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Federal Trade Commission
Office of the Secretary, Room H-113 (Annex J)
600 Pennsylvania Avenue, NW
Washington, DC 20580

Re: FTC-2022-0061-0002

Dear Secretary Tabor:

As the premier trade association representing the manufacturers of medical imaging equipment, radiopharmaceuticals, contrast media, and focused ultrasound devices, the Medical Imaging & Technology Alliance (MITA) is writing in response to the Advance Notice of Proposed Rulemaking (ANPRM) on the Energy Labeling Rule. Specifically, our comments focus on the "right to repair" section of the ANPRM and our concerns about application of such policies to medical devices.

Historically, "right to repair" policy discussions have focused on consumer products such as household appliances, cellular telephones, and automobiles. More recently, advocates for "right to repair" policies have expanded their advocacy efforts to include medical devices regulated by the Food and Drug Administration (FDA). The basis for these efforts is unsupported claims that medical devices were not being appropriately maintained during the COVID-19 pandemic due to manufacturer-imposed restrictions. We have not seen any concrete evidence that medical imaging devices have gone unrepaired or un-serviced during the COVID-19 pandemic.

MITA is deeply concerned that application of "right to repair" policies to FDA regulated medical devices would have significant unintended consequences, presenting new and unnecessary risks to competition, patient and operator safety, device performance, and cybersecurity.

As is discussed in greater detail below, medical devices are heavily regulated throughout their lifecycle by the FDA, except in cases when a device is being repaired by a non-manufacturer servicing organization. Independent servicing organizations (ISOs) are not regulated or monitored by the FDA, nor are they required to have any quality, safety, or regulatory controls in place to ensure that they return the device to safe and effective condition for its intended use after servicing, maintenance, or repair activities. Original equipment manufacturers (OEMs), on the other hand, are subject to extensive regulatory requirements. OEMs are required to make themselves known to the FDA via registration, implement and maintain a quality management system to ensure consistent and controlled servicing processes, and file Medical Device Reports (MDRs) for device malfunctions that have caused or are likely to cause serious injury to patients and operators.

Knowledge of and compliance with FDA regulatory requirements is essential to performance of medical device servicing activities in a way that results in the safe and effective operation of the medical device. Operating within a quality management system as codified by FDA in 21 CFR 820: Quality System Regulation helps ensure that medical devices consistently meet applicable specifications and

requirements. Currently, non-OEM medical device servicing operations are not required to implement quality management systems that conform with 21 CFR 820, and thus, are not subject to the same rigorous quality standards that help preserve patient safety.

In order to further their business interests, ISOs have made expansive demands for proprietary servicing materials such as service manuals, software keys, schematics, and tools. These same businesses have consistently refused to implement even basic quality or safety controls.

Despite the claims made by these businesses, adequate performance of medical device servicing activities is not dependent only on possession of certain materials. In fact, uncontrolled use of proprietary, highly technical service materials by entities that are not required to have appropriate processes and controls in place could lead to improper servicing of a medical device, dramatically increasing risks to patient safety, device performance, and cybersecurity. Safe and effective servicing is not merely acquisition of certain documentation or materials—it is the implementation of and adherence to a set of policies, practices, and procedures which consistently return the device to a state of safe and effective operation.

We want our devices to always perform safely and effectively for patient care. Application of "right to repair policies" to FDA regulated medical devices would, unfortunately, work counter to this objective.

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1. Medical device "right to repair" policies are a solution in search of a problem

Demands for medical device "right to repair" policies are based on certain misunderstandings about how the medical device servicing market is currently functioning. Advocates for these policies claim that independent servicing organizations (ISOs) are suffering unfairly under the weight of OEMs and that there is inadequate information available to properly service medical devices. Both of these claims are false. The medical device servicing industry is robust and thriving and ISOs already have sufficient information that would enable them to properly service medical devices so long as they implemented and adhered to appropriate quality and safety standards and processes.

a. The medical device servicing industry is highly competitive

Medical device owners and operators have numerous options available to them when selecting a medical device servicer. In a May 2018 report titled "FDA Report on the Quality, Safety, and Effectiveness of Servicing of Medical Devices" the FDA estimated that the total number of firms performing medical device servicing in the United States is between 16,520 and 20,830.[1] By contrast, a recent study estimated that there are 6,500 medical device manufacturers in the U.S.[2] Further, third party medical device servicing is dominated by big business with multiple largescale acquisitions occurring in recent years.[3,4]

b. Medical device servicing is conducted under a number of freely chosen business models

There is no single valid business model by which medical devices are serviced. Service models and contractual terms are established at the point of sale, enabling health care facilities to decide what level of

[1] https://www.fda.gov/media/113431/download
[2] https://www.themadeinamericamovement.com/reshoring/u-s-medical-device-industry/
[3] https://www.medtechdive.com/news/trimedx-to-buy-aramark-unit-in-300m-health-tech-merger/532710/
[4] https://24x7mag.com/maintenance-strategies/preventive-maintenance/medical-equipment-maintenance-market-worth-74-2-billion/

servicing they would like to purchase from the manufacturer versus take on themselves or contract out to a third party.

