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June 1, 2001

BY HAND DELIVERY

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

Re: Docket No. 01P-0148

Dear Sir or Madam:

The Association of Medical Device Reprocessors (AMDR) respectfully submits the following comments to the above-referenced docket, in response to the Citizen Petition submitted to the Food and Drug Administration (FDA) by the Association of Disposable Device Manufacturers (ADDM), asking FDA to (1) issue an announcement that a reprocessor's failure to remove original equipment manufacturers' (OEM) trademarks from a reprocessed "single use" device or failure to remove references to an OEM in the labeling of a reprocessed "single use" device constitutes misbranding under section 502 of the Food, Drug, and Cosmetic Act (FDCA), (2) conduct investigations and take necessary enforcement action to identify and curtail these alleged acts of "misbranding," and (3) refuse to approve premarket approval applications (PMAs) or to clear premarket notifications (510(k)s) for reprocessed "single use" devices unless the applicant represents that the device in question will not be so "misbranded" as of the date of approval or clearance.[1]

As set out below, in AMDR's view, there is no basis in law – or in the reality of clinical practice – for ADDM's position. Rather, the ADDM Citizen Petition is simply another in a series of failed attempts by OEMs to eliminate the economic threat posed by medical device reprocessing.

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[1] Citizen Petition from Thomas Scarlett, Esq., Association of Disposable Device Manufacturers (ADDM) to FDA 2 (Mar. 22, 2001) [hereinafter ADDM Citizen Petition].

01P-0148

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I. ADDM's Legal Premises Are Incorrect

A. Reprocessed Devices Bearing OEM Trademarks Are Not "False or Misleading"

ADDM's petition argues that the presence of OEM trademarks on reprocessed devices or references to the OEM in the labeling of reprocessed devices are false and misleading, rendering the products misbranded under section 502 of the FDCA (21 U.S.C. § 352). ADDM bases this argument on its assertion that "the trademark announces to the device user that the device has the quality of the original single use device, and that the OEM not only made, but stands behind the quality of, the marked product."[2] ADDM argues that allowing reprocessors to market products bearing the OEM's trademark "will lead physicians and other health professionals to assume that the device has the quality typically seen in devices manufactured by, and is backed by the good name of, the OEM."[3] ADDM further asserts that,

> When the label on a reprocessed single use device bears the OEM's name in addition to the reprocessor's name, the label is misleading because it erroneously implies [either] . . . that two entities are responsible for manufacturing the device . . . [or] that a cooperative relationship exists between the OEM and the reprocessor. . . . [I]f a medical device bears the name of both the OEM and the reprocessor, the user of the device will infer, not that the OEM is the source of raw material – the single use device – for manufacture into a finished device product – the reprocessed device. Rather, the user will [mistakenly] infer that the OEM is a direct participant in making the finished reprocessed device product available.[4]

Because, in ADDM's view, all of these impressions would be contrary to fact, the presence of an OEM trademark on a reprocessed device or references to an OEM in the labeling of a reprocessed device are false or misleading, rendering the device misbranded.[5]

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2 *Id.* at 9.

3 *Id.* at 7.

4 *Id.* at 15-16.

5 *Id.* at 9.

In AMDR's view, there is no basis in law – or in the reality of clinical practice – for ADDM's position. As a threshold matter, FDA's new enforcement policy deeming reprocessing to be a manufacturing function[6] treats used "single use" devices as raw materials/off-the-shelf components of reprocessed finished devices.[7] Nothing in the FDCA or FDA's implementing regulations prohibits finished device manufacturers from utilizing off-the-shelf components, even if those components bear their manufacturer's trademarks. In fact, off-the-shelf components bearing the original manufacturer's trademark frequently are used by finished device manufacturers. Common examples include convenience kits, powered devices utilizing off-the-shelf batteries, and telemedicine devices utilizing off-the-shelf personal computers. Users of such products are not "misled" into thinking that the component manufacturer is "a direct participant in making the finished . . . device," or that "a cooperative relationship" exists between the component maker and the finished device manufacturer.

The reality, of course, is that the users of reprocessed devices, i.e., physicians and hospitals, do not view reprocessing as a manufacturing function, but, rather, as a device cleaning, testing, and sterilizing service. Hospitals and physicians that utilize reprocessing services actively choose to do so – because they understand that certain devices labeled as "single use" can be safely reused. Indeed, the practice of reprocessing initially emerged because, approximately two decades ago, OEMs began to change the label on some devices from "reusable" to "single use," without making any structural changes in the devices that would preclude safe reuse.

