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EXAMINING IMPROVEMENTS TO THE REGULATION

OF MEDICAL TECHNOLOGIES

TUESDAY, MAY 2, 2017

House of Representatives,

Subcommittee on Health,

Committee on Energy and Commerce,

Washington, D.C.

The subcommittee met, pursuant to call, at 10:03 a.m., in Room 2123, Rayburn House Office Building, Hon. Michael Burgess, M.D. [chairman of the subcommittee] presiding.

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

Also Present: Representatives Dingell and Costello.

Staff Present: Ray Baum, Staff Director; Zachary Dareshori, Staff Assistant; Daryll Dykes, Health Fellow; Paul Edattel, Chief Counsel, Health; Jay Gulshen, Legislative Clerk, Health; Katie McKeough, Press Assistant; Carly McWilliams, Professional Staff Member, Health; Alex Miller, Video Production Aide and Press Assistant; Danielle Steele, Policy Coordinator, Health; John Stone, Senior Counsel, Health; Jeff Carroll, Minority Staff Director; Samantha Satchell, Minority Policy Analyst; Kimberlee Trzeciak, Minority Senior Health Policy Advisor; and C.J. Young, Minority Press Secretary.

Mr. Burgess. The Subcommittee on Health will now come to order. The chair recognizes himself for 5 minutes for the purposes of an opening statement.

Today's hearing is another step in the subcommittee's work to reauthorize the Food and Drug Administration's user fee agreements with industry. This subcommittee has held three hearings on the user fee program, during which time members have examined proposed agreements for generic drugs, biosimilar products, branded drugs, and medical devices.

Last month, bipartisan leaders of the Senate and House Committees on Health released a discussion draft to reauthorize those agreements. Today, we will consider several bipartisan bills intended to further improve the regulation of medical technologies. This is one of my top priorities, is to build upon this committee's work in the 21st Century Cures Act to get safe and effective treatments to patients and providers without unnecessary delay. H.R. 1652, the Over-the-Counter Hearing Aid Act of 2017, would implement recommendations from the President's Council of Advisors on Science and Technology and the National Academies of Sciences, Engineering, and Medicine.

Specifically, H.R. 1652 would direct the Food and Drug Administration to promulgate regulations establishing a category for over-the-counter hearing aids. This category of over-the-counter hearing aids would be limited to use by adults with mild to moderate hearing loss. Representatives Blackburn, Kennedy, and Carter introduced this bill to safely increase access and affordability in

the hearing aid market for millions of Americans from whom it would benefit.

Representatives Costello and Peters introduced H.R. 2009, the Fostering Innovation and Medical Imaging Act of 2017. This bill seeks to improve the regulation and the oversight of medical imaging devices intended for or used in conjunction with contrast agents.

H.R. 2009 takes targeted steps to reduce excessive regulatory burdens so that patients and physicians have access to a robust market of medical imaging technologies.

H.R. 2118, the Medical Device Servicing Safety and Accountability Act, also introduced by Representatives Costello and Peters, would require all medical device servicers to register with the Food and Drug Administration and maintain a compliant handling system.

Currently, only original equipment manufacturers are required to register and report. This bill seeks to increase visibility and accountability for all parties servicing medical devices in order to ensure that devices that are used for patient care continue to perform safely and effectively.

Representatives Bucshon, Peters, Brooks, and Butterfield introduced the fourth bill we will consider today, H.R. 1736. This bill would modernize the Food and Drug Administration's device inspections to increase its consistency and transparency. More specifically, H.R. 1736 would establish risk-based inspections, the schedule for device facilities, standardized inspection processes, and increased transparency around FDA determinations related to

inspections.

Each of these bills we will examine today is intended to increase innovation and increase access to medical devices and technology by making certain that the regulatory environment is consistent, effective, and agile, ensuring that patients and providers continue to benefit from safe and innovative medical technology.

This is a shared priority in our work to reauthorize the Food and Drug Administration user fee programs. I will thank all of our witnesses in advance for being here. I look forward to hearing from each of you about how these proposals might improve our ability to meet this goal.

I would like to yield my remaining time to Dr. Bucshon from Indiana for his opening statement.

[The prepared statement of Mr. Burgess follows:]

******** INSERT 1-1 ********

Mr. Bucshon. Thank you, Mr. Chairman.

H.R. 1736 seeks to improve the inspections process for medical technology manufacturers. The legislation achieves this goal by applying a risk-based approach to the frequency and nature of device establishment inspections resulting in a reduction of the burden on establishments with a strong history of compliance and by allowing the FDA to focus its resources where they are needed most.

H.R. 1736 also enhances the communication between the FDA and manufacturers to provide more certainty and stability for device establishments. I would like to thank Mrs. Brooks, Mr. Butterfield, Mr. Peters, for their leadership on this legislation.

I look forward to working with you, Dr. Shuren, as we move the legislation forward.

I yield back the balance of my time.

[The prepared statement of Mr. Bucshon follows:]

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

The chair now recognizes the ranking member of the subcommittee, Mr. Green of Texas, 5 minutes for an opening statement, please.

Mr. Green. Thank you, Mr. Chairman.

Thank you to our witnesses for being here today.

Today, we are examining legislative proposals to improve the regulation of medical technologies. Many of these ideas follow up on the work we did in 21st Century Cures Act and build on negotiated agreements between the FDA and stakeholders to reauthorize the medical device user fee agreement.

I want to thank the bill sponsors, the FDA, and the broader stakeholder community for their efforts to improve the innovation pipeline and ultimately giving patients access to technologies and therapies that can improve their lives.

One of the bills we are considering, H.R. 1652, the Over-the-Counter Hearing Aid Act, establishes a category for over-the-counter, or OTC, hearing aids. Approximately 30 million Americans have hearing loss, and that number will only get bigger as the baby boomer population ages. Despite being a common problem that has significantly hampered quality of life if left untreated, only 15 to 30 percent of the people who benefit from assistive hearings technologies actually use them. There are several reasons for low adoption rates, but one of the main barriers is cost. The legislation builds on a recommendation made by the President's Council of Advisors

in Science and Technology in 2015 and the National Academies of Sciences, Engineering, and Medicine in 2016 to allow for safe and effective OTC hearing aids to be developed.

The goal is to find an easier, less costly way to address hearing loss while providing for standards in products and FDA oversight to ensure safety. I look forward to hearing more about this important legislation.

We are also considering H.R. 1736, which would improve the process of FDA inspections of medical device establishments and for granting export certificates to foreign countries. The FDA is responsible for inspecting medical devices and medical device establishment to ensure consumer safety. Under current law, registered establishments of moderate- or high-risk devices are to be inspected every 2 years, though real-world feasibility of this has created discrepancies in the inspection process across the sector, which can be disruptive and don't necessarily advance patient safety. This bill models off of improvements we have made in inspections of drug facilities. It will help ensure the FDA is able to use its resources to protect patient safety while giving industry additional certainty and predictability and reduce preventable disruptions in the daily workflow.

We are also H.R. 2009, the Fostering Innovation in Medical Imaging Act. Contrast agents complement innovations in diagnostic imaging. They must be improved by FDA for specific use; however, due to the labeling constraints, FDA is hamstrung in its ability to improve the use of a contrast agent that has been approved for one part of the body

to be used in another despite extremely similar parameters of use. This legislation would allow FDA to improve the imaging device using a contrast agent if the contrast agent has the same dose rate and route of admission, affecting the same region of the body, used in the same patient population as the same imaging modality as the initial approval without the agent having to submit a supplemental application.

This challenge reminds me of what we dealt with when trying to improve the process in which antimicrobial susceptibility test can be used to update break points to test for resistance. I look forward to learning more about this commonsense reform.

Finally, we are considering legislation to bring more oversight and patient protections to the third-party servicing process. Many medical devices require servicing and maintenance over their lifecycle. This can be done by the original manufacturer or a third party. While original manufactures are required to registered with the FDA and comply with quality systems regulations and avoid adverse events, third-party services are not. There is a growing concern that not all third-party providers are equally qualified and that alterations to the devices, high-risk products, like an MRI machine, are not documented and can impact safety of use. Like a mechanic working on your car, improper servicing can have safety implications.

H.R. 2118, the Medical Device Servicing Safety and Accountability Act, will require third-party providers to register with the FDA, to maintain a complaint handling system, and submit severe adverse reports if they become aware of major malfunctions. I look forward to hearing

more about this important legislation.

Each of these proposals has been introduced in a bipartisan manner, and I hope to learn more about these worthy ideas.

And I want to thank our witnesses, again, for being here this morning.

Mr. Chairman, I yield back my time.

[The prepared statement of Mr. Green follows:]

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

The chair recognizes the gentleman from Oregon, Mr. Walden, chairman of the full committee, 5 minutes for opening statement, please.

The Chairman. I thank the gentleman from Texas, the chairman, for holding this hearing and our witnesses for your testimony today. It is very instructive and helpful in our work.

We meet today to once again discuss the FDA's vitally important user fee programs, as you all know. Throughout these hearings we have held examining them this year, I have reiterated the full committee's support for a timely reauthorization of these user fee agreement programs. Good news is we are well on our way.

To date, the Health Subcommittee has held hearings on each of these proposed agreements that were initially submitted to Congress back in January. Since that time, we have translated those agreements into legislative text, and the committee released that with the Senate Health Committee last month, bipartisan, bicameral. As part of that announcement, I have noted we will continue discussions in the House on other member priorities that could strengthen this important legislation.

So today's hearing is a great opportunity for us to learn more about four bipartisan medical device bills that could potentially be included in this effort.

H.R. 1652, the Over-the-Counter Hearing Aid Act, introduced by

Representatives Kennedy, Carter, and Blackburn, would require the FDA to issue regulations establishing a category of OTC hearing aids for adults with perceived mild to moderate hearing loss. Both the President's Council of Advisors in Science and Technology and the National Academies have called for this approach. I understand that some patient safety concerns have been raised, and I appreciate the testimony of the FDA and our other witnesses on this matter.

H.R. 2118, the Medical Device Servicing Safety and Accountability Act, introduced by Representatives Costello and Peters, would require both original medical equipment manufacturers and third-party service providers to register with the FDA and submit adverse event reports.

Now, several small businesses have raised concerns about the costs they would incur in registering. I am committed to ensuring patient safety while minimizing regulatory burden, and I look forward to learning more about this bill as it goes forward.

Meanwhile, H.R. 2009, the Fostering Innovation in Medical Imaging Act, also introduced by Representatives Costello and Peters, would clarify FDA's regulation of imaging devices and contrast agents. This bill includes commonsense changes that would streamline the regulatory review of these important technologies.

Finally, Representatives Bucshon, Brooks, Peters, and Butterfield have introduced H.R. 1736, which would improve FDA's risk-based approach for inspecting medical device manufacturing facilities both domestically and abroad.

We thank all of our committee members for bringing these bills

forward. We thank the testimony of our witnesses to help inform our decisions, and I look forward to discussing these bills further as we move this process along.

With that, I would yield to the gentlelady from Tennessee the balance of my time.

[The prepared statement of The Chairman follows:]

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Mrs. Blackburn. Thank you, Mr. Chairman.

And I want to thank you, Dr. Shuren, and all of our witnesses who are here today.

And, Mr. Chairman, I thank you for the hearing and being able to move these bills forward. It is so nice when we can say we have bipartisan legislation that we are moving forward. And Mr. Kennedy and I are pleased to have worked on the hearing aid bill, as it is called, H.R. 1652, and to see it finally moving forward.

I do want to say for the record that the Academy of Doctors of Audiology, the oldest independent national audiology association and the leading authoritative body in private practice audiology, has been a proponent of this legislation. It is a win-win situation for consumers, for patients, and for innovation. And the ADA notes that creating an FDA-regulated OTC hearing device market will foster competition, broaden consumer choice, improve affordability, and accelerate innovation without increasing existing risk to the public. As I said, this creates a win-win environment.

Additionally, in support of H.R. 1652, the Over-the-Counter Hearing Aid Act of 2017, I would like to submit a letter for the record authored by my Senate colleagues, Senators Warren, Grassley, Hassan, Isakson, and a letter of support by the Consumer Technology Association.

Mr. Burgess. Without objection, so ordered.

[The information follows:]

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Mrs. Blackburn. Thank you, Mr. Chairman.

I yield back.

[The prepared statement of Mrs. Blackburn follows:]

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

The chair now recognizes the gentleman from New Jersey, ranking member of the full committee, Mr. Pallone, for 5 minutes of opening statement, please.

Mr. Pallone. Thank you, Mr. Chairman.

Today we are examining additional legislation that would help to improve the way the Food and Drug Administration reviews medical device products. Medical devices have made enormous advances over the last few decades, and new and emerging technologies hold a promise to treat and cure diseases in ways previously not thought of. While not the subject of today's hearings, reauthorizing the medical device user fee amendments will help to ensure that FDA has the resources and personnel needed to continue to improve upon the medical device review process and to work with industry to bring devices to market more efficiently. And I look forward to working with my colleagues to have all of the user fee agreements considered and sent to the President hopefully early this summer.

I understand that members are interested in exploring the possibility of attaching additional policy to the user fee agreements. This hearing provides the opportunity to learn more about whether these bills meet the test of being noncontroversial and enjoying broad bipartisan support. And today we will be hearing from witnesses about the following four bills. I think that we have pretty much covered these bills. So I don't want to go into the details about them because

I think my colleagues have already done that.

So I just wanted to say I look forward to learning more from Dr. Shuren as well as our stakeholders about their interest in the legislation before us, and I would yield the balance of my time or whatever time he wants to Mr. Kennedy.

[The prepared statement of Mr. Pallone follows:]

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Mr. Kennedy. Thank you to Mr. Pallone.

I want to thank Chairman Walden -- both of them -- for convening this important bipartisan hearing today.

By beginning these conversations now, we can begin to prepare for innovation taking place in our districts across the country.

To all of the witnesses, thank you for taking the time to testify before our committee to help guide us as we consider these four bills. And I would specifically be interested in hearing your thoughts on our Over-the-Counter Hearing Aid Act.

Finally, to my cosponsor, Congresswoman Blackburn, it has been an honor to work with you on this bill. I am looking forward to working with you in the months ahead. I think the idea of a Blackburn-Kennedy-Warren-Grassley combination is a winning one going forward on a whole bunch of stuff.

So many of us here today have experienced the pain and frustration of loved ones beginning to lose their hearing. Shared experiences at large gatherings, like sporting events, concerts, become less enjoyable. Balance and health begin to decline. And even personal one-on-one conversations become challenging. Nearly half of Americans over 60 years old experience hearing loss. But a pair of hearing aids can cost anywhere from $4,000 to $6,000, and Medicare will not cover them. Too many of our neighbors, friends, colleagues, relatives will simply choose to suffer without relief.

With the innovation taking place in our districts and increased competition among businesses, we can improve the quality of hearing

aids and protect patients while simultaneously lowering costs. That is why Congresswoman Blackburn and I introduced this bipartisan legislation and why it already has the support of consumers, doctors, and industry. For Americans who are beginning to lose their hearing and the families who love them, we should pass this bill quickly.

Thank you very much to Mr. Pallone.

I yield back.

[The prepared statement of Mr. Kennedy follows:]

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Mr. Pallone. And I note -- thank you. I don't know if any of my other Democratic colleagues wanted time.

