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AdvaMed
Advanced Medical Technology Association

February 2, 2018

The Honorable Michael Sirotkin
Chair, Senate Committee on Economic Development, Housing & General Affairs
Vermont Senate
Burlington, Vermont 05633

Dear Senator Sirotkin:

On behalf of the members of the Advanced Medical Technology Association, AdvaMed, I want to share our concerns with S.180, relating to a right to repair. Since the manufacture, use, maintenance and repair of medical devices is overseen by the Food and Drug Administration, and the FDA is currently preparing a report to Congress on medical device repair, medical devices should not be included in the legislation.

AdvaMed, is a trade association leading the effort to advance medical technology to achieve healthier lives and healthier economies around the world. AdvaMed represents 80 percent of medical technology firms in the United States and acts as the common voice for companies producing medical devices, diagnostic products and health information systems. Our members produce nearly 90 percent of the health care technology purchased annually in the United States and more than 40 percent purchased annually around the world. AdvaMed's member companies range from the largest to the smallest medical technology innovators and companies.

There are several unique characteristics about medical devices that set them apart from other products within the scope of S.180 and make it inappropriate for them to be included in the legislation. First, unlike most of the products targeted by your legislation, medical devices are generally not consumer products. Instead, for the most part, they are designed to be used in health care settings by medical professionals. Second, medical devices are used in the diagnosis and treatment of diseases and other health conditions. Third, due to their life-saving and life-enhancing capability, devices are strictly regulated by the FDA.

Medical devices are maintained and repaired by manufacturers, independent servicers, and hospital technicians. Attached is a document that provides background information on device servicing and oversight and on why it is critical to patient safety that medical devices be maintained and repaired by properly trained professionals with appropriate replacement parts.

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Among the concerns with the maintenance and repair of medical devices:

- There have been instances where the inappropriate repair of medical devices has caused patient harm. In one example, a serious adverse event occurred when an infusion pump, repaired with an improper replacement part, delivered a dangerously high dose of medication to the patient;
- For devices relying on computer software, cybersecurity issues could pose a threat from non-credentialed third-party service providers; and
- Improper repair of medical scopes may result in the device failing after certain sterilization procedures and may result in poor image quality;

We appreciate that the legislation recognizes in the exclusions provisions in Section 6104 (b) that medical devices are unique and should be treated differently. However, the double negative of the section makes it meaningless. Instead, we would respectfully request that the committee consider replacing it with the language below which is from pending Washington HB 2279. Similar language is also in pending Minnesota legislation.

"Nothing in this section applies to manufacturers or distributors of a medical device as defined in the federal food, drug, and cosmetic act (21 U.S.C. Sec. 301 et seq.) or a digital electronic product or embedded software manufactured for use in a medical setting including diagnostic, monitoring, or control equipment or any product or service that they offer. A digital electronic product otherwise subject to the provisions of this chapter is not considered a medical device or considered manufactured for use in a medical setting by virtue of its ability to be used in conjunction with a medical device or with a digital electronic product or software manufactured for use in a medical setting."

We appreciate your consideration of our concerns.

Sincerely,

Thomas E. Tremble
Vice President and Managing Director, State Government Relations