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BY HAND DELIVERY

Food and Drug Administration
Dockets Management Branch (HFA-305)
5630 Fishers Lane
Room 1061
Rockville, Maryland 20857

Re: Docket No. 99N-4491

Dear Sir or Madam:

Hyman, Phelps & McNamara, P.C., on behalf of the Association of Disposable Device Manufacturers (ADDM), respectfully submits these comments in response to the Notice entitled, "FDA's Proposed Strategy on Reuse of Single Use Devices"¹ (hereinafter, FDA Proposed Strategy) and the subsequent Draft Guidance entitled, "Reprocessing and Reuse of Single Use Devices: Risk Categorization Scheme"² (Risk Categorization Guidance).

¹ See 64 Fed. Reg. 59782 (Nov. 3, 1999).

² See Draft Guidance: Reprocessing and Reuse of Single Use Devices: Risk Categorization Scheme, Office of Device Evaluation (ODE), Center for Devices and Radiological Health (CDRH), FDA (Dec. 9, 1999).

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ADDM is a trade association of medical device manufacturers dedicated to providing information and industry perspectives on issues impacting single use devices.³ ADDM's goal is to bring about the appropriate regulation of reprocessed single use devices. Such regulation will ensure patient safety, conform to the Federal Food, Drug, and Cosmetic Act (FDC Act),⁴ demonstrate regulatory fairness, and result in proper allocation of U.S. Food and Drug Administration (FDA or the agency) resources. ADDM has previously submitted an alternative strategy on the regulation of single use device reprocessing (ADDM Strategy) to this docket.⁵ ADDM continues to believe that the ADDM Strategy should be implemented in lieu of the FDA Proposed Strategy. Nonetheless, this submission provides general comments on the FDA Proposed Strategy followed by comments addressing each of its eight specific components.

I. General Comments

A. Single Use Devices that are Reprocessed Must be Regulated as Reusable Devices

The Medical Device Amendments of 1976 (MDA) were designed to protect patients from unsafe and ineffective devices, whether single use or reusable.⁶ Reprocessing a single use device changes the intended use of that device from single use to multiple use, rendering reprocessors manufacturers of reusable devices. Appropriate regulation of disposable medical device reprocessing would therefore involve enforcement of all provisions of the FDC Act applicable to reusable devices.

Despite FDA's recognition that Congress intended reprocessors to be subject to the same legal requirements as other manufacturers, the agency has, without justification,

³ The term "single use device" is used throughout this comment to mean a medical device labeled or otherwise intended by its manufacturer, and cleared or approved by FDA, to be used in a single patient during a single procedure.

⁴ See Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended 21 U.S.C. §§ 301 et seq. (1994)).

⁵ See Letter from Josephine Torrente, Esq., President, ADDM, to FDA Dockets Management Branch (FDA Docket No. 99N-4491) (Dec. 2, 1999).

⁶ Pub. L. No. 94-295, 90 Stat. 539 (1976) (codified at 15 U.S.C. § 55 and 21 U.S.C. §§ 31, 331).

refused to enforce certain key safety controls on reprocessors.⁷ This refusal exposes the American public to medical devices whose safety and effectiveness are, at best, unknown. The FDA Proposed Strategy perpetuates this regulatory inaction for many reprocessed disposable devices putting the FDA Proposed Strategy at odds with the agency's congressional mandate to protect patients from unsafe and ineffective medical devices. No rationale designed to protect public safety can support FDA's continued failure to enforce premarket controls for all reprocessed single use devices.

Unlike the FDA Proposed Strategy, the ADDM Strategy recognizes reprocessed single use devices for what they are: reusable devices. Moreover, the ADDM Strategy safeguards patients by requiring premarket clearance or approval of all reprocessed single use devices. Safety is ensured through FDA regulations, guidances, policies, and enforcement practices already developed for oversight of reusable medical devices. Complying with both the letter and the spirit of the FDC Act, the ADDM Strategy allows for exemption from premarket controls only after FDA reviews data in conjunction with a publicly available petition for exemption. Like all other reusable devices, those reprocessed single use devices for which there is a demonstrated lack of risk would be exempted from premarket submission, thus properly allocating FDA's resources to higher risk products. FDA's implementation of the ADDM Strategy would achieve the parallel goals of increased patient safety, conformance with the FDC Act, parity in regulation of manufacturers, and conservation of agency resources.

B. The FDA Proposed Strategy is Inconsistent with the Requirements of the FDC Act and the Administrative Procedures Act (APA)

1. The FDC Act requires premarket submissions for reprocessed single use devices

The FDC Act requires that, prior to their introduction into interstate commerce, all new medical devices must be FDA-cleared or approved through the premarket notification

⁷ See Letter from Larry Spears, Director, Division of Enforcement III, Office of Compliance (OC), CDRH, FDA, to Stephen Terman, Esq., Olsson, Frank & Weeda, P.C. (July 9, 1999) ("Third-party reprocessing of devices labeled for single use is unlawful unless those engaged in this practice comply with all regulatory requirements for manufacturers, including premarket notification requirements. FDA has exercised and will continue to exercise regulatory discretion for all premarket notification requirements.").

(510(k)) or premarket approval (PMA) process. This process requires submission of data by the party that intends to market the device. For a single use device, the original equipment manufacturer (OEM) demonstrates that the device is safe and effective for use on a single patient in a single procedure, and the device is therefore cleared/approved for only that use. Reprocessing significantly modifies a single use device by changing its intended use to multiple use. Manufacturers of reusable devices, including single use device reprocessors, are required to submit a new 510(k) or PMA, including data to support the safety and effectiveness of the device for multiple use, prior to marketing the device for use in other patients.⁸ While FDA agrees that reprocessors of single use devices are manufacturers under the FDC Act and its implementing regulations,⁹ and, as such, reprocessors are subject to the provisions of the FDC Act that require manufacturers to obtain clearance of a 510(k) or approval of a PMA,¹⁰ the agency has clearly announced its intention to permit reprocessed single use devices to be marketed without its clearance/approval, and has subjected them only to some degree of *post-market* regulation. In a July 9, 1999 letter, FDA noted that, “third-party reprocessing of devices labeled for single use is unlawful unless those engaged in this practice comply with all regulatory requirements for manufacturers, *including premarket notification requirements.*” However, “FDA has exercised and will continue to exercise regulatory discretion for all premarket

⁸ Guidance: Deciding When to Submit a 510(k) for a Change to an Existing Device, ODE, CDRH, FDA, at 10-11 (Jan. 10, 1997).

⁹ See *supra* note 7; FDC Act § 510(a)(1), 21 U.S.C. § 360(a)(1); 61 Fed. Reg. 52602 (1996). Although the FDC Act does not globally define the term “manufacturer,” various provisions of the Act authorize FDA to regulate the manufacturers of medical devices. For example, the establishment registration and device listing requirements set forth in section 510 apply to any entity engaged in the “manufacture, preparation, propagation, compounding or processing” of devices for commercial distribution. In the 1996 Quality System Regulations (QSR), FDA developed its own definition of the term “manufacturer” as “any person, [including any repacker and/or relabeler] who designs, manufactures, fabricates, assembles, or processes a finished device.” 61 Fed. Reg. at 52656. In the QSR, FDA acknowledged that reprocessing entities fall within the broad definition of manufacturers, as intended by the FDC Act.

¹⁰ See 21 C.F.R. Part 807, Subpart E and Part 814 (1999).

notification requirements.”¹¹ This unjustified use of enforcement discretion is perpetuated for many reprocessed single use devices under the FDA Proposed Strategy.

The MDA requires pre-clearance by all device manufacturers, whether they are OEMs or reprocessors. The MDA was enacted for the purpose of implementing *pre-market* review of devices because Congress was concerned that post-marketing regulation of medical devices was inadequate to protect public health.¹² The design of the MDA reveals Congress’ belief that post-market controls are insufficient to regulate medical devices. In today’s world of increasingly complex medical devices and heightened concern over disease transmission, the regulatory discretion FDA has proposed to use under the FDA Proposed Strategy, is inconsistent with Congress’ intent. In enacting the MDA, Congress’ goal was to protect patients from unsafe and ineffective devices, regardless of the identity of the device’s manufacturer. As such, there is no justification for a patient to receive less protection from FDA merely because the device used for the patient’s treatment was a reprocessed single use device rather than an FDA-cleared reusable device. FDA is, in effect, creating a *de facto* exemption from the premarket review requirements for most reprocessed single use devices – and in doing so, is violating its congressional mandate.

2. *The APA requires that FDA regulate similarly situated parties in similar fashion*

Under the APA, a court may review and hold unlawful an agency decision that is arbitrary or capricious.¹³ Under the “arbitrary and capricious” standard, courts have held that treating two similarly situated companies in a different manner is a violation of the APA. In the area of single use devices, FDA has disparately treated two similarly situated parties –OEMs and reprocessors– as exemplified by FDA’s inconsistent enforcement of the premarket controls.

¹¹ Letter from Larry Spears, Director, Division of Enforcement III, OC, CDRH, FDA to Stephen Terman, Esq., Olsson, Frank and Weeda, P.C. (July 9, 1999) (emphasis added).

¹² See H.R. Rep. No. 94-853 (1976).

¹³ See 5 U.S.C. § 706(2)(A) (“The reviewing court shall . . . (2) hold unlawful and set aside agency action, findings, and conclusions found to be (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. . . .”).

For example, in order to market a single use surgical stapler for use in multiple patients, an OEM must first obtain clearance of a 510(k) from FDA. A reprocessor that wishes to market that same stapler for use in multiple patients is currently free to do so without a 510(k). Not only is this dichotomy arbitrary, it is also illogical since the OEM has full knowledge of the design criteria and specifications of the device and is in a far better position than the reprocessor to determine whether the device can be reused. When asked what the OEM's regulatory obligation would be if the OEM merged with the reprocessing company that reprocesses the OEM's stapler, FDA responded that the OEM "would have a problem."¹⁴ While FDA did not expand on what that problem might be, there are at least two possibilities. First, because of the lack of a cleared 510(k), the OEM's new reprocessing subsidiary might not be permitted to continue reprocessing the OEM's staplers, yet it might be permitted to reprocess single use devices made by other companies. Second, and equally absurd, the OEM, through its ownership of the reprocessor, might be permitted to reprocess its own single use devices without a 510(k) clearance, yet it might not be permitted to label them for multiple use. Both situations underscore the unfair and illogical nature of FDA's position.

In Federal Election Comm'n v. Rose, the United States Court of Appeals for the District of Columbia held that, "an agency's unjustifiably disparate treatment of two similarly situated parties works a violation of the arbitrary-and-capricious standard."¹⁵ Such behavior by federal agencies is prohibited by the APA.¹⁶ By assigning unequal regulatory burdens to OEMs and reproducers, FDA violates this principle. Recently, in Bracco Diagnostics, Inc. v. Shalala, the United States District Court for the District of Columbia addressed a situation where FDA applied different premarket review standards to two similar products.¹⁷ Bracco, the manufacturer of an injectable contrast imaging agent, successfully challenged FDA's determination that its product should be regulated as a drug, while a competitor's similar product was classified under the regulatory regime of a device. The court, enjoining any action on these products until FDA decided on a uniform

¹⁴ Remarks made by Casper Uldricks, Special Assistant to the Director, OC, CDRH, FDA, at the FDLI/FDA 42nd Annual Educational Conference (Dec. 16-17, 1998) (transcript unavailable).

¹⁵ 806 F.2d 1081, 1089 (D.C. Cir. 1986) (citation omitted).

¹⁶ See 5 U.S.C. § 706(2)(A).

