ASSOCIATION OF DISPOSABLE DEVICE MANUFACTURERS
Providing industry views on single patient use medical devices

August 31, 2001

BY HAND DELIVERY

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

Re: Docket No. 01D-0232: Premarket Guidance: Reprocessing and Reuse of Single-Use Devices; Draft Guidance for Industry and FDA Staff

Dear Sir or Madam:

The undersigned, on behalf of the Association of Disposable Device Manufacturers ("ADDM"), respectfully submits these comments to the Food and Drug Administration's ("FDA's" or "the Agency's") draft guidance document, titled "Premarket Guidance: Reprocessing and Reuse of Single-Use Devices,"[1] which was noticed in the Federal Register on June 1, 2001.[2] ADDM appreciates the opportunity to comment on the Premarket Guidance.

I. Background

ADDM is a trade association of medical device manufacturers whose mission is to provide information and industry perspectives on issues concerning single use medical devices. Since its formation almost three years ago, ADDM has sought appropriate FDA regulation of entities that reprocess single use devices contrary to their labeling and approval. Such regulation would include enforcement of all parts of the Quality System Regulation ("QSR") and enforcement of the premarket submission requirements of the Federal Food, Drug, and Cosmetic Act ("FDC Act").[3] ADDM has commented extensively

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1 Center for Devices and Radiological Health ("CDRH"), FDA, Draft Guidance for Industry and FDA Staff, Premarket Guidance: Reprocessing and Reuse of Single-Use Devices (June 2001) (hereinafter Premarket Guidance).

2 See 66 Fed. Reg. 29822 (June 1, 2001).

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

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◆P.O. Box 344, 1429 G. Street, N.W., Washington, D.C. 20005 Telephone: 202-737-7554, Fax: 202-737-9329◆

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clean and functional devices;[5] and (3) enforce the QSR as a compliment to, rather than as a substitute for, true enforcement of premarket submission requirements.

II. Reprocessed Single Use Devices are Intended for Use on Multiple Patients and Must be Regulated as Reusable Devices

The Premarket Guidance implies that, despite a reprocessor's intent that its device be used on multiple patients, the device may be labeled "single use only" and thereby avoid the more rigorous premarket requirements imposed on new devices intended for multiple use.[6] As discussed in detail in Section II of these comments, OEMs who design and manufacture devices intended for multiple use must provide FDA with premarket data to demonstrate that the devices are safe and effective after multiple cleaning, disinfection and sterilization cycles, and identify the number of times a device can be reused. Reprocessors – entities that are not involved in device design – can apparently avoid these data requirements by blatantly misrepresenting the intended use of the device as "single use only." As a result, higher risk products are subjected to a lower regulatory standard. Such a policy is inconsistent with the protection of the pubic health, and results in the marketing of reprocessed single use devices that are both adulterated and misbranded.

ADDM recently submitted a citizen petition on this issue requesting FDA recognition that reprocessed single use devices are reusable devices and cannot be labeled, cleared or approved for "single use only."[7] The Citizen Petition further requests that FDA refuse to approve Premarket Approval Applications ("PMAs") or clear premarket notifications ("510(k)s") for reprocessed single use devices that are labeled "single use only" or for which adequate data for multiple use are not provided. Rather than repeat each of the Citizen Petition arguments in detail here, this section provides a brief listing of those issues and incorporates the Citizen Petition by reference (Attachment B).

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5 CDRH, FDA, Reviewer Guidance, Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities (April 1996) (hereinafter Reusable Device Guidance).

6 Premarket Guidance at 6 ("Provided there is sufficient valid scientific information, a reprocessor has the option of labeling a reprocessed [single use device] for ... single use . . ."). See Letter from Larry G. Kessler, Sc. D., Director, Office of Surveillance and Biometrics, CDRH, FDA to Josephine M. Torrente, President, ADDM (Oct. 30, 2000).

7 Citizen Petition, FDA Docket No. 01P-0340 (Aug. 3, 2001) (hereinafter "Citizen Petition").

In essence, the Premarket Guidance, if finalized without change, would permit reprocessed devices intended for multiple use to be labeled as single use devices and to thereby avoid the statutory requirements for premarket clearance or approval applicable to multiple use devices. Reprocessed single use devices marketed pursuant to FDA's proposed policy would be misbranded because they would falsely state that they are for single use. In addition, the reprocessed devices would not be shown to be substantially equivalent to multiple use predicate devices, and would be unapproved, adulterated Class III devices. Premarket approval of reprocessed devices labeled for single use would also be unlawful because the conditions of use stated in the devices' labeling would not be those under which the devices are intended to be used, and because the labeling would be false.

CDRH's proposed policy of permitting "multiple single uses" is contrary to logic and the FDC Act. Not only does it countenance violations of the statute, but it is also irrational, results in disparate treatment of similarly situated manufacturers, constitutes an unexplained departure from existing approval or clearance standards, and fails to protect patients from reprocessed single use devices for which there are inadequate safety and effectiveness data.

III. Reprocessor 510(k)s Must Demonstrate Substantial Equivalence to a Reusable Predicate Device and Include Details of Reprocessing Procedures and Outcomes

A. Appropriate Predicate Devices

Manufacturers of non-exempt medical devices must establish that their devices are substantially equivalent to a device with the same intended use (510(k)) or that their devices are safe and effective (PMA). "Single use" or "reuse" is part of the device's intended use.[8] A 510(k) for a reusable device, therefore, must be found insufficient if it uses, as a predicate, a single use device absent additional cleaning and performance data supporting the expansion in intended use.[9] This paradigm is well established and has been used for years by FDA to regulate devices intended for use on multiple patients. The Premarket Guidance, however, departs from this established FDA precedent, asserting that

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[8] CDRH, FDA, Guidance, Deciding When to Submit a 510(k) for a Change to an Existing Device (Jan. 19, 1997) at 10-11.

[9] CDRH, FDA, Premarket Notification Review Program, Blue Book Memorandum K86-3 (June 30, 1986).

FDA reviewers "should not ordinarily consider the reprocessing of [a single use device] as a new intended use."[10]

B. Regulatory Precedent Requires Reprocessor 510(k)s to Contain Cleaning and Sterilization Process Information

Devices used on multiple patients present obvious additional concerns over new single use devices. Cleaning, disinfection and sterilization of devices previously used on patients is necessarily more challenging than sterilization of a new device because the amount, character and resistance of contamination is unknown. Moreover, harsh cleaning chemicals and methods may damage medical devices.[11]

As noted in the Premarket Guidance, "a 510(k) submission must contain enough information for FDA to determine whether the device is as safe and effective as a legally marketed predicate device."[12] A determination that a reprocessed single use device is as safe and effective as the underlying OEM device cannot be made without an understanding of the reprocessing methods that the device will be subjected to. Reprocessing may introduce new failure modes into the device. The FDA reviewer will be unable to adequately review the 510(k) – that is, discern whether adequate testing was performed – absent a familiarity with the reprocessing methods used. FDA has long recognized the need for cleaning and sterilization process information in the 510(k)s of all other devices used on multiple patients.[13]

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10 Premarket Guidance at 9.

11 AAMI, Designing, Testing and Labeling Reusable Medial Devices for Reprocessing in Health Care Facilities: A Guide for Device Manufacturers, AAMI TIR No. 12-1994 (Nov. 24, 1994) at 9, 10, 27 and 32 (hereinafter TIR 12). ("Damage to polymeric materials increases with higher disinfectant/sterilant concentrations, higher temperatures, and longer exposure times." "[E]xposure of a device to a critical stress or load combined with exposure to a chemical disinfectant or sterilant can accelerate device or component degradation. While the polymeric material may be able to hold up to the stresses and chemical exposure separately, exposure to both at the same time could cause failure.")

