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COMMENTS

REPROCESSING AND REUSING SINGLE-USE ONLY MEDICAL DEVICES: SAFE MEDICAL PRACTICE OR RISKY BUSINESS?

Diane Carey*

INTRODUCTION

In early 1999, a piece of metal broke off of a catheter and lodged inside the heart of a thirty-two year old Kansas woman.¹ The catheter was designed and labeled by the manufacturer to be used only one time; yet in fact, it had been used six times.² This incident reignited the debate over the reuse of single-use only medical devices.³ Unfortunately, this was not an isolated incident. Other incidents include the death of a patient in a Colorado hospital due to a bacterial outbreak following the use of a contaminated reused cardiac catheter,⁴ and reports of transmission of the

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2. Debate, USA TODAY, Nov. 29, 1999, at 28A. The authors explain that the practice does not involve low risk medical devices only, such as blood pressure cuffs. Hospitals also reuse invasive devices such as biopsy needles, breathing circuits, and cardiac catheters.


hepatitis B virus when a single-use finger stick was used for blood sampling on more than one patient.\textsuperscript{5} It has been reported that many reused devices retrieved from hospitals in exchange for new devices either had blood or tissue remaining on them, or were so damaged that they could not have met the standards the Food and Drug Administration (FDA) had set for the original manufacturer.\textsuperscript{6}

Many hospitals in the United States and other countries reprocess and reuse medical devices designed and labeled for single-use only. The Health Industry Manufacturers Association (HIMA) defines reuse "[a]s using a device for its intended use more times than is described in the device's labeling."\textsuperscript{7} Currently, there are more than two hundred different types of single-use medical devices.\textsuperscript{8} Single-use devices commonly recycled include electrophysiology catheters used for cardiac testing; biopsy forceps used for removing tissue samples; drills, bits, and blades used in orthopedic surgery; and endoscopic retrograde cholangiopancreatography (ERCP) catheters used to remove gallstones.\textsuperscript{9} These single-use devices are designed for hundreds of different purposes, including diagnostics and treatments.\textsuperscript{10} Many of these devices are intricate and complex and some are made of fragile components such as electrical wires and hinges.\textsuperscript{11} Such devices are safe and effective when used initially, but may not be durable enough to be cleaned, resterilized and used

\begin{itemize}
\item \textsuperscript{5} John Lockhart, The Coalition for the Advocacy of Reuse Awareness' Position on Reprocessing Single-Use Medical Devices, \# 5 SURGICAL SERVICES MGMT., Jan. 1999, at 42.
\item \textsuperscript{6} See Cong. Rec., supra note 4.
\item \textsuperscript{7} Health Industry Manufacturers Association: Position Paper on the Reuse of Single-Use Medical Device at 1. [Hereinafter HIMA].
\item \textsuperscript{8} Lockhart, supra note 5, at 42.
\item \textsuperscript{9} Weinberg, supra note 4, at 124; see Sylvia Pagan Westphal, Risky Reuse of Medical Equipment is on the Rise, L.A. TIMES, Aug. 2, 1999, at A1. Other devices include anesthesia breathing circuits, electro-surgical devices, respiratory therapy breathing circuits, biopsy needles, and hemodialyzers. Dateline: Braced for the Truth, (NBC Television Broadcast, Mar. 9, 1999) (transcript on file with author) (stating that orthodontists routinely remove parts of braces that have been used in one person's mouth, sterilize them and then use them in another person's mouth, even though the manufacturer has labeled them for single-use only) ; PROCEDURES 519 (HELEN KLUSEK HAMILTON et al., eds. 1985). An ERCP procedure (endoscopic retrograde cholangiopancreatography), is a radiographic examination of the pancreatic ducts and hepato-biliary tree to evaluate the cause of obstructive jaundice.
\item \textsuperscript{10} Lockhart, supra note 5, at 42.
\item \textsuperscript{11} Id.
\end{itemize}
again. Single-use devices that are reused should not be confused with medical devices that are designed to be reused and are made from materials, such as stainless steel, which permit safe resterilization and reuse.

Until recently, there has been little public outcry about the practice of reusing single-use medical devices because most patients and their families are not aware of this practice. U.S. News and World Report calls the practice "[m]edicine’s dirty little secret." Hospitals are under pressure from health care insurers and Medicare to decrease costs. Because of this pressure, thousands of hospitals in the United States recycle millions of disposable instruments used for invasive procedures, such as cardiac angioplasty and orthopedic surgery.

Prior to 1980, almost all medical devices and instruments were made of glass, rubber or metal. These devices were easy to clean and sterilize, and therefore, safe to use for many different patients and procedures. However, with recent advances in plastic technology, medical devices have become smaller, more flexible, and more intricate, allowing physicians to treat patients less invasively. For example, cardiologists are using these devices to repair blocked blood vessels in the heart.

12. Id.
13. Id.
14. Id.; See CONG. REC., supra note 4. Senator Durbin said, “When you go in for heart surgery or these diagnostic treatments, it never crossed your mind to ask the doctor: Incidentally, will all the devices you are going to use in the course of my treatment be used for the first time?” Id. See Weinberg, supra note 4, at 126. A nurse in Ohio notes, “If a cardiologist or some other important person undergoes a procedure, the hospital uses a new instrument.” The fact that physicians do not want reused devices utilized on them sends an important message. Id.
15. Dana Hawkins, News You Can Use: Risky Recycling, U.S. NEWS & WORLD REPORT, Sept. 20, 1999, at 62. The majority of health care professionals asked by U.S. NEWS AND WORLD REPORT if they would want reused devices used on them or a family member said no. It is possible for a patient to protect himself by inserting an additional line on the informed consent form stating “Do not reuse single-use devices without my written permission.” Although this is rarely done, it does work. One physician says he only knows of it being done one time, but the hospital complied and used a new catheter on the patient as requested. Id. at 67.
16. Id. at 63.
17. Id.
18. Id.
19. Id.
without resorting to open-heart surgery.  
Against the advice of medical device makers, hospitals and outside reprocessors take the devices, apply toxic chemicals and use high temperatures to clean and sterilize the devices, then use the devices in other patients. Hospitals and reprocessors have been able to do this without federal or industry oversight. The practice of reprocessing single-use medical devices is growing, with approximately forty million dollars spent annually on reprocessing.

The debate over reprocessed single-use medical devices continues. Device manufacturers want to have the practice banned; reprocessors are encouraging the growth of the practice; the FDA and Congress are trying to decide how to regulate the practice; and the public is caught in the middle, unaware and unprepared.

This Comment examines the debate over the reuse of medical devices. Part I discusses recent congressional action. Part II addresses both the benefits and risks of the practice and explains the proponents' and opponents' views. Part III examines informed consent issues. Part IV examines the ethics of experimentation and the studies that have been conducted to determine whether or not it is safe to reuse single-use only medical devices. Part V looks at product liability and warranty issues implicated when single-use medical devices are reprocessed and reused. Part V also examines patent issues and trademark infringement. Part VI discusses the current position being advanced by the FDA. The author concludes that the practice of reprocessing single-use medical devices unnecessarily puts the American public at risk of illness or injury, and should be banned until the safety and efficacy of the practice has been determined satisfactorily.

