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CITIZEN PETITION

The undersigned, on behalf of the Association of Disposable Device Manufacturers (ADDM), submits this petition pursuant to sections 502, 510(k), 513, and 515 of the Federal Food, Drug, and Cosmetic Act (FDCA)[1] and 21 C.F.R. § 10.30.

The petition relates to the misbranding of reprocessed single use medical devices. Device reprocessors do not always remove the trademark of the original equipment manufacturer (OEM) from the device. Also, device reprocessors may refer to the OEM, or use the OEM's trademark, in the labeling of the reprocessed device without explaining the OEM's relationship to the reprocessed device. These practices misbrand the reprocessed device. ADDM is aware of no information that the Food and Drug Administration (FDA) has taken action to stop these practices, or that it has advised device reprocessors that the practices violate the FDCA.

1 All cited FDCA provisions are in 21 U.S.C. §§ 321 et seq.

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Display of OEM trademarks on reprocessed devices, and references to the OEM in reprocessed device labeling, have an exceptionally direct and powerful capacity to mislead physicians and other practitioners about the true manufacturer of the reprocessed device and to create a false impression about the reprocessed device's quality and fitness for use. Because of the immediacy of the harm they cause, and the obviousness of the FDCA violations they represent, these practices should not continue to be disregarded by FDA.

A. ACTION REQUESTED

We request the Commissioner of Food and Drugs to direct the Center for Devices and Radiological Health (CDRH) to do the following:

(1) Issue an announcement that failure to remove the OEM trademark from a reprocessed single use device, and references to the OEM in the label of the reprocessed single use device, constitute misbranding under section 502 of the FDCA.

(2) Conduct investigations, and take enforcement action as necessary, to identify and curtail these acts of misbranding.

(3) Refuse to approve premarket applications (PMAs) and to clear premarket notifications (510(k)s) for reprocessed single use devices unless the applicant represents to CDRH that the device in question will not be misbranded as specified in (1) as of the date of the PMA approval or 510(k) clearance.

B. STATEMENT OF GROUNDS

1. Introduction

FDA considers the reprocessing of single use medical devices to be a manufacturing activity. Consequently, reprocessors are subject to all regulatory requirements imposed on manufacturers of new medical devices.[2] FDA has traditionally exercised its enforcement discretion in two key areas with respect to reprocessing. First, the agency has declined to enforce the premarket requirements of the FDCA (PMAs and

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[2] See Letter from D.B. Burlington, M.D., CDRH, FDA, to N. Singer, Health Industry Manufacturers Association (July 13, 1998).

510(k)s) on commercial or hospital reprocessors. Second, the agency has not enforced the FDCA's general controls on hospital reprocessors. In addition, notwithstanding FDA's public position that commercial device reprocessors are fully subject to all of the FDCA's general controls, it does not appear that the agency has held these manufacturers to the same rigorous standards it applies to other device manufacturers.

In the past two years, FDA has made a commitment to increase the level of regulatory control over single use device reprocessing. The agency has convened public meetings, testified before both houses of the United States Congress, and issued several strategy and guidance documents on the subject. The agency's position has now evolved to one of full enforcement with respect to both commercial and hospital reprocessors.[3]

In FDA's regulatory paradigm, the reprocessor is the sole manufacturer of a reprocessed single use device. The OEM is not the manufacturer of the device. Consistent with this paradigm, the OEM's disposable device is no longer a "device" after it has been used for its intended purpose. Rather, it is raw material for the reprocessed device.[4]

The Enforcement Guidance states that reprocessors "are subject to all the regulatory requirements currently applicable to original equipment manufacturers."[5] Specifically, device requirements, including registration and listing, medical device reporting (MDR), medical device tracking, medical device corrections and removals,

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3 See CDRH, FDA, Guidance for Industry and FDA Staff, Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospital at 1 (Aug. 14, 2000) (Enforcement Guidance).

4 See id. at 1. The Enforcement Guidance itself does not attempt to characterize the regulatory status of the used OEM device. However, once a single use device is used, it has no further lawful purpose as a device under the FDCA, and must be discarded as medical waste. The OEM's device therefore ceases to exist after it is used as intended. Reprocessing the used device does not, and legally cannot, recreate the OEM's device. Rather, reprocessing is the manufacture of a new device from raw material consisting of the OEM's discarded device. This view is reflected in the statements of several FDA officials. See Larry G. Kessler, Sc.D., Director, Office of Surveillance and Biometrics (OSB), CDRH, FDA, Speech at the Regulatory Affairs Professionals Society Meeting "FDA and the Reuse of Single Use Devices: Policy Now Established" (Oct. 4, 2000) (Kessler Speech); Letter from M. Plaisier, FDA to Rep. T. Bliley, Jr., Committee on Commerce, House of Representatives at 2 (Nov. 29, 2000).

