

**EXAMINING IMPROVEMENTS TO THE REGULATION
OF MEDICAL TECHNOLOGIES**

HEARING
BEFORE THE
SUBCOMMITTEE ON HEALTH
OF THE
COMMITTEE ON ENERGY AND
COMMERCE
HOUSE OF REPRESENTATIVES
ONE HUNDRED FIFTEENTH CONGRESS
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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, DC.

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.

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

Mr. BURGESS. The Subcommittee on Health will now come to order. The chair 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 treat-

ments 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.

[The prepared statement of Mr. Burgess follows:]

PREPARED STATEMENT OF HON. MICHAEL C. BURGESS

The Subcommittee will come to order.

The Chair will recognize himself for an opening statement.

Today's hearing is another step in this subcommittee's work to reauthorize the Food and Drug Administrations' user fee agreements with industry. The subcommittee has held three hearings on the user fee program, during which time members 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. It is my top priority 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 Science Engineering and Medicine. Specifically, H.R. 1652 would direct FDA to promulgate regulations establishing a category for over-the-counter hearing aids. This category of OTC hearing aids would be limited to use by adults with mild to moderate hearing loss. Representatives Kennedy, Blackburn, and Carter introduced this bill to safely increase access and affordability in the hearing aid market for the millions of Americans that could benefit from it.

Representatives Costello and Peters introduced H.R. 2009, the Fostering Innovation in Medical Imaging Act of 2017. This bill seeks to improve the regulation and oversight of medical imaging devices intended for 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 and Accountability Act, also introduced by Representatives Costello and Peters, would require all medical device servicers to register with the FDA and maintain a complaint 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 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 FDA's device inspections process to increase its consistency and transparency. More specifically, H.R. 1736 would establish a risk-based inspections schedule for device facilities, standardize inspection processes, and increase transparency around FDA determinations related to inspections.

Each of the bills we will examine today is intended to increase innovation and 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 is a shared priority in our work to reauthorize the FDA user fee programs. I thank all of our witnesses for being here, and I look forward to hearing from each of you about how these proposals might improve our ability to meet this goal.

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

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.

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.

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

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 hearing 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.

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.

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

Mr. WALDEN. 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 Mr. Walden follows:]

PREPARED STATEMENT OF HON. GREG WALDEN

Thank you Chairman Burgess.

As I have previously stated and will reaffirm today, the Energy and Commerce Committee is fully committed to a timely reauthorization of FDA's vitally important user fee programs. The good news is that we are well on our way.

The Health Subcommittee held hearings on each of the proposed agreements that were initially submitted to Congress in January. Since that time, we have translated those agreements into legislative language which the committee released with the Senate HELP committee several weeks ago.

As part of that release, I noted that as the legislative process proceeds I look forward to continued discussions with my colleagues in the House on other member priorities that could strengthen this important legislation.

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

H.R. 1652, the Over-the-Counter Hearing Aid Act, introduced by Reps. Kennedy, Carter, and Blackburn would require 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 on Science and Technology and the National Academies have called for this approach. I understand that some patient safety concerns have been raised and I look forward to hearing more about that from FDA and our witnesses on the second panel.

H.R. 2118, the Medical Device Servicing and Accountability Act, introduced by Reps. 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. 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 look forward to learning more about this bill going forward.

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

Last but not least, Reps. Buschon, 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.

Thank you to all of our witnesses for their testimony and I yield back the balance of my time.

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 appears at the conclusion of the hearing.]

Mrs. BLACKBURN. Thank you, Mr. Chairman.

I yield back.

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.

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

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:]

PREPARED STATEMENT OF HON. FRANK PALLONE, JR.

Thank you, Mr. Chairman. Today we are examining additional legislation that will 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 the promise to treat and cure diseases in ways previously not thought of. While not the subject of today's hearing, 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. I look forward to working with my colleagues to have all of the user fee agreements considered and sent to the President 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 non-controversial and enjoying broad bipartisan support.

Today we will be hearing from our witnesses about the following four bills:

- H.R. 1652, sponsored by Representatives Kennedy, Blackburn, and Carter, would direct FDA to establish by regulation a category of over-the-counter hearing aids for adults with perceived mild to moderate hearing loss. This bill could open up access to affordable hearing aid devices for the more than 37 million American adults who suffer from hearing loss today.
- H.R. 2009, sponsored by Representative Peters and Costello, would clarify the FDA review process for new indications of contrast agents used with medical imaging devices.
- H.R. 2118, also sponsored by Representative Peters and Costello, would require third party service providers of medical devices to register with the FDA, maintain

a complaint handling system, and submit adverse event reports as original equipment manufacturers do today.

•And finally, H.R. 1736, sponsored by Representatives Peters, Butterfield, Buschon, and Brooks, would move FDA inspections of medical device facilities to a risk-based schedule, and would improve communication between FDA and industry throughout the inspection process.

I look forward to learning more from Dr. Shuren, as well as our other stakeholders, about their interests in the legislation before us.

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.

Mr. PALLONE. 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:]

**“Examining Improvements to the Regulation
of Medical Technologies”**

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

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

May 2, 2017

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

Thank you for having me here today. I am Jeff Shuren, Director of the Center for Devices and Radiological Health (CDRH) at the Food and Drug Administration (FDA). I am pleased to be back here today 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 MDUFA IV.

As you know, MDUFA has been reauthorized every five years since Congress first created the program in 2002. In fact, several current members of this committee were instrumental in the enactment of MDUFA I. As the program has evolved, FDA and industry have successfully negotiated agreements to improve patient access to safe and effective medical devices and streamline regulatory processes.

As we discussed a few weeks ago, timely reauthorization of MDUFA is critical to maintain adequate staffing levels and support our mission of protecting and promoting the public health, with the ultimate goal of getting treatments to the patients who need them. Like you, we at CDRH want patients and providers to continue to have timely access to safe, effective, and high-quality medical devices, first in the world. Retaining the knowledge and expertise of our scientific staff is critical to providing predictable and timely medical device reviews.

Changes we have made at CDRH to our culture, policies, and processes—in addition to user fee funding and changes to federal law—have resulted in reduced decision times, an improved medical device pipeline, and innovative technologies being introduced in the U.S. earlier than in the past. We want to continue this upward trend.

While reauthorization of MDUFA is the key to maintaining this trajectory, we know that there are additional areas of shared interest to improve patient access to safe and effective medical devices. Today's hearing is an important opportunity to explore some of these options. FDA is ready to work with Congress to make measurable improvements consistent with the approach outlined in the Administration's Blueprint Budget, which proposes a different way of financing the program.

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, "little to no meaningful benefit to patients."

Can you 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 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 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 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 manufacturers 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.

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 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, 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 hearing 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, 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 the 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 classifica-

tion, 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 where Dr. Burgess left off dealing with the third-party medical equipment. I know you were talking about in the last hearing you are in 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. Not at this time. 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. OK. A couple of years back we met in my office and 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 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 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 benefit-risk of the technologies but the benefit-risk trade-offs 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 stand up 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 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. OK. 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. 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 does not make anything magical. And over the counter, does that connote 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.

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 G&P surveillance inspections. So we can't even live up to the law.

And then we are pulled toward 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. 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, “OK, 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, 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, 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. OK. 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. 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 appears at the conclusion of the hearing.]

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 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. 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, 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, things like cholesteatoma, acoustic neuroma, you add all those up, the really serious causes of hearing loss are maybe well under 1 percent. 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 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.

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 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 egregious photos of quick or maybe not even quick repairs to equipment. 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?

Dr. SHUREN. Well, you can comfortably say anecdotes. And 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, 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 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.

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 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, for risk-based would be very helpful to us. 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 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. OK. 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—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 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. OK. 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. OK. 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 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. 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 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 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 appears at the conclusion of the hearing.]

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 by 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 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 non-sharing 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 follow-up 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. OK.

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 follow-up.

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 rec-

commend 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 appears at the conclusion of the hearing.]

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:]



May 2, 2017

Chairman Michael Burgess and Ranking Member Gene Green
U.S. House of Representatives Energy and Commerce Committee
Subcommittee on Health
2125 Rayburn House Office Building
Washington, DC 20515

RE: Examining Improvements to the Regulation of Medical Technologies

Dear Chairman Burgess and Ranking Member Green:

The Hearing Industries Association (HIA) appreciates the opportunity to provide testimony on the hearing before the Subcommittee on Health entitled “Examining Improvements to the Regulation of Medical Technologies.” HIA is the national trade association of manufacturers of hearing aids, assistive listening devices, component parts, and power sources. HIA’s membership consists of 17 companies representing approximately 30 hearing aid brands that constitute over 90 percent of the hearing aids sold in the United States on an annual basis. These companies invest over \$600 million per year on hearing aid research and development. Our members collectively employ more than 6,000 engineers and scientists who develop sophisticated hearing aids and algorithms to process sound so that it resembles natural hearing with minimal power consumption.

HIA has substantial interest in the policies proposed in the **Over-the-Counter Hearing Aid Act of 2017 (H.R. 1652)**, which are being considered by the Subcommittee today. The bill is designed to improve the accessibility and affordability of hearing aids by requiring FDA to establish an over-the-counter category for hearing aids. Before Congress proceeds in adopting the proposed legislation to create an OTC sales model for hearing aids, caution is warranted. Although promoting the goals of affordability and

accessibility are important, they should be secondary to assuring the safety and efficacy of hearing aids through the FDA's review processes and promoting the clinical interests of the patient. There are no studies demonstrating a person can accurately self-diagnose and self-manage the degree or cause of hearing loss, which would be required for successful implementation of an OTC sales channel for hearing aids. HIA recommends that the current draft of H.R.1652 should be amended to allow OTC sales for mild hearing loss only, as the consequences of ineffective treatment in this segment are relatively low.

The hearing industry is rapidly innovating, leading patients to receive more advanced technology at the same cost as a few years ago. Over the past decade some of our members have successfully miniaturized hearing devices through nanotechnology and flex circuitry, developed Bluetooth and wireless features for content streaming, and linked hearing aids with smart phones to maximize performance in a wide variety of listening environments. Smart hearing aids have won multiple awards from several groups as a result of these innovations.¹ Despite these impressive technological advances, hearing aid technology has become more affordable, with some HIA members manufacturing hearing aids that can be purchased for as little as \$500 with the necessary professional services included.²

The hearing aid market is not the stagnant and outdated market that some recent reports would have one believe.³ The new practical functions and enhanced features of today's hearing aids are associated with increased satisfaction rates and usage.⁴

¹ HIA, Hearing Aid Industry Report (2017) (awarded the Consumer Technology Association's CES "Best of Innovation Awards"; SXSW Interacting Innovation Awards & Edison Awards; Bluetooth Breakthrough Awards; German Design Awards; Good Design Awards; Red Dot Awards; and several others).

² See Costco for a variety of hearing aids made by various manufacturers, including ReSound, Siemens (Costco's Kirkland brand), and others, starting at \$499, including professional services, <https://www.costco.com/hearing-aid-styles.html>.

³ See President's Council of Advisors on Science and Technology, Letter to President Obama, 2 (Oct. 2015) ("PCAST Report"), https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/PCAST/pcast_hearing_tech_letterreport_final.pdf.

⁴ Harvey B. Abrams, PhD, and Jan Kihm, MS, *An Introduction to MarkeTrak IX: A New Baseline for the Hearing Aid Market*, Hearing Review (May 15, 2015), <http://www.hearingreview.com/2015/05/introduction-marketrak-ix-new-baseline-hearing-aid-market/>.

Consumer satisfaction with current hearing aids is high and growing, with a 91 percent satisfaction rating for those obtained since 2014; 77 percent for hearing aids obtained between 2010 and 2013; and 74 percent for hearing aids obtained prior to 2010.⁵ Furthermore, overall satisfaction has increased from 74 percent in 2008 to its current level of 81 percent.⁶ Based on more than 30 years of data from MarkeTrak – a tracking survey of the hearing aid market – overall satisfaction with hearing aids is at its highest level ever. Better products and better experiences with hearing care professionals contribute to the improving satisfaction rates.

HIA appreciates the Subcommittee’s interest in pursuing legislation to promote the affordability and accessibility of hearing aids through the Over-the-Counter Hearing Aid Act of 2017 (H.R. 1652). But affordability and accessibility must not come at the cost of safety or effectiveness. Hearing aids are, after all, medical devices intended to treat a disease or condition. To that end, HIA believes that all hearing aids, regardless of method of sale, should be required to comply with the general controls established by the Food and Drug Administration (FDA).

If enacted, the Over-the Counter Hearing Aid Act of 2017 would create a new OTC delivery channel for hearing aids. While OTC purchases may result in increased access and affordability, the evidence suggests the proposed OTC delivery channel may be effective only for a subset of hearing loss patients. Creating a new OTC distribution channel will not change the technology, but only a new mechanism for delivering the product. The relevant question is whether consumers can diagnose their own hearing loss and program their own hearing aids to best address their specific type and level of hearing loss or whether professional assistance is needed.

With adequate FDA controls in place, HIA believes that OTC may be suitable to address mild hearing loss only. The consequences of ineffective treatment for mild hearing loss are low, whereas the risks of failure and further delay in treatment for moderate hearing loss are significantly greater. Such treatment failure leaves the

⁵ *Id.*

⁶ *Id.*

individual at greater risk of isolation, depression, falls, dementia and other conditions related to untreated hearing loss.

I. Congress and FDA should limit any potential OTC Hearing Aid Sales to the Treatment of Mild Hearing Loss. H.R. 1652 Should be Amended to Allow OTC Sales of Hearing Aids for Patients with Mild Hearing Loss Only.

Hearing aids are the treatment of choice for the vast majority of adults with hearing loss, and they play a critical role in improving communication function and quality of life. The scientific literature shows that untreated hearing loss is associated with social isolation, loss of independence, depression, dementia, and increased risk of falls.⁷ Though hearing loss is a common corollary to aging, its impact can be serious.

Hearing loss is a multifactorial condition, which requires a complex and skill-based approach to its treatment. There is a significant sensorineural component to hearing loss suffered by the vast majority of adults. Increasing audibility alone is often not sufficient to resolve their complex communication issues.⁸ In addition to diminished audibility, hearing loss often involves diminished frequency resolution (difference in pitch), diminished temporal resolution (timing), or diminished loudness perception (range between softest and loudest sounds). Some hearing loss is also situational: discussions of hearing loss include not just idiosyncratic etiologies, but different levels of loss and audibility in differing settings. Hearing aids incorporate advanced signal processing algorithms that are designed to address the complex interactions between a damaged sensory organ, the desired input speech signal, and interfering environment sounds. Consequently, expertise in the selection, fitting and programming of these devices, as well as counseling patients in the likely benefits and limitations of amplification, is often critical for optimizing treatment outcomes.⁹

⁷ Seniors Research Group, *The Consequences of Untreated Hearing Loss in Older Persons*, Nat'l Council on the Aging (May 1999); Stig Arlinger, *Negative Consequences of Uncorrected Hearing Loss—A Review*, 42 Int'l J. of Audiology 2S17 (July 2003); NAS Report, *supra* n.13, 273-74.

⁸ Julia Calderone, *Hearing Loss: No More Suffering in Silence?*, Consumer Reports (Feb. 2, 2017), <http://www.consumerreports.org/hearing-aids/hearing-loss-no-more-suffering-in-silence/>.

⁹ Larry Humes et al., *The Effects of Service-Delivery Model and Purchase Price on Hearing-Aid Outcomes in Older Adults: A Randomized Double-Blind Placebo-Controlled Clinical Trial*, 26 Am. J. Audiology 53 (Mar. 2017).

The extent of hearing loss and its impact on different individuals varies. There is no technology or product that can be sold as a “one-size-fits-all” hearing solution for all hearing loss. The FDA defines hearing loss across five categories based on the decibel scale with mild hearing loss ranging from a 20 to 40 decibel hearing loss and moderate hearing loss ranging from 40 to 70 decibels. With two-thirds of all Americans with hearing loss having mild loss and only an estimated 12 percent of these people currently wearing hearing aids,¹⁰ OTC hearing aids could improve adoption rates for Americans with mild hearing loss while presenting a favorable benefit-risk profile. Conversely, an estimated 50 percent of individuals with moderate hearing loss currently use hearing aids.¹¹ This population, which is already utilizing hearing aids at a substantial rate, is much less likely to be able to self-diagnose and self-manage with OTC hearing aids, and the impact of an erroneous treatment would be much greater.

Mild hearing loss, which is generally defined as difficulty hearing soft speech or sounds,¹² is more amenable to self-treatment through OTC hearing aids than more severe degrees of hearing loss. Treatment of moderate hearing loss involves a more comprehensive audiogram configuration. Further, simple amplification across all frequency ranges is not likely to provide the anticipated clinical benefits, potentially resulting in patient frustration and abandonment by moderate hearing loss patients. Despite the abundance of hearing technology and related hearing health care services information available to potential patients, some of that information may be difficult for patients to understand without a learned intermediary. Adult-onset hearing loss is a complex condition, and the modern hearing aid represents state-of-the-art digital technology with hundreds of possible style-feature combinations. Consequently, consumers generally benefit from conversations with a hearing health professional to

¹⁰ HIA, Final Report, MarkeTrak 9: A New Baseline, Estimating Hearing Loss And Adoption Rates and Exploring Key Aspects of the Patient Journey, slide 39 (Mar. 2015) (“MarkeTrak 9”).

¹¹ There are varying classifications for degrees of hearing loss, and FDA combines “moderate” and “moderately severe” hearing loss into an all-encompassing “moderate” category. This would mean people with very significant 70dB hearing loss would be advised to purchase an OTC device. This is yet another reason why HIA believes that referring people who will know they have a “moderate” hearing loss to purchase an OTC device is not sound policy.

¹² Calderone, *supra* n. 8. There is, however, complexity in this definition, as a patient may have one type of hearing loss in one ear and another in the other ear.

understand the complex nature of their particular hearing loss and associated hearing aid needs. Without this assistance, it is very difficult for the patient to discern which hearing aid will be most effective or which settings or programmable features to select in that hearing aid.

The nature of hearing loss is highly individualized.¹³ Combining individual physical characteristics, such as the size, shape, and volume of the ear canal, with non-auditory factors such as cognitive function, motivation, manual dexterity, and family dynamics, creates a unique challenge.¹⁴ Situational hearing loss adds further complexity.¹⁵ Additionally, as described, there is a surplus of information available on hearing aids and health care; parsing through this information to decide which OTC hearing aid is appropriate would likely be challenging for many consumers. For these reasons, moderate or more severe hearing loss is a medical condition that is not readily susceptible to self-treatment. HIA therefore does not support OTC access for moderate or more severe hearing loss, as the risks of abandonment or ineffective treatment are high given the co-morbidities related to untreated hearing loss.

A recent placebo-controlled, double-blind, randomized clinical trial illustrated the advantages of consultations with a hearing health professional in the hearing aid selection and fitting process. The study and associated paper by Larry Humes et al. compared different service-delivery models among participants with hearing loss. The results suggested that there were no significant differences between the two approaches on five of the six outcomes – the exception, however, was the critical measure of satisfaction. Satisfaction significantly increased for those participants who initially received OTC devices following additional treatment under the audiology best practices (AB) model in which the patients received assistance from audiologists.¹⁶ While 81 percent of the

¹³ Calderone, *supra* n.12 (“You can have two people with identical audiograms who have very different functionality”) (internal quotations omitted).

¹⁴ American Speech-Language-Hearing Association, Hearing Aids for Adults (last visited Mar. 24, 2017), http://www.asha.org/PRPSpecificTopic.aspx?folderid=8589935381§ion=Key_Issues.

¹⁵ Donald J. Schum, PhD, *Situational Performance of Noise Reduction and Directionality*, Audiology Online (May 16, 2011), <http://www.audiologyonline.com/articles/situational-performance-noise-reduction-and-830>.

¹⁶ Humes et al., *supra* n.9. Of note, the study used only technologically-advanced hearing aids.

participants who were assigned to the AB group said they would keep their hearing aids, only 55 percent of the participants in the OTC group said the same.¹⁷ At the end of the initial six-week trial, 44 of 53 (83%) in the AB group actually purchased their hearing aids compared to only 1 of 51 (2%) in the OTC group. Following the six-week trial, 49 participants in the OTC model participated in an additional four-week trial that included professional adjustments to their OTC hearing aids before deciding to purchase. Notably, after four weeks of assistance from an audiologist, the percentage of willing purchasers in the OTC group jumped significantly.¹⁸

It should be stressed that the research participants in both the AB and OTC groups received baseline audiologic evaluations and the same high-end, commercially-available digital hearing aids – conditions that *will not* occur in the real world of OTCs. The authors wrote, “the observation that the CD participants self-select hearing aids that are somewhat under-powered may explain some of the inferior outcomes observed in this group compared to the AB participants.”¹⁹ And while HIA agrees that affordable and accessible hearing aids are clearly in the best interests of the consumer. HIA also believes that the best hearing aid for a consumer is the one that is worn. HIA therefore believes that the risks of under-treatment or failed treatment leading to the potential abandonment of more effective hearing loss treatment are far greater for people with moderate hearing loss than those with mild hearing loss.

Even for patients with mild hearing loss, self-treatment will not be a panacea. Some speculate that increased self-treatment will act as a gateway for consumers who will struggle with hearing in certain situations by reducing cost barriers to hearing aid purchases and related medical visits.²⁰ But this is an untested hypothesis, at least in the United States.²¹ With the same evidence, one could conclude that ineffective self-

¹⁷ This group was not fully representative of an OTC group, e.g., the patients were evaluated by a hearing professional against study inclusion/exclusion criteria.

¹⁸ *Id.*

¹⁹ *Id.* at 75.

²⁰ Comments of CTA, Docket No. FDA-2013-D-1295, 5 (May 6, 2016).

²¹ In South Korea and Japan the results were the opposite. Both countries allow OTC hearing aids, and both countries have low adoption and satisfaction rates.

treatment may lead some to frustration and further delay in getting effective therapy based on a belief that if an OTC hearing aid does not work, no hearing aid will work. And this possibility is of particular concern because of the variable nature of hearing loss – it is much more complicated than simply amplifying sounds – and the complexity and critical importance of proper and customized programming and fitting of the device (collectively known as “fit” in the industry). It is expected that many patients will not be successful with self-fit OTCs.²²

Limiting OTC sales to mild hearing loss will not have a significant impact on patient access for hearing aids for individuals with moderate hearing loss. In recent years, the hearing aid distribution model has evolved, making hearing aids available to consumers through new channels at affordable costs.

Most notable is the addition of “big box” stores to the hearing aid market. Warehouse stores, like Costco and Sam’s Club, have implemented “Hearing Aid Centers” to offer the full array of hearing health services at value pricing. Big box stores now account for at least 10 percent of the private United States hearing aid market, and their market share continues to grow.²³ All of these stores provide safe and effective FDA-compliant hearing aids while providing increased economical access. These stores have been able to bring down costs for consumers while providing professional services, warranties, and advanced technology. Other types of distributors, such as pharmacy chains, have announced they are considering entering the market to provide professionally-fit hearing aids as well.²⁴

Additionally, the internet has opened up other avenues of sales that increase access to services and lower prices of both goods and services. For example, the internet has

²² National Academies of Sciences, Engineering, Medicine, *Hearing Health Care for Adults: Priorities for Improving Access and Affordability* 35 (June 2, 2016) (“NAS Report”); see also Humes et al., *supra* n.9 (“CD service-delivery model [self-selected pre-programmed high-quality hearing aids via an OTC model] was efficacious, with similar effect sizes. However, CD group had a significantly ($p < .05$) lower satisfaction and percentage (CD: 55%; AB: 81%; P: 36%) likely to purchase hearing aids after the trial).

²³ *US Hearing Aid Unit Sales Increased by 8.7% in 2016*, Hearing Review (updated Feb. 9, 2017), <http://www.hearingreview.com/2017/01/us-hearing-aid-unit-sales-increased-8-7-2016/>.

²⁴ See, e.g., Laura Northrup, *CVS Will Experiment With Selling Glasses and Hearing Aids in Some Stores*, Consumerist (Oct. 5, 2015), <https://consumerist.com/2015/10/05/cvs-will-offer-glasses-and-hearing-aids-in-stores-as-pilot-project/>.

made it easier to locate and identify service providers, and patients in underserved areas can consult with hearing health professionals on the phone or through webcasts to address issues with hearing aids. And some companies have adopted a direct-to-consumer model of sales through the internet.²⁵ This model requires the submission of an audiogram conducted by a hearing health professional or a programming kit at an additional cost, but proper fit remains an issue. Other companies, like Hearing Planet, are researching ways to make online consultations work as technology continues to evolve. These new sales and distribution models are indeed having a positive impact on the accessibility of hearing aids.

These caveats notwithstanding, HIA supports the endeavor to reduce the barriers to access hearing loss treatment. Regardless of the method of sale, HIA members will continue to design and innovate to improve the quality of life of individuals with hearing loss. HIA urges the Committee to amend H.R. 1652 to protect patients from the potential shortfalls of self-treatment by amending the bill to permit OTC sales of hearing aids for mild hearing loss only.

II. HIA Strongly Supports the Continued Regulation of Hearing Aids as Medical Devices by the FDA.

Any product “intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease” or “to affect the structure or any function of the body of man or other animals, and which does not achieve [any of] its primary intended purposes through chemical action” is a medical device under the Federal Food, Drug, and Cosmetic Act (FDCA).²⁶ FDA classifies devices based on their level of risk.²⁷ Currently, air conduction hearing aids are classified as a Class I device, the lowest risk classification.²⁸ Those that incorporate wireless or bone conduction

²⁵ See, e.g., iHear Hearing Solutions, <http://ihearmedical.com/hearing-solutions#comparisonChart>.

²⁶ FDCA § 201(h), 21 U.S.C. § 321(h).

²⁷ *Id.*; see also FDCA § 513, 21 U.S.C. § 360c.

²⁸ 21 C.F.R. § 874.3300(b); FDA, What does it mean for FDA to “classify” a medical device? (last updated Dec. 28, 2015), <https://www.fda.gov/AboutFDA/Transparency/Basics/ucm194438.htm>.

features are considered Class II, or moderate risk devices.²⁹ Class II devices require greater regulatory controls to provide reasonable assurance of safety and effectiveness. Approximately 88 percent of hearing aids sold in the United States in 2016 contained wireless features and were therefore categorized as Class II devices. Regardless of classification, all hearing aids are subject to the Quality System Regulations (QSRs),³⁰ as well as other general controls, such as establishment registration, device listing, labeling requirements, reporting, and correction and removal notification requirements. FDA regulations also require all medical device labeling or promotional claims to be supported by valid evidence.

HIA strongly supports FDA regulation of hearing aids as medical devices and believes all FDA labeling requirements, electromagnetic capability (EMC) standards, and any standards implicating safety should be retained for OTC hearing aids.

Additionally, HIA strongly believes that FDA review of a marketing application for a manufacturer's initial hearing aid device would help ensure device safety and effectiveness. FDA can establish guidance documents that would clearly state the data needed to support this 510(k), facilitating entry into the market. Subsequent hearing aids by the manufacturer would be 510(k) exempt and could be marketed without FDA review, absent changes that under FDA's regulation would require a 510(k).

Furthermore, the FDA should incorporate consumer comprehension into its analysis of OTC hearing aids. It is imperative to ensure that consumers can understand the directions and conditions for OTC hearing aids. FDA studies have shown that consumer comprehension is a major barrier to the effective use of all medical devices. If a complex medical device is to be available to consumers without a learned intermediary, it is essential to the safe and effective use of the device that consumers can adequately understand and follow the directions on the labeling. FDA routinely requires consumer

²⁹ FDA, What does it mean for FDA to "classify" a medical device? (last updated Dec. 28, 2015); 21 C.F.R. § 874.3305(b).

³⁰ See 21 C.F.R. Part 820.

comprehension studies of OTC drug products and home-use medical devices.³¹ FDA can set clear expectations for how these studies should be done. FDA can also provide guidance on the data needed for effective home testing that is the *sine qua non* for OTC hearing aids.

III. Any OTC Distribution Model Must Protect Patients by Assuring that Personal Sound Amplifiers Are Not Marketed as Products for the Treatment of Hearing Loss.

Only devices intended to treat hearing loss are considered hearing aids, which excludes Personal Sound Amplifiers (PSAPs). PSAPs are intended only for non-hearing impaired consumers. They are designed to accentuate sounds in specific listening environments, such as bird watching or hunting, but they are not intended for everyday use or to correct hearing loss.³² As recognized by the National Academy of Sciences (NAS), “PSAP manufacturers and distributors are not supposed to be offering their products for the purpose of compensating for hearing loss. This legal and regulatory distinction between hearing aids and PSAPs might not be readily apparent to users, and it might not be fully respected by PSAP sellers who explicitly or implicitly offer their products to compensate for hearing loss.”³³ But because PSAPs are not intended to diagnose, treat, cure or mitigate disease and do not alter the structure or function of the body, they are not devices as defined in the FDCA. As such, FDA has very limited regulatory authority over PSAPs, and PSAPs are not subject to regulatory controls or premarket notification.

The distinction between a hearing aid and a PSAP is an important one for protecting patients. The products are not interchangeable and cannot be considered as

³¹ FDA, FDA CDRH Public Workshop: Guidance on Medical Device Patient Labeling (Sept. 29, 2015), <https://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM465733.pdf>; FDA, Device Labeling Guidance #G91-1 (Mar. 8, 1991), <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081368.htm>; FDA, Guidance for Industry: Label Comprehension Studies for Nonprescription Drug Products (Aug. 2010), <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM143834.pdf>.

³² FDA, Guidance for Industry and FDA Staff: Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Product (Feb. 25, 2009), <https://www.fda.gov/MedicalDevices/ucm127086.htm>.

³³ NAS Report, *supra* n.22, at 189.

such. The embedded chip technology in a hearing aid is much more sophisticated than that of the standard PSAP currently marketed; directional measurements, compression ratios, frequency manipulations, and feedback management all require sophisticated intervention. PSAPs are designed to amplify only and therefore *cannot* be used to treat sensorineural hearing loss. Because PSAPs are not intended to treat hearing loss, they cannot be fitted or tailored to an individual's specific communication requirements.

Furthermore, because PSAPs are not medical devices, they are not subject to safety and efficacy oversight or regulatory controls.³⁴ FDA has no authority to require that a PSAP be recalled should patient safety issues arise or PSAPs be ineffective. Nor does a PSAP manufacturer need to inform FDA of a recall. PSAP manufacturers are not even required to submit a report should their product injure a consumer.³⁵ The Federal Trade Commission (FTC) has said “[i]f your hearing is impaired don’t use a PSAP as a substitute for a hearing aid. That may delay the diagnosis of a potentially treatable condition, and cause more damage to your hearing.”³⁶ The NAS Report recommended maintaining the distinction between PSAPs and hearing aids “to ensure that consumers with hearing loss receive the benefits relating to quality, performance, compatibility, and labeling envisioned under the OTC wearable hearing device category.”³⁷

Consumer electronic products (like PSAPs) and other non-medical devices should remain prohibited from advertising that their products are designed to treat hearing loss. Permitting consumer electronic products to advertise for hearing loss would be akin to complete deregulation of the industry. HIA believes the FTC can play an important role in ensuring consumers receive accurate information about the differences between PSAPs and hearing aids. Since PSAPs are not devices, they are not subject to FDA regulation

³⁴ Unless the PSAP is an electronic product that emits sonic vibrations and is subject to the electronic product provisions of the FDCA that also apply to non-device products. See FDCA §§ 531-542 (21 U.S.C. §§ 360hh-36ss); NAS Report, *supra* n.22, at 180.

³⁵ And this is indeed a risk. According to a recent Consumer Reports article, “these devices have the potential to cause additional hearing damage by overamplifying sharp noises, such as the wail of a fire engine” and “[PSAP machines that cost less than \$50] don’t seem to help much—if at all—and could actually further diminish your ability to hear.” Julia Calderone, *Can PSAPs Help Your Hearing?*, Consumer Reports (Feb. 2, 2017), <http://www.consumerreports.org/hearing-ear-care/can-psaps-help-your-hearing/>.

³⁶ FTC, Sound Advice on Hearing Aids, 2 (Sept. 2010), http://www.devicewatch.org/reports/ftc_hearing_aids.pdf.

³⁷ NAS Report, *supra* n.22, at 192.

(although FDA can intervene if PSAP manufacturers do promote their products in a manner that renders them devices). FTC regulation of false or misleading claims, regardless of whether they make medical device claims or general amplification claims, would help protect consumers.

The consumer electronics market operates very differently from the medical device market. As such, there are serious risks associated with the development of PSAPs to treat hearing loss. New consumer electronic technologies are often disseminated at an early stage through beta tests to accelerate, commercialize, and gain feedback, but this model is not appropriate for a medical product. Medical devices are carefully tested for safety and efficacy before being commercialized; consumer product testing is primarily directed toward performance, not safety. And FDA regulates the investigational studies of new devices.³⁸ Thus, PSAPs need to be treated only as amplification devices, not as substitutes for hearing aids, and this requirement must be enforced. Failure to recognize and enforce these differences would lead to complete deregulation of the hearing industry. FDA should review and finalize its 2013 Draft PSAP Guidance to accomplish these goals.

Complete deregulation of the hearing aid industry should not be considered a viable option. Past experiments with deregulation have shown that the unregulated hearing aid market does not work. Prior to hearing aid regulation, an FDA Task Force in 1976 investigated hearing aids and discovered that many of the hearing devices sold “basically didn’t work.”³⁹ In 1985, Colorado experimented with deregulation of hearing aid sales and determined that complaints filed for hearing aids jumped from an average of 14 per year to 100.⁴⁰ The most common complaints included refusal to provide legally mandated refunds, problems with fittings and repairs, and contract and fraud issues. Colorado eventually decided to reinstate licensing requirements for hearing aid

³⁸ 21 C.F.R. Parts 50, 56, and 812.

³⁹ FDA, Transcript from Streamlining Good Manufacturing Practices for Hearing Aids Workshop, 12 (Apr. 21, 2016) (Statement of Commissioner Robert Califf), <https://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM502750.pdf>.

⁴⁰ *Id.* at 183-84.

distribution.⁴¹ Complete deregulation of OTC hearing aids would likely result in a recurrence of the same behaviors and problems. And with the internet, it would be easier to commit fraud and confuse people than before.

Conclusion

HIA appreciates the opportunity to provide testimony at today's hearing. HIA supports the effort to promote innovation in the field of hearing technology and increase access for consumers. HIA believes that new distribution models and new informational resources are already helping to advance these goals. HIA applauds the efforts of the Congress, the FDA and the FTC to work together to ensure more accessible and affordable hearing loss treatment for all.

