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EXAMINING FDA'S MEDICAL DEVICE USER FEE PROGRAM

TUESDAY, MARCH 28, 2017

House of Representatives,

Subcommittee on Health,

Committee on Energy and Commerce

Washington, D.C.

The subcommittee met, pursuant to call, at 10:15 a.m., in Room 2123 Rayburn House Office Building, Hon. Michael Burgess [chairman of the subcommittee] presiding.

Present: Representatives Burgess, Guthrie, Upton, Shimkus, Murphy, Blackburn, Lance, Griffith, Bilirakis, Long, Bucshon, Brooks, Mullin, Hudson, Collins, Carter, Walden(ex officio), Green, Schakowsky, Butterfield, Matsui, Castor, Schrader, Kennedy, Eshoo, DeGette, and Pallone (ex officio).

Staff present: Zachary Dareshori, Staff Assistant; Jordan Davis, Director of Policy and External Affairs; Paul Edattel,

Chief Counsel, Health; Adam Fromm, Director of Outreach and Coalitions; Jay Gulshen, Legislative Clerk, Health; Katie McKeough, Press Assistant; Carly McWilliams, Professional Staff Member, Health; Jennifer Sherman, Press Secretary; John Stone, Senior Counsel, Health; Hamlin Wade, Special Advisor, External Affairs; Jeff Carroll, Minority Staff Director; Tiffany Guarascio, Minority Deputy Staff Director and Chief Health Advisor; Dan Miller, Minority Staff Assistant; Olivia Pham, Minority Health Fellow; Samantha Satchell, Minority Policy Analyst; Kimberlee Trzeciak, Minority Health Policy Advisor; and C. J. Young, Minority Press Secretary.

Mr. Burgess. [presiding.] The Subcommittee on Health will now come to order.

The Chair starts by recognizing himself for 5 minutes for the purpose of an opening statement.

Dr. Shuren, welcome back to our subcommittee. I am glad to say that your center at the Food and Drug Administration certainly, since 2012, I just have to acknowledge that there has been a -- you have come a long way since the User Fee Agreement authorization from 2012.

Today is this subcommittee's third hearing to consider the reauthorization of the Food and Drug Administration User Fee Programs that are set to expire in September. The Medical Device User Fee Agreement gives the Food and Drug Administration the authority to collect fees from the medical device industry and to support product review activities. This must be renewed every 5 years. The Energy and Commerce Committee has taken the necessary actions to renew this authority three times before, and this committee remains dedicated to completing this fourth authorization in a timely manner.

While there can always be room for improvement, the Medical Device User Fee Agreements Program has significantly enhanced the efficiency, the transparency, and the uniformity of the product review process at the Food and Drug Administration. Leading up to the 2012 reauthorization of the Medical Device Agreements, this

subcommittee heard repeatedly about the sometimes slow, sometimes onerous, sometimes arbitrary process by which devices were reviewed at the Center for Devices and Radiological Health. The state of affairs at the Center for Devices was driving away investment in research and development and significantly hindering the pace at which American patients had access to new medical technologies. Through the Food and Drug Administration Safety and Innovation Act, Congress reauthorized the Medical Device User Fee Agreements, and the paradigm started to shift in what I consider to be the right direction.

The Food and Drug Administration Safety and Innovation Act included meaningful regulatory reforms, improved communication between the industry and the Food and Drug Administration, and increased accountability at the Centers for Devices and Radiological Health. It is important that the next Medical Device User Fee Agreement continue to build upon the progress that was made in the last FDA reauthorization bill as well as the good policies that members of this subcommittee championed during the discussions on the 21st Century Cures Act.

I am encouraged that the proposed agreement transmitted to Congress in January contains many promising elements that will be good for the Food and Drug Administration, good for the industry, but, most importantly, good for our patients. In the proposed agreement, the Food and Drug Administration has agreed

to further decrease the total time it takes from submission of an application to a final decision on approval. This is a good thing because it will get safe and effective products to doctors and to patients faster.

Further, the Food and Drug Administration would enhance patient engagement by more formally involving patient preference and patient-reported outcomes in the review process. It is vital that the Food and Drug Administration routinely incorporate the patient perspective in its decisionmaking process.

The proposed agreement would also establish process improvements and goals that ought to foster a more timely and efficient approval process if implemented. For instance, the process for pre-submission and interactions between the Food and Drug Administration and the industry would be updated and improved upon. In addition, the proposed agreement would establish a pilot program to examine the use of real-world evidence for pre-market activities.

Furthermore, the proposed agreement provides for improved transparency and for greater responsibility. A wide array of new measures, new tools, and reports will provide data that is necessary to ensure that the Food and Drug Administration is meeting the goals of the agreement. Reauthorizing the Medical Device User Fee Agreements and the user fee programs we have previously discussed would increase efficiency at FDA and ensure

that American patients benefit from advances in biomedical technology, that American patients benefit from advances and innovations as soon as safely possible.

I want to thank all of our witnesses for being here today on both panels. I look forward to hearing from each of you about how the substance of the proposed User Fee Agreement will accomplish its stated goal.

It is now my pleasure to recognize the ranking member of the subcommittee, Mr. Gene Green of Texas, for 5 minutes for the purpose of an opening statement.

Mr. Green. Thank you, Mr. Chairman, and thank Dr. Shuren and our other witnesses for being here this morning.

Modeled after the successful Prescription Drug User Fee Agreement, the Medical Device User Fee Agreement was first established in 2002. It authorizes the FDA to collect fees from medical device manufacturers to support the work of reviewing device applications and other components of medical device oversight.

We are here today to learn about the fourth iteration of the Medical Device User Fee Agreement, or as we call it, PDUFA. This, similar to other user fee agreements, is an important tool to help ensure that the FDA can evaluate devices efficiently while upholding its gold standard of approval.

Today is markedly different from where we were five years

ago. There was widespread frustration with the program and the challenges facing the FDA. Medical device companies, and patients were in need. Thanks to investments provided by the industry, congressional leadership, and a commitment from the agency to double-down and address inadequacies head-on, substantial progress has been made.

From 2009 to 2015, the time it takes for the FDA to issue a decision on PMA is down by 35 percent and down by 11 percent for 510(k) submissions. Critically, this has happened without any sacrifice in the FDA's gold standard for safety and effectiveness.

And I want to thank Dr. Shuren for his leadership in changing the culture and policies and the processes of the Center for Devices and Radiological Health. This along with user fee funds and reforms instituted by Congress have resulted in an improved medical device pipeline, most importantly, innovative device technologies reaching patients in the United States earlier than in the past.

Progress made since MDUFA III demonstrates the importance of user free programs and underscores how critical it is that Congress reauthorize the program without delay. We also recognize that more work remains to improve the innovation and ecosystem and realize the full potential of scientific breakthroughs, so patients can access new cures and treatments.

Past efforts, combined with the provisions of this new User Fee Agreement, will keep things headed in the right direction.

Measuring the total time for submission to an FDA decision on an application is a central measure of the user fee process. The MDUFA IV agreement would continue to drive towards reducing the total time that is spent reviewing submissions which brings innovator companies additional certainty and ensures breakthroughs get from the lab table to the bedside in a timely manner.

The agreement also includes provisions to further enhance the predictability and efficiency of the review process. These provisions lay the groundwork for further performance improvements and advances in patient safety.

MDUFA IV includes a new Quality Management Program to improve consistency and predictability in the review process. It will allow the FDA to strengthen partnership with patients to make sure that the patient remains at the center of the develop and review consideration.

MDUFA IV will help get the National Evaluation System for health Technology, or NEST, off the ground. Harnessing real-world data collected during the routine care, NEST has the potential to shorten the time and lower the cost it takes to bring a new device to market, expand approved uses for products already in the market, and meet post-market reporting requirements.

Critically, NEST will enable faster identification of safety issues. This will allow the FDA to be more proactive in addressing safety concerns, which will reduce harm to patients and liability for companies.

21st Century Cures included a number of improvements to the medical device pre- and post-market review processes. I am pleased, as agreement builds on past User Fee Agreements and reforms included in Cures, it maintains our shared commitment to ensuring patients benefit from innovative, safe devices necessary for public health and fostering a robust pipeline of new treatments and cures.

The MDUFA IV agreement is supported by a broad range of stakeholders and is a result of extensive public input and review during the drafting process. It will expedite the availability of innovative products and continue to increase the efficiency of FDA. In short, this agreement is good for the medical device industry, healthcare providers, the FDA, and, most importantly, good for patients.

I want to thank the FDA and the industry and patient advocates and providers and other stakeholders for their work on this agreement.

And I want to thank again our witnesses for being here today. I look forward to your testimony and response to our committee's question.

I yield back my time.

Mr. Burgess. The Chair thanks the gentleman. The gentleman yields back.

The Chair now is pleased to recognize the chairman of the full committee, Mr. Greg Walden from Oregon, 5 minutes for your opening statement, please.

The Chairman. Thank you, Chairman Burgess, for your work on this and many other issues.

I want to welcome all of our witnesses. I have read through your testimony. It is most helpful as we work on this matter.

The last time Congress reauthorized Medical Device User Fee Amendments, MDUFA, in 2012, we heard story after story about venture capital drying up, innovation, medical technology companies launching their products overseas. We heard oftentimes years before American patients could benefit from them.

Witnesses from all sides of the political spectrum came before the subcommittee. They highlighted the burdensome, inconsistent, and opaque nature of the FDA review process as the primary driver for these alarming trends. That was 2012. What a difference five years makes.

Thanks to Dr. Burgess and others, the Food and Drug Administration Safety and Innovation Act included a number of common-sense regulatory improvements that greatly benefitted

patients and have spurred innovation.

I would like to specifically thank Dr. Jeff Shuren who is with us today. Thank you for your leadership. You have done great work.

All the legislation in the world could not change the deeply-rooted cultural issues that were plaguing the Device Center at FDA. Dr. Shuren, you took constructive feedback to heart. You put these new legislative authorities to work and you got results for the American people.

Since 2009, the number of innovative devices approved by the FDA has almost quadrupled, resulting in American patients benefitting from safe and effective American technologies sooner. In 2009, it took an average of 427 days before the FDA even reached the decision on a Pre-market Approval Application, a PMA. As of 2015, the average review time was down to 276 days. That is a 25-percent decrease.

More work lies ahead, but great strides have been made. Building upon the successful implementation of the previous User Free Agreement, 21st Century Cures legislation, heralded through this process by my friend from Michigan, Mr. Upton, and others, that also included a number of additional bipartisan process reforms reauthorizing MDUFA in a timely fashion, which I remain steadfastly committed to doing. It will ensure that we continue to move in the right direction.

Today's hearing continues these positive efforts. This is a good agreement that will build upon some recent successes and strengthen the agency, improve the lives of patients, and bolster America's medical technology sector, which has brought hundreds of thousands of high-paying jobs to our communities. It is also a critical next step after the game-changing 21st Century Cures Act became law just a few months ago. So, let's continue to build upon these remarkable and bipartisan advancements that put patients first.

Thank you again for the hard work that has gone into this agreement. We look forward to hearing from all of you and moving ahead in this area.

With that, Mr. Chairman, if there are other seeking time, I would be happy to yield the balance. Otherwise, I will yield back and we can get on with the hearing.

Mr. Burgess. The Chair thanks the gentleman. The gentleman yields back.

The Chair, then, recognizes the ranking member of the subcommittee -- I'm sorry -- ranking member of the full committee, Mr. Pallone of New Jersey, 5 minutes for your opening statement, please.

Mr. Pallone. Thank you, Mr. Chairman.

I appreciate the opportunity today to discuss the reauthorization of the Medical Device User Fee Amendments. I am

pleased to see the progress that has been made under MDUFA in reducing review times for medical devices as well as ensuring that the Center for Devices and Radiological Health is well-resourced and well-staffed.

I would also be remiss if I didn't acknowledge the positive response from industry in terms of how MDUFA III is working, a dramatic shift from where things stood prior to reauthorization in 2012.

A lot has been accomplished in meeting the goal of reduced review times under the MDUFA program. Average total review times for 510(k)s are down by 11 percent and average total review times for pre-market applications are down by 35 percent, or 150 days.

Importantly, CDRH also approved the highest number of novel devices in the history of the MDUFA program in 2016, approving 91 new devices. While more work needs to be done, this progress has resulted in patient access to safe and effective medical devices more quickly, which is a goal I think we all share.

And MDUFA IV will build on these successes by working to improve the Medical Device User Free Program. It will advance the use of the patient perspective and the risk/benefit assessment of medical devices. It will also establish a system called the NEST to utilize real-world data for pre-market approval of new indications and post-market safety monitoring. It tailors the use of the third-party review program and improves pre-submission

communications with sponsors. All of these actions will help to improve the consistency, efficiency, and effectiveness of medical device reviews.

Just as I have said before on the other User Fee Agreements, the agreement before us today is the result of many negotiations with industry and stakeholders, consultations with patients and consumers, and solicitation of public input. The resulting recommendations were transmitted to Congress in meeting the January 15th statutory deadline.

Transmitting new recommendations at this point would go against this requirement and run the very real risk of MDUFA not being reauthorized before the program expires on September 30th. Any delays would endanger the review of innovation medical devices and threaten the jobs of thousands of FDA employees.

So, I intend to continue to work with my colleagues on the committee and across the Capitol as well as industry to ensure that we do not let this happen. This is a strong agreement and one that deserves our support, and I look forward to continuing our work on all of the User Fee Agreements to ensure that they are signed into law as soon as possible.

I have two minutes left. I don't think anybody wants the time. But, with that, I will yield back, Mr. Chairman.

Mr. Burgess. The gentleman yields back. The Chair thanks the gentleman.

And that concludes member opening statements. The Chair would like to remind members that, pursuant to committee rules, all members' opening statements will be made part of the record.

Again, we want to thank our witnesses for being here today, for taking time to testify before the subcommittee. Each witness will have the opportunity to give an opening statement, followed by questions from members.

We will have two panels of witnesses today, and we are going to begin with Dr. Jeffrey Shuren, the Director for the Center for Devices and Radiological Health at the Food and Drug Administration, no stranger to this subcommittee.

Welcome back, Dr. Shuren. We look forward to your testimony. You are recognized for 5 minutes, please.

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

Dr. Shuren. Chairmen Walden and Burgess, Ranking Members Pallone and Green, and Members of the Subcommittee, thank you for the opportunity to discuss the reauthorization of the Medical Device User Fee Amendments, or MDUFA, today.

When I was last here testifying about MDUFA, I am sure many of you recall, and have already mentioned, that the program was in a much different place. Since then, much has changed for the better, but we have more work to do.

