ATTACHMENT "C"

AMDR
Association of Medical Device Reprocessors

April 11, 2000

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BY HAND DELIVERY

Food and Drug Administration
Dockets Management Branch (HFA-305)
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Re: Docket No. 00D-0053

Dear Sir or Madam:

The Association of Medical Device Reprocessors (AMDR) respectfully submits the following comments in response to the Food and Drug Administration's (FDA) draft guidance documents entitled "Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme," and "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals." 65 Fed. Reg. 7,027 (Feb. 11, 2000) (hereafter, "draft guidance documents"). AMDR is a Washington, D.C.-based trade association representing the legal and regulatory interests of third-party reprocessors of medical devices labeled for single use. It is estimated that AMDR members perform approximately 80% of the third-party reprocessing done in the United States.

AMDR is pleased to have the opportunity to provide comments on FDA's draft guidance documents. AMDR has always believed that strong FDA regulation of medical device reprocessing is critical to ensuring the safety of reprocessed devices, and we appreciate FDA's timely and comprehensive response to this matter.

In AMDR's view, however, the premarket review scheme first introduced in FDA's "Proposed Strategy on Reuse of Single-Use Devices," 64 Fed. Reg. 59,872 (Nov. 3, 1999), (hereafter, "Proposed Strategy"), and further described in the draft guidance documents, is unnecessary to protect public health, and could result in a dramatic increase in the country's already spiraling health care costs. As described in Section I below, proper medical device reprocessing is

Office 1400 16th Street NW, Suite 400, Washington, DC 20036 Phone (202) 518-6796 Fax (202) 234-0399 Web www.amdr.org

a patient-safe practice embraced by America's finest hospitals and physicians as a way to achieve significant cost savings without compromising patient care. If reprocessing is eliminated as an option for hospitals, certain medical devices and procedures will no longer be available for some patients, because they simply will be too expensive. Thus, "over-regulation" of reprocessing would have a direct, negative impact on patients.

From AMDR's perspective, patient safety always must be the highest priority. As discussed in Section I, the safety record of third-party reprocessing under the current regulatory regime has been excellent, and there is no evidence to suggest that a premarket review scheme is necessary to protect public health. However, despite this lack of evidence, it is clear that FDA is, nonetheless, moving forward to impose a premarket review scheme. As such, AMDR seeks to work with the agency to assure that its premarket review scheme is implemented in a reasonable manner, taking into account the strong evidence of the safety of medical device reprocessing, as well as the potentially serious consequences of unnecessarily restricting reprocessing. In Section II below, we provide detailed comments on both draft guidance documents.

I. Given the Strong Evidence of the Safety of Medical Device Reprocessing, FDA's Premarket Review Scheme is Unnecessary to Protect Public Health.

In AMDR's view, there is one, critical element missing from the agency's premarket review scheme: Nowhere does FDA provide a compelling public health rationale for changing the current regulatory framework. Indeed, when the agency first introduced its premarket review scheme, it stated that it is "committed to reevaluating its position on the reuse of SUDs (single use devices)," and that its "primary goal is to protect the public health by assuring that the practice of reprocessing and reusing SUDs is based on good science." Proposed Strategy at 7. However, neither the Proposed Strategy nor the draft guidance documents present any evidence that reprocessing has posed or is posing a threat to public health.

From AMDR's perspective, it is not surprising that the agency has failed to demonstrate a public health necessity for disrupting the current regulatory regime and replacing it with a premarket review scheme. As discussed below, not only is there no evidence to indicate that reprocessing threatens public health, to the contrary, there is substantial, affirmative evidence showing that proper reprocessing is safe. Given the demonstrated safety of reprocessing, the costly and burdensome premarket review framework proposed by FDA is unwarranted. Rather, the current regime – which emphasizes compliance with Quality System Regulation (QSR) requirements – is well-suited to protecting public health.

A. Done properly, medical device reprocessing is safe.

1. Hospital and physician perspective

As FDA acknowledges in its Proposed Strategy, United States hospitals have been reprocessing medical devices labeled for single-use for over two decades. See Proposed Strategy at 2. According to most estimates, at least 50% of U.S. hospitals reprocess some devices labeled for single use -- either at in-hospital reprocessing centers or through the use of third-party reprocessors.[1] Reprocessing is standard practice at a broad spectrum of health care institutions, including many of the nation's top research hospitals.

The inception of medical device reprocessing can be traced to arbitrary label changes on a number of medical devices: Approximately two decades ago, manufacturers began to change the label on certain devices from reusable to single use, without making any structural changes in the devices. Thus, it quickly became evident to hospitals that "single use" does not necessarily mean "single use," and that certain devices designated by original equipment manufacturers (OEMs) as "single use only" can, in fact, be safely reprocessed. Examples of the arbitrariness of the single use label are abundant:

- In a 1980 letter to a hospital-customer, USCI Cardiology & Radiology Products (USCI) explained that, although it 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 they have been in the past." **(Attachment A).**

- In a 1987 letter, Boston Scientific Corporation's Microvasive division informed a hospital that its "BICAP Hemostatic Probes are recommended for single use only. However this recommendation does not prohibit reuse under certain specific conditions . . . ." **(Attachment B)**

- The December 11, 1998, episode of NBC's news magazine "Dateline" exposed Johnson & Johnson's practice of labeling as "single use" contact lenses that were virtually identical to the lenses that the company had been marketing as reusable. When asked why it had designated the lenses as single

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[1] See, e.g., "Survey: ORs are split on reuse of single-use items," OR Manager, Vol. 15, No. 9 (Sept. 1999).

> use, Johnson & Johnson stated: "If we had changed the label and marketed for general use, then we couldn't advertise and create this single-use, daily disposable category. We made that decision because we felt it was a good business decision to do it that way."[2]

Given that the single use label is, in many cases, a "business decision" rather than a patient safety decision, it is not surprising that the medical community regards the reprocessing of "single use" devices as a patient-safe practice that allows precious health care resources to be directed toward what matters most: providing patients with the best possible care. Indeed, Dr. William Jarvis of the Centers for Disease Control and Prevention (CDC) recently observed that, with regard to the reuse of devices labeled for single use, he "would just be absolutely amazed if this is a major public health problem and the (leading hospitals) have failed to realize it."[3] As detailed below, hospital and physician groups have articulated overwhelming support for the safety of reprocessing:

- The American College of Cardiology has stated: "When it comes to treating patients, our number one concern is patient safety. The reprocessed medical devices used in diagnosing and treating cardiac patients are in fact safe and effective." (**Attachment C**)

- The North American Society of Pacing and Electrophysiology has stated: "After studying thousands of patients who have undergone cardiology procedures with re-sterilized catheters, findings indicate there is no increased risk of infection for patients. Re-sterilization of cardiac catheters for electrophysiology studies has been an ongoing practice for over twenty years with no known patient adverse outcomes." (**Attachment D**)

- The American Hospital Association has stated: "The clinical use of reprocessed medical devices is safe, effective, and efficient. Hospitals have reprocessed devices labeled 'single use' or 'disposable' for years with excellent success." (**Attachment E**)

See also Letter from Dr. Stephen Hammill, Director, Electrocardiography and Electrophysiology Laboratories, Mayo Clinic, to Senator Paul Wellstone (June 23, 1998) (**Attachment F**).