5 Enforcement Guidance at 1.

quality systems, labeling, and premarket requirements,[6] apply to both third party and hospital reprocessors.[7]

FDA intends to phase in the enforcement of the medical device requirements.[8] Premarket submission requirements must be met according to a timeline based on the classification of the device. For a Class III device, FDA must receive a 510(k) or PMA by February 14, 2001, and the device must be cleared or approved by August 14, 2001. For a Class II non-exempt device, the corresponding dates are August 14, 2001, and February 14, 2002, and for a Class I non-exempt device, February 14, 2002, and August 14, 2002. FDA intends to examine, on a case-by-case basis, whether reprocessed Class I and Class II exempt devices should continue to be exempt from premarket submission requirements.[9]

With respect to the FDCA's general controls, including labeling requirements, commercial reprocessors must currently be in compliance and hospital reprocessors must be in compliance by August 14, 2001.[10]

2. Reprocessed Device Labeling

The labeling of reprocessed single use devices raises a number of issues peculiar to this class of product. Nevertheless, other than referencing an existing device labeling

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6 With respect to the premarket requirements for reprocessed single use devices, the reprocessor must have either a cleared 510(k) or an approved PMA unless the classification regulation exempts the device from premarket submission requirements. A Class I or Class II device will require a 510(k) unless it is exempt. A Class III device will require either a 510(k) or a PMA. FDA will evaluate a 510(k) for a reprocessed single use device to determine substantial equivalence to a legally marketed predicate device. Reprocessed Class I or Class II single use devices need not be substantially equivalent to the OEM device. See Barbara Zimmerman, Office of Device Evaluation, CDRH, FDA, Statement at FDA Satellite Videoconference "Reprocessing Single-Use Devices in Hospitals: An FDA Primer" (Dec. 13, 2000) (Zimmerman Statement) ("[Reprocessors] do not need to use the predicate device for the original equipment manufacturer. They can use any predicate device that they determine is substantially equivalent to their device.").

7 See Enforcement Guidance at 13.

8 See id. at 6.

9 See id.

10 See id. at 30-31.

guidance document,[11] FDA has been silent about how reprocessors are to comply with the device labeling rules.

This petition relates to only one such labeling issue, but it is an important one. Single use devices often bear the trademark of the OEM on the device itself. As required by the FDCA and FDA's regulations, the label for a single use device also bears the name of the OEM. According to ADDM's information, when a single use device is reprocessed, the reprocessor often leaves the OEM's trademark on the device. The reprocessor also creates a new label for the reprocessed device. The new label usually contains the name of the OEM, the trademark of the device, or both. The label may or may not contain the name of the reprocessor.[12]

ADDM has not conducted a comprehensive survey to determine the extent of the practices just described. Not all single use devices bear a trademark on the device itself. Of those that do, some may have the OEM trademark printed on the surface, attached by an adhesive label, or engraved or molded into one or more components.[13]

Device reprocessors may, in some cases, remove, mask, or obliterate these OEM trademarks. However, ADDM has examples of reprocessed devices in which this was not done.[14] Moreover, it seems reasonable to assume that often, and perhaps routinely, no such measures are taken. First, many trademarks cannot easily, or even feasibly, be removed or covered. Second, device reprocessors have an obvious interest in not obscuring the identity of the single use device, because customers will want to select reprocessed devices based on their experience with, or knowledge of, the single use devices made by the OEMs.

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11 See id. at 18 (citing CDRH, FDA, Labeling Regulatory Requirements for Medical Devices (Aug. 1989)).

12 Commercially reprocessed devices bear a label with the name of the reprocessor, and, in at least some cases, the OEM's name or trademark as it appears on the single use device. See Exhibit A. Devices reprocessed by hospitals may more commonly be labeled with the OEM's name or trademark alone.

13 The five examples in Exhibit B demonstrate various trademarks and tradenames printed or embossed onto single use medical devices.

14 The two examples in Exhibit C show both the reprocessor's label and the reprocessed device, which continues to bear the OEM's trademark. In the first example, an OEM name (Microvasive®) remains molded into the plunger of the reprocessor's biopsy forceps. In the second, both an OEM name (Boston Scientific Microvasive®) and trademark (Contour™) remain visible on an adhesive label attached to the reprocessor's ERCP cannula.

With respect to labeling for reprocessed single use devices, ADDM has no reason to believe that the four examples in Exhibits A and C are atypical. The labels identify the reprocessor, and also identify the OEM next to the abbreviation "mfg." or "mfg. name," without any explanation of what, if any, relationship the OEM has to the reprocessed device.

Continued display of the OEM's trademark on a reprocessed single use device, and references in the label to the OEM, especially in association with "manufacturing," are not compatible with the FDCA. The reprocessor, not the OEM, is the manufacturer of the reprocessed device.[15] Once used, the OEM's device ceases to exist as a lawful product and becomes waste material the reprocessor recycles to manufacture its own device product. It is therefore misleading for the OEM's trademark to appear on the reprocessed device, or for the OEM to be identified in the reprocessed device's labeling. Nevertheless, FDA has not publicly objected to these reprocessor labeling practices. This petition discusses several legal and policy problems created by FDA's lack of guidance and enforcement in this area, and requests that CDRH be directed to take action to address those problems.

a. Trademarks

FDA does not enforce the law of trademarks. However, trademarks serve many of the same purposes as the misbranding provisions of the FDCA. The device misbranding provisions protect physicians and patients from being misled about the source and quality of medical products. Trademarks and trade names[16] identify a company and its products, and distinguish them from the company's competitors and their products, so as to avoid marketplace confusion about the source and quality of trademarked products. Just as section 502 of the FDCA prohibits device misbranding, section 43(a) of the Lanham Act protects trademarks from infringement. The objective in both cases is assuring that decisions to buy and use products are based on accurate information.

