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Report to Congressional Requesters

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SINGLE-USE MEDICAL DEVICES

Little Available Evidence of Harm From Reuse, but Oversight Warranted

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Contents

Abbreviations

CDC	Centers for Disease Control and Prevention
EP	electrophysiology
FDA	Food and Drug Administration
GI	gastrointestinal
HCFA	Health Care Financing Administration
HHS	Department of Health and Human Services
HIV	human immunodeficiency virus
JCAHO	Joint Commission on Accreditation of Healthcare Organizations
MDR	Medical Device Reporting
PMA	premarket approval
SUD	single-use device
VA	Department of Veterans Affairs

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Health, Education, and
Human Services Division

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The Honorable James M. Jeffords
Chairman
The Honorable Edward M. Kennedy
Ranking Minority Member
Committee on Health, Education, Labor, and Pensions
United States Senate

The Honorable Bill Frist
Chairman
Subcommittee on Public Health
Committee on Health, Education, Labor, and Pensions
United States Senate

The Honorable Mike DeWine
The Honorable Christopher Dodd
The Honorable Richard Durbin
The Honorable Mike Enzi
The Honorable Patty Murray
The Honorable Jack Reed
United States Senate

Medical devices approved for sale in the United States as single-use devices (SUD) sometimes are reprocessed and used again on other patients.[1] Reprocessing involves cleaning and sterilizing a device and verifying that it functions properly. Some reprocessed devices are relatively simple items for external use, such as sequential compression devices (inflatable sleeves to improve blood circulation), while others are complex and invasive, such as catheters that are inserted into the heart to monitor cardiac functioning. Some devices, both SUDs and those marketed as reusable, have been reprocessed in-house by hospitals and other treatment facilities for decades. An industry of third-party medical device reprocessing companies has developed within the last 10 years. The practice of SUD reprocessing raises public health concerns, primarily regarding the potential risks of infection and device malfunction, and has led to complaints by the original

[1]SUDs are also referred to as disposable devices because they are intended to be discarded after one use.

device manufacturers that the Food and Drug Administration (FDA), the federal agency within the Department of Health and Human Services (HHS) that approves medical devices for marketing, has not maintained consistent regulatory standards for different types of medical device companies.

When manufacturers seek approval to market a device as single-use, FDA cannot require them to show that reusing the device would be inappropriate or hazardous. Manufacturers that intend to market a device as reusable must give FDA supporting data demonstrating to the agency's satisfaction that a device can be cleaned and sterilized without impairing its function. All other devices are intended for single-use. Thus, a device may be marketed for single-use because the manufacturer believes that it cannot be safely and reliably used more than once or because the manufacturer chooses not to conduct the studies needed to prove that the device should be labeled as reusable. In effect, because FDA can only evaluate a device relative to the use intended for it by its manufacturer, its approval of a device as single-use means that a device can be used safely and reliably once, not necessarily that it cannot be used safely and reliably more than once if it is appropriately reprocessed.

You asked us to review the practice of SUD reprocessing in the United States. We focused our work on (1) the extent of SUD reprocessing, (2) the health risks associated with SUD reprocessing, (3) the cost savings from SUD reprocessing, and (4) FDA's oversight of SUD reprocessing. We looked only at the practice of reprocessing SUDs for use on another patient; we did not examine devices approved for marketing as reusable, the resterilization of opened but unused devices, or devices reprocessed for additional use on the same patient. To conduct our work, we reviewed the relevant scientific literature, met with FDA officials, reviewed FDA documents and documents submitted to FDA by interested parties; interviewed officials at the Centers for Disease Control and Prevention (CDC) and the Health Care Financing Administration (HCFA); gathered information from other experts in government and industry; contacted third-party reprocessing companies; and interviewed physicians, hospital administrators, and other health care providers. We conducted our work between November 1999 and May 2000 in accordance with generally accepted government auditing standards.

Results in Brief

While it is clear that some health care institutions have chosen to reprocess and reuse some kinds of SUDs, accurate and comprehensive information

about the number of facilities that use reprocessed SUDs and the types of SUDs that are reprocessed is not available. Surveys by professional associations and other groups have found that approximately 20 to 30 percent of American hospitals reported that they reuse at least one type of SUD and that at least one-third of the hospitals that do so contract with third-party reprocessing companies. Most hospitals using reprocessed SUDs reuse only a few types of devices. It is likely that some hospitals do not report their use of reprocessed SUDs, and the estimates do not fully include ambulatory surgery centers or physicians' practices that also may reuse SUDs.

Although SUD reprocessing does pose theoretical health risks, clinical evidence shows that certain devices can be reprocessed safely. In addition, some infection control experts told us that the careful reprocessing of appropriate SUDs has not been demonstrated to be a public health risk. Almost all of the professional associations we contacted believe that selected devices can be reprocessed safely if appropriate procedures are followed and closely monitored. We found that several reports of patient adverse events allegedly due to SUD reprocessing that we identified were inaccurate or not relevant to the debate. However, this does not mean that SUD reprocessing is always safe. Current surveillance systems almost certainly do not detect all infections and injuries resulting from the use of reprocessed SUDs (or from the use of medical devices in general). Furthermore, FDA, device manufacturers, and third-party reprocessors generally agree that many types of SUDs cannot be safely cleaned and sterilized, and even for devices that usually can be reprocessed, some models are impossible to clean and sterilize effectively.

Substantial cost savings can be achieved by reprocessing SUDs. Independent reprocessing firms charge hospitals approximately one-half the price of a new device for a reprocessed device, while the in-house cost of reprocessing some devices can be less than 10 percent of the price of a new device. The competition created by SUD reprocessing appears to have caused some original device manufacturers to reduce their prices to certain purchasers.

FDA's regulation of SUD reprocessing for different types of device manufacturers has been inconsistent, but the agency is about to institute a new regulatory framework intended to address this concern. Currently, although third-party reprocessing firms are considered by FDA to be manufacturers of reusable medical devices, they are not required to seek premarket approval to reprocess SUDs, and FDA until now has chosen not

to exercise its jurisdiction over hospitals and other health care institutions that reprocess SUDs in-house. Under the revised framework, independent reprocessing firms and hospitals will have to obtain FDA's approval before they can reprocess many devices labeled for single-use. The revised regulatory framework will give FDA more information about SUD reprocessing and strengthen its oversight of reprocessing. However, there are significant barriers to the framework's successful implementation. FDA told us that the additional work involved in reviewing applications for SUD reprocessing may interfere with the agency's ability to complete timely reviews of premarket applications for new medical devices. Also, the framework will involve the agency in regulating SUD reprocessing practices in hospitals. To get help with the monitoring of reprocessing in these facilities, FDA has asked HCFA and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) to include SUD reprocessing in their hospital quality-of-care standards. Neither HCFA nor JCAHO has committed to do this in the near term.

