking from those lessons learned, and now piloting that, if you will, in peacetime. And by doing this, the reason you will see the growth also in products is that we are sort of rolling this out. We will start with one of our offices, you know, learn from that, be iterative, be like an innovator, do this like a skunkworks, and then we will start rolling it out to other offices, and then include the opportunity for more products to come in.

And this, in particular, can be a major game changer for, you know, your small, innovative companies who don't have the same bandwidth for trying to get that product to market. Again, it has got to be safe and effective, the science has got to support it. But we know, from experience, these are the things that can really make a big difference.

*Ms. Kuster. And how do you expect FDA will balance the resource needs of the program with the demands of a growing stack of pre-market submissions?

*Dr. Shuren. Well, this is one of the reasons too we got added resources in -- or would get, you know, if enacted -- that would then give us the capability for handling those additional submissions that are coming in the door outside of TAP.

And the add-on payments that are put in as an accountability factor is another mechanism for kind of assuring that we keep, if you will, our eyes focused on a variety of actions that we have committed to meet and to take over the course of MDUFA V.

We also sort of factored in for the pilot -- is that it is up to a certain number. So if it turns out, you know, we are not completely right on the resource needs, and we would have needed more, we can kind of scale back, if you will, the number of products that come into it. So we really can test drive, and that is the nice thing about doing a pilot in this

case. We really can learn, factor that in. And if things look good, we will have a conversation with industry about where we go from here. And if it doesn't look good, you know, we can pull the plug.

But most of the people we are hiring are your review folks who are doing the other bread-and-butter work. So we see this as a win, and we think MDUFA V has already built in a number of aspects to assure that we are well positioned to make good on our other commitments, as well.

*Ms. Kuster. Great. And one last one: How will the FDA ensure that patient advocates and outside stakeholders are involved in the process?

And how will you ensure that the focus remains on safety and efficacy?

*Dr. Shuren. Well, it is very important that the agreement for MDUFA V, whatever gets enacted, does not change our independence on decision-making, it is not to get money in return for making a particular policy decision or any decisions on product. Absolutely essential that this is really about improving performance, not to influence our decision-making. And we think what we have gotten to with industry, in trying to reach consensus around there, achieves that objective.

And of course, you know, moving forward, we do view the perspective of patients as being very important in the work

that we do. And investments from MDUFA V are going to expand our abilities to advance that work on the science of patient input, and broaden patient engagement into medical device development evaluation.

*Ms. Kuster. Great. Thank you so much. My time is up --

*Ms. Eshoo. The gentlewoman's time is --

*Ms. Kuster. -- I yield back.

*Ms. Eshoo. Yes, the gentlewoman's time has expired. The chair is pleased to recognize another one of the doctors on our subcommittee, Dr. Dunn of Florida, for your five minutes.

*Mr. Dunn. Thank you very much, Madam Chair, for hosting this hearing today to discuss the agreement between the FDA and the industry regarding medical user fees.

And let me say thank you, Dr. Shuren, for your insights today, and for your stamina putting up with these marathon questions, and for your enthusiasm for this. It is -- it shows through. We appreciate a good witness who comes and really informs us. Thank you.

Let me say innovation in the device space is exciting for patients and doctors. Like, more and more advanced medical devices come to market, and Congress just has to make sure that FDA is adequately equipped to properly evaluate these new and emerging technologies.

We also have to guarantee that the patients have access to the latest and greatest technologies without significant delays, and that those delays that collect patient information keep that information secure.

We have learned a lot over the course of the pandemic. We witnessed the FDA efficiently grant emergency use authorizations to numerous diagnostic tests and devices. And I would like to see us continue to tune that process to continue these rapid and safe approvals to make it more available to the patients. And I certainly appreciate you being here to inform us on that today, Dr. Shuren.

I understand that, during the MDUFA IV reauthorization process, the committee sought additional information regarding the servicing of medical devices. As a result, the FDA put out in 2018 a report on the matter, concluding that OEMs and third-party servicers both provide high-quality, safe, and effective servicing of medical devices. I know this to be true from my own personal experiences. I ran a large practice with a number of complex machines, used linear accelerators for radiotherapy, PET scanners, CT scanners, et cetera.

Utilizing third-party services was critical to maintain high-volume, high-quality care in a cost-effective manner. So I commend the FDA for following through on this committee's concerns about enhanced post-market surveillance

and transparency by requiring disclosure of servicing on the MDR 3500 Form, and especially for providing clarity on the definition of re-manufacturing in your draft guidance.

So, Dr. Shuren, I understand CDRH has worked hard to provide a clear, transparent process for entities to understand if they are engaged in servicing or in re-manufacturing of devices. And is it correct that the FDA concluded in 2018 there was not -- no significant safety concerns related to the third-party servicing of medical devices?

*Dr. Shuren. We did conclude that there weren't widespread concerns.

*Mr. Dunn. Excellent, excellent. How much feedback has the agency received on your 2021 draft guidance regarding re-manufacturing?

*Dr. Shuren. Actually, I don't know the numbers, offhand.

*Mr. Dunn. Do you have a feel -- some of it, not much of it?

*Dr. Shuren. I would rather get you the right information.

*Mr. Dunn. Okay. Didn't -- okay. When do you expect that guidance to be finalized?

*Dr. Shuren. It is, you know, on our list to try to move forward in the coming year.

*Mr. Dunn. In this year?

*Dr. Shuren. In this year.

*Mr. Dunn. Excellent, excellent.

As you know, in the CARES Act, Congress granted FDA temporary authorities limited to the duration of the emergency to require additional reporting related to medical device shortages. You addressed that earlier in one of your comments. The FDA subsequently listed only 30 devices on a shortage list such as PPEs, diagnostics, ventilators, et cetera.

In January of this year the FDA issued draft guidance outlining their vision for reporting requirements beyond the public health emergency. It is my understanding that they are pursuing authorities to issue blanket requirements for the entire industry, including hundreds of thousands of devices. It seems to me, surely, there are only a few hundred critical devices we should be tracking in that detail.

And can we look at some kind of threshold for reporting on all those requirements? Does the CDRH even have the expertise in the supply chain management to look at those things?

*Dr. Shuren. Yes, so what we are putting forward is still a narrow list of devices.

*Mr. Dunn. Oh, excellent.

*Dr. Shuren. Yes, it is, and --

*Mr. Dunn. We would like to know what that is, but that -- thank you.

*Dr. Shuren. Yes. No, it is, and it is really the things that are critically important.