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15 See footnote 4.

16 Trademarks identify and distinguish a company's goods while trade names are used to distinguish companies and symbolize the reputation of a business as a whole. See 15 U.S.C. § 1127. Courts rarely distinguish between trademarks and trade names because trade names often function as trademarks. See Accuride Int'l, Inc. v. Accuride Corp., 871 F.2d 1531, 1534-35 (9th Cir. 1989). Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), protects both trademarks and trade names from uses that may cause confusion or deception as to the origin of goods. See id. Some OEM names might be protected as trademarks and others might be protected as trade names. Because both are protected under section 43(a) of the Lanham Act, however, we do not distinguish between trademarks and trade names in this section.

Use of trademarks by OEMs for medical device products reinforces FDA's device misbranding provisions. Trademarks have commercial value as symbols of quality; they are central to an OEM's competitive position and promotional strategies. OEMs have an incentive to ensure that trademarked products consistently deliver the quality buyers expect, and, conversely, that medical device products not made by them do not falsely use the OEM's trademarks.

The efficiency of the trademark in communicating device product quality means that an FDCA misbranding violation involving the misuse of a trademark is correspondingly more dangerous: When a medical product is backed by a strong trademark, the user's reliance on the trademark – rather than on personal judgment or independent sources of information – is at its highest. If the user's reliance is misplaced, because the trademark is being falsely used by another entity for a different product, the user has been deterred from taking adequate measures to determine the product's true quality.

For this reason, ADDM believes that FDA should not affirmatively allow, or continue to acquiesce in, labeling practices of reprocessors in which OEM trademarks appear on reprocessed medical devices or the OEM's name or trademark is used in reprocessed device labeling. These practices 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.

Neither of these assumptions is true. To take an obvious example, according to FDA, a 510(k)ed reprocessed device need not be substantially equivalent to the OEM device, but may be cleared if it is substantially equivalent to a different predicate device.[17] Such a reprocessed device would therefore not even be substantially equivalent to the OEM device whose trademark appears on the product.

In the more typical case, ADDM expects that an assertion of equivalence would be based on the OEM's single use device. ADDM does not believe that a reprocessed single use device can be regarded as equivalent to the OEM's device. Whether or not FDA agrees, however, physicians and others should assess a reprocessed device as a distinct, free-standing product and reach their own conclusions about whether to use the device without being confounded by the presence of trademarks and other indicia of quality associated with the OEM's original single use device. Not only are these markings irrelevant after the OEM's device has been used, discarded and then converted into raw

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17 See Zimmerman Statement ("[Reprocessors] do not need to use the predicate device for the original equipment manufacturer. They can use any predicate device that they determine is substantially equivalent to their device.").

material for reprocessing, they are also contradictory of the design and intended use of the OEM's product. Most OEMs, rather than place their reputation behind their single use devices after being reprocessed, affirmatively warn against reuse.

Identifying the reprocessor in the labeling of a reprocessed trademarked device does not address the problem. The reprocessor is the only manufacturer of the device; the OEM is not the manufacturer of the device. Yet, the purpose of the OEM's trademark is to communicate the message that the product bearing the mark is manufactured by the OEM and is backed by the OEM's good name and reputation.

A reprocessor of a single use device cannot negate the immediacy and strength of the message conveyed by the OEM's trademark merely by attaching a label bearing the reprocessor's name. Putting aside the contradiction between identifying the reprocessor as "the" manufacturer of a product bearing another manufacturer's trademark, the reprocessor's label is simply ineffective: the only message likely to be received by persons examining the product will be the OEM's trademark.[18]

The protection afforded a trademark under the Lanham Act is based on the same general principles underlying the FDCA's device misbranding provisions. The principle is that it is important to protect the ability of product purchasers to know what they are buying and to distinguish among competing producers of similar goods.[19] By prohibiting misuse and infringement, the Lanham Act strengthens the ability of the trademark to fulfill this consumer protective purpose. It also gives manufacturers an incentive to use the trademark as a vehicle for communicating product quality. The trademark owner's reputation and good will – ultimately, its commercial viability – are based on whether the product it sells lives up to the claim implied in the trademark.

This petition does not take a position on whether, as a technical matter, the use of OEM trademarks on reprocessed devices generally, or in specific cases, violates federal trademark law.[20] Rather, it explains why, given FDA's regulatory paradigm, the

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18 The examples in Exhibit B demonstrate the visual impact of an OEM trademark. It is unrealistic to suppose that a physician who examined, for example, the endoscopic linear cutters marked "ETS Compact-Flex Ethicon Endo-Surgery" would have the impression that the reprocessed version of this product was not the device manufactured by the OEM, Ethicon Endo-Surgery.