Once again, HIA emphasizes the importance of safety and efficacy in the hearing aid industry. The health of the patient must be foremost; only after assuring safety and efficacy can the discussion about cost proceed. For this reason, HIA believes that OTC hearing aids subject to the appropriate FDA regulatory controls may be an effective cost-reducing option for those with mild hearing loss, but strongly encourages limiting the category to *only* those with mild hearing loss. HIA urges the Subcommittee to amend H.R. 1652 to permit OTC hearing aid sales to patients with mild hearing loss only.

⁴¹ *Id.* at 185.

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 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:]

“Examining Improvements to the Regulation of Medical Technologies”

Testimony of

Frank R. Lin, M.D. Ph.D.

Associate Professor

Departments of Otolaryngology-Head & Neck Surgery,

Geriatric Medicine, Mental Health, and Epidemiology

Johns Hopkins University

Before the

United States House of Representatives

Committee on Energy and Commerce

Subcommittee on Health

May 2, 2017

Chairman Burgess, Ranking Member Green, and Members of the Subcommittee:

Thank you for inviting me here today. My name is Frank Lin, and I'm an Associate Professor in the Departments of Otolaryngology-Head & Neck Surgery and Geriatric Medicine at the Johns Hopkins School of Medicine and in the Departments of Epidemiology and Mental Health at the Johns Hopkins Bloomberg School of Public Health. From a clinical perspective, I'm a board-certified otolaryngologist with fellowship training in otology, and I am 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 (H.R.1652) stems directly from this background.

The OTC hearing aid act introduced by Representatives Blackburn and Kennedy directly reflects the earlier recommendations made by 2 expert committees—the President's Council of Advisors on Science and Technology issued a report in October 2015¹, and this was then followed by a National Academies consensus study report² on Affordable and Accessible Hearing Care for Adults in June 2016. I advised PCAST on their report and was 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 would immediately benefit public health and Americans.

The importance of the present bill instructing that the FDA carry out this recommendation is immense for public health. Over the past several years, research from Johns Hopkins as well as from other academic institutions has demonstrated that hearing loss, while being a usual process of aging for nearly all Americans, is not without consequence. These studies have demonstrated that individuals with hearing loss are at a greater risk of developing dementia³⁻⁵, having falls^{6,7}, becoming hospitalized^{8,9}, and having greater health care costs¹⁰. These research studies also clearly suggest that hearing loss treatments such as using hearing aids and other forms of amplification could potentially decrease these risks and lead to real and tangible benefits for individuals, families, and society. And yet, presently, <20%¹¹ of the nearly 38M Americans¹² with a significant hearing loss currently has access to hearing aids.

The reason for this low rate of use stems largely in part from a current regulatory framework that only allows for a one-size-fits-all model of obtaining hearing care—that is, for an American to obtain hearing aids, he or she has to make repeated trips back and forth to a licensed hearing professional who serve as the gatekeepers to consumers being able to obtain hearing aids. While this model is appropriate for those with more complex hearing losses, this model is extremely expensive and is clearly not needed by every one of the 38M Americans with hearing loss. At present, the average cost of obtaining 2 hearing aids in the U.S. under this model is approximately \$4700² which 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 to be directly available to consumers. Based on the scientific literature¹³, such devices could safely provide levels of amplification that would be effective for those individuals with mild-to-moderate hearing losses. Both established hearing aid manufacturers as well as innovative new startup companies and 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. At present, with current regulations prohibiting direct access to consumers and 98% of the world's hearing aid marketplace being controlled by 6 companies, there is little incentive or ability for innovation and for new companies to enter the market.

Importantly, the availability of OTC hearing aids does not in any way preclude the invaluable services in counseling, education, and programming that a hearing professional could provide. One would expect that many adults would in fact still want to seek out a hearing professional to learn how to use these 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 would bring hearing technologies out from under the explicit control of a group of individuals (such as me) and allow consumers to choose what level of hearing care best meets their needs and priorities.

I should note that some critics of OTC hearing aids raise concerns about the safety of these devices for consumers without having a professional exam, the risk of children using these devices, and the suitability of these devices for mild-to-moderate hearing loss. 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 in improving the lives of Americans with hearing loss and advancing public health. These latter priorities are what mainly concern me and what also concerned PCAST and the National Academies in their recommendations that serve as the basis of the present OTC hearing aid act.

Possible concerns raised about OTC hearing aids

Device safety One of the most important aspects of the current legislation is that the FDA would establish evidence-based performance standards for OTC hearing aids to ensure that they are both safe (e.g., maximum sound output levels) and effective. At present and without this regulatory classification, the market is awash with unregulated hearing devices (i.e., personal sound amplification devices) commonly found in drugstores and advertised in magazines that make wild and unsubstantiated claims about performance and many of which have unsafe sound output levels. Consumers seeking out more affordable hearing technologies often turn to these devices, but without proper FDA regulation, they have no way of knowing which devices could in fact benefit them. FDA re-regulation would bring clarity to the marketplace ensuring that consumers could have access to safe and effective devices.

Consumer safety Some clinicians make the argument that obtaining a hearing aid without first having a medical exam is unsafe. While this argument is sound for children, it doesn't make sense for adults where 2 of every 3 adults over 70 years have a hearing loss¹⁴. In the absence of signs such as a draining ear, sudden hearing loss, etc. (all of which would be listed as warning signs to see a doctor for in the labelling of an OTC device), the chances of missing important clinical diseases are minute ² (e.g., an acoustic neuroma [a benign hearing nerve tumor] is diagnosed in ~0.001% of people per year) and far outweighed by the benefits of ensuring access to hearing technology

for the millions of people who currently do not seek help for their hearing loss. By the same extension, we as a society have long accepted the risk and benefits of OTC reading glasses (despite the fact that poor vision could be from glaucoma which is prevalent in 5% of older adults) or OTC aspirin for headaches (despite the fact that headaches may be masking neurologic conditions or that aspirin can and does occasionally lead to fatal internal bleeding). In both of these latter cases and as with OTC hearing aids, the benefit of access to these OTC products for society far exceeds any theoretical risks.

More importantly, there is an even greater likelihood that the availability of OTC hearing aids will intensify awareness of hearing loss in society and lead even more (rather than fewer) Americans to seek a hearing professional's evaluation of hearing once affordable OTC hearing aids are known to be available. At present, many consumers avoid seeking out professional hearing evaluations because of the perceived lack of affordable treatment options for hearing loss.

Device effectiveness for mild-to-moderate hearing loss and consumer ability to self-diagnose and self-fit hearing aids: The strongest scientific study to date consisting of a definitive NIH-funded randomized controlled trial¹³ demonstrated that consumers can self-fit OTC hearing aids and that these devices benefit consumers with a mild-to-moderate hearing loss. There is absolutely no medical reason or rationale to consider limiting the intended use of OTC hearing aids (and hence the FDA performance standards of these devices) to only those individuals with a mild hearing loss.

Risk to children Some individuals have raised the concern that children with hearing loss may be given OTC hearing aids by their parents rather than being taken for medical and audiological evaluation. As a medical and surgical expert in hearing loss, I agree that this would not be in the child's best medical interest, but any concern that I have is tempered by the actual circumstances concerning how pediatric hearing loss is already managed in the U.S. Presently, universal newborn hearing screening and school-age hearing screening programs have long been active in all states, and children are thereafter referred appropriately for follow-up. For low-income families with children qualifying for Medicaid, the Early and Periodic Screening, Diagnosis, and Treatment

Program under Medicaid already mandates coverage of all medically-necessary hearing aid services and hearing aids for children. As such, it is highly unlikely that a significant hearing loss in a child would go unrecognized in the current environment such that a parent would take it upon themselves to feel compelled to self-diagnose and treat their child without consulting with a medical and/or audiological professional.

As a society, we have also long ago accepted that many OTC products could theoretically be inappropriately used by children and cause harm, but that the overall benefits to society far outweigh these theoretical risks. For example, using the case of aspirin discussed above, when given to children recovering from viral illnesses aspirin can increase the risk of Reye's syndrome, a potentially fatal condition involving brain swelling. However, with proper labelling instructing parents to avoid giving aspirin to children with viral-like illnesses, this condition remains very rare, and we continue to recognize the benefits to society of having OTC aspirin widely available despite the theoretical risks.

Conclusion

The OTC hearing aid bill under consideration by Congress would enable the FDA to sensibly re-regulate hearing aids to ensure that 38M Americans with hearing loss have access to safe and effective OTC hearing technologies that can enable them to communicate and fully engage in society. The benefits of OTC hearing aids for improving public health, promoting innovation in the hearing technology marketplace, and lowering costs are substantial and profound. Passage of this bill represents a 'win-win' for the 38M Americans¹² with hearing loss (in particular American seniors of whom nearly 2 of 3 have a significant hearing loss¹⁴), hearing health professionals who will have a wider range of hearing technologies to choose from with which to help their patients, and both established hearing aid and other technology companies who will now be able to develop innovative new hearing technologies that can be offered directly to American consumers.

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

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- 2 Hearing health care: Priorities for improving access and affordability. National Academies of Science, Engineering, and Medicine. Washington, D.C., 2016.
- 3 Lin, F. R. *et al.* Hearing loss and incident dementia. *Arch Neurol* **68**, 214-220, 2011.
- 4 Gallacher, J. *et al.* Auditory threshold, phonologic demand, and incident dementia. *Neurology* **79**, 1583-1590, 2012.
- 5 Lin, F. R. & Albert, M. Hearing loss and dementia - who is listening? *Aging Ment Health* **18**, 671-673, 2014.
- 6 Viljanen, A. *et al.* Hearing as a predictor of falls and postural balance in older female twins. *J Gerontol A Biol Sci Med Sci* **64**, 312-317, 2009.
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- 8 Genter, D. J. *et al.* Association Between Hearing Impairment and Risk of Hospitalization in Older Adults. *Journal of the American Geriatrics Society* **63**, 1146-1152, 2015.
- 9 Genter, D. J., Frick, K. D., Chen, D., Betz, J. & Lin, F. R. Association of hearing loss with hospitalization and burden of disease in older adults. *JAMA* **309**, 2322-2324, 2013.
- 10 Foley, D. M., Frick, K. D. & Lin, F. R. Association between hearing loss and healthcare expenditures in older adults. *Journal of the American Geriatrics Society* **62**, 1188-1189, 2014.
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- 13 Humes, L. E. *et al.* The Effects of Service-Delivery Model and Purchase Price on Hearing-Aid Outcomes in Older Adults: A Randomized Double-Blind Placebo-Controlled Clinical Trial. *American journal of audiology* **26**, 53-79, 2017.
- 14 Lin, F. R., Thorpe, R., Gordon-Salant, S. & Ferrucci, L. Hearing loss prevalence and risk factors among older adults in the United States. *J Gerontol A Biol Sci Med Sci* **66**, 582-590, 2011.

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

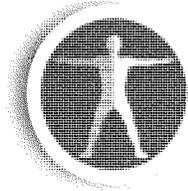
number of non-manufacturer independent service organizations who repair and maintain medical devices. In what is probably a surprise to many, currently only service activities performed by a manufacturer are regulated by the FDA. Service activities performed by a third-party independent service organization 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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STATEMENT

OF

JOE ROBINSON

**SENIOR VICE PRESIDENT OF HEALTH SYSTEMS SOLUTIONS FOR
PHILIPS NORTH AMERICA**

ON BEHALF OF

THE MEDICAL IMAGING & TECHNOLOGY ALLIANCE (MITA)

REGARDING A HEARING ON

“Examining Improvements to the Regulation of Medical Technologies”

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

Tuesday, May 2, 2017

SUMMARY OF TESTIMONY

- MITA fully supports H.R. 2009, the Fostering Innovation in Medical Imaging Act of 2017 and H.R. 2118, the Medical Device Servicing and Accountability Act and urges their inclusion in the MDUFA IV legislation.
- H.R. 2009 will help manufacturers of medical imaging devices clear unnecessary regulatory hurdles and improve access to advancements in medical imaging that help physicians detect disease earlier when it's more treatable. It will also permit, but not require, medical imaging contrast agent manufacturers to conform the indications to the new device indication by adding the new device indication through a NDA supplement. Removing impediments to technological advancements in medical imaging will encourage innovation and allow physicians to better diagnose and treat patients in the United States in a manner that is consistent with medical practice internationally.
- H.R. 2118 will help to ensure patient safety and medical device performance by requiring that medical device servicing organizations register with the FDA, maintain an internal complaint handling system, and file adverse event reports. This legislation seeks to protect patients and ensure effective device performance through increased visibility and accountability for medical device servicers.

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 for Philips North America and chair of the MITA Board of Directors. I'm here today to testify on behalf of the Medical Imaging and Technology Alliance (MITA).

MITA is pleased to submit the following testimony on H.R. 2009, the Fostering Innovation in Medical Imaging Act of 2017 and H.R. 2118, the Medical Device Servicing and Accountability Act. These very important pieces of legislation will help patients get the care they need safely and effectively.

MITA also supports H.R. 1736, also the subject of this hearing, to make improvements to the FDA's inspections process.

* * * *

H.R. 2009 – THE FOSTERING INNOVATION IN MEDICAL IMAGING ACT OF 2017

MITA is the collective voice of medical imaging equipment and radiopharmaceutical manufacturers, innovators and product developers. It represents companies whose sales comprise more than 90 percent of the global market for medical imaging technology. These technologies include: magnetic resonance imaging (MRI), medical X-Ray equipment, computed tomography (CT) scanners, ultrasound, nuclear imaging, radiopharmaceuticals, and imaging information

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

The Council on Radionuclides and Radiopharmaceuticals (CORAR) is an association comprised of companies who manufacture and distribute radiopharmaceuticals, radionuclides, and contrast agents primarily used in medicine and life science research. CORAR advocates for regulations and legislation that facilitate innovation in diagnosis and therapy to advance health care for patients and providers. Specifically, CORAR focuses on manufacturing, transportation, safety, security, government reimbursement, and regulatory issues that can impact the radiopharmaceutical, radionuclide, sealed source, and contrast agent industries. CORAR pursues a proactive agenda which includes education of the Congress and regulatory bodies on the benefits of radiopharmaceuticals, radionuclides, and contrast agents to medical and life sciences.

FDA CLEARANCE OF IMAGING DEVICES AND THE USE OF CONTRAST IMAGING AGENTS

Contrast agents and radiopharmaceuticals may be prescribed by physicians for use with diagnostic imaging equipment for a number of clinical applications to enhance images allowing for improved visualization and characterization of organs and tissues for diagnostic purposes. For contrast agents, these uses include pediatric diagnosis, MRI for adults, MRA of the brain, CT and many other imaging uses as stipulated in the contrast agents' indications for use. The use of contrast agents has become a central part of modern clinical practice including ultrasound scans,

x-ray exams, computed tomography scans and magnetic resonance imaging. Although some imaging procedures may be performed without contrast agents, the administration of contrast agents improves the clarity of the images obtained. Radiopharmaceuticals are integral to nuclear medicine and positron emission tomography (PET) procedures, as there is no image generated without the use of the radiopharmaceutical.

Contrast agents and radiopharmaceuticals are administered in different ways. Some are administered orally; others are injected or delivered through an intravenous line. After the imaging procedure, most are naturally excreted by the body.

The United States Food and Drug Administration (FDA) is currently not willing to approve or clear imaging devices, or imaging device enhancements, for use with currently approved contrast agents if the contrast agents are not also labeled for that use. Since a contrast agent manufacturer often has no need or incentive to revise the labeling, updates to contrast agent labeling are not keeping pace with the technological advancements of medical imaging devices, and such advancements are not being approved or cleared by FDA. FDA believes that their regulations prevent them from approving or clearing a device for use with an approved contrast agent where the use is not also specified in the contrast agent labeling. The purpose of this bill is to authorize FDA, under narrowly specified conditions, to approve or clear an imaging device or an imaging device enhancement (called an “applicable medical imaging device” in the bill) for use with a contrast agent in a new indication that is not among the approved indications of the contrast agent.

MITA, CORAR, and their respective members have been working collaboratively with the FDA for nearly 20 years to find a reasonable solution to this issue. In fact, the topic was addressed as part of the MDUFA II agreement in 2007. Ten years later, the problem has yet to be

resolved by the Agency. Therefore, we are asking Congress to pass H.R. 2009, the *Fostering Innovation in Medical Imaging Act of 2017* to provide clarification to the Agency on an appropriate clearance and approval pathway for imaging devices used with contrast agents.

WHY THIS MATTERS TO PATIENTS AND PHYSICIANS

Diagnostic imaging that utilizes contrast agents to enhance the image is a safe and invaluable tool for clinicians and the standard of care in many cases. Neither physicians nor patients benefit from the current situation as new imaging innovations are being held up at the Agency or are being omitted from equipment in order to obtain approval or clearance, while being widely available in other parts of the world. Without the benefit of new imaging innovations, physicians know less about a patient's condition and must make a less informed decision about the required course of treatment.

This legislation would allow patients to have more rapid access to new imaging technologies that involve the use of contrast agents. We believe this would allow for a broader and more equitable adoption of the latest innovation in the use of medical imaging. Currently, there can be a disparity between research centers of excellence and the community hospitals that serve most patients across the country. Research centers have the capability and resources to conduct the research necessary to use imaging technology in an expanded way. Through this research, they develop advanced imaging techniques. Generally, device manufacturers are then able to use the research and seek clearance or approval for expanded indications. For indications that include the use of contrast agents, the regulatory pathway for expanded indications is confusing and cumbersome, and manufacturers have been unable to obtain clearance or approval. Therefore, information about the new indications is not reaching outside of the research centers, meaning many American patients do not have access to the latest innovation. In some cases, new

indications for contrast agents and medical imaging devices are widely available in other countries years before they are available to American patients.

MITA urges Congress to pass H.R. 2009, the *Fostering Innovation in Medical Imaging Act of 2017* to ensure that patients and physicians, regardless of the type of institution, have access to innovative diagnostic imaging capabilities.

FDA TREATMENT OF NEW CONTRAST INDICATIONS FOR DEVICES

In December 2009, FDA released a guidance document entitled: “Guidance for Industry: New Contrast Imaging Indication Considerations for Devices and Approved Drug and Biological Products.” This Guidance was part of an agreement under the Medical Device User Fee Amendments of 2007 (MDUFA). Specifically, FDA agreed to develop a guidance document for medical imaging devices used with “contrast agents or radiopharmaceuticals” to help both FDA reviewers and industry to understand the appropriate pathway for approval or clearance of these products.

Imaging device manufacturers requested this guidance from FDA because for years they had struggled to find a consistent pathway through the FDA regulatory process and anticipated the guidance providing stability and transparency. Unfortunately, the 2009 guidance did not provide the clarity manufacturers’ were seeking. In many ways it is so restrictive that it has made the process more confusing and cumbersome than before, essentially restricting the regulatory process for innovative imaging devices that may be used with contrast agents, where the device indication is not described in the labeling of the contrast.

Over the course of 2010, as the guidance was implemented, the Center for Drug Evaluation and Research (CDER) and the Center for Devices and Radiological Health (CDRH) struggled to interpret the guidance with regard to the circumstances in which the use of contrast

agent may be acceptable. As a result, imaging devices that had been cleared by FDA even a year or two before guidance was issued, that included features involving the use of approved contrast agents were no longer being cleared or approved by the Agency. This left manufacturers with few options for FDA clearance short of stripping new devices of contrast imaging functionalities — in effect “defeaturing” devices — turning back the clock on technology and running counter to the practice of medicine. Further, these basic features are not new or novel.

In 2011, the FDA met with key stakeholders, including MITA and the American College of Radiology (ACR) to discuss the potential public health consequences of continued implementation of the guidance. The FDA agreed to a non-enforcement policy for a period of two years while they considered a more efficient method for approving medical imaging equipment that may be used with contrast agents with non-conforming labels. The two-year period has long since expired, and the guidance is still in place on the FDA website, which could lead to further confusion in the marketplace and the Agency. MITA and CORAR have met with FDA throughout the intervening years to discuss the issue, but no resolution has been forthcoming.

H.R. 2009, FOSTERING INNOVATION IN MEDICAL IMAGING ACT OF 2017

The current situation for contrast agent and medical imaging device approval and clearance hinders the Agency’s goals of fostering medical device innovation, enhancing regulatory predictability, improving patient safety and promoting public health. The Fostering Innovation in Medical Imaging Act of 2017 makes clear that CDRH has the authority to consider and approve or clear, under certain specified conditions, a premarket application or notification for a medical imaging device for use with a contrast agent even if the labeled indications do not match. The bill also specifies that contrast agent manufacturers are permitted, but not required, to

update their labels to add the new device contrast indication through an NDA supplement. MITA and CORAR support the passage of this legislation.

Specifically, CDRH may clear or approve a medical imaging device for a new indication involving the use of an approved contrast agent where the contrast agent is not approved for that indication, as long as the contrast agent is not used:

- in a concentration, rate of administration, or route of administration that is different from those described in the approved labeling of the contrast agent;
- in a region, organ, or system of the body that is different from those described in the approved labeling of the contrast agent, unless the Secretary determines, based on information contained in the device application or 510(k) notification, that the difference does not affect the safety of the contrast agent when used with the device;
- in a patient population different from the patient population described in the approved labeling for such contrast agent, unless the Secretary determines that there is no increased risk; or
- in an imaging modality, such as ultrasonic, ionizing radiation, or magnetic resonance, that is different from those described in the approved labeling of the contrast agent.

By clarifying the process for imaging equipment manufacturers to gain approval or clearance for new technologies that utilize formerly approved contrast agents, this bill will spur even more innovation. This is an opportunity to ensure patient access to new imaging technology and give their physicians even more specific information when considering treatment options. This bipartisan bill provides medical imaging device and contrast agent manufacturers a clear regulatory pathway to ensure all patients have timely access to innovative advanced

medical imaging technologies. Many of these new medical imaging technologies are indicated with previously approved contrast agents. In many instances, medical imaging technology advancements have outpaced the approved contrast agent labels.

H.R. 2009, the Fostering Innovation in Medical Imaging Act of 2017 will help manufacturers of medical imaging devices clear unnecessary regulatory hurdles and improve access to advancements in medical imaging that help physicians detect disease earlier when it's more treatable. It will also permit, but not require, contrast agent manufacturers to conform the indications to the new device indication by adding the new device indication through a NDA supplement. Removing impediments to technological advancements in imaging will encourage innovation and allow physicians to better diagnose and treat patients in the United States in a manner that is consistent with medical practice internationally. This bill builds on the 2017 user fee agreements and will ultimately allow patients in all communities to access the cutting edge innovation in diagnostic imaging by labeling products with new indications for use.

* * * *

H.R. 2118 - THE MEDICAL DEVICE SERVICING AND ACCOUNTABILITY ACT

Currently, only servicing activities performed by medical device manufacturers are held to any quality, safety, or regulatory requirements by the FDA. Non-manufacturer entities have no FDA oversight and do not have to follow FDA regulations. This is an important problem because performance of servicing activities within a quality system by properly trained personnel using

qualified properly sourced parts reduces the risk of harm to the patient, healthcare provider, or device operator and reduces risk of poor performance of the device.

The medical device servicing industry has changed significantly since the issue of device servicing was last seriously considered by the FDA in 1997-98. The number of unregulated and unregistered organizations and persons servicing medical devices has increased over the last twenty years without any comparable adjustment in the regulatory framework governing these activities. Unregulated and unregistered service providers are a growing and significant portion of the industry about which the FDA, healthcare providers, patients, and manufacturers know very little due to the lack of regulatory oversight, registration, or reporting.

Our goal is to ensure that performance of these activities always results in the safe and effective operation of medical devices. H.R. 2118, the Medical Device Servicing and Accountability Act takes an important first step toward this goal by requiring that all medical device servicers register with the Food and Drug Administration (FDA), maintain an internal complaint handling system, and report adverse events to the FDA.

MITA member companies are responsible for the innovation, original design, manufacture, packaging, labeling, assembling and upgrading of medical devices. Original equipment manufacturers also often provide servicing activities for installed devices both their own and those originally manufactured by other companies.

Whether or not the manufacturer is also the entity which services a device, it has a stake in all service activities. Improper servicing presents significant concerns to the manufacturer, including creating challenges such as:

- Difficulties in future manufacturer-provided servicing operations and the potential for significant periods of downtime if poorly performed previous repairs must be remedied;
- Difficulties in providing future field upgrades or field corrections to the device if improper parts have been used or if the device has otherwise been altered;
- Lack of required regulatory reporting and incomplete device history does not allow for tracking of significant events, root cause investigation, or prevention of adverse events;
- Voided existing device certifications (e.g. UL certifications);
- Diminished brand value due to unsafe and ineffective operation of the device; and
- Liability concerns for the manufacturer if the device injures directly or indirectly a patient or operator.

Due to the fact that our member companies and their service departments regularly encounter these and other challenges, we have raised this issue with the FDA several times over the past few years. In raising this issue, our goal is to ensure the performance of servicing activities always results in the safe and effective operation of medical devices.

More specifically, our interest in this issue is driven by patient safety. It is because of patient need that medical imaging devices exist. Medical imaging is essential for the screening, diagnosis, staging, therapy guidance, therapy monitoring, risk stratification, and surveillance of a multitude of medical conditions. For this reason, the patient is the most important stakeholder in medical device servicing. Patients and their healthcare providers count on the safe, effective, and reliable operation of medical devices. If medical devices do not perform properly or do not perform at all due to improper servicing, patients may not be able to receive the care they need and healthcare professionals are unable to do their job effectively.

The nature of the risk to the patient is discussed in greater detail below, but, in general, there are two main categories of patient harm:

- 1) Direct bodily harm resulting from improper functioning of the device due to mechanical, maintenance, or calibration issues¹ or healthcare-associated infections²
- 2) Indirect harm resulting from delayed diagnosis or misdiagnosis due to poor image quality³

Generally there is a risk of delivering non-conforming devices if servicing activities are not properly performed as defined by the original equipment manufacturer. A non-conforming device means that the device does not fulfill its specifications and poses a risk in regards to the safety and effectiveness of the device, and thus potentially also to the health and safety of patients and users.

Although this is not a comprehensive list, there are a number of specific risks depending on the kind of device in question:

- **Electrical shock**—All medical imaging devices require electricity to function. If the device has not been properly wired, has incorrect parts, etc..., then there is the risk that a living being interacting with the device could receive an electrical shock.
- **Over exposure to radiation**—Some imaging devices, including X-Ray and CT scanners, emit radiation, resulting in potential over-exposure if not properly calibrated or maintained, leading to bodily harm.

¹ E.g. excessive radiation from incorrectly calibrated equipment or physical injury from mechanical failure

² E.g. infections resulting from improperly sealed ultrasound transducers

³ E.g. blurry images due to miscalibration, resulting in obfuscation of malady

- **Poor image quality**—If improper servicing leads to a device being improperly calibrated, the images the device produces could be of poor diagnostic quality due to artifacts or other issues. This could lead to misdiagnosis including both false positives and false negatives. It could also require re-imaging due to poor image quality.
- **Mechanical failure**—If the device in question experiences mechanical failure due to improper servicing, bodily harm to the patient ranging from pinching to crushing could result.
- **Air embolism**—In the case of injection devices, if the device has not been properly serviced, the patient could experience an air embolism and die.
- **Infection**—In the case of ultrasound and other devices, if the device has not been properly scaled as part of servicing activities, patient infection could result.
- **Explosion**—If the magnet in an MRI machine is not properly vented, pressure can build up inside the magnet resulting in eventual explosion.
- **Burns**— Incorrect replacement materials or parts in an MRI machine may disrupt the path of radiofrequency energy, causing excessive heating and resulting in patient burns.
- **Interference with other equipment**—If a device's electromagnetic shielding has been improperly serviced, operation of the device could be potentially detrimental to other equipment in surrounding area.
- **Asphyxiation**—If the magnet in an MRI is improperly vented, then helium gas could displace air in the room, resulting in asphyxiation.

The patient has the most at stake if the device fails to perform in a safe and effective manner due to improper servicing. Patients should be able to assume an equivalent level of safety and efficacy regardless of the service provider. Performance of these activities within a quality system by properly trained personnel using qualified, properly sourced parts greatly reduces the risk of harm to the patient.

Unfortunately, it is not currently possible to know the full scope of problems that have occurred when there has been no prior scrutiny or any regulatory oversight of non-manufacturer service providers and other third parties which would require reporting of problems. The only way to determine the magnitude of the problems associated with improper performance of these activities would be through regulation of all entities which perform these activities, including registration and reporting.

Although further steps will be necessary to ensure consistent safety and quality, the Medical Device Servicing and Accountability Act will take a crucial first step in addressing this issue by requiring that non-manufacturer 3rd party servicing organizations step out of the dark and make themselves known to the FDA and the American public, maintain an internal complaint handling system, and report adverse events to the FDA.

Often, a manufacturer does not learn of an issue with its device unless the owner or operator of the device or a third party service entity reports an issue to the manufacturer. This does not happen in all cases. Further, the manufacturer often is not notified of an issue with the device until the device has failed or encountered some other problem which the servicer has been unable to resolve. Although the manufacturer may be made aware of the issue at this juncture, the manufacturer is not necessarily informed of the issues which led to this event. In many cases, there will have been a series of problems with the device for which assistance from a non-

manufacturer entity was sought. These activities performed by the non-manufacturer entity are not required to be reported to the FDA or to any other organization which would be compiling and trending a comprehensive database of problems.

Further complicating the situation is the fact that it is often difficult for manufacturers to determine the source of observed problems because third parties generally do not place any labeling on the device to indicate it has passed through their hands. Awareness of device problems will decrease as equipment becomes less traceable due to turnovers in service providers and equipment ownership.

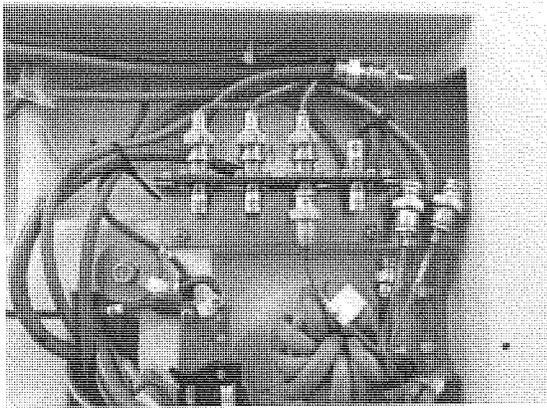
Manufacturers regularly encounter examples of improper servicing. Although they are in no way comprehensive or inclusive, the examples below serve as a sample of the issues that are regularly encountered. In some cases, we have photographic documentation of the issue. However, not all situations easily lend themselves to visual representation.

IMPROPER SERVICING OF AN MRI SYSTEM

The following photos were obtained in January 2017 from an MRI system being used to scanning patients. The manufacturer was contacted to service the system due to poor image quality that the third party was unable to correct. The system was found to be in significant disrepair with several components damaged, poorly repaired or missing. After a detailed evaluation the manufacturer recommended a significant amount of repair that was similar to deinstalling and reinstalling the system to replace the necessary components and recalibrate the system.

Receive Channels Disconnected

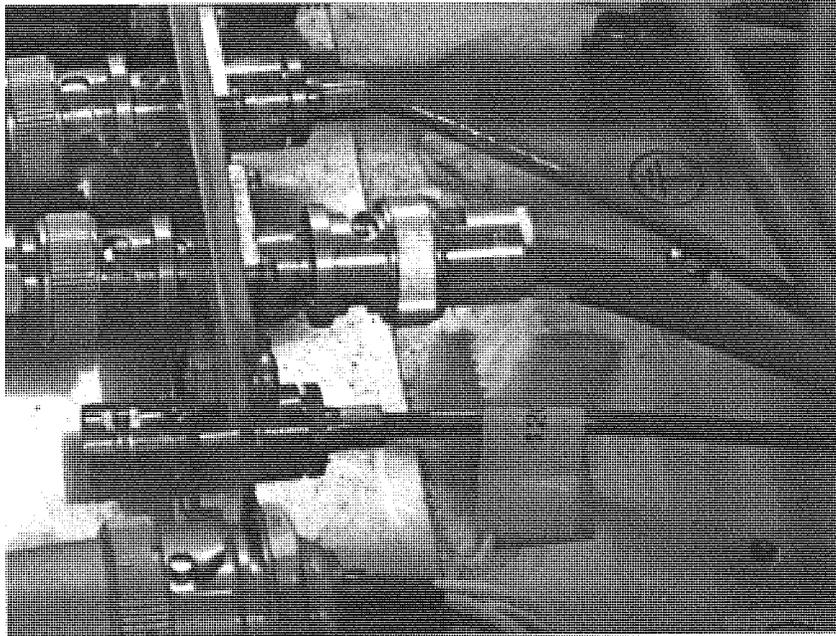
This MRI system includes four receive channels from the coils used to scan different portions of the anatomy. As shown in this photo, three of the four channels were disconnected because they were nonfunctional. Troubleshooting showed all three other were open and the fourth connected line was also compromised with readings that were outside of specification.



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Incorrect Cable Replacement

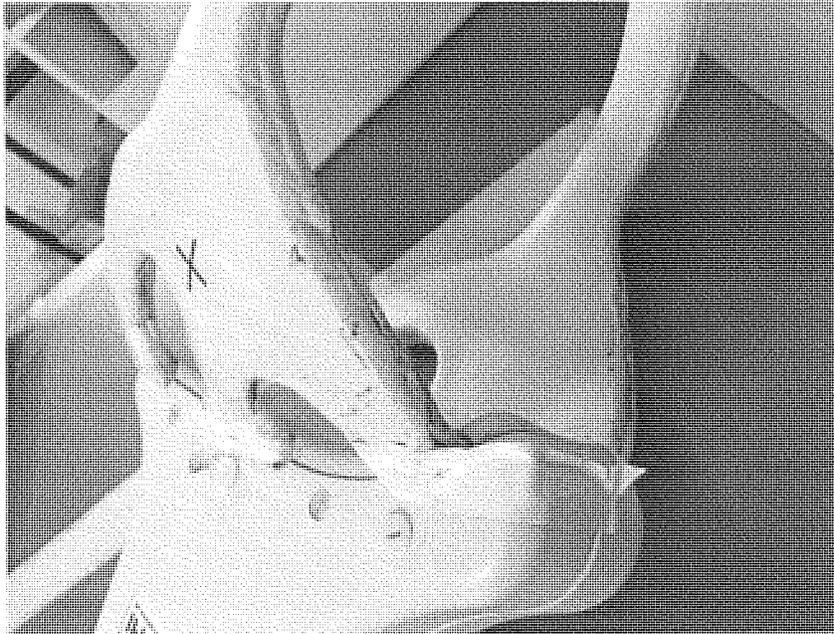
At the foot of the patient table one of the 4 receive cables (the only remaining functional) was replaced with the incorrect cable. The incorrect cable is the larger diameter cable the center of the photo.