If not, Mr. Chairman, I will yield back.

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

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

And we do 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 begin with Dr. Jeffrey Shuren, friend of the subcommittee, Director, Center for Devices and Radiological Health at the Food and Drug Administration. We certainly appreciate you being here again today, Dr. Shuren. You are now recognized for 5 minutes for an opening statement.

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

Dr. Shuren. Well, thank you. Chairman Burgess, Ranking Member Green, members of the committee. Thank you for having me here today. I am pleased to be back to discuss potential changes to the medical device program.

I first want to say that I greatly appreciate your support for timely reauthorization of the medical device user fee amendments, or the MDUFA IV.

As you are well aware, MDUFA has been reauthorized every 5 years since Congress, including several members on this committee, first created the program. And as the program has evolved, FDA and industry have successfully negotiated agreements to improve patient access to medical devices and streamline regulatory processes. As we discussed just a few weeks ago, timely reauthorization of MDUFA is critical in order to maintain adequate staffing levels and ensure we fulfill our mission of protecting and promoting the public health.

Like you, we at CDRH want patients and healthcare professionals to have timely access to high-quality, safe, and effective medical devices first in the world.

Changes we have made at CDRH to our culture, policies, processes, in addition to user fee funding and direction from Congress through changes to Federal law, have resulted in reduced decision times,

improved medical device pipeline, and innovative technologies being introduced in the U.S. earlier than in the past. We want to continue on this course, and we appreciate that additional changes to the law can further advance this upward trend. Therefore, I appreciate the opportunity to discuss the bills before us today, and I look forward to answering your questions.

[The prepared statement of Dr. Shuren follows:]

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Mr. Burgess. The chair thanks the doctor for his testimony.

And we will move into the question-and-answer portion of the hearing. I recognize myself 5 minutes for questions.

And, Dr. Shuren, let me ask you: The Food and Drug Administration recently published guidance indicating that it would no longer enforce the requirement that adult patients provide a physician's medical evaluation or sign a waiver to purchase certain hearing aids. In making this announcement, the FDA noted that the medical evaluation requirement provided, quote here, "little to no meaningful benefit to patients," close quote.

Can you kind of take us through the FDA's decision to no longer enforce this requirement that had been in place since the 1970s?

Dr. Shuren. Yes. There had been several studies that had been done looking at the FDA's requirement that there be a medical evaluation if not the signing of a waiver. The conclusions were that this was serving more as a barrier, not providing benefit to patients, and then this was further reinforced by the recent recommendations by both PCAST and the National Academies of Sciences, Engineering, and Medicine, who both recommended that we no longer enforce that requirement.

Mr. Burgess. So, to the extent that it was an impediment, has it impacted consumer access to hearing aids over the years?

Dr. Shuren. That is our understanding from both consumers who have been asked about it as well as other experts in the field.

Mr. Burgess. And so the current -- the FDA's position currently aligns with recommendations put forth by the President's Council of

Advisors on Science and Technology and the National Academies of Sciences, Engineering, and Medicine?

Dr. Shuren. Yes.

Mr. Burgess. So Dr. Lin will testify on the second panel that there is absolutely no medical reason or rationale to consider limiting the intended use of over-the-counter hearing aids to only those individuals with a mild hearing loss. Do you agree?

Dr. Shuren. Yes.

Mr. Burgess. What, then, would be the implications of broadening that so that it included the mild and moderate designations in that category?

Dr. Shuren. Well, so, if there is an over-the-counter hearing aid category, it makes sense, then, it should apply to mild- and moderate-risk consumers, that the appropriate limits, let's say in output and labeling, could be put on those technologies for appropriate use by consumers. Limiting it to just mild, patients with mild hearing loss, may deny access for other patients who could benefit from hearing aids who otherwise won't be getting it.

You have to remember: Today, we have over 30 million Americans who may be suffering from hearing loss, but only around 20 percent actually go and get hearing aids. So most people don't even bother to get it. We have to find better ways to provide better access and better competition in the marketplace through technology.

Mr. Burgess. And then how could we address the concern -- like children are a special category with hearing aids, having had a family

member who went through this many, many years ago. What are the protections, then, that would exist for -- what would prevent a parent from just purchasing a hearing aid without an evaluation for a child?

Dr. Shuren. Well, we are still maintaining the requirement in place that there is medical evaluation, the signing at least of a waiver, for those individuals who are under the age of 18.

Mr. Burgess. Let me ask you: On the medical device -- the medical equipment issue, the FDA recently held a public hearing on whether and to what extent additional regulation of third-party service providers was necessary. I would ask you, first, what your takeaways were from that meeting and then, secondly, the comments that were submitted to the FDA? And if you need to provide those in separate testimony, that will be acceptable as well.

Dr. Shuren. Certainly. Well, we received about, I think, 176 comments to the docket. And the comments fell into two broad buckets. We heard from the original equipment manufacturers concerns about, at least in some cases, the quality of servicing that was provided by third parties, for example, some anecdotal cases where the safeguards in place in imaging technology to prevent overdose of radiation had been bypassed or cases where lower quality parts were used in the servicing, replacement of those parts for endoscopes.

We also heard concerns from those manufactures that some of the third-party servicers were not providing information about problems that were occurring. So they didn't have a good window of what was happening with their technology.

On the flip side, third-party servicers were complaining about the fact that they had some manufacturers who weren't making device specifications available, and they had proprietary testing methods that they were not making available, sometimes the need for training that was not made available, and sometimes parts, the replacement parts, not being made available and, therefore, challenges for them to provide good servicing. But everyone agreed there is a critically important role for third-party servicers in our healthcare system.

Mr. Burgess. So the underscore there was there was a critical need for the third-party servicers?

Dr. Shuren. Yes.

Mr. Burgess. Very good.

I yield back the balance of my time.

I recognize the gentleman from Texas, Mr. Green, 5 minutes for questions, please.

Mr. Green. Thank you, Mr. Chairman.

And, again, thank you for being here today, Doctor, and also the work that the FDA, last session, on the cures package.

Making hearing aids available over the counter holds a potential to help reduce costs and thereby increasing access to hearing assistance that might not otherwise be available for certain adult patients. As the FDA and Congress moves forward with the creation of an overall category for over the counter for hearing aids, there has been discussion about the need to ensure that we are adequately protecting patient safety to prevent patients from suffering any

further damage in their hearing.

Dr. Shuren, last fall, the FDA announced that it is committed to considering creating a category of OTC hearing aids and noted that OTC hearing aids could deliver new and innovative and lower cost products to millions of consumers. Can you discuss the benefits of creating such a category and how OTC hearing aids could improve access and affordability for patients but also to make sure these patients on their own are getting the right hearing assistance?

Dr. Shuren. So, on the one hand, as was mentioned, most people with hearing loss who would benefit from the hearing aid do not seek that out. So providing the opportunity for more access and affordability through competition could lead to then both a drive down on costs as well as better products on the market and easy access because they are over the counter. At the same time, we could see better safeguards put in place.

You know, in reality, there kind of is OTC products already there. So, for years, we have had these personal sound amplifications products where people with hearing loss are using them. They are not intended for patients with hearing loss, but they amplify sound, and so people are getting the wrong product for their needs. And there is a broad range of quality on them.

The second is, since the regulations we put in effect in 1977, we have allowed mail order of hearing aids -- you just have to provide the waiver -- and, since then, have allowed for internet access, and you can provide the waiver online as long as that is acceptable to the

State. What we don't have, though, is the right information for patients out there and output limits for some of those technologies to appropriately tailor for the needs of consumers.

So, if we went with an -- a true OTC category, we now could have better product available for consumers for what they really need, truly hearing aids rather than these personal sound amplifications, and available in places like the big-box stores that can provide good oversight, you know, the Walgreens of the world, better information for them so they know how to use it.

And then, lastly, we are seeing a change in technology. You know, before you had these preprogrammed hearing aids, and you really needed someone to fit them. Now we are seeing increasingly development of self-fitting, self-programmable hearings aids, which now allows, then, for better tailoring by the patients themselves, which means that, through OTC, we could provide the right product in the right way.

Mr. Green. Thank you. Thank you for your work and folks at the FDA last session, when we -- in your -- I want to recognize your engagement on the SOFTWARE Act. I think we got to a good place with that and deeply appreciate your input.

One of the provisions in the part of Cures requires FDA to evaluate device accessories on their own merit as opposed to classifying them just based on sophistication of the parent device. As I understand it, implementing the accessories provision is challenging. The FDA doesn't have any tools to do this efficiently.

Dr. Shuren, how is implementation of that provision progressing?

Do you feel that you have the necessary authorities to carry out these accessories provision in the least burdensome manner both to the FDA and the companies?

Dr. Shuren. Well, currently, we have some process challenges. If we are going to move an accessory that is currently in one classification and should appropriately be moved to another classification, the process is so burdensome that it draws away resources from our other day-to-day activities. So having a streamlined process could be very helpful to the agency. It would make us use our resources more wisely, and it would lead to the right reduction on unnecessary regulatory burden on manufacturers. None of this changes the scientific decisionmaking that the agency goes through to decide the appropriate classification.

Mr. Green. Thank you. I think this committee should consider following up on our previous work and look at ways to make the regulation of accessories more streamlined so that the intent of the SOFTWARE Act that was part of Cures can be realized. I look forward to working with the FDA.

And I yield back the balance of my time, Mr. Chairman.

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

The chair now recognizes the gentleman from Kentucky, Mr. Guthrie, the vice chairman of the committee, 5 minutes for questions, please.

Mr. Guthrie. Thank you, Mr. Chairman.

Thanks, Dr. Shuren, for being here again.

I want to pick up, I guess, where Dr. Burgess kind of left off dealing with the third-party medical equipment. I know you were talking about you are -- in the last hearing -- data-gathering mode. You were talking about the different comments that you received. At this point, has FDA made any determination on what direction to go?

Dr. Shuren. We have not. We are still talking with people, still gathering information.

Mr. Guthrie. Do you have any idea as you move forward what the registration would be like, or what would happen in them moving forward, or what fees might be associated with it?

Dr. Shuren. Right. So not at this time. I mean, I will say that, under current law, if you register with the FDA, then there are user fees that are applied, at least under current law.

Mr. Guthrie. Okay. A couple of years back, I guess we met in my office, and we discussed manufacturing of medical devices in the United States versus people relocating because of the regulatory environment. And we discussed how we can do things safely and effectively but also be less regulatory -- or be more friendly in a regulatory environment while securing safety and effectiveness.

And I have heard positive comments from different people about what is moving forward. Could you kind of talk about what is happening now with FDA in trying to safeguard the public but also have an opportunity to be more friendly in terms of people remaining here and not moving jobs overseas?

Dr. Shuren. So we have made a conscience effort over the past few years to make changes in our culture, our policies, our processes to sort of strike the right balance. What is the smart regulation to have in place? And, you know, when I first came to CDRH in 2009, by the end of that year, we had approved only 24 novel devices. By 2016, that number was 91, and it had gone up every year except for one.

In 2016, that is the most number of novel device we had approved since the start of the user fee program; second highest was the year before. And a lot of it comes to putting in place patient-centric benefit-risk frameworks, where we take into account not just the benefits-risks of the technologies but the benefits-risk tradeoffs of the decisions that we make. We have had a smart focus, I think, on the safety side, how we better use real-world evidence both to help technologies come to market but also to identify problems once they are on the market.

Mr. Guthrie. Thank you. And I guess I have heard very positive comments from people trying to do their business here in the United States and hire American workers. What is FDA doing to address the discrepancies between inspections of domestic and foreign manufacturing facilities, and what about discrepancies across different districts in the U.S.?

Dr. Shuren. So our field staff, which is under our Office of Regulatory Affairs, or ORA, is about to standup their program alignment, under which they are moving from a geographically based system, their inspectors, to one that is based on commodity. So now

there will be a medical device program with a director and where there are inspectors who only inspect device facilities that are across the country, but they report up to the same line of management. And like I said, that will get unveiled in the middle of May. Well, it will probably take about until -- about a little over another year to finish off the structure. We are also going to be looking at changes in their processes and their policies so that there is greater consistency in the inspections, both domestically and foreign, as well as people who are better focused on, I think, device inspections, which means getting higher quality reviews than they already do today.

Mr. Guthrie. Okay. Thank you.

I appreciate the work and the effort that you are doing.

That completes my questions. I will yield back. If you need more time, Mr. Chairman?

Mr. Burgess. The chair will be happy if the gentleman yields back.

And I will recognize the gentlelady from California, Ms. Eshoo, for 5 minutes of questions, please.

Ms. Eshoo. Thank you, Mr. Chairman.

Good morning, Doctor. Nice to see you. Welcome back.

The first comment, question I have, when I was preparing for today's hearing last evening, I immediately went to your testimony, and it is the first time I have seen testimony that really isn't testimony. I mean, you essentially say: "Good morning. It is nice to be here. We are reauthorizing this and looking forward to chatting

with you." That may not be the most professional description of it.

Why -- because we have I think, what, four bills before us, isn't there any comment or examination of today's hearing?

Dr. Shuren. So both the agency, Department of Health and Human Services, have been going through the legislation. We have been asked to provide technical assistance, and so that will be coming in time for review by the committee. But it has not finished going through clearance, and that is why you don't see --

Ms. Eshoo. Clearance for what?

Dr. Shuren. For the technical assistance. Just the usual process as that is reviewed and provided back to Congress.

Ms. Eshoo. I don't quite get that. You are not supposed to comment on what is before us in this hearing?

Dr. Shuren. Yes, I am commenting. I know people would like --

Ms. Eshoo. But I mean in written testimony.

Dr. Shuren. Yes, but because the technical assistance has not yet been finalized, that would be the substance if we were going into specific aspects on the testimony.

Ms. Eshoo. Well, I don't quite get it. But at any rate, it is the thinnest written testimony that, I think, I have ever seen in a packet. But at any rate, two questions: On the over-the-counter hearing aids, I think that the legislation moves in the direction that we need to go. What will protect people from buying the wrong thing? Just because it is over the counter is not make anything magical. And over the counter, does that connotate a savings in the mechanisms that

are bought? So, first of all, do we know that there will be savings, A? And, B, what about the consumer? How do they know what is best for them? They know that they need help, but I think the question is still out there between moderate and -- what is it? -- moderate and mild? There are two categories. That is my first question.

My second question is on inspections. In examining the legislation relative to both domestic and foreign inspections, does the legislation advance, I don't know, a level of thoroughness? Do we lose anything? What are we gaining? I am not so sure I understand what the difference is between foreign and domestic inspections.

Now, you just alluded to where you want to improve. It is going to take all of about a year to put things together. You are not quite ready for prime time to come out with that.

What does this -- does this legislation track with what you are attempting to do? Does it go beyond it? So those are my two questions.

Dr. Shuren. Certainly.

Ms. Eshoo. Questions within questions.

Dr. Shuren. Yes. So, regarding the OTC hearing aids, you first have to start with the practical reality that roughly about 80 percent of people with hearing loss who would benefit from a hearing aid never go to get one in the first place. So they never get --

Ms. Eshoo. So, if it is over the counter, you would calculate that, of the 80 percent that don't, that maybe 60 percent of the 80 percent will?

