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EXAMINING FDA'S MEDICAL DEVICE USER FEE PROGRAM

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

ONE HUNDRED FIFTEENTH CONGRESS

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[1] Dr. Shuren, Ms. Bens, and Mr. Daly did not answer submitted questions for the record by the time of printing.

EXAMINING FDA'S MEDICAL DEVICE USER FEE PROGRAM

TUESDAY, MARCH 28, 2017

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HEALTH,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

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.

Members 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 for 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.

OPENING STATEMENT OF HON. MICHAEL C. BURGESS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. BURGESS. 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 presubmission 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.

[The prepared statement of Mr. Burgess follows:]

PREPARED STATEMENT OF HON. MICHAEL C. BURGESS

The subcommittee will come to order.

The Chair will recognize himself for an opening statement.

Dr. Shuren, welcome back to our subcommittee. I am glad to say that your Center at FDA has come a long way since the 2012 reauthorization of the Medical Device User Fee Amendments (MDUFA).

Today is this subcommittee's third hearing to consider the reauthorization of FDA user fee programs set to expire in September. MDUFA gives FDA authority to collect fees from the medical device industry to support product review activities, and 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 will always be room for improvement, the MDUFA program has significantly enhanced the efficiency, transparency, and uniformity of the product review process at FDA. Leading up to the 2012 reauthorization of MDUFA, this subcommittee heard repeatedly about the slow, onerous, and arbitrary process by which devices were reviewed at the Center for Devices and Radiological Health (CDRH).

The state of affairs at CDRH 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 (FDASIA) Congress reauthorized MDUFA and the paradigm started to shift in the right direction.

FDASIA included meaningful regulatory reforms, improved communication between industry and FDA, and increased accountability at CDRH. It is important that the next medical device user fee agreement continue to build upon the progress made in FDASIA, as well as the good policies members of this subcommittee championed in 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 FDA, industry, and most importantly, patients.

In the proposed agreement, FDA has agreed to further decrease the total amount of 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 patients faster.

Further, FDA would enhance patient engagement by more formally involving patient preference and patient reported outcomes in the review process. It is vital that FDA routinely incorporate the patient perspective in its decision-making 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 interactions between FDA and 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 premarket activities.

Furthermore, the proposed agreement provides for improved transparency and greater responsibility. A wide array of new measures, tools, and reports will provide data that is necessary to ensure FDA is meeting the goals of the agreement.

Reauthorizing MDUFA 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 and innovation as soon as safely possible.

I thank all of our witnesses for being here, and I look forward to hearing from each of you about how the substance of the proposed agreement will accomplish this goal.

Mr. BURGESS. 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.

OPENING STATEMENT OF HON. GENE GREEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

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 5 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.

OPENING STATEMENT OF HON. GREG WALDEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OREGON

Mr. WALDEN. 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 5 years makes.

Thanks to Dr. Burgess and others, the Food and Drug Administration Safety and Innovation Act included a number of commonsense 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 others seeking time, I would be happy to yield the balance. Otherwise, I will yield back and we can get on with the hearing.

[The prepared statement of Mr. Walden follows:]

PREPARED STATEMENT OF HON. GREG WALDEN

Thank you, Chairman Burgess.

What a difference 5 years makes. The last time Congress reauthorized the Medical Device User Fee Amendments (MDUFA) in 2012, we heard story after story about venture capital drying up and innovative medical technology companies launching their products overseas, oftentimes years before American patients could benefit from them. Time after time, witnesses from all sides of the political spectrum came before this subcommittee and highlighted the burdensome, inconsistent,

and opaque nature of the FDA review process as the primary driver of these alarming trends.

Thanks to Dr. Burgess and others, the Food and Drug Administration Safety and Innovation Act (FDASIA) included a number of common-sense regulatory improvements that greatly benefitted patients and spurred innovation. I also want to thank Dr. Jeff Shuren for his leadership. All of the legislation in the world could not change the deeply rooted cultural issues that were plaguing the device center at FDA. He took these criticisms to heart and then put these new legislative authorities to work.

Since 2009, the number of innovative devices approved by the FDA has almost quadrupled and American patients are benefiting from safe and effective American technologies sooner. In 2009, it took an average of 427 days before FDA even reached a decision on a premarket approval application (PMA). As of 2015, the average review time was down to 276 days—a 35 percent decrease.

Building upon the successful implementation of the previous user fee agreement, 21st Century Cures included a number of additional bipartisan process reforms. Reauthorizing MDUFA in a timely fashion-which I remain steadfastly committed to doing-will ensure that we continue to move in the right direction. This is a good agreement that will further 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.

Mr. WALDEN. With that, Mr. Chairman, if there are others 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 full committee, Mr. Pallone of New Jersey, 5 minutes for your opening statement, please.

OPENING STATEMENT OF HON. FRANK PALLONE, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

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.

[The prepared statement of Mr. Pallone follows:]

PREPARED STATEMENT OF HON. FRANK PALLONE, JR.

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 (CDRH) is well-resourced and well-staffed. I would also be remiss if I did not 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.

MDUFA IV will build on these successes by working to improve the medical device user fee program. It will advance the use of the patient perspective in the risk-benefit assessment of medical devices. It also establishes a system called the NEST to utilize real world data for premarket approval of new indications and post-market safety monitoring. It tailors the use of the Third Party Review program, and improves pre-submission communication 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 15, 2017 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 30. Any delays would endanger the review of innovative medical devices and threaten the jobs of thousands of FDA employees.

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 they are signed into law as soon as possible.

Thank you.

Mr. PALLONE. I have 2 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., DIRECTOR, CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

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 3 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 nongovernment 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 Dr. Shuren follows:]

"Examining FDA's Medical Device User Fee Program"

Testimony of
Jeffrey Shuren, M.D., J.D.
Director, Center for Devices and Radiological Health

Before the
United States House of Representatives
Committee on Energy and Commerce
Subcommittee on Health

March 28, 2017

U.S. Department of Health and Human Services
U.S. Food and Drug Administration
www.fda.gov

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INTRODUCTION

Chairman Walden, Ranking Member Pallone, Chairman Burgess, Ranking Member Green, and members of the committee:

Thank you for having me here today. I'm Jeff Shuren, Director of the Center for Devices and Radiological Health (CDRH) at the Food and Drug Administration (FDA). I'm pleased to be here today to discuss reauthorization of the Medical Device User Fee Amendments, or MDUFA IV.

The MDUFA reauthorization proposal described below was submitted to Congress in January under the previous Administration, and reflects a different approach to the Federal Budget. The Blueprint Budget supports many of the goals of the reauthorization proposal but proposes a different way of financing these goals. The Administration looks forward to working with Congress, with industry input, to develop a reauthorization proposal that speeds the development and approval of vital medical devices that are safe and effective.

MDUFA

Enacted by Congress in 2002, MDUFA is a user fee program through which medical device companies pay fees to FDA when they submit a request for marketing authorization or register their establishments with FDA. The program includes commitments between the U.S. medical device industry and FDA to improve the predictability, transparency, and consistency of regulatory processes, which are intended to reduce the time for FDA to make a decision about whether to authorize marketing of a device.

MDUFA has been reauthorized every five years since Congress created the program. As the program has evolved, FDA and industry have successfully negotiated agreements to improve patient access to medical devices and streamline regulatory processes.

During the 2012 MDUFA III testimony, many of you may recall that the program was in a much different place[1]:

[1] See Appendix A: "U.S. Food and Drug Administration, Center for Devices and Radiological Health: Progress in Achieving Our Vision of Patients First."

- In FY 2009, it took an average of 427 days to reach a decision on a premarket approval application (PMA), the submission type required for the highest-risk devices.
- In FY 2010, it took an average of 150 days to reach a decision on a premarket notification submission (also known as a 510(k)), the submission type required for low to moderate-risk devices.

Thanks to the investment provided by industry, and direction provided by Congress, we have made substantial progress toward reducing decision times. As of 2015:

- It took an average of just 276 days to reach a decision on a PMA, a 35 percent decrease in six years; and
- It took an average of just 133 days to reach a decision on a 510(k), an 11 percent decrease in five years.

Further, we went beyond our MDUFA III commitments to reduce the median time to approve an Investigational Device Exemption (IDE) study to just 30 days in FY 2015, down from 442 days in FY 2011—a 93 percent decrease in four years. This improvement has allowed companies to begin their clinical trials earlier so they can begin collecting data to support a decision on their submission requesting marketing authorization. In addition, we reduced the average time to reach a decision on a De Novo classification request, the submission type typically used by novel low or moderate-risk devices, to 259 days in FY 2014, down from 770 days in FY 2009—a 66 percent decrease in five years.

Changes we have made at CDRH to our culture, policies, and processes—in addition to user fee funding and changes to federal law—have resulted in an improved medical device pipeline and innovative technologies being introduced in the U.S. earlier than in the past. For example, since 2009, the number of innovative devices we have approved has almost quadrupled. In 2016, we approved 91 innovative devices—the highest of any year since the user fee program began in 2003. In 2015, we approved the second highest number of innovative devices.

An example of an innovative technology that FDA approved first in the world is the "artificial pancreas," something many members of this Committee supported. Working interactively with the device manufacturer from the earliest stages of development to assist in making this

technology available as quickly as possible, FDA approved the first device in the world that is intended to automatically monitor glucose levels around the clock and automatically provide appropriate insulin doses.

While we have made progress in many areas, we also recognize that more work remains and there are additional opportunities for improvements. We look forward to working with industry and Congress to ensure there are sufficient user fees resources as we strive to make these improvements. MDUFA IV agreement includes a new quality management program that will enhance consistency and predictability in premarket review processes.

MDUFA IV agreement would also allow FDA to move forward in some critical and strategic areas such as strengthening our partnerships with patients[2]. Strengthening patient input will allow us to promote more patient-centric clinical trials, advance benefit-risk assessments that are informed by patient perspectives, and foster earlier access to new devices.

