SB 361

LINDA LINGLE
GOVERNOR OF HAWAII

CHIYOME LEINAALA FUKINO, M.D.
DIRECTOR OF HEALTH

STATE OF HAWAII
DEPARTMENT OF HEALTH
P.O. Box 3378
HONOLULU, HAWAII 96801-3378

In reply, please refer to:
File:

Senate Committee on Health

SB 361, RELATING TO SINGLE-USE MEDICAL DEVICES

Testimony of Chiyome Leinaala Fukino, M.D.
Director of Health

February 9, 2009
2:45pm

Department's Position: The Department respectfully opposes this bill.

Fiscal Implications: The Department opposes this measure because it would adversely impact the priorities set forth in the Executive Biennium Budget for Fiscal Years 2009-2010.

Purpose and Justification: This bill amends HRS Chapter 328 by introducing new language that requires the Department to provide oversight and the creation of new rules pertaining to reprocessed single-use medical devices.

We appreciate the intent of the bill however the U.S. Food and Drug Administration (FDA) already regulates reprocessors of single-use medical devices and had determined that the use of single-use medical devices does not pose an elevated health risk. We therefore find this bill unnecessary and redundant.

Since 2000, FDA has taken a number of steps to enhance its regulation of reprocessed single-use medical devices both before they go to market (premarket review) and afterwards (postmarket oversight). In 2000, FDA published guidance that clarified its policies on the regulation of reprocessed single-use medical devices. And in 2002, following the passage of the Medical Device User Fee and Modernization Act (MDUFMA), FDA imposed additional requirements for about 70 types of

reprocessed devices and implemented new labeling requirements. The MDUFMA required, as of August 1, 2006, that reprocessed single-use devices shall prominently and conspicuously bear the name, abbreviation, or symbol of the reprocessor on the device itself, on an attachment to the device, or on a detachable label, depending on the physical characteristics of the device. The Act also directed FDA to increase its oversight of these devices by identifying reprocessed single-use devices that should not be marketed unless the reprocessing company first provided data demonstrating effective cleaning, sterilization, and functional performance. FDA inspects all reprocessors and monitors and investigates reports of adverse events (e.g. infections, injuries to patients or providers, or breakage) involving reprocessed single-use medical devices. In 2003, FDA further modified its reporting forms to better identify and analyze those adverse events involving reprocessed single-use medical devices.

FDA believes that reprocessed single-use device that meet FDA's regulatory requirements are as safe and effective as a new device. The law and regulations in place are designed to protect the public health by assuring that the practice of reprocessing and reusing of single-use devices is based on sound science.

The Department believes the safety issues regarding the use of single-use medical devices are already being appropriately addressed by FDA and the further oversight by the Department would detract efforts and resources from known hazards in the areas of food and drug safety.

Thank you for the opportunity to testify.

THE QUEEN'S MEDICAL CENTER

1301 Punchbowl Street • Honolulu, Hawaii 96813 • Phone (808) 538-9011 • Fax: (808) 547-4646

Senator David Y. Ige, Chair
Senator Josh Green, M.D., Vice Chair

Monday, February 9, 2009 – 2:45 p.m.
State Capitol, Conference Room 016
SENATE COMMITTEE ON HEALTH

SB 361 Relating to Single-Use Medical Devices

Chair Ige, Vice Chair Green and Members of the Committee,

My name is Robin Fried, I am the Director of Risk Management at The Queen's Medical Center, the largest private tertiary care hospital in the State of Hawaii. We offer specialized care in the areas of cardiology, neuroscience, orthopedics, behavioral health, oncology, women's health, emergency services and trauma care. We are committed to ensuring the safety and quality of care for the patients we care for. I am testifying for The Queen's Medical Center in opposition to Senate Bill 361, relating to single-use medical devices for the following reasons:

The proposed legislation departs from mainstream tort and products liability law and is unnecessary because of the federal medical device regulatory framework. These devices do not present an elevated health risk for patients. Utilization of reprocessed single use medical devices ("SUDs") is an area regulated under federal law. In January 2008, after reviewing eight years of FDA data, the federal Government Accounting Office (GAO) weighed in with a report concluding there is **no evidence** that reprocessed SUDs create an elevated health risk for patients. In addition, 3rd party reprocessed devices meet the same standards and must comply with the same regulations as brand new devices.

Informed consent, as related to devices, is meant for experimental treatments, clinical trials and Non-FDA approved devices, not for devices that are legally marketed and approved by the FDA. We believe it is inappropriate to impose a consent requirement on the use of FDA-cleared reprocessed devices. The FDA does not require physicians to obtain informed consent for medical devices that the FDA has cleared, which perform the same as new devices.

