

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.