

**ATTACHMENT G**

4900 '99 MAY 21 09:49

May 20, 1999

Larry R. Pilot  
202-496-7561  
larry\_pilot@mckennacuneo.com

Dockets Management Branch  
Food and Drug Administration  
Department of Health and Human  
Services  
Room 23  
12420 Parklawn Drive  
Rockville, MD 20857

**Re: Citizen Petition To Ban Reprocessed Single Use Devices**

Dear Sir/Madam:

The Medical Device Manufacturers Association (MDMA) submits this petition in accordance with 21 C.F.R. § 10.30 and pursuant to the requirements described in Section 516 of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 360f, to request the Commissioner of Food and Drugs to issue a proposed regulation identifying reprocessed single use devices as banned devices and declaring such proposed regulation to be effective upon its publication in the Federal Register (F.R.).

The MDMA is a trade association which represents approximately 130 manufacturers of various devices, many of which are not intended for reuse by or on subsequent patients because of a variety of unreasonable risks to such patients. These devices are accompanied by labeling which makes clear that the device is "single use only," "not for reuse," "to be disposed after use," or through similar language to prevent the reuse of the device. For many devices, the Food and Drug Administration (FDA), has approved the device through a Premarket Approval (PMA) application or a premarket (510 (k)) notification, which requires that the labeling make clear that the device is not intended for reuse.

99P-1516

CP1

Dockets Management Branch  
May 20, 1999  
Page 2

**A. Action Requested**

The MDMA requests that the Commissioner issue a regulation to appear in Title 21 of the Code of Federal Regulations (C.F.R.) identifying as banned devices "Reprocessed single use devices." The proposed regulation describing the banned device is as follows:

§ 895. xxx Reprocessed Single Use Devices.

Reprocessed single use devices are devices which the original manufacturer of the finished device has released with labeling that clearly identifies the device as "Single Use Only," "Not For Reuse," "Do Not Reuse," and/or includes similar statements which clearly indicate that the original manufacturer does not intend for the device to be reused. The finished single use device as released by the original manufacturer may be either sterile or unsterile.

**B. Statement of Grounds**

**I. Background**

Since prior to the enactment of the 1938 FDCA, various devices<sup>1</sup> have been available to consumer and health care personnel for repetitive use or reuse on

---

<sup>1</sup> The term "device" as defined in 201(h) of the FDCA, 21 U.S.C. § 321(h), "...means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is -

- (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
- (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease, in man or other animals, or
- (3) intended to affect the structure of any function of the body of man or other animals, and

*(Footnote cont'd on next page.)*

individuals. Devices such as heating pads, ice bags, elastic wrappings, crutches, etc. have been available to consumers without any limitation as to the number of uses or the number of users exposed to the device. For some devices, instructions for cleansing of the device or other conditions relating to reuse have been described in the labeling or are understood by custom of usage.

Other devices such as surgical instruments or diagnostic products used by health care professionals have required special handling procedures including, but not limited to, institutional repackaging and sterilization of devices. This latter activity is generally performed in hospitals by central supply services which apply state-of-the-art technology, manufacturer instructions, and/or compliance with voluntary standards. For example, the Association for the Advancement of Medical Instrumentation (AAMI) has developed comprehensive standards relating to health care institutional sterilization practices. Additionally, organizations such as the American Society of Healthcare Central Service Professionals (ASHCSP) and the International Association of Healthcare Central Supply Material Management (IAHCSMM) exist and function on behalf of their members to assure application of state-of-the-art practice for patient benefit.

As the FDA began to expand its administrative activities in 1970 after release of the Cooper Committee Report<sup>2</sup> and prior to passage of the Medical Devices Amendments of 1976 (the "1976 Amendments")<sup>3</sup>, considerable interest was directed toward the practice of reusing devices that were labeled for single use.

---

*(Footnote cont'd from previous page.)*

which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

<sup>2</sup> A Department of Health, Education, and Welfare, Study Group on Medical Devices, under the Chairmanship of Theodore Cooper, M.D., issued a report in September, 1970 titled "Medical Devices: A Legislative Plan." This report represented the foundation for subsequent legislative changes in 1976.

<sup>3</sup> Public Law No. 94-295, May 28, 1976.