¹⁷ See 963 F. Supp. 20 (D.D.C. 1997).

regulatory regime, held “[t]he disparate treatment of functionally indistinguishable products is the essence of the meaning of arbitrary and capricious.”¹⁸

FDA acknowledges that it “has not regulated OEMs, third-party reproducers, and health care facilities in the same manner with respect to [single use devices].”¹⁹ In the FDA Proposed Strategy, FDA lists the seven requirements of the FDC Act to which OEMs must adhere: 1) registration and listing; 2) premarket notification and approval requirements; 3) submission of adverse event reports under the Medical Device Reporting (MDR) regulation; 4) manufacturing requirements under the Quality Systems Regulation (QSR); 5) labeling requirements; 6) Medical Device Tracking; and 7) Medical Device Corrections and Removals.²⁰ Of these requirements, FDA acknowledges that reproducers have only been subject to four –registration and listing, QSR,²¹ labeling requirements, and MDR reporting requirements.²² This discrepant treatment by itself violates the APA. Moreover, the

¹⁸ See id. at 28 (citation omitted); see also United States v. Diapulse Corp. of America, 748 F.2d 56, 62 (2d Cir. 1984) (holding that FDA must act “evenhandedly” and may “not ‘grant to one person the right to do that which it denies to another similarly situated.’”); Willapoint Oysters, Inc. v. Ewing, 174 F.2d 676, 697 (9th Cir.), cert. denied, 338 U.S. 860 (1949); Int’l Rehabilitative Sci., Inc. v. Kessler, Civil No. SA-93-CA-0242, slip op. At 23 (W.D. Tex. June 28, 1993) (finding that FDA’s “divergent treatment” of the devices was “glaring evidence of arbitrary action.”).

¹⁹ FDA Proposed Strategy at 4.

²⁰ See id.

²¹ While FDA has acknowledged that reproducers of single use devices must comply with the QSR, the agency has failed to address how compliance can be possible in certain instances. For example, a reproducer may not be able to verify that devices continue to function safely post-reprocessing. This is because the reproducer does not have sufficient knowledge of the device’s design to determine which functional tests must be carried out or to know the acceptable range of outcomes for those tests. A reproducer’s verification of only those specifications listed on the device’s labeling is insufficient to assure safety and effectiveness of that device.

²² That reproducers are currently not required to comply with even the Medical Device Correction and Removals regulation is particularly telling since this is one of FDA’s most important conduits for receipt of adulterated or misbranded device information having safety ramifications (i.e., Class I and Class II recalls). In addition, even the four requirements that FDA lists as applicable to reproducers are not generally

requirement of greatest consequence and complexity, and the one most important for patient safety –the premarket notification and approval requirement– is not being enforced against reprocessors. The FDA Proposed Strategy violates the APA by continuing to treat reprocessors and OEMs differently. Specifically, the FDA Proposed Strategy will require premarket submissions for OEMs to change any single use device to reusable, but only imposes preclearance requirements on reprocessors for certain single use devices.

This disparate treatment seriously compromises public safety. Devices are being marketed that have not been demonstrated safe and effective as required by law. FDA is effecting a double standard that lowers the burden for reprocessors as compared to OEMs and thus, amounts to arbitrary and capricious activity under the APA. The APA and the protection of U.S. patients both require that FDA regulate all manufacturers in the same manner, regardless of whether those manufacturers are deemed OEMs or reprocessors.

C. Scientific Evidence of Risk to Patients

The FDC Act establishes a presumption that all medical devices are unsafe, and requires that the safety and effectiveness (or substantial equivalence) of new devices be affirmatively demonstrated prior to their entrance into interstate commerce.²³ In addition, FDA regulations have established that substantially modified devices should be regulated as new devices. Claiming that a single use device may be reused causes the device to be

complied with by the reprocessing industry. Only seven of the over twenty existing reprocessors are registered with FDA, and it is not clear whether even those seven provide device lists. Reprocessed device labels do not typically contain necessary information such as applicable latex warnings and proper instructions for use. Because the OEM's name, not the reprocessor's name, appears on the reprocessed device, most adverse events are reported to the OEM by the hospital, resulting in very few MDR reports from reprocessors.

²³ See United States v Bowen, 172 F.3d 682, 687 (9th Cir. 1999) (“The procedure for classifying devices initially places *all* new devices in class III.”) United States v. An Article of Device . . . Stryker Shoulder . . . Ligament Prosthesis, 607 F. Supp. 990, 998 (W.D. Mich 1985) (“A ‘new device’ . . . is automatically placed in the class III category, and immediately triggers the requirement for premarket approval.”) (citation omitted). See H.R. Rep. No. 94-853 (1976) at 40 (“Under the proposed legislation, the burden of providing evidence substantiating the safety and effectiveness of a medical device rests upon the manufacturer.”).

treated as a new device under FDA's regulatory scheme.²⁴ Yet, for years FDA has thwarted this clearly stated congressional intent by allowing reprocessed single use devices to be used on patients without requiring or reviewing the necessary data. Instead, FDA determined that it need not take action until it is presented with "clear evidence that reprocessing presents an unreasonable and substantial risk of illness or injury"²⁵ – a standard quite different from the one established by Congress.²⁶

FDA first evidenced its intent to circumvent the FDC Act when it refused to require that reprocessors demonstrate safety and effectiveness of their products, but instead suggested that OEMs provide data regarding the risks associated with reprocessing.²⁷ Although FDA's shifting of the burden was improper, the OEM industry expended substantial effort to test reprocessed single use devices. The data from that testing, all of which has been submitted to FDA, overwhelmingly indicates serious safety concerns. In addition, FDA's Office of Science and Technology (OST) simultaneously generated its own independent data confirming the risks of reusing certain single use devices. FDA has consistently ignored the OEM studies and has sought to discredit its own data.

In addition to the studies performed by OEMs and OST, additional data has been generated by independent hospital studies, by published literature reports, and by actual patient injuries and device malfunctions reported to FDA through the MedWatch system. Despite the volume of such data on file at FDA, officials at the CDRH have publicly claimed that there is little or no credible scientific evidence available demonstrating that the

²⁴ 21 C.F.R. Part 807, Subpart E; Part 814.

²⁵ Letter from David Feigal, Jr., M.D., M.P.H., Director, CDRH, FDA, to Larry Pilot, Esq., McKenna and Cuneo, L.L.P. at 1 (Oct. 6, 1999) (FDA Docket No. 99P-1516) (responding to MDMA citizen petition requesting FDA to ban reprocessed single use devices).

²⁶ See United States v. 789 Cases of Latex Surgeons' Gloves, 799 F. Supp. 1275, 1286 (D.P.R. 1992) ("[A]fter-the- fact regulatory action would offer little or no protection to those members of the public already exposed to – or harmed by – unsafe or ineffective medical devices.").

²⁷ Letter from Bruce Burlington, M.D., Director, CDRH, FDA, to Nancy Singer, Esq., Special Counsel, HIMA, at 2 (July 15, 1998) (FDA Docket No. 97P-0377) ("[W]e are encouraging...OEMs...to provide any data demonstrating adverse patient outcomes from the use of reprocessed 'single use only' devices.").

reuse of disposable medical devices is unsafe. At FDA's November 1999 videoconference, in response to a question regarding FDA's knowledge of such data, the Director of OST stated that, "we haven't had any formal submissions of data on which to make a call for reuse decisions."²⁸ This statement is a serious mischaracterization of the ADDM studies and other scientific submissions filed with CDRH over the past year and misleads the public. On November 22, 1999, ADDM submitted sixteen abstracts summarizing key studies that had previously been submitted to, or conducted by, FDA.²⁹ These abstracts verify that FDA has valid scientific data on file confirming the physical, microbiological, and functional performance failures associated with reuse of used single use devices.

1. Stakeholder data

At least nineteen scientific studies involving approximately 1000 individual devices have been submitted to FDA on this topic.³⁰ These studies have been conducted by independent scientists, hospitals, OEMs, and, as mentioned above, FDA's own laboratory personnel. Many of the devices used in these studies were obtained directly from hospital shelves where they were "ready for use" in seriously ill patients (e.g., patients suffering from cancer, heart disease, and requiring major abdominal, cardiovascular or thoracic surgery).

Devices studied included biopsy forceps, angioplasty balloon catheters, electrophysiology catheters, surgical trocars, staplers, papillotomes, and other general surgical instruments. Approximately 75% of the samples studied failed, either due to the presence of blood and/or proteinaceous matter, bacterial contamination, non-functionality, or defective packaging. In each of seven studies with reprocessed biopsy forceps, a lack of sterility assurance was reported in over 45% of the samples tested. This particular failure

²⁸ Statement of Donald Marlowe, Director, OST, CDRH, FDA, at the FDA Satellite Videoconference on the Proposed FDA Strategy for Reuse of Single Use Devices (Panel I) (Nov. 10, 1999) (videotape on file at Hyman, Phelps & McNamara, P.C.).

²⁹ See Letter from Josephine Torrente, Esq., President, ADDM, to David Feigal, Jr., M.D., M.P.H., Director, CDRH, FDA (Nov. 22, 1999).

³⁰ It is interesting to note that, while minimizing these nineteen studies, the FDA, in promulgating its final rule on labeling for devices containing latex, relied on only four studies to conclude that "there are numerous reports that levels of natural latex proteins found in dry rubber can cause allergic reactions." 62 Fed. Reg. 51021, 51023 (Sept. 30, 1997).

was not unexpected. As recently as last October, FDA issued a warning letter to one of the largest commercial third-party reprocessors, not only citing major QSR violations, but specifically citing the reprocessor's failure to adequately validate the sterilization process.³¹ These nineteen separate studies clearly demonstrate that reusing a single use device may seriously compromise the integrity and subsequent safety and efficacy of that device.

2. *FDA data*

CDRH's failure to recognize and respond to the patient safety issues raised by these data is compounded by its recent attempts to minimize or discredit the results of studies performed in the OST. At FDA's November 1999 videoconference, FDA responded to questions about these studies by dismissing them, stating that they were not intended to be exhaustive.³² However, in numerous other contexts, FDA has taken enforcement action or directed that recalls be initiated based on anecdotal or scattered reports. FDA's failure to concede, at the very least, that the current data regarding reprocessing of single use devices raises potentially serious safety and effectiveness concerns is inexplicable.

To date, FDA has failed to make public any study reports summarizing OST's data. Nonetheless, public presentations by OST scientists clearly indicate that these findings include safety and effectiveness concerns with percutaneous transluminal coronary angioplasty (PTCA) catheters, electrophysiology catheters, and biopsy forceps.³³ One presentation revealed PTCA catheters with non-patent lumens, crimped guidewires, and

³¹ See Warning Letter from Douglas Tolen, Director, Florida District Office, FDA, to Charles Masek, Jr., President & CEO, Vanguard Medical Concepts, Inc., at 2 (Oct. 14, 1999).

³² See Statement of Donald Marlowe, Director, OST, CDRH, FDA, at the FDA Satellite Videoconference on the Proposed FDA Strategy for Reuse of Single Use Devices (Panel I) (Nov. 10, 1999) ("Our own data was developed in-house, specifically to help us begin to understand the areas of concern. . . . None of this was intended to be exhaustive.").

³³ See Transcript of May 5-6, 1999 FDA/Association for the Advancement of Medical Instrumentation (AAMI) Conference on the Reuse of Single-Use Devices at 66 (statement of Katherine Merritt, Ph.D., Research Biologist, Division of Life Science and Technology, OST, CDRH, FDA) ("In terms of the PCTA catheters, we know we have many models. Not all of them behave the same Some guidewire lumens kink easily. Some get clogged and some leak.").

plugged balloons or balloon channels. In some instances, cleaning chemicals and blood could not be removed from the device lumens. Some reprocessed PTCA balloons varied in size by more than 10% of the approved specifications. The result of such variation is a lack of certainty in whether a cardiologist will actually utilize the particular balloon size originally intended for the patient.

3. *Published literature*

FDA has generally based a decision that a device is safe on prospective controlled studies rather than on published literature reports. With respect to single use device reprocessing, however, FDA has repeatedly referenced specific “researchers” and “publications” that purport to have demonstrated the safety of reprocessing. There is no justification for FDA to rely on published literature as a substitute for premarket submissions. In addition, ADDM has serious concerns with the science supporting the cited literature. A stakeholder at FDA’s December 1999 Stakeholder Meeting noted that these particular studies would not be accepted under traditional peer review standards.³⁴

While citing articles that reportedly found no safety problems, FDA has not recognized published literature demonstrating the risk of reuse of disposable devices. The agency has disregarded at least three published scientific reports that confirm the physical, microbiological, and functional performance failures that are associated with reprocessed single use devices.