I. CONGRESSIONAL ACTION

Senators Richard Durbin (D-IL) and Edward (Ted) Kennedy (D-MA) addressed the United States Senate on August 3, 1999, regarding the reuse of single-use medical devices. Senator Durbin said the issue
revolves around "[h]ighly invasive and high-risk devices, devices that come in contact with the patient's blood or other bodily fluids." Senator Durbin expressed concern that reuse occurs without the knowledge of patients and without a requirement that the devices be safe and effective after reprocessing. Senator Durbin told members of the Senate about some of the known incidents that have occurred with reused devices. He then introduced legislation requesting one million dollars to aid the FDA in monitoring the situation better and the Senate approved the request.

Senator Kennedy, in his remarks before the Senate, addressed the fact that many of the single-use devices are made from heat sensitive plastics and have intricate, inaccessible parts which can be difficult, if not impossible, to clean and sterilize. Referring to studies conducted by the FDA on balloon angioplasty catheters, Senator Kennedy said, "[t]he studies concluded that many of the narrow spaces in these catheters were contaminated with blood, and that the balloons no longer inflated properly." In a letter to the United States General Accounting Office (GAO), the Committee on Health, Education, Labor and Pensions, chaired by Senator James M. Jeffords (R-VT), noted that "The American public relies on the FDA to ensure that medical devices are safe and effective. The Committee asked the GAO to initiate a comprehensive evaluation of the practice of reusing single-use medical devices.

26. Id.
27. Id. Senator Durbin said in his comments, "One has to wonder why we spend any money on device safety if the device only has to be safe when it is used initially."
29. CONG. REC. S10171, supra note 24. Senator Kennedy also noted that there is a serious danger that there will be contamination of the device with blood, respiratory secretions or other body fluids. He cited independent studies that have shown eighty percent of biopsy forceps were contaminated with blood, tissue or fecal matter. Id.
30. Id. "When hospitals, or third-party reprocessors, prepare a 'single-use only' device for use again in another patient, they do not supply the FDA with any information on the safety and efficacy of the device and they do not notify the FDA of their intent to remarket the used device." Id.
32. Id. Specifically, the Committee asked the evaluation to include, but not be limited to, the following questions:
On October 26, 1999, H.R. 3148 was introduced by Representatives Anna Eshoo (D-CA) and Fred Upton (R-MI). The bill was introduced "[t]o amend the Federal Food, Drug, and Cosmetic Act to require any person who reprocesses a medical device to comply with certain safety requirements and for other purposes." The bill includes the following findings:

FDA data show that reprocessed single-use medical devices have been associated with serious injury and have the potential to cause serious injury; The devices are being used without patient knowledge, against the advice of the original manufacturer and without the FDA's determination that the devices are safe and effective; The reprocessing of single-use devices is occurring without the required premarket approval or notification to the FDA; The FDA has the appropriate knowledge and expertise to evaluate reprocessed devices; The only way to protect the public is for the FDA to enforce the provisions of this Act; and

What evidence is there that a threat to public health exists because of the practice?
What are the current FDA regulations governing reprocessors and to what extent does the FDA enforce them?
How widespread is the practice, how many devices are reprocessed each year, and how many different types of devices are being reprocessed?
How many companies currently reprocess single-use medical devices?
What is the economic impact of reprocessing single-use devices, what are the savings to the hospitals, and what are the potential costs associated with adverse outcomes linked to the use of reprocessed devices?
What would the cost be if the FDA were required to assure the safety and efficacy of reprocessed medical devices?

Id.

34. See H.R. 3148, supra note 33.
35. Id.
36. Id.
37. Id.
38. Id.
39. Id.
The public needs to have assurance that medical devices are being properly regulated by the FDA so as to guarantee the safety and effectiveness of the devices.\footnote{Id.}

The purpose of the bill was to

- require that the Food and Drug Administration implement and enforce all provisions of this Act that are applicable to reprocessed medical devices, including device registration, listing, and premarket safety controls; and
- require the informed consent of patients prior to using reprocessed class II, class III, and critical class I medical devices.\footnote{Id.}

The bill required the Commissioner of the FDA to submit a report to Congress within nine months of the date of enactment and to describe the findings from current FDA studies on the safety and efficacy of reprocessing single-use only medical devices.\footnote{Id.} The bill further required that informed consent be obtained from the patient when such a device is to be used.\footnote{Id.} It also required that a record, as part of the patient's medical record, be kept by the person or institution that uses such a device.\footnote{Id.}

On February 10, 2000, the House Commerce Subcommittee on Oversight and Investigations questioned the FDA Device Center Director, David Feigal, as to why the FDA “[h]as been slow to take enforcement action to address the re-use of single-use devices (SUDs).”\footnote{Id.} Much of the hearing focused on the new guidelines published by the FDA that require reprocessors and hospitals that reprocess single-use devices to meet FDA requirements.\footnote{Id.} Feigal said that since the FDA does not have jurisdiction over the practice of medicine, it cannot intervene when

\footnote{Id. See Hearings on H.R. 3148 Before the Subcomm. on Commerce, 106th Cong. 106-89 (2000) (statement of Rep. Eshoo) [hereinafter Hearings]. “H.R. 3148 will increase awareness about reprocessed devices by requiring a patient’s informed consent before that single-use medical device is used on them, and by requiring hospitals to monitor and report injuries or infections that occur as a result.” Id. at 8.}

\footnote{Id.}

\footnote{Id.}

\footnote{Id.}

\footnote{Id. The contents of the medical record shall include the name of the person or business that reprocessed the device, the batch or lot number of the device, and the identity of the manufacturer of the device. Id.}

\footnote{House Panel Grills FDA on Inactivity on Reuse of Single-Use Devices, FDA WEEK, Feb. 11, 2000, at 3 [hereinafter House Panel].}

\footnote{Id.}
hospitals reuse a device. The FDA however, can regulate the sterilization process, because the reprocessing of the devices turns hospitals and reproprocessors into manufacturers.

II. RISKS AND BENEFITS OF REPROCESSING

A. Risks of Reprocessing Single-Use Only Medical Devices

Some experts blame the rise in the infection rate on reprocessing and reuse of single-use medical devices. While no one can point to a specific infection known to be caused by the unauthorized reuse of such devices, almost two million patients become sick and ninety thousand die from nosocomial (hospital acquired) infections each year. The endoscope, a device designed for visualizing inside the body and approved for reuse, has been linked to several known infectious outbreaks. Device makers tell frightening stories, such as the tip of a reused catheter nearly breaking off in the patient’s heart, finding items that have been reprocessed with traces of blood and bile left on them after reprocessing and finding forceps with bleach residue remaining on them after cleaning. The risks of reprocessing also include the potential of adversely affecting the properties of the device and of failing to remove or destroy every harmful organism acquired when the device is exposed to the blood stream of the previous user.