*Mr. Dunn. And I actually got your point earlier that it is critically important. I just didn't want to see, you know, the bureaucracy bogged down with chasing hundreds of thousands of different supply chains for reporting, especially on a biweekly basis.

*Dr. Shuren. We don't want to, either.

*Mr. Dunn. It seems to me -- yes. No, I mean, I think -- I don't know that I could do biweekly reporting like that, so -- thank you very much again, Dr. Shuren, you have been a really excellent witness, and a great guy. Thank you.

I yield back.

*Ms. Eshoo. Isn't that lovely? Isn't that nice for you to hear, Dr. Shuren?

Thank you, Dr. Dunn.

All right. We have one more member to question before we take a break. There are eight votes, and I will return ASAP upon the last vote being cast for the second panel.

The gentlewoman from Massachusetts, Congresswoman Trahan, is recognized for your five minutes.

*Mrs. Trahan. Well, thank you, Chairwoman Eshoo,

Ranking Member Guthrie, for convening us here today to discuss the importance of medical devices.

You know, I just want to start with an issue that has dominated the conversation around supply chain shortages, and that is semiconductor chips. Over the last few months my office has heard from several companies facing dire chip shortages, critical devices, from mammography screening to defibrillators to diagnostic scanners. The chip shortage is hindering companies' ability to upgrade equipment, meet market demands, and sustain a thriving job market.

So, Dr. Shuren, in your position have you heard much about this challenge?

Is there a role for the FDA, either through cooperation with the Department of Commerce or working with companies, to facilitate upgrades from legacy chips to advanced chips?

*Dr. Shuren. The answer is yes. We have heard a lot. We have talked to a lot of manufacturers. We have had conversations with the Department of Commerce and other folks in government to sort of convey the importance of these chips to a variety of medical devices.

And, of course, the shortage on chips is, of course, leading to and contributing to shortages on medical devices. And appreciate, too, those chips are used in a variety of technologies, and there is lots of needs out there. But we have really been trying to advocate for the needs here in

public health.

And certainly, when it comes to, like, the Defense Production Act too, we have got HHS, who plays, you know, the lead role here, or one of the lead roles in trying to advance that, in partnership with other parts of the government.

*Mrs. Trahan. Great. I appreciate that.

You know, in recent years we have seen an influx of software using artificial intelligence in the medical device space, ranging from imaging tools used in radiology to insulin pumps that automatically adjust. And, unlike a scalpel or X-ray machine, AI-powered medical software needs to be continually updated by design. These tools are built so that they continue to learn and improve from data they collect while they are deployed.

And the FDA requires that software that undergoes significant changes go through that approval process a second time. This is a necessary safeguard, but can slow the approval process for updated versions of medical software, especially those using data collected post-market.

So, as a part of its proposed artificial intelligence action plan, the FDA has described accepting a pre-determined change control plan as a part of the pre-market submission process for software as a medical device. And in the control plan a manufacturer could -- would detail ahead of time how it plans to change its software and establish how those

changes will not alter the safety and effectiveness of the software.

So how would pre-determined change control plans in pre-market applications affect the approval process for software as a medical device?

*Dr. Shuren. So where it may be applicable to have a plan like that where the manufacturer is laying out here are the changes we will -- we want to make, and here is how we will assure that those changes are not, for example, adversely impacting the safety or effectiveness of the technology, and if we are looking at that, and that plan makes sense, and that is going to work, and we go ahead and authorize that either as part of authorizing the device -- or a company could come in later and just come in with that plan, then you are expediting updated, modified devices within the context of that plan, expediting patient access, because the FDA isn't going to look at it. We have already looked at what the manufacturer will be doing.

What is important, though, of course, is assuring that you have got the safeguards in place, that when those changes are made, in fact, it remains safe and effective technology, and we have the ability to take action if problems arise in the future.

*Mrs. Trahan. That is great. And there are other regulatory tools that the FDA can use to promote continued

evaluation of software as a medical device throughout its product Life Cycle?

*Dr. Shuren. Well, we think this is a perfect opportunity for sort of marrying up, you know, more of a continued evaluation from Real-World Evidence.

That is why, you know, part of our investment in those real-world data sources is can we be using that to, you know -- if you got technology out there, and we are just -- you know, we are learning from it, we are kind of keeping tabs. And software as a medical device, including with AI capabilities, is really ripe candidates for doing that. Even, you know, where we can, leveraging information that the device itself is collecting on itself -- almost like a black box in an airplane. So we think those kinds of methods are really things we would incorporate.

Where we are limited, though, is some of the constraints that we have under the current law, and another reason why we think having more flexibility to tailor pathways that better fit these and other kinds of technologies, but do it voluntarily, you know -- so, Company, pick the old way or pick the new way, and if you like -- and want to change your mind, flip to the other later.

But if we can do that and build it right, then we can take advantage and get the best of both worlds. We would actually have better assurances of safety and effectiveness,

and more expedited time to the market.

*Mrs. Trahan. Thank you. I know my time --

*Ms. Eshoo. The gentlewoman's time has expired.

*Mrs. Trahan. Thank you.

*Ms. Eshoo. Dr. Shuren, thank you. Thank you for your patience today with our schedule. Thank you for the work that you have done, what your entire team, the center -- this has been a test like no other, the last two years. And, you know, the work that you and everyone at -- you know, at the center at the FDA have done -- extraordinary work under extraordinary circumstances. So bravo to you, to all of the people there. Thank you for the work that has been put into this negotiation. We will, of course, move it along. And we look forward to continuing to work with you to really produce for the American people. So thank you.

The committee is going to recess now, and I just want to close -- because she won't be here when we come back for the second panel -- to recognize Kim -- what is the matter with me? Too much talking today. Kim, we miss you, but it is great to see you out there.

And Dr. Shuren, you are fortunate. You are fortunate to have Kim right there with you. Bravo.

Okay, so we are going to go and vote. We will be back as soon as we can after the eighth vote is cast, and hear from our second panel. Thank you again. Bravo.

[Recess.]

*Ms. Eshoo. The Health Subcommittee will reconvene, and I want to thank our -- the witnesses of our second panel, and I now would like to introduce them.

Ms. Janet Trunzo is the senior executive vice president of technology and regulatory affairs for the Advanced Medical Technology Association. We know them as AdvaMed.

Welcome to you, and thank you.

Ms. Diane Wurzburger is the executive of regulatory affairs for GE Healthcare, and is testifying on behalf of the Medical Imaging and Technology Alliance, MITA, M-I-T-A, where she serves on the board of directors and chair of the technical and regulatory committee.