One article draws a correlation between the increased incidence of pneumonia in pediatric patients and the reuse of tracheostomy tubes, which are devices labeled as “single use only.” Tracheostomy tube reuse was reported by 55% of the sixty participants. Approximately 60% of the pediatric patients on whom reprocessed tracheostomy tubes were used developed pneumonia within the previous year, compared to only 25% of pediatric patients on whom new tracheostomy tubes were used in the same time period.

³⁴

See Transcript of Dec. 14, 1999 FDA Public Meeting: FDA’s Proposed Strategy on Reuse of Single Use Devices at 57 (statement of Janet Schultz, RN, MSN, Jan Schultz & Assoc.) (“[T]here have been some studies in the medical literature purporting to demonstrate the safety of reuse. On closer examination, few, if any, of these would pass scientific peer review in the areas of microbiologic or epidemiologic methods. And for those that claim to be patient outcome studies, few have adhered to even the most basic FDA requirements for research on human subjects when it comes to informed consent.”).

Other potential variables, such as patient age, diagnosis, method of tube cleaning, and frequency of tube change showed no correlation to increased incidence of pneumonia. Tracheostomy tube reuse was the only predictor of pneumonia and thus it is not surprising that the authors' conclusion questions the safety of reusing these single use devices.³⁵

Another article reports that a 57 year-old man experienced a sudden loss of vision in one eye during a cardiac catheterization for coronary angiography after a heart attack. The loss of vision was due to a reprocessed catheter, the tip of which fragmented and lodged in the central retinal artery on the optic nerve head of the patient's right eye, leaving that eye with only light perception vision. At the end of a six-month follow-up, the patient's right eye vision remained limited to perception and nasal projection of light. The catheter fragmentation was attributed to the reautoclaving process and the reuse of the single use device. The authors recommend compliance with manufacturers' single use label to prevent this type of complication.³⁶

A third article highlights a very important public health issue associated with reprocessing single use devices: *antibiotic resistance*. The report reveals that reprocessed stopcocks labeled "single use only" led to a pseudo-outbreak in which nine patients were misdiagnosed as being infected with *Aureobasidium*, a genus of the fungus known as "black yeast." Had this erroneous diagnosis involved a bacterial organism, these patients would have likely received unnecessary antibiotic treatment for their "infections." This article demonstrates that reprocessed single use devices have the potential to be serious contributors to the growing problem of antibiotic resistance in the United States.³⁷

Because these articles, like those cited by FDA and the reprocessing industry, point to safety issues associated with particular types of devices, they can not be used as a basis

³⁵ Susanne C. Bahng, et al., Parental Report of Pediatric Tracheostomy Care, 79 Arch Phys Med. Rehabil. 1367 (1998).

³⁶ Dietrich Hallerman, M.D. and Guridner Singh, M.D., Iatrogenic Central Retinal Artery Embolization: A Complication of Cardiac Catheterization, 16 Annals of Ophthamology 1025 (Nov. 1984).

³⁷ Stephen J. Wilson, et al., A Pseudo-Outbreak of *Aureobasidium* Lower Respiratory Tract Infections Caused by Reuse of 'Single Use' Stopcocks During Bronchoscopy, Infections Disease Society of America (IDSA) Conference (Nov. 18-21, 1999) (This abstract was included in materials distributed at the IDSA Conference).

for generalized statements regarding the safety of reprocessing all devices. At most, particular studies can speak to the safety of the specific model of device reprocessed.³⁸ Only device-specific, model-by-model data can demonstrate whether a particular single use device, reprocessed by a particular entity, is likely to be safe. Such data must be submitted to, and cleared or approved by, FDA in a 510(k) or PMA before the safety and effectiveness of a reprocessed single use device is truly known.

4. *MedWatch reports*

While, FDA has acknowledged that reports in its MDR database suggest that problems may exist with reprocessed single use devices, it has discounted such reports because, in FDA's opinion, the device failure often cannot be definitively linked to the reprocessing.³⁹ Others have suggested that if a reused single use device fails by a failure mode that has also occurred with new devices, then that failure should not be attributed to the reprocessing. This is an unjustified conclusion. If the device is being used a second, third or sixth time, the device must have functioned properly the first time—as intended. If the device had been used once and discarded, in accordance with its labeling, it would not have failed. Exhaustion of the device's safety margins by reprocessing will cause the device to fail, perhaps by a failure mode that has also occurred with new devices. This overlap in failure modes does not absolve the reprocessor from responsibility for the device's failure and certainly does not substantiate claims that reprocessing is safe.

³⁸ Transcript of May 5-6, 1999 FDA/AAMI Conference on the Reuse of Single-Use Devices at 77 (statement of Richard Kozarek, M.D., Chief of Gastroenterology, Virginia Mason Medical Center and Clinical Professor of Medicine, University of Washington at Seattle) (“I can't say that [another OEM's] devices could be reprocessed the same way. I can't comment on triple lumened sphincterotomes when I studied double and single lumened sphincterotomes. . .”).

³⁹ See Statement of Larry Kessler Sc.D., Director, Office of Surveillance and Biometrics (OSB), CDRH, FDA, at the FDA Satellite Videoconference on the Proposed FDA Strategy for Reuse of Single Use Devices (Panel I) (Nov. 10, 1999) (“Some reports we have in that system suggest some problems associated with products that might have been reprocessed; so we might see cracking of some catheters, but I need to remind people who look to that system that its an excellent system for signaling potential problems, but it's not great for cause and effect. It's not the same as systematic science to prove a problem. So we have some suggestions of some problems but they're limited and it's not clear or documented scientific evidence that we can count on.”).

FDA's willingness to disregard MDR reports that it deems not unquestionably linked to reprocessing is also inconsistent with the agency's traditional use of the MDR database. FDA has previously used MDR reports as evidence that a problem exists and needs to be addressed. This is true even if the causal relationship is tenuous, as in cases of device misuse. For example, if a practitioner uses a medical device in a way that was clearly not intended and reports a device failure, that failure is attributable to the manufacturer. Nonetheless, under FDA's current thinking, it appears that failures associated with reprocessed single use devices must be *definitively* linked to the reprocessing for FDA to consider them as an indication of the risk of reprocessing.

Despite its admonitions that reports in the MDR database do not definitively demonstrate patient risk for reprocessed disposable devices, FDA has allowed the converse inference to be drawn – that the database *does* demonstrate a *lack of* patient risk. At FDA's November 1999 videoconference, FDA failed to correct a panelist's statements that this database amounts to a "staggeringly extraordinary safety record."⁴⁰ It is telling that twice during that same panelist's comments he stated that when a reprocessed device fails during use he throws it away –never filing an MDR report.⁴¹ The apparent safety record of reprocessing will continue to be characterized as "extraordinary" if device failures are not reported.

⁴⁰ See Statements of Douglas B. Nelson, M.D., gastroenterologist, Veterans Affairs Medical Center, Minneapolis, MN and Assistant Professor of Medicine, University of Minneapolis, at the FDA Satellite Videoconference on the Proposed FDA Strategy for Reuse of Single Use Devices (Panel III) (Nov. 10, 1999) ("Twenty years of MDR reporting or fifteen years of MDR reporting -again, FDA's own statement that FDA has been unable to find clear evidence of adverse patient outcome associated with the reuse of single use devices from any source. To put that into perspective, fifteen to twenty years of doing procedures approximately ten million procedures per year without adverse events. That is a staggeringly extraordinary safety record.").

⁴¹ See *id.* (Dr. Nelson made the following two statements: "If I put a device through my endoscope and it looked great but happened to go down there and failed, what is the down side to that? I pull it out and throw it away," and "What happens to a GI device if it fails? If I put this small instrument into my endoscope and it comes out and doesn't work, I have to pull it out and throw it away. That costs about ten seconds.").

FDA has failed to recognize the demonstrated patient safety risks associated with reprocessing single use devices despite the volumes of data to the contrary. Reprocessing amounts to a misuse of medical devices that can only add to the nation's preventable medical error rate. The agency's congressional mandate to protect the public will not be served by reversing the burden of proof and awaiting a proven public health disaster before taking action.

D. FDA has a Long History of Unclear and Inconsistent Policies Regarding Single Use Device Reprocessing

The history of FDA's policy regarding reprocessed single use devices is marked with inconsistency. From FDA's public acknowledgment of the safety hazards posed by reprocessing single use devices in 1987 to the 1999 publication of the FDA Proposed Strategy recommending continued FDA inaction for many devices, the agency has failed to articulate a coherent policy or analytical framework. The solution to this tortured regulatory construct is simple: full enforcement of the FDC Act, including all device regulations and premarket submission requirements, on reprocessors of single use devices. Such enforcement would result in a clear and coherent policy that can be applied equitably to reprocessors and OEMs and will ensure patient safety.

I. Compliance Policy Guide (CPG) 300.500

In 1987, FDA revised section 300.500, "Reuse of Medical Disposable Devices," of CPG 7124.16. In the CPG, FDA concluded that "[t]he reuse of disposable devices represents a practice which could affect both the safety and effectiveness of the device."⁴² FDA made this assertion based on a lack of data "establish[ing] conditions for the safe and effective cleaning and subsequent resterilization and/or reuse of any disposable medical devices."⁴³ At that time, FDA appropriately recognized that such a lack of data should result in a "single use label" for patient protection. FDA further recognized that to establish the safety and effectiveness of a single use device, a reprocessed device must demonstrate all three of the following criteria:

- (1) that the device can be adequately cleaned and sterilized;

⁴² FDA Compliance Policy Guide 7124.16, § 300.500, "Reuse of Medical Disposable Devices" (1987).

⁴³ Id.

- (2) that the physical characteristics or quality of the device will not be adversely affected by such processing; and
- (3) that the device remains safe and effective for its intended use after such reprocessing.⁴⁴

While the CPG appropriately recognized these three key criteria for ensuring patient safety, it inappropriately placed the burden for demonstrating safety and effectiveness on the user rather than the reprocessor. In fact, under the CPG, the reprocessor has no regulatory obligation whatsoever –not even compliance with the QSR or registration and listing requirements. The CPG also fails to place any obligation on FDA to review data and clear or approve these devices. Had the onus been appropriately placed on reproducers and FDA to ensure that the elements of the CPG were met, patients would have been protected from unsafe and ineffective reprocessed single use devices for the past thirteen years.

2. FDA letter to manufacturers and facilities

In a December 27, 1995 letter from FDA to the American College of Healthcare Executives, the agency attempted to clarify its policy on single use devices. FDA stated,

[C]onsistent with existing regulations, any person or firm that reprocesses medical devices for health care facilities and engages in repackage [sic.] relabeling, or sterilization operations (including any associated processing activities; e.g., cleaning), are [sic.] required to comply with the Good Manufacturing Practice (GMP) and device labeling requirements of the Federal regulations.⁴⁵

The letter, however, failed to state that 510(k)s are required for such reprocessing, but instead noted that “FDA is evaluating those situations in which submission of a 510(k) or PMA supplement would be required for reprocessing of devices.”⁴⁶ Had FDA announced, in 1995, that all reproducers of single use devices must obtain premarket

⁴⁴ Id.

⁴⁵ Letter from Lillian Gill, Director, OC, CDRH, FDA, to the American College of Healthcare Executives, at 1 (Dec. 27, 1995).

⁴⁶ Id.

clearance or approval, patients would have been afforded the protection they are due under the FDC Act.