This interest coincided with the development of increasingly sophisticated interventional devices used initially by cardiologists. These devices represented technological breakthroughs for which proper handling of these devices was critical to safe and effective use. Notwithstanding admonitions from the manufacturer, some institutional users believed that reuse was possible. In January of 1975 the Bureau of Health Insurance of the Social Security Administration issued a letter to state government agencies stating that disposable guidewires and catheters were not to be reused.

The FDA subsequently issued a Compliance Policy Guide (CPG) on "Reuse of Medical Disposable Devices (CPG 7124.16). The CPG recognized that "The reuse of disposable devices represents a practice which could affect both the safety and effectiveness of the device." However, it stopped short of expressing any opinion relating to device adulteration or misbranding, even though it was common knowledge that devices labeled for single use were being reused contrary to the explicit admonition in the labeling. Rather, the FDA expressed the position that "since disposable devices are not intended by the manufacturer or distributor for reuse, any institution or practitioner who reesterilizes and/or reuses a disposable medical device must bear full responsibility for its safety and effectiveness."

The FDA's decision to avoid expressing a clear statement of policy has continued through to the present. Yet, technological developments for many of these delicate and sensitive single use devices has generated refinements for which the manufacturer cannot guarantee safety or effectiveness beyond the initial use. The complexity of these devices for their intended use severely constricts any possibility of cleaning and sterilizing the device in order to restore it to its original unused condition. Additionally manufacturers of many of these devices have been required to obtain FDA approval (i.e., PMA) or clearance (i.e., 510(k) order) for which the FDA required labeling must clearly indicate that the device is single use and not to be reused. Such labeling is required because information has not been submitted to the FDA to demonstrate that reprocessing of the device will not adversely affect its safety or effectiveness.

On December 23, 1997, the FDA published an advance notice of proposed rulemaking in the Federal Register to announce its intention to review and, as necessary, revise or amend its compliance policy guides and regulatory requirements relating to the remarketing of used medical devices. Many comments which were submitted in response to this "proposed rule" expressed concern about the reuse of single use devices and requested that FDA take action to assure that

any reprocessed device was to comply with the release specifications of the finished device as manufactured by the original single use device manufacturer.

## II. Statutory Authority

### a. 1976 Medical Devices Amendments

The objective of the 1976 Amendments was to expand the authority of the federal government, through the FDA, to provide the public with greater assurance about the safety and effectiveness of medical devices. This was to be accomplished through a classification of devices and involvement by the FDA prior to commercial distribution of a device. This prior involvement by the FDA through the 510(k) and PMA process was intended to reduce the possibility of entry into commercial distribution of unsafe, ineffective, adulterated, or misbranded devices. Moreover, the 1976 Amendments provided greater enforcement authority for the FDA to take remedial actions against devices in commercial distribution and prevent future distribution. One of these authorities was to enable the FDA to identify a device as a banned device which would make the availability of such device a prohibited act. For example, a banned device would be subject to seizure and those responsible for the availability of a banned device subject to criminal penalties.

### b. Banned Device Authority

#### (i) Legislative History

Congress recognized the need for the FDA to have authority to ban certain types of devices. This need was prompted by the recognition that the exercise of FDA's seizure and/or injunctive remedy could be insufficient to prevent the availability of a violative device in interstate commerce. Such litigation, through the efforts of the Justice Department, to pursue seizure or injunctive relief was a costly and time-consuming process. Furthermore, where different manufacturers of the same type of device were manufacturing and/or distributing the device throughout the United States (U.S.), the FDA had to pursue individual seizure actions or injunctive relief against each device or manufacturer.<sup>4</sup>

---

<sup>4</sup> H.R. Rep. No. 94-853, 94<sup>th</sup> Cong., 2d. Sess., at 6,7,12-13 (1976).