The re-use of SUDs is a "green" practice that decreases the adverse environmental impact of medical waste and is an established practice in hospitals throughout the country.

Queen's opposes this legislation because there is no evidence that reprocessed SUDs create an increased health risk for patients. In addition, regulations as proposed in this bill will result in increased healthcare costs without appreciable benefit to the public, and will limit the ability of Hawaii hospitals to access safe and cost effective processed medical devices.

The Queen's Medical Center urges you to vote against Senate Bill 361. Thank you for the opportunity to testify.

Robin Fried, JD, MS
Director, Risk Management
The Queen's Medical Center

1319 Punahou Street • Honolulu, HI 96826

KAPI'OLANI MEDICAL CENTER FOR WOMEN & CHILDREN

(808) 983-6000 • kapiolani.org

Monday, February 9, 2009
Conference Room 016
2:45pm

The Senate Committee on Health

To: Senator David Y. Ige, - Chair
Senator Josh Green, MD - Vice Chair

From: Pam Courtney, RN MSN
Manager, Materials Management
Kapi'olani Medical Center for Women & Children

RE: Testimony in Opposition to SB 361

My name is Pam Courtney, Manager of Materials Management at Kapi'olani Medical Center for Women & Children an affiliate of Hawaii Pacific Health (HPH), which is the four-hospital system of Kapi'olani Medical Center for Women & Children, Kapi'olani Medical Center at Pali Momi, Straub Clinic & Hospital, and Wilcox Hospital/Kauai Medical Clinic.

I am writing in opposition to SB 361 which would require health care providers to obtain informed consent from patients for use of certain reprocessed medical devices and would require the director of health to provide oversight and to adopt rules for reprocessed single use devices.

The administrative burden and cost of these regulations greatly outweigh the benefits of avoiding the perceived risks associated with the use of reprocessed single use devices (SUD). SUDs are already stringently regulated by the Federal Drug Administration. Furthermore the Hawaii hospitals, the Government Accounting Office (GAO) already determined in a study of these devices that "...no causative link has been established between reported injuries or deaths and reprocessed SUDS."

Hawaii hospitals, like over half the hospitals in the United States have long enjoyed the benefits of SUDs. The use of these devices is safe for patients, environmentally friendly and an economical practice that has saved health care providers in Hawaii almost a million dollars in device costs. Just as important – the use of SUDs have eliminated over 13,000 lbs of regulated medical waste from Hawaii incinerators and landfills.

This bill would effectively discourage the use of SUDs by forcing hospitals to incur unnecessary costs by requiring informed consent for reprocessed devices. We ask that you do not pass SB 361 from this committee. Thank you for the opportunity to testify.

Testimony of Lory Graves Olsson,
Vice President, Field Operations,
Association of Medical Device Reprocessors
(AMDR)

Senate Health Committee of the Hawaiian Legislature: "Relating to Single Use Medical Devices" (SB 361)

February 9, 2009

Mr. Chairman, members of the Committee:

Good afternoon. My name is Lory Olsson; I am the Vice President of Field Operations for the Association of Medical Device Reprocessors, or AMDR. AMDR represents the third-party medical device reprocessing industry. I am here today to express our concern over SB 361 – an attempt to limit access to third-party reprocessing.

Most Hawaiian hospitals, like the majority of hospitals in the U.S., have long enjoyed the benefits of reprocessing. Last year, AMDR third-party reprocessing companies saved hospitals in Hawaii almost a million dollars in device costs, and helped to eliminate over 13,000 pounds of regulated medical waste from Hawaii landfills and incinerators Reprocessing plays a crucial role in helping these hospitals, and the top rated hospitals in the country, to control spiraling healthcare

Office 1400 16th Street NW, Suite 400 Washington, DC 20036 **Phone** (202) 518-6796 **Fax** (202) 234-0399 **Web** www.amdr.org

costs, reduce regulated medical waste, and preserve financial resources that are better spent on things like hiring more personnel, buying new medical technology, or providing indigent care.

FDA-regulated reprocessing is supported by a multitude of clinical and professional organizations, including the *American Hospital Association*, the *American Association of Orthopaedic Surgeons*, *Heart Rhythm* and the *Association of Professionals in Infection Control* to name a few. We provide safe, FDA-regulated devices to our hospital partners, at a savings of about 50% of the cost of purchasing original devices.