12 Premarket Guidance at 5.

13 See generally Reusable Device Guidance.

Reprocessing methods must be included in the labeling for reusable devices, and are reviewed by FDA staff to determine the appropriateness of reprocessing methods for the subject devices.[14] In addition, reusable device labeling must set out "how many times the product can be reused, or provide a mechanism to ascertain that the device is still within specifications."[15] Finally, reusable device manufacturers must provide a 510(k) summary of the validation method including "protocols, specifications, pass/fail criteria and procedures which describe when the instructions must be requalified (e.g., if the device is modified)."[16] Although such information is primarily included in labeling for the benefit of the user, FDA staff also review it to "determine whether the basis for validation is relevant, or whether the summary raises serious concerns."[17]

The Premarket Guidance, however, implies that reprocessing procedures will not be evaluated during 510(k) review for reprocessed single use devices unless they are evaluated for the underlying single use OEM product.[18] While this standard initially appears sensible and equitable, it is, in fact, completely illogical. The OEM's product was intended for one use while the reprocessor's is intended for multiple use. It is this distinction that creates the potential for new failure modes, and the need for review of reprocessing procedures in the 510(k) for the reprocessed device. The ability to be reprocessed multiple times is a critical property of the reprocessed device but is irrelevant to a new single use device.

Reusable device manufacturers are required to include certain specific data in their 510(k)s demonstrating, for instance, that cleaning and sterilization agents do not adversely

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14 Id. at 4-5. ("FDA reviewers will not accept less than the minimum acceptable level of reprocessing.").

15 Id. at 8.

16 Id. at 11.

17 Id. at 12.

18 Not only does the Premarket Guidance imply the reprocessing procedures will not be evaluated, it notes that if the reprocessor does submit process information and the FDA reviewer determines that there are deficiencies in this information, the reviewer should not consider those deficiencies in the 510(k) review. Such information is, however, among the most critical components of determining whether the device is as safe and effective as its single use counterpart and is the very reason that the 510(k) is required.

affect device materials and biocompatibility.[19] Despite these well-established requirements, the Premarket Guidance implies that such data is beyond the scope of reprocessed device 510(k)s. Reprocessed single use devices are reusable devices. Permitting such devices to be labeled single use only again and again, does not alter the clinical reality that the devices have been used in previous patients and therefore present the same cross-contamination and failure risks as devices labeled "reusable." There can be no public health purpose behind circumventing basic reusable device premarket requirements for reprocessed single use devices. The key difference between devices marketed by reprocessors and reusable devices marketed by OEMs is that the reprocessed devices are sold for a use that is inconsistent with their design. One might reasonably expect this sort of inconsistency to heighten, not lessen, FDA scrutiny.

IV. True Enforcement of Both the QSR and Premarket Review is Essential to Patient Safety

For years, FDA essentially ignored reprocessing of single use devices in hospitals and enforced only a severely diluted version of the QSR on third party reprocessors. In 1998, FDA formally announced that it would rely primarily on the QSR to regulate third party reprocessing, and that it intended to continue exercising enforcement discretion with respect to the premarket requirements for reprocessed devices.[20] One year ago, however, in the face of mounting public and congressional criticism, FDA ostensibly reversed this long-standing position when it issued a guidance document, titled "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals."[21] At that time, FDA stated that increased safety would be achieved, in part, through the enforcement of premarket controls and enhanced QSR oversight of all reprocessors. Consistent with that representation, the Enforcement Guidance called for premarket requirements for reprocessed single use devices to be phased in over a two-year period.[22] The Agency communicated to patients and committees in the U.S. House of Representatives and the

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19 Reusable Device Guidance; TIR 12.

20 See Letter from D. Bruce Burlington, M.D., Director, CDRH, FDA to Nancy Singer, Esq., Special Counsel, Health Industry Manufacturers Association (July 15, 1998) (hereinafter Response to HIMA Petition).

21 CDRH, FDA, Guidance, Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals (Aug. 14, 2000) at 40 (hereinafter Enforcement Guidance).

22 See generally Enforcement Guidance.

U.S. Senate its intention to hold reprocessors to the same health-based standards as the Agency imposes on OEMs.[23]

Since that time, however, FDA has repeatedly demonstrated its unwillingness to follow through on its commitment. Instead, FDA has continued to emphasize compliance with a diluted version of the QSR as the central element in reprocessed device regulation, while ignoring the most essential QSR provisions and weakening the premarket review requirements beyond recognition.

A. 510(k) Review Under the Premarket Guidance Will Result in Rubber-Stamp Clearances of Unsafe Reprocessed Devices

The Premarket Guidance renders all but meaningless the 510(k) review process for reprocessed single use devices. According to the Premarket Guidance, 510(k) clearance for these devices will likely require asking only one question: whether descriptive information asserts that the reprocessed device has similar specifications to the new single use device.[24] This watered-down review is made possible by two sweeping, erroneous assumptions. First, FDA reviewers are instructed to ignore the threshold 510(k) question of whether the device has the same intended use as the predicate. As established above, however, if the predicate is a single use device, then the reprocessed device does have a different intended use – reuse.[25]

Having dispensed with that question without so much as an explanation as to why the reviewer should ignore both logic and FDA precedent, the Premarket Guidance goes on to tackle the next question in the 510(k) review process with equal brevity. FDA reviewers, faced with determining whether the reprocessed device presents new types of safety questions, are instructed to ignore the obvious issues of compromised sterility and breach of material integrity that reprocessing may cause (issues not of concern in the review of

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23 Hearing on Reprocessing of Single-Use Medical Devices, 106th Cong. (June 27, 2000) (statement of David W. Feigal, M.D., Director, CDRH, FDA); Reuse of Single-Use Medical Devices, 106th Cong. (Feb. 10, 2000) at 9 (testimony of David W. Feigal, M.D., Director, CDRH, FDA).

24 Premarket Guidance at 9.

25 As discussed in the Citizen Petition, FDA cannot remedy this situation by permitting reprocessors to misbrand their devices with the label "single use only."

510(k)s for new single use devices), and determine that the reprocessed device presents no new types of safety issues.[26]

The Premarket Guidance has removed the rigor from the Agency's premarket submission requirements. Under FDA's standard, for reprocessors, 510(k)s will receive rubber-stamp clearances regardless of whether the reprocessed device is actually safe. In reality, FDA's policy is no different today than it was in July 1998, when the Agency emphasized the role of the QSR in the regulation of reprocessors.[27]

B. FDA's Intent to Continue Relying Almost Exclusively on QSR Compliance for Reprocessors is Apparent in the Premarket Guidance and Other FDA Actions

FDA has not stepped up regulation of reprocessing in the past few years notwithstanding the Agency's representations to the contrary. In 1998, FDA provided a candid summary of its view on reprocessing: compliance with QSR is sufficient – premarket review is unnecessary.[28] The Agency's view has apparently not changed since then, but has become publicly and politically unpopular. FDA's solution to the resultant negative attention is to devise a scheme that it can publicly tout as "premarket review," but under which no true substantive review will occur. In this way, the Agency can continue to rely on the QSR as it has done, and wanted to do, for years.

FDA's true intent has been evidenced in several recent events and documents. FDA dismissed an academic paper authored by the former deputy director of CDRH's Office of Device Evaluation and a well-respected biomedical engineer that discusses the scientific issues important to a meaningful premarket review for reprocessed devices.[29] Notably, Agency officials agreed that the issues raised by the authors were critical, but determined that the QSR was a sufficient system for their review. Similarly, in responding to a series of congressional questions regarding premarket review for reprocessed devices, FDA emphasized the importance of QSR inspection in each answer and diminished the value of

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26 Premarket Guidance at 9.