Another critical area supported by the MDUFA IV agreement is the development of the National Evaluation System for health Technology, or NEST[3]. The NEST is system owned and operated by multiple stakeholders that will use real-world data collected as part of routine clinical care. A robust NEST will enable manufacturers to harness real-world evidence that could enable them to drive down the time and cost of bringing a new device to market, expand the indications for already approved devices, and meet postmarket reporting requirements. The NEST will also enable faster identification of safety issues, reducing harm to patients and liability for companies.

The MDUFA IV agreement, which was supported by a broad array of stakeholders during the public review of the draft agreement, will expedite the availability of innovative new products, and its enhancements will continue to increase the efficiency of FDA's programs. Improvements in total time to decision, transparency, consistency, and predictability will benefit industry, healthcare providers, and, most importantly, patients.

[2] See Appendix B: "Center for Devices and Radiological Health (CDRH): 2016-2017 Strategic Priorities – 2016 Accomplishments."
[3] See Appendix B: "Center for Devices and Radiological Health (CDRH): 2016-2017 Strategic Priorities – 2016 Accomplishments."

CONCLUSION

The Medical Device User Fee Program has allowed FDA to speed the application review process without compromising the Agency's high standards. MDUFA offers a strong example of what can be achieved when FDA, industry, and other stakeholders work together towards the same goal. The user fees provide a critical way to ensure that FDA has the resources needed to conduct reviews in a timely fashion. While we have made demonstrable progress in partnering to bring medical devices to market in as timely a manner as possible, we know that more work remains to be done to further enhance and optimize our processes. The reauthorization MDUFA will allow FDA to build upon the demonstrated success of this program, and in so doing, further benefit patients and affirm our nation's standing as a global leader in biomedical innovation.

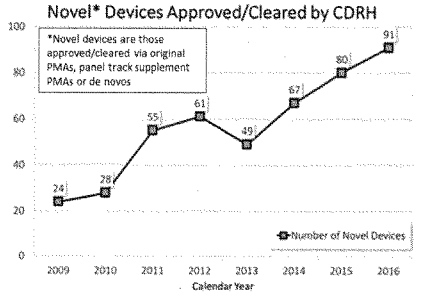
Appendix A

U.S. Food and Drug Administration
Center for Devices and Radiological Health:
Progress in Achieving Our Vision of Patients First

In the early part of this decade, industry argued that FDA regulation hindered innovation and contributed to the growing number of device companies seeking marketing authorization for their devices abroad before introducing them in the United States, and the increasing gap between when a device is approved in another country and when it is approved in the US. This reality, its adverse impact on patients, plus CDRH's own awareness of our declining performance over almost a decade, led CDRH to implement new programmatic changes. These changes, along with increased user fee funding and changes in Federal law have helped us strengthen our performance and better address the rapidly-evolving field of medical device innovation. To guide us in our mission to improve the health and quality of life of patients, in 2012 we adopted a new vision[4] to reflect this change in mindset, that: **Patients in the US have access to high-quality, safe and effective medical devices of public health importance first in the world.**

Doing Business Better

Since late 2009, CDRH has continuously improved the way we do business through a series of culture, policy and process changes. This can be seen through our commitment to providing excellent customer service, new patient-centered paradigms, and our strong performance across a range of objective measures, including the time it takes to review several types of medical device submissions. These improvements are reflected **by the nearly four-fold increase in the annual number of novel medical device approvals.**

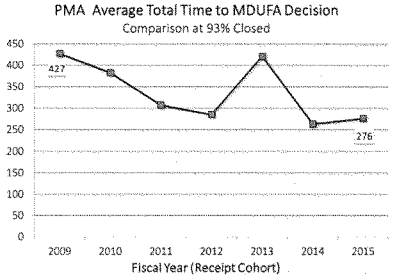


Fast Facts CDRH oversees approximately **175,000 medical devices** on the US market, more than **18,000 medical device manufacturers,** and more than **25,000 medical device facilities worldwide.** Each year we receive some **22,000 premarket submissions** (includes supplements and amendments) and more than **1.4 million reports on medical device adverse events and malfunctions.**

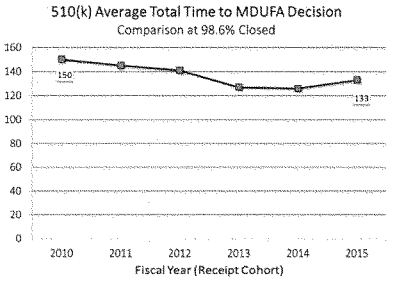
[4] CDRH Mission, Vision and Shared Values

Time Time, with its cost implications, plays a critical role in an innovator's decision as to whether and when to bring a new technology to the US. What good is a new technology if patients do not have timely access to it? How helpful is a new technology that doesn't benefit patients or poses unacceptable risks? By reducing the time of every regulatory stage of the total product life cycle, including the review of medical device submissions, while still assuring robust but appropriate (least burdensome) evidence generation and high-quality decision making, we help patients get access to safe and effective medical technologies and foster innovation. After steadily worsening performance from 2002 to 2010 on a variety of measures, including premarket review times, CDRH has reduced the decision time on all key premarket submission types.

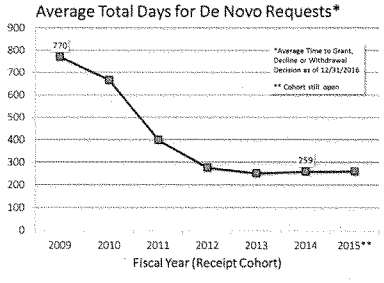
PMA While premarket approval applications (PMAs) only account for approximately one percent of all premarket medical device submissions, they represent medical devices with the highest risk to patients (Class III devices) and, therefore, require more data and a more rigorous review by CDRH. In 2009, it took an average of 427 total days to reach a decision on a PMA. **By 2015, we had reduced the total decision time by 35 percent.**



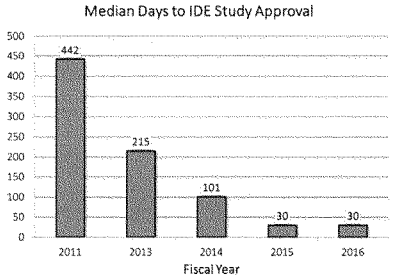
510(k) Named after its section number in federal law, this category represents the bulk of premarket submissions for medical devices. Manufacturers submit 510(k)s to CDRH for devices with low to moderate risk to patients (Class II), and our review standard is based on substantial equivalence (whether a device is at least as safe and effective as a device already on the market). In 2010, it took an average of 150 total days to reach a decision on a 510(k). **By 2015, we had reduced the total decision time by 11 percent.**



De Novo *De novo* classification is a pathway that enables manufacturers of certain low to moderate risk novel devices for which there are no similar marketed devices to come to market, instead of having to submit a PMA. In 2009, it took an average of 770 total days to reach a *de novo* decision. **By 2014, we had reduced the total decision time by 66 percent.**



IDE Manufacturers submit Investigational Device Exemptions (IDEs) for certain devices they want to study via a clinical trial. CDRH reviews an IDE submission before a manufacturer can begin to collect clinical data that may be necessary for future approval. **CDRH slashed median review times for IDE full approvals by more than a year** between 2011 and 2015.



DOING BUSINESS DIFFERENT

Since 2009, CDRH has been evaluating all of our programs to address concerns from patients, industry, health care providers, our own staff, and other customers about issues including review times, backlogs, and our expertise in increasingly complex technology. We have sought to address these concerns by **changing our culture** to put **patients first** and recognizing that **advancing innovation and assuring patient safety are not mutually exclusive**, revising or eliminating old policies, and developing new policies and approaches with an eye on meeting measurable objectives. Increased medical device user fees have supported these efforts so that we are better positioned to respond to the needs of patients.

•Clinical Trials In addition to dramatically improved performance[5] in reviewing IDEs, CDRH has encouraged the use of **innovative methodologies and study designs in clinical trials.** We recognize that manufacturers need CDRH input early and often so that the ultimate **device review process moves as quickly and smoothly as possible.** In 2013, CDRH issued final guidance for manufacturers on early feasibility studies to encourage conducting these studies in the US. Innovators tend to market their technologies sooner in countries where they elect to conduct their early clinical studies. Since 2013, **the number of early feasibility studies approved has more than doubled—from 17 in FY 2013 to 40 in FY 2016.**

CDRH encourages the use of innovative clinical trial designs and statistical methods such as adaptive clinical trials[6] and Bayesian statistics[7] because, where appropriate to use, they can reduce the time and cost of a clinical study. In recent years, many devices have come to market based on the results of clinical trials using adaptive trial designs. **For the period from 2007 to May of 2013, CDRH received 201 submissions that were adaptive.**

CDRH continues to develop computational models that can, in some instances, supplement or replace data from clinical investigations, such as the Virtual Family (VF)[8]—a set of highly detailed, anatomically correct, computational whole-body models, designed to mimic humans of both sexes at various stages of growth. **Since 2007, more than 160 submissions have included Virtual Family research.**

[5] CDRH Clinical Trial Enterprise Targets and Performance
[6] Guidance Document: Adaptive Designs for Medical Device Clinical Studies Issued July 27, 2016
[7] Guidance for the Use of Bayesian Statistics in Medical Device Clinical Trials
[8] Virtual Family

•Flexible, Risk-Based Regulatory Approaches CDRH continues to adapt our oversight policies to emerging new technologies. In a manner consistent with our statutory mission, we now approach a medical technology by first asking whether active CDRH oversight will be value-added. If not, we take a less active regulatory approach. If it would, we focus on assuring timely patient access to technologies that will benefit patients by considering the device's innovation cycles and evidence generation needs.

For example, widespread adoption and use of digital health technologies is creating new and innovative ways to improve health and health care delivery. In **one of the biggest de-regulatory actions for CDRH in decades**, to foster greater innovation in the digital health space while promoting public health, we have exercised our enforcement discretion to cease subjecting certain lower-risk medical devices (such as apps for patient care management and medication reminders) to medical device requirements.

Additionally, balancing data needs between what's collected before the device comes on the market (premarket) and what's collected after it is on the market (postmarket) reflects our approach to best assure timely patient access to safe and effective devices.