Background

FDA is responsible for ensuring the safety and effectiveness of medical devices sold in the United States, ranging from bandages and thermometers to cardiac catheters and artificial hearts. Approximately 80,000 to 100,000 models of medical devices are currently in use in the United States, and the domestic market for medical devices totaled roughly $56 billion in 1999. FDA regulates the safety and effectiveness of medical devices, the packaging and labeling that describes how they should be used, and the facilities that manufacture them. FDA's requirements for approving devices for marketing depend on the device's potential for harming patients. Class I, or low-risk, devices include such things as elastic bandages and orthopedic saw blades. Medium-risk devices, class II, include items like urethral catheters and blood pressure cuffs. Class III devices, such as heart valves and balloon angioplasty catheters, support or sustain human life and present significant risk of patient injury. Most class I devices can be marketed without obtaining prior approval from FDA. FDA requires the manufacturers of most class II and class III devices to submit either a premarket notification application (510(k)) to show that the device is substantially equivalent to one already on the market or an application for premarket approval (PMA), which provides evidence, often including clinical data, demonstrating that the device is safe and effective. FDA

requires a satisfactory inspection of a manufacturer's facilities before a PMA is approved.[2] FDA received 4,458 510(k) applications and 72 PMAs for medical devices in fiscal year 1999. Manufacturers are required to register with FDA, list the devices they produce, follow good manufacturing practices, and inform FDA about problems with their marketed devices. Manufacturers also are subject to inspection by FDA. In fiscal year 1999, FDA inspected 30 percent of the nearly 3,500 domestic manufacturers of class II and class III medical devices.

Generally, FDA can evaluate applications to market new devices only in terms of a device's intended use as described on its label.[3] Thus, manufacturers that wish to market a device as single-use need to convince FDA only that it can be used safely and effectively once—they do not need to demonstrate that the device cannot be used more than once. Conversely, manufacturers that wish to market a device as reusable must either provide data demonstrating that the device will be safe and effective for a specified number of uses or provide a measure to determine whether or not a reprocessed device still meets performance specifications. They must show that the device can be cleaned and sterilized and that its function will not degrade with repeated uses. Devices that are not marketed as reusable are intended for single-use.[4]

The Extent of Reprocessing

Single-use device reprocessing is a small part of the large and varied medical device industry. FDA has confirmed the existence of only a small number of third-party reprocessing firms, although it suspects there are more. Surveys by professional associations and other groups have consistently found that roughly 20 to 30 percent of American hospitals reported reusing at least one type of SUD. Many health care professionals told us that they believe manufacturers market devices with a single-use

[2]Manufacturers submitting 510(k)s for class III devices must have been inspected by FDA in the 2 years preceding the 510(k) application. Facility inspection is not required for other 510(k) applications.

[3]Food and Drug Administration Modernization Act of 1997 (P.L. 105-115), 205(b), adding 513(i)(1)(E)(i) to the Federal Food, Drug, and Cosmetic Act.

[4]FDA did not require manufacturers of reusable devices to include cleaning and sterilization instructions with them until 1995, following the release of reprocessing standards for reusable devices by an industry association. FDA also has the authority to require a manufacturer to change the label of a device that it markets for an intended use other than that on the label and that poses a health risk.

label because of the economic benefits of doing so and that they therefore believe many SUDs can be reused.

SUD Reprocessing Is a Small Part of the Medical Device Industry

Third-party reprocessing firms and some hospitals and other health care institutions reprocess SUDs. While the exact size of the reprocessing industry is unknown, it is clearly only a small part of the medical device industry. For example, FDA has identified only 13 third-party reprocessing companies, although it suspects that more are in operation. Last year, a trade association representing major third-party firms said that its members collectively received about $20 million annually for their services. Although there are many hospitals (more than 6,000) and ambulatory surgery centers (about 2,700) in the United States, evidence indicates that only a minority of them reprocess SUDs in-house. Furthermore, reprocessors (both third-party firms and hospitals) each typically reprocess only a few types of SUDs.

A Minority of Hospitals Report Reusing SUDs to Some Extent

While it is clear that some health care institutions have chosen to reprocess and reuse some kinds of SUDs, neither FDA nor any other organization has accurate and comprehensive information about the number of facilities that use reprocessed SUDs or the types of SUDs that are reprocessed. Table 1 presents the results of six surveys about SUD reprocessing by professional associations and other groups. The surveys typically asked members of selected professional groups to describe the SUD reprocessing practices at the institution with which they were affiliated. Most of the surveys found that approximately 20 to 30 percent of American hospitals reused at least one type of SUD and that at least one-third of the surveyed hospitals that reused SUDs contracted with independent reprocessing companies. While the results of the various surveys are fairly consistent, it is difficult to assess the validity of the findings because the response rates for the surveys are low. The only survey with a response rate greater than 50 percent, from the Metropolitan Chicago Healthcare Council, unfortunately does not have separate results for the reprocessing of SUDs used on patients—its findings combine SUD reprocessing and the resterilization of opened but unused devices.

Table 1: Surveys of SUD Reprocessing

Source	Sample	Date	Response rate	Percentage of institutions that reprocess SUDs used on patients	Percentage of institutions that have third-parties reprocess SUDs
ECRI[a]	Hospital subscribers to ECRI publications	1996	7% (N=more than 280)	31	7
R.J. Cheung and others[b]	Random sample of membership of the American Society for Gastrointestinal Endoscopy	1997	40% (N=294)	29[c]	[d]
American Society for Healthcare Central Service Professionals[e]	ASHCSP members	1998	22% (N=214)	21	7
OR Manager[f]	Random sample of readers of publication	1999	44% (N=132)	Between 18 and 31	24[g]
Metropolitan Chicago Healthcare Council[h]	Member hospitals	1999	72% (N=71)	20[g]	17[g]
J.W. Birk and others[i]	Membership of the Society of Gastroenterology Nurses and Associates	1999	46% (N=223)	16[c]	[d]

[a]ECRI, *Special Report: Reuse of Single-Use Medical Devices: Making Informed Decisions* (Plymouth Meeting, Pa.: ECRI, 1997), pp. 85-86.

[b]R.J. Cheung and others, "GI Endoscopic Reprocessing Practices in the United States," *Gastrointestinal Endoscopy*, Vol. 50, No. 3 (1999), pp. 362-68.

[c]GI endoscopic instruments only.

[d]Question not included in survey.

[e]ASHCSP, presentation at conference, "The Re-Use of Single-Use Devices: Practice, Patient Safety and Regulation," May 5-6, 1999.