27 See Response to HIMA Petition.

28 Id.

29 ADDM Meeting with FDA (Nov. 21, 2000). West DL, Topoleski, LDT, McFarland W. Scientific and Regulatory Considerations for the Review and Approval of Reprocessed Single Use Device Premarket Submissions (Aug. 2000).

premarket review.[30] Even the Agency's training video on compliance with the new enforcement scheme allocates nearly five times as much time to QSR as to premarket review. The video fails to even identify the core components of a 510(k), but cuts away to two special segments detailing QSR issues.[31]

Two very recent FDA pronouncements are the most telling in terms of the Agency's reticence to require premarket review. First, FDA refused to even initiate the regulatory process necessary to determine whether premarket data should be required for reprocessed single use biopsy forceps, despite the Agency's prior determination that such devices are high risk and its commitment to revoke premarket exemptions for high risk reprocessed devices on a case-by-case basis.[32] And, earlier this month, FDA responded to a reprocessor citizen petition submitted only six days earlier agreeing to extend the approval deadline for reprocessor PMAs despite FDA's internal determination that the data in those PMAs are not sufficient for approval.[33]

FDA's decision to "enforce premarket requirements" appears aimed more at quieting the public and congressional uproar than at actually reviewing data that will protect patients. In fact, FDA's plan merely pays lip service to the 510(k) requirements while not really changing its position from 1998 – requiring compliance only with a diluted QSR.

V. Conclusion

Reprocessed single use devices are reusable devices and must be regulated as such. As with 510(k)s for all other reusable device, reprocessed single use device 510(k)s must demonstrate substantial equivalence to a reusable predicate and provide information

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30 See Letter from Melinda K. Plaiser, Associate Commissioner for Legislation, FDA to The Honorable Thomas J. Bliley, Jr., Chairman, Committee on Commerce, U.S. House of Representatives (Nov. 29, 2000).

31 FDA Videoconference, "Reprocessing Single-Use Devices in Hospitals: A Primer on FDA Requirements" (Dec. 13, 2000).

32 See Letter from Linda S. Kahan, Deputy Director for Regulations and Policy, CDRH, FDA to Beatrice M. Biebuyck, Esq., Boston Scientific Corporation (June 28, 2001).

33 See Letter from David W. Feigal, Jr., M.D., M.P.H., Director, CDRH, FDA to Patrick Fleischhacker, Vice President Regulatory Affairs and Quality Control, SterilMed, Inc. (Aug. 14, 2001).

regarding cleaning and sterilization. The Premarket Guidance is another in a series of documents and events demonstrating FDA's unwillingness to fully enforce the FDC Act on reprocessors. In August 2000, FDA announced that it would increase regulation of reprocessors and that such increased regulation would increase the safety of reprocessed devices. Instead, FDA has created a charade of regulation that fails to result in safe devices and calls into question the Agency's reputation s the world's premier patient protection agency.

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ADDM appreciates the opportunity to submit these comments and looks forward to working closely with FDA to ensure swift implementation of a patient-focused, law-abiding policy on reprocessed single use devices.

Respectfully submitted,

Josephine M. Torrente

JMT/eam/dmh
Attachments

DRAFT GUIDANCE OUTLINE
FOR
PRE-MARKET REVIEW PARAMETERS
REUSE OF USED SINGLE-USE DISPOSABLE DEVICES

Proposed by:
Association of Disposable Device Manufacturers
September 28, 1999

DRAFT GUIDANCE OUTLINE
FOR
PRE-MARKET REVIEW PARAMETERS
REUSE OF USED SINGLE-USE DISPOSABLE DEVICES

INTRODUCTION

FDA regulates the introduction of medical devices into interstate commerce. A person intending to reprocess a used single use disposable device (USUDD) and market that device for use on subsequent patients has changed the intended use of the device from 'single use' to 'reusable'. FDA has established and published in its guidance document entitled " Deciding When to Submit a 510(k) for a Change to an Existing Device, 510(k) Memorandum #K97-1 January 10, 1997", that such a change in intended use is deemed to be significant since it may have a serious effect on patient safety and efficacy. This guidance document (Labeling, A1) specifically addresses a change from single use to reuse:

> Rather than referring to "intended use" as a determinant in deciding when to submit a 510(k), this guidance identifies several specific labeling changes or modifications that have a major impact on intended use and thus would require the submission of a 510(k). Two common labeling changes that impact intended use and would usually require submission of a 510(k) are:
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> 1. reuse of devices previously labeled "single use only;" and
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> 2. changes from prescription to over the counter (OTC).

Consistent with this position, FDA has a long history of having accepted, reviewed and cleared numerous premarket review applications for reusable devices based on their substantial equivalence to safe and effective devices already in interstate commerce. These applications are typically reviewed with a primary focus on demonstrating that reuse can be accomplished in a safe and efficacious manner for both the patient and the healthcare practitioner.

Therefore, in accordance with existing FDA precedent and based on FDA's ability to review applications which specifically address reusable devices, such a person must file with FDA the appropriate pre-market review application (e.g. 510(k), PMA, PDP) prior to introducing the device into interstate commerce.

The intent of this draft guidance document is to provide FDA reviewers and applicant sponsors specific directions regarding information and data which should be submitted to FDA in a submission for a reprocessed used single use disposable device.

In the past, FDA's position regarding reprocessed used single use devices focused on the general absence of adverse event data and concluded that reprocessors need only comply with QSR and/or GMP regulations as an adequate measure to protect the public health (CPG 7124.16 Sec.300.500).

More recently, based on published information, MDR reports as well as FDA's own laboratory testing demonstrating that reprocessing used single use devices may have a significant effect on device safety and efficacy, FDA has now concluded that reprocessors of these devices must file pre-market review applications containing data demonstrating that the individual device may be reprocessed in a safe and efficacious manner for a specific number of reuse cycles. This requirement coupled with the ongoing need for QSR/GMP compliance will provide more appropriate assurance regarding public health protection.

FORMAT/CONTENT

Regulations governing the general content and format of 510(k), PMA and PDP submissions are codified under 21 Code of Federal Regulations, Part 807. These and other regulatory requirements pertaining to the marketing of a new medical device are discussed in guidance documents available from the CDRH Division of Small Manufacturers Assistance (DSMA). Specific guidance regarding the content and format required for 510(k) applications may be found in "Premarket Notification 510(k): Regulatory Requirements for Medical Devices, HHS Publication FDA 95-4158, August 1995."

FDA has already established minimum data requirements for pre-market review of reusable devices. Since a reprocessed used single use disposable device fits the definition of a reusable device, submissions filed pursuant to this guidance must comply with all existing ODE requirements regarding reusable device filings.

SCOPE

This document provides guidance for the pre-market review of reprocessed used single use disposable devices. Reprocessing includes but is not limited to disassembling, cleaning, replacing/refurbishing of components, re-assembling, labeling, packaging and sterilizing a single use disposable device which has already been used on an individual patient and is now intended for use on subsequent patient(s).

PURPOSE

This guidance is intended to:

1. Guide FDA review staff in conducting and documenting the review of pre-market review applications for reprocessed used single use disposable devices;

2. Assist persons (manufacturers, distributors, or importers) in the organization and preparation of premarket submissions intended to support reprocessing of used single use disposable devices;

3. Achieve consistency in meeting the requirements and in the presentation of premarket review data for these purposes.

OVERVIEW

a. Provide a complete overview of the reprocessing procedure. This description should consist of detailed drawings, photographs, and diagrams. Process and product flow should be described including any provision for repairing, replacing and/or refurbishing the device or any of its components.

b. Provide reprocessing procedure details including any use of water, enzyme cleaners, detergents, lubricants, abrasives, brushes, air lines, packaging, labeling and sterilization methods.

c. Include a clear statement regarding the maximum number of reuse cycles allowed as part of the premarket application.