As you have heard, between 2010 and 2016, we reduced the average total time to reach a decision on the 510(k), the submission type for lower-risk medical devices, by 11 percent. Between 2009 and last year, we reduced the average total time to reach a decision on a PMA, the submission type for a high-risk device, by 35 percent, reducing by 150 days.

But we went beyond our MDUFA III commitments. For example, we reduced the median time to approve a clinical trial submission from 442 days in 2011 to just 30 days in 2015 and 2016, a 93-percent decrease. Changes we have made at the Center for Devices and Radiological Health, or CDRH, to our culture, our policies, and our processes, the investments provided by industry through user fee funding, and the direction provided by Congress through

changes to federal law, have resulted in improved medical device pipeline and innovative technologies being introduced in the U.S. earlier than in the past. In fact, the number of novel devices we have approved has almost quadrupled from 24 in 2009, when I first came to CDRH, to 91 in 2016, the highest since the start of the User Fee Program in 2003.

Last year we approved the first artificial pancreas, working interactively with the device manufacturer from the early stages of development. We approved the first device in the world that is intended to automatically monitor glucose levels around the clock and automatically provide insulin doses. Overall, working with the manufacturer, we helped bring this technology to market three years earlier than the company originally intended to do.

MDUFA IV could continue that trajectory for more timely patient access to novel technologies, supporting CDRH's vision that patients in the U.S. have access to high-quality, safe, and effective medical devices of public health importance first in the world.

The MDUFA IV proposal submitted to Congress in January includes programmatic enhancements, such as a new quality management program that will improve consistency, efficiency, predictability, and the application of the least-burdensome approach in our pre-market review processes and decisionmaking. The proposal would allow FDA to move forward in some critical and

strategic areas, such as strengthening our partnerships with patients, allowing us to promote more patient-centric clinical trials, advanced benefit/risk assessments that are informed by patient perspectives, and foster earlier patient access to new devices.

Another critical area is the development of the National Evaluation System for health -- with a small "h" -- Technology, or NEST. The NEST is a non-government system that will be operated by stakeholders of the medical device ecosystem, including patients, providers, and the device industry, and it would facilitate the use of real-world data, collected as a part of routine clinical care, such as from electronic health records and registers, consistent with the goals of 21st Century Cures.

A robust NEST will enable manufacturers to harness real-world evidence that could enable them to drive down the time and cost of bringing new devices to market, expanding the indications to already-marketed drugs, meeting post-market reporting requirements, and obtaining payer coverage and reimbursement. The NEST will also enable faster identification of safety issues, reducing harm to patients and liability for companies.

In conclusion, the authorization of the Medical Device User Fee Program would expedite the availability of innovative new products, create jobs, protect patients, and provide the

enhancements that will continue to increase the efficiency of FDA's programs. Improvements in total time to decision, transparency, consistency, predictability, efficiency, and assuring a least-burdensome approach will benefit industry, healthcare providers, and, most importantly, patients.

Thank you for the opportunity to testify here today. I look forward to answering your questions.

[The prepared statement of Jeffrey Shuren, M.D., J.D. follows:]

**********INSERT 1**********

Mr. Burgess. The Chair thanks Dr. Shuren for his testimony, and we will move into the question portion of the hearing. I will begin with the questioning and recognizing myself for 5 minutes.

I do want to stress to members that we do have a lot of members on the subcommittee on are anxious to interact with Dr. Shuren. So, let us try to keep our question time to 5 minutes. If necessary to do followups afterwards, perhaps we can arrange to do that.

But, Dr. Shuren, I remember several of these rounds before, and I just have to say how optimistic your statement is and how optimistic the approach that your Center is taking to this process. For that, I thank you. There is a difference.

You talked in your opening remarks about a least-burdensome approach, and certainly that is something that we heard from a number of people at some of these hearings in 2012, that they were anxious to see that.

So, I just ask you, what has changed at your Center culturally to allow for things to be so different today than they were 5 years ago?

Dr. Shuren. I think one of the biggest differences in culture is we are putting the emphasis on the other side of our mission. For so long, we focused on protecting public health. We also have to think about promote public health. It is not just assuring that medical devices are safe and effective, but also

that patients have timely access. And we facilitate device innovation. That is what you see in our vision statement, and that is why it is so important. That first in the world is really not about beating other countries. It is about getting timely patient access. That is simply a good metric.

We have moved towards more of a flexible benefit/risk paradigm in how we think about technologies. It helps bring them to market more quickly, but appropriately.

We are factoring in the perspectives of patients. What are the values, the tradeoffs, they are willing to make in decisions? And now, we are relying more and more on real-world evidence, which can be generated in a number of cases in less time and lower cost.

Mr. Burgess. Well, you mentioned in your opening remarks about the artificial pancreas. And I can remember discussions with patient groups and parents and folks who were interested in that, the difficulty with getting DS on that. So, I certainly acknowledge what a milestone that was.

I just can't tell you the relief and gratitude that I have heard, particularly in parents' voices when they say that, you know, "My iPhone alerts when my child's glucose is getting outside of the prescribed range..." and to be able to deliver some measure of control back to the patient, back to their caregivers, that is an enormous gift.

Five years ago, I was critical because it was taking too long.

I am glad that you moved it along. I am glad that it was accelerated. I think it underscores what you were saying, that we are not just about protecting patients; we have got to deliver for patients. And I think the artificial pancreas is probably the No. 1 case that makes that point. I welcome the cultural changes, and whatever was required on your part to achieve those, I think we are grateful for that.

Now in 21st Century Cures you participated in some of the roundtables. I know we had a number in this very room. It was configured a little differently, for those who are watching on television, but it was here in the main committee room.

We heard about patient participation in drug and device development and the product review process. Can you talk about how the Review Division staff in the Device Center will now be incorporating patient perspectives into their decisionmaking?

Dr. Shuren. We have started that process already. One of the areas we started to focus on is, how do you better understand the perspectives of patients? I mean, you can ask people, but, you know, within that patient population they substratify. So, we have been advancing the science of patient preferences. What are the tools you can use to more quantitatively assess the tradeoffs patients are willing to make?

We did this in a study on obesity devices. In 2007 to 2014, we hadn't --

Mr. Burgess. Sir, what type of devices?

Dr. Shuren. For obesity. And we hadn't approved anything from 2007-2014. When we incorporated patient perspectives, we changed our paradigm, we approved a device then. We have approved five more since then. The pipeline is rich.

So now, what we are doing is we have put out policy on factors to consider in doing these studies. Companies are now coming to us. We are training our staff. And with MDUFA IV, we will have the resources to build a patient engagement program, giving us the expertise to provide advice on the design and use of patient preference information, patient-reported outcomes, and better designing clinical trials around patients' needs and their preferences.

Mr. Burgess. I am glad you mentioned that because, of course, many of the device manufacturers are very small and perhaps lack the resources of their larger counterparts. I am going to submit that question for the record, but I am interested in the answer to that question.

In the interest of time, I am going to recognize the gentleman from Texas. Five minutes for questions, please.

Mr. Green. Thank you, Mr. Chairman.

Again, Dr. Shuren, I want to thank you and your staff for the progress, because bringing in the patients, the patient advocates, it just expands it, and it is much better if everybody

is at the table, particularly patient advocates who come in with resources and experience that helps you.

I understand the National Evaluation System for health Technology, or NEST, has the potential to make it less expensive to bring new device to market, expand or approve users for existing products, and post-market requirements for harnessing real-world data collected during the routine care. Can you explain what the NEST is and how it is incorporated into the agreement? Specifically, how does NEST differ from the CDRH currently and how it will generate value to patients, the FDA, and the medical device industry?

Dr. Shuren. One of the great inefficiencies we have in our healthcare system is that we gather information every single day in patient encounters, but we can't make great use of it because it may not be standardized; it may be incomplete; it may be of poor quality. And it sits in electronic health records, registries, payer claims.

What NEST is about is, how do you use market-based principles? How do you use the collective purchase power of the ecosystem to drive towards greater standardization and consistency, drive down the time and cost of being able to leverage that information and, then, to use it to inform decisionmaking, generate the evidence for products to come to market, as well as to meet post-market requirements?

So, for example, in this past year we approved a device, a balloon stent. It was based solely on real-world evidence that came from device registries.

We have expanded labeling indications based on device registries. Companies today are leveraging device registries for their post-market study requirements. They are finding a 40-to-60-percent decrease in the cost of those studies. So, it is already having an impact.

What NEST does is it makes it more systematic. Cost goes down further, and it can be readily available for more device types and more device companies.

Mr. Green. Thank you.

The 2015 decision time decreased 35 percent. While this is great in understanding the most recent MDUFA Quarterly Report, the FDA's time for metrics to review PMA devices went up. Do you know what is behind this increase and what sort of tools are included in the new MDUFA agreement that would help prevent these sorts of total time increases in the future?

Dr. Shuren. We are starting to see a little bit of an upturn, which is why it is so important that you are monitoring the data constantly. We are in the midst of doing a deeper dive and we are looking at a variety of factors. One is the increased workload that we saw under MDUFA III, and particularly for the most innovative devices, like PMAs and de novos.

So, in fact, one of the contributors might be the success of the program is leading to the more innovative, more complex technologies coming to the U.S., which is a good time. But we are looking into it and we will take the appropriate action.

What MDUFA IV will provide is certainly more resources to be able to do the work, but I also think do the work more efficiently by building in a quality management system to help us drive towards improving our processes, reduce waste, lower cost, and improve the effectiveness of our programs.

Mr. Green. And, of course, while we are working on MDUFA, if you have any suggestions for it? I know there has been a partnership over the last number of months, and years even, to working. But, if we can help that, what we need to do with this legislation, just please let us know. And that is really a bipartisan issue.

I know digital health is a key area and focus for FDA. I want to thank the agency for its work with us in the last Congress. Advances in technology have potential to transform medical care, ensuring FDA has the right tools in place to ensure patient safety, and appropriate oversight of the category of devices as a goal. Software as a medical device and software inside medical devices are two specific addressed in MDUFA IV. Can you talk about the commitment has to build expertise and enhance the review process for such software?

Dr. Shuren. Well, one of the key components of MDUFA IV reauthorization would be to establish digital health units centrally within the Center to help drive rate of coordination and consistency. The way we will set this up is that our review staff who deal with software as in medical devices, they will get basic training. They will sort of be yellow belts. They will deal with more general issues.

Then, within the offices, we will have better trained people, kind of the green belts. You can think about this Digital Health Unit. These are the black belts who get involved in the more challenging submissions who can oversee training, assure consistency.

But the other part of this agreement is to continue our international harmonization work and the International Medical Device Regulators Forum, IMDRF, which is critical, driving more international harmonization, but also revisiting the paradigm. So, we are looking to change the paradigm on software as a medical device to better meet the rapid innovation cycles we see in these technologies. We are working collaboratively with others on trying to establish that new paradigm.

Mr. Green. Thank you, Mr. Chairman.

Mr. Burgess. The gentleman yields back. The Chair thanks the gentleman.

The Chair recognizes the gentleman from Michigan, Mr. Upton,

chairman emeritus of the committee. Five minutes for questions, please.

Mr. Upton. Thank you, Mr. Chairman.

And, Dr. Shuren, thank you. Jeff, thank you very much for all your participation. You were really terrific as we moved 21st Century Cures to the goal line. Your participation in this room and as part of a number of roundtables, your participation around the country in roundtables was very important, and we really appreciated all your work on that.

You give us some really good news in terms of the progress that you have made over the last five or six years. It reminds me of when I was going through a major facility in our district, Stryker, years ago, before this process really started. I can remember going with the then-chairman of Stryker looking at 6-7 hundred thousand new square foot manufacturing facility in Michigan. And I said to him, I said, "Jeff," I said, "what do you think?" And he said, "I just wondered if we should have built this in China."

And that was because we were lagging behind. We didn't have these approval rates like we have now. You could talk about the artificial pancreas approval three years ahead of what the experts thought would happen; it is really great news. Because not only are we seeing those benefit the patients that need them, but I have got to believe that that is going to be built here in the

U.S. That is going to be the jobs that we all want, the high-tech jobs that are going to be there that we all want.

So, I guess your colleague Dr. Woodcock was here about a week ago. She talked about, if we don't get this done, heaven forbid, but if we don't get it done and send the signal probably by the end of June or July, the end of July, that they would expect that they would perhaps a 70-percent reduction, and they would have to start sending out RIF notices to folks. We are going to do everything we can to make sure that that doesn't happen, that we are going to work together to get it done.

But what would be the impact and what is the timing as it relates to PDUFA for your large chapter of where we want to head as well? What is the latest that you need to hear from us?

Dr. Shuren. Well, first, let me take the moment to thank you and Congresswoman DeGette, and all the members on the subcommittee and on the committee, for your leadership in the 21st Century --

Mr. Upton. We didn't lose a one, I want you to know. It was unanimous in this committee, thanks to the leadership on both sides.

Dr. Shuren. So, the impact and the timing for us, if MDUFA were to sunset, not get reauthorized in time, we would lose about a third of our staff. As Dr. Woodcock said, it is about 60 days before that law sunsets that we need to start the process on a

reduction-in-force, RIF.

So, it has huge implications, and it is not just even the people you lose, but for the people who remain. Your best and your brightest leave because they see it is a sinking ship and they are going to get off and move on to other things.

So, it is our hope that we would have the law reauthorized before we need to start that process for a RIF.

Mr. Upton. So, my next question is, great news about the artificial pancreas, and we have been watching that a while and what it would do, and particularly to the diabetic community across the country.

What are some of the devices that you have in the pipeline that you think may be -- you know, assuming that things go well, tell us a little bit about that next chapter. What are some of the things that you see on the horizon for us getting done?

Dr. Shuren. Well, you know, I think where technology is going, you are going to see more and more use of robotics. You are going to see technology get smaller and smaller, you know, micro-sized. You are going to see less-invasive surgeries happening.

Another great example is on the transcatheter aortic heart valve. When we first approved it here, it was four-and-a-half years after it came CE-marked in Europe. This past year we just approved expanding use in another population. It was 18 days

after Europe for similar technology.

But we are going to see other things like using maybe ultrasound, instead of a scalpel, ultrasound that drives down to start to do surgery under the skin. So, there are amazing things that have happened. And I think the U.S. can truly be the world's leader if we continue on the trajectory we have been on.

Mr. Upton. Thank you. Thanks again for your work, and we look forward to working with you in the days ahead.

I yield back my time.

