BSI
Health Technology Consulting

February 24, 2026

Commerce & Economic Development Committee
Vermont State House
115 State Street 115 State Street
Montpelier, VT 05633

Re: H.160 – An Act Relating to Creating a Right to Repair for Medical Devices

Honorable Members of the Commerce & Economic Development Committee:

I am honored and humbled to provide this written comment to this Committee on H.160 aimed at creating a right to repair for medical devices.

Before providing information and my comments, please allow me to introduce myself so you can understand my perspective on this subject (a biography is also attached). After earning a Doctor of Science degree from the Massachusetts Institute of Technology (MIT), I taught biomedical engineering and supervised research projects at the State University of Campinas in Brazil, as well as founding the Center for Biomedical Engineering to conduct research and development of medical technology, and servicing medical equipment for the two university hospitals. Later, I served as the Special Advisor on Medical Equipment to the Sao Paulo state's Secretary of Health, coordinating the procurement and management of medical equipment for over 560 health care facilities (HCFs) of that State, which had ~33 million inhabitants.

I returned to the US in 1990 invited by the National Institutes of Health (NIH) in Bethesda to conducted research, as a visiting scientist, on the recording, stimulation, and imaging of the brain. Afterwards, I entered the private sector and worked for the next 30+ years for 3 of the largest medical equipment service companies (aka independent service organizations - ISOs) as their vice-president for quality and regulatory affairs. Those 3 companies were MEDIQ, Aramark, and Sodexo. In this capacity, I oversaw servicing of over 1 million pieces of medical equipment deployed in over 350 hospitals around the country, varying from small rural hospitals to major teaching hospitals, such as the University of North Carolina, University of Texas Medical Branch, and University Hospitals system in Cleveland OH. I also had the opportunity to work for a few American manufacturers of medical devices as their quality and regulatory compliance officer and liaison with the Food and Drug Administration (FDA).

Therefore, my comments on H.160 is not based on a single stakeholder's perspective—namely medical device servicer—but a comprehensive and balanced opinion that considers the challenges and interests of all stakeholders, with the ultimate goal of providing the best and safest medical devices at reasonable costs for the benefit of patients and healthcare providers.

Before diving into the specifics of my comments on H.160, I would like to clarify what I mean by the term "service material" to avoid possible confusion. In my mind, "service material" includes

not only the ”documentation,” “tools” and “parts“ as defined in H.160, but also detailed technical specifications of the device and its components.

During my 30+ years of work in the medical device field, I participated in the provision of critical medical equipment during several major national emergencies such as the Oklahoma City bombing, 911 attacks, Hurricane Katrina, and the COVID pandemic. In these emergencies, the prompt availability of safe and reliable medical devices is essential for the care of the victims and safe their lives. While most manufacturers were quite willing to help, they simply did not have the necessary manpower in the right places and at the right times. So most of them agreed to provide the in-house biomed staff and ISOs with the “service material” so they could provide the clinical staff with the essential equipment, such as ventilators and infusion pumps. Unfortunately, after those emergencies, many OEMs decided to fall back to their traditional position of refusing to provide those “service material” alleging several concerns, some of which I would like to address next.

1) Patient Safety

In response to a congressional mandate, the FDA conducted an extensive review of the safety and quality of services provided by ISOs and concluded in its 2018 report[1] (please see attached a copy of that report’s Executive Summary) that: (i) “… *the objective evidence indicates that many OEMs and third-party entities provide high quality, safe, and effective servicing of medical devices*,” (ii) *“[t]he continued availability of third party entities to service and repair medical devices is critical to the functioning of the U.S. healthcare system*,” and (iii) *“[a] majority of comments, complaints, and adverse event reports alleging that inadequate ‘servicing’ caused or contributed to clinical adverse events and deaths actually pertain to ‘remanufacturing’ and not ‘servicing’*.” In fact, most of these “remanufacturing” activities are likely to be the result of servicers eager to help the healthcare provider but did not have access to specifications contained in service material and, thus, ventured outside of the servicing boundaries. The remanufacturing issue was later addressed by the FDA through a final guidance document entitled “Remanufacturing of Medical Devices” published in 2024[2].

2) Regulatory Oversight

In that 2018 report, FDA also stated unequivocally that while it has full authority to regulate servicing, *“[t]he 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*.” So medical device servicing is under the purview of the FDA but it decided not to impose specific regulatory requirements. In addition, hospitals are required by the FDA’s sister organization, the Centers for Medicare & Medicaid Services– CMS, to comply with the Conditions of Participation (CoPs) of the Social

[1] https://www.fda.gov/media/113431/download
[2] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/remanufacturing-medical-devices

Security Act (42 CFR 482), in order to receive Medicare & Medicaid reimbursements. Within the CoPs, there are strict requirement on the servicing of medical devices to ensure patient safety. So, in addition to the FDA, medical device servicing is also indirectly regulated by CMS.