19 See S. Rep. No. 79-1333, 79th Cong., 2d Sess. 3, 5 (1946), reprinted in 1946 U.S.C.C.A.N. 1274, 1277.

20 In U.S. Surgical Corp. v. Orris, Inc., 5 F. Supp 2d 1201 (D. Kan. 1998), the court held that reprocessing a single use device without removing the OEM's trademark did not constitute "use" of the trademark "in commerce," and therefore did not cause the trademark to be

(...continued)

agency's continued toleration for reprocessors' use of OEM trademarks violates the FDCA. In that context, the visual impact of the trademark, and the powerful message it communicates to buyers and users of medical products, must be recognized in evaluating the significance of device misbranding under the FDCA that involves the misuse of trademarks.

b. Retaining the OEM's trademark on the reprocessed device

Under the FDCA, it is objectionable for a reprocessor of a single use device to retain the OEM's trademark on the reprocessed device. First, the reprocessed device is misbranded under section 502(a) of the FDCA because its labeling is false or misleading. Second, by selling a reprocessed single use device with the OEM's trademark on it, the reprocessor is selling both an imitation device and a counterfeit device. The FDCA does not create separate misbranding violations for imitation and counterfeit devices. However, the section 502(a) device misbranding violation caused by trademark misuse on reprocessed devices is underscored by the fact that such misuse also results in a device that meets the specific FDCA criteria for an imitation or counterfeit product.

(1) Misbranding under section 502(a) of the FDCA – false and misleading

Section 502(a) of the FDCA provides that a device is misbranded "[i]f its labeling is false or misleading in any particular." The OEM's name on the device is labeling under section 201(m)(1) of the FDCA because it is "written, printed, or graphic matter . . . upon" the regulated device. A reprocessed single use device with the OEM's trademark on it is falsely labeled. The trademark represents that the manufacturer of the device is the OEM. It also represents that the device is the OEM's device. According to FDA, the OEM did not manufacture the reprocessed device. Further, the device is not the OEM's device, but a distinct, different device manufactured by the reprocessor.

The significance of this false labeling is magnified by the fact that it involves the use of a trademark. 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. Both messages are contrary to fact. As reprocessed, the device is manufactured only by the reprocessor; the OEM's discarded

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infringed. The court's decision was based on the premise that the reprocessing constituted a "repair" of the OEM's device. Id. at 1208-09. The court did not have before it FDA's current regulatory paradigm, in which the reprocessing of a single use device is not a "repair" of the OEM's device but creates a distinct, new device manufactured by the reprocessor.

single use device is merely a raw material. The OEM, far from standing behind the reprocessed device's quality, either recommends against reprocessing, or has no control over or information about the reprocessing to which the device has been subjected, and therefore could not validly make any representation about the reprocessed device, even if it wanted to.

It is not acceptable under the FDCA for a reprocessed device to continue to bear the OEM's trademark. The trademark falsely represents that the device is made by the OEM. It falsely implies that the OEM has some greater involvement in the device's manufacture than that of a source of raw material.[21] It conveys assurance of quality from the OEM – for that is what a trademark is for – that is false, both because the OEM has made no such assurance about the product that bears the mark – the reprocessed device – and because the OEM has no knowledge about the reprocessed device product on which to base any conclusion as to its quality.

If an OEM were to approach FDA with a proposal to affix a second company's trademark to the OEM's device, while pointing out to FDA that the second company not only had no relationship with the OEM but was also completely ignorant of both the OEM's device and the OEM's intention to use the second company's trademark, we are confident the agency would advise the OEM that the device would be misbranded and that the OEM would be held legally responsible for violating the FDCA were it to carry out its plan. It is not reasonable for FDA to tolerate trademark misuse by device reprocessors that would, if engaged in by OEMs, be condemned as plainly illegal.

Accordingly, ADDM requests FDA to direct that CDRH explicitly state that failure to remove the OEM's trademark from a reprocessed single use device causes the reprocessed device to be misbranded. ADDM further requests that FDA direct CDRH to state its intention to enforce the misbranding provisions of the FDCA against any such misbranded reprocessed device, and any reprocessor that is responsible for the misbranding.

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21 This petition does not address situations in which a trademark of a product intended for use as a raw material or a component of another product appears on, or is included in the labeling of, the other product in a way that is not misleading. This situation occurs in consumer products generally, although it is not clear that it would be permissible for devices under the FDCA. See 21 C.F.R. § 801.1.