Mr. Burgess. The Chair thanks the gentleman. The gentleman yields back.

The Chair, then, recognizes the gentlelady from California, Ms. Eshoo. Five minutes for questions, please.

Ms. Eshoo. Thank you, Mr. Chairman.

And welcome back, Dr. Shuren. It is good to see you.

I want to commend you and your entire team for the report that you have brought forward. It contains a great deal of good news, and that good news affects patients, No. 1, I think. It is a compliment to you and the industry for the work that you have done together.

This is a very important American industry. We want to keep it that way and keep it vibrant. I can't help but, as the mother of MDUFA -- it was my legislation that created this process -- it is deeply gratifying to see how it has really come along, and

that we are where we are today. So, bravo to you.

I also want to thank you for meeting on a quarterly basis with Congressman Erik Paulsen and myself, as Co-Chairs of the Medical Technology Caucus. We have done this for some time. We bring up the issues just the way they are presented to us by constituents, by patients, and I hope that you think that those meetings have been as rewarding as we do. And we are very grateful to you for that.

How much money is in the user fees for this go-around, for this reauthorization?

Dr. Shuren. So, for this reauthorization, without adjusting for inflation, the total over the five years would be about $999.5 million.

Ms. Eshoo. And it is adjusted for inflation as opposed to what you are operating under now? Or did the industry come up with more?

Dr. Shuren. MDUFA III also was adjusted for inflation, too, for over time.

Ms. Eshoo. And how many staffers do the user fees pay for?

Dr. Shuren. So, currently, if you just said --

Ms. Eshoo. I think you said, what, a third of the --

Dr. Shuren. Yes, so it is about a third of --

Ms. Eshoo. -- a third of your Division?

Dr. Shuren. If you were paying for full salary, in reality,

the number of people who work in the User Fee Program in one way, shape, or form is probably a little over 90 percent of the program.

Ms. Eshoo. Well, I think every member of this subcommittee, and hopefully the full committee, will have a deep appreciation of that.

No. 1, I think the negotiations that you have completed should be accepted by the Congress. I mean, it has been worked out. I don't think there is anything to meddle with, unless members have something that they think needs to be brought up. But I think that this is ready for primetime.

So, I don't have anything that I want to add to it. What I would like to know is, I know that the FDA participates in the International Medical Device Regulators Forum. I know it is a voluntary body of device regulators around the world to talk about future directions in the medical technology world and in regulatory harmonization, which I think is very, very important because these products end up being global.

What can you tell us about that? What is news with it? Where do you see things moving? What are some of the activities that the FDA is working on in this area? And then, of course, the operational question around here always is, what else do you think needs to be done?

Dr. Shuren. So, the latest is in the past year we officially stood up medical device single audit programs, so a surveillance

inspection conducted by one participating jurisdiction is relied on in whole or in part by another jurisdiction. So, that reduces a lot of cost to companies. You have fewer inspectors coming in the door. It is good for government because we have a broader view of the facilities out there.

Our work is advancing on harmonizing international regulation on software as a medical device. We are doing work to advance the use of standards, international and national standards, very important for also driving down time and cost and greater consistency.

And the next place where we are just starting in, and I think will be the biggest project we have taken on, is pulling the building blocks together to, hopefully, establish a Medical Device Single Review Program, where the approval decisions by one participating jurisdiction, again, are relied on in whole or in part by another jurisdiction. That would probably be one of the most fundamental changes in the medical device arena. And if there is anything that is going to push a least-burdensome approach, it is that effort. And the U.S. is the one who proposed it and we are the ones who are leading it.

Ms. Eshoo. Bravo. Thank you very, very much, and to your entire team. Great to see you.

Thank you, Mr. Chairman.

Mr. Burgess. The gentlelady's time has expired. The

gentlelady yields back.

The Chair recognizes the gentleman from Pennsylvania, Mr. Murphy. Five minutes for questions, please.

Mr. Murphy. Thank you, Mr. Chairman, and thank you, Dr. Shuren, for being here.

A recent survey found that the majority of Americans believe that proper servicing and maintenance of medical and radiation-emitting electronic devices is crucial to protecting patients, and that all medical services should be consistently regulated by the FDA, regardless of whether they are an original equipment manufacturer or a third party.

Can you give us some update on where things stand on rules for third-party service of medical devices in order to ensure this safety?

Dr. Shuren. Yes. Well, we agree both that we need safe servicing, but also the importance of having good servicing available. We held a workshop back in October of last year, and we heard a great input from the original equipment manufacturers as well as from the third-party servicing industry, from patients, and from others. Right now, we are still going through the feedback we received, and we still have groups who are coming in and talking to us. So, we are still in the data-gathering mode at this point.

Mr. Murphy. Do you anticipate any dates by which you are

going to have some resolution of this?

Dr. Shuren. I don't at this point, and this is also an issue that we will be discussing and working with our colleagues at HHS on.

Mr. Murphy. But you agree with the general concept that you have to make sure that services are more or less approved in going through with this?

Dr. Shuren. We do want to make sure that they are of high quality, and we heard issues on both sides, both from the original equipment manufacturers, the importance of having people who are well-trained, using appropriate parts. We also heard from the servicers, making sure that they have access to the right training. Couldn't they get the parts that they needed?

So, finding sort of what is the best path forward to address concerns and make sure we have a safe, but rich environment out there will be important.

Mr. Murphy. Thank you. I look forward to getting updates from you on that.

Next, I just want to talk this global economy here. I am interested in ways we can harmonize regulatory processes around countries, so the companies can realize efficiencies and patients can have access to lifesaving devices in a more timely manner, part of what was approached in 21st Century Cures.

But I want to know about harmonization efforts here that you

are working on or that you would ask Congress to consider. Could you comment on some of those?

Dr. Shuren. Well, I think the big one that allows that sort of fast-to-our-patient access is this Medical Device Single Review Program. We just put in place policy under this International Medical Device Regulators Forum, IMDRF, for competency, training, and conduct of third-party reviews. So, that is the very first building block.

We just adopted a new work item to revisit sort of a foundational document that we call the Central Principles on Health and Safety, and safety and performance, that we will be working on next.

So, it is going to take a little bit of time. There are other issues, too, related to harmonization that we will need to tackle as a country. And it is things that we are in discussion with HHS about, and I hope we have an opportunity to maybe discuss again when there is more information to provide.

The last piece is MDUFA IV also provides greater support for a more robust third-party review program, which is going to be important if we are ever to get to the place of that harmonized single review program. It is not just about more efficiencies domestically, but it can give us a leg up for moving to truly a global medical device review program.

Mr. Murphy. Thank you.

Next, I want to talk about security, more particularly, more specifically, cybersecurity as it relates to the privacy of the records of devices, of manufacturing, et cetera. But it frequently comes up in the context of these medical technologies. How has FDA been engaging in this issue about cybersecurity with devices?

Dr. Shuren. So, to date, we have put out several policies on cybersecurity, both on the pre-market and post-market. We have been adopting national and international standards. We have been working with other agencies, particularly with the Department of Homeland Security through their ICS-CERT, with the Department of Commerce, with FTC, and with the HHS Cybersecurity Working Group.

One of our more recent efforts is an MOU with the NH-ISAC, the National Health Information Sharing and Analysis Center, to establish what we call an information-sharing and analysis organization. It is essentially a community that allows sharing amongst members in the device ecosystem about vulnerabilities and about safeguards to take.

This is a critical part about cybersecurity. It is a shared responsibility. It doesn't fall to one entity. And we need the members of the ecosystem sharing information, working what we call researchers, the white hat hackers, so we can identify what are the vulnerabilities and put in safeguards, recognizing that

because the people who hack, they get smarter and smarter, and the risks continue to evolve. You have to constantly keep up on this. So, you need that kind of active forum.

Mr. Murphy. Thank you, Mr. Chairman. I will submit the rest of my questions for the record. I yield back.

Mr. Burgess. The gentleman yields back. The Chair thanks the gentleman.

The Chair now recognizes the gentlelady from Colorado, Ms. DeGette. Five minutes for questions, please.

Ms. DeGette. Thank you, Mr. Chairman.

First of all, I would like to add my thanks, Dr. Shuren, for the approval of the artificial pancreas, on behalf of the Diabetes Caucus, but also on behalf of my family because, as you know, my daughter is a type 1 diabetic and will be one of the first users of this. So, thank you very much.

I want to talk to you a little bit about some of what President Trump's Executive Orders are doing to the agency and what this will mean for the implementation of 21st Century Cures. Because we are all having what we feel is a much-recognized bipartisan lovefest around our great committee achievement last year, and we are really proud of it and what it has done in the medical device arena. But we are concerned about, at least I am concerned about some of the announcements emanating from the administration. I would like to get some clarification from you, if you have some.

Some of us sent a letter to the administration a couple of weeks ago about the hiring freeze. And we are concerned in the medical device arena that the hiring freeze will stop us from hiring the right people that we need to implement the bill. And we are awaiting a response for that.

But there is another issue that also I think threatens Cures and the user fee implementation. That is President Trump's repeated calls to deregulate the FDA. A couple of weeks ago, he said he wants to cut up to 75 to 80 percent of all FDA regulations.

And the problem I have, you know, nobody likes unnecessary or overly-burdensome regulations. Nobody ever, ever wants that to happen. But what the President seems to do is he sort of seems to do this with a meat axe. So, for example, he had issued this Executive Order saying that, if you are going to have a new regulation, then you are going to drop two regulations without looking at what the arena is that you are talking about or what the regulations are.

And I think this is of particular concern with the FDA when it comes to agency guidance because, when you guys issue agency guidance, then that helps the stakeholders understand how the FDA is implementing and interpreting the rules and laws. Even when the stakeholders don't agree, at least they know where you are coming from.

And so, I am concerned, if you have this repeal two for every

one you adopt, then that is going to also -- not only is it going to hurt with the agency guidance, but it is going to help with many of the provisions for 21st Century Cures. The breakthrough device pathway is a really good example. And the CLIA waiver provisions in Cures, they call for new guidance. So, how are we going to drop two if we are enacting one? It is also going to complicate issuance of guidance documents under MDUFA IV, such as third-party review.

So, my question to you, has the Trump administration clarified to the extent to which an Executive Order applies to a guidance issued by an agency?

Dr. Shuren. Well, first of all, I will say we recognize the importance of issuing appropriate guidances and regulations.

Ms. DeGette. Right.

Dr. Shuren. Right now, we are working with our colleagues at HHS on implementation of the Executive Order. But I can tell you we are already moving forward to implement 21st Century Cures.

Just a few weeks ago, we put out a notice of medical devices that are Class II that we are proposing should no longer have to submit at 510(k).

Ms. DeGette. That is great.

Dr. Shuren. And that, you know, we will look at public comment, but that would deregulate, if you will, over 1,000 medical devices. So, we are already moving forward on those.

Ms. DeGette. So, you are trying to work with HHS on interpreting what that Executive Order means at this point with respect to guidances?

Dr. Shuren. Yes.

Ms. DeGette. Okay. Now, if you are not able to issue new guidances, will the Cures implementation be impacted by that?

Dr. Shuren. Yes.

Ms. DeGette. Breakthrough devices is the perfect example.

Dr. Shuren. That is correct, because we are called on in the statute to also issue certain guidances. But, again, as of right now, we have been able to put in place the things we need to do to meet statutory deadlines and --

Ms. DeGette. That is good. Will you please let us know if you start seeing impediments to implementing 21st Century Cures because of this? And I know we can work on both sides of the aisle to make sure that the implementation goes smoothly.

Thank you.

Thank you very much, Mr. Chairman. I yield back.

Mr. Burgess. The gentlelady yields back. The Chair thanks the gentlelady.

The Chair recognizes the gentleman from Indiana, Dr. Bucshon. Five minutes for questions, please.

Mr. Bucshon. Thank you, Dr. Shuren, for being here.

I am interested in bringing more predictability and

consistency to the device inspections process. It is a little bit off the beaten path. But, for routine inspections, the FDA should be able to give companies a reasonable heads-up about what they are inspecting as well as provide regular communications throughout the inspection. I think you probably agree with that.

Additionally, should the FDA find an issue that needs to be addressed during an inspection, companies have 15 days to submit a remediation plan to FDA, but there is no such timeline for the FDA to respond to companies, to communicate whether the remediation plan meets FDA expectations.

Can you comment on what CDRH might be able to do to address these issues?

Dr. Shuren. Well, although we are not the lead on this -- our Office of Regulatory Affairs oversees the fields -- we do work very closely with our colleagues over in ORA. And I can tell you, as a part of the program alignment effort, which is getting officially stood up in the coming weeks, as part of that, I know ORA -- and we will be working with them -- is looking to revisit their standard operating procedures and other processes to make device inspections more efficient, more timely, and to have the right kind of engagement back with the companies.

Mr. Bucshon. Great, and I think that is important that you do engage in that process really to try to improve everything across the spectrum as it relates to the device industry.

My colleague Ms. Brooks and Mr. Butterfield and Mr. Peters introduced legislation yesterday to try to address some of these issues. And so, I look forward to working with everyone on trying to improve that situation.

Mr. Chairman, I yield back.

Mr. Burgess. The gentleman yields back. The Chair thanks the gentleman.

The Chair recognizes the gentlelady from Florida, Ms. Castor. Five minutes for questions, please.

Ms. Castor. Well, thank you, Mr. Chairman, for calling this hearing today.

And welcome, Dr. Shuren.

Patients understand better than anyone about the impact treatment will have on their daily lives, and they have a unique perspective to add, as the benefits and risks of different treatments are considered. There has been considerable interest from the patient community and families in incorporating the patient perspective into both the drug and device regulatory review process and the development process.

Dr. Shuren, please discuss how the proposed MDUFA IV agreement works to further incorporate the patient perspective into the medical device regulatory process. And if you would, give us a few examples.

Dr. Shuren. Well, it will build on work that we have done

to date and establish sort of a patient engagement program within CDRH; allow us to have the expertise we need to provide greater advice and abilities in reviewing studies that are conducted to assess patient preferences, to advance the incorporation and the voluntary use of patient-reported outcomes, so we are measuring the things that matter the most to patients; how we more systematically incorporate the perspectives of patients in the design of clinical trials. We have to design studies not around the needs of the investigators, but the lifestyles of the patients who participate in those studies.

This is a journey we have been on now for over five years, starting with our Benefit-Risk Framework we put in place for product approvals back in 2012, where we made a decision that we would explicitly make a factor in our decisionmaking to be patient preferences.