3. *FDA response to the Health Industry Manufacturers Association (HIMA) citizen petition*

In September 1997, HIMA filed a citizen petition seeking to clarify FDA's regulatory position with respect to premarket submissions for reprocessed single use devices.⁴⁷ In a July 13, 1998 response to that petition, the agency restated its position in the December 27, 1995 letter that reprocessors of single use devices must adhere to medical device Good Manufacturing Practices (GMPs)/QSR and labeling regulations. The letter further stated that reprocessors are subject to MDR requirements, and that based on MDR data, there is a "general absence of evidence of adverse patient outcomes attributed to the reuse of single-use devices."⁴⁸ Based on the apparent assumption that a lack of MDR reports confirms safety, the agency concluded that there is a reasonable assurance that reprocessed single use devices meet the "appropriate specifications for safety and performance,"⁴⁹ and stated that "compliance with GMP requirements provides an appropriate measure of public health protection for patients and health care providers by ensuring sufficient control over the individual firm's manufacturing and quality assurance operations."⁵⁰

FDA's refusal to enforce the premarket requirements because of a supposed lack of evidence of harm stands the FDC Act on its head. It is the obligation of the party that wishes to market the device—in this case the reprocessor—to show that the device is safe and effective.⁵¹ FDA's reliance on a lack of MDR reports is inconsistent with the agency's

⁴⁷ See HIMA Citizen Petition to FDA Dockets Management Branch, at 1-2 (FDA Docket No. 97P-0377) (Sept. 5, 1997) (requesting FDA to apply "all applicable FDA regulations governing medical device manufacturing" to commercial reprocessors of disposable medical devices).

⁴⁸ Letter from Bruce Burlington, M.D., Director, CDRH, FDA, to Nancy Singer, Esq., Special Counsel, HIMA, at 2 (July 15, 1998) (FDA Docket No. 97P-0377).

⁴⁹ Id.

⁵⁰ Id.

⁵¹ See supra note 23.

typical interpretation of the evidence in that database. This is especially inappropriate in light of the unique factors surrounding reprocessed single use devices. Physicians often incorrectly report device failures of reprocessed devices to the OEM, or simply fail to report reprocessed device failures at all.⁵²

4. *FDA letters to AMDR*

In a later-rescinded October 19, 1998 letter to the Association of Medical Device Reprocessors (AMDR), FDA stated “[t]hird-party reprocessing of devices labeled for single use is lawful in the United States provided that the reprocessing firm complies fully with all regulatory requirements currently imposed on them. The most significant regulatory requirement, at this time, is compliance with the newly developed Quality System regulation.”⁵³ The letter made no mention of premarket submission requirements. Based on this letter and FDA’s response to the HIMA citizen petition, reprocessors began to assert in their marketing materials and elsewhere that FDA considered reprocessed single use devices to be safe and lawful.⁵⁴

Nine months later, the agency finally corrected its statements. In a July 9, 1999 letter to AMDR, the agency rescinded the statement quoted above and replaced it with the following statement: “Third-party reprocessing of devices labeled for single use is *unlawful* unless those engaged in the this practice comply with *all* regulatory requirements for manufacturers, *including premarket notification requirements.*”⁵⁵ Although this statement

⁵² During FDA Satellite Videoconference on the Proposed FDA Strategy for Reuse of Single Use Devices (Nov. 10, 1999), one panel member/physician commented that if a reprocessed single use device fails during a procedure, he simply discards of the device. He made no mention of filing an MDR. See supra note 41.

⁵³ Letter from Larry Spears, Director, Division of Enforcement III, OC, CDRH, FDA, to Stephen Terman, Esq., Olsson, Frank and Weeda, P.C. (Oct. 19, 1998).

⁵⁴ See Letter from Josephine Torrente, Esq., Hyman, Phelps & McNamara PC, to Lillian Gill, Director, OC, CDRH, FDA (Feb. 4, 1999) (alerting FDA to reprocessors’ use of published articles to distort the agency’s position regarding reprocessing single use devices).

⁵⁵ Letter from Larry Spears, Director, Division of Enforcement III, OC, CDRH, FDA, to Stephen Terman, Esq., Olsson, Frank and Weeda, P.C. (July 9, 1999) (emphasis added).

accurately represents the correct regulatory status of reprocessed single use devices, FDA again announced its intention to ignore violations of the premarket requirements.

5. *FDA Response to Medical Device Manufacturers Association (MDMA) citizen petition*

On May 20, 1999, the MDMA submitted a citizen petition to FDA requesting that the agency ban the practice of reprocessing single use devices.⁵⁶ On October 6, 1999, FDA denied MDMA's petition citing a lack of "evidence that reprocessing presents 'an unreasonable and substantial risk of illness or injury.'"⁵⁷ FDA's explanation for denying the petition was unduly brief and failed to address the content of the petition. Further, while FDA acknowledged receipt of adverse event reports related to reprocessed single use devices, the agency did not specifically reference any of the information it has in its possession. It was the responsibility of the agency to provide a more thorough explanation for why it denied the petition. This response prompted MDMA to resubmit the citizen petition and request that FDA place all relevant materials in the docket.⁵⁸

6. *Other guidance documents and letters*

In addition to the documents discussed above, several other recent agency pronouncements point to FDA's inconsistent approach to the regulation of single use device reprocessing and demonstrate the agency's unwillingness to recognize the seriousness of the issue.

a. *FDA/CDC Endoscope Guidance*

In a September 10, 1999 FDA and Centers for Disease Control and Prevention (CDC) public health advisory entitled "Infections from Endoscopes Inadequately Reprocessed by an Automated Endoscope Reprocessing System," FDA recommends that to

⁵⁶ See MDMA Citizen Petition to FDA Dockets Management Branch (FDA Docket No. 99P-1516) (May 20, 1999).

⁵⁷ Letter from David Feigal, Jr., M.D., M.P.H., Director, CDRH, FDA, to Larry Pilot, Esq., McKenna & Cuneo, L.L.P. (counsel for MDMA), at 1 (Oct. 6, 1999) (FDA Docket No. 99P-1516) (quoting one criterion for banning a medical device).

⁵⁸ Letter from Larry Pilot, Esq., McKenna & Cuneo, L.L.P., to David Feigal, Jr., M.D., M.P.H., Director, CDRH, FDA (FDA Docket No. 99P-1516) (October 21, 1999).

avoid contamination of *reusable* endoscopes, health care facilities should, “[b]e sure that all staff who handle soiled endoscopes *comply with the endoscope manufacturer’s instructions for cleaning* the endoscope.”⁵⁹ It is curious that in the case of a reusable device, such as an endoscope, the agency recommends that reprocessing should be done only in accordance with an OEM’s instructions since the device manufacturer best understands the device’s ability to be reprocessed; yet, in the case of single use devices, FDA allows the OEM’s instructions to be ignored. Devices marketed as “single use only” are designed and manufactured for one patient use only. In fact, without data demonstrating the safety and effectiveness of a device for multiple use, FDA requires a single use label. Since FDA recommends that healthcare facilities which reprocess endoscopes follow the OEM’s instructions, the agency should also advise healthcare facilities to defer to an OEM’s instructions on single use devices.

b. *Human Dura Mater Guidance*

On October 14, 1999, FDA issued a guidance document entitled, “Guidance for the Preparation of a Premarket Notification Application for Processed Human Dura Mater.” In that document, FDA, acknowledging the contamination issues associated with reprocessing certain devices, states that human dura mater “procedures should require the use of only disposable . . . surgical instruments[,] . . . [b]ecause FDA is unaware of any procedure or reagent that is validated to totally inactivate the CJD-causing agent”⁶⁰ FDA’s position recognizes that a substantial risk of cross-contamination is associated with reprocessing devices that are used in human dura mater grafts. These devices, however, are the same as, or similar to, devices used for other invasive procedures which FDA permits to be reprocessed and used in multiple patients without any premarket showing of safety and effectiveness.

According to the human dura mater guidance document, the use of reprocessed devices must be justified to FDA *prior to implementation*.⁶¹ Similarly, because of the risks to which patients are exposed when reprocessed single use devices are used during many

⁵⁹ FDA and CDC, Public Health Advisory, Infections from Endoscopes Inadequately Reprocessed by an Automated Endoscope Reprocessing System, at 2 (Sept. 10, 1999) (emphasis added).

⁶⁰ Guidance for the Preparation of a Premarket Notification Application for Processed Human Dura Mater, CDRH, FDA, at 7 (Oct. 14, 1999).

⁶¹ Id. (emphasis added).

other procedures, reproprocessors should be required to demonstrate through a premarket submission that the device is safe and effective for its intended use prior to implementation. FDA – consistent with its historical practice – did not, in this instance, wait for evidence of patient injury or death before acting.

c. The Electrode Store and Breath of Life Warning Letters

As stated above, a change from single use to multiple use is a significant change in the intended use of a device that could significantly affect the safety and/or effectiveness of a device, and therefore, requires a 510(k) or PMA regardless of whether this change is implemented by the OEM or the reproprocessor. In warning letters and other guidance documents issued to OEMs, FDA has consistently held that “[i]n order to market a single use device as reusable, a new 510(k) is required since there is a potential impact on the safety and effectiveness of the device.”⁶² For example, in a May 9, 1997 warning letter to Breath of Life, FDA cited the manufacturer for failure to submit a 510(k) for a change from single use to reusable because of a kit that was distributed with its emergency manual resuscitator. FDA claimed that the kit effectively changed the intended use of the device from single use to multiple use and thus necessitated a 510(k) clearance.⁶³ In a similar warning letter issued to The Electrode Store on June 21, 1999, FDA, using the same reasoning as in its warning letter to Breath of Life, stated that “[w]ith regard to the reusable monopolar and concentric needle electrodes . . . [marketed by The Electrode Store], CDRH has determined that a 510(k) is necessary *because the indications have been changed from single use to multiple use.*”⁶⁴

⁶² Questions and Answers for the FDA Reviewer Guidance: Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities, CDRH, FDA, at 6 (Sept. 3, 1996). This statement was made in response to the following question: “I have a device which is cleared for single use. If I want to market it as reusable what is required?” *Id.*

⁶³ Warning Letter from Lillian Gill, Director, OC, CDRH, FDA, to Robert Chester, Breath of Life, at 2 (May 9, 1997).

⁶⁴ Warning Letter from Roger Lowell, District Director, Seattle District Office, FDA, to Timothy Cooke, President, The Electrode Store, Inc., at 2 (June 21, 1999) (emphasis added).

d. Third-Party Reprocessor Warning Letters

In the past six months, FDA has issued at least three warning letters to reprocessors. The deficiencies evidenced in these letters reveal violative practices in an industry that is not required to prove its claims before subjecting patients to its devices. For instance, in an October 14, 1999 warning letter sent to a major reprocessor, FDA noted a failure to appropriately validate the sterilization process, a lack of recorded data on various processes, and incomplete sterilization of devices.⁶⁵ In a December 23, 1999 warning letter to another major reprocessor, FDA reported findings of inadequately trained personnel who were unaware of FDA's QSR, in addition to incomplete or missing records on facility and equipment maintenance and cleaning.⁶⁶ Similarly, in a January 6, 2000 warning letter to a reprocessing company, FDA notes that devices resterilized with ethylene oxide (EtO) are not adequately tested for EtO residues, tensile strength or other degradation.⁶⁷ If premarket submission requirements had been enforced, the greater FDA oversight may have prevented these violations from occurring.

In at least one situation, FDA's actions provided too little protection for a particular patient. An April 1998 warning letter to a major third party reprocessor noted, among other things, that the reprocessor failed to establish the maximum number of reprocessing cycles

⁶⁵ See Warning Letter from Douglas Tolen, Director, Florida District Office, FDA, to Charles Masek, Jr., President and CEO, Vanguard Medical Concepts, Inc. (Oct. 14, 1999).

⁶⁶ See Warning Letter from Douglas Tolen, Director, Florida District Office, FDA, to Rick Ferreira, CEO, Alliance Medical Corp. (Dec. 23, 1999) (noting Alliance Medical Corporation's "[f]ailure to establish and implement a quality policy [,] [f]ailure to establish and maintain procedures to ensure that device history records are maintained [,] [f]ailure to establish and maintain procedures for implementing corrective and preventive action [,] [f]ailure to monitor production and process controls to ensure that inspection, measuring, and test equipment is suitable and capable of performing its intended purpose [,] [f]ailure to adequately train personnel to perform their assigned responsibilities [, and] [f]ailure to document cleaning and maintenance of the facility and process equipment").