Dr. Shuren. I don't think anyone knows the percent --

Ms. Eshoo. We just don't know, right.

Dr. Shuren. What we keep hearing, even from consumers, is --

Ms. Eshoo. And we want them to get help. I want them to get help.

Dr. Shuren. Exactly. So that could get them in the door.

The second is their -- putting in place, are there ways in which consumers can better identify maybe the extent of hearing loss they had and what would be a better option for them.

Ms. Eshoo. How are they to know that, though?

Dr. Shuren. So there is going to be a meeting by the National Academies of Sciences, Engineering, and Medicine on June 9. That is going to be one of the topics of conversation. There is also we are seeing increasingly where some of the technology is building in the capability for us to assess the hearing capability of the individual, and that is one of the places where we see the marketplace going. So you have technology or at least opportunities through the internet for some assessment of the individual that may, then, help in the selection of the technology. And the other is, as we see more and more technologies that are self-programmable -- so they may not be locked in. They can then change the setting. But that is not going to happen if we don't create the competitive marketplace for it. That is the challenge that we face.

Ms. Eshoo. And inspections?

Dr. Shuren. And then regarding inspections, so for the thoroughness of foreign and domestic, both of them are thorough inspections. We spend the time we need to do. I think the challenge

people have raised is, why is it that foreign inspections may take less time than domestic? And in part, that is when we send our inspectors to other countries. That is all they are there for: They do the inspection. They are done. They are out.

On the domestic side, that inspector may get called away for another inspection, a for-cause inspection. They may be in the midst of one when they start another. Our field realizes they need to shrink that overall time for domestic inspections so that companies have better assurances it will be done more quickly. The overall time to do inspection, though, is pretty much the same. Most of those inspections are done in less than 4 or 5 days. Some of them are even done in one day.

In terms of the legislation, it is not inconsistent with what our field is doing. In fact, it is complementary. It is one of the challenges of the law today is we are supposed to inspect everybody every 2 years. Well, there are over 25,000 medical device facilities worldwide. We do about 2,400, you know, G&P surveillance inspections. That is -- so we can't even live up to the law.

And then we are kind of pulled towards you got to see everybody. We should be focused on and we can see the value in focus where there are the greatest risks and then tailor or our inspections appropriately. So that would be complementary to the change that ORA is going to make to the program.

Ms. Eshoo. Thank you.

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

The chair recognizes the gentleman from Texas, Mr. Barton, for 5 minutes of questions, please.

Mr. Barton. Thank you, Mr. Chairman. It is good to have you back. It is good to see you again.

On the hearing aid issue, what and who determines whether you have mild hearing loss or moderate hearing loss?

Dr. Shuren. So one is there are standards out there, and what we will likely do is start looking at, are there ways -- first of all, what matters most is, do consumers get the technology that is going to best meet their needs, putting aside what the definition of what mild to moderate is? And so part of what we are looking at is, are there ways to help consumers identify what would be the better technology for them. And we are seeing more and more from the technology developers then starting to create those services for consumers.

Mr. Barton. Would there be some sort of -- if you were going to -- let's say go to Walmart and they are allowed to sell over-the-counter hearing aids, would there be some sort of a protocol that there would be a sales clerk who could run some test and have a chart and say, "Okay, based on this, you have got mild," or "based on that, you have got moderate"? Something like that?

Dr. Shuren. I think it is premature to sort of say what would be the right mechanism to put in place. That will be part of further dialogue. Because if we were to move forward with an OTC category, it would be through a rulemaking process. So there would be lots of

other public engagement. That is why I -- you know, as I mentioned, there is going to be another meeting from the National Academies of Sciences that is going to start addressing these issues.

But there are a number of different options that may be in place. Like I said, there may -- some of the technologies themselves are starting to provide or will be providing tools for assessment. You may see there is also over-the-counter now audiometric testing that is available. And those will be part of a dialogue that we would have about, what is the right things to put in place?

The other piece is we would likely also put output limits on hearing aids depending upon for which of the patient population --

Mr. Barton. Well, at some point in time, if it were obvious that the individual seeking to purchase a hearing aid over the counter had more than mild loss, would the entity that was selling the over-the-counter hearing aid be required to refer them to a specialist so that you prevent somebody who really needs more than what the over-the-counter product can provide -- you give them a way that they refer to some of the trained people who can help them?

Dr. Shuren. So I don't want to get ahead of things, but that is one of the considerations about what do you do in the circumstance if the needs of the consumer is not being met. And that may be either through the recommendations we made back to the consumers or those who are providing assessment services.

Mr. Barton. Okay. On two of the other bills, 2118, the Medical Device Servicing Safety and Accountability Act, that would require

original equipment manufacturers and third-party providers, service providers, to register with the FDA.

Is that something that is a necessity that we need to do? Do you support that, or is that an open question?

Dr. Shuren. Well, we are still in the midst of looking at what would be the appropriate, if any, steps to take regarding third-party servicers. What registration does do is it at least gives you a window on who are those entities that are providing that kind of service.

Mr. Barton. But under current law, apparently, they are not required to register and to maintain a complaint system. So I am just trying to figure out, is there an issue in the marketplace today that would require that type of legislation? Is that a problem that is not being addressed and this is the correct remedy?

Dr. Shuren. Right. And so we are not at the stage where the agency or the administration has made a determination one way or the other on whether or what action should be taken. But we do view, if Congress has a perspective on what we should be doing, that would be very helpful.

Mr. Barton. You mean you are going to listen to the Congress? That is refreshing?

Dr. Shuren. We always do what you tell us to.

Mr. Barton. I mean, you always personally listen.

And I would ask the same general question about the 1736, the modernization of the FDA's risk-based approach. I strongly support a risk-based approach and would just be interested if the FDA has a

position on that legislation.

Dr. Shuren. Yes. So we do see great value in having a risk-based approach to inspections.

Mr. Barton. I yield back, Mr. Chairman.

Mr. Burgess. The gentleman yields back.

The chair thanks the gentleman.

The chair recognizes the gentleman from Massachusetts, Mr. Kennedy, for 5 minutes for nonconfrontational questions, please.

Mr. Kennedy. Never, Mr. Chairman. Thank you.

I wanted to start, Mr. Chairman, in a nonconfrontational way by submitting letters of support for the record for AARP, the ADA, the National Committee to Preserve Social Security & Medicaid --

Mr. Burgess. Without objection, so ordered.

Ms. Kennedy. Consumers United -- I still have a couple more to go. -- Hearing Loss Association of America and the Consumer Technology Association.

Mr. Burgess. I could hear you. I just wasn't listening.

Without objection, so ordered.

[The information follows:]

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

Mr. Kennedy. I need more coffee this morning. And thank you, again, Mr. Chairman.

Doctor, it is a pleasure to be with you. I appreciate your testimony.

I wanted to flesh out a little bit of your testimony earlier, and some of the questions I know have been asked by our colleagues on both sides of the aisle, of the dais here this morning.

One of the issues that has come up and that you did comment on briefly is around patients' ability to self-diagnose. And there is a critique out there saying that patients can't, and they are not entirely certain. They might know that they are losing some access to hearing, but some uncertainty as to how we might be able to craft a product that could meet their need given their unfamiliarity with it as a new product in the way that people now can go in and buy over-the-counter eyeglasses, but it might have been a little bit odd to do so when those first came on the market. I was wondering if the FDA might be able to -- if you could talk a little bit about the concern there and what the FDA has done in any research to mitigate that concern.

Dr. Shuren. So, at this point, since we haven't created that OTC category, we have not worked through all the issues about how patients might be able to appropriately self-diagnose and select other technology for them to use.

So we are still going -- we would go through a public process in crafting that. We would look forward to working with, you know, the clinical community, the patient community, the industry, and others.

That is likely to also be an evolving world, as also there is more competition in the marketplace. People will compete around their ability to provide assessments on hearing loss, not just simply the technologies to address hearing loss.

But all of this, keep in the context of the world today, where most people with hearing loss, and they are putting themselves at risk, greater risk, for dementia and falling and hospitalization, they are just not getting the technology they need. So I think whatever we do, there are going to be tradeoffs. I mean, we have to walk into this with our eyes wide open. But the public health challenges today are so great and the status quo today is not adequately addressing the needs of the majority of patients with hearing loss that an over-the-counter hearing aid category could be one way of trying to address those concerns if they are done right and ultimately provide consumers with more choice.

Mr. Kennedy. And we have seen some progress already around innovation. The FDA did approve an app, if you will, called iHear back in 2016, from what I understand, that does -- and it provides consumers with some ability to discern their needs. Is that so?

Dr. Shuren. That is correct. We will see more of that out there, particularly if there is a marketplace for consumers who would need testing within an OTC environment.

Mr. Kennedy. You also touched on a little bit before and just now the issue that patients should see a doctor. The question goes to whether the loss of hearing might be a precursor to a more serious

medical condition and that the ability to get something, a product, over the counter, might delay somebody from going and seeking the more advanced medical support that might be able to diagnose such an issue. Can you touch on those concerns at all?

Dr. Shuren. I think the real concern on the medical side is, do you have someone with a treatable hearing loss who otherwise didn't get medical attention? And then the practical reality is that you have only got about 20 percent of the people with hearing loss who are going for a hearing aid. And then, of those, you know, the anecdotal numbers are anywhere from 60 to 95 percent of those individuals opt to sign a waiver. So they are not even getting a medical evaluation.

So you have a tiny segment who are getting it. Then, in terms of the risky conditions, you know, things like cholesteatoma, acoustic neuroma, you add all those up, the really serious causes of hearing loss are maybe well under 1 percent. You know, your biggest treatable is probably ear wax, around 1 to 2 percent. So you are not likely going to miss many people. And most people, they are never going for the evaluation in the first place.

Now, on the flip side, if you had an over-the-counter category and we had information out for consumers, we could start telling them, "Look, if you have particular signs of symptoms," because most of the serious conditions have signs and symptoms, "so if you have drainage from your ear, go see your doctor," where right now they are not even getting that information to notice these. So it is possible, depending upon how this is crafted, we might get more people in, at least people

who should get a medical evaluation, to get one.

Mr. Kennedy. Thank you, sir.

And I yield back.

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

The chair recognizes the gentleman from Illinois, Mr. Shimkus, 5 minutes for questions, please.

Mr. Shimkus. Thank you, Mr. Chairman.

Thanks for being here, Dr. Shuren.

I am going to just kind of focus on this Medical Device Servicing Safety and Accountability Act. Can you describe your understanding of how medical equipment service providers are organized? Do you know how they are organized?

Dr. Shuren. As an industry or --

Mr. Shimkus. As an industry, association, et cetera.

Dr. Shuren. So there are trade associations for third-party service providers.

Mr. Shimkus. Do some of these work for the original manufacturers, or do they work for hospitals and clinics, or are they independent? Do you know?

Dr. Shuren. So you kind of have a mix. Some of these are independent, and then they may be contracted with by a hospital. Some have a very close relationship with the original equipment manufacturer. So the industry is somewhat varied.

Mr. Shimkus. Yes. So, in the second panel, we are going to have

testimony from Joe Robinson from the Medical Imaging & Technology Alliance and then Robert Kerwin from the Association of Medical Equipment Remarketers and Servicers, and obviously, there is going to be a conflict here between the two.

So I get -- and I think in some of the other questions and statements, there has been a -- you know, the basic question is -- I need an answer, but I am going to put it again -- right now, do you believe there is sufficient justification for the U.S. to legislate at this time?

Dr. Shuren. So we haven't taken a position on, you know, what, if any, is the right course to take. And so part of this dialogue is helpful to us.

Mr. Shimkus. Is there a survey being done or -- again, in the second panel, in the testimony, you will see some what I think anybody would say are kind of egregious photos of quick or maybe not even quick repairs to equipment. Is that a one -- you don't know if that is a one-time snapshot of one piece of equipment, or is that endemic of this sector of the healthcare delivery system?

Dr. Shuren. Right. So what we have at the moment is the anecdotes, which you have seen in testimony.

Mr. Shimkus. Is it anecdote or anecdotes?

Mr. Shuren. Well, I think it is -- you can comfortably say anecdotes. And this is -- one of the challenges we face is we don't have reporting requirements by third-party services in terms of problems that they may encounter or for complaints that they have, you

know, adverse events that occur, malfunctions, or complaints. And as a result, there isn't a great window on exactly what is happening out there as opposed to the individual experiences that you may get from an equipment manufacturer, from a hospital dealing with the service provider. And that is one of the issues of the absence of evidence. It doesn't mean the absence of a problem. It is just that it is hard to sort of say the state of it without having that ability for any kind of postmarket data collection.

Mr. Shimkus. And I think just why I think it is important to get information from you all before we move to see how endemic this might be as a problem overall because a couple of things: In rural America, small facilities, remarketing of equipment is very, very important. It is a great use for areas that don't have the ability to purchase new. The second thing is, obviously, we want these areas to be safe, but we also worry about the folks who are servicing those through organizations that they -- they don't incur additional costs where, then, they don't have the access to those medical device technologies in smaller rural areas.

I would hope that, as we move forward, you could be helpful with an analysis to say, yes, it is a huge problem, or, no, it is not a huge problem and how we can address this to ensure patient safety but also make sure we don't lose access to the smaller, more rural communities for the services that can be provided.

So, with that, I think this is a great hearing. These are all pretty important bills.

And I yield back the balance of my time.

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

The chair recognizes the gentlelady from Michigan, Representative Dingell, for 5 minutes of questions.

RPTR BAKER

EDTR SECKMAN

[12:00 p.m.]

Mr. Burgess. The chair recognizes the gentleman from Maryland, Mr. Sarbanes, 5 minutes for questions.

Mr. Sarbanes. I shouldn't take the full 5 minutes.

Thank you for your testimony. I was just curious, kind of as an aside, is the incidence of hearing loss increasing? Is there any evidence of that in the population? Not just because of an older cohort demographically, but just otherwise.

Dr. Shuren. We are seeing an increase in hearing loss in younger individuals, and that may be due to more people using, you know, headphones and earplugs.

Mr. Sarbanes. I am just looking for ammunition for when I tell my kids to stop using earphones all the time. So thank you for that.

Dr. Shuren. For ammunition, I would talk to ATF.

Mr. Sarbanes. I was curious if there are some other examples you could give of situations where there was a technology and service bundled together in a way that made it fairly expensive for people, particularly since there wasn't coverage by a private health insurance plan or by Medicare, where those, either the bundling has been pulled apart or it has led to the kind of over-the-counter solution that we are looking at in this particular case, or whether it might have led to a reevaluation of whether it ought to be covered by Medicare, for

example, and then Medicare became a leader on how that is handled, in terms of the commercial plans, et cetera. Are there any analogies you can point us to that are instructive either to the process that you are undertaking or generally to our understanding of this particular issue?

Dr. Shuren. I am not an expert in the area on the bundling of payments. So I don't have one offhand that is completely analogous. I know some people point to what has happened with reading glasses, but there are differences between that scenario and hearing aids.

Mr. Sarbanes. All right. Well, I will save that for another panel. Thank you.

I yield back.

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

The chair recognizes the gentleman from New Jersey, Mr. Lance, 5 minutes for questions, please.

Mr. Lance. Thank you, Mr. Chairman.

