Agency for Healthcare Research and Quality (AHRQ's) Role in Climate Change and Environmental Justice:
Suggestions from the Association of Medical Device Reprocessors

AMDR
ASSOCIATION OF MEDICAL DEVICE REPROCESSORS

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The Association of Medical Device Reprocessors (AMDR) is the global trade association representing the interests of regulated, commercial medical device reprocessing companies. We respectfully submit these comments in response to the above-referenced docket. We provide answers to questions 1,-3 and 8-11. Though, as many concepts have considerable overlap, we opted to provide a short list of our recommendations below.

We also attach a background document (*The Reprocessing Solution: Reducing Greenhouse Gas Emissions and Lowering Healthcare Costs*) that offers foundational information about the existing, regulated use of reprocessed "single-use" devices (SUDs) in over 10,000 hospitals in the US, Canada, in a number of EU countries, the UK, and Japan.

FDA has cleared over 300 types of devices (consisting of thousands of models) to be reprocessed: devices that are labelled by their manufacturer for "single-use," but can safely be collected, shipped, traced, cleaned, tested, disinfected/sterilized, repackaged, returned to hospitals, and re-used – without the clinician having to change treatment approach or device preference. Although our members report that they reprocessed nearly 32 million devices to hospitals in 2020, we know this to represent a small fraction of the number of devices that could be reprocessed and put back into a safe regulated, circular economy for healthcare products.

FDA has exerted its oversight authority over this practice for 22 years. All reprocessed SUDs must be cleared or approved as safe and effective, meeting the same requirements as originally marketed devices. With over 20 years of reprocessing programs at thousands of American hospitals, there is no known increased risk to patient safety. In fact, FDA and independent data indicate that reprocessed devices may fail *less* because faulty, new devices are discarded and removed from the reprocessing stream and because reprocessors test or inspect every device.[1]

We strongly encourage reading the background document to be better informed on the history, regulatory framework, and the urgent need to strengthen US healthcare supply chains, reduce emissions and control costs through the safe reprocessing of these products. We believe medical device reprocessing is a well-established, proven circular solution that can ensure immediate, measurable benefits. A more circular economy in health would defy the traditional "take-make-dispose" mentality to resource consumption that pervades healthcare. A regenerative approach to product usage can help us to consume less, preserve the environment and reduce costs.

FDA and most medical device regulatory authorities incentivize manufacturers to label devices for single-use. Not only do manufacturers sell more devices because of their decision to label devices for single-use, but the premarket regulatory burden is less. This incentivizes original equipment manufacturers (OEMs) to promote wastefulness, from both an environmental and budgetary standpoint. Specifically, manufacturers submitting devices marked for single-use

[1] Loftus T, A Comparison of the Failure Rate Between Original Equipment Manufacturer and Reprocessed Single-Use Energy Devices," **ASME Journal of Medical Devices** (August 2015). *See also*, U.S. **Government Accountability Office**, GAO-08-147, Reprocessed Single-Use Medical Devices: FDA Oversight Has Increased, and Available Information Does Not Indicate That Use Presents an Elevated Health Risk (January 2008), at 21.

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need not validate cleaning or sterilization protocols. They need not write cleaning or reprocessing instructions. They rely on the end user simply throwing the device away.

The reality, however, is there is no "away." Instead, the spent device becomes the hospital and local community's problem. This wasteful mindset contributes to the over 80% of healthcare emissions – those that originate from the supply chain. Disposal of SUDs contributes to a shocking amount of costly medical waste that is often incinerated, creating greenhouse gas and other toxic emissions that are known to make humans sicker. Studies show people living near incinerators are nine times more likely to suffer from wheezing or coughs, and twice as likely to develop asthma and other respiratory diseases.[2]

In a field where care providers commit to "doing no harm," by failing to reduce Scope 3 emissions – especially where we have "low hanging fruit solutions readily available - we're unfortunately doing harm to the health of our population.[3]

In AMDR's comments below, we urge AHRQ to promote research, collaboration and innovation of circular economy solutions and value-based payment models that promote supply chain resiliency, and reduce healthcare supply chain emissions and costs.