⁶⁷ See Warning Letter from Edward R. Atkins, Acting Director, Florida District Office, FDA, to Louis L. Rudt, President, Visions in Endosurgery, Inc. (Jan. 6, 2000).

that electrophysiology catheters could withstand.⁶⁸ Less than one year later, an electrophysiology catheter that had been reprocessed five times by that company failed catastrophically while being used on a patient. A portion of the catheter's metal electrode became lodged in the right atrium of the patient's heart.

As is evident from these documents and others like them, FDA's position on the safety of reprocessed single use devices and the degree of regulatory control necessary to achieve acceptable levels of safety has vacillated. In the eighteen months since FDA denied the HIMA citizen petition, FDA has (1) implied that reprocessing single use devices is safe, (2) noted that devices should not be reprocessed except in accordance with the OEM's instructions, (3) required prior justification for reuse of surgical instruments in certain procedures, (4) noted that a change from single use to reusable could affect safety and effectiveness and therefore requires a 510(k) clearance, (5) failed to require 510(k)s from reprocessors by stating that compliance with the QSR was sufficient to ensure patient safety, (6) cited reprocessors for multiple QSR violations, (7) relied on a lack of substantial numbers of MDR reports to claim that reprocessing single use devices is safe, and (8) demanded corrective action by OEMs based on isolated events. FDA's incoherent policy can be easily fixed by applying the FDC Act to reprocessors of single use devices.

E. The FDA Proposed Strategy Further Delays Appropriate Regulation of Reprocessing

FDA has had numerous opportunities to address the issue of reprocessed single use devices by fully enforcing the FDC Act, including the requirements for premarket submissions. A myriad of meetings and proposals, however, has delayed reprocessors' compliance with the law. The latest such proposal is the FDA Proposed Strategy. The FDA Proposed Strategy provides no substantive resolution to this issue despite more than four years of ongoing debate. The agency must abandon the FDA Proposed Strategy and instead enforce the FDC Act, including the requirements for premarket submissions.

The May 1999 FDA/AAMI meeting provided ample opportunity to address the issue of reprocessing single use devices and demonstrated the need for immediate FDA action. At the meeting, numerous presenters, including practicing physicians, expressed concern about the safety of reprocessing single use devices and requested that FDA take action.

⁶⁸ See Warning Letter from Ballard H. Graham, Director, Atlanta District Office, FDA, to William T. Stover, Chairman and Chief Executive Officer, Paragon Healthcare Corporation (April 14, 1998).

Despite its consideration of the issue, however, FDA seemed unwilling to act. For example, one FDA official noted that “what FDA needs to do is help take the leadership role in creating a shared vision for what the manufacturing and reprocessing systems should look like *in five and ten years*.”⁶⁹ Another FDA official commented that “there will be ample opportunity for *multiple* comments on [this] plan.”⁷⁰ Other officials noted that developing and implementing a policy on reuse would take tremendous time and effort and would strain agency resources.⁷¹ Despite the purported lack of resources to address the problem in the United States, however, one FDA official suggested that FDA should expand discussion on the issue to a global audience.⁷²

Six months after the meeting, FDA published the “FDA Proposed Strategy.” This is a misnomer since it is not truly a strategy at all. Rather, it appears to be a list of things the agency would like to take into account in developing a strategy. In lieu of setting requirements, the FDA Proposed Strategy uses terms such as “explore,” “examine,” and “consider.” The effort spent on exploring, examining, and considering alternatives to what current law already demands from reprocessors should instead be spent enforcing that law.

Furthermore, the FDA Proposed Strategy lacks sufficient detail to allow meaningful comment. One startling example is section four which says, “consider requesting OEMs to

⁶⁹ Transcript of May 5-6, 1999 FDA/AAMI Conference on the Reuse of Single-Use Devices at 253 (statement of Larry Kessler, Sc.D., Director, OSB, CDRH, FDA) (emphasis added).

⁷⁰ *Id.* at 6 (statement of Elizabeth Jacobson, Acting Director, CDRH, FDA) (emphasis added).

⁷¹ In reference to developing a new regulatory framework for reprocessed single-use devices, one FDA official said, “it requires a lot of time and effort to work up a new program, a new issue like this, and any way you cut it, it’s going to mean time and effort.” *Id.* at 224 (statement of Timothy Ulatowski, M.S., Director, Division of Dental Infection Control and General Hospital Devices (DDIGD), ODE, CDRH, FDA).

⁷² An FDA official stated, “this isn’t just the US FDA perspective . . . this is a worldwide . . . global concern. I do think that we’ve got to expand the discussion on this.” *Id.* at 233-234 (statement of Lillian Gill, Director, OC, CDRH, FDA).

provide information on their labels about risks associated with the reuse of SUDs.”⁷³ This section, which proposes to significantly reinterpret the FDC Act’s device labeling provision, and place a significant burden on OEMs, is described in a mere eight lines, four of which explain current law. The FDA Proposed Strategy continues, “[o]ne option the [a]gency is considering . . .,”⁷⁴ but fails to adequately explain the option and does not mention any alternatives. A strategy that proposes to significantly re-write the FDC Act certainly deserves more explanation than this.

In addition to lacking adequate explanation, the FDA Proposed Strategy does not include a deadline for the submission of comments. Without a firm comment deadline, a quick resolution of this important public safety issue is unlikely. The lack of a comment deadline may also force the agency to delay publishing a final document as new comments continue to be submitted to the docket. On December 9, 1999, FDA released the Risk Categorization Guidance on the internet. This document is intended to complement the FDA Proposed Strategy. Although this second guidance document *does* establish a comment deadline of ninety days post-publication in the Federal Register, to date, FDA has failed to formally publish the Risk Categorization Guidance.

At FDA’s December 1999 Stakeholder Meeting on the FDA Proposed Strategy, the agency proposed several measures that largely duplicate the guidances and policies that already exist for reusable devices. These include the development of guidance on sterility validation, the development of guidance on registration and listing, the development of auditing programs, the development of regulation on labeling, and the development of horizontal and vertical standards. All of these duplicative actions would take significant time to draft, complete, and implement. Meanwhile, patients would be left unprotected from the risks associated with using reprocessed single use devices.

Despite its prolonged gestation period, the FDA Proposed Strategy fails to conform to the Food and Drug Administration Modernization Act of 1997’s (FDAMA’s) provision and FDA’s own regulations governing guidance documents. Section 405 of FDAMA guarantees that “[t]he Secretary shall ensure uniform nomenclature for [informal agency statements, and] . . . that guidance documents . . . indicate the nonbinding nature of the documents.”⁷⁵ The FDA Proposed Strategy is not even identified as a guidance document,

⁷³ FDA Proposed Strategy at 13.

⁷⁴ Id.

⁷⁵ See Pub. L. No. 105-115, 111 Stat. 2296 (1997) § 405.

an advanced notice of proposed rulemaking or any other recognizable regulatory publication. This oversight has led FDA to coin a neologism to identify the FDA Proposed Strategy: “an advanced notice of a proposed guidance with options.”⁷⁶ FDA must abandon this approach and publish the direct to final rule set forth in the ADDM Strategy.⁷⁷ That rule establishes staggered temporary exemptions from premarket submission requirements for reprocessed Class I and Class II single use devices, and sets deadlines for submissions for all reprocessed single use devices.

F. The FDA Proposed Strategy Confuses Issues Surrounding Reprocessing

The FDA Proposed Strategy introduces ancillary concepts to the current controversy surrounding the reprocessing of single use devices, and uses imprecise and incorrect terminology causing confusion over the issue. The inconsistencies set out in this section further illustrate why the FDA Proposed Strategy is fundamentally flawed.

1. Inclusion of opened but unused devices

The FDA Proposed Strategy unnecessarily refers to opened but unused single use devices. Because these have not been exposed to patients and because they are not subjected to harsh cleaning techniques, they pose different safety risks than do reprocessed used single use devices. FDA, at the May 1999 FDA/AAMI meeting on reuse, recognized this difference and considered opened but unused devices to be outside the scope of that meeting. Incorporating opened but unused devices into the FDA Proposed Strategy only confuses and complicates the discussion of patient safety issues. FDA’s second guidance document on reprocessed single use devices, issued only one month after the FDA Proposed Strategy, properly excludes open but unused devices.

The FDA Proposed Strategy suggests a working definition of “single use devices” that appears to include both used and unused disposable devices, and refers throughout to regulation of “single use devices,” thereby including both. FDA’s suggested working definition of single use devices blurs the distinction between used single use devices and opened but unused single use devices, and, in turn, confuses the focus of the FDA Proposed Strategy. FDA’s resources would be better used, and the public health better served, by

⁷⁶ Karen Riley, FDA discloses reuse plans as political pressure grows, Clinica: World Medical Device & Diagnostic News, Oct. 11, 1999, at 1.

⁷⁷ See supra note 5.

ensuring that reprocessors of *used* single use devices comply with the FDC Act. FDA should continue to recommend that open and unused devices should only be resterilized in accordance with directions provided by the OEM. If the OEM provides no directions for a particular product, then that device should not be resterilized.

2. “Reuse” vs. “reprocessing”

The very title of the FDA Proposed Strategy, “FDA’s Proposed Strategy on the Reuse of Single Use Medical Devices,” confuses regulation of the medical practice of reuse with the manufacturing activity of reprocessing. FDA has the authority to regulate only the latter. The purpose of the FDA Proposed Strategy should be to design a regulatory framework to ensure that the *manufacturing activity of reprocessing* single use devices does not jeopardize patient health. It should not establish a regulatory framework for the *medical practice of reuse* of single use devices. FDA’s own proposed working definitions of “reuse” and “reprocessing” suggest that there is a significant difference between the two terms.⁷⁸ While the definition section of the FDA Proposed Strategy acknowledges this distinction, the remainder of the FDA Proposed Strategy often uses the two terms interchangeably. Once again, this illustrates the analytical carelessness pervading the document.

⁷⁸ The FDA Proposed Strategy suggests the following definitions for the terms “reuse” and “reprocessing:”

Reuse: the repeated use or multiple uses 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.

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.

3. *Regulation of “low” risk devices*

In addition to the inconsistent treatment of opened but unused devices, the FDA Proposed Strategy and the agency’s interpretation of the Risk Categorization Guidance are at odds with respect to how devices characterized as “low” risk will be regulated. The FDA Proposed Strategy specifically notes that “FDA plans to exercise enforcement discretion not to enforce 510(k) submission requirements” for devices deemed to be “low” risk.⁷⁹ Nonetheless, at FDA’s December 1999 Stakeholder Meeting on this issue, an FDA official characterized the risk categorization scheme as “a scheme to *prioritize* submissions of premarket applications . . . a way to prioritize the receipt and review of these applications,”⁸⁰ implying that even “low” risk devices would be required to be cleared or approved by FDA. When questioned about the discrepancy, FDA was unable to reconcile the two statements or to tell which is correct.⁸¹

⁷⁹ Id. at 10-11.

⁸⁰ Transcript of Dec. 14, 1999 FDA Public Meeting: Reuse of Single Use Devices- FDA Proposed Strategy at 134-35 (statement of Timothy Ulatowski, M.S., Director, DDIGD, ODE, CDRH, FDA) (emphasis added).

⁸¹ One FDA official stated that “[FDA’s] intention, our major intention here in terms of public health[,] is to get what we think are the most significant devices that are reused looked at very quickly and to pause with the others to allow for data collection and let the scheme play a little bit in regard to mitigation of risk, perhaps with data collection.” Id. at 178 (statement of Timothy Ulatowski, M.S., Director, DDIGD, ODE, CDRH, FDA).