Dockets Management Branch

May 20, 1999

Page 6

The remedy which Congress selected to prevent access to certain types of adulterated or misbranded devices was to authorize an administrative procedure to identify certain types of devices as banned devices. Congress believed "...that the proposed new authority will enable the Secretary to move quickly to protect the public from fraudulent or hazardous medical devices in commercial distribution that will not compromise the rights of device manufacturers."<sup>5</sup>

The 1976 Amendments described the criteria and procedures that were to be applied to the identification of a banned device. These criteria included the need for a finding that "...a medical device presents a substantial deception or an unreasonable and substantial risk of illness or injury before he can initiate a proceeding to ban the device."<sup>6</sup> However, the Committee Report further explained its position as follows:

"By using the term "substantial," the Committee intends that the Secretary make a determination that the deception or risk incurred through continued marketing of such a device is important, material, or significant. In determining that a device is deceptive, it is not necessary that the Secretary find that there was intent to mislead users of the device. Nor is actual proof of deception or injury to an individual required.

A finding that a device presents the requisite degree of deception or risk is to be made "on the basis of all available data and information", including information which the Secretary may obtain under other provisions of the proposed legislation, and information which may be supplied by the manufacturer in response to the proceeding relating to the safety, effectiveness, or labeling of the device."<sup>7</sup>

---

<sup>5</sup> Id. at 19.

<sup>6</sup> Id. p. 19.

<sup>7</sup>Id.

Dockets Management Branch

May 20, 1999

Page 7

The Committee Report further explained its justification for this significant new authority and the administrative procedure which it believed would not compromise the rights of the manufacturer. The Congress was satisfied with the rationale and justification for this new authority and Section 516 of the FDCA became law on May 28, 1976.

(ii) **FDCA Section 516, 21 U.S.C. 360f**

The applicable provision in the FDCA is direct and succinct. Section 516 of the FDCA directs as follows:

- (a) General rule – Whenever the Secretary finds, on the basis of all available data and information that –
- 1) a device intended for human use presents substantial deception or an unreasonable and substantial risk of illness or injury;
  - 2) in the case of substantial deception or an unreasonable and substantial risk of illness or injury which the Secretary determined could be corrected or eliminated by labeling or change in labeling and with respect to which the Secretary provided written notice to the manufacturer specifying the deception or risk of illness or injury, the labeling or change in labeling to correct the deception or eliminate or reduce such risk, and the period within which such labeling or change in labeling was to be done, such labeling or change in labeling was not done within such period;

he may initiate a proceeding to promulgate a regulation to make such device a banned device.

- (b) Special effective date – The Secretary may declare a proposed regulation under subsection (a) of this section to be effective upon its publication in the Federal Register and until the effective date of any final action taken respecting such regulation if (1) he determines, on the basis of all available data and information, that the deception or risk of illness or injury associated with the use of the device which is subject to the regulation presents an unreasonable, direct, and

substantial danger to the health of individuals, and (2) before the date of the publication of such regulation, the Secretary notifies the manufacturer of such device that such regulation is to be made so effective. If the Secretary makes a proposed regulation so effective, he shall, as expeditiously as possible, give interested persons prompt notice of his action under this subsection, provide reasonable opportunity for an informal hearing on the proposed regulation, and either affirm, modify, or revoke such proposed regulation."

Although the statutory language and legislative history make clear the intent of this provision in the FDCA and the procedure to be followed, the FDA through notice and comment rulemaking promulgated regulations to provide for implementation of a procedure. These regulations are found in 21 C.F.R. Part 895.

**(iii) Banned Devices Regulations, 21 C.F.R. Part 895**

The "Banned Devices" regulation provides a comprehensive description of procedures for banning a device. It also explains the criteria to be applied by the FDA to identify a banned device and the opportunity to utilize a revision of labeling and, additionally, advertising for restricted devices to reduce the possibility of risk. Further, the preamble to the final rule explains the FDA response to comments and clarifies its interpretation of various provisions of this regulation.<sup>8</sup>

**III. FDA Banned Devices History**

Since enactment of the 1976 Amendments, the FDA has applied the banned device authority on only one occasion. This resulted in the identification of prosthetic hair fibers as banned devices. These fibers were made of commonly available synthetic materials which were purchased by promoters and made available to licensed practitioners for implantation into the scalp. Although no deaths were associated with the use of prosthetic hair fibers, there were numerous

---

<sup>8</sup> 44 Fed. Reg. 29213, (May 18, 1979).

Dockets Management Branch  
May 20, 1999  
Page 9

reports of incidents which required medical intervention. In particular, the FDA expressed concern about infection, tissue scarring, and surgical procedures necessary to address complications associated with prior implantation of these synthetic fibers.

