September 1, 2015

Christopher M. Zahn, MD
Vice President of Practice Activities
American College of Obstetricians and Gynecologists
P.O. Box 96920
Washington, DC 20090-6920

Re: ACOG's Committee Opinion (Number 537; October 2012 and reaffirmed in 2014) regarding Reprocessed "Single-Use" Devices (SUDs)

Dear Dr. Zahn,

My name is Daniel J. Vukelich and I am President of the Association of Medical Device Reprocessors ("AMDR"), a global trade association located in Washington, D.C. representing the legal, regulatory and other trade interests of the regulated, commercial "single-use" medical device reprocessing industry.[1] This letter concerns ACOG's Committee Opinion (Number 537; October 2012 and reaffirmed in 2014) ("Opinion") regarding reprocessed "single use" devices ("SUDs").

I contacted Caitlin Phelps, Association Director of Gynecology, who instructed AMDR to provide you with materials for the Committee on Gynecologic Practice's consideration in support of our request for a review of ACOG's Opinion. Ms. Phelps underscored that ACOG's guidelines are informed by evidence-based medicine and urged us to provide supporting literature. Therefore, we appreciate this opportunity to respond to the Opinion, provide a brief overview of the available data demonstrating the safety and efficacy of FDA-regulated reprocessed SUDs, and welcome an opportunity to meet with you and/or the Committee to discuss the facts surrounding SUD reprocessing and any forthcoming opportunity there may be to update the Opinion.

Overview

AMDR appreciates the attention ACOG has given to the SUD reprocessing issue by releasing its Opinion. Further, AMDR shares ACOG's values of promoting safety, quality, cost-effectiveness and transparency to physicians and patients, as highlighted in the Opinion. AMDR is respectfully requesting a re-review of the both the evidentiary standard ACOG has applied to reprocessing and the evidence used to support the Opinion's final conclusion. The commercial SUD reprocessing industry most certainly appreciates being held to a high standard, but AMDR does not believe SUD reprocessing has been granted equitable consideration in the ACOG Opinion as compared to other medical device manufacturing activities.

FDA is the Evidentiary Standard for Safety and Effectiveness

As noted in the Opinion, the FDA regulates SUD reprocessing. This regulation falls within the broader mandate of FDA to evaluate the safety and effectiveness of all medical devices. Reprocessed devices, like all medical devices, are subject to FDA's full set of medical device

[1] For more information about AMDR, please visit our website at www.amdr.org.

manufacturer requirements including premarket review. Thus, to be lawfully marketed in the U.S., an SUD reprocessor, like other device manufacturers, must obtain clearance from FDA for devices requiring premarket notification ("510(k)").

In obtaining clearance from FDA, reprocessors must provide in a 510(k) submission sufficient data to evidence substantial equivalence. Substantial equivalence means that the new device is at least as safe and effective as the predicate. FDA has cleared countless reprocessed devices, determining that the devices are "substantially equivalent" or are at least as safe and effective as the predicate devices originally labeled for single use. "FDA believes that reprocessed SUDs that meet FDA's regulatory requirements are as safe and effective as a new device."[2] AMDR appreciates ACOG's efforts to ensure reprocessed SUDs are safe; however, the Opinion's conclusion ignores that the regulatory standard for SUD reprocessors ensures safe and effective devices. FDA's determinations as to safety and efficacy are the standard in the U.S., and AMDR does not think it fair for ACOG to single out SUD reprocessors (and not other FDA-cleared or -approved medical devices) to conclude that the jury is still out with regard to the safety of such products.

FDA's Medical Device Reporting Requirements

AMDR does not think it fair to suggest, without evidence, that safety issues with reprocessed devices might go unreported. Further, there is no evidence to support the claim that reprocessed device failures are erroneously reported to the original equipment manufacturers ("OEMs"), or that infections resulting from reprocessed SUDs cannot be traced back to the reprocessor. This speculation is unfounded and ultimately results in reprocessors being held to an inappropriately higher standard.