Many OEMs choose to service their own devices. Other medical device companies choose to partner with ISOs to extend their ability to keep their devices operating safely and effectively. Many OEMs establish a contractual relationship to make servicing materials and parts available. Each kind of relationship also differs in its specifics with varying kinds and degrees of support provided under a variety of contractual arrangements.

Medical device manufacturers build their service capacity based upon installed base and adhere to rigorous service level agreements at all times. This includes use of overtime, travel out of regions, supplementing with highly trained contractors, etc...

Given this, purchasers of medical devices and associated servicing activities have a sufficient amount of information to make informed buying decisions regarding the preferred devices and servicing options that are available.

c. Medical device servicing organizations have a wealth of resources already available to support their work

Organizations engaged in medical device servicing or remanufacturing activities have a wealth of resources already available to them. Proper application of these resources will enable an entity engaged in these activities to determine their regulatory responsibilities as well as a path for returning the device to safe and effective condition for its intended use.

Commonly available resources and their corresponding use include:

<u>Adherence to Regulation and Guidance</u>

Medical devices are heavily regulated by the FDA. Entities that engage in the servicing of medical devices should be aware of the regulatory context in which the medical device exists.

Relevant regulation and guidance documents include:

- United States Code of Federal Regulations Title 21 Part 820, Quality System Regulation
    - Establishes the quality management system requirements for the manufacture and remanufacture of medical devices
- Product-specific 510(k) guidance documents
    - Provides information about the expected contents of a 510(k) submission, and in many cases outline what kinds of modifications to specific device types require submission of a new 510(k), a good analog for remanufacturing
- Remanufacturing of Medical Devices Draft Guidance
    - Provides information on which activities performed on devices are likely "remanufacturing." Such clarification is intended to help provide consistency and better understanding of applicable statutory and regulatory requirements.
- *Deciding When to Submit a 510(k) for a Change to an Existing Device*, Guidance for Industry and Food and Drug Administration Staff
    - Provides guidance on when modifications to a device require submission of a new 510(k)

Adoption of Best Practices and Standards

Widely adopted best practices and industry Standards for the technical support of medical devices have been developed by a number of stakeholders. These best practices—some of which are enumerated below—outline the recommendations and requirements for ensuring the safe and effective performance of a medical device across its lifecycle.

Industry Standards and best practice resources include:

- ANSI/AAMI/ISO 11607-2, *Validation requirements for forming, sealing and assembly processes*
- ANSI/AAMI/ISO 10993, *Biological evaluation of medical devices*
- AAMI EQ56, *Recommended practice for a medical equipment management program*
- AAMI EQ89, *Guidance for the use of medical equipment maintenance strategies and procedures*
- IEC PAS 63077 (NEMA/MITA 1), *Good refurbishment practices for medical imaging equipment*
- ISO 14971, *Application of risk management to medical devices*
- ISO 13485, *Quality management systems—Requirements for regulatory purposes*
- NEMA/MITA 2-2019, *Requirements for Servicing of Medical Imaging Equipment*
- NEMA/MITA RMD P1-2019, *Considerations for Remanufacturing of Medical Imaging Devices*
- IEC 60601-1:+A1:, *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*
- IEC 62353, *Medical electrical equipment - Recurrent test and test after repair of medical electrical equipment*
- ISO 13372, *Condition monitoring and diagnostics of machines – Vocabulary*
- ISO 10993-1, *Biocompatibility of patient contact materials*

Use of Generally Available OEM-provided Information

OEMs make available information which is required by contract or regulation to the owners or operators of the device. Generally available OEM-provided information includes:

- Publicly available device labeling information that includes a full statement of the intended use, directions for use, and other potentially relevant information
- User manuals provided at point of sale as part of device labeling or contractual agreement that include basic cleaning, troubleshooting, and maintenance information. Facility codes and accreditation schemes such as NFPA 99 and Joint Commission EC.01.01.01, EP 3 require that healthcare providers maintain a library of documents, including service manuals for their medical devices. It is the responsibility of the healthcare facility to maintain these documents.
- Assemble, Install, Adjust, Test (AIAT) Information for X-Ray equipment as required under statute to ensure a device meets Federal performance standards (21 Code of Federal Regulations sec. 1020.30(g)).