The FDA on June 3, 1983 declared that prosthetic hair fibers to simulate natural hair or conceal baldness "... present substantial deception and an unreasonable and substantial risk of illness or injury."<sup>9</sup> It further declared that the deception or risk could not be corrected or eliminated through labeling and that the device presented an unreasonable, direct, and substantial danger to the health of individuals.

#### IV. Basis For Request To Ban Reuse Of Single Use Devices

##### a. Single Use Determination

The manufacturer of a device is responsible for determining whether a device is suitable for unlimited or limited use. This decision is based on design control procedures which reflect the research and development that is necessary to support claims for the intended use. When devices are to be used by licensed practitioners, the manufacturer must carefully consider whether the device can be reused on the same patient or reused on different patients<sup>10</sup>. Because of the possibility of infection or contamination resulting from application of a device on one patient for subsequent use on another patient, the manufacturer must decide whether reuse of its device exposes a subsequent patient to an unreasonable and substantial risk of illness or injury. For certain devices that are inserted into blood-circulating vessels or are otherwise in direct contact with blood, the risks associated with reuse on another individual are foreseeable and unacceptable.

---

<sup>9</sup> 48 Fed. Reg. 25125 (June 3, 1983).

<sup>10</sup> For example, some hemodialysis device accessories can be processed for reuse, but this reuse is limited to use only by or on the patient on whom the device accessory was first used.

Dockets Management Branch

May 20, 1999

Page 10

In addition, the manufacturer must decide whether it can guarantee that, after a device has been used, the device can be restored to the condition of the finished device that the manufacturer released into commercial distribution. Factors that must be considered include whether the device performance characteristics can be adversely affected by expected use conditions (e.g., bending, twisting, scraping, abrasion, etc.) and whether the cleaning of the device can result in absence of all foreign material and damage caused by foreign material. For example, the presence of a single virus or bacteria which is viable could fatally infect a patient who is subsequently exposed to a reused cardiac catheter or similar device. In addition, the constituents of blood may affect the properties of the device through chemical reactions, or the process of cleansing/sterilizing a previously used single use device may alter the properties of the device.

After a device has been approved or cleared by the FDA for commercial distribution, manufacturers must comply with pervasive FDA regulations relating to Quality System (QS) unless specifically exempted by the FDA. The QS regulation appearing at 21 C.F.R. Part 820 requires the preparation and maintenance of over 100 specific records ranging from design control through final device release and user complaint review. The FDA through its field resources inspects manufacturers to assure compliance with the QS regulation. For example, a specific provision for final acceptance activities requires that "each manufacturer shall establish and maintain procedures for finished device acceptance to ensure that each production run, lot, or batch of finished devices meets acceptance criteria." 21 C.F.R. §820.80(d). When a device does not meet acceptance criteria, it must be rejected for release. Failure to reject a device which does not meet acceptance criteria is a violation of the FDCA, and the device itself is considered adulterated.

Because any unnecessary risk to a patient who is to be exposed to a surgical procedure utilizing delicate invasive devices is unacceptable, manufacturers display considerable caution as part of the decision-making process. Moreover, the authority of the FDA under the FDCA is to assure, among other considerations, that a device is neither adulterated nor misbranded. Consequently, the decision by the manufacturer to label a device for "single use" carries with it the recognition that any subsequent use of that device will misbrand or adulterate the device itself and make any subsequent use a violation of the FDCA.

**b. FDA Responsibility**

For many devices, the manufacturer has the responsibility to obtain permission from the FDA to market a device. Irrespective of whether this permission occurs through a PMA or 510(k) order, the FDA does review and accept the labeling as part of this permission. If the FDA believes that a device cannot be safely or effectively reused, it can insist that the device be labeled as "single use", "not for reuse", or by some similar or combination of designations. Likewise, if the FDA believes that a device proposed for single use could be reused, it could insist that the manufacturer label the device accordingly and include procedures applicable to reuse.

Once the FDA has determined or accepted the manufacturer's determination that a device cannot be reused, any reuse of that device represents a violation of the FDCA for which sanctions range from civil to criminal penalties. Moreover, the FDA inspects the manufacturer to assure compliance with applicable provisions of the FDCA and regulations relating to manufacture and release of devices labeled for single use. The FDA cannot ignore subsequent packaging, labeling, or manufacturing violations by others unless it intends to abandon its role as a public health protection agency of the federal government.

