

ATTACHMENT E



September 5, 1997

1879 '97 SEP -5 P2:34

BY HAND DELIVERY

Dockets Management Branch
Food and Drug Administration
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

CITIZEN PETITION

Dear Sir or Madam:

The undersigned, on behalf of the Health Industry Manufacturers Association ("HIMA" or "the Association"), 1/ submits this Petition to the Food and Drug Administration ("FDA" or "the agency") pursuant to § 553(e) of the Administrative Procedure Act 2/ and 21 C.F.R. §§ 10.30. The Association requests that the Commissioner of the Food and Drug Administration require commercial reprocessors 3/ of disposable medical devices to comply with

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- 1/ The Health Industry Manufacturers Association is a Washington, D.C.-based trade association representing more than 700 manufacturers of health care products, including medical devices, *in vitro* diagnostics, and health care information systems. Many of these companies manufacture single-use medical devices.
 - 2/ 5 U.S.C. § 553. The Administrative Procedure Act is codified at 5 U.S.C. §§ 551 et. seq., 701 et seq., 3105, 3344, 5372, 7521 (1994) [hereinafter "APA"].
 - 3/ The terms "commercial reprocessor" and "third-party reprocessor" are used interchangeably throughout this Petition to refer to entities that engage in reprocessing as a commercial, "for profit" venture. For purposes of this petition, these terms do not encompass user facilities which may engage in limited device reprocessing incidental to provision of medical services. Because user facilities generally do not engage in reprocessing for profit, and in light of FDA's "practice of medicine" policy, it is the

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all applicable FDA regulations governing medical device manufacturing, such as premarket ("510(k)") notification or premarket approval ("PMA"), ^{4/} establishment registration and device listing, ^{5/} good manufacturing practices ("GMPs"), ^{6/} device labeling, ^{7/} and medical device reporting. ^{8/} HIMA also requests that the Commissioner refrain from requiring original manufacturers of single-use devices to test or label those devices for reuse. ^{9/}

As discussed in greater detail in the body of this Petition, although FDA has recognized that commercial reprocessors are device manufacturers, the agency currently does not require commercial reprocessors to comply with many of the regulations that apply to original device manufacturers. FDA's current policy does not fulfill the agency's obligation to protect the public health because it leaves changes in intended use and significant manufacturing operations by commercial reprocessors unregulated, thereby allowing patients and users to be at risk from improperly reprocessed devices that are used contrary to their labeling or are made without attention to FDA quality control rules. FDA's policy also exposes doctors, hospitals and original

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Association's position that the agency's resources should initially be allocated to regulation of commercial reprocessors rather than user facilities that engage in reprocessing solely for internal use.

^{4/} 21 C.F.R. Part 807, Subpart E and Part 814 (1996).

^{5/} 21 C.F.R. Part 807, Subparts B and C (1996).

^{6/} 21 C.F.R. Part 820 (1996).

^{7/} 21 C.F.R. Part 801 (1996).

^{8/} 21 C.F.R. Part 803, Subparts A, B, and E (1996).

^{9/} The actions requested in this Petition do not apply to reprocessors of disposable hemodialyzers, as these entities are subject to a separate FDA policy. *Guidance for Hemodialyzer Reuse Labeling* (October 6, 1995).

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product manufacturers to products liability actions if inadequate or improper reprocessing leads to adverse health effects.

I. ACTION REQUESTED

HIMA requests that the Commissioner of the Food and Drug Administration interpret the terms "manufacturer" or "remanufacturer," as defined under the Federal Food, Drug, and Cosmetic Act ("FDC Act") and FDA regulations to encompass all commercial entities that reprocess single-use medical devices for reuse. ^{10/} The Association also requests that FDA consistently apply the same regulatory requirements to commercial reproducers of disposable devices as to other device manufacturers, including, but not limited to, the following:

10/

Although the FDC Act does not generally define the term "manufacturer," it does state that, as used in the section outlining establishment registration and device listing requirements:

the term 'manufacture, preparation, propagation, compounding, or processing' shall include repackaging or otherwise changing the container, wrapper, or labeling of any drug package or device package in furtherance of the distribution of the drug or device from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user; . . . [.]

FDC Act § 510(a)(1), 21 U.S.C. § 360a(1). FDA also has defined the term "manufacturer" by regulation. *See, e.g.*, 61 Fed. Reg. 52602, 52656 (1996) (codified at 21 C.F.R. Part 820). For example, the new Quality System Regulation, *id.*, defines "manufacturer" as "any person who designs, manufactures, fabricates, assembles, or processes a finished device. Manufacturer includes but is not limited to those who perform the functions of contract sterilization, installation, relabeling, remanufacturing, repacking, or specification development, and initial distributors of foreign entities performing these functions." 21 C.F.R. § 820.3(o).