In fact, the regulatory reality suggests just the opposite. First, ACOG's opinion on FDA's medical device reporting requirements is not accurate. The Agency does not rely exclusively upon voluntary reporting – 21 C.F.R. Part 803 contains specific *mandatory* requirements for all medical device manufacturers and user facilities. Manufacturers, including SUD reprocessors, are required to report to the FDA when they learn that any of their devices may have caused or contributed to a death or serious injury.[3] Manufacturers and SUD reprocessors must also report to the FDA when they become aware that their device has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. Medical device user facilities, including hospitals, are required to submit reports to FDA and the manufacturer when they become aware of information that reasonably suggests that a device has or may have caused or contributed to the death of a patient.[4] Moreover, user facilities are required to report to the manufacturer when they become aware of information that "reasonably suggests" that a device has or may have caused a serious injury to a patient of the facility.[5] ACOG does not appear to recognize or consider that FDA has mandatory reporting requirements that apply to SUD reprocessors.

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[2] 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). (Further, "FDA believes that reprocessed SUDs that meet FDA's regulatory requirements are as safe and effective as a new device").

[3] *See* http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm

[4] 21 C.F.R. § 803.30(a).

[5] *Id*.

In addition, Congress and FDA took great pains to ensure that end-users know they are using a reprocessed SUD and know how to report adverse events correctly. ACOG's allegations regarding underreporting or inaccurate reporting are not founded on any evidence. The Federal Medical Device User Fee and Modernization Act (MDUFMA) of 2002 amended the adverse event reporting process to specifically identify whether particular devices are reprocessed.[6] Section 301 of the Medical Device User Fee Stabilization Act (MDUFMSA) of 2005 further required that, in addition to medical device manufacturer labeling requirements, SUD reprocessors must also mark or place an attachment on all of their reprocessed devices, further minimizing any ambiguities concerning whether or not one is using an original or reprocessed device.[7]

Outside the user facility reporting requirements, FDA encourages other healthcare professionals, patients, caregivers and consumers to submit voluntary reports of significant adverse events or product problems with medical products through FDA's MedWatch program.[8] To date, AMDR is not aware of FDA reporting any evidence of erroneous filings to the OEM for reprocessed devices. In fact, no evidence has been presented from FDA, OEMs, hospitals, or reprocessors that would indicate original manufacturers have been inappropriately identified as responsible parties rather than the relevant third-party SUD reprocessors. Regardless, FDA regulations already require erroneously filed adverse events to be reported to the proper OEM, or to FDA.[9]

Based on the foregoing, a lack of data in FDA's database of serious adverse events associated with reprocessed SUDs may indeed reflect a general absence of a patient safety problem.

Informed Consent and Patient and Physician Transparency

Reprocessed SUDs are not investigational or experimental devices. Therefore, there is no legal, medical or ethical basis for imposing a requirement to seek informed consent for the use of reprocessed devices but not for the use of original devices.[10] SUD reprocessing has been regulated by FDA for well over a decade, and all sources indicate it does not pose an increased risk to patients. AMDR is unaware of any FDA-cleared or -approved drug or device for which informed consent is required. Nevertheless, reprocessors continue to support full transparency, and some of the items called for in the Opinion are already required by federal law, such as having devices clearly labeled as reprocessed and the reporting of adverse events to FDA.

The Clinical Evidence Cited in ACOG's Opinion is Irrelevant, Inaccurate and Misleading

Even if the standard for safety and effectiveness were the volume of peer-reviewed literature and not FDA's findings of the safety and effectiveness of reprocessed SUDs, the citations offered in the ACOG Opinion do not provide an evidentiary basis to conclude that an insufficient level of data exists concerning the safety of reprocessed devices.