Furthermore, while regulatory oversight is necessary, it is not sufficient to ensure safety and quality of medical devices produced by the OEMs. FDA's recall database shows the number of devices recalled per year has been increasing continuously in the last couple of decades, and by the end of 2025, there were 331 million devices under recall[3]. As the US Government Accountability Office reported in 2011[4], the FDA needs to enhance its oversight of recalls by "*us[ing] recall data to proactively identify and address the risks presented by unsafe devices*." So the real challenge is not the lack of regulations but the lack of enforcement.

3) Intellectual Property and Service Revenue

The European Union (EU) has mandated the release of service material (except for maintenance software access) since 1993[5] and reiterated it in 2017[6]. If such Right to Repair mandate could cause the OEMs to suffer substantial losses of intellectual property and/or service revenue, one would think that they would have ceased their operations there and moved their businesses elsewhere. So this concern is obviously untrue. In fact, providing service materials does not require OEMs to reveal trade secrets or intellectual property, which are typically protected by patents and other legal means.

4) Cybersecurity Risks

Cyber vulnerabilities in medical devices have been clearly demonstrated by researchers and some cybersecurity companies have reported that malware have been uncovered in some medical devices installed in HCFs. However, it is often unclear when and how the malware was introduced (e.g., via HCF's network or through the medical devices themselves). Unlike hackers or persons seeking monetary gains from cyber-attacks, in-house servicers and ISOs have nothing to gain in such attacks. In fact, they may lose jobs or revenue if the attacked hospitals were locked down for extended period of time. So, in-house biomed staff and ISOs are typically eager to assist their hospitals in monitoring and addressing cyber vulnerabilities and attacks, as well as applying software patches when made available by the respective OEMs.

5) Federal Fair Repair Act Exemption

Not all medical devices are exempted in the federal bill being discussed as claimed by some OEMs. Several states, namely Colorado, California, Nevada, Oregon, and Washington, have

[3] https://marketing.sedgwick.com/acton/media/4952/2025-us-recall-index-report-tl
[4] https://www.gao.gov/products/gao-11-468
[5] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:01993L0042-20071011
[6] https://eur-lex.europa.eu/eli/reg/2017/745/oj/eng

already passed Right to Repair for powered wheelchairs[7], which are deemed as Class 2 medical devices by FDA (i.e., the same classification as infusion pumps used in HCFs).

In essence, access to "service material" (i.e., Right to Repair) is critical for safe and prompt delivery of care to Americans, especially for those located in rural and remote areas which have been struggling to survive over the last two decades and many of them are at risk of closure. Even for hospitals located in metropolitan areas, Right to Repair allows them to keep using the medical devices safely and effectively much longer than their estimated useful lives, thus avoiding premature replacement and saving precious investment capital[8]. Furthermore, by extending the device useful lives, it is possible to help contain the accelerated rise of healthcare costs, reduce toxic waste and lessen detrimental impact on the environment.

Thank you for your precious time and attention. I shall be happy to answer any questions via email or telephone.

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Attachments:

- Binseng Wang's bio
- FDA 2018 Report's Executive Summary

[7] https://www.openassistivetech.org/right-to-repair/
[8] https://24x7mag.com/maintenance-strategies/asset-management/are-we-extending-the-lives-of-medical-equipment/

BINSENG WANG, ScD, CCE

Binseng Wang is a principal consultant with BSI, a health technology consulting firm based in Henderson, NV – USA. He provides consulting services to a broad variety of companies within the health technology industry, such as investment companies, research laboratories, manufacturers, distributors, healthcare delivery organizations, service organizations, insurance companies, law firms, regulatory agencies, quality and accreditation organizations, international health organizations, and multilateral financing organizations. More details can be found at the firm's website: www.bsi-consulting.com. Dr. Wang is also a Board member at Repair.org as a volunteer fighting for the Right to Repair of medical devices (https://www.repair.org/).

Previously, Dr. Wang was Vice President, Program Management, with Sodexo Healthcare Technology Management (HTM), a leading medical equipment independent service organization (ISO) under the umbrella of Sodexo USA, supporting ~100 hospitals and managing ~650,000 pieces of equipment. Before joining Sodexo, he was Director, Quality & Regulatory Affairs for Greenwood Marketing LLC/WRP32 Management, Inc., a holding company that manufactures orthoses and infection-prevention medical devices. Prior to joining Greenwood, he was VP, Quality & Regulatory Affairs, for Sundance Enterprises, Inc., a manufacturer of pressure ulcer prevention and therapy devices. He was also VP, Quality and Regulatory Compliance, for Aramark Healthcare Technologies (another ISO) for over a decade, as well as VP, Quality Assurance and Regulatory Affairs, for MEDIQ/PRN Life Support Services, a medical equipment rental company that also produced medical devices, for over a dozen years. In addition, he worked as a visiting scientist at the National Institutes of Health. Prior to coming to the USA, he taught biomedical and clinical engineering at the State University of Campinas, where he founded the Center for Biomedical Engineering (CEB-UNICAMP), and served as the equipment advisor to the Secretary of Health of Sao Paulo state, where he introduced clinical engineering to the major public hospitals and managed international medical equipment loans to public and private hospitals.