Mr. Mark Leahey is the president and chief executive officer of the Medical Device Manufacturers Association, MDMA.

And with us here in person -- patiently waited, I am sure, just about all day -- Dr. Richard Kovacs. He is the chief medical officer and past president of the American College of Cardiology. He is also a practicing cardiologist and a professor at the Indiana University School of Medicine.

Thank you very much, Dr. Kovacs, and welcome to our subcommittee.

We thank all of the witnesses for joining us today. We are looking forward to your testimony.

And we will go straight to you, Dr. Kovacs. You are recognized for five minutes. I think you probably know what the lights are.

Turn your microphone on, and a warm welcome to you, and the gratitude of the entire committee for being with us.

STATEMENT OF RICHARD J. KOVACS, M.D., Q.E. AND SALLY RUSSELL PROFESSOR OF MEDICINE, INDIANA UNIVERSITY SCHOOL OF MEDICINE, CHIEF MEDICAL OFFICER, AMERICAN COLLEGE OF CARDIOLOGY; MARK LEAHEY, PRESIDENT & CEO, MEDICAL DEVICE MANUFACTURERS ASSOCIATION; JANET TRUNZO, SENIOR EXECUTIVE VICE PRESIDENT, TECHNOLOGY AND REGULATORY AFFAIRS, ADVANCED MEDICAL TECHNOLOGY ASSOCIATION (ADVAMED); AND DIANE WURZBURGER, EXECUTIVE OF REGULATORY AFFAIRS, GE HEALTHCARE

STATEMENT OF RICHARD J. KOVACS

*Dr. Kovacs. Chairwoman Eshoo and Ranking Member Guthrie and the distinguished members of the subcommittee, I am Dr. Richard Kovacs. I have been introduced. I am proud to represent the ACC, a 54,000-member professional society whose care team members work to transform cardiovascular care and improve heart health.

The college's activities include leading in education, bestowing credentials on highly-qualified individuals, accrediting high-quality institutions, publishing leading medical journals, and maintaining national cardiovascular data registries to improve care.

Today I am here to discuss re-authorization of MDUFA from a clinician's perspective, with special emphasis on four topics: listening to the patient; attention to the Total

Product Life Cycle; use of Real-World Evidence for safety and efficacy; and advancing regulatory science.

We and my colleagues use medical devices on a daily basis to serve and heal our patients. We ask our patients what is important to them, and we listen carefully.

Let me give you an example. Before I flew to Washington last night, I saw Richard, an 86-year-old man from northwestern Indiana. He likes to work in his yard. He, unfortunately, suffered from aortic stenosis, a severe narrowing of the main outlet valve of his heart. Three weeks ago he couldn't walk fifty feet from his car into the hospital door because he was so short of breath. He received a transcatheter aortic valve replacement, left the hospital within 48 hours, has no scar on his chest, and feels great. When I saw him yesterday, he is back in his garden.

But in the longitudinal care, our care doesn't stop with the implantation of a device like this.

A few weeks ago I had to say goodbye to another patient, Carlos, a 70-year-old man from northeastern Indiana who I met in 1989, when he needed an aortic valve replacement. We selected a mechanical valve. It was implanted surgically. Yes, he did have a scar, but that valve functioned flawlessly for the next 33 years, until he passed away from another disease.

So we urge you to listen to patients, and engage the

patient voice from the earliest phases of development and throughout the life cycle of the medical device. The patients will tell you what really matters to them.

We have specific recommendations in our written submission. They correspond a lot to what Dr. Shuren said earlier today.

Clinicians like me use these devices every day. And like the example of Carlos, I may manage a patient for decades. Cardiology is a specialty where the pace of change is rapid, and innovations in our DNA. Clinicians have a great deal to offer in this process. We support the TPLC Advisory Program and its efforts to facilitate the early involvement of clinicians in the product life cycle.

It is impossible to know everything about a device from early clinical trials. So Real-World Evidence of safety and efficacy, evidence that can be gleaned from clinical data registries like our National Cardiovascular Data Registry is what I rely on through the product life cycle. We should leverage these data for the public good.

Registries can be cost savings. Sponsors that have used registries to house post-approval studies have achieved savings of 40 to 60 percent over the usual clinical trials.

Safety and efficacy are also best supported by sound regulatory science. Science is a team sport these days, and teams of industry employees, academics, and regulators can

solve these problems. The Cardiac Safety Research Consortium is such a collaboration, and it has made important advancements in drug safety. The ACC supports the FDA Network of Experts program, and can expand access to experts in cardiovascular disease.

Finally, I want to say we also support the efforts to provide additional cybersecurity. I have had the experience of working in two hospitals that have been hacked, and the care deteriorates dramatically.

So thank you for your interest. And on behalf of our patients and our profession, thank you for allowing us to be part of this process, and I look forward to any questions.

[The prepared statement of Dr. Kovacs follows:]

**********COMMITTEE INSERT**********

*Ms. Eshoo. Thank you, Doctor.

Next, Mr. Leahey, you are recognized for your five minutes of testimony, and thank you.

[Pause.]

*Ms. Eshoo. We have a problem, or --

*Voice. He needs to go off mute.

*Ms. Eshoo. Pardon me?

*Voice. He needs to go off mute.

*Ms. Eshoo. Oh, I see.

*Mr. Leahey. Can you hear me now?

*Ms. Eshoo. You have to unmute yourself, Mr. Leahey.

*Mr. Leahey. Yes, can you hear me?

*Ms. Eshoo. We can hear you, yes.

*Mr. Leahey. Okay, great.

STATEMENT OF MARK LEAHEY

*Mr. Leahey. Thank you, Chairwoman Eshoo, Ranking Member Guthrie, and members of the subcommittee, for the opportunity to testify today. My name is Mark Leahey, and I am the president and CEO of the Medical Device Manufacturers Association, a national trade association representing hundreds of medical technology companies.

MDMA was founded in 1992 to be the voice of the innovative and entrepreneurial sector of the industry. While the industry is broadly represented throughout the United States, one of the unique components of this vibrant part of America's innovation ecosystem is that the majority of companies are small businesses. According to data from the Department of Commerce, over 98 percent of med tech companies have fewer than 500 employees, and more than 80 percent have less than 50 employees, yet they are the major source of innovation in America's competitive advantage in medical technology.