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[6] Medical Device User Fee and Modernization Act of 2002, Pub. L. No. 107-250, 116.
[7] Medical Device User Fee Stabilization Act of 2005, Pub. L. No. 109-43, 119. *See also*, Guidance from FDA, http://www.gpo.gov/fdsys/pkg/FR-2004-02-17/html/04-3333.htm
[8] *See* http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.
[9] 21 C.F.R. 803.22(b)(1), "any reportable event information that is erroneously sent to a manufacturer shall be forwarded to FDA, with a cover letter explaining that the device in question was not manufactured . . . by that firm."
[10] For information on FDA requirements for informed consent see: FDA Informed Consent.

First, studies from Europe or Argentina are irrelevant in evaluating the safety of devices reprocessed in the United States under FDA oversight because FDA does not regulate in Europe or South America.

Second, studies of hospital reuse of SUDs prior to 2000 are irrelevant because the law in the United States has since developed to fully regulate SUD reprocessing.

Third, studies of unregulated reprocessed SUDs are also inapplicable to the current review. Devices reprocessed by hospitals or by manufacturers which are not in compliance with FDA regulation are unlawful in the U.S. To draw conclusions about an FDA-regulated commercial industry based upon the non-compliant activities of hospitals or manufacturers is incontrovertibly misleading and ultimately provides an inappropriate standard of comparison.

Fourth, OEM-sponsored studies must be considered suspect given that OEMs who have funded these studies possess an inherent economic incentive to see that their devices are *not* reprocessed. Further, for the two OEM-sponsored papers cited, the devices in question appear to have been provided by the *manufacturers*. When considering the studies' lack of accounting for the chain of custody of the product, the low sample sizes, and the appearance of bias, AMDR cannot conclude that these studies are credible.

In conclusion, none of the four studies cited in the ACOG Opinion are relevant to, or representative of, the current standards in place for SUD reprocessing. As such, we strongly urge ACOG's reconsideration of their inclusion in assessing the safety of SUD reprocessing and instead request ACOG's reliance upon the accepted U.S. standard which is FDA's evaluation of data substantiating safety and efficacy.

We urge ACOG to review and consider AMDR's "Backgrounder" white paper on SUD reprocessing which contains an overview of independent, peer-reviewed literature that supports the safety of SUD reprocessing. In addition, the Backgrounder document contains other supporting information outlining FDA regulatory requirements of reprocessors consistent with (and, in some cases, exceeding) original manufacturer requirements, as well as FDA and U.S. Government Accountability Office ("GAO") findings as to the safety of FDA-regulated reprocessed SUDs.

Conclusion

SUD reprocessing is lawful and stringently regulated as device manufacturing, resulting in the availability of safe and effective devices at approximately half the cost of original equipment. The safety record of SUD reprocessing has been noted by both FDA and GAO, and the practice has enjoyed wide clinical acceptance for nearly a decade. Reprocessing also reduces medical waste and stimulates price competition. We hope that ACOG, like other professional healthcare associations whose members utilize reprocessed SUDs, will consider revising its Opinion to recognize that SUD reprocessing conducted by FDA-regulated third party vendors represents a proven safe, regulated and cost-saving option for physicians in the gynecological setting.

Like all responsible medical device manufacturers, AMDR members fully support FDA regulation. FDA's conclusions as to medical device safety are well established, widely respected by the clinical community, and frequently recognized as an international standard. We urge ACOG not to disregard FDA's conclusions, SUD reprocessing's track record, or evidence-based literature with respect to reprocessed devices.[11]

I would be happy to answer any questions that you may have at this time, and I would also look forward to arranging a meeting with ACOG at the convenience of you and your colleagues in order to further discuss the matter.

Thank you for your consideration of this important issue.

Sincerely,

Daniel J. Vukelich
President
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[11] Other professional and clinical organizations–including the American Hospital Association, American Nursing Association, Association for Professionals in Infection Control & Epidemiology, among several others–have issued statements in support of FDA regulation of SUD reprocessing. These organizations embrace the outstanding safety record of reprocessing and understand that it is one of the most important initiatives hospitals are implementing today as a way to contain costs and support quality care enhancements.