The old way of saying that we take into account the tradeoffs our reviewers make is not what we should do. Devices are used on or in patients. And so, the tradeoffs they are willing to make are the ones that should factor into our decisionmaking. And MDUFA IV will help us advance that work.

Ms. Castor. And you provide a few examples when a patient organization had some ideas and came to you and how it improved the situation or altered the situation?

Dr. Shuren. Yes. So, one, I had mentioned this study we

had done with obesity treatments. That has already led to now products coming on the market. We are looking to replicate that in other areas.

The other thing patient groups have done -- and we have set this up -- is getting them to come in and speak to everyone in our Center. I believe every single person in CDRH needs to be interacting with patients. That is even our secretaries. So, when they answer the phone, they return an email, they understand the patient's perspective when they do so.

So, last year we hosted 21 events for our staff in our Center, and 34 patient groups participated in that. We are establishing mechanisms where we now have, rather than just a network of scientific and engineering and healthcare professional experts which we set up, we have a network of patient groups, patient volunteers who are working with us.

And then, the next stage this year is the official launch for our Patient Engagement Advisory Committee, where for the first time at the agency there is an advisory committee made up just of patient representatives to tackle the issues that matter most to them.

Ms. Castor. Great. I appreciate your emphasis on that, and we will be following up with some more specific questions. Thank you.

Mr. Burgess. The gentlelady yields back. The Chair thanks

the gentlelady.

I now recognize the gentlelady from Indiana, Ms. Brooks. Five minutes for questions, please.

Mrs. Brooks. Thank you, Mr. Chairman, and thank you, Dr. Shuren, for being here.

In the information you provided us in your written testimony, you talked about the diagnostics for national emergencies. I would like to focus a little bit on that because I have been focused here on trying to strengthen our public health infrastructure for national emergencies, but I have been more focused, along with Congresswoman Eshoo, on incentivizing vaccines and treatment for public health emergencies and pandemics. But I know from your testimony that, obviously, the diagnostic piece and the testing initially is so very critical, and I appreciate the rapid response that has been undertaken by FDA and applied the high volume of the emergency use authorizations granted and reauthorized.

But, unfortunately, as we know, whether it was Ebola in 2014 or, most recently, Zika virus in 2016, we know that FDA has focused significant time and resources to these diagnostics. But can you speak not just to what has happened in the last five years, but what can we anticipate going forward from CDRH? Because I know there is a lot of concern when we have these outbreaks, I know as we get ready to go into the warm season once again with Zika, we don't have vaccines yet. We don't have treatments.

Can you please share with us with respect to national emergencies what your offices, what the focus is, whether or not the resources that we have been providing are sufficient? What more should we be doing?

Dr. Shuren. Well, certainly on the device side for diagnostics, we have sort of invested in our infrastructure to try to best handle, when there is an emergency, that we have the capacity to be able to deal with new diagnostics that may be coming in. To date, we have already authorized about 50 EUAs, and, also, in a fairly rapid time. You know, the median time to approve an EUA for Zika was about five days.

Mrs. Brooks. Excellent.

Dr. Shuren. The other thing that we do in these circumstances is we develop templates for the product developers that make it easier for them to be able to gather the evidence under that standard, get it to the agencies. So, again, this moves much more quickly.

I would say the greatest challenge developers face today is more about access to samples and the clinical information linked to that sample. It is not under FDA's purview, but that is what we hear from the companies, because the samples help them design the technology and, then, validate it.

More broadly, when we deal with these national emergencies, it is certainly an issue -- I know your interest -- I will take

back, but it really is sort of a question about more on the national level, are we prepared as a nation? And I will ask this rhetorically, because I am not the one to answer it, but are we prepared as a nation when we have the next outbreak? Because there is going to be a next outbreak. As we see, we are just constantly bombarded with new organisms and things that really stretch our scientific knowledge and capabilities.

Mrs. Brooks. Well, and thank you for that. It is reassuring, actually, to hear that it was only a five-day turnaround with respect to Zika.

It kind of leads into my next question about global harmonization. If you say that you don't have enough samples, what kind of cooperation is there and what kind of harmonization is there between our partners in other countries? With their regulatory process and our own, how can we possibly work on that to help particularly with emergency use?

Dr. Shuren. I know already that there is strong relationships between CDC, who normally handles that aspect, with other organizations internationally, like the World Health Organization. We certainly, then, work very closely with CDC. And when there are needs for making available more samples, we will also go to them and sort of encourage can we get and make those available to developers.

Mrs. Brooks. So, you don't need authority beyond what you

have to work with other regulatory bodies? You feel like you have sufficient authorities in place? Or is there anything that impedes your work with other regulatory bodies?

Dr. Shuren. I think we have the authority we need for the kind of work we do. When you think more broadly in terms of the response, when we deal with samples and others, I would say that may be questions to direct to the other involved agencies. And certainly, that is something we will take back within HHS. If there are any additional needs that HHS feels are warranted for the other agencies, we will bring that back to you.

Mrs. Brooks. Thank you for your work.

I yield back.

Mr. Burgess. The Chair thanks the gentlelady. The gentlelady yields back.

The Chair recognizes the gentleman from North Carolina, Mr. Butterfield. Five minutes for questions, please.

Mr. Butterfield. Thank you very much, Mr. Chairman. It is good to sit next to you. And thank you so much for calling this hearing today, and thank you for your friendship and thank you for your leadership.

The medical device industry, Mr. Chairman, is important certainly to all of us, and including my constituents down in North Carolina, both in the Triangle area and in the eastern part of my state. Because this industry actually is a job-creator. They

employ thousands of my constituents. But, also, because medical devices can help improve health outcomes and improve the quality of life for many lives of those suffering from complex medical conditions.

My home state is home to many large and small medical device developers like CVRx, which I understand is on the next panel, which is represented here today. The advances made possible by the User Fee Agreement III, including increased communication with patient and consumer organizations is a step in the right direction. It is a step in the right direction for transparency and patient involvement in the process.

Meaningful reforms included in the negotiated agreement for MDUFA IV will further advance those goals and stand to improve outcomes for patients. Specifically, the potential benefits of using real-world evidence to help develop medical devices can benefit my constituents and citizens throughout the country.

Also, the proposed National Evaluation System for health Technology, known as NEST, can help ensure the use of real-world evidence is scientifically-based and effective. There is great potential for this agreement to facilitate innovation and improve health outcomes. However, the potential can only be realized if the administration invests in the overall budget of the FDA, does not hamstring its mission through hiring freezes.

Now, Dr. Shuren, I am going to ask you a couple of questions.

I am going to ask you about the funding at the agency. I think we know the circumstances there. That is our jurisdiction. So, we are going to deal with that politically on this end.

But I am very interested in the NEST proposal and the agreement. Can you discuss how stakeholders will be chosen to own and operate NEST? And will patient advocacy groups be included in that process?

Dr. Shuren. Certainly. So, NEST, again, it is a non-government system; it is a non-government entity. And it does not own or control the data sources. It is setting up agreements and policies regarding use of data that may be owned, let's say, by healthcare systems or by a registry.

We have already supported the creation of what we call a Coordinating Center. The Medical Device Innovation Consortium, a public/private partnership, is serving in that capacity. They now have put out a call for members of a governing committee that would be representative of the ecosystem. Patients will be represented on that governing committee. So, they are going to have a say in how NEST is run, and we are now in the process of hiring an executive director. MDUFA IV will provide additional support to now operate the Coordinating Center and invest in pilots.

Beyond the governing committee though, the plans are to establish other forums for different communities. So, looking

for beyond having those representatives from the patient community on the governing committee, forums for the patient community to engage directly with NEST and to have their input taken into account.

Mr. Butterfield. Under the NEST proposal, what steps do you envision for bringing new devices to market?

Dr. Shuren. Well, I think one of the critical is your device needs to be safe and effective, which you may demonstrate directly with high-risk devices or, you know, lower-risk "me, too" devices. It is substantial equivalence.

But it is the science that drives that decisionmaking. And the question is, when you need clinical data, the cost to do a traditional clinical trial is very, very high. If you are able to leverage data that is already being collected, it is a good enough quality, and you can control for other biases, then that data can be leveraged to support that product coming to market in ways that let you gather the data more quickly and at lower cost. And that leads to technology not just getting to market more quickly, because the time to develop the evidence goes down, but the amount you have to invest to do it means you can put that money to develop other products.

Mr. Butterfield. Running out of time, my last question, what steps do you envision for the expansion of indications for already-approved devices under the agreement?

Dr. Shuren. Again, being able to leverage those data sources may allow us to expand a labeling indication. And we have already done that, for example, in the case of a transcatheter aortic heart valve. The company was planning to do a clinical study to expand its indications. We looked at the registry data and said the data is already there; why don't you just ask us to expand the indication? So, what would have taken years took weeks.

Mr. Butterfield. Thank you. I yield back.

Mr. Burgess. The Chair thanks the gentleman. The gentleman yields back.

The Chair recognizes the gentleman from Oklahoma, Mr. Mullin. Five minutes for questions, please.

Mr. Mullin. Thank you, Mr. Chairman.

Doctor, thank you for being here.

During the series that we have been going through, we had a hearing about our generic drug user fee, and I got an opportunity to talk with Dr. Woodcock about the concerns we have heard from industries about the inconsistency with the FDA inspections. Companies are concerned about the lack of transparency, predictability, and efficiency, and consistency. And I hear that the inspections of foreign device establishments are often more efficient than domestic inspections. Have you heard about this?

Dr. Shuren. Yes, I have.

Mr. Mullin. Could you explain maybe what steps you are taking to make sure that there is consistency through standard operating procedures?

Dr. Shuren. So, we are working with our Office of Regulatory Affairs, who is actually responsible for the field staff. It is true that domestic inspections may take longer than foreign inspections.

Mr. Mullin. Why is that?

Dr. Shuren. So, for foreign inspections, they are making arrangements for that inspector to go over for that inspection. So, that is all they are there for. They come back.

On the domestic side, that inspector may be finishing up with another inspection or they get called away for a for-cause inspection. That said, on average, most domestic and foreign inspections occur in four days or less, sometimes within one day. But I do know that ORA -- and we are working with them as part of this program alignment effort -- is revisiting its SOPs, so that it reduces the time for domestic inspections.

I think folks understand it can be disruptive to companies. Someone comes in the door, they leave, they come back, rather than they come in and they finish their work, they are done, and they move on.

Mr. Mullin. So, paraphrasing what you said, the issue we are having here domestically versus foreign is that they are

distracted?

Dr. Shuren. Is? Excuse me?

Mr. Mullin. They are distracted?

Dr. Shuren. That they may be doing more than --

Mr. Mullin. Well, I mean, what I am saying is that they can go over there and they can focus on one task. And when they are here, they are focusing on 15 or 20 different tasks?

Dr. Shuren. Well, not from 15 or 20, but when they --

Mr. Mullin. Two or three, four or five?

Dr. Shuren. Maybe or they may be focused on the one. Like I said, most of the time they are doing that inspection in just a few days.

Mr. Mullin. Do the same individuals inspect foreign and domestic? Or do you have a certain group that only does foreign and a certain group that only does domestic?

Dr. Shuren. As of right now, there are some individuals who, a very small number, who do primarily foreign, but many of them are people who do domestic and foreign.

Under the program alignment effort, part of that effort is to move away from the other challenge, which is inspectors who they not only inspect a device company, they inspect a food company and a drug company. Program alignment is to establish these more vertical commodity-specific programs, so you just have a device inspector and that is all they do. And that will allow them to

also better focus and have the right expertise and training. And that will start to drive greater consistency and more timeliness in the conduct of --

Mr. Mullin. How long do you think these changes are going to be implemented?

Dr. Shuren. To be fully up and running, it will take a few years. As of in a few weeks, that official program will be stood up in the various commodity areas, and over the next two to three years most of the pieces will be in place.

Mr. Mullin. I guess help me understand why two or three years. What is going to take so long to make the changes?

Dr. Shuren. In part, because ORA is responsible for all the product areas. So, they are not just dealing with medical devices. They have their program for pharmaceuticals, for human food. So, they have to handle all of those, and it is, in part, the huge workload ongoing from people are geographically-oriented in an organization and now is focused within a region instead, to say, I have a national organization where people may be in different places, but we run it centrally. They got to standardize the training. They have got to change their standard operating procedures. The systems have to be, the IT systems have to be changed. There is just a lot of work that goes into it.

Mr. Mullin. And I completely understand everything you are saying. I just can't wrap my head around, when we see that there

is already issues going on, why it would take roughly two or three years after the program is stood up to fully implement it. I would like to think there is a more efficient way for us to be able to get that implemented than its taking two or three years. Because once you issue the SOPs, then it is just a matter of people willing to do their job and the training that it is going to take to get it. I mean, if they have already been in that field to some degree, then we are moving distractions away and it seems like they could be able to be more focused on just the job at hand.

And I say that because I get implementing changes in a big organization, that it can take time to turn the ship around. But our companies are struggling, which means that our consumers are struggling, which means that we have rising costs, and, eventually, it gets passed down to the ultimate person that we are here all trying to help prevent higher costs and get the drugs needed to the individual that needs it, the patient.

So, if there is a way that we can help through this process, as I offered my help to Dr. Woodcock, I would offer it to you, too. Any way that I can help, this committee can help, or our office can help, we want to be helpful because this is important.

Thank you, sir.

I yield back.

Dr. Shuren. Thank you. And I will just say, you are preaching to the choir because having better consistency and being

able to deal with just a set of individuals, that is easier for my Center as well. So, I will take this back.

And I do know, when they stand up the program, the program is organized, but they still have to do all the training and the SOPs. That work is yet to come.

Mr. Mullin. And I will say your sincerity comes through, through body language and tone. So, I really appreciate that.

Mr. Burgess. The gentleman yields back. The Chair thanks the gentleman for his questions.

The Chair recognizes the gentlelady from California. Five minutes for questions, please.

Ms. Matsui. Thank you, Mr. Chairman, and thank you for holding this hearing today.

And thank you, Dr. Shuren, for being here also.

This is the last of three hearings on the User Fee Agreements negotiated between FDA and industry. I am glad that all parties are satisfied with the outcomes, and I think we have all worked together to ensure that FDA has the resources it needs to continue making sure that drugs and devices are safe and effective for America's consumers.

I am particularly pleased with provisions in the User Fee Agreements that will benefit the rare disease patient community. In MDUFA, this includes increased patient engagement. This is perhaps more tangible with medical devices because the size and

convenience of a medical device directly impacts patients' quality of life, even if it doesn't necessarily affect a device's effectiveness. Similarly, I think the additional real-world experience evidence and data will help incorporate the patient experience in a quantifiable way.

