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Comment from American Consumer Institute

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Comment

The American Consumer Institute ("ACI") hereby submits this comment opposing the petition to renew the 2021 exemption governing, "Computer programs that control medical devices or systems, and related data files, for diagnosis, maintenance, or repair of the device or system."

ACI is a nonprofit (501c3) educational and research institute with the mission to identify, analyze and protect the interests of consumers in selected policy and rulemaking proceedings related to information technology, health care, retail, insurance, energy, postal and other issues.

Often, rulemakings decisions, like this one, can yield more costs than benefits to consumers if not appropriately considered. We would therefore like to the urge the Librarian to seriously consider how the exemptions for medical devices could jeopardize patient safety during this ninth triennial rulemaking mandated by the Digital Millennium Copyright Act.

This year, ACI established the Safe Repair Project. A new initiative to keep American consumers and patients safe from potentially dangerously and incorrectly repaired medical equipment. Our goal aims to educate and advocate for sensible policy solutions that ensure patient safety remains at the forefront of the right to repair debate.

The exemption undermines the maintenance and repair standards laid out by the U.S. Food Drug Administration (FDA) for the equipment employed in patient care. Medical devices are regulated by the FDA because they are intricate and sensitive machines that require precision and expert training to conduct necessary repairs. The FDA requires specific technical requirements, specifications and expertise when manufacturing these regulated products.

However, independent servicers (ISOs) are neither regulated nor monitored, and not required to adhere to the FDA's Quality System Regulations or report adverse repair events. We have strong federal regulations on the manufacturers in this market, but none related to third-party servicers. This gap puts patients at

serious risk.
Moreover, because these unregulated repair shops have no obligation to uphold the highest repair standards or report adverse incidents, we are potentially exposing patients to poorly serviced or malfunctioning medical devices.

While our organization's mission is rooted in consumer sovereignty — the freedom for consumers to make their own choices and the importance of giving consumers better information to make those choices – there are certain industries that require oversight and accountability to maintain the public interest. A decision to continue the exemption from 2021 from the Librarian would undermine that system.

Repairs by unregulated ISOs increase patient risk and a continued exemption would only serve to undermine the quality and safety standards that patients and medical professionals rely on to ensure patient safety.

If your loved one needed an emergency diagnostic evaluation, you certainly would want that equipment to be maintained by a licensed professional with the same knowledge and training required by the FDA. Patients deserve better.

Thank you for your consideration of our comments.

Respectfully submitted,

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American Consumer Institute

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