In 2015, CDRH completed a retrospective review[9] of the benefit-risk profile of all types of high-risk devices to determine if we could reduce premarket data collection requirements for at least some devices. As a result, for 30 percent of high-risk medical devices, **CDRH determined, based on the current body of evidence and experience, we could consider some devices candidates for down-classification, eliminate some data requirements or shift some premarket data requirements to the postmarket setting.** In 2016, CDRH reached out to stakeholders for input on the results of the retrospective reviews, in order to determine next steps.

•Patient-Centered Benefit-Risk For the past 5 years, CDRH has encouraged the use of **a more flexible, patient-centric, and transparent benefit-risk framework** to evaluate medical devices, starting with a 2012 guidance on the factors to consider when making benefit-risk determinations in support of device premarket approval decisions, which includes patient perspectives on potential benefits and risks. We are focusing more on what matters to patients.

In 2016 and 2017, CDRH expanded this approach by revising the 2012 guidance to include additional patient-centric factors[10], and issuing two additional benefit-risk guidance documents: one which outlines the principal factors CDRH considers when making benefit-risk determinations during the premarket review process for IDEs[11], and one which outlines factors to consider when determining whether and what postmarket actions[12] we may take to address a problem, such as a recall, based on the benefits and risks of that action to patients.

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[9] CDRH Strategic Priorities and Updates

[10] Guidance Document: Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and DeNova Classification (Aug. 24, 2016)

[11] Guidance Document: Factors to Consider When Making Benefit-Risk Determinations in Medical Device Investigational Device Exemptions

[12] Guidance Document: Factors to Consider When Making Benefit-Risk Determinations in Medical Device Product Availability, Compliance, and Enforcement Decisions

•Patients as Partners CDRH had traditionally determined whether the benefits of a device outweighed its risks based on the trade-offs we thought were acceptable. However, patients who live with a disease or condition often have their own perspectives on what benefits and risks related to medical devices they are willing to accept. CDRH collaborates with patient scientists and other experts outside the FDA to help us advance the scientific field of assessing patient preferences and incorporate the patient perspective into our benefit-risk assessments and decision-making.

For example, in 2014, CDRH funded a collaborative study on patient preferences that led to changes in our review paradigm for obesity devices, and used the results to inform our decision to approve the first medical device for treating obesity since 2007. Better understanding of patient preferences can also help **rejuvenate development pipelines**; since then, CDRH has approved or granted marketing applications for five more medical devices that address obesity or weight loss.

In 2016, CDRH issued a final guidance that outlined patient preference information (PPI)[13] that CDRH may use in decision making. Since then manufacturers have begun to submit—and we have approved—IDEs with patient preference studies.

CDRH's efforts to incorporate the voice of patients in our decision making also are reflected in medical device clinical studies, which have been increasingly assessing what matters most to patients. Between 2009 and 2014, the number of **premarket submissions that included clinical studies with patient reported outcomes (PROs) increased by more than 500 percent** and half of IDE pivotal clinical studies now include PROs.

In 2015, CDRH established the first FDA advisory committee focused on the interests and needs of patients, and recruited potential new members in 2016. The Patient Engagement Advisory Committee[14] **will hold its first meeting in 2017**.

•National Evaluation System for health Technology (NEST)

Despite rigorous premarket evaluation, we cannot fully understand how well a medical device works until it is used day-to-day by patients, caregivers, and clinicians. Premarket clinical trials provide critically important information but we don't understand the long-term benefit-risk profile until it is used in routine clinical practice. Currently our nation is limited in its ability to make widespread use of real-world evidence (RWE) to best inform all members of the medical device ecosystem.

CDRH intends for NEST to increase the quality and use of real-world data (RWD) collected as part of routine clinical care, which should also help reduce the time and cost of evidence generation. Ongoing implementation of the Unique Device Identification (UDI) system also will enable NEST to perform enhanced analyses of devices on the market, providing a clear and standard way to identify devices in electronic medical records.

CDRH is already relying on RWE to approve new devices, expand the indications for already marketed devices, and reduce the time and cost for device makers to meet their postmarket study requirements. In 2016, CDRH documented access to more than 28 million electronic patient records (from national and

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[13] Guidance Document: Patient Preference Information – Voluntary Submission, Review in Premarket Approval Applications, Humanitarian Device Exemption Applications, and De Novo Requests, and Inclusion in Decision Summaries and Device Labeling

[14] The Patient Engagement Advisory Committee

international clinical registries, claims data, and electronic health records) that included device identification and awarded $3 million to the Medical Device Innovation Consortium to establish the NEST Coordinating Center.

•Streamlining the Pathway from FDA Approval to Payer Coverage

Timely access to innovative medical technologies has been identified as a significant issue in the delivery of high quality health care. Manufacturers of innovative medical products have said that after undergoing the FDA approval process the availability of their products to consumers is often slow because, in order to obtain coverage and payment from third-party payers, the manufacturers must go through a second review process by such payers. Therefore, CDRH established the Payer Communication Task Force (PCTF) to facilitate communication between device manufacturers and payers to shorten the time between FDA approval or clearance and coverage decisions. By communicating earlier, manufacturers may design their pivotal clinical trials to produce both the data required for regulatory approval or clearance, and positive coverage determinations.

To support these efforts, CDRH and the Centers for Medicare & Medicaid Services (CMS) began to pilot an approach in 2011 called Parallel Review that would give eligible device makers the voluntary option for CMS to start their national coverage determination process while the device is under review by CDRH. This process serves the public interest by reducing the time between FDA marketing approval or clearance decisions and CMS national coverage determinations. In 2016, CDRH and CMS established Parallel Review as a permanent program. Last year, CDRH also established an additional opportunity for device manufacturers to invite CMS, private payers, or health technology assessment groups (HTAs) to join FDA pre-submission meetings to provide early feedback on clinical trial design.

EVIDENCE OF IMPACT

Our investments are starting to pay off. For example, in 2016, CDRH approved 91 novel medical devices—the highest number since the advent of the user fee program in 2003. This followed the second highest number from 2015, and continued a 7-year trend that has resulted in a marked increase in the annual number of novel device approvals since 2009. These novel technologies, which can help improve the quality of life of patients, especially those that require day-to-day maintenance and ongoing attention, are yielding promising results. In addition, several of these devices are reaching US patients much earlier than they would have in previous years.

• "Artificial Pancreas" Approximately five percent of diabetics have Type 1 diabetes, also known as juvenile-onset diabetes. People with type 1 diabetes have to constantly monitor their glucose levels throughout the day and have insulin therapy through injection with a syringe, an insulin pen, or an insulin pump, to avoid becoming hyperglycemic (high glucose levels). Working interactively with the sponsor from the earliest stages of development to assist in making this technology available as quickly as possible while assuring it is safe and effective, **CDRH, in 2016, approved the first automated insulin delivery (AID) device in the world that is intended to automatically monitor glucose (sugar) and provide appropriate basal insulin doses—what some have called a first-generation "artificial pancreas[15]."**

[15] The Artificial Pancreas Device System

•Transcatheter Aortic Valve Replacement (TAVR) Therapy

About 80,000 surgical aortic valve replacements (SAVR) are performed in the US annually. One-third of these patients are at intermediate surgical risk for death or complications. An aortic valve replacement that can be inserted through the blood vessels or, in some cases, through the tip of the heart by a catheter, rather than through open surgery, could avoid the risks of surgery and provide an alternative effective treatment to patients who are in the "intermediate surgical risk" category.

In 2011, CDRH approved the first TAVR device in the US for patients who are not surgical candidates for SAVR, more than four years after the device entered the European Union (EU) market. When, in 2016, CDRH approved the expanded indication[16] for use for a TAVR device in patients at intermediate surgical risk for death or complications, the positive impact of CDRH initiatives was evident. The gap between EU and US approval for the expanded indication for use was reduced from over four years to only 18 days. US Medicare coverage is also a factor in patients' access to devices. For TAVR devices, access to real-world evidence—what NEST hopes to expand—proved to be a valuable asset. The US Medicare program immediately covered TAVR devices due to the ongoing collection of real-world evidence on these devices in a national registry—there was no delay between US approval and access to this technology. **As a result, more than 25,000 additional patients each year are now eligible for this life-saving procedure.**

•Diagnostics for National Emergencies Accurate detection and diagnostics are critical to addressing national public health threats. For example, in 2016, CDRH authorized the use of fourteen diagnostic tests for Zika[17] virus under our Emergency Use Authorization (EUA) authority—twelve tests to diagnose active infection and two tests to assess whether individuals who may have recently been exposed to Zika were actually infected. This rapid action provided timely patient access to Zika tests before the summer of 2016, when officials detected the virus in the U.S. **Since 2009, CDRH has granted 50 EUAs, reauthorized 19 EUAs, and granted 30 amendments for tests to help meet the country's needs during a national public health emergency, such as outbreaks from Zika, Ebola, and H1N1.**

[16] Press Release: FDA approves expanded indication for two transcatheter heart valves for patients at intermediate risk for death or complications associated with open-heart surgery – Aug. 2016

[17] Zika Virus Response Updates from FDA

Appendix B

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH)

2016-2017 STRATEGIC PRIORITIES – 2016 ACCOMPLISHMENTS

Establish a National Evaluation System for Medical Devices

To successfully harness real-world evidence ("evidence from clinical experience") in an efficient manner, the U.S. must develop the necessary infrastructure – a National Evaluation System for health Technology (NEST).

Goal: Increase Access to Real-World Evidence to Support Regulatory Decision Making	
2016 Target	**Results**
25 Million By December 31, 2016, gain access to 25 million electronic patient records (from national and international clinical registries, claims data, and EHRs) with device identification.	**28.6 Million** Gained access to more than 28 million electronic patient records (from national and international clinical registries, claims data, and EHRs) with device identification using a variety of mechanisms, such as cooperative agreements and access through regulatory process.

Goal: Increase the Use of Real-World Evidence to Support Regulatory Decision Making	
2016 Target	**Results**
40% By December 31, 2016, increase by 40 percent the number of premarket and postmarket regulatory decisions that leverage real-world evidence. (compared to FY2015 baseline)	**85%** The number of premarket and postmarket regulatory decisions that used real-world evidence increased by 85 percent in 2016. (compared to FY2015 baseline)

Supporting Actions

In 2016, CDRH took a number of actions to achieve the goals and targets established for this priority.