Whenever an invasive procedure is performed on a patient, the most important factors that protect the patient from infection are the sterility of the equipment being used and the aseptic technique (e.g., good hand washing, using sterile equipment, wearing a mask, sterile gloves and gown and maintaining the sterility of the sterile field) of the health care practitioner performing the procedure. If the sterility of the equipment is

47. Id.
48. Id. However, the FDA has the authority to inspect reproprocessors' good manufacturing processes (GMPs) and can ensure the integrity of the process.
49. Hawkins, supra note 15, at 67. Proving that a connection between the reuse of single-use only devices and higher infection rates has been difficult because of poor patient tracking. Some of the infections can take weeks or months to develop and often the hospitals are only tracking the patient for twenty-four to forty-eight hours. Id.
50. Weinberg, supra note 4, at 124.
51. Id.
52. Id.
compromised or if there is a break in the aseptic technique of the practitioner, then the patient is at an increased risk for infection or other complications.

An FDA study of reused balloon catheters showed that the catheters' balloons did not always reinflate to the intended size.\textsuperscript{4} In cardiac procedures, the risk to a patient if the balloon over-inflates is that the balloon could rupture a vessel in the heart and require the patient to undergo emergency open-heart surgery.\textsuperscript{5} If the balloon under-inflates, the physician will have to remove the catheter, causing the patient to endure a longer procedure and possibly increasing the risk of damage to the cardiac vessel.\textsuperscript{6}

B. Cost Benefits of Reprocessing Single-Use Medical Devices

Reprocessing and reuse of single-use medical devices may reduce health care costs for hospitals and can decrease the accumulation of wastes for disposal.\textsuperscript{7} The Mayo Clinic reuses single-use only catheters in its electrophysiology lab and claims that they have not had a single problem associated with the practice.\textsuperscript{8} Stephen Hammill, the director of

\begin{itemize}
  \item 54. Hawkins, \textit{supra} note 15, at 67.
  \item 55. \textit{Id}.
  \item 56. \textit{Id}.
  \item 57. Susan V.M. Kleinbeck, et al., \textit{Reprocessing and Reusing Surgical Products Labeled for Single Use}, \textit{4 SURGICAL SERVICES MANAGEMENT} 21 (1999). For some single-use medical devices, the cost of meeting the industry standards may outweigh any potential savings. Hospital managers should not assume that reprocessing is guaranteed to save money. \textit{Id}. at 22. Most medical facilities charge the same price whether a new or reused device is used. In the current reimbursement system, it is virtually impossible to pass the savings on to the patient. \textit{Id}. at 23; Hawkins, \textit{supra} note 15. Many contend that it is unethical to charge for a new device when a reused device is used. \textit{Id}. at 66. \textit{But see} Hearings, \textit{supra} note 41, at 67, testimony of John H. Fielder stating, “But what exactly are the benefits to the patient? See, this is where we hit the ethical brick wall. The patient is getting no benefit by being treated with a reprocessed device.”
  \item 58. Hawkins, \textit{supra} note 15, at 64-5; Weinberg, \textit{supra} note 4, at 123. An electrophysiology catheter is a long, wiry device that is inserted in the patient’s groin and travels through the cardiovascular system to the heart in order to monitor the patient’s cardiac function. Westphal, \textit{supra} note 9. The cost of two new cardiac catheters used during an electrophysiology procedure is approximately $2,000. By using reprocessed or recycled devices, the hospital can save thirty to fifty percent of the cost. \textit{Id}. \textit{But see} Hawkins, \textit{supra} note 15. Using a reused angioplasty catheter could potentially save $500, but Jon Resar, Director of the Catheterization Lab at Johns Hopkins Medical Center says, “But that’s not enough to compensate for how unsafe it is.” \textit{Id}. at 66.
\end{itemize}
the lab, estimates that reprocessing has saved his lab about nine million dollars over the course of twenty years.\textsuperscript{59}

The Association of Medical Device Reprocessors (AMDR), a trade association in Washington, D.C., claims that reprocessing single-use devices can result in a fifty percent savings when compared to purchasing a new device from the manufacturer.\textsuperscript{60} Reprocessors maintain that they are usually able to offer reprocessing for significantly less money than in-hospital reprocessing and that the reprocessors' sterility is the same or better than in-hospital reprocessing.\textsuperscript{61}

The claims of monetary savings give rise to many questions. Who is reaping the benefits? When a patient has a procedure and pays full price for the new device, is that patient to be reimbursed if the device is subsequently used on another patient? If the device is used six different times, is the price shared among the six patients? Will the patient who received the initial use of the device receive credit if it is used again a few weeks after the patient is discharged? Are third-party payers, such as insurance companies, HMOs and Medicare given a discount when the hospital uses a reprocessed device, and do the third-party payers offer a reduced premium to their members? How likely is it that hospitals and/or practitioners will report any incidents that occur when a single-use device is reused and fails? If the patient does not receive the savings and the hospital retains the savings, then should the hospital have to make that fact known to the patient? In \textit{Moore v. Regents of the University of California}, the court held that the plaintiff had a cause of action against the physician for breach of fiduciary duty and lack of informed consent when the physician failed to inform the plaintiff that the physician had a financial interest.\textsuperscript{62}

\begin{itemize}
\item \textsuperscript{59} Hawkins, \textit{supra} note 15, at 66. But see Pilot, \textit{supra} note 53. The claims of health care cost savings would need to take into consideration any illness or injury caused by the device, any loss incurred during litigation if the device failed, and that the reuse of such devices prevents competing manufacturers from decreasing prices through increase in sales and production. \textit{Id.} at 19.
\item \textsuperscript{60} Association of Medical Device Reprocessors, \textit{AMDR and the Reprocessing Industry} 5.
\item \textsuperscript{61} \textit{Id.} But see House Panel, \textit{supra} note 45. Members of the House of Representatives raised questions related to the practice of billing the patient the same amount whether a new or reused device is used and noted that any costs saved are kept by the hospital. \textit{Id.} at 3.
\item \textsuperscript{62} 51 Cal. 3d 120, 148 (1990).
\end{itemize}
I. Proponents' Position

Proponents of reuse say that many of the devices that manufacturers labeled as single-use only are labeled in that manner because the manufacturers want to sell more devices. One-third or more of the hospitals in the United States routinely reuse single-use only disposable medical devices and defend the practice as prudent and harmless.

The AMDR represents third-party reprocessors (as opposed to in-hospital reprocessors) of medical devices labeled for single-use only. AMDR members perform almost eighty-five percent of the reprocessing done in the United States. The AMDR defines a reprocessor as

[A]n entity that, at the request of a customer, inspects, functionally tests, cleans, packages, and sterilizes medical devices labeled for single-use in such a manner that:

The quality, physical characteristics, and performance functions of the device are not significantly affected,

and

The device remains safe and effective for its appropriate clinical use.