CLEANING

a. The evaluation of the cleaning parameters should demonstrate the effectiveness of the cleaning process independently of any other steps in the process. The applicant should define the endpoint for cleaning, provide the scientific rationale for the endpoint and show how it relates to clinical use. The testing should evaluate the ability of the cleaning step to remove a defined challenge. It is recommended that the challenge be representative of the types to which devices are exposed during clinical use. The test data should demonstrate that the endpoint is consistently achieved for the device intended to be reprocessed.

b. Identify each cleaning method intended for use in the reprocessing procedure along with the identity of each material contained in the device intended for reprocessing.

c. Provide test methodology, specifications and validation data demonstrating that the cleaning methods used are reliable and effective in removing any existing debris including blood, tissue, adhesives, lubricants, etc. when subjected to the maximum number of reuse cycles being applied for in the premarket application. Include limits of detection.

d. Include data demonstrating that the cleaning methods used have no short term or long term adverse effects on the finished device and /or any of its components when subjected to the maximum number of reuse cycles being applied for in the application.

e. Identify processing steps employed to remove all cleaning material residues. Provide analytical test methodology (including sensitivity limits) for residue analysis along with validation data demonstrating the absence of these residues.

f. The application should include an assessment of the level of any residues, (e.g. detergents, lubricants, and germicides) remaining on the medical device after processing including a toxicological evaluation of these residues. This can be satisfied by reviewing the available toxicity data of the particular residual chemical from animal toxicity studies sponsored by the applicant of the chemical or from published literature. This evaluation is needed to determine the potential health risk of the residues remaining on the device to the patient and the end user.

REPROCESSING PARAMETERS

a. Provide feasibility rationale for reprocessing the device.

b. Describe all process parameters including time, temperature, water quality, preprocessing conditions, postprocessing conditions, etc. Identify the factors that affect the effectiveness of the processes and state how they are controlled.

c. Provide the rationale for each process parameter. The process parameters should be based on sound scientific studies which show that each phase of the process achieves its stated purpose.

DESIGN AND COMPONENT CONTROLS

a. Provide the original equipment device manufacturer's (OEM) design parameters and specifications. This should include all materials/components and design changes made to the device by the OEM for the specific device intended to be reprocessed.

   The applicant must also demonstrate the ability to address ongoing design changes made to the device by the OEM including changes in materials, components, assembly and sterilization procedures, packaging and labeling. If the OEM design parameters, manufacturing processes and related specifications are not used, then the applicant must provide justification including validation data to support any alternate parameters/specifications intended to be utilized.

b. Establish rationale and minimum criteria for determining whether any individual used single use disposable device is suitable for reprocessing. Factors to be used in making this determination should include the physical and/or microbiological condition of the device at the time it is received for reprocessing.

c. Identify parameters associated with repairing, refurbishing and/or replacing any of the device components as part of the reprocessing procedure. This should include data demonstrating that any such component is equivalent in all aspects of form, fit and function with respect to the indented use of the device, including the number of reuse cycles applied for in the application.

RESTERILIZATION

a. Identify specific sterilization methods (i.e. ETO, gas plasma, steam, radiation, etc.) intended for use in the reprocessing procedure.

b. Submit validation data (including all test protocols) from industry standard protocols/guidances regarding sterility assurance levels (SAL's). The resterilization validation data should support the maximum number of reuse cycles petitioned for the device in the application. These data should also demonstrate the suitability of the resterilization process in terms of final device function.

c. Pursuant to FDA's "Guidance for Industry Modifications To Devices Subject to Premarket Approval - The PMA Supplement Decision Making Process, August 6, 1998," the applicant should specifically include data which addresses the following:

(16.1) Pyrogens. If the device will be labeled as non-pyrogenic, state what process controls will be used to control pyrogens; and, state what method, such as the Limulus Amebocyte Lysate (LAL) or USP Rabbit test, will be used to determine that each lot is non-pyrogenic. This information is required for devices that contact blood or cerebrospinal fluids.

(16.2) Sterilization by User. The labeling for devices intended to be sterilized by the user must identify one validated method of sterilization. The instructions should be detailed and specific enough for the user to follow and obtain the required SAL. The instructions should also adequately describe any precautions to be followed such as: special cleaning methods required; any changes in the physical characteristics of the device that may result from reprocessing and resterilization, especially those which may affect the safety, effectiveness, or performance; and any limit on the number of times re-sterilization and reuse can be done without adversely affecting the safety,

REPROCESSED DEVICE TESTING

1. Functional Testing:

The applicant should provide data demonstrating that the reprocessed device meets all physical, chemical, microbiological and/or performance specifications assigned by the OEM at the time the device was initially introduced into interstate commerce. These data should directly relate to safety and efficacy regarding the device's Intended Use/Indications for Use. In satisfying this requirement, the applicant may not rely upon or otherwise reference any or all portions the premarket review application filed by the OEM and cleared/approved previously by FDA for the device.

Testing should evaluate the performance of the reprocessed used single use disposable device up to and including the maximum number of reuse cycles applied for in the application including laboratory bench testing, animal studies, and/or clinical studies where appropriate.

2. Sterility Testing:

The applicant should provide data from the sterilization validation program demonstrating that devices subjected to the reprocessing procedures meet or exceed a minimum SAL of 6.0 at the maximum number of allowed reuse cycles.

3. Residue Testing

To ensure safe conditions of use of the medical device following processing, the applicant must present data which demonstrate that there are no residues remaining on the device or that the process cycle removes the residues to a nontoxic level. The applicant must also present data which

demonstrate that there is no accumulation of residues over the maximum number of reuse cycles for the device which could present a health risk to the patient and the user.

PACKAGING/LABELING

a. The submission must contain proposed labels, labeling, and other promotional materials sufficient to describe the device, its indications for use/intended use, and the directions for use [21 CFR 807.87(e)]. Labels include the information affixed directly to the device and its packaging. Labeling also includes the users manual, service manual, and any other information that accompanies the device.

   Submit revised Instructions For Use including a statement that the device is a reprocessed Single-Use Device, the number of reprocessing cycles allowed as well as already performed on the device, and the revised expiration date for the device.

b. The labeling must meet the requirements of 21 CFR Part 801 as it relates to a determination of intended use. ODE will concentrate on the following:

   Subpart A, Sections 801.4 and 801.5, related to intended uses and adequate directions for use.

   Subpart B, Sections 801.109 and 801.116, related to prescription devices and commonly known directions.

c. Submit new product labeling, omitting OEM name/logo, and replacing it with the reprocessor's name. Include documentation verifying the removal of the OEM name from the device itself.

d. Provide package integrity data including ship testing and stability data in support of a maximum expiration date.

e. Statement regarding use of and/or exposure to latex during any reprocessing procedures.

ASSOCIATION OF DISPOSABLE DEVICE MANUFACTURERS
Providing industry views on single patient use medical devices

August 3, 2001

BY HAND DELIVERY

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

CITIZEN PETITION

The undersigned, on behalf of the Association of Disposable Device Manufacturers (ADDM), submits this petition pursuant to sections 501(f), 502(a), 513(f), and 515 of the Federal Food, Drug, and Cosmetic Act (FDCA) and 21 C.F.R. § 10.30 to request that the Commissioner of Food and Drugs regulate reprocessed single use medical devices as reusable medical devices.

This petition relates to a policy of the Food and Drug Administration (FDA), adopted by FDA's Center for Devices and Radiological Health (CDRH), under which reprocessed single use devices intended for multiple use through repeated reprocessing are permitted to be labeled as single use devices and are not required to meet the statutory requirements for premarket clearance or approval applicable to multiple use devices. Multiple use devices marketed pursuant to FDA's policy are misbranded, because they falsely state that they are for single use. In addition, multiple use devices not shown to be substantially equivalent to multiple use predicates are unapproved Class III devices and therefore adulterated. Premarket approval of multiple use devices labeled for single use is unlawful, because the conditions of use stated in their labeling are not those under which the devices are intended to be used, and because the labeling is false.