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[2] Transcript of December 11, 1998, Dateline episode at 5 (emphasis added).

[3] Neergaard, Lauran, "Debate on Reuse of Medical Devices," Associated Press (Aug. 13, 1999).

Thus, the message emanating from the doctors and hospitals who use reprocessed devices every day -- and who have done so for over two decades -- is clear and consistent: Properly reprocessed devices are safe and effective; there simply is no factual basis to support the notion that medical device reprocessing poses a threat to public health.

2. Scientific support

A significant body of independent, peer-reviewed scientific literature confirms the medical community's confidence in the safety of reprocessing devices labeled as single use. Indeed, studies demonstrating the safety and efficacy of reprocessing have been published in a number of highly esteemed medical journals, including *Gastrointestinal Endoscopy*, *The American Journal of Gastroenterology*, *Journal of the American College of Cardiology*, *Journal of Thoracic Cardiovascular Surgery*, *Pacing and Clinical Electrophysiology (PACE)*, *American Journal of Cardiology*, *Medical Journal of Australia*, *Canadian Journal of Surgery*, and *Canadian Journal of Cardiology*.[4]

For example, the work of Dr. Richard Kozarek, Chief of Gastroenterology at the Virginia Mason Medical Center in Seattle, Washington, and former President of the American Society for Gastrointestinal Endoscopy, has been published in *Gastrointestinal Endoscopy* and the *American Journal of Gastroenterology*. Dr. Kozarek has conducted a number of independent studies demonstrating the reusability of certain endoscopic accessories. In the area of sphincterotomes labeled as single use, for instance, Dr. Kozarek found that "[d]ouble channel sphincterotomes marketed as one-time-use items can be reused safely when properly cleaned."[5] Likewise, with respect to argon beam plasma coagulation (APC) probes labeled for single use, Dr. Kozarek concluded:

> The combination of manual cleaning and ETO sterilization consistently cleaned APC probes. Ninety percent of the probes showed no sign of physical deterioration and 100% maintained their electrical activity after 10 uses. APC probes can potentially

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[4] We have enclosed a bibliography and summary of these studies as **Attachment G**.

[5] R.A. Kozarek, M.D., S.L. Raltz, R.N., M.S.N., T.J. Ball, M.D., J.J. Brandabur, M.D., "Reuse of disposable sphincterotomes for diagnostic and therapeutic ERCP; a one-year prospective study." Gastrointestinal Endoscopy, Vol. 49 (1999) at 39.

> be safely and effectively reused up to 10 times, and a significant procedural savings is possible with reuse."[6]

As another example, Dr. Edward V. Platia, a nationally recognized electrophysiologist at the Washington Hospital Center in Washington, D.C., conducted an extensive multi-center study of the reuse of electrophysiology (EP) catheters, involving 14,640 EP cases and 48,075 catheter uses. Dr. Platia concluded that

> the sterilization and reuse of non-lumen, woven Dacron pacing catheters is safe, and does not appear to result in any increase in the risk of infection. The catheters are sufficiently durable to allow them to be reused well in excess of five times. One-time use of such catheters appears to be an unnecessary and expensive policy.[7]

What is, perhaps, most striking about the rigorous body of scientific evidence supporting the safety and efficacy of reprocessed devices is its dramatically superior quality, as compared to the "studies" offered by the OEMs that oppose reprocessing. Indeed, most of the "scientific evidence" submitted by the opponents of reprocessing should be disregarded, as (i) much of it is based on "studies" conducted or sponsored by the OEMs themselves, rather than independent entities, and, as such, is tainted by the OEMs' clear economic incentive to portray reprocessing in a negative light; and (ii) much of it is plagued by fundamental scientific deficiencies, such as lack of an adequate sample size, and, as a result, cannot serve as a basis for any conclusions about the safety of reprocessed devices.

3. The safety record of reprocessing

Based on FDA's own database of device-related patient adverse events, the safety record of reprocessing is excellent. Pursuant to the agency's Medical Device Reporting (MDR) regulation, hospitals must notify FDA when they learn that a device may have caused or contributed to a patient death or serious injury. 21 C.F.R. § 803.30. Every year, FDA receives over 100,000 MDR reports. Significantly, there have been only a handful of MDR reports associated with reprocessed devices. Indeed, FDA itself recently remarked that the number of MDR reports involving reprocessed devices

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[6] S.K. Roach, R.A. Kozarek, M.D., S.L. Raltz, R.N., M.S.N., and S.E. Sumida, Ph.D., "*In Vitro* Evaluation of Integrity and Sterilization of Single-Use Argon Beam Plasma Coagulation Probes," The American Journal of Gastroenterology, Vol. 94 (1999) at 139.

[7] S. O'Donoghue, E.V. Platia, M.D., "Reuse of Pacing Catheters: A Survey of Safety and Efficacy," PACE, Vol. 11 (Sept. 1988) at 1280.

is "tiny" compared with other problems.[8] Furthermore, the incidents reported in the few MDRs involving reprocessed devices are identical to problems that have occurred in new devices. Thus, it is not at all clear that these incidents were caused by reprocessing.[9]

Despite the excellent safety record of reprocessing, OEMs continue to pressure FDA, Congress, and State legislatures to address the "safety problem" posed by reprocessing. From AMDR's perspective, the OEMs' efforts are particularly troubling, given that the safety record of reprocessed devices is as good or better than the safety record of new single-use devices. Indeed, new single use devices account for several thousand more reports of patient injury and device malfunction than reprocessed devices.[10]

For example, a 1994 outbreak of post-surgical infections has been attributed to bacteria-contaminated sutures manufactured by a division of Johnson & Johnson, a member of the Association of Disposable Device Manufacturers (ADDM) and one of the primary opponents of reprocessing. The contamination allegedly resulted from a malfunction in the company's sterilization system.[11] As another example, FDA recently found that an improperly functioning coronary stent system manufactured by Boston Scientific Corporation (BSC) -- another ADDM

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[8] See Device & Diagnostics Letter, Vol. 26, No. 48 (Dec. 17, 1999) at 1.

[9] As one example, an MDR report was submitted to FDA concerning a reprocessed electrophysiology (EP) catheter whose tip became detached. See MDR Report Number 1062310-1999-00001 (**Attachment H**). However, the identical incident has been reported for new EP catheters. See MDR Report Numbers 4501350000-1995-0088 and 6000087-1998-00002 (**Attachment I**).

[10] We are enclosing as **Attachment J** a table comparing the number of MDR reports for new single use devices with the number of MDR reports for reprocessed devices.

[11] See, e.g., Lance Williams, "Common thread in illnesses: sutures lawsuits blame postsurgical infections on a single source," San Francisco Examiner (Feb. 21, 1999); Lance Williams, "Patients wounded by infections across the country, lives have been torn by post-op complications," San Francisco Examiner (Feb. 21, 1999); Lance Williams, "How suture maker kept lid on infection suits despite recall, Ethicon said product was harmless," San Francisco Examiner (Feb. 22, 1999); Lance Williams, "Patients who suffered," San Francisco Examiner (Feb. 22, 1999).

member -- caused 26 patient injuries, and may have been a factor in the death of one individual.[12] Thus, the truth is that the very companies who are clamoring for a "crackdown" on the alleged "public health threat" associated with reprocessing are responsible for manufacturing devices which, on their first use, have very likely caused serious patient injury.

