



September 12, 2023

Representative Tyrone Carter, Chair  
Committee on Regulatory Reform  
Michigan House of Representatives  
House Office Building, Room 519  
Lansing, MI  
48909

**RE: Substitute for House Bill No. 4562** – The “Digital Electronic Equipment Repair Act”

Dear Members of the Committee,

On behalf of the Advanced Medical Technology Association (AdvaMed), Medical Device Manufacturers Association (MDMA), Medical Imaging & Technology Alliance (MITA) and Michigan Biosciences Industry Association (MichBio), we write today to thank you for acknowledging our concerns with the right-to-repair legislation HB 4562. Our membership comprises the full spectrum of health technology innovators and manufacturers, who work every day to deliver high-quality healthcare for patients worldwide.

Patient safety is our membership’s top priority, and this legislation prevents putting patients in Michigan at an increased risk of harm or death.

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. We commend the sponsor for recognizing the need to hold medical

devices and medical device manufacturers harmless in HB 4562, as have the sponsors of bills introduced this past session in Washington, and recently signed legislation in New York and Minnesota.

Safety and security are paramount to our members and the patients they serve. We appreciate your consideration of our concerns with the exemption language included in this legislation. Feel free to contact any of our organizations with additional questions. Thank you again, and we look forward to working with you.

Sincerely,



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