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Advanced Medical Technology Association

Testimony of Thomas Tremble
before the Vermont House Commerce Committee
on S. 180
for
The Advanced Medical Technology Association, AdvaMed

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Good morning, Representative Botzow 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.

Thank you for the opportunity to testify today on S. 180. AdvaMed is opposed to the inclusion of medical devices in this legislation.

As introduced, S. 180 would have required manufacturers of virtually all digital electronic products to provide repair information to users and independent servicers. There was language in the bill to exclude medical devices from its provisions in certain circumstances. The language was ambiguous and we recommended the bill be amended to clearly exempt medical devices. In its current form, the bill language continues to be confusing and ambiguous.

First, before I point out some of the concerns with the current language and discuss our overall concern with including medical devices in the legislation, it might be helpful for me to take a minute to provide some information on medical devices.

Medical Device Background

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.

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.

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

- 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. However, even some Class I devices would be impacted by the legislation.

Medical devices should not be included in S. 180 because:

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

   The FDA's Quality Systems Regulations (CFR 21, Section 820) specifies requirements for the maintenance and repair of medical devices. These 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, with these regulations not applicable to third-party servicers, there is a two-tier system where patients are not assured an equivalent level of quality, safety and regulatory oversight regardless of who services the medical device.

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. Next month, the FDA is expected to issue a report to Congress on device repair, including repair by independent service organizations. The report is expected to include options for enhancing FDA's regulation of device servicing to ensure the safety and effectiveness of medical devices.

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FDA Oversight

Electronic medical devices should be maintained and repaired by manufacturer field representatives or independent servicers who manufacturers contract with to perform the servicing. Manufacturers' 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.

Identifying and Addressing Patient Risks

There is growing concern with risks to patient safety from repairs being done by servicers without 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.

Exempting Devices

Last week, similar legislation (attached) pending in California was amended to clearly exclude medical devices from its provisions. The sponsor of that bill recognized the inappropriateness of including FDA-regulated products in the bill. Whether it is a study, or other language, we urge the committee to exclude medical devise in a similar manner. I have also provided an additional document that provides questions and answers on third-party servicing of medical devices.

Study Committee

Finally, I want to briefly mention concerns with the latest bill language.

- The Powers and Duties provision specifically refers to "consumer electronic devices", but then subsequently contradicts that by providing that the task Force would consider the "scope of products to include".
- Later in number (8), the Powers and Duties section provides that it shall consider "any other issues the Task Force considers relevant…including regulation of business consumer products or other products the Task Force finds appropriate".
- Section 2(c) addresses stakeholder engagement and provides that the Task Force shall solicit input from …"medical device, and other trade groups having an interest in consumer or business electronic product repairs".

These provisions create confusion as to whether the task force would consider consumer products or "business electronic products" and what each of those terms entails. If the committee determines to support creation of a study committee, we would urge that the scope of the task force be clarified and that medical devices are clearly excluded.

Conclusion

I would conclude by reiterating our primary concerns as to why medical devices, which are unlike any of the other products that would be impacted by this bill, should not be included in state right to repair legislation, including ones setting up study committees:

- Life-saving and life-enhancing medical devices, are regulated by the FDA. Their inclusion in state right to repair legislation would create ambiguity and confusion for health care providers and manufacturers.

- In May, the FDA will be releasing a report to Congress on ways to enhance medical device servicing, including from third parties.

- This is not a matter of manufacturers maintaining control-it is a matter of patient safety.

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.