Establish the National Evaluation System for health Technology (NEST)

In Progress: A multi-stakeholder Planning Board and the Medical Device Registry Task Force issued a series of reports that outlined an organizational structure and infrastructure for the NEST Coordinating Center (February 2015[18], April 2016[19], September 2016[20], and August 2015[21]). In 2016, FDA awarded $3 million to the Medical Device Innovation Consortium (MDIC) to establish the Coordinating Center, and $1 million to other organizations to continue projects that generate real-world evidence on device performance.

Develop a framework for the incorporation of real-world evidence into regulatory decision making.

In Progress: Issued draft guidance[22] to describe how real-world evidence may be used to support pre- and postmarket regulatory decisions. Final guidance is planned for 2017.

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[18] *Recommendations for a National Medical Device Evaluation System*
[19] *The National Evaluation System for health Technology: Priorities for Effective Early Implementation; Planning Board Report*
[20] *The National Evaluation System for health Technology: Priorities for Effective Early Implementation; Planning Board Report*
[21] *Recommendations for a National Medical Device Evaluation System*
[22] *Guidance Document: Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices*

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH)

2016-2017 STRATEGIC PRIORITIES – 2016 ACCOMPLISHMENTS

Partner with Patients

We believe that if CDRH is to successfully achieve a mission and vision in the service of patients, we must interact with patients as partners and work together to advance the development and evaluation of innovative devices, and monitor the performance of marketed devices.

Goal: Promote a Culture of Meaningful Patient Engagement by Facilitating CDRH Interaction with Patients	
2016 Target	**Results**
10 Organizations By December 31, 2016, establish one or more new mechanisms for CDRH employees to obtain patient input on key pre- and postmarket issues facing CDRH and foster participation of 10 patient groups.	**34 Organizations** CDRH staff participated in 21 patient interaction opportunities, involving 34 patient organizations.
50% By December 31, 2016, 50 percent of CDRH employees will interact with patients as part of their job duties.	**68%** More than 68 percent of CDRH interacted with patients in 2016. When asked, 99 percent of staff who interacted with patients described their interaction as meaningful and 89 percent as relevant to their jobs.

Goal: Increase Use and Transparency of Patient Input as Evidence in Our Decision Making	
2016 Target	**Results**
50% By September 30, 2016, 50 percent of PMA, *de novo* and HDE decisions will include a public summary of available and relevant patient perspective data considered.	**65%** In FY 2016, 65 percent of PMA, *de novo*, and HDE decisions included a public summary of available patient perspective data.
1 By September 30, 2017*, increase the number of patient perspective studies (e.g., evaluating patient reported outcomes (PRO) or patient preference information (PPI)) used in support of premarket and postmarket regulatory decisions. (compared to FY 2015 baseline) *2017 Target	**65%1 PRO and 41 PPI** Increased by 65 percent the number of approved IDEs (pivotal studies only) with patient reported outcomes (PRO). Increased to four (from none) the number of patient perspective studies conducted by sponsors in support of pre- and postmarket regulatory decisions.

Supporting Actions

In 2016, CDRH took a number of actions to achieve the goals and targets established for this priority:

Patient Engagement Advisory Committee Convene the Patient Engagement Advisory Committee to discuss high priority topics regarding patient input in the total product lifecycle.

In Progress: CDRH chartered and began to recruit members for FDA's new Patient Engagement Advisory Committee (PEAC). PEAC members will be selected and announced in 2017.

Education and Training Develop education and training for CDRH staff and industry on the development and use of the science of measuring and communicating patient input throughout the total product lifecycle.

In Progress: CDRH trained more than 80 staff members on patient reported outcomes (PRO) and patient preference information (PPI), to advance staff understanding and CDRH review capacity in these areas.

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH)

2016-2017 STRATEGIC PRIORITIES – 2016 ACCOMPLISHMENTS

Promote a Culture of Quality and Organizational Excellence

A manufacturer's ability to design and make high-quality, safe and effective devices and CDRH's ability to provide the necessary oversight to assure devices on the market are high-quality, safe and effective will increase as manufacturers and CDRH embrace a culture of quality and excellence throughout our respective organizations.

Goal: Strengthen FDA's Culture of Quality within the Center for Devices and Radiological Health	
2016 Target	**Results**
10% ↑ By September 30, 2016, increase by 10 percent the number of CDRH staff with quality and process improvement credentials to improve organizational excellence. (compared to FY 2015 baseline)	300% ↑ In FY 2016, CDRH tripled the number of staff with quality credentials by providing on-site quality training and certification examinations.

Goal: Strengthen Product and Manufacturing Quality within the Medical Device Ecosystem	
2016 Target	**Results**
By September 30, 2016, develop metrics, successful industry practices, standards, and tools that manufacturers can use to evaluate product and manufacturing quality beyond compliance with regulatory requirements.	Partnered with MDIC to develop metrics and best practices to assess quality system performance, and analytical tools to assess device quality by hospital value analysis committees.
By December 31, 2016, pilot voluntary use of product and manufacturing quality metrics and evaluation tools.	Partnered with MDIC and Capability Maturity Model Integration (CMMI) Institute on a proof-of-concept and pilot with three device manufacturers, to evaluate use of the CMMI appraisal process as a foundation for a future third party program.

Supporting Actions

In 2016, CDRH took a number of actions to achieve the goals and targets established for this priority:

Quality Management Framework Resources permitting, continue to implement the CDRH Quality Management Framework.
In Progress: CDRH completed development of its document control system (DCS). DCS will ensure that current and approved quality program and key processes documentation—standard operating procedures, work instructions, forms, templates and process maps—is available to staff.

Education and Training Develop education and training for CDRH staff to facilitate adoption of practices characteristic of a culture of quality and organizational excellence.
In Progress: CDRH became an American Society for Quality (ASQ) enterprise member—enabling every employee at FDA to take advantage of ASQ's vast collection of learning resources. CDRH also offered on-site quality training to 150 staff. More than 90 percent of those who participated in the training earned ASQ quality certifications (Certified Quality Auditor and Certified Quality Improvement Associate).

Case for Quality As part of the Case for Quality, collaborate with members of the medical device ecosystem to identify, develop, and pilot metrics, successful practices, standards, and evaluation tools that will be specific to the medical device industry and focus on assuring product and manufacturing quality.
In Progress: In partnership with MDIC, CDRH collected input from stakeholders through six Case for Quality Forums; developed metrics and best practices designed to assess quality system performance using pre-production, production and post-production data; and led development of a product quality dashboard to assist hospital value analysis committees in identifying high quality devices.

Voluntary Program Identify external partnerships and mechanisms to support a sustainable, voluntary third party program that will utilize quality metrics, practices, standards, and evaluation tools to assess and promote medical device product and manufacturing quality within industry beyond compliance with regulatory requirements.

In Progress: Continuing partnership with MDIC, CMMI Institute and other stakeholders, to expand application of maturity appraisal process; with the goal of developing the framework for a voluntary program in 2017.

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 who 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 5 or 6 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 a 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 3 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 4 1A½ 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 5 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 [continuing]. 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. OK. 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 5 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 ini-

tially 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 5 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 nongovernment system; it is a nongovernment 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 3 years most of the pieces will be in place.

Mr. MULLIN. I guess help me understand why 2 or 3 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 2 or 3 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 2 or 3 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. OK? 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. OK. 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. OK. 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. OK. 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 5 years in anticipation of you having the staffing levels that you have right now for the next 5 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. OK. 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 6 years, and for a 510(k) in 2015 by 11 percent over 5 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. OK. 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. OK. 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 2 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 Web site, 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 postmarket 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. OK.

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. OK. 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 5 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 CHIEF EXECUTIVE OFFICER, COHERA MEDICAL; AND DIANE WURZBURGER, EXECUTIVE OF REGULATORY AFFAIRS, GE HEALTHCARE, ON BEHALF OF THE MEDICAL IMAGING & TECHNOLOGY ALLIANCE

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 fur-

ther 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 Ms. Bens follows:]

Testimony of Cynthia A. Bens, Vice President of Public Policy
Alliance for Aging Research

United States House of Representatives
Energy and Commerce Committee, Subcommittee on Health
Hearing on "Examining FDA's Medical Device User Fee Program"

March 28, 2017

Mr. Chairman, Ranking Member Green, and Members of the Subcommittee:

It is an honor and a privilege to speak with you today about the reauthorization of the Medical Device User Fee Act (MDUFA) program, on behalf of the Alliance for Aging Research.

I am Cynthia Bens, the Vice President of Public Policy at the Alliance. The Alliance for Aging Research is the leading non-profit organization dedicated to accelerating the pace of scientific discoveries and their application to improve the experience of aging and health. We believe that advances in research help people live longer, happier, more productive lives and reduce health care costs over the long term.

Most of us are keenly aware that our population is aging at an unprecedented rate. Ten thousand Baby Boomers are turning 65 each day. This is up from 6,000 per day just 6 years ago. People age 85 and older are the fastest growing segments of our population. Right now, approximately 10 percent of the U.S. population is age 80 or older. This 80+ age group will reach 30 percent of the U.S. population by 2050.

Many older adults today are fortunate to experience better health as they age than previous generations. But the truth is that most older adults still face significant periods of illness and disability later in life, often from multiple chronic conditions that require complex care

management. They 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 respond to the physical declines people face as they age has never been greater. We believe that we will only realize the benefits of these medical technologies if the U.S. Food and Drug Administration (FDA) has access to the resources and expertise necessary to evaluate them, the medical device industry is certain that their products will be assessed in a timely manner, and patients are at the center of new product development.

For more than a decade, the Alliance for Aging Research has been working directly with the FDA, other patient advocates, researchers, and industry on ways to streamline the regulatory process for the benefit of older adults. We understand that user fees play an essential role in maintaining FDA review processes that efficiently deliver safe and effective medical devices to patients who need them, and that is why we engage in the MDUFA reauthorization process.