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- the premarket notification ("510(k)") requirements set forth in 21 C.F.R. Part 807, Subpart E and the premarket approval requirements set forth in 21 C.F.R. Part 814;
- the establishment registration and device listing requirements set forth in 21 C.F.R. Part 807, Subparts B and C;
- applicable requirements of the good manufacturing practices ("GMP") and quality system regulations set forth in 21 C.F.R. Part 820;
- applicable device labeling requirements set forth in 21 C.F.R. Part 801; and the medical device reporting requirements set forth in 21 C.F.R. Part 803, Subparts A, B, and E.

II. STATEMENT OF GROUNDS

A. Background

Since 1976, FDA occasionally, and with only limited efforts, has attempted to control the reuse of a variety of single-use devices. The types of devices that have been reused range from "noncritical" devices, such as insulin syringes and endoscopic surgical products, to "critical" devices, such as cardiac catheters and arthroscopic surgery blades. ^{11/} Cost containment pressures and business opportunities have led to continuing growth in the reuse of certain medical devices that neither were designed nor intended for multiple uses.

^{11/} See Proceedings of the First International Conference of Medical Device Regulatory Authorities (IMDRA), Section IIIA.5 (June 2-6, 1986).

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On September 24, 1987, the agency issued a revised compliance policy guide regarding reuse of disposable medical devices. This guide appropriately placed responsibility for reuse squarely on the reuser/reprocessor, stating that:

The FDA . . . finds that there is a lack of data to support the general reuse of disposable medical devices. . . . The fact that devices are labeled disposable is indicative of this lack of data. In order for a device to be considered "reusable", it must be capable of withstanding necessary cleaning and resterilization techniques and methods, and continue to be safe and reliable for its intended use.

The FDA has concluded, therefore, that the institution or practitioner who reuses a disposable medical device should be able to demonstrate: (1) that the device can be adequately cleaned and sterilized, (2) that the physical characteristics or quality of the device will not be adversely affected, and (3) that the device remains safe and effective for its intended use. Moreover, since disposable devices are not intended by the manufacturer or distributor for reuse, any institution or practitioner who resterilizes and/or reuses a disposable medical device must bear full responsibility for its safety and effectiveness. ^{12/}

Thus, the agency's policy guide requires the commercial reprocessor to demonstrate the safety and efficacy of the processes it uses to restore the device to its original condition.

FDA currently is revising this compliance policy guide apparently, in part, because of the difficulty the agency has experienced in regulating commercial reproducers as well as reprocessing in individual device user facilities. As an FDA official explained at the April 9, 1996 meeting of the Association for the Advancement of Medical Instrumentation

^{12/} Compliance Policy Guide 300.500 (formerly CPG 7124.16) (emphasis added).

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("AAMI"), the reprocessing policy articulated in the agency's 1987 compliance policy guide placed a "heavy burden . . . [of] liability and responsibility" on individual user facilities that reprocessed devices, because it required them to "prove that the device meets the original specifications . . . [and this] criteria is very hard to meet." ^{13/} The FDA representative also explained that although reprocessing by user facilities was "not something that the agency ever encouraged . . . it wasn't something that the agency could say absolutely, definitely 'no' [to] because there was some issue of [the] practice of medicine [policy]." ^{14/}

B. FDA Regulation of Medical Device Manufacturers

The Medical Device Amendments of 1976 ^{15/} and the Safe Medical Devices Act of 1990 ^{16/} both were intended by Congress to expand FDA's ability to regulate the safety and effectiveness of medical devices. Key to this regulatory scheme was FDA jurisdiction over the

^{13/} *Single-Use Device Reprocessing FDA Draft Policy Expected This Summer*, Gray Sheet, April 22, 1996 (Remarks of Kim Trautman, Office of Compliance, Center for Devices and Radiological Health).

^{14/} *Id.* The practice of medicine policy permits *physicians* to use approved devices for off-label indications in their practices, provided they do not promote the off-label use(s). Investigational Device Exemption Manual, at 4-61 (June 1996). The practice of medicine policy does not allow physicians to manufacture and/or market devices without appropriate approvals.

As noted above, however, this Petition does not apply to reprocessing by health care facilities incidental to the provision of medical services, but rather is limited to commercial reprocessing. *See supra* note 3.

^{15/} P.L. 94-295, 90 Stat. 539 (1976) (codified at 15 U.S.C. § 55 and 21 U.S.C. §§ 31, 331 *passim*).