4. *Creation of the term "SUD"*

The FDA Proposed Strategy substitutes the term "SUDs" for single use devices. Reference to single use devices as "SUDs" incorrectly implies that these are a homogenous group of devices capable of being regulated as a set. In fact, devices designed and labeled for single use only may be (1) made from a variety of materials including metals, ceramics, and various plastics, (2) intended to be used in or on various parts of the body including the heart, the gastrointestinal tract or the intact skin, (3) designed to include long lumens, flat surfaces, coiled wires or delicate interfaces, and (4) categorized into Class I, II or III based on their risk level. FDA's reference to these devices as "SUDs" creates the false impression that, once reprocessed, they can be standardized and regulated as a group when, in fact, each model of each device type must be regulated individually. FDA should abandon using the acronym "SUD" which implies a false level of uniformity.

G. **FDA's Exercise of Enforcement Discretion Raises Significant Medicare Reimbursement Issues**

The agency's position to date, which allows unlawfully reprocessed devices to be used in hospitals, has created reimbursement issues. The Health Care Financing Administration (HCFA) will allow reimbursement for reprocessed medical devices only if such reprocessing is otherwise lawful. In a letter dated September 8, 1999, HCFA clarified that, "[i]f FDA's current position is that reprocessing of single-use medical devices is unlawful absent premarket notification, these devices will not be covered under Medicare."⁸² The agency's statements to date, and the FDA Proposed Strategy, have put hospitals in an untenable position with respect to Medicare. The scenario created by FDA's actions is perpetuated by the FDA Proposed Strategy causing potentially significant reimbursement concerns for many health care providers.

The Medicare reimbursement issues can be easily resolved: FDA must discontinue its use of enforcement discretion and ensure that any reprocessed disposable devices used in hospitals are reprocessed in accordance with the FDC Act. The FDA Proposed Strategy fails to achieve this goal. In fact, devices characterized as "low" risk or "moderate" risk under the Risk Categorization Guidance would continue to be reprocessed unlawfully leaving both HCFA and hospitals in regulatory limbo.

⁸² Letter from Grant Bagley, M.D., Director, Coverage and Analysis Group, HCFA, to Josephine Torrente, Esq., Hyman, Phelps & McNamara, P.C. (Sept. 8, 1999).

The FDA Proposed Strategy precludes hospitals from obtaining *any* Medicare reimbursement for reprocessed single use devices. While it has always been apparent that healthcare facilities cannot recoup the full cost of a new device when a less expensive reprocessed device is used, the September 8, 1999 HCFA letter makes clear that even the cost of the reprocessed device is not reimbursable if the device is reprocessed without a 510(k) or PMA because the reprocessing itself is unlawful. Unlike the FDA Proposed Strategy, the ADDM Strategy resolves these Medicare issues by ensuring that all reprocessed devices are lawfully marketed.⁸³

H. FDA Must Utilize its Resources to Enforce the FDC Act

FDA has repeatedly defended its lack of action against reprocessed single use devices on the basis of limited resources. However, FDA has proposed a strategy that squanders resources while never definitively making safety and effectiveness determinations for most devices. The FDA Proposed Strategy requires development of consensus standards, administration of outreach programs, and enlargement of OST research efforts. While each of these initiatives may be laudable for an agency with limitless funds, none is a substitute for the core statutory requirement of premarket review. In addition, the need for these initiatives would be largely obviated by FDA's determinations of device safety and effectiveness in connection with premarket submissions.

In justifying its claim of inadequate resources, FDA has erroneously hypothesized that thousands of hospitals and reprocessors would each submit thousands of 510(k)s simultaneously if FDA were to enforce the law. FDA is aware, however, that due to several factors, only a very limited number of premarket submissions are likely to be submitted, and that these will be staggered over time. First, hospitals are not likely to submit 510(k)s, but will instead contract with third-party reprocessors if such submissions are required.⁸⁴ Only approximately twenty-three third-party reprocessors are reported to

⁸³ See supra note 5 (proposing an alternative to the FDA Proposed Strategy).

⁸⁴ See Transcript of May 5-6, 1999 FDA/AAMI Conference on the Reuse of Single-Use Devices at 167 (statement of Frank Sizemore, Central Service Manager, Wake Forest University Baptist Medical Center and Representative, American Society of Healthcare Central Service Providers) ("The idea of presenting a 510(k) for reprocessing is very interesting. From a health care perspective, hospitals I doubt, seriously doubt, would ever consider doing such a thing. I don't think that would cause a flood of applications.").

exist –a far more manageable number.⁸⁵ Second, each reprocessor must develop data demonstrating the safety and effectiveness of each product prior to submission. Because single use devices are not designed to be cleaned and to retain their functional requirements, ADDM believes that reprocessors will be unable to generate such data for most devices. The net result of twenty-three reprocessors submitting 510(k)s/PMAs for a small subset of single use devices is a modest increase in the number of premarket reviews. In order to assist the agency with this increase, Congress has appropriated \$1,000,000 of FDA's fiscal year 2000 budget for reprocessed device review.⁸⁶ Moreover, FDA simply lacks the legal authority to exempt devices because of regulatory burdens.⁸⁷

II. Specific Comments on the Eight Components of the FDA Proposed Strategy

The FDA Proposed Strategy specifically discusses eight components in FDA's plan to regulate reprocessing of single use devices. While ADDM believes that those components have not been adequately developed by FDA to enable it to provide

⁸⁵ See id. at 231 (statement of Anne Cofiell, C.R.C.S.T., Consultant, Cofiell Consulting Services and Representative, International Assoc. of Healthcare Central Service Material Management) (“I don't know whether these numbers are correct, but we heard that there were 23 companies out there that are reprocessing single use disposable items.”).

⁸⁶ See Pub. L. No. 106-78, 113 Stat. 1135, 1159 (“For necessary expenses of the [FDA] . . . (5) \$154,271,000 shall be for the [CDRH] . . . of which \$1,000,000 shall be for premarket review, enforcement and oversight activities related to users and manufacturers of all reprocessed medical devices authorized by the [FDC Act] . . .”).

⁸⁷ See Hoffmann-La Roche Inc. v. Weinberger, 425 F. Supp. 890, 894 (DDC 1975) (“[T]he argument that FDA [] lacks the administrative resources to insure compliance with section 355 cannot be permitted to postpone to some indefinite future date the implementation of the required preclearance approval of new drug applications). See American Pub. Health Ass'n v. Veneman, 349 F. Supp. 1311, 1317 (DDC 1972) (“When, as is the case here, Congress has shown an awareness of a problem and has acted accordingly, it seems inappropriate for the agency to adopt procedures which extend the grace period far beyond that envisioned by the statute, and which effectively stay implementation of the congressional mandate that drugs in the marketplace be both safe and effective.”).

meaningful comment, ADDM has considered each component and summarized its impressions below.

A. Reconsideration of FDA's Current Policy on Single Use Device Reprocessors

FDA claims that the FDA Proposed Strategy would enable FDA to regulate reprocessors in the same manner that it has regulated OEMs. This is not the case since reprocessors of "low" and "moderate" risk devices may not be required to file premarket submissions.⁸⁸ All reprocessors, whether they reprocess single use devices characterized by the Risk Categorization Guidance as "low," "moderate," or "high" risk, are manufacturers of reusable devices and should be regulated as such. FDA's uniform regulation of all manufacturers will ensure that patients are afforded the same level of protection.

FDA should treat these reusable devices as it would any other reusable device, and require the same data regarding cleaning, sterility, and functionality that have always been required for reusable devices. On September 28, 1999, ADDM submitted a proposed guidance document for premarket review of reprocessed single use devices to FDA.⁸⁹ The data that would be submitted under this proposed guidance are consistent with FDA's review requirements for reusable devices. FDA has offered no justification for developing different or less stringent data requirements for reprocessed single use devices.

The FDA Proposed Strategy discusses regulating some subset of reprocessed single use devices as it would new devices. For those devices which fall into FDA's ill-defined "moderate" and "low" risk categories, however, reprocessors would not be required to submit data to FDA. In fact, for "low" risk devices, the agency has advised reprocessors that they will not likely be inspected, thereby decreasing their incentive to comply with any

⁸⁸ In fact, it seems curious that FDA is more concerned about protecting patients from reuse of medical devices when an OEM legitimately designs, manufactures, and labels a reusable product than when a reprocessor, without adequate knowledge of fundamental device design criteria, exposes a second patient to a device that was *not designed* to be reused. There is absolutely no patient safety rationale that could justify this disparate treatment of devices, manufacturers, and patients.

⁸⁹ See Letter from Josephine Torrente, Esq., President, ADDM, to David Feigal, Jr., M.D., M.P.H., Director, CDRH, FDA (Sept. 28, 1999).

requirements. Equitable treatment of all manufacturers of reusable devices is mandated under the APA and is necessary to ensure patient safety.

B. FDA's Proposed Categorization Scheme is Unnecessary and Unclear

1. A risk-based classification system for medical devices already exists

Central to the FDA Proposed Strategy is the development and implementation of a risk categorization scheme for the regulation of reprocessed single use devices. ADDM does *not* agree that a new risk-based system should be developed specifically for this subset of reusable devices. In addition to wasting FDA resources, the development of a new scheme delays implementation of premarket submission requirements and continues to jeopardize patient protection.

As initially described in the FDA Proposed Strategy, the new classification scheme classifies a reprocessed single use device into one of three classes –“low,” “moderate,” or “high” risk– based on criteria loosely identified by FDA. For devices characterized as “low” or “moderate” risk, premarket submissions are not be required despite a lack of device-specific data demonstrating that these devices are safe for use in patients. After substantial public criticism that the FDA Proposed Strategy effectively ignored the risk-based classification system for medical devices put in place by Congress over 25 years ago, an FDA official “clarified” that this new scheme *may* serve only to prioritize FDA review of premarket submissions.⁹⁰ This clarification seems mostly a matter of semantics since FDA has not announced deadlines for requiring premarket submissions for “low” and “moderate” risk devices. Developing an elaborate categorization scheme intended to allow the distribution of unapproved devices is a misuse of agency resources.

2. Continued inadequate regulation of most devices

⁹⁰ See Transcript of Dec. 14, 1999 FDA Public Meeting: Reuse of Single Use Devices- FDA Proposed Strategy at 134-35 (statement of Timothy Ulatowski, M.S., Director, DDIGD, ODE, CDRH, FDA) (“I think there’s been much misunderstanding in regard to what the scheme is that we’re hatching in regard to the premarket process. What we are discussing this afternoon is a scheme to prioritize the submissions of premarket applications, be they 510(k)s, premarket approval applications, whatever, a way to prioritize the receipt and review of these applications.”).

Under the FDC Act, premarket submissions must be required of all reprocessed single use devices that are not legally exempted from such a requirement. While FDA has announced that “high” risk devices will be required to comply with this requirement,⁹¹ the agency must clarify whether it intends to *enforce* the premarket submission requirements for devices characterized as “low” or “moderate” risk and, if so, announce timelines for implementation of such enforcement practices.

Premarket control is as essential to the regulation of reprocessed single use devices as it is to the regulation of all other medical devices. Nonetheless, FDA has evidenced its intention to ignore or substantially delay enforcement of the premarket controls for many reprocessed single use devices. For devices characterized as “low” risk, FDA has announced plans to ignore the premarket requirements and to de-prioritize establishment inspections.⁹² As for “moderate” risk devices, the FDA Proposed Strategy claims that “FDA would enforce applicable premarket requirements to ensure that the reprocessed device remains . . . safe and effective. . . .”⁹³ However, for products in this category, FDA then declares that a reprocessor’s declaration of conformity to consensus standards may satisfy this requirement. This reliance on consensus standards enables FDA to continue its history of non-enforcement while declaring that the premarket submission requirements are being complied with for “moderate” risk devices.⁹⁴

While the requirement for premarket submissions can be satisfied by an exemption under the FDC Act, such an exemption must be based on device-specific data available for public inspection and comment. In contrast, the FDA Proposed Strategy exempts broad categories of devices from premarket submission by fiat. While factors such as those mentioned in the Risk Categorization Guidance may play a role in making individual exemption decisions, they cannot be used to exempt all “low” risk devices.

⁹¹ See FDA Proposed Strategy at 10.

⁹² See id. at 10-11.

⁹³ Id. at 11.

