AMDR Comments to the European Commission's Inception Impact Assessment on Empowering the Consumer for the Green Transition

The Association of Medical Device Reprocessors (AMDR) appreciates the Commission's efforts to promote a green transition. We welcome the opportunity to provide feedback to the Inception Impact Assessment on Empowering the Consumer for the Green Transition. AMDR strongly encourages the Commission to amend existing consumer protection legislation OR create a new stand-alone consumer protection instrument.

Further, we urge the Commission to include health care consumers — the individuals who make purchasing decisions at hospitals and health care systems that have enormous impact on environmental performance, and thus health care products — within the scope of this work. The European Environmental Agency recently identified air pollution as a top environmental health challenge in the EU. The health care sector is a major source of pollution. The World Health Organization points to the incineration of health care waste as a source of dioxins, furans, and particulate matter emissions that pollute our air.[1] Additionally, health care's contribution to greenhouse gas emissions (GHG) has been studied and linked to acid rain, photochemical smog, and respiratory disease. These studies suggest health care itself is making people sicker.[2]

Hospitals and patients are both consumers, and they deserve to know the environmental impact of the medical decisions (and products used to implement these decisions) they make.

AMDR members, located in Europe and the United States, are professional medical device reprocessing and remanufacturing companies, subject to the European Union's Medical Device Regulation's (MDR) (2017) requirements, ensuring that remanufactured medical devices meet the same safety and efficacy standards as original equipment. Specifically, Article 17 of the EU MDR sets forth requirements

[1] World Health Organization, *Health-Care Waste,* https://www.who.int/news-room/fact-sheets/detail/health-care-waste 8 February 2018.
[2] Eckelman, MJ, Sherman, JD, 2018. *Estimated Global Disease Burden from US Health Care Sector Greenhouse Gas Emissions*, **American Journal of Public Health** 108 (S2), S120-S122 (April 2018): https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5922190/#bib2

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for "single-use" device (SUD) reprocessing and requires commercial firms to meet manufacturer standards, thus adoption of the term "remanufactured" in Europe. AMDR members are independent of original equipment manufacturers (OEMs) and subsidiaries of OEMs.

Health care delivery is particularly expensive and toxic. However, hospitals can contribute to more sustainable consumption in their own activities in order to reduce environmental, occupational and public health problems arising as a result of such activities., Solutions such as medical device remanufacturing help promote a more resilient, cost-effective, and environmentally sustainable health care supply chain. Medical device remanufacturing also builds a circular health care economy, creating jobs in the EU and keeping financial resources at home, within health institutions, rather than spent on unnecessary supplies from a global supply chain. Unfortunately, Europe has been slow to adopt this solution.

We ask the Commission to consider inclusion of health care consumers in its plans to promote more circular economies in Europe, to introduce SUD remanufacturing, to address impediments to greater growth of a circular economy for medical devices, and to address the three core prongs of the Impact Statement as it relates to medical device remanufacturing.

Our detailed comments can be found in the attached document.

The Need to Bring Circular Economy Initiatives to the Health Care Supply Chain

Health care delivery is particularly unsustainable: how it currently uses and disposes of majority of products is emblematic of our linear economy. Expanding the circularity of products and materials used in the medical sector needs to be supported. The COVID-19 crisis has fueled the health care waste crisis.

While we recognize that the intention of the Commission is to provide treater protection to the individual when they are purchasing a product, significant sources by considering guidance for the individuals at hospitals who manage purchasing decisions. We respectfully request consideration of guidance to hospital purchasing representatives to inform these individuals on the ease with which they could choose environmentally preferable options including remanufactured medical devices labelled for single use.

The pandemic is generating tons of additional medical waste as clinicians dispose personal protective Equipment (PPE) and ancillary medical devices used on COVID patients.[3] The strain on the health care supply chain has led to shortages of desperately needed PPE and other medical devices. Further, beyond shortages,

[3] Calma, Justine, *The COVID-19 Pandemic Is Generating Tons of Medical Waste*, **The Verge**, 26 March 2020: https://www.theverge.com/2020/3/26/21194647/the-covid-19-pandemic-is-generating-tons-of-medical-waste

there are now additional costs associated with these unprecedented demands, additional waste, additional waste disposal costs and the obviously adverse environmental costs.