Good morning to you, Dr. Shuren. Regarding the third-party medical device servicing industry, do you know, Doctor, how many third-party companies are there?

Dr. Shuren. Offhand, I don't know the exact number.

Mr. Lance. Thank you. We have a bill, 1736, that tries to streamline the communications process during a facility inspection between industry and the FDA. If you would, Doctor, could you briefly comment on how the proposed changes in the bill could improve FDA's

ability to oversee device facilities and ensure efficient priority resources?

Dr. Shuren. From the inspection side?

Mr. Lance. From the inspector side. And do you think that it is likely that this would be a significant improvement in moving forward?

Dr. Shuren. So moving forward, you know, for risk-based would be very helpful to us. I mean, right now, given where the law is, we try to spread our resources around so we have a better sort of window on what goes out there. But being just focused on putting our resources where they are most needed would just be a smarter use of our resources and I think a greater public health bang for the buck overall.

Mr. Lance. Thank you very much.

And, Mr. Chairman, I yield back the balance of my time.

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

The chair recognizes the gentleman from Missouri, Mr. Long, 5 minutes for questions.

Mr. Long. Thank you, Mr. Chairman.

Doctor, do you believe that there are any safety issues introduced in using a contrast agent to image a different part of the body than is indicated in the contrast agent label?

Dr. Shuren. So there are some cases where that may be the case. If we are dealing with changes where we now could, like under the bill that has been introduced, have the ability to now approve some new

indications for the use of a contrast agent with the medical technology through the device presubmission application, I think one of the important features is we are able to make that determination based on safety and effectiveness, which is what we do, and then the ability not to go ahead and approve it if there would be an adverse impact on the safety and effectiveness of that contrast agent.

Mr. Long. Are you aware of any examples of the use of medical imaging technology with a contrast agent that was approved for use in other countries before it was approved for use in the U.S.?

Dr. Shuren. Yes. I don't have offhand, but, yes, there are things that occur in other countries that do not necessarily --

Mr. Long. So you are aware that there --

Dr. Shuren. As I understand. I don't have the --

Mr. Long. Can you have your folks get with my staff and let me know?

Dr. Shuren. Yes.

Mr. Long. It is my understanding that the regulatory situation for medical imaging devices used with contrast agents has gone unresolved for nearly 20 years. What do you think it will take for the agency to provide a reasonable regulatory pathway for medical imaging devices and contrast agents?

Dr. Shuren. The challenge we faced is attorneys have interpreted that we cannot go ahead and approve a medical device with a drug, like a contrast agent in that case, that is inconsistent with the labeling, the drug labeling, for that contrast agent. And that has been the

problem we have been dealing with all these years. We certainly see the value, public health benefits, in providing the opportunity for us to now go ahead and approve or clear the use of a contrast agent with an imaging technology through the device submission and, therefore, in the device labeling and maybe inconsistent with the drug labeling. And, again, as long as we have the ability, which seems to be in the bill, that we wouldn't approve or clear if there was an adverse effect on the safety and effectiveness of that drug, namely that the inconsistency doesn't lead to a problem otherwise in the safety and effectiveness of the drug, which that, under the bill, we have that ability not to then approve the product in that circumstance. This gives us a flexibility that today we don't have and gives us the ability to make those approval and clearance decisions in a least burdensome manner.

Mr. Long. Okay. Thank you.

And, Mr. Chairman, I yield back.

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

The chair recognizes the gentleman from Oklahoma 5 for minutes questions, please.

Mr. Mullin. I wasn't expecting that. I was expecting Bucshon to go next. Your question has been answered?

Well, thank you so much, Doctor, for being here.

Thank you, Mr. Chairman, for recognizing me.

At our last Medical Device User Fee Act hearing, we discussed my

concerns about the inconsistency that we see throughout the agency and especially the inconsistency that we see from inspections that happen here versus overseas. Has anything changed on that as far as implementing some standard operating procedures?

Dr. Shuren. Well, not since the last hearing.

Mr. Mullin. Do you think that Mr. Bucshon's bill would help this?

Dr. Shuren. So I think it may not directly address, but the opportunities for better interaction/collaboration between the inspectors and the firm that is being inspected is a step forward, and I think ultimately -- and this was a question you also had asked the last time -- you know, why will it take so long to make a change? Because ultimately, the big change that has to be made is a change in culture. And that is something the field recognizes, but as the head of a center that has been going through a culture change, I can tell you it takes a long time. Regarding the SOPs, they do plan to change the SOPs for conducting inspections so that they are constraining the amount of overall time it takes to do a domestic inspection. Right now, they have been focused on standing up the organizational structure on program alignment, but that will be officially launched as of May 15, and then they will be moving on to the other things they need to do, like changes in that SOP.

Mr. Mullin. If you are talking about the culture through the agency, how do you change that? I mean, legislation doesn't fix that. I was hoping that there would be something that we could point to that we could work together. As you and I had discussed, we want to work

with you. I think my colleague, Mr. Bucshon, that is the whole point of this legislation is helping to move that process forward to give you authority to build and go and implement. I mean, 3 years is what you said at the last hearing, that it would take roughly 3 years to implement it. As a business owner, I just can't see that. I can't see where it would take 3 years. Either people are on board or they are not on board; and if they are not on board, then they shouldn't be in that position.

Dr. Shuren. I appreciate that. First off, changes will occur in the program. And, again, I am speaking on behalf of another part of the agency, but I think people will start seeing changes in the program a lot sooner than that. But for the full change in the program, quite frankly, to change culture, you can't change it overnight. And, honestly, ask any company that has been through it, it does take a while.

Mr. Mullin. Sir, you don't have to ask any company. Ask me. I have been through it. We have several businesses. My wife and I, we have several hundred employees. I get it. We have purchased companies. We brought them in. There has been a difference. But when you send out standard operating procedures, "this is our policy," they are either on board or they are not on board. I understand the personnel, the training, and everything else does take time, but implementing a policy change shouldn't take 3 years to put in place.

And we are wanting to work with you. And I think that is the whole point of this legislation, is to work with you, but like we are here to help. So I am not wanting to get in a back-and-forth with you, but

I don't buy the whole thing that it is going to take 3 years. Yes, it can take several months. It could even take 12 months to completely change because it does take time to go through and educate people. Three years, though, at some point, they are not interested in doing their job. At that point, they are interested in just getting a paycheck, and that has to change.

Dr. Shuren. I appreciate that. And I do think in terms of getting to less time spent for domestic inspections, the overall time, that is not going to take years. That will take significantly less time. Putting the SOP in place, making changes, getting people trained up on that, and implementing that, I agree with you, is more on the order of a shorter term undertaking.

Mr. Mullin. And you may answer this, and then I will yield back after this, but do you support this legislation that my colleague is trying to push forward?

Dr. Shuren. We do see the value in moving to risk-based inspections and the importance of having better interaction and collaboration between the inspectors and the firms being inspected. And we do need, for export certificates, having that better streamlined and the resources we need to fully implement that and provide the export certificates can be helpful.

Mr. Mullin. So I am going to take that as a yes.

Dr. Shuren. [Nonverbal response.]

Mr. Mullin. All right.

Mr. Chairman, I yield back.

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

The chair recognizes the gentleman from Georgia 5 minutes for questions, please.

Mr. Carter. Thank you, Mr. Chairman.

Doctor, thank you for being here.

Some real quick questions, and then we will be done. I just want to make sure that we do have indepth studies that we can point to, for instance, from the President's Council of Advisors on Science and Technology and also from the National Academies of Sciences, Engineering, and Medicine, that they have noted through indepth studies that the requirement to obtain a medical evaluation before getting a hearing aid has really provided little usefulness and really become a barrier. True?

Dr. Shuren. True.

Mr. Carter. Secondly, that there is really no credible research that demonstrates that the medical evaluation requirement actually leads to the identification and treatment of conditions that you wouldn't probably catch anyway.

Dr. Shuren. So, while there can be value in a medical evaluation in select individuals, on a population basis and as it is currently applied, we see very little value.

Mr. Carter. Very little. Okay. And then, thirdly, there is really no evidence that the required medical evaluation as a condition to purchasing a hearing aid is going to improve the outcome for a patient

seeking hearing health care?

Dr. Shuren. No. I agree, within the current context of today, no, because also most people aren't even coming for the medical evaluation, or they are signing a waiver not to do it.

Mr. Carter. Right. Right. Okay. Finally, you are comfortable, you are comfortable that making hearing aids available OTC and unregulated devices, like the personal sound amplifiers, that this is not going to be somehow dangerous to consumers?

Dr. Shuren. We think that overall for the population of patients with hearing loss, this is likely going to be -- our sense is -- we see the value -- that we will receive greater benefit from this approach than harm that may occur.

Mr. Carter. So the benefit outweighs the risk?

Dr. Shuren. Yes.

Mr. Carter. Thank you, Mr. Chairman. I yield back.

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

The chair recognizes the gentleman from Michigan, Mr. Upton, 5 minutes for questions, please.

Mr. Upton. Thank you. I was sorry I didn't get the door opened fast enough. It was stuck when I came in the door, which is why it slammed. So I didn't get here in time for the gavel. But most of my questions have already been asked. So I just want to take this opportunity to again thank you for your help on 21st Century Cures. From the beginning, we wanted to make sure that the FDA, both on the

device side and the pharmaceutical side, had the right resources to be able to expedite the approval of these, particularly in a domestic way, knowing the jobs would stay here. And your participation nationwide was extremely helpful and constructive.

I know that one of the major issues that this subcommittee is going to be looking to move with Dr. Burgess' and Chairman Walden's support is both the PDUFA and the MDUFA bill. And I would hope that we could move those in the next number of weeks because we are all concerned that, without those resources, you will have to RIF the people that are there in the agency to make these various approvals by midsummer or so. So I just want to thank you for your good work. We look forward to continuing to partner with you and make sure that you have the appropriate resources to really benefit Americans as well as folks all across the globe.

So, with that, I yield back.

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

The chair recognizes the gentlelady from Michigan, Mrs. Dingell, 5 minutes for questions, please.

Mrs. Dingell. Thank you, Mr. Chairman. Thank you for allowing me to sit on the subcommittee today. I think this is a very important hearing, and it, quite frankly, is one of my passions, and I am going to confine myself to the OTC hearing aid legislation introduced by Mr. Kennedy and thank him for his leadership on the issue. It has been one of the issues that I have been working on since coming to Congress.

So I have my own legislation I would love to lobby my colleagues on to ensure that Medicare covers hearing aids.

Many of my questions have been answered, but I think I would like to clarify some of the numbers because I think people don't understand what the real impact is in society today and what is happening to people. Hearing loss is a quality of life, plain and simple. Nobody should feel isolated, confused, or shut out. And you and I both know, and so many of us in this room, that a lot of people are just because they can't afford to get the treatment they need; they don't have access.

Because of the groundbreaking research done by my friend, Dr. Lin, who we are going to hear from later, we know that hearing loss is linked to increased hospitalizations, and now we are beginning to see even dementia, early-onset Alzheimer's. So, to me, it is clear that we would have potential in reduced health costs and improved outcomes by increasing access to hearing aids. I think you would agree with me on that?

Dr. Shuren. Yes.

Mrs. Dingell. Thank you. So let me just clarify some figures because we have been dancing all around it. Dr. Shuren, is it correct that the National Academies of Sciences found that 30 million Americans today suffer from hearing loss?

Dr. Shuren. Yes.

Mrs. Dingell. And is it also correct that the prevalence of hearing loss increases with age?

Dr. Shuren. Yes.

Mrs. Dingell. Forty-five percent of people age 70 to 74 have hearing loss, and 80 percent 85 or older is what I am told. Is that pretty much what you have been told too?

Dr. Shuren. That sounds about right.

Mrs. Dingell. But even though it is a common condition and hearing aids have been around for decades, most people don't have access, and it has got a negative impact on their overall health. Is it correct that 67 to 86 percent of adults who may benefit from a hearing aid do not have access to one?

Dr. Shuren. Yes, that is about right.

Mrs. Dingell. The National Academies of Sciences I think said that only 15 percent of people who need the hearing aids of the 30 million may have actual access to them. So would you agree that the high cost of hearing aids is a major reason and that more people who suffer from hearing loss are not using them, and we need to find a way to do that?

Dr. Shuren. Well, we do need to find a way to have better access, and our understanding is that cost is one of the drivers.

Mrs. Dingell. So you did -- and you talked about it in your earlier comments -- that you issued the guidance not enforcing the FDA regulations that mandates the medical evaluation. Do you believe that creating an over-the-counter category for hearing aids will lower costs? You kind of danced it. You wouldn't commit to it. How far are you willing to go today to tell us how you think that that might be letting the marketplace -- my colleagues always want to talk about

the marketplace -- letting the marketplace work might help?

Dr. Shuren. We do think that, certainly in other scenarios, the marketplace would drive down the cost of those products, particularly as they are offered over the counter.

Mrs. Dingell. And it is important that we continue to put patient safety first. Anna and I have been sitting here, my colleague and I, for this entire time, but new innovative hearing aids are now more safer than ever, I understand. Is it correct that FDA did not receive any reports of corrections or removals regarding hearing aids between 2011 and 2015, and what does that tell us about the safety of products that are already on the market?

Dr. Shuren. I believe that is the case. I will have to go back to confirm.

Mrs. Dingell. And from an FDA workshop. Not that I studied the issue or anything. So, to me, it is clear that the current market is broken. I thank you for your work and hope we can all work together to find a way to really address this hearing issue.

Thank you, Mr. Chairman.

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

The chair recognizes the gentlelady from Indiana, Mrs. Brooks, 5 minutes for questions, please.

Mrs. Brooks. Thank you, Mr. Chairman.

I am very pleased that the committee is examining legislation. I worked with my Hoosier colleague, Congressman Bucshon, Mr. Peters,

and Mr. Butterfield, because the goal of H.R. 1736 is to bring more predictability and consistency to the device inspection process, and I hope the committee will include this bipartisan, bicameral measure in the final user fee agreement.

But I also appreciate the committee's attention to the oversight of third-party medical device service providers, because concern for patient safety should drive our decisions here. And when there are questions around how the work of some bad actors can hurt patients, it is our responsibility to examine this current system and see how we can improve on it. But, further, for those service providers who operate responsibly, we must be conscious of the precedent that legislation we might consider or might get set under H.R. 2118 certainly warrants discussion. I appreciate the opportunity we have here today.

Dr. Shuren, maintaining a safe and effective medical equipment management program is vital to any hospital or healthcare system. And according to industry estimates, a medium-size hospital -- I know we heard about rural hospitals -- a medium-size hospital can spend $5 million per year on equipment maintenance. An average-size health system can spend up to $50 million per year on such costs. TriMedx, which is located in my district, is the country's largest independent third-party service provider of medical equipment. They employ and manage almost 1,500 associates, who maintain more than 1.7 million pieces of equipment in over 240 hospitals across 32 States.

Mr. Chairman, I would ask unanimous consent to support TriMedx's written statement for the record. Thank you.

[The information follows:]

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

Mrs. Brooks. Dr. Shuren, independent third-party service providers -- and you talked about the importance, especially after receiving comments kind of on both sides of this issue -- who deliver this in-house medical equipment service, repair, and maintenance, such as TriMedx, act as agents for their hospital customers and ensure that their hospital customers comply with applicable regs. This includes, of course, overseeing or assisting with any internal investigations and reporting required. Because hospitals are already required, as I understand, to provide this information to the FDA, do you consider it redundant to also require third-party service providers to deliver the same information to the FDA?

