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.

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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 docs 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