The responsibility of the FDA becomes the object of a very clear and sharp focus with regard to the reuse of a manufacturer's single use device. Unless the processor/reprocessor, whether practitioner, institution, or any third party, can demonstrate that the reprocessed single use device meets the acceptance criteria of the original finished device manufacturer or acceptance criteria authorized by the FDA through the PMA or 510(k) notification process, the reprocessed device is adulterated and likely misbranded.

In order for the FDA to discharge its responsibility equitably and consistently, the processor/reprocessor would have to demonstrate with scientific evidence that the reused single use device is identical to the original manufacturer's single use device in all respects which relate to safety and effectiveness.

It is inconceivable that the FDA would hold the reprocessor to lower or unknown final release acceptance criteria than that of the original finished device manufacturer. Yet, if the single use finished device manufacturer were to accept a used single use device for reprocessing and release it under acceptance criteria that are less than that of the never-used finished device, the FDA would have no

alternative but to charge a violation of the FDCA. Simple logic directs that the FDA cannot have it both ways and cannot justify a double standard.

**c. Grounds For Request To Ban Reused Single Use Devices**

Practitioner, institutional, and commercial third party processors are processing/reprocessing and distributing single use devices for reuse with no knowledge of the final release acceptance criteria applied by the original single use device manufacturer. The clear adulteration of single use devices is compounded by the fact that with each reuse of an adulterated device, the possibility of deception and risk to the patient increases.

Section 516 of the FDCA authorizes the FDA to ban a device if use of the device presents substantial deception or an unreasonable and substantial risk of illness or injury. Once the original manufacturer has determined that a device is not to be reused after the initial single use, particularly if the FDA has accepted this determination through a PMA or 510(k) order, any subsequent use clearly involves a violation of the FDCA by those responsible (e.g., health care institution, practitioner, commercial reprocessor, etc.), the user, and anyone who aids or abets those who further such use.

Where infection or transmission of a deadly disease (e.g., HIV virus) or other communicable disease (e.g., Hepatitis C) is a possibility, and there is neither consent nor knowledge by the patient both criteria (i.e., deception and risk) in Section 516 of the FDCA apply.

**(i) Substantial Deception**

Any device which enters lawful interstate commerce as a single use device accomplishes the intended use when the health care practitioner or ultimate consumer uses the device. Upon completion of this use, the device has served its purpose and cannot be reused except for application of one possibility. This possibility would involve recognition of the used device as a raw material to be used in the manufacture of a new device accepted by the FDA through issuance of a PMA or 510(k) order in compliance with all applicable provisions of law and regulation. If such a possibility is realistic, the previously used device would be identical in every respect to every other finished device of its type released for distribution by the original manufacturer. However, the original manufacturer could not be identified in any way with the "new" device.

Consequently, any reprocessing of a previously used single use device for reuse results in misbranding and adulteration of the device for which violations under the FDCA are quite clear.<sup>11</sup> Because most of these single use devices are used by health care practitioners on patients, the ultimate consumer may not be aware of the fact that a device intended for single use may have been manipulated in the blood stream of another person. Yet, the patient is charged for the use of the device without knowledge of either the prior patient's communicable disease status, the number of previous uses of a "single use" device, or that the device is not the device of the original manufacturer. The absence of such knowledge imparted to the patient before reuse of a single use device is deception.

Regardless of whether a third party reprocessor can guarantee that a reused single use device is identical to the original manufacturer's finished device, the patient would have to provide informed consent in order to avoid deception. The nature of such informed consent could be enormously complex for a variety of reasons. For one, the manufacturer of the original device is no longer the manufacturer of the reused device and cannot be identified with the reprocessed device. The liability of the original manufacturer would have to be waived and the practitioner, institution, and/or third party reprocessor would have to accept the liability. For another, it is reasonable to expect that the patient would be advised of the health condition of each individual on whom the device had been used.<sup>12</sup>

---

<sup>11</sup> The concept of adulteration or misbranding in the FDCA exceeds dictionary definitions. Sections 501 ad 502 of the FDCA describe these conditions to include those that involve misrepresentation and danger to health. For example, the objective the PMA or 510(k) order is for the FDA to confirm reasonable assurance of safety and effectiveness. Any reprocessor who avoids this responsibility cannot claim to provide reasonable assurance for the safety and effectiveness of a reused single use device. Thus, both deception and risk exist contrary to the very intent of the FDCA.