Our industry is dedicated to one mission: to alleviate human suffering and to improve patient care. Our industry has a proud tradition of answering the needs of patients and providers, and perhaps no example is more profound than what innovators have done since the outset of the COVID-19 pandemic. Whether it was respiratory devices, diagnostics,

advanced patient monitoring, or personal protective equipment, the medical technology industry worked tirelessly to help the United States and the entire world to confront this challenge, and they continue to do so today.

In addition to the extraordinary efforts of this industry and to health care professionals, I would also like to take a moment to acknowledge the dedicated professionals at the FDA who worked 24/7 -- COVID and non-COVID medical technologies to improve patient care during the pandemic. Their efforts ensured that patients had timely access to safe and effective medical technologies.

The MDUFA V draft agreement that we are discussing today and the historic increase in user fee funding that it contains demonstrates our commitment to provide additional capacity and expertise to further advance the FDA's mission. MDUFA V five provides over $2 billion in investable funding to FDA.

As a point of reference, MDUFA [inaudible] totaled approximately $150 million over the 5 years of the program. While each MDUFA typically provides funding for an additional 200 new hires, under MDUFA V FDA will be able to hire a minimum of 273 people, and up to 387 new people to support the MDUFA program. This represents a historic increase in both overall funds and people, and it is our hope and expectation that this will be the last major investment

needed for the MDUFA program, and that moving forward, any necessary increases will be much more modest and targeted.

With these significant investments, MDUFA V also establishes more transparency around the use of funds, including ensuring that annual hiring targets are met. FDA will also conduct an HR assessment during the MDUFA V to identify how many MDUFA-funded vacancies exist. Currently, CDRH is only able to track MDUFA IV and later FTEs. Public reports in 2016 indicated MDUFA-funded vacancies exceeded 25 percent, and innovators want to ensure that the additional capacity that we are funding through user fees is realized in new additional hires and backfilling any vacancies that arise.

Beyond the financial accountability and transparency provisions that MDUFA V contains, performance goals associated with the de novo and PMA total time to decision also improved over the course of the agreement.

One goal that was elusive under MDUFA IV was the 510K total time to decision goal in fiscal year 2022 of 108 days. As was mentioned earlier, COVID did impact FTE capacity, including the ability to meet certain MDUFA IV goals. Under MDUFA V, the 510K total time to decision goal will ramp down each year, hopefully achieving 108 days by fiscal year 2026.

MDUFA V also expands investments in patient science and engagement to enhance the patient perspective into the

medical device evaluation process. As we all know, America's medical technology ecosystem was not built overnight. It took decades of work to account [inaudible] countless stakeholders including Congress, the FDA, innovators, physicians, patient groups, and more to design the regulatory pathways that has resulted in the gold standard of safety and efficacy. At the same time, we all recognize that this is a delicate balance to ensure that the right policies are in place to support innovation and to spur the next generation of cures, therapies, and diagnostics that patients are relying on.

As I noted, this is a historic investment in the FDA, and it will be critical over the coming years to meet the goals and milestones within the user fee agreement help ensure that the United States remains the global leader in medical technology development.

It is also critical that Congress continues its vital oversight role in providing the necessary resources and investments to FDA for it to achieve its mission.

MDMA and our member companies remain committed to working closely with you to reach our shared goal of providing safe and effective medical technologies to patients and providers in a timely manner. Thank you once again for this committee's passionate leadership on this important work, and I look forward to answering any questions that the

committee members may have. Thank you very much.

[The prepared statement of Mr. Leahey follows:]

**********COMMITTEE INSERT**********

*Ms. Eshoo. Thank you, Mr. Leahey. And for all the work that you and your colleagues put into the negotiations, bravo.

Ms. Trunzo, you are now recognized for your five minutes of testimony.

[Pause.]

*Ms. Eshoo. You need to unmute.

[Pause.]

*Ms. Eshoo. Can you hear me?

*Ms. Trunzo. Yes, I can.

STATEMENT OF JANET TRUNZO

*Ms. Trunzo. Thank you --

*Ms. Eshoo. Okay.

*Ms. Trunzo. -- very much, Chairwoman Eshoo, Ranking Member Guthrie, and members of the committee. Thank you so --

*Ms. Eshoo. There you are.

*Ms. Trunzo. -- much for inviting --

*Ms. Eshoo. Thank you.

*Ms. Trunzo. -- the Advanced Medical Technology Association, or AdvaMed, to testify on the reauthorization of the Medical Device User Fee Program.

This legislation is critical to patients continuing to have access to innovative, safe, and effective medical technologies, and we are grateful for the opportunity to offer our insights today.

AdvaMed is the world's largest trade organization representing medical technology companies. AdvaMed represents more than 400 medical device manufacturers, of which there are 300 small companies. I had the pleasure of representing AdvaMed during the discussions of the very first user fee program, the Medical Device User Fee and Modernization Act of 2002, and each of the re-authorizations since then.

The ongoing public health emergency created uncertainties that presented a significant challenge to our MDUFA discussions. Yet AdvaMed believes that the collective efforts of the industry and FDA have produced an agreement that will further strengthen the medical device pre-market review program. This will advance the ultimate shared goal of patients having timely access to safe and effective medical devices.

From the very first user fee program in 2002, the underlying principle is that user fees supplement existing appropriations so that FDA has the resources necessary to support timely review of submissions. While user fees support overall timeliness and predictability, they neither guarantee a particular result nor guarantee the timing of any particular application review. Those remain completely under FDA's authority.

Industry and FDA have taken the opportunity during each re-authorization to refine and improve the goals. Each MDUFA cycle included significant increases in investments by increasing the number of new FTEs to support the anticipated workload. For MDUFA V, AdvaMed and the industry representatives approached the re-authorization with the same two overarching principles we have had in the past: patients must continue to benefit from access to safe and effective medical devices; and the associated goals of the user fee

program should be refined and improved.

However, we also recognize that the COVID-19 public health emergency had required a significant effort on the part of FDA. As a result, we believe the device center needed to focus on the fundamentals of the device review program, which we refer to as Back to Basics. AdvaMed believes the package is well crafted to provide significant resources and capacity for FDA, greater predictability for the industry, and is in the best interests of patients.

It has the following key components.

First, the general goal structure for submissions is unchanged. Over the course of MDUFA V we expect to see improvements in review times compared to MDUFA IV goals, or compared to current performance, depending upon the submission type.

Second, the package provides significant additional resources to ensure that FDA can provide timely feedback to companies seeking pre-submission guidance from the agency. This process enhances the likelihood of an efficient review of the product submission.

Third, this package will fund targeted initiatives to support the pre-market review program. For example, there is increased funding for patient science and engagement to enhance the incorporation of the patient experience into the medical device evaluation process.