Overview:
AMDR makes the following recommendations:

- **Fund and disseminate Life Cycle Assessment (LCA) studies of healthcare products to better inform healthcare purchasers** of the carbon emissions associated with disposable versus reusable or commercially reprocessable products. AMDR urges AHRQ to, in the scope of its Life Cycle Assessments or other research, encourage independent product evaluations to also:
    a. assess supply chain vulnerabilities that may be associated with disposable medical equipment as compared to an alternative to that product;
    b. include cost comparisons, such as
        i. head-to-head prices for comparable disposable versus reusable or reprocessable products;
        ii. lifetime costs (or full life cycle or "cost per use") of products; and
        iii. disposal costs, incurred by health institutions, for the proper disposal of disposable equipment versus reusable or reprocessable version; and
    c. assess how the lowering of supply chain costs associated with longer life cycle products may be used to provide more equitable, quality and affordable care to a wider array or underserved patient populations. We urge AHRQ, for example, to investigate greater surgical intervention potential associated with cardiac ablation procedures, for example, if prices were lowered for the diagnostic medical devices (we believe that in the US, there is an underserved population of potential patients due to costs). Further AHRQ could advise hospitals that savings from reprocessing could be used to offset the cost of additional environmental remediation efforts.

- **Advise US healthcare facilities of "best practices" to improving supply chain reliability, promoting products with preferential life cycle assessments, and lower long-term cost**. Suggestions include:
    a. Coordinate with group purchasing organizations (GPOs) to identify impediments for using more environmentally sustainable medical device options and advise on

[2] Waste Incineration and Public Health, National Academy Press, ISBN 0-309-06371-X, **National Academy of Sciences**, 2000, p. 120.

[3] Scope 3 emissions are the result of activities from assets not owned or controlled by the reporting organization, but that the organization indirectly impacts in its value chain. Scope 3 Inventory Guidance, **US Environmental Protection Agency.**

policies to help overcome roadblocks. Our members can also help to explain these barriers.

b. Identify and highlight existing circular economy business models, including medical device reprocessing, to help address Scope 3 emissions in healthcare. We hope AHRQ will evaluate such programs for their supply chain, environmental and cost benefits.
c. Focus first on "wins" or immediate, easy to adopt supply chain "best practices" that will provide guidance to hospitals across the country on reducing Scope 3 emissions at US-funded healthcare delivery networks, particularly the Veterans Health Administration — the only US integrated delivery network not reprocessing its SUDs with FDA regulated reprocessors.
d. For federally run or reimbursed health institutions, require participation in FDA regulated reprocessing programs or other existing circular economy solutions, as a means of seizing "low hanging fruit," and to begin to move institutions into greater adoption of circular business models.

- **Collaborate with the Federal Trade Commission and the Food and Drug Administration** in efforts to address "repair restriction" issues as they relate to healthcare products. We urge AHRQ to issue a report to compliment FTC's "Nixing the Fix: An FTC Report to Congress on Repair Restrictions."
    a. Specific to healthcare, we urge AHRQ to investigate forced obsolescence practices used by healthcare manufacturers to intentionally limit device use and require greater healthcare acquisitions and source consumption;
    b. AMDR encourages AHRQ to collaborate with FDA to specifically look at overuse of the "single-use" label in healthcare as a means of identifying opportunities to promote greater life cycle and value from taxpayer paid for medical devices and equipment. We hope AHRQ can work with FDA to prioritize reuse and reprocessing options over single-use and undo the strong regulatory incentive to market products as disposable; and
    c. In the absence of any regulatory controls over forced obsolescence, AMDR urges AHRQ to prepare a report to healthcare purchasers so they may make more informed purchasing decisions and to allow healthcare delivery organizations to exert counterpressure to the linear sales models placed upon them by the current industry.

- We urge AHRQ **to investigate ways to independently and without market influence, "certify" environmentally preferrable products** (such as those for which a Life Cycle Assessment has been conducted AND evaluated, objectively, by the agency) as a means of addressing "green washing," or specious manufacturer environmental claims. We urge AHRQ, consistent with waste reduction paradigms, to prefer reuse functions, like reprocessing, over end-of-life options, like recycling.

- AHRQ's unique research, data/analytics and practice improvement focus make the agency well suited to begin to **develop the metrics that CMS should implement to reward value, not volume, in medical device and supply purchases.** AMDR urges AHRQ and CMS to adopt value-based payment incentives for the use of environmentally preferrable products.

Answers to Questions:

1. What should AHRQ's role be at the intersection of climate change, healthcare, and environmental justice to maximize the agency's impact?