<sup>12</sup> During a conference sponsored by the Association For The Advancement of Medical Instrumentation (AAMI) on May 5-6, 1999, it has been reported in the trade press that at a health care institution, a study is underway to evaluate issues relating to infection associated with reuse of single use devices. Some type of

(Footnote cont'd on next page.)

At present, patients on whom a reused single use device is used without their knowledge are deceived. The FDA cannot ignore the existence or possible consequence of this deception. Clearly, the FDA has and would object to the reuse of a previously implanted cardiac pacemaker or similar type of implantable device for which there may be a long life expectancy. Presumably, the FDA position is based on public policy grounds relating to safety, effectiveness, misbranding, adulteration, and/or deception. The FDA position cannot be different for the reuse of single use devices.

(ii) **Unreasonable and Substantial Risk of Illness or Injury**

As previously described, the manufacturer determines whether its device can be safely and effectively reused. Often this decision is confirmed or directed by the FDA through approval or clearance procedures. Design control and QS regulation requirements greatly influence this decision, as does the possibility of products liability litigation.

For delicate devices that are used through interventional cardiovascular procedures, the realistic potential risks to any subsequent patient when a device is reused are enormous. Blood and constituents (e.g., drugs, nutrients, etc.) of the blood may adversely interact with the materials in the device. Manipulation of the device may alter its properties to deviate from the manufacturer's finished device specifications. The subsequent cleaning and sterilization procedures applied by the practitioner, institution and/or third party processor likewise may affect adversely the properties of the single use device. Finally, there is the very real possibility that cleaning and sterilization will not remove or destroy every harmful organism

---

*(Footnote cont'd from previous page.)*

informed consent is used, but it is not clear whether injury to a patient from malfunction of a device is also being studied. Moreover, because the investigation involving a new indication for use involves issues relating to a new indication (i.e., reuse of a single use device), it is not clear whether this investigation involves a "significant risk" device and whether the institution is complying with the Investigational Device Exemption (IDE) regulation at 21 C.F.R. Part 812.

derived from the blood of the previous patient. This possibility is real as demonstrated by experiences associated with transmission of disease through blood transfusions or use of cadaveric tissue (e.g., Creutzfeldt-Jakob disease).

The properties of the single use device can be materially altered during the initial use to the extent that the device may not meet the release acceptance criteria of the original finished device manufacturer. The petitioner refers the FDA to the comments submitted in response to the December 23, 1997 F.R. Proposed Rule on Medical Devices, Refurbishers, etc. at p. 67011. These comments can be located in Docket No. 97N-0477 and include many well-documented submissions by manufacturers to demonstrate that the characteristics of the single use device are adversely affected by use, cleansing, sterilization and/or reuse. Clearly, the FDA would not tolerate the release of such devices into commercial distribution by the original manufacturer. Yet to date, it has acquiesced to the misbranding and adulteration of single use devices by practitioners, institutions, and/or third party processors. Acceptance by the FDA of these practices defy the remedial nature of the FDCA and the expectations of the public that the FDA is devoted to public health and safety.<sup>13</sup>

Moreover, the FDA has conducted an evaluation of reused single use devices. During the previously referenced May 5-6, 1999 AAMI Conference, representatives of FDA's Center for Devices and Radiological Health (CDRH), Office of Science and Technology (OST), reported on a study it began nearly two years ago. These representatives reported that an analysis of previously used percutaneous transluminal coronary angioplasty (PTCA) catheters demonstrated that reprocessing altered the characteristics of some PTCA catheters.

Finally, a Position Statement of the International Association of Healthcare Central Supply Material Management (IAHCSMM) ". . .discourages the practice of

---

<sup>13</sup> The Supreme Court has concluded that the remedial purpose of the FDCA justifies a broad interpretation, United States v. Bacto-Unidisk, 394 U.S. 784 (1969).