[f]*OR Manager*, Vol. 15, No. 9 (1999), pp. 1, 11, 14.

[g]Includes opened but unused SUDs in addition to SUDs that have been used on a patient.

[h]Metropolitan Chicago Healthcare Council survey.

[i]J.W. Birk and others, "A National Survey on the Re-Use Patterns of 'Single Use Only' ERCP Supplies," *Gastrointestinal Endoscopy*, Vol. 49, No. 4 (1999), p. AB139.

The estimate of 20 to 30 percent may be low because some hospitals and other health care facilities do not report this practice. For example, representatives of manufacturers told us that their examination of SUDs that malfunctioned indicated that devices from some hospitals had clear evidence of reprocessing, even though the institutions denied reusing SUDs. Similarly, an official of the Department of Veterans Affairs (VA) told us that some VA hospitals reuse single-use cardiac catheters, even though SUD reprocessing is contrary to VA policy.[5] The surveys also may not completely capture the use of reprocessed SUDs in ambulatory surgery centers, physicians' practices, or other nonhospital institutions.[6]

The frequency of reprocessing varies widely among different devices, and most hospitals that reuse SUDs reuse only a few types of devices. For example, electrophysiology (EP) catheters (devices inserted into the heart to measure and correct cardiac rhythm disorders) have been reprocessed for 20 years, even though all models of them were approved for single-use only. Some types of EP catheters are relatively easy to clean (because they do not have long, hollow tubes), sterilize, and test. They also are expensive (ranging roughly from $100 to $1,500), and a typical EP procedure could involve the use of several catheters. In the course of our work, we contacted representatives of nine EP centers; seven of them acknowledged using reprocessed EP catheters. Several hospitals told us that EP catheters were among the very few SUDs they reused. Conversely, gastrointestinal (GI) biopsy forceps are more difficult to reprocess. The forceps are long and have hollow tubes and delicate mechanisms that make them harder to clean and sterilize. We contacted physicians from 17 gastroenterology centers, and none of these physicians said that their facilities reused GI biopsy forceps. (A list compiled by FDA of frequently reprocessed SUDs is in app. I.)

[5]The same VA official told us that there had been no reported problems with reused catheters.

[6]This is because some of the surveys did not include nonhospital institutions.

Many Health Care Professionals Question Single-Use Label

Many health care personnel believe that some SUDs can be reused. They told us they distrust the single-use label for some devices because (1) FDA cannot require manufacturers to support the designation of a device as single-use, (2) they perceive that manufacturers have an economic incentive to market devices as single-use that could just as well be sold as reusable, and (3) FDA's approval requirements for SUDs are less extensive than those for reusable devices. In addition, the application of the single-use label to noncritical medical devices erodes its meaning for some health care personnel.[7]

On occasion, manufacturers have contributed to the sense that compliance with the single-use label is not always necessary. We found three examples of this. First, a major manufacturer of pulse oximeter sensors (devices that measure blood oxygen levels) has a program to "recycle" the sensors, essentially offering to sell "remanufactured" sensors for reduced prices to health care institutions that return their used single-use sensors to the company. These SUDs are also reprocessed by third-party reprocessing firms, which cite the manufacturer's recycling program as evidence that the single-use label on these devices is not meaningful. Second, in a 1998 U.S. District Court case, the judge found that the manufacturer's only purposes in labeling a device for single-use were to comply with FDA's requirements and to limit its own liability from reuse, not to prevent a hospital from using it more than once.[8] Third, manufacturers have written letters to hospitals containing detailed instructions for the sterilization of SUDs. The letters typically caution against resterilizing the SUD and then give detailed sterilization instructions. Some of the letters note that the sterilization procedures may be used for open but unused devices, but others do not include that restriction. One letter volunteered that the manufacturer had verified that the device could be resterilized three times, although the manufacturer had not tested devices that had been used on patients. One hospital we talked with used the instructions in the letters as guidelines for its in-house reprocessing program.

[7]In addition, we repeatedly heard two claims that we were unable to verify. Health care personnel told us that they believed that some SUDs were identical to reusable devices. Similarly, FDA officials and health care personnel told us that they recalled that the labels of some devices were changed from reusable to single-use in years past without significant design changes.

[8]*United States Surgical Corp. v. Orris, Inc.*, 5 F. Supp.2d 1201 at 1207.

Evidence Indicates That Safe Reprocessing of Certain Devices Is Possible

While SUD reprocessing does pose some theoretical health risks, the available evidence indicates that some SUDs can be safely reprocessed and reused on other patients. The safety of reprocessing some types of devices, such as some types of EP catheters, is supported by a well-developed clinical literature. The infection control and patient safety experts we consulted told us that the reprocessing of certain SUDs is not a demonstrated public health risk, and SUD reprocessing is seen as safe by many associations representing health care professionals. Several reports of patient adverse events allegedly related to SUD reprocessing that we investigated were inaccurate, not relevant to the debate, or difficult to interpret. However, this does not mean that SUD reprocessing is always safe. For example, some reports of nonsterile reprocessed SUDs merit further investigation, and current surveillance systems are unlikely to detect all infections or injuries caused by reprocessed SUDs.

Reprocessing Procedures

To successfully reprocess a device that has been used on a patient, institutions must be able to clean it thoroughly, sterilize it to acceptable standards, and ensure that reprocessing and reuse will not degrade its functioning. Cleanliness is important because even measurably sterile devices can harbor biological material from previous uses that may prove a health risk for subsequent patients. Potentially, this biological residue by itself can prove toxic to new patients, and it also can form a crust to shield harmful bacteria from sterilization procedures. For these reasons, reprocessors assert that they choose devices to reprocess carefully, rejecting those that cannot be cleaned thoroughly or that are damaged by sterilization or reprocessing procedures.

The reprocessors we contacted, both third-party firms and hospitals, followed similar reprocessing procedures. Devices to be reprocessed are collected following established procedures and are frequently rinsed or otherwise cleaned soon after use, before they are sent to the reprocessing facility. There the devices are cleaned, refurbished, inspected, and sterilized. The third-party reprocessors told us that they check the function of every device before it is sterilized and returned to the client. These firms also told us that they do not mix devices from different hospitals—each hospital receives only devices from the batch it sent to the reprocessor. According to the reprocessors, many devices are rejected during reprocessing because they have been damaged, even among device models that are especially amenable to reprocessing. The reprocessors also told us that they or their client health care facilities set limits on the maximum

number of times an individual device can be reused. They also said that they keep track of the number of uses for each device and discard the devices when the limit is reached.

Reprocessors also resterilize open but unused SUDs. These are devices that were opened in preparation for a surgical procedure—and are therefore no longer sterile—but were not used on a patient. FDA, device manufacturers, and hospitals all agree that there is less risk in reprocessing these devices. Manufacturers told us that hospitals frequently ask them for sterilization instructions for opened but unused SUDs and that the manufacturers either provide instructions or advise the hospitals that the devices cannot be resterilized.