AMDR believes that AHRQ can serve as the driving force for urgently implementing an evidence-based approach to reducing greenhouse gas emissions from the American health

sector. AHRQ can begin by serving as a clearinghouse that identifies, organizes and disseminates published literature on the subject to guide purchasing patterns and behavior at US health facilities. Further, AHRQ can best lead near term efforts to fill gaps where evidence is needed to provide guidance for the health sector on building more resilient healthcare supply chains and reducing healthcare emissions and costs. Specifically, AMDR urges AHRQ to identify funds and/or fund Life Cycle Assessment studies that assess comparable products with the aim of better informing purchasers. To further guide hospital purchasing decisions, Life Cycle Assessment evaluations should also include costs: up front, head-to-head costs for comparable products, total life cycle costs and disposal costs for medical equipment.

2. How can AHRQ incorporate climate change and environmental justice issues into its core competencies of healthcare systems research, practice improvement, and data & analytics?

Research
In addition to establishing a greater cache of evidence of environmentally preferrable products by funding greater Life Cycle Assessments of healthcare products, AHRQ's unique research, data/analytics and practice improvement focus make the agency well suited to develop the metrics that CMS should implement to reward value, not volume, in medical device and supply purchases. AMDR urges AHRQ and CMS to adopt value-based payment incentives for the use of environmentally preferrable products. Value-based payment models should promote supply chain resiliency and reduce healthcare supply chain emissions and costs.

Data Sharing
Foundational work and research may be required to "certify" environmentally preferrable products, and will likely require a large volume of public input and cooperation from research organizations, think-tanks, hospital and device associations, or NGOs such as Healthcare Without Harm. "Greenwashing" in healthcare can be addressed by requiring LCA's, or other relevant research, to support environmental claims by device manufacturers. Ultimately, it is our hope AHRQ's work in this area will result in a certification system whereby healthcare products will have an "emissions" or similar rating. We seek a mechanism whereby healthcare purchasers will be able to make superior product choices for reducing greenhouse gas emissions.

Attention to Forced Obsolescence and Greenwashing
We also believe government should play a role in eliminating the growing practice of intentionally designing products for single-use, as it contributes to global warming through unnecessary take-make-waste processes. We propose AHRQ, or partnering agencies like FDA or FTC, recommend to legislators that agencies be given the authority to question technological changes to iterative generations of medical devices that contain suspected "forced obsolesce." "Kill chips," software "upgrades," the cheapening of materials used in construction, or intentional design mechanisms aimed at thwarting subsequent device repair or remanufacturing should not be allowed for consumer products such as cell phones and most certainly not for devices we use to treat and cure our patients.

We urge AHRQ to collaborate with FDA and FTC:

- When reprocessable versions of SUDs have achieved FDA clearance, FDA should be given the authority to question subsequent iterations of that device from the original manufacturer to ensure forced obsolescence measures are not being employed to needlessly make hospitals procure more devices. Software "upgrades" should be evaluated to reduce efforts to use the tactic to curtail environmentally preferable practices such as medical device reprocessing or repair/refurbishing;
- We urge AHRQ to report to health institutions when FDA has cleared or approved a product for reprocessing so they are aware of a competitive, circular option that can improve supply chain resiliency, reduce emissions, waste, and costs. We also urge AHRQ to collaborate with FDA to evaluate or justify, for healthcare purchasers who would not

otherwise know, the true advantageous or disadvantages with adopting iterative generations of equipment;

- We urge AHRQ to collaborate with FDA to elevate a new labeling claim for reprocessed or other circular medical device products to encourage circular solutions, instead of the current reusable or disposable solutions of a take-make-waste paradigm; and
- To the extent legally feasible, we urge AHRQ to explore empowering FDA, FTC, or NIST (or coordinate with them) to score products for their impact on reducing (or elevating) greenhouse gas emissions so healthcare consumers know the impact of these emissions for the products it clears for marketing and sales. At a minimum, the standard should be applied to government run or funded health facilities, which not only reduces Scope 3 emissions but also serves as an example to the private sector. Manufacturers make environmental claims now, some of which may be dubious. For example, some medical device manufacturers promote device "recycling" programs to counter lost revenue to reprocessors. Recycling is demonstrably a lesser environmental solution that has greater impact on the environment than reuse functions such as reprocessing. Requiring premarket public health impact and waste management assessments will help counter misinformation and make healthcare purchasers more informed about the full health and environmental impact of their medical device choices.

