AdvaMed
Advanced Medical Technology Association

The Fallacy of Right to Repair for Medical Devices

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 or compliance to quality standards. Such a move only serves to put patients and device users at greater risk. Legislative proposals that attempt to impose Right to Repair on medical devices are toeing a dangerous line with patient safety and erode the standards already in place that protect the quality, effectiveness, and innovation patients rely on when they go to their doctor.

MYTH 1: 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 true cost is the prolonged time a machine is out of operation due to hospitals cutting corners in their service repairs, resulting in poor or dangerous third-party servicing which places patients at risk of delayed or incorrect diagnosis and treatment. The cost and length of training is dependent on the products and level of training involved. Costs are at the higher end of the range if the trainee is provided customer service tools (generally the manufacturer's intellectual property) to use after the training. Training costs and length are commensurate with the sophistication of the device (for example, devices range from simple blood pressure cuffs to complex computerized tomography (CT) scan machines) and typically comprise a small percentage of the total cost of ownership.

MYTH 2: Study Shows that OEMs Don't Make Devices Safer

FACT: Advocates of Right to Repair site an ECRI study to make their case, but in doing so, are conveniently hiding data that says otherwise. According to 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 as a result of their repairs. Given these findings, it's clear that the ECRI Institute's conclusion not to regulate third parties is deeply flawed. Separate analysis conducted by AdvaMed from 2012-2017 identified even more confirmed incidents than ECRI Institute's study.

MYTH 3: 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. Some devices require over 90 custom-made tools for servicing. Many OEM replacement parts for medical devices are also very specialized and precise in design and function. There is a great risk that a third party attempting to duplicate these parts will not make parts that are identical in quality and design. For some devices, modifications of less than a thousandth of an inch – either through ineffective repair or use of inappropriate replacement parts – can negatively impact the safety of a device resulting in serious patient injury or death.

MYTH 4: The FDA Does Not Want to Regulate Third Party Medical Device Service Repair

FACT: Right to Repair advocates are obfuscating the key point that FDA is making because third-parties do not submit MDRs, 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 5: 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. An absolute requirement preventing OEMs from determining who may have access to service manuals, replacement parts, and specialized repair and calibration equipment or programming software or forcing OEMs to sell these parts or information at cost may result in unsafe and ineffective devices which would cause substantial harm to patients.

MYTH 6: Third Parties Are Already Regulated

FACT: The Centers for Medicare and Medicaid (CMS) and The Joint Commission (TJC) policies on equipment maintenance focus *only* on the maintenance choices of the hospital, and do not govern the activities of the servicer. Moreover, Both CMS and TJC only establish minimum requirements for hospitals for the maintenance of equipment, but their policies do not apply to all facilities and clinics. TJC provides accreditation for some, but not all hospitals, and the presence of requirements to meet an accreditation organization's equipment maintenance requirements is not the same as a universal requirement for all healthcare providers or for all healthcare equipment servicers, as is regulated by the FDA. The claim that third parties are regulated or undergo any comparable level of scrutiny and oversight is false.

Oppose Right to Repair Legislation

Tens of thousands of unregulated third-party servicers are working 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 for the sake of patients, third-party servicers should be required to follow the same regulatory requirements as they do to ensure the devices they service continue to meet the highest standards of safety and effectiveness.