Fourth, this package contains specific accountability measures for the evaluation of the program by funding a quality management program and two independent assessments of the review process.

Finally, this agreement provides enhanced public transparency of MDUFA financing, including clarity on the use of the carryover balances.

On behalf of AdvaMed, we look forward to working with Congress, FDA, and stakeholders on the re-authorization of the Medical Device User Fee Program so that our common goal of timely patient access to safe and effective medical devices is realized. Thank you.

[The prepared statement of Ms. Trunzo follows:]

**********COMMITTEE INSERT**********

*Ms. Eshoo. Thank you, Ms. Trunzo. You have been there from the beginning, so bravo to you. And it is wonderful to have you as a witness.

Next, Ms. Wurzburger, you are recognized for five minutes for your testimony, and welcome, and thank you.

STATEMENT OF DIANE WURZBURGER

*Ms. Wurzburger. Thank you and good afternoon, Chairwoman Eshoo, Ranking Member Guthrie, and distinguished members of the subcommittee. Thank you for the opportunity to appear before you today to discuss the FDA's Medical Device User Fee Program on behalf of the Medical Imaging and Technology Alliance, also known as MITA.

MITA is the primary trade association and standards development organization representing the manufacturers of medical imaging technologies, including magnetic resonance imaging, medical X-ray equipment, computed tomography scanners, ultrasound, nuclear imaging, radiopharmaceuticals, AI-enabled imaging software, and other products. MITA member companies' technologies play an essential role in our nation's health care infrastructure and are integral in the care pathways of evaluating, staging, managing, and effectively treating patients with cancer, heart disease, neurological degeneration, COVID-19, and numerous other medical conditions.

By catching disease early, reducing the need for invasive inpatient procedures, and facilitating shorter recovery times, medical imaging saves money and improves efficiency in the healthcare system. Medical imaging technologies have revolutionized health care delivery in

America and around the world, extending human vision into the very nature of disease.

A consistent and timely FDA review process is essential to timely patient access to these technologies. MITA continues our strong support for an effective, well-resourced FDA capable of fulfilling its mission to protect and promote the public health. The medical imaging industry supported enactment of FDA's user fee programs in 2002 and its subsequent re-authorizations in 2007, 2012, and 2017. We participated alongside our industry colleagues in the MDUFA V negotiations, and support enactment of the proposed agreement, which will provide the FDA device program with ample resources, establish new accountability measures, and allow for exploration of new review paradigms such as the Total Product Life Cycle Advisory Program, also known as TAP.

User fees provide for an efficient pre-market review process, allowing the safe and effective medical device innovations to get patients -- to get to patients and health care providers in an expedient, consistent, and transparent manner. Supplementing FDA funding with user fee brings stability and predictability to the device review process and timelines.

The goals of the medical device industry and FDA commit to, and FDA's subsequent performance are critical to timely patients' access to safe and effective medical advancements.

Without a consistent and timely FDA review process conducted by well-trained FDA staff, access to diagnostic imaging technologies will be delayed, and industry's ability to deliver technological advancements will be compromised.

We, therefore, will continue to partner with FDA and other stakeholders in asking Congress to re-authorize this important program that supports patient access to safe and effective medical imaging innovations.

MDUFA V was negotiated during turbulent times for all parts of our healthcare system, including innovators, regulators, health care providers, and patients. The COVID-19 pandemic strained every part of our society. FDA and industry strived to meet the challenges presented by this public health emergency by ensuring safe and effective medical devices could be delivered to patients in an expeditious manner.

The last several years created significant resource challenges for FDA, and as it seeks to recover its operations and get back to pre-pandemic performance, it will need to be sufficiently resourced to meet its obligations and continue to review products for safety and effectiveness.

The MDUFA V agreement will raise the Center for Devices and Radiological Health's funding significantly, allowing the center to meet its pre-market review commitments. It will also be able to hire new FTEs and meet rising payroll costs.

And the agency will also continue to invest in successful programs that support the use of standards and Real-World Evidence in regulatory pre-market decisions; the advancement of digital health technologies; the expansion of patient engagement opportunities to inform the development and evaluation of innovative technologies; FDA's engagement with international regulators and the promotion of regulatory convergence; as well as continued FDA collaboration with accredited third-party reviewers to support a voluntary alternate review pathway.

MDUFA V will bring new accountability measures and ensure FDA -- excuse me, user fee dollars are being appropriately invested in shared goals, and also support multiple independent assessments of performance and generate recommendations on how the center can continue to improve its operations.

In closing, MITA urges Congress to move quickly to enactment of MDUFA V. This agreement, negotiated between FDA and the medical device industry over the last year-and-a-half, will ensure ongoing patient access to safe and effective devices.

Thank you for the opportunity to present our views today. I am happy to answer any questions you may have.

[The prepared statement of Ms. Wurzburger follows:]

**********COMMITTEE INSERT**********

*Ms. Eshoo. Thank you, Ms. Wurzburger. And that concludes the testimony of our five witnesses. And thank you once again for being with us today, and your patience in terms of the House schedule. We will now move to member questions, and the chair will recognize herself for five minutes to do so.

Dr. Kovacs, in your written testimony you said that more needs to be done to use patient input to inform clinical study design in order to recruit and retain a diverse patient sample. In your view, what else should the FDA and the medical device manufacturers be doing to recruit more diverse patients in device clinical investigations?

*Dr. Kovacs. I think that Dr. Shuren had many good points to make this morning: going to where the patients are, to approach them in their environment; to use telemedicine and telecommunications to reach patients that otherwise are unreachable. And I would add one additional point to what Dr. Shuren mentioned this morning, and that is also to diversify our investigators.

The actual clinical investigators need to look like the patients that are enrolled in these trials. Outside the scope of MDUFA, but within the scope of what could be -- help with legislation to improve the training, to increase our pipeline. The college is working on this, but we realize we are a small organization trying to get way upstream of this

to diversify our investigative team.

*Ms. Eshoo. Excellent. Well, Dr. Shuren stayed because he wanted to hear your testimony and that of the others that are with you today. So he is listening very intently.

To Ms. Trunzo, you said that the device review program needs to, quote, "go back to the basics'' in order to balance COVID-19 demands with the center's regular workload. How does MDUFA V help address the center's capacity gap, in your view?

[Pause.]

*Ms. Eshoo. You need to unmute.

[Pause.]

*Ms. Eshoo. Are we putting each other to sleep?

[Laughter.]

*Ms. Trunzo. So sorry.

*Ms. Eshoo. That is all right.