The AMDR maintains that its members are committed to complying with all applicable FDA requirements. The association states that the single-use label is completely arbitrary and that the device makers, not the FDA, choose when to label a device as single-use only. When discussing the safety record of AMDR members, the association claims the record is excellent, with few problems involving the more than nine million devices that its members have reprocessed. The AMDR claims that the FDA

63. Neergaard, supra note 1.
64. Weinberg, supra note 4, at 123. But see Lisa Scott, Researchers Test Safety of Medical Devices, MODERN HEALTH CARE, Apr. 24, 1995, at 78. Generally, hospitals that do not recycle single-use devices fear that the device might fail or infect a patient the second time it is used.
65. AMDR, supra note 60, at 1.
66. Id.
67. Id.
68. Id. at 2. The AMDR maintains that its members must carry at least five million dollars in liability insurance and in some cases, the AMDR member carries at least twenty-five million dollars in liability insurance.
69. Id. at 3.
70. Id. But see Westphal, supra note 9. The lack of adverse reports is easily explained by a system where the tracking of reprocessed medical devices is poor; the reports will frequently register as a problem with the actual device without noting that the device was reprocessed. Neither the hospital nor the physician
regulates third-party reprocessors, who must register with the FDA. The AMDR also maintains that reprocessors must adhere to all applicable Quality System Regulation requirements, and reprocessors must be in compliance with Medical Device Reporting Regulations requirements.

The AMDR does not advocate the reprocessing of every single-use only medical device, and reports that only a small percentage of the devices used by hospitals are reprocessed. Indeed, "AMDR's guiding principle is that a device should only be reprocessed if it can be scientifically proven and validated that the device can be cleaned, functionally tested, sterilized, and reused without harm to the patient." However, independent, peer-review studies related to the practice of reusing disposable medical devices are rare. The few studies that have been done have not been substantial enough to conclude whether or not reprocessing is safe.

2. Opponents' Position

Many hospitals and physicians are concerned about reusing single-use only medical devices. Dr. J.P. Abenstein, Chairman of the Equipment Subcommittee at the Mayo Clinic, explains that most disposable devices become contaminated with fluids such as blood, urine, and saliva, and that these devices were not meant to undergo resterilization. Dr. Abenstein states, "Given the fairly convincing literature that high temperatures and caustic chemicals change the nature of the materials, I'd be leery of reusing disposable (devices)."

HIMA is a Washington, D.C. trade association that represents more
than seven hundred manufacturers of health care products and medical devices. HIMA has adopted principles pertaining to the reuse of single-use devices which include: Supporting the right of the manufacturers to design and label devices for single-use only; opposing promotion of the reuse of devices that were designed and/or labeled for single-use; opposing efforts by government regulatory authorities' to require that manufacturers of single-use devices test or label those medical devices for multiple uses; and asserting that the FDA must exert its regulatory authority over reprocessors of single-use devices. HIMA maintains that manufacturers have longstanding concerns related to the practice of reusing single-use medical devices that include product quality, product safety, and product liability.

The Medical Device Manufacturers Association (MDMA), a Washington, D.C. trade association, represents approximately 130 medical device manufacturers. MDMA claims that the decision to label a device for single-use only is based on whether or not the manufacturer determines its device would expose a second patient "[t]o an unreasonable and substantial risk of illness or injury." The manufacturer must also make a determination whether or not it can guarantee that its device can be restored to the original condition. MDMA states, "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."

III. INFORMED CONSENT

Patients must trust their physicians and other health care professionals to tell them of the risks involved with medical procedures, treatments and

79. HIMA, supra note 7, at 1.
80. Id.
81. Id.
82. Pilot, supra note 53, at 1. Many of these manufacturers make medical devices that are intended for single-use only. Id.
83. Id. at 9.
84. Id. at 10.
85. Id. at 15. An FDA evaluation of reused percutaneous transluminal coronary angioplasty (PTCA) catheters showed that reprocessing changed the characteristics of some of the catheters. Id. The petition states in part, "Although the user facility is required to report such events (failure of the device) to the FDA in accordance with the Medical Device Reporting (MDR) regulation, 21 C.F.R. Part 803... The objective of this petition is to prevent the occurrence of a single event." Id. at 16.
care through the informed consent agreement.\textsuperscript{86} However, patients are not told when medical devices have been used in other patients, or that these devices were manufactured and designed to be used only once.\textsuperscript{87} A recent poll of five hundred people in the United States found that a vast majority felt "[a]ngry, frightened and betrayed" by the idea that they or a loved one might be subject to increased health risks related to the practice of reusing single-use only medical devices.\textsuperscript{88}

Congress and the FDA are not alone in examining the issue of reusing single-use devices. Illinois and Florida are attempting, with limited success, to regulate reprocessed medical devices by requiring informed consent from patients before such devices can be used.\textsuperscript{89}

Even if the reprocessor can guarantee that a reused device is identical to the manufacturer's original specifications, the patient should give informed consent for the use of the device.\textsuperscript{90} Obtaining such informed consent creates a number of problems: the original manufacturer is no longer the manufacturer and cannot be identified with the device; liability of the original manufacturer must be waived and the reprocessor must accept the liability; and the patient should be informed of the health status/risk of the prior patients on whom the device had been used.\textsuperscript{91} Some of a patient's pertinent medical history, such as HIV status, may not be known to the health care professional who uses the device on the first patient. Therefore, that information would not be available to be passed on to the next patient who is having a procedure with the same device. In order to accurately and fully obtain all pertinent information, the patient on whom the device is initially used would have to provide detailed information that the patient has a right to keep private.

\begin{thebibliography}{99}
\item[86.] Lockhart, \textit{supra} note 5, at 44.
\item[87.] \textit{Id.} at 42.
\item[88.] \textit{Id.} at 44. The results of the survey indicate that consumers had concerns that the device would be damaged by excessive cleaning, and were concerned about the possibility of device contamination. Almost ninety percent of those surveyed would choose a hospital with a policy against reusing single-use devices, and would be angry upon being billed for a new device when a reused one had been utilized. Thirty-nine percent of the people in the survey said they "[w]ould consider buying their own new medical devices." \textit{Id.}
\item[89.] Chad Terhune, \textit{Legislator Wants Hospitals to Stop Reusing Devices}, \textit{WALL ST. J.}, Nov. 24, 1999. Florida State Rep. Bob Henriquez wants to ban the reuse of medical devices because of the risks of infection, injury and mechanical failure. If his bill passes, violators could be sentenced for up to sixty days in jail and fined $500. \textit{Id.}
\item[90.] Pilot, \textit{supra} note 53, at 13.
\item[91.] \textit{Id.}
\end{thebibliography}
Southard v. Temple University Hospital addressed the issue of informed consent for medical treatment. Southard involved a coordinated litigation with numerous plaintiffs and defendants. In Southard, the plaintiff brought a malpractice action claiming that the defendant physician and hospital had failed to obtain informed consent. The plaintiff's claimed the defendants had not advised the plaintiff that the FDA had classified the bone screws used in his surgery as a Class III medical device under the Medical Device Amendment Act, when used in the spine. The plaintiff appealed the grant of partial summary judgment to the physician and hospital as to the defendant's failure to inform the plaintiff of the FDA classification. The appellate court found that the lower court erred in granting partial summary judgment.