CDRH's policy is contrary to the FDCA. Not only does it countenance violations of the statute, but it is also irrational, results in disparate treatment of similarly situated manufacturers, constitutes an unexplained departure from existing standards, and fails to protect patients from reprocessed single use devices for which there are inadequate safety and effectiveness data.

◆P.O. Box 344, 1429 G. Street, N.W., Washington, D.C. 20005 Telephone: 202-737-7554, Fax: 202-737-9329◆

A. ACTION REQUESTED

We request that the Commissioner of Food and Drugs direct CDRH to do the following:

(1) Issue an announcement that reprocessed single use devices are "reusable devices" and cannot be labeled, cleared or approved for "single use only."

(2) Refuse to approve PMAs or clear 510(k)s for reprocessed single use devices that are labeled "single use only" or for which adequate data for multiple use are not provided.

B. STATEMENT OF GROUNDS

1. Introduction

A single use, or disposable, medical device is one "intended to be used on one patient during a single procedure. It is not intended to be reprocessed (cleaned, disinfected/sterilized) and used on another patient."[1] Disposable devices are designed without regard to device cleanability or repeated functionality, and are approved or cleared by FDA without data demonstrating their safety and effectiveness for multiple use. Despite the public health implications that arise due to these limitations, healthcare facilities and third-party companies often attempt to reprocess such devices for use on subsequent patients in order to reduce costs.[2] Typically, when a hospital or third party undertakes reprocessing of used devices, it intends to engage in repeated reprocessing of those devices. This intention is incompatible with single use status, and in fact fits the definition of a reusable device: "[a] device intended for repeated use . . . with appropriate decontamination and other reprocessing between uses."[3] A reusable device is properly labeled as such, and cleared or approved only on the basis of data pertinent to multiple use.

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1 CDRH, FDA, Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals (Aug. 14, 2000) at 40 (Enforcement Guidance).

2 United States General Accounting Office, "Single-Use Medical Devices: Little Available Evidence of Harm From Reuse, but Oversight Warranted" (June 2000).

3 CDRH, FDA, Reviewer Guidance, Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance (April 1996) at 21 (Reusable Device Guidance).

FDA has tolerated single use device reprocessing. The Agency has historically relied on the Quality System Regulation (QSR) to regulate the practice, and has exercised enforcement discretion with respect to the premarket requirements for reprocessed devices.[4] On August 14, 2000, however, in the face of mounting public and Congressional criticism, FDA reversed this long-standing position. At that time, FDA stated that enhanced safety would be achieved, in part, through the addition of premarket review and controls to the QSR and post-market monitoring already in place.[5] Consistent with that representation, the Enforcement Guidance called for premarket requirements for reprocessed single use devices to be phased in over a two-year period.[6] The Agency thus communicated to patients and committees in both Congressional houses its intention to hold reprocessors to the same health-based standards as the Agency imposes on original equipment manufacturers.[7] Since that time, however, FDA has repeatedly demonstrated its unwillingness to follow through on its commitment. Instead, FDA has continued to emphasize compliance with QSR as the central element in reprocessed device regulation,[8]

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4 See Letter from D. Bruce Burlington, M.D., Director, CDRH, FDA to Nancy Singer, Esq., Special Counsel, Health Industry Manufacturers Association (HIMA) (July 15, 1998).

5 Enforcement Guidance.

6 Enforcement Guidance; FDA has filed and is currently reviewing five PMAs for reprocessed single use electrophysiology ablation catheters. (The Gray Sheet (July 2, 2001)). ADDM believes that at least some of these PMAs include "single use only" labeling and fail to comply with FDA's requirements for reusable device submissions. (Reusable Device Guidance). FDA is expected to announce approvability decisions for these devices on August 14, 2001. (Enforcement Guidance).

7 Reuse of Single-Use Medical Devices, 106th Cong. (Feb. 10, 2000) at 9 (testimony of David W. Feigal, M.D., Director, CDRH, FDA); Hearing on Reprocessing of Single-Use Medical Devices, 106th Cong. (June 27, 2000) (statement of David W. Feigal, M.D., Director, CDRH, FDA).

8 ADDM meeting with FDA (Nov. 21, 2000); Letter from Melinda K. Plaiser, Associate Commissioner for Legislation, FDA to The Honorable Thomas J. Bliley, Jr., Chairman, Committee on Commerce, U.S. House of Representatives (Nov. 29, 2000) (Plaiser Letter); FDA Video conference, "Reprocessing Single-Use Devices in Hospitals: A Primer on FDA Requirements" (Dec. 13, 2000).

while rendering the FDCA's premarket review requirements meaningless by characterizing reprocessing as the repeated manufacture of new devices rather than as the reprocessing of one device for multiple uses.

The latest departure from true premarket review is the Agency's recently issued draft premarket guidance for reprocessing single use devices.[9] Both the Premarket Guidance and previous FDA correspondence to ADDM make clear that FDA will not require crucial data regarding multiple use in reprocessor's PMAs and 510(k)s. In these documents, FDA states that a reprocessor may label a reprocessed single use device "single use only" even when the device has not only been previously used but will be reprocessed again after the current use.[10] The practical effect of this policy is that, unlike submissions for all other reusable devices, reprocessor's premarket submissions will not contain data demonstrating that the device is safe and effective after multiple reprocessing procedures, or data establishing the maximum number of reuses for a given device.[11]

This petition discusses several legal and policy problems created by FDA's intention to regulate reprocessed single use devices as single use devices even though they are intended for multiple use, and requests that CDRH be directed to take appropriate action.

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9 CDRH, FDA, Draft Guidance for Industry and FDA Staff, Premarket Guidance: Reprocessing and Reuse of Single-Use Devices (June 2001) (Premarket Guidance).

10 Premarket Guidance at 6; See Letter from Larry G. Kessler, Sc.D., Director, Office of Surveillance and Biometrics, CDRH, FDA to Josephine M. Torrente, President, ADDM (Oct. 30, 2000) (Kessler Letter).

11 This petition does not relate to situations, if any, where a reprocessor intends that a reprocessed device be discarded after the next use rather than reprocessed and used again. Although any reprocessing contrary to the original manufacturer's labeling, including one-time only reprocessing, raises legal and policy issues of its own, this petition concerns only those reprocessed devices intended for repetitive reprocessing, and FDA's policy of treating those devices as single use devices. ADDM believes that most devices that are reprocessed at all are intended to be reprocessed multiple times.

2. Reprocessed Single Use Devices are Reusable Devices and Must be Regulated Accordingly

a. Reprocessed Single Use Devices are Intended for Multiple Use

The intended use of a medical device is determined by the objective intent of the device's manufacturer[12] and encompasses not only the clinical functionality of the device, but also whether the device is "single use" or "reusable."[13] With respect to reprocessed single use devices, the reprocessor's objective intent that the device be used on multiple patients is readily discernible from the circumstances surrounding the device's distribution. For example, the reprocessors purport to track the number of device uses, provide decontamination and shipping instructions to the hospital, and validate their procedures for multiple reprocessing. In addition, reprocessors cite literature suggesting multiple reuse of these devices.[14] Reprocessors do not maintain, and FDA does not suggest, that most reprocessed devices are intended to be discarded after one use.[15] In fact, no party to the

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12 21 C.F.R. § 801.4.

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

14 The Vanguard Process, http://www.safe-reuse.com/infokit/vanguardprocess.html; AMDR Capitol Hill Staff Briefing Slides and Handouts (Jan. 10, 2000).

