AMDR
ASSOCIATION OF MEDICAL DEVICE REPROCESSORS

Monday, July 17

Electronically submitted to www.regulations.gov

Docket No. FDA-2022-N-0593

Tammy Beckham, DVM, PhD
Associate Director, Resilient Supply Chain Program (RSCP)
Offices of Strategic Partnerships and Technology Innovative (OST)
Center for Devices and Radiological Health (CDRH)
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

Dear Dr. Beckham:

The Association of Medical Device Reprocessors (AMDR) sincerely thanks FDA for including the medical device reprocessing industry as a collaborator in the above noted FDA workshop. We further appreciate the opportunity to submit these comments to the associated docket.

AMDR is the global trade association representing the interests of regulated, commercial medical device reprocessing companies. Our members reprocess "single-use" medical devices (SUDs) and are regulated by FDA and similar regulatory authorities abroad. In 2020, our members reprocessed over 31.6 million devices for over 10,300 healthcare facilities in 13 countries.[1] AMDR members provide a safe, regulated, sustainable solution that reduces Scope 3 (supply chain) emissions, which account for 82% of all greenhouse gas emissions from the health sector.[2] The first of several anticipated life cycle assessments showed that a reprocessed EP catheter cut greenhouse gas emissions in half compared to using original devices with each patient.[3]

Use of commercially reprocessed SUDs improves supply chain resilience by reducing reliance on imports of new equipment because the practice keeps existing devices in circulation longer. Reprocessing is conducted more locally, further reducing dependence on foreign manufacturing as hospitals can have their existing medical device assets reprocessed. The availability of reprocessed devices improves resilience by supplying an alternative to new devices in situations with supply chain disruptions or shortages, particularly for "chipped" laparoscopic surgical and diagnostic cardiovascular devices for which there are current shortages. Multi-sourcing of needed medical devices further builds resilience and reliability to healthcare practitioners. SUD reprocessors, in essence, become a second supplier source, reducing risks of device shortages due to supply chain disruptions. Furthermore, reprocessed devices typically cost 25 to 40% less than original devices, resulting in nearly $438M in savings to hospitals in 2020.[4] These

substantial cost savings can be used to offset the costs for environmental remediation efforts, to purchase new equipment or invest in staff.

Overview

A primary driver of Scope 3 (supply chain) emissions in healthcare is the "take-make-waste" thinking that underpins the predominantly linear economy for healthcare products – where materials are created, used once, then thrown in the trash. In AMDR's view, addressing climate change and reducing healthcare's outsized toll on the environment, requires shifting to circular economy solutions. Circular economy solutions, like reprocessing, extend the life of existing materials as long as possible, extending product life cycles. It reduces waste to a minimum, creating more value for consumers, and reduces consumption of finite resources.[5] Furthermore, given supply chain shortages and disruptions for certain medical products, and the risk of continued disruptions,[6] reprocessing provides an impactful solution to mitigating against potential device shortages. For the medical device sector, incentivizing the use of reusable or reprocessed products helps achieve both emissions and resilience goals.

Commercial SUD reprocessing provides a case study of a rare quadruple win for healthcare systems, patients, and the planet: increased supply chain resilience, reduced waste, and reduced cost and greenhouse gas emissions. The more devices are reprocessed, the more the benefits are realized. Most U.S. hospitals already have medical device reprocessing programs, but we believe there is considerable opportunity for expansion of these programs that in turn will further reduce greenhouse gas emissions, while maximizing waste and cost reductions. AMDR recently issued a report on the lost potential for U.S. hospitals when they don't use as many reprocessed devices as they could. AMDR's announcement of the report is available at our website and the full report is attached.

Based on the lessons that can be learned from the reprocessing industry, AMDR proposes FDA consider the following to help build supply chain resilience:

Prioritize FDA Review of Reusable or Reprocessable Devices

FDA has a role to play in building resilience in the supply chain for healthcare products. To help expedite the availability of reusable or reprocessable devices, which reduces dependence on foreign produced products, AMDR calls on FDA to prioritize the review of products labeled reusable or single-use that are commercially reprocessed. This would incentive manufacturers, in the development stage of new products, to consider longer total product life cycles that helps improve supply chain resilience for hospital customers, reduces waste, emissions and costs.

Encourage Domestic Device Manufacturing and Reprocessing

Further, having devices available "more locally," can help mitigate against disruptions and lessen dependency on foreign manufacturing. We urge FDA to give priority review to devices made or reprocessed in America.

Address "Forced Obsolescence" Built into Devices Seeking Regulatory Review

AMDR also urges FDA to pay particular attention to new versions of devices that contain microchips, which may be used to force obsolescence into the devices –e.g., stopping

them from working after a single use. AMDR believes forced obsolescence measures such as this are only intended to increase medical device manufacturer profits at the expense of healthcare consumers and the environment. Several manufacturers are reporting to customers that supply disruptions are likely to occur for devices with chips used in laparoscopic surgery and in the Electrophysiology lab. We ask FDA specifically review applications of devices containing chips to identify forced obsolescence practices used to intentionally limit device use and require greater healthcare acquisitions and source consumption. We ask FDA to not clear or approve future products if the primary intent of the chip's function is intended to thwart reuse.

We also urge FDA to foster collaboration between manufacturers and reprocessors to help mitigate supply chain disruptions for devices for which there is an FDA regulated, reprocessed alternative. A greater overall supply of products will reduce risk of future disruptions or shortages. We especially urge FDA to encourage manufacturers of chipped surgical and electrophysiology devices to work with reprocessors to build greater supply of such products to build reserves against expected shortages.

Educate Hospitals on Reprocessed Device Availability:

Given FDA has cleared over 300 single use device types for reprocessing, we urge the agency to help educate hospitals on the availability of such products so that they may more greatly build resilience into their own supply chains by maximizing the value of their existing products via FDA regulated reprocessing programs. *An FDA webpage as a resource identifying which devices have been cleared for reprocessing would be helpful, particularly if it focused on devices for which there are threatened supply chain disruptions*. Some manufacturers are reporting to customers that supply disruptions are likely to occur for devices with chips used in laparoscopic surgery and in the electrophysiology lab. We urge FDA to take specific action to alert hospitals to the additional supply option that exists by reprocessing.

We appreciate this opportunity to further amend our verbal comments made during the public workshop and hope the agency will consider these measures as it contemplates all potential mechanisms at its disposal to address the healthcare supply chain.

Thank you,

Dan Vukelich, Esq.
President
dvukelich@amdr.org

---

[1] AMDR, "Hospitals Reprocessed over 31 Million "Single-Use" Medical Devices in 2020," December 28, 2021.

[2] Eckelman MJ, Haung K, et. al (2020) Healthcare Pollution and Public Health Damage in the United States: An Update, **Health Affairs** 39:12. 2071-2079.

[3] Schulte A, et. al., Combining Life Cycle Assessment and Circularity Assessment to Analyze Environmental Impacts of the Medical Remanufacturing of Electrophysiology Catheters, **Sustainability**, 2021, *13*(2), 898.

[4] AMDR, *supra* 1.

[5] European Commission, Circular Economy: Definition, Importance and Benefits. *See also*, Ellen Macarthur Foundation, Circular Economy Introduction.

[6] Amy Feldman, Supply-Chain Snags Create Shortages Of Lifesaving Medical Supplies In U.S., **Forbes**, May 3, 2022. *See also*, Bjorn Finke, Are Heart Valves and Catheters Becoming Scarce? **Sueddeutsche Zeitung**, July 5, 2022.