Dr. Shuren, can you talk about how additional patient engagement, as well as real-world evidence through the NEST program, will help advance devices for patients with rare diseases?

Dr. Shuren. Well, first, I fully agree with you that those two pieces will be important for rare diseases. You know, one of the challenges is gathering information and evidence to support that that device, in fact, meets the standard for a rare disease coming on the market. And it can be very hard to get the patients enrolled and in studies. But, if we are able to leverage data that may be part of their routine care, then we can maybe get that evidence and help bring those products to market and to do so in less time and lower cost.

And by the same token, too, we should be measuring the things that really matter most to patients. When we decide is the evidence sufficient, because there is always going to be uncertainty in the evidence on benefit and risk, then for patients and often with rare conditions, they are willing to accept more uncertainty for treatment. And so, we need to be willing to

accept that uncertainty, too. I think that will help.

The last plug I will put in is I think 21st Century Cures is going to help patients with rare disorders as well, broadening the definition of what constitutes a rare disorder for purposes in medical devices. So, again, thank you to the subcommittee for that.

Ms. Matsui. Thank you very much.

Many patients use medical devices every day, everything from surgical plants like knee replacements or pacemaker to wound care technology, to lab and diagnostic equipment. In recent years, we have seen some headlines about equipment that ends up contaminated or defective. This is generally a post-market problem, meaning that the devices themselves are safe and effective, but that something happens at the facility or a hospital that compromises that.

While I understand that MDUFA is meant to address only pre-market issues, I think that post-market review is an important part of what FDA does to keep us safe. In fact, it is a good reason to keep funding FDA using appropriated dollars and not just user fees.

Dr. Shuren, I would like to ask about the NEST program and how the incorporation of post-market clinical data, such as patient registries, may help ensure that devices are safe and effective throughout their life cycle.

Dr. Shuren. Well, while in the MDUFA agreement, the commitment letter, we talk about pilots that are primarily pre-market, that is because, for purposes of the user fee reauthorization, we have to stay within the confines of the scope of MDUFA. However, NEST is operated by the independent Coordinating Center, and they can and are planning to also look more broadly in terms of leveraging for post-market safety. And it can address two of the challenges we have today.

First off, for post-approval studies, we know that patients, once a device has been approved, lack incentives to enroll in clinical trials. So, clinical trials, often they may not get conducted; they may not get finished. In fact, we are making phone calls now on some of our 522 studies to encourage people, hospitals and practitioners, to enroll patients. But, if that data is being collected like in a registry, as we are finding today, then we get that data and we get it in a more timely manner. That is great for the company. It is great for patients. It is great for us.

The other is today, for safety problems, we often rely on adverse event reports. That means somebody had to identify that a problem occurred and may be associated with a device and take the time to report it. And there are a lot of things. You may get information that is not right.

Now, when we move toward larger datasets that will allow us

to use software tools to try to look for are there particular problems and, then, do a deeper dive on it, that ultimately enhances patient safety and reduces liability for companies. That is a win all around.

Ms. Matsui. Well, thank you, Dr. Shuren.

And I yield back.

Mr. Burgess. The Chair thanks the gentlelady. The gentlelady yields back.

The Chair recognizes the gentleman from Georgia, Mr. Carter. Five minutes for questions, please.

Mr. Carter. Thank you, Mr. Chairman.

And thank you, Dr. Shuren, for being here. We appreciate it.

I am from the state of Georgia. We have got quite a few medical device companies in our state, as well as the CDC. So, I appreciated your comments earlier about the relationship with the CDC and how you work closely with them. That is very important, and we are very proud of the work that they do for our country, located right there in the state of Georgia.

I want to ask some basic questions. Okay? I am not going to go by my notes that my staff provided me. They do such an outstanding job. But I just want to ask you something.

I am new to the committee. As I understand this process, it is somewhat of a process that is just kind of a speeding-up

process, if you will, that manufacturers, the medical device companies, agree to pay if they can help to get the process sped up. Am I correct in saying that?

Dr. Shuren. That has been a main focus without jeopardizing the quality of --

Mr. Carter. And that is what I want to ask you. I want to ask you -- and I want your true opinion here -- have there been instances where you have looked back and you have said, "Gee, I wish we would have slowed down some. I wish we would have done something else."?

First of all, have there been any recalls of devices that were approved that, through this process, through the MDUFA process, have there been any recalls?

Dr. Shuren. Yes.

Mr. Carter. Okay. In those instances, have you asked yourself, you know, had we slowed down some, would this have happened?

Dr. Shuren. I don't believe so. That has not come up. And again, the way the goals are designed, it is also it is not 100 percent. So, we know, too, if we need to take additional time to make a decision, then we will do it in the individual case. I think, if anything, if there isn't enough time, the pressure is, then, we are going to say no if there are issues. But the way they are designed is that it gives us flexibility that a

percentage may go a little bit beyond the timeframes. And so, if we do need to take additional time, we will take the additional time.

Mr. Carter. Okay. Well, in those cases where there was a recall, I am sure you went back -- I would hope you did -- and reviewed what you did and said, could we have done anything differently to have prevented this?

Dr. Shuren. So, we do take a look, what was the cause for the recall? Was it something that maybe we should have picked up when we were doing review? Most of the things are a lot of times issues that either come up after the product is on the market. Or anytime you review a product and you have the evidence, you don't have 100 percent certainty on the true benefit/risk profile of that technology. You would have to study it so in-depthly, you would never get a single product out there on the market.

And sometimes, with more use, you find out there may have been some issue in the design that could affect performance, and we need to deal with it post-market.

Mr. Carter. Okay. Let me shift gears here for just a second. The President has made it clear that he wants to cut down on regulations. Earlier you heard someone say his Executive Order; you are aware of it. You know, for every new regulation that you pass, you have got to cut two.

If, indeed, this President is cutting back, and if, indeed, as I hope we do cut back on a lot of regulations, isn't that going to cut back, if you don't have to follow as many regulations, are you going to have to have as many people? Are you going to have to have as much of a staff? I mean, should we reauthorize this for five years in anticipation of you having the staffing levels that you have right now for the next five years?

Dr. Shuren. So, our workload, first of all, continues to go up. We have seen that. One of the most popular programs is our pre-submission meetings. That has been going up, like requests, by about 10 percent a year. And we are seeing more of the innovative medical device submissions come in the door.

Part of MDUFA IV is a recognition that the program needs additional funding just to keep pace with the work we currently have, as well as strategic investments in programs like patient engagement and real-world evidence that can help enhance and speed access to safe and effective devices.

Mr. Carter. Okay. One last question. I am a pharmacist, currently the only pharmacists serving in Congress. A lot of the clinical tests that we sell in the drugstores, they are very important to me to make sure that what I am selling to a patient is actually legitimate. And I know this is, from what I understand -- and again, I am new member of the committee -- but, from what I understand, this has been somewhat of a debate within

the FDA about what role they should play in approving some of these.

I will tell my age here. There was a time when I sold Drano in my pharmacy and it wasn't to unclog drains. For those of you who don't know, before we had gender tests, that is the way a lot of people tested to see if they were having a boy or a girl. That is folklore.

So, I guess my question is, I know that is a big, big discussion about the FDA's role in approving some of these. And I didn't know if you had an opinion on that or not.

Dr. Shuren. So, our perspective has been that tests, regardless of what is out there, you want tests that are simply accurate, reliable, and clinically-meaningful. And that is just good for our patients. It is good for healthcare practitioners.

Mr. Carter. Are all of them coming through you? Are you approving all of them? I mean, we had the situation with Walgreens and fairness and some of the tests that were being sold there.

Dr. Shuren. No, they don't all come through us.

Mr. Carter. Do you think they should?

Dr. Shuren. Well, I think that issue is one that we know is of great interest to many Congressional Members, to stakeholders, and it is a topic that we will talk about with our colleagues at HHS. We haven't had that conversation yet. So,

I am just not in a position now to talk about it.

Mr. Carter. Right. Well, I appreciate it very much.

Thank you, Mr. Chairman. I appreciate your indulgence.

Mr. Burgess. The gentleman yields back. The gentleman's time has expired.

The Chair recognizes the ranking member of the full committee, Mr. Pallone of New Jersey. Five minutes for questions.

Mr. Pallone. Thank you, Mr. Chairman.

Dr. Shuren, let me ask -- and I think I said some of this before -- but the Medical Device User Fee Amendments, or MDUFA, was first established in 2002. Prior to that, the medical device program was suffering from long-term loss of resources, lag in medical device review timetables, out-of-date guidance, and a lack of expertise among FDA personnel. And MDUFA has been a success in addressing these issues, reducing the average total time to a decision on a pre-market approval in 2015 by 35 percent over six years, and for a 510(k) in 2015 by 11 percent over five years. And I understand that in 2016 FDA approved 91 novel devices, the highest since the creation of MDUFA.

As you know, the statute outlines a detailed process for reauthorization that requires FDA to not only negotiate with industry to develop recommendations, but also to solicit public input, hold public meetings, consult periodically with Congress

and patient and consumer groups, among others. The recommendations that are the result of this process must also be available publicly for a period of public comment and, ultimately, are required by statute to be transmitted to Congress.

So, can you discuss further the process FDA undertakes to prepare recommendations for reauthorization of the User Fee Agreements and, in particular, the timeline for these activities?

Dr. Shuren. We will quick establish a team, an interagency team. We have senior leadership for the agency that provides strategic direction and advice. We engage in discussions with the device industry. Usually, start-to-finish, when we first sit down to when a package comes to Congress is about 18 months. Along the way, we have a public meeting in the beginning; at the end, opportunity for public comment on the proposed package. And we also have monthly meetings with patient and consumer groups. So, a very interactive, thoughtful process.

Mr. Pallone. I thank you.

So, you mentioned that if we do not reauthorize MDUFA by September 30th, CDRH would lose about one-third of its personnel. Can you discuss further the types of positions and personnel that would be subject to RIF notices?

Dr. Shuren. Physicians, nurses, engineers, a whole variety of scientists from, you know, biologists, physicists, chemists. It will run the gamut.

Mr. Pallone. Okay. Now the User Fee Agreements between FDA and industry are the end result of many months of negotiations which are submitted to Congress after careful consideration of public comments and consultation with patients and consumers. And there are very real implications in terms of patient access to treatments and the personnel at FDA if Congress doesn't authorize this program before it expires on September 30th. And I am committed to working with my colleagues across the aisle and across the Capitol to ensure that we meet this deadline.

But I wanted to ask you, also, Dr. Shuren -- and I know we are running out of time -- FDA has increasingly focused on shifting data from the pre- to post-market setting for devices to facilitate innovation. However, central to this approach is an assurance that FDA and manufacturers will have the data they need to detect safety problems that are harming patients. FDA envisioned the creation of the National Evaluation System for health Technologies, or NEST, to help collect the information using electronic health records, registries, and claims data. There is already considerable progress and momentum in adding unique device identifiers to EHRs, and there are now positive steps in adding unique device identifiers to health insurance claims data.

So, speaking specifically to adding unique device identifiers in health insurance claims, what are the benefits

unique to the incorporation of device identifiers to claims data from which FDA researchers and others can benefit?

Dr. Shuren. Well, one of the challenges with some of the other data sources like registries is they collect data on a patient for a short period of time. Claims data would allow us to have more long-term information on that patient, what is happening to them with the medical device. In some respects, linking up the claims data with other data sources, then, becomes a rich bod of evidence to use.

Mr. Pallone. Okay. I actually didn't run out of time. Thank you, Mr. Chairman.

Thank you, Dr. Shuren.

Mr. Burgess. The Chair thanks the gentleman. The gentleman yields back.

The Chair recognizes the gentleman from Florida, Mr. Bilirakis. Five minutes for questions, please.

Mr. Bilirakis. Thank you, Mr. Chairman. I appreciate it very much.

Dr. Shuren, in the 21st Century Cures Act, we were able to pass reform language to modernize the Office of Combination Products. As you know, combination products are products on the market that have elements of a medical device and a drug, like inhalers or insulin injectors. Many patients need and rely on combination products.

While we worked on the 21st Century Cures, I asked FDA about the innovation in the drug and device space, as more and more innovative products may be combination products. At the time, there were complaints from innovators about the slow and burdensome FDA process for approving combination products. At a hearing, you stated that this problem with combination products was a place that does require probably further discussion, and whether or not there are changes to be thought about it to make that intersection work better than it currently does.

I was able to have language in the 21st Century Cures, again, to address some of these problems with combination products. Can you update us on what the FDA is doing on the device side to implement the Cures language for combination products and what was agreed to in the Medical Device User Fee Agreement?

Dr. Shuren. So, first off, let me say thank you for that provision, and I think it will be important, helpful in the work that we do on combination products, which we agree increasingly are becoming more and more important in our health care.

So, we are working. The agency has an interagency group, first off, coordinated on implementation. We are a part of that group, and we will be engaged in the various pieces that have to be implemented for combination products.

We have also, prior to that, set up a Combination Product Policy Council that already started to make improvements in how

we handle combination products. For starters, we have had a pilot underway that will be a full-fledged program very soon on streamlining consults between the involved centers, so that we are better working together, let's say us and our Center for Drugs and our Center for the Biologics. So, again, getting the right expertise in a timely manner to facilitate those reviews of combination products.

Mr. Bilirakis. Very good. Thank you.

This question is a little bit outside the full scope of FDA. But what are the challenges that patients wrestle with for the coverage of FDA-approved medical devices? I have had conversations with doctors and patients who wanted to get an FDA-approved medical device, but CMS hasn't approved that device for coverage.

CMS lack of coverage for PET scans, for example, for Alzheimer's diagnosis is, again, one example of backwards-thinking from Medicare. There are a number of FDA-approved medical devices that CMS has been slow to cover.

I know that FDA was working with CMS on these types of payer issues with the Parallel Review Program. Can you update us on where things stand with your work with CMS and other payers? Do we see a reduction in devices getting covered? Do you have any metrics or data on how things have changed or improved?

Dr. Shuren. Well, this is an area we have devoted a lot of

time and attention to because true patient access isn't just a technology on the market. Particularly for our more expensive technologies, if there isn't adequate reimbursement, then patients don't have real access to it.

That said, CMS and payers operate under a different standard that is appropriate for payers versus a regulator like us. So, we have been working with CMS and others, how do you streamline that pathway to market, and from market to coverage reimbursement?

