March 25, 2024

Representative Scott Conklin, Chair
House Commerce Committee
Room 515, Irvis Office
Harrisburg, PA
17125

Representative Joe Emrick, Chair
House Commerce Committee
Room 515, Irvis Office
Harrisburg, PA
17125

RE: Right to Repair – House Commerce Committee

Chair Conklin, Chair Emrick and Members of the Committee,

On behalf of the Advanced Medical Technology Association (AdvaMed), AdvaMed Imaging, and the Medical Device Manufacturers Association (MDMA), we write today to express comments on the right to repair and its impact on medical technology. 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 concept unnecessarily exposes patients to an increased risk of harm or death. Often, unauthorized repair 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 both New York and Minnesota's laws, the only two broad right to repair laws that have been in enacted in the U.S. In California and Oregon, right to repair was passed in a much narrower scope that held medical devices and technology harmless and kept patients safe.

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 you 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 Kozyckyj
Director, State Government and Regional Affairs
AdvaMed

Clayton Hall
EVP, Government Affairs
MDMA

Adrienne Frederick
Senior Manager, Health Policy & State Government Affairs
AdvaMed Medical Imaging Division

AdvaMed
Advanced Medical Technology Association

The Fallacy of Right to Repair for Medical Devices

Fact: The Risk to Patient Safety is Too High

Proponents of the Right to Repair movement demand that unregulated, third-party servicers be given unlimited access to service manuals and other proprietary Original Equipment Manufacturer (OEM) information, while skirting any meaningful oversight of quality and safety standards. Legislative proposals establishing Right to Repair policies for medical devices can significantly compromise patient safety and erode existing standards that protect the quality, effectiveness, and innovation patients rely on.

Common Myths on the Right to Repair Medical Devices

MYTH

OEMs Charge More to Maintain Devices

FACT

Any discounts unregulated third-party servicers may provide come from not having to comply with FDA's patient safety regulations. The cost for servicing depends on the sophistication of the device, which could range from simple blood pressure cuffs to a computerized tomography (CT) scan machine which requires longer and more complex training. Trainings that provide customer service tools for use after the training, like the manufacturer's intellectual property, are also more costly.

MYTH

Study Shows that OEM Servicing Does Not Make Devices Safer

FACT

Proper service and repair of complex medical technology is often a life-or-death matter for patients. Proponents of Right to Repair legislation often cite a flawed Emergency Care Research Institute (ECRI) study while failing to provide critical information from the FDA. The FDA's report to Congress on the Quality, Safety, and Effectiveness of Servicing of Medical Devices found 4,301 adverse events associated with inadequate third-party device repairs and replacement parts, including 40 deaths and 294 serious injuries. This evidence was gathered despite third parties not being required to report any adverse events during or resulting from their repairs.

MYTH

More Options for Repair Reduces Equipment Downtime

FACT

There is no substitution for the extensive training, knowledge, and expertise of an OEM or an authorized third-party repair. In fact, an OEM is often called in after a third party has attempted and failed to repair a machine. Many OEM replacement parts are highly specialized and precise in design and function, with some devices requiring more than 90 custom tools for servicing. Most third-party services cannot replicate the caliber or quality necessary to properly service a device, which can negatively impact the device's safety and lead to possible injury or death of the patient.

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MYTH

The FDA Does Not Want to Regulate Third Party Medical Device Service Repair

FACT

Third parties do not submit Medical Device Reports (MDR), so there is insufficient evidence for FDA to make a determination. The full quote from the 2018 FDA study actually states: "The currently available objective evidence is not sufficient to conclude whether or not there is a widespread public health concern related to servicing, including by third party servicers of medical devices that would justify imposing additional/different, burdensome regulatory requirements at this time."

MYTH

All Technical Material Must Be Available to Service Medical Devices Properly

FACT

Authorized service entities and medical technology manufacturing competitors can and do expertly repair medical devices, after the proper training from an OEM, without access to intellectual property. Right to Repair advocates falsely claim that they need this proprietary information to properly repair medical devices. Preventing OEMs from determining who may have access to service manuals, replacement parts, specialized repair equipment, or programming software may result in additional unsafe and ineffective devices compromising patient safety.

MYTH

Third Parties Are Already Regulated

FACT

The claim that third parties are regulated or undergo any comparable level of scrutiny and oversight is false. The Centers for Medicare and Medicaid Services (CMS) and The Joint Commission (TJC) policies only establish minimum requirements on hospitals for the maintenance of equipment, not servicers, and the requirements do not apply to all facilities or clinics. TJC provides accreditation for some, but not all hospitals, and the prerequisite to meet an accreditation equipment maintenance requirement is not the same as a universal requirement for all healthcare equipment servicers to be regulated by the FDA.

Bottom Line

Tens of thousands of unregulated third-party servicers work on complex medical devices without proper training and sometimes without appropriate equipment and replacement parts. OEMs and their authorized servicers recognize that — despite the additional cost— compliance with FDA regulations is vital to helping companies fulfill their commitment to patient safety. OEMs believe any service or repair on complex medical technology should be done only by trained and authorized servicers to ensure continued adherence to the highest levels of effectiveness and patient safety.

