U.S. PIRG IAMERS

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: Public interest and healthcare organizations oppose H.R.7253 and changes to definition of medical device remanufacturing

Dear Chair Pallone and Ranking Member McMorris,

We write to follow up on our March 25 letter opposing Congressional changes to the definition of medical device remanufacturing. Now that H.R.7253 has been finalized, we want to share our analysis of the bill and why we oppose it.

As a reminder, our organizations have worked for decades to reduce the cost of healthcare while maintaining its quality—either as public interest advocates or service providers. The pandemic exposed how healthcare costs and patient safety are compromised by manufacturer policies to restrict access to necessary repair parts, manuals and software keys to only their branded technicians, locking hospital clinical engineering departments and independent service Organizations out of making many repairs on medical equipment.[1]

We engaged extensively in the campaign for Medical Right to Repair to make sure that third party entities can continue to service and repair equipment, which a 2018 FDA report describes as, "critical to the functioning of the U.S. healthcare system."[2] These efforts are included in the Biden Administration's priorities to spur more competition in the economy.[3]

Along with our partners in the push for Medical Right to Repair, including IAMERs, we oppose H.R. 7253 and Congressional action that would change the

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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] "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

[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/

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.

As we stated in our previous letter, 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.

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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

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 voting against H.R.7253.

Sincerely,

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

- *U.S. PIRG is a federation of independent, state-based, citizen-funded Public Interest Research Groups in 25 states.*

Robert Kerwin, International Association of Medical Equipment Remarketers and Servicers General Counsel

- *IAMERS represents member companies that sell, service and finance pre-owned medical imaging devices around the world.*

The Alliance for Quality Medical Device Servicing, including member companies Agiliti, Crothall, the InterMed Group, Sodexo and TRIMEDX

- *Agiliti is a medical equipment management and services company dedicated to helping more than 9,000 healthcare organizations across the country access, manage and maintain medical equipment.*
- *Crothall is a healthcare support services provider serving more than 1,400 healthcare clients in 46 states.*
- *The InterMed Group is a healthcare technology management services provider.*
- *Sodexo provides Clinical Technology Management services, with 500 highly qualified engineers stationed in 100 healthcare delivery organizations around the country.*
- *TRIMEDX is an independent clinical asset management company that helps healthcare providers in more than 4,500 locations increase patient safety and reduce expenses.*

Gay Gordon-Byrne, Repair.org Executive Director

- *Repair.org, or the Repair Association, is a trade association representing the repair industry.*

Courtney Nanney, CommonSpirit Health National Quality Manager

- *CommonSpirit Health is the nation's leading provider of Medicaid service, operating 140 hospitals and more than 1,000 care sites across Arizona, Arkansas, California, Colorado, Georgia, Indiana, Iowa, Kansas, Kentucky, Minnesota, Nebraska, Nevada, North Dakota, Ohio, Oregon, Pennsylvania, Tennessee, Texas, Washington, West Virginia and Wisconsin.*

Chris Briggs, Providence Group Vice President of Strategic Technology Enablement
Stephen Ellithorpe, CHTM, Providence Executive Director Clinical Technology Services

- *Providence is a nonprofit healthcare system operating 52 hospitals, 1,085 clinics and a comprehensive range of health and social services across Alaska, California, Montana, New Mexico, Oregon, Texas and Washington.*

Perry Kirwan, Banner Health Vice President of Technology Management

- *Banner Health is one of the largest, nonprofit healthcare systems in the country, operating 30 hospitals across Arizona, California, Colorado, Nebraska, Nevada and Wyoming.*

Gary Barlow, Advocate Aurora Health Vice President of Health Technology Management

- *Advocate Aurora Health is one of the country's premier not-for-profit healthcare systems, with 27 hospitals and more than 500 care sites across Illinois and Wisconsin.*

Nader Hammoud, John Muir Health Integrated Health Technology Manager

- *John Muir Health includes four hospitals serving Northern California.*

Barbara Maguire, ISS Solutions Vice President of Health Technology Management

- *ISS Solutions delivers healthcare technology management solutions that enable maximum effectiveness in patient care to Geisinger Health System and other medical providers in the Northeast.*

Darren Kneeland, MultiMedical Systems Chief Executive Officer
Michael McRoberts, MultiMedical Systems Senior Vice President of Business Development

- *MultiMedical Systems provides comprehensive clinical engineering services to healthcare providers throughout the West Coast.*

Dustin Zimmerman, Avante Health Solutions Vice President

- *Avante Health Solutions is a single source provider of medical, surgical, diagnostic imaging, and radiation oncology equipment, including sales, service, repair, parts, refurbishing, and installation.*

Tony Lively, ZRG Medical President

- *ZRG Medical the leading medical asset disposition vendor in Southern California, with additional customers in the Northwest and Midwest.*

DJ Conrad, RS&A Chief Executive Officer
Samantha Bentley, RS&A OEM and Regulatory Affairs Specialist

- *RS&A is a leading independent service provider within the radiation therapy community.*

Trish Payne, Block Imaging OEM & FDA Liaison

- *Block Imaging, based in California and Michigan, serves health care providers across the country.*

Priya Upendra, American College of Clinical Engineering President

- *ACCE is a nonprofit professional organization that represents the professional interests of clinical engineers by establishing standards of competence and promoting excellence in clinical engineering practice, promoting the safe and effective application of science and technology in patient care, defining the body of knowledge on which the profession is based, and serving as an advocate for the profession.*

Leticia Reynolds, Colorado Association of Biomedical Equipment Technicians President

- *CABMET is a professional biomedical society that seeks to advance the field by providing education and certification.*

Stephen Ellithorpe, CHTM, Washington State Biomedical Association President

- *WSBA is the professional society for the Biomedical and Clinical Engineering community in Washington State. Its purpose is to provide a forum for discussion and education for those who provide technology support to the healthcare community.*