Sadly, health care was environmentally wasteful well before COVID-19. Health Care Without Harm (HCWH) estimates that "if the global health care sector were a country, it would be the fifth-largest greenhouse gas emitter on the planet."[4] Their report notes that the "lion's share of emissions—71% are primarily derived from the health care supply chain through the production, transport, and disposal of goods and services," including "medical devices, hospital equipment, and instruments." These findings are premised and corroborated in peer-reviewed publications.[5] HCWH calls on Europe to "decarbonize the health care supply chain. Health ministries, hospitals, and health systems should set criteria for low-carbon or zero emissions procurement. Suppliers and manufacturers should decarbonize their operations and products."

A disposable culture has emerged in hospitals and surgical centers in recent decades, predicated on the false belief that many medical instruments can only be used once, or hospitals are at risk of exposing patients to infections. The shift to disposable products has contributed to a mountain of waste generated by hospitals.

Background on Medical Device Regulation and Labeling

With the advent of better plastics in the early 1980s, and the then threat of the little understood HIV virus, the market for disposable medical devices exploded. The Commission addressed the shift to single-use medical devices in the 1980s in its 2010 report on SUD reprocessing.[6] A culture in health care has since enshrined the belief that disposables are safer, less expensive and more convenient.[7] Only in recent years have environmental Life Cycle Assessments demonstrated this to often not be true.

From a regulatory perspective, medical device requirements have traditionally looked at devices as either "reusable" (multiple-use devices) or disposable (single-use devices). This black or white paradigm assumes no gray area; a medical device is essentially reusable indefinitely, assuming the reprocessing technicians in

[4] *Health Care's Climate Footprint: How the Health Sector Contributes to the Global Climate Crisis and Opportunities for Action*, **Health care Without Harm**, September, 2019: https://noharm-global.org/sites/default/files/documents-files/5961/HealthCaresClimateFootprint_092319.pdf

[5] *See,* Eckelman MJ, Sherman J (2016) Environmental Impacts of the U.S. Healthcare System and Effects on Public Health. **PLOS ONE** 11(6): e0157014. doi:10.1371/journal.pone.0157014 and Eckelman MJ, Sherman JD and MacNeill AJ 2018 Life cycle environmental emissions and health damages from the Canadian health care system: an economic-environmental epidemiological analysis **PLOS Med**. 15 e1002623.

[6] European Commission, Report from the Commission to the European Parliament and the Council, Report on the Issue of the Reprocessing of Medical Devices in the European Union, in Accordance with Article 12a of Directive 93/42/EEC, 27 August 2010.

[7] Chahaun, MN, et.al, *Use of Plastics Products in Theatres in NHS and Environment Drive to Curb Use of Plastics*, World Journal of Surgery and Surgical Research, http://www.surgeryresearchjournal.com/pdfs_folder/wjssr-v2-id1088.pdf, 9 January, 2019.

hospitals adequately disinfect, clean, and sterilize the equipment in compliance with the reprocessing instructions provided by the OEM. Alternatively, a device is marketed as disposable or for single-use and can only be used on one patient.

Manufacturers clearly develop many disposable medical devices out of infection control concerns. Inadequate reprocessing of devices in the hospital setting can create cross-contamination, and thus hospital-acquired infections amongst patients. But manufacturers also have an enormous incentive to label devices for single use. First, to market a device as reusable under the MDR, the manufacturer needs to submit validated cleaning and reprocessing instructions to a Notified Body.[8] Simply labeling a device for single use is far less expensive and time consuming than labeling as reusable. Second, by marking devices for single use, manufacturers create an unending demand for their product. Medical device sales representatives and the companies that employ them make more money the more products they sell. Thus, in Europe and the United States, a medical device may become "single use," by default, because the manufacturer chose NOT to do a cleaning validation. As a U.S. Government Accountability Office Report concluded:

> **"… the decision to label a device as single-use or reusable rests with the manufacturer. If a manufacturer intends to label a device as reusable, it must provide data demonstrating to FDA's satisfaction that the device can be cleaned and sterilized without impairing its function. Thus, a device may be labeled as single-use because the manufacturer believes that it cannot be safely and reliably used more than once, or because the manufacturer chooses not to conduct the studies needed to demonstrate that the device can be labeled as reusable."[9]**

Beginning in the 1980s, but later influenced by the European Medical Device Directive of 2007,[10] OEMs began to change the labels on some medical devices from "reusable" to "single-use." Originally, this shift in labeling was not required by EU authorities or the U.S. FDA. Indeed, to this day, no agency of which AMDR is aware, requires any device to carry a single-use label. As OEM documentation from this time demonstrates, it appears that, in some cases, device labeling was changed

[8] Article 52, **Conformity Assessment Procedure,** subsection 7(c), Annex I, General Safety and Performance Requirements, Chapter II, Requirements Regarding Design and Manufacture, subsection 11.2, Chapter III, Requirements Regarding the Information Supplied with the Device, subsections 23.4(k) and 23.4 (n) from European Regulation 2017/745 of the European Parliament and of the Council, 5 April 2017, On Medical Devices, Amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and Repealing Council Directives 90/385/EEC and 93/42/EEC, *hereinafter,* Directive *See also*, **Compliance and Enforcement Group (COEN)**, Instructions For Use for Reusable and Re-Sterilisable Medical Devices, 2014.