^{16/} P.L. 101-629, 104 Stat. 4511 (1990) (codified at 21 U.S.C. §§ 301 *passim* and 42 U.S.C. §§ 263b-n).

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regulation of device manufacturing. Various provisions of the FDC Act authorize FDA to regulate the *manufacturers* of medical devices. For example, the Act applies the establishment registration and device listing requirements to those who engage in the "manufacture, preparation, propagation, compounding, or processing" of devices for commercial distribution. ^{17/} The FDC Act does not, however, provide a global definition of the term "manufacturer." ^{18/} As discussed below, FDA has, therefore, developed its own definitions of the term "manufacturer" in a number of regulations and guidance documents. ^{19/}

1. Good Manufacturing Practices ("GMPs") and Quality System Regulations

In the recently issued quality system regulations ("QSR"), ^{20/} the term "manufacturer" is defined as: "any person, including any repacker and/or relabeler, who manufactures, fabricates, assembles, or processes a finished device." "Finished device" is in turn defined as "a device, or any accessory to a device, which is suitable for use, whether or not packaged or labeled for commercial distribution." ^{21/}

FDA has recognized that facilities that reprocess medical devices for reuse are

^{17/} FDC Act § 510(a)(1), 21 U.S.C. § 360(a)(1).

^{18/} See *supra* note 10.

^{19/} *Id.*

^{20/} 61 Fed. Reg. 52602, 52656 (1996).

^{21/} *Id.*

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device manufacturers. 22/ The agency also has acknowledged that device reprocessing may have a significant impact on safety and efficacy. 23/ Despite this, FDA chose to temporarily exclude many types of commercial reprocessors, *i.e.*, “servicers” 24/ and “refurbishers,” 25/ from the recently published QSR regulations. 26/ Instead, FDA elected to address these entities in a separate rulemaking, explaining that:

FDA is not including the terms “servicer” or “refurbisher,” as they relate to entities outside the control of the original equipment manufacturer, in this final regulation, even though it believes that persons who perform such functions meet the definition of manufacturer. Because of a number of competitive and other issues, including sharply divided views by members of the GMP Advisory Committee . . . , FDA has elected to address application of the CGMP requirements to persons who perform servicing and refurbishing functions outside the control of the original manufacturer in a separate rulemaking later this year, with another

22/ *Id.* at 52610. The definition of “manufacturer” explicitly includes “remanufacturers,” *i.e.*, “any person who processes, conditions, renovates, repackages, restores, or does any other act to a finished device that significantly changes the finished device’s performance or safety specifications or intended use.” *Id.* See also *Working Draft of the Current Good Manufacturing Practice (CGMP) Final Rule*, July 1995, at 37 (“GMP Working Draft”).

23/ GMP Working Draft, *supra* note 22, at 37.

24/ The term “servicing” was defined in an earlier draft of the rule as “maintenance or repair of a finished device after distribution for purposes of returning it to its safety and performance specifications established by the original finished device manufacturer and to meet its original intended use, prior to the device’s established end-of-life or before it is considered to be nonrepairable.” *Id.*, at 189.

25/ The term “refurbisher” was defined in the Working Draft as “any person who processes, conditions, renovates, or restores a finished device which has been previously distributed and has reached its established end-of-life or is considered to be nonrepairable.” *Id.*

26/ 61 Fed. Reg. 52602, 52610 (1996).

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opportunity for public comment. 27/

Regardless of whether concerns may have been expressed by the members of the GMP Advisory Committee, in order to fulfill its statutory mandate, FDA must exercise its regulatory control over any entity meeting the definition of manufacturer, including commercial reproducers. Electing not to regulate third-party reproducers is a dereliction of FDA's statutory authority and sends the wrong message to entities that, for public health reasons, should be required to comply with FDA rules and regulations.

FDA has already acknowledged the need for quality control in reprocessing. 28/ Therefore, in the forthcoming QSR rulemaking, FDA should subject commercial device reproducers to all of the relevant provisions of the GMP and QSR regulations that apply to original device manufacturers to ensure that reprocessing is carried out under appropriate controls to provide adequate product performance.

2. Premarket Notification

In addition to requiring commercial reproducers of single-use medical devices to

27/ *Id.*, 52610 (emphasis added).

28/ An FDA official recently commented that a review of inspection reports for reprocessing facilities subject to GMP inspections revealed "significant good manufacturing practices deficiencies." *Cardiac Catheter Reuse Targeted by FDA; Lab Testing of Used Catheters Planned*, Gray Sheet, July 7, 1997 (comments of Larry Spears, Director, Division of Enforcement III, Office of Device Evaluation, Center for Devices and Radiological Health). FDA also has issued warning letters in the past to device reproducers for failure to comply with GMP requirements.