2. Implementation of medical device "right to repair" policies would create new and unnecessary risks to competition and patient safety

"Right to repair" policies would require medical device manufacturers to provide to their competitors certain materials that would otherwise be considered proprietary or provided only under contract. Required disclosure of these materials would create competitive issues between the FDA regulated segment of the industry and the segment of the industry that escapes all oversight. Medical device "right to repair" policies would also create significant new risks to patient safety.

a. Forcing regulated manufacturers to provide proprietary information to non-regulated competitors will exacerbate competitive issues in the marketplace and erode trade secret protections

Unregulated independent medical device servicing businesses have repeatedly made inappropriate, expansive demands for manufacturer proprietary information. These demands have gone well beyond what would be necessary to repair a medical device to include OEM proprietary information and trade secrets. Unregulated servicing businesses have attempted to use legislation and regulation to compel regulated medical device manufacturers to release proprietary service manuals, device schematics, wiring diagrams, mechanical layouts, tools, cybersecurity-sensitive servicing keys, and other materials typically held confidential or released only under contract.

We are deeply concerned that wide release of proprietary servicing materials will create an irrevocable loss of trade secret protection for manufacturers. If implemented, medical device "right to repair" policies would allow for uncontrolled replication and distribution of OEM proprietary information, potentially into the hands of malicious actors. We have already seen a willingness of unscrupulous actors to distribute OEM proprietary information via such uncontrolled channels as the iFixIt website.

Not only do manufacturers invest significant resources into the manufacture and design of medical devices, they also invest heavily in innovation and development of servicing tools, training, and protocols. These specific proprietary resources are not necessary for the successful servicing of devices. For example, OEMs invest in these materials and use them in order to demonstrate traceability (i.e. that a device was properly manufactured, and subsequent repairs were completed according to specifications in the case of an adverse event).

As voluntary entrants into the market, independent servicing businesses should be required to accept responsibility for ensuring the return of medical devices to safe and effective operation and can do so by adopting appropriate quality systems and investing in the development of their own valid servicing protocols, tools, and training. Many non-OEM servicers also already make these kinds of investments in servicing tools, training, and protocols for the same reasons that OEMs do and are entities with whom medical device manufacturers regularly and willingly contract.

Requiring regulated medical device manufacturers who have made significant investments in regulatory compliance and development of servicing processes to provide company confidential or proprietary information to unregulated competitors will have significant negative consequences for innovation and competition in this industry.

Importantly, in many cases, one manufacturer may be contracted by a healthcare provider to service another manufacturer's device. Forcing one device manufacturer to turn over company confidential information or trade secrets such as design specifications or software access to a competing manufacturer when acting as a third-party servicer would be disastrous for competition and innovation.

b. FDA exercises oversight over the medical device ecosystem, except non-manufacturer medical device servicers

Medical devices designed, manufactured, and serviced by OEMs are categorically different than consumer and other goods in that they are regulated by the Food and Drug Administration (FDA) throughout their lifecycle to ensure safe and effective operation for an intended use, except with regard to servicing activities performed by an entity other than the OEM. The FDA has established strict pre- and post-market requirements for manufacturers of medical devices, including:

- Establishment Registration (21 CFR Part 807)
- Medical Device Listing (21CFR Part 807)
- Premarket Notification (21 CFR Part 807 Subpart E) or Premarket Approval (21 CFR Part 814)
- Quality System Regulation (21 CFR Part 820)
- Labeling (21 CFR Part 801)
- Medical Device Reporting (21 CFR Part 803)
- Corrections and Removals (21 CFR Part 806)

Adherence to these regulations requires investment in people, processes, and technologies by medical device manufacturers.

Despite the ongoing servicing and maintenance activity of medical devices, non-manufacturer entities—such as ISOs—have no FDA oversight and do not have to follow FDA regulations. Currently, only servicing activities performed by medical device manufacturers are held to quality, safety, or regulatory requirements by the FDA. This is important because performance of servicing activities within a quality management system by properly trained personnel using qualified, properly sourced parts reduces the risk of harm to the patient, healthcare provider, and device operator and reduces risk of poor performance of the device.