4. FDA's Statements

FDA's observation regarding the scarcity of MDR reports involving reprocessed devices is not the only time the agency has commented on the striking lack of evidence indicating a safety problem with reprocessing. In May 1999, for example, the Medical Device Manufacturers Association (MDMA) submitted a Citizen Petition to FDA requesting that reprocessing be banned. Five months later, FDA denied MDMA's request, explaining that the agency

> has received adverse event reports where a reprocessed single use device was involved; however, in each of those cases, it was not clear that reprocessing caused the problem reported. In fact, FDA has been unable to find clear evidence of adverse patient outcomes associated with the reuse of a single use device from any source.[13]

Similarly, in July 1998, FDA denied a Citizen Petition submitted by the Health Industry Manufacturers Association (HIMA), in which HIMA had requested that the agency impose premarket clearance requirements on third-party reprocessors. In its denial letter, the agency stated, among other things, that "FDA notes the general absence of adverse patient outcomes attributed to the reuse of single-use devices."[14]

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[12] See, e.g., Ronald Rosenberg, "Boston Scientific, FDA spar over stent," The Boston Globe (October 10, 1998).

[13] Letter from Dr. David Feigal, Director, Center for Devices and Radiological Health, FDA, to Larry R. Pilot, Esq., Counsel to MDMA (October 6, 1999) (emphasis added) **(Attachment K)**.

[14] Letter from Bruce Burlington, M.D., Director, Center for Devices and Radiological Health, FDA, to Nancy Singer, Esq., Special Counsel, HIMA at 2 (July 13, 1998) **(Attachment L)**.

B. The current regulatory regime is well-suited to protecting public health and should be maintained.

Notwithstanding the medical community's endorsement of the safety of reprocessing, the significant scientific support for reprocessing, the paucity of MDR reports involving reprocessed devices, and FDA's own observations regarding the lack of evidence indicating a safety problem with reprocessing, the agency has, nonetheless, decided to impose a costly and burdensome premarket review scheme on reprocessing. In AMDR's view, this premarket review scheme is unwarranted. Rather, the current regulatory framework governing third-party reprocessing is well-suited to ensuring the safety and efficacy of reprocessed devices.

Under the present regime, third-party reprocessors are required to comply with a number of FDA regulatory requirements, the most significant of which is the Quality System Regulation or QSR.[15] The QSR is an extensive set of quality assurance provisions governing every aspect of a reprocessor's operations, including production and process controls, process validation, control of non-conforming product, and finished device acceptance. Pursuant to these QSR requirements, for example, third-party reprocessors must control and monitor production processes to ensure that a device conforms to its specifications; validate with a high degree of assurance that their reprocessing processes ensure that specified requirements are met; and establish and maintain procedures for reprocessed device acceptance to ensure that each production run, lot, or batch meets acceptance criteria. See 21 C.F.R. Part 820. In other words, reprocessors must document that they have developed comprehensive systems to assure that a reprocessed device is clean, sterile, and able to perform its originally intended clinical function. Third-party reprocessors must make all required QSR information and data available for FDA inspection[16], and firms that fail to comply with these requirements are subject to agency enforcement action.

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[15] In addition to complying with applicable FDA requirements, AMDR members regulate themselves through adherence to several fundamental safety principles: (i) AMDR companies perform functionality testing on every single device they reprocess, whereas OEMs test only a small sampling of their devices; (ii) AMDR members are highly selective as to the devices they reprocess, and, in fact, reprocess only a small percentage of the thousands of devices used by hospitals; (iii) AMDR companies utilize sophisticated systems for tracking reprocessed devices and for enabling hospitals to trace reprocessed devices to the specific patients on whom they were used; and (iv) AMDR members must undergo an annual, independent, third-party audit to ensure compliance with QSR requirements.

[16] All AMDR companies have been inspected by FDA in the last 12 months.

Given the nature of medical device reprocessing, an FDA regulatory regime focusing on QSR compliance -- and, in particular, on process validation and finished device acceptance requirements -- makes sense. Indeed, reprocessors provide a device cleaning, sterilization, and testing service for hospitals. Reprocessors do not market products; rather, they perform a process on products which, in most cases, have already been cleared through the agency's premarket review process. Therefore, from a safety perspective, what is most critical is that reprocessors validate their processes, i.e., demonstrate that their cleaning, sterilization, and testing processes will, on a consistent basis, yield devices that are as safe and effective as new devices.

Furthermore, it is important to emphasize that FDA's current QSR-centered regulatory framework for reprocessors is entirely consistent with longstanding agency policy in other areas of medical device regulation. Indeed, FDA historically has viewed demonstrated compliance with QSR requirements as an acceptable substitute for premarket notification submission in certain instances. For example, in its manual addressing compliance with QSR requirements, FDA informs manufacturers that, when manufacturers with highly qualified personnel or substantial experience feel confident that a particular change in a device, component, or manufacturing process will not significantly affect the safety or effectiveness of the device, there may be no need to submit a premarket notification submission. Medical Device Quality Systems Manual: A Small Entity Compliance Guide (December 1996) at 96.

Thus, rather than impose a new, burdensome premarket review framework on medical device reprocessing, AMDR believes that FDA should maintain the current regulatory regime. As FDA states in its draft guidance document entitled "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals" (hereafter, "Enforcement Priorities draft guidance document"), under the current regime, third-party reprocessors must comply with registration, listing, QSR, labeling, MDR, and medical device corrections and removals requirements. Enforcement Priorities draft guidance document at 17. Significantly, however, while FDA has historically enforced -- and continues to enforce -- these requirements with respect to third-party reprocessors, there is an important component of the current regulatory regime, which, to date, the agency has failed to enforce with respect to OEMs. Specifically, FDA's own regulations state that

> if a manufacturer knows, or has knowledge of facts that would give him notice that a device introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it. he is required to provide adequate labeling for such a device which accords with other such uses to which the article is to be put.

21 C.F.R. § 801.4. As discussed above, according to most estimates, at least 50% of hospitals reuse certain devices labeled as single use. Thus, the manufacturers of these devices clearly "know[] or have knowledge of facts that would give [them] notice" that -- despite the single use label -- hospitals are using these devices more than once. As such, we respectfully request that FDA enforce § 801.4, and require manufacturers to provide adequate labeling on their "single use" devices.[17]

II. Given that FDA Appears to be Moving Forward to Implement a Premarket Review Scheme, AMDR Urges the Agency to Proceed in a Reasonable Manner, and is Troubled by Many Aspects of the Draft Guidance Documents.