Dr. Shuren. I think one of the issues is there is different information to be provided regarding problems that may be occurring with those devices in terms of servicing. For example, if there are complaints that are received to the third-party servicer, how are those being handled? Are they being followed up on? Are there records of them?

And you raised an important point. From what we understand in the marketplace, third-party servicers, the quality of what they provide runs the gamut. You have some exceptional firms who provide excellent servicing, and you have some that, from what we can tell, do not provide the same level of quality. There is sort of a discrepancy within the marketplace.

Mrs. Brooks. But the third-party service providers, their customer is the hospital. And when you say there is different

information, is that information that could be provided to the FDA by the hospital if the third-party providers -- if the hospital required it of the third-party providers?

Dr. Shuren. So some of that information wouldn't be information that a hospital otherwise would be required to report to the FDA.

Mrs. Brooks. But the hospital does have a number of requirements, of course, that it is required to provide. And so would that be an expansion of hospital requirements, because I don't think a patient -- and certainly, this is not always based on patient issues, but the technicians and other issues. Anyone would go to the hospital, would they not, with issues with respect to equipment in their own hospitals?

Dr. Shuren. No. So they may have equipment that is used on them, and they may complain to the original manufacturer, may complain to their doctor, any number of places where they may complain. And for the hospital's device user facilities, there is authority for sort of limited reporting to the FDA, which is different from the fuller spectrum of requirements that could apply -- do not have to apply -- to manufacturers, such as third-party servicers.

Mrs. Brooks. And all of the items when you gave your opening testimony that you listed as issues about third-party service providers or that the third-party service providers had about the manufacturers, is there a way, in your opinion, to remedy that nonsharing of information between the manufacturers and the independent service providers?

Dr. Shuren. There may be a way to do that. I mean, we certainly have in cases where there is high risk, higher risk, we have required that information on servicing and maintenance is made available with the technology. So we have done that, for example, with laser products.

Mrs. Brooks. Thank you. I am sorry. My time is up.

I yield back.

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

Dr. Shuren, we do thank you for being here. Ranking Member Green and I each had one followup observation or question, and I am going to go to Mr. Green first for his question.

Mr. Green. Thank you, Mr. Chairman.

Dr. Shuren, can you discuss the rules and requirements that currently apply to third-party service providers? For example, are they required to register with the FDA, label products they have repaired or remanufactured, or submit adverse event reports associated with their work?

Dr. Shuren. So, in our regulation on quality systems, we had made clear that third-party servicers are manufacturers, but they have been subject to enforcement discretion. We have not enforced those requirements.

Mr. Green. Okay.

Thank you, Mr. Chairman.

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

gentleman.

Dr. Shuren, we are going to hear testimony in just a few minutes from the Medical Imaging & Technology Alliance. And in that testimony, in the written testimony that was provided to the subcommittee, they talked about December 2009, the FDA released a guidance document entitled "Guidance for Industry for New Contrast Imaging Indication Considerations."

And that guidance was apparently part of an agreement under the medical device user fee amendments of 2007. I was here in 2007 on this committee. I sat way down in the front row on the minority side. You were not at the agency in 2007, were you? Do I recall that correctly?

Dr. Shuren. I was at the agency, but in a different position.

Mr. Burgess. In a different role. So I guess my observation or where you could be helpful to this subcommittee is, obviously, we want to get this done. And you heard Chairman Upton talk about the timeliness being important, and certainly everyone on this subcommittee feels that.

At the, same time, when I am reading this paragraph from the testimony from one of our next witnesses, Mr. Robinson, it occurs to me that language we put forward in this user fee agreement, I mean, here it is 10 years later, from 2007 to 2017. And I guess my request to you was, we so want to get this done, but we also want to get it done correctly, and we don't want to leave the burden in 10 years' time to another Congress to deal with problems that we have created that turned out to be insurmountable without another user fee agreement.

Do you understand what I am asking of you?

Dr. Shuren. I do. And I think the guidance that was put out in 2009 went as far as the agency was able to go under current law. So it has not addressed the concerns that we are seeing from the imaging technology makers and also by the contrast makers too, who have come together, I know, with a proposal.

So the bill, the value on the bill, we can see the potential public health value of now addressing situations that we could not address under the current law but may make sense to do for public health purposes.

Mr. Burgess. Very well. I thought we were through with questions, but I see the gentlelady from Tennessee is here. Let me yield to her 5 minutes for questions.

Mrs. Blackburn. Well, thank you so much. And I am not going to use 5 minutes. I apologize. I had to skip to a meeting.

I want to echo what Mr. Green said about the SOFTWARE Act and your work there with us. We were pleased to get that across the finish line in 21st Century Cures.

And on the over-the-counter hearing aid, I honestly believe this is something that does answer a problem. And for my colleagues, I give you a great example. I have a 92-year-old mother who is a pistol, and she is into everything. She is a busybody. They told her she needed a hearing aid, and she didn't like that. So she doesn't wear the hearing aid because she needs to go back to the doctor to get it fixed. Now, somebody like my mother, who is a DIY aficionado, if she can't

fix it herself, it is just going to have to wait because she doesn't have time for it. This is the kind of person who would buy it at the pharmacy, would go read it, and then would be able to use it because she has got one over here she can't use because it means she has to set an appointment and interrupt her day and get to the doctor and get back. And I think that is where, you know, for someone that has a mild or moderate hearing loss and knows it and is aware of it, this is an item of convenience. And just as readers have been a boon for baby boomers because you need a little bit of help reading, but you don't have any serious problems, or shoe inserts -- look at how that has helped for people with orthopedic issues -- or bandages or wraps or Benadryl cream, any of those other things that have moved to over the counter.

So I do see it as being consumer-friendly and something that, as you do have a generation of baby boomers coming along, will move people in the right direction for getting the health care they need. How many times have we heard people say, "Well, I have outgrown my readers. So I need to go and get a different" -- oh, Billy Long, I know that is you. You are outgrowing your readers there.

So, anyway, I just want to thank you for that. I do know that from what you have said -- you have already answered the question that I have -- is that you rely on the research from the National Academies and the guidance from the National Academies. So I thank you for that.

I yield back.

Mr. Burgess. The chair thanks the gentlelady. The gentlelady

yields back.

And, Dr. Shuren, this will conclude the question portion of this hearing. And we want to thank you for spending so much time with us this morning, and thank you for your thoughtful answers to the questions from the committee.

We are not going to recess. We are just going to go directly into our second panel.

So, Dr. Shuren, you are excused.

And we will get our second panel seated and immediately transition into opening statements from the second panel.

We do want to thank the witnesses on the second panel for taking time to be here today, taking time to testify before the subcommittee. As a reminder, each witness will have the opportunity to give an opening statement, and then this will be followed by questions from members.

We will wait for the second panel to be seated, and I will introduce them.

Again, we thank our second panel for being with us today. Introducing down the witness table, starting with Dr. Thomas Powers of Powers Consulting; Dr. Frank Lin, associate professor of otolaryngology, Johns Hopkins University; Mr. Joe Robinson, senior vice president of Health Systems Solutions, Philips North America; Mr. Robert Kerwin, general counsel, International Association of Medical Equipment Remarketers and Services; and Ms. Patricia Shrader, vice president of global regulatory affairs at Medtronic. We appreciate all of you being here today.

I will begin the panel with Dr. Powers. You are recognized for 5 minutes for a summary of your opening statement, please.

STATEMENTS OF THOMAS POWERS, PH.D., POWERS CONSULTING, LLC; FRANK LIN, M.D., PH.D., ASSOCIATE PROFESSOR OF OTOLARYNGOLOGY, HEAD AND NECK SURGERY, GERIATRIC MEDICINE, MENTAL HEALTH, AND EPIDEMIOLOGY, JOHNS HOPKINS UNIVERSITY; JOE ROBINSON, SENIOR VICE PRESIDENT, HEALTH SYSTEMS SOLUTIONS, PHILIPS NORTH AMERICA; ROBERT KERWIN, GENERAL COUNSEL, INTERNATIONAL ASSOCIATION OF MEDICAL EQUIPMENT REMARKETERS AND SERVICERS; AND PATRICIA SHRADER, VICE PRESIDENT, GLOBAL REGULATORY AFFAIRS, MEDTRONIC.

STATEMENT OF THOMAS POWERS, PH.D.

Mr. Powers. Chairman Burgess, Ranking Member Green, and members of the subcommittee, thank you for inviting me today. My name is Thomas Powers. I am currently a consultant to the hearing health industry. I received my doctorate in audiology from Ohio University and was in an audiology-based private practice and spent 35 years working in the hearing health field.

I am speaking today on behalf of the Hearing Industries Association, which is the national association of hearing aid manufacturers. These companies spend over $600 million per year on research and development for hearing aids which are at the cutting edge of hearing technology. HIA is supportive of efforts to enhance hearing affordability and accessibility.

We note that the market is already adapting to expand access and

affordability. Big-box stores, such as Costco and Sam's Club, now account for more than 10 percent of the market. In addition, CVS last week announced its major entry into the hearing aid market. All of these channels include professional testing, fitting, and followup.

NAS has recommended the creation of an OTC category of hearing aids, and we agree that such a category should be regulated by FDA, to ensure such products are safe and effective. As with existing hearing aids, OTC hearing aids should be required to demonstrate effectiveness through FDA's review process, as are other medical devices. Also, FDA should clearly differentiate hearing aids from unregulated personal sound amplifiers.

There are no studies to demonstrate that a person with hearing loss can accurately self-diagnose the degree and cause of their hearing loss. However, we believe that an OTC option may still provide a gateway to the hearing health treatment for many, if that option were promoted carefully and with the risks minimized.

When people finally address their hearing loss, often after many years of delay, if an OTC device promoted as a solution fails to meet the expectations, this may lead to frustration, further treatment delay, and even abandonment of efforts to address their hearing loss. Such treatment failure leaves the individual at greater risk of isolation, depression, falls, dementia, and other conditions related to untreated hearing loss. Given this risk, it is critical that OTC hearing aids be recommended for people with mild hearing loss, where the risks of failure and further delay of treatment are reduced. H.R.

1652, as drafted, would mandate the FDA recommend OTC hearing aids for people with moderate hearing loss as well.

Mild hearing loss is marked by having difficulty hearing soft speech sounds. Professionally fit hearing aids would certainly benefit this group. Mild hearing loss, as we have heard, impacts two-thirds of all Americans with hearing loss, although only 12 percent of these individuals currently use hearing aids. And, firstly, about 50 percent of individuals with moderate hearing loss use hearing aids. The degree of hearing loss is measured via an audiogram, using a decibel scale, and is classified by the FDA in five ranges, according to normal to profound. And I would like to enter this chart from the FDA into the record.

Mr. Burgess. Without objection, so ordered.

[The information follows:]

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Mr. Powers. Mild hearing loss ranges from 20 to 40 decibels loss; and moderate loss ranges from 40 to 70. A moderate hearing loss is not an insignificant condition. From my 35 years of experience in audiology, simple amplification is not ideal for people with a moderate hearing loss, as they may have more complicated audiometric configurations, such as high-frequency loss or hearing loss in the middle or low frequencies.

In addition, as the hearing loss progresses to the moderate category, the ability to understand speech may decrease significantly. Simply providing amplification across the range of speech frequencies may not provide the anticipated benefits and could lead to frustration with the process.

We do believe that FDA should create strict labeling requirements for the OTC hearing aids. Given this reliance on labeling, we believe it is more important that Congress and FDA only recommend OTC hearing aids for people with mild loss. People who have had their hearing loss diagnosed at a moderate level should be discouraged from self-treatment options. Output limits proposed in this legislation should be configured to set the gain levels appropriate for mild loss.

Access and affordability are important goals, but creating a new OTC hearing aid category should be done with care. Focusing on people with mild hearing loss would minimize the risks while at the same time providing an option for the vast majority of people with hearing loss who have not yet entered the hearing healthcare system.

Thank you very much.

[The prepared statement of Mr. Powers follows:]

******** INSERT 2-1 ********

Mr. Burgess. The chair thanks the gentleman.

Dr. Lin, you are recognized for 5 minutes for an opening statement, please.

STATEMENT OF FRANK LIN, M.D., PH.D.

Dr. Lin. Chairman Burgess, Ranking Member Green, and members of the subcommittee, thank you for inviting me here today. My name is Frank Lin, and I am an associate professor in the Johns Hopkins School of Medicine and the Johns Hopkins Bloomberg School of Public Health. From a clinical perspective, I am a board-certified otolaryngologist with fellowship training in otology and an expert in the medical and surgical management of hearing loss and other conditions affecting the ear. From a research perspective, I am a public health expert on the impact that hearing loss has on older adults and society. My interest in and testimony on the Over-the-Counter Hearing Aid Act stems directly from this background.

The OTC hearing aid bill, which we have been discussing, introduced by Representatives Kennedy, Carter, and Blackburn, directly reflects the early recommendations made by two expert committees: the President's Council of Advisors on Science and Technology, or PCAST, in 2015; and a National Academies of Sciences, Engineering, and Medicine consensus study in 2016. I advised PCAST on their report and was also a member of the National Academies' expert committee.

Both of these expert bodies concluded that the creation of an FDA

regulatory classification for OTC hearing aids for mild to moderate hearing loss would immediately benefit public health and Americans. The importance of the present bill instructing the FDA to carry out this recommendation is immense for public health. Over the past several years, research from Johns Hopkins as well as other academic institutions has clearly demonstrated that hearing loss, while being a usual process of aging for all Americans, is not without consequence. These studies have demonstrated that individuals with hearing loss are at a greater risk of developing dementia, having falls, and having greater healthcare costs. These research studies also clearly suggest that hearing loss treatments, such as using hearing aids, potentially decrease these risks and lead to real and tangible benefits for society.

And yet, currently, less than 20 percent of nearly -- updated figure -- 38 million Americans with hearing loss currently have access to hearing aids. The reason for this low rate of use stems largely in part from the current regulatory framework that only allows for a one-size-fits-all model of obtaining hearing care; that is, for an average American nowadays to obtain hearing aids, he or she has to make repeated trips back and forth to a licensed hearing professional, who basically serve as the gatekeepers now to consumers being able to obtain hearing aids. While this model is clearly appropriate for people with more severe hearing losses and more complex hearing losses, this model is extremely expensive, and it is clearly not needed by every one of the 38 million Americans with hearing loss. At present, the average cost of obtaining two hearing aids is about $4,700, which, when put

into perspective, means that, for the average American, a pair of hearing aids could be their third largest material purchase in life after a house and a car.

The passage of the OTC hearing aid bill would allow for hearing aids meeting explicit performance standards that would ensure safety and effectiveness for mild to moderate hearing loss to be directly available to consumers. Based on the scientific literature, the best studies we have to date, such devices could safely provide levels of amplification that would be effective for individuals with mild to moderate hearing loss. Both established hearing aid manufacturers as well as consumer technology companies that have economies of scale in manufacturing would then be able to enter the marketplace to sell devices directly to consumers that will come at a lower cost as many more are sold.

