AMDR Statement
U.S. International Trade Commission Hearing
February 28, 2012
U.S. Remanufacturing Industries, Markets and Trade

The Association of Medical Device Reprocessors (AMDR) appreciates this opportunity to participate in the U.S. International Trade Commission's hearing on Remanufactured Goods: *An Overview of the U.S. and Global Industries, Markets and Trade*.

AMDR Summary

AMDR is a Washington, D.C.-based trade association representing the legal, regulatory and legislative interests of the U.S.-based, Food and Drug Administration (FDA)-regulated, third-party reprocessors of medical devices labeled by the original manufacturer as for "single-use." AMDR estimates that its members perform approximately 95 percent of the third-party reprocessing in the U.S. today. AMDR's members serve a majority of U.S. hospitals including *all* of the honor roll hospitals, *i.e.,* the top 17 institutions nationwide as listed by *U.S. News & World Report* for 2011-2012. AMDR's members also serve *all* of the top 10 cardiovascular and heart surgery hospitals and 9 of the top 10 cancer and ear, nose and throat hospitals.

In today's environment, hospitals must grapple with increased demands for healthcare services and, at the same time, decreasing reimbursements. With the implementation of healthcare reform in the U.S. and the paradigm shift from volume-based to value-based healthcare delivery, the nation's third-party reprocessors (TPR) are positioned to lead the device industry in providing the same high quality medical devices, at greatly reduced prices. Like the generic drug industry, hospitals contracting with TPR firms provide an *immediate* savings opportunity with no compromise concerning the clinical safety or effectiveness of the medical devices on which hospitals rely.

In addition, TPR offers hospitals a solution to the growing problem of medical device waste. In March 2010, researchers at Johns Hopkins University reported that American healthcare facilities alone dispose of over four billion pounds of waste annually into landfills and commercial incinerators, making the U.S. health industry the second-largest contributor to landfills after the food service industry. Consistent with medicine's adage of "do no harm," America's third-party reprocessors are helping hospitals do less harm to the environment.

Worldwide, hospitals are in desperate need of safe, lower-cost and environmentally preferable medical devices. Hospital use of reprocessed medical devices is one of the most critically important ways that hospitals have been able to reduce medical device spending and decrease the amount of hospital-generated medical waste. With ever-increasing attention to healthcare costs across the globe, the U.S. medical device reprocessing industry is well poised to become a worldwide leader in lower-cost and environmentally preferable medical devices.

Industry Summary

Third-party "single-use" medical device reprocessors, such as AMDR's members, are *manufacturers* of "single-use" medical devices. In short, medical device reprocessors contract

with hospitals and surgical centers to collect previously used (and in some cases opened-but-unused) medical devices - labeled by their original equipment manufacturer as a "single-use" device (SUD). Using scientifically supported, FDA-accepted methods, they reprocess the devices for another "single-use." To reprocess a device safely, the manufacturer (third-party reprocessor) must *individually* decontaminate, clean, remanufacture/repair, function-test/inspect, package, and sterilize each device before returning it to a hospital. This process continues for a device until it can no longer successfully complete a reprocessing cycle or upon reaching "end of life" status (*i.e.,* the number of cycles the device can undergo before it must be discarded, which is cleared by FDA).

Commonly reprocessed medical devices include lower-risk, non-invasive devices such as sequential compression sleeves, tourniquet cuffs, and pulse oximeter sensors, to invasive surgical devices including laparoscopic graspers, scissors, forceps, scalpels, orthopedic blades, bits, burs, external fixation clamps, bolts and components, and even very expensive electrophysiological cardiac catheters.

Reprocessing is Strictly Regulated by FDA

The U.S. third-party reprocessing industry has an excellent safety record. By complying with strong FDA-regulatory requirements, reprocessors offer a product that is "as safe and as effective as a new device."[1] Since 2000, the U.S. Food and Drug Administration (FDA) has considered third-party reprocessors of SUDs to be "manufacturers" and, therefore, subject to the agency's full range of medical device manufacturer requirements. FDA explained in 2000 that a "manufacturer can market a device for one more single use from a raw material that was a previously-used, [single-use device] if that device meets the specifications of the device described in the market clearance."[2]

Why reprocess so-called "single-use" medical devices? It is important to know that the "single use" label is a designation chosen by medical device manufacturers, not FDA. In a report, made public March 3, 2008, the U.S. Government Accountability Office ("GAO") wrote:

> 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

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[1] Testimony of Dr. Daniel Schultz, Director, Center for Devices and Radiological Health, U.S. Food and Drug Administration (FDA), before the U.S. House Committee on Government Reform (09/26/2006) [hereinafter Schultz Testimony]. For a more detailed discussion of FDA's requirements for medical device reprocessors, the "single-use" label, and the safety record of reprocessed devices, *see* AMDR's Best Clinical Practice Background paper.