Whether or not the manufacturer is also the entity which services a device, the OEM has a stake in all servicing activities for its devices. Improper servicing by unregulated entities presents significant concerns to the OEM, including creating challenges such as:

- Difficulties in providing future field upgrades or field corrections to the device if service history is unknown, improper parts have been used, or if the device has otherwise been altered;
- Lack of required regulatory reporting and incomplete device history does not allow for tracking of significant events, root cause investigation, quality or safety improvement opportunities for the device, or prevention of adverse events;
- Voided device electrical safety certifications (e.g. UL certifications);
- Diminished brand value due to unsafe and ineffective operation of the device; and
- Liability concerns for the manufacturer if the device injures directly or indirectly a patient or operator.

c. Medical devices present unique patient and user safety risks that would be exacerbated by uncontrolled distribution of servicing materials

Improper repair or servicing of a medical imaging device can present a wide range of risks for both the patient and others who interact with the device, including the servicer. These risks would be exacerbated by improper distribution of proprietary OEM materials to unregulated parties. If an unregulated party improperly repairs a device, the device cannot reasonably be relied on to safely and effectively meet its intended use.

Although this is not a comprehensive list, there are a number of specific risks associated with improper servicing of medical imaging devices, depending on the imaging modality in question:

- **Electrical shock**—If after a service event, the device has not been properly rewired or has unvalidated parts installed, the risk that an individual interacting with the device will receive an electrical shock is significantly increased.
- **Over exposure to ionizing radiation**—Some imaging devices, including X-Ray and CT scanners, emit ionizing radiation. There is a risk of radiation over-exposure if these devices are

not properly calibrated or maintained. While there are numerous built-in safeguards in this respect, improper servicing which bypasses these safeguards could lead to significant and irreversible harm.

- **Mechanical failure**—If a device experiences mechanical failure due to improper servicing, significant and irreversible harm to the patient or user, ranging from painful pinching to serious crushing, could result.
- **Air embolism**—In the case of injection devices (such as imaging contrast agent power injectors), if the device has undergone improper servicing, the patient could experience a potentially fatal air embolism.
- **Improper dosing**—In the case of injection devices, if the device has undergone improper servicing, a patient could experience a potentially fatal under or overdose of medication
- **Infection**—In the case of ultrasound probes and other patient contact devices, if the device has not been properly sterilized or disinfected as specified by the OEM requirements and instructions, transfer of infection or disease between patients could result.
- **Burns**—Incorrect replacement materials or parts in an MRI system may disrupt the path of radiofrequency energy, causing excessive heating and potentially resulting in significant and irreversible patient burns.
- **Interference with other equipment**—If a device's electromagnetic interference (EMI) shielding has undergone improper servicing, operation of the device could potentially interfere or degrade the proper operation of other equipment in the surrounding area.
- **Cybersecurity**—Whenever software is installed or adjusted for a medical device, or if software tools are used to access a device for diagnostic and maintenance purposes, the integrity of the software may be compromised. Unvalidated software without confirmed authenticity or system integration may present significant potential security vulnerabilities and operational issues. Additionally, expanded and uncontrolled access to medical device operating systems and software applications creates the potential for increased cybersecurity risks, as the opportunity to intentionally or unintentionally introduce security vulnerabilities to the device and to any networks to which the device is connected (e.g. hospital) also expands.
- **Delay in patient care—**Any failure in a device to perform when needed as a result of improper servicing, or to provide accurate results, may result in a delay of care, including incorrect diagnosis, resulting in delayed or incorrect treatment of a patient's condition.
- **Misdiagnosis—**Improper servicing could cause a medical imaging device to perform in such a way that it does not produce diagnostic-quality images. This could mean that a patient is misdiagnosed.

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MITA supports policies that promote the safety and efficacy of medical devices and promote competition in the marketplace. We are concerned that implementation of "right to repair" policies for medical devices would negatively impact competition and erode the safety and efficacy of FDA regulated products.

If you have any questions, please contact Peter Weems, Senior Director, Policy & Strategic Operations, at 703-841-3238 or by email at pweems@medicalimaging.org.

Sincerely,

Patrick Hope
Executive Director, MITA

MITA is the collective voice of medical imaging equipment and radiopharmaceutical manufacturers, innovators and product developers. It represents companies whose sales comprise more than 90 percent of the global market for medical imaging technology. These technologies include: magnetic resonance imaging (MRI), medical X-Ray equipment, computed tomography (CT) scanners, ultrasound, nuclear imaging, radiopharmaceuticals, and imaging information systems. Advancements in medical imaging are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. The industry is extremely important to American healthcare and noted for its continual drive for innovation, fast-as-possible product introduction cycles, complex technologies, and multifaceted supply chains. Individually and collectively, these attributes result in unique concerns as the industry strives toward the goal of providing patients with the safest, most advanced medical imaging currently available.