Importantly, the availability of OTC hearing aids for mild to moderate hearing loss does not in any way preclude the invaluable services in counseling, education, device programming that a hearing professional could provide. One would expect -- and we already see this, actually -- that many adults would, in fact, still want to seek out a hearing professional to learn how to use the devices and customize the device to their hearing needs, while others may learn to use these devices on their own, much like any other consumer electronic.

The important point is that the availability of OTC hearing aids for mild to moderate hearing loss would bring hearing technology out from under the explicit control of hearing professionals, such as me,

and allow consumers to choose what level of hearing care best meets their own needs and priorities.

I should note that some critics of OTC hearing aids commonly raise concerns about the safety of these devices to consumers, the risk of children using these devices, and whether these devices should only be for mild hearing losses. While, as a medical and surgical expert on hearing loss, I can appreciate where these concerns are coming from; these concerns are misguided and more often than not are being raised by parties who are more interested in preserving the status quo rather than truly improving the lives of Americans with hearing loss and advancing public health. These latter priorities are what mainly concern me as an academic as well as a physician, but also concern PCAST and the National Academies in their recommendations that serve as the direct basis of the wording of the over-the-counter hearing aid bill.

I provide a more extensive discussion of these concerns in my written testimony, and I am also more than happy to address further in questions from any of the subcommittee members. Thank you for allowing me to share my views with you.

[The prepared statement of Dr. Lin follows:]

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Mr. Burgess. The chair thanks the gentleman.

The chair recognizes Mr. Robinson 5 minutes for questions, please.

STATEMENT OF JOE ROBINSON

Mr. Robinson. Thank you, Chairman Burgess, Ranking Member Green, and distinguished members of the subcommittee. Thank you for the opportunity to appear before you today to discuss improvements to the regulation of medical technologies.

I am Joe Robinson, senior vice president of Health Systems Solutions at Philips North America and the chair of the MITA board of directors. I am here today to testify on behalf of the Medical Imaging & Technology Alliance in support of H.R. 2009, the Fostering Innovation in Medical Imaging Act, and H.R. 2118, the Medical Device Servicing and Accountability Act.

Before I get started, I want to also indicate MITA's support for H.R. 1736, also the subject of the hearing, to make improvements to the FDA's inspection process. And I will tell you that, after listening to my colleagues here on the panel, I very much support your hearing aid bill as well.

Let me start with contrast, H.R. 2009. Contrast agents may be prescribed by physicians for use with diagnostic imaging equipment to enhance imaging, allowing for improved visualization and characterization of organs and tissue. The use of contrast agents has

become an essential part of the clinical practice for a variety of imaging modalities. The FDA has not been willing to approve or clear imaging devices or enhancements for use with current approved contrast agents if they are not also labeled for that use, as Dr. Shuren had mentioned earlier. FDA believes that their regulations prevent them from doing so.

The purpose of H.R. 2009 is to provide clarification to the agency on an appropriate clearance approval pathway for imaging devices with contrast agents. Neither physicians nor patients benefit from the current situation, as new innovations are being held up at the agency, I believe you referenced earlier, since 2007, which was part of our submission. This legislation would allow patients to move in the U.S. to have more rapid access to new imaging technologies that involve the use of contrast agents.

MITA and CORAR have been working collaboratively with the FDA for decades to find a reasonable solution to the issue. In fact, the topic was addressed, as, again, I referenced just a moment ago, in MDUFA II, the agreement of 2007.

Mr. Chairman, you brought that up yourself.

Ten years later, the problem has yet to be resolved and continues to hinder the agency's goals of fostering innovation, improving patient safety, and promoting public health. This legislation builds on the 2017 user fee agreements, reduces unnecessary regulatory hurdles, and allows patients in all communities to access cutting-edge innovation and diagnostic imaging that helps physicians detect disease earlier

when it is more treatable.

To address service, H.R. 2118. As medical imaging device manufacturers, we are not only responsible for making the devices, but we also often provide servicing activities for devices, both our own devices and manufactured by other companies. There are also a number of nonmanufacturer independent service organizations who repair and maintain medical devices. In what is probably a surprise to many, currently only service activities performed by a manufacturer are regulated by the FDA. Service activities performed by a third-party independent service organization do not have the same oversight or quality, safety, and regulatory requirements. Third parties are not even required to register with the FDA -- I believe that came up earlier in some of the questions -- creating an enormous blind spot. Unfortunately, unregulated third parties have caused a number of patient safety issues in their attempts to repair medical devices. We have raised these concerns with the FDA and included examples in my written testimony, which I believe all of you received. In raising these issues, some have questioned our motives, accusing us of wanting to overburden third-party service providers. I want to emphatically state that our only goal is to ensure that all service and maintenance always results in safe and effective operation of medical devices. This is a patient safety issue, pure and simple.

H.R. 2118 takes an important first step toward the accomplishment of this goal by requiring that all independent service organizations step out of the dark and register with the FDA, file adverse event

reports, and maintain a complaint handling system. That is it; that is what we are asking for here today. These are reasonable, basic requirements which device manufacturers already meet, by the way, 80 percent of which are small businesses with fewer than 20 employees. These are minimum requirements that will give the agency information about how many businesses are engaging in servicing medical equipment and we hope will help get a better handle on adverse events to ensure that they never happen again. From a patient safety and adverse event avoidance perspective, this is the very least we can do for patients.

Patients and doctors have enough to worry about. H.R. 2118 seeks to protect patients and ensure effective device performance, to increase visibility and accountability for the medical device servicers. MITA urges Congress to include both H.R. 2009 and H.R. 2118 in the MDUFA IV reauthorization. Passage of both of these bills will protect the patient safety and ensure timely access to the most innovative technologies.

I want to thank you for the opportunity to testify and present my views in front of you today. I am happy to answer questions.

[The prepared statement of Mr. Robinson follows:]

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Mr. Burgess. The chair thanks the gentleman.

Mr. Kerwin, you are recognized for 5 minutes for an opening statement.

STATEMENT OF ROBERT KERWIN

Mr. Kerwin. Thank you, Mr. Chairman, Ranking Member Green, and members of the subcommittee, for this opportunity.

On behalf of the International Association of Medical Equipment Remarketers -- we call ourselves IAMERS -- we wish to express our thanks to the committee in permitting IAMERS to testify on behalf of the independent service organizations and small-business owners in our diagnostic imaging association. IAMERS members sell and service diagnostic imaging. We are not in the dark. We sell MRIs, CT, ultrasound, nuclear medicine, and general radiography. They are often alumni of OEM training programs who have gone on their own and service equipment at a much lower price in regional and rural hospitals. And we also assist the manufacturers, who may find a need for their assistance on multivendor programs.

Without further ado, we wanted to offer the top five reasons why this legislation should not be supported.

Reason No. 5: This is a solution for which there has been no evidence of a problem. As with the auto industry, not every repair needed go to a dealer or manufacturer. We are speaking of manufacturers as the largest companies in the world. Our small- and

medium-size businesses have been safely serving and servicing without registration with the FDA for many years. While some can present anecdotal stories of bad workmanship -- and we, in turn, can present some on behalf of the manufacturer should that have any merit, and we think not -- there has been no evidence to support a systemic problem. I am sure the hospitals would be contacting this body if such were happening, but don't take our word.

The respected scientific research institute, ECRI, after reviewing FDA MAUDE reports, has concluded there is no evidence to date that a patient safety problem exists.

The American College of Clinical Engineering also weighed in and commented that there is no real-world evidence needed to support further regulation.

The Joint Commission commented, and I quote, "No knowledge of any statistically significant level of safety problems resulting from activities of any kind of maintenance/service providers."

Penn State Health commented: very little evidence of systemic problems existing.

Reason No. 4: Independent service organizations offer their services at a significantly lower cost than manufacturers: $150 to $200 per hour versus $500 to $600 per hour, with a 4-hour minimum in some cases. Although, once competition is in the marketplace, we sometimes hear that, in fact, the manufacturers do lower their price. Our people are important for manufacturing competition.

Registration, however, with the FDA, as this legislation would

require, is, respectfully, a changed equilibrium and much more than filing a piece of paper. The act is burdensome and a costly process and would seek to impose many of the requirements currently imposed on a manufacturer for quality system service.

Reason No. 3: With the extra paperwork comes significant additional cost to be shouldered by the small- and medium-size business owners or passed on to the owners or possibly not continue. As detailed specifically or more specifically in my written statement, the complaint management system, the staffing, the training, the assessment costs, the outside auditors, there are significant additional costs that this legislation would require compliance with 21 CFR 820.198. This section basically requires every repair that is done to be cataloged, documented, and processed. In an area of smart regulation, this seems to be at odds.

Reason No. 2: This legislation will hurt rural and regional health care. The National Rural Health Care Association reports on its website that more than 75 rural hospitals have closed and 673 are vulnerable. Some of our members, indeed, service rural America. These are the small hospitals with dedicated staff but not all the resources of the larger facilities, and they depend on independent service organizations. Imposing these extra costs will require dealing with it somehow, some way, and perhaps passing those costs on. We are not seeing the corresponding benefit in either adding the cost or potentially having independent servicing less accessible. If this was such a significant problem, we again say, why have we not heard

the hospitals clamoring for this?

Reason No. 1: Put aside all the reasons for the moment. There is a body of information -- the chairman referred to it -- which may be tapped from the 177 comments to the FDA public record and the 2 days of an FDA workshop on this issue last year, in October of this last year. This information in its totality will not support passage of this act. And I ask respectfully -- and I believe Dr. Shuren may have referenced it -- if the transcript of the 2 days of proceedings, October 27 and 28, before the FDA may be entered into this record as perhaps the comments provided to the FDA on its electronic docket.

[The information follows:]

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

Mr. Burgess. Without objection, so ordered.

Mr. Kerwin. The conclusion is that we think if this was a significant problem, we would have heard the hospitals clamoring. At a time of rising healthcare costs and the demand for smart regulation, adding to the regulatory burden, which only serves to burden the small business, this is troubling and shouldn't be supported. This is an opportunity for industry collaboration, especially as independents do not always receive the passwords, the equipment manuals, and training from the original equipment manufacturer at reasonable cost. It is truly a time together to work for patient safety. Thank you.

[The prepared statement of Mr. Kerwin follows:]

******** INSERT 2-4 ********

Mr. Burgess. The chair thanks the gentleman.

The chair recognizes Ms. Shrader 5 minutes for your opening statement, please.

STATEMENT OF PATRICIA SHRADER

Ms. Shrader. Thank you, Chairman Burgess, Ranking Member Green, and members of the committee, for the opportunity to testify today.

My name is Pat Shrader. I am the vice president for global regulatory affairs at Medtronic.

Today, I am pleased to testify on behalf of AdvaMed, the Advanced Medical Technology Association. We believe we are on the right track with FDA's device center and that recent progress, combined with the provisions of the new user fee agreement, promise to keep things heading in the right direction to strengthen the med tech innovation ecosystem. We appreciate this committee's commitment to reauthorizing this important program, and we urge Congress to act as a whole to promptly reauthorize the Medical Device User Fee Program.

We also appreciate the committee's work in holding this hearing to consider additional measures that would improve the regulation of medical devices by advancing commonsense policies that will continue to improve the agency's operation.

We are speaking today in strong support of H.R. 1736, introduced by Representatives Bucshon, Peters, Brooks and Butterfield, to improve the medical device inspections process. The current inspection

process is plagued by challenges that lead to significant inefficiencies for both manufacturers and the FDA. There are great discrepancies in inspections between facilities in the U.S. as well as between facilities of the same company within the U.S. and outside. These discrepancies result in facilities being held to different standards.

RPTR GENEUS

EDTR SECKMAN

[11:57 a.m.]

Ms. Shrader. I do want to be clear about the next point. H.R. 1736 does not in any way limit or restrict FDA's authority to inspect medical device facilities at any time.

Medtronic, like other companies in our industry, understands the robust FDA inspections serve an important oversight function to ensure the public that we are succeeding in producing safe and high-quality medical devices.

What H.R. 1736 will do is improve the device inspection process to increase consistency, predictability, and transparency and to ensure that both FDA and industry resources are best targeted to public health needs.

H.R. 1736 has three main provisions: First, it establishes a risk-based inspection schedule for device facilities based on the risk profile of the facility. This commonsense shift to the risk-based approach to device inspections would ensure that FDA is inspecting where the risk to patients is greatest and is not utilizing important resources to repeatedly inspect facilities with good compliance profiles.

Second, the bill proposes standardized and enhanced processes including communications between FDA and the facility prior to, during, and after inspections. It is important to note that standardizing

processes and enhancing communications have played a key role in the improvements in the premarket review process leading to reduced review times. These will have a similar impact on FDA inspections. Timely communication can also help speed corrective action by companies being inspected where a correction is needed.

The last provision of the bill involves the lack of transparency that currently exists in the export certification process. In order to market medical devices in many countries, there is a requirement for documentation that devices are legally marketed in the U.S. and are in compliance with U.S. law. This documentation is called a certificate to foreign governments, or CFG. Due to an unclear interaction between FDA's inspection process and the CFG process, device companies can be caught in bureaucratic red tape that results in devices being lawfully marketed in the U.S. being denied certification for marketing in other countries. Clarifying this process would enable device manufacturers to continue to market our products to other parts of the world, thus strengthening our economy.

Again, we strongly support 1736 and urge the committee to pass this important legislation. I would like to note that we support a number of the other proposals that we believe would help improve the medical device regulatory process: H.R. 2144, which builds on 21st Century Cures to provide a streamlined procedural mechanism for reclassification of device accessories. We support 2118, an important step to assure that FDA has visibility into third-party servicing companies to ensure that devices in service remain safe and effective

in use. And, finally, I would note that several AdvaMed member companies also support H.R. 2009.

In conclusion, I appreciate the committee's work in considering these measures that enhance and complement the underlying user fee agreement to improve the regulation of medical devices. We look forward to continuing to work with you on these important issues and on timely reauthorization of the user fee program. Thank you.

[The prepared statement of Ms. Shrader follows:]

******** INSERT 3-1 ********

Mr. Burgess. The chair thanks the gentlelady and all of our witnesses for their testimony today.

We will go to the question portion of the hearing. And I will recognize the gentleman from Illinois 5 minutes for questions, please.

Mr. Shimkus. Thank you, Mr. Chairman.

Just two questions. Let's, first -- this one goes to Mr. Robinson, Mr. Kerwin. Obviously, there is a dispute here and which might likely cause this bill not to be included unless you all get together and work something out that seems to be helpful.

These people who repair the equipment are trained how, Mr. Robinson?

Mr. Robinson. As an OEM, we have -- and I can speak for Philips in my case -- we have Philips supply training, you know, based on factory protocols and engineers and --

Mr. Shimkus. So, if there is an independent person, they still have to be trained by you on your equipment. Is that correct?

Mr. Robinson. We offer training -- and, again, I am speaking for Philips --

Mr. Shimkus. That is fine. I am assuming most people are probably going to be similar.

Mr. Robinson. There are certain types of training that we offer to third parties as well.

You know, I would also add that Philips and all the member companies, as Mr. Kerwin had mentioned as well, we leverage and utilize third-party service a lot ourselves and, in many cases, are third-party

servicers --

Mr. Shimkus. Right.