Historical Perspective on the MDUFA Program

Prior to the third reauthorization of MDUFA, patient and consumer organizations were not able to engage in the negotiations between the FDA and industry. Thanks to you and your colleagues in Congress, the Alliance for Aging Research and other groups were represented throughout the patient/consumer stakeholder consultation phase leading up to third reauthorization of MDUFA. We had an opportunity to provide feedback to the FDA as negotiations were taking place and propose enhancements to be included in the final commitment letter that emerged from the negotiations.

Going into monthly consultation meetings with the FDA, we had two goals for MDUFA III. The first was to make sure that the Center for Devices and Radiological Health (CDRH) had sufficient

resources under MDUFA III to carry out timely reviews. The second was to secure support for a process through which CDRH would include patient views on the benefits and risks of devices during product reviews. After several monthly meetings with the agency, industry's desire for a more predictable and collaborative review process came into focus and the FDA expressed a desire to address personnel issues within CDRH. These challenges seemed to be impeding device review and delaying patient access.

MDUFA III allowed the application of user fees to help cultivate existing CDRH staff and to recruit and retain new talent. To strengthen the FDA's device review capacity, fees were aimed at hiring additional reviewers and reducing the ratio of reviewers to managers. MDUFA III also continued the FDA's third-party review program. This program is intended to reduce the review burden for lower-risk devices, by allowing FDA to leverage external experts.

To address the need for more predictability and collaboration in the review process for devices, MDUFA III included provisions aimed at improving formal and informal communication between the FDA and device makers. FDA took an important step by developing a formalized approach to address specific questions from industry prior to their submission of applications for products. FDA also implemented revised submission acceptance criteria, including an updated "refuse to accept" checklist, by which FDA would evaluate submissions to ensure that agency resources were focused on reviewing complete applications.

FDA's creation of a process for incorporating patient views on the benefits and risks of medical devices was an Alliance priority under MDUFA III. CDRH was a leader among regulators in aggressively pursuing a transparent and structured benefit-risk framework. Finalizing a benefit-risk guidance for devices was one of CDRH's first actions in MDUFA III implementation. The benefit-risk guidance, first issued by FDA in 2015, broadly defines the benefits they are interested in understanding. The type of benefit CDRH specifically calls out are not just a device's impact on clinical management of a disease and patient health, but also patient satisfaction, improvement in quality of life, improvement in function, reduction in lost function,

reduction in probable mortality, and symptom relief. For diagnostics, benefit could be assessed according to the public health impact, the ability to identify a specific disease and potentially prevent its spread, predicting future disease onset, providing earlier diagnosis of diseases, or identifying patients more likely to respond to a given therapy.

The benefit-risk guidance also laid out the ways in which CDRH assesses the magnitude of benefit, the probability of a patient experiencing benefit, and the duration of benefit. The guidance provides details, some examples, and a copy of the worksheet that reviewers use in their benefit-risk determinations.

Benefit-risk calculation is discussed frequently but there is the potential for this type of exercise to be more tokenism than substance. We feel that CDRH got the substance of the patient experience right and we think that is because they actively engaged with the patient advocacy community to best characterize disease severity and unmet need from the start.

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

MDUFA IV Agreement Benefits to Patients

The Alliance for Aging Research was fortunate to offer patient perspectives to the FDA through monthly stakeholder consultations and public meetings held over the last year as the agency negotiated the MDUFA IV agreement. We strongly support the continuation of this user fee program. 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. We would like to call your attention to the following sections of the agreement that we offered comment, during the stakeholder meetings.

I.) Supporting CDRH Workforce

MDUFA IV will lead to significant reductions in the time it takes the FDA to review the most common types of medical device applications. This will not only benefit industry, but also accelerate patient access. Under MDUFA IV, the FDA has committed to reduce the days for review of 510 (k) applications and for premarket approval (PMA) applications. FDA also set goals for reviewing *De Novo* applications. The number of *De Novo* requests has increased steadily since the pathway was created. The limited resources currently available to the agency for *de novo* requests have resulted in missed target dates for review in all but 40 percent of cases. Section II. E of the MDUFA IV agreement specifies that the agency set a goal of reviewing 70 percent of *de novo* requests on time by FY 2020.

Having expert FDA staff to carry out user-fee-funded activities is paramount. Without the necessary number and types of staff, the FDA will not be able to meet the ambitious performance goals for which the MDUFA IV resources are intended. Problems with FDA recruitment and hiring have existed for years because the agency lacked hiring processes and pay scales that were competitive with the private sector. The 21st Century Cures Act included some positive provisions to help FDA attract and hire new senior staff, but MDUFA IV provides CDRH with needed funding to hire across medical device review activities and cultivate existing staff. Specifically, Section III, B. of the MDUFA IV agreement, permits CDRH to apply user fees for the improvement of its scientific and regulatory review capacity. With these fees, CDRH intends to increase the retention rate of high-performing supervisors, reduce the ratio of review staff to supervisors, hire new device application reviewers, and utilize recruitment support to augment existing human resource services.

The Alliance for Aging Research is supportive of Section IV. E of the MDUFA IV agreement that seeks to bolster the third-party review program within CDRH. We advocated for the use of MDUFA III fees for the third-party review program so that CDRH's staff would have more time

to devote to higher-risk device applications. It is our understanding that third-party review continues to be valuable for lower-risk devices, but the program requires improvements to make it more efficient. We are glad that CDRH continues to have the resources and flexibility to employ outside experts as needed under MDUFA IV and that there will be improvements made to the third-party review program to ensure its integrity.

II.) Expanding Patient-Centered Medical Device Development

The Alliance for Aging Research applauds the FDA for fostering the use of patient preference information in the review and approval of medical devices. Of late, industry has begun including patient-centered endpoints in development programs, signaling a growing interest by industry to employ patient-reported outcomes in device trials with more regularity. FDA has responded by drawing patient representatives earlier into the device review process, developing a systematic benefit-risk framework for the evaluation of new devices, and creating a Patient Engagement Advisory Committee.

Section IV. F of the MDUFA IV agreement details activities that CDRH will take to further advance patient input and involvement in the regulatory process. CDRH will develop scientific expertise and expand staff capacity to respond to device submissions containing publicly available and validated, patient preference information or patient reported outcomes. This section also calls for public meetings to discuss approaches for incorporating patient preference information and patient reported outcomes as evidence in device submissions, as well as other methods of advancing patient engagement. CDRH will also explore ways to use patient input to inform clinical study design and reduce barriers to patient participation by facilitating recruitment and retention. The MDUFA IV agreement calls on the FDA to identify priority areas in which patient preference information could inform regulatory decision making and requires publication of these priorities in the *Federal Register*.

III.) Utilizing Real-World Evidence

The Alliance sought the application of MDUFA IV resources to elevate CDRH's ability to further real-world evidence generation for the purposes of informing regulatory activities. We believe that the collection of data generated through routine clinical care can help broaden our understanding of how products are working in the real world, support the incremental process of medical device development, and lead to optimal care.

Under Section IV. H of the MDUFA IV agreement, CDRH can utilize user fees to hire staff with expertise in the use of real-world evidence and establish a Coordinating Center for the National Evaluation System for health Technology (NEST). NEST will link health claims, electronic records, and registry data. In the future, these activities have the potential to decrease the number of stand-alone clinical trials, increase enrollment efficiencies, and make patient follow up less burdensome.

With MDUFA IV funds, the NEST Coordinating Committee will undertake a pilot program to explore the usability of real-world evidence for determining expanded indications for device use, new device approval, and device malfunction reporting. The NEST pilot program is particularly meaningful for our organization since older adults are not adequately represented in most clinical studies.

The Alliance for Aging Research requests one change to the MDUFA IV agreement. Section IV. H. states that "Industry representation on the NEST governing board will make up at least 25 percent of the governing board membership." MDUFA IV generally references anticipated representation of the patient community on the NEST governing board. We believe that the enacting legislation should detail the composition of the remaining 75 percent of the governing board and include representatives of patient populations most likely to be affected by increased utilization of real-world evidence (e.g. the elderly, those with multiple chronic conditions, women, etc.). If patient preference is truly a priority for the FDA and industry,

representation by patient representatives on the NEST governing board should be more clearly outlined.

Conclusion

As mentioned previously, the Alliance for Aging Research supports the continuation of the medical device user fee program through the negotiated MDUFA IV agreement. The Alliance advocates for increased overall funding of the FDA with strong emphasis on finding the right balance between user fees and appropriated funding. We think that the size of the proposed fees within the MDUFA IV agreement is necessary to increase the efficiency of regulatory processes, reduce the time it takes to bring safe and effective medical devices market, and put patients at the heart of medical product development.

Despite the opportunities afforded by MDUFA IV, we are all in jeopardy if the FDA's budget authority remains flat or is significantly reduced in the coming fiscal year. As you are aware, not all FDA activities can be supported through user fees. Crucial safety and surveillance activities as well as oversight of over-the-counter medications and other products, fall outside of the user fee programs. While FDA appropriations are not under the jurisdiction of this Committee, it is our hope that you will join us in calling for sufficient budget authority to maintain the overall health of this essential agency.

Thank you for the opportunity to present our views today. The Alliance for Aging Research looks forward to working with you on enacting legislation to reauthorize this important program. I am happy to answer any questions you may have.

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 5 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 Mr. Kieval follows:]

Testimony of Robert Kieval

Founder and Chief Development Officer, CVRx

Board Member, Medical Device Manufacturers Association (MDMA)

"Examining FDA's Medical Device User Fee Program" Hearing

March 28, 2017

House Energy and Commerce Committee, Subcommittee on Health

Thank you Chairman Burgess, Ranking Member Green and Members of the subcommittee for this opportunity to testify today. My name is Robert Kieval and I'm the Founder of CVRx, a small company that provides implantable medical technologies to treat patients suffering from heart failure or problematic high blood pressure. These are among the most prevalent, debilitating and expensive diseases for our health care system to manage, and our therapy, which is available today in Europe and hopefully will be soon in the U.S., stands to both improve patients' lives and significantly reduce the staggering costs associated with their care.

I'm also here today on behalf of the Medical Device Manufacturers Association, which was founded in 1992 to be the voice of the innovative and entrepreneurial sector of our industry. 98% of med tech companies have fewer than 500 employees, while more than 80% 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, remain 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 whom we're working to serve.