As explained above, AMDR does not believe that FDA's proposed premarket review scheme for reprocessing is necessary to protect public health. To the contrary, as outlined in Section I, the evidence clearly shows that the current regime is well-suited to ensuring the safety and efficacy of reprocessed devices. Nonetheless, FDA appears to be moving forward to implement a premarket review scheme. As such, AMDR is eager to provide input on the agency's proposed scheme, to ensure that it is carried out in a reasonable manner. Moreover, AMDR notes that, pursuant to its mandate under the Food and Drug Modernization Act of 1997 (FDAMA), FDA is obligated to implement its premarket review scheme in a manner that minimizes the time and expense burden that premarket review requirements potentially could create for reprocessors. Congress through FDAMA specifically directs the agency to "consider, in consultation with the applicant, the least burdensome appropriate means of evaluating device effectiveness that would have a reasonable likelihood of resulting in approval."[18] 21 U.S.C. § 360c(a)(3)(D)(ii).

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[17] It is important to emphasize that AMDR does not support FDA's proposal that OEMs include on their labeling "any information of which they are aware regarding the potential risks associated with reusing their SUDs." Proposed Strategy at 13. In AMDR's view, requesting OEMs to put reprocessing-related "risk" information on their labels simply would serve as an invitation for OEMs to place inflammatory and unsubstantiated statements on their products, thereby scaring hospitals away from reuse. Indeed, from a liability perspective, hospitals certainly would be reluctant to reprocess devices that are labeled with a litany of "risks" allegedly associated with reuse. Furthermore, AMDR believes there is little sense in empowering OEMs to define reprocessing-related risks. Simply because a device manufacturer believes there are certain risks associated with reprocessing a device, does not mean a third-party reprocessor would encounter those risks. OEMs have no economic incentive to prove that a device can be reprocessed, and, in fact, have every incentive to show that it cannot be reprocessed.

[18] In its draft guidance document interpreting FDAMA's "least burdensome" (continued...)

While AMDR appreciates the daunting challenge FDA faces in implementing premarket review requirements on reprocessed devices and recognizes the amount of time and resources the agency has already devoted to this complicated issue, as discussed below, AMDR is troubled by many aspects of the agency's draft guidance documents. Most fundamentally, AMDR believes that the complex scheme contained in FDA's draft guidance document entitled "Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme" (hereafter, "RPS draft guidance document") is wholly unnecessary. In its RPS draft guidance document, the agency sets out an elaborate Review Prioritization Scheme (RPS) – two flowcharts containing a series of questions – which it uses to categorize reprocessed devices as "high," "moderate," or "low" risk. Under FDA's proposed approach, a device's risk category would determine the length of the "enforcement discretion" period permitted for compliance with premarket review requirements.

As shown below, we believe that FDA's newly-constructed risk assessment tool could lead to confusing and arbitrary results, thus making a reasonable and workable transition to a premarket review regime exceedingly difficult. Furthermore, we see no reason for FDA to invest the time and resources that would be needed to correct the serious deficiencies in the RPS and accurately apply it to the devices labeled for single use that are currently being reprocessed. Indeed, rather than attempting to construct an elaborate new "high-moderate-low" risk assessment tool, AMDR strongly urges the agency to rely on the existing device classification system as a mechanism for determining enforcement priorities. In other words, we recommend that FDA simply assign appropriate enforcement discretion periods based on the device's classification, i.e. Class I, Class II, or Class III. Given that the existing device classification system is inherently based on an assessment of a device's risk, we see no reason to depart from it. Moreover, it would ensure an orderly and predictable transition to a premarket review regime for reprocessing, because there would be no ambiguity as to whether a premarket review submission is required or when it is due. Both of these questions would be answered by ascertaining the device's classification.[19]

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[18](...continued)
provisions, the agency itself recognizes this principle. Specifically, FDA states that the agency is required to consider the "'least burdensome means' that will allow appropriate premarket development and review of a product without unnecessary delays and expense to manufacturers." "Evidence Models for the Least Burdensome Means to Market," CDRH Draft Guidance (Sept. 1, 1999) (emphasis added).

[19] Notably, ADDM, the trade association representing OEMs who oppose reprocessing, has expressed support for utilizing the existing device classification system as a mechanism for implementing premarket review requirements with respect to reprocessed devices.
(continued...)

AMDR recognizes, however, that FDA may, ultimately, choose to preserve its proposed approach, rather than adopting AMDR's recommendation. Thus, in the discussion below, we identify what we view as the most serious problems and inaccuracies with FDA's proposed scheme, and, where possible, we offer alternative approaches.[20]

A. Structural problems with FDA's Review Prioritization Scheme make accurate risk designation difficult.

In its RPS draft guidance document, FDA acknowledges that "many of the questions asked in the flowcharts may require subjective responses," and further notes "the possibility of different interpretations." RPS draft guidance document at 4. In AMDR's view, FDA itself has identified the most serious problem with the RPS: It is built – not on a foundation of objective questions and easily defined terms – but, rather, on subjective, ambiguous questions that create confusion rather than clarity. For example, Question 3, Flowchart 1, asks:

> Does the SUD include features that could impede thorough cleaning and adequate sterilization/disinfection? Some design features, such as narrow lumens and interlocking parts, can harbor debris that cannot be readily accessed and removed during cleaning unless the device can be disassembled or otherwise serviced and all surfaces of the devices exposed for manual cleaning. If a device cannot be adequately cleaned, terminal reprocessing to disinfect or sterilize the device will not be successful and the SUD presents a greater risk of disease transmission. If a device does not incorporate any of these hard to clean features, then the SUD presents a low risk of disease transmission.

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[19](...continued)
See e.g., Letter from Josephine Torrente, President, ADDM, to FDA Dockets Management Branch (December 2, 1999).

[20] FDA's draft guidance documents primarily address the imposition of premarket review requirements on reprocessors, and, as such, AMDR's comments mainly focus on premarket review issues. However, the draft guidance documents also briefly describe other FDA regulatory requirements, e.g., registration and listing, medical device reporting, labeling, etc. See Enforcement Priorities draft guidance documents at 5-9. In AMDR's view, additional clarification is needed with regard to certain of these requirements, and, as such, we respectfully request the opportunity to meet with the agency to discuss these matters.

RPS draft guidance document at 6 (emphasis added).. In AMDR's view, the four highlighted phrases above – "could impede," "narrow lumens," "readily accessed," and "hard to clean" – raise more questions than they answer, and, as such, cannot be relied upon as criteria for assigning risk. Indeed, a device that FDA or an OEM views as "hard to clean," may well be quite "easy to clean" for a third-party reprocessor who has invested time and resources in reverse engineering the device and developing a validated cleaning protocol. Similarly, any judgment as to whether features "could impede" thorough cleaning, or whether debris can be "readily accessed," or whether a lumen is "narrow," is entirely subjective. Responses to these questions will differ dramatically depending upon who is answering them.

In order to illustrate the extreme subjectivity of the RPS, AMDR applied the RPS to 14 of the 30 reprocessed devices that FDA categorized as "high risk." For all of the 14 devices examined, AMDR reached the conclusion that these devices are either "low" or "moderate" risk, not "high risk." In other words, AMDR asked the same questions that FDA asked, but reached different answers. For example, AMDR determined that electrophysiology recording catheters[21] are "low risk" according to the following analysis:[22]

Flowchart 1 – Infection Risk:

1.) *Question: Is the SUD a non-critical device?* AMDR Answer: No – Under the "Spaulding" definition of device criticality, the electrode recording catheter or electrode recording probe engages the vascular system, meaning it enters the bloodstream.