(2) Misbranding under section 502(a) of the FDCA – MDR confusion

Misbranding by misrepresenting the identity of the reprocessed device's manufacturer is especially objectionable because of its effects on other aspects of device regulation, most notably the MDR system. See FDCA § 519(a)-(c); 21 C.F.R. pt. 803. Under the MDR system, hospitals (and other medical device user facilities) must alert FDA or the manufacturer to information "reasonably suggest[ing] that a device may have caused or contributed to the death ... [or] serious injury of a patient." 21 C.F.R. § 803.30. Manufacturers must report that information, as well as information about device malfunctions. 21 C.F.R. § 803.50. It is from such reports that FDA constructs the MDR database. The MDR database allows FDA and others to monitor trends in device failure and injury. The presence of the OEM trademark on a reprocessed single use device leads to inaccurate reporting when hospital personnel responsible for MDR compliance assume that the OEM made the device.

While the ability to identify the manufacturer from the product itself is important for drugs, it is often indispensable for devices. Drugs are ingested (or otherwise consumed). If there is an adverse event, the reporter must refer to the drug's label to identify the manufacturer; the markings on the dosage form are irrelevant, because the drug no longer exists. However, the device associated with an adverse event is generally intact and available for inspection. The reporter will likely look only at the device to identify the product and its manufacturer. In this scenario, the reporter will erroneously identify the OEM as the manufacturer of a reprocessed device, unless the OEM's trademark is removed by the reprocessor.

The likelihood that the reporter will fail to consult the reprocessor's label is highest for surgical devices because the wrapper containing the label is frequently discarded when the device is placed into the sterile surgical area in advance of the procedure. If the device fails, the user has no option but to determine the manufacturer of the device by inspecting the device itself.

But even in the case where the reprocessor's label is available, there is a significant possibility that the presence of the OEM's trademark will be interpreted as signifying the "true" manufacturer of the device to which MDRs should be reported. Again, it is important to keep in mind the power of a trademark, and its function as a mechanism for identifying the origin of a product: The very fact that a trademark is allowed – by FDA – to be present on a device product will likely be interpreted as signifying that the trademark's owner – the OEM – made the product and stands behind it. Inevitably, MDRs associated with reprocessed devices will be reported to the OEM rather than to the manufacturer of the reprocessed device.

In sum, when devices that have been reprocessed bear the names of the OEMs instead of their actual manufacturers, the result will be underreporting of adverse events associated with reprocessed devices and overreporting of adverse events attributable to the single use device that has been reprocessed. For this additional reason, CDRH must require OEM trademarks to be removed from reprocessed devices.

(3) Misbranding under section 502(a) of the FDCA – violation of 21 C.F.R. § 801.6

FDA's regulations implementing the FDCA's misbranding provisions state that a device is misbranded if its labeling contains a "false or misleading" reference to another device. 21 C.F.R. § 801.6. A reprocessed device which bears the OEM's trademark contains a reference to the OEM's device. The OEM's device and the reprocessed device are two different devices. Leaving the OEM's trademark on the reprocessed device implies that the reprocessed device was manufactured by the OEM or is the same as the OEM's product. Such an implication is false and misleading. Therefore, a reprocessed device bearing the OEM's trademark is misbranded under section 502(a) by reason of the explicit terms of 21 C.F.R. § 801.6.

(4) Misbranding under section 502(a) of the FDCA – imitation and counterfeit device

A reprocessed single use device that bears the trademark of the OEM is an imitation of the OEM's device. Section 502(i)(2) of the FDCA speaks directly to misbranding by imitation of another drug. This provision does not apply to devices, but the principle underlying the provision is that a product that imitates another product is inherently "false or misleading" to the user even if it bears no labeling at all. An "imitation drug" is one "that (1) resembles a second drug, and (2) is inferior in some sense to the second drug product, e.g., the 'imitation' drug product does not contain the ingredients or pharmacological properties of the 'real' drug product."[22]

By this analysis, a reprocessed device that bears the OEM's trademark is an imitation device. The reprocessed device "resembles" the single use device of the OEM. The reprocessed device is "inferior" to the OEM product in that (1) it has previously been used in patients and therefore bears a risk of cross-contamination not present in a new device, and (2) its structural components have been subjected to the fatigue of previous use, thereby potentially decreasing their lifespan and increasing the likelihood of sudden failure. Finally, a reprocessed device has minimal labeling, and that labeling is often removed before the reprocessed device is provided for use by physicians and other

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22 United States v. Articles of Drug, 825 F.2d 1238, 1245 (8th Cir. 1987) (emphasis in original).

professionals. Therefore, the physical characteristics of the device itself are the dominant, or only, source of information to the user of the reprocessed product, and the OEM's trademark not only invites, but virtually forces, the erroneous conclusion that the product is, in actuality, the product of the OEM, not the reprocessor.

Reprocessed devices bearing the OEM trademark are not within the scope of the "imitation drug" misbranding provision. Nevertheless, they have the same inherently "false or misleading" characteristics as imitation drugs, and thus the misbranding of those devices under section 502(a) by use of the trademark is all the more objectionable.

A reprocessed single use device that bears the OEM trademark is also a counterfeit device. Although the "counterfeit" definition in the FDCA, section 201(g)(2), applies only to drugs, its terms specify the characteristics that justify characterizing a product as "counterfeit." Thus, a "counterfeit drug" is:

> a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, packer or distributor.