When colleagues of mine testified before this committee five years ago, our industry faced a crisis. A grandmother with heart failure in Sweden or an injured construction worker in Sicily could be treated with American medical technology years before they could have been here in the U.S. The regulatory pathways had become unreasonable, unpredictable and opaque, and the harsh reality was that American patients who desperately needed our innovations couldn't get access to them.

Over the past five years, under MDUFA III and other reforms including the FDA Safety and Innovation Act (FDASIA), the process has become more reasonable,

consistent and transparent. Implemented correctly, we believe that the proposed MDUFA IV agreement will further improve access for American citizens to safe and effective new medical technologies.

While speed is always important when lives hang in the balance, the MDMA membership overwhelmingly endorsed prioritizing quality, predictability and transparency in our negotiations. MDUFA IV contains ongoing provisions that include shared performance goals and process improvements, and important new elements including the establishment of a quality management infrastructure at FDA, consideration of patient perspectives in the design of clinical trials, and steps toward incorporation of real world evidence in the approval process. Here are just a few highlights:

As innovators, it's frustrating to us when we receive requests for data or deficiency letters that are unreasonable, without reason or aren't germane to the evaluation of a product's safety or efficacy. These result in needless delays and wasted resources for both us and the FDA. Under MDUFA IV, reviewers would now need to cite the

specific justification and applicable regulation for any deficiency letter or data request. This will ensure that queries are meaningful and that time spent by both parties is productive.

As FDA continues to grow and evolve, it's critical that it remains efficient, and MDUFA IV institutes a quality management program for this purpose. The team will report on the 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 it's incumbent upon 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 safety.

Surely, our health care 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 health care to deliver these as quickly and efficiently as possible. Thank you.

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 5 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 Mr. Daly follows:]

Testimony of Patrick Daly, Cohera Medical
House Energy & Commerce Health Subcommittee Hearing
"Examining FDA's Medical Device User Fee Program"
3.28.17

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. We develop surgical adhesives and sealants, including the first synthetic adhesive approved for internal use.

I'm pleased to testify today on the medical device user fee agreement on behalf of AdvaMed, which we, along with our sister associations MITA and MDMA, negotiated with FDA.

I thank you for convening today's hearing, and for your interest in improving medical device regulation for patients and industry.

The U.S. Medical Technology Industry

AdvaMed's member companies produce the medical devices, diagnostic products, and digital health technologies that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. Our members range from the largest to the smallest medical technology innovators and companies. Collectively, we are committed to ensuring patient access to life-saving 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. Fundamental advances in knowledge of human biology down to the molecular level and continued progress in a range of disciplines – computing, communications, materials science, physics and engineering – are fueling innovation, and the potential to save and improve patients' lives is almost limitless.

Patient access to advanced medical technology improves outcomes, enhances care quality, and generates efficiencies and cost savings for the health care system. For example, between 1980 and 2010, advanced medical technology helped cut the number of days people spent in hospitals by more than half and added five years to U.S. life expectancy while reducing fatalities from heart disease and stroke by more than half.

I've been encouraged by 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 start-up companies. Unfortunately, we have seen a sharp

decline in the number of new medical technology start-up companies each year, going from around 1,500 annually 30 years ago to around 600. Since the early 1990s venture capital (VC) investment in the industry has gone from about 13 percent of total VC dollars to about 4 percent in recent years. The time horizon for getting a new innovation from the bench to the bedside remains too long, and as a result investors are looking elsewhere.

FDA Regulation of Medical Devices – MDUFA IV

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 heading in the right direction to strengthen the medtech innovation ecosystem.

The ground-breaking process improvements that were built into the MDUFA III agreement, and the oversight done by this Committee, have led to improvements in FDA's regulation of medical devices. FDA has brought down the total time it takes to receive a decision from FDA on a product submission, while still maintaining the strongest standards for evaluating safety and effectiveness. Opportunities for engagement between applicants and FDA throughout the device review process have increased, leading to fewer misunderstandings and false starts, and a better understanding of FDA data needs. As a result, the consistency and predictability of the FDA review process has shown improvement.

Of course, there are many areas where FDA could further enhance the predictability and efficiency of its review process, and the new MDUFA IV agreement lays the groundwork for further FDA performance improvements through more ambitious goals, important process changes, and increased accountability, supported by additional resources.

This agreement is good for industry. It is good for FDA. And most of all, it is good for patients. We urge this Committee and the Congress as a whole to act promptly to reauthorize the user fee program and enact this agreement into law. Failure to act would not only jeopardize the critical improvements made by the new agreement but would have a devastating impact on our industry's ability to bring innovative diagnostics, treatments and cures to patients.

The user fee agreement builds the conditions for success in a number major ways:

Significant Improvements for Total Review Time Goals

Measuring the total time from submission to an FDA decision to either make that technology available to patients or deny approval is the most meaningful measure of the process. Total time goals were first included in MDUFA five years ago, and have been a meaningful measure for both industry and FDA. Building on the total time goal, this MDUFA IV agreement will continue to drive towards reducing the total time that is spent reviewing a submission.

The MDUFA IV goals for total time reviewing a product represent substantial improvements over current performance. For 510(k) products, which are moderate risk medical devices, the total time goal is currently 124 days. The MDUFA IV agreement lowers that goal to 108 days by the fifth year. This represents a 13% decrease, which returns the total time to historical norms.

For PMA products, which are the most innovative and highest risk products, the total time to decision goal is currently 385 days. The MDUFA IV agreement lowers that goal to 290 days by the fifth year. This represents a 25% decrease.

And for the first time, the MDUFA IV agreement includes goals for de novo products, which are generally moderate risk products but brand new innovations, which FDA has never evaluated before.

Patient Input and Involvement in the Regulatory Process

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. FDA's device center has taken several steps to incorporate the patient perspective into the device review process, through efforts such as voluntary patient preference information and voluntary patient reported outcomes, and this agreement will continue to support that work.

Process Improvements

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 such example is that the agreement provides for meaningful presubmission interactions between FDA and companies. Interactions between the sponsor of a medical device application and the FDA, prior to the formal submission of a product application, can provide helpful guidance that aids the sponsor in ensuring their application contains all necessary information. This presubmission process was first put into place five years ago, in MDUFA III, and has benefitted both industry and the FDA. This MDUFA IV agreement builds upon this success by adding in a specific time commitment tied to pre-submission meetings. Under the MDUFA IV agreement, FDA will be required to provide meaningful, written feedback to companies at least five days prior to a presubmission meeting, ensuring that the meeting will be a productive one.

Additionally, the agreement supports FDA's efforts to establish a National Evaluation System for Health Technologies, or the NEST. MDUFA funding will be used for a pilot to assess whether real-world evidence can be used to support premarket activities. This NEST pilot will determine the usability of real-world evidence for expanded indications for use, new clearances and approvals, and improved adverse event reporting.

Greater Accountability

Fourth, the agreement provides for greater accountability. Greater accountability means that FDA's success under this 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.

One of these critical accountability measures involves process reforms for deficiency letters, or letters that applicants receive when their submission is found by FDA to be lacking needed information. Under this MDUFA IV agreement, all deficiency letters will include a statement of what information was provided in a submission and why it is not sufficient, including specific reference to the basis for the deficiency determination. Additionally, all deficiencies will undergo supervisory review by management prior to being issued. These provisions ensure that deficiency letters focus on real data needs and that FDA is clear on what data they require.

In addition, the agreement provides for two analyses of FDA's management of the device review process. This review, or independent assessment, was a critical part of the MDUFA III agreement that helped lead to improvements in FDA performance. The MDUFA IV agreement continues this success by including funds for two additional independent reviews, one at the beginning of MDUFA IV and one at the end.

Enhanced Resources

Finally, to give FDA additional tools to meet the new goals, the agreement provides $999.5 million (FY15 dollars) in user fees for 2018-2022. This is built off of a baseline of approximately $679 million from MDUFA III, along with an additional $228 million in new resources to improve the device review process. In addition, there are $92.5 million in onetime costs for items such as IT and infrastructure improvements. Collectively, the 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 the sum of its parts. Each of the elements of the agreement reinforces the others.

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 the Congress will also be important. Patients are depending on all of us.

Conclusion

Finally, I should note that we are appreciative of 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, which should be the shared goal of all involved.

For example, legislation has been proposed to improve the consistency and transparency of FDA inspections of medical device facilities and to move to a risk-based system for device inspections. These common-sense proposals will ensure that FDA's inspections resources are best targeted to public health needs and that companies and FDA are working together.

I appreciate the committee's work in considering these and other appropriate measures that enhance and compliment the underlying user fee agreement, and its focus on enactment of this legislative package as soon as possible.

To reiterate, the MDUFA IV agreement is good for industry. It is good for FDA. And most of all, it is good for patients. We strongly support the vital improvements made by the new agreement and believe that a failure to act would have a destructive impact on our industry's ability to bring new, innovative treatments and cures to patients.

I thank the Committee for the opportunity to testify and urge you to act promptly to reauthorize this program, which is so critical to our industry, to the FDA, and to patients.

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 premarket 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 Ms. Wurzburger follows:]

STATEMENT

OF

DIANE WURZBURGER

EXECUTIVE OF REGULATORY AFFAIRS FOR GE HEALTHCARE

ON BEHALF OF

THE MEDICAL IMAGING & TECHNOLOGY ALLIANCE (MITA)

REGARDING A HEARING ON

"Examining FDA's Medical Device User Fee Program"

BEFORE THE
U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON ENERGY AND COMMERCE
SUBCOMMITTEE ON HEALTH

Tuesday, March 28, 2017

Summary of Testimony:

The Medical Imaging and Technology Alliance (MITA) represents manufacturers of medical imaging equipment and radiopharmaceuticals. 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.