Mr. Robinson. -- of other folk's equipment. So we actually have to send people for training on other equipment as well and organizations that do that.

Mr. Shimkus. Right.

Mr. Kerwin.

Mr. Kerwin. Congressman, many times however the equipment manufacturer, if you don't have a contractual relationship with them, will withhold the training. And we are always concerned about this because, from time to time, they will cite uneven levels of performance, and, yet, when we ask to have members trained, unless you have a contractual relationship, more often than not it is declined. I kind of look at it by the football analogy of knocking someone down on the field with a hard hit and then claiming later there might be a delay of game.

Mr. Shimkus. Well, you know, this is a very similar debate that we have had in this committee -- and I think it was alluded to -- to the automobile manufacturers and the independent repair folks who always there is a debate about getting the data, getting -- being able to hook up to the computer module or also what type of equipment to replace. So it seems like the similar type of dispute that we have had.

And I guess I would just say there are -- also, part of the discussion was cost incurred to -- and I said is this in my opening -- in

the opening round of questions, the projected costs incurred to small, rural, or regional hospitals. So, Mr. Robinson, do you accept that as part of the concern?

Mr. Robinson. The costs -- first of all, I want to get -- be clear. What we are requesting here is the registration and a complaint system. That is it. That is the request --

Mr. Shimkus. But Mr. Kerwin said there would be -- every repair, visit, would require additional -- a filing of what occurred. Is that correct?

Mr. Robinson. I don't think that is the case for a complaint filing. You file a complaint when there is a problem or an adverse event. That is when that occurs.

Now, what they would incur, as I think Dr. Shuren implied, under the current regulation, there is a registration fee to register with the FDA. I am not sure of the exact amount of fee. I think it is a few thousand dollars. It would be required by everybody who registers, but, you know, I think it would also be in the discretion of the FDA if they wanted to waive that fee as a point if that were burdensome to the small business. But that is not our request.

Mr. Shimkus. I am going to stop on this. I am going to just for the hearing aid debate, and I think it is just helpful because a lot of us aren't practitioners in the field. So I looked up -- so hearing loss is classified in mild, moderate, moderately severe, severe, profound, and deaf. Is that correct?

So the only dispute that you all have is between mild and moderate

while we still have moderately severe, severe, profound, and deaf. Is that correct?

Mr. Powers. Yeah. I would agree. I think that there is also, I think, a small difference in defining mild, moderate, and then moderately severe, how many categories you really have, and where does it extend? I think the concern comes from the current definition used within FDA, up to 720 dB hearing loss, which is a significant hearing lost, and those folks in many cases may require the services of a professional. So our view is that the mild hearing loss is certainly one that should be promoted through the OTC category for the vast majority of people have mild hearing loss and would benefit the most from.

Mr. Shimkus. And Dr. Lin, you think -- you all -- in your testimony, you think that OTC could also comply with the moderate hearing loss?

Dr. Lin. Yes, absolutely. I mean, from the several perspectives. I mean, from the clinical perspective, mild to moderate is on a natural continuum. There are no sharp barriers. We see right now moderate hearing loss affects about 30 percent of everyone with a hearing loss. So you are talking about cutting out 30 percent of the marketplace, and consumers could benefit from the mild to moderate. But from a clinical perspective, there is no such thing right now as a hearing aid only for mild hearing loss or hearing only for moderate hearing loss. Right now, it is the same thing, basically. So, by trying to limit to mild hearing loss, we are essentially limiting the

functionality of that hearing at eventually to 30 percent of the people with hearing loss out there, saying, "I am sorry, but you will have to go through the standard channels and pay $4,500."

More from a research perspective, the best clinical trial to date funded by the NIH, completely independent academic medical center, demonstrably showed that treatment of mild to moderate hearing loss with over-the-counter hearing aids is effective. So that is a scientific perspective.

Now, more important, I think from a larger perspective, I think it is easy to frame this as an either/or. You have to either get an over-the-counter hearing aid, or you have to go see a clinician. There is nothing in between. It is just not true. It is a very much an "and" phenomenon.

And already what we are seeing right now with availability of and more attention paid to over-the-counter devices is that more patients are coming to my clinic now and seeing my colleagues saying, "You know, I have heard of this an over-the-counter device. Would this be relevant for me? Could I use this?" So, in many cases, you may have someone with a maybe moderate hearing loss. They try a device. They think it works. It may not be great. It drives them to see the clinician. The clinician can help them. It is not an either/or phenomenon.

By limiting it to mild hearing loss, that means when a patient goes to see, let's say, an audiologist, then the audiologist can't even help them anymore with the over-the-counter device because there is

a cap placed on how much benefit could be obtained from it. I think -- it comes under safety, and it comes under efficacy. I think both have already been well established both clinically. I think it is a testament to the American Doctors of Audiology, the leading audiology group for private practice audiologists, already coming on full support of this as well as multiple medical organizations.

Mr. Shimkus. Excellent. Thank you.

I yield back.

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

The chair recognizes the gentleman from Texas, Mr. Green, 5 minutes of questions, please.

Mr. Green. Thank you, Mr. Chairman.

And, Dr. Lin, I know you have been involved in research that led to recommendations by two expert committees, both of which concluded that the creation of an FDA regulatory classification for OTC hearing aids would benefit the public. Can you elaborate on this work? I think you did that in your testimony and some other -- it would help, obviously, for the cost, but it also may drive people to a professional because they find out that they don't -- that the over-the-counter may not work. It is kind of like my colleague's reading glasses that he bought at the drugstore.

Dr. Lin. Yes. So very much I think that is the case, Representative Green. I think what we are seeing right now is already, with increased attention paid to hearing loss over-the-counter

devices, it is driving people to ask about their hearing, to come in to get evaluated, and then they may still go and get an over-the-counter device, but a lot of times under the guidance or advice.

I think the tendency is to think, well, if you have an over-the-counter device, all of the sudden, people are going to want to avoid doctors; they are going to want to avoid audiologists. It is exactly the opposite. As we have a regular over-the-counter category, which is broadly applicable to the vast majority of Americans with hearing loss, it drives someone to ask more questions about hearing loss. It drives more people to go to their physicians and say, "I have heard these devices are available. Would you help me decide?" It is a very much the opposite, I think, in terms of what would actually be projected to happen by some people in the industry.

Mr. Green. Thank you.

Mr. Robinson, we know certain types of medical devices and types of technology often require servicing and maintenance and repair. Hospitals and health systems have a right to rely on any of the original or a third-party service entity to fulfill that maintenance decision. The bill that we are considering today, H.R. 2118, would require third-party service entities to register and report certain adverse events and malfunctions to the FDA.

In your understanding, is that all this bill does?

Mr. Robinson. Yes. That is all this bill does. And the other thing I would point out: it excludes hospital-owned in-house service --

Mr. Green. So if you are an employee of the hospital, you know

where the responsibility is?

Mr. Robinson. Right. Exactly.

Mr. Green. Can you discuss briefly why you feel legislation in this area is needed and the types of issues associated with third-party servicing that your company is aware of?

Mr. Robinson. Say -- can you repeat the question, sir.

Mr. Green. How did you -- since you support the legislation, what types of issues associated with third-party servicing that your company has become aware of?

Mr. Robinson. Oh. Well, what we -- as MITA, we submitted, I don't know, a big document of a number of adverse events that have been documented by member companies when they have been encountered and not being serviced by them. So it is a -- I don't know; there are over 30 examples that are in there.

I would also tell you: In terms of complaints in general or adverse effects in general, I know the ECRI study claims that there is, you know, nothing wrong here; so why should we do anything? There is nobody reporting, you know. So what I would suggest is maybe a good place to look is the FDA's own database around adverse complaints that are reported by the manufacturers who are required to do that.

Mr. Green. Under current law, the FDA rules and regulations are on manufacturers that perform servicing are required to comply with it. And what FDA rules and regulations are third-party service entities required to comply with?

Mr. Robinson. None that I am aware of.

Mr. Green. Okay. In your opinion, does H.R. 2118 help to address the service issues witnessed by your company?

Mr. Robinson. Yes. I think it would help. I think it would help the industry in general and the FDA as you work and track complaints.

You know, as an example, if we have a piece of equipment, whether it is Philips or General Electric, any member company, and it is not being serviced by us and there have been a number of issues that occur that become redundant and common that we are not seeing, we don't know to address them. You know, so a common complaint handling system would escalate and elevate that.

Mr. Green. Under current law, what FDA regulations are the manufacturers that perform servicing required to comply with?

Mr. Robinson. I can't cite the exact law, but there is one, and we are all required to have quality management systems. And they are inspected and audited on a -- I think it is a biannual basis. And we report proactively, you know, complaint handling system that rolls up.

Mr. Green. Thank you, Mr. Chairman. I have run out of time unless you want to give me 5 minutes more.

Mr. Burgess. No. That would be a no. The chair thanks the gentleman. The gentleman does yield back.

The chair recognizes the gentlelady from Tennessee 5 minutes for questions, please.

Mrs. Blackburn. Thank you, Mr. Chairman.

And thank you to each of you for being here today. I am happy

to see so much love and support for over-the-counter hearing aids. We appreciate that.

Mr. Robinson, I thank you that you have come in line saying you even support, even though --

Mr. Robinson. I have aged in-laws that suffer with this.

Mrs. Blackburn. You can relate to the story of --

Mr. Robinson. I can relate to the story.

Mrs. Blackburn. Yes, absolutely.

Ms. Shrader, we thank you for your presence in Tennessee. We appreciate that Medtronic is one of our companies there and your presence in Memphis, and that one out of every four jobs in Memphis, Tennessee, is a medical-device-related job. So we appreciate that presence.

Dr. Lin, I think that you have pretty much stated why this is important having the over-the-counter hearing aids, and I appreciate that.

Let's look for just a minute, though. One more thing I want to touch on very quickly, State laws and why we may need to preempt those State laws as we look at the availability, especially in underserved areas. So just a couple of seconds on that, and then, after he finishes, Mr. Chairman, I will yield back.

Dr. Lin. Thank you, Representative Blackburn. Right now as the act you help coauthor clearly states, there is a very narrow preemption of State law specifically for this over-the-counter class of hearing aids. And this follows in line with what the National Academies and

PCAST recommended, is we want to make these devices broadly available to 38 million Americans with hearing loss. We don't want some States saying, "Well, this can't be given over the counter." So it does call for a very, very narrow preemption only for this one specific class of hearing aids.

Right now, certain -- many -- actually, all States right now have on their books that hearing aids cannot be sold over the counter, and those regulations evolve 40 years ago when the hearing aids back then could not be safely given over the counter. But clearly now, with the purpose of this act, it would create a narrow regulatory classification for a safe and effective hearing aid that could be given over the counter and, hence, the need for a very narrow limited set of State preemption for this.

Mrs. Blackburn. I appreciate it.

I yield back.

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

The chair now recognizes the gentleman from North Carolina, Mr. Butterfield, for 5 minutes of questions, please.

Mr. Butterfield. Thank you very much, Chairman Burgess. Thank you for holding this hearing today and including H.R. 1736 in the list of bills that we are considering today. I am proud of bipartisan legislation that I introduced with my friends and colleagues, Dr. Bucshon, Mrs. Brooks, and Mr. Peters. This bipartisan legislation will improve patient safety by ensuring that the FDA is making the best

use of its inspection resources. And so this may be the beginning of more bipartisanship in this Congress, and that is a good thing.

This legislation, Mr. Chairman, will provide much-needed consistency and transparency in the routine inspections process by establishing rules of the road -- rules of road for FDA inspectors, including inspecting device facilities and regular communications between FDA inspectors and the facility both before and during and after the inspection.

Importantly, nothing in this bill takes away or limits the FDA's ability to inspect. It directs the FDA to focus its inspection resources on the more significant risk to public health.

My clock is not running, Mr. Chairman. Thank you. You must have known I had a birthday last week.

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

Mr. Butterfield. No. I am just going to have one or two questions momentarily. I won't take up the full time. I am proud to work with my colleagues and thank the witnesses for their testimony.

Ms. Shrader, I will just do one or two questions with you and call it a day. I have heard from other companies based in North Carolina that, when FDA comes to inspect a facility, it is an all-hands-on-deck situation and that, with FDA inspectors coming and going with no regular schedule, not communicating to the facility when they will be back, it creates a problem.

Can you speak to that, please?

Ms. Shrader. Certainly. And thanks for the question. You

described very well what happens in some of the less pleasant FDA inspections where we can't be sure from day to day whether the investigator or investigators will be on the premises or not, and where they are not willing to share their concerns with us.

This, of course -- as you mentioned, we can have 100 people on call for an FDA inspection in order to answer all the questions that might be asked with the appropriate level of expertise, pull documents, make copies, et cetera, to ensure that the inspection goes very smoothly.

Obviously, when the investigators are willing to share concerns with us, we can have a discussion about those concerns and, in many cases, we can take immediate corrective action.

Mr. Butterfield. That leads me into my next question --

Ms. Shrader. Okay.

Mr. Butterfield. -- about the timeframe. What happens when an FDA inspector does find a shortcoming during the inspection that a company needs to address? Is there a timeframe that companies are required to get their correction back to the FDA?

Ms. Shrader. By FDA policy, we typically have 15 days from the end of the inspection until a written response to any inspection or observations is required.

If we don't respond within that period of time, we are at risk of receiving a warning letter from FDA. At the same time, I would note that there is no specified period of time for FDA to review our response and give us feedback if they feel that the response hasn't been

adequate.

Mr. Butterfield. I know this is time-consuming for the companies, but are there costs associated with waiting for FDA to get back with their decision, financial costs?

Ms. Shrader. Yes, there certainly are. Of course, you know, the cost of delay translates into, perhaps, manufacturing delays while we wait to hear whether --

Mr. Butterfield. It is the uncertainty. It is the uncertainty. Am I right about it?

Ms. Shrader. Right. Exactly.

Mr. Butterfield. Thank you, Mr. Chairman. As promised, I yield back.

Mr. Burgess. The chair thanks the gentleman.

The chair recognizes the gentleman from Indiana, Mr. Bucshon, for questions, please.

Mr. Bucshon. Thank you, Mr. Chairman.

Mr. Robinson, I have a question for you. Wouldn't you agree that it would be imperative that whoever is servicing or maintaining medical equipment must have access to the materials, tools, and support necessary to properly service and maintain the equipment in accordance with State and Federal law? That would seem like that --

Mr. Robinson. Yes. And we do that today.

Mr. Bucshon. So if you have a third -- if you have, for example, and I am just -- you can just speak for your own company -- equipment that is serviced by a third party and they need information, you provide

that?

Mr. Robinson. We supply information to the owner of the equipment. So it can be a hospital, a doctor's office, whoever.

Mr. Bucshon. Okay. So then they would be able to through that --

Mr. Robinson. And they would access it.

Mr. Bucshon. Do you think that is an industrywide approach? Do you know?

Mr. Robinson. I think so. I think that that is the common practice.

Actually, Bob, you might know better than me if that is a common practice.

Mr. Bucshon. Mr. Kerwin, you can comment on that.

Mr. Kerwin. We have approached the FDA many times over the years because, sadly, it is not a common practice. Though we believe, since 1973, there have been regulations in place, which require delivery of the AIAT and other information, sir.