15 Even assuming that reprocessors were to make such a claim, FDA would still have the authority to regulate these products as reusable devices based on the true, rather than labeled, intended use. FDA has previously required certain device manufacturers to label their devices reusable when their objective intent was inconsistent with the single use only label. For many years hemodialyzers were labeled as single use only. Despite such labeling, however, the devices were allegedly marketed for multiple use on the same patient. (See Letter from Byron Tart, Acting Director, Promotion and Advertising Policy Staff, Office of Compliance, CDRH, FDA to Julie Zawisza, Director, Diagnostic and Biomedical Technology Programs, HIMA (Dec. 1, 1993)). FDA responded to these allegations by requiring hemodialyzer manufacturers to "provide adequate instructions for safe and effective reuse of the device" to facilities known to reuse hemodialyzers and to "provide FDA with scientific documentation of the safety and effectiveness of each recommended reprocessing method," and to label the device accordingly. (CDRH, FDA Guidance for Hemodialyzer Reuse Labeling (Oct. 6, 1995) (Hemodialyzer

debate disputes that the devices are repeatedly shipped back to the reprocessor for additional reprocessing and reuse.

Nonetheless, in the face of this clear intent that the devices be reused, FDA has adopted a policy under which reprocessed single use devices intended for multiple use may be labeled, and cleared or approved, as single use devices, regardless of the number of prior uses or the likely number of subsequent reprocessings.[16] This policy is based on the notion that, after each use, the device reverts to a "raw material" to be used by the reprocessor to manufacture a "new device."[17] In this view, the used device ceases to exist, becoming raw material instead. After the raw material is cleaned, etc., a new and different device emerges. This sequence is then repeated. According to FDA's logic, other than one that bears directions for hospital reprocessing, a reprocessed device is never intended for multiple use, because it is always intended to become a raw material, and thus to cease to exist, upon its first use after reprocessing.[18]

FDA's characterization of device reprocessing as creating a raw material bears no relation to what actually occurs. A device that is used does not cease being that device simply because its label says "single use only" rather than "reusable." Rather, it is the same device, but in a used condition. That used device is then reprocessed contrary to its labeling.

For FDA to portray this sequence of events as involving the temporary creation of raw material followed by the manufacture of a new device is a transparent attempt to circumvent the premarket review requirements applicable to devices intended for multiple use by calling reprocessing something other than what it is. That FDA's policy rests on a

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Guidance)). Hemodialyzer 510(k)s must now contain laboratory data demonstrating "the effect of each recommended reprocessing agent and/or process on the performance of the hemodialyzer" after various numbers of reprocessings. (Hemodialyzer Guidance).

16 Premarket Guidance; Kessler Letter ("Reprocessors who wish to reprocess a SUD for another single use, are expected to assure the agency that the finished, reprocessed SUD meets specifications *each and every time* the finished device is returned for use on the next patient.") (Emphasis added.)

17 Plaiser Letter.

18 Premarket Guidance; Kessler Letter.

fiction is shown by the fact that the Agency requires the reprocessor to comply with the QSR as though the device were reusable. In fact, the policy is so contrived that FDA itself cannot maintain the fiction when describing what reprocessors do. In a recent, widely-distributed article regarding application of the QSR to reprocessed single use devices, FDA notes, "Remanufacturers of [single use devices] produce a finished medical device that has a different intended use – that of more than one use."[19] Similarly, in describing certain data required for reprocessed device clearance, FDA states that performance and other testing should be conducted considering the "maximum number of times [the] device is to be reprocessed."[20] Finally, in discussing QSR issues, the Premarket Guidance itself notes that reprocessors must "maintain a record of how many times the device has been reprocessed. . . ."[21] Were FDA faithful to its "raw material" theory, such testing and tracking should be unnecessary because the device is a "new" device that has existed only since it last left the reprocessing facility. These inconsistencies confirm that FDA itself understands, correctly, that reprocessed devices labeled for single use are really intended for multiple use, and that the Agency's "single use/raw material/new device" characterization of reprocessing is a result-driven terminological convenience whose purpose is to shelter reprocessors from the demands of true premarket review of multiple use devices.

FDA cannot use semantics to suspend the operation of the FDCA. The agency does not even pretend that device reprocessors do anything other than reprocess a used device, and reprocess that device repeatedly. As the Association of Medical Device Reprocessors (AMDR) itself has stated, "in the day-to-day reality of clinical practice, reprocessing is simply a cleaning, testing and sterilizing service performed on a device manufactured by an [original equipment manufacturer]."[22] Calling this service the repeated "manufacture" of a

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19 Kimberly Trautman, M.S., Biomedical Engineer, "Applying the Quality System Regulation to Hospitals that Reprocess SUDs," User Facility Reporting, Issue 34, at 5 (Spring 2001).

20 Miriam C. Provost, Office of Device Evaluation, CDRH, FDA, "Premarket Review Considerations for Reprocessed SUDs" at FDA Reuse Workshop (May 10-11, 2001 and May 30-31, 2001).

21 Premarket Guidance at 11.

22 See Letter from Pamela J. Furman, Executive Director, AMDR to FDA Docket No. 01P-0148 at 5 (June 1, 2001). As ADDM has pointed out, AMDR benefits from FDA's decision to ignore "the reality" that reprocessing constitutes reuse of a device

"new device" from "raw material" consisting of the same device that was just used and that will be reprocessed and used again does not negate the underlying reality that there is only one device and that the reprocessor intends that the device be reprocessed multiple times. FDA has a duty, and a legal obligation, to apply the FDCA's premarket review requirements to what is actually occurring in the real world.

This is not a situation in which FDA may legitimately point to the label of a device as circumscribing the Agency's ability to characterize intended use.[23] The "single use" designation of a reprocessed device intended for multiple use is not meant by the device's manufacturer as an accurate description of what is to be done with the device after it is used. Rather, the term merely implements FDA's own unlawful policy of permitting multiple use devices to be labeled and regulated as single use devices.

Because such devices are, in fact, intended to be reusable devices, FDA ignores its statutory mandate of clearing or approving only those devices that are safe and effective, by basing premarket clearance and premarket approval determinations on data sufficient only for devices that are, in fact, intended to be disposed of after the first use. An agency that has "'consciously and expressly adopted a general policy' that is so extreme as to amount to an abdication of its statutory responsibilities" may open the door to judicial review, and runs the risk of having its actions judged arbitrary and capricious.[24] This is precisely the outcome that FDA should anticipate if it persists in adhering to its extreme and increasingly brittle policy of turning a blind eye to the fact that reprocessed single use devices are, by all objective measures, intended for reuse.

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rather than the manufacture of a new device. See Letter from Thomas Scarlett, Esq., Hyman, Phelps & McNamara, P.C., to FDA Docket No. 01P-0148 (July 13, 2001). AMDR, however, does not want to accept the burdens that accompany the Agency's fiction. Thus, if a reprocessed single use device is to be regarded as a new device made from a raw material, then continuing to display the original equipment manufacturer's name and trademark is false. AMDR, however, resists that conclusion and has opposed ADDM's petition that FDA enforce the FDCA's misbranding provisions in that circumstance.

23 See FDCA § 513(i)(1)(E)(i).

24 *Heckler v. Chaney*, 470 U.S. 821, 833 n.4 (1985) (*citing Adams v. Richardson*, 480 F.2d 1159 (D.C. Cir. 1973) (en banc)).

A reprocessed single use device intended for multiple reprocessing and use, but cleared for marketing in accordance with FDCA § 510(k) only as substantially equivalent to a single use device, is adulterated. If the reprocessed device is intended for multiple use, appropriate premarket notification would demonstrate substantial equivalence to a reusable device or otherwise establish safety and effectiveness for multiple use. Absent such appropriate notification, the device is a Class III device under FDCA § 513(f) and does not have an approved PMA in effect pursuant to FDCA § 515(a). The device is therefore adulterated in that the reprocessor failed to submit information to FDA demonstrating the safety and effectiveness of the device for multiple use.[25]

For these devices and for devices whose original classification requires premarket approval, the FDCA's premarket approval provisions require FDA to review data sufficient to support a determination of whether or not there is a reasonable assurance that the device is safe and effective under conditions of use recommended in the labeling.[26] The data required to support a determination of safety and effectiveness for devices designed to be used only once are justifiably of a lesser order and magnitude than the data required to support such a determination for devices intended for multiple use.