You mentioned Parallel Review, and that started as simply a process change, so that CMS could start engaging on a national coverage decision before we had approved the product. What we have now made available is, for interested companies, and on a voluntary basis, and if CMS and we agree, they can come and talk to us before they have done their big pivotal clinical trial, so that they can design their evidence generation to meet the needs, the standards for FDA and the standard for CMS. And we have had some interest, and one product, in particular, went through that and probably saved two years for their time to ultimately get reimbursement.

We have been working with CMS also about can we better leverage real-world evidence. This case of transcatheter aortic heart valve replacement, when we first approved it, we worked with two healthcare professional societies on setting up a registry and with CMS. So, when we approved that device, Medicare covered

it under a coverage with evidence development decision. And now, every time we approve a new indication, it is automatically covered by Medicare, which is different than many other countries.

The other thing we have done is set up a similar opportunity with private payers. Again, if a company would like to do it and the payer would like to do it, we are happy to have a meeting and share what our respective needs may be.

Mr. Bilirakis. Very good. Thank you, Doctor.

I yield back. Thank you, Mr. Chairman.

Mr. Burgess. The Chair thanks the gentleman. The gentleman yields back.

The Chair recognizes the gentlelady from Illinois, Ms. Schakowsky. Five minutes for questions, please.

Ms. Schakowsky. Thank you, Mr. Chairman.

I want to thank you, Dr. Shuren, for being with us today.

Over the past few months, I have become increasingly concerned with the safety of two defibrillators manufactured by St. Jude Medical, which was recently acquired by Abbott. This issue first came to my attention when a staff member of mine was forced to undergo surgery to have her St. Jude defibrillator replaced because her device was no longer working properly. This is a young woman who has a congenital heart condition.

Last October, FDA released a safety communication regarding battery depletion for two of St. Jude's devices. At the time,

two patients had died as a result of this faulty device and another 47 had reported dizziness or fainting. The rapid draining of a battery can happen in a matter of days, leaving patients with little time to rectify this issue before facing possibly grave consequences.

Then, in January, FDA released another communication detailing a possible cybersecurity threat for these same devices manufactured by St. Jude's Medical. Given the severity of these issues, I am very concerned for patients with these devices.

In addition, I am appalled that patients are left to figure out how to pay for the required surgery to replace the device, despite finding themselves in that circumstance through no fault of their own.

Finally, it is concerning that in some cases patients will learn about the problems with their device in the news before hearing about it from their doctor.

So, Dr. Shuren, how are patients notified when there are problems with their device, and how does the FDA ensure that patients are given this information in a timely way? And if the safety communication is given to doctors, how do you ensure that doctors are communicating that information to patients?

Dr. Shuren. First of all, let me say that I am sorry to hear about what happened with your staffer.

In terms of communications, while we can't compel physicians

to tell their patients, what we do is we put out information like with the safety communication, put it up on our website, but, then, we push it out to other organizations who push information or where healthcare professionals and patients get their information. Also, one of the reasons you will see it in newspapers is because patients get their information from the news. So, we push it out to those news services as a way of getting into patients, since, otherwise, it is hard for us to reach into people's homes to get it there.

And then, we try to provide the best information possible for both patients and healthcare professionals to make the best informed decisions that is right for their particular care.

Ms. Schakowsky. Let me ask you -- I have a few more questions -- how is the FDA notified of these problems in the first place? Do you rely on the device manufacturer to report any issues?

Dr. Shuren. So, sometimes we hear from the device manufacturer. We get adverse event reports. We get complaints. We can go in the door, conduct an inspection. We may identify problems. There is a lot of tools that we have.

Ms. Schakowsky. Are they required, though, however, the manufacturers, are they required, if they discover a problem, to report it?

Dr. Shuren. If they discover a problem of that kind of a serious nature, then, yes, they would be contacted.

Ms. Schakowsky. And did St. Jude's?

Dr. Shuren. We did have conversations with St. Jude and we have been working with St. Jude on the steps to take to address those two particular issues.

Ms. Schakowsky. How does the FDA plan to improve their post-market surveillance system, to improve notification of problems with medical devices, and to better track cases of patients who have been impacted by faulty devices?

Dr. Shuren. Yes. So, first off, in terms of better communication out, there are certain tools -- there is a limitation of the tools that we may have, but our healthcare system may start driving that more and more. I have seen increasingly patients having access, if you will, to their own record and healthcare professionals communicating directly to them. Even my wife just had that instant messaging between her and her treating physician.

In terms of how we have a better sense of patients who are affected, NEST is one of those areas that can help how we are better able to leverage data that is out there that is being collected on patients. Including a unique device identifier in like electronic health records will make it easier for us to link the specific device that is being used that may be subject to a recall, let's say, with the patients who get them.

But, that said, it is absolutely critical --

Ms. Schakowsky. Let me ask about a recall. So, if a device manufacturer continues to manufacture defective devices or has an ongoing recall or safety notification, what tools or authority does FDA have available to ensure patient safety?

Dr. Shuren. So, we have a variety of enforcement tools. The first thing we will do with the company is will they work with us to resolve the problem. So, in a recall, most of them are voluntary because, if we contact the company and they work with us, we can address that problem much more quickly than if we went with an FDA-mandated recall, which is going to take a lot more time.

If a company is not working with us, then we may move to a variety of steps. There may be a warning letter if products shouldn't be on the market. We may have an injunction. We may have a seizure. If there are issues more broadly with the company, we may put them under a consent decree.

Ms. Schakowsky. Thank you. I yield back.

Mr. Burgess. The Chair thanks the gentlelady. The gentlelady yields back.

The Chair recognizes the gentleman from Missouri, Mr. Long, for 5 minutes for your questions, please.

Mr. Long. Thank you, Mr. Chairman.

And, Dr. Shuren, there are a number of commitments in this agreement that complement provisions in the 21st Century Cures.

Can you highlight a few of these provisions and speak to whether FDA would be able to implement them if Congress did not reauthorize this User Fee Agreement by September?

Dr. Shuren. So, there are several provisions in there on patient engagement in MDUFA IV and real-world evidence. While the complementary provisions in 21st Century Cures do not apply to devices -- they are focused on drugs -- we consider them important and they dovetail with what Congress would like to see more generally.

I think as well the provisions on clinical trials and their moving from local IRB to a central IRB is going to help speed the conduct of clinical trials that are going to support coming through market and review under the User Fee Program. I think some of the clarity around valid scientific evidence also is related to the work that we do under the User Fee Program. The same for combination products because those two are subject to the User Fee Program. So, I see lots of synergy between 21st Century Cures and MDUFA IV.

In terms of what happens if we are not able to reauthorize MDUFA IV, then we are going to lose a third of our staff immediately. We will see more that leave afterwards, and we will not be able to make good on not only our current MDUFA commitments, which would all sunset, but just running the program to do anything is going to be challenging.

Mr. Long. Several consumer groups have raised concerns that the use of real-world evidence could ultimately result in FDA approving products based on insufficient clinical data. Can you please address those concerns?

Dr. Shuren. No, I don't think either MDUFA IV or anything else that has come on the table is going to adversely impact the data that we are able to rely on to make informed decisions. So, for example, real-world evidence, part of this is looking at the pilots not only for setting up the program and looking at return on investment, but nothing says that we have to accept a particular data source.

Mr. Long. Okay.

Dr. Shuren. That evidence still has to be relevant to the question. It has got to be sufficiently reliable for us to make a decision. So, this doesn't change any of the standards on which we make decisions. It doesn't change what we will expect to have adequate evidence to make a decision.

Mr. Long. Okay. Thank you for being here and thank you for your testimony today.

Mr. Chairman, I yield back.

Mr. Burgess. The gentleman yields back. The Chair thanks the gentleman.

Just a note. We will be going immediately to the second panel after the conclusion of Dr. Shuren's questions.

Now I would like to recognize the gentleman from New Jersey. Five minutes for questions, please.

Mr. Lance. Thank you very much, Mr. Chairman.

Good morning to you, Dr. Shuren.

I understand that in the most recent MDUFA Quarterly Report FDA's total time metrics to review pre-market approval devices is rising. This is not the direction any of us wish to see things go. Do you know what is behind the increase and what sort of tools are included in the new MDUFA agreement that might help prevent these sorts of total time increases in the future?

Dr. Shuren. Yes, we have seen a small uptick, but we are in the process of looking into it. We are looking into a variety of factors. One I had mentioned is the increased workload we saw in MDUFA III, particularly, for example, submissions from some of the most innovative technologies.

So, on the one hand, we are seeing more innovative technology come to the U.S. That is a good sign. It also means the workload goes up with it, and that might be one of the contributors. But we will have a better sense in the coming weeks.

I think MDUFA IV is going to help in terms of providing more resources for the people that we need for doing the work, to enhance some of our IT systems, to establish a quality management system which also can drive greater efficiencies, and other steps that I think will drive greater consistency as well in our work.

And all of that will help us have a better-running program.

Mr. Lance. Thank you very much, Doctor.

I have heard from many device companies that the pre-submission process has been a positive addition. It was established in the previous MDUFA agreement, and that it helps improve consistency and predictability in the device review process.

Doctor, would you please explain what the pre-submission process is and how the next MDUFA agreement will improve upon it?

Dr. Shuren. So, pre-submission process is an opportunity for a company to request to meet with the agency to have specific questions answered. You know, traditionally, a lot of times this is around what evidence do they need to bring a product to market.

What MDUFA IV will do is it puts in performance goals for the timing of those meetings. It would have us commit to provide answers to the questions that are being asked at least five days before the meeting. And then, a company may be, "You know what? We don't even need to meet." Or we can meet, but we will have a better-informed discussion because we already got feedback from the Center.

Mr. Lance. Thank you very much, Dr. Shuren.

And, Mr. Chairman, I yield back 2 minutes 34 seconds.

Mr. Burgess. The Chair thanks the gentleman for his generosity. The gentleman yields back.

Dr. Shuren, this was not a plant, I guess, but on Gene Green's desk was a printout of the Houston Chronicle from I guess this morning, today's Houston Chronicle. And you were asked the question about what is on the horizon, and you mentioned robotics; you mentioned minimally-invasive surgery. So, you are on the front page of the Houston Chronicle, where, after all, heart surgery was invented, right, Mr. Green? Well, maybe not, but maybe a little bit of poetic license. I went to medical school in Houston, so I have got a lot of affection for the city.

But there is an article on the front page about doing just what you talked about, replacing an aortic valve through a tiny, little incision in the chest, and sparing that patient what used to be a much more major operation just to expose the operative field in order to replace the valve. So, it is really a game-changer, really groundbreaking, and we have been part of it this morning, for which we are all extremely fortunate.

Mr. Green. Mr. Chairman, since you mentioned that, you know, Dr. DeBakey and Dr. Cooley, who have since passed away, but they set -- for heart surgery, it is just amazing in the Texas Medical Center, one at Baylor College of Medicine, another one at University of Texas, the Health Science Center there.

So, thank you. Thank you for that plug.

Mr. Burgess. Again, Dr. Shuren, seeing no other members wishing to ask questions, we are going to conclude this portion

of the hearing. As we transition to our second panel of witnesses, Dr. Shuren, especially we want to thank you for spending so much time with us this morning, for being willing to come back to our committee, our subcommittee, and give us the current update on the Medical Device User Fee Agreements.

Again, I would just stress that we all look forward to having that accomplished, and I realize there may be people who talk about improvements along the way. We welcome that discussion. But, make no mistake about it, we are going to get our work done, and we will have it done in a timely fashion.

So, thank you much, Dr. Shuren, for your time this morning.

And we will go immediately to our second panel who I will introduce in just a moment.

Dr. Shuren, you are excused. Thank you.

And again, as we transition to our second panel, I want to thank our second panel of witnesses for being here with us today and taking time to testify to the subcommittee on this important topic.

As a reminder, each witness will have the opportunity to give an opening statement, followed by questions from members.

Our second panel of witnesses today include Ms. Cynthia Bens, vice president of public policy for the Alliance for Aging Research; Mr. Robert Kieval, founder and chief development officer at CVRx; Mr. Patrick Daly, president and CEO of Cohera

Medical, and Ms. Diane Wurzburger, executive, Regulatory Affairs, U.S.-Canada Global Strategy, Policy, and Programs at GE Healthcare.

We appreciate all of you being here with us today. We thank you for your forbearance during the first panel.

And we will begin this panel with you, Ms. Bens, and you are recognized for five minutes for an opening statement, please.

STATEMENTS OF CYNTHIA A. BENS, VICE PRESIDENT OF PUBLIC POLICY, ALLIANCE FOR AGING RESEARCH; ROBERT KIEVAL, FOUNDER AND CHIEF DEVELOPMENT OFFICER, CVRx, PATRICK DALY, PRESIDENT AND CEO, COHERA MEDICAL; AND DIANE WURZBURGER, EXECUTIVE, REGULATORY AFFAIRS U.S. AND CANADA, GLOBAL STRATEGIC POLICY AND PROGRAMS, GE HEALTHCARE

STATEMENT OF CYNTHIA A. BENS

Ms. Bens. Mr. Chairman, Ranking Member Green, and Members of the Subcommittee, it is an honor to speak to you today about the reauthorization of the Medical Device User Fee Program on behalf of the Alliance for Aging Research.

The Alliance is the leading nonprofit organization dedicated to accelerating the pace of scientific discoveries and their application to improve the experience of aging and health.

Right now, approximately 10 percent of the U.S. population is age 80 or older. This 80-plus age group will triple by 2050. Many older adults are fortunate to experience better health as they age than the previous generation. But the truth is that most older adults still face significant periods of disability and illness later on life.

The develop one or more forms of cardiovascular disease, cancer, diabetes, bone and joint degeneration, muscle wasting, vision and hearing loss, neurological diseases, and incontinence.

In our view, the need for innovative medical devices that help diagnose and better respond to the physical declines people face as they age have never been greater.

And we believe we will only realize the benefits of these medical technologies if the FDA has access to the resources and expertise necessary to evaluate them, the medical device industry is certain that their products are going to be assessed in a timely manner, and, most importantly, that patients are at the center of new product development.

Thanks to you and your colleagues in Congress, the Alliance and other groups were represented throughout the patient/consumer/stakeholder consultation phase leading up to the third reauthorization of MDUFA. We had two goals for MDUFA III, and we are pleased to report that both were achieved.

The first was to make sure that CDRH had sufficient resources to conduct timely reviews, and the second was to secure support for a process through which CDRH would include patient fees on the benefits and risks of devices during their product reviews.

MDUFA III allowed for the application of user fees to higher additional reviewers, reduce the ratio of reviewers to managers, and continue the FDA's third-party review program.