Mr. Robinson. So we are required by law, and as Philips, we fulfill the requirement.

Mr. Bucshon. Yes. Because it would seem to me, if a hospital or third-party provider under a contractual relationship agreed to protect their proprietary information, for example, which there is proprietary information on these products -- I get that -- and/or pay for it, there shouldn't be any reason why they shouldn't be able to get that information?

Mr. Robinson. Yes.

Mr. Bucshon. Great. Thank you.

Ms. Shrader, first of all, thank you -- over here. That is okay. It is hard to find who is in this room. You can't tell which direction it is coming from.

First of all, thank you for your support of the legislation, and I think you pretty much answered the question with some of your comments, 1736. But just to further clarify, I mean, it sounds like that you feel and your company feels that it would provide meaningful improvement to the FDA inspections with less delay to do it that way?

Ms. Shrader. That is correct, yes.

Mr. Bucshon. Yes. And Dr. Shuren pretty much talked about that also about how the vast numbers of inspections -- I think 25,000 a year or something in that area -- and, hence, the reason we put together this bipartisan legislation so -- because we want them to be able to focus on areas where it is most needed and people that have been in long-term compliance not to be as much of the focus. So I appreciate your support.

And, Mr. Chairman, I yield back.

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

The chair recognizes the gentleman from Massachusetts, Mr. Kennedy, for 5 minutes of questions.

Mr. Kennedy. Thank you, Mr. Chairman.

Dr. Lin, thank you for your testimony and your advocacy on behalf

of hearing health. Thank you for some of the questions that you answered earlier with regards to H.R. 1652.

I want to flesh out a little bit, there has been -- in your testimony you talked to this, and I know there is some questions about it too about the value of how -- of crafting that legislation from mild and moderate hearing loss versus just mild hearing loss. I was hoping that you could just flesh out for me the medical difference between mild and moderate in terms of the causes and in terms of treatment to start.

Dr. Lin. So, from a clinical medical perspective, there is no difference. It is on a natural continuum. People progress from mild to moderate. That currently encompasses, again, about 95 percent of people with hearing loss have a range from mild to moderate. From a clinical perspective now, when you see an audiologist, they don't necessarily distinguish a different device for mild versus moderate. It is the same device; you just program it a little differently. That was very much the basis for the National Academies' recommendations that I served on as well as PCAST, recognizing there is a broad base of hearing loss that is very much treated the same way, and, hence, if we can have devices that are over the counter that are safe and effective for that broad range, why are we purposely handicapping it? So we say 30 percent of the people with hearing loss, they have to go through the traditional model. I think it is a little paternalistic from a medical point of view to say that.

Now, I think importantly too, as I mentioned before, it is not

an either/or phenomenon. Already what we are seeing is people who have access or learn about over-the-counter devices are coming to the physician a lot of times asking, you know, "What I should I do? What should I get?" So, in many cases, you can imagine -- and I think this is where the American Doctors of Audiology sees this going, is it is just another avenue of a way to help patients that come to see you, is that I can recommend to you my services. I can recommend to you a custom-fitted, super customized hearing aid, or I can help you use an over-the-counter hearing aid. So to purposely limit it to a mild hearing loss only handicaps the clinicians who are out there to help the patients, basically, and, hence, a broad need to address mild to moderate in this classification.

Mr. Kennedy. And why would not requiring for a professional visit be safe for those with mild loss but unsafe for those with moderate loss?

Dr. Lin. I can think of none. From a medical and surgical standpoint, there is no distinction between the two. If it is safe for mild, it would be safe for moderate too as well as effective. I think as you go to more severe forms of moderate hearing loss, it is not that it becomes not effective. It becomes -- it gradually diminishes. You might need more assistance. But, again, this is why it is not an either/or phenomenon. That is when you would go see a clinician, and they could help you use that over-the-counter device, help you program it to adapt it to your lifestyle.

Mr. Kennedy. Great.

Mr. Chairman, I also ask unanimous consent to submit two studies for the record: one from the National Academies of Sciences, Engineering, and Medicine, and the other, as referenced by the witness, the President's Council of Advisors in Science and Technology, both studies.

Mr. Burgess. Without objection, so ordered.

[The information follows:]

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Mr. Kennedy. Thank you. And I yield back.

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

The chair recognizes the gentleman from New York, Mr. Engel, 5 minutes for questions.

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

And thanks to our witnesses for being here and sharing your expertise.

At some point or another, every one of us is going to use a medical device without even realizing it. I keep getting asked when I go through to take an airplane trip, if I have any medical devices on me. I guess it is with age that comes along.

But some need devices to go about their daily activities more comfortably, and some may depend on one for their very survival; therefore, we all have a stake in the issue. And it is important, of course, that we assure medical devices are effective, safe, and readily accessible to those who need them. And I think that is a principle that we can agree on.

Let me ask you, Dr. Lin. I have a few questions for you. During your testimony, you mentioned some of the concerns that have been raised with respect to over-the-counter hearing aids. You also noted that less than one-fifth of the nearly 38 million Americans with substantial hearing loss presently have access to hearing aids. Could you elaborate, please, on how the potential risks of over-the-counter hearing aids stack up in comparison to the risks of unaddressed hearing

loss?

Dr. Lin. So I think that is exactly the question. I think anything we ever do policywise is a balance of benefits versus risks. And I think the benefits here now, now that we know from research that hearing loss is linked with things like dementia, higher healthcare costs, falls, is that anything we can do to address hearing loss to increase usage could only benefit public health. So those are clear, tangible, real benefits for our parents, for our seniors, for society right now.

The risks, on the other hand, I would say are minute. When you talk about hearing loss in older adults, two out of every three adults over 70 have a hearing loss. As FDA described before, again, not every person needs to be medically evaluated. The vast majority of hearing loss that is of a, quote/unquote, "dangerous nature" from a surgical perspective, things like cholesteatoma, tumors, things like that, invariably in almost all cases have warning signs -- either it is only a unilateral hearing loss, not in both ears, it is one hearing in the ear, you have pain, you have drainage, you have dizziness, you have vertigo -- all of which would be clearly labeled at the outset in the labeling of these devices.

So I think the minute chances of an undetected condition that do have not presenting symptoms are very, very, very small and clearly outweighed by several orders of magnitude of the benefits of allowing the 80 percent of people who do not have hearing treatment now to get some form of help.

Mr. Engel. Dr. Lin, late last year, FDA actually signaled that it might create a category of over-the-counter hearing aids. And, similarly, I understand that FDA released guidance in December outlying its decision not to enforce a requirement that adults undergo a doctor's exam or sign a waiver for purchasing hearing aids. As an expert in hearing loss and as a medical professional, do you feel these are sound decisions on the part of FDA?

Dr. Lin. I am sorry. The last one? Do I agree with these decisions?

Mr. Engel. Yes, do -- yes.

Dr. Lin. Yes. No, I fully agree, and that is coming from my perspective as having served on the National Academies, advising PCAST, as well as my own role of, again, otolaryngologist and otologist at an academic medical center.

Mr. Engel. Thank you. And, finally, how does this bill affect consumer protections regarding the safety and effectiveness of hearing aids? And by that, I mean, in your professional opinion, is there any reason to believe that consumers would be less safe as a result of legislation before us today?

Dr. Lin. No. And I think, as I mentioned before, I think they are actually far safer in fact. I think the reason why that is, is because, as you have an over-the-counter regulated class that is broadly applicable to the 95 percent of people with hearing loss out there, it drives interest and it drives questions. It causes consumers and patients to ask more about hearing loss, to ask their physicians

about hearing loss, to go see an audiologist to get their advice. It doesn't drive people away from hearing care; it drives people toward hearing care by offering them an avenue that they can now approach on their own terms.

Mr. Engel. Thank you very much.

I yield back.

Mr. Burgess. The chair thanks the gentleman.

The chair recognizes himself for 5 minutes for questions.

Dr. Lin, I really do appreciate your testimony and your forthright answers to all the questions. Just so I am clear on this, are there any illnesses that would present with mild hearing loss that would be different from illnesses that would present with moderate hearing loss?

Dr. Lin. No, absolutely not. From the clinical and medical perspective, it is on a natural continuum from one to another. There is no difference between the two in terms of how necessarily manage it with existing devices.

Mr. Burgess. And I thank you for your written testimony. You actually addressed some of the concerns I had about children and the screening tests done at birth and the school testing done. In your opinion, is that going to be an adequate catchment for those individuals?

Dr. Lin. Absolutely. I mean, fortunately, the way we manage pediatric care in most of this country is actually very well done. We have universal newborn screening. Every State has some degree of

school-based screening. If you are low income, Medicaid in all 50 States covers hearing aids and services for children. So the medical system for hearing loss and kids is completely different in many ways, fortunately. So I do not see virtually any risk of these being inadvertently or improperly used in children. There is no reason to.

Mr. Burgess. Very well.

Mr. Kerwin, Mr. Robinson, I want to talk about the devices. You know, Mr. Robinson, someone mentioned about anecdotes. I think we have established in this committee that the plural of anecdote is not data. But, nevertheless, you had the plural of anecdote in your testimony.

When I first started looking through that, I thought, the world isn't like that. And then I looked at some of the examples and saw tape on the equipment, and I thought, oh, that totally happens. You see that, unfortunately, all the time.

So I guess, Mr. Kerwin, you said there is no evidence to support a problem with the servicing of medical equipment. Mr. Robinson has provided some compelling visual data that suggests otherwise.

Shouldn't each entity that is hired to fix or refurbish equipment be equally responsible for documenting and submitting adverse-related problems that may be connected to their work?

Mr. Kerwin, that is to you.

Mr. Kerwin. Mr. Chairman, I believe that we are responsible. Our members, we have contractual obligations to the hospital. The hospitals have the ability to vote with their feet if we do not satisfy

those obligations, notwithstanding we have long-term relationships. We voluntarily report adverse events. And in the ECRI study that Mr. Robinson referred to, they had analyzed 137,000 MAUDE reports, and there was only a total of 0.1 percent of total events: 241 incidents in the ECRI study. And I recognize that was a little while ago.

But we say, Mr. Chairman, that the enormous amount of resources that would be dedicated toward reporting for, perhaps, 0.1 percent of total events, when it will create a sea change in the manner in which the rural and regional hospitals deal with the independents, and we feel, on balance, we do report, and we do have energetic internal trade association programs on medical devices, on adverse events, on UDI, on best practices for all of the events. And we recognize patient safety is our paramount interest.

Mr. Burgess. Just so I am clear, Mr. Robinson, for the original equipment manufacturer, are you required to report adverse events to the Food and Drug Administration?

Mr. Robinson. We are required. And if volunteer were good enough, maybe we should request the FDA to make it all voluntary, but I don't think there would be an interest in doing that.

Mr. Burgess. And I was going to say that there is probably not many constituents clamoring for that. So I guess that is a question that I have at the end of this lengthy hearing. And, again, I do appreciate all of you putting so much time in with us today. If you are each doing the same servicing work, why the different treatment by the Food and Drug Administration?

Mr. Robinson. I couldn't answer that for you. And I think, actually, Dr. Shuren had made a reference to there were some guidelines in place that there was, I think his words were, "lacks enforcement of." So there seems to be something in place, but there is not a requirement to implement it. That is my take from his comment, but I am not 100 percent sure.

Mr. Burgess. Mr. Kerwin, you look like you wanted to say something.

Mr. Kerwin. Mr. Chairman, this was examined 20 years ago. And, again, it is being examined today. And during this entire time of 20 years, we have not heard of the reporting of adverse events or the underreporting of adverse events. I understood that Dr. Shuren was referring to laparoscopic issues, and I had seen some publications relative to this. I have not heard, with respect to diagnostic imaging, anything of this nature. And it would seem that if we had followed the report from ECR, that if we are looking at a total of 0.1 percent of total events, is it really, in our era of having smart regulation, appropriate to now create a change in the manner in which all of these hospitals, particularly these rural hospitals, do business?

Mr. Robinson. The good news is there is no new regulation. We are simply asking for the distribution of the existing regulation to the independent services.

Mr. Burgess. And I appreciate that it is infrequent, but we know, as you look at some of these pictures that were provided to us, would

I want a family member to be utilizing that equipment --

Mr. Robinson. I would not.

Mr. Burgess. -- would I be perfectly comfortable with -- and, honestly, some of it -- I mean, some of it is quite sophisticated, like the cooling mechanism for the magnet in an MRI, but some of it is fairly mundane, like cracks in the plastic -- or the rubberized guard on a patient mat on a gurney.

Mr. Kerwin. Mr. Chairman, if I may speak to that?

Mr. Burgess. Turn your mike on.

Mr. Kerwin. Mr. Chairman --

Mr. Burgess. Is your microphone on?

Mr. Kerwin. My apologies.

Mr. Burgess. Thank you.

Mr. Kerwin. In preparation for our hearing today, we contemplated, would we bring our pictures? Would we show areas where we have taken over for the manufacturer? And I have been assured by several companies that, if necessary, we, too, can produce. But we thought the attribution to nameless independents paints an entire industry and perhaps unfairly. And we would like to focus on the collegiality.

At one point in 1997, FDA assisted in the collaboration with AME and with all the stakeholders working toward a solution, an industry solution, relative to this. Let's turn over the passwords, equipment manuals, and training; let's cooperate relative to the reporting. And, unfortunately, the person at AME who was coordinating much of that

departed, and we did not reach closure. We called for a collaborative effort during the October 27, 28 meeting before FDA. We think this belongs with industry, particularly where there is no real-world evidence to back this up. And I still await attribution of these nameless independents for whom we have pictures. And if the committee wishes, we can bring pictures, but we don't think that is the ultimate solution.

Mr. Burgess. Mr. Robinson, what about that? What about the sharing of data and passwords?

Mr. Robinson. Yeah, we comply with all the laws. And every one of the member companies, to the best of my ability, you know, complies with those laws and regulations. We supply the servicing and preventive maintenance manuals to the owners of the equipment, as required.

What I would tell you is the industry is, in general -- no industry is perfect. The people who repair machines are people. The people who build machines are people. And that is why they break. And that is why companies like ours do service. And the OEMs, in terms of pictures or adverse events, are an open book. We have to report it to the FDA. All we are asking for is the same open book. Don't -- you know, let's not have it in nameless pictures. Let's have everyone report the same way, and that is all we are requesting in this.

Mr. Burgess. Well, obviously, that does not conclude this discussion, but it concludes our hearing.

Mr. Robinson. But thank you for your time and attention.

Mr. Kerwin. Thank you for your time.

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

We have received outside feedback from a number of organizations on these bills. So there are statements to submit for the record from AARP, from the International Hearing Society, from the American Speech-Language-Hearing Association, from the Academy of Doctors of Audiology, from the American Academy of Otolaryngology-Head, and Neck Surgery, Consumer Technology Association, Aramark, Consumers Union, Repair.org.

Without objection, so ordered. Those will be entered into the record.

[The information follows:]

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

Mr. Burgess. Pursuant to committee rules, I remind members they have 10 business days to submit additional questions for the record.

And I ask the witnesses to submit their responses within 10 business days upon receipt of those questions.

And, without objection, the subcommittee is adjourned.

[Whereupon, at 12:39 p.m., the subcommittee was adjourned.]