This shift in labeling was not required by FDA, but, rather, was done solely at the discretion of the manufacturer, and it has catalyzed significant skepticism in the clinical community. As a recent General Accounting Office (GAO) report noted, health care personnel "distrust the single-use label for some devices because," among other things, "FDA cannot require manufacturers to support the designation of a device as single-use," and "they perceive that manufacturers have an economic incentive to market devices as single-use that could just as well be sold as reusable."[8]

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6 *See* CDRH, FDA Guidance for Industry and for FDA Staff: Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals (Aug. 14, 2000).

7 *See* Letter from Melinda K. Plaisier, Associate Commissioner for Legislation, FDA, to Rep. Thomas J. Bliley, Jr., Chairman, Committee on Commerce, House of Representatives at 2 (Nov. 29, 2000) (Attachment A).

8 United States General Accounting Office, Report to Congressional Requesters, *Single-Use Medical Devices: Little Available Evidence of Harm From Reuse, but Oversight Warranted* 11 (June 2000) [hereinafter GAO Report] (Attachment B).

Cognizant that an OEM's decision to label a device as "single use" is more often driven by marketing objectives than patient safety concerns, many hospitals and physicians have chosen to reprocess certain "single use" devices. However, the decision to reprocess is reached only after a thorough review of all relevant safety and economic issues. Typically, hospitals convene a "reuse committee" comprised of physicians, infection control practitioners, and risk managers, who deliberate carefully before choosing to reprocess. Hospitals that decide to outsource their reprocessing needs often tour several third-party reprocessing facilities before selecting a reprocessor.

In light of this reality – i.e., that the users of reprocessed devices are the same persons or entities that have chosen to have the devices reprocessed -- ADDM's contention that the presence of an OEM trademark on a reprocessed device is "false and misleading" is simply absurd. Indeed, in *United States Surgical Corp. v. Orris, Inc.*,[9] the United States District Court for the District of Kansas rejected this very same argument.[10] In *United States Surgical*, the court found that the presence of a trademark belonging to an OEM on a reprocessed device does not confuse or deceive physicians, because, although it identifies the OEM to the end user, it does not imply that the OEM has sanctioned reprocessing. As the court explained,

> [The reprocessor's] advertising does not imply that it is an authorized agent of [the OEM]. ...[the reprocessor] conducts in-service training and holds meetings with surgeons and other hospital personnel to inform them regarding [the reprocessor's] services . . . . After [the reprocessor] cleans, resterilizes, and/or resharpens the instruments, it returns the instruments in packages labeled "reconditioned" that contain [the reprocessor's] name and address. [The reprocessor] returns each instrument to the same hospital that purchased the instrument from [the OEM] . . . . [and] the instruments are

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9 5 F. Supp.2d 1201 (D. Kan. 1998), *aff'd*, 185 F.3d 885 (Fed. Cir. 1999).

10 *Id.* The *United States Surgical* case involved a suit by one of the leading OEM manufacturers against a third-party reprocessor of "single use" devices, alleging that the reprocessing of devices bearing the OEM's trademark(s) violated federal patent, trademark, and unfair competition laws, as well as a variety of state law principles.

> maintained in such packaging until hospital staff removes the packaging . . .[11]

The court then found that, because reprocessed devices are not sold on the open market, but rather are simply returned to the user from which they came, there is no likelihood of confusion on the part of the institutional users of reprocessed devices.[12] The court also rejected the argument that patients or physicians would be misled in any relevant way.[13]

In short, ADDM's argument that the presence of an OEM trademark on a reprocessed device or references to an OEM in the labeling of a reprocessed device are "false and misleading" is unsupportable. Physicians and hospitals choose to utilize reprocessed devices because they understand that certain "single use" devices can be safely reused. The fact that a reprocessed device may contain a reference to the OEM does not "mislead" the user of that device. Rather, physicians and hospitals that send a device to be reprocessed have every expectation that the reprocessed device will reference the OEM, because, 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 OEM. Indeed, for hospitals and physicians, it would be misleading not to reference the OEM on the reprocessed device.

