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AdvaMed
Advanced Medical Technology Association

Testimony on S. 180
By
The Advanced Medical Technology Association, AdvaMed
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Good morning, Senator Sirotkin and committee members, my name is Tom Tremble. I am vice president of state government relations at the Advanced Medical Technology Association, or AdvaMed. AdvaMed is the primary national association of medical device manufacturers.

AdvaMed is opposed to the inclusion of medical devices in this legislation.

We are opposed to medical devices being included in S. 180 because:

1. The production, distribution, use, maintenance and even the repair of medical devices are regulated by the FDA. To be more precise, the FDA regulates the maintenance and repair of devices by the original manufacturer, but not by independent servicers;

2. Unlike other products within the legislation's scope, it can be a matter of life or death for medical devices to be repaired by inappropriately-trained individuals using unapproved replacement parts; and

3. The FDA is currently preparing a report to Congress on device repair, including repair by independent service organizations.

<u>Medical Device Background</u>
A medical device is any product, other than a drug, used to diagnose or treat a health care condition. Medical devices range from bandages and needles to artificial joints to highly sophisticated electronic equipment, such as PET and MRI machines.

This legislation would impact a wide-range of life-saving and life-enhancing medical equipment including magnetic resonance imaging, mammography, ultrasound and x-ray machines, computed tomography, robotic surgery systems, medical lasers, and even clinical laboratory diagnostic equipment.

The FDA classifies medical devices based upon the level of risk associated with the device:

- Class I devices, such as bandages, sutures, centrifuges and some lab testing equipment, generally pose little, or no, risk to patients.
- Class II devices, such as neurosurgical lasers, infusion pumps, ventilators, endoscopy systems, MRI machines, PET scanners, X-rays machines, robotic surgery systems, pose a moderate level of risk
- Class III devices, such as automated external defibrillators, implanted cardiac defibrillator, and pacemakers are generally the highest risk devices.

Most electronic medical devices are classified as Class II or III because of their potential risk to patients; though even some Class I devices would be impacted by the legislation. The higher classification a device has the more scrutiny it receives from FDA before being cleared or approved for market.

FDA Oversight

Currently, electronic medical devices should be maintained and repaired by manufacturer field representatives or independent servicers who manufacturers contract with to perform the servicing. Manufacturer employees and contractors receive training in the proper methods, equipment, and replacement parts critical to maintain and repair the device. These activities when performed by manufacturers, or their agents, must be conducted in accordance with FDA regulations and are subject to FDA inspections.

However, maintenance and repair activities of third-party servicers are not subject to those regulations.

The FDA has requirements covering the maintenance and repair of medical equipment by manufacturers, but not by third-party servicers. The FDA's Quality Systems Regulations (QSR)(CFR 21, Section 820) specifies requirements addressing the maintenance and repair of medical devices. These QSR requirements include Personnel Controls, Document Control, Calibration of Inspection and Test Equipment, Control of Non-Conforming Product, and Servicing among others. Under Subpart N of the QSR, manufacturers are required to analyze service reports and inform FDA of adverse events.

Unfortunately, there is a lack of parity, with these regulations not applicable to third-party servicers, which creates a two-tier system where patients are not guaranteed an equivalent level of quality, safety and regulatory oversight regardless of who services the medical devices.

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Identifying and Addressing Patient Risks

There is growing concern with threats to the safety of patients from repairs being done by servicers who do not have adequate training and/or are not using appropriate replacement parts. Ensuring proper servicing by third-parties needs more than the manufacturers' repair documentation and software updates. Suitable training and adherence to regulatory requirements set by the FDA is essential to appropriate servicing.

It would pose a potential safety risk to patients for device manufacturers to be required to provide repair information to untrained servicers who may use inappropriate replacement parts. There are reports of incidents where the failure to properly repair a medical device, or using unapproved replacement parts, has put patients at risk.

- In one case with an infusion pump, which delivers controlled doses of medication over a period of time to patients, a repair was performed incorrectly, resulting in an excess dosage such that an 18-hour opioid infusion was completed in less than 3 hours.

- In another instance, an infusion pump was repaired with a part not intended for that device. The faulty part caused an unregulated flow, which seriously harmed the patient.

Regulating Third-Party Servicers

AdvaMed has been working with the FDA and Congress as they consider ways to increase oversight of third-party servicing of devices and strongly believe that the FDA is the appropriate entity to be addressing the maintenance of medical devices.

The FDA is considering ways to reduce patient risks by regulating third-party servicers. In 2016, FDA solicited comments and held a public workshop on patient safety issues relating to the maintenance and repair of medical devices by third-party servicers.

Legislation passed by Congress last month included language to require the FDA to report, by Spring of 2018, on the quality, safety, and effectiveness of devices after servicing. The report is to include options for improving FDA's regulation of device servicing to ensure the safety and effectiveness of medical devices, including actions that FDA could take to track adverse events caused by servicing errors.

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Exempting Devices

We appreciate that language in Section 6104 (b) of the bill recognizes that medical devices are different from other products and should be treated differently. However, that language is confusing and not helpful.

Two other states, Washington and Minnesota, have had hearings in Right to Repair bills this year. We would urge the committee to consider the medical device exemption language (attached) that was included in the Washington bill (top of page 8) and that the sponsor of the Minnesota bill has committed to amend onto the bill in that state. I have also provided an additional document that provides questions and answers on third-party servicing of medical devices.

Conclusion

With their life-saving and life-enhancing purpose and stringent oversight by the FDA, medical devices are unlike any of the other products that would be impacted by this legislation. It is not a matter of manufacturers maintaining control-it is a matter of patient safety. It is important that FDA's role not be weakened by state laws that would interfere with its science-based oversight of medical devices, including their maintenance and repair. Therefore, for the reasons I have outlined, AdvaMed is opposed to the inclusion of medical devices in the legislation. We would welcome an opportunity to continue to work with the committee on this important issue.

Thank you. I would be glad to answer any questions.