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comply with the applicable GMP and QSR regulations, FDA also should require these entities to obtain clearance of a premarket notification ("510(k) notice") or approval of a PMA or PMA supplement for any devices they reprocess. Whether a 510(k) notice or a PMA or PMA supplement is required for the reprocessed device will depend on whether the original device was cleared through the premarket notification process or approved through the PMA process.

FDA has issued a guidance document that discusses when a change to a device that previously has been cleared through the 510(k) notification process requires the manufacturer to file a new 510(k) notice. ^{29/} In the guidance, the agency states that labeling changes that provide for reuse of a device that was previously labeled for "single use only" change the intended use of the device. ^{30/} Thus, when a manufacturer changes the labeling for a device from single use only to multiple use, the manufacturer must submit a new 510(k) notification to support the change. ^{31/} Although the 510(k) Guidance was not intended to apply to remanufacturers or refurbishers, ^{32/} the change from single use to multiple use clearly has the same impact on safety and efficacy whether it is effected by the original manufacturer or by a reprocessor. If the change is being made by the commercial reprocessor, it is the reprocessor

^{29/} *Deciding When to Submit a 510(k) for a Change to an Existing Device* at 9-11 (January 10, 1997) ("510(k) Guidance").

^{30/} *Id.* at 11.

^{31/} *Id.*

^{32/} 60 Fed. Reg. 53624, 53624 (1995).

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who should be responsible for filing a 510(k) notice. ^{33/} Nonetheless, contrary to the agency's earlier statements on this issue, ^{34/} an FDA official recently stated that the agency was exercising its "regulatory discretion" not to require third-party reproprocessors to submit 510(k) notices for reprocessed single-use devices. ^{35/}

FDA's current policy not to require 510(k) notices from third-party reproprocessors of single-use devices is especially troublesome since only the reproprocessor can provide information on how it will make a device suitable for reuse. As the agency itself has noted, the commercial reproprocessor's method of reprocessing a disposable device may necessarily vary from the original manufacturer's instructions, depending on the equipment available at the reprocessing location. ^{36/} This concern is true regardless of where the reuse takes place or who is responsible for it. In its draft guidance for reviewers of labeling for reusable devices, the

^{33/} This analysis applies only to commercial reproprocessors of single-use devices, not to reproprocessors of devices that manufacturers intend for reuse, because reproprocessors of reusable devices do not change the intended use of the product. Subsequent arguments also are limited to commercial reproprocessors of devices that are intended for single use only.

^{34/} In a previous draft policy statement, the agency defined reproprocessors of single-use devices for reuse as "remanufacturers." *Trial Balloon: Draft Policy on Servicing/Remanufacturing of Used Medical Devices* (Sept. 20, 1995). The guidance also suggested that remanufacturers "are, in effect, marketing a new device, or contributing to the marketing of a new device," and, therefore, would have required remanufacturers to obtain premarket approval or premarket clearance. *Id.*

^{35/} *Data on Disposable Device Reuse to be Gathered by FDA in Upcoming Meeting*, Gray Sheet, Nov. 25, 1996; *Reprocessed Single-Use Devices*, Gray Sheet, October 28, 1996.

^{36/} See Canadian Hospital Association, Report on the Reuse of Single-Use Medical Devices (1995) (Medical Device Integrity) ("CHA Report").

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agency therefore stated that:

The process [for reconditioning a used device] must be feasible considering the intended location of reprocessing. Persons reprocessing reusable devices must have the ability to carry out the reprocessing steps. 37/

Although a manufacturer may propose a commonly understood process, only the commercial reprocessor can determine whether that method is "feasible considering the intended location of reprocessing" and the capabilities of the reprocessor, as discussed above. FDA therefore should review, under a 510(k) notice, the labeling and processes of the commercial reprocessor.

In addition, FDA's current policy not to require 510(k) notices for reprocessed single-use devices is inconsistent with the agency's treatment of commercial reproducers under a number of other regulatory provisions. For example, third-party reproducers are apparently considered "manufacturers" as the term is defined under the establishment registration and device listing regulations, 38/ and thus are required to register their establishments and list their

37/ *Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: Draft Reviewer Guidance* (April 1996).

38/ The device listing and establishment registration provisions apply to the owner or operator of an establishment that engages in the "manufacture, preparation, propagation, compounding, assembly, or processing of a device." The terms "manufacture, preparation, propagation, compounding, assembly, or processing" are defined to mean:

[T]he making by chemical, physical, biological, or other procedures of any article that meets the definition of device in section 201(h) of the act. These terms include the following activities:

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reprocessed devices.