Because FDA and FTC review products and marketing claims made by manufacturers, they are in unique positions to weed out forced obsolescence and "greenwashing" by medical device companies. But, as FDA's mission is squarely focused on safety and effectiveness, no consideration is given to implications for the supply chain, waste/emissions or cost concerns. Further, FDA has unique, holistic oversight of both OEM and reprocessor devices as the Agency has access to both the OEM and reprocessor design files and submissions. We believe AHRQ collaboration with FDA may help bridge the divide, coupling for healthcare consumers safety and effectiveness determinations WITH product evaluations that also contemplate the supply chain, waste/emissions and cost.

Marketplace stakeholders like hospitals, medical device companies and reprocessors, need a third-party, vendor-neutral arbiter to evaluate new products for their sustainability. Ignoring this "gaming of the system" whereby some manufacturers force needless additional consumption of new medical devices has contributed to the current supply chain crises, generates waste and emissions and drives up costs to the taxpayers.

3. What are the most pressing healthcare-related areas of climate change and environmental justice research and actions that AHRQ could address? Relatedly, what evidence do healthcare systems and policymakers need to make decisions on responding to climate change?

Foundationally, AMDR strongly urges AHRQ to focus on Scope 3, or supply chain-based emissions, as the evidence demonstrates that it is the supply chain which accounts for over 80% of all greenhouse gas emissions in healthcare.[4] AHRQ should evaluate, through well-designed Life Cycle Analyses, a comparison between various products and coordinate with related regulatory authorities, as necessary, to make recommendations for those with the lowest possible footprint, products that demonstrate less overall waste and cost. As per the outline above, AMDR believes that LCAs, and supply chain reliability, full life cycle costs and waste disposal costs are the data points currently missing to help healthcare systems make better purchasing decisions.

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

Second, there is immense lost opportunity now, that requires little to no further research to address. While hundreds of thousands of medical devices are sent to commercial reprocessors each year (saving hospitals millions of dollars), even more are used once and thrown out, resulting in use of an additional original product on the next patient. AHRQ's role in data and analytics can shed light on lost opportunities to federally funded facilities and such data, shared with the public sector, can spur more responsible spending. **AMDR members' internal analysis finds this number to be about $2.5 billion from hospitals in the U.S. that do not reprocess as many devices as they could**. These savings could be plowed back into more costly remediation efforts required to reduce climate change from the health sector.

As ne example, the largest hospital system in the country represents the use once and waste mindset. The Veterans Health Administration (VHA), refuses to use any reprocessed devices, spiking their greenhouse gas emissions (and increasing procedure costs unnecessarily). AMDR notes that the VHA is the only health system in the country NOT availing itself of FDA regulated, reprocessed devices. We would like AHRQ to advise or require the VHA, DoD and HHS-regulated or reimbursed hospitals, to implement evidence-based, Scope 3 emissions reduction programs to identify environmentally preferrable solutions like reprocessing.

Third, as a condition of participation in CMS reimbursement programs, hospitals should be expected to act more prudently in controlling waste, cost, and, now more than ever, securing a resilient supply chain. AMDR urges AHRQ to condition reimbursement participation in CMS programs upon hospital adoption of reprocessing programs. By requiring hospital participation in FDA regulated reprocessing programs, US healthcare could improve supply chain reliability by keeping devices "at home" (and not relying exclusively on imports from abroad), reduce waste, emissions and waste disposal costs, and save billions of dollars a year.

Fourth, AMDR urges AHRQ to research and introduce waste management responsibilities into the medical device supply chain for the above noted institutions, with a focus on minimizing needless purchasing of devices when reusable/reprocessed equivalents exist. We urge AHRQ to:

- Provide unbiased information to health institutions to help them assess the "true cost" of a medical product (its per use cost and end of life disposal, included);
- contemplate mechanisms that would make producers responsible for the end-of-life waste disposal costs associated with America's disposable healthcare culture; and
- require end of life greenhouse gas emissions estimates from manufacturers as part of premarket product evaluations.

Therefore, AMDR encourages AHRQ to assess the environmental and financial costs of disposal of products as these (along with the emissions associated with their incineration) fall to hospitals and adversely impact local communities.

Fifth, AMDR urges AHRQ to create an independent, evidence-based "Best Sustainability Practices" document for hospital purchasers focused on limiting Scope 3 emissions. This could integrate assessments from Healthcare Without Harm and other reputable nonprofits who have already studied some drivers of Scope 3 emissions.

8. What key research has been conducted to assess or mitigate the impact that healthcare has on climate change? What are effective strategies to measure and reduce the carbon footprint and other environmental impacts of the healthcare sector?