*Ms. Trunzo. I believe that the investment from MDUFA V that we have discussed in our testimony of about $1.78 billion in guaranteed funding allows for FDA to hire the additional FTEs needed so that there is sufficient resources and capacity for FDA to get back to basics.

It is -- if you look at the number of additional FTEs that FDA will get as a result of this investment, it will support the medical device review program and get us back to basics. Thank you.

*Ms. Eshoo. Thank you.

To Ms. Wurzburger, do you think the term -- and we discussed this earlier today with Dr. Shuren -- do you think the term "re-manufacturing'' needs further clarification in statute, despite the FDA's draft guidance? And if so, why?

*Ms. Wurzburger. Thank you. Yes. MITA agrees with Dr. Shuren that clarification is needed, and the legislation recently [inaudible] Representatives Peters, Schrier, and Joyce provides that clarity.

While the FDA guidance remains in draft form, there is [inaudible] providing greater clarity via statute [inaudible] activities that could significantly [inaudible] performance or safety specifications, or intended use [inaudible] device are clear.

Additionally, the legislation -- legislative proposal also includes provisions to provide public education and transparency [inaudible] awareness of manufacturers' regulatory responsibilities, and to promote compliance. Thank you.

*Ms. Eshoo. Thank you.

I am going to yield back my time and recognize our wonderful ranking member of our subcommittee, Mr. Guthrie, for your five minutes of questions.

*Mr. Guthrie. Thank you. Before I get to my questions, earlier today -- I am glad Dr. Shuren is still here -- we

were talking about device shortage, the proposal, and we are all for patient safety. That is premier, first and foremost, moving forward. And I think someone said -- I don't remember who, exactly -- the difference in pharmaceutical and device. And it is all about patient safety.

So those -- there is no difference between the two, except I know that, when we did the pharmaceutical, I was hearing a lot of calls from people who were -- I had, like, people driving ambulances say they didn't have basic pharmaceuticals. They were canceling surgeries because they didn't have the basic pharmaceuticals. And when you looked at it, it was small. It was high volume, small margin, usually one supplier, and so forth.

And we were really concerned that you just couldn't plan. It would be like you are getting 100,000 -- I am making the number up, but say you are supposed to get 100,000 a week from this supplier, and you get 50 one week, 120 one week, 30 next week, it depends on the disruptions. And that is what we were looking for, and that is what hearings are for. Maybe there is the same problem in device.

But there is a difference. I am a manufacturing -- not -- aluminum parts, not pharmaceutical. But there is a big difference in just not hitting your targets week in and week out, and all of a sudden committing to 100,000, and all of a sudden you need a million. I mean, that is kind of what

happened with our pandemic. And that is a different problem. And it is just a different problem.

I just want to -- if you are going to expect somebody to go from 100,000 to 10 times, or 5 times, or however much they need there, the government has to buy the capacity or they have to store it. I mean, the storage. And that is something that we need to work through, and to make sure we have the -- it correctly.

But if the same problem is we are just not getting the devices on a regular basis, like the same thing, we need to address that, too. We need to address that, too. So that is what we need to sort out in the hearing.

But the other thing I asked about this morning with Dr. Shuren is emerging signals. And again, we are all -- patient safety is premier. But Ms. Trunzo, is there a way that you can -- we can balance, or make sure that we have -- we promote innovation and we get this right with the signaling without compromising patient safety?

[Pause.]

*Mr. Guthrie. Ms. Trunzo? Did --

*Ms. Trunzo. Sorry. I believe there is --

*Mr. Guthrie. Okay.

*Ms. Trunzo. I am sorry. I believe there is a way to balance the emerging signals program. I think it is really important that the program allows for, if FDA does detect an

emerging signal, that there is an opportunity for the company to interact with FDA, because sometimes the company may have supplemental information that may be crucial to the evaluation process that FDA is undertaking.

And I think the other important factor in an emerging signal program is the ability for FDA to -- because it is emerging signals and it may not be confirmed, and if it later is confirmed, or later confirmed ought to be an emerging signal, then it would be important for the FDA to somehow communicate that to health care providers during that process. But there are --

*Mr. Guthrie. Okay, on that -- I should have muted my phone, so we don't get that -- I mean my talk button, so I don't get the feedback, but I -- but on that, Dr. Shuren, I thought, brought a valid point about how the timing that could take to get that done. If it is -- is there a proposal that you are moving forward that would say, if it is an emergency situations -- I understand that there is -- FDA detect emerging signal, and you want -- need the time to respond, because you want to make sure that you have the opportunity to, and I understand that and fully support that, except is there a criticalness to the time, the timing of some are and some aren't, I guess? And so how do we decide which ones are and which aren't?

*Ms. Trunzo. I believe that there -- that is a delicate

balance to achieve of the actual timing of that information. And I think that goes back to why it is so important.

If FDA, through the data sources that FDA has access to, if FDA does determine that there might be an emerging signal, that initial interaction with the company is really -- it should be part of the process, because the company may be able to provide additional information, which would then make that process more efficient and timely in the final determination that FDA will make.

*Mr. Guthrie. Okay. I have one quick -- if I can get it in really quickly. So the -- Ms. Trunzo, the Breakthrough Device Program, we believe it has been innovative. And what improvements can we make to the path -- this pathway to incentivize further investments in emerging technologies?

*Ms. Trunzo. Well, I think the breakthrough process has seen a lot of emphasis, most recently -- especially after the 21st Century Cures Act, where the whole breakthrough process was well defined, there was a timeline built into the breakthrough designation process so that FDA had a specific time of 60 days to respond to requests for getting that breakthrough designation.

And I think the investment in the Total Product Life Cycle Program that is part of MDUFA V, which will -- once that designation is made, and that sponsor participates in this program, there are -- will be significant resources to

support the pre-submission process, such that when that final submission is made to FDA as a result of that investment of the additional resources to help the company through that process, that product will have a more efficient review and get into the hands of patients and health care providers.

*Mr. Guthrie. Thanks. My time is expired. I appreciate the answers, and I yield back.

*Ms. Eshoo. The gentleman yields back. You know, on this issue of shortages, it is not just in the -- on the pharmaceutical side. Lucile Packard Children's Hospital, right in the heart of my congressional district, reported to us that they have a heparin syringe shortage right now. So, you know, we have to look after all of this.

And Dr. Shuren, you are here, and I know you are going to follow up on that. So thank you.

All right, the chair now recognizes the gentleman from California, Mr. Cardenas, for your five minutes of questions.