Available Evidence Suggests That Some Types of SUDs Can Be Safely Reprocessed

To assess the health risks of reprocessed SUDs relative to the risks from new devices, it would be best to compare the rates of patient injuries and illnesses caused by each. Unfortunately, neither comprehensive data about the numbers of adverse events caused by medical devices nor data about the numbers of patients exposed to particular devices exist today. Furthermore, new medical devices are not always perfect, and some patient injuries or infections are caused by SUDs at their first use. This means that individual cases of adverse events associated with reprocessed SUDs are not informative because we do not know how often these events occur with new SUDs. Therefore, to assess the safety of reprocessed SUDs, we evaluated information from a variety of complementary, but less than ideal, data sources.

Four types of information indicate that some devices labeled for single-use can be reprocessed safely and used again on other patients. First, the safety of reprocessing some types of devices has been established by well-developed clinical studies. Studies have shown both that reprocessing procedures can be safely accomplished and that patient outcomes are not adversely affected by the use of reprocessed SUDs. For example, several studies have documented the safe reprocessing and reuse of EP catheters. One study of more than 14,000 EP procedures found that the overall rate of patient infections was very low and did not differ between clinical centers

that reused EP catheters and centers that used each catheter only once.[9] A later study of 69 EP catheters used in 336 procedures concluded that carefully reprocessing one model of single-use catheter up to 5 times posed no increase in health risks.[10] Similarly, some evaluations of the reprocessing of single-use endoscopic instruments published in peer-reviewed scientific journals found that those SUDs could be reused at least several times without increasing patient risk.[11]

Second, the hospital infection control practitioners, risk management executives, and patient safety experts we interviewed all told us that careful reprocessing of the types of SUDs that can be properly cleaned and sterilized does not pose a risk to patient health. For example, the hospital infection control practitioners we contacted told us that all types of infectious bacteria and some key viruses (including human immunodeficiency virus (HIV) and hepatitis C) can be destroyed if devices are properly cleaned and sterilized and that they were not aware of any infections resulting from the reuse of SUDs in their hospitals. Hospital infection experts at CDC told us that the evidence showed that SUD reprocessing poses minimal, if any, public health risk. The CDC experts said that they were not aware of patient illnesses caused by SUD reuse in the last decade.[12] The head epidemiologist of CDC's Hospital Infection Program told us that although CDC does not specifically monitor SUD reuse, he was confident hospital infection surveillance systems would have uncovered infections resulting from SUD reuse if they had occurred. Risk management professionals told us that the hospitals they worked with had not received any claims of patient injury caused by the use of reprocessed SUDs. An official of a health quality consulting organization told us that his firm could find no evidence in its databases that treating patients with reprocessed SUDs was more dangerous than using new devices.

[9]S. O'Donoghue and E.V. Plata, "Reuse of Pacing Catheters: A Survey of Safety and Efficacy," *Pacing and Clinical Electrophysiology*, Vol. 11, No. 9 (1988), pp. 1279-80.

[10]B. Avitall and others, "Repeated Use of Ablation Catheters: A Prospective Study," *Journal of the American College of Cardiology*, Vol. 22, No. 5 (1993), pp. 1367-72.

[11]J. Cohen and others, "A Prospective Study of the Repeated Use of Sterilized Papillotomes and Retrieval Baskets for ERCP: Quality and Cost Analysis," *Gastrointestinal Endoscopy*, Vol. 45, No. 2 (1997), pp. 122-27; and R.A. Kozarek and others, "Reuse of Disposable Sphincterotomes for Diagnostic and Therapeutic ERCP: A One-Year Prospective Study," *Gastrointestinal Endoscopy*, Vol. 49, No. 1 (1999), pp. 39-42.

[12]However, CDC is aware of infections caused by hemodialyzers that were reprocessed for reuse on the same patient.

Partly because of the clinical literature and expert opinion just described, with the exception of groups representing device manufacturers, all of the professional organizations with positions on SUD reuse that we contacted or that submitted comments to FDA on the agency's regulatory proposal expressed at least qualified support for this practice. None sought to ban SUD reprocessing, although some supported FDA's plan to more closely regulate SUD reprocessing. These organizations included groups representing physicians, nurses, in-hospital sterilization professionals, infection control practitioners, and health care facilities.[13] Some of these associations and other organizations have issued guidelines to help hospitals develop SUD reprocessing programs. The guidelines usually give advice about assessing the costs and benefits of reprocessing SUDs, choosing devices that can be reprocessed safely, and evaluating the services offered by third-party reprocessing companies.

Third, only a very small percentage of the reports FDA has received through its Medical Device Reporting (MDR) program concerned patient adverse outcomes associated with reused SUDs, although this program probably underestimates the number of injuries with reprocessed SUDs.[14] For a roughly 3-year period ending in December 1999, FDA's Manufacturer and User Facility Device Experience database received nearly 125,000 reports of patient injuries, device malfunctions, or other potential problems associated with SUDs. FDA told us that 1,131 of those reports involved SUDs that had been reprocessed but that nearly 700 of them concerned dialysis equipment that was reprocessed for use on the same patient. Only 49 of the reports were for SUDs that are included on FDA's list of frequently reprocessed devices (36 for malfunctions, 9 for injuries, and 4 for other

[13]The organizations included the American College of Cardiology, the North American Society for Pacing and Electrophysiology, the American College of Surgeons, the American Society for Gastrointestinal Endoscopy, the Association of periOperative Registered Nurses, the Society of Gastroenterology Nurses and Associates, the American Society for Healthcare Central Service Professionals, the International Association of Healthcare Central Service Material Management, the Association for Professionals in Infection Control and Epidemiology, and the American Hospital Association.

[14]This is because the information on MDR reports that identifies SUDs as reused is inconsistent and probably incomplete. For example, an FDA official told us that FDA had received only six MDR reports that mentioned a third-party reprocessing firm by name and that three of them were for the same incident.

reasons), and it is not known whether those injuries were caused by reprocessing, by device failure unrelated to reprocessing, or by some other aspect of the medical procedure.[15]

Fourth, several of the reports we identified of patient adverse events allegedly related to SUD reprocessing were inaccurate, not relevant to the debate, or difficult to interpret. For example, it was reported that a recent patient death occurred in a Colorado hospital as a result of an infection transmitted by a reprocessed cardiac catheter. CDC officials told us that this incident occurred some time ago in a hospital that did not use reprocessed cardiac catheters. The infection ultimately was traced to improperly sterilized glass medicine cups. Similarly, it was alleged that SUD reuse caused increased rates of pneumonia in one group of children.[16] This was supported by a study of home use of tracheostomy tubes in children with breathing difficulties.[17] This is not relevant to the current debate because the reused tubes were cleaned at home with hydrogen peroxide, vinegar, or soap and water for use on the same child, not reprocessed by hospitals or third-party companies for use on other patients. Likewise, FDA received a report that the tip of a reused EP catheter broke off and lodged in a patient's heart. However, FDA also received two reports of similar injuries resulting from procedures with new, not reprocessed, EP catheters. In addition, a published report of blindness caused by the broken tip of a reused EP catheter migrating to a retinal artery is difficult to interpret because of the year and location of the case. It occurred overseas in 1984, and the sterilization procedures used on the catheter were different from the ones used today in the United States.