"The essence of counterfeiting is the unauthorized use of the trademark, trade name, or other identifying mark. Thus, even if tablets were chemically indistinguishable from Motrin, counterfeiting could still be found."[23]

A device reprocessor who leaves the OEM's trademark on a reprocessed device counterfeits a device, because the reprocessed device is no longer the OEM's device, but a separate device manufactured only by the reprocessor. A counterfeit device is objectionable for the same reason as an imitation device: It induces in the user the false belief that the device is made by a manufacturer whose reputation is a guarantor of the quality of the trademarked device. In reality, that manufacturer has no involvement in the fabrication of the device. As the FDA noted with respect to counterfeit drugs:

> The counterfeit drug is not manufactured under the controls or with the care that is necessarily taken for the legitimate drug it

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[23] United States v. Jamieson-McKames Pharmaceuticals, Inc., 651 F.2d 532, 543 n.22 (8th Cir. 1981).

> imitates, and there is no guarantee that the counterfeit drug contains the amounts, quality, and kinds of ingredients the legitimate drug contains. A consumer who is sold a counterfeit drug may have his health and even his life dependent on a product which has little or no resemblance to the drug prescribed by his physician, except for labeling or appearance. In turn, his physician may be misled in his intended therapeutic regimen by the different response of the patient to the drug from that anticipated.[24]

These types of concerns plainly arise in the device reprocessing context. Consider FDA's paradigm for clearing 510(k)s for reprocessed devices. FDA has stated that for a reprocessor to demonstrate that a reprocessed single use device is substantially equivalent to a legally marketed device, the reprocessor need not use the underlying single use device as the predicate.[25] As a result, Manufacturer A's device, after reprocessing, can be marketed by showing that it is substantially equivalent to a device made by Manufacturer B. If a reprocessed device bears the name of the OEM who manufactured the underlying device, and yet is marketed based on substantial equivalence to the single use device of another OEM, the reprocessed device may not perform as the physician would expect based on the trademark of the OEM that appears on the device. If the OEM's trademark remains on the reprocessed device, the result exactly tracks the "counterfeit" product concerns stated by FDA to Congress over 30 years ago.

If the FDCA singled out imitation and counterfeit devices, as it does imitation and counterfeit drugs, a reprocessed device bearing the OEM's trademark would be per se illegal. The FDCA does not have imitation and counterfeit device provisions, of course, but the point remains. Imitation drugs are misbranded because their physical resemblance to other drugs makes them inherently false or misleading. Counterfeit drugs are a subclass of imitation drugs for which more severe enforcement sanctions are considered necessary. The purpose of the imitation and counterfeit drug provisions of the FDCA is to dispense with the necessity for pointlessly debating whether such drug products are "false or misleading" under section 502(a). But if they meet the "imitation" and "counterfeit" criteria, they are, in fact, "false or misleading." It follows that devices that possess the same features that make a drug an "imitation" or "counterfeit" product – physical resemblance, use of another manufacturer's trademark – are likewise "false or

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24 Hearings Before the Committee on Interstate and Foreign Commerce of the House of Representatives, on the Drug Abuse Control Amendments of 1965, H.R. 2, 89th Cong. 31 (statement of George P. Larrick, Commissioner, FDA).

25 See Zimmerman Statement.

misleading" under section 502(a). A reprocessed device that bears the OEM's trademark is, as an imitation and a counterfeit product, a misbranded device under section 502(a) – without need for debating the issue.

FDA should not allow or tolerate the presence in the medical device market of reprocessed devices that are misbranded under section 502(a) by reason of being imitation, counterfeit versions of single use devices because they bear the OEM's trademark.

c. Using the OEM's name or trademark on the reprocessed device label

A commercial reprocessor will generally label a reprocessed single use device with both the name of the OEM of the single use device and the reprocessor's own name. Identification of the OEM may include the use of the abbreviation "mfg."[26] This labeling practice, with or without the qualifier "mfg.," renders the device misbranded under subsections 502(a) and (b) of the FDCA.

(1) Misbranding under section 502(a) of the FDCA

Identifying both the OEM and the reprocessor on the label of a reprocessed single use device misbrands the reprocessed device. A device is misbranded "if its labeling is false or misleading." 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 one of two possibilities. One possibility is that two entities are responsible for manufacturing the device. The second is that a cooperative relationship exists between the OEM and the reprocessor.

Under FDA's regulations,[27] and in accordance with industry practice, companies identified in the labeling of a finished medical product have a direct involvement in the manufacture, packing, or distribution of the product. It is not common practice to identify the source of the raw material used in a drug or a device on the device's label. In fact, it is not clear that doing so would be consistent with the agency's labeling regulations. See 21 C.F.R. §§ 201.1, 801.1. Accordingly, if 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 infer that the

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26 See Exhibit A.

27 See 21 C.F.R. §§ 201.1, 801.1.

OEM is a direct participant in making the finished reprocessed device product available. This implication is inconsistent with the underlying reality and is therefore misleading.

