May 9, 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: Medical device repair professionals oppose H.R. 7253 and Congressional changes to definition of medical device remanufacturing

Dear Chair Pallone and Ranking Member McMorris,

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]

These manufacturer-imposed restrictions on repair make it hard for us—the biomedical repair technicians, clinical engineers and health technology managers on the frontlines of the fight against COVID—to treat patients. That is why we support Medical Right to Repair, an effort included in the Biden Administration's priorities to spur more competition in the economy.[3]

As medical device repair professionals working for hospitals, the military and Independent Service Organizations (ISOs) to deliver timely, effective, and safe service to medical devices, we oppose H.R. 7253 and Congressional action that

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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/

would change the definition of "remanufacturing" to potentially include activities that have long been considered as servicing or refurbishing.

H.R.7253 would make the definition of "remanufacturing" overly broad and vague. The legislation would amend applicable sections of the Federal Food, Drug & Cosmetic Act to provide that remanufacturing is "any act that could significantly change the performance or safety specifications or intended use," including changes to the design of the equipment. Such a change might well have the practical effect of making every service or repair act, however small, remanufacturing. It would hardly clarify what is or what is not remanufacturing.

That would require many ISOs and hospital departments to register as manufacturers with the FDA, despite not conducting actual manufacturing activities, to continue service operations. The additional regulatory requirements that H.R.7253 would impose on ISOs could seriously strain their business, at the very least requiring them to increase their prices. The net result would be further reduced competition in the medical equipment servicing market. We saw how manufacturers' anticompetitive practices led to service bottlenecks and delays during the pandemic. The changes H.R.7253 proposes would make these problems worse to the detriment of patient safety and the affordability of healthcare.

This bill would also incentivize monopolization of device repair by providing manufacturers with additional mechanisms to wedge out competition. Many manufacturers do not provide ISOs with the information and materials needed to determine whether or not an activity will constitute this definition of remanufacturing. Because H.R.7253 would require the FDA to inspect, "establishments *otherwise believed* to be engaged in remanufacturing," manufacturers could report hospitals that employ independent servicers—parties that manufacturers might not provide with necessary service materials—to the FDA.[4] That gives manufacturers leverage to further drive out competition.

Importantly, there is no data to show that the changes introduced in H.R.7253 will do anything to improve patient outcomes. The FDA examined all complaints and allegations from 2009 to when the report was written in 2018 and found only 28 complaints[5]—an exceedingly low number for a nine-year period.

The FDA has engaged more than 80 equipment service stakeholders since last June to reach an appropriate solution that does not favor any one party. Passing H.R.7253 would bypass the FDA's comprehensive process to the benefit of manufacturers.

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

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[4] The FDA draft Remanufacturing Guidance has said that the absence of diagnostic information could cause a servicers' actions to be deemed to be remanufacturing. It is possible for a manufacturer to decline to provide service manuals and thereafter to claim that the servicer has engaged in remanufacturer.

[5] "FDA Report on the Quality, Safety, and Effectiveness of Servicing of Medical Devices"; *FDA*; May 2018; available at https://www.fda.gov/media/113431/download

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 medical device repair professionals, ask you to allow the process to run its course by voting against H.R.7253.

Sincerely,

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