The court in Southard explained that Pennsylvania's informed consent doctrine is based on the "prudent patient" standard. Therefore, the issue of informed consent must be viewed from the perspective of the patient. For informed consent to be adequate, the patient must be informed of "[m]aterial facts, risks, complications and alternatives to surgery, which a reasonable man in the patient's position would have considered significant in deciding whether to have the operation." The court went on to say, "In an informed consent action, the relevant inquiry

93. Id. at 608.
94. Id.
95. Id. at 608; George D. Pozgar, Legal Aspects of Health Care Administration (1999). The law imposes a duty for physicians "[t]o disclose known and existing dangers associated with a specific course of treatment." Id. at 207; see Leggett v. Kumar, 570 N.E.2d 1249 (1991). A physician has a duty to adequately inform a patient of the risks associated with surgery. Id. at 1262.
96. Southard, 731 A.2d at 609.
97. Id. at 612.
98. Id. at 610.
99. Id.

Informed consent means... the consent of a patient to the performances of health care services by a physician... provided... that prior to consent having been given, the physician... has informed the patient of the nature of the proposed procedure or treatment and of those risks and alternatives to treatment or diagnosis that a reasonable patient would consider material to the decision whether or not to undergo treatment or diagnosis.

731 A.2d at 610, n.9.
is whether a prudent patient would consider significant a particular fact, risk, complication or alternative to a surgical procedure; if so, that information must be disclosed.”

The court also said that it believed that a prudent patient would want to know whether or not the FDA had approved a medical device as safe and effective for a particular use when deciding whether or not to give consent for a surgical procedure.

Extending the Southard rationale to the immediate issue causes one to ask whether a prudent patient would want to be informed whether the medical device being used on him had been used before, and whether that device was manufactured and labeled for single-use only. Any hospitalization that requires an invasive procedure has some inherent risks that cannot be completely eliminated. A patient undergoing such a procedure is informed of the risks, informed of the benefits, informed of alternatives, and then makes an informed decision whether or not to have the procedure or surgery performed. It is safe to assume that most patients prefer the procedure or surgery to be performed with the lowest possible risk. By inference, most patients would not want to increase their risks unnecessarily by allowing a reused medical device to be used on them when that device was not manufactured, marketed or approved for more than a single-use.

101. Southard, 731 A.2d at 612.

102. Id. But see Klein v. Biscup, 673 N.E.2d 225, 231 (1996), holding “[a]ccordingly, we conclude that failure to disclose FDA status does not raise a material issue of fact as to informed consent.” Id. The court noted that the off-label use of a medical device is not a risk of a therapeutic procedure, noting the FDA does not regulate the practice of medicine. Id. See also Pennsylvania Appeals Court: Guaranty Fund Entitled to Setoff in Malpractice Case, 4 MEALEY'S EMERGING DRUG & DEVICES, Dec. 3, 1999 at 17.

In a suit for medical malpractice, a jury found doctors liable on the issue of informed consent because the doctors failed to advise the plaintiff that the bone plates and screws were new and experimental in nature. Id. The court's decision in Southard is the only decision holding that a patient needs to be told of the FDA's classification. See Mark Herrmann 'Single Use' Medical Devices: Tempest in a Teapot, 4 MEALEY’S EMERGING DRUGS & DEVICES, Dec. 3, 1999 at 20, 22; Earle v. Ratliff, 998 S.W.2d 882 (1999), Hansen v. Universal Health Services Inc., 974 P.2d 1158, 1159, (1999), Alvarez v. Smith, 714 So2d 652, 65-4 (1999). The court in Alvarez said, “Regarding the FDA status, the majority of reported cases hold that as a matter of law doctors are not required to disclose the FDA status of pedicle screws because such status is not a medical risk of surgery.” Id. The Pennsylvania Supreme Court has a petition for allocatur pending to review the decision in Southard. Herrmann, supra at 22.
IV. THE ETHICS OF EXPERIMENTATION

John Fielder, a bioethicist and expert on reuse says the practice of medical device reuse is "[m]edical experimentation without benefit, written consent – or even patient knowledge." There are many official policies that govern medical research using human subjects. The principles articulated by the Nuremberg Code require "[t]hat there be informed consent from the subject before the experiment begins and during the continuation of the experiment and the requirement that there be appropriate benefits and risks." The latter requirement means that the amount of harm to the patient should be minimized and that the potential benefits should be sufficient to outweigh the harms that are associated with the research. In the United States, the FDA regulates medical experiments and requires advanced approval of most medical research by independent committees called Institutional Review Boards. Some forms of research on human subjects can be performed legitimately without informed consent from the patients, such as chart reviews and interviews, because they seem to pose few risks to the patient. Informed consent is not always required in emergency situations when there is neither the time nor a competent patient to give informed consent.

The regulation of medical devices was not seriously undertaken by the FDA until the mid-1970s. Under current statutory authority the FDA

103. See Hawkins, supra note 15, at 63.
105. Id. at 33, 34; See also S. SANDY SANBAR, et al., LEGAL MEDICINE 631 (1998). The Nuremberg Code states:

The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated so as to exercise free power of choice, without intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion, and should have sufficient knowledge as to enable him to make an understanding and enlightened decision . . . . The duty and responsibility for ascertaining the quality of consent rests upon the individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity. Id. at 631.
106. BRODY, supra note 104, at 34.
107. Id. at 35.
108. Id. at 38.
109. Id. at 39.
110. Id. at 164. See also Medical Device Amendment (1976); THOMAS J. DUESTERBERG, et al., HEALTH CARE REFORM, REGULATION AND INNOVATION IN
has placed medical devices in three classes: Class I, Class II, and Class III devices.\(^{111}\) Class I devices are not required to meet any standards or to obtain premarket approval.\(^{112}\) Class II devices must meet certain standards.\(^{113}\) Class III devices require premarket approval by the FDA.\(^{114}\)

The FDA generally requires clinical testing before a device can be marketed.\(^{115}\) Clinical testing or experimentation needs to be conducted in order to determine the safety and efficacy of reusing single-use only medical devices. Little literature is available regarding medical research on the reprocessing of single-use devices. One study, performed in Quebec, Canada, examined the reuse of angioplasty catheters.\(^{116}\) The initial results of the study suggested that the rate of complications increased in the hospital that reused catheters.\(^{117}\) However, the investigators found significant differences that could account for the increased complications without blaming the reused catheters.\(^{118}\) Other established risk factors, such as the severity of the underlying pathology in the patients studied, were independent predictors of adverse outcomes.\(^{119}\) When the study was reanalyzed, comparing only inpatients with stable angina, there was essentially no difference in outcomes of the patients in which the catheters had been used only once and those in which the

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THE MEDICAL DEVICE INDUSTRY 75 (1994). "The 1976 amendments to the Food and Drug Act established the basic regulatory framework for the device industry, but as would quickly become clear, they did not resolve the basic question of how to protect the public health and safety through effective regulation of the industry." \(\text{Id.}\)

111. BRODY, supra note 104, at 164; 21 U.S.C. § 360c (1997) Classes of devices; § 360(c)(a)(A) Class I, General Controls; § 360(c)(a)(B) Class II, Special Controls; and § 360(c)(a)(C) Class III, Premarket Approval.