The medical imaging community has been consistent in its desire for more predictability, consistency, transparency and timeliness throughout the device premarket review process. MITA and its members believe that all MDUFA commitments should be backed by appropriate, measureable and predictable performance goals that support these principles. MITA worked in good faith with other industry stakeholders and the FDA to negotiate the MDUFA IV agreement. We are particularly interested in:

- Reduction in 510(k) total time to approval;
- Performance metrics for the pre-submission process;
- The center-wide Quality Management program;
- The Accreditation Scheme for Conformity Assessment (ASCA) Program; and
- Third party independent assessment

We are committed to ensuring the ultimate beneficiaries of these negotiations, the American public, benefit from continued improvements in timely access to the innovative devices and diagnostics necessary for the public health. MITA urges Congress to move quickly to reauthorize MDUFA IV. This agreement, negotiated between FDA and the medical device industry, advances our shared goals of ensuring that patients have timely access to the most innovative devices and diagnostics necessary for the public health.

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 and User Fee program. I am Diane Wurzburger, J.D., RAC, Executive of Regulatory Affairs for GE Healthcare. I'm here today to testify on behalf of the Medical Imaging and Technology Alliance (MITA). I am an active MITA member, serving on the Board of Directors as well as Chair of the Technical and Regulatory Committee. 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. It represents companies whose sales comprise more than 90 percent of the global market for medical imaging technology. These technologies include: magnetic resonance imaging (MRI), medical X-Ray equipment, computed tomography (CT) scanners, 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 healthcare 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 toward the goal of providing patients with the safest, most advanced medical imaging currently available.

Value of Medical Imaging:

Medical imaging helps detect and diagnose disease at its earliest, most treatable stages and guides physicians and patients in determining the most appropriate and effective care. Our

technologies are fundamental to standards of care. By catching disease early, reducing the need for invasive, in-patient procedures and facilitating shorter recovery times, medical imaging saves money and improves efficiency in the health care system. Medical imaging technologies have revolutionized health care delivery in America and around the world. Extending human vision into the very nature of disease, medical imaging enables a new and more powerful generation of diagnosis and intervention.

Over the last 20 years, imaging has contributed to significant advances in healthcare delivery, leading to better health outcomes and reduced costs. For example, 20 years ago, an X-ray was used to detect lung nodules, but was limited in its capacity to detect small nodules. Now, low dose lung computed tomography (CT) finds tiny tumors the size of a grain of rice. This reduces lung cancer deaths by 20% compared to chest x-ray.

Today, technology that was once unimaginable is now the medical standard of care. The next generation of imaging technologies will further advance healthcare and the practice of medicine. A consistent and timely FDA review process is essential to timely patient access to these devices.

MDUFA:

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, ensuring that American patients have timely access to safe and effective medical devices. We support the FDA in proposing this

agreement to Congress and we will continue to partner with FDA and other stakeholders in asking Congress to reauthorize this important program.

User fees provide for a more efficient pre-market clearance process allowing for life-saving devices to get to market more quickly. We believe that enhanced FDA funding brings stability and predictability to the device review process and timelines. The goals that the medical device industry and FDA agree on and FDA's subsequent performance are critical to timely patient access to safe and effective medical advancements. 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.

MDUFA IV:

With this in mind, the medical imaging community has been consistent in its desire for more predictability, consistency, transparency and timeliness throughout the device premarket review process. MITA and its members believe that all MDUFA commitments should be backed by appropriate, measureable and predictable performance goals that support the principles of predictability, consistency, transparency and timeliness.

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 will the 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 includes a formal written request from a device sponsor for feedback from the FDA which is provided either in writing or during a meeting or teleconference. 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, measureable metrics under the MDUFA IV agreement.

To support the reduction in total time to decision, MITA believes that the FDA intention to include the basis for deficiencies in all deficiency letters will lead to a more consistent approval process. Being able to trace deficiencies to specific sections of a rule, final guidance, recognized standard or scientific or regulatory issue will lead to reduced total time to decision, align reviewer practices across branches and divisions and provide more predictability for sponsors.

Intense negotiations between FDA and industry led to the inclusion of a variety of programs in the MDUFA IV agreement that MITA is committed to working with the FDA to implement. Real World Evidence, Patient Input, Digital Health and 3rd Party 501(k) Review have the potential to support MITA's tenets of predictability, consistency, transparency and timeliness, and we look forward to participating in the development of appropriate infrastructure for these programs to ensure that they align with industry expectations, patient needs and support FDA's mission of protecting the public health by assuring the safety, effectiveness, quality and security of medical devices.

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 premarket 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 (ASCA) Program

. This program allows for devices to be evaluated according to specific recognized consensus standards by certified testing laboratories. FDA has agreed not to review full test reports from certified testing 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 premarket review program is providing a more consistent, predictable and timely decision by the FDA. We look forward to participating in the comprehensive assessment of the process for the review of device applications and think that it's important to not only complete the evaluation that was started under MDUFA III but to also begin evaluating the programs funded by MDUFA IV.

MITA maintains that the performance goals set forth in MDUFA IV are achievable and have easily understood and transparent metrics. These goals focus on reducing pre-market review times and improving the consistency of reviews.

Advancements in medical imaging are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. MITA looks forward to working collaboratively with FDA and Congress to develop a robust legislative proposal providing improved performance goals and reasonable user fees for value. 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 in timely access to the innovative devices and diagnostics necessary for the public health.

MITA urges Congress to move quickly to reauthorize MDUFA IV. This agreement, negotiated between FDA and the medical device industry, advances our shared goals of ensuring that patients have timely access to the most innovative devices and diagnostics necessary for the public health.

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

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 4 or 5 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 innova-

tive 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——

[Laughter.]

Mr. BURGESS. Recognized for 5 minutes for questions.

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 submis-

sions 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.]

[Material submitted for inclusion in the record follows:]

GREG WALDEN, OREGON
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FIFTEENTH CONGRESS

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April 27, 2017

Dr. Jeffrey E. Shuren
Director
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Shuren:

Thank you for appearing before the Subcommittee on Health on March 28, 2017, to testify at the hearing entitled "Examining FDA's Medical Device User Fee Program."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on May 11, 2017. Your responses should be mailed to Jay Gulshen, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to jay.gulshen@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Michael C. Burgess, M.D.
Chairman
Subcommittee on Health

cc: The Honorable Gene Green, Ranking Member, Subcommittee on Health

Attachment

[Dr. Shuren did not answer submitted questions for the record by the time of printing.]

Attachment — Additional Questions for the Record

The Honorable Gus Bilirakis

1. Why I have a question related to the topic of 3rd party repair of medical devices. Based on the information obtained by the FDA in the open docket and insight gathered at the public forum, do you see a need for FDA intervention to protect patients? Why or why not? If so, can you provide the Committee with insight around specific problem areas and next steps to address the areas of concern?

2. The Administration has imposed a "regulatory freeze" across the federal agencies, including the FDA. How does the freeze potentially impact the FDA's ability to move to next steps to mitigate patient risks associated with these patient safety and third party repair? With critical patient safety issues at play, can you offer any insight into the timeline of where the FDA is on this issue and what steps the Agency is now contemplating to address this issue?

The Honorable Richard Hudson

North Carolina is home to a vibrant life sciences industry and a large number of device companies. A priority for me is ensuring these companies have access to the most efficient review process possible. I understand that the MDUFA IV agreement continues the independent assessment process that was begun under MDUFA III, where an outside management consultant was brought in to evaluate the device review process.

1. Did you find that independent assessment process helpful?

2. Can you explain how it will be continued under this new MDUFA agreement?

The Honorable Michael C. Burgess

1. The overwhelming majority of medical device manufacturers are small, innovative companies that may only have one product on the market, if any, at a time. Can you talk about how FDA works with these types of companies to ensure a smooth submission and review process? How are small businesses accounted for in this proposed agreement?

The Honorable Frank Pallone, Jr.

National Evaluation System for health Technologies (NEST)

The National Evaluation System for health Technologies, or NEST, is a nongovernment system run by external stakeholders that will utilize real world data collected during clinical care that can be used in the pre-market review of medical devices, as well as post-market reporting and safety monitoring. I understand that the standing up of NEST has been a priority for the agency.

Q1: How will a robust NEST help with pre-market medical device reviews, as well as post-market safety monitoring of medical devices?

Q2: I understand that funding for NEST under MDUFA IV is limited to pre-market activities. Given the potential for NEST to help with post-market surveillance, why did MDUFA IV limit funding for NEST to pre-market activities?

Third Party Review

Under current law, FDA accredits external third parties to conduct reviews of certain low and moderate risk devices if desired by the device developer. The goal of this program was to allow FDA to prioritize its resources for higher-risk and complex device reviews, and to improve the review of low and moderate risk devices.

MDUFA IV outlines a number of steps the agency will take to improve the Third Party Review Program, including increased training for third parties, issuing guidance for accreditation criteria, and eliminating routine re-review. The commitment letter also notes that the agency intends to tailor the program.

Q1: Please describe further how the Third Party Review program was intended to work, as well as any issues FDA has identified with how the program is working currently.

Q2: How will MDUFA IV help to address the issues identified by the agency and ensure that the Third Party Review program is reviewing devices appropriately?

Pre-Submission Communication

Timely and meaningful communication between FDA and sponsors is critical to ensuring that both parties have a clear understanding of the standards and expectations for review, as well as the actions needed to receive timely approval of their device application. I understand that both FDA and industry agree that meaningful communication pre-submission can help to improve the efficiency of the device review process.

Q1: Can you please discuss further how the pre-submission process has been working in the MDUFA Program, and the steps MDUFA IV will take to further improve the pre-submission process?

The Honorable Anna Eshoo

FDA Pediatric Device Consortia Program

1) Please describe some of the successes of the Pediatric Device Consortia program.

2) Can you describe how the Pediatric Device Consortia program has helped to support the development of pediatric medical devices?

3) How has the consortia leveraged FDA's funding with other sources of funding to support pediatric medical device projects?

Pediatric Device Extrapolation

1) To what extent are device companies using the pediatric extrapolation guidance to support the appropriate labeling of devices for use in children?

2) Can you provide examples of how FDA's pediatric device extrapolation guidance has been used to approve pediatric labeling of medical devices?

3) How does the FDA currently inform companies that they can use pediatric device extrapolation?

Lack of Progress on Pre-Market Application Labeling for Children

1) In recent years, less than 5% of pre-market application (PMA) devices have been approved for use in children under the age of 16. What improvements can be made to the FDA's approval process so that the agency is approving more PMAs labeled for children under the age of 16?