2.) *Question: Does postmarket information suggest that using the reprocessed SUD may present an increased risk of infection when compared to the use of an SUD that has not been reprocessed?* AMDR Answer: No – There is substantial postmarket information that supports the safety of proper reprocessing of the electrode recording catheter and the electrode recording probe. See, for example:

- Aton, EA, Murray, P, Frase, V, Conaway, L, Cain, ME, *"Safety of Reusing Cardiac Electrophysiology Catheters: A Prospective Study,"* **American Journal of Cardiology**, 1994, 74: 1173-1175
- Avitall, B, Kahn, M, Drum, D, Jazayeri, M, Hare, J, *"Repeated Use of Ablation Catheters: A Prospective Study,"* **Journal of the American College of Cardiology**, 1993, 22: 1367-1372

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[21] Electrophysiology recording catheters (electrode recording catheters and electrode recording probes) are Class II devices. See 21 C.F.R. § 870.1220. FDA has assigned these devices product code DRF.

[22] We are enclosing as **Attachment M** AMDR's risk assessment of 14 reprocessed devices that FDA categorized as "high risk."

- Dunnigan, A, Roberts, C, McNamara, M, Benson, DW, Bendit, DG, *"Success of Re-Use of Cardiac Electrode Catheters,"* **American Journal of Cardiology**, 1987, 60: 807-810
- Ferrell, M, Wolf, CE, Ellenbogen, KA, Wood, MA, Clemo, HF, Gilligan, DM, *"Ethylene Oxide on Electrophysiology Catheters Following Resterilization: Implications for Catheter Reuse,"* **American Journal of Cardiology**, 1997, 80:. 1558-1561
- O'Donoghue, S, Platia, EV, *"Reuse of Pacing Catheters: A Survey of Safety and Efficacy,"* **Pacing and Clinical Electrophysiology**, 1988, 11: 1279-1280

3.) ***Question: Does the SUD include features that could impede thorough cleaning and adequate sterilization/disinfection?*** AMDR Answer: No – An electrode recording catheter or electrode recording probe is a sealed lumen device that is reprocessed regularly by AMDR companies without any cleaning difficulties.

AMDR CONCLUSION: LOW RISK

Flowchart 2 – Inadequate Performance Risk:

1.) ***Question: Does postmarket information suggest that using the reprocessed SUD may present an increased risk of injury when compared to the use of an SUD that has not been reprocessed?*** AMDR Answer: No – Postmarket information suggests that proper reprocessing of an electrode recording catheter or electrode recording probe poses no increased risk of injury (see articles listed in Flowchart 1).

2.) ***Question: Could failure of the device cause death, serious injury or permanent impairment?*** AMDR Answer: Yes – The failure of an electrode recording catheter or electrode recording probe - new or reprocessed - could potentially cause death, serious injury or permanent impairment.

3.) ***Question: Does the SUD contain any materials, coatings or components that may be damaged or altered by a single use or by reprocessing and/or resterilization in such a way that the performance of the device may be adversely affected?*** AMDR Answer: No – While the materials, coatings or components of electrode recording catheters or electrode recording probes are sometimes altered during their first use, AMDR members do not reprocess damaged electrode recording catheters or electrode recording probes. Indeed, an electrode recording catheter or electrode recording probe whose materials, coatings or components have been damaged or altered by a single use in such a way that the performance of the device has been adversely affected would not be a suitable candidate for reprocessing and would be rejected by AMDR companies. With respect to the potential effects of reprocessing, AMDR companies have validated cleaning and sterilization protocols that enable them to reprocess electrode recording catheters or electrode recording probes with no damage to the materials, coatings or components. This is achieved through AMDR companies' research, reverse engineering, and the cleaning and sterilization protocol validation process that is completed before any electrode recording catheter or electrode recording probe is reprocessed. Every electrode recording catheter or electrode recording probe reprocessed by AMDR companies is tested for functionality and is examined under high magnification for any signs of wear or damage. If a problem is detected, the electrode recording catheter or electrode recording probe is rejected and is not returned to the hospital that had requested reprocessing.

2a.) *Question: Are there recognized consensus performance standards, performance tests recommended by the OEM or a CDRH guidance document that may be used to determine if the performance of the SUD has been altered due to reprocessing and use?* AMDR Answer: No.

2b.) *Question: Can visual inspection determine if performance has been affected?* AMDR Answer: Yes – AMDR companies visually inspect every electrode recording catheter or electrode recording probe. This visual inspection encompasses both functionality testing and examination under high magnification for any signs of wear or damage. If reprocessing has affected the performance of the electrode recording catheter or electrode recording probe, it is rejected and not returned to the hospital that had requested reprocessing.

AMDR CONCLUSION: LOW RISK

As the above example and the other examples contained in Attachment M clearly demonstrate, the RPS is an inappropriate mechanism for assigning risk because the questions are subject to a range of interpretations. In addition to the subjectivity of the RPS questions, AMDR sees other structural problems with the scheme. For instance, Flowchart 2, Question 2a asks:

> Are there recognized consensus performance standards, performance tests recommended by the OEMs, or a CDRH guidance document that may be used to determine if the performance of the SUD has been altered due to reprocessing and use? FDA has recognized numerous domestic and international standards that may be used for design and performance aspects of the reprocessed SUD. The list of FDA-recognized standards is available on FDA's WEBsite. OEM-recommended performance tests (e.g., manufacturer-developed tests, standards that are not recognized) may also be applicable. In addition, there are CDRH guidance documents on FDA's WEBsite, which may include specifications, test protocols, and acceptance criteria.

RPS guidance document at 9 (emphasis added). This question conspicuously omits any reference to reprocessor-recommended performance tests. It is reprocessors who have the most extensive knowledge base regarding how to evaluate whether a device's performance has been altered due to reprocessing and use. Thus, it is troubling to AMDR that the above question permits reliance on OEM-recommended performance tests, but fails to acknowledge the importance of reprocessor-recommended and developed performance tests.

Another significant problem with the RPS is its reliance on the "Spaulding" definitions of "critical," "semi-critical," and "non-critical" devices. As Flowchart 1, Question 1 states, under the "Spaulding" system:

- A non-critical device is a device that is intended to make topical contact and not penetrate intact skin;

- A semi-critical device is a device that is intended to contact intact mucous membranes and not penetrate normally sterile areas of the body; and

- A critical device is a device that is intended to contact normally sterile tissue or body spaces during use.

RPS draft guidance document at 5. What the flowchart fails to convey, however, is that the "Spaulding" scheme was initially designed as a mechanism for determining the appropriate level of disinfectant, and, therefore, the Spaulding definitions of criticality are of little use when it comes to evaluating the risk of a reprocessed device. Rather, a much more relevant exercise is to evaluate criticality from the standpoint of functionality, i.e., what will be the consequences for the patient if the device fails? Obviously, reprocessed devices whose failure is likely to cause significant patient harm should be categorized as higher risk than those whose failure would have little or no effect on the patient.