As a preliminary matter, FDA must under the FDCA deny approval for a premarket application for a reprocessed single use device labeled for single use only because the conditions of use included in the proposed labeling are false and misleading, i.e., the device is truly intended to be reprocessed and used multiple times.[27] Nevertheless, if FDA proceeds under the terms of its Premarket Guidance, reprocessors' PMA submissions will not contain data demonstrating that their devices are safe and effective after repeated processing procedures, and FDA will approve such devices on the basis of data insufficient to support a finding of safety and effectiveness for multiple use. As a result, FDA will increasingly approve devices for which there is inadequate assurance of safety and effectiveness for the intended use, and thereby will fail to meet its statutory responsibility for ensuring that only safe and effective devices are used to provide for the public health. In contravention of the intent behind the Medical Device Amendments of 1976, FDA's policy lowers the data burden for devices that present the highest risk to patients: those that are reused multiple times despite the absence of design features supporting cleanability.

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25 FDCA § 513(f)(1)(B).

26 FDCA §§ 515(c)(1); 515(d)(1)(A).

27 FDCA §§ 515(d)(1)(A); 515(d)(2)(D).

b. Reprocessed Single Use Devices Labeled Single Use Only Are Misbranded

Under sections 301(a)-(c) of the FDCA, it is unlawful for a party to (1) introduce or deliver for introduction into interstate commerce a misbranded device, (2) misbrand a device while in interstate commerce, or (3) receive a misbranded device in interstate commerce. A reprocessor that follows FDA's Premarket Guidance and labels a reprocessed single use device for single use only despite the reprocessor's intent that the device be returned to the reprocessor for further reprocessing and reuse will violate the FDCA's prohibitions on misbranding.

Section 502(a) of the FDCA provides that a device is misbranded "[i]f its labeling is false or misleading in any particular."[28] A reprocessed single use device that is labeled for single use violates the FDCA prohibition on misbranding because the device's labeling is inherently false and misleading. As is explained in greater detail elsewhere in this petition, a reprocessed single use device is actually a disposable device being turned into a "reusable medical device" because it is now intended for use on multiple patients. To label such a device "single use only" would imply that the device has never been used before and that it will be discarded after the current use. This implication is utterly false. In fact, the device has likely been used and reprocessed numerous times.

In addition to violating the letter of the FDCA, such false statements also prevent a physician from being able to exercise his medical judgment to choose a device best suited to an individual patient. For example, a physician caring for an immuno-compromised patient, or a highly infectious patient, might request a "single use device," confident in the assumption that he will be provided with a medical device that has truly never been used before and will be discarded. The misbranding caused by the labeling scheme proposed in FDA's Premarket Guidance, however, may make it impossible for the physician's orders to be executed, much to the detriment of patients.

FDA can be granted some latitude in constructing legal fictions in order to better regulate industry or to provide for the public health. There are limits, however, to the extent to which such legal fictions can be stretched. When the fiction expressly encourages

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28 Section 201(m) of the FDCA defines "labeling" as "all labels, and other written, printed, or graphic matter" that are affixed to the device or to "any of its containers or wrappers," or that "accompany" the device.

the unlawful misbranding of devices to the detriment of the public health, FDA has clearly exceeded all reasonable boundaries.

c. FDA's Policy is Arbitrary and Capricious and a Violation of the Administrative Procedure Act (APA)

In setting forth its policy in the Premarket Guidance, FDA has failed to adhere to basic principles requiring that federal agencies follow a consistent course, regulate similarly situated parties with equity, and acknowledge industry's reliance on its policy statements and guidances by articulating a reasoned explanation for departures from prior policies. Key provisions of the Premarket Guidance are inherently inconsistent with the definitional framework for single use and reusable device reprocessing established earlier by the Agency, and relied on to date by the device industry. FDA's policy also perpetuates the disparate treatment of original manufacturers and reprocessors by requiring premarket data supportive of multiple use for reusable devices manufactured by original equipment manufacturers while essentially waiving this requirement for reprocessors. The Premarket Guidance also advances definitions of single use and reusable devices that are without practical distinction, and that create an illogical labeling conundrum for hospitals that choose to reprocess single use devices. In addition, FDA has failed to provide a reasoned explanation for why it now proposes to alter the definitional framework that the medical device industry has relied on for more than five years.

(1) FDA's Multiple Single Use Policy is a Departure from Agency Precedent

In 1996, FDA formalized the distinction between single use and reusable devices when it defined "reusable medical device" as "[a] device intended for repeated use either on the same or different patients, with appropriate decontamination and other reprocessing between uses."[29] One year ago FDA further clarified the distinction between single use and reusable devices when it set forth a single use device definition. In a final guidance issued in August 2000, FDA stated that:

> [a] single-use device, also referred to as a disposable device, is intended to be used on one patient during a single procedure. It is not intended to be reprocessed (cleaned/disinfected/sterilized) and used on another patient. The

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29 Reusable Device Guidance at 21.

> labeling may or may not identify the device as single use or disposable and does not include instructions for reprocessing.[30]

FDA thereby expressly confirmed the clear distinction between single use and reusable devices that it had implicitly established in 1996.

FDA's new policy, however, effectively eradicates this distinction. The Premarket Guidance grants a reprocessor "the option of labeling a reprocessed [single use device] for either single use or multiple use (reusable)" even though the device is intended for use on multiple patients and fits the 1996 definition of reusable device.[31] If a reprocessed single use device is earmarked for multiple use, i.e., reuse, *by the end user*:

> the reprocessor must provide data to demonstrate that the device is safe and effective after undergoing multiple cleaning, disinfection and/or sterilization procedures. Furthermore, the reprocessor must clearly identify the number of times the device can be reused.[32]

Conversely, if a reprocessed single use device is labeled for single use, the reprocessor need only "assure the agency that the finished, reprocessed [single use device] meets specifications each and every time the finished device is returned for use on the next patient."[33] Implicit in the latter transaction is the understanding that once it is used, the end user will not reprocess the single use device, but rather will return it to the third party reprocessor for another round of reprocessing. According to this new definitional construct, although both "single use" reprocessed devices and "multiple use (reusable)" devices are "reusable devices" as the term has been defined for the past five years under FDA's Reusable Device Guidance, only the latter are actually regulated as reusable devices. This new distinction in regulatory treatment is based solely on the identity of the party responsible for reprocessing the device after it has been used.[34]

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30 Enforcement Guidance at 40.

31 Premarket Guidance at 6.

32 Kessler Letter.

33 Kessler Letter.

34 The fact that the definition of a reusable medical device appears in a guidance whose title refers to reprocessing in health care facilities has no bearing on the issues

In addition, as a result of its linguistic contortions, FDA has effectively abolished an entire device category – i.e., those that are truly intended for single use – without sufficient explanation, and without following the procedures normally associated with such an agency action. Because the term "single use" has become merely a proxy for "reusable" under FDA's new paradigm, manufacturers cannot be certain that labeling a device for single use will ever again successfully convey to physicians and patients that the manufacturer intends for the device to be discarded after being used once.

FDA cannot so abruptly abandon established definitional standards, or so dramatically deviate from its established precedents, without providing a reasoned analysis justifying the departure.[35] This it has failed to do.

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presented in this petition. Whether an activity is reprocessing depends on what is done, not where. Since issuance of the Reusable Device Guidance, hospitals have increasingly contracted with independent third parties for reprocessing services. The third party reprocessors are agents of the hospitals, and perform the same services in accordance with the same standards that apply to hospitals that have continued to reprocess devices in-house. See also CDRH, FDA, Questions and Answers for the FDA Reviewer Guidance, Labeling Reusable Medical Devices For Reprocessing In Health Care Facilities at 2 (Sept. 3, 1996) (Q&A). The Q&A states that the Guidance does not apply to "reuse of single use devices." The Guidance applies only to the reprocessing of reusable devices, but of course, the activity that constitutes reprocessing is the same in either case. At that time, FDA simply chose not to address reprocessing of single use devices.