CDRH engaged with the patient advocacy community to best characterize disease severity and unmet need. And this led to the benefit/risk guidance that we heard a lot about this morning

that broadly defines the benefits CDRH is interested in understanding and started the process for incorporating these views into product reviews.

Recognizing that there were many process improvements instituted through MDUFA III, we sought further support for CDRH's workforce, expansion of the patient-centered device development, and the utilization of real-world evidence in MDUFA IV.

MDUFA IV contains critical commitments and funding for the FDA that will benefit patients. We are pleased that the reauthorization of the User Fee Agreements is a priority for this committee.

MDUFA IV will lead to significant reductions in the time it takes the FDA to review the most common types of medical device applications, and that is not only going to benefit industry; it is going to accelerate patient access.

Having expert FDA staff to carry out user-fee-funded activities is paramount, and the MDUFA IV agreement permits CDRH to apply user fees to increase the retention of high-performing supervisors, reduce the ratio of review staff to supervisors, and hire new medical device application reviewers, as well as to recruit additional HR support services, which is something that we were all encouraged by in 21st Century Cures.

The MDUFA IV agreement seeks to bolster and ensure the integrity of the third-party review program, and we are glad that

CDRH continues to have the resources and flexibility to employ outside experts as needed under MDUFA IV.

CDRH will further advance patient involvement in the regulatory process. They will expand staff capacity to respond to device submissions containing validated patient preference information and patient-reported outcomes.

CDRH will hold public meetings to discuss approaches for incorporating this type of information into device submissions, as well as other methods for advancing patient engagement.

CDRH will explore ways to use patient input to inform clinical study design and reduce barriers to patient participation in clinical trials.

MDUFA IV will elevate CDRH's ability to further real-world evidence generation for the purposes of informing regulatory activities.

The collection of data generated through routine clinical care can help broaden our understanding of how products are working, support the incremental process of medical product development, and optimize care.

CDRH can utilize MDUFA IV fees to hire staff with expertise in the utilization of real-world evidence and further establish the Coordinating Center for the National Evaluation System for health Technology. NEST will link health claims, electronic records, and registry data.

MDUFA IV funds, the NEST Coordinating Committee, they are going to be able to establish a patient-incorporated pilot program to explore the usability of real-world evidence for determining expanded access as well as new device approvals, and better understand how devices are malfunctioning.

The NEST public program is particularly meaningful for our organization since older adults are not adequately represented in clinical studies. The MDUFA IV agreement actually specifies that industry will have 25-percent representation on the NEST Governing Board, and we hope that the enacting legislation will further specify the remaining 75 percent of the Governing Board composition and give particular attention to patient populations most likely to be affected by increased utilization of real-world evidence.

The MDUFA IV agreements will increase efficiency of the regulatory process, reduce the time it takes to bring safe and effective medical devices to market, and put patients at the heart of medical product developments.

So, I am going to close by offering our support for the continuation of the MDUFA program.

Thank you for the opportunity to present our views today.

[The prepared statement of Cynthia A. Bens follows:]

**********INSERT 2**********

Mr. Burgess. And we thank you for your testimony.

Mr. Kieval, you are recognized for 5 minutes. Summarize your opening statement, please.

STATEMENT OF ROBERT KIEVAL

Mr. Kieval. Thank you, Mr. Chairman Burgess, Ranking Member Green, and Members of the Subcommittee, for this opportunity to testify today.

My name is Robert Kieval, and I am the founder of CVRx, a small company that provides implantable medical technologies to treat patients suffering from heart failure and problematic high blood pressure. These are among the most prevalent debilitating and expensive diseases for our healthcare system to manage, and our therapy which is available today in Europe -- and, hopefully, will be soon here in the U.S. -- stands both to improve patients' lives and significantly reduce the staggering costs associated with their care.

I have also been asked to testify here today on behalf of the Medical Device Manufacturers Association, founded in 1992 to be a voice of the innovative and entrepreneurial sector of our industry. CVRx is also a proud member of AdvaMed, whom my colleague Mr. Daly is testifying for today.

Ninety-eight percent of medtech companies have fewer than 500 employees, while more than 80 percent have less than 50. Yet, we are the major source of innovation and America's competitive advantage in medical technology. Together, we comprise a diverse group of engineers, physicians, and entrepreneurs who dedicate

our lives to alleviating human suffering and improving patient care.

My personal journey with CVRx is now in its 16th year. As a small company with one product and no other revenue streams, CVRx, like many others in our position, is dependent on outside investment to be able to continue our work. To garner financing, our investors need assurance that the regulatory process be reasonable and consistent. Our capital is limited and precious, and regulatory delays can have devastating consequences for our company and for the patients who we are working to serve.

Over the past five years under MDUFA III, the FDA Safety and Innovation Act, and FDA's commitment to those reforms, the regulatory process has become more reasonable, consistent, and transparent. With the additional resources provided in MDUFA IV and, if implemented correctly, we believe that this proposed agreement can help further improve access for American citizens to safe and effective new medical technologies.

While speed is always important when lives hang in the balance, our membership overwhelmingly endorsed prioritizing quality, predictability, and transparency in our negotiations. MDUFA IV includes important updates and new elements to strengthen and balance the regulatory environment. Here are a few highlights:

There are new provisions to include consideration of

patient's perspectives in the design of clinical trials, which will help tie product evaluation to outcomes that are important to patients.

A pilot to establish the value of real-world evidence and linkages among data sources to enable greater use of this information, to accelerate patient access in a pre-market setting.

To help keep the review process focused, reviewers would now be asked to cite the specific justification and applicable regulation for any deficiency letter or data requests that they issue. This will ensure that queries are meaningful and that time spent by both parties to resolve them is productive.

A new quality management program will help FDA remain efficient as it continues to grow and evolve. The quality team will monitor and report on performance across the various branches of the agency and help ensure that deficiencies and inefficiencies are identified and addressed. This will provide more transparency within the FDA and help ensure that our new heart failure therapy receives the same quality of review in the Cardiovascular Division that a new incontinence treatment would in the Urology Division.

Finally, the agreement establishes new performance goals aimed at placing new technologies into the hands of patients and providers within a reasonable period of time. These include

updated decision time targets for 510(k)s and PMAs and now also review time goals for de novo technologies and pre-submissions.

We believe that MDUFA IV can strengthen and provide increased confidence in the regulatory process. We also acknowledge that it is incumbent upon our industry to ensure that our work and our submissions are also of the highest quality.

We thank FDA for these productive negotiations, and we look forward to continuing to work with them and with you to maintain a regulatory environment that rewards innovation while ensuring patient care.

Surely our healthcare system will continue to face pressing challenges in the 21st century. Patients and providers will continue to seek therapies that alleviate suffering and save lives. My colleagues and I remain committed to finding the solutions they need and to working with our fellow stakeholders in the healthcare ecosystem to deliver these as quickly and efficiently as possible.

Thank you very much.

[The prepared statement of Robert Kieval follows:]

**********INSERT 3**********

Mr. Burgess. The Chair thanks the gentleman for his testimony.

Mr. Daly, you are recognized for 5 minutes to summarize your opening statement, please.

STATEMENT OF PATRICK DALY

Mr. Daly. Thank you, Chairman Burgess and Ranking Member Green, and Members of the Committee, for the opportunity to testify today.

My name is Patrick Daly, and I am the president and CEO of Cohera Medical. Cohera Medical is a rapidly-growing, North-Carolina-based medical device company with 36 full-time employees and over 18 contract employees. Cohera Medical develops surgical adhesives and sealants, including the first synthetic adhesive approved for internal use.

I am pleased to testify today on the Medical Device User Fee Agreement on behalf of AdvaMed. Collectively, the medical device industry is committed to ensuring patient access to lifesaving and life-enhancing devices and other advanced medical technologies. I am very optimistic about what this industry can do for patients if the right policies are in place.

I have been encouraged by the progress at FDA's Device Center in recent years, but the innovation ecosystem that supports our industry remains stressed. One key barometer of the health of our ecosystem is the level of investment in startup companies. Unfortunately, we have seen a sharp decline in the number of new medical device technology startup companies each year and decreased venture capital investment. The time horizon for

getting a new innovation from the bench to the bedside remains far too long. And as a result, investors are looking elsewhere.

Despite these concerning statistics, we believe we are on the right track at FDA's Device Center and that recent progress, combined with the provisions of this new User Fee Agreement, promise to keep things headed in the right direction and strengthen the medtech innovation ecosystem.

Of course, there are many areas where FDA could further enhance the predictability and efficacy of its review process, and the new MDUFA IV agreement lays out the groundwork for further FDA performance improvements through five key areas: more ambitious goals, greater patient involvement, important process changes, and increased accountability, all supported by additional resources. And I would like to quickly describe these five key areas.

First, MDUFA IV goals for total time reviewing product represent substantial improvements over current performances. Measuring the total time from submission to FDA decision to either make the technology available to the patients or deny approval is the most meaningful measure of progress.

For 510(k) products, the total time goal of MDUFA IV decreased by 13 percent, which returns the total time to historical norms. For PMA products, which are the most innovative and high-risk products, the total time to decision goal

was lowered by 25 percent.

Second, as we all know, patients have a critical voice in product development and evaluation. This MDUFA IV agreement will have increased resources dedicated to supporting patient involvement in the medical device regulatory process.

Third, the agreement includes process improvements that we anticipate will enhance the consistency and timeliness of the review process independent of the specific time goals. One example of a process improvement, that the agreement provides for meaningful pre-submission interaction between FDA and companies. Interactions between the sponsor of the medical device application and the FDA prior to formal submission of a product application can provide helpful guidance that aids the sponsor in ensuring their application contains all necessary information. This pre-submission process was first put into place five years ago in MDUFA III and has benefitted both industry and FDA. This MDUFA IV agreement builds upon this success by adding in specific time commitments tied to pre-submission meetings.

Fourth, the agreement provides for greater accountability. Greater accountability means that FDA's success under the agreement will be transparent to FDA management, to industry, to patients, and to Congress and the administration, so that any problems that arise can be corrected promptly. New reporting tools and two independent management reports will provide key data

to track FDA performance, highlight any failures to meet key goals, and provide the basis for corrective actions.

Lastly, to give FDA additional tools to meet these goals, the agreement provides additional funds for FDA. These resources will give FDA what it needs to continue to improve performance. Each of the provisions of this agreement has the potential to make a difference in continuing to improve FDA performance, but the whole is truly greater than some of its parts. Each of the elements of the agreement reinforces the other. And, of course, no agreement, no matter how good on paper, is self-executing. Making it work as intended will require the full efforts of FDA's dedicated staff and managers. Our industry is committed to work with FDA in any way we can to make it a success. Continued oversight and interest from Congress will also be important. Patients are depending on us.

Finally, I should note that we are appreciative of the efforts by all Members who seek to give the FDA the tools and structure it needs to succeed. Legislative reforms that do not alter the substance of the negotiated agreement between FDA and industry hold the potential to create a legislative reauthorization package that maximizes the opportunity for success at the agency.

I appreciate the committee's work in considering these and other important measures that enhance and complement the

underlying User Fee Agreement.

I want to thank the committee for their time today.

[The prepared statement of Patrick Daly follows:]

**********INSERT 4**********

Mr. Burgess. Thank you, Mr. Daly, for your testimony.

And now, I recognize Ms. Wurzburger for 5 minutes to summarize her written testimony.

STATEMENT OF DIANE WURZBURGER

Ms. Wurzburger. Chairman Burgess, Ranking Member Green, 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.

I am Diane Wurzburger, executive, Regulatory Affairs for GE Healthcare. I am here today to testify in support of the MDUFA IV agreement and on behalf of the Medical Imaging and Technology Alliance. I served as a MITA industry representative to the MDUFA IV negotiations with FDA.

MITA is the collective voice of medical imaging equipment and radiopharmaceutical manufacturers, innovators, and product developers. These technologies include MRI, x-ray, CT, ultrasound, nuclear imaging, radiopharmaceuticals, and imaging information systems.

Advancements in medical imaging are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. The industry is extremely important to American health care and noted for its continual drive for innovation, fast-as-possible product introduction cycles, complex technologies, and multifaceted supply chains. Individually and collectively, these attributes result in unique concerns as the industry strives towards the goal of providing

patients with the safest, most advanced medical imaging currently available.

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 Program in 2002 and its subsequent reauthorizations in 2007 and 2012. We participated in the MDUFA IV negotiations and believe that this agreement, if enacted, will improve FDA review of medical devices, assuring that American patients have timely access to safe and effective medical devices.

User fees provide for a more efficient pre-market clearance process, allowing for lifesaving devices to get to market more quickly. We believe that enhanced FDA funding provides stability and predictability to the device review process and to timeliness. Without a consistent and timely FDA review process conducted by a well-trained staff, access to new diagnostic imaging equipment is delayed and industry's ability to deliver technological advancements is compromised.

With this in mind, the medical imaging community has been consistent in its desire for more predictability, consistency, transparency, and timeliness throughout the device pre-market review process. MITA and its members believe that all MDUFA commitments should be backed by appropriate, measurable, and

predictable performance goals that support these principles.

We are particularly pleased to see performance metrics for reduction in total time to review for 510(k)s to 108 days. The MDUFA IV agreement will make key improvements to the device review program, providing the agency with resources necessary to expedite the pre-market process while maintaining FDA's standards for safety and effectiveness.

Similarly, we support the metrics for the pre-submission program. A pre-submission provides the opportunity for a manufacturer to obtain feedback prior to the submission of a device application. This program has brought value to industry and will continue to do so in a more predictable, consistent, and timely way with specific measurable metrics under the MDUFA IV agreement.

MITA fully supports the center-wide Quality Management Program. We believe that an effective quality management framework will support more consistent and predictable device review. The FDA will identify an annual audit plan and conduct those audits with an eye for sharing high-performing pre-market review processes between divisions in the agency. MITA believes that identifying good practices throughout the agency and sharing them will lead to improved efficiency and effectiveness.

Included in the MDUFA IV agreement is the establishment of an accreditation scheme for conformity assessment program. This

program allows for devices to be evaluated according to specific recognized standards by certified testing laboratories. FDA has agreed not to review full test reports from these laboratories except as part of a periodic audit. MITA is a strong proponent of the use of voluntary consensus standards and believes that the ASCA program will reduce time to decision and provide more predictability to the process.

Finally, MITA believes that a third-party independent assessment is critical to determine whether the investment in the pre-market review program is providing a more consistent, predictable, and timely decision by the FDA. We look forward to participating in the comprehensive assessment of this process for the review of device applications and think it is important to not only complete the evaluation that was started under MDUFA III, but to also begin evaluating the programs funded by MDUFA IV.