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Shoulder Coil Serviced With Tape

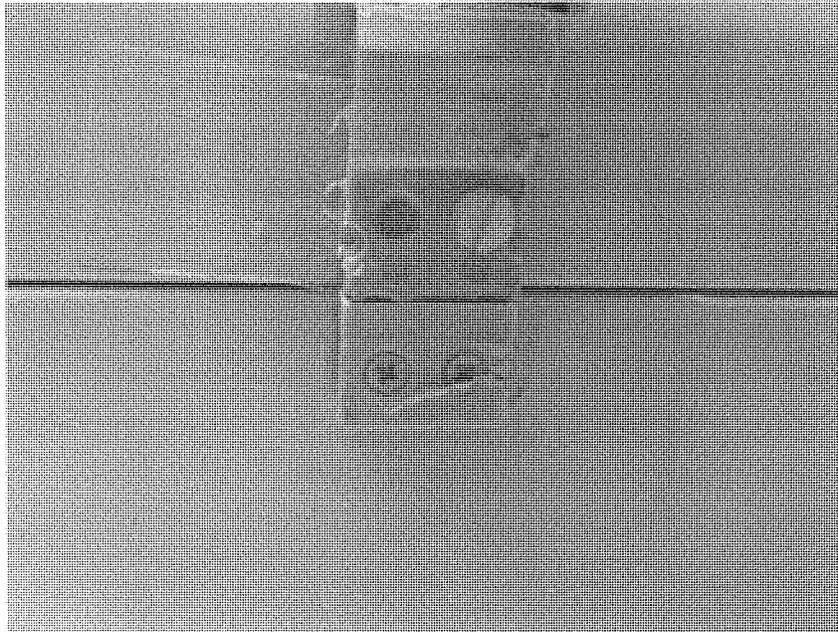
The shoulder coil was found damaged with several attempted repairs using a white tape. The use of tape would prevent proper cleaning of the coil. The coil failed to meet specification when tested.



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Head Coil Latch Damaged and Non Functional

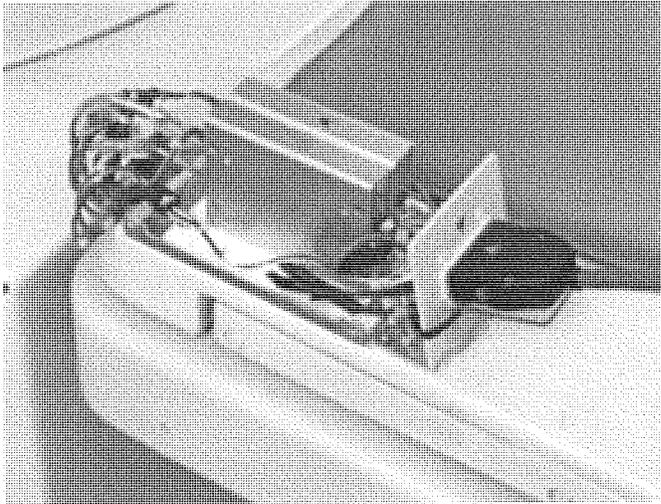
The screw holes on both sides of the coil latch were stripped out. Repairs were attempted with incorrectly sized screws and tape. The top portion of the coil could not be properly secured to assure a good connection of the receive lines in the top portion of the coil.



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Missing Signal Amplifiers

The patient table is equipped with 4 pre-amps. The manufacturer found two of the pre-amps were missing from the system and had not been replaced.

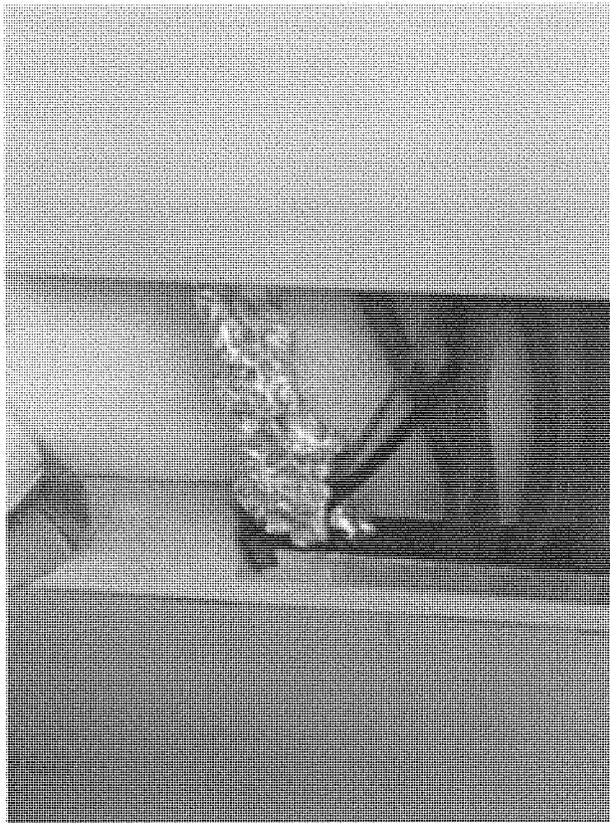
Incorrect Computer Replacement

The manufacturer found the commercial grade SUN workstation normally used to operate the system replaced with a consumer grade system. The possible impact on system performance is not clear and would require extensive testing to validate and verify proper operation when combined with the entire MRI system. No photo available. Additionally the system indicated it was upgraded but the proper software upgrade was not loaded. This would indicate an incorrect software reload was performed.

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Aluminum Foil Used for Shielding

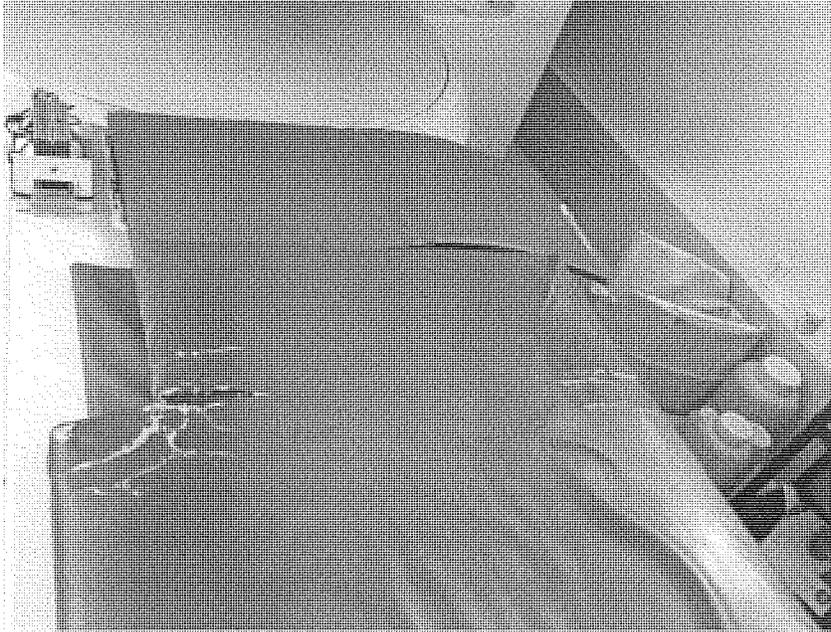
The manufacturer found aluminum foil used to shield some of the cables in the scan room. It is believed this was an effort to shield the receive cables to correct poor signal and artifacts in the images. This can present safety and electrical issues when used within the MRI filter panel that contains high voltage.



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Patient Table Pads Damaged

The patient table pads were damaged and should be replaced to allow for proper cleaning.



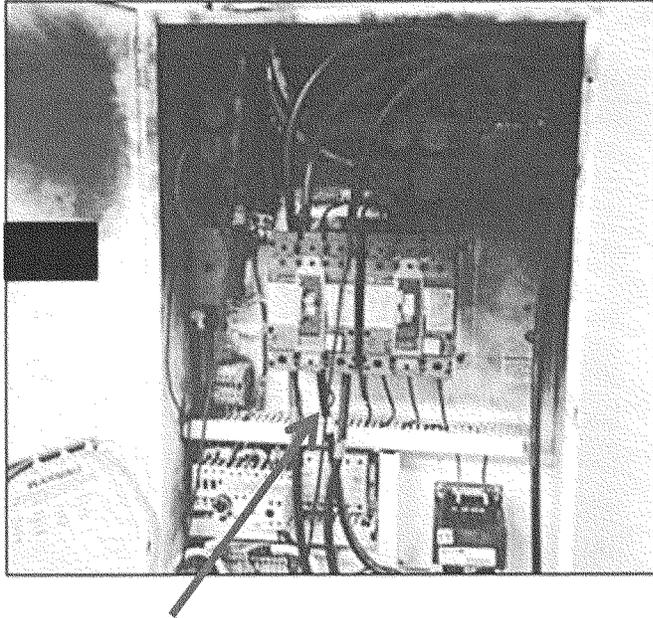
IMPROPER SERVICING OF AN MRI SYSTEM

A third party service sub-contractor hired by an onsite contractor was working at a customer site troubleshooting an MRI system. The servicer was working in the service panel with the power on when an arc flash occurred resulting in burns to the contractor. The blast knocked him back and onto the floor. Other people working in the area said the event sounded like an explosion. The event also resulted in approximately half of the hospital losing power.

It is not known with total certainty what the servicer was doing at the time of the event or what caused the event to occur. He was going to be hooking up a power monitor to the system, but at what stage of that process he was at is unknown. He could have been checking the voltages prior to connecting the monitor or performing some other troubleshooting activity.

It is known, however, that he did not have on his Arc Flash Personal Protection Equipment (PPE) at the time of the event. The PPE itself would not have prevented the incident from occurring, but it would have prevented or lessened the severity of the injuries that occurred. This is potentially an example of inadequate training and non-compliance which resulted in bodily harm, equipment damage, and loss of power to the hospital.

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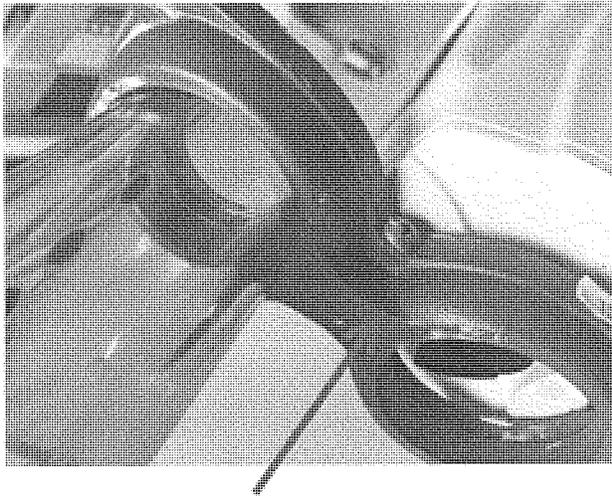


Panel where arc flash occurred

IMPROPER PART IN AN ANGIOGRAPHIC POWER INJECTOR SYSTEM

During a recent service call for an angiographic power injector, it was observed that a third-party service vendor inappropriately substituted an original equipment manufacturer's steel pin with a simple sheet metal screw to hold a syringe turret in place.

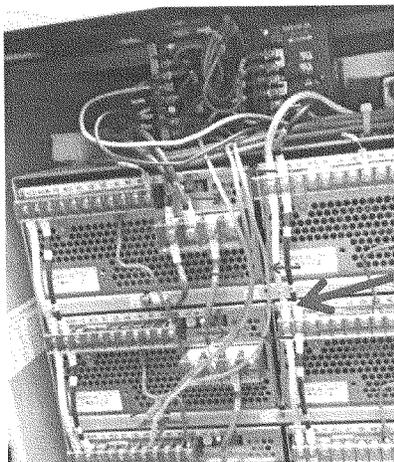
Angiographic power injectors of this class can inject fluid at pressures of up to 1200 psi. If this substituted sheet metal screw were to break or otherwise fail during a procedure, the turret could break free, potentially causing the turret and connected syringe to act as dangerous projectiles. Additionally, this improper part could cause vibrations during the injection, thereby leading to ancillary issues such as delay of procedure and eventual diagnosis due to unexpected equipment behavior.



Common sheet metal screw substituted for steel pin

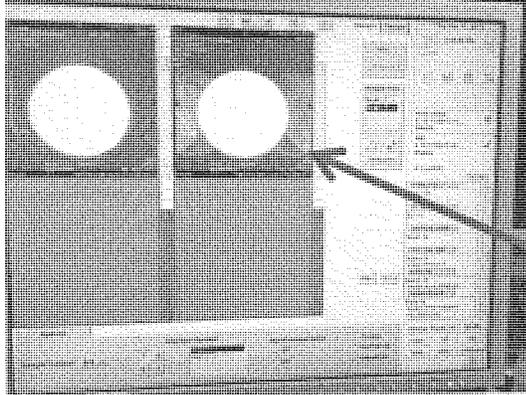
IMPROPER SERVICING OF AN MRI SYSTEM

In this example a customer called the manufacturer and requested service on a 0.3T permanent magnet MRI due to ghosting on multiple images. The customer had been experiencing machine downtime due to the inability to properly scan patients. It is unknown for how long this problem existed. The manufacturer determined that the device had been improperly serviced, noting that additional wiring had been added to the electronics cabinet with no markings and terminations using hand-secured wire nuts. Further, the primary power supply cables lacked strain relief and protection from abrasions.

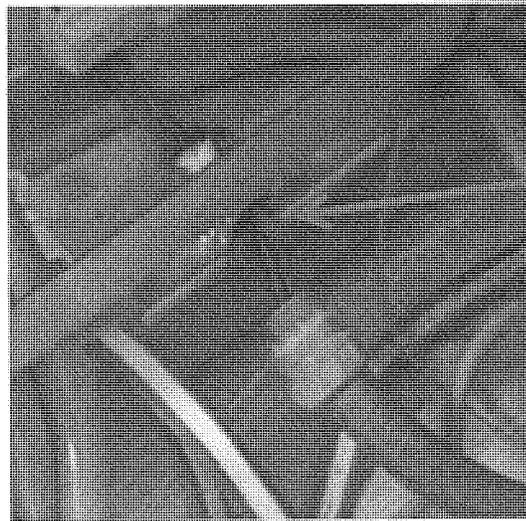


Speaker wire
connecting power
supply to
unknown points
and terminated
with wire nuts

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Example of ghosting on medical images



The primary power supply cables lacked strain relief and protection from abrasion

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This posed a risk of patient harm for a number of reasons:

- Ghosting which may require additional patient scans, delaying care or causing a misdiagnosis;
- Noise bands which may require additional patient scans, delaying care or causing a misdiagnosis;
- Additional wiring which may void any NRTL listing of the system (i.e. UL or ETL certification) and may not meet electrical codes;
- The primary power supply cables entering the electronics cabinet did not have the proper strain relief and were not properly protected from abrasion where they entered the cabinet, potentially causing an electrical short, fire, or electrocution; and
- These issues may have resulted in the device no longer meeting electrical codes.

This improper servicing caused decreased equipment performance due to the resulting poor image quality as well as the electrical issues which may have caused an electrical short, fire, or electrocution.

The customer was advised to discontinue use of the system and was provided with a proposal to perform a full system installation review for repair and calibration.

IMPROPER SERVICING OF A CT SCANNER

In a CT scanner it was discovered that the computer cooling ducts, image control system, and image reconstruction cabinet had clogged filters and ducts. Further, it was noted that:

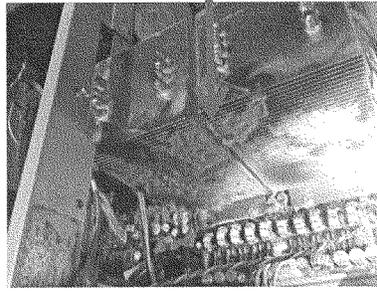
- The image evaluation system software back-up was out of date;
- The image evaluation system CD drive did not work;
- The image reconstruction system computer CD drive did not work, requiring computer replacement;
- The gantry water temperature was showing as “Out of Tolerance”;
- The gantry water pressure was too low and out of specification;
- The gantry left front cover safety switch required replacement;
- The CT control box buttons were worn out;
- The table vertical drive was emanating scraping noises; and
- The network node (creation/deletion) problem had existed for approximately one year.

This resulted in the reliability of the image control system being compromised. The database could not be rebuilt, causing slow system performance. Further, the image reconstruction system was compromised, causing slow image reconstruction. The CT scanner was offline for several days while the issue was remedied.

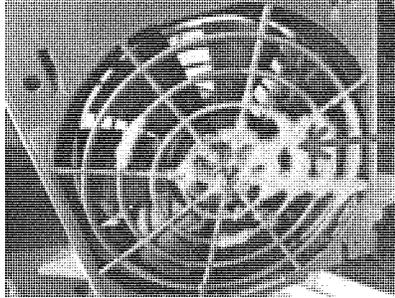
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Clogs resulting from improper servicing



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Clogs resulting from improper servicing



IMPROPER SERVICING OF A NUCLEAR MEDICINE CAMERA

A manufacturer was contacted by a dealer who was dealing with a customer complaint about their nuclear medicine camera. The customer had been using a third party servicer which improperly serviced their device and was now refusing to return and correct the issue.

The device had numerous masked adjacent pixels in the detector image which could also mask any heart defects in the image. Further, the cooling unit was improperly connected to external power, bypassing the system's isolated power and grounding system potentially compromising patient safety and device performance.

When adjacent pixels are removed, a portion of the imaging detector is lost, so portions of the heart would not be imaged, meaning a heart defect could go undetected by the reviewing physician. When one pixel fails, the system uses data from adjacent pixels surrounding the failed pixel to extrapolate. If two adjacent pixels are bad, then the system does not have a complete sampling of data surrounding the pixels to get a good image. The resulting image would have a blurred spot, resulting in lower diagnostic quality.

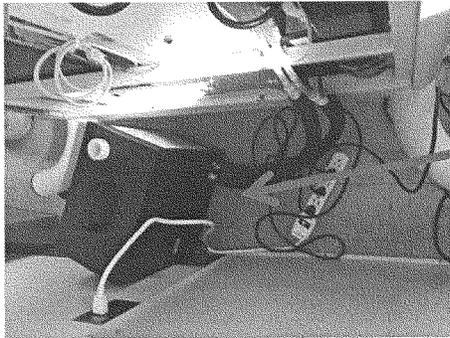
With respect to the improper power connection of the cooling system, the way in which the system was connected violates the manufacturer's power and grounding isolation scheme, potentially compromising patient safety and device performance. Further, this issue could have led to the detector overheating and pixels failing. These modifications violate the Nationally Recognized Test Lab (NRTL) (e.g. UL/EL) listing of the device.

This resulted in such great degradation to the detector head that the customer could not use the device.

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Remote chiller installed outside the unit on the floor with the cover of the unit off, exposing the camera internals

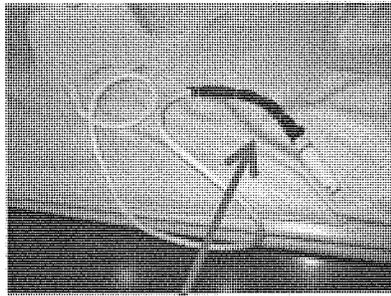


Remote chiller installed outside the unit on the floor with the cover of the unit off, exposing the camera internals

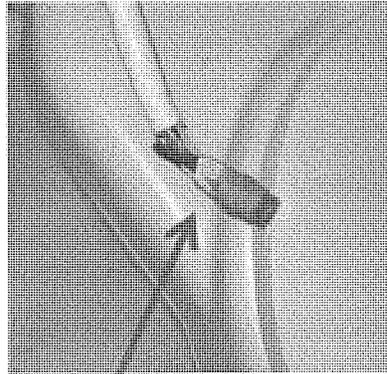
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IMPROPER REPAIR OF AN MRI COIL

In a 0.3T permanent magnet MRI RF coil the signal cable had been pulled out of a connector housing and was repaired with zip ties and plastic tubing. It is unknown for how long the hazard was present.



Coil with plastic tubing and zip ties used to cover damaged cable



Example of failed coil that was hidden using zip ties and plastic tubing

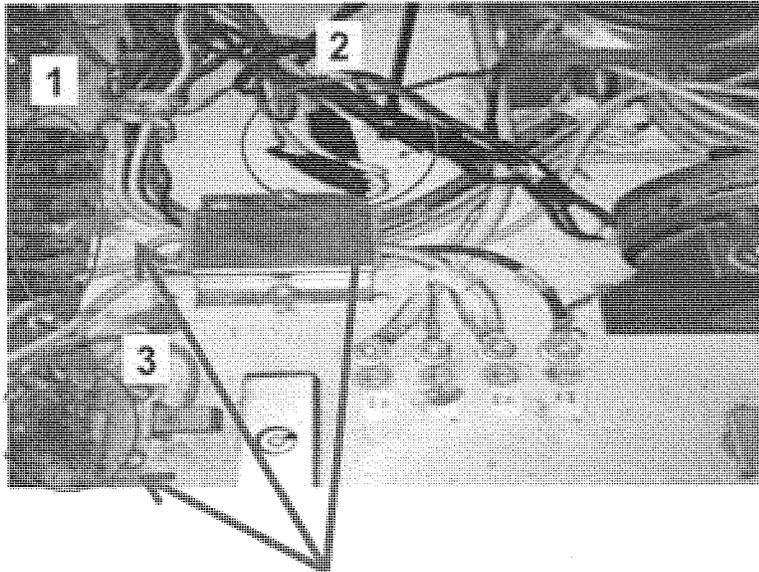
This posed a risk of patient harm for a number of reasons:

- Cable failure may result in:
 - Lost signal or image artifacts causing misdiagnosis or requiring additional scans
 - Electrical arcing causing electrocution or burns
- Zip tie edges are not smooth and may catch on patient skin or clothing;
- Zip ties and plastic tubing did not appear to be material tested and approved for patient contact;
- Zip ties and tubing did not provide proper strain relief for the cable and may have allowed further cable failure; and
- Plastic tubing may have further hidden additional cable failure

This improperly repaired coil did not meet manufacturer quality specifications and was removed from service and repaired.

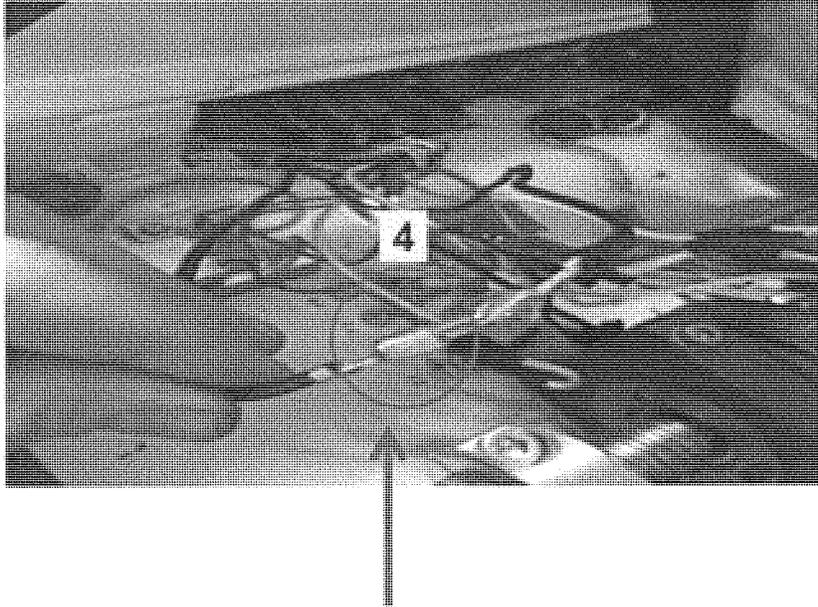
IMPROPER SERVICING OF A CT SCANNER

A facility reported to the manufacturer that it had been having issues with a CT table, workstation, and tube for approximately six months. The manufacturer's service engineer identified table cabling connections that were modified to be non-standard, exposed wiring, non-manufacturer fuses installed, improperly exposed and non-manufacturer soldering connections, cable connections routed and repaired using electrical tape, bent table bolt, and defective transmit cable.

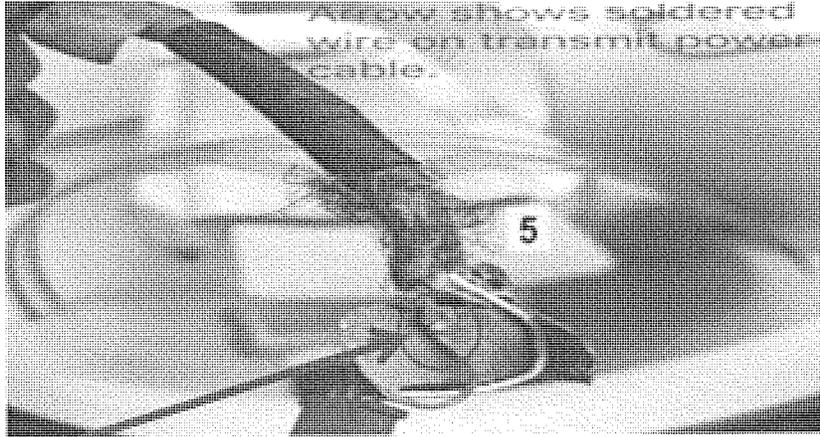


1. The bank of black fuses is not connected to cables, per original equipment manufacturer design and manufacturing specifications
2. Cables have been field repaired with fuses taped to the cable
3. Grease identified in cabling area

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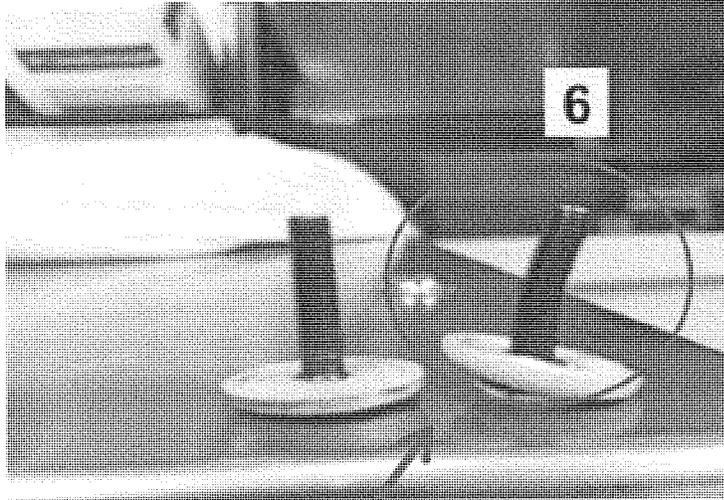


4. Non-qualified fuse, with field repair to reform connector to fit around non-qualified fuse



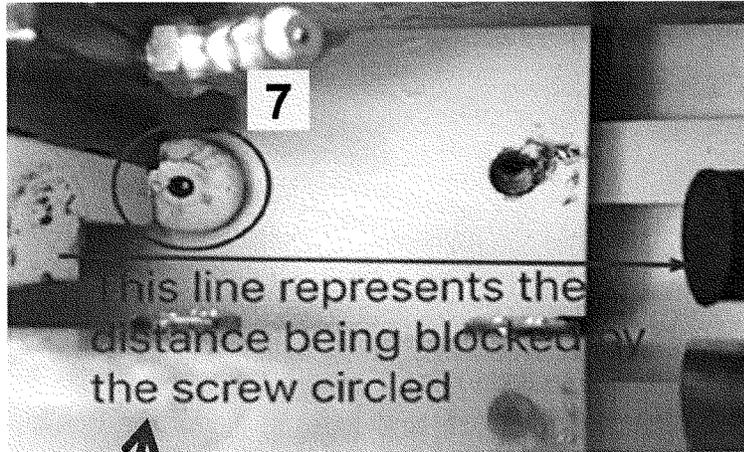
5. Transmit wire connection repaired previously and taped and visible and exposed at joint of green wire

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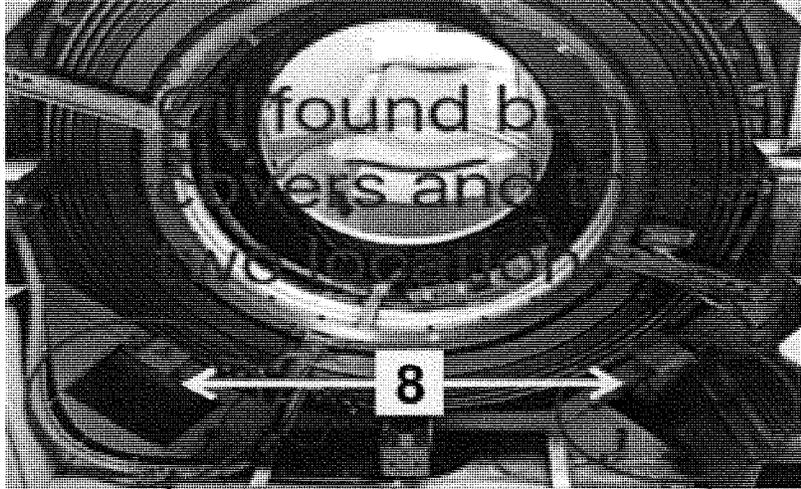
6. Bent screw found, preventing table from full range of horizontal motion

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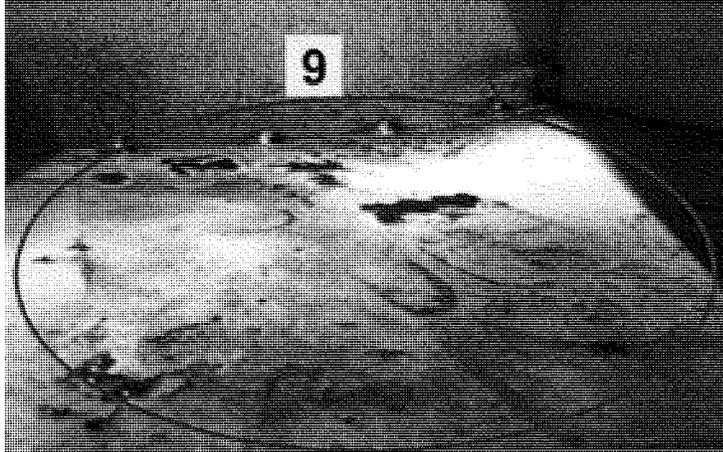
7. Manufacturer's service engineer identified horizontal travel distance blocked by bent screw

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8. Excessive oil identified

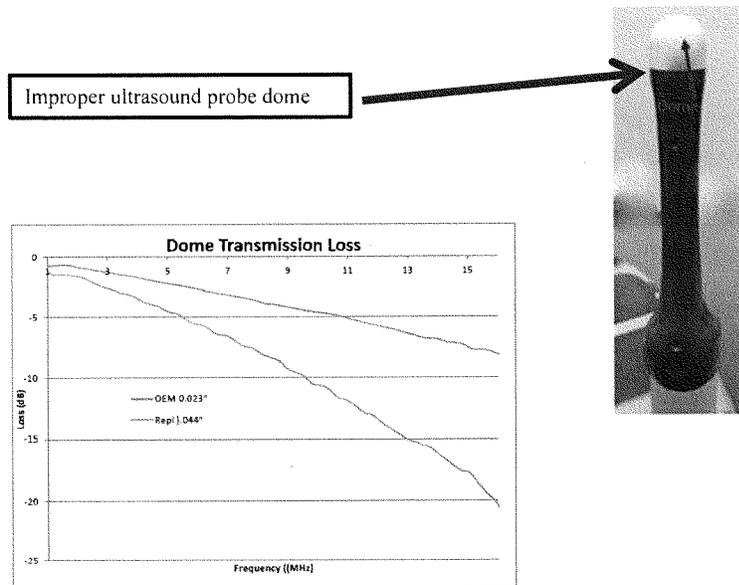
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9. Oil and debris identified in back corners of gantry

Improper Repair of an Ultrasound System

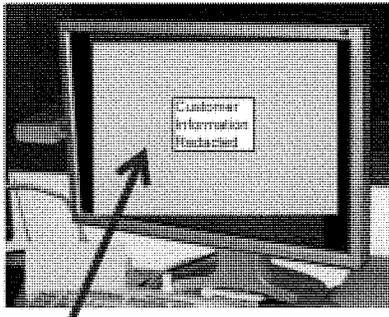
An ultrasound endocavitary probe was received for testing from a US hospital. The dome had been replaced as part of a repair done by a third party. The dome material and thickness were different than that of the original device. The result was significantly more attenuation of the acoustic signal as shown below. The clinical user was complaining of lack of depth of penetration in the B-Mode image of the "repaired" probe.



This improper repair could have resulted in delayed diagnosis or misdiagnosis as well as health conditions associated with a non-biocompatible material.

Improper Parts in an MRI System

In a 0.3T permanent magnet MRI the system CPU and monitor were replaced with unknown aftermarket units that were not tested and validated to operate with the manufacturer's software. It is unknown for how long the hazard was present.



Aftermarket monitor installed on the MRI system



Aftermarket CPU installed on the MRI system

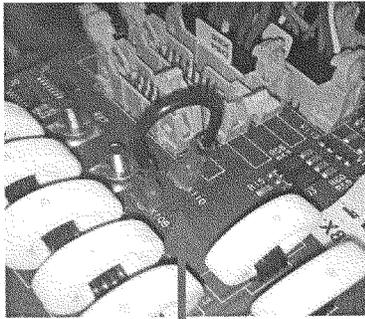
This posed a risk of patient harm for a number of reasons:

- Potential for improper operation or failure of the MRI software due to unknown or untested drivers for the computer components and monitor, and
- Since the monitor was not properly sourced, there is the potential for incorrect calibration or inadequate function for displaying patient images.

These improper parts were removed and replaced with qualified parts.

Improper Servicing of a Fluoroscopy/Radiography System

In this example, the detector on a fluoroscopy/radiography system had been replaced with a third party detector system which included the third party's user-console and radiation release button. Further, the third party had installed a jumper cable on circuitry to allow grid movement and sensing to be bypassed. This also allowed for multiple exposures to be taking on a single cassette without reseating/resetting the bucky. This, in effect, removed the manufacturer's double-exposure safety feature.