SUD Reprocessing Is Not Always Safe

While the evidence shows that carefully controlled reprocessing of some SUDs is safe, it is also clear that some SUDs cannot be safely reprocessed, procedures for safe reprocessing are not always followed, and the limitations of the information available about SUD reprocessing argue for monitoring of the practice. FDA researchers, original device

[15]The remaining reports were for devices other than those on FDA's list of frequently reprocessed devices or for devices that were reused on the same patient.

[16]Statement of Robert H. O'Holla, before the Oversight and Investigations Subcommittee, House Committee on Commerce (Feb. 10, 2000).

[17]S.C. Bahng and others, "Parental Report of Pediatric Tracheostomy Care," *Archives of Physical Medicine and Rehabilitation*, Vol. 79, No. 11 (1998), pp. 1367-69.

manufacturers, and third-party reprocessors all agree that many types of SUDs cannot be reprocessed safely. For example, the largest third-party reprocessing firm told us that it reprocesses only 15 "families" of devices and that many of these involve only the resterilization of opened but unused devices. There is also agreement that, even for some categories of SUDs that can be reprocessed, some models can be thoroughly cleaned and sterilized, while others cannot. For instance, two third-party reprocessing firms told us that they identify for clients particular device models that can be successfully reprocessed. Thus, the hospitals and ambulatory surgery centers that contract with these reprocessing firms can, in purchasing new devices that they intend to reuse, avoid ones that the firms will not reprocess.

For devices that can be reprocessed safely, cleaning and sterilization procedures are not always followed correctly. For example, a 1997 survey of gastrointestinal endoscopy physicians found that about one-quarter of endoscopic facilities failed to follow all of a professional association's guidelines for cleaning and sterilizing endoscopic instruments.[18] Four percent of the respondents to that survey reported patient infections associated with endoscopic procedures, although there was no indication that the infections resulted from the use of reprocessed SUDs. Also, underlining the potential risks of SUD reprocessing, infection outbreaks occur occasionally that are due to sterilization failures for devices approved for marketing as reusable. The outbreaks are detected in hospitals when unusually high numbers of patients become ill with the same infectious agent. For example, CDC reported that the failure of automatic cleaning machines to properly clean bronchoscopes and endoscopes led to at least five infectious outbreaks.[19]

For reprocessed SUDs, device manufacturers have forwarded to FDA reports of allegedly damaged, unclean, or nonsterile devices taken from hospital stocks that had been reprocessed by third-party reprocessing firms. FDA found that at least one of these claims had merit. In March 1999, a manufacturer told FDA that six of its reprocessed GI biopsy forceps it

[18]R.J. Cheung and others, "GI Endoscopic Reprocessing Practices in the United States."

[19]CDC, "Nosocomial Infection and Pseudoinfection from Contaminated Endoscopes and Bronchoscopes—Wisconsin and Missouri," *Morbidity and Mortality Weekly Report*, Vol. 40, No. 39 (1991), pp. 675-78; and CDC, "Bronchoscopy-Related Infections and Pseudoinfections—New York, 1996 and 1998," *Morbidity and Mortality Weekly Report*, Vol. 48, No. 26 (1999), pp. 557-60.

retrieved from a Florida hospital were not sterile. The devices were labeled for single-use only and had been reprocessed by a third-party reprocessing company. These biopsy forceps are nearly 8 feet long, and the sterility testing procedure used by the manufacturer involved cutting the devices into segments to allow better access to the center portions of the hollow tubing. Using established test procedures that did not segment the biopsy forceps, both FDA and the reprocessing firm subsequently tested devices from the same lot and found them to be sterile. FDA now believes that the sterility test protocol it used was not the best one for these devices, and it is preparing a new protocol. Although there is no evidence that these reprocessed devices have harmed patients, this case demonstrates the possibility that some reprocessed SUDs sterilized according to current protocols may not be free of bacterial contamination.

Current surveillance systems for medical errors and adverse events almost certainly do not detect all infections and injuries resulting from the use of reprocessed SUDs (or from the use of medical devices in general). It is well known that surveillance systems based on spontaneous reports by health care providers and manufacturers are plagued by underreporting, incomplete reports, and other problems.[20] As we have previously reported, FDA's surveillance system for medical devices—the MDR program—is no exception.[21] For example, when FDA conducted a pilot test of a sentinel system for gathering adverse event reports for medical devices (working closely with selected health care institutions to increase reporting rather than trying to maximize reporting among all institutions), it received adverse event reports at a rate 10 times greater than the MDR program, even though MDR regulations mandate the reporting of the same types of events. In addition, FDA officials and infection control experts told us that it is often difficult to identify the source of infections in individual patients, and it is particularly difficult to trace infections back to the use of specific medical devices.

[20]See *Adverse Events: Surveillance Systems for Adverse Events and Medical Errors* (GAO/T-HEHS-00-61, Feb. 9, 2000).

[21]See *Medical Device Reporting: Improvements Needed in FDA's System for Monitoring Problems With Approved Devices* (GAO/HEHS-97-21, Jan. 29, 1997).

SUD Reprocessing Reduces Hospital Costs for Medical Devices

Reprocessed SUDs cost less than new devices. Independent reprocessing firms charge hospitals and ambulatory surgery centers approximately one-half of the price of a new device for each reprocessed SUD, while three hospitals that reprocess EP catheters in-house told us that their reprocessing costs were less than 10 percent of the price of a new device. Although there is some debate about how to calculate the true costs of reprocessing (including, for example, the staff time needed to study the safety and cost-effectiveness of reprocessing particular devices and to perform quality-control functions), hospitals that use reprocessed SUDs told us that they save money by doing so. For example, one group of hospitals that uses reprocessed SUDs estimated that their annual savings per hospital were $44,000 for sequential compression devices, $17,000 for pulse oximeter sensors, and $115,000 for EP catheters. Other hospitals with active cardiology services gave us higher estimates for their savings from reusing EP catheters, ranging from $200,000 to $1 million annually.