While commercial reproprocessors are deemed manufacturers for purposes of device listing, establishment registration, and other regulatory provisions, 39/ FDA has decided to exercise regulatory discretion and not treat them as specification developers or manufacturers for purposes of the premarket notification provision. This interpretation is subjective and contrary to the express language of the premarket notification regulation, which states that the premarket notification requirement applies to any person who is required to register his establishment. 40/

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- (1) Repackaging or otherwise changing the container, wrapper, or labeling of any device package in furtherance of the distribution of the device from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer;
- (2) Distribution of domestic or imported devices; or
- (3) Initiation of specifications for devices that are manufactured by a second party for subsequent commercial distribution by the person initiating specifications.

21 C.F.R. § 807.3(d) (1996). This would presumably include commercial reproprocessors who restore used devices to the original specifications to permit reuse.

39/ In addition to filing 510(k) notices, registering, and listing, commercial reproprocessors also should be required to comply with other regulations that are imposed on other device manufacturers, including medical device reporting ("MDR"). See 21 C.F.R. § 803.3(n) (1996). If an adverse event occurs as a consequence of reprocessing, it should be the commercial entity responsible for reprocessing the device who files the MDR, not the original manufacturer, who lacks knowledge of reuse and the remanufacturing process and the harm it may have caused.

40/ 21 C.F.R. § 807.81(a) (1996).

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By choosing not to require commercial reproprocessors to file 510(k) notices for reprocessed single-use devices, the agency has relinquished necessary oversight over these entities. This problem is compounded by the fact that many commercial reproprocessors also are not presently required to adhere to the GMP and QSR regulations, at least pending completion of the agency's separate rulemaking on device servicers and refurbishers. Reprocessed devices should be subject to both the premarket notification requirement and all of the relevant provisions of the GMP and QSR regulations to ensure their safety and efficacy.

3. Premarket Approval

For many of the same reasons outlined above, FDA also should require commercial reproprocessors to obtain approval of a PMA or PMA supplement to reprocess devices that were originally approved through the PMA process. FDA regulations provide that "before making a change affecting the safety or effectiveness" of a PMA-approved device, absent designation of an alternate procedure by FDA, ^{41/} the applicant must obtain approval of a PMA supplement. ^{42/} While the applicant has primary responsibility for determining whether a particular change to the device requires a PMA supplement, the regulation specifies certain types of changes for which a supplement is required, including:

1. New indications for use of the device.
2. Labeling changes.

^{41/} *Id.* § 814.39(e).

^{42/} *Id.* § 814.39(a).

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3. The use of a different facility or establishment to manufacture, process, or package the device.
4. Changes in manufacturing facilities, methods, or quality control procedures.
5. Changes in sterilization procedures.
6. Changes in packaging.
7. Changes in performance or design specifications, circuits, components, ingredients, principle of operation, or physical layout of the device.
8. Extension of the expiration date of the device based on data obtained under a new or revised stability or sterility testing protocol that has not been approved by FDA. 43/

Further, depending on the nature of the change and the information required to support it, a commercial reprocessor may need to obtain an independent PMA to establish the safety and efficacy of the remanufactured device.

Reprocessing may impact many of the above criteria, including the indications for use of the device, the device labeling, the manufacturing facilities and processes, the quality control procedures, the sterilization processes, the device packaging, and the performance characteristics and specifications. Moreover, as discussed above, these types of changes have the same impact on device safety and effectiveness whether they are implemented by the original manufacturer or a third-party reprocessor. Therefore, commercial reproducers should be

43/ *Id.*

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required to obtain approval of a PMA or PMA supplement, like other manufacturers of PMA-approved devices, before implementing these changes to ensure that devices remain safe and effective after reprocessing.

C. Risks to Public Health

As noted above, the agency has recognized the potentially significant impact reprocessing may have on the safety and efficacy of medical devices. For example, the physical act of disassembling, cleaning and manipulating the device during reprocessing may result in damage to the device that changes its performance characteristics and may alter its safety or effectiveness. Also, various sterilization and disinfection methods used in reprocessing may alter important device characteristics, and some sterilization and disinfection methods may damage certain types of devices or materials. For example, certain devices that incorporate flexible plastics, including flexible endoscopes, cannot withstand the heat of steam sterilization, and may thus require ethylene oxide (EtO) sterilization. ^{44/} Improper use of steam sterilization with these devices may cause cracking of the plastic components. FDA also has noted the possibility that radiation sterilization may damage certain optical devices, such as neuro endoscopes, by reducing the optical fiber capacity for color transmission, which is critical to

^{44/} See ECRI, *Reuse of Single-Use Medical Devices: Making Informed Decisions 59* (1997) ("ECRI Reuse Report"); see also *ENT Endoscopic Sheath Barrier Claims Should be Based on 30 nm or Smaller Virus Size, FDA Says*, Gray Sheet, Nov. 11, 1996.