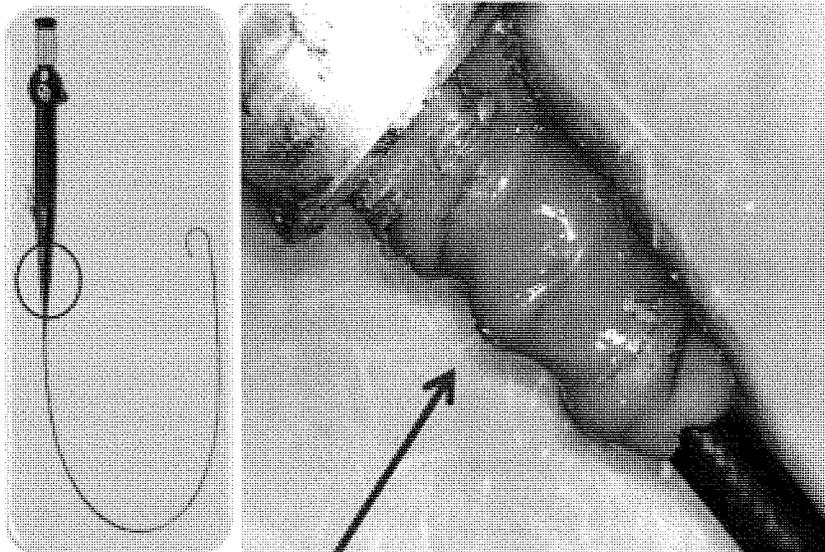
Third party installed a jumper cable on manufacturer circuitry to allow grid movement and sensing to be bypassed



Manufacturer detector replaced with non-qualified detector system which included their user-console and radiation release button (manufacturer exposure button covered over w/Plexiglas plate to

Improper Materials Used to Seal an Endoscope

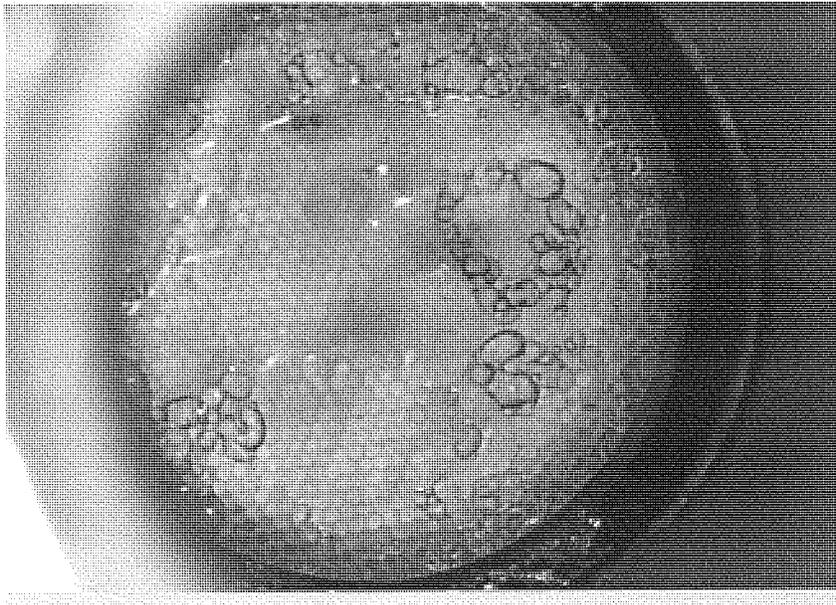
In this example, a porous unidentified material has been used by a non-manufacturer to seal the shaft from the handle of an endoscope. Being porous, there is a chance for bioburden to infiltrate the device and potentially cause cross contamination. Further, it is unclear whether this material will hold up to sterilization parameters. The scope could fail during use if the shaft were to disconnect from the handle.



Unidentified porous material used to seal the shaft of an endoscope.

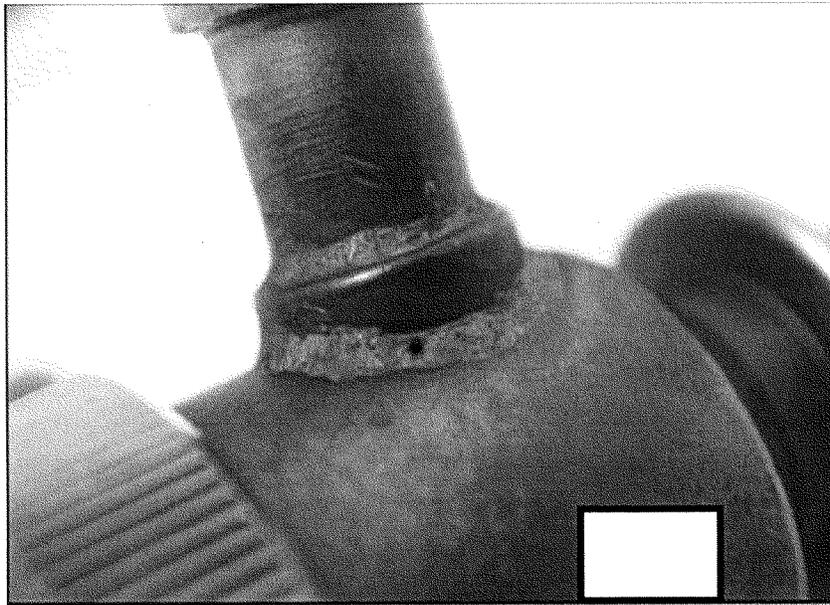
Improper Materials Used to Seal a Laparoscope

In this example, the light post of a laparoscope has been improperly sealed using non-manufacturer epoxy. The epoxy is failing and bubbling. This improper material will not hold up to sterilization parameters. Further, epoxy can harbor bioburden. Charring is also visible in this picture due to pyrogenic reaction. This could cause the light post to overheat and potentially ignite.



Improper Sealing on an Optical Forcep

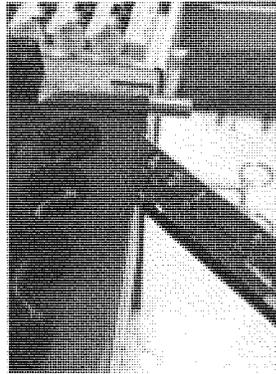
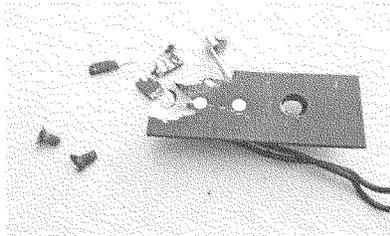
In this example, non-manufacturer epoxy has been used on the flushing end of an optical forcep. This material would not hold up to reprocessing and sterilization. The material is pitting and the pitted areas can harbor bioburden. Further, a hole has formed in the material. The integrity of this material could fail and the port could break off during a surgical procedure.



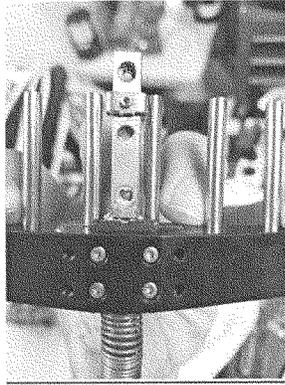
Improperly Serviced Hemostasis Management System

In this example, the field service technician was asked to service a Hemostasis Management System due to motor stalls. The unit was previously serviced by a 3rd- Party provider on June 17th, 2016. Upon inspection of the unit, the field service technician found the x – motor slide assembly completely inoperable, due to dried grease on the gear. While repairing the unit, the field service technician found multiple other errors, such as a bad ADU board, xy interface board, spring sensor, stripped out hardware, resulting in a \$13,000 repair of the unit.

This is a time-sensitive multi-functional testing system that is used to help preserve patient's clotting factors, assist in the prevention of thrombus formation, and monitor multiple aspects of clot formation. The benefits of the system include fewer complications associated with excess blood loss, preservation of the coagulation system, resulting in fewer transfusions, and fewer surgical reoperations.



(Continued on next page)



Improperly Serviced Hemostasis Management System

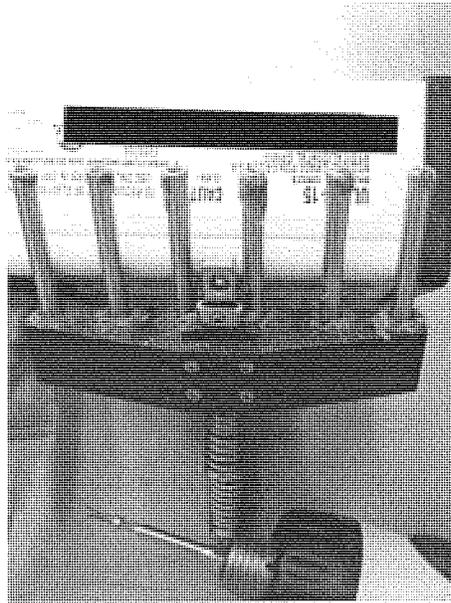
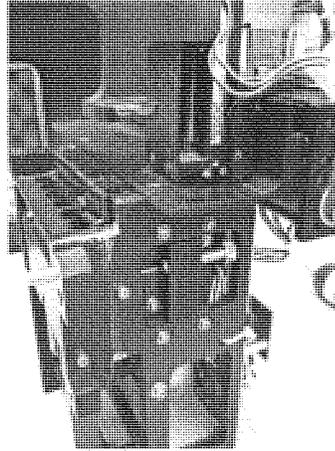
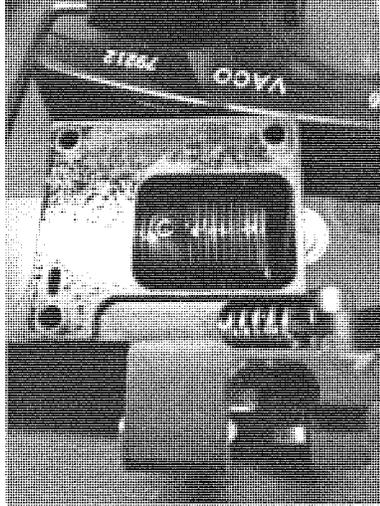
In this example, the field service technician was asked to service a hemostasis management system due to motor stalls. Upon arrive the field service technician noted that the unit has a PM sticker from a 3rd party service provider indicating a preventive maintenance (PM) was completed a few weeks prior on the unit.

Per procedures, the unit is required to be disassembled, cleaned, lubricated, and verification of calibrations. The attached images indicate that the unit was never opened to complete the requirements of a PM.

Improper lubrication of the unit, as in this case, could cause inaccurate dispensing volumes and inaccurate test results.

Improper cleaning may cause the EQC to give false error codes or actual test cartridges not to function properly, enhance possible false or erroneous results to the patient.

(Continued on next page)



Improperly Serviced Blood Transfusion System

In this example, the field service technician was contacted by the hospital to service their autologous blood transfusion system due to noise coming from the centrifuge bowl. The unit was serviced by a 3rd party provider. Based on the field service technician's assessment he determined that:

- The roller assembly was never removed for cleaning
- The roller assembly significant issues of rust and corrosion
- The centrifuge holder was not in proper position and was pushing the centrifuge assembly to one side of the unit.

This would cause improper function of the roller head for processing blood, additional wear and tear to the disposable tubing, improper volume calculations, and potential motor stalls to the point of not being usable during a case.



Improperly Serviced Cardiopulmonary Bypass Unit

In this example, the field service technician was at the facility to complete service on a cardiopulmonary bypass unit. The technician noted autologous blood transfusion system unit with a calibration tag dating back to January of 2015. The technician informed the hospital biomedical engineer that the unit was overdue for service. The hospital biomedical engineer informed the field service technician that the unit was recently serviced by a third-party provider.

The field service technician showed the attached image to the hospital biomedical engineer and informed her that the autologous transfusion system contains internal filters, and if these filters become obstructed, such as in this case can lead to equipment malfunctions of improper operation inadequate vacuum and overheating.



Improperly Serviced Cardiopulmonary Bypass Unit

In this example, the field service technician noticed an issue with a cardiopulmonary bypass procedures. As a good faith gesture, the field service technician powered on the equipment to confirm the unit was functioning. The field service technician noticed a third-party service card that indicated the unit was just serviced.

The unit failed to power-on due to depleted batteries which are a critical safety feature of the device. Concerned for the increased risk to the patient and operator, had the operator tried using this unit in the battery mode, the operator would have to change to the hand crank operation to maintain proper flow for the patient until AC power was available, the field service technician, notified the customer of the issue. The hospital submitted a P.O. to service the equipment resulting in additional charges to the hospital over what the hospital paid the third-party service provider.

The image is the manufacturer's 'tamper' sticker that remained intact after the unit was serviced by the third-party. Verifying that the unit's cover was not removed by the third-party service provider to conduct proper servicing, which is also necessary to test or replace the unit's batteries.

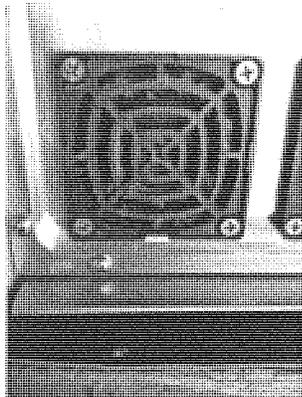


Improperly Serviced Speed Controller System

In this example, the field service technician was called to service a Speed Controller System. The unit was just serviced by a 3rd- party provider, however, when they turned the unit to battery (back- up for power failure or unavailability of power), the unit stopped functioning. If the battery fails during patient support, the perfusionist must operate in manual mode and hand crank the blood through the system until an alternate power source can be identified.

Based on the state of the equipment, the field service technician determined that the unit was not removed from the base of the heart lung machine. The unit contains two external filters. One filter was obstructed (over-heating, improper performance) and the other was completely missing, allowing dirt and contaminants to get into the electro-mechanical parts.

Along with debris getting inside the unit with the potential to over-heat the equipment, if the operator needed to use this unit in the battery mode, it would increase patient and operator risk. The operator would have to change to the hand crank operations to maintain proper flow for the patient until AC power was available.



An informal survey of the manufacturer community also revealed several other frequently encountered issues with improper servicing:

- Conversion of analog X-ray systems to digital, which include interfacing and modification of circuits. Modifications of this nature have been performed by multiple third party entities. These modifications resulted in rewiring, the blockage of safety features, and changing, at least in part, the intended use of the device. These modifications are being done without coordinating with the manufacturer to ensure that safety, efficacy, and other product requirements are maintained.
- Angiographic X-ray systems:
 - Breaking the video circuit for various purposes (video capture for storage and manipulation). In many cases, the exposure circuit was also broken to trigger the video. In these events, rarely is the equipment isolated or properly grounded. This leads to noise injected into the video and can create a safety issue in which equipment could be touched by the patient while a wire is in him or her.
 - Installation of various wire guidance devices or ultrasound systems physically attached to system. Power and data are typically run on the outside of the system and usually are taped or Velcroed to the imaging system. The improper parts may actually be physically attached to the device, creating grounding loops.
- Mobile Conversions to MR and CT Systems: In general the manufacturer has learned of instances in which third parties have been installing fixed site equipment into uncertified mobile trailers. These installations do not meet planning guide requirements that certified trailer manufacturer's must adhere to. The manufacturer's mobile conversion kits were

not installed and the manufacturer's mobile planning guide not followed. It is important to note that the device was not ordered from the factory as a mobile device and the manufacturer's 510(k)s are not filed for certain MR and CT systems to be used as mobile equipment.

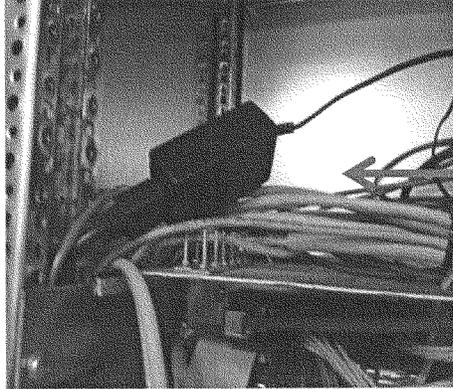
- Converting a fixed site MRI system into an uncertified trailer without using mobile specific components creates an unsafe, unserviceable system. The system did not have proper magnet venting and magnetic shielding. The system's cabling had been modified, compromising access to electronics. The magnetic shielding did not contain magnetic field, posing significant risks. The quench vent had not been validated. The magnet venting had not been rated for high altitude. The serial number was not recognized as a mobile system by factory. Safety updates specific to mobile equipment will not be issued.
- Host computer swap on a mobile MR system:
 - In general this creates an issue as any software updates issued will not be compatible with the host installed as updates are serial number-specific. This also results in software licenses that were purchased for a particular serial number being used on a completely different piece of equipment.
- In a case involving maintenance by a third-party company, an overhead counterpoise support system arm (accessory to a powered contrast injector system) separated and fell, striking a radiology technologist due to a support arm separation. That company, which had the maintenance contract for this equipment, also did not maintain adequate service history records for the system. When the manufacturer was called to address the incident, it was unclear if the equipment had been regularly inspected and maintained appropriately. Regular preventive maintenance is important in ensuring that the device

continues to meet its performance specifications. Thus, the cause of this failure may have been identified and prevented from occurring if routine preventive maintenance had been conducted.

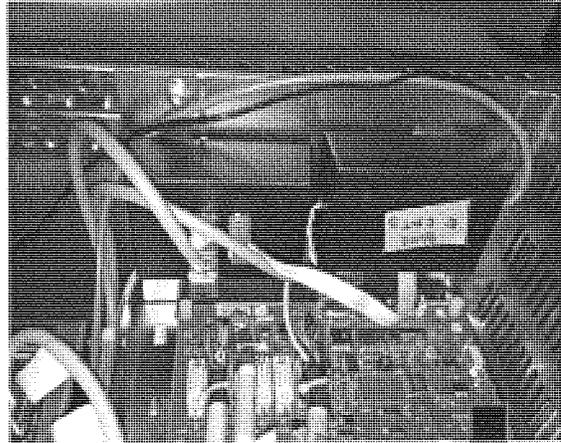
- A case was recently logged detailing a third-party service vendor that had improperly removed a printed circuit board from a powered contrast injector during servicing. During the manufacturer's investigation, it was determined that the service vendor had applied excessive force to the connector, pulling it away from the Servo/CPU board. This instance resulted in several damaged components that had to be replaced in order to restore the equipment to normal operation.
- Improper third party parts installed as depicted in pictures below:

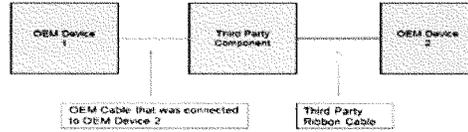


Wires soldered to exposure switch circuit board by third party vendor (it is unknown what these wires do)



Third party vendor power supply and other cables inside control box





A third party component and cable were inserted on the cable that was connecting Device 1 to Device 2 as seen in the diagram and picture

The above examples in no way are a fully comprehensive or inclusive list of the problems or kinds of problems which have been caused by improper servicing. A true statistical analysis and a complete understanding of the extent of the problems caused by improper servicing cannot be achieved unless all service providers are held to the same regulatory, registration, and reporting requirements.

CONCLUSION

All entities engaged in servicing of medical devices should be required to have an appropriately scaled quality system adequate to the activity being performed, meet minimum quality, safety, and regulatory requirements. Although further steps will be required to address all of these concerns, the Medical Device Servicing and Accountability Act takes an important first step in requiring that all servicers register with the FDA and maintain a complaint handling system to address device safety and performance issues caused by poor servicing.

* * * *

MFTA urges Congress to include both H.R. 2009 and H.R. 2118 in the MDUFA IV reauthorization. We believe that passage of both of these bills will protect the safety of patients and ensure patients have timely access to the most innovative devices and diagnostics necessary. Thank you for the opportunity to present our views.

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, "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 Web site 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.

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:]



**STATEMENT OF
ROBERT J. KERWIN, GENERAL COUNSEL,
INTERNATIONAL ASSOCIATION OF MEDICAL
EQUIPMENT REMARKETERS AND SERVICERS, INC.
BEFORE THE SUBCOMMITTEE ON HEALTH ON
“EXAMINING IMPROVEMENTS TO THE REGULATION
OF MEDICAL TECHNOLOGIES”**

MAY 2, 2017

Mr. Chairman, Ranking Member Green, and Members of the Subcommittee, thank you for the opportunity to offer testimony on behalf of the independent service organizations and small business members of our diagnostic imaging trade association, the International Association of Medical Equipment Remarketers and Servicers, Inc. (“IAMERS”) with regard to the “Medical Device Servicing Safety and Accountability Act”.

Summary

1. This Legislation is a solution for which there has been no evidence to support there is a Problem.
The respected scientific research institute, ECRI Institute, after reviewing the FDA MAUDE reports, submitted to the FDA in March 2016 a report (110 pages) which concluded that there

is no evidence to date that a patient safety problem exists. The American College of Clinical Engineering also stated that there is no real-world evidence to support further regulation.

2. This Legislation will require Independent Servicers to absorb the cost of complying with the Quality System Regulations as if the Servicers were Manufacturers or pass these costs along.

3. This Legislation Will hurt Rural and Regional Healthcare. Rural and regional Hospitals rely heavily on independent servicers for competition and lower prices and if the independent servicer is not available, this greatly impacts the rural hospitals. Some servicers will not be able to compete.

BACKGROUND: IAMERS

For almost 24 years, IAMERS has been the leading voice of the secondary market sellers and servicers of diagnostic imaging equipment. The imaging modalities of IAMERS members are MRI, CT, ultrasound, nuclear medicine and general radiography. IAMERS members safely service regional and rural hospitals throughout the United States. IAMERS members offer quality services at a lower cost than the original equipment manufacturers ("OEMs"). IAMERS members offer competition in a healthcare marketplace dominated by the largest companies in the world. IAMERS' Independent Service Organizations (ISOs) are much valued and nowhere more so than in rural America. To the rural hospitals of West Virginia, Kentucky, Alabama, and many other rural areas of the country, ISOs are an essential component in the healthcare ecosystem.

The majority of our members are made up of small independents including sellers and servicers who are alumni of OEMs. IAMERS members work closely with OEMs and are hired to support OEM multi-vendor programs (hospital programs in which the OEM is responsible for handling another OEM's equipment which may be located at a particular hospital). This subcontracting is significant as the OEMs trade organization, the Medical Imaging Technology Alliance ("MITA"), a division of the National

Association of Electrical Manufacturers Association) has claimed for some time on behalf of the OEMs a 'lack of uniform performance' and yet.... its members continue to hire IAMERS ISOs to perform multi-vendor service contracts or to service their customers in remote locations. ISOs are also hired by OEMs to service, install and move the OEM's systems that are now considered legacy and no longer within the expertise of the OEM. OEMs hire ISOs because the ISOs perform their work with skill and dedication to patient safety. Skill and patient safety are at the core of IAMERS values. So, if the ISOs are so bad, why are the OEMs hiring them to fulfill their contractual obligations?

IAMERS ETHICS, EDUCATION AND BEST PRACTICES

Among the things which separate IAMERS from other medical device organizations is that we require our members to adhere to a Code of Ethics. This isn't just lip service. If a complaint is raised by a hospital, group medical practice or other IAMERS member, the complaint is considered by the Ethics Committee. Adverse determinations have resulted in public reprimands or expulsions. No member is excluded from this requirement.

Last year both our American and European members unanimously passed a program for Best Practices. This program now includes specific templates to be customized by a member to supplement the member's business practices. These templates include recommended practices as to inventory management, traceability, complaint management, data management and other key components. It is an extensive voluntary program but it does not require the retention of a compliance officer to address the quality system requirements which the proposed legislation may well *de facto* require.

We have long maintained a robust educational agenda for our members which occurs at every meeting. For much of the last twenty years we have had participation in our meetings and educational programs from the FDA, Compliance Consultants, and others. Past programs have been conducted on

FDA inspections, UDI requirements, reporting of adverse events and many other areas which impact patient safety.

IAMERS WORKS WITH ALL STAKEHOLDERS

IAMERS also has longstanding and much valued OEM members including GE, Siemens, Toshiba and Philips. Several OEMs will join us, as usual, for our annual meeting this week. We welcome their presence. We are fortunate also to have at our meeting this week FDA Chief Scientist Dr. Maisel as well as Mark Bruley, Vice President for Accident and Forensic Investigation at ECRI Institute. We have been fortunate to have past faculty from the Center for Medicare and Medicaid Services, the Medical Device Manufacturer's Association and of course other OEMs. IAMERS has a proud tradition of education, training and outreach and we wish to do more. Our members value quality and understand education and training are important components.

**2016 FDA PUBLIC DOCKET ON SERVICING
And FDA OCTOBER WORKSHOP DO NOT SUPPORT
THIS LEGISLATION**

This Legislation is, however, a solution for a problem which has not been shown to exist. In March 2016, the FDA opened a public docket to solicit comment on (among other things) whether to regulate servicers. The FDA received comments from 177 interested parties. See <https://www.regulations.gov/docket?D=FDA-2016-N-0436>. It is interesting to note that there was almost a complete absence of negative comments from hospitals and group medical practices with respect to independent service organizations. It is perhaps worth repeating then.....if this legislation is truly addressing a serious health care issue, why is there no clamor from the hospitals to impose a change? Respectfully we urge the Committee not simply to accept the statement of IAMERS but look at the comments submitted on the FDA Public Docket by independent industry observers. The nationally recognized leader in performance measurement, the Joint Commission, in its comment filed in the FDA

docket, stated that the Joint Commission “has no knowledge of any statistically significant level of safety problems resulting from the activities of any kind of maintenance/service provider.” In its comment, Penn State Health stated “[v]ery little evidence of systemic problems exists.” Citing four statistical analyses which reviewed the root cause of events, Penn State further stated the “analyses above clearly show that inappropriate servicing and maintenance is not a statistically significant root cause for safety events”

In October 2016, the FDA held a two-day workshop on October 27-28, 2016 entitled the “Public Workshop-Refurbishing, Remarketing, Remanufacturing and Servicing of Medical Devices Performed by Third Party Entities and Original Equipment Manufacturers. Over 500 people attended in person and many more attended via web access. Over 40 speakers presented and 20 additional attendees voiced their opinions. MITA showed pictures of equipment issues, attributed to nameless independents and advocated for further regulation. The American College of Clinical Engineering offered that there was a lack of real world evidence to support MITA’s advocacy for additional regulation. IAMERS advocated that the FDA should not regulate by anecdote. The FDA has advised that it is preparing a summary of the information gathered at the workshop. In the last few months, the FDA has contacted stakeholders to clarify and confirm stakeholder information and identify takeaways from the workshop. The FDA report has not, yet, issued.

**IF THERE IS A HEALTH SAFETY ISSUE: WHY HAVE NOT THE MAJORITY OF THE HOSPITALS
ADVOCATING FOR ISO REGULATION?**

If independent servicing is such a significant healthcare problem, we respectfully inquire again: why has the Committee not heard from hospitals clamoring for further regulation of ISOs? Perhaps the more relevant question is: why is it that the OEM trade organization, MITA, advocating so strongly for passage? We believe that the motivation is because ISOs represent a competitive and viable alternative to OEM domination of the hospital servicing marketplace. Such domination may well result in an ever upward spiral in the cost of providing diagnostic imaging services.

INDEPENDENT SERVICERS ARE A COST-EFFECTIVE ALTERNATIVE

To offer a brief cost contrast: the cost of a service call by an independent service organization ("ISO") is typically in the range of \$150-\$250 per hour. The cost of a service call by an OEM is reportedly in the range of \$500-\$600 per hour with a 4- hour minimum requirement. Plainly ISOs offer competitive choices for hospitals who are keenly aware that capital equipment costs are often 45% of their budget. Time after time ISOs provide appropriate high quality maintenance services and do so at lower cost to the healthcare provider, thus easing their budgetary restrictions. How good are the ISOs in servicing medical devices? As noted, the OEMs routinely hire ISOs to perform their multi-vendor work or to service medical facilities in remote areas and in facilities in which they have a system wide contract (and may lack the knowledge required to service imaging devices of other OEMs and older versions of their own devices). OEMs have advocated for the further regulation of ISOs with the possible intent of making it even more challenging for the ISO segment of the market to exist and be able to offer competitive services as a cost-effective alternative to the OEM.

**RIGHT TO REPAIR: NOT EVERY REPAIR HAS TO BE
UNDERTAKEN BY THE MANUFACTURER**

To borrow from the auto industry: every time you need an oil change, tune-up, or any other auto repair, the manufacturer is not the only option. Perhaps that is why some states have pending for consideration 'right to repair' legislation.

Consideration of the implications of the "Medical Device Servicing Safety and Accountability Act" raises a significant question: Will the U.S. healthcare ecosystem become like the European model, where there are very few ISOs or will we support our hospitals having choices? Perhaps the system works in Europe where most hospitals are reportedly single payer government supported institutions. As this Committee is aware, the private hospital system is different in the U.S.

The hospitals and the regulatory bodies including CMS, the Joint Commission, and other accrediting agencies require third parties to use manufacturer's recommendations for servicing equipment. Hospitals have the ability to detect and as appropriate, weed out inadequate players. Stated otherwise, these hospitals and group medical practices can (and do) vote with their feet by imposing contractual consequences which all parties need to observe if services are inadequate.

The Proposed Legislation Will Impose Significant Additional Costs On ISOs

Under Sec. 2 of the proposed legislation, entitled "Registration of Servicers of Devices" section 510 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360) would be amended by requiring all servicers to be registered:

"... not later than 18 months after the date of the enactment, the FDA is to issue final regulations requiring any person who owns or operates any establishment in any State engaged in the servicing of a device..... to register..."

Registration would impose the reporting requirements of a manufacturer or remanufacturer. Among the requirements to be mandated is that the FDA require the ISO to implement a complaint handling system

equivalent to the manufacturer's requirements under 820.198 of title 21. This complaint system requires virtually every repair to be recorded even where no adverse event or MDR is involved.

According to existing FDA regulations as they apply to manufacturers, a complaint means:

“any written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness or performance of a device after it is released for distribution (emphasis supplied)”

ISOs would need then to consider any repair service work as a complaint and keep a complaint record in accordance with 820.198. This imposes substantial extra work and may well require a quality control or compliance officer to be employed. It is not altogether clear that this extra cost and extra work on the part of the ISO, would substantially advance information on device failures. We are informed that most of the service calls relate to scheduled maintenance or repair of the device. However, the ISO would be required (if the provisions of 820.198 were to be followed) to undertake the burden of record keeping for the extremely rare instance when an adverse event occurs. A web based request system would have to be implemented to capture more data. ISOs would likely need to purchase new systems.

Manufacturer lobbyists have long been pushing for this requirement so that ISOs would fall under the same FDA quality system regulations as the manufacturers. The measure at its core benefits the original equipment manufacturer by burdening the independent servicer with substantial additional costs without a concomitant safety benefit. ISOs will have to charge more to absorb the costs. Additional staff such as quality managers would be needed for the documentation requirements. At a minimum, an ISO would need to have training provided to at least one employee or perhaps multiple employees for a quality management system and to address the FDA requirements. The average cost of quality system management training has been reported to IAMERS to be no less than \$3,000 per employee. If the ISO elects at one location to become either 9001 or 13485 certified by a registered body the minimum cost might be \$10,000 for the first year. An external auditor, if retained to audit the

quality management system, might well charge \$5,000. On average, the ISO might well be required to pay in addition to the retention of an employee, possibly \$20,000 exclusive of the costs of training other employees on processes and on additional regulatory or state requirements as they are imposed.

If FDA applies the same registration process that currently exists for manufacturers and importers, it could be rather costly for small service companies. The registration fee for a small manufacturer was reported as approximately \$4000 in 2016. We understand that an increase has been proposed. These costs, when considered as a whole, will have a significant effect on the ability of the ISO to offer the ISO's services at competitive rates.

If Patient Safety Is The Goal- Why Does The Legislation NOT Require OEMs To Cooperate in Providing AIAT and Service Key Information At A Reasonable Cost

If the genesis of this legislation was truly to address patient safety, provisions could have been included which require the delivery by the OEMs at reasonable cost of equipment manuals, passwords and training. Each year including this year, IAMERS receives reports of ISOs who encounter resistance by the OEMs to providing this information.

Conclusion

As one respected Stephen Grimes has noted, many hospitals are spending 8 to 10 times over what they spent annually 10 years ago on medical capital equipment. These hospitals welcome competition and service from independent service organizations. Imposing manufacturer quality system and reporting requirements upon independent servicers only serves to burden the ISO with additional costs—which are either passed on or absorbed—if the ISO's cost structure permits. This legislation, if implemented, may well jeopardize the independent servicer business model without real world evidence as to the need. The additional compliance burdens of the new legislation will make them challenging for small business owners to comply. In the absence of real world evidence establishing the

need for further regulation of ISOs, the "Medical Device Servicing, Safety and Accountability Act" should not be supported.

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.

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:]

Testimony of Patricia Shrader, Medtronic
House Energy & Commerce Health Subcommittee Hearing
“Examining Improvements to the Regulation of Medical Technologies”
May 2, 2017

Thank you Chairman Burgess and Ranking Member Green and members of the Committee for the opportunity to testify today.

My name is Pat Shrader, and I am the Vice President for Global Regulatory Affairs for Medtronic. Medtronic is among the world’s largest medical technology, services and solutions companies-alleviating pain, restoring health and extending life for millions of people around the world. Medtronic therapies improve the lives of two people every second.

I’m pleased to testify today on behalf of AdvaMed, the Advanced Medical Technology Association, and speak specifically to improving the FDA regulation of medical technologies. I have been part of this industry for 40 years and have seen the enormous advances in healthcare due to medical devices over this period of time. Assuring that new safe and effective technologies can be made available to the American public via robust and sensible regulation is personally very important to me and my family as users of medical devices, including implants and as a person who has seen up close the amazing impact devices can have on life and health.

The U.S. Medical Technology Industry

AdvaMed’s member companies produce the medical devices, diagnostic products, and digital health technologies that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. Our members range from the largest to the smallest medical technology innovators and companies. Collectively, we are committed to ensuring patient access to life-saving and life-enhancing devices and other advanced medical technologies.

I am very optimistic about what this industry can do for patients if the right policies are in place. Fundamental advances in knowledge of human biology down to the molecular level and continued progress in a range of disciplines – computing, communications, materials science, physics and engineering – are fueling innovation, and the potential to save and improve patients’ lives is almost limitless.

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

FDA Regulation of Medical Devices – MDUFA IV

We believe we are on the right track at FDA's device center, and that recent progress -- combined with the provisions of this new user fee agreement -- promise to keep things heading in the right direction to strengthen the medtech innovation ecosystem.

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

Of course, there are many areas where FDA could further enhance the predictability and efficiency of its review process, and the new MDUFA IV agreement lays the groundwork for further FDA performance improvements through more ambitious goals, important process changes, and increased accountability, supported by additional resources. MDUFA IV also recognizes the importance of the global market and of global regulatory efficiencies to patients, regulators, and companies and supports harmonization via new funding for international standards and enhancement of the third party review process.

The MDUFA IV agreement is good for industry. It is good for FDA. Most importantly, it is good for patients and, in fact, specifically addresses and provides funding for an enhanced role for patient engagement in the FDA decision-making process. We appreciate this Committee's commitment to reauthorizing this important program and we urge Congress as a whole to act promptly to reauthorize the medical device user fee program and enact this agreement into law. Failure to act would not only jeopardize the critical improvements made by the new agreement but would have a devastating impact on our industry's ability to bring innovative diagnostics, treatments and cures to patients.