2) What is the FDA doing to ensure that device technologies approved for adults and that could be beneficial in children are being studied and labeled for use in children, regardless of whether it is for the same disease or condition?

Humanitarian Use Devices

The Federal Food, Drug and Cosmetic Act requires to seek the approval of a local institutional review board (IRB) prior to using a humanitarian use device (HUD). HUDs are devices intended to benefit patients by treating or diagnosing a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year.

IRBs exist to review research, so this requirement seems to imply that HUDs are experimental devices that are not approved for marketing. This could negatively impact securing payment from insurers for HUDs, which thousands of patients rely on to treat rare disease and conditions.
1) Are HUDs experimental devices that are not approved for marketing? If they are not, are there other entities, other than IRBs, that are better suited to ensuring the safe use of HUDs?

The Honorable G. K. Butterfield

1. Do you believe NEST can address clinical trial enrollment efficiencies and can it be helpful in enabling greater diversity in clinical trials? How will PDUFA VI help with the development and approval of rare disease treatments?

2. Does the agreement also include funding to protect patient information used for real-world evidence?

3. Can you discuss the current process for FDA inspections of medical device manufacturers?

4. Does FDA provide any sort of advance warning to manufacturers before inspections occur?

5. Does FDA inspect all manufacturers with the same level of regularity and in the same manner?

6. I understand that hearing loss is not simple, where one description fits everyone's medical issue. You can have problems with the middle ear or in the inner ear or the hearing nerve or even a combination of the two. There are different treatment strategies for each. Then there's the issue of diagnosing the severity of the hearing loss in each ear, and it can be different in each ear. That's a lot of self-diagnosis to expect from consumers. What data exists to demonstrate that patients can (1) distinguish between conductive, sensorineural, and mixed hearing loss and (2) calibrate the severity of their hearing impairment so that they can self-treat with a hearing aid?

7. Primary care physicians are on the front lines of patient care, treating the whole patient over time, and referring to other providers when needed. They see the impact of hearing loss, and have recommended hearing loss screening be included in routine patient exams. The American Academy of Family Physicians practice recommendations also specifically state that older patients with likely hearing loss should be referred for audiometric testing. A recent study comparing professionally fitted hearing aids with pre-programmed out-of-the-box devices had each patient undergo the standard-of-care audiometric testing. It appears that pursuing this very broad category of OTC devices is designed to eliminate that step even when hearing loss is interfering with an individual's ability to hear and participate in conversations. I am concerned that eliminating all testing looks a bit like an experiment. If there isn't current scientific evidence that warrants ignoring recommendations of clinicians, what plans are in place to ensure the data supports the broad OTC category before it's implemented?

8. When you look at the various hearing loss severity scales, there is a 50 decibel range from the beginning of the "mild" category to the ceiling of the "moderate" category. Just 20 decibels separates this range from normal hearing on one end and profound hearing loss on the other. That means that these OTC devices, even with output limits, will have the potential to do damage. What studies have been or are being done to determine the safeguards these devices will require for safety?

GREG WALDEN, OREGON
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FIFTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115
Majority (202) 225-2927
Minority (202) 225-3641

April 27, 2017

Ms. Cynthia Bens
Vice President of Public Policy
Alliance for Aging Research
1700 K Street, N.W.
Suite 740
Washington, DC 20006

Dear Ms. Bens:

Thank you for appearing before the Subcommittee on Health on March 28, 2017, to testify at the hearing entitled "Examining FDA's Medical Device User Fee Program."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on May 11, 2017. Your responses should be mailed to Jay Gulshen, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to jay.gulshen@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Michael C. Burgess, M.D.
Chairman
Subcommittee on Health

cc: The Honorable Gene Green, Ranking Member, Subcommittee on Health

[Ms. Bens did not answer submitted questions for the record by the time of printing.]

Attachment — Additional Questions for the Record

The Honorable Frank Pallone, Jr.

Hiring Freeze and MDUFA

User fees under MDUFA also assist FDA in hiring and retaining the staff necessary to support the activities associated with the review of medical device applications. Under MDUFA IV, FDA has agreed to hire up to 217 employees by fiscal year 2022.

Q1: FDA has consistently had issues recruiting and retaining personnel in part due to the long hiring process, but largely due to the agency's inability to compete with the salaries of the private sector. While 21st Century Cures worked to address this issue, I am concerned that the federal hiring freeze proposed by this Administration endangers the ability for success. Can you discuss further what impact a federal hiring freeze could have on FDA and the medical device review process?

Trump Budget

I have grave concerns with the recent budget announcement from the Administration. In his proposal, the President proposes doubling user fees for medical product review to $2 billion, while simultaneously cutting the agency's budget authority. As you know, not all of FDA's critical public health responsibilities are funded with user fee dollars.

Q1: Will you please discuss further the types of public health activities at FDA that could be scaled back or negatively impacted by this proposal?

Third Party Review

Under current law, FDA accredits external third parties to conduct reviews of certain low and moderate risk devices if desired by the device developer. The goal of this program was to allow FDA to prioritize its resources for higher-risk and complex device reviews, and to improve the review of low and moderate risk devices.

MDUFA IV outlines a number of steps the agency will take to improve the Third Party Review Program, including increased training for third parties, issuing guidance for accreditation criteria, and eliminating routine re-review. The commitment letter also notes the agency intends to tailor the program.

Q1: Does the Alliance for Aging Research support the use of third parties in the medical device review process? If yes, please explain why. If no, please explain why.

Q2: How do you think MDUFA IV will help to ensure that the Third Party Review program is reviewing devices appropriately?

The Honorable G. K. Butterfield

1. What do you envision the pilot project for real-world evidence looking like? How will real world evidence help to combat health disparities?

2. How do you envision CDRH using patient input to inform clinical study design and how can that benefit your constituency?

3. How do you intend to share patient preference information with the FDA? How can smaller patient advocacy organizations also participate?

4. How do you see NEST helping to increase enrollment efficiencies and do you believe it will be helpful in enabling greater diversity in clinical trials?

5. You mention that currently on 40 percent of de novo requests are reviewed on time. MDUFA 4 sets the goal of reviewing 70 percent of de novo requests by 2020. What type of impact could that have on your constituency?

GREG WALDEN, OREGON
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FIFTEENTH CONGRESS

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April 27, 2017

Mr. Patrick Daly
President and CEO
Cohera Medical
227 Fayetteville Street
Suite 900
Raleigh, NC 27601

Dear Mr. Daly:

Thank you for appearing before the Subcommittee on Health on March 28, 2017, to testify at the hearing entitled "Examining FDA's Medical Device User Fee Program."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

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Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Michael C. Burgess, M.D.
Chairman
Subcommittee on Health

cc: The Honorable Gene Green, Ranking Member, Subcommittee on Health

Attachment

[Mr. Daly did not answer submitted questions for the record by the time of printing.]

Attachment — Additional Questions for the Record

The Honorable Richard Hudson

1. Mr. Daly, first thank you being here. It's an honor to have a North Carolina company representing the device industry on this panel. The medical device community is made up of both large manufacturers and small ones like yours. The MDUFA agreement includes improvements to total time review goals. Can you comment on these total time goals and what they mean for companies like yours?

The Honorable Frank Pallone, Jr.

Hiring Freeze and MDUFA

User fees under MDUFA also assist FDA in hiring and retaining the staff necessary to support the activities associated with the review of medical device applications. Under MDUFA IV, FDA has agreed to hire up to 217 employees by fiscal year 2022.

Q1: How did FDA and industry determine the number of additional employees that would be needed to help implement MDUFA IV recommendations?

Q2: Why is the hiring of an additional 217 employees at the Center for Devices and Radiological Health (CDRH) important to the implementation of MDUFA IV?

Support for MDUFA IV

Current statute outlines a detailed process for the reauthorization of the Medical Device User Fee Amendments. FDA is charged to not only negotiate with industry to develop recommendations, but also to solicit public input and hold public meetings, and 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 by January 15, 2017. The process that led to the ultimate transmittal of the MDUFA IV recommendations kicked off over a year and a half ago in September 2015.

Q1: Will you discuss further industry's role in the reauthorization of MDUFA, and in particular, the timeline for these activities?

Q2: As you know, the statute requires that the recommendations be transmitted to Congress no later than January 15, 2017, a deadline that FDA has already met. Does the statute allow FDA to transmit recommendations for the reauthorization of MDUFA at an alternative date?

Q3: MDUFA IV expires on September 30, 2017. What would be the impact to your company, and the member companies at AdvaMed if Congress does not pass the reauthorization of MDUFA before September 30th?

Q4: Do you support the MDUFA IV recommendations as transmitted to Congress?

Timeline for Review

Prior to the establishment of MDUFA, the medical device program was suffering from a lag in medical device review timelines, a lack of expertise among FDA personnel, and insufficient resources to maintain the program. MDUFA was first enacted in 2002 and has since worked to address these issues. One area MDUFA has had clear success in is reducing the total time to decision for medical device applications. The average total time to a decision on a pre-market approval (PMA) in 2015 has been reduced by 35 percent or 150 days over six years, and the average total time to decision for a 510(k) in 2015 has been reduced by 11 percent over five years.

Q1: The MDUFA IV agreement includes additional improvements on the total review time goals. Can you discuss further the improvements made in MDUFA IV and what they mean for companies like yours?

Pre-Submission Communication

Timely and meaningful communication between FDA and sponsors is critical to ensuring that both parties have a clear understanding of the standards and expectations for review, as well as the actions needed to receive timely approval of their device application. I understand that both FDA and industry agree that meaningful communication pre-submission can help to improve the efficiency of the device review process.

Q1: How has the pre-submission process been working from your perspective, and what steps will MDUFA IV take to further improve the pre-submission process?

The Honorable G. K. Butterfield

1. Can you discuss the current process for FDA inspections of medical device manufacturers?

2. Does FDA provide any sort of advance warning to manufacturers before inspections occur?

3. Does FDA inspect all manufacturers with the same level of regularity and in the same manner?

4. Does the MDUFA 4 agreement address any of the concerns the industry has related to inspections?

5. What can be done to bring more predictability and transparency into the process?

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