Significantly, FDA itself has historically viewed device criticality in terms of the consequences of device failure. Indeed, in its Good Manufacturing Practice regulations, which preceded the current QSR requirements, FDA defined "critical device" as

> . . . a device whose failure to perform when properly used in accordance with the instructions for use provided in the labeling can be reasonably expected to result in significant injury to the user.

Previous 21 C.F.R. § 820.3 (removed October 7, 1996). AMDR strongly urges FDA to utilize the above definition of device criticality, rather than relying on the Spaulding scheme.

B. FDA should disclose the detail underlying its risk assignments.

Given the structural problems with the RPS, AMDR, not surprisingly, takes issue with the risk category assigned to many of the devices in FDA's "List of Frequently Reprocessed SUDs." Indeed, as noted above, AMDR applied the RPS to 14 devices designated as "high risk," and found that each of the devices should, more accurately, be categorized as "moderate" or "low risk." However, except for the three examples provided in the RPS draft guidance document, FDA provides no information as to how it arrived at the risk assignments in its "List of Frequently

Reprocessed SUDs." Thus, it is impossible for AMDR to identify where our analysis diverged from the agency's, and, as such, we are hampered in our ability to offer FDA useful, thorough comments on its application of the RPS. Accordingly, we respectfully request that the agency make public the detail underlying its risk assignments, thereby enabling stakeholders to constructively challenge, or concur with, FDA's risk assignments.

C. FDA's "List of Frequently Reprocessed SUDs" appears to be incomplete.

It is AMDR's understanding that, in its "List of Frequently Reprocessed SUDs," FDA hopes to capture the entire universe of devices labeled for single use that are currently being reprocessed. Based on AMDR's review of the list, it appears that many of the devices that AMDR members reprocess are not on the list. However, the list contains numerous ambiguities and inaccuracies, which make it difficult to verify whether all of the devices currently being reprocessed are properly represented.[23] Therefore, to ensure that FDA has a complete list, we are enclosing a database of the devices that, to the best of AMDR's knowledge, are presently being reprocessed.[24] In addition, AMDR respectfully requests the opportunity to meet with FDA in order to reconcile our database with the agency's list, so as to ensure that the agency has a complete understanding of the devices currently being reprocessed.[25]

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[23] For example, in a number of instances, devices are matched with incorrect regulation numbers and/or product codes. In addition, in some cases, FDA's device groupings are overly broad, thus making it difficult to discern which specific products the agency intends to include.

[24] See **Attachment N**. We are also enclosing a list of devices that AMDR companies may begin reprocessing in the near future. See **Attachment O**.

[25] AMDR also respectfully requests that FDA clarify what, if any, role the "List of Frequently Reprocessed SUDs" will play once the final guidance document is issued. For example, FDA states that it "anticipates using the RPS in the future in response to requests from the public on the category of a reprocessed SUD not listed in Appendix 2. Such requests should be directed, in writing, to the contact noted in the Preface. FDA will periodically publish a revised list of categorized devices based upon these requests.... FDA will consider any SUD not on the current list or subsequently revised lists to be one that poses a high risk if it is reprocessed." RPS draft guidance document at 2. These statements appear to conflict with other elements of the draft guidance documents. Thus, we respectfully request that, in its final guidance document, FDA formally address and clarify these ambiguities.

D. FDA's proposed grace periods for submission of premarket review applications are unreasonably short and should be lengthened.

In its Enforcement Priorities draft guidance document, FDA proposes to require that premarket review submissions, i.e., 510(k)s and PMAs, be filed for "high risk" reprocessed devices within six months of the issuance of a final guidance document. Premarket review submissions for "moderate risk" reprocessed devices would have to be filed within 12 months; submissions for "low risk" reprocessed devices would be due within 18 months of issuance of a final guidance document. Enforcement Priorities draft guidance document at 15. In AMDR's view, these grace periods are unreasonably short and should be lengthened.

Significantly, FDA's proposed grace periods are dramatically shorter than the grace periods that historically have been permitted for similarly situated entities. For example, in 1994, when FDA determined that software products used by blood establishments to manage donor information were subject to regulation as medical devices, the agency initially provided an entire year for manufacturers to submit PMAs or 510(k)s, and the agency subsequently extended the deadline for another year. See 59 Fed. Reg. 44, 991 (Aug. 31, 1994); 60 Fed. Reg. 51, 802 (Oct. 3, 1995).

Likewise, when Congress enacted the Medical Device Amendments of 1976, manufacturers of pre-amendment devices were allowed a minimum of 30 months from the time a device was classified as Class III to submit a PMA. 21 U.S.C. § 351(f)(2). In contrast, FDA proposes to require reprocessors to submit PMAs within 6 months.

As Congress clearly recognized, firms unaccustomed to complying with FDA's premarket review requirements must be given adequate time to prepare proper submissions. Indeed, a company traditionally subject to premarket review requirements would be unable to assemble a satisfactory PMA within six months. To impose such a deadline on an industry that is facing premarket review requirements for the first time -- and for numerous different devices -- is not only unprecedented, it is unnecessary and unfair. If there were compelling evidence that protection of the public health warranted requiring such a draconian grace period, AMDR would, of course, support FDA's proposal. However, the facts clearly show that no such public health threat exists. Indeed, FDA itself acknowledges that it has "been unable to find clear evidence of adverse patient outcomes associated with the reuse of a single use device from any source."[26]

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[26] Letter from Dr. David Feigal, Director, Center for Devices and Radiological Health, FDA, to Larry R. Pilot, Esq., Counsel to MDMA (October 6, 1999) (emphasis added) (**Attachment K**).

In fact, AMDR is concerned that the public health may well be harmed if FDA maintains its proposed grace periods. Confronted with impossibly short deadlines for submitting premarket review applications on numerous devices, reprocessors may be compelled to stop reprocessing certain devices. As a result, hospitals could face shortages of important devices and be forced to discontinue providing certain medical procedures. For patients in need of such procedures, the implications are potentially devastating.

Therefore, as an alternative to FDA's approach, AMDR respectfully requests that the agency increase each proposed grace period by at least six months. Accordingly, premarket review submissions for "high risk" devices would have to be submitted within 12 months of the issuance of a final guidance document. Submissions for "moderate" and "low risk" devices would be due within 18 and 24 months, respectively.[27]

E. "Enforcement discretion" periods should not depend upon FDA responding to the reprocessor's premarket review submission within a predetermined timeframe.

In addition to our above objections to the length of FDA's proposed grace periods, AMDR strongly objects to the notion that, under FDA's draft guidance documents, the duration of agency "enforcement discretion" would depend upon FDA responding to premarket review submissions for reprocessed devices within a predetermined timeframe. For example, FDA states that it intends to continue to exercise its discretion to not enforce premarket requirements for third party reprocessors and hospital reprocessors of devices that are considered high risk for one (1) year from the date of issuance of a final SUD enforcement guidance provided:

> 1. FDA receives a 510(k) submission or a PMA application within six (6) months of the issuance of the final SUD enforcement guidance;
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> 2. The 510(k) submission or PMA application is complete and is of sufficient quality to be acceptable for substantive review . . . ; and

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[27] If, as AMDR strongly urges, FDA abandons the RPS, and instead simply assigns submission grace periods to each device class, AMDR recommends the following grace periods: 12 months for Class III devices, 18 months for Class II devices, and 24 months for Class I devices.