B. Reprocessed Devices Bearing OEM Trademarks Are Not In Violation of Section 502(b) or FDA's Implementing Regulation

Perhaps recognizing the weakness in its argument that it is misleading for the labeling of reprocessed devices to bear OEM trademarks, ADDM also attempts to construct a facial violation of the FDCA and FDA's implementing regulations. Specifically, ADDM asserts that a reprocessed "single use" device whose labeling contains the name of both the reprocessor and the OEM facially violates both section 502(b) of the FDCA and FDA's implementing regulation, set forth at 21 C.F.R. § 801.1(c).[14] ADDM does not, however, quote any specific part of the referenced statutory or regulatory provisions that are violated by the presence of the OEM's trademark on a reprocessed

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11 *Id.* at 1209.

12 *Id.* at 1210.

13 *Id.*

14 ADDM Citizen Petition, *supra* note 1, at 16.

device. The petition does not do so because, in AMDR's view, it cannot do so. There simply is no violation of either of the cited provisions.

Section 502 of the FDCA provides, in relevant part, that "a drug or device shall be deemed to be misbranded . . . [i]f in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count."[15] Nothing in this statutory provision precludes a reprocessed "single use" device from bearing the name or trademark of an OEM, or a finished device from containing a component that bears the component manufacturer's name or trademark.

The same can be said for section 801.1 of Title 21 of the Code of Federal Regulations which reads, in its entirety,

> Sec. 801.1 Medical devices; name and place of business of manufacturer, packer or distributor.
>
> (a) The label of a device in package form shall specify conspicuously the name and place of business of the manufacturer, packer, or distributor.
>
> (b) The requirement for declaration of the name of the manufacturer, packer, or distributor shall be deemed to be satisfied, in the case of a corporation, only by the actual corporate name which may be preceded or followed by the name of the particular division of the corporation. Abbreviations for "Company," "Incorporated," etc., may be used and "The" may be omitted. In the case of an individual, partnership, or association, the name under which the business is conducted shall be used.
>
> (c) Where a device is not manufactured by the person whose name appears on the label, the name shall be qualified by a phrase that reveals the connection such person has with such device; such as, "Manufactured for _____", "Distributed by _____", or any other wording that expresses the facts.

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15 21 U.S.C. §§ 352, 352(b).

> (d) The statement of the place of business shall include the street address, city, State, and Zip Code; however, the street address may be omitted if it is shown in a current city directory or telephone directory. The requirement for inclusion of the ZIP Code shall apply only to consumer commodity labels developed or revised after the effective date of this section. In the case of nonconsumer packages, the ZIP Code shall appear on either the label or the labeling (including the invoice).
>
> (e) If a person manufactures, packs, or distributes a device at a place other than his principal place of business, the label may state the principal place of business in lieu of the actual place where such device was manufactured or packed or is to be distributed, unless such statement would be misleading.[16]

ADDM points to nothing in this regulation that precludes a device from bearing a trademark belonging to a component manufacturer. Nonetheless, ADDM boldly asserts that

> [t]he regulation assumes that identification of a person on the label of a device implies that the person either manufactured the device or has "a connection" with the device, such as being a distributor of a device manufactured by an unnamed company. . . . Hence, the only "connection" with a device that supports the presence of a device company's name on the label is one of active involvement in the manufacture or distribution of the labeled device.[17]

ADDM continues,

> In the case of a reprocessed single use device, the OEM is the source of raw material, not an active participant in the manufacture or distribution of the reprocessed device. The OEM has no "connection with" the reprocessed device in the sense intended by

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16 21 C.F.R. § 801.1.

17 ADDM Citizen Petition, *supra* note 1, at 17 (emphasis added).

> the regulation. Accordingly, any identification of the OEM on the device label is a violation of 21 CFR § 801.1.[18]

Notwithstanding ADDM's assertions to the contrary, however, nothing in the regulation requires or assumes that the identification of a component manufacturer somewhere in the labeling of a reprocessed device implies that that manufacturer has an "active involvement in the manufacture or distribution of the device." The purpose of section 502(b) and FDA's implementing regulation is to impose a positive obligation for the label of a finished device, in order to accurately identify the manufacturer, the packer and/or the distributor of the device, so that the agency and the user know, or can determine, the entity that bears legal responsibility for putting the device into commercial distribution. In the case of reprocessed devices, the labeling makes clear that the device is reprocessed, and it identifies the reprocessor. Nothing in the regulation precludes (or is intended to preclude) a reprocessor from identifying the supplier of components and raw materials, as long as the positive requirements of the regulation are met.