*Mr. Cardenas. Thank you. Thank you very much, Madam Chairwoman and Ranking Member, I really appreciate this opportunity to talk to this second esteemed panel.

In your -- Dr. Kovacs, in your testimony you talk about the importance of the patient perspective, and share some stories from your own experience. Many times we talk about improving devices and therapies, and somewhere along the way the impact on real people can get lost.

My first question for you is, how big of a difference can these devices make in a person's life?

And when we talk about the expeditious approval of safe and effective devices, what does that actually look like for patients in their day-to-day lives?

*Dr. Kovacs. Thank you for the question. These devices range from lifesaving devices in what I do in cardiology, to a life-altering devices: the difference between being able to work or not work, the difference to being able to be mobile or not mobile, the difference between being able to enjoy one's family or not. So these make huge differences.

But the differences that they make to the patients, I would reemphasize, we should be asking the patients. What is the most important thing to the patient? What may be important to one patient in one situation may be different to another patient.

This revolves around the whole science of patient-reported outcomes to the statistical analysis of these patient-reported outcomes, and to bringing these into part of the equation for designing the trials in the first place.

So we need to -- and as we said, we need to diversify the number of the types of patients that are in these trials to understand the differences in patient desires for the outcomes that they are hoping for these novel therapies.

*Mr. Cardenas. Thank you. You also note in your

testimony the importance of emphasizing patient engagement in the medical device approval process. Among your recommendations to improve these processes, you advocate for "patient input to inform clinical study design,'' which would reduce barriers for diverse patient samples.

How would you recommend the FDA receive and operationalize this kind of input?

Can you explain what this would look like on the ground, from the patient perspective?

*Dr. Kovacs. This would look like, first of all, engaging the patients, engaging that diverse patient population into the design of the studies, and the endpoints of the studies which determine the scientific rigor of the study.

Is this -- this goes all the way back to the definitions. What is a patient-reported outcome? Is it meaningful to be able to walk from -- for 50 feet? Is it more meaningful to be able to walk for a mile? And those are nuanced, those required crisp data definitions, and they require careful analysis by the FDA, hopefully in conjunction with the patients and other experts.

*Mr. Cardenas. Okay. So you are describing a collaboration of sorts, an understanding of what is going on with these studies, and getting feedback from the patient, and also FDA to be involved in that, as well?

*Dr. Kovacs. Correct. I hang around with a lot of movement disorders neurologists who tell me that when they -- and they use telemedicine, they want to observe these patients with Parkinson's disease, for example, in their environment. And what that therapy does to their ability to function in their daily life is what is important to that patient. Not necessarily a biomarker or a test result, but what the how the patient actually functions.

*Mr. Cardenas. Well, thank you. In their own environment. Thank you very much.

Why is it important to ensure patient input is elevated, and that diversity is a priority in the trial process?

How much of an impact will this ultimately have on patient experience?

*Dr. Kovacs. The patients that we want to apply these therapies to -- the patients in the trials that approved these devices should look like the patients that we intend them -- they intend them to.

We have numerous examples of unintended consequences of not including the right types of patients in clinical trials to not understand whether a device is effective in a significant proportion of our population. Women, for example, respond differently to device therapy than men, and we need to understand that going forward.

*Mr. Cardenas. Thank you very much. My time is

expired.

Thank you so much, Madam Chairwoman. I yield back.

*Ms. Eshoo. The gentleman yields back. Thank you for participating in this part of our hearing today, Mr. Cardenas.

The chair is -- oh, the chair is pleased to recognize the -- go to Dr. Joyce?

Okay, back to you, Dr. Joyce. You are recognized for five minutes for your questions, the gentleman from Pennsylvania.

*Mr. Joyce. Thank you, Madam Chair. Thank you, everyone, for being here at this hearing, which we recognize was originally convened at 9:00 this morning.

During the first panel we heard from Dr. Shuren -- and Dr. Shuren, thank you for being here this afternoon, as well -- on this committee and proposed expansion of shortage reporting on medical devices beyond the context of the public health emergency. My question is first for Ms. Trunzo.

Can you please comment on the burden that this proposal would place on device manufacturers, particularly the impact it may have on small manufacturers, as well as what manufacturers do already to ensure supply chain continuity?

[Pause.]

*Ms. Trunzo. I can start --

*Mr. Joyce. Ms. Trunzo --

*Ms. Trunzo. Yes, I can start with the latter. The -- our -- the companies take great efforts in managing their supply chains. It is an art and a science to manage those supply chains to ensure that there is not a shortage.

As far as the burden goes of what is [inaudible], it depends on what is asked to be reported on, what kinds of information is part of the reporting, and does it apply to all medical devices or just a subset of medical devices, and does it go beyond reporting, beyond the public health emergency, or in advance of the public health emergency. So the burden is variable, depending upon the extent to which the reporting is required.

*Mr. Joyce. Well, specifically, beyond the context of the current public health emergency, would that add additional burdens?

*Ms. Trunzo. We believe that it would. We support -- I will be very clear to you, first of all, that we are very much supportive of working with the committee on any kind of additional mandatory shortage reporting.

But the way medical device manufacturers often -- there are multiple manufacturers for a specific device type. And so what might not be a disruption in the supply chain for one manufacturer doesn't necessarily mean that there are -- there is a shortage for that particular device type on [inaudible] entirety.

Having shortage reporting be in place at all times for all medical devices could very much be burdensome to our industry.

*Mr. Joyce. Thank you.

Mr. Leahey, I am going to ask you to weigh in on this, particularly the impact on small manufacturers to ensure the supply chain is ready, the impact and the burden of this reporting.

*Mr. Leahey. Thank you very much. Well, as Janet just said, you know, there are instances through the public health emergency where issues have arose.

But I think it is important to recognize the difference between drugs and devices. For the overwhelming majority of medical devices, there are multiple companies selling competing devices, and that competition creates resiliency. And [inaudible] seen in global demand for devices [inaudible] respond to the pandemic created supply challenges, no doubt, early in the pandemic. But industry has responded.

We think the CARES Act, which allows HHS and the FDA to collect shortage information in advance and during the public health emergency, is appropriate. But our members would have concerns about broad new authorities to collect supply chain information for hundreds of thousands of devices on the market at -- not at risk of supply chain disruption.

*Mr. Joyce. And I would like to turn to Dr. Kovacs.

Clinically, I practiced medicine for 25 years, and my decision to go into medicine was because, at the age of 6, I lost my 5-year-old brother after an atrial septal defect repair, something which is now done as an outpatient, which is done by interventional cardiologists, and these young people who have atrial septal defects have this and are, literally, sent home within hours from the procedure.