Today I'd like to briefly provide you with a description of the U.S. Food and Drug Administration's stringent regulations for device reprocessors, including a discussion of the "single use" label. In the limited time we have, I'll also briefly address what the legislation proposes, and how that would needlessly drive up the cost of healthcare, and increase medical waste, in Hawaii.

Reprocessing is Stringently Regulated by FDA

Reprocessors of medical devices labeled for "single use" are stringently regulated by the U.S. Food and Drug Administration (FDA). In fact, pursuant to federal

legislation of 2002, reprocessors are now more stringently regulated than even original equipment manufacturers (OEMs). Medical device reprocessors are treated by FDA as device manufacturers, and reprocessors must not only meet all the same requirements as the original makers of these devices, but must also provide additional premarket data to FDA that ensures reprocessed devices are clean, functional and sterile, prior to ever being brought to market. In testimony before Congress in September, 2006, FDA said, and I quote, "reprocessed [single use devices] that meet FDA's regulatory requirements are as safe and as effective as a new device."[1]

The patient safety record of the industry is excellent. In the past ten years of regulated third-party reprocessing, and after reprocessing over 50 million devices, there have been no deaths caused by a failed reprocessed device; no lawsuits filed against device reprocessors for failed product or injury to patient; and not a single FDA-initiated recall of reprocessed devices. Compared to other device manufacturers, this safety record is simply stellar. Indeed, FDA's own data of adverse events associated with all medical devices shows fewer absolute errors associated with reprocessed devices, than with original devices. This data was confirmed in 2008 by an independent report of the federal Government

[1] *Emphasis added. See* Testimony of Dr. Daniel Schultz, Director, Center for Devices and

Accountability Office, or GAO (a full copy and summary of which are attached to this testimony). The safety record of reprocessing is beyond reproach, well-documented, and overwhelmingly supported by the clinical community.

The "Single Use" Label

I'd like to briefly address regulations surrounding the "single use" label because I think this is the source of most of the confusion and misinformation about reprocessing. The "single use" label is not an FDA requirement. Rather, it is a designation chosen by the *manufacturer*, and that choice is frequently made as a way to sell more devices – not for patient safety reasons. The best evidence of just how meaningless the "single use" label can be is that some OEMs offer reprocessing programs of their own "single use" devices, and in fact some partner with AMDR companies to do the reprocessing – again these are devices that the OEM has labeled as "single use."

Although I have not had the opportunity to meet with any of you prior to this hearing, I would like to show you some of the devices manufacturers label for "single use." They include titanium clamps, stainless steel surgical blades, and even tourniquet cuffs. It becomes obvious just looking at these devices that they do not belong in a landfill after just one use when science and engineering proves they

can be safely used again. Third-party reprocessors recover only Class I and Class II (low & moderate risk) devices – no implants, no high-risk (or Class III) devices.

Legislative Analysis

The provisions of S.B. 361 are designed to burden reprocessing to such an extent that hospitals will be forced to limit or cease their use of reprocessed devices. SB 361 will do three things. First, it would require a new and burdensome system of reporting on healthcare providers, the Hawaii Department of Health and reprocessors regarding manufacture, purchasing patterns, and usage of reprocessed devices. I would ask this committee to be aware that these reporting provisions are redundant of current federal requirements and would add to the paperwork burdens of health care providers and the Department of Health without any corresponding benefit to patients. In fact, AMDR believes these requirements are pre-empted by federal law.

Second, the legislation would require healthcare providers to obtain needlessly burdensome "informed consent" from patients before using a reprocessed device. AMDR has consulted with several acknowledged authorities on what constitutes appropriate content for informed consent documentation, including the American

Medical Association, the Joint commission, and the American Hospital Association – nowhere are there any recommendations for informed consent for FDA-cleared or approved devices. In fact, devices are not listed as appropriate for informed consent at all with any of these clinical authorities, unless those devices are experimental, or investigational – reprocessed devices are neither.

The purpose of informed consent is to advise a patient of factors that are risks and dangers associated with a particular procedure or diagnosis. By requiring a specific informed consent for reprocessed devices, there is an implication of increased risk, which in fact is not true, or evidenced in any peer-reviewed literature on the practice. I would point to the GAO report released just last year on third-party reprocessed devices as a prime example, the title: ***Reprocessed Single-Use Medical Devices --FDA Oversight Has Increased, and Available Information Does Not Indicate That Use Presents an Elevated Health Risk*.** The evidence, as gathered and reported by the GAO shows that reprocessed devices are as safe and effective as original equipment and are, in fact, more stringently regulated. Therefore, there is no legal, consumer safety, or ethical basis *or precedent* for imposing an informed consent requirement on reprocessed devices, or any FDA-cleared or approved device for that matter.

