AMDR
ASSOCIATION OF MEDICAL DEVICE REPROCESSORS

21 March 2018

[redacted]

RE: JCI Reuse of Single-Use Devices White Paper

Dear [redacted] and [redacted]:

I write regarding the Joint Commission International White Paper, *Reuse of Single-Use Devices: Understanding Risks and Strategies for Decision-Making for Health Care Organizations*, by Jeannell M. Mansur. We've been in contact directly with Ms. Mansur to relay our concerns and, upon our request, she provided your names as those to whom we should direct our detailed concerns and request that the paper be rescinded.

The Joint Commission International (JCI) is a well-respected organization and we know that hospitals look to JCI Resources for guidance. The subject of single-use device (SUD) reprocessing can be complex and we share JCI's goal to provide helpful resources to international hospitals on the subject. However, while perhaps unintentional, we believe the paper inaccurately intermingles the concepts of unregulated hospital *reuse* of SUDs with regulated, commercialized *reprocessing* of SUDs, giving an inaccurate and misleading understanding of the respective risks.

Further, Ethicon has a long history of opposing SUD reprocessing as it is a company that stands to gain if SUDs are not reprocessed. Its sponsorship of a paper devoted specifically to SUD reprocessing appears to us to be a clear conflict of interest that undermines the paper's credibility. In short:

- We believe the paper fails to make the necessary distinction between unregulated SUD reuse and regulated SUD reprocessing. To suggest the two are interchangeable and that both present the same level of risk of potential harm results in a misleading paper. Where regulated—such as in the U.S.—SUD reprocessing is held to *manufacturing* standards and presents NO additional risks to patients. It is false, misleading and disparaging to the legitimate, regulated commercial SUD reprocessing industry to characterize its operations and products as presenting the same risks and challenges associated with unregulated hospital reuse;

- If the goal of the document is to address SUD reuse in those jurisdictions wherein it is NOT regulated, that is unclear. Instead, the position paper treats regulated SUD reprocessing as equivalent to unregulated, unvalidated in-hospital reuse. These practices are not the same; thus, the distinction between them should be clearly established and all references to the risks associated with SUD reuse involve instances that are UNREGULATED;

- If the paper intends to document risks associated with regulated reprocessing, said risks should be substantiated with evidence; otherwise, the paper maligns a legitimate, regulated commercial industry. In fact, the only study referenced to demonstrating the risks of SUD reuse is a study of *reusable*—rather than *reprocessed single-use* devices. Thus, the reference is irrelevant and should therefore be removed; and

- Ethicon's sponsorship of the JCI white paper is inappropriate. Johnson & Johnson, including their Ethicon subsidiary, is well-known for its anti-reprocessing views. JCI's publication and dissemination of a white paper critical of SUD reprocessing, funded by Ethicon—or any company with a financial stake in the topic—puts JCI's credibility and reputation at stake. Ethicon is a company that stands to gain financially when SUDs are not reprocessed, thereby forcing hospitals to buy more Ethicon devices. There is a clear conflict of interest that jeopardizes JCI's credibility as an independent, neutral source. So, while the paper purports to be a JCI official white paper, either willfully or unwittingly, it has become an Ethicon marketing tool.

For these reasons, we respectfully request this paper be rescinded.

That said, we applaud JCI and encourage it to issue unbiased and accurate information on SUD reuse and regulated reprocessing. For the same reasons outlined above and below, neither Ethicon nor the commercial reprocessing industry should be permitted inappropriate influence over the content of such a paper. The current draft, in our view, is unduly influenced by Ethicon as it characterizes all SUD reprocessing as suspect. As the trade association representing the commercial reprocessing industry, AMDR is happy to assist in providing neutral, factual information and hopes that JCI will consider including AMDR as a resource on this topic moving forward.

Below are specific examples and more detailed responses to what we believe amount to misleading elements of the white paper. This is not a comprehensive list, but an overview of the more important portions.