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device performance. ^{45/} Similarly, in a guidance document on preparation of 510(k) notices for liquid chemical germicides, the agency stated that:

Liquid chemical germicides used to reprocess devices may damage the devices or lead to deterioration of the materials, and thus adversely affect the safety and effectiveness of the device. For example, surface cracking or pitting will make the device more difficult to clean and may cause injury during use For these reasons, the 510(k) must include data confirming the compatibility of the germicide with medical devices and component materials that are indicated in germicide labeling as compatible. The data should address the effects of the germicide on the functionality, biocompatibility, and specifications of the claimed compatible medical devices/materials. ^{46/}

For these reasons, FDA recently initiated an investigation of cardiac catheter reuse, including testing to compare the performance of reprocessed catheters to new catheters. ^{47/}

In addition, even if an appropriate sterilization method is selected, bacterial contamination may result from inadequate cleaning, disinfection, or sterilization of the

^{45/} *Draft Neuro Endoscope Guidance* (July 7, 1994).

^{46/} *Guidance on the Content and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Germicides* (April 26, 1995) ("Germicide Guidance"); see also CHA Report, *supra* note 36 (Table 3); *Guidance for the Content of Premarket Notifications for Biopsy Devices Used in Gastroenterology and Urology* (Feb. 10, 1993). As indicated in the Germicide Guidance, FDA presently requires both the original device manufacturer and the germicide manufacturer to provide information on the safety and efficacy of a particular chemical sterilant when used with a specific device. However, the Guidance places primary responsibility for providing sterilization instructions on the device manufacturer. See Germicide Guidance, *supra*.

^{47/} See *Cardiac Catheter Reuse Targeted by FDA; Lab Testing of Used Catheters Planned*, Gray Sheet, July 7, 1997; ECRI Reuse Report, *supra* note 44, at 6-16.

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device. 48/ Because of these risks, FDA recently issued a letter to industry regarding inadequate sterilization and cleaning of reusable medical equipment by third-party contractors. 49/ Among other things, the letter noted that:

In some cases, third-party suppliers may also reprocess or refurbish medical devices between uses. When the contract calls for these services, the health care facility should ensure that the supplier is familiar with the device manufacturer's specifications for the product. Health care facilities may wish to establish quality assurance procedures to be sure that reprocessed or refurbished devices fulfill these specifications.

These same concerns apply to commercial reprocessing of disposable devices as to reusable devices. Rather than recommending implementation of quality assurance procedures by hospitals, as above, FDA should directly regulate the commercial reprocessors to ensure proper cleaning and sterilization.

Moreover, while inadequate disinfection, *i.e.*, due to overdilution of the chemical disinfectant, may lead to bacterial or viral contamination, underdilution also may have serious health effects. Many commercial reprocessors use formaldehyde, a known carcinogen, for disinfection. Underdilution of the sterilization solution may leave residual formaldehyde on the reprocessed device, which may then be infused into the patient's bloodstream. 50/

48/ See, e.g., ECRI Reuse Report, *supra* note 44, at 6-8.

49/ Letter from D. Bruce Burlington, Director, Center for Devices and Radiological Health, to Health Care Facilities (April 17, 1997).

50/ ECRI Reuse Report, *supra* note 44, at 6-8; see also Germicide Guidance, *supra* note 46.

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Furthermore, to ensure safe and effective reprocessing and protect patients and users from failures of reprocessed devices, it is important to determine the maximum number of reprocessing cycles. ^{51/} The third-party reprocessor also should be able to identify deterioration signaling the need to discard the device prior to reuse. ^{52/} Commercial reprocessors may have greater difficulty identifying indicators of potential failure in single-use devices than in devices intended for reuse because disposable devices are not designed to incorporate any mechanism for signaling device deterioration. ^{53/}

D. State Regulation of Device Reprocessing

Because of the risks presented by reuse of disposable medical devices, as discussed above, in the absence of federal regulation, several states, including Texas, Ohio, New Jersey, Illinois, and the District of Columbia have enacted legislation regarding reuse or reprocessing of single-use devices.

In August 1997, Illinois enacted legislation which prohibits "the unregulated

^{51/} See, e.g., *Draft Neuro Endoscope Guidance* (July 7, 1994); *Foley Catheters (Conventional and Antimicrobial): 510(k) Guidance* (September 12, 1994).

^{52/} See *Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: Draft Reviewer Guidance* (April 1996).