An alternative interpretation for the presence of the OEM's name in the labeling for a reprocessed device is that the OEM has a contractual arrangement with the reprocessor. That implication, too, is contrary to fact. The misleading nature of the implication is not trivial. An OEM that contracted, or otherwise cooperated, with a device reprocessor to the extent compatible with the use of the OEM's name in the reprocessed device's labeling would be expected to have independently verified the acceptability of the reprocessor's manufacturing choices and the integrity of the reprocessed device as its minimal obligation to the end users who will see the OEM's name in the label of the reprocessed device. But the OEM does not do these things. The OEM has no contractual or cooperative relationship with the reprocessor. Accordingly, use of the OEM's name in the labeling of the reprocessed device causes the labeling to be misleading and the device to be misbranded.

It is not tenable to maintain that both the OEM's and the reprocessor's names can be used in the labeling of a reprocessed device without giving rise to a false inference about the role of the OEM or its relationship to the reprocessor. The most likely inferences are that the OEM is a "manufacturer" of the reprocessed device or that it supports the reprocessor's activity. But even if no specific inference were drawn from the presence of the OEM's name in the labeling of the reprocessed device, at a minimum, the presence of both manufacturers' names is potentially confusing – a situation that results in misbranding under section 502(a).[28]

(2) Misbranding under section 502(b) of the FDCA

Section 502(b) of the FDCA provides that a device is misbranded "unless it bears a label [that] contain[s] ... the name of the manufacturer, packer, or distributor." FDA's implementing regulation is specific with respect to how persons involved in the manufacturing or distribution of a device may be described. 21 C.F.R. § 801.1(c). A reprocessed single use device whose labeling contains the name of both the reprocessor and the OEM violates the statute and regulations.

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28 See United States v. 400 Cases, More or Less, Civil No. 3898 (W.D.N.Y. Oct. 28, 1950) reprinted in Vincent A. Kleinfeld & Charles W. Dunn, Federal Food, Drug, and Cosmetic Act; Judicial and Administrative Record 1949-1950, vol. II, at 922-923 (1951), in which a package of frozen strawberries the label of which stated "This one pound package serves 4." and "net weight 14 oz." was deemed misbranded.

The 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. The parallel regulation for drugs, issued under the same statutory provisions[29] as the device regulation, recognizes that the identification of any person on the label of a product implies that the person has performed a manufacturing operation, including packing, or is a distributor. The drug regulation prohibits the identification on the label of any person "other than the manufacturer, packer, or distributor." Id. § 201.1(h). 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.

Neither the device nor the drug regulation accommodates the identification of a raw material source on the label of a finished product. In the case of drugs, the regulation explicitly prohibits the identification of any person that does not participate in manufacturing or distribution. The basis for this prohibition is that such identification would be false or misleading under section 502(a). The device regulation is less specific. It requires only that any person identified on the label have a "connection" with the device. In context, however, this limitation is the same as for drugs: It is meaningless to have "a connection with" a device without being a direct participant in manufacturing or distributing the device. A source of raw material does not have "a connection with" a device sufficient to support inclusion of the source's identity on the device label. 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 the regulation. Accordingly, any identification of the OEM on the device label is a violation of 21 C.F.R. § 801.1.

(3) Disclosure of additional facts would be insufficient to avoid misbranding

Assuming that 21 C.F.R. § 801.1 could be interpreted to permit identification on a device label of a company with no active participation in making or distributing the device, such identification would be subject to sections 502(a) and 201(n) of the FDCA. Under those provisions, no false or misleading statement is permitted in device labeling, and even an accurate statement is misleading if there is a failure "to reveal facts material in the light of" the statement in question.

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29 The regulations implement both sections 502(a) and 502(b) of the FDCA.

The OEM is the manufacturer of a single use device that is raw material for a reprocessed device manufactured and distributed by another company. ADDM is not aware of the full range of labeling practices in the reprocessed device industry. Plainly, the practice of using the OEM's name or trademark in association with the abbreviation "mfg." or similar terms, as in the case of the examples in Exhibits A and C, is affirmatively misleading and prohibited under the statute and regulations. It is possible, however, that other device reprocessors use labels that do not imply that the OEM is the "manufacturer" of the reprocessed device.

Nevertheless, a reprocessed device label that identified the OEM in any form would violate the label regulations and, more generally, would be misleading by implying a relationship of the OEM to the reprocessed device. Even use of the OEM's name or trademark with an explanation that the OEM's device is "raw material" (or similar phraseology) would not remedy the problem. Such a statement would erroneously imply that the OEM intended to provide the single use device to the reprocessor for the purpose of serving as raw material to be reprocessed. It would also convey related false inferences, such as that the OEM had determined that the single use device was fit for the purpose of being reprocessed for one or more additional uses.

FDA should not permit these misleading inferences. The OEM of a single use device has not provided its device for the purpose of recycling, and it has made no determination that the device is fit for that purpose. Further, in most cases, the OEM affirmatively recommends against the reuse of a single use device.