The exact prices paid for new SUDs result from negotiations between individual manufacturers and individual purchasers. The competitive alternative offered by SUD reprocessing has affected negotiations between manufacturers and purchasers and may have caused some manufacturers to lower their prices to some purchasers. For example, we found evidence that manufacturers sometimes offer lower prices to facilities that agree not to reprocess. We obtained copies of marketing materials from a manufacturer of single-use sequential compression devices offering to reduce prices if the purchasing hospital signed a contract stipulating that it would not reprocess the devices. For two hospitals we contacted, manufacturers offered to reduce the price of new EP catheters by as much as one-half, matching the price of third-party reprocessing, if the facilities would agree to not reprocess the devices. A major third-party reprocessing firm told us that some hospitals stopped using its services when offered this arrangement by manufacturers. We were not able to determine how often manufacturers offer these price breaks.

The overall prices of some SUDs that are reprocessed appear to have decreased in recent years, even for health care institutions that do not reuse them, although we were unable to attribute the price drops to reprocessing. For instance, one third-party reprocessing firm showed us evidence that the prices its clients paid for new GI biopsy forceps, pulse oximeter sensors, and sequential compression devices had declined 20 percent or more over the last few years. A manufacturer of one of these devices confirmed to us that its prices had declined, although the company

cited reasons other than reprocessing. Similarly, a majority of the gastroenterologists we contacted told us that the prices their facilities paid for new single-use GI biopsy forceps had decreased, and none of them reprocessed these devices.

FDA's Proposed Regulatory Framework Will Extend Requirements Faced by Manufacturers to Most SUD Reprocessors

FDA's current regulatory scheme results in uneven requirements for FDA review. Its proposed revisions would treat most SUD reprocessors as manufacturers. The proposed framework also would give FDA more information about SUD reprocessing and strengthen its oversight of reprocessing. However, there are significant barriers to the framework's successful implementation.

Limitations of FDA's Current Regulatory Scheme

FDA's current regulation of SUD reprocessing represents a balance between its regulatory obligations, its judgment that SUD reprocessing has not posed a significant risk to the public health, and its limited resources. FDA categorizes all entities that reprocess SUDs, including third-party reprocessing firms, hospitals, and ambulatory surgery centers, as device manufacturers,[22] and therefore they are technically required to comply with good manufacturing practices, FDA inspection, and manufacturers' adverse events reporting regulations. FDA has enforced these provisions for third-party reprocessing firms but not for hospitals and other health care institutions that reprocess SUDs. In addition, because FDA has not required reprocessors to seek premarket approval for reprocessing SUDs, technically all reprocessors are engaged in the practice of selling adulterated medical devices. However, because FDA has judged that SUD reprocessing has not posed a significant risk to the public health, it has exercised "regulatory discretion" to allow SUD reprocessing to continue and to focus its limited enforcement resources in other areas. FDA has the authority to immediately halt any practice that threatens the public's health and has not done so with SUD reprocessing because it believes there has been no evidence that the public health has been threatened.

Some manufacturers have complained that FDA's inconsistent enforcement of premarket requirements has disadvantaged them relative to

[22]21 C.F.R. 820.3 (o). All reprocessors of SUDs are considered manufacturers.

reprocessors. Manufacturers that want to market a reusable device must submit data to FDA, through a 510(k) or PMA, that convinces the agency that a device can be safely reprocessed for a set number of times without compromising its function. Currently, while third-party firms must register with FDA and meet FDA's standards for good manufacturing practices, they can reprocess SUDs without seeking premarket approval from FDA. FDA has not regulated hospitals and other health care institutions that reprocess SUDs in-house.

Another difficulty with the current policy has been FDA's inability to inspect all third-party reprocessors because it has been unable to identify them. In early June 2000, FDA officials told us that FDA had identified 14 reprocessing facilities operated by 13 different reprocessing firms and that the agency had inspected all but two of those facilities. FDA discovered two of the third-party reprocessors only when the firms identified themselves to the agency by submitting comments on FDA's proposed regulatory framework. In the course of our work, we found one third-party reprocessing firm that was not known to FDA, and we forwarded information about it to the agency. FDA suspects that there are more third-party reprocessors that have not registered with the agency.

FDA's Proposed Regulatory Framework Will Enforce Current Requirements for Reprocessors

FDA's proposed regulatory framework will make major changes to the oversight of SUD reprocessing. The framework will extend enforcement of all of FDA's requirements for device manufacturers to hospitals that reprocess SUDs and third-party reprocessing firms.[23] There will be three major changes. First, hospitals will be expected to satisfy all the requirements now faced by third-party reprocessing firms, such as registering with FDA, telling FDA which devices they reprocess, fulfilling the MDR reporting requirements for manufacturers (in addition to current user facilities' MDR requirements),[24] using reprocessing procedures that meet the standards for good manufacturing practices, and facing inspection by FDA. Second, both hospitals that reprocess SUDs and third-party reprocessing firms will be required to meet all applicable premarket

[23]FDA, *Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals* (Rockville, Md.: FDA, Feb. 2000).

[24]MDR reporting requirements for manufacturers include reporting deaths, serious injuries, and malfunctions to FDA within 30 days; reporting events that require immediate remedial action to FDA within 5 days; and filing baseline reports to communicate basic data about each device that is the subject of a report.

requirements. That is, they will have to conduct the appropriate studies and submit relevant documentation to FDA as if they were seeking to market a new device. Thus, for many devices, SUD reprocessors will be required to submit a 510(k) demonstrating that the reprocessed device is substantially equivalent to a device already on the market, presumably the same device before it has been reprocessed. For other devices with higher risk, SUD reprocessors will be required to conduct clinical trials and gather other information to submit a PMA to show that the device is safe and effective. For example, among reprocessed devices, GI biopsy forceps will require a 510(k), and cardiac ablation catheters (a type of EP catheter) will require a PMA. Finally, all reprocessors will be required to follow general requirements for labeling SUDs, including providing adequate instructions for use. Neither the hospitals nor the third-party reprocessors we contacted now include instructions for use on their labels because reprocessed devices ordinarily are returned to facilities that already have instructions from the manufacturer's original labeling of the device.[25]

FDA's proposed regulatory framework for SUD reprocessing specifically exempts opened but unused SUDs. The proposed framework also does not apply to health care facilities other than hospitals that reprocess SUDs in-house. By at least temporarily excluding ambulatory surgery centers, physicians' practices, and other nonhospital health care institutions from regulation, the proposal maintains the inconsistency of the current policy by exempting some categories of reprocessors from FDA oversight.