35 *Atchison T. & S.F.R. Co. v. Wichita Bd. of Trade*, 412 U.S. 800, 808 (1973); *Greater Boston Television Corp. v. FCC*, 444 F.2d 841, 852 (D.C. Cir. 1970), *cert denied*, 403 U.S. 923 (1971); *Greyhound Corp. v. ICC*, 551 F.2d 414, 416 (D.C. Cir. 1977); *Office of Communication of the Church of Christ v. FCC*, 560 F.2d 529 (2d Cir. 1977); *Public Interest Research Group v. FCC*, 522 F.2d 1060, 1065 (1st Cir. 1975), *cert. denied*, 424 U.S. 965 (1976); *Contractors Transport Corp. v. United States*, 537 F.2d 1160, 1162 (4th Cir. 1976).

(2) Implementation of FDA's Policy will Result in Disparate Treatment of Similarly Situated Parties

Under the APA, a court may review and hold unlawful an agency decision that is arbitrary or capricious.[36] 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.[37] In the area of single use devices, FDA has disparately treated two similarly situated parties –original equipment manufacturers and reprocessors– as exemplified by FDA's regulation of devices intended for use in multiple patients.

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."[38] Such behavior by federal agencies is prohibited by the APA.[39] By assigning unequal regulatory burdens to original manufacturers and reprocessors, 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.[40] 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 regulatory regime, held that "[t]he disparate treatment of functionally indistinguishable products is the essence of the meaning of arbitrary and capricious."[41]

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36 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. . . .").

37 *Contractors Transport Corp. v. United States*, 537 F.2d 1160, 1162 (4th Cir. 1976).

38 806 F.2d 1081, 1089 (D.C. Cir. 1986) (citation omitted).

39 See 5 U.S.C. § 706(2)(A).

40 963 F. Supp. 20 (D.D.C. 1997).

41 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.*

FDA's "multiple single use" fiction violates the APA by continuing to treat reprocessors and original equipment manufacturers differently. Specifically, it requires premarket data supporting reuse from original manufacturers of devices intended for multiple use, but no such data from reprocessors who manufacture devices with the same intended use. The net effect of FDA's departure from prior policy is that FDA now seeks to treat single use device reprocessors and original equipment device manufacturers differently. Unlike their reprocessing counterparts, original equipment manufacturers cannot seek to lighten the obligations imposed by FDA's premarket requirements by electing to label their reusable devices for single use only. Under either scenario the practical result is the same – the device will be reprocessed again for use in another patient – but the regulatory treatment is not.

This disparate treatment also seriously compromises public safety. Devices are being marketed that have not been demonstrated safe and effective for their intended use as required by law. FDA is affecting a double standard that lowers the burden for reprocessors as compared to original manufacturers, an arbitrary and capricious action under the APA. The APA and the protection of patients both require that FDA regulate all manufacturers in the same manner, regardless of whether those manufacturers are deemed original manufacturers or reprocessors.

(3) FDA's Policy is Illogical and Results in Arbitrary Outcomes

The illogical nature of the definitional construct created by the Premarket Guidance, and the untoward effect it will have on industry, is illustrated in the case of a hospital that reprocess its own devices. In this instance, the hospital, which is both a "reprocessor" and an "end user," must engage in a nonsensical decision-making exercise. It must determine whether to (1) distribute the reprocessed single use device to itself (as an end user) for one use, and then return the device to itself (as a manufacturer) for reprocessing, thereby treating the device as a "single use" device, or (2) distribute the device to itself (as an end user) while providing itself with adequate directions for reprocessing, thereby creating a "reusable" device. The activities engaged in by third party reprocessors are quintessentially the very ones the hospital uses. Distinguishing reprocessing for FDCA regulatory purposes based on geographic location is irrational.

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denied, 338 U.S. 860 (1949).

The Premarket Guidance is not only irrational on its own terms, it is inconsistent with previous Agency policies and precedents in that the definition of "single use device" that emerges from the Premarket Guidance conflicts with the Agency's established definition of the term. FDA's definition of "single use device" contained in its Enforcement Guidance states that such a device "is not intended to be reprocessed (cleaned/disinfected/sterilized) and used on another patient."[42] The Premarket Guidance's definitional framework, however, does not preclude a single use device from being reprocessed. Instead, it only appears to prohibit an end user from reprocessing a device labeled for single use. In addition, the single use device definition expressly states that such a device "does not include instructions for reprocessing." As noted earlier, however, reprocessors do provide hospitals with initial sorting, decontamination and shipping instructions for further third party reprocessing. Accordingly, a device that falls within the ambit of the definition of "single use device" that emerges from the Premarket Guidance is not a "single use device" as the term has been previously defined by FDA and understood by the device industry and device users.

In sum, the definitional framework that emerges from FDA's Premarket Guidance is illogical and internally inconsistent. More importantly, it fundamentally conflicts with a prior definitional framework that industry has relied on for the past five years. FDA has an obligation to tread with care when altering the contours of its discretionary powers. "Once it channels its discretion in a certain manner . . . the agency should follow that course consistently or articulate reasons for departure."[43] In its current form, the Premarket Guidance represents an illogical and confusing departure from FDA's previous policy and precedents – a departure that appears to lack a clear basis, and for which FDA has failed to provide a reasoned explanation.

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42 Enforcement Guidance at 40.

43 *Rhodia v. FDA*, 608 F.2d at 1376, 1379 (D.C. Cir. 1979); See *Telecommunications Research and Action Center v. FCC*, 800 F.2d 1181 (D.C. Cir. 1986) ("When an agency undertakes to change or depart from existing policy, it must set forth and articulate a reasoned explanation from prior norms.").

3. FDA Must Regulate Reprocessed Single Use Devices as Reusable Devices

The Medical Device Amendments of 1976 were designed to protect patients from unsafe and ineffective devices, whether single use or reusable.[44] Reprocessing a single use device changes the intended use of that device from single use to multiple use, transforming reprocessors into manufacturers of reusable devices. Appropriate regulation of disposable medical device reprocessing must involve enforcement of all provisions of the FDCA applicable to reusable devices.

Despite FDA's public façade of increased reprocessor regulation, the Agency has, without justification, refused to regulate reprocessed single use devices as it does all other reusable devices. This refusal exposes the American public to medical devices whose safety and effectiveness for their intended use are, at best, unknown. FDA's "multiple single use" fiction perpetuates the Agency's long-standing inadequate regulation of reprocessed disposable devices putting the FDA fiction 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 refusal to regulate all reprocessed single use devices as reusable devices.

The safety of such products can only be assured through FDA regulations, guidances, policies, and enforcement practices already developed for oversight of reusable medical devices. FDA's recognition of reprocessed single use devices as reusable products would achieve the parallel goals of increased patient safety, conformance with the FDCA, and parity in regulation of manufacturers and reprocessors.

C. ENVIRONMENTAL IMPACT

A claim for categorical exclusion from the requirements for an Environmental Assessment is made under 21 C.F.R. § 25.34(a) and (d).

D. ECONOMIC IMPACT

An economic impact statement will be submitted at the request of the Commissioner.

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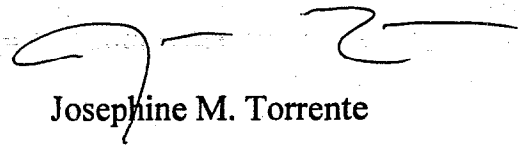
44 Pub. L. No. 94-295, 90 Stat. 539 (1976) (codified at 15 U.S.C. § 55 and 21 U.S.C. §§ 301 et seq.).

E. CERTIFICATION

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Respectfully submitted,



Josephine M. Torrente

JMT/dmh