- Executive Summary:
  - The second bullet of the Executive Summary states "this practice carries significant risk to the patient." This is a false statement. Unregulated reuse of SUDs may present risk to patients, but the paper neither cites evidence nor is AMDR aware of any source indicating that SUD reprocessing, when subject to regulation, presents any increased risk to patients. To omit this distinction to conflate regulated reprocessing with unregulated reprocessing is false and misleading;
  - The third bullet's claim that "cleaning efforts, either by hospitals or third-party reprocessors, may be inadequate" is patently false, misleading and disparaging. This is an irresponsible statement, as third-party reprocessors are explicitly included in this generalization. Not only does the claim lack evidence in the paper, there exists no known evidence of inadequate cleaning associated with regulated, third-party reprocessing whatsoever. In fact, the FDA's clearance and approval of reprocessed SUDs as "safe and effective" contradicts this unsubstantiated claim, particularly because the Agency requires commercial SUD reprocessors to include cleaning validation data in their premarket submissions;
  - Similarly, the fourth bullet says "reprocessing and reuse may compromise the product's performance . . ." Again, in this instance, no distinction is made

between unregulated reuse and regulated reprocessing and/or the two are intentionally muddled. No evidence is provided-nor is there any available to our knowledge¯to support the claim that regulated reprocessing compromises a product's performance and, as with the cleaning of reprocessed SUDs, FDA requires device performance validation in premarket submissions; and

- The final bullet claims the objective of the paper is to "raise awareness of this threat to patient safety," among other things, with no distinction between regulated reprocessing and unregulated hospital reuse. By intentionally mixing validated, regulated reprocessing subject to oversight authority with inappropriate, unvalidated hospital reuse, the paper disparages the legitimate commercial industry.

- The Azizi and Basile study does NOT question the safety of regulated SUD reprocessing nor does it question the safety of hospital reprocessed SUDs, at all. Rather, the report is a study of the challenges in reprocessing certain ***reusable*** devices reused *by hospitals* (Page 5). The words "single-use" do not appear in the study. Citation to the report as evidence of potential harm from SUD reuse is false and misleading. Azizi and Basile do not suggest that SUDs present "unique challenges to cleaning and verification of cleanliness," are "virtually impossible to visually inspect the critical surfaces.... to confirm all contaminants have been removed" or that "residue is still present after processing." At worst, the JCI paper is a grotesque misrepresentation of the content of the study and, at best, is a dangerously misleading extrapolation. AMDR has had the pleasure of working with Mr. Basile on AAMI WG 93 for TIR 30, *Cleaning of Reusable Medical Devices*. Mr. Basile's integrity is beyond repute and he has never publicly, to our knowledge, suggested, contrary to claims found in the JCI paper, that regulated SUD reprocessing presents these challenges. The citation suggests that Mr. Basile gave permission for use of this article; however, AMDR sincerely doubts Mr. Basile intended to have his paper extrapolated to further the agenda of one manufacturer—Ethicon—that seeks to disparage reprocessing. Absent JCI's removal of this citation, we will take the matter up directly with Mr. Basile;

- "Use of a reprocessed device presents no value to the patient or the physician" (Page 6). There is no citation or evidence given for this claim and to make it, absent substantiation, inappropriate and biased. AMDR contends there is plenty of evidence suggesting otherwise. For example, regarding patient benefit, AMDR members save U.S. hospitals nearly half a billion dollars a year and prevent millions of tons of medical waste from going to landfills. Indigent patients who would not otherwise have access to laparoscopic surgery can thank reprocessing for the savings reprocessing incurs, allowing their hospitals to provide more uncompensated care. Electrophysiology patients who might not otherwise have had access to an advanced, ultrasound catheter can thank reprocessing for freeing up resources allowing their hospitals to invest in the newer technology. AMDR-member hospital partners have long used reprocessing to offset the cost of indigent care, make investments in new technology, or invest in/retain nursing staff. There are even studies demonstrating that reprocessed SUDs fail less than new devices— another patient benefit. AMDR can also provide independent evidence from Practice GreenHealth and other organizations on the health and environmental benefits associated with reprocessing and would be happy to do so upon request;