112. BRODY, supra note 104, at 164; DUESTEBERG, supra note 110, at 75-6. "Class I devices are those with minimal risk, such as cotton swabs, tongue depressors and bandages." \(\text{Id.}\)

113. BRODY, supra note 104, at 164; DUESTEBERG, supra note 110, at 76. "Class II devices were defined as those with intermediate risk, such as syringes, hearing aids, anesthesia-delivery machines, and electrocardiac machines." \(\text{Id.}\)

114. BRODY, supra note 104, at 164; DUESTEBERG, supra note 110, at 76. "Medical devices in the highest risk category, classified by the FDA as Class III devices, included implantable devices and life-sustaining equipment." \(\text{Id.}\)

115. BRODY, supra note 104, at 164.


117. \(\text{Id.}\) at 718.

118. \(\text{Id.}\)

119. \(\text{Id.}\)
catheters had been reused. The authors of the article acknowledged the limitation of their study and said, "It would be reassuring if these results are corroborated by other randomized studies that are being planned in Canada and in the United States."\textsuperscript{121}

A second study reported in the \textit{Journal of the American Medical Association} (JAMA) examined the effect of dialyzer reuse.\textsuperscript{122} The study reported higher mortality in dialysis facilities that reprocessed dialyzers than in facilities not reprocessing dialyzers.\textsuperscript{123} While the study was unable to determine whether the reprocessing of the dialyzers or other factors caused the higher morbidity rate, the findings raised significant concerns about "[potentially avoidable mortality among US hemodialysis patients treated in dialysis facilities reprocessing hemodialyzers."\textsuperscript{124}

Canadian researchers performed a third study to determine whether reuse of disposable laparoscopic instruments was safe and cost effective.\textsuperscript{125} The study determined that, "Under carefully monitored conditions and strict guideline reuse of disposable laproscopic and thoracoscopic (used to visualize the internal condition of the lungs) instruments can be cost-effective."\textsuperscript{126}

When discussing the practice of reusing single-use devices, Larry Spears, a senior compliance official with the FDA, said "There isn't [sic]
data to show that this is a safe practice." 127 If, as Dr. Fielder suggests, the reuse of single-use medical devices constitutes experimentation, the practice is not being properly monitored as required by the FDA. While reuse of single-use medical devices carries risks for the patient, the practice holds no benefits for the patient. In order to justify such experimentation, the patient must benefit in some manner from the experiment. The concern raised by Dr. Fielder needs to be addressed as yet another unresolved issue surrounding the controversy.

V. OTHER ISSUES IMPLICATED BY THE REUSE OF SINGLE-USE ONLY MEDICAL DEVICES

A. Warranties and Product Liability

"Strict liability (i.e., not negligence based) is imposed on manufacturers, sellers, and distributors of unreasonably dangerous and defective products for injuries resulting from their use." 128 When a manufacturer places a product into the marketplace, it guarantees that the product is safe and effective if used properly. To recover under a cause of action based on a breach of warranty, the plaintiff must first establish whether the warranty was express or implied. 129 The manufacturer of a product makes an express warranty when it includes specific promises or affirmations to the buyer. 130 Implied warranties "[a]re in effect when the law implies that one exists by operation of law as a matter of public policy for the protection of the public." 131 The original manufacturer of a single-

128. POZGAR, supra note 95, at 64.
The following elements must all be present for a plaintiff to proceed with a case based on the basis of strict liability:
The product must have been manufactured by the defendant.
The product must have been defective at the time it left the hands of the manufacturer or seller. A defect in the product, and/or an absence or inadequacy of warning for the use of the product.
The defective product must have been the proximate cause of injury to the plaintiff.

Id. If a medical device fails, the manufacturer can be held strictly liable if the product was defective and the defect was the proximate cause of the patient’s injuries. 129 Id. at 63.
129. Id. at 63.
130. Id.
131. Id.
use medical device makes both express and implied warranties.

"Reprocessing single-use products negates the manufacturer's warranties and could interfere with the original function of the product." 132 If a hospital or medical facility performs the reprocessing, it assumes liability if the device fails to perform properly. 133 If a hospital or medical facility contracts with a reprocessing company, liability will depend upon the warranty provided by the reprocessor. 134 Dr. Larry Spears said that when hospitals reuse single-use medical devices, "They go beyond the intended use on the label—and at their own risk." 135

It is easy to envision what would happen if a reprocessed device failed and caused serious injury to a patient. The manufacturer would deny any liability because the device was designed, manufactured and labeled for single-use only. The reprocessor would deny liability and blame the manufacturer for a defect in the product. The hospital would deny liability and place the blame on the manufacturer or reprocessor. The insurance companies, very likely, would claim not to be liable because the hospital or reprocessor violated the FDCA.

B. Patent and Trademark Infringement Issues

The FDA regulates medical devices, many of which are patented by the manufacturer. One such manufacturer brought an action for patent infringement and inducement to infringe against a reprocessor of medical devices in Mallinckrodt Inc. v. Medipart Inc. 136 In that case, Mallinckrodt, the manufacturer, sold its patented product to hospitals. The hospitals used the device, sent it to Medipart for servicing, then reused the device. 137 In reversing summary judgment for the reprocessor, the appellate court said, "[U]se in violation of a valid restriction may be remedied under the patent law, provided that no other law prevents enforcement of the

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133. Id. See generally Janice M. Hogan & Thomas E. Colonna, Products Liability Implications of Reprocessing and Reuse of Single-Use Medical Devices, 53 FOOD AND DRUG L. J. 358 (1998). The authors state, "[p]roduct recondition to extend useful life is more likely to support a strict liability claim than is mere repair or maintenance that does not demonstrably impact useful life." Id. at 394. In the event of device failure, reprocessors may be liable for breaches of implied or express warranties. Id. at 400.
135. Id. at 23.
137. Id. at 701.
The court explained that the enforceability of a restriction on the use of patented products was derived from the patent grant, which includes, under property terms, the right to exclude. Moreover, the holder of the patent may waive this right to exclude. Quoting United States v. General Electric Co., the court said "The patentee may grant a license upon any condition the performance of which is reasonably within the regard which the patentee by grant of the patent is entitled to secure." In remanding the case, the appellate court held that the district court erred in holding that the restriction on reuse was unenforceable and found that if the restriction on reuse was within the scope of the patent, then an action for patent infringement could be valid.

