



AdvaMed
Advanced Medical Technology Association

MDMA
The Voice for Medical Innovation



MITA[®]
MEDICAL IMAGING
& TECHNOLOGY ALLIANCE
A DIVISION OF **NEMA**

April 17, 2023

Chair Chip Curry
Innovation, Development, Economic
Advancement and Business
Committee
3 State House Station
Augusta, ME 04333-0003

Chair Tiffany Roberts
Innovation, Development, Economic
Advancement and Business
Committee
Maine State House
2 State House Station
Augusta, ME 04333

RE: LD 1487, An Act to Ensure That Residents of the State Have the Right to Repair Their Own Electronic Devices - Oppose

Dear Chair Curry, Chair Roberts, and Members of the Committee,

On behalf of the Advanced Medical Technology Association (AdvaMed), Medical Device Manufacturers Association (MDMA), and Medical Imaging & Technology Alliance (MITA), we write today to express concerns with the right-to-repair legislation LD 1487 in Maine. 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 unnecessarily exposes patients to an increased risk of harm or death. As introduced, LD 1457 requires medical technology providers to share proprietary design and repair information with third-party servicers. Often, these providers lack the necessary training to repair complex medical systems. Patients and consumers rely on a technology's accuracy to provide proper diagnosis and maintain safety standards.

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 introduced in Minnesota, Washington, and recently signed legislation in New York.

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 the legislature on this critical issue. Feel free to contact any of our organizations with additional questions. Thank you again, and we look forward to working with you.

Sincerely,



Roxy Kozycky
Director, State Government and Regional Affairs
AdvaMed



Clayton Hall
EVP, Government Affairs
MDMA



Patrick Hope
Executive Director
MITA