FDA plans to issue a final guidance document in July 2000, with the new requirements taking effect over an 18-month period starting then. Hospitals that reprocess SUDs will be subject to FDA's manufacturer facilities requirements (registration, listing, inspection, and MDR reporting) 6 months after the final guidance is issued. Premarket approval requirements for frequently reprocessed SUDs will also begin to take effect 6 months after the final instructions are issued for devices FDA considers high risk, in 12 months for moderate-risk devices, and in 18 months for low-risk devices. FDA is phasing in the enforcement of these requirements for several reasons: (1) it believes that its regulatory activities should be implemented in accordance with the potential health risk associated with the reprocessed device; (2) the potential exists for unintended and unpredictable consequences if FDA enforces all requirements immediately,

[25]To the extent that these instructions infringe on the copyrighted instructions of the original manufacturers, it may be very difficult for reprocessors to meet this requirement.

such as shortages of reprocessed SUDs in certain hospitals; (3) hospitals need time to learn about and comply with FDA regulations; and (4) FDA lacks the resources to immediately enforce all regulatory requirements.

SUD Reprocessors and FDA May Have Difficulty Implementing the New Framework

FDA's proposed regulatory framework imposes a structure designed to oversee the manufacture of new medical devices onto the different enterprise of SUD reprocessing. Implementation of this new framework will face a number of barriers, including SUD reprocessors' inexperience with FDA's regulations for medical device manufacturers.

Hospitals that reprocess SUDs have no experience with FDA's regulation of medical devices and device manufacturers, even though FDA technically considers them to be device manufacturers now. And, while third-party reprocessing firms already collect some of the data FDA will require for premarket approval of reprocessed SUDs, their ability to adjust to the new requirements is not assured. For example, third-party reprocessors may find it difficult to conduct the clinical studies needed to submit PMAs. FDA and some third-party reprocessors are working together to develop prototype premarket applications for reprocessing.

Important details about the operation of the new framework that will affect its implementation have yet to be finalized by FDA. For instance, the extent to which FDA will accept premarket applications for groups of similar devices, rather than for each model of a device, has yet to be determined. Similarly, some manufacturers have told FDA that some class I devices that are exempt from premarket approval would pose risks if reprocessed. The number of SUDs requiring FDA approval to be reprocessed could increase if FDA agrees with that assessment.

Another implementation hurdle is that FDA will probably not be able to identify all of the reprocessors that will be subject to the new regulatory framework, at least in the short term. FDA has not yet located all of the third-party reprocessing firms that it suspects operate today. In addition, although it is engaged in an outreach effort to educate hospitals that reprocess SUDs in-house about the new requirements, we believe FDA will find it difficult to identify reprocessing hospitals unless they voluntarily register with the agency.

Furthermore, the potentially large number of additional premarket applications and manufacturing facilities to inspect could overburden FDA's already stretched resources. FDA officials told us that the agency has

about 500 staff involved in reviewing premarket applications for medical devices and inspecting device manufacturers. These staff reviewed about 5,000 premarket applications and completed approximately 1,050 inspections of medical device manufacturing facilities in fiscal year 1999. FDA's fiscal year 2001 budget request includes an additional 5 staff years for work on reprocessing issues. The number and complexity of 510(k)s and PMAs that will be submitted for reprocessing are unknown, as is the number of hospitals that will register with the agency. But FDA could receive many premarket applications because applications are required from each entity for each device that it wishes to reprocess. A large number of applications may impede FDA's ability to oversee reprocessing and may compromise its work in other areas. For example, premarket submissions for reprocessing will be placed in the same queue as 510(k)s and PMAs for new medical devices. An FDA official told us that this additional work may decrease the percentage of marketing applications for new devices that are reviewed in a timely manner.

Recognizing its resource constraints, FDA has asked HCFA and JCAHO for assistance in monitoring SUD reprocessing in hospitals.[26] We found that neither HCFA nor JCAHO plans to make a substantial contribution to this effort in the near term. HCFA could potentially affect SUD reuse in two ways—by altering its coverage policies or by changing the terms of participation for hospitals to participate in Medicare. Regarding coverage policies, Medicare generally does not cover medical devices that are not approved by FDA, and HCFA has agreed that it will not pay for SUDs reprocessed without FDA's approval. In commenting on a draft of this report, HHS stated that HCFA will review Medicare coverage and payment rules once FDA's new framework takes effect. However, HCFA currently lacks the means to determine whether it is paying for a new or a reprocessed device because it pays for the treatment of particular conditions, not for individual pieces of equipment that may be used in treatment. For the terms of participation, a HCFA official told us that it has no plans to include requirements about the reuse of SUDs in any of its standards for Medicare conditions of participation for health care facilities.

[26]HCFA administers Medicare and its related facility survey and certification programs. JCAHO is a private organization that inspects and accredits hospitals for participation in Medicare. JCAHO surveys hospitals every 3 years.

FDA has consulted with JCAHO with the hope that it could eventually perform inspections to FDA's standards for SUD reprocessing in hospitals.[27] This would include providing hospital identifying information to FDA so that FDA could take enforcement actions. As of mid-May 2000, JCAHO had agreed to inform hospitals about FDA's policy on SUD reuse and to ask three questions about in-house SUD reprocessing on FDA's behalf during its hospital surveys for a 6-month period: (1) Does the hospital reprocess and reuse devices labeled for single-use, and if so, which devices does it reprocess or reuse? (2) Is the hospital aware of FDA's requirements for registration and listing of the devices it chooses to reprocess and reuse? (3) Does the hospital intend to continue to reprocess and reuse such devices? JCAHO will provide the answers to FDA on an aggregate basis, without identifying individual hospitals. FDA is paying JCAHO a small fee for this service. In the long term, JCAHO's suitability for conducting inspections on FDA's behalf has not been established. For example, JCAHO's survey practices and policies for protecting confidential hospital information may conflict with FDA's need to take public enforcement actions.[28] In addition, if their collaboration proceeds, FDA may need to pay JCAHO for these inspections.

FDA's New Framework May Decrease SUD Reprocessing in Hospitals

FDA's proposed framework imposes significant new requirements on institutions that reprocess SUDs, but it also grants specific FDA approval for SUD reprocessing. Because of these conflicting consequences, the net effect on SUD reprocessing is uncertain. It may lead to an overall decrease in the number of SUDs that are reprocessed, at least until the new regulatory system is functioning well. If this happens, there is a chance that the price of new devices will increase as the competitive alternative of SUD reprocessing becomes less viable. Also, an FDA official expressed concern that temporary shortages of reprocessed SUDs may occur in some hospitals, causing the hospitals to seek devices from other sources.