What is the impact of the ability to advance the development of medical devices, and how do those medical devices impact you in your clinical practice?

*Dr. Kovacs. The practice of cardiology -- and I am sorry to hear about you're your sibling, but the -- and Happy Doctors Day.

*Mr. Joyce. Thank you, sir. Happy Doctors Day.

*Dr. Kovacs. My specialty is one that is crucially dependent on this, and crucially dependent on innovation to advance this.

As I mentioned two patients in my testimony, one who probably spent 10 days in the hospital recovering from cardiac surgery, one who went home without a scar within 48 hours. That has ripple effects down the line entirely in hospital care, fewer hospital days, lower costs, less time in the hospital, less recovery time, less burden on the family to take care of a family member who has been incapacitated. The benefits go on and on.

We need to continue to spur innovation. Cardiology is a particularly innovative sub-specialty, and we need to remove barriers to that innovation.

*Mr. Joyce. I thank you for your answer.

And Madam Speaker, my time has expired, and I yield.

*Ms. Eshoo. The gentleman yields back. I may be the chairwoman, but I know I am not Speaker.

[Laughter.]

*Ms. Eshoo. But thank you for the elevation for three seconds.

The chair is very pleased to recognize the ranking member of the full committee, Congresswoman McMorris Rodgers, five minutes for your questions.

*Mrs. Rodgers. Thank you, Madam Chair.

Ms. Trunzo, as medical device technology increasingly relies more on software updates and algorithm changes to improve performance, how can FDA ensure that patient safety is preserved, while also enabling these updates to be made in a timely manner?

*Ms. Trunzo. Look, I think that -- I believe that one way in which that can be accomplished is with a pre-determined change protocol approach, where those medical device software medical devices are constantly being updated because of the nature of the device being a software base, that if there is a pre-determined change protocol in place,

it ensures that the manufacturer's company will be able to do [inaudible] under a pre-approved protocol that FDA has pre-approved, and ensures the safety, and at the same time allows [inaudible] to be made in a safe manner. And I think that is the way to solve that problem.

*Mrs. Rodgers. Thank you. As a -- I would also like to ask -- the FDA currently has limited authority to collect information on potential device shortages during or in advance of a public health emergency.

Is the experience of your member companies -- or in the experience of your member companies, how has FDA used this data to prevent or mitigate shortages thus far?

And that was for Ms. Trunzo and Mr. Leahey.

*Ms. Trunzo. Well, so the way -- the information has been submitted to FDA as a result of the shortage reporting requirement during the public health emergency, and in advance of one.

The way in which FDA uses that information is -- we are not exactly sure how FDA uses the information and what actions FDA takes with that information. Presumably, there is an analysis of it. And then, once the information is published, there is a list published on the FDA website that identifies where the shortages are, the information that continues to be presented to FDA, how they analyze that. And then, when the -- when that shortage no longer exists, and

how they -- how FDA changes that shortage reporting list, I think is not well -- it is not well understood, from our perspective.

*Mrs. Rodgers. Okay, okay, okay. Thank you.

Mr. Leahey?

*Mr. Leahey. I would echo what Janet said. Obviously, [inaudible] scope right now publicly available, but how that information is being analyzed, used to provide flexibility maybe for substitution in parts [inaudible] a shortage, I think that is an area where we don't have a lot of visibility, but FDA has been reaching out, I think, to industry with [inaudible] the group that is handling supply chain resiliency.

So again, we are supportive of FDA having these conversations with industry, trying to work through these problems. But broad-based new authorities here are certainly of concern to our members.

*Mrs. Rodgers. Okay. Are there -- as a follow-up, are there certain types of medical devices for which you think it would be helpful for FDA to collect this information?

*Mr. Leahey. Again, I think the current list right now that exists related to products during a public health emergency -- you know, we know PPE, there were ventilator issues, other areas that likely could continue, and the Secretary, under the CARES authority, has the ability to

continue this during a public health emergency or in advance of one.

So I think the scope of the universe of products that FDA is looking at right now seems right size. If there are other, you know, targeted areas that we can have conversations around, I think we are open to that. But again, having something that is cascading that would, you know, apply to orthopedic implants and cardiovascular devices and everything across the sun just seems well beyond the scope of an efficient regulatory process.

*Mrs. Rodgers. Ms. Trunzo, would you care to add anything?

[Pause.]

*Mrs. Rodgers. Maybe -- oh, is she muted?

*Ms. Trunzo. I believe -- yes, I believe that the current list that FDA has published for purposes of reporting shortages during the public health emergency is a sufficient and good list.

*Mrs. Rodgers. Okay, okay. Thank you.

Thank you, Madam Chair. I yield back.

*Ms. Eshoo. The gentlewoman yields back. I am not aware of any other members that are --

*Mr. Guthrie. No, none --

*Ms. Eshoo. Not on the Republican side and not on the Democratic side. So let me thank the witnesses of our second

panel.

Dr. Kovacs, thank you so much. You gave wonderful testimony, all through the lens of your patients, and telling their stories. So, you know, the way you presented, the way you addressed this overall issue was made very real by -- you personalized the testimony. We appreciate it very much, and also the patience of each one of you.

So to Mr. Leahey, it is great to see you. Thank you for the work that you have done on this.

To Ms. Trunzo, thank you for your testimony. Thank you for unmuting.

And thank you to Ms. Wurzburger.

You are all real pros. You know all of this, certainly in your lane, for whomever you are representing.

But I think that, you know, the best thing that we learned today is that it was a combination of all, you know, the stakeholders, patients, the organizations that negotiated with FDA so that we can move this legislation forward.

And also, we heard many things that were raised of what we have learned during the pandemic, and what we need to be really cognizant of as we move forward. That is very important, that we are wise enough to examine our shortcomings so that we -- another day, another time it won't be experienced again.

So I have a request, unanimous consent, to enter the

following document -- we only have one -- into the record. It is a letter from public interest and health care organizations.

*Mr. Guthrie. No objection.

*Ms. Eshoo. Okay, so without objection, so ordered.

[The information follows:]

**********COMMITTEE INSERT**********

*Ms. Eshoo. And I think -- is there anything else that we need to include at the end of the hearing?

Members do have 10 business days to submit additional questions for the record.

So to the witnesses, please respond promptly if you receive questions from members.

And at this time, the subcommittee is adjourned.

[Whereupon, at 5:15 p.m., the subcommittee was adjourned.]