H.R. 1736

We appreciate the Committee's work in holding this hearing to consider measures that would enhance the MDUFA agreement, and improve the regulation of medical devices. When the committee last took up a Medical Device User Fee reauthorization, the relationship between the FDA and industry was strained, and performance at the agency was at an all-time low. As I noted, there have been significant improvements since that time. But more work remains, and I am encouraged that the committee is open to advancing common-sense policies that will continue to improve the agency's operations. We should continue to look for ways that we can make the process more rational and predictable for innovators and the patients that we serve.

We strongly support H.R. 1736, introduced by Representatives Bucshon, Peters, Brooks and Butterfield, and we appreciate your leadership on the issue of improving the medical device inspections process.

Regulatory compliance is essential to the production of safe and high quality medical devices. This is a shared goal between industry and the FDA. Unfortunately, the current inspection process is plagued by challenges that lead to significant inefficiencies, both for manufacturers and the FDA. The problems of inconsistency and a lack of transparency and predictability work against attempts to ensure an ongoing and mutual understanding of what is required to comply with regulations. These also hinder the ability of companies to assure they are taking appropriate corrective actions, when they are required.

The medical device industry is concerned with the vast discrepancies in inspections, between facilities across U.S. districts, as well as between facilities of the same company within the U.S. and outside the U.S. These discrepancies result in facilities being held to different standards, solely based on location.

I want to be clear about this next point: H.R. 1736 does not limit or restrict FDA's authority to inspect medical device facilities in any way. Medtronic, just like all other companies in our industry, understands that robust FDA inspections serve an important oversight function to ensure the public that we are succeeding in producing safe and high quality medical devices. This is an important partnership. What H.R. 1736 will do is improve the device inspections process to increase predictability and transparency of FDA routine inspections, and to ensure that both FDA and industry resources are best targeted to public health needs.

H.R. 1736 has three main provisions, and I'd like to go into further detail about each of them.

First, the bill establishes a risk-based inspections schedule for device facilities based on the risk profile of facility. The frequency and nature of inspections of device facilities is not consistent within the United States or around the world. Also, the U.S. FDA is not the only regulatory agency performing facility inspections; numerous regulators inspect to standards that are very similar to FDA's Quality Systems requirements for devices. Some facilities are inspected multiple times each year; some facilities may go much longer periods of time between inspections (and this is only for routine inspections—I'm not referring to for cause inspections). For example, we have facilities that manufacture class III devices. While the facilities have positive compliance profiles, they routinely experience as many as a half dozen regulatory inspections a year; including multiple inspections by FDA (this includes pre-approval and post-approval inspections, as well as routine surveillance audits). Establishing a risk-based schedule for device facility inspections would focus FDA inspection resources on the more significant risks to public health. Factors for FDA to consider when deciding on the extent and frequency of device inspections include compliance history; record, history and nature of recalls; inherent risk of the device(s) manufactured at the facility; inspection frequency and history of the

establishment; and inspection by foreign governments. This common-sense shift to a risk-based approach to device inspections would ensure that FDA is inspecting where the risk to patients is greatest.

Second, the bill proposes standardized and enhanced processes including communications between FDA and the facility—prior to, during, and after inspections. To understand the importance of these process improvements, I think it's first critical to set the scene of an FDA inspection. When an FDA investigator comes to a facility to conduct an inspection, it is an "all hands on deck" situation. The manufacturer might have as many as 100 employees involved in responding to and interacting with the FDA investigator. The employees supporting the inspection are typically highly skilled team members—engineers, clinical personnel, regulatory and/or legal experts—who are taken away from their current projects. Device facilities in the U.S. are often given very short advance notice of an inspection. This short notice, plus the often erratic schedules of investigators, leads to challenges in assembling the appropriate team members to provide the required documents and materials requested by the FDA. While we recognize that FDA investigators sometimes have to deal with urgent matters elsewhere, it is an incredible challenge to manage workflow when an investigator initiates an inspection and then calls each morning to let the facility know whether or not she will be on site that day. Technical experts and other resources are required to be on stand-by at the location which disrupts productivity as they are unable to plan more than 1 day in advance. It is also difficult to maintain continuity in an inspection conducted over a long period of time, with an investigator who may be on site for a day or two, then elsewhere for a period of time (sometimes several days) before returning to the facility. Medtronic has experienced both of these types of challenges.

H.R. 1736 would address these issues by standardizing procedures for inspections, including communications between FDA and industry, before, during and after an inspection. The communication prior to an inspection enables the investigator to gather background information and give the company an opportunity to assemble the records and personnel that will be needed for the inspection. The communications during an inspection provide an opportunity to clarify any information or misunderstandings so that the most accurate outcome can be assured. It may also enable the company to make corrections during the inspection, which the investigator can then verify prior to concluding the inspection. The post-inspection communication is particularly important for ensuring that any remaining issues that are noted during the inspection are promptly addressed.

If an inspection leads to a company having to make a correction, companies have 15 days to submit a remediation plan to FDA. Unfortunately, there is no such timeline for FDA to respond to the proposed plan of correction. Thus, companies are left in an awkward situation of wanting to make the correction as soon as possible, but being unsure if they have fully understood the scope and intent of the finding and that their correction will address the issue to FDA's satisfaction. There also is the concern that if the correction and timetable are not sufficiently detailed, further enforcement action, such as a Warning Letter, may be taken by FDA.

Depending on the type of correction that is needed, some remediation activities are extremely costly and time-consuming and may not be appropriate. H.R. 1736 would require FDA to provide non-binding feedback to proposed remediation plans. This feedback would allow companies to confidently move forward with their correction plans in a timely manner, or make important course corrections before investing in process improvements.

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 certain countries, those countries require documentation that the device is legally marketed in the U.S. and that it is in compliance with U.S. law. This documentation is called a CFG—certificate to foreign governments. Due to an unclear interaction between FDA's inspections process and the CFG process, device companies are frequently caught in bureaucratic red tape which can result in devices that are lawfully marketed in the U.S. being denied certification for marketing in other countries because the appropriate correction of deficiencies noted in inspections has not been confirmed by FDA. In some instances, the company may have made the corrective actions months or even years ago. To alleviate this situation, the draft legislation requires that, if FDA refuses to issue a CFG, it will provide a written justification for the denial and summarize the specific deficiencies preventing issuance of the certificate. The legislation also requires that FDA provide a process for resolution of a refused certification to allow for establishments to present new information related to addressing identified deficiencies. Clarifying this process would enable device manufacturers to continue to market our products to other parts of the world, thus strengthening our country's economy.

Again, we strongly support H.R. 1736, and urge the Committee to pass this important legislation.

Other Proposals

There are a number of other proposals that would improve the medical device regulatory process by bringing more predictability and consistency to the review process. I'd like to note a few of these:

1. We support H.R. 2144, a bill recently introduced by Congresswomen Walters and Kuster. This bill builds upon the good work done by this Committee in the 21st Century Cures law by providing FDA with a streamlined mechanism for considering medical device accessories. Accessories are devices that are intended to support, supplement, and/or augment the performance of one or more parent devices. For example, a plastic tray that holds a LASIK instrument is an accessory. Prior to passage of Cures, FDA evaluated accessories based on their parent device's risk classification. Thus, the tray, a very low risk device, was regulated as a class III high risk device, because the LASIK instrument is high risk. This makes no sense. Cures included a provision that directed FDA to classify a device accessory independent of the parent device. While this provision was very much needed, FDA lacks a procedural mechanism to carry that out. H.R. 2144 provides for streamlined processes for FDA to carry out its regulation

of accessories, both those that are on the market but inappropriately classified, and those that would come before FDA in future submissions.

2. We support establishing an alternative pathway to market for certain moderate risk medical devices that are well-understood. Currently, for these particular devices, the statute requires companies making these devices to both demonstrate to FDA that their product complies with special controls established by FDA for that particular type of device, and companies must demonstrate that the product is substantially equivalent to a legally marketed device. This duplication of information and effort is simply redundant and does not provide FDA with additional, meaningful information. In addition, the revised pathway is more consistent with requirements for lower risk devices in other countries, further supporting global harmonization of regulatory requirements.

3. We support streamlining the process to make simple, low-risk modifications to already approved medical devices. The House-passed 21st Century Cures bill included a provision that reduced the review burden on FDA and on companies by allowing companies to make certain changes to devices without a premarket submission if their quality systems are certified as capable of evaluating such changes. Quality systems are the organizational structure, responsibilities, procedures, processes and resources for implementing quality management, which includes a system for assessment and control of device changes. Manufacturers whose quality system was certified by an FDA-authorized third party would not be required to submit and await approval by FDA for certain low-risk changes to already approved medical devices. Taking these items off of FDA's plate, while still ensuring that companies are accountable, would be a significant reduction in FDA's workload, allowing it to focus on higher-priority activities, and would represent a significant cost and time saving for companies.

Lastly, I would also like to add my voice of support for H.R. 2118. This bill is an important step in ensuring that FDA has visibility into third-party servicing companies. These third-party servicers are sometimes hired to perform maintenance on medical devices. Requiring third-party servicers to register with the FDA is an important common sense, first step in assuring that patient safety is not put at risk by well-intentioned but poorly-carried out repairs or substandard or inappropriate parts. Also, I'd note that several AdvaMed member companies support H.R. 2009, and we appreciate its inclusion in this hearing.

Conclusion

In conclusion, I appreciate the Committee's work in considering these measures that enhance and compliment the underlying MDUFA user fee agreement, and that seek to improve regulation of medical devices. Your focus on improvements to the medical device regulatory landscape enables our companies to continue to innovate, and ensures that these innovations get to patients in a predictable and timely manner. We look forward to continuing to work with you on these important issues, and on timely reauthorization of the MDUFA program.

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. 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.

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 [continuing]. 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 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, this is a very similar debate that we have had in this committee to the automobile manufacturers and the independent repair folks who always there is a debate about getting the data, 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. First of all, I want to 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 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 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. Yes. I would agree. I think that there is also 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 loss, 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, in your testimony, you think that OTC could also comply with the moderate hearing loss?

Dr. LIN. Yes, absolutely. 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, “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 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. 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 the over-the-counter may not work. It is 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. Can you repeat the question, sir?

Mr. GREEN. 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, as MITA, we submitted 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. There are over 30 examples that are in there.

In terms of complaints in general or adverse effects in general, I know the ECRI study claims that there is nothing wrong here; so why should we do anything? There is nobody reporting. 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. OK. 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—I think it is a biannual basis. And we report proactively, 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, all States have on their books that hearing aids cannot be sold over the counter, and those regulations evolved 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.

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. OK.

Mr. BUTTERFIELD [continuing]. 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, 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 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. OK. 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 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 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, 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 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, 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, in your testimony you talked to this, and I know there is some questions about it too about the value 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 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.

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 “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.

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, 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. 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. 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 are 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 [continuing]. Would I be perfectly comfortable with, honestly, 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 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. Yes, we comply with all the laws. And every one of the member companies, to the best of my ability, 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, 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. 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 appears at the conclusion of the hearing.]

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.]

[Material submitted for inclusion in the record follows:]

Statement in Support of the Over-the-Counter Hearing Aid Act of 2017

We are pleased to join a bipartisan group of our House colleagues to support the *Over-the-Counter Hearing Aid Act of 2017*, which would increase access to affordable hearing aids by giving consumers new options, increasing competition, and removing unnecessary barriers to innovative technology.

The time to increase access to affordable hearing technology is now. Hearing loss in older adults is widespread. More than two-thirds of people in their seventies have hearing loss, and that figure jumps to nearly ninety percent of people over the age of 80. Indeed, the risk of hearing loss in older adults is about 10 to 20 times higher than the risk of heart disease – and 100 times higher than the risk of cancer. Untreated hearing loss can be socially isolating, and is associated with serious health conditions such as cognitive decline, falls, and depression.

And recent research from the CDC finds that about 1 in 4 American adults who report excellent to good hearing already have some form of irreversible hearing loss without knowing it, meaning the need for hearing aids will only grow over time as these individuals age and as seniors make up an increasingly large share of our population.

Unfortunately, only 14 percent of the roughly 48 million Americans with hearing loss use a hearing aid – and cost is a major reason for this treatment gap. The average cost of one hearing aid is more than \$2,000, and most people need two devices.

The *Over-the-Counter Hearing Aid Act* implements recommendations made by the National Academies of Sciences, Engineering, and Medicine and creates an FDA-regulated category of hearing aids that would be available directly to consumers. The legislation has been endorsed by consumer and senior groups, hearing health practitioners, and hearing loss advocates.

Hearing aids shouldn't be a luxury only available to those who can afford steep out-of-pocket costs. This bill is a commonsense, bipartisan approach to bringing down costs, loosening up outdated regulations, and improving hearing healthcare, and we urge continued support for it in both chambers of Congress.

Senator Elizabeth Warren
Senator Chuck Grassley
Senator Margaret Wood Hassan
Senator Johnny Isakson

Consumer
Technology
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May 1, 2017

The Honorable Michael C. Burgess
Chairman, Subcommittee on Health
House Energy and Commerce Committee
U.S. House of Representatives
Washington, DC 20515

The Honorable Gene Green
Ranking Member, Subcommittee on Health
House Energy and Commerce Committee
U.S. House of Representatives
Washington, DC 20515

RE: Support for the Over-the-Counter Hearing Aid Act of 2017

Dear Chairman Burgess and Ranking Member Green,

The Consumer Technology Association (CTA)[™] applauds the Subcommittee on Health for convening its May 2, 2017 hearing on "Examining Improvements to the Regulation of Medical Technologies." Specifically, CTA strongly supports the Over-the-Counter Hearing Aid Act of 2017 (H.R. 1652), as introduced by Chairman Blackburn and Representative Kennedy. As the trade association representing 2,200 world-class technology innovators, CTA has deep experience promoting technologies to change people's lives for the better. In fact, CTA's affiliated public, national CTA Foundation was launched in 2012 with the mission to link seniors and people with disabilities with technologies to enhance their lives, and providing affordable hearing solutions is an important piece of that mission.

The Over-the-Counter Hearing Aid Act of 2017 will change lives for the better by directing the Food and Drug Administration (FDA) to create a new regulatory class of hearing aids that could be sold over the counter. This new regulatory class will address the needs of adults with mild to moderate hearing loss, a population that desperately warrants attention. According to a June 2016 report published by the National Academies of Sciences, Engineering, and Medicine, age-related hearing loss is an increasing public health concern as the population of older adults grows. Indeed, the NAS report, *Health Care for Adults: Priorities for Improving Access and Affordability*, notes that,

"Hearing is a vital human sense that is important to communication and health and can affect quality of life. Yet for a variety of reasons, many people with hearing loss do not seek out or receive hearing health care. Estimates of hearing aid use are that 67 to 86 percent of people who may benefit from hearing aids do not use them, and many hearing assistive technologies as well as auditory rehabilitation services are not fully utilized."



Today, hearing aids range in price from \$1,000 to \$6,000, while devices such as a class of over-the-counter hearing devices are a fraction of that cost – \$100 to \$600. CTA's own research study, *Personal Sound Amplification Products: A Study in Consumer Attitudes and Behavior*, found that most adults with hearing problems do not get the hearing assistance they need. Key barriers to addressing hearing problems include: the high cost of hearing aids, inconvenience, and the cost of doctor appointments.

The Over-the-Counter Hearing Aid Act of 2017 would dramatically change the environment for adults suffering from mild to moderate hearing loss by allowing them easier and more affordable access to hearing assistance devices.

CTA is accredited by the American National Standards Institute (ANSI) to write standards for the consumer technology industry. Closed captioning is one well-known example of CTA's important accessibility-related standards. In January 2017, CTA released ANSI/CTA-2051, *Personal Sound Amplification Performance Criteria*, which sets out minimum performance requirements to be considered a high quality OTC hearing aid. The goal is to assure the FDA and consumers that manufacturers who build to this standard have built a quality, reliable OTC hearing aid. In short, industry-led standards can help to pre-package the set of rules that the government and consumers can rely on. CTA will work with the FDA to incorporate this standard into any FDA-promulgated regulations on over-the-counter hearing aids.

The Over-the-Counter Hearing Aid Act of 2017 will ensure that Americans with mild to moderate hearing loss get the hearing assistance they need and deserve at a reasonable and affordable price. We pledge our support and urge immediate passage.

Sincerely,

A handwritten signature in black ink, appearing to read "Greg Walden". The signature is fluid and cursive, with the first name "Greg" being more prominent than the last name "Walden".

President & CEO

CC: The Honorable Greg Walden, Chairman, House Energy and Commerce Committee
The Honorable Frank Pallone, Ranking Member, House Energy and Commerce Committee
Members, Subcommittee on Health, House Energy and Commerce Committee



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March 28, 2017

The Honorable Joseph P. Kennedy III
434 Cannon House Office Building
Washington, DC 20515

The Honorable Marsha Blackburn
2266 Rayburn House Office Building
Washington, DC 20515

The Honorable Buddy Carter
432 Cannon House Office Building
Washington, DC 20515

Dear Representative Kennedy, Representative Blackburn, and Representative Carter:

AARP is pleased to endorse the Over-the-Counter Hearing Aid Act of 2017, which would implement recommendations from the President's Council of Advisors on Science and Technology's (PCAST) and the National Academies to help the millions of Americans affected by hearing impairment.

Your bill, by making certain types of hearing aids available over the counter, requiring the FDA to issue regulations on this new category of over-the-counter hearing aids, and requiring the FDA to update its guidance on Personal Sound Amplification Products (PSAPs), among other reforms, would help create a more consumer-friendly market for hearing devices.

At AARP, part of our mission is ensuring older Americans continue to lead active and engaging lives. A person's ability to hear greatly affects how they interact with other people, loved ones, and the environment around them. Difficulty hearing creates a barrier to social interaction, and can have a negative health impact. Roughly 40 percent of the over-60 population experiences hearing loss. Unfortunately, hearing aid usage by those experiencing hearing loss is very low, with only about 20 percent of those affected using a hearing aid. A significant factor in the lack of utilization is the cost of hearing aids – which average over \$2,000 per ear. Cost and other factors, such as access and social stigma, prevent people from using these life-altering technologies.

AARP believes your bill will improve consumers' access to affordable hearing technologies that can improve their daily living. Thank you for your leadership on this important issue. If you have any questions, please feel free to contact Andrew Scholnick of our Government Affairs staff at ascholnick@aarp.org or 202-434-3770.

Sincerely,

Joyce A. Rogers
Senior Vice President
Government Affairs

Alabama | Alaska | Arizona | Arkansas | California | Colorado | Connecticut | Delaware | District of Columbia | Florida | Georgia | Hawaii | Idaho | Illinois | Indiana | Iowa | Kansas | Kentucky | Louisiana | Maine | Maryland | Massachusetts | Michigan | Minnesota | Mississippi | Missouri | Montana | Nebraska | Nevada | New Hampshire | New Jersey | New Mexico | New York | North Carolina | North Dakota | Ohio | Oklahoma | Oregon | Pennsylvania | Puerto Rico | Rhode Island | South Carolina | South Dakota | Tennessee | Texas | Utah | Vermont | Virgin Islands | Virginia | Washington | West Virginia | Wisconsin | Wyoming



ADA Supports Bipartisan, Bicameral Over-the-Counter Hearing Aid Act of 2017

March 22, 2017

The Academy of Doctors of Audiology (ADA) supports [S. 670/H.R. 1652](#), the Over-the-Counter Hearing Aid Act of 2017, and commends Senators Warren and Grassley, and Representatives Blackburn and Kennedy for their foresight in introducing this legislation, which if enacted, will remove unnecessary and burdensome barriers to hearing care for millions of Americans.

The Over-the-Counter Hearing Aid Act of 2017 would allow hearing aids, intended to be used by adults to compensate for mild to moderate hearing impairment, to be sold over the counter (OTC), and would eliminate the requirement that adult consumers obtain a medical evaluation or sign a waiver in order to acquire these hearing aids. This landmark legislation also directs the FDA to issue regulations containing safety and labeling requirements for this new category of OTC hearing aids and to update FDA draft guidance on Personal Sound Amplification Products (PSAPs).

The Over-the-Counter Hearing Aid Act is consistent with [ADA's longstanding position](#) to implement recommendations from the President's Council of Advisors on Science and Technology (PCAST) and the National Academies of Sciences, Engineering, and Medicine (NASEM), which have both recommended making some types of hearing aids available over the counter and removing the requirement of a medical evaluation in order to allow millions more Americans to access hearing aids.

The availability of FDA-registered OTC hearing devices will allow consumers to make better informed decisions about their treatment options, and will also facilitate increased competition, enhance quality and improve transparency with regard to the purchase of direct-to-consumer hearing amplification products.

"The ADA is unaware of any credible research demonstrating that the medical evaluation requirement actually leads to the identification and treatment of medical conditions that would not otherwise be identified appropriately by the patient," said ADA President, Angela Morris, Au.D. "There is no evidence that the required medical evaluation, as a condition of purchasing a hearing aid, improves the outcome for patients seeking hearing health care. Further, anecdotal evidence suggests that the medical evaluation waiver is widely used."

The ADA stipulates that there are risks with self-treatment, including overlooking conditions that warrant medical intervention. However, we contend that in the current regulatory environment, those risks are already being taken by consumers with either limited information--or worse yet, misinformation.

There is a preponderance of data available today that demonstrates that, when it comes to hearing loss, the risk of non-treatment may be greater than the risk of self-treatment. The tremendous co-morbidities and maladies associated with untreated hearing loss are well documented, as are the benefits of amplification in improving quality of life and mitigating serious health conditions. Therefore, the public will be best served if basic hearing devices are available to consumers over the counter, just as they are already available over the internet.

The regulatory environment has struggled to keep pace with rapid advances in hearing amplification technology. Creating an OTC hearing device market will foster competition, broaden consumer choice, improve affordability, and accelerate future innovation. As consumers already have direct-to-consumer internet access to hearing aids and similar unregulated technologies, the creation of a regulated OTC class will not increase existing risks to the public.

The ADA and its members seek expanded access for consumers to audiology services. We strive to accomplish this goal through the advancement of practitioner excellence and high ethical standards in the provision of quality audiologic care. The Over-the Counter Hearing Aid Act will help to facilitate these objectives and is consistent with the ADA's mission and philosophy.

In summary, the removal of the medical clearance requirement and the availability of a regulated OTC hearing device, which calls for FDA to include appropriate labeling and safety measures, will expand access to quality hearing health products and services, reduce duplicative costs, and remove unnecessary, non-beneficial barriers to care. For this reason, the ADA is pleased to support the Over the Counter Hearing Aid Act.

Contact:

Stephanie Czuhajewski, CAE
Executive Director
446 E. High St.
Lexington, KY 40507
sczuhajewski@audiologist.org
859-977-7444



April 18, 2017

The Honorable Elizabeth Warren
United States Senate
Washington, DC 20510

The Honorable Charles Grassley
United States Senate
Washington, DC 20510

The Honorable Maggie Hassan
United States Senate
Washington, DC 20510

The Honorable Johnny Isakson
United States Senate
Washington, DC 20510

Dear Senators Warren, Grassley, Hassan and Isakson:

On behalf of the millions of members and supporters of the National Committee to Preserve Social Security and Medicare, I am writing to endorse S. 670, the "Over-the-Counter Hearing Aid Act of 2017," which you introduced.

Hearing loss is the third most prevalent chronic health condition facing older adults. Yet 70 percent of Americans between age 65 and 84 with hearing loss are not using hearing aids because Medicare does not cover them, and paying for the devices out-of-pocket is expensive. In a recent study, *Consumer Reports* found that where the wholesale price of the aids could be verified, the average retail markup was 117 percent. The cost is high because a small group of companies control the hearing aid market, and many health care professionals who sell the devices bundle their costs in the final price paid by consumers. Better access to more affordable over-the-counter (OTC) devices could be helpful to individuals with mild to moderate hearing loss. Your bill, the "Over-the-Counter Hearing Aid Act of 2017," would encourage the development of these devices by requiring that the Food and Drug Administration provide for the regulation of OTC hearing aids within three years of enactment of the bill.

Medicare should cover hearing aids. Until that happens, seniors will need more affordable options to treat hearing loss. Your bill fills this gap. For that reason, the National Committee supports the "Over-the-Counter Hearing Aid Act of 2017," and we look forward to working with you towards enactment of this needed legislation.

Sincerely,

Max Richtman
President and CEO



April 17, 2017

The Honorable Elizabeth Warren
The Honorable Chuck Grassley
The Honorable Maggie Hassan
The Honorable Johnny Isakson
United States Senate
Washington, DC 20510

Dear Senators Warren, Grassley, Hassan, and Isakson:

Consumers Union, the policy and mobilization arm of Consumer Reports, is pleased to support S. 670, the “Over-the-Counter Hearing Aid Act of 2017,” your legislation to help make hearing aids available to consumers more conveniently and affordably.

As noted in our recent article in the March 2017 issue of Consumer Reports,¹ price considerations keep many Americans from getting hearing assistance instruments that could make a big difference in their quality of life.

S. 670 would broaden the range of hearing aids available over the counter to adults with mild to moderate hearing loss. These devices would then be available for purchase separately from medical evaluations and services, giving consumers more affordable and accessible options.

We believe the bill would preserve and reinforce important consumer safety protections, including state laws holding manufacturers responsible for harm caused by unsafe and defective products, while overriding state laws designed to block or impede consumer access to over-the-counter hearing aids. This would include overriding state laws that require medical exams as a prerequisite for purchasing these over-the-counter products. We continue to encourage consumers with hearing loss problems to seek medical evaluation, to rule out other possible medical issues. But consumers can benefit from a system in which the medical evaluation is separated from the purchase of the device, so consumers are able to make their own choices, to shop around for medical services and hearing aids that best suit their needs and their budget.

¹ Insights: No More Suffering in Silence?, <http://consumersunion.org/research/consumer-reports-insights-no-more-suffering-in-silence/>.

We look forward to working with you to enact this beneficial consumer legislation into law. Thank you for your leadership on this important issue.

Sincerely,



Lisa McGiffert
Director, Safe Patient Project
Consumers Union



George P. Slover
Senior Policy Counsel
Consumers Union



The Nation's Voice for People with Hearing Loss

May 1, 2017

The Honorable Michael Burgess, Chairman
The Honorable Brett Guthrie, Vice Chairman
The Honorable Gene Green, Ranking Member
House Committee on Energy and Commerce
Subcommittee on Health
United States House of Representatives
Washington, DC 20515

Dear Representatives Burgess, Guthrie and Green:

On behalf of the nation's foremost organization representing people with hearing loss, I am pleased to offer our enthusiastic endorsement of legislation to expand access to over-the-counter hearing aids. The "**Over-the-Counter Hearing Aid Act of 2017**" HR 1652 will dramatically improve the lives of millions of Americans living with hearing loss.

Of the estimated 30 million Americans who have age-related hearing loss, only about 14 percent of them are currently using hearing aids. The primary reason for this disparity is the high cost of hearing aids. The average cost of one hearing aid is \$2,000 and most people need two. Medicare and most insurance do not cover hearing aids. Each and every day, our office receives letters, phone calls and emails from people with hearing loss inquiring about financial assistance to purchase hearing aids, up to 10 requests a day. The financial help page on hearingloss.org is the number one visited page on HLAA's website. Sadly, there are few financial aid resources. Creating a category of over-the-counter hearing aids will go a long way toward making these essential devices affordable for the millions of Americans who need them.

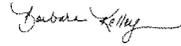
The approval of over-the-counter hearing aids will also cut through the red tape and confusing federal, state and local regulations that currently make purchasing a hearing aid intimidating even for those who can afford them. As hearing aids become more affordable and easier to purchase, HLAA believes that far more Americans will take advantage of them.

The current regulatory framework regarding hearing aids was developed at a time when over-the-counter devices provided little real benefit and too often added to the frustration of those experiencing hearing loss. Technological advances in recent years have made over-the-counter hearing aids a viable option for many people with mild and moderate hearing loss.

The benefit of making hearing aids more affordable and accessible extends far beyond the well-being of the individual with hearing loss and his or her family. As more consumers with hearing loss make use of hearing aids, workers become more productive creating a potential economic benefit to the nation at large.

Thank you for your leadership on this important issue. The Hearing Loss Association of America and our thousands of members across the nation stand ready to work with you to see this vital legislation become law.

Sincerely,



Barbara Kelley
Executive Director



March 20, 2017

Bose Corporation
100 The Mountain Road
Framingham, MA 01701

The Honorable Joseph Kennedy III
United States House of Representatives
434 Cannon House Office Building
Washington, DC 20515

Dear Representative Kennedy,

As a leading Massachusetts-based consumer electronics company with a long history of expertise in hearing science and audio engineering, we are writing to commend you and Representative Blackburn for your work to address the major problem of lack of access to innovative, high quality hearing health products for many Americans.

We applaud your leadership in introducing the Over-the-Counter Hearing Aid Act of 2017 to address the barriers to innovative hearing health solutions. Your legislation would invigorate competition, spur innovation, and facilitate access to affordable solutions to help millions of Americans hear better. We support this legislation, and the goal of addressing unmet hearing needs.

Sincerely,
BOSE CORPORATION

A handwritten signature in black ink, appearing to read "Bryan Fontaine", is written over a horizontal line.

Bryan Fontaine
Executive Vice President

**WRITTEN TESTIMONY OF TIMOTHY A. MCGEATH,
SENIOR VICE PRESIDENT AND GENERAL COUNSEL,
TRIMEDX HOLDINGS, LLC**

**UNITED STATES HOUSE OF REPRESENTATIVES
ENERGY AND COMMERCE COMMITTEE, SUBCOMMITTEE ON HEALTH
HEARING ON "EXAMINING IMPROVEMENTS TO THE
REGULATION OF MEDICAL TECHNOLOGIES"**

MAY 2, 2017

MR. CHAIRMAN, RANKING MEMBER GREEN AND MEMBERS OF THE SUBCOMMITTEE:

As a national provider of "in-house" medical equipment service and maintenance management, TriMedx has developed a safe, efficient and effective model to work directly with hospitals and other healthcare facilities to manage their medical equipment and technology. Founded in 1998, TriMedx began as the hospital clinical engineering department for St. Vincent Hospital in Indianapolis, Indiana. Effectively created by healthcare to serve healthcare, TriMedx's focus was and is to enhance the patient experience through innovative on-site equipment management programs designed to optimize equipment service and reduce costs. Ascension Health, the largest non-profit healthcare system in the country, has provided TriMedx the sole responsibility for managing the service, maintenance and repair of equipment for all hospitals within its system. The value proposition contained in the original vision for TriMedx – creating an independent, provider-oriented technology management company driven by core values – has been validated by TriMedx's rapid growth outside of Ascension Health. Over the past decade, TriMedx has become a meaningful and important strategic partner to some of the nation's most prominent healthcare providers, including a broad range of nonprofit health systems, academic medical centers and for-profit health systems. Today, TriMedx:

- serves more than 240 hospitals and 1,800 healthcare provider locations across 32 states;
- maintains data for more than 1.7 million pieces of equipment (including more than 60,000 unique models);
- employs and manages approximately 1,500 associates nationwide; and
- has saved hundreds of millions of dollars in capital expenditures and operating costs for its client partners through its comprehensive program.

EQUIPMENT SERVICE MODELS – ISOS AND OEMS.

The National Healthcare Expenditure Accounts estimate the cost of healthcare in the United States accounted for 17.5% of the nation's Gross Domestic Product in 2014.¹ Reports have shown that a medium size facility can spend \$5 million per year on equipment maintenance and an average system can spend \$50 million per year on such costs. It is clear that an effective equipment management program is a key component in reducing costs, optimizing services and ultimately freeing up financial resources.

¹ Centers for Medicare & Medicaid Services, <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html>.

In an effort to support such healthcare providers, the clinical engineering industry developed managerial programs focused on asset and strategic management of equipment inventory. These programs are typically offered through independent third-party service organizations, or "ISOs" and may include: (i) outsourcing of a traditional in-house clinical engineering department; (ii) medical equipment management services, including consulting services for the acquisition, maintenance and disposal of medical equipment; and/or (iii) the provision of specialty maintenance and repair services.

Independent third-party service providers play a key role in ensuring that healthcare is delivered in a cost-effective manner. By providing alternative and additional service options to original equipment manufacturer ("OEM") services, third-party service providers not only increase market competition but also drive other OEMs to maintain quality and cost-effective programs for healthcare providers.

EXISTING STATUTES AND REGULATORY FRAMEWORK.

Under the Federal Food, Drug, and Cosmetic Act (the "Act"), except for very limited and specific circumstances, the Food and Drug Administration ("FDA") has appropriately exercised little authority related to the manner in which healthcare providers and hospitals service and maintain their own equipment. Likewise, the FDA's regulations do not currently apply to independent third-party servicers of equipment when the independent third-party service provider contracts directly with the hospital or healthcare provider. Therefore, TriMedx interprets the FDA's current position to mean that independent third-party service providers are governed by the same regulatory framework as its hospital customers.

This interpretation is further supported by the fact that a hospital's service, repair and maintenance of equipment is subject to various existing statutory/regulatory schemes and accreditation conditions, including the Clinical Laboratory Improvement Act, the Safe Medical Devices Act of 1990, the CMS Conditions of Participation and conditions of The Joint Commission, depending upon the specific type of equipment at issue. As a hospital service provider, TriMedx is obligated to abide by the rules and regulations applicable to its customers, in addition to several others. Since TriMedx and other ISOs provide services as an agent or arm of the hospital, we are bound by the same laws.

In fact, as we shared in our comments to the FDA, healthcare providers and hospitals are already subject to a substantial amount of regulation and reporting through the existing federal, state and accreditation framework. Given that TriMedx offers a comprehensive medical device management program to its hospital customers, it assists them every step of the way in complying with the existing rules and regulations. Adding an additional reporting and audit burden would, we fear, simply add more cost and confusion to this highly regulated space.

FDA'S REQUEST FOR COMMENTS REGARDING SERVICING OF MEDICAL DEVICES.

TriMedx would like to take this opportunity to commend the FDA for its continued diligence around the refurbishing, rebuilding, remarketing, remanufacturing and servicing of medical devices. On March 4, 2016, the FDA issued a request for public comments, asking that stakeholders provide information regarding the refurbishing, reconditioning, rebuilding, remarketing, remanufacturing and servicing of medical devices performed by third-party service

providers and OEMs ("Request for Comments"). The FDA received an overwhelming response to this request that included over 175 comments from hospitals, OEMs, independent third party service providers, clinical engineers and other interested stakeholders.