[9] 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 1 (emphasis added) [hereinafter 2008 GAO Report].

[10] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, amended by Directive M5, 2007/47/EEC of the European Parliament and of the Council of 5 September 2007.

from "reusable" to "single-use" without any significant design, performance or material changes to the devices that would preclude safe reuse.[11]

This change in labeling was perceived by many hospitals for what it was—a marketing strategy aimed at increasing sales of new products. It was clear that certain devices designated by OEMs as "single use" could be safely reprocessed/remanufactured. Hospital skepticism of the single-use label was noted in a 2000 GAO Report. According to the report, health care personnel "distrust the single-use label for some devices" because, among other things, the regulator "cannot require manufacturers to support the designation of a device as single-use," and "they perceive that manufacturers have an economic incentive to market devices as single-use that could just as well be sold as reusable."[12]

In part to address this hospital skepticism, the EU instituted new requirements with the Medical Device Directive amendments of 2007. To address inconsistencies in product labeling across the community, the 2007 amendment to the Directive requires that, "if the device is intended for single-use, … [a] manufacturer's indication of single-use shall be consistent across the Union."[13] This well-meaning regulatory requirement provides further incentive for device companies to market their devices for single-use.

The environmental impact of decisions to encourage single-use devices should not be minimized. In the U.S. and Canada, 7.2 million kilograms of single-use devices were diverted from landfills and incinerators through regulated reprocessing (remanufacturing) programs in 2018 alone.[14]

The financial and environmental costs associated with this disposable culture are astounding

Current European regulations create incentives to make devices disposable, and no incentives exist to make devices reusable—or to remanufacture them. Further, while the MDR now opens the door to the marketing of remanufactured medical devices (see Article 17.1 and 17.2), Member States can elect to NOT allow such products in their territories (Article 17.1, 9) as the MDR requires that not only must remanufactured versions of medical devices meet the same requirements as new

[11] AMDR records on file of manufacturer communications to hospital clients on change of labeling. See, e.g., Letter from Brian Dowling, Product Manager, USCI Cardiology & Radiology Products (July 24, 1980) (explaining that, although USCI was changing the label on its intracardiac electrodes from "reusable" to "single use," "our manufacturing processes . . . have not changed. These electrodes are made with the same materials and in the same manner as they have been in the past"). *See also,* Letter from Geoffrey M. Allen, Boston Scientific Corp., Microvasive Division (May 1, 1987), at 2 (informing a hospital that its "BICAP® Hemostatic Probes are recommended for single use only. However, this recommendation does not prohibit reuse under certain specific conditions. . .").
[12] U.S. Government Accountability Office, GAO/HEHS-00-123, Single-Use Medical Devices: Little Available Evidence of Harm From Reuse, but Oversight Warranted (June 2000), at 11 [hereinafter 2000 GAO Report].
[13] Directive, Annex I section 23.2(n) of Directive 93/42/EEC
[14] AMDR http://amdr.org/reprocessing-by-the-numbers/

devices, but they must also be allowed on the individual Member State markets, as permitted by national law. See further discussion below.

Despite this critical analysis of the SUD label and existing regulations, AMDR supports the cornerstone principle of the MDR's Article 17, which concludes that reprocessing of SUDs is manufacturing, and thus subject to the same requirements as any other medical device placed on the market. This regulatory vehicle ensures a path to market for device companies wishing to offer environmentally beneficial remanufactured device options. However, we urge the Commission, as outlined below, to contemplate how health care consumers can, in the context of the Impact Statement, be assured greater transparency and given additional tools to make more prudent medical device choices.

Remanufacturing Certain Medical Devices – The Easy, Sustainable Change

Solutions such as medical device remanufacturing help promote a more resilient, cost-effective, and environmentally sustainable health care supply chain. Medical device remanufacturing also builds a circular health care economy, creating jobs in the EU and keeping financial resources at home, within health institutions, rather than spent on unnecessary supplies from a global supply chain. However, Europe has been slow to adopt this solution.

