

GAO

Testimony

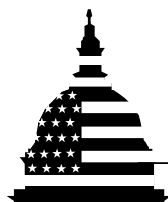
Before the Committee on Health, Education, Labor, and Pensions, U.S. Senate

For Release on Delivery
Expected at 10:00 a.m.
Tuesday, June 27, 2000

MEDICAL DEVICES

**Reprocessing and Reuse of
Devices Labeled Single-
Use**

Statement of Janet Heinrich, Associate Director
Health Financing and Public Health Issues
Health, Education, and Human Services Division



G A O

Accountability * Integrity * Reliability

Medical Devices: Reprocessing and Reuse of Devices Labeled Single-Use

Mr. Chairman and Members of the Committee:

I am pleased to have the opportunity to testify as the committee considers issues relating to the reprocessing and reuse of medical devices marketed for single use. As you know, 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. The practice of SUD reprocessing reduces the costs of medical devices for hospitals and other health care facilities, but it also raises public health concerns, primarily regarding the potential risks of infection and device malfunction, and has led to complaints that the Food and Drug Administration (FDA) has failed to provide consistent oversight. You asked us to discuss the results of our recent report on this issue.²

I will summarize the key findings of our report, which focuses 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 reesterilization of opened but unused devices, or devices reprocessed for additional use on the same patient. SUDs are those devices for which manufacturers have not submitted evidence to FDA that they can be used multiple times; this does not necessarily mean that they cannot be used more than once if appropriately reprocessed.

It is clear that some health care facilities have chosen to reprocess and reuse some kinds of SUDs, but accurate and comprehensive information about the number of facilities that use reprocessed SUDs and the types of SUDs that are reprocessed is not available. According to various surveys, approximately 20 to 30 percent of American hospitals reported that they reuse at least one type of SUD and at least one-third of the hospitals that do so contract with third-party reprocessing companies. The results of clinical studies show that selected devices can be reprocessed safely if appropriate procedures are followed and closely monitored, a view shared by many professional organizations and infection control experts. However, this does not mean that SUD reprocessing is always safe.

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

²*Single-Use Medical Devices: Little Available Evidence of Harm From Reuse, but Oversight Warranted* (GAO/HEHS-00-123, June 20, 2000).

Current medical device 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, and there is general agreement that many types of SUDs cannot be effectively cleaned and sterilized. Reprocessing SUDs can produce substantial cost savings, with independent reprocessing firms charging 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. FDA is about to institute a new regulatory framework for SUD reprocessing that will require independent reprocessing firms and hospitals to obtain FDA's approval before they can reprocess many devices labeled for single use. The framework will provide FDA with more information and strengthen its oversight of reprocessing. However, there are significant barriers to the framework's successful implementation.

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 describe how they should be used, and the facilities that manufacture them. FDA's requirements for approving devices for marketing depend on the devices' potential for harming patients, with greater data and documentation required for higher-risk 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 Manufacturers that wish to market a device for 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. Thus, FDA's approval of a device for 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. 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 it will still meet performance specifications after reprocessing.

³Food 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.

Manufacturers 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 sold for single use.⁴

The Extent of Reprocessing

Third-party reprocessing firms and some hospitals and other health care facilities 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 reprocessing firms said that its members collectively received about \$20 million annually for their services. Evidence indicates that only a minority of the approximately 6,000 hospitals and 2,700 ambulatory surgery centers in the United States reprocess SUDs in-house.

While it is clear that some health care facilities 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. We found six surveys about SUD reprocessing conducted 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 are affiliated. Most 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, with only one survey having a response rate greater than 50 percent, and health care facilities that use reprocessed SUDs may have disproportionately declined to respond to the surveys. The surveys also may not completely capture the use of reprocessed SUDs in ambulatory surgery centers, physicians' practices, or other nonhospital facilities.⁵

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

⁴FDA 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.

⁵This is because some of the surveys did not include nonhospital facilities.

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, sterilize, and test. They also are expensive enough for hospitals to consider the cost savings from reprocessing sufficient to warrant considering reuse. 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, and none of the gastroenterology centers we contacted said that they reused these devices.

Available Evidence Suggests That Some Types of SUDs can be Safely Reprocessed

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.⁶

The hospital infection control practitioners, risk management executives, and patient safety experts we interviewed told us that careful reprocessing of the types of SUDs that can be properly cleaned and sterilized does not pose an additional risk to patient health. Hospital infection experts at the Centers for Disease Control and Prevention told us that the evidence showed that SUD reprocessing poses minimal public health risk. 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. 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 SUD reprocessing and reuse. 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.

⁶S. 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.

We found little indication in reports of adverse events related to medical devices that SUD reprocessing is unsafe. 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 from reprocessed SUDs.⁷ 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 (less than 1 percent) of those reports involved SUDs that had been reprocessed but that nearly 700 of the reports concerned dialysis equipment that was reprocessed for use on the same patient. Only 49 of the reports were for SUDs included on FDA's list of frequently reprocessed SUDs, and it is not known whether those injuries and malfunctions were caused by reprocessing, by device failure unrelated to reprocessing, or by some other aspect of the medical procedure.⁸

Several of the public reports we identified of patient adverse events allegedly related to SUD reprocessing were inaccurate, did not involve the type of reprocessing discussed here, or were difficult to interpret. For example, it was alleged that SUD reuse caused increased rates of pneumonia in one group of children.⁹ This was supported by a study of home use of tracheostomy tubes in children with breathing difficulties.¹⁰ This is not relevant to the current discussion 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 EP catheters.