As noted above, AMDR urges AHRQ to put research resources into product Life Cycle Assessments. To assess if medical device reprocessing is beneficial to addressing climate change, researchers from Germany's prestigious Fraunhofer Institute conducted an LCA of an electrophysiology (EP) catheter and found it to reduce ozone depleting emissions by nearly 90%, and climate change-specific emissions by over 50%, compared to using an original device. The

study was peer reviewed and published in the Journal Sustainability in January 2021.[5] More research is needed to confirm that these findings extend to *other types* of FDA-cleared, reprocessed SUDs. We recommend LCAs of noninvasive products like pulse oximeters, compression sleeves and transfer matts, and surgical tools like electrosurgical scalpels and trocars. The EP catheter LCA findings from Fraunhofer serves as a strong example as to where AHRQ could help intervene and immediately reduce greenhouse gas emissions substantially.

9. What has been learned about health systems' capacity and limitations during the COVID-19 pandemic that can help care delivery organizations better address climate change impacts and reduce disparities?

The pandemic has shaken US healthcare and the healthcare supply chain, revealing vulnerabilities, creating an alarming amount of medical waste and driving up costs. AMDR urges AHRQ to focus its research efforts on medical device and supply chain resilience, waste and cost. We believe that research focused in these areas will reveal that the linear economy and disposable culture that has emerged in US healthcare can be steered into circular models to improve supply chain reliability, reduce toxic medical waste, and save taxpayers' dollars. When hospitals use reprocessed devices they save money – typically 30 to 40% off the cost of original equipment. These savings can be put into environmental and pandemic remediation strategies.

Further evidence and shared knowledge with healthcare purchasers will foster greater healthcare commitments to product offerings such as reprocessed medical devices. Reprocessed products are circular in their model: by reprocessing, hospitals are required to buy less original equipment, reprocessing offers a more localized manufacturing, and reprocessing costs less than buying new. Each of these variables reduce healthcare reliance on a global supply chain and instills greater reliability for healthcare product availability.

10. How might AHRQ take advantage of the existing national infrastructure to advance quality and safety (e.g., measurement standards, accrediting bodies, learning networks, incentives) to accelerate work on climate health and equity?

We urge AHRQ to avail itself of the data being produced in global sustainability reports from Healthcare Without Harm. We further urge AHRQ to work collaborative with FDA and FTC on device "forced obsolescence" issues, and with CMS on value-based payment incentives for environmentally preferrable products. Further, as there are ISO standards that are widely accepted for Life Cycle Assessments, we urge AHRQ to steer research dollars for LCAs using those widely accepted standards to promote better product evaluation inclusive of total product life cycle.

As SUD reprocessing is already regulated by FDA, and US hospitals are aware of the requirements placed on them and commercial firms, this is a low hanging fruit solution to drastically and rather abruptly improve health, environmentally emissions, cost and supply chain reliability. Further, as the whole of government moves to adopt more circular solutions, we believe placing value-based incentives on reprocessing will spur further growth in other areas of healthcare.

11. Which organizations working on climate change response in healthcare should AHRQ learn from and collaborate with? Please describe the nature of the organization's work, evidence, and solutions, as applicable.

We urge collaboration with the National Academy of Medicine's Action Collaborative on Decarbonizing the Healthcare Sector. Professor Jodi Sherman at the Yale University School of

[5] 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.

Public Health, Professor Andrea MacNeil and the Planetary Healthcare Lab at the University of British Columbia, and Professor Cassandra Thiel at NYU Langone Department of Population Health are all well respected and well established authorities in the field of medicine and sustainability. Healthcare Without Harm is a leading non-governmental organization working toward the reduction of greenhouse gas emissions in hospitals and health centers worldwide that also makes meaningful contributions to the space.

The United Kingdom's National Health Service (NHS) promotes the use of reprocessed (referred to as "remanufactured" in the UK and Europe) devices as part of its Net Zero commitment. An interview reprinted below with Alan Wain, Chief Operating Officer for Supply Chain Coordination, National Health System UK offers a look into the Scope 3 commitments we would like to see from the US VHA, DoD, and HHS. NHS Remanufacturing Guidelines attached. See also, Enterprise Ireland report on the need to create sustainable, circular business models within the medical technology industry.

Thank you and sincerely,

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See attached: Enterprise Ireland report and NHS Guidelines on Remanufacturing.