Consistent with the objectives and policy options currently contemplated, we urge the Commission to include health care consumers (i.e., hospitals, medical professionals, purchasers, and the like) in the scope of any future initiatives aimed at promoting the circular economy. Medical device remanufacturing is one immediate, regulated solution that can "facilitate preparing for re-use and recycling of waste in the EU."[15]

Promoting these initiatives will "generate additional economic activities in the sectors of recycling and trade/transport of recycled materials, especially within the EU,"[16] and promote the generation of high-tech, medical technology sector jobs such as biomedical and mechanical engineers, collections technicians, and cleaning and sterilization professionals. This will incentivize development of a larger EU medical device remanufacturing industry or encourage the manufacturers "to become more circular, resource-efficient and reduce their carbon footprint, in line with the climate and energy goals of the EU."[17]

[15] European Commission, Inception Impact Assessment, Waste Shipments – Revision of EU Rules, 2020.
[16] *Id.*
[17] *Id.*

Reliable and Relevant Information at Point of Sale

AMDR encourages the Commission to include medical devices in the revision of any existing policy instruments on products' environmental performance. In health care, as in other sectors, consumers often lack reliable, consistent, or relevant environmental characteristics data. Further, there is a false perception that regulated, remanufactured SUDs may be inferior to new devices, despite both being subject to the same safety and efficacy standards.

Information from the Commission to health care consumers on what it means to be a remanufactured SUD would greatly assist already overwhelmed hospitals as they make medical device purchasing decisions. As the Impact Statement specifically addresses three subcategories of concerns, we provide brief comments below related to medical device consumers:

Product Sustainability

AMDR is unaware of any uniform mechanism by which to identify environmentally preferable options. AMDR is aware of efforts by Health Care Without Harm to promote environmentally preferable options in health care,[18] but no "green certification" exists. The development of a uniform "Green" seal, of course, is no small undertaking, but should the Commission seek to revise existing policy instruments to make products' environmental performance available, AMDR would greatly support such an initiative. We believe device manufacturers would thereby be appropriately incentivized to make medical devices that allow the consumer to get more value or lifespan from devices, and thereby create less medical waste.

Availability of Repair Services

AMDR supports more information on the availability of repair, reprocess, or remanufacturing options. Broadly speaking, if a remanufactured equivalent of an existing medical device achieves a Conformite Europeenene (CE) mark, indicating conformity with health, safety, and environmental protection standards for products sold in the EU, AMDR greatly supports making that information available to all health care consumers, perhaps making this information required in the labeling of both new and remanufactured medical devices. This would encourage medical device makers to extend the life of medical devices, rather than generate more wasteful, disposable options. Such a move would foster the growth of European remanufacturing operations rather than rely on the import of disposables from Asia.

[18] https://noharm-europe.org/

Software Upgrades/Updates

One of the biggest threats to a Circular Economy for medical devices is OEM use of software "updates" or "upgrades" that have the intended effect of preventing remanufactured versions of medical devices from working with consoles or generators. OEMs make both the consoles/generators and the instruments used with them. By manufacturing the devices with microchips and updating the software on the generators, some OEMs are cutting out competition and increasing a hospital's reliance on the OEM by preventing remanufactured versions of medical devices from working. AMDR believes this activity is anticompetitive and wasteful. AMDR has received reports that hospitals' generators and consoles have had their software upgraded without the hospital's permission. AMDR has created the resource at link (and cited below) to address this issue in further detail and to provide instruction for hospitals on how to combat unwanted software upgrades.[19] AMDR supports any Commission initiative to strengthen health care consumers' rights when it comes to software updates or upgrades.

Commercial Practices that Cause Confusion and Misinformation to Dampen the Purchase of Remanufactured Medical Devices

In addition to software upgrades or updates aimed at ensuring hospitals buy more unnecessary equipment, AMDR believes the use of EPROM microchips in the handles of surgical and diagnostic medical devices are being used for the same purpose. Employed based on asserted "patient safety" claims, these chips are inserted to shut the device off after a single use. AMDR has evidence that an OEM with its own reprocessing/remanufacturing division, includes such chips, not just to discourage remanufacturing, but to discourage remanufacturing with competing vendors. AMDR has also created a resource on this topic to address the issue and provide instruction for hospitals on how to avoid unwanted device upgrades with new microchip-enabled forced obsolescence.[20]

