May 12, 2025

Representative Michael Marcotte, Chair
Commerce & Economic Development
Vermont State House
115 State Street
Montpelier, VT 05633

Representative Edye Graning, Vice-Chair
Commerce & Economic Development
Vermont State House
115 State Street
Montpelier, VT 05633

RE: H. 161 – An Act Relating to the Vermont Fair Repair Act

Chair Marcotte, Vice-Chair Graning, and Members of the Committee,

On behalf of AdvaMed, the Medical Device Manufacturers Association (MDMA), and the Consumer Health Products Association (CHPA), we write today to express our concerns with H. 161. Our membership comprises the full spectrum of health technology innovators and manufacturers, who work every day to deliver high-quality healthcare for patients worldwide. While a broad right to repair bill impacting consumer electronics is the intent, the exemption currently in the bill is not sufficient.

Patient safety is our membership's top priority, and the proposed bill will put patients at an increased risk of harm or death. Patients and consumers rely on a technology's accuracy to provide proper diagnosis and maintain safety standards. There is no credible evidence of systemic shortages or delays in medical equipment repair. Further, medical device manufacturers regularly authorize third-party servicers to repair their equipment. There are more than 21,000 companies currently servicing medical devices, according to the FDA. Often, these other repair providers lack the necessary training to repair complex medical systems.

Original Equipment Manufacturers (OEMs) are subject to strict regulations by the Food and Drug Administration (FDA) to ensure patient safety. These regulations protect the safety and efficacy of medical devices and include registration with the FDA, implementation of quality and safety controls, proper training, and qualification of replacement parts. Independent third-party service providers are not held to the same standards. A 2018 report by the FDA found more than 4,300 adverse events – including 294 serious injuries and 40 deaths – from devices repaired by unauthorized third-party providers.

These complex issues are accounted for in federal legislation known as the Fair Repair Act – a right-to-repair bill that provides a full exemption for medical device manufacturers. Similar exemptions are provided in bills in New York, Minnesota, and Oregon. California's law is scoped narrowly and does not impact medical devices.

We propose the following language to fully exempt medical devices:
Nothing in this chapter shall apply to manufacturers or distributors of a medical device as defined in the federal food, drug, and cosmetic act, Title 21 U.S.C. Sec. 301 et seq.

Safety and security are paramount to our members and the patients they serve. We appreciate your consideration of our concerns and are committed to working with you on this critical issue. Feel free to contact any of our organizations with additional questions, thank you.

Sincerely,

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