Dockets Management Branch

May 20, 1999

Page 16

healthcare facilities becoming involved in the reprocessing of single-use medical devices and does not recommend it."<sup>14</sup>

The present public record provides ample support for the doubts associated with reuse of single use devices. Congress in 1976 did not expect the FDA to wait for a disaster to occur before it took action to prevent threats to the public health. The FDA has had ample experience with devices which could create harmful, even fatal, disease conditions. These include mid-trimester septic abortions associated with intrauterine devices, toxic shock syndrome with tampons, latex protein sensitivity, AIDS transmission through transfusions or reuse of needles, Creutzfeldt-Jakob Disease through use of processed cadaveric tissue, or numerous other examples of regrettable experiences.

In addition to the possibility of illness caused by transmission of harmful – even fatal – organisms, there is the added risk of injury. Each reuse of a device is likely to alter its performance characteristics. When a reused single use device (e.g., PTCA catheter or device with electronic/electrical properties) fails because of altered performance characteristics, the patient suffers. The nature of this suffering could range from inconvenient preventative medical intervention to death. Although the user facility is required to report such events to the FDA in accordance with the Medical Device Reporting (MDR) regulation, 21 C.F.R. Part 803, whether such reports have been submitted or will be submitted is irrelevant. The objective of this petition is to prevent the occurrence of a single event.

There is no reason why the FDA with its comprehensive and pervasive statutory authority under the FDCA should tolerate a practice which demonstrably defies the very statute it exists to enforce. The petitioner recognizes that the FDA has displayed an interest in this issue, but it cannot understand why the FDA would ignore the continuous and notorious adulteration and misbranding of single use devices.

---

<sup>14</sup> IAHCSMM, 213 West Institution Place, Suite 307, Chicago, IL 60610-9432.

**d. Labeling**

The Banned Devices regulation directs that the FDA consider whether labeling, change of labeling, or change in advertising if the device is a restricted device would correct or eliminate the deception, risk of illness or injury, or the danger to the health of individuals. In theory, changes to labeling or advertising could address deception if there is informed consent. However, this will not eliminate or diminish the risk of illness or injury. In order to consider acceptance of labeling that would be adequate to eliminate deception, the practitioner, institution, or third party processor would be required to step forward as the manufacturer of a new device. All references to the identity and labeling provided by the original manufacturer would have to be completely eliminated. New labeling/advertising would have to be created to reflect the reprocessing (i.e., cleaning, packaging, sterilization, prior use, etc.) that has occurred. Unless the reprocessed device has received a PMA or 510(k) order, the labeling would have to advise the patient of the prior use(s) of the single use device in order to provide opportunity for informed consent.

The prospect of using labeling as a possible remedy is further complicated by the fact that many single use devices are available as restricted or prescription devices. As such, the patient is rarely privy to the labeling unless there is voluntary or mandatory patient labeling. Assuming that a reused single device could be labeled adequately for use by a health care practitioner, additional labeling would have to be provided to the patient. The patient labeling would have to be complete in every particular to assure that the consent being considered by the patient is truly informed.

Even if the labeling/advertising for reused single use devices providing for informed consent could legally address any concern about deception, this does nothing to address the inherent risks of illness or injury previously described and supported by comments appearing in FDA Docket No. 97N-0477. For these and other reasons, including the logic articulated in banning synthetic hair implants, changes to the labeling/advertising do not provide a remedy.

As a final comment, Section 516 of the FDCA directs that the manufacturer be provided with written notice relative to labeling as a remedy. As a practical matter this approach would be difficult to implement, because each individual processor (practitioner, institution, other third party) would have to be notified as a manufacturer.

## V. Summary

The commercial distribution of all devices is subject to pervasive regulation by the FDA. The manufacturer is responsible for complying with an incredible number of provisions of law and regulation administered by the FDA. This compliance consideration begins with the identification of a possible device for commercial distribution and proceeds through research and development and ultimately to a decision that must be affirmed by the FDA through a PMA or 510(k) order. Once the FDA has cleared a device for commercial distribution, the manufacturer must assure compliance with applicable provisions of the FDCA and regulations including, but not limited to, those relating to Quality System, Medical Device Reporting, Tracking, Labeling, Registration, and Listing.

The FDA has the responsibility to enforce the law to assure that devices are not misbranded, adulterated, or otherwise in violation of the FDCA. This is accomplished through inspection and surveillance activities for which considerable resources are available to the FDA at headquarters and in the field.