In short, just as the inclusion of an OEM's trademark in the labeling of a reprocessed device is not false or misleading, it also is not a violation of section 502(b) or 21 C.F.R. § 801.1. Moreover, if FDA were to grant ADDM's request, and interpret section 502 of the FDCA to require that "single use" reprocessors remove references to OEMs from their devices, such an interpretation would be inconsistent with the regulatory approach the agency has taken with similarly situated industries. Specifically, device "servicers and refurbishers" – i.e., those companies that act as third-party servicers and refurbishers of capital equipment – are not required to remove OEM references from their devices, even though the agency considers these firms to be device manufacturers. Rather, FDA permits this industry to police itself through a system of voluntary labeling controls, which specify that servicers/refurbishers include only certain "basic" information in their labeling, such as a description of the work performed and the date the work was performed.[19]

II. ADDM's Citizen Petition Is Simply Another Effort on the Part of OEMs To Eliminate Reprocessing

Although couched as a "wake-up call" to FDA to enforce the law and take action against allegedly violative labeling practices, the petition's elaborate legal argumentation does little to

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18 *Id.*

19 *See* 61 Fed. Reg. 52,610 (Oct. 7, 1996); Mary Beth Hatem, *From Regulation to Registration* 33 BIOMEDICAL INSTRUMENTATION AND TECHNOLOGY, Sept./Oct. 1999 at 393-398 (Attachment C).

disguise ADDM's true motive. Like the numerous petitions and lobbying efforts ADDM has initiated over the last several years, the current petition is simply another attempt by OEMs to eliminate the economic threat posed by reprocessing.

For OEMs, reprocessing poses a two-fold economic threat. First, reprocessed devices are significantly less costly than new devices. Thus, hospitals often choose to utilize a reprocessed device, rather than purchase a new one. In addition, the very existence of reprocessing has resulted in a decrease in the price of certain new devices. Indeed, the GAO found that the "overall prices of some [single use devices] that are reprocessed appear to have decreased in recent years, even for health care institutions that do not reuse them."[20] It appears that "[t]he competitive alternative offered by [single use device] reprocessing has affected negotiations between manufacturers and purchasers and may have caused some manufacturers to lower their prices to some purchasers," in exchange for an agreement with the hospital purchasers not to engage in reprocessing.[21] For example, one OEM informed a hospital-customer that it

> would be willing to supply [the hospital] with new catheters at the price of each returned reprocessed catheter, if I [the hospital's Chief of Infection Control Service] would stop reprocessing . . . . Being dumbfounded with this offer of cutting the price in half for each new catheter, I immediately asked her [the OEM representative] where her integrity was with keeping the price so high all this time? She had no answers.[22]

Faced with the economic threat posed by the reuse of "single use" devices, OEMs have worked hard to eliminate reprocessing, or, at the very least, impose an overly burdensome level of regulation on the practice. For example, in September 1997, the Health Industry Manufacturers Association (HIMA) submitted a Citizen Petition to FDA requesting that the agency strengthen its regulation of reprocessing, on the grounds that, among other things,

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20 GAO Report, *supra* note 8, at 19.

21 *Id.*

22 Letter from Dana Gruber, Chief, Infection Control Service, Brooke Army Medical Center, to William B. Stoermer, Jr., Executive Vice President, Alliance Medical Corporation (Dec. 29, 1999) (Attachment D).

> 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.[23]

In July 1998, FDA denied HIMA's petition, explaining that, among other things, the agency "has seen no documented evidence that the treatment of patients with, or other patient use of, these reprocessed devices has caused adverse clinical outcomes."[24]

Similarly, in May 1999, the Medical Device Manufacturers Association (MDMA) submitted a Citizen Petition to FDA requesting that the agency ban the reprocessing of devices labeled as "single use" on the grounds that reprocessed "single use" devices, among other things, pose an "unreasonable and substantial risk of illness or injury."[25] In October 1999, FDA denied MDMA's petition, explaining that "there is no clear evidence that reprocessing presents 'an unreasonable and substantial risk of illness or injury,'" and that FDA "has been unable to find clear evidence of adverse patient outcomes associated with the reuse of a single use device from any source."[26]

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[23] Citizen Petition from Nancy Singer, Esq., Health Industry Manufacturers Association (HIMA) to FDA 2 (Sept. 5, 1997) (Attachment E).

[24] Letter from D. Bruce Burlington, M.D., Director CDRH, FDA, to Nancy Singer, Esq., HIMA 2 (July 15, 1998) (Attachment F).