FDA officials, hospital administrators, physicians, and device manufacturers all told us that hospitals will be much less likely to maintain in-house SUD reprocessing operations under the new framework. Some hospitals that currently reprocess in-house are likely to contract with third-

[27]In lieu of inspections by FDA, manufacturers can now pay to be inspected by independent organizations that are acceptable to FDA.

[28]HHS, Office of Inspector General, *The External Review of Hospital Quality: Holding the Reviewers Accountable*, OEI-01-97-00053 (Washington, D.C.: HHS, July 1999).

party reprocessing firms for that work. This shift may ease FDA's task of inspecting hospitals that reprocess SUDs. It also could increase the costs of reprocessing to hospitals, because, according to the hospitals we contacted, third-party firms are more expensive than their internal reprocessing operations. At least some third-party firms anticipate an increase in business, both because of the expected shift in reprocessing from hospitals and because they expect that FDA's formal approval of the reprocessing of particular SUDs will improve their marketing success.

Conclusions

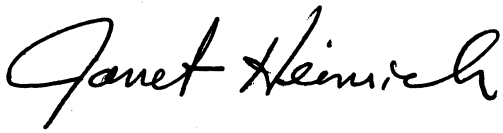
The evidence suggests that some SUDs can be safely reprocessed if appropriate cleaning, testing, and sterilization procedures are carefully followed. However, SUD reprocessing is not invariably safe, and relatively little is known about the practice of SUD reprocessing in health care institutions. For this reason, FDA has taken steps to increase its oversight of SUD reprocessing. Nonetheless, the new framework does not treat all types of reprocessors consistently and will be difficult to implement. Furthermore, because the demonstrated health risks from SUD reprocessing are small, it may have only a limited impact on public health.

Agency Comments

In its comments on a draft of this report, HHS said that the report accurately describes current reuse practices, the potential health risks of SUD reprocessing, and current and planned regulatory approaches to SUD reprocessing. HHS also emphasized that FDA is the lead agency for the regulation of medical devices and that HCFA will review its policies when FDA's new regulatory framework takes effect. HHS also provided technical comments, which we incorporated where appropriate. (HHS' comments are in app. II.)

As arranged with your offices, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days after its issue date. We will then send copies to the Honorable Donna E. Shalala, Secretary of Health and Human Services, and the Honorable Jane E. Henney, Commissioner of FDA. We will also make copies available to others who request them.

The major contributors to this report were Elizabeth A. Bradley, Marcia Crosse, Martin T. Gahart, Janina R. Johnson, and Stefanie Weldon. If you or your staffs have any questions, please contact me at (202) 512-7119.



Janet Heinrich
Associate Director, Health Financing and
Public Health Issues

FDA's List of Frequently Reprocessed SUDs

Cardiovascular Devices	Angiography catheter Blood pressure cuff Cardiac ablation catheter Cardiac guidewire Compressible limb sleeve Electrophysiology recording catheter Intra aortic balloon catheter Needle Percutaneous transluminal coronary angioplasty (PTCA) catheter Percutaneous transluminal angioplasty (PTA) catheter Syringes Trocar
Respiratory Devices	Breathing mouthpiece Endotracheal tubes Masks Oral and nasal catheters Respiratory therapy and anesthesia breathing circuits Tracheobronchial suction catheter
Gastroenterology/Urology Devices	Biliary sphincterotomes Biopsy needles Endoscopic guidewires Endoscopic staplers Extraction balloons/baskets Non-electric biopsy forceps Trocar Urethral catheters
Nephrology Devices	Hemodialysis blood tubing
OB-GYN Devices	Laparoscopic dissectors Laparoscopic graspers

	Laparoscopic scissors
	Trocar
Orthopedic Devices	Arthroscopy instruments
	Carpal tunnel blade
	Drill bits
	External fixation device
	Flexible reamers/drills
	Saw blades
	Surgical drills
Surgery Devices	Biopsy forceps
	Biopsy needles
	Burr
	Electrosurgical electrodes/handles/pencils
	Endoscopes
	Endoscopic blades
	Endoscopic guidewires
	Endoscopic staplers
	Fascia holders
	Laproscope
	Laser fiber delivery systems
	Scissor tips, removable inserts
	Surgical cutting accessories
	Trocar
Other Medical Devices	Stapler
	Glucometer lancets
	Keratome blade
	OR drapes
	Phacoemulsification needle
	OR gowns
	Sharps containers
	Syringes, piston
	Infusion pump, implanted
	Syringe, irrigating

Source: FDA, Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme (Feb. 8, 2000).

Comments From the Department of Health and Human Services

Note: A GAO comment supplementing those in the report text appears at the end of this appendix.

DEPARTMENT OF HEALTH & HUMAN SERVICES Office of Inspector General

Washington, D.C. 20201

JUN 12 2000

Ms. Janet Heinrich
Associate Director, Health Care Financing
and Public Health Issues
United States General
Accounting Office
Washington, D.C. 20548

Dear Ms. Heinrich:

The Department of Health and Human Services appreciates the opportunity to comment on the General Accounting Office's (GAO) draft report, "Single-Use Medical Devices: Little Evidence That Reprocessing Endangers Public Health" before its publication.

The draft report accurately summarizes current reuse practices, the limited risks currently known to be associated with reprocessed devices, and current and planned regulatory approaches with respect to reprocessing devices.

It should be noted, however, that we do not believe the draft report's characterization of the Department's Health Care Financing Administration's (HCFA) role and position regarding reuse of single-use medical devices is accurate. While HCFA is committed to assuring safe and effective care of Medicare beneficiaries, we believe that the issue of reprocessed single-use devices concerns quality of care for all patients, not just Medicare beneficiaries. With respect to HCFA's role in implementing regulatory policies established by the Department's Food and Drug Administration (FDA), the GAO report should state that HCFA recognizes that FDA regulates the manufacture of medical devices. Therefore, FDA will take the lead in finalizing policy on reprocessing single-use devices. Once FDA has established the policy, HCFA will review Medicare coverage and payment rules to determine if any changes are necessary to ensure consistency. It is not HCFA's responsibility to include requirements concerning reuse of single-use devices until such time as FDA has completed their rulemaking.

See comment 1.

The Department also provided some technical corrections directly to your staff.

These comments represent the tentative position of the Department and are subject to reevaluation when the final version of this report is received.

Sincerely,

Michael Mangano
for June Gibbs Brown
Inspector General

The Office of Inspector General (OIG) is transmitting the Department's response to this draft report in our capacity as the Department's designated focal point and coordinator for General Accounting Office reports. The OIG has not conducted an independent assessment of these comments and therefore expresses no opinion on them.

The following is GAO's comment on the Department of Health and Human Services' letter dated June 12, 2000.

GAO Comment

1. We have added language to the report to indicate that HCFA will review Medicare coverage and payment policies once FDA's new regulatory framework takes effect.

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