[2] Letter from Melinda K. Plaisier, Associate Commissioner for Legislation, FDA, to The Honorable Thomas J. Bliley, Jr. (November 29, 2000), at 2. *See also* Letter from D. Bruce Burlington, M.D., Director, Center for Devices and Radiological Health (CDRH), FDA, to Nancy Singer, Special Counsel, Health Industry Manufacturers Association (HIMA, now AdvaMed) (July 15, 1998), stating "reprocessors are inspected in accordance with the current Quality System regulation [QSR], Title 21, Code of Federal Regulations (CFR), Part 820, and they are subject to the labeling requirements of 21 CFR part 801. . . . In fact, FDA has considered such reprocessing firms to be manufacturers under the GMP regulations [which preceded the QSR] . . ." (emphasis added). Further, *See also,* CDRH, FDA, *Guidance for Industry and FDA Staff: Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Medical Devices* (Sept. 25, 2006), at 15. *See also, Guidance for Industry and for FDA Staff, Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals* (August 14, 2000), at 1.

> 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.[3]

FDA's stringent regulatory requirements have resulted in reprocessed SUDs that are manufactured to be as safe and effective as original devices and pose no increased risk to patients. In addition to the decade of safe clinical use, both FDA and the independent GAO have concluded that there is no evidence of harm to patients from FDA-regulated reprocessed devices.[4]

Reprocessed Devices Cost Less

FDA-regulated reprocessed devices are much less costly – typically about half the cost of an original device.[5] This 50% savings incorporates all of the third-party reprocessors' costs, including research and development, equipment and materials, staff, and the cost of recycling devices when they have reached the end of their life, among many other operational costs.

The supply chain is traditionally one of the most costly departments of a hospital. As far back as 2000, GAO found that facilities using reprocessed devices saved between $200,000 and $1 million annually, on average.[6] Currently, reprocessors estimate that a typical 200-bed hospital, if taking advantage of a reprocessor's full product line, can save between $600,000 and $1 million dollars a year and divert between 5,000 and 15,000 pounds of waste from landfills.[7] The savings generated by reprocessed medical devices often affords healthcare executives the opportunity to allocate limited resources toward other operational needs such as additional nursing hires, upgrades to technology, indigent care offerings, and necessary improvements to infrastructure.

Reprocessed Devices Reduce Medical Waste

Regulated medical waste (RMW), or "red bag waste," is another wasteful expenditure that typically costs hospitals 5 to 10 times more to dispose of than regular solid waste. Fortunately, many medical devices that end up in a hospital's RMW are actually eligible for reprocessing multiple times, eliminating the needless generation of more RMW while also reducing

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[3] 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).

[4] *Id.,* at 14-19 , which, among other things, concluded, "After reviewing the available evidence—including FDA's process for identifying and investigating device-related adverse events reported to involve reprocessed SUDs, peer-reviewed studies published since 2000, and the results of our and FDA's consultations with hospital representatives—we found no reason to question FDA's analysis indicating that no causative link has been established between reported injuries or deaths and reprocessed SUDs. That is, the available information regarding safety, while not providing a rigorous safety comparison between reprocessed SUDs and other devices, does not indicate that reprocessed SUDs currently in use pose an increased safety threat" (emphasis added).

[5] 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 5.

[6] *Id.,* at 19.

[7] Individual hospital results will vary. Savings and waste reduction estimates are based on averages achieved by actual customers using the full line of reprocessed devices. Contact a third party reprocessor to complete a facility analysis and get a more accurate estimated savings potential based on a facility's device usage data.

unnecessary waste disposal costs. Among the inventory of devices reprocessed annually, ninety-five percent (95%) are recycled at the end of their life cycle rather than sent to landfills. AMDR's members recycle a variety of raw materials from devices that cannot be reprocessed or have reached their maximum number of reprocessing cycles, including stainless steel, aluminum, titanium, gold, polycarbonate and polyurethane parts.

Reprocessing has allowed some hospitals to divert over 8,000 pounds of RMW from landfills each year, while larger systems can divert more than 50,000 pounds. Groups like the American Nursing Association, the Association of peri-Operative Registered Nurses, and Practice Greenhealth have recognized or endorsed reprocessing as a way to reduce waste.[8]

The "Triple Bottom Line" on Reprocessing and Savings

Reprocessing medical devices benefits all segments of healthcare. Doctors and nurses are using "single-use" devices that are equivalent new devices; healthcare executives are generating savings for the hospital *and* reducing medical waste; and patients are receiving uncompromised healthcare that also allows limited healthcare resources to be maximized.