On October 27th and 28th, the FDA held a public workshop, which afforded stakeholders an additional opportunity to share their thoughts and viewpoints. The FDA indicated it would review the findings and recommendations before taking further action. We found the workshop to be an invaluable opportunity to exchange concerns and recommendations. It also helped to ensure that FDA understands the interplay between hospitals, health systems, ISOs and OEMs and the impact that additional regulation may have on each. We left with an even greater appreciation for the complexities that come to bear when one of the pieces of the existing regulatory framework shifts.

In response to a question posed by a member of this Committee during its recent hearing on the Medical Device User Fee Program, Dr. Jeffrey Shuren, Director of the Center for Devices and Radiological Health, testified that FDA continues to review the feedback it received and "is still in the data gathering mode." We appreciate the time and resources that Dr. Shuren and his very knowledgeable, experienced team at the FDA have dedicated to this and look forward to reviewing their recommendations regarding the current regulatory framework.

MEDICAL DEVICE SERVICING SAFETY AND ACCOUNTABILITY ACT (H.R. 2118).

The Medical Device Servicing Safety and Accountability Act (H.R. 2118) would require ISOs to register with the FDA, establish a complaint handling system equivalent to that applicable to OEMs, and comply with the same reporting requirements. The bill also creates an exemption for in-house service departments. Put differently, if a device user facility, such as a physician office, ambulatory surgery center, or hospital, were to elect to maintain, service and repair its own equipment, without contracting through an OEM or an ISO, these same registration and reporting requirements would not apply.

At TriMedx, as with many other service providers around the country, our number one priority is patient safety. We believe TriMedx can positively impact that priority by ensuring the medical devices are safely and effectively maintained, repaired and available for safe patient use by healthcare providers. As a result, we support any initiatives that clearly advance the common goal of ensuring patient safety. TriMedx appreciates the Committee's interest in furthering the safe and effective use of medical devices. However, we are concerned that H.R. 2118 is only the first step to more comprehensive and burdensome regulatory requirements without a clear and corresponding benefit to patient safety. Therefore, we urge the Committee to approach this issue with caution and offer the following concerns and recommendations regarding the measure as currently drafted.

THE FDA IS WORKING TO ADDRESS THIS ISSUE.

As noted above, the FDA received substantial input through its request for comment and its public workshop. In fact, it is still in the process of gathering information before recommending next steps. Consequently, we are concerned that this legislation is premature and believe, given the extensive work the FDA has already done around this very issue, the agency should be allowed to complete its work before Congress intervenes with legislation.

THE REGISTRATION LANGUAGE IS VAGUE.

In addition to requiring servicers of medical devices to register with the FDA, H.R. 2118 permits the FDA to "specify the timing, format, and information" that must be submitted. While we appreciate the need to provide the FDA with flexibility to determine what information must be submitted, it should not be information that will be burdensome and costly to produce. By itself, the notion of registering with the FDA does not appear to be overly burdensome and we would be happy to comply, but we believe the application and maintenance of the registration should not be unduly burdensome and provide a commensurate benefit.

THE COMPLAINT HANDLING AND REPORTING REQUIREMENTS ARE DUPLICATIVE AND CREATE AN AWKWARD CONSTRUCT.

Federal regulations (21 C.F.R. 820.198) require manufacturers to maintain a complaint reporting process and procedure. This is designed to ensure that any potential concerns with a particular device are relayed to one party, the manufacturer, for further investigation and analysis. If the same reporting requirements are extended to servicers, it is unlikely that the manufacturer will know the number of complaints received and may not be able to understand the scope of a problem, which will hinder its ability to provide a remedy as soon as possible. Additionally, while a servicer may investigate an issue and report its findings to the manufacturer, it is likely that the manufacturer will still conduct its own analysis. These duplicative efforts are unlikely to bring any benefit to our healthcare system and, instead, represent a further diversion from the shared goal of delivering care in a safe and cost-effective manner.

Section 519(a) of the Act (21 U.S.C. 360i) contains two primary reporting categories: subsection (a), which applies to manufacturers and importers; and subsection (b), which applies to device user facilities. The legislation amends Section 519(a) to apply the manufacturer and importer complaint processing requirements to ISOs. Unfortunately, this would be duplicative because, as the manager of a device user facility's medical equipment, ISOs like TriMedx are responsible for helping their hospital customers comply with subsection (b). In fact, these ISOs assist with the internal investigation, gather information and help produce the report that is submitted to the FDA. Thus, they are already indirectly responsible for complying with subsection (b) under this existing regulatory framework.

We appreciate the need for these current regulations and believe the reporting requirements in subsection (b) are designed to provide the FDA with the information that is necessary to identify and manage equipment that is not safe or effective. Likewise, subsection (a) is tailored to require manufacturers and importers to provide information to which they are privy and which allows the FDA to ensure that devices are safe and effective for their intended use. While manufacturers and importers are governed by the same regulation, the reporting requirements applicable to each vary under part 803 of title 21 of the Code of Federal Regulations. Part 803 provides more specific guidance regarding the amount of information to be reported, the reports that must be maintained and the follow-up work that may need to occur in the event of a report. The guidelines under Part 803 are different for manufacturers, importers and device user facilities.

Put differently, there are already carefully crafted reporting requirements in place which strike the balance of ensuring that the right information is delivered at the right time. As mentioned above, many ISOs are already working with their clients, the device user facilities, to deliver this

information to the FDA. We believe the current reporting framework is sufficiently comprehensive and appropriately tailored to require delivery of information that is most readily available to the reporting party. However, if it is determined that changes are needed, we recommend that the legislation take into account existing reporting requirements in order to avoid redundancy.

Finally, by adding "servicers" to the manufacturer and importer reporting requirements additional regulatory action will need to be taken to craft reporting requirements that identify the information ISOs must produce. Simply adding the term "servicers" into obligations intended for manufacturers creates an awkward and unintended construct and has the potential of creating more confusion when it becomes unclear as to where the ISOs' obligations end and the OEMs' responsibilities begin. Moreover, we strongly believe the result would be reporting requirements identical to those of the device user facilities, which would result in a surplus of duplicative information being provided to the FDA that only adds to the cost of the device user facilities and to our already overburdened healthcare system.

THE LEGISLATION COULD REDUCE COMPETITION.

TriMedx firmly believes a marketplace that encourages equipment owners, operators, their chosen service providers and OEMs to work openly and collaboratively to further advance quality outcomes and decrease costs is one that will present the best opportunity for optimization, innovation and continued advancements in the delivery of safe patient care. As noted herein, hospitals and the ISOs who act as their agents are subject to certain regulations designed to ensure that equipment is maintained in a manner that best facilitates the provision of high quality patient care and ensures patient safety. The registration and reporting requirements add another layer of administrative tasks and, consequently, costs that smaller ISOs may not be able to bear. Therefore, we are concerned that H.R. 2118 may have an adverse impact on a competitive marketplace.

PROVISIONS THAT REQUIRE AND PROMOTE COLLABORATION SHOULD BE ADDED.

TriMedx believes a regulatory framework that promotes collaboration and information sharing between OEMs and ISOs would benefit healthcare providers, hospitals and patients. Since the Quality System Regulation rule was proposed in 1993, many OEMs have been unwilling to share servicing and maintenance procedures and methodologies with their customers. In fact, a 2013 CMS memorandum on servicing and maintenance acknowledges that, "*Hospitals may find that manufacturer's recommendations for some equipment are not available to them or their contractors . . .*" At a meeting on November 6, 2012, relative to revising its position, CMS inquired, "*It seems that manufacturers keep their manuals proprietary and do not share the information needed to maintain equipment. What happens in cases where no service manual is available for the equipment?*"

CMS's current position recognizes that OEMs generally do not provide this information to their customers, that it lacks the authority to compel the OEMs to provide such information and that, without such information, a healthcare provider, hospital and their respective agents may not be able to comply with OEM-recommended maintenance schedules, procedures and specifications. TriMedx has also encountered OEMs that have precluded it or the hospital customer from purchasing supplies or parts needed for repairs unless the hospital entered into an OEM service

agreement. These practices frustrate those customers' preferences, as they are ultimately prevented from implementing a comprehensive in-house program or purchasing the same services from independent third-party service providers.

The end result is an increase in the overall cost of healthcare and a diversion of the healthcare dollar that could otherwise be allocated to enhancing the patient experience, improving population health or serving the disadvantaged. The needs of our current healthcare landscape demand that OEMs be required to work collaboratively with ISOs and their hospital customers. Indeed, if this legislation is truly intended to place the same requirements on ISOs as OEMs, then it is only fair that those OEMs who do not cooperate with qualified ISOs be required to provide the materials, tools and support necessary to ensure not only patient safety, but a level and competitive playing field.

CONCLUSION.

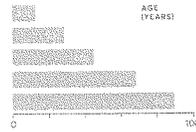
TriMedx is guided by the principle that patient care should be delivered in the safest, most effective and efficient way possible. While we will always support initiatives that are intended to improve the quality of patient care, we believe this legislation, as drafted, may be trying to solve a problem that has not properly been defined and would create additional and duplicative regulatory requirements without a clear and corresponding benefit to patient safety. Thus, we hope the concerns and recommendations set forth herein will receive your careful consideration.

Thank you for the opportunity to provide this written testimony and we look forward to working with the Committee on these important issues.

Insights

Notable news and smart solutions

HEARING LOSS INCIDENCE IN ONE OR BOTH EARS INCREASES AS WE AGE



No More Suffering in Silence?

Hearing loss is a widespread health problem associated with depression and even dementia. We report on affordable solutions and what's being done to give everyone access to treatment.

by Julia Calderone



ILLUSTRATION BY PETER D'ANTONIO

Source: Archives of Internal Medicine, Nov. 14, 2011, 15

Insights

AGE-RELATED HEARING loss has long been thought of as an inevitable part of getting older and more a nuisance than a life-altering medical condition—at least by those not experiencing it. But that's all changing. In the past two years, the President's Council of Advisors on Science and Technology (PCAST) and the National Academy of Sciences (NAS) have published reports calling untreated hearing loss a significant national health concern, one that's associated with other serious health problems, including depression and a decline in memory and concentration. Several studies suggest a link between hearing loss and dementia.

The estimated 48 million Americans affected by hearing impairment didn't need that memo. More than 100 years ago, Helen Keller, who was deaf and blind, described the isolation caused by hearing loss aptly when she said: "Blindness separates people from things.

Deafness separates people from people." Lise Hamlin, director of public policy for the nonprofit Hearing Loss Association of America (HLAA) echoes that sentiment: "We're social creatures. When you shut down the ability to talk and interact with people, that isolation affects your health and your ability to participate in society."

Most sufferers, not so surprisingly, are older adults. Recent research shows that the number of people with hearing loss has declined slightly among Americans of working age, but continues to be a problem for seniors, affecting about 28.6 million Americans ages 60 and above.

Despite of the prevalence of hearing loss and the negative impact it can have on health and quality of life, relatively few people seek treatment. Almost half of the 131,669 Consumer Reports subscribers surveyed for our 2015 Annual

Some advocacy groups say that hearing aids are more expensive than they should be and that cost is an obstacle to treatment.

Fall Questionnaire reported having trouble hearing in noisy environments, yet only 25 percent had their hearing checked in the previous year. And according to research published in the Archives of Internal Medicine, just 14 percent of those who could benefit from hearing aids actually buy them.

People don't seek help for several reasons, but one of the most common is that they can't afford it. Hearing aids, according to NAS, cost an average of \$4,700 per pair in 2013 and can climb to almost twice that price. And they're usually not covered by health insurance or Medicare.

No wonder the market for less expensive over-the-counter hearing helpers known as PSAPs (personal sound amplification products) is growing.

We've dug deep to find out why the treatments for hearing loss are so costly and what's being done to bring solutions

Now Hear This

Where do you fall on the hearing-loss spectrum?

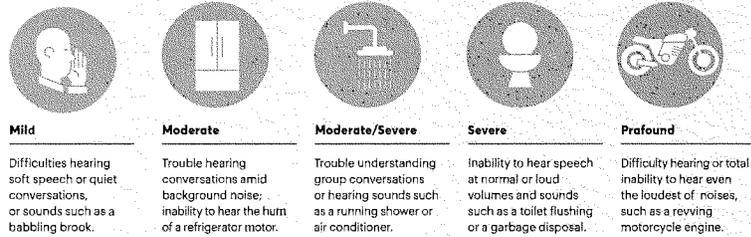
There are two main types of hearing loss. **Sensorineural**, the most common, is usually caused by the destruction of hair cells in the inner ear due to aging, heredity, certain drugs, loud noises, and nerve damage from illnesses like

mumps. It's the type that most affects people over 60 and is treated with hearing aids or cochlear implants, devices that send sound signals directly to the auditory nerve. **Conductive** hearing loss occurs when a physical block such as earwax

or a malformation stops sound from traveling through the ear canal. Removing the blockage usually restores hearing.

Hearing loss is measured by degrees ranging from mild to profound. Although the only way to know for certain whether

you have hearing impairment—and to what degree—is to see an audiologist or other hearing professional, the chart below can give you an idea of where you may fall on the scale.



within reach. We also tested several PSAPs to determine whether they're an affordable alternative to hearing aids for some people. Here's what we uncovered.

Great Strides in Treating Hearing Loss

Though most of us take our hearing for granted until we begin to lose it, the ability to perceive and make sense of sound is a marvel. In simple terms, sound waves travel through the air to the inner ear. There, microscopic hair cells convert them into electrical signals that are shuttled to the brain, which interprets them into meaningful sounds, language, music, and more.

But a constellation of abnormalities in various parts of the auditory system can cause this process to malfunction. For those who have mild to severe hearing problems (see "Now Hear This," on the facing page) such as difficulty understanding conversation in noisy restaurants or hearing a TV program at normal levels, hearing aids have traditionally been the solution.

These prescription devices contain a microphone, which picks up and converts sound waves into electrical signals, and an amplifier, which makes the signals louder. The amplified sounds are directed to the inner ear, where hair cells detect them and direct them to the brain.

Worn in or behind the ear, hearing aids have come a long way since the handheld ear trumpets of the 19th century, particularly in the past 20 to 30 years. Today's aids are smaller and, thanks to digitization, better at amplifying sound specifically in the frequencies where it's needed. Most aids can now be adjusted by wearers for a variety of environments, from quiet rooms to loud parties.

Modern hearing aids are also better at reducing unpleasant feedback and background noise, and often have telecoils, small copper wires that improve

sound clarity by picking it up directly from phones and public-address systems. At the higher end, hearing aids have features such as Bluetooth connectivity, allowing users to stream music and take phone calls through them.

The result of this progress is that 46 percent of our survey respondents reported they were very or completely satisfied with their aids; only 3 percent tried aids and found they didn't work.

Despite the advances, compensating for hearing loss continues to be a challenge. For instance, experts say that even the most sophisticated devices can't fully normalize impaired hearing. As Marvin M. Lipman, M.D., Consumer Reports' chief medical adviser, notes: "No hearing aid can match the efficiency and function of the human ear. There's nothing like the real thing."

Some people benefit more from hearing aids than others. "You can have two people with identical audiograms who have very different functionality," says Debara Tucci, M.D., a professor of otolaryngology at Duke University Medical Center, referring to a commonly used hearing test.

Other impediments to treatment include people hearing negative experiences from friends or family members or being unaware they need help.

Then there's the matter of image: Hearing aids are still sometimes viewed as a sign of faltering health. "There's much more of a stigma for wearing a hearing aid than there is for wearing glasses," says James C. Denney III, M.D., who is CEO of the American Academy of Otolaryngology-Head and Neck Surgery.

Priced Out of Treatment Options

But by far the biggest barrier to treatment is price. You can buy the newest smartphone—a far

5 Ways to Save Money on Prescription Hearing Aids

If you're considering hearing aids but worry about the cost, these steps can guide you to some affordable solutions

- 1. Investigate your coverage.** Veterans, some children and federal workers, and residents of Arkansas, Connecticut, New Hampshire, and Rhode Island can get them covered by insurance. A few plans, including some from Medicare Advantage, offer partial coverage or discounts. If you have a high-deductible insurance plan, you can put up to \$3,400 in a health savings account to pay for aids with pretax dollars. With a flexible spending account, you can use up to \$2,600 in pretax dollars for aids, batteries, and maintenance.
- 2. Don't buy more hearing aid than you need.** Skipping extras you won't use—such as Bluetooth capability—can slash your bill by hundreds of dollars.
- 3. Ask for a price break.** Almost half of the survey respondents who tried to negotiate received a lower price.
- 4. Shop around.** Costco, which was highly rated for customer satisfaction in our survey (see "Ratings of Hearing Aid Retailers," at right), offers no-cost screenings and hearing aids for about \$500 to \$1,500 each. Only some stores have on-site audiologists or hearing specialists, so call ahead. Buying aids online can save you upward of \$2,000 a pair, but you may need to mail them back for adjustments or pay a local specialist to do so.
- 5. Check out groups that can help.** Some government, state, and independent organizations such as the Lions Club may help you pay for hearing aids or offer discounts. (Go to asha.org.)

READERS WEIGH IN ON HEARING AID RETAILERS
Criteria include hearing evaluations, product options, staff courtesy, and follow-up adjustments.

Hearing Aid Retailer	Overall Score	HOW WE SURVEYED
Connect Hearing	85	Scores are based on purchases of 6,276 individual hearing aids or matched hearing aid pairs by 6,053 Consumer Reports' subscribers. A score of 100 would mean all respondents are completely satisfied; 80, that respondents are very satisfied on average. Differences of fewer than 4 points are not meaningful.
Costco	84	
Sam's Club	83	
HearUSA	82	
HearingPlanet	81	
Audibel	80	
Miracle-Ear	79	
Beltone	78	
Zounds Store	77	
Starkey Store	76	

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more complex device than any hearing aid, for less than \$1,000 dollars. But hearing aids cost \$3,300 to \$8,000 per pair—and prices continue to rise.

Groups such as NAS and PCAST say that hearing aids are more expensive than they should be. The PCAST report cites a 2010 study that found that the cost of hearing aid components could be purchased for less than \$100.

But many of the professionals who sell hearing aids, most of whom are audiologists with doctoral degrees, note that the price also covers many services. These include hearing tests, assessments to determine which device is best and which features are needed most, fittings, and follow-up. As Todd Ricketts, Ph.D., director of graduate studies in hearing and speech sciences at Vanderbilt University Medical Center, explains, evaluating people and then making adjustments to ensure that their hearing aids works as well as possible is exacting and time-consuming.

But “bundling” the price of the product with services this way makes it more difficult for people to know exactly what they’re paying for. According to a recent NAS report, the lack of transparency with bundling also forces consumers to pay for services they don’t actually need. (See “5 Ways to Save Money on Prescription Hearing Aids,” on page 17, for tips on unbundling.)

What’s more, neither Medicare nor a majority of commercial insurance plans—which often follow Medicare’s lead—generally cover the cost. Nor do they offer coverage for an additional fee, as many plans do with dental and vision care.

Given the established link between hearing loss and other serious health problems, why don’t insurers or Medicare pay for hearing aids?

“I don’t know why we don’t cover the cost of hearing aids,” said a spokesman for Aetna, Matthew Clyburn, when we asked. “Medicare doesn’t

cover them either, so it doesn’t seem to be highly out of the ordinary,” he added.

When we requested an interview with a representative from Medicare, a spokeswoman sent an email explaining that she couldn’t address why hearing aids are excluded from Medicare coverage. And she suggested that we refer to the Congressional Record of 1965—the year that Medicare was signed into law—for an answer.

Likely reasons for the exclusion of hearing aids when Medicare was created are that they were far more affordable at that time, the industry was poorly regulated, and hearing loss was not yet viewed as a significant health concern. As Kim Cavitt, Au.D., an audiologist and adjunct lecturer at Northwestern University, says, “You don’t die from hearing loss.”

But the continued lack of Medicare and health insurance coverage has not gone unnoticed by certain members of Congress, who are pushing to make hearing aids more affordable and easily available.

“We know now that 70 percent of all seniors between the ages of 65 and 84 who need a hearing aid simply do not get one because they can’t afford it,” says Rep. Debbie Dingell, D-Mich., who introduced a bill in 2015 that would require Medicare to pay for hearing aids. “People with untreated hearing loss are cut off from their communities,” she said. “They feel isolated and depressed. We must get agreement in Congress that people need to hear.”

Dingell’s bill failed to find traction in 2015, but she says she plans to reintroduce it this year. In December, Senators Elizabeth Warren, D-Mass., and Chuck Grassley, R-Iowa, introduced legislation that would make simple, more affordable hearing aids easier for consumers to obtain by allowing them to

Are OTC Hearing Helpers Any Good?

Personal sound amplification products are much cheaper than hearing aids. But do they work? We tested a handful to find out.

PERSONALSOUND amplification products, or PSAPs, cost a fraction of the price of the average hearing aid. The most expensive ones are about \$500 each. Prescription aids generally start at about \$1,660 each, including fees for the services of an audiologist or hearing-aid specialist. (Some less expensive prescription aids are available online and through retailers such as Costco.)

The Food and Drug Administration currently doesn’t allow PSAPs to be marketed as devices to improve impaired hearing. But the National Academy of Sciences and the President’s Council of Advisors on Science and Technology have recently said that PSAPs can help some people with mild to moderate hearing impairment. Both groups are calling for the FDA to allow PSAPs to be marketed as a way to address hearing loss.

To find out whether these hearing-aid look-alikes can help people with hearing loss, we had three CR employees who were diagnosed with mild to moderate hearing impairment try four PSAPs (from \$20 to \$350) for three to seven days at the office, at home, in restaurants, and in our audio labs, where we tested how well they could help pick out words in a noisy environment. For an expert opinion, we had a hearing-aid researcher test each PSAP in areas such as

amplification, battery and microphone function, and sound distortion.

We found that some PSAPs, if properly fit and adjusted, can help people with mild to moderate hearing loss (see “Degrees of Hearing Loss,” on page 16). As with prescription hearing aids, PSAPs aren’t one-size-fits-all, so it’s best to have a professional hearing test first and to consider asking an audiologist or hearing-aid specialist for guidance in determining which device might be best for you.

When Pinching Pennies Can Hurt You

Our PSAP evaluations included two very inexpensive models—the Bell & Howell Silver Sonic XL and the MSA 30X — priced at \$20 to \$30 each. These devices showed very little benefit in any of our tests, and sometimes actually blocked incoming sounds the way earplugs do.

Even more concerning: Our hearing expert says these devices have the potential to cause additional hearing damage by overamplifying sharp noises, such as the wail of a fire engine.

Our expert recommends avoiding very inexpensive models, which are generally in the \$10 to \$30 range. They don’t seem to help much, if at all, and could actually further diminish your ability to hear.

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Conversation Piece



SoundWorld Solutions CSSO+
\$350

This rechargeable device offers some background noise reduction, settings for entertainment, everyday, and restaurant environments, and Bluetooth capability. It can be customized with a smartphone app to amplify the frequencies a user needs most.

WHAT WE LIKED

Panelists found it comfortable and easy to use; two out of three felt it improved their ability to hear a TV and conversations. Our expert noted that it's the only PSAP we tested that allowed them to tweak settings to amplify sounds in the frequencies where they have the most trouble hearing, a feature similar to what you'd find in a basic hearing aid. The directional microphone can pick up sounds in front of the user, making it easier to hear conversations in noisy places like a crowded restaurant. Panelists also found it useful to be able to pair this PSAP with smart devices via Bluetooth, which allowed them to take phone calls and stream music while wearing it.

WHAT WE DIDN'T LIKE

The CSSO+ didn't help wearers decipher conversations in the noisy environment we created in our lab. One panelist felt it minimally improved hearing but found it useful for streaming music. Our expert noted that none of the three panelists was able to adjust the customizable settings to optimally compensate for their hearing loss.

OUR DEVICE ADVICE

The CSSO+ could be of use to people with early or mild to moderate hearing loss. The customizable settings and smartphone connectivity mean the device can potentially work as well as a simple hearing aid for some people, though only if fit and settings are adjusted correctly. The device protects your ears by limiting overamplification of sharp, hearing-damaging sounds, such as a wailing fire engine, though not as much as the Bean (below).

Tuned Into TV



Etymotic Bean (no T-Coil)
\$299 (\$550 if purchased as a pair)

An in-ear device that runs on disposable batteries that last about one to two weeks, the Etymotic Bean has an omnidirectional microphone that picks up sounds around the wearer. A toggle switch controls volume levels.

WHAT WE LIKED

Panelists found the Etymotic Bean easy to use and inconspicuous; they reported that it improved their ability to hear a television. Our expert liked that it requires no initial adjustments, is ready to use right out of the box, and that—unlike less expensive devices—it protects against overamplification of sharp sounds, which could damage hearing.

WHAT WE DIDN'T LIKE

The Etymotic Bean didn't help wearers decipher conversations in the noisy environment we created in our lab. Panelists reported that the device squeals unpleasantly until it's placed firmly in the ear, and that it can turn on when stored in the case, draining the battery. Our expert says that the shallow tip could lead to a blocked or stuffy feeling in the ear. He also noted that the small parts may be challenging to manipulate and that the device doesn't amplify sounds in the lower pitches, such as vowel sounds like the letter "o" in the word "pot."

OUR DEVICE ADVICE

The Etymotic Bean can be helpful for those with early or mild to moderate hearing loss in the higher frequencies. But it probably won't amplify sound enough if your hearing loss is in the low frequencies (think bass drum) or extremely high frequencies (the whine of a mosquito). Although it doesn't reduce background noise, placing the device in the ear properly may block out some unwanted sounds.

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be sold over-the-counter and eliminating the requirement that people have a medical exam or sign a waiver before purchasing them. And the Food and Drug Administration recently announced that it would no longer enforce the medical exam or waiver requirement.

Affordable Over-the-Counter Solutions

Given the high cost of hearing aids, it's no surprise that we're seeing a growing array of less expensive OTC products, such as wireless headphones for TV watching and phone apps that amplify sound. But PSAPs, which range from about \$10 to \$500 each, are the most common OTC option.

They sit in or behind the ear and contain some of the same components as hearing aids: a receiver, a microphone, and an amplifier. In theory, they should boost the volume of the sounds you have trouble hearing. And depending on the device, they should reduce background noise, just as many prescription hearing aids can.

Most PSAPs are fairly basic, offering few adjustments for varied environments—say,

outdoor spaces or movie theaters—or none at all. And unlike a majority of hearing aids, PSAPs are generally analog, not digital, so they're usually less able to reduce annoying feedback and they consistently target only the frequencies in which users really need amplification. "That's a big difference," says Cavitt, who co-authored a 2016 study comparing PSAPs with hearing aids. "When the sound comes in, does it merely amplify it, or can it also suppress feedback or extraneous noise?"

That may be challenging for consumers to figure out. PSAPs aren't regulated by the FDA as hearing aids are, and manufacturers aren't permitted to call them hearing aids or claim that they improve impaired hearing. (In fact, according to the FDA, the devices aren't meant for those with hearing loss but are "intended for non-hearing impaired consumers to amplify sounds in certain environments.")

And because PSAPs are so loosely regulated, consumers have no way of knowing whether one is better than another, says Neil DiSarno, Ph.D., chief

"We must get agreement in Congress that people need to hear," says Rep. Debbie Dingell, D-Mich.

staff officer for audiology at the American Speech-Language-Hearing Association (ASHA).

Experts agree that people who already have moderate to severe hearing loss won't benefit from PSAPs. To see how well they work for those with mild to moderate hearing loss, Consumer Reports had three volunteers who fit that definition test four devices (see "Are OTC Hearing Helpers Any Good?", on page 18). We found that the higher-end PSAPs helped our volunteers hear better, especially while watching TV.

Ricketts urges consumers to see a hearing professional to determine their level of hearing loss and which ranges need amplification most. (A hearing specialist can also diagnose more easily remedied issues such as earwax buildup or more serious problems such as ear-canal tumors.) Audiologists usually don't sell PSAPs or adjust those that consumers buy on their own, although this might soon be changing. "Even if PSAPs are not perfect," Denmeny says, "they may give people a relatively simple entry point into the healthcare system at a markedly reduced cost.

↓ | RECALLS

 <p>FOOD PROCESSORS The main processing blade—used for cutting, chopping, and dicing—on about 8 million Cuisinart food processors has been recalled because it can crack and break over time. There have been 69 reports from consumers who found small metal pieces from a cracked blade in their food; in 30 cases, they suffered cuts to the mouth or tooth injuries. The processors were sold online and at stores from July 1998 through December 2015.</p> <p>What to do Stop using the blade immediately and contact Cuisinart at 877-339-2534 or go to cuisinart.com to get a free replacement blade. You can still use the processor with its other attachments.</p>	 <p>SMOKE/CO ALARMS Kidde is recalling about 3.6 million NightHawk combination smoke/CO alarms. Once the backup batteries are replaced, the units can fail to chirp when they reach their seven-year end of life, which may lead users to think they're still working. That means that consumers may have no alert during a fire or CO incident. The alarms were sold online and at electrical distributors and home centers nationwide from June 2004 through December 2010.</p> <p>What to do Replace the alarm. Contact Kidde at 855-239-0490 or go to kidde.com for a free replacement alarm or a discount on a new alarm.</p>	 <p>DEHUMIDIFIERS The manufacturers Gree and Midea are recalling about 5.9 million dehumidifiers because they can overheat, smoke, and catch fire, posing serious fire and burn hazards. Midea is recalling 51 brands sold at stores nationwide from January 2003 through December 2013. Gree is recalling 13 brands sold online and at stores from January 2005 through August 2013.</p> <p>What to do Stop using the appliance. Go to midea.com/us/ or greedehumidifierrecall.com for details on affected brands and model names. Call Gree at 866-853-2802 for a full refund or Midea at 800-600-3055 for a replacement or partial refund.</p>
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**Written Testimony of the
International Hearing Society
To the House Energy and Commerce Subcommittee on Health
In Opposition to
H.R. 1652, the Over-the-Counter Hearing Aid Act of 2017
May 2, 2017**

Dear Chairman Burgess, Ranking Member Green, and Members:

Thank you for the opportunity to provide comments on H.R. 1652, the Over-the-Counter Hearing Aid Act. The International Hearing Society (IHS) commends the Subcommittee and sponsors of the legislation for their interest in hearing health care issues, including exploring options for expanding access to those individuals who could benefit from the use of hearing aids but are not yet using them. As an association that represents hearing aid dispensing professionals, our members see the positive impact that hearing aid use and aural rehabilitation has on their patients, including their overall health and improved function in their daily lives and relationships. IHS supports the ultimate goal at stake here of increasing competition and reducing cost.

Respectfully, our society must stand in opposition to H.R. 1652, the Over-the-Counter Hearing Aid Act of 2017. We take this position due to concerns that individuals are not able to accurately self-diagnose and self-treat their hearing impairment and there being a lack of associated evidence to the contrary; that federal preemption of state licensing laws will lead to an unregulated distribution market that will in turn lead to poor satisfaction, poor adoption, and patient harm; and the absence of professional involvement at any point during the process of over the counter (OTC) hearing aid acquisition, as proposed, compromise consumer safety and efficacy.

There is also ample evidence that recent innovations in the delivery of care, technology, and access are already moving the needle in the direction of greater acceptance of hearing aids while adhering to the reasonable and limited regulatory standards that exist today. Panelists at the Federal Trade Commission workshop held April 18th discussed these advancements at length. Just two weeks ago, CVS announced an expansion into the hearing healthcare delivery system through the establishment of hearing aid centers into 50 of its clinics and future clinic model.

The FDA Safety & Effectiveness Standards for OTC Products dictate that OTC products must meet the "same standards as prescription drugs, and consumers must be able to 1) self-diagnose, 2) self-treat, and 3) self-manage [the condition], which can be assessed through label comprehension studies and actual use studies."¹ As you may know, the recommendation for OTC hearing aids originated from the President's Council of Advisors on Science and Technology (PCAST) and the National Academies of Science, Engineering, and Medicine (NAEM). However, in public forums, representatives of these groups have stated that their recommendations were made on the presumption that individuals are able to self-diagnose, self-treat, and self-manage their loss. OTC hearing aids do not pass the litmus test, and

consistent with FDA standards, it is IHS's position that any movement to create such a category must be predicated on the production of validated evidence that a consumer can reliably self-diagnose, self-treat, and self-manage his/her hearing loss. To date, the evidence contradicts this goal. A recent study – the first of its kind – conducted by AZ Marketing Research for Amplifon found that of individuals who had self-perceived mild or moderate hearing loss: only 1 in 4 individuals correctly assessed their hearing loss, 13% had an FDA Red Flag (condition requiring medical referral), 10% had no hearing loss, 37% had a more severe loss than what they self-reported, and 20% self-selected a hearing device (online hearing aid or personal sound amplifier) with an output above safe levels (120db+).¹¹ Further, a self-diagnosis goes beyond just assessing the degree and type of hearing loss. Hearing loss is a symptom of an underlying medical or functional disorder. For example, someone with the symptom of hearing loss may have the diagnosis of a cholesteatoma, bilateral age-related hearing loss, impacted cerumen, an ear infection, otosclerosis, or a variety of other conditions. A self-administered pure-tone hearing test alone cannot provide a proper diagnosis, nor are individuals capable of reliably self-diagnosing the reason why they may be experiencing a hearing loss.

As proposed by H.R. 1652, a reliance on individuals' self-diagnosing and self-treating their "perceived" hearing loss is likely to result in their purchasing hearing aids unnecessarily or when they may have an underlying medical condition (thereby delaying care), or purchasing the wrong hearing aid for their loss. The physiology (and psychology) of hearing loss is unique to each individual. The proper evaluation of hearing loss involves several important tests to include a patient history and audiometry, as well as the identification of possible related medical conditions, speech testing, and an otoscopic evaluation – each of which require, by necessity, the involvement of a licensed professional. If hearing aids are appropriate, optimal outcomes depend upon the proper fit of the hearing aid, aural rehabilitation (counseling), and ongoing follow-up care. Consider this - according to a survey conducted by IHS in 2015 of hearing aid dispensing professionals, the average new hearing aid patient has at least five appointments with their provider within the first year. This demonstrates the level of professional attention necessary to achieve a satisfactory result.

The alternative – creating an over the counter hearing aid classification – would most certainly lead to patient harm and poor outcomes for the thousands, or perhaps millions, of individuals seeking hearing aids. And perhaps equally as concerning, these poor outcomes will lead to the widespread lowering of hearing aid adoption rates and use. We have seen this happen in Asian markets like in Japan where professional intervention is minimal and hearing aids are widely available over the counter. Japan has a 39% satisfaction rate (compared to 81% in the US) and a 14.1% adoption rate (compared to 30.2% in the US). Interestingly, at the same time the U.S. is considering lowering its standards, the International Organization for Standardization is looking to establish a Hearing Aid Fitting Management standard based on the U.S. model, which is considered the gold standard for safe and effective care. This work comes as the result of a request from South Korea, which lacks professional standards and consequently has low adoption and satisfaction rates.