^{53/} FDA has recognized the impact of device design on successful reuse and reprocessing. For example, the agency has stated that, "[a]s a rule, a reusable device should be designed so that it can be adequately cleaned. If a device cannot be adequately cleaned, any subsequent disinfection or sterilization process may not achieve the desired result." *Id.*

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reuse, recycling, and refurbishing of single-use surgical devices," including cardiac catheters, balloon catheters for angioplasty, arthroscopic knee surgery blades, and other devices designated by rule as unsuitable for reuse. ^{54/} The law permits reprocessing, however, by facilities that have complied with FDA's establishment registration requirements and any other applicable FDA regulations, or by hospitals licensed under the Hospital Licensing Act or the University of Illinois Hospital Licensing Act.

The District of Columbia also has enacted legislation governing reprocessing and reuse of hemodialyzers and certain other disposable devices. ^{55/} Among other things, the statute requires the Mayor to establish standards for the reprocessing and reuse of hemodialyzers, dialysate port caps, and blood port caps. ^{56/} The statute also prohibits hospitals and renal dialysis facilities from reusing two other types of disposable devices: blood tubing and transducer protectors. Finally, the statute requires user facilities to obtain informed consent from patients prior to reuse of certain devices, stating that:

(5) No hospital or renal dialysis facility shall reuse a hemodialyzer or dialyzer caps on a patient unless that patient has first signed a written consent form after having been orally advised by a

^{54/} Illinois Food, Drug and Cosmetic Act, Ch. 420, §620/16.5, 1997 Ill. Legis. Serv. P.A. 90-0398 (West).

^{55/} D.C. Code Ann. § 32-1304(i) (1996).

^{56/} Until such standards are implemented, the statute requires that facilities reprocessing disposable hemodialyzers for reuse satisfy, at a minimum, the Recommended Practice for Reuse of Hemodialyzers published by the Association for the Advancement of Medical Instrumentation and applicable recommendations by the Center for Disease Control ("CDC"). See Association for Advancement of Medical Instrumentation, *Recommended Practice for Reuse of Hemodialyzers* (2d ed. 1993) (ANSI/AAMI RD47-1993).

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physician of the potential risks, benefits, and uncertainties surrounding reuse and the disinfection process.

In the absence of further regulatory action by FDA, many additional states may elect to impose standards for reprocessing. The development of individual reprocessing standards within states would be undesirable for several reasons. First, if states enact statutes similar to the Illinois law, the effect on reprocessing would presumably turn on the extent of FDA regulation. ^{57/} Under FDA's current policy, the effects would be minimal, as most commercial reprocessors are not presently required to comply with premarket notification or GMPs. Second, while some states with substantial public health resources may be able to implement stringent requirements for reprocessing, many states may lack the enforcement capacity to ensure compliance with such standards. ^{58/} Finally, inconsistent state regulation of reprocessing would be undesirable because it could result in substantial confusion and lack of uniformity and, thus, adversely affect device quality. Therefore, there is a public health need for uniform federal regulation of commercial reprocessing of disposable devices.

^{57/} The Illinois law explicitly exempts reprocessors who are "registered with and regulated by the United States Food and Drug Administration." In light of the fact that FDA presently does not require most reprocessors to comply with 510(k) notification or GMP requirements, the effect of the Illinois law may be minimal because it presumably would merely require reprocessing facilities to fulfill FDA's establishment registration requirements.

^{58/} Presumably, differential levels of regulation across states also would increase interstate sales of reprocessed devices, which could make it more difficult to monitor the number of times a device had been reprocessed, unless a uniform, effective tracking and/or labeling system was implemented. This could best be achieved through federal regulation.

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E. Regulation of Device Reprocessing by Foreign Health Authorities

A number of foreign health authorities have determined that reprocessing of disposable devices does not provide adequate public health protection and, thus, should be prohibited. For example, in 1994, the Australian Therapeutic Goods Administration issued a policy statement, *Draft Statement of Commonwealth Policy on the Reuse of Single-Use Therapeutic Devices*, which states in pertinent part that:

The Commonwealth Department of Human Services and Health does not approve of the reuse of any therapeutic device which is labeled by the manufacturer as single use only.

Devices which are designed, manufactured, and tested for single use must be labeled accordingly. Manufacturers must comply with regulations and standards which ensure the safety and effectiveness of devices and cannot control the use of devices subsequent to supply.