Current U.S. Reprocessing Industry

U.S.-based TPRs can trace their roots to small, privately held start-up companies who envisioned a solution for hospitals to rein in the escalating cost of healthcare. With the passage of time, these small companies have evolved into a multi-million dollar industry, represented by two of the most respected names in the medical device manufacturing industry: SterilMed, Inc. (Maple Grove, MN), a division of Ethicon Endo-Surgery, Inc. (a Johnson & Johnson company), and Stryker Sustainability Solutions, Inc. (Phoenix, AZ), a division of Stryker Corporation.

Together, these companies conduct 95% of the third-party reprocessing done in the U.S. today. Current estimates place the U.S. market for reprocessed devices at roughly a quarter of a billion dollars annually. To give some perspective on the growth of our industry, in 2000, AMDR's members did $20 million in business. Domestically, AMDR's members estimate the market cap is $2 billion based only on current product offerings. Independent analysts put year-over-year growth for the reprocessing industry (and thus savings to the healthcare system) at 12-25% through 2013.[9]

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[8] American Nursing Association, Resolution: Safety and Effectiveness of Reprocessed Single-Use Devices in Healthcare (2010); Association of peri-Operative Registered Nurses, AORN Position Statement on Environmental Responsibility (2006); Practice Greenhealth, Regulated Medical Waste.

[9] *See*, Millennium Research Group, *US Markets for Reprocessed Devices 2009 (*May 2009), Reprocessed Device Market Booming During the Economic Crisis ("According to Millennium Research Group's (MRG's) *US Markets for Reprocessed Devices 2009,* hospitals are under significant pressure to lower spending due to the global economic crisis and the rising cost of health care within the US. Health care providers are therefore increasingly purchasing lower-priced products, such as reprocessed devices, which cost approximately 40 to 60% less than original equipment manufactured goods. As a result, market growth for reprocessed devices will exceed 12% annually through 2013."); *see also Caris & Company*, *Medical Device Reprocessing Accelerating, 10% Penetrated* (August 6, 2009) ("Unprecedented hospital budget constraints and the eco-friendly recycling movement are driving 20-25% YoY equipment reprocessor revenue growth from a $250-300 MM industry revenue base." Further, Caris expects continued year-over-year reprocessing revenue growth of 25% through 2012 with "20%+ annual growth prospects for the next 5-10 years.").

However, one potentially adverse factor affecting the U.S. TPR industry is the upcoming 2.3 % excise tax on medical devices that will go into effect in 2013. This tax was enacted as part of healthcare reform legislation and is expected to cost American medical device manufacturers, including reprocessors, $2.2 billion annually between 2013 and 2019. This tax is of significant concern to the reprocessing industry due to its potential negative impact on global competitiveness, innovation and job creation.

International Situation

Outside the U.S., the reprocessing of SUDs is thought to be quite commonplace, but it is seldom regulated. Perhaps spurred by the current economic climate, the growth of the U.S. TPR industry, or a combination of both, other nations are now looking to regulate reprocessing as a safe and effective way to reduce healthcare costs and waste.

For example, the European Union (EU) does not have a comprehensive regulatory framework regarding the reprocessing of SUDs. The European Parliament has identified the reprocessing of SUDs as an issue in need of additional clarification, and a European Commission released a report in August 2010 highlighting the risks of unregulated reprocessing. Currently, the EU is in the process of revising its medical device regulatory framework to include provisions that will more thoroughly address reprocessed devices on the European market.

In Canada, although reprocessing is regulated at the Provincial level, there are no comprehensive federal regulatory requirements for SUD reprocessors. This had led to a varying system where some provinces allow hospitals to contract with American third-party firms while others do not. AMDR understands that Health Canada may be re-evaluating the agency's position on reprocessing.

AMDR has drafted a summary that outlines, to the best of our knowledge, the legal and regulatory status of SUD reprocessing in a number of jurisdictions, including the European Union (EU), Australia, Canada, South Korea, Saudi Arabia, and Israel.

Canada and the European Union present a significant market opportunity for American TPRs. To AMDR's knowledge, there are no third-party medical device reprocessing operations in Canada or Europe that meet, as AMDR's members do, internationally- accepted standards equivalent to medical device manufacturers. The U.S. TPR industry is well poised to capitalize on these forthcoming regulatory changes and become the world leader in medical device reprocessing.

Additionally, as developing nations around the world seek to expand access to healthcare – and subsequently seek access to safe, lower-cost and environmentally friendly medical devices – AMDR's members and their products are primed to play a critical role in helping these nations achieve their healthcare goals.

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AMDR appreciates this opportunity to introduce our industry to the U.S. International Trade Commission. As governments worldwide grapple with rising healthcare costs and growing

medical waste, our industry's hope is that U.S. policymakers will assist the American reprocessing industry in capitalizing on the aforementioned market growth opportunities. Furthermore, we hope this will spur ongoing discussions in other industries about the benefits of remanufactured goods as a driver for economic growth and environmental sustainability.

Thank you.

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