In our increasingly socially-connected world, we know more about the experiences and opinions of our personal network (friends and family) than ever. According to the American Express Global Customer Service Barometer survey conducted in 2014, "When it comes to poor customer service experiences, nearly all (95%) consumers talk about them, with 60% reporting that they talk about these experiences all of the time. On average, consumers tell 8 people about their good experiences, and over twice as

many people (21) about their bad experiences.” These statistics don’t bode well for the concept of an OTC hearing aid market since we know that satisfaction and hearing aid use is tied to the involvement of the licensed provider and use of best practices.ⁱⁱⁱ

IHS understands the intention of the legislation is to not bind a consumer to a licensed practitioner in the purchase of a device. However, we see the potential for many unintended harmful patient outcomes under the proposed model beyond just the implications described above. Specifically, the federal preemption of state licensing laws will lead to the natural development of an incompetent and unlicensed group of individuals opening up shop to sell, customize, and service individuals who have purchased OTC hearing aids from another source. It is presently a common occurrence that a consumer will take an internet hearing aid or personal sound amplifier to a hearing aid specialist or audiologist for assistance. The public will have no understanding of the difference between a licensed and non-licensed provider, and will undoubtedly be harmed by the lack of competency and standards, as well as sales tactics that come along with unregulated providers. At a meeting of the Hearing Industries Association in March 2017, Dr. Dan Blazer, co-chair of the NASEM Committee on Hearing Health Care for Adults expressed to an IHS representative that the intention of the committee’s recommendation was not to create an unlicensed class of providers, yet H.R. 1652 would do just that. As a result, not only is the consumer at risk of receiving inappropriate, unsafe, and/or unethical care through an unscrupulous, incompetent, and unlicensed provider, but poor outcomes will erode consumer trust and create negative perceptions of hearing aid providers and hearing aids.

In 1986, the State of Colorado determined that the regulation of audiologists and hearing aid specialists was no longer needed because of a lack of complaints by consumers and subsequently eliminated professional licensure and all standards that went along with licensure. This action essentially created an OTC hearing aid marketplace in the state. The result of unregulated hearing aid sales spoke for itself. Within months unscrupulous, untrained, unlicensed, and incapable would-be sales people flocked to the state. These were people who could not get licensed previously or had their licenses revoked either in Colorado or in other states, or who were merely trying to make a quick dollar. They would open storefronts or operate out of their vehicles, but when a client needed services, they would often disappear. Many would hold seminars for the public promising phenomenal results, taking money from those in need, and not deliver on their promises. People with hearing loss, including the elderly, were hurt in these transactions both financially and psychologically, and the recovery, once licensure was reinstated, took several years. In its 1999 Sunset Review, the Colorado Department of Regulatory Agencies Office of Policy and Research stated, “This sunset review found that there is significant actual public harm by the unregulated practice of hearing aid sales,” and as a result the department recommended continued regulation of hearing aid dealers.^{iv, v} This is in spite of the fact that during the deregulation period - from 1986 through 1995 - the regulation of hearing aid sales had been governed by the state’s Consumer Protection Act. Even with state oversight, licensure of those dispensing hearing aids was still deemed necessary.

The concept of reestablishing this model across the country, and with our most vulnerable population as the target, is of significant concern. Federal and state regulations governing who can dispense hearing aids and requirements associated with the sale are a necessary safeguard and must be maintained in order to prevent the widespread abuse and mistrust that would inevitably arise out of the establishment of an OTC hearing aid classification. Not to mention the lack of state-based consumer protections that

would no longer be afforded the patient who purchases an over the counter hearing aid. The mistakes corrected after Colorado's failed experiment should not be repeated on a nationwide scale.

Over time, the hearing aid dispensing community has worked diligently to improve patient satisfaction and acceptance of hearing aids as a solution, and most importantly build trust within their communities and with prospective and existing patients. Their efforts are reflected in the current satisfaction rates for hearing care providers (hearing aid specialists and audiologists). A recent study shows that 95% of owners and 87% of non-owners are satisfied with the health care providers they have seen in the last five years. The same study shows that satisfaction with hearing aids is high as well, with satisfaction at "91% for hearing aids obtained in the last year; 77% for hearing aids obtained 2-5 years ago; and 74% for hearing aids obtained 6 or more years ago." The overall satisfaction rate is at 81%.^{vi} Comparatively, cellular telephone companies' (oftentimes affiliated with consumer electronics) satisfaction rates are on average 79%, with a maximum satisfaction rate of 81% in 2016.^{vii} The aforementioned efforts by the hearing care provider community to build trust and a respected reputation is critical because of an overall wariness by individuals with hearing loss to obtain hearing aids due to stigma, vanity, and denial. Stigma being the number one reason that people choose not to seek out hearing aids is a difficult challenge, but IHS believes that other recommendations made by the NASEM to include increasing consumer education and awareness and engage primary care physicians can help move the needle in a positive way.

While the eyeglass analogy tends to be used in comparison to hearing aids - truly an apples and oranges comparison in terms of the complexity in identification, physiological and medical implications, and treatment of hearing loss - the regulation and delivery of eyeglasses and contacts can serve as a useful model for drawing the line between expanded competition and the overall lowering of cost, and patient safety. The current model allows for individuals to purchase eyeglasses and contacts from online and other retailers if they have a prescription from a licensed ophthalmologist or optometrist within the previous six months. This model ensures that the eyeglasses or contacts are appropriate for the patient/consumer, yet still allows for them to investigate the delivery model that will best meet their needs and shop around. If hearing aids were to be sold direct to the consumer, building in a requirement that the consumer obtain an order from a licensed professional within the previous six months that affirms the individual has had an audiometric evaluation and visual inspection of the ear, has mild to moderate hearing loss, and could benefit from the use of a hearing aid, coupled with FDA regulations governing the safety of the devices, would minimize patient safety and efficacy concerns. This model would create an informed consumer who could then explore all the options available to him/her, which would be a better alternative than the complete elimination of the hearing care provider in the process. Further, most hearing aid providers offer free hearing screenings, so this requirement would not add a cost barrier.

It is for the aforementioned reasons that the International Hearing Society opposes H.R. 1652 in its current form. IHS believes the creation of an FDA-approved classification of OTC hearing aids should only be considered following a comprehensive actual use study to validate whether individuals can reliably self-diagnose, self-treat and self-manage their hearing loss. If they cannot, such study should determine which mechanisms must be put into place to ensure safe and effective care, such as having an in-person hearing evaluation from a licensed provider (a hearing aid specialist, audiologist, or physician, preferably an otolaryngologist) within six months of purchasing a device over the counter. This model

will enable consumers to be informed consumers and make a decision on which treatment model they prefer once they fully understand their hearing loss and options. Finally, we would ask for a resolution to our concerns with full federal preemption of state licensing laws related to OTC hearing aids so that consumers can be assured that individuals who dispense, fit and modify OTC hearing aids are competent, held to an accepted standard, and that protections exist if they are harmed. Therefore, IHS respectfully asks that you delay further consideration of H.R. 1652 until the studies are completed and the appropriate model based on evidence be determined. Alternatively, IHS would be pleased to offer amendment language for the subcommittee's consideration.

IHS respectfully also suggests time be given to see through new initiatives that are being undertaken within the hearing healthcare field and marketplace, each of which can have a profound impact on hearing aid adoption rates before seeking to take the extreme step of legislating an over the counter hearing aid category. These initiatives, for which agreement was made at the December 2016 NASEM meeting to move forward, include a public awareness campaign, outreach to the medical community to promote hearing loss as an important health care issue, the establishment of standards for hearing aid outcomes and metrics for patients to use to assess their hearing ability, and creating consensus standards for community-based service providers. These are in addition to the other NASEM recommendations that are being implemented by individual organizations just as we are doing at IHS. Fortunately, hearing aid use, outcomes, and accessibility are presently on a positive trajectory. It would be a detriment to overall healthcare outcomes to place this positive momentum at risk at this time.

Thank you for your consideration. With questions or to discuss further, please contact IHS Government Affairs Director Alissa Parady at 734.522.7200 or aparady@ihsinfo.org.

Founded in 1951, the International Hearing Society represents hearing aid dispensing professionals worldwide, including dispensing audiologists, dispensing physicians, and the approximately 9,000 hearing aid specialists licensed in the U.S. presently. Hearing aid specialists dispense and provide professional services to approximately half of the non-VA hearing aid market, operate in both urban and rural areas, and often perform nursing home and home visits – delivering care to those in need, including those in remote locations. IHS promotes and maintains the highest possible standards for its members in the best interests of the hearing-impaired population they serve by conducting programs in competency accreditation, testing, education and training, and encourages continued growth and education for its members through advanced certification programs.

¹ <https://www.fda.gov/downloads/aboutfda/centersoffices/cder/ucm148055.pdf>

² <http://www.hearingreview.com/2016/12/implications-counter-approach-hearing-healthcare-consumer-study/>

³ "MarkeTrak VIII: The Impact of the Hearing Healthcare Professional on Hearing Aid User Success: Correlations between dispensing protocols and successful patient outcomes." Hearing Review, April 2010.

⁴ <http://hermes.cde.state.co.us/drupal/islandora/object/co%3A4646>

⁵ Also known as hearing aid specialists, hearing instrument specialists, hearing aid dispensers, and hearing aid fitters.

⁶ <http://www.hearingreview.com/2015/05/introduction-marketrak-ix-new-baseline-hearing-aid-market/>

⁷ http://www.theacsi.org/index.php?option=com_content&view=article&id=147&catid=&Itemid=212&i=Cellular+Telephones



AMERICAN
SPEECH-LANGUAGE-
HEARING
ASSOCIATION

**American Speech-Language-Hearing Association
Statement for the Record for the Health Subcommittee of the
Energy and Commerce Committee
Regarding Over-the-Counter Hearing Aids (H.R. 1652)**

While the American Speech-Language-Hearing Association (ASHA) continues to maintain that the best model of hearing health care features audiologists and consumers collaborating on treatment options, it recognizes instances where that model can be modified. There may be advantages to making hearing aids directly available to some consumers with mild hearing loss. Less costly over-the-counter (OTC) hearing aids could serve as an early gateway for users with mild hearing loss to explore whether they could eventually adapt to hearing technology without significant financial outlay. It is already the case that consumers with perceived mild hearing loss can seek amplification on their own, without professional involvement, by purchasing unregulated personal sound amplification products or other products and devices that are indirectly marketed for hearing loss.

ASHA recommends the following changes H.R. 1652:

- restrict OTC hearing aids to mild hearing loss;
- establish safe levels of gain and output (power) for these hearing aids;
- ensure that OTC hearing aids are only available for adults;
- establish a means for collecting information on consumer safety and other potential complaints;
- require labeling that strongly recommends seeking audiologic diagnostic and rehabilitative services; and
- require labels that provide consumers with warning signs for conditions that require medical treatment.

Furthermore, ASHA strongly encourages the Subcommittee to take a more holistic approach to access to and affordability of hearing aids. A parallel effort must be undertaken to ensure the establishment of both public and private insurance coverage for patients with hearing loss who do not benefit from OTC hearing aids. These additional categories of services would include coverage of the professional auditory rehabilitation services of an audiologist that would allow a person with hearing loss to maximize their communication abilities with amplification. Without meaningful coverage of all hearing health care services for all individuals with hearing loss, there is a high probability that these individuals will inappropriately self-prescribe OTC hearing aids and fail to receive appropriate care; thereby, not achieving the sufficient benefit from OTC hearing aids.

ASHA supports efforts by Congressman Gus Bilirakis related to Medicare coverage of professional services provided by an audiologist, and is working with him and his staff for reintroduction of this legislation in this Congress. We urge the Subcommittee to consider and pass this legislation, which would allow Medicare beneficiaries to receive coverage of these important hearing health care services.

We respectfully request that the Subcommittee move cautiously forward. Hearing loss is permanent, and over-amplification can cause further damage to the ear and greater degrees of hearing loss. Conversely, under-amplification may cause the consumer to become frustrated and leave their hearing problems untreated. Therefore, inappropriately chosen OTC hearing aids present a significant health risk to individuals. By limiting the legislation to mild hearing loss and requiring data collection on consumer safety and complaints, the U.S. Food and Drug Administration (FDA) can

better assess both the positive and negative implications of a “do-it-yourself” model for hearing health care.

Background

Hearing loss is a medical condition that can be categorized by which part of the auditory system is damaged. There are three types of hearing loss: conductive, sensorineural and mixed. Some conductive loss can be corrected by medical or surgical intervention and include such conditions as a build-up of wax in the ear, ear infections, or a perforated eardrum. Sensorineural hearing loss involves damage to the inner ear or a nerve pathway from the inner ear to the brain. This type of hearing loss cannot be medically or surgically corrected, and is the most common type of permanent hearing loss. Sensorineural loss can occur through aging, illness, head trauma, or exposure to loud noise. An individual can experience both conductive and sensorineural hearing loss at the same time, which is referred to as mixed hearing loss.

Individuals cannot self-diagnose the cause or the magnitude of their hearing loss nor can they self-treat the hearing disability that results from hearing loss. Access to devices used to treat moderate to profound hearing loss should remain under FDA regulation, and access to necessary professional services should not be eliminated for these individuals through a “do-it-yourself” OTC option. Individualized treatment and counseling are necessary to most effectively address the multi-faceted and disabling effects of this chronic health condition. Given that hearing loss is a medical condition with the potential for other health implications, it stands to reason that medical devices that are intended to treat moderate to profound hearing loss should be made available only after an evaluation and consultation with an audiologist.

Hearing aids are not analogous to OTC reading glasses. They are more analogous to contact lenses. Much like an individual would not place contacts in their eyes without the appropriate prescription, one should not use hearing aids without first understanding the magnitude of their hearing loss and, particularly, the difficulties related to understanding speech in background noise, which can only be addressed through a professional audiologic evaluation. Those in favor of OTC hearing aids believe that a device alone can ameliorate hearing loss. This is far from the truth. A device alone cannot and does not address the hearing health care needs of a consumer. Without professional involvement, consumers run the risk of either exacerbating their condition with over-amplification or becoming frustrated with the device due to under-amplification, which may result in a decision to not seek further professional care for their hearing loss. Both pose serious health and safety risks to the consumer.

While the legislation being considered is intended for adults, there are no safeguards in the legislation to ensure that children do not have access to OTC hearing aids. **It is imperative that OTC hearing aids should not be permitted for children.** Children treated with these devices are at risk for severe complications due to untreated ear disease; inadequate amplification **leading to severe, permanent, and disabling language impairment**; as well as additional hearing loss due to inappropriate levels of amplification. The effects of hearing loss on children are far greater than those of adults.

The American Speech-Language-Hearing Association (ASHA) is the national professional, scientific, and credentialing association for 191,500 members and affiliates who are audiologists; speech-language pathologists; speech, language, and hearing scientists; audiology and speech-language pathology support personnel; and students. For more information, contact Ingrida Lusic, ASHA's director of federal and political advocacy, at ilusic@asha.org.



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Statement of the Academy of Doctors of Audiology Supporting the Over-the-Counter Hearing Aid Act of 2017

Introduction

The Academy of Doctors of Audiology (ADA) supports [H.R. 1652/S.670](#), the Over-the-Counter Hearing Aid Act of 2017, and commends Representatives Blackburn and Kennedy, and Senators Grassley and Warren for their foresight in introducing this legislation, which if enacted, will remove unnecessary and burdensome barriers to hearing care for millions of Americans.

Congress should enact this legislation to allow adult consumers with mild-to-moderate hearing loss to purchase some types of hearing aids over the counter (OTC), and eliminate the requirement that adult consumers obtain a medical evaluation or sign a waiver in order to acquire these hearing aids. This landmark legislation will also direct the U.S. Food and Drug Administration (FDA) to issue regulations containing safety and labeling requirements for this new category of OTC hearing aids, and to update FDA draft guidance on Personal Sound Amplification Products (PSAPs).

The Over-the-Counter Hearing Aid Act is consistent with [ADA's longstanding position](#) that the FDA should implement recommendations from the President's Council of Advisors on Science and Technology (PCAST) and the National Academies of Sciences, Engineering, and Medicine (NASEM), which have both independently suggested establishing a regulatory framework that permits OTC hearing aid sales and abolishes medical clearance requirements for adults, in order to improve access to life-changing hearing technologies for consumers nationwide.

Hearing Health Care Challenges in the United States

According to a recent report from the Centers for Disease Control (CDC), hearing loss is the third-most common chronic physical condition among adults in the United States after hypertension and arthritis, and is twice as likely as diabetes or cancer.¹ Hearing loss is associated with low employment rates, lower worker productivity, and high health care costs. In addition, adults with hearing loss are more likely to have low income and be unemployed or underemployed than adults with normal hearing.

¹ <https://www.cdc.gov/mmwr/yy/mmwr/volumes/66/wr/mm6604a3.htm>

Unclear pathways to care, inconsistent and incongruent state and federal laws and regulations, and ambiguous classifications regarding emerging amplification and assistive technologies, create confusion and impede access to care for many Americans. Therefore, Congress' commitment to work with the FDA to streamline and modernize hearing aid regulations is both warranted and welcomed.

Hearing technology has advanced significantly over the past several years, and today's hearing aids are more sophisticated, user-friendly, and powerful than ever before. Unfortunately, hearing aid usage rates have not improved over the same time period; far too many Americans live with hearing loss and treatment is too expensive. Only about 14 percent of the 37 million Americans with hearing loss actually use a hearing aid – and one major reason for this treatment gap is cost. Prices for different types and models of hearing aids can vary, but the average cost of a device, with services, is about \$2,400. Most people need two hearing aids, one for each ear, and devices typically need to be replaced every five years. Several prominent national organizations and federal governmental bodies, including Congress,² have sought to address the high cost of hearing care over the past few years through administrative and legislative efforts, designed to make hearing aids and/or associated hearing health care services more affordable and accessible.³

According to the Better Hearing Institute, the consumer-facing arm of the Hearing Industries Association, 33% of individuals with hearing loss have incomes of less than \$30,000 per year and 68% of those with hearing loss cite financial constraints as a core reason they do not use hearing aids.⁴

Access to care is another key barrier to treatment for hard of hearing adults. The 10.8 million U.S. adults who currently use hearing aids only account for 26% of those who could benefit from hearing amplification.⁵ There are fewer than 25,000 providers who dispense hearing aids (including audiologists, physicians and hearing aid specialists). Practically speaking, there are an average of 1,700 hearing impaired consumers for every single licensed dispenser today—and there will be 10,000 consumers turning 65 years old each and every day from now until 2030⁶. The number of providers is not growing—but the number of consumers who will need hearing aids is growing dramatically. The current provider-driven model will not be able to keep up with the demand for hearing healthcare services in the years to come. Introducing OTC hearing aid options for consumers with mild-to-moderate hearing loss will ease pressure on provider-reliant networks, allowing audiologists to focus on providing specialized treatment for complex cases.

In ADA's estimation, the single greatest barrier to hearing aid adoption is awareness. Hearing health is not prioritized to the same degree as vision and dental health are, even among other health care providers, despite the high risks associated with untreated hearing loss. Most physicians do not include hearing screening or hearing testing in their annual, preventive care visits.

What's more, Medicare, the largest payer of health care in the elderly, does not include a hearing screening or evaluation in the "Welcome to Medicare" evaluation that every new Medicare beneficiary has available to

² <https://www.healthypeople.gov/2020/topics-objectives/topic/hearing-and-other-sensory-or-communication-disorders>, <https://www.nidcd.nih.gov/workshops/accessible-and-affordable-hearing-health-care/2009>, https://www.whitehouse.gov/sites/default/files/microsites/ostp/PCAST/pcast_hearing_tech_letterreport_final.pdf, <http://www.nap.edu/catalog/23446/hearing-health-care-for-adults-priorities-for-improving-access-and>, <https://www.consumer.ftc.gov/articles/0168-buying-hearing-aid>

³ 114th Congress: Hearing Aid Assistance Tax Credit Act (H.R. 1882/S. 315), Medicare Hearing Coverage Act (H.R. 1653), Help Extend Auditory Relief Act (H.R. 2748), Audiology Patient Choice Act (H.R. 2519), Medicare Audiology Services Enhancement Act (H.R. 1116) <http://www.nap.edu/catalog/23446/hearing-health-care-for-adults-priorities-for-improving-access-and>, <https://www.consumer.ftc.gov/articles/0168-buying-hearing-aid> 114th Congress: Hearing Aid Assistance Tax Credit Act (H.R. 1882/S. 315), Medicare Hearing Coverage Act (H.R. 1653), Help Extend Auditory Relief Act (H.R. 2748), Audiology Patient Choice Act (H.R. 2519), Medicare Audiology Services Enhancement Act (H.R. 1116)

⁴ <http://www.hearingaidtaxcredit.org/faqs.cfm>

⁵ <http://hearinghealthmatters.org/hearingeconomics/2015/assessing-the-validity-of-market-rx-adoption-rates/>

⁶ <http://www.pewresearch.org/fact-tank/2010/12/29/baby-boomers-retire/>

them when they enter the payment system.⁷ This lack of attention to prevention and early detection of hearing loss, by the broader health care community is a major barrier to the ultimate adoption of amplification and other treatments.

The OTC Hearing Aid Act Offers a Responsible Solution for Millions of Americans

The ADA believes that a widespread commitment to prevention and early diagnosis could have a significant impact on the social stigma associated with hearing loss. Enactment of the Over the Counter Hearing Aid Act, and the widespread availability of OTC hearing aids for use by those with mild-to-moderate hearing loss will help integrate the importance of evaluation and treatment into the health care landscape, and individuals will begin to see hearing health as a greater health care concern.

Safety and Efficacy

The ADA is pleased that the Over the Counter Hearing Aid Act mandates the Health and Human Services Secretary, in conjunction with the FDA to complete the following:

- (A) include requirements that provide reasonable assurances of the safety and efficacy of over-the-counter hearing aids;
- (B) include requirements that establish or adopt output limits appropriate for over-the-counter hearing aids;
- (C) include requirements for appropriate labeling of the over-the-counter hearing aids, including how consumers may report adverse events, any conditions or contraindications, and any advisements to consult promptly with a licensed physician; and
- (D) describe the requirements under which the sale of over-the-counter hearing aids is permitted, without the supervision, prescription, or other order, involvement, or intervention of a licensed person, to consumers through in-person transactions, by mail, or online.

The OTC Hearing Aid Act will not de-regulate hearing aids. Rather, it will re-regulate them in a way that standardizes safety, efficacy, consumer protection and access for all Americans. The availability of FDA-registered OTC hearing devices will allow consumers to make better informed decisions about their treatment options, and will also facilitate increased competition, enhance quality and improve transparency in the purchase of direct-to-consumer hearing amplification products. Opening the market to FDA-regulated OTC hearing aids is a responsible means of providing consumers, with mild-to-moderate hearing loss, with more affordable, more efficient access to care than exists now.

The ADA recommends that over-the-counter (OTC) hearing aids be very specifically labeled and include a strong recommendation that a patient seek a comprehensive audiologic evaluation from an audiologist or physician prior to purchasing any device for the treatment of hearing loss, especially if the patient exhibits any of the warning signs of ear disease (tinnitus, dizziness, drainage from the ear, sudden hearing loss, asymmetric hearing, foreign body in the ear, cerumen impaction, pain, congenital or traumatic deformity of the ear).

⁷ 1 Chapter 16, (2008). In Medicare Benefit Policy Manual (pp. 1-28). Marblehead, MA. Retrieved October 29, 2015 from <http://www.cms.gov/>. 2 Chapter 15, (2008). In Medicare Benefit Policy Manual. Retrieved October 29, 2015, from www.cms.gov. 3 Your Medicare Coverage. (n.d.). Retrieved October 29, 2015, from <https://www.medicare.gov/coverage/preventive-visit-and-yearly-wellness-exams.html>

With regard to amplification gain and output, appropriate safety measures should be undertaken for all amplification devices including hearing aids, smart phones, headphones, hearables, assistive listening devices (ALDs), and PSAPs. The ADA is pleased that the legislation includes requirements that establish or adopt appropriate output limits for OTC hearing aids.

ADA suggests that one potential mechanism for ensuring that OTC hearing aid products are confined to use by the intended consumers (those with mild-to-moderate hearing loss), is to implement amplification gain and output threshold specifications that stay within the ranges that will only provide a meaningful benefit to those with mild-to-moderate hearing loss.

While a comprehensive evaluation and treatment by an audiologist remains the recommended standard of care, it is not the chosen pathway to care for every consumer. There is a preponderance of data available today that demonstrates that, when it comes to hearing loss, the risk of non-treatment may be greater than the risk of self-treatment.⁸ Untreated hearing loss is associated with serious health risks, such as depression, dementia, and social isolation. Seniors with untreated hearing loss are also at a higher risk of falls – the leading cause of fatal injury among older adults. The tremendous co-morbidities and maladies associated with hearing loss are well documented,⁹ as are the benefits of amplification in improving quality of life and mitigating serious health conditions.¹⁰ Therefore, the public will be best served if the FDA allows hearing devices to be available to consumers over the counter, just as they are already available over the Internet.

There are promising new tools being developed that offer promise for consumers self-identify “red flag” and other serious medical conditions of the ear. For example, the Consumer Ear Disease Risk Assessment (CEDRA), developed by Dr. David Zapala, is designed to effectively assist consumers in making informed decisions about the need for further medical evaluation.¹¹ Additionally, home hearing tests such as the FDA-approved iHEAR, as well as screening tools such as Jacoti Hearing Suite and the National Hearing Test, can be used by consumers to help determine if an OTC product may be suitable for their type and degree of hearing loss.

State consumer protection laws offer specific recourse and information to consumers regarding the requirements for the sale and return of hearing aids. Existing product liability laws and regulations for the manufacture of hearing aids offer sufficient protections for consumers, in terms of product safety.

Exclusion of Children

The Over the Counter Hearing Aid Act specifically and appropriately excludes children. OTC hearing aids are not designed for or indicated for use in children. Children inappropriately treated with these devices are at risk for severe complications due to untreated ear disease. In addition, children inappropriately treated may be at risk for speech or language delays, poor school performance and/or cognitive delay.

Regulatory precautions should be taken to ensure that OTC hearing aids do not fall into the hands of children; however, there is no evidence that indicates any demand for adult hearing aids for use in children, and there is no reason to believe that adult hearing aids would be purchased OTC by or for children.

Low income families have far more options available to address hearing loss in children than adults. The Early and Periodic Screening, Diagnosis and Treatment (EPSDT) Program provides a national mandate for hearing

⁸ <http://www.ncbi.nlm.nih.gov/books/NBK233884/>, http://ncasmfoundation.org/Portals/0/hearing_loss.pdf

⁹ <http://www.ncbi.nlm.nih.gov/pubmed/24598528>

¹⁰ http://www.hearthehearing.org/sites/default/files/quality_of_life.pdf, <http://www.ncbi.nlm.nih.gov/pubmed/26480922>

¹¹ <https://php.sibs.sites.medinfo.ufl.edu/files/2012/11/UF-IDM-DISEASE-RISK-PRESENTATION-.pdf>

aid coverage for children under 21¹². EPSDT is the child health component under Medicaid (42 U.S.C. 1396a(a)(10)(A); 1396d(a)(4)(B); 1396d(r)). EPSDT services are mandated for children from birth through age 21. A state must provide to Medicaid beneficiaries under age 21 hearing services, including appropriate screening, diagnostic, and treatment, including hearing aids. Specifically, EPSDT covers the following medically necessary audiological services for children who are at risk for hearing impairment: Audiological assessments; Hearing aid evaluation; and Medically necessary hearing aid services, including hearing aids and hearing aid accessories and services. These hearing services must be provided periodically at intervals that meet reasonable standards of medical practice. Medicaid coverage requirements will go a long way to ensure that families would not seek OTC hearing aid options to try to treat children.

Just as with OTC medications and other FDA-regulated OTC products, OTC hearing device warning labels should include information detailing contra-indications for use in children. FDA warning labels are shown to be largely effective in deterring the use of OTC products in children when they pose dangers. The ADA acknowledges that there have been instances where OTC products were used by, and caused harm to, children. For example, Reye's Syndrome, a rare but serious condition in children, has been linked to aspirin use. Even so, the benefits of selling aspirin over the counter far outweigh the potential risks to children. Similarly, the low potential for contra-indicated OTC hearing aid use by children presents a low risk, which does not outweigh the potential benefits of OTC hearing aids for the millions of American adults with hearing loss who would achieve clinical and functional benefits from their use.

Consistency, Clarity and Continuity in Rulemaking

The ADA stipulates that there are risks with self-treatment by adults who suspect that they have hearing loss, including overlooking conditions that warrant medical intervention. However, the ADA contends that in the current regulatory environment, those risks are already being taken by consumers with either limited information--or worse yet, misinformation. The Over the Counter Hearing Aid Act will bring about much needed consistency, clarity and continuity for the sale of hearing aids to adults across the United States.

Hearing aids have been widely purchased over the internet and through the mail for decades without government interference. The courts upheld online hearing aid sales without professional intervention, in 2006, with the case: *Missouri Board of Examiners for Hearing Instrument Specialists v. Hearing Help Express, Inc.* The 8th District Court of Appeals overturned the Missouri (state) ban on online hearing aid sales without prior fitting or testing, noting that the existing FDA regulations (allowing for widespread use of the waiver for the required medical evaluation) preempted the state ban. The Court's opinion was as follows:

*"We conclude that the requirements of Mo. Stat. § 346.110(1) are in addition to the federal requirements applicable to the sale of hearing aids and that they directly relate to the safety of consumers and the effectiveness of the devices. The Missouri statute therefore "interfere[s] with the execution and accomplishment of the objectives of the FDA's hearing aid regulation," 45 Fed.Reg. at 67327, and must be deemed preempted by the MDA (Medical Devices Amendment)."*¹³

As consumers already have direct-to-consumer Internet access to hearing aids and similar unregulated technologies, the creation of a regulated OTC class will not increase existing risks to the public. Audiologists will continue to play a critical role in a system that includes OTC hearing aids.

¹² <http://www.hearingloss.org/content/medicaid-regulations>
¹³ <http://case9aw.fed0aw.com/us-8th-circuit/1432490.html>

Many audiologists will elect to offer these products through their practices, just as they currently offer traditional hearing aids. Many consumers will seek audiology services after purchasing OTC devices, regardless of whether they purchase them online, over-the-counter, or at the audiologist's office.

In addition to creating a consistent regulatory framework for the direct-to-consumer purchase of hearing aids, the Over the Counter Hearing Aid Act will also permanently remove archaic medical evaluation requirements, which channel consumers towards a narrow set of providers, and pose undue interference in clinical practice. Existing FDA regulations for the requirement for a medical evaluation prior to the purchase of a hearing aid, or the use of a waiver for adults to opt-out of the evaluation¹⁴, was first promulgated in 1977 and can be found in Section 21 CFR 801.421.

The regulations state:

*(1) Except as provided in paragraph (a) (2) of this section, a hearing aid dispenser shall not sell a hearing aid unless the prospective user has presented to the hearing aid dispenser a written statement signed by a licensed physician that states that the patient's hearing loss has been medically evaluated and the patient may be considered a candidate for a hearing aid. The medical evaluation must have taken place within the preceding 6 months.*¹⁵

*(2) Waiver to the medical evaluation requirements. If the prospective hearing aid user is 18 years of age or older, the hearing aid dispenser may afford the prospective user an opportunity to waive the medical evaluation requirement.*¹⁶

As early as 1993, it became clear that the medical clearance requirement was simply not functioning as the FDA intended. In his 1993 testimony to the U.S. Senate, Dr. David Kessler, then Director of the FDA, reported that the medical waiver provision was used far more extensively than expected and did not fulfill its original mission. He further noted that an audiological evaluation would suffice and testified that state licensure ensures competency and that consistent training should replace medical clearance.¹⁷

Anecdotal evidence also indicates that use of the waiver is widely utilized. The ADA is unaware of any credible research demonstrating that the medical evaluation requirement actually leads to the identification and treatment of medical conditions that would not otherwise be identified appropriately by the consumer.

On June 2, 2016, the NASEM released a landmark report, *Hearing Health Care for Adults: Priorities for Improving Access and Affordability*, which affirms this recommendation. The NASEM Committee stated, *"In examining the Food and Drug Administration's (FDA's) requirements for physician evaluation prior to obtaining hearing aids, the committee finds no evidence that the required medical evaluation or waiver of that evaluation provides any clinically meaningful benefit. In weighing the rareness of the medical conditions, the incidence of hearing loss in adults, the widespread need for hearing health care, and the wide use of the medical waiver, the committee recommends removing this regulation to serve consumers' best interests."*¹⁸

Evidence suggests that more than 90 percent of adults with hearing loss have sensorineural hearing loss that is not due to a medically and surgically treatable condition.¹⁹ It should also be noted that hearing loss is

¹⁴ Code of Federal Regulations Title 21: Chapter 1, Subchapter H, Section 501 <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cdfr/cfsearch.cfm?cfrpart=801&showfr=1&subpartnode=21.8.0.1.1.2.7>

¹⁵ <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cdfr/CFRSearch.cfm?fr=801.421>

¹⁶ <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cdfr/CFRSearch.cfm?fr=801.421>

¹⁷ https://archive.org/stream/hearingaidmarket00units/hearingaidmarket00unit_djvu.txt

¹⁸ <http://www.nasem.edu/read/23446/chapter/285>

¹⁹ http://audiology-web.s3.amazonaws.com/migrated/SafetyofAudiologyDIaAcc.pdf_6386c8bf06e0b4_53934137.pdf

identified through diagnostic audiologic testing, not through a medical evaluation.

The FDA agrees that the medical evaluation requirement should be removed. As of December 7, 2016, the FDA has voluntarily ceased enforcement of the medical evaluation requirement, for adults over 18 years of age, because “it offers little or no meaningful clinical benefit.”²⁰ Unfortunately there are still many state laws that contain medical clearance requirements, which mirror the FDA regulation. Congress should, therefore, take immediate action to eliminate the medical evaluation requirements (including the use of a waiver) for adults pursuing amplification devices across the 50 states and U.S. territories by enacting the Over the Counter Hearing Aid Act.

PSAP Guidance

The Over the Counter Hearing Aid Act will direct the Secretary to update and finalize the draft guidance of the Department of Health and Human Services entitled, “Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products (PSAPs).” This is important since it is no longer possible to distinguish unregulated and regulated hearing devices by intended use. Nor is it always possible to use technological features or performance to differentiate hearing aids from non-regulated products such as PSAPs.