There is a growing trend among hospitals to send medical devices out for unauthorized repair. This includes remanufacturing of the medical device. Karl Storz manufactures endoscopes for use by hospitals, which send them to unauthorized companies for repair, often using nongenuine components. Storz is seeking a court order requiring a repaired endoscope to bear a "permanent label indicating that a repair has been made, and by whom and with respect to rebuilt scope, that labeling is not sufficient so that the repair shops remove all of Karl Storz's trademarks, thus alerting the user that it is no longer a Karl Storz product." Storz believes that by leaving the name "on the remanufactured products it creates the completely false and potentially dangerous impression in the minds of surgeons, nurses, and OR personnel, that these are genuine Karl Storz products."

138. Id.
Every patent shall contain a short title of invention and a grant to the patentees, his heirs or assigns, of the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States, and if the invention is a process the right to exclude others from using, offering for sale or selling throughout the United States, or importing into the United States, products made by the process, referring to the specification for the particular thereof.
140. Mallinckrodt, 976 F.2d at 703.
141. Id. at 704.
142. Id. at 709.
144. Id. at 41.
145. Id. at 43.
146. Id.
Courts have repeatedly ruled that the manufacturer of a product has the "[r]ight to control the manufacturing process and quality of products bearing its trademark . . . . The wrong inheres in involuntarily entrusting one's business reputation to another's business."\textsuperscript{147}

By analogy, any single-use medical device that is reprocessed for reuse will usually retain the trademark of the original manufacturers. The physicians and nurses who use the products rely on the reputation of the products and their knowledge of the reliability of the products based on prior experience. If the health care team is unaware that the device had been reprocessed, the team may be placing its confidence in an undeserving device.

C. Adulteration and Misbranding

It is unlawful in the United States to distribute or import articles that are misbranded or adulterated.\textsuperscript{148} The term "adulterated" refers to articles that are defective, unsafe, or manufactured under unsanitary conditions.\textsuperscript{149} "Misbranding" includes statements and designs in labeling that are misleading or false, as well as the manufacturer's failure to label the product with information required by law.\textsuperscript{150} "Consequently, any reprocessing of a previously used single use device for reuse results in misbranding and adulteration of the device for which the violations under the FDCA are quite clear."\textsuperscript{151}

VI. THE FOOD AND DRUG ADMINISTRATION

The MDMA submitted a petition on May 20, 1999, requesting the Commissioner of the FDA "[t]o 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.)."\textsuperscript{152} In its petition, the MDMA contends that the manufacturers of certain medical devices are required by the FDA to label those devices for single-use only.\textsuperscript{153} The MDMA also states that such devices cannot be reused because information has not been offered to the FDA to show that reprocessing of the device will not impair its

\textsuperscript{147} Id.
\textsuperscript{149} 21 U.S.C. § 343, 352, 363 (1994); SANBAR, supra note 105, at 588.
\textsuperscript{150} SANBAR, supra note 105, at 588.
\textsuperscript{151} Pilot, supra note 53, at 13.
\textsuperscript{152} Id. at 1.
\textsuperscript{153} Id.
safety or effectiveness.\textsuperscript{154}

The FDA has the authority to ban medical devices if the use of the device presents substantial deception or an unreasonable risk of illness or injury.\textsuperscript{155} The 1976 Medical Device Amendment described the criteria and procedure necessary to identify a banned device.\textsuperscript{156} The criteria require a finding that a medical device presents an unreasonable risk of injury or illness before proceedings to ban a device can be initiated.\textsuperscript{157}

Manufacturers of medical devices are ultimately responsible for deciding whether a device is reusable or not.\textsuperscript{158} In making that decision, manufacturers are understandably cautious, because any unnecessary risk to the patient is an unacceptable risk.\textsuperscript{159} If the FDA determines that a device cannot be reused safely, the FDA can require that the device be labeled for single-use only.\textsuperscript{160} The MDMA petition submits that the hospitals and reprocessors "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."\textsuperscript{161}

On October 6, 1999, the FDA denied the petition requesting a ban on the reuse of single-use medical devices. In its denial, the FDA found that

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\textsuperscript{154} Id. at 4.


\textsuperscript{156} Pilot, \textit{supra} note 53, at 6.

\textsuperscript{157} Id. FDCA § 516, 21 U.S.C. § 360(f)(1994).

General rule—Whenever the Secretary finds, on the basis of all available data and information that—

a device intended for human use presents substantial deception or an unreasonable and substantial risk of illness or injury in the case of substantial deception or an unreasonable and substantial risk of illness or injury which the Secretary determined could be corrected or illuminated 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 such labeling or change in labeling was to be done, such labeling or change was not done, such period: he may initiate a proceeding to promulgate a regulation to make such a device a banned device.

\textit{Id.}

\textsuperscript{158} Pilot, \textit{supra} note 53, at 9.

\textsuperscript{159} Id. at 10.

\textsuperscript{160} Id. at 11.

\textsuperscript{161} Id. at 12.
There is no clear evidence that reprocessing presents an unreasonable and substantial risk of illness or injury, which is one of the criteria for banning a medical device.\footnote{162} The FDA, in its denial, acknowledged that it had received "[a]dverse event reports where a reprocessed single use device was involved; however, in each of those cases, it was not clear that reprocessing caused the problem reported."\footnote{163} Although the FDA did not ban the reprocessing of medical devices, it said "Significant reevaluation of FDA's position with regard to reuse of single use devices is in order."\footnote{164} On October 21, 1999, the MDMA petitioned the FDA for reconsideration of its petition to ban the reprocessing of single-use devices.\footnote{165} The petition for reconsideration states:

1) The petition demonstrates that relevant information or views contained in the administrative record were not previously or adequately considered.

2) The petitioner's position is not frivolous and is being pursued in good faith.

3) The petitioner has demonstrated sound public policy grounds supporting reconsideration.

4) Reconsideration is not outweighed by public or other public interest – to the contrary, public health and public interest justify the need for the FDA to prevent unequivocal adulteration and misbranding of single use devices rather than act after death or serious injury has occurred.\footnote{166}

In enacting the Medical Device Amendment, Congress established the means by which the FDA can regulate the manufacturing and sale of medical devices.\footnote{167} Medical devices are classified, inter alia, by the regulatory controls necessary to provide reasonable assurance of safety and effectiveness.\footnote{168} The FDA requires Class I devices to meet certain

\footnote{162. Letter from David W. Feigal Jr., Director, Center for Devices and Radiological Health, FDA, to Larry R. Pilot, Counsel to Petitioner, Medical Device Manufacturer Association (Oct. 6, 1999) (on file with author).}

\footnote{163. Id.}

\footnote{164. Id.}

\footnote{165. Larry R. Pilot, Petition for Reconsideration, Oct. 21, 1999, at 1 (on file with author).}

\footnote{166. Id. at 4.}


\footnote{168. Medical Device Amendment Act, 21 U.S.C. § 360(c) (1994). General controls are those used for devices that do not support or sustain life. Special controls are for devices that are not classified as Class I devices and general controls are insufficient to provide reasonable assurance of safety and effectiveness. Premarket approval is for devices that are used to support or
registration and record keeping requirements (general controls); for Class II devices, the FDA requires the manufacturers to comply with standards and maintain patient registries (special controls); and for Class III devices the FDA requires that the manufacturer complete a rigorous application process and receive FDA approval prior to marketing the device (premarket approval). 169