[25] Citizen Petition from Larry R. Pilot, Esq., McKenna & Cuneo, L.L.P., Counsel to Medical Device Manufacturers Association 12-16 (May 20, 1999) (Attachment G).

[26] Letter from David W. Feigal, Jr., M.D., M.P.H., Director, CDRH, FDA, to Larry R. Pilot, Esq., Counsel to Medical Device Manufacturers Association (MDMA) 1-2 (Oct. 6, 1999) (Attachment H). On October 21, 1999, MDMA petitioned FDA for reconsideration of its decision to deny MDMA's request for a ban on the reprocessing of "single use" devices. *See* Letter from Larry R. Pilot, Esq., to FDA (Oct. 21, 1999) (Attachment I). FDA denied MDMA's petition for reconsideration on February 9, 2001. *See* Letter from David W. Feigal, Jr., M.D., M.P.H., to Larry R. Pilot, Esq. (Feb. 2, 2001) (Attachment J).

To date, OEMs have been unsuccessful in their efforts to eliminate reuse. To the contrary, there are strong indications that the practice of reprocessing not only will survive, but will greatly expand over the coming years. Indeed, the August 14, 2000, release of FDA's new regulatory approach to reprocessing has reconfirmed for the health care community that the agency intends to play a vigorous role in the oversight of reprocessing. As a result, reprocessing – which always has enjoyed overwhelming support in the clinical community[27] – increasingly will be embraced as a safe and effective cost savings mechanism.

As the current petition demonstrates, however, despite their past failures, OEMs have not abandoned their quest to eliminate reprocessing as an option for hospitals. In the instant matter, their approach ostensibly is to persuade FDA to enforce the trademark law in a way that the federal courts have declined to do. As noted above, in 1998, one of the leading OEMs sued a third-party reprocessor, alleging that the reprocessing of devices bearing the OEM's trademark(s) violated federal patent, trademark, and unfair competition laws, as well as a variety of state law principles.[28] The United States District Court for the District of Kansas rejected all of these arguments, and this decision was affirmed by the United States Court of Appeals for the Federal Circuit.[29]

Furthermore, ADDM admits that "many trademarks cannot easily, or even feasibly, be removed or covered."[30] ADDM's request that FDA enforce federal trademark law by deeming misbranded any reprocessed device bearing a trademark of an OEM is thus an obvious attempt to eliminate reprocessing, because if the presence of a trademark that cannot be removed or covered renders a reprocessed device misbranded, it cannot legally be distributed in interstate commerce.

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27 *See* Letter from Rick Pollock, Executive Vice President, American Hospital Association, to Senator Thad Cochran (June 23, 1999); Letter from Arthur Garson, Jr., M.D., F.A.C.C., President, American College of Cardiology, to Senator Richard Durbin (June 25, 1999); Letter from Gerald Naccarelli, M.D., President, North American Society of Pacing and Electrophysiology, to Senator Richard Durbin (June 22, 1999); Letter from Stephen C. Hammill, M.D., Professor of Medicine and Director of Electrocardiography and Electrophysiology Laboratories, Mayo Clinic, Rochester, Minnesota, to Senator Paul Wellstone (June 23, 1999) (Attachment K).

28 United States Surgical, 5 F. Supp.2d, *supra* note 9; ADDM acknowledges that the protection afforded a trademark under the Lanham Act is based on the same general principles underlying the FDCA's device misbranding provisions. ADDM Citizen Petition, *supra* note 1, at 6.

29 *See U.S. Surgical, aff'd* 185 F.3d 885, *supra* note 9.

30 ADDM Citizen Petition, *supra* note 1, at 5.

Such an interpretation would therefore effectively put reprocessors out of business. ADDM implicitly acknowledges that this is precisely the result it intends to accomplish, stating up front that "ADDM does not believe that a reprocessed single use device can [ever] be regarded as the equivalent to the OEM's device."[31]

III. Conclusion

In conclusion, for the reasons set forth above, AMDR opposes ADDM's request that FDA prohibit the marketing of reprocessed devices that bear a trademark belonging to an OEM. As demonstrated above, in AMDR's view, there is no legal basis for ADDM's request. Furthermore, granting the relief sought by ADDM would have the effect of ending reprocessing in this country. This result, which is the true objective of ADDM, is contrary to the public interest, as hospitals and physicians rely on proper reprocessing as a means of conserving health care resources and re-allocating them towards improvements in patient care.

Respectfully submitted,

Pamela J. Furman
Executive Director

PJF:la

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31 *Id.* at 7.