Dr. Wang has provided consulting services to the Pan-American Health Organization (PAHO/WHO), World Health Organization (WHO), Inter-American Development Bank, and World Bank for advice on medical device regulation, management and maintenance in numerous countries around the world, as well as international consulting and investment companies.

Dr. Wang is a fellow of the American College of Clinical Engineering (ACCE) and American Institute of Medical & Biological Engineering (AIMBE), a senior member of American Society for Quality (ASQ) and Institute of Electrical and Electronics Engineers (IEEE), and a member of Association for the Advancement of Medical Instrumentation (AAMI), and Health Technology Technical Advisory Group of the World Health Organization (WHO). He received the 2010 AAMI Clinical/Biomedical Engineering Achievement Award and the 2015 ACCE Lifetime Achievement Award, was inducted to the Clinical Engineering Hall of Fame by ACCE in 2017 and received the inaugural AAMI-TRIMEDX John D. Hughes Iconoclast Award in 2019. He was granted an honorary life membership by the International Federation of Medical and Biological Engineering (IFMBE) in 2022. He was bestowed the ICON-Lifetime Achievement Award by TechNation in 2025. He frequently publishes in trade magazines and peer-reviewed journals and delivers lectures at national and international conferences.

He holds BSc degrees in both Physics and Electronics Engineering from the University of Sao Paulo, Brazil, a MSEE from the State University of Campinas, Brazil, and earned a Doctor of Science (ScD) degree from the Massachusetts Institute of Technology (MIT). Dr. Wang is also a Certified Clinical Engineer (CCE).

U.S. FOOD & DRUG ADMINISTRATION

May 2018

FDA Report on the Quality, Safety, and Effectiveness of Servicing of Medical Devices

In accordance with Section 710 of the Food and Drug Administration Reauthorization Act of 2017 (FDARA)

Executive Summary

The Food and Drug Administration Reauthorization Act (FDARA) became law on August 18, 2017. Section 710 of FDARA charges the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, to issue a report on the continued quality, safety, and effectiveness of medical devices with respect to servicing.

FDA has considered information including but not limited to the information presented at a public workshop, responses to a request for comments, and evaluation of objective evidence related to the quality, safety, and effectiveness of medical device servicing in the compilation of this report. Stakeholders have differing views about the quality, safety, and effectiveness of servicing performed by original equipment manufacturers (OEMs) and third party entities, and the need for imposing additional regulation. Based on the available information, we have concluded:

- 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;
- Rather, the objective evidence indicates that many OEMs and third party entities provide high quality, safe, and effective servicing of medical devices;
- A majority of comments, complaints, and adverse event reports alleging that inadequate "servicing" caused or contributed to clinical adverse events and deaths actually pertain to "remanufacturing" and not "servicing"; and
- The continued availability of third party entities to service and repair medical devices is critical to the functioning of the U.S. healthcare system.

We believe the currently available objective evidence is not sufficient to conclude whether or not there is a widespread public health concern related to servicing of medical devices, including by third party servicers, that would justify imposing additional/different burdensome regulatory requirements at this time. Although we do not believe that additional, formal regulatory action is warranted, based on the available information and findings, we intend to pursue the following actions:

1. Promote the Adoption of Quality Management Principles;
2. Clarify the Difference Between Servicing and Remanufacturing;
3. Strengthen Cybersecurity Practices Associated with Servicing of Medical Devices; and
4. Foster Evidence Development to Assess the Quality, Safety and Effectiveness of Medical Device Servicing.

As part of its 2018-2020 strategic priorities, FDA's Center for Devices and Radiological Health (CDRH) has committed to establishing "Collaborative Communities." The hallmark of a Collaborative Community, is a continuing forum where public and private sector members proactively work together to solve both shared problems and problems unique to other members in an environment of trust and openness, where participants feel safe and respected to communicate their concerns. Members share a collective responsibility to help each other obtain what they need to be successful. We believe there may be value in the creation of a public-private forum, such as a Collaborative Community, to address the challenges associated with delivering high quality, safe, and effective servicing of medical devices. If there is sufficient interest and broad willingness to participate by stakeholder groups, we would facilitate the creation of such a community.