> 3. The applicant receives an FDA order finding the device substantially equivalent and cleared for marketing, or an order approving a premarket approval application within six (6) months of the filing date.

Enforcement Priorities draft guidance document at 15 (emphasis added). According to this criteria, a reprocessor that submits an administratively complete premarket review application within the specified grace period would, nonetheless, be forced to stop reprocessing the device in question if FDA takes longer than six months to respond to the application.

AMDR strongly objects to such an approach. Because of agency resource constraints, delay in reviewing and responding to premarket review applications is common, and, given that FDA reviewers have little experience with submissions for reprocessed devices, there is likely to be more delay than normal. Moreover, in proposing to penalize an industry because of FDA's failure to approve or deny a submission within a predetermined timeframe, the agency has, once again, dramatically departed from prior practice. Indeed, as described in the example above, manufacturers of pre-amendment devices are permitted at least 30 months from the time a device is classified as Class III to submit a PMA. As long as the manufacturer submits a timely PMA, its device may remain on the market until the PMA is approved or denied -- even if the approval/denial process takes several years. In other words, manufacturers of pre-amendment Class III devices are not forced to stop marketing their products simply because FDA fails to respond within a predetermined timeframe.

Thus, AMDR strongly urges the agency to eliminate any link between the duration of agency enforcement discretion and the agency approving or denying premarket review submissions within a pre-set time period. Rather, reprocessors who file timely and administratively complete submissions should be permitted to continue reprocessing until their applications are approved or denied -- regardless of how long this process takes.

F. Submission of an "administratively incomplete" application should not terminate FDA's exercise of enforcement discretion.

AMDR also is concerned that, under FDA's proposed scheme, it appears that submission of an "administratively incomplete" premarket review submission could automatically terminate FDA's enforcement discretion with respect to premarket review requirements. The agency states, in pertinent part:

> FDA will initially review your 510(k) submission or PMA application to make a threshold determination as to whether it contains sufficient information to begin substantive review. If the submission does not on its face, contain all the information required under 21 C.F.R. 807.87 (for 510(k)s) or 21 C.F.R. 814.20 (for PMAs), FDA will not review that application or submission any further and the file will be placed on hold. . . . You may submit the additional information to complete the file, but FDA does not intend to exercise enforcement discretion described in this document for reprocessed SUDs that are not the subject of complete applications or submissions. In other words, FDA may take immediate enforcement action for failure to comply with premarket requirements upon determining that a 510(k) submission or PMA application is administratively incomplete.

Enforcement Priorities draft guidance document at 12.

According to the above provision, if FDA were to find a reprocessor's premarket review submission "administratively incomplete," this would trigger an end to agency enforcement discretion, and the reprocessor would be vulnerable to enforcement action for failure to comply with premarket review requirements -- even if FDA's finding of "administrative incompleteness" came before the reprocessor's grace period for submission had ended. Thus, if, hypothetically, a final guidance document were issued on July 1, 2000, under FDA's proposed scheme, reprocessors would have one year -- until July 1, 2001 -- to submit premarket review applications for "moderate risk" devices. The above language suggests that a reprocessor who submitted a premarket review application on August 1, 2000, and learned on September 1, 2000 that the application was "administratively incomplete," would, as of September 1, 2000, be subject to FDA enforcement action for failure to comply with premarket review requirements -- even though that reprocessor could have waited until July 1, 2001 to initially submit its application.

In informal conversations with FDA, AMDR was told that the agency did not intend for the above provision to deprive reprocessors of the benefit of a full grace period for submission of their premarket review applications. When presented with the above hypothetical, the agency informed AMDR that a reprocessor who learned on September 1, 2000 that its application was "administratively incomplete" would continue to enjoy agency enforcement discretion with respect to premarket review requirements until the specified grace period had ended, i.e., July 1, 2001. AMDR respectfully requests that, in the final guidance document, FDA formally address and clarify this issue.

AMDR also respectfully requests that, in its final guidance document, FDA specify that, as long as a reprocessor files a timely premarket review submission – even if the submission is filed at or near the very end of the designated grace period – the reprocessor will be permitted an additional 60 days to make appropriate modifications, if FDA finds that the application is "administratively incomplete." FDA would exercise enforcement discretion with respect to premarket review requirements during this 60-day period, and, as long as the re-submitted application were found to be "administratively complete," enforcement discretion would continue. However, if FDA determined that the re-submitted application was "administratively incomplete," enforcement discretion would cease, and the reprocessor would be subject to enforcement action for failure to comply with premarket review requirements.

Given that the reprocessing industry has never before been required to comply with premarket review requirements, and, further, that FDA has little experience in reviewing premarket review submissions for reprocessed devices, there will be a steep "learning curve" as reprocessors become familiar with what is required for an "administratively complete" submission, and as FDA reviewers learn what a submission for a reprocessed device should look like. Thus, in AMDR's judgment, a fair and logical approach would be to permit reprocessors at least one opportunity to make necessary corrections to an "administratively incomplete" premarket review submission.

G. In order to address HCFA-related Medicare reimbursement concerns, FDA should clarify its historical and ongoing rationale for using "enforcement discretion" with respect to premarket review requirements.

As FDA acknowledges in its Enforcement Priorities draft guidance document, the agency has, to date, utilized its enforcement discretion not to enforce premarket review requirements with respect to reprocessors of devices labeled for single use. Enforcement Priorities draft guidance document at 14. Likewise, FDA's proposal to begin imposing premarket review requirements on reprocessed devices depends heavily on the exercise of agency enforcement discretion. Indeed, rather than requiring immediate compliance with premarket review requirements, FDA proposes to "phase-in" compliance, allowing different grace periods depending on the perceived risk of the reprocessed device. During the grace periods, the agency plans to use its enforcement discretion not to enforce premarket review requirements.

If premarket review requirements are going to be imposed at all on reprocessors, implementation must be done on a gradual basis. However, AMDR is concerned about the Health Care Financing Administration-related Medicare reimbursement implications of FDA utilizing its enforcement discretion to implement a "phased-in" approach. Indeed, in the last several months, questions have arisen as to whether the Health Care Financing Administration (HCFA) will allow

reimbursement for medical procedures involving reprocessed devices. This uncertainty stems from FDA's current policy of using its enforcement discretion with respect to premarket review requirements, as well as certain FDA statements regarding the "lawfulness" of reprocessing conducted absent premarket review.[28]

Given that the HCFA-related uncertainty surrounding FDA's use of enforcement discretion could have potentially devastating consequences for the reprocessing industry and for the thousands of hospitals that utilize reprocessed devices, AMDR strongly urges FDA to clarify its historical and ongoing rationale for using enforcement discretion with respect to premarket review requirements. As an example, we believe that including the following language in FDA's final guidance document could help to quell some of the uncertainty this issue has generated:

> *To date, FDA has used its enforcement discretion not to enforce premarket review requirements against third-party reprocessors -- and will continue to use the same enforcement discretion to "phase in" the enforcement of premarket review requirements against third-party reprocessors -- because FDA has not found sufficient evidence to suggest that reprocessing, absent FDA premarket review, presents a threat to public health.*

H. FDA's proposed definitions should be revised.

In Appendix A of the Enforcement Priorities draft guidance document, FDA proposes definitions for "hospital," "single-use device," "opened-but-unused," "reuse," "reprocessing," and "resterilization." AMDR recommends the following revisions to FDA's proposed definitions:

1. Single use device

FDA proposes the following definition for "single-use device":

> Single-use device: a single-use device that is intended to be used on one patient during a single procedure. It is not intended to be reprocessed (cleaned and

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[28] See, e.g., Letter from Larry Spears, Director, Division of Enforcement III, Office of Compliance, Center for Devices and Radiological Health, to Stephen D. Terman, Esq., Olsson, Frank and Weeda, P.C. (July 9, 1999); Letter from Grant P. Bagley, M.D., Director, Coverage and Analysis Group, HCFA, to Josephine Torrente, Esq., Hyman, Phelps & McNamara, P.C. (**Attachment P**).