The FDA states, “A hearing aid is a wearable sound-amplifying device that is intended to compensate for impaired hearing. Hearing aids are usually programmed to address an individual’s degree of hearing loss across sound frequencies to improve speech intelligibility. Additionally, hearing aids may be coupled acoustically or wirelessly to external electronic products such as televisions, MP3 players, and telephones. A hearing health professional (such as an audiologist or a hearing aid dispenser) is usually required to program and optimize the performance of hearing aids with these more complex features.

In contrast, a Personal Sound Amplification Product or PSAP is a wearable electronic product that is not intended to compensate for impaired hearing, but rather is intended for non-hearing impaired consumers to amplify sounds in certain environments, such as for hunting or other recreational activities. PSAPs typically are simpler sound amplification devices with fewer features and less functionality than hearing aids, although some of the technology and functionality of hearing aids and PSAPs may be similar.”²¹

Contrary to the FDA’s statement, many of today’s PSAPs are technologically equivalent to hearing aids.²² Further, technologies will undoubtedly continue to emerge and advance for both classifications of devices. Attempts to categorize or differentiate these products merely by technological features are counterproductive.

The purposeful allowance of an OTC category of hearing devices, for adults, will streamline regulations in a manner that encourages all hearing device manufacturers to register and market their products transparently and responsibly, therefore increasing consumer choice and aligning the products’ intended and actual uses. The availability of OTC hearing devices will allow the public to make better informed decisions about their treatment options, and will also likely lower the cost of hearing aids for the hearing impaired.

²⁰ <https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm532005.htm>

²¹ <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm373461.htm>

²² <http://hearinghealthmatters.org/hearinginprivatepractice/2015/boundary-areas-between-psaps-and-hearing-aids-part-1/>

Additional Considerations for Congress to Ensure Access to Audiology Services Under Medicare

Treatment for hearing loss can be complex and include anatomical, physiological, emotional, psychological, social, and vocational issues that need to be addressed for any given patient. Moreover, clinical treatment for hearing loss is most often focused on improving patients' communicative ability. That "treatment" goes well beyond the utilization of any device, be it a hearing aid, an assistive listening device (ALD), a PSAP, or a smart phone application. Functional improvement in communication is the primary goal for patients with hearing loss.

Providing consumers with mild-to-moderate hearing loss with streamlined access to OTC hearing aids is a step forward, but it alone does not complete the journey to better outcomes for patients. Efforts in Congress to improve access to audiology services for Medicare patients are underway — and will be integral to widespread patient success with OTC hearing aids. Many older adults, in particular, will require audiology care for successful treatment. We are pleased to report that the Audiology Patient Choice Act will be reintroduced in the 115th Congress by Representative Tom Rice (R-5C).

The Audiology Patient Choice Act will modernize existing Medicare regulations that undermine access and affordability for many older Americans. For example, Medicare Part B patients are currently required to obtain a medical order before Medicare will cover an audiologic evaluation from a licensed audiologist. There is absolutely no sound rationale for this approach now that the medical evaluation requirement has been voluntarily removed by the FDA, because it offers no benefit to the patient.

Medicare Part B patients are also shuffled back and forth between providers in an inefficient process, because audiologists are only recognized under Medicare Part B as diagnosticians, despite the fact that they are licensed to provide Medicare-covered rehabilitative services. The Audiology Patient Choice Act, if enacted, will alleviate many of these barriers within the Medicare system, and allow Medicare Part B beneficiaries to have the same access to audiology care as Medicare Advantage beneficiaries and most Americans do.

Technological advances have made it possible for audiologists to utilize telehealth for hearing screening, hearing aid counseling and aural rehabilitation and some hearing aid fitting, orientation and follow-up services. Unfortunately, licensure and reimbursement models have not kept pace with this technology. The success of the Over the Counter Hearing Aid Act will be greatly fortified if Congress also takes action to enact the Audiology Patient Choice Act to ensure that consumers have access to comprehensive diagnostic and rehabilitative audiology services.

Conclusion

According to statistics compiled by the National Institute on Deafness and Other Communication Disorders (NIDCD), 37.5 million American adults, aged 18 and older, report some form of hearing loss. However, only 30% of adults aged 70 and older and 16% of adults aged 20 to 69 who could benefit from wearing hearing aids have ever used them.²³

Lack of awareness, among consumers and the medical community, regarding the importance of protecting and optimizing hearing over a lifetime, is well documented, as are associated co-morbidities and the substantial risks of non-treatment of hearing disorders.

²³ <https://www.nidcd.nih.gov/health/statistics/quick-statistics-hearing>

Most consumers wait 7-10 years to seek treatment after they discover that they have a hearing loss. For many it is cost, for others access—and still more don't recognize the importance of optimizing their hearing over their lifetimes.

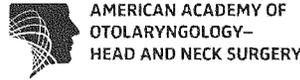
The regulatory environment has struggled to keep pace with rapid advances in hearing amplification technology. Creating an OTC hearing device market will foster competition, broaden consumer choice, improve affordability, and accelerate future innovation. OTC products will also provide an additional entry point that may guide consumers into the hearing healthcare system sooner, so that they can get the help that they need.

The ADA and its members seek expanded access for consumers to audiology services. We strive to accomplish this goal through the advancement of practitioner excellence and high ethical standards in the provision of quality audiologic care. The Over-the Counter Hearing Aid Act will help to facilitate these objectives and is consistent with the ADA's mission and philosophy. ADA further encourages Congress to consider a holistic approach to hearing healthcare that will also ensure streamlined access to audiology services.

In summary, the removal of the medical clearance requirement and the availability of a regulated OTC hearing devices, which include appropriate labeling and safety measures, will expand access to quality hearing health products and services, reduce duplicative costs, and remove unnecessary, non-beneficial barriers to care. For this reason, the ADA is pleased to support the Over the Counter Hearing Aid Act.

Contact:

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AMERICAN ACADEMY OF
OTOLARYNGOLOGY—
HEAD AND NECK SURGERY

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**Statement for the Record re: H.R. 1652
To the U.S. House of Representatives Committee on Energy and Commerce
Health Subcommittee Hearing Regarding
“Examining Improvements to the Regulation of Medical Technologies”
Tuesday, May 2, 2017**

The American Academy of Otolaryngology—Head and Neck Surgery (AAO-HNS) thanks the Subcommittee on Health for the opportunity to submit a statement for the record regarding H.R. 1652, the “Over-the-Counter Hearing Aid Act of 2017.”

Hearing loss is one of the most common issues faced by individuals as they age, and unfortunately, many adults fail to seek appropriate intervention when symptoms of hearing loss first appear. If enacted, H.R. 1652 would help provide a new pathway for consumers to access assistive hearing devices by establishing a new category of “basic” or “over-the-counter” (OTC) hearing aids for adults with mild-to-moderate hearing loss. **The AAO-HNS supports the concept of OTC hearing aids for adults with mild-to-moderate hearing loss, but respectively urges members of the Committee to consider the following comments/recommendations prior to advancing H.R. 1652 as a standalone bill and/or including it in any comprehensive piece of legislation.**

As background, the AAO-HNS is the world’s largest medical organization representing specialists who treat the ear, nose, and throat, and related structures of the head and neck. The Academy represents approximately 11,000 otolaryngologist—head and neck surgeons in the United States who diagnose and treat disorders of those areas. The medical disorders treated by our physicians are among the most common that afflict all Americans, young and old. They include chronic ear infection, sinusitis, snoring and sleep apnea, hearing loss, allergies and hay fever, swallowing disorders, nosebleeds, hoarseness, dizziness, and head and neck cancer. And, in the context of the hearing healthcare “debate,” otolaryngologist—head and neck surgeons are the only healthcare providers with the breadth of training and medical expertise to treat *all aspects* of hearing loss.

The AAO-HNS recognizes the continued momentum in the United States and worldwide to increase the utilization of hearing healthcare services, particularly the adoption of technology designed to improve the hearing of those with mild-to-moderate hearing loss. We also acknowledge that to achieve this goal, structural changes regarding access to, and the delivery of, hearing healthcare services will be necessary.

There are many reasons why those with hearing loss are not participants in the current system, including, but not limited to: failure to realize the problem, denial of the problem, perceptions regarding a potentially complex system, and cost. **The AAO-HNS supports continued efforts to mitigate these barriers. However, a preoccupation with increased utilization and broader access (by easing entry and reducing costs) must not overshadow the equally important need to ensure the quality and safety of hearing healthcare services and/or devices.**

As such, the AAO-HNS continues to support the concept of denoting a “basic” category of hearing aids, which would be more easily available for purchase OTC by adults/seniors.

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Empowering otolaryngologist—head and neck surgeons to deliver the best patient care

1650 Diagonal Road, Alexandria, Virginia 22314-2857 U.S.A. 1-703-836-4444 1-703-683-5100 fax www.entnet.org

Although the AAO-HNS believes providing access to a lower-cost or “basic” hearing aid could/would likely benefit a large portion of the adult (especially senior) population, **we caution that specific action should first be taken to ensure a particular individual/patient’s condition actually falls into the category where non-surgical, air-conduction hearing aids intended to address bilateral, gradual onset, mild-to-moderate age-related hearing loss would be of value.** Although we find ourselves in a period of disruptive technology that has made it possible for many patients to participate in self-screening, early detection, and monitoring of many diseases, **we assert it is an overstatement to conclude that all patients/consumers could or would be able to self-diagnose, self-treat, and self-monitor their hearing loss.**

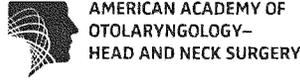
Although the Food and Drug Administration (FDA) announced in December 2016 that it would no longer enforce the requirement for a medical evaluation/waiver prior to purchasing a hearing aid (for adults), **the AAO-HNS stands by its recommendation regarding the benefits of a medical evaluation by a physician, followed by a standardized hearing test (via a hearing health professional or appropriate online/technological source), BEFORE an individual purchases any type of basic hearing aid or other FDA-regulated assistive hearing device.** Even if the resulting end-product is purchased OTC, a patient will still benefit, and will certainly not be harmed, by receiving an appropriate evaluation of their actual hearing loss.

Therefore, the AAO-HNS urges lawmakers to consider amending H.R. 1652 to include the following provisions, before it is advanced on its own, or via a broader legislative package:

- i. **Requirement for medical evaluation/hearing screening.** This initial step will ensure an individual’s hearing loss falls into the category where non-surgical, air-conduction hearing aids intended to address bilateral, gradual onset, mild-to-moderate age-related hearing loss would be of value.
- ii. **Requirements relating to the standardization of OTC hearing aid packaging and inserts.** Ensuring consumers receive consistent information and adequate protections regarding any OTC hearing device is critical. Per its December 2016 guidance, the FDA agrees that the inclusion of the following notice should remain a requirement for all prospective hearing aid device packaging:

“Good health practice requires that a person with a hearing loss have a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before purchasing a hearing aid. Licensed physicians who specialize in diseases of the ear are often referred to as otolaryngologists, otologists, or otorhinolaryngologists. The purpose of the medical evaluation is to assure that all medically treatable conditions that may affect hearing are identified and treated before the hearing aid is purchased.”

The AAO-HNS also recommends that lawmakers instruct the FDA to revise the above-stated notice to also include “medically treatable conditions” associated with hearing loss. Specifically, conditions that need medical management to prevent further hearing loss and possibly eliminate the need for a hearing aid. Such conditions include: cerumen (wax) impaction; infection; perforation of the ear drum; Meniere’s disease; tumors of the ear; otosclerosis; and sudden sensorineural hearing loss.



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In addition, all package inserts should also notify consumers of the FDA “Red Flag” warnings for ear disease. These warning conditions include:

- (i) *Visible congenital or traumatic deformity of the ear;*
 - (ii) *History of active drainage from the ear within the previous 90 days;*
 - (iii) *History of sudden or rapidly progressive hearing loss within the previous 90 days;*
 - (iv) *Acute or chronic dizziness;*
 - (v) *Unilateral hearing loss of sudden or recent onset within the previous 90 days;*
 - (vi) *Audiometric air-bone gap equal to or greater than 15 decibels at 500 hertz (Hz), 1,000 Hz, and 2,000 Hz;*
 - (vii) *Visible evidence of significant cerumen accumulation or a foreign body in the ear canal; and*
 - (viii) *Pain or discomfort in the ear.*
- iii. **Structured mechanism for at least five years of data collection.** The potential availability of OTC hearing aid devices represents a substantial shift in the paradigm for hearing healthcare. As such, the AAO-HNS supports a simultaneous effort to collect data to assist in the analysis of consumer/patient and provider satisfaction and usage. Such data will help mitigate issues regarding any future or “next generation” hearing-related devices.

Finally, we emphasize that the above comments/recommendations are framed in the context of a specific type of hearing loss (bilateral, gradual onset, mild-to-moderate, age-related) and for specific patient populations (adults/seniors). **We strongly believe any/all potential OTC hearing devices are inappropriate for individuals under the age of 18.**

Again, we thank the Subcommittee for its interest in creating a new pathway for adults with mild-to-moderate hearing loss to access assistive devices, and appreciate the consideration of the above-stated recommendations. The AAO-HNS looks forward to working the Committee, the bill’s authors, as well as others in the hearing health community, to ensure safe, timely, and affordable access to hearing healthcare services. If you have any questions or would like additional information, please contact the AAO-HNS Legislative Advocacy team at legfederal@entnet.org.

Consumer
Technology
Association

1919 S. Eads St.
Arlington, VA 22202
703-907-7600
CTA.tech

May 1, 2017

The Honorable Michael C. Burgess
Chairman, Subcommittee on Health
House Energy and Commerce Committee
U.S. House of Representatives
Washington, DC 20515

The Honorable Gene Green
Ranking Member, Subcommittee on Health
House Energy and Commerce Committee
U.S. House of Representatives
Washington, DC 20515

RE: Support for the Over-the-Counter Hearing Aid Act of 2017

Dear Chairman Burgess and Ranking Member Green,

The Consumer Technology Association (CTA)[™] applauds the Subcommittee on Health for convening its May 2, 2017 hearing on "Examining Improvements to the Regulation of Medical Technologies." Specifically, CTA strongly supports the Over-the-Counter Hearing Aid Act of 2017 (H.R. 1652), as introduced by Chairman Blackburn and Representative Kennedy. As the trade association representing 2,200 world-class technology innovators, CTA has deep experience promoting technologies to change people's lives for the better. In fact, CTA's affiliated public, national CTA Foundation was launched in 2012 with the mission to link seniors and people with disabilities with technologies to enhance their lives, and providing affordable hearing solutions is an important piece of that mission.

The Over-the-Counter Hearing Aid Act of 2017 will change lives for the better by directing the Food and Drug Administration (FDA) to create a new regulatory class of hearing aids that could be sold over the counter. This new regulatory class will address the needs of adults with mild to moderate hearing loss, a population that desperately warrants attention. According to a June 2016 report published by the National Academies of Sciences, Engineering, and Medicine, age-related hearing loss is an increasing public health concern as the population of older adults grows. Indeed, the NAS report, *Health Care for Adults: Priorities for Improving Access and Affordability*, notes that,

"Hearing is a vital human sense that is important to communication and health and can affect quality of life. Yet for a variety of reasons, many people with hearing loss do not seek out or receive hearing health care. Estimates of hearing aid use are that 67 to 86 percent of people who may benefit from hearing aids do not use them, and many hearing assistive technologies as well as auditory rehabilitation services are not fully utilized."



Today, hearing aids range in price from \$1,000 to \$6,000, while devices such as a class of over-the-counter hearing devices are a fraction of that cost – \$100 to \$600. CTA's own research study, *Personal Sound Amplification Products: A Study in Consumer Attitudes and Behavior*, found that most adults with hearing problems do not get the hearing assistance they need. Key barriers to addressing hearing problems include: the high cost of hearing aids, inconvenience, and the cost of doctor appointments.

The Over-the-Counter Hearing Aid Act of 2017 would dramatically change the environment for adults suffering from mild to moderate hearing loss by allowing them easier and more affordable access to hearing assistance devices.

CTA is accredited by the American National Standards Institute (ANSI) to write standards for the consumer technology industry. Closed captioning is one well-known example of CTA's important accessibility-related standards. In January 2017, CTA released ANSI/CTA-2051, *Personal Sound Amplification Performance Criteria*, which sets out minimum performance requirements to be considered a high quality OTC hearing aid. The goal is to assure the FDA and consumers that manufacturers who build to this standard have built a quality, reliable OTC hearing aid. In short, industry-led standards can help to pre-package the set of rules that the government and consumers can rely on. CTA will work with the FDA to incorporate this standard into any FDA-promulgated regulations on over-the-counter hearing aids.

The Over-the-Counter Hearing Aid Act of 2017 will ensure that Americans with mild to moderate hearing loss get the hearing assistance they need and deserve at a reasonable and affordable price. We pledge our support and urge immediate passage.

Sincerely,

A handwritten signature in black ink, appearing to read "Greg Walden". The signature is fluid and cursive, with the first name "Greg" being more prominent than the last name "Walden".

President & CEO

CC: The Honorable Greg Walden, Chairman, House Energy and Commerce Committee
The Honorable Frank Pallone, Ranking Member, House Energy and Commerce Committee
Members, Subcommittee on Health, House Energy and Commerce Committee



Kristi McDermott
President, Aramark Healthcare Technologies

The Honorable Michael Burgess, M.D.
Chairman, Subcommittee on Health
House Energy and Commerce Committee
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Gene Green
Ranking Member, Subcommittee on Health
House Energy and Commerce Committee
U.S. House of Representatives
Washington, D.C. 20515

Re: H.R. 2118 – Medical Device Servicing Safety and Accountability Act

Dear Chairman Burgess and Ranking Member Green:

Aramark appreciates the opportunity to submit this written testimony to the House Energy and Commerce Subcommittee on Health, regarding its consideration of H.R. 2118, the Medical Device Servicing Safety and Accountability Act. As described below, as one of the largest independent providers of medical device maintenance services to hospitals and healthcare facilities across the United States, and a stakeholder in the Food and Drug Administration's ("FDA") comprehensive review of medical device servicing issues, we respectfully request that the Subcommittee defer further consideration of H.R. 2118 until the FDA completes its review of these issues.

Aramark, through its various sectors and affiliates, is a leading global provider of a broad range of services to businesses; educational, healthcare and governmental institutions; and sports, entertainment and recreational facilities. Within Aramark's Healthcare Sector, the Company's Healthcare Technologies business unit is among the largest independent providers of healthcare technology management services in the United States, and has been providing multi-vendor medical device services for more than 40 years through approximately 1,600 trained technicians, engineers, and staff. We are proud to provide high quality repair, service, and technology management for medical devices every day at over 550 healthcare facilities in 45 states across the United States. Collectively, Aramark's clients have entrusted to our care more than 1,300,000 active medical devices covering 87 classes of medical devices and more than 43,000 distinct model numbers. These devices include both biomedical devices (e.g., dialysis equipment, infusion pumps, critical care monitors, ventilators, and defibrillators), as well as high-end, diagnostic imaging devices such as CT, MRI, vascular/cardiac catheterization laboratory, ultrasound, nuclear medicine, and mammography devices.

Aramark conducts medical device repair, service, and reconditioning activities on-site at a client's facilities, including at hospitals, surgery centers, imaging centers, and physicians'

offices. Aramark provides these services either by comprehensive, on-site management of the operation of the facility's clinical engineering department or through field-based support for a facility's medical devices. Clients look to Aramark because our deep technical expertise and scale allow us to tailor customized service solutions to their needs. When providing comprehensive management services, Aramark brings expertise to our clients throughout all phases of the lifecycle of medical devices, including: planning capital spending, assisting with a healthcare facility's evaluation of medical device acquisition options, project management around the installation of medical devices, everyday maintenance and support for medical devices, and consulting regarding medical device disposition and replacement.

Aramark also provides aftermarket part repair, sales, and equipment refurbishment activities. Through ReMedPar, Aramark's wholly-owned aftermarket parts and equipment refurbishing organization, Aramark sources, repairs, and distributes medical device parts and components and reconditions and refurbishes diagnostic imaging devices for its field personnel, hospital and other healthcare clients, and other customers. ReMedPar's quality system and processes are compliant with international industry standards (ISO 9001:2008).

Aramark's focus is on quality and patient safety. Through its Technology & Innovation Center, a 105,000 square foot facility located in Charlotte, North Carolina, the Company has made a significant investment in enhancing the technical capabilities and training of our personnel as well as expanding the services we provide to our healthcare clients. In the field, the Company's personnel utilize their expertise and resources to help their healthcare partner facilities meet existing federal and state regulatory and accreditation requirements. Aided by resources and scale, Aramark meets our commitment to quality and patient safety while also achieving savings for our clients in today's challenging, cost-sensitive healthcare environment.

As the Subcommittee is aware, the FDA is currently reviewing many of the issues addressed by H.R. 2118. The Agency requested comments in March 2016 on medical device servicing and maintenance activities and held a public workshop on these matters on October 27-28, 2016. Over 170 comments were submitted to the docket, representing a wide range of views from various sectors. The comments reveal that the issues are complex, and affect multiple aspects of delivery of health care, including efforts to reduce hospital and other facility costs without sacrificing patient health and safety.

Aramark supports and appreciates FDA's efforts to gather information and to study the stakeholders and maintenance activities for medical devices, and we believe that all stakeholders and the healthcare system deserve the benefit of the FDA's and its new Commissioner's careful, informed evaluation of these issues. We also believe that any action seeking to change the laws or regulations in this area should be thoughtfully considered and with the input of all stakeholders. Aramark believes that the existing requirements and standards of other regulatory agencies and accrediting bodies appropriately address the quality and safety of medical device maintenance activities. Additionally, Aramark ensures the quality and safety of our medical device maintenance activities by focusing on the education and training of our employees, and establishing standardized, rigorous operational practices that meet existing regulatory requirements and accreditation standards. Additional federal mandates will merely duplicate existing requirements, thus adding costs to our health care system at a time when we should be

looking for ways to reduce those costs. We, therefore, respectfully request that consideration of this legislation be deferred until the FDA completes its review.

We appreciate the opportunity to present our views and look forward to working with the Subcommittee as it considers legislation to improve the regulation of medical technologies.

Sincerely,



Kristi McDermott
President
Aramark Healthcare Technologies

ConsumersUnion®

POLICY & ACTION FROM CONSUMER REPORTS

United States House of Representatives
Washington, DC 20515

May 1, 2017

Dear Representative:

On behalf of Consumers Union, the public policy arm of nonprofit Consumer Reports, we write to express our support of H.R. 1652, the “Over-the-Counter Hearing Aid Act of 2017.” As we noted in our recent article in the March 2017 issue of Consumer Reports,¹ price considerations keep many Americans from getting hearing assistance instruments that they need. This legislation will help make hearing aids available to consumers more conveniently and affordably and help improve their quality of life.

H.R. 1652 would broaden the range of hearing aids available over the counter to adults with mild to moderate hearing loss. These devices would then be available for purchase separately from medical evaluations and services, giving consumers more options, including more affordable options. According to a 2015 survey of Consumer Reports subscribers, half of the respondents reported having trouble hearing in noisy environments, yet only 25% had their hearing checked the previous year. The Archives of Internal Medicine published research that finds that just 14% of consumers who could benefit from hearing aids actually use them.

Cost is a major concern as the price of hearing aids can range between \$3,000 and \$8,000 and is not covered by Medicare or most commercial insurance plans. Many seniors and others with hearing loss who could benefit from these devices simply cannot afford them. We believe H.R. 1652 would preserve and reinforce important consumer safety protections, including state laws holding manufacturers responsible for harm caused by unsafe and defective products, while overriding state laws designed to block or impede consumer access to over-the-counter hearing aids. The legislation requires the FDA to establish standards for these over the counter products that would address safety and efficacy and appropriate labeling.

We continue to encourage consumers to seek medical evaluation before purchasing a hearing aid, to rule out other possible medical issues, yet we think consumers can benefit from a system in which the medical evaluation is separated from the purchase of the device. This gives consumers the ability to make their own choices, to shop around for medical services and hearing aids that best suit their needs and their budget.

We look forward to working with you and your cosponsors to enact this beneficial, common sense consumer legislation into law. Thank you for your attention on this important issue.

Sincerely,

George Slover

Lisa McGiffert

Victoria Burack

Cc: House Energy and Commerce Committee

¹Insights: No More Suffering in Silence?, Consumer Reports, March 2017.



House Energy and Commerce Subcommittee on Health

2125 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Burgess and Committee Members:

Re HR 2118 Medical Device Servicing and Accountability Act

About Repair.Org

Repair.Org is a 501(c) 6 non-profit trade association representing the industry repair industry for technology-enabled assets such as computers, communications, consumer electronics, and technology enabled medical equipment. Our members include companies in the business of independent medical equipment repair, hospitals, and Biomedical Engineering Technicians (BMET).

HR 2118 will increase, rather than decrease OEM Repair Monopolies

Our primary concern with HR 2118 is the impact this bill will have on independent repair businesses and the health care facilities that hire them. Currently, competition for repair services is being destroyed for high-tech medical equipment by manufacturers that refuse to provide access to the basic information and materials necessary for repair, including directly to their customers. These are true repair monopolies and have been determined as such as recently as April 27, 2017 where GE was found in violation of anti-trust law for monopolizing repair of anesthesia equipment.¹

Repair businesses only operate under the supervision of regulated hospitals, physicians, and BMETs. These are the parties responsible for patient care, not the repair business. These users are not demanding more regulation of repair and are seeking our help driving legislation to improve competition for repair services.

It appears to us that the primary impetus behind HR 2118 is to help OEMs reduce their exposure to competition for repair as a business. We know these OEMs are in opposition to state legislative efforts to expand access to modern repair, and it does not surprise us to see attempts to use the FDA and Congress to achieve their aims.

¹ See Red Lion Medical v GE <https://www.law360.com/cases/54f64405a09caa5024000001>

Registration Requirement will Kill Jobs and Damage Patient Care

Repair businesses are nearly all small business – and the financial burdens of registration alone will cause many to go out of business. Thousands of repair technicians that support older equipment will lose their jobs, and hospitals will lose the option of keeping older equipment in use. Patients will have less access to technology enabled medical services as fewer and fewer facilities will be able to afford equipment.

Driving competition out of business is a benefit to the OEMs that can sell new equipment to replace unsupported models and command arbitrary labor rates and parts prices.

Purpose of Registration:

We have heard the theory that independent repair businesses are not subject to the same rules as OEMs. This is framed as a matter of fairness – which would be reasonable if the two businesses were the same. They are not. Repair and Manufacturing are two totally separate industries. It happens that some OEMs engage in both manufacturing and repair, but repair businesses are not manufacturers.

Independent repair providers do not, and cannot, fix problems that originate with the manufacturer – such as poor design or buggy software. The FDA requires registration from OEMs because they are responsible for oversight of patient safety and can demand corrections from OEMs. We agree that if repair providers engage in manufacturing they should be required to register – but without a manufacturing function there is nothing for the FDA gain through registration.

Reporting Requirement is Duplicative:

The requirement to require independent repair providers to report on patient outcomes will not improve information flow to the FDA. Repair technicians, both OEM and ISP, are called on to repair a specific product and following completion return the equipment to the user for return to service. Service technicians are not privy to patient records and would not have any knowledge of patient outcomes. Only the user (hospital, supervising physician, or BMET) would be able to report on patient outcomes to the FDA.

Common Misconceptions about Repair:

Repair is restoration of equipment to full function using the documentation, tools, and parts designed by the OEM for the purpose of repair. Repair is not tinkering, customization, or modification. If repair information is hidden or blocked – the business of repair is monopolized to the OEM.

OEMs write service documentation and diagnostics so that technicians can quickly identify the hardware failure, remove the failed part, insert a spare, and re-run diagnostics to confirm the repair is complete. This process is identical regardless of if the technician is employed by the OEM, ISP, or a hospital (BMETS). The only difference between OEM and ISP repair is availability of the information intended to be used for repair.

Incomplete Repair:

Technically, it is difficult to consider any device repaired if it does not "fully execute" its original diagnostics. This has been the standard for digital electronics repair for decades and eliminates any guesswork based on the relative skills of the technician. It may take a poorly trained tech longer to complete a repair, but the repair itself is just as complete once the unit successfully executes its diagnostics.

Projections of patient harm due to incomplete repair are therefore suspect.

Post-Repair Problems:

Following repair, some devices may undergo further processing, such as sterilization, before patient use. These services may be provided by independent providers, but these services are not repair. Issues of improper handling for invasive surgical procedures should not become an excuse to further monopolize repair.

We welcome the opportunity to work with all stakeholders to make sure that all care facilities have access to the highest quality repair services.

Thank you for your consideration.

Sincerely

Gay Gordon-Byrne

Executive Director, Repair.Org

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973-949-5164 (office)

201-747-4022 (cell)



May 1, 2017

Mr. John Stone
Ms. Carly McWilliams
Energy and Commerce Subcommittee on Health
Rayburn Office Building
Washington, DC

Mr. Stone and Ms. McWilliams,

I am writing to oppose H.R. 2118 and request an audience for Independent Service Organizations (ISO's) to provide perspective on the value that is delivered daily to healthcare providers.

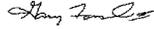
To summarize, the Association of Medical Device Service Organizations (AMDSO) believes that patient safety should be the focal point of activities from various perspectives such as diagnosis, treatment, device development, device service as well as legislation. H.R. 2118 seeks to create legislation for which there is no evidence to support there is a problem. Secondly, this legislation would require Independent Servicers to absorb unneeded costs of complying with regulations designed for manufacturers. Thirdly, this legislation will limit healthcare systems right to choose service and drive up costs.

There is no evidence supporting that a problem exists when an Independent Service Organization repairs a device. The 2016 FDA public docket, soliciting comment on regulation of servicers, ECRI Institute report submitted in March 2016 and the Joint Commission comment filed in the FDA docket, all indicate and support there is little, if any, evidence of problems. At the FDA hosted workshop on October 27-28, 2016, the American College of Clinical Engineering offered a lack of real world evidence to support additional regulations. AMDSO members participated in the workshop and continue to work with the FDA to provide insight into technician training as well as demonstrate Quality Systems they have in place.

Independent Service Organizations provide healthcare systems the right to choose service and keep costs down. As ISO's work with healthcare systems to reduce repairs through education and training, they help improve provider efficiency. Additionally, they often extend the useful life of devices, which helps avoid premature and costly replacement. There is no data identifying a difference in quality between an OEM and ISO repair. Requiring a service organization to comply with regulations written for device manufacturers will burden the ISO with unneeded costs and endanger their ability to continue to provide the financial benefit many healthcare systems desire and choose daily to receive education, training, service and repair.

AMDSO believes the evident benefits that ISO's offer healthcare systems daily, along with the lack of evidence there is a problem with quality, indicate there is no need to lose these benefits by further consideration of the "Medical Device Servicing Safety and Accountability Act". The Subcommittee on Health is urged to not support H.R. 2118.

Sincerely,



Gary Fansler II
Executive Director



May 1, 2017

Ms. Carly McWilliams
Mr. John Stone
House Subcommittee on Health
Rayburn Office Building
Washington, DC

Ms. McWilliams and Mr. Stone,

I am writing to you to express opposition to H.R. 2118, Medical Device Servicing and Accountability Act which is scheduled to be discussed on May 2, 2017 at a subcommittee hearing on various proposals to improve regulation of medical technologies.

There is no evidence to suggest that H.R. 2118 will improve public health as intended. According to the only definitive, independent analysis of the FDA's data on adverse events resulting from malfunctioning reusable medical devices, a mere 0.005% of the reportable events were related to servicing regardless of who (manufacturer or independent service organization) performed the service¹. No objective evidence that has been presented to date through the FDA's multi-year and exhaustive analysis of this subject supports the need for regulation of independent service organizations.

Provider organizations make the choice to use independent servicers every day as thousands of devices are successful and cost-effectively repaired. One reason there are few incidents and providers embrace independent service organizations is that reusable device repair and maintenance is subject to regulatory scrutiny through existing CMS rules on hospital's maintenance programs. This existing framework ensures that devices are maintained according to manufacturer recommendations and is enforced through The Joint Commission and state health departments.

The proposed legislation would do irreparable harm to the independent service industry by imposing rules that were designed for medical device design and manufacture on companies who repair existing devices to their original operating condition. The regulatory burden of the legislation will drive independent servicers from the market resulting in greater market control by manufacturers. The impact will be felt in at least three key areas.

1. Patient Safety. By making repair and maintenance services convenient and accessible, health care providers are more likely to properly maintain their equipment than if they must send it to a manufacturer for service. Independent servicers also provide vital education and advice to clinicians on caring for devices to help improve patient safety.

¹ Refer to the ECRI Institute comments submitted June 1 to FDA located at <https://www.regulations.gov/document?D=FDA-2016-N-0436-0126>

Letter to Subcommittee on Health
May 1, 2017
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2. Device Efficacy. When devices are maintained properly, the critical diagnostic and treatment functions performed with the devices are assured and outcomes for patients improve.
3. Cost Control. By providing an alternative to manufacturer service, independent service organizations eliminate the virtual service monopolies that manufacturers operate and reduce the cost of repairs by as much as 50% compared to manufacturer service. Further, when devices are maintained properly, they last longer and reduce the need to buy a replacement.

It is not coincidental that the proposed legislation has been put forward by a consortium of for-profit, medical device imaging system manufacturers. The consortium has much to gain by reducing competition for service and I believe that their motives have more to do with profits than protection of patients. Faced with increased scrutiny of new regulations from the White House, the consortium has turned to Congress to advance its agenda.

Rejecting FDA action and turning to a legislative solution is at best premature. As recently as the Subcommittee hearing on MDUFA IV in March, Dr. Shuren of the FDA stated that agency staff is still collecting information, meeting stakeholders, and analyzing options regarding oversight for independent servicers. In addition, it is not coincidental that the proposed legislation includes an "exemption" for hospital staff who perform services on millions of devices each year. These individuals repair each year would not be subject to oversight even when the work performed is the same as an independent servicer. It seems clear the "exemption" is present so manufacturers can avoid alienating the buyers of their equipment while reducing competition from independent servicers.

Lacking evidence of a problem to be solved, realizing that 0.005% of reportable events involved service activities, and the high likelihood that safety, efficacy, and costs would be adversely impacted, this legislation is neither necessary nor justified. This is an example of manufacturers turning to legislative action to enhance their commercial opportunities. The Subcommittee should reject this legislation and let the FDA perform their statutory responsibilities without external influence.

I would welcome an opportunity to meet with you or members of the Subcommittee to more fully explain our positions and ensure that you have the perspective of independent service organizations as you consider this legislation. I can be reached at 404-518-1486 or danbari@mobileinstrument-ga.com.

Sincerely,



David Anbari
Vice President and General Manager