March 25, 2022

Chairman Frank Pallone
House Energy & Commerce Committee
2107 Rayburn HOB

Chairwoman Anna G. Eshoo
Subcommittee on Health
272 Cannon HOB

Ranking Member Cathy McMorris
House Energy & Commerce Committee
1035 Longworth HOB

Ranking Member Brett Guthrie
Subcommittee on Health
2434 Rayburn HOB

Re: Public interest and healthcare organizations oppose Congressional changes to definition of medical device remanufacturing

Dear Chair Pallone and Ranking Member McMorris,

For decades, our respective organizations worked to reduce the cost of healthcare while maintaining its quality—either as public interest advocates or service providers. The pandemic exposed important flaws in our current medical device repair environment. Manufacturers restrict access to necessary repair materials like parts, manuals and software tools to only their branded technicians, reducing competition by effectively locking hospital clinical engineering departments and independent service organizations (ISOs) from making many repairs on medical equipment.[1] When equipment repair needs increased, these restrictions caused bottlenecks. In a survey conducted by U.S. PIRG in December 2020, 80% of biomedical repair technicians reported having equipment that they could not service because of restrictions to service keys, parts or other repair materials.[2]

It is for this reason that we engaged extensively on Medical Right to Repair to remove manufacturer-imposed restrictions on repair that not only run up costs, but make it hard for people on the frontlines of the fight against COVID to treat patients. These efforts are included in the Biden Administration's priorities to spur more competition in the economy.[3]

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[1] K. O'Reilly and N. Proctor; "Hospital Repair Restrictions"; *U.S. PIRG*; 8 July 2020; available at https://uspirg.org/reports/usp/hospital-repair-restrictions

[2] Kevin O'Reilly; "Hospital technicians renew urgent call for Right to Repair medical equipment"; *U.S. PIRG*; 10 February 2021; available at https://uspirg.org/blogs/blog/usp/hospital-technicians-renew-urgent-call-right-repair-medical-equipment

[3] "FACT SHEET: Executive Order on Promoting Competition in the American Economy"; *The White House*; 9 July 2021; available at https://www.whitehouse.gov/briefing-room/statements-releases/2021/07/09/fact-sheet-executive-order-on-promoting-competition-in-the-american-economy/

Along with our partners, including IAMERS, in the push for Medical Right to Repair, we oppose efforts by medical device manufacturer industry groups to include language in the Medical Device User Fee Amendments (MDUFA V) that would change the definition of "remanufacturing" to include activities that have long been considered as servicing or refurbishing.

For example, the trade association legislative draft being circulated would drop from the definition of an equipment change deemed to be 'remanufacturing' the word 'significant.' This proposed change should be declined as it hardly clarifies. Rather it might well have the practical effect of making every change, however small, remanufacturing.

Should such a change be implemented, the ability of hospitals and independent service organizations to repair and maintain critical medical equipment could be severely curtailed or eliminated, drastically reducing competition in the process. Service delays and high repair costs have already been a problem throughout this pandemic and before it. Further reducing competition with this amendment would only make these problems worse.

The question of what activities constitute remanufacturing vs servicing is one that the FDA has been investigating since last June and issued a draft remanufacturing guidance.[4] In the process, the FDA has asked for public comment and has engaged more than 80 equipment service stakeholders to reach a proper and appropriate solution. Including legislative changes on this matter would constitute an end run around FDA's process of gathering important stakeholder input and indeed in many ways, render it moot.

Congress should be increasing the competition that will improve hospital choices and patient safety towards the important goal of driving down healthcare costs -- not advancing policy that might well result in only manufacturers being able to repair equipment. Congress should allow the FDA stakeholder engagement process to continue. It is for these reasons that we, the undersigned healthcare and public health groups, ask you to allow the process to run its course by not adding any language on the matter to MDUFA V.

Sincerely,

Kevin O'Reilly and Nathan Proctor, U.S. Public Interest Research Group

Robert Kerwin, IAMERS General Counsel

Gay Gordon-Byrne, Repair.org Executive Director

Scott Trevino, TRIMEDX Senior Vice President of Cybersecurity

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[4] "Remanufacturing of Medical Devices"; *FDA;* June 2021; available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/remanufacturing-medical-devices

Mike McRoberts, MultiMedical Systems Senior Vice President of Business Development

Ariel Kocourek, Radiotherapy Service Engineer Association President

Samantha Bentley, RS&A OEM and Regulatory Affairs Specialist

Dustin Zimmerman, Avante Health Vice President

Priya Upendra, American College of Clinical Engineering President

Courtney Nanney, CommonSpirit Health National Quality Manager