It is important that device users understand: That if a device is used in a manner other than that specified by the manufacturer, the user assumes the full responsibility and liability should any adverse incident occur, and, there is a responsibility to inform the patient about any additional risk resulting from the 'off label' use of the device. 59/

In addition, several European countries, including Italy and Spain, have prohibited reuse of single-use devices. Spain's policy on reuse is set forth in Circular 27/85, which states, in part, that:

[I]t is clear that re-use of single-use sterile medical and surgical

59/ Therapeutic Goods Administration, *Draft Statement of Commonwealth Policy on the Reuse of Single-Use Therapeutic Devices* (1994).

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supplies and instruments is a practice excluded from this regulation and is not permitted.

Moreover, re-use of this type of material by re-sterilization may alter a series of parameters on which its safety, effectiveness, and harmlessness are based, such as:

1. Sterility, which can only be guaranteed by adequate validation and inspection of the sterilization procedure used.
2. The presence of sterilizing agent residues above initially permissible limits, with the consequent risk of toxicity.
3. Possible change in the physical, chemical or biological nature of the materials of which these devices are made, with consequent biocompatibility problems.
4. Possibility of pyrogenic reactions due to the presence of bacterial endotoxins at their surface.
5. Alteration in function, since they were designed and developed by a manufacturer based on the condition of one-time use only. 60/

For similar reasons, a number of other countries, including England and France, also have issued statements disapproving reuse of disposable devices. 61/

F. Products Liability Consequences of Device Reprocessing

In addition to the regulatory issues discussed above, FDA's current policy on reprocessing of disposable devices may expose doctors, hospitals, and original device manufacturers to costly products liability litigation. As noted above, reprocessing could

60/ Circular 27/85 on the Reuse of Single-Use Sterile Medical and Surgical Supplies and Instruments (June 13, 1983), *reprinted in* ECRI Reuse Report, *supra* note 44, at 38.

61/ See CHA Report, *supra* note 36 (International Perspectives).

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negatively impact the safety and effectiveness of the device, and could adversely affect patients and/or users. In a litigious society, these injuries to patients and users often result in lawsuits. Because the original manufacturer's name, not the commercial reprocessor's, typically continues to appear on the device after reprocessing, the original manufacturer generally is named as a defendant in any resulting lawsuit. In addition, once a device is reprocessed, it is difficult to determine whether a failure was caused by the original manufacturer or the third-party reprocessor. Moreover, even if the manufacturer can demonstrate improper reprocessing or otherwise avoid liability, device failures will damage the manufacturer's reputation. It is unreasonable for FDA's policy to place the original manufacturer at risk of these types of actions when the manufacturer has no control over the subsequent reprocessing of the device once it is sold to a distributor or end user and when the manufacturer has no assurance that FDA is making sure that the reprocessing is done in a safe and effective manner.

G. Conclusion

As FDA itself has acknowledged, reprocessing disposable devices presents the potential for serious adverse health effects. FDA has an obligation to fulfill its responsibility under the FDC Act to protect the public health by directly regulating commercial device reprocessors. A number of foreign health authorities and several states have implemented measures to regulate reprocessing, while FDA has been criticized in the past for failing to implement a policy on medical device reuse that adequately protects the public health. In order to ensure the safety and effectiveness of reprocessed single-use devices, and recognizing that

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commercial reproprocessors are device manufacturers, FDA should require these entities to comply with all of the regulations that apply to the original device manufacturer. To do otherwise, *i.e.*, exercising regulatory discretion in not treating commercial reproprocessors as manufacturers, jeopardizes patient, employee, and user safety and is not in keeping with FDA's stated mission to protect the public health. Moreover, the agency's current policy exposes original manufacturers to unwarranted products liability suits.

Thus, in addition to requiring commercial reproprocessors to fulfill device listing and establishment registration obligations, the agency also should require these reproprocessors to obtain premarket clearance of the reprocessed devices, to comply with all the relevant provisions of the GMP and QSR regulations, and to meet the same Medical Device Reporting obligations and device labeling requirements as other manufacturers. In light of the public health risks associated with reprocessing of disposable devices, HIMA urges FDA to implement these measures as expeditiously as possible to ensure that patients and users receive equally safe and effective products whether they are newly manufactured devices or reprocessed devices.

III. ENVIRONMENTAL IMPACT

The actions requested in this Petition have no significant environmental impacts and are categorically exempt from the environmental assessment requirement under 21 C.F.R. § 25.24(c)(10).

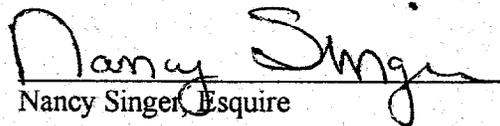
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IV. ECONOMIC IMPACT

Information on the economic impact of the present FDA requirements and the action requested in this Petition will be submitted upon request of the Commissioner.

V. 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 representative data and information known to the Petitioner which are unfavorable to the Petition.


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