Because the FDCA directs its concern for compliance in the context of the device itself, others in addition to the original manufacturer have a similar responsibility to comply with provisions of law and regulation to avoid adulterating or misbranding a device or otherwise committing violations in relation to the distribution and/or use of a violative device. Few examples of clear violation could be as notorious as the reuse of a device that is clearly labeled as "single use." Those who encourage, promote, or otherwise facilitate the reuse of a single use device commit a prohibited act. Thus, practitioners, institutions, and third party reproducers are liable under a statute where the civil and criminal liability is without fault.<sup>15</sup>

The intent of the petitioner is to assure that patients receive the best possible health care and protection from any reasonable possibility of illness or injury. Members of the MDMA and all conscientious manufacturers are mindful of their responsibility to the patient and proud of the advances in health care for which

---

<sup>15</sup> U.S. v. Dotterweich 320 (1975) 227, 64 S.Ct. 134(1943); U.S. v. Park 421 US 658, 95 S.Ct 1903 (1975).

innovators have supplied their talent. The MDMA supports any reasonable effort to protect present and future patients from any possible harm.

By accepting this petition, the FDA can confirm the remedial potential of the FDCA through prevention rather than punishment arising from a failure by the FDA to enforce uniformly the FDCA and regulations promulgated under the authority of the FDCA.

**C. Environmental Impact**

The petitioner makes a claim for categorical exclusion under 21 C.F.R. § 25.24.

**D. Economic Impact**

Although not required, the petitioner believes it is useful to comment on this subject because of claims that have been expressed about savings in health care costs.

Whether there truly is a saving in the cost of health care because of reprocessing of single use devices is questionable for several reasons. If there should be any illness or injury attributed to use of a reprocessed single use device, there is a health care cost to treat the illness or injury. In addition to this loss there is the potential loss associated with litigation against practitioners, institutions, and/or reproducers. These costs could exceed any real or theoretical savings. However, liability insurers may refuse to defend claims under a policy, because the activity responsible for the claim involves a violation of law. Additionally, the continued reuse of single use devices deprives competitive manufacturers from lowering prices through increased production and sales volume.

Presumably, the first patient on whom a single use device is used pays for the cost associated with that device. Subsequent users of the single use device will be charged at what should be a lesser cost to cover the expenses associated with reprocessing. Depending on the number of times a single use device is reused, the cost for each use could result in some saving to the subsequent patient purchaser of the device. However, if the first patient on whom the single use device was used covered the initial cost of the device for the practitioner or institution, it is fair to inquire as to whether that patient is the owner of the device. Irrespective of the answer to the question of ownership, if subsequent patient users are to derive a

Dockets Management Branch  
May 20, 1999  
Page 20

benefit from the expense incurred by the first patient, should the first patient be compensated for each subsequent use to assure that all patients are charged an equal amount for sharing in the cost associated with reuse of a single use device? The possible answer to this question and other questions that flow from the challenge of developing an answer become more complicated when there is a third party payer such as the Federal Government or insurance carrier. Where the Federal Government is the payer<sup>16</sup>, questions may arise as to whether reimbursement activities may be associated with the possibility of fraud or deception.

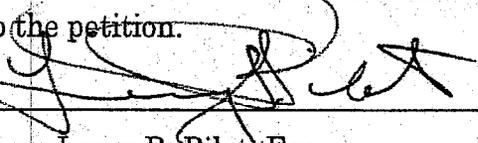
The petitioner is hopeful that the Commissioner will interact with other components of the Federal Government to determine current use practices and whether there are savings to the government. Finally, the petitioner reserves the right to supplement this petition with additional comments and support as these are created or become available.

E. Certification

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

(Signature) \_\_\_\_\_

(Name of petitioner) by

  
Larry R. Pilot, Esq.  
McKenna & Cuneo, L.L.P.  
Counsel to Petitioner  
Medical Device Manufacturers Association  
1900 K Street, N.W. Washington, D.C. 20006  
(202) 496-7561

---

<sup>16</sup> The Federal Government can also be a direct purchaser and user such as with Veterans Administration, National Institutes of Health, or military hospitals. The petitioner expects that such federal government purchasers would not violate the FDCA by reusing single use devices.