⁹⁴ The FDA Proposed Strategy also discusses time periods for implementation of certain requirements. See FDA Proposed Strategy at 11. ADDM disagrees with the extraordinary long implementation schedule, and advocates the grace periods set forth in the ADDM Strategy.

The FDA Proposed Strategy suggests that all reprocessed Class I and Class II exempt single use devices would be characterized as “low” risk.⁹⁵ This would result in automatic exemptions for those devices. Thus, Class I exempt biopsy forceps would be reprocessed without premarket submission despite the additional safety concerns introduced by reprocessing that would place that device in a “high” risk category under the Risk Categorization Guidance.⁹⁶ Such a policy would not be consistent with ensuring patient safety. In exempting certain single use devices, FDA and its expert panels did not consider that the device would be subjected to reprocessing and be used in multiple patients. Reuse introduces risks that were not factored into the exemption. If reprocessing truly presented no new risks, then FDA would allow OEMs to relabel their single use Class I and Class II exempt devices as reusable without FDA clearance of a 510(k).

3. *The FDA classification scheme is ambiguous*

Should FDA proceed with implementation of the Risk Categorization Guidance for any purpose, it must more specifically define the decision-making criteria to prevent the same device from being placed into multiple categories. The FDA Proposed Strategy strongly implies that only Class III devices will fit into the “high” risk category.⁹⁷ The FDA Proposed Strategy also concludes that all Class I and Class II exempt single use devices will be “low” risk. Nonetheless, in applying the scheme in the Risk Categorization Guidance, many reprocessed Class I and Class II devices, including exempt devices, must be categorized as “high” risk.

For instance, biopsy forceps and sphincterotomes, which are critical devices with narrow lumens and inaccessible parts that impede cleaning and sterilization, would be categorized as “high” risk (Grade 2 on FDA’s Flowchart 1) under the FDA scheme. Nonetheless, in a recent article, the president of the American Society for Gastrointestinal

⁹⁵ “The agency anticipates that the low-risk category would include . . . Class I and Class II exempt, and some Class I and II non-exempt” devices. FDA Proposed Strategy at 10.

⁹⁶ The Risk Categorization Guidance details a method for determining whether a particular reprocessed single use device would be regulated as a “high,” “moderate” or “low” risk device under the FDA Proposed Strategy.

⁹⁷ “Considering the type and regulatory class of SUDs that may be included in [the high risk] category, it is likely that premarket data will be . . . submitted through the premarket approval process.” FDA Proposed Strategy at 10.

Endoscopy states that “gastrointestinal endoscopy accessories will likely fall into the FDA-proposed category of ‘moderate risk’ based on inherent design characteristics and intended use.”⁹⁸

Similarly, anesthesia breathing circuits would be “high” risk under FDA’s Flowchart 2. This is because of their corrugated, often concentric multiple lumens, and “Y” connectors that could be damaged during single use or reprocessing, jeopardizing performance due to increased potential for leakage and inadvertent disconnection.⁹⁹ No performance standards exist for these devices and performance cannot be evaluated on visual inspection alone. Despite these features, the Risk Categorization Guidance cites anesthesia breathing circuits as an example and erroneously concludes that these devices would be “low” risk. The example concludes that the device contains no “components [that] may be damaged or altered by single use [in such a way that] performance of the device may be affected.”¹⁰⁰ This conclusion demonstrates a lack of understanding of the device, and compels the conclusion that technically qualified individuals at CDRH must implement the risk categorization scheme. These decisions clearly can not be left in the hands of the reprocessors. Yet FDA still has apparently not resolved the fundamental question of who will categorize devices under its scheme.¹⁰¹

⁹⁸ James T. Frakes, M.D., M.S., *Reuse of Single Use Devices: Lesson in Science, Economics, and Politics*, at 11 ASGE News (Dec. 1999).

⁹⁹ See Letter from Anthony P. Martino, Vice President, Quality Assurance and Regulatory Affairs, Vital Signs Inc. to FDA Dockets Management Branch (FDA Docket No. 99N-4491) (Jan. 14, 2000) (“[Anesthesia Breathing Circuit] SUD tubing is ‘corrugated’ and does not have a smooth lumen making cleaning difficult . . . [Anesthesia Breathing Circuit] SUD tubing not only ‘conveys’ gases to the patient, but also transports exhalation gases away from the patient. This presents a source of ‘contamination.’”).

¹⁰⁰ Risk Categorization Guidance at 5.

¹⁰¹ See Transcript of Dec. 14, 1999 FDA Public Meeting: Reuse of Single Use Devices-FDA Proposed Strategy at 153 (statement of Timothy Ulatowski, M.S., Director, DDIGD, ODE, CDRH, FDA) (“I think FDA’s going to have to do a categorization run-through of the frequently reprocessed devices, at least, that are on the list, to give an indication of where FDA feels the devices fall out. But I don’t think we’re going to run through each and every device known to man that may be presented for reprocessing. And I think some of the categorizations and decision-making will

4. *Rethinking the categorization scheme flowcharts*

FDA has recently clarified that the proposed categorization scheme may serve only to prioritize receipt of premarket submissions for reprocessed single use devices.¹⁰² ADDM disagrees with this approach because of its continued authorization of reprocessing and because of the lack of a deadline for premarket submissions for devices that would be characterized as “low” risk under FDA’s scheme.

ADDM agrees with the Risk Categorization Guidance that the three key factors in determining the risk of reusable devices, including reprocessed single use devices, are the inherent risk of the device, the risk of disease transmission/infection, and the risk of inadequate/unacceptable device performance. These factors cannot, however, be assessed across broad categories via flowcharts, but must be evaluated using model-by-model data. ADDM suggests that the flowcharts in the Risk Categorization Scheme be amended as demonstrated in Attachments 1 and 2 hereto. Once modified, these flowcharts should be used only to aid in granting data-based exemptions under the FDC Act.

Both flowcharts are amended by removing the Grade 1 and thereby eliminating the “moderate” risk category. A device whose risk is unknown must be treated as unsafe and ineffective, and will therefore be deemed “high” risk. In addition, in Flowchart 1, question 4 and in Flowchart 2, question 1 are revised to recognize that use of the device, as well as reprocessing, may damage device materials, coatings or components. Flowchart 2 is further amended by deleting questions 2 and 3. The existence of standards and ease of visual inspection are a critical part of a device’s 510(k) submission and review, but cannot be used in a flowchart to determine risk.

In addition to these changes, the terminology used in the flowcharts needs clarification to promote consistency. For instance, Flowchart 1 includes the term “narrow lumen” yet it was clear at FDA’s December 1999 Stakeholder Meeting that the lumen of a device could be narrow in the eyes of one person and not in the eyes of another.¹⁰³

have to be downloaded to the people doing it. At least that’s my first opinion. But it’s a matter of discussion. . . .”).

¹⁰² See supra note 90.

¹⁰³ See Transcript of Dec. 14, 1999 FDA Public Meeting: FDA’s Proposed Strategy on Reuse of Single Use Devices at 156 (statement of David Greenwald, M.D., Chairman, Gastroenterology Endoscopes Subcommittee, American Society for

C. FDA's Draft List of Frequently Reprocessed Single Use Devices

Section three of the FDA Proposed Strategy identifies twenty-two devices that FDA has assembled into its "draft list of frequently reprocessed SUDs." The purpose of the draft list, however, is unclear. The draft list is prefaced by a short one sentence introduction and no further explanation is provided. The draft list is inconsistent with the Risk Categorization Guidance. In that document, FDA properly identifies risk, not frequency of reprocessing, as the most important factor to consider in determining the regulation of reprocessed single use devices.

Section three of the FDA Proposed Strategy fails to specify criteria for a device's inclusion or exclusion from the draft list. Without identifying the criteria by which a device is evaluated, the draft list is not only arbitrary, but it also does not afford interested parties the opportunity to assess whether a particular device should be placed on a future draft of the list nor does this list account for newly developed single use devices. If a device is not on the draft list, it is unclear whether, or when, a premarket submission is required to reprocess that device. In addition, FDA does not provide a mechanism for adding new devices to the draft list. Moreover, the significance of a device's inclusion on the draft list is unclear. FDA must explain clearly the importance of being placed on the list.

Even more important, the approach taken by the draft list is fundamentally flawed. FDA noted correctly at the May 1999 FDA/AAMI meeting that the decision to reprocess a device must be based on specific models of devices.¹⁰⁴ FDA recognized this shortcoming in its Risk Categorization Guidance when it specifically identified a cardiac ablation catheter as a "high" risk device, instead of evaluating "cardiac catheters and guidewires" as identified in the FDA Proposed Strategy's draft list. Similarly, some surgical staplers may present a higher risk to patient health if reprocessed than others.

Testing and Materials) ("[W]hat's a narrow lumen? . . . [FDA] said it didn't have a narrow lumen. I mean it has a narrow lumen compared to other devices . . .").

¹⁰⁴ One FDA researcher noted that "we need model by model [evaluation] . . . [We] can't do device, [we] can't do manufacturer, we've go to go model by model. I don't think serial number by serial number yet, but certainly model by model." Transcript of May 5-6, 1999 FDA/AAMI Conference on the Reuse of Single-Use Devices at 78 (statement of Katherine Merritt, Ph.D., Research Biologist, Division of Life Sciences, OST, CDRH, FDA).

FDA's grouping of devices under the umbrella term "frequently reprocessed single use devices" does not take into account the differences between devices that perform similar functions. Instead of a frequency-based evaluation, devices should be evaluated by FDA on a model-by-model basis. The most appropriate and effective process for such evaluation is the premarket submission process. Following such a process will fulfill FDA's stated goal in issuing the FDA Proposed Strategy – "to protect the public health by assuring that the practice of reprocessing and reusing [single use devices] is based on good science."¹⁰⁵

D. Labeling Regarding the Risks of Reprocessing

The FDA Proposed Strategy suggests implementation of new labeling requirements for single use devices. This suggestion is incompatible with Congress' most recent pronouncements on FDA review of medical device labeling, and it raises potential liability issues for FDA's stakeholders.

1. History of the single use label

For nearly a century, the medical community had routinely reused most medical devices. In the late 1950s, this practice changed when a New Jersey dentist unwittingly used improperly sterilized hypodermic needles and injected nine patients with a fatal hepatitis virus. In response, laws prohibiting the reuse of hypodermic needles were enacted. As similar incidents occurred both in the United States and abroad, organizations such as the Association of Operating Room Nurses became increasingly alarmed at the potential for harm associated with device reutilization and became advocates for strict standards of device cleanliness and performance. FDA and medical device manufacturers began implementing a requirement that certain devices be labeled "single use only."

At the same time, the use of single use devices expanded significantly due to their convenience and efficiency. This was particularly true during the Korean War, when single use plastic fluid containers eliminated the need to remove, re-sterilize, and then return to the battlefield glass bottles filled with IV fluid. Additionally, with the improvement of plastic technology, devices became smaller, more reliable in design, and more effective. They saved space, were lightweight, and eliminated breakage. They also improved patient care. For example, plastic intravenous catheters were more flexible and comfortable than needles and greatly reduced trauma to the patient.

¹⁰⁵ FDA Proposed Strategy at 7.

Many of the interventional technologies that have revolutionized medicine, such as balloon angioplasty catheters, controlled radial expansion balloons, and tools to repair brain aneurysms, are only possible because of the design features that would be impossible to achieve in a reusable device. Single use devices are designed for optimal performance, not for ease of cleaning. Whereas most reusable devices are easily disassembled, have smooth surfaces, and are made of durable material, a single use device may be seriously compromised or destroyed by cleaning and reprocessing techniques.