⁷This 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.

⁸The 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.

⁹Statement of Robert H. O'Holla, before the Oversight and Investigations Subcommittee, House Commerce Committee (Feb. 10, 2000).

¹⁰S.C. Bahng and others, "Parental Report of Pediatric Tracheostomy Care," *Archives of Physical Medicine and Rehabilitation*, Vol. 79, No. 11 (1998), pp. 1367-69.

SUD Reprocessing Not Always 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 the practice. FDA researchers, original device manufacturers, and third-party reprocessors all agree that many types of SUDs cannot be reprocessed safely. 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 distinguish for clients particular device models that can, or cannot, be successfully reprocessed.

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.¹¹ Also underscoring the potential risks of SUD reprocessing, infection outbreaks occur occasionally that are due to sterilization failures for devices approved for marketing as reusable.¹²

Device manufacturers have forwarded to FDA reports of allegedly damaged, unclean, or nonsterile reprocessed SUDs 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 reprocessed GI biopsy forceps it 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

¹¹R.J. Cheung and others, "GI Endoscopic Reprocessing Practices in the United States."

¹²CDC, "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.

possibility that some reprocessed SUDs sterilized according to current protocols might 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.¹³ 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 can be particularly difficult to trace infections back to the use of specific medical devices.

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, hospitals that use reprocessed SUDs told us that they save money by doing so. For example, hospitals gave us estimates for their savings from reusing EP catheters ranging from \$115,000 to \$1 million annually.

The exact prices paid for new SUDs are arrived at during negotiations between individual manufacturers and individual purchasers. The competitive alternative offered by SUD reprocessing appears to have affected negotiations between manufacturers and purchasers and may have caused some manufacturers to lower their prices to some purchasers. For example, 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.

¹³See *Adverse Events: Surveillance Systems for Adverse Events and Medical Errors* (GAO/T-HEHS-00-61, Feb. 9, 2000).

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

FDA categorizes all entities that reprocess SUDs—including third-party reprocessing firms, hospitals, and ambulatory surgery centers—as device manufacturers, 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 facilities that reprocess SUDs. Currently, manufacturers that want to market a reusable device must submit data to FDA that convinces the agency that a device can be safely reprocessed for a set number of times without compromising its function. 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.

A difficulty with the current policy has been FDA's inability to inspect all third-party reprocessors because it has been unable to identify them. This month, 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 suspects that there are more third-party reprocessors that have not registered with the agency.

FDA has proposed a new regulatory framework that 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.¹⁴ 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, using reprocessing procedures that meet the standards for good manufacturing practices, and facing inspection by FDA. Second, hospitals that reprocess SUDs and third-party reprocessing firms will be required to meet all applicable premarket requirements. That is, they will have to submit relevant documentation to FDA as if they were seeking to market a new device. Finally, all reprocessors will be required to follow general requirements for labeling SUDs, including providing adequate instructions for use.¹⁵ FDA

¹⁴FDA, *Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals* (Rockville, Md.: FDA, Feb. 2000).

¹⁵Neither 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. To the extent that these required instructions infringe on the copyrighted instructions of the original manufacturers, it may be difficult for reprocessors to meet this requirement.

plans to issue a final guidance document in July 2000, with the new requirements taking effect over an 18-month period starting then.

FDA's proposed regulatory framework 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 and other nonhospital health care facilities from regulation, the proposal maintains the inconsistency of the current policy by exempting some reprocessors from FDA oversight.

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.

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. In addition, although it is engaged in an outreach effort to educate hospitals that reprocess SUDs in-house about the new requirements, we believe that FDA will find it difficult to identify reprocessing hospitals unless they voluntarily register with the agency.

The potentially large number of additional premarket applications and manufacturing facilities to inspect could overburden FDA's already stretched resources. The number and complexity of marketing applications that will be submitted for reprocessing is 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. Premarket submissions for reprocessing will be placed in the same queue as marketing applications for new medical devices and 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.

**FDA's New Framework
May Decrease SUD
Reprocessing in Hospitals**

FDA's proposed framework imposes significant new requirements on institutions that reprocess SUDs. 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-party reprocessing firms for that work. At least some third-party firms anticipate an increase in business.

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 facilities. For this reason, FDA has taken steps to increase its oversight of SUD reprocessing. Nonetheless, the new framework is cumbersome and will be difficult to implement.

This concludes my prepared statement, Mr. Chairman. I will be happy to respond to any questions that you or Members of the Committee may have.

**Contacts and
Acknowledgments**

For future contacts regarding this testimony, please call Janet Heinrich at (202) 512-7119. Key contributors include Lisanne Bradley, Marcia Crosse, Martin T. Gahart, Janina R. Johnson, and Stefanie Weldon.

(201074)

Ordering Information

Orders by Internet

For information on how to access GAO reports on the Internet, send an e-mail message with "info" in the body to:

Info@www.gao.gov

or visit GAO's World Wide Web home page at:

<http://www.gao.gov>

To Report Fraud, Waste, and Abuse in Federal Programs

Contact one:

Web site: <http://www.gao.gov/fraudnet/fraudnet.htm>

E-mail: fraudnet@gao.gov

1-800-424-5454 (automated answering system)