New iterations of devices are consistently placed on the market, often with little to no evidence of improved performance, cost, or other positive variables necessitating adoption of newer generations. Health care consumers have had little option but to accept the latest model medical equipment, which often means accepting devices that have wasteful, built-in planned obsolescence. This dramatic tilting of the scales in favor of the device companies disfavors health care consumers, patients,

[19] AMDR, Software "Updates" Aimed to Thwart Reprocessing, 19 April 2018.
[20] Forced Obsolescence Designed Into Devices, AMDR, 19 April 2018.

and taxpayers, creating additional unnecessary manufacturing of original devices when more environmentally sustainable remanufacturing could be used. The incentives placed on manufacturers are to sell more, not develop better, longer lasting, and more environmentally sustainable products. Education for health care consumers on forced early failure efforts by device companies would provide a strong counterbalance to the power of the device industry and would encourage such manufacturers to be more holistic in future medical device development and design.

Effective Enforcement of Consumer Protection Rules

First, Directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE) exempts electronic medical devices if they are "expected to be infective prior to end of life."[21] Commonly remanufactured single-use electronic devices include diagnostic and ablative cardiac catheters, laparoscopic electrosurgical instruments such as trocars and ultrasonic scalpels, and even pulse oximeter sensors and ECG leads.[22] AMDR does not believe a continued broad-based exclusion for medical devices is warranted, and provides further incentive for medical device makers to make more SUDs while discouraging more sustainable remanufacturing.

Second, should the Commission revisit existing consumer law (the UCPD and the CRD), we would support inclusion of consumer protections against unwanted software "updates" and unsought technological "upgrades" to force obsolescence into medical devices, as unfair commercial practices. While also a major undertaking, AMDR supports a broad-based set of specific rules and/or guidance to counter all types of manufacturer early failure efforts (forced obsolescence).

The Opt-In Process Unfairly Discriminates Against a Healthier EU

Finally, as eluded to earlier, the existing EU regulation for Medical devices places an unlevel regulatory burden on medical device remanufacturing, thus discouraging a circular economy in the medical device sector.[23] While medical devices must bear a CE mark to be lawfully marketed, indicating conformance with the Regulation or

[21] Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on Waste Electrical and Electronic Equipment (WEEE), recast.
[22] For samples of such devices, please see AMDR members' various product pages: Vanguard (Berlin), Arjo/Renu (Everett, Washington, corporate HQ, Malmo, Sweden), Innovative Health (Scottsdale, Arizona), Medline ReNewal, a Medline company (Redmond, Oregon), Northeast Scientific (Waterbury, Connecticut), Stryker Sustainable Solutions (Phoenix, Arizona) and Sustainable Technologies, a Cardinal Health Business.
[23] *See* Article 17.1, "reprocessing and further use of single-use devices may only take place where permitted by national law and only in accordance with this Article . .", Regulation (EU) 2017/745 of the European Parliament and of the Council, 5 April 2017, On Medical Devices, Amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and Repealing Council Directives 90/385/EEC and 93/42/EEC.

Directive's requirements, EU Member States must also affirmatively "opt in" to allowing remanufactured devices within their territory.

This anti-competitive measure runs counter to sound science and good environmental policy. To allow Member States to supplant their judgement, without evidence or any review of the scientific data ordinarily required of a product seeking to be placed on the market, undermines the purposes of the EU MDR and circumvents the normal Notified Body procedure. This also runs afoul of decades of EU law that allows CE marked products to be marketed across the Union. AMDR can find no other example where a carve out exists in EU regulations whereby Member States are allowed to prospectively reject otherwise CE mark entitled products, absent any existing safety concerns (The Safeguard Clause (Article 8) of the MDD).[24]

This additional National law requirement deprives many in the EU of access to safe, lower cost and environmentally preferable medical device options. This "opt in" provision creates an enormous disincentive in Europe for hospitals to be good environmental stewards by remanufacturing their devices, despite Regulations ensuring the safety and efficacy of such products. We strongly urge the Commission to have this section of the Regulation re-evaluated and/or provide guidance and instruction to Member States on the safety and efficacy of medical device products, including remanufactured devices, that meet the MDR's requirements.

When it comes to remanufacturing of single-use medical devices, hospitals and patients can reduce environmental impact, reduce costs, build a more resilient supply chain and encourage a more competitive environment for healthcare products. But we need the European Commission to play an active role to make it so. We urge the Commission to consider remanufacturing of single-use medical devices to empower the consumer for the green transition.

Thank you for your consideration and for this opportunity to comment.

Sincerely,

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[24] Article 8, European Council Directive 93/42/EEC 14 June 1993 concerning medical devices.