- Patient consent (Page 6). This paragraph, again, suggests that hospital reuse of SUDs is equivalent to commercially available, regulated reprocessed SUDs. This assumption is false and misleading. AMDR understands JCI may want to speculate

on hospital use of informed consent for in-hospital reuse, but laws and regulations are clear regarding regulated SUDs. At least domestically, the informed consent process is defined by FDA regulation (21 CFR Part 50) as a means of informing patients of the use of investigational and/or experimental devices. Under the federal Food, Drug and Cosmetics Act (FDCA), reprocessed devices are subject to the FDA's premarket clearance or approval requirements documented in FDA Guidance of 2000 (among other requirements) and, once cleared or approved, reprocessed devices are deemed to be "substantially equivalent" to new devices. Thus, reprocessed devices are NOT investigational or experimental and informed consent is NOT required under FDA regulations. There is no legal, ethical or scientific basis presented in the white paper to suggest FDA cleared reprocessed devices are any different from any other cleared or approved devices;

- The stated UK MHRA position (Page 7) is false. MHRA does not strictly advise "against reprocessing;' it advises against hospital reuse/reprocessing but allows commercial, regulated SUD "remanufacturing." In fact, the entire Guidance goes to great lengths to make the distinction between unregulated hospital reprocessing and regulated commercial SUD remanufacturing. The date of the MHRA report is 2016 and JCI's white paper is dated 2017; this citation should have been corrected before publication. *See*, "Medicines & Healthcare Products Regulatory Agency, Single-Use Medical Devices: UK Guidance on Re-manufacturing," (June 2016);

- Adverse event generalizations (Page 8). The paper notes "concerns that reprocessed single-use devices may be at higher risk for failure..." but provides no evidence to support them. AMDR is aware of no data suggesting higher risk and the FDA's data, in fact, suggests the opposite. As noted, AMDR is aware of at least one independent study indicating lower failure rates in reprocessed devices versus new. The paper's unsubstantiated claim to the contrary disparages the regulated, commercial SUD reprocessing industry; and

- Peer-reviewed data: As with the JCI paper, use of peer-reviewed studies documenting safety concerns over hospital reused SUDs to second guess the safety of regulated SUD reprocessing is misleading. It is also false and misleading to conclude that there is "little or poor data to provide clear direction" (page 10) on the safety of reprocessing. Page 6 contains the editorial statement that the absence of data suggests the jury is out on reprocessing. However, AMDR contends that the absence of evidence of harm to patients IS evidence of the safety of SUD reprocessing. The assumption to the contrary is just that—an assumption—an ultimately unsubstantiated one, at that. The commercial SUD reprocessing industry has obtained well over 100 510(k) clearances from the FDA for reprocessed SUDs, and the FDA data standards for reprocessed SUDs are as great or greater than that of new SUDs. *See* Testimony of Dr. Daniel Schultz, Director, CDRH, FDA (September 26, 2006): "Congress mandated a number of new requirements for SUD reprocessors including, for certain SUDs, the pre-market submission of data to the agency that exceeded the requirements for the original manufacturers (OEMs)") [emphasis added]. To claim there is a "paucity of data" is unsupported considering FDA requirements.

The Association of Medical Device Reprocessors respectfully requests that JCI remove from circulation, its website or any other medium, the SUD reuse white paper as it contains unsubstantiated, false, misleading and disparaging claims about the commercial, regulated single-use device reprocessing industry. Claims made to disparage the reprocessing industry are NOT supported by the evidence supplied in the white paper nor by other independently available sources. FDA-regulated reprocessed SUDs do **not** present an elevated patient health risk and are

not linked to hospital-acquired infections or increased failure rates. In addition, irrelevant reports, studies, or opinions—such as the Basile paper—characterized as relevant to FDA-regulated SUD reprocessing, are false and misleading. Finally, the bias in the document against the commercial industry reflects the views shared by the paper's funding source, Ethicon, further undermining the credibility of both the paper itself and JCI as an independent source of information "furthering JCI's efforts to improve quality and safety."

The FDA has regulated reprocessors of SUDs since 2000 and all AMDR members possess exemplary safety records. AMDR requests that you act immediately to rescind this paper and looks forward to JCI's efforts to provide truthful and accurate information on this subject to ensure that the deceptive claims, statements and materials described above are immediately discontinued and removed from circulation on all mediums.

Sincerely,

Daniel J. Vukelich, Esq.
President

CC : [redacted]