We believe that the MDUFA IV agreement will lead to an improvement in patient access to safe and effective medical devices. Most importantly, we are committed to ensuring the ultimate beneficiaries of these negotiations, the American public, benefit from continued improvements and timely access to the innovative devices and diagnostics necessary for the public health. MITA urges Congress to move quickly to reauthorize MDUFA IV.

Thank you for the opportunity to present our views today.

I am happy to answer any questions you have.

[The prepared statement of Diane Wurzburger follows:]

**********INSERT 5**********

Mr. Burgess. The gentlelady yields back, and the Chair thanks all of our witnesses for their testimony today.

And the Chair would note that Dr. Shuren has remained in the audience, and I certainly thank him for that.

As we move into the question-and-answer portion for our second panel, I want to recognize Dr. Bucshon of Indiana. Five minutes for questions.

Mr. Bucshon. Thank you, Mr. Chairman.

Mr. Daly, I know that the medical device industry is dominated by small companies. Indiana has over 300 medical device companies, including small companies all the way to some of the big-name companies that all of us know.

So, my question is, I understand the MDUFA agreement has some provisions in there that are directed toward smaller companies. Can you explain these provisions that are helpful to smaller companies?

Mr. Daly. Thank you very much.

I think the overall climate at FDA is helpful for small companies. Obviously, we do not have the staff that a larger company would. So, one example is what Dr. Shuren mentioned this morning, the pre-IDE meetings, having those communications prior to the meetings. Right now, we get those now five days in advance. It allows us to prepare. More importantly, it allows FDA to ask questions in a timely manner. I will give you an example.

Prior to this, when we were still in a slower stage, we had a personal example of we flew my team down here for a meeting that we got the questions the night before. I don't think it was as effective a meeting.

And I do want to compliment Dr. Shuren, Dr. Maisel, and his entire staff, for really putting a lot of effort into this over the last four or five years to make that a better process.

Mr. Bucshon. Thank you.

And just a general question of interest to me, to anyone. I will start with you, Ms. Wurzburger. A more, what I would call, streamlined and effective review process that cuts down on the time to get a product to the marketplace, what would you estimate is the potential savings to overall medical costs and to your ability to get products to the market? Because if you stretch out a process and it takes you longer, it costs you more money. I mean, do you have any thoughts, just general thoughts, on that and the importance of a process that works as expediently as possible?

Ms. Wurzburger. I believe an efficient process, a more predictable process allows a manufacturer to plan internally for their own quality system processes and those other testing requirements that are needed to prepare that submission effectively.

I would say that, just generally, with diagnostic imaging

and the technologies, as we are able to bring those to the market more efficiently and more timely, that there is an impact on the overall healthcare costs, I believe, on the system, as we are able to have innovations that will better diagnose patients and perhaps impact a patient's treatment plan more rapidly.

Mr. Bucshon. Yes, I think I will just comment on it. I was a cardiovascular and thoracic surgeon before I was in Congress. You can't underestimate the long-term savings of getting really innovative products to patients earlier, and some people have mentioned that. If it improves people's quality of life and keeps them out of the hospital and keeps them from getting constantly more expensive medical care over a prolonged period of time, which could be decades even, that is something that I think is extremely important.

Does anyone else have any comments on the -- yes, Mr. Kieval?

Mr. Kieval. Thank you.

Yes, first off, with the diseases that we treat, particularly heart failure, you know, survival is a big problem. I mean, annual mortality rates and heart failure can be over 10 percent. Five-year mortality is over 50 percent. So, really, time is life with our therapies.

And to your point, our therapies are intended to return patients to full life, keep them out of the hospital, which is a major source of financial burden to the healthcare system.

Even as a small company with the most efficient operations that we can muster, our monthly burden rate exceeds a million dollars a month. So, every month of delay due to -- whether it is for good reason or not for good reason -- is another million-dollar turn of the crank for our company. That is money that is taken away from innovation and further efficiency in the system. So, I think that streamlining the system can have lots of benefits, from saving lives, improving lives, reducing costs, and fostering innovation.

Mr. Bucshon. I think it was you that mentioned the ability to attract venture capital investment in startup companies or smaller companies is impacted by this also, by this process, right?

Mr. Kieval. Absolutely. I think, as we look, two big hurdles for companies in our position have both been talked about, regulatory approval and, then, reimbursement. And reimbursement is not the focus of this panel.

But the more that we can do to provide a sense of assurance and confidence to prospective investors in the function of these processes, not necessarily in the outcome, but in the efficient function of these processes, the more they are going to be interested in returning to participate.

Mr. Bucshon. I yield back, Mr. Chairman.

Mr. Burgess. The gentleman yields back. The Chair thanks

the gentleman.

The Chair recognizes the gentleman from Houston, Texas, Mr. Green, the ranking member of the subcommittee.

Mr. Green. Only because he is from Denton, Texas. So, we don't have to have an interpreter --

Mr. Burgess. Recognized for 5 minutes for questions.

[Laughter.]

Thank you.

Mr. Green. Thank you, Mr. Chairman.

Our committee and I worked on breakthrough pathway for device precision. It was in the 21st Century Cures. I am delighted the provision is now in law.

Mr. Daly, in my understanding, your company received Expedited Access Pathway, or EAP, designation for one of your products which was a precursor to the breakthrough designation. Can you explain what the EAP program is and what it means for your company?

Mr. Daly. Congressman Green, thank you for the question.

As a sidebar, I was a sales representative for Dr. DeBakey down in Houston 25 years ago. So, you brought back some memories.

Mr. Green. I have a picture that is probably 25 years old.

[Laughter.]

Mr. Daly. So, the Expedited Access Pathway, you know, basically, for us, as our company, our product is called Sylys.

It is a second PMA product, a pre-market-approved product that we have. What it does is it is a sealant that goes around a stable or suture line for colorectal surgery or gastric bypass surgery. What this does is it reduces leaks by 70 percent.

What this has been able to do through the EAP program is take about a year-and-a-half off the process for us to get into a pilot study. As was mentioned here, at a million dollars a month, that is a significant savings.

We are really excited that we were the first product approved through EAP program, and we are working through that. What it has done, too, for us, as an investor or as a company, is we have brought in some pretty significant investment. Over $50 million came because of our EAP designation. So, it has been a very big windfall for us.

Mr. Green. It is not often that Members of Congress hear something that goes right. Normally, we hear that it goes wrong. And thank you and I am excited about the potential not only for you, but the breakthrough pathway for medical devices and these agreements here.

Mr. Kieval, you mentioned in your testimony that agreement includes new performance goals aimed at getting new technologies to patients by including updated decision time targets for 510(k)s and PMAs and review time goals for de novo technologies and pre-submissions. Can you elaborate on these enhanced

performance goals and how you feel they would benefit industry and the patients?

Mr. Kieval. Yes, thank you for that question. By the way, we are also participating in the Expedited Access Pathway Program.

Mr. Green. Great.

Mr. Kieval. And I would echo Mr. Daly's comments on that.

So, from my perspective, I think speed is a great byproduct of an improved regulatory process, but I am not sure that, you know, I interpret the new performance goals under MDUFA IV as speed for speed's sake. I think there are important improvements to the process, important efficiencies to be gained, and that we can expect, as a result, greater speed because there is less wasted time, less unnecessary questions in going back and forth between innovators and the FDA.

So, the goals are meaningful because, once again, it is going to enhance access to patients whose lives hang in the balance, at least with the diseases that we are treating. It is going to make sure that resources are used most efficiently for innovation purposes. It is going to provide predictability for the investment community. So, I think it is going to have, these new goals are going to have myriad forms of benefits, but, again, as a byproduct of an improved process, not as a means to an end in and of themselves.

Mr. Green. Thank you.

Ms. Wurzburger, do you have anything to add to that question?

Ms. Wurzburger. No, I would just echo that I think that, although we are a larger organization than some of the small companies represented by my colleagues here, for us as well an efficient process allows us to reinvest in our innovations, in our R&D, resources that we need internally to ensure our products are safe and effective coming out the door.

Mr. Green. Ms. Bens, the Alliance for Aging Research has been a leading advocate for the inclusion of patient views on the benefits and risks of devices during the product reviews. Can you talk about how this agreement builds on MDUFA III to expand patient-centered medical device development?

Ms. Bens. Absolutely. Thank you very much for the question.

The one thing that I point to that was most beneficial to organizations like ours was the ability to interact with CDRH right from the start in defining what the unmet needs were for patients as well as what their most important benefits were that they were going to potentially see from medical products.

And I would give Dr. Shuren and the rest of the staff at CDRH a lot of credit for how comprehensive that risk/benefit guidance really was and setting the stage for a framework where not only developers can really be pointing to the criteria that CDRH was going to use for evaluating benefit/risk, but also groups like

ours could play more of a proactive role in identifying different types of research that could better fill those gaps and lead to endpoints that were going to be more meaningful to patients.

And I would say the next step that CDRH really took was the establishment of their Patient Engagement Advisory Council. That is something that we are really excited about, and we know that they are already in the process of planning their first meeting. But this will take the additional step of really implementing that guidance in a way that is going to be transformative.

I know there was a little bit of talk earlier about the issue of guidance and the FDA's ability to issue guidance. And this is one area where the PEAC is going to be a bit different from other types of patient engagement activities at the FDA. There is really going to be the opportunity for patients and their representatives to have a seat at the table in helping to provide guidance to the Commissioner on how they can develop guidances that are truly going to be patient-centered and lead to better studies. So, we are really excited about that. And the MDUFA fee funds really going hand-in-hand with funding those types of activities.

Mr. Green. Thank you, Mr. Chairman, and I thank our witnesses for being here.

Mr. Burgess. The gentleman yields back.

The Chair recognizes himself for 5 minutes for purposes of questions. And let me ask a question of our three industry representatives because this is apropos of you and, then, Ms. Bens, I am going to include you in something in just a moment.

But, of course, we are talking about the FDA, what the FDA/CDRH can do to make its path more straightforward. But, as an industry, what are you all doing to make certain that your submissions are of the highest quality to lessen the likelihood of having to come back and retrace steps?

Now, Ms. Wurzburger, let me start with you and, then, we will just go down the line.

Ms. Wurzburger. Sure. Thank you for the question.

Yes, I think, as we have heard through some of the testimony, a lot of the processes that are funded through this new User Fee Program, such as the pre-submission process, is very, very useful for us as manufacturers. That interactive dialog with the agency and discussion around the endpoints they expect and the data that they are looking for in those submissions allows us to go back into our internal processes and ensure that the submissions we are putting together are robust and contain that information on the first round. We are constantly improving that, as we acquire additional feedback from the agency and from other sources. So, it is very helpful for us.

Mr. Burgess. Mr. Daly?

Mr. Daly. Mr. Chairman, I think what you see collectively up here are companies that are part of trade organizations and organizations that really do, in my view, an excellent job, whether it is MITA or MDMA or AdvaMed, of taking the side that industry needs to also do a good job in presenting their either 510(k) or PMA.

And so, if you look across all three of these particular agencies, they do a very good job of training new companies, providing companies access to the bigger company information. As an example, I am chairman of, within AdvaMed, Excel, which is a part of AdvaMed that is companies that have less than $100 million in revenue. It makes up about 80 percent of our membership for all of AdvaMed. So, they do a really good job of helping companies navigate and get the right information.

Mr. Burgess. Thank you.

Mr. Kieval?

Mr. Kieval. Yes, I think my colleagues really summarized those very well. We are a small company. We are a single-product company. This is all we have got. If we run out of money before we get it across the goal line --

Mr. Burgess. Can I ask you about that?

Mr. Kieval. Sure.

Mr. Burgess. Because, I mean, I was struck in your written testimony and your testimony here. I mean, you are right, you

are a small company. You have got one thing. You have got one job, as they say. And so, if we make your life hard, harder, impossible, I mean, it has a profound effect, then, not just on you and your employees, but, of course, patients who depend on the products.

And it sounds like -- we haven't really gotten into what the products are that your particular company is dealing with -- but, I mean, in your testimony you said that the sweetest grandmother waiting for the device and someone else who was waiting for it. And these are outside the country. And so, our patients inside the country are still waiting for those devices, is that correct?

Mr. Kieval. So, in our own experience, our products have been on the market for a few years outside the United States, in Europe. We are excited about being able to treat patients there. We are very eager to have our products approved here in the United States.

We are very fortunate to be, as part of the Expedited Access Pathway program, and we are in the middle of what we hope is our definitive clinical trial to bring our product to the U.S. market. So, we have continued throughout our 16-year history -- it has always been a goal to bring our product here to the United States. I think it has been a difficult process. It has been a worthwhile process. We have welcomed the enhancements under MDUFA III. We are looking forward to the enhancements under MDUFA IV and working

with the FDA to complete that development process to bring this innovation to U.S. patients.

Mr. Burgess. Well, I think I have heard it said more than once today on the panel in front of us the words "alleviate suffering". And, Ms. Wurzburger, I think in your testimony you talked about things that were at one time science fiction are now the standard of care.

And when I talk to groups of medical students, residents, people sometimes despair of what they see on the policy side up here and we never agree on anything and we are fighting about everything. But, honestly, the next generation of doctors is going to have tools at their disposal that no generation of physicians has ever known, thanks to the work of the agency and thanks to the work of the innovators and the advocacy groups, the things that all of you put your heart and soul into.

So, for that, I want to thank you. I want to thank you for being here today.

I was going to recognize Mr. Carter, but he is exiting. He is exiting stage right, and he will submit for the record.

Mr. Green is already gone. So, I can't ask him for a followup.

But it has been a fascinating day and a fascinating panel. I think you have heard throughout the discussion today how the goodwill exists to get this done. And while things may move into

the headlines that like to highlight where we can't agree on a single thing, this is something where we all agree.

We have heard it said other times during the hearing that, yes, we welcome submissions and inputs. If people have better ideas, if there is a better way, talk to us. But, make no mistake about it, we are getting our work done.

And again, I think I credit Dr. Shuren for staying here through the industry testimony. I think that is indicative of how everyone wants this process to not just conclude, but to conclude successfully.

So, seeing that there are no further members wishing to ask questions, I do want to thank our witnesses for being here today.

And pursuant to committee rules, I remind members they have 10 business days to submit additional questions for the record.

I ask witnesses to submit their responses within 10 business days of the receipt of those questions. And we had no unanimous consent requests? No unanimous consent requests.

Without objection, the subcommittee is adjourned.

[Whereupon, at 12:45 p.m., the subcommittee was adjourned.]