In the last ten years, FDA has increasingly focused on the need for OEMs to include labeling for “single use only” on certain devices. For example, in 1992, FDA published in a draft 510(k) guidance document for cortical electrodes, the requirement that the device label specify whether the device is intended for single use or multiple use.¹⁰⁶ In 1996, FDA reclassified acupuncture needles from Class III to Class II with the implementation of special controls including labeling for single use.¹⁰⁷ FDA issued a document in 1998 that required aqueous shunt manufacturers to include a statement that the device is for single use only.¹⁰⁸ Most recently, in a 1999 document addressing the proposed classification for external penile rigidity devices, FDA required that the label address the disposable/single use status.¹⁰⁹ These are only a few examples of the many instances where FDA has required labeling for “single use only.” While OEMs have complied with such requirements, the reprocessing industry and others now assert that the single use label is not a FDA requirement, but rather a label to be used arbitrarily by the OEM.¹¹⁰ That is, they

¹⁰⁶ See FDA Reports and Publications for Specific Products (Aug. 10, 1992). (While this guidance was never formally finalized, Neil B. Ogden, Director, General Surgery Devices, ODE, CDRH, FDA, confirmed that cortical electrode manufacturers must comply with its requirements.) (Personal Communication, Jan. 28, 2000.)

¹⁰⁷ See Reclassification of Acupuncture Needles for the Practice of Acupuncture, 61 Fed. Reg. 64616 (Dec. 6, 1996).

¹⁰⁸ See FDA Reports and Publications for Specific Products (Nov. 16, 1998).

¹⁰⁹ See Proposed Classification for the External Penile Rigidity Devices, 64 Fed. Reg. 62 (Jan. 4, 1999).

¹¹⁰ See AMA Talking Points, AMDR (“Manufacturers choose to label devices as single-use; it is not a FDA requirement”); statement of Timothy Ulatowski, M.S., Director, DDIGD, ODE, CDRH, FDA, at the FDA Satellite Videoconference on the Proposed FDA Strategy for Reuse of Single Use Devices (Panel I) (Nov. 10, 1999) (“[I]t’s the

deem “single use only” to be an optional labeling statement. As is evidenced by these examples and many others like them, this statement is wholly untrue.

Others have asserted that OEMs should be required to develop safe and effective reprocessing techniques and then add device-specific instructions regarding select methods of reesterilization or reprocessing to their labels. Such statements completely ignore design considerations surrounding single use devices. Some single use devices have failed testing for multiple use. While others have not been tested for multiple use, this lack of testing is generally the result of the OEM’s recognition, based on its understanding of the device’s design, that the device would fail such testing.

A medical device can only be labeled for what it has been demonstrated to do safely and effectively. All single use devices have been cleared or approved by FDA for one use because they have been demonstrated to be safe and effective when used on a single patient in a single procedure. It is an illogical, hazardous approach to establish a multiple-use label as the “default” label when there are no data regarding a device’s safety and effectiveness after reprocessing. The burden has always been on the manufacturer of a reusable device to show that reuse is safe. Reversing the burden would be improper and unprecedented.

2. The FDA Proposed Strategy –Requirements of the FDC Act

Furthermore, requiring OEMs to provide, as part of a single use device’s labeling, information of which they are aware regarding the potential risks associated with reprocessing would be unlawful. FDAMA prohibits FDA from requiring OEMs to include the potential risks associated with reusing single use devices in their device labeling.¹¹¹ FDAMA added to the FDC Act a new section 513(i)(1)(E)(i). That section limits FDA’s determination of the intended use of a device that is the subject of a premarket notification to the sponsor’s proposed labeling. Thus, FDA may review only that information which the manufacturer included in the draft label or any accompanying information, such as directions for use or promotional materials. FDA has no authority to require that OEMs add information to the label regarding the potential risks of reuse.

device manufacturer who writes the label for their product. . . . They have to have the data and information to support the claims that they have in labeling As long as the manufacturers promote their device and the device is used predominantly for the use in the labeling, then we don’t take issue with the claims.”).

¹¹¹ See Pub. L. No. 105-115, 111 Stat. 2296 (1997).

The Senate Report on FDAMA finds that, “[s]imply put, the committee does not want FDA to exceed its jurisdictional responsibilities by incorporating into the review process claims not before the agency for review consideration.”¹¹² FDA will be exceeding the scope of its authority if it requires that OEMs include warnings of the potential risks of reprocessing in single use device labeling.

FDAMA does identify, and a January 1998 FDA guidance document addresses, the “rare instances in which the design of the device or published literature referencing the subject device or a similar device would lead one to believe that there may be an intended use different than that appearing in the labeling.”¹¹³ In this exceptional situation, FDA must determine “(I) that there is a reasonable likelihood that the device will be used for an intended use not identified in the proposed labeling for the device; and (II) that such use could cause harm.”¹¹⁴ If both of these criteria are met, then the 510(k) submitter must be provided the opportunity for a consultation with the Director of CDRH where one possible outcome is that FDA will issue a “substantial equivalence letter with limitations” in which the agency may require the inclusion of information about the off-label use for the device.¹¹⁵

However, FDA cannot apply the exception in its review of 510(k) submissions for single use devices. “Reuse” is a different intended use than “single use.”¹¹⁶ A new 510(k) is required for “[a] major change or modification in the intended use of the device.”¹¹⁷

¹¹² S. Rep. No. 105-43 at 27 (July 1, 1997).

¹¹³ See Determination of Intended Use for 510(k) Devices – Guidance for Industry and CDRH Staff, ODE, CDRH, FDA (Jan. 30, 1998).

¹¹⁴ FDC Act § 513(i)(1)(E)(i)(I)(II), 21 U.S.C. § 360c(i)(1)(E)(i)(I)-(II).

¹¹⁵ See id.

¹¹⁶ 21 C.F.R. § 801.4 defines “intended uses” as “the objective intent of the persons legally responsible for the labeling of devices.” While this section further states that “[i]t may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised,” section 205 of FDAMA generally limits FDA review of 510(k)s and PMAs to a sponsor’s proposed condition of use, therefore this section prevents FDA from requiring labeling regarding non-proposed uses.

¹¹⁷ Id. § 807.81(a)(3)(ii).

Both prongs of the FDAMA exception must apply before FDA may require the 510(k) submitter to include labeling information regarding an unintended use. Here, reuse is not just an unintended use, but is the opposite use –and one that is actively warned against by OEMs. Therefore, the analysis under the second prong, whether reuse could cause harm, need not be addressed.

3. *The FDA Proposed Strategy –Liability issues*

FDA has proposed requiring OEMs to include the potential risks associated with reusing single use devices in their labeling.¹¹⁸ FDA's proposed requirement would have the effect of increasing the likelihood that OEMs, physicians, and hospitals will be subject to costly products liability litigation. For physicians and hospitals that reuse single use devices, FDA's proposed requirement may create additional malpractice claims as a result of the numerous additional warnings that single use device labels would contain.¹¹⁹

It is unrealistic for FDA to impose on OEMs the burden of knowing all the potential risks that could result from reprocessing, and, including only those risks known to the OEM may mislead hospitals and physicians into believing that only those risks exist. An OEM cannot predict all the potential hazards that a reprocessor might introduce into a device, or all the potential ways in which the device might fail should the reprocessor improperly handle it. By listing some failure modes, the OEM leaves itself open to liability if the device fails through some other means. For example, if an OEM warns of five risks associated with reprocessing, the OEM may be sued for not listing a different failure mode which materialized.¹²⁰

Rather than require that OEMs warn of the potential risks of reprocessing, FDA should require reprocessors to provide such information and remove the OEM name from the device and its label. In this way, device failures will be reported to the reprocessor and not to the OEM. In addition, such a requirement will decrease OEMs' liability exposure and place the burden for failed reprocessed single use devices where it belongs –on the

¹¹⁸ See FDA Proposed Strategy at 13.

¹¹⁹ Remarks made by James M. Wood, Esq., Crosby, Heafey, Roach & May, at the FDLI/FDA 43rd Annual Educational Conference (Dec. 16-17, 1999) (transcript unavailable).

¹²⁰ See MacDonald v. Ortho Pharma. Corp., 394 Mass. 131, 475 N.E. 2d 65 (MA) cert. denied, 474 U.S. 920 (1985).

reprocessor. Leaving the OEM's name on a reprocessed device can wrongfully result in the OEM being dragged into the litigation.

E. Working Definitions for Certain Terms

The FDA Proposed Strategy contemplates the need to establish uniform definitions for four terms and proposes a draft definition for each. While ADDM agrees that standardized definitions would be helpful, ADDM proposes the following alternative definitions.

Single Use Device: a device labeled by the manufacturer, and cleared or approved by FDA, to be used for one procedure on one patient and not to be reprocessed or reused. This term is synonymous with "disposable device."¹²¹

FDA's definition of single use devices is confusing in that "opened but unused single use device" is different from "single use disposable," rather than a subset of it. FDA's definition also fails to indicate that the intended use is proposed by the OEM and cleared or approved by FDA.

Reuse: the repeated use or multiple use of any medical device, whether a single use device or a reusable device, on different patients with reprocessing between uses.

FDA's definition of reuse inappropriately includes multiple uses of the same device on the same patient. By so doing, FDA has decreased the utility of the term "reuse" by including dialyzers in the term.

Reprocessing: the process to which a used single use device or used reusable device is subjected in an attempt to make the device appropriate for use in another patient. Reprocessing steps may include cleaning, sterilization, functional testing, repackaging and relabeling, among others. Reprocessing does not include steps taken to sterilize an opened but unused single use device, a device whose expiration

¹²¹ This proposed definition has been adapted from a definition stated in the Emergency Care Research Institute's (ECRI's) special report on the reuse of single-use devices. ECRI defines a single-use device as a "[d]evice labeled by the manufacturer to be used for one procedure on one patient and not to be reused. A specific type of disposable medical device." ECRI, Special Report: Reuse of Single-Use Medical Devices: Making Informed Decisions, at 43 (1997).

date has expired, or a single use or reusable device provided to the user as non-sterile.

FDA's definition of reprocessing incorrectly includes pre-use sterilization of devices provided to the user non-sterile with instructions for sterilization.

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.

For single use devices resterilization may only be appropriate for opened but unused devices or for devices whose expiration dating has passed prior to use.

F. The Inapplicability and Impracticability of Consensus Standards and Performance Standards

The FDA Proposed Strategy proposes the application of recognized consensus standards and the development of new consensus standards to evaluate the safety and effectiveness of reprocessed single use devices. Such an approach, however, is inadequate because consensus standards are voluntary and do not evaluate the performance of each reprocessed device. FDA has also proposed the development of performance standards to evaluate reprocessed single use devices. Experience has shown that developing performance standards is an extraordinarily slow process. In addition, performance standards would not address present concerns about patient safety. Only submission of a 510(k) or PMA can adequately address the safety and effectiveness concerns raised by reprocessing single use devices.

Consensus standards are too broad to adequately address the safety and effectiveness concerns raised by reprocessing single use devices. A consensus standard would be appropriate to the extent the *practice* of reprocessing needs to be better defined, simplified, and homogenized. Reprocessing single use devices, however, presents issues about the *performance* of individual devices that cannot simply be remedied by conformance to a consensus standard. For instance, consensus standards cannot be used to delineate how the materials used in a single use device will perform after reprocessing. Heightened FDA scrutiny is necessary. The most appropriate form of FDA scrutiny for reprocessed single use devices is a premarket submission.

Moreover, the use of performance standards is impractical. Since the passage of the MDA twenty-four years ago, FDA has issued and implemented only *one* mandatory

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all reproprocessors of single use devices. The ADDM Strategy provides a method for implementing these requirements. ADDM again urges FDA to adopt and implement the ADDM Strategy.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Josephine M. Torrente', with a stylized flourish at the end.

Josephine M. Torrente

JMT/dmb
1486.001/outline.doc

Infection Potential

Is device non-critical?	yes →	Grade 0
↓ no		
Does device have features impeding cleaning, disinfection or sterilization?	yes →	Grade 2
↓ no		
Does postmarket info suggest increased infection risk over new device?	yes →	Grade 2
↓ no		
Does device contain coatings, materials or components that may be damaged/ altered by single use or reprocessing ?	yes →	Grade 2
↓ no		
Grade 0		

Failure Potential

Does device contain materials, coatings or components that may be damaged/altered by single use **or reprocessing** affecting performance? no → Grade 0

↓ yes

Grade 2