Reprocessing is being performed by both third-party reprocessors and hospital in-house facilities. 170 Approximately one million devices are reprocessed each year, resulting in a burgeoning reprocessing industry that services the needs of one-third of the hospitals in the United States. 171 In the next year, the reprocessing industry expects sales to double and estimates that hospitals are resterilizing and reusing far more devices than the reprocessors make available for reuse. 172

Currently, if a manufacturer of a disposable device wants to change the label from single-use to reusable, the manufacturer is required by the FDA to submit documentation, called “premarket notifications” demonstrating that the change in labeling and use of the device is safe. 173 However, reprocessors are not required to adhere to similar documentation requirements, even though the reprocessors essentially change the single-use device to a reusable device. 174 Manufacturers contend that many reprocessors are not even registered with the FDA, and that of the estimated twenty-three reprocessors, only seven are actually registered as required by the FDA. 175

The FDA leaves the decision of whether or not to reuse single-use only medical devices up to the hospital, but it says hospitals that reuse disposable devices are liable for the safety and effectiveness of the product. 176 The Original Equipment Manufacturer (OEM) is subject to sustain human life or those of substantial importance in preventing impairment of human health. Id.

170. Westphal, supra note 9, at A1; Weinberg, supra note 4. The FDA requires outside reprocessors to register with the FDA, but it acknowledges that not all reprocessors are registered and the FDA does not know how many are in the business. Id. at 123.
171. Westphal, supra note 9, at A1.
172. Weinberg, supra note 4, at 124.
173. Westphal, supra note 9, at A1.
174. Id.
175. Id. The article states, “FDA registration for reprocessors, however is essentially voluntary . . . That registration loophole could allow shady operators to go undetected and uninspected by the FDA.” Id.
176. Scott, supra note 64, at 78.
requirements of the Federal Food, Drug and Cosmetic Act (FDCA), including registration, premarket notification, approval requirements, submitting adverse event reports under the Quality Systems Regulation, labeling requirements, Medical Device Tracking and Medical Device Corrections and Removals. Hospitals that do in-house reprocessing are required to ensure that the devices are adequately cleaned and sterilized, in addition to maintaining safety, effectiveness and quality of the device. Currently, third-party reprocessors are subject to registration, listing quality systems regulations, medical device reporting regulations and premarket requirements. The FDA has issued warning letters to third-party reprocessors for a number of violations, including failure to comply with quality system requirements, failure to validate sterilization procedures and failure to label the devices with adequate directions for use. The FDA has not regulated the OEMs, the third-party reprocessors and the health care facilities in a consistent manner with regard to single-use devices.

The FDA is currently in the process of reevaluating its position on the reuse of single-use medical devices. The agency maintains that its primary goal is "[t]o protect the public health by assuring that the practice of reprocessing and reusing SUDs is based on good science." To accomplish this goal, the FDA held an open meeting in Rockville,

179. Id. at 4.
180. Id. at 5; Letter from Douglas D. Tolen, Director, Florida District, FDA to Rick Ferreira, CEO, Alliance Medical Corporation, Dec. 23, 1999 (on file with author). The FDA cited a reprocessor for six violations including failure to establish a quality policy as required by law, failure to establish and maintain procedures to ensure device history records are maintained, failure to adequately document cleaning and maintenance of the facility and process equipment, and three other violations. Id.; Letter from Edward R. Atkins, Acting Director Florida District, FDA to Louis L. Rudt, President, Visions in Endosurgery, Inc., Jan. 6, 2000 (on file with author) (citing seventeen violations by the reprocessing facility).
182. Id. at 1, 2.
183. Public Comment, supra note 178, at 7.
Maryland, on December 14, 1999, in order to obtain information from interested parties on its proposed strategy on the reuse of single-use devices.\(^\text{184}\)

Following the open meeting, the FDA created a list of issues that needed to be addressed before a comprehensive regulatory strategy could be implemented.\(^\text{185}\) This list includes: Clarification of the FDA action plan; sterility validation guidance; guidance on registration for health care facilities; developing an auditing program; regulating labeling of single-use devices; and use of quality systems with reused medical devices.\(^\text{186}\) The FDA acknowledged the need to change the manner in which reuse of single-use medical devices has been regulated.\(^\text{187}\) The FDA believes that there are medical devices whose reuse probably poses significant risk to the public.\(^\text{188}\)

In February 2000, the FDA said "it will begin requiring both hospitals and third parties that reprocess single-use devices (SUDs) to meet the same premarket approval and other FDA requirements traditionally applied to SUDs."\(^\text{189}\) Reprocessors and hospitals will be allowed six months to meet all applicable requirements for "high risk" SUDs, twelve months for devices that are "moderate risks" and eighteen months to meet requirements for "low risk" medical devices.\(^\text{190}\)

CONCLUSION

The FDA missed an opportunity to fulfill its mandate and to protect the health of the American public. The FDA should consider banning the use of reprocessed medical devices until sufficient scientific data are available to show that the practice is safe and effective. Instead, the FDA is essentially allowing the practice to continue until it is proven unsafe. In the meantime, patients' health and lives are being put at risk unnecessarily.

Reprocessing and reusing single-use only medical devices may be a safe, harmless and cost effective alternative to expensive new devices. If the practice continues, OEMs will not be able to bring down the costs of new devices. Rather, costs are likely to increase to cover expenses and

\(^{184}\) Open Meeting, supra note 181.

\(^{185}\) Id. at 5.

\(^{186}\) Id.

\(^{187}\) Id.

\(^{188}\) Id. at 1.

\(^{189}\) House Panel, supra note 45, at 4.

\(^{190}\) Id.
development in manufacturing. However, at the current time, too many questions remain regarding the safety and efficacy of the practice. Legitimate concerns related to the lack of informed consent have not been addressed. If informed consent were required, undoubtedly all but a few patients would agree to the risks associated with the reused medical devices. The question that consumers need to ask is whether they would want such a device used on themselves or on their loved ones.

Before the practice should be allowed to continue, extensive medical and clinical research needs to be conducted to determine whether or not the practice is safe. Then each transformed or reprocessed device would need to receive FDA approval.

No data demonstrate that the practice is cost efficient. But if it does save money, who should receive those savings? Obviously, the person who is paying for the device or service should reap the benefits. The difficulties surrounding how to return the savings to the patient would create an accounting maze. The claims of costs savings do not currently take into account how much money will be needed to bring reprocessors into compliance with all applicable FDA regulations or how much money the FDA will need to monitor properly the reprocessors.

Considering all of the problems, risks and unknown solutions to the issues created by the reuse of single-use only medical devices, much work must be done before, if ever, the practice is found acceptable. The issues surrounding reuse remain unresolved.