ADDM believes it is unlikely that device reprocessors can create labeling that would both identify the OEM and effectively avoid misrepresenting the relationship of the OEM to the reprocessed product. Any labeling for a reprocessed product would have to reveal such material facts as:

- The source of the single use device used as raw material is not the OEM but the institution (e.g., the hospital) from which the reprocessor obtained the device.
- The OEM has made no determination that the single use device is fit for the purpose of reprocessing.
- Where applicable, the OEM recommends against reprocessing.
- Where applicable, the reprocessed device has not been shown to be substantially equivalent to the OEM's single use device.

Labels that referenced the OEM's name or trademark but disclosed the material fact that, for example, the OEM recommends against reuse would be internally contradictory and

confusing. More importantly, simply providing additional facts on the reprocessed device label would not overcome the implicit representation inherent in the use of the OEM's name or trademark. That representation is that, notwithstanding the reprocessor's disclaimers and qualifying information, the reprocessed device remains, in some important sense, the same product that the OEM manufactured and distributed for single use only. Accordingly, the label of a reprocessed device can avoid misbranding the product only by omitting all references to the OEM's name or trademark.

(4) Reprocessed device labels should omit references to the OEM's name or trademark

For the reasons in (1) – (3), reprocessed single use device labels should not contain references to the OEM's name or trademark. The potential inherent in such references for misleading buyers, physicians, and others as to the OEM's degree of involvement in the creation of the new product from the "raw material" is too great to be tolerated within an enforcement scheme meant to assure that medical judgments are based on complete and accurate information.

Even assuming that FDA could develop criteria for identifying the OEM in the label of reprocessed single use devices consistent with subsections 502(a) and (b) of the FDCA, those criteria would be undermined if the single use devices themselves continued to bear the OEM's trademark after being reprocessed. The trademark would not only be inconsistent with the label, it would overwhelm the label. Furthermore, the label of a reprocessed device is often removed before the device is provided to the persons who actually use the device. Hence, the OEM's trademark cannot remain on a reprocessed single use device under any acceptable interpretation of the FDCA's device misbranding provisions.

3. FDA Should Enforce the FDCA

FDA has stated that commercial device reprocessors have been expected to comply with the FDCA's general controls for years, and that beginning August 14, 2001, FDA will no longer exercise enforcement discretion with respect to hospital reprocessors. Based on ADDM's information, and on reasonable assumptions about real world circumstances, commercial reprocessors of single use devices are not, in fact, in compliance with the device labeling provisions of the FDCA with respect to the OEM's name and trademark. Moreover, unless FDA clearly announces a specific position against device misbranding involving the OEM's name and trademark, violations by commercial and hospital reprocessors are certain to persist: FDA's past toleration of these label practices engaged in by commercial reprocessors will be interpreted as a signal that they will be tolerated indefinitely in the future in both commercial and hospital reprocessing contexts.

Such a result would make a mockery of the FDCA's labeling rules. The foundation of CDRH's acceptance of single use device reprocessing as consistent with the FDCA is the principle that the reprocessed device is a distinct product, wholly separate from the single use device that has been reprocessed. In this paradigm, the single use device is merely raw material. If that is so, then the FDCA's labeling rules, interpreted in accordance with CDRH's own theory, forbid the appearance on the reprocessed product of the trademark for the single use device. The single use device on which the mark appears no longer exists, and the mark is therefore false.

The OEM has no involvement in the activities that eventuate in the reprocessed device. The OEM does not even "supply" the single use device for purposes of later becoming a "raw material" for the manufacture of a new device. Instead, the OEM's used and discarded device is scavenged for recycling into a wholly different product by a reprocessor. References to the OEM's name or trademark in the label of this product are therefore deceptive.

Because the misuse of the OEM's name and trademark in connection with reprocessed single use devices is directly contrary to CDRH's regulatory paradigm and causes blatant violations of the FDCA, the Commissioner should direct CDRH to issue a specific announcement that these practices are illegal and must cease immediately, and follow up with appropriate investigations and enforcement actions.

The Commissioner should also direct that CDRH announce that 510(k)s will not be cleared, and PMAs will not be approved, for any reprocessed single use devices unless the applicant states that the marketing of the device pursuant to the clearance or approval will not involve acts of misbranding consisting of the misuse of the OEM's name or trademark. With respect to 510(k)s, CDRH procedures do not include a detailed review of labeling to assess whether or not a product is, or will be, misbranded. Nevertheless, CDRH should not permit the 510(k) procedure to become a means for indirectly ratifying objectionable labeling practices. Therefore, CDRH should require all 510(k) applicants to represent that the reprocessed single use device proposed for clearance will not bear the OEM's trademark, and that its label will not violate subsections 502(a) and (b) by reason of misleading references to the OEM's name or trademark.

C. ENVIRONMENTAL IMPACT

A claim for categorical exclusion from the requirements of 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.

E. CERTIFICATION STATEMENT

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 to the petitioner which are unfavorable to the petition.

Respectfully submitted,

Thomas Scarlett