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Hospitals' Ability to Control and Maximize the Value of Medical Devices at Heart of Amicus Brief to the Supreme Court

- **Association of Medical Device Reprocessors submits amicus brief to U.S. Supreme Court ahead of hearing on federal Computer Fraud and Abuse Act**
- **An appellate court ruling, if affirmed by the Supreme Court, could lead to higher healthcare costs and more medical waste -- inflicting further damage to an already fragile supply chain**
- **AMDR argues that FDA-cleared, single-use medical device reprocessing includes resetting devices for additional uses and does not constitute "unauthorized access" or "hacking"**

WASHINGTON, July 14, 2020 -- The Association of Medical Device Reprocessors (AMDR) today announced that it filed an amicus curiae brief with the U.S. Supreme Court encouraging justices to consider the implications for hospital supply chains and healthcare costs when deliberating *Nathan Van Buren v. United States* (No. 18-12024). The case could expose reprocessors, and potentially broad swaths of computer users, to additional liability under the federal Consumer Fraud and Abuse Act's (CFAA) anti-hacking statute.

The CFAA was written in 1986 and defined the term "computer." Today, by that definition, many common medical devices constitute computers, including ultrasonic scalpels, diagnostic cardiac catheters and even pulse oximeter sensors. The Food and Drug Administration has cleared these and other devices to be reprocessed, including processes to unlock or reset microchips, to extend the life of these medical device assets and thereby reduce cost and waste. Some medical device manufacturers insert microchips or update software to force obsolescence into their devices after just a single use.

AMDR argues, in keeping with precedent, once these devices are purchased and owned by the hospital, the hospital owner maintains the right to do with its product what it wishes, including reprocessing the device. Further, by unlocking these devices for another use, AMDR members do not exceed "authorized access" to the original manufacturers' computer, nor do reprocessors alter the functionality of the device. Please see AMDR's amicus brief for further details.

"Although the definition of 'computer' now includes smartphones, household appliances, and even farm tractors and medical devices, the balance remains the same – an individual can do as he or she so pleases with their own device but may not 'hack' into a device owned by

someone else," said Daniel J. Vukelich, President and CEO, AMDR. "The justices should confirm that hospitals have the right to partner with FDA regulated reprocessors to maximize the value of the medical devices they own."

By using reprocessed single-use medical devices, over 7,300 hospitals in the U.S and Canada saved nearly $500 million in 2018, strengthening the supply chain, reducing costs and medical waste. Hospitals that expand reprocessing programs can address the cost burden associated with COVID-19, better control their supply chain and invest savings to prepare for future threats.

About AMDR

The Association of Medical Device Reprocessors is the global trade association for the regulated, professional single-use device reprocessing and remanufacturing industry. For 20 years, AMDR has promoted reprocessing as an important healthcare strategy that helps hospitals and healthcare providers increase quality, reduce costs, and strengthen the supply chain. AMDR protects the interests of its members in regulation, legislation and standard-setting.

AMDR members include Innovative Health, Medline Renewal, NEScientific, ReNu Medical, Stryker Sustainable Solution, Sustainable Technologies (a Cardinal Health Business), and Vanguard AG.

Having played a key role in the establishment of the reprocessing industry, AMDR continues to push the medical technology industry and lead the way for reprocessing to play a defining role in the evolution and use of new device technologies.

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