AdvaMed
The MedTech Association

The Impact of State Right to Repair Beyond Manufacturers

Bottom Line: State right to repair legislation likely leads to shifting the burden of liability for patient injury onto hospitals.

Hospitals will face a greater burden to ensure properly functioning equipment, and increased liability when it doesn't.

- The inevitable result of state right to repair legislation is a greater burden placed on hospitals to ensure their equipment is always functioning properly, and an increased risk of liability when equipment does not function as intended.

- Plaintiffs would argue, for example, that because the statutes require medical device manufacturers to provide parts, tools, and training materials to repair their medical devices, hospitals have easy access to the parts and services they need to ensure their medical equipment remains in pristine condition.

Hospital internal repair policies, and its ready access to parts, will be a litigation tool.

- Hospitals will be expected to develop internal policies and procedures for obtaining repair parts from the original manufacturer, sending medical devices to manufacturers for repair, and the training of its employees and staff on the use and repair of such equipment. These policies will become another tool plaintiffs will use to show that a hospital failed to take reasonable care to ensure that its equipment is safe and adequate.

Unauthorized, untrained third parties won't be on the hook for bad repairs.

- Third-party repairers are not likely to be found to owe a duty to injured patients, which will minimize hospitals' ability to spread liability.

AdvaMed
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The Power of Medtech: Pennsylvania

AdvaMed is the leading national trade association promoting medical technology to achieve healthier lives worldwide.

The United States is the largest incubator for lifesaving, life-enhancing medical technology, leading a global industry. Each state has a medtech presence, from multinational corporations to the vast majority of medtech companies, startups (94 percent) with fewer than 20 employees (82 percent). All play a critical role, from creating new technology to diagnose cancer and manage diabetes to supplying heart valves, knee replacement joints, and complex scanners to detect disease or injury.

Pennsylvania is the fourth-biggest medtech center nationwide in revenue, fifth-biggest in payroll, and sixth-biggest in jobs. Medical device and diagnostics manufacturers drive significant economic value to the state, local communities, and residents, from providing opportunities for high-skilled and high-paying jobs in various sectors to pioneering life-changing health care technologies for patients all over the world.

LSPA
Life Sciences Pennsylvania

Life Sciences Pennsylvania is the State Medtech Alliance member organization in Pennsylvania.

17,900 jobs

in Pennsylvania are supported by medtech

Medtech in Pennsylvania is a **$7.6 billion industry.**

Pennsylvania medtech employees make an average of

$72,203 per year.

Pennsylvania is home to 42 AdvaMed member sites and 10 AdvaMed Accel members for small, emerging companies:

ALLENTOWN
B Braun
Medtronic

BELLEFONTE
Actuated Medical, Inc.*

BETHLEHEM
B Braun
STERIS

BREININGSVILLE
Olympus Corporation of the Americas

CENTER VALLEY
Olympus Corporation of the Americas

DOWNINGTON
Danaher Corporation

EXTON
Danaher Corporation (2)
Lungpacer Medical, Inc.*
Medartis, Inc.*
Teleflex

HARRISBURG
Zimmer Biomet

INDIANOLA
Bayer Corporation

LINWOOD
Philips

MALVERN
Actuated Medical, Inc.*
Fujirebio Diagnostics, Inc.*
Philips
Siemens Healthineers
TELA Bio, Inc.*

MOUNT PLEASANT
Philips

MURRYSVILLE
Philips

NEW KENSINGTON
Philips

NORTH WALES
Siemens Healthineers

O'HARA
Bayer Corporation

PHILADELPHIA
Avisi Technologies*
Proscia, Inc.*
Roche Diagnostics

PITTSBURGH
ALung Technologies, Inc.*
Cook Medical
Forest Devices*
LivaNova
Philips
Smith & Nephew
ZOLL Medical Corporation

PLYMOUTH
Siemens Healthineers

SAXONBURG
Bayer Corporation
STERIS

SHARON
STERIS

SHARON HILL
STERIS

SINKING SPRING
Alcon

SKIPPACK
STERIS

STATE COLLEGE
Olympus Corporation of the Americas

VANDERGRIFT
Cook Medical

WARRENDALE
Cardinal Health

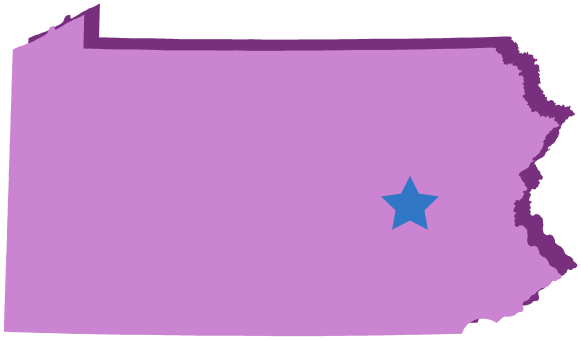
WAYNE
Teleflex

WEST CHESTER
Johnson & Johnson

WEXFORD
Zimmer Biomet

WYOMISSING
Teleflex

ZELIENOPLE
BD
STERIS



Source: The Economic Impact of the Medical Technology Industry report, MACRO Policy Advisers
https://bit.ly/47d01HA

*AdvaMed Accel member