> disinfected/sterilized) and used on another patient. The labeling identifies the device as disposable and does not include instructions for reprocessing. Some single-use disposable devices are marketed as non-sterile and include appropriate pre-use sterilization or processing instructions to make the device patient-ready.

AMDR is troubled by the above definition because it links the notion of single use to what the manufacturer "intends." However, it is not at all clear what "intent" means in this context. Rather, in AMDR's view, a device should come within the definition of single use only if it is labeled to be used on one patient during a single procedure. As such, AMDR recommends that the above definition be modified as follows:

> *Single use device: A device that is labeled to be used on one patient during a single procedure. The labeling identifies the device as disposable and does not include instructions for reprocessing. Some single use devices are marketed as non-sterile and include appropriate pre-use sterilization or processing instructions to make the device patient-ready.*

2. **Opened-but-unused**

> FDA proposed the following definition for "opened-but-unused":
>
> Opened-but-unused: an opened-but-unused device is a single-use device whose sterility has been breached or whose sterile package was opened but the device has not been used on a patient.

As explained above, AMDR believes that any definition incorporating the notion of "single use" must be confined to explicit single use labeling. Thus, AMDR proposes to define "opened-but-unused" as follows:

> *Opened-but-unused: An open-but-unused device is a device that is labeled to be used on one patient during a single procedure, whose sterility has been breached or whose sterile package has been opened, but which has not been used on a patient.*

3. Reuse

FDA proposes the following definition for "reuse":

> Reuse: the repeated use or multiple use of any medical device including reusable and single-use medical devices, on the same patient or on different patients, with applicable reprocessing (cleaning and disinfection/sterilization) between uses.

In AMDR's view, the above definition is unnecessarily repetitive and complex. Instead, AMDR recommends that "reuse" be defined as follows:

> *Reuse: The use of a device more than once.*

4. Reprocessing

FDA proposes to define "reprocessing" as follows:

> Reprocessing: includes all operations performed to render a contaminated reusable or single-use device patient ready or to allow an unused product that has been opened to be made patient ready. The steps may include cleaning and disinfection/sterilization. The manufacturer of reusable devices and single-use devices that are marketed as non-sterile should provide validated reprocessing instructions in the labeling.

AMDR believes that the above definition is incomplete because it does not include the functional testing or packaging steps of reprocessing. In addition, this definition fails to reflect that reprocessing may be performed on open but unused devices. Therefore, AMDR recommends that FDA adopt the following definition of "reprocessing":

> *Reprocessing: All operations performed to render a used or opened but unused device patient-ready. Reprocessing steps may include cleaning, functional testing, packaging, and sterilization. The manufacturers of reusable devices and single use devices that are marketed as non-sterile should provide validated reprocessing instructions in the labeling.*

5. Resterilization

FDA proposes the following definition of "resterilization":

> Resterilization: the repeated application of a terminal process designed to remove or destroy all viable forms of microbial life, including bacterial spores, to an acceptable sterility assurance level.

AMDR believes that the following definition of resterilization is more scientifically accurate and should be adopted by FDA:

> *Resterilization: The repeated application of a terminal process designed to reduce the bioburden to an acceptable sterility assurance level.*

III. Conclusion

In conclusion, AMDR wishes to reiterate its support for a strong, rational FDA regulatory regime governing reprocessing. AMDR believes that patient safety is best served through vigorous FDA oversight of medical device reprocessing. While AMDR feels that premarket review for reprocessed devices is unnecessary, we hope that a reasonable premarket review scheme can be achieved, and we look forward to working with the agency and other stakeholders to accomplish this.

From AMDR's perspective, the utilization of consensus standards must play a critical role in moving towards a workable premarket review scheme for reprocessing. In this regard, we applaud the agency's participation in the Association for the Advancement of Medical Instrumentation's (AAMI) development of a Technical Information Report for the cleaning of medical devices. Going forward, AMDR is eager to work with FDA, AAMI, manufacturers, hospitals, physicians, and other interested parties to develop additional consensus standards.

Finally, AMDR feels it is important to emphasize that, by far the strongest opposition to reprocessing comes from companies that have an overwhelming economic incentive to advocate for a regulatory regime so burdensome that it will effectively eliminate reprocessing as an option for hospitals. As discussed above, these manufacturers argue that reprocessing is unsafe. Yet, as demonstrated in Section I, the facts clearly show that proper reprocessing is absolutely safe. These manufacturers also argue that FDA is obligated to impose premarket review requirements on reprocessors because it considers reprocessors to be "manufacturers." However, it is clear that the agency has no such obligation. To the contrary, quite recently, FDA decided not to apply premarket review requirements to the device servicing and refurbishing industry – despite the fact

that the agency considers servicers and refurbishers to be manufacturers.[29] It is unclear to AMDR why the agency has chosen to treat reprocessors of devices labeled for single use differently than device servicers and refurbishers.

Conspicuously missing from the manufacturers' rhetoric, however, is any acknowledgment of the economic agenda driving their campaign against reprocessing. Indeed, from the OEMs' perspective, every time a hospital safely uses a reprocessed device, rather than purchasing a new one, this is a lost sale. Thus, as FDA finalizes its draft guidance documents, AMDR urges the agency to avoid being swayed by the tremendous financial and political pressure exerted by the OEMs who oppose reprocessing. Rather, we respectfully request that FDA take into account the strong safety record of reprocessing, and the direct, negative impact on patients of unnecessarily restricting reprocessing.

* * *

AMDR appreciates the opportunity to provide comments on FDA's draft guidance documents. Should the agency have any questions regarding the information presented in this document, please do not hesitate to contact us.

Respectfully submitted,

Pamela J. Furman
Executive Director

PJF:la
Enclosures

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[29] Apparently, FDA studied the risks presented by servicing and refurbishing, and concluded that "self-regulation" of this set of device manufacturers was adequate to protect public health. Indeed, rather than imposing a complex premarket review scheme on the device servicing and refurbishing industry, FDA is permitting the industry to police itself through a system of voluntary controls. See Hatem, Mary Beth, "From Regulation to Registration," Biomedical Instrumentation and Technology, Vol. 33 (Sept./Oct. 1999).