Finally, the proposed legislation would immunize original device manufacturers from all liability associated with their devices if the device happens to be reprocessed, even from liability attributable to problems caused by the manufacturer's own acts or omissions. This is contrary to well-settled principles of tort law. Indeed, the subsequent alteration of a product has never, by itself, absolved the original manufacturer of liability for injuries caused by its own actions– even if the original manufacturer clearly cautions against such alteration.

Conclusion

U.S. health care facilities derive significant cost-savings from reprocessed devices – on average a 50% cost-savings as compared to purchasing a new device, and these savings help pay for important patient care improvements, like adding more healthcare jobs, investments in new medical technology, or providing indigent care. Further, reprocessing has significant environmental benefits. Reprocessors are responsible for diverting over 10,000 tons of medical waste from landfills in the U.S. last year alone. As I mentioned earlier, in Hawaii last year, that amounted to 13,000 lbs of regulated medical waste eliminated from your incinerators and landfills.

Thank you for the opportunity to speak with you about this important topic. I realize that Hawaiian hospitals are under the same financial pressure as all U.S. hospitals: low or inadequate reimbursement rates, rising costs, and the ongoing pressures of trying to provide the absolute best quality of patient care, within a system that is increasingly unsustainable, both environmentally and financially.

Hawaii has a deficit in its state owned hospital budget of over 60million dollars this year - I urge this committee to avoid limiting these facilities ability to control costs through reprocessing. In fact, I urge you to consider reprocessing of "single use" devices as a patient safe and, viable method of controlling costs for the state hospitals for which you are responsible.

I am hoping you will be convinced to discard this well-intentioned, but misguided legislation by focusing on the facts and engineering science about reprocessing, not scare tactics, or unsubstantiated allegation. Thank you for your time - I would be happy to answer any questions.

* * *

Excerpts from Statement of
Daniel Schultz, M.D., Director, Center for Devices and Radiological Health, FDA
before Committee on Government Reform, House of Representatives on September 26, 2006

INTRODUCTION
FDA has been actively engaged in the single use device (SUD) reuse issue for some time, and our efforts have included research, outreach, pre-market review, inspections, and compliance investigations. We have held numerous public meetings and conferences with industry, healthcare professionals, and consumers over the years to determine the extent, magnitude, and changing nature of this practice. FDA has carefully evaluated and conducted research to develop the scientific basis for addressing SUD reprocessing. We have inspected third party reprocessors, evaluated and investigated reports of patient injuries, and reviewed numerous pre-market submissions. Taken together, the Agency believes that these efforts have provided, and will continue to provide, reasonable assurance of safety and effectiveness of reprocessed SUDs for patients.

THE REGULATION OF REPROCESSED SINGLE USE MEDICAL DEVICES
The reprocessing of SUDs is legally permissible in the United States under the FD&C Act. Currently, only Class I and II SUD device types have been cleared by FDA for reprocessing. No Class III SUDs have been cleared/approved for reprocessing. Prior to issuance of this guidance, reprocessing of SUDs was frequently performed by hospital personnel without regulatory oversight or regard to the level of device risk. In addition, many third party reprocessors contracted with hospitals to perform similar tasks and these contractors did not consistently adhere to FDA's Good Manufacturing Practice Requirements.

CHANGES ENACTED WITH MDUFMA
In 2002, with enactment of the Medical Device User Fee and Modernization Act (MDUFMA), Congress mandated a number of new requirements for SUD reprocessors including, for certain SUDs, the pre-market submission of data to the Agency that exceeded the requirements for original manufacturers (OEMs). In addition to the requirements specified in our 2000 Guidance Document, certain reprocessed SUD types that potentially could pose the greatest risk of infection and inadequate performance following reprocessing and that were previously exempt from any pre-market submission requirements, are no longer exempt. In addition, MDUFMA required a change to FDA's MedWatch voluntary and mandatory reporting forms (Forms 3500 and 3500A, respectively) to facilitate the reporting of adverse events involving reprocessed SUDs. Finally, MDUFMA required, as of August 1, 2006, that reprocessed SUDs prominently and conspicuously bear the name, abbreviation, or symbol of the reprocessor on the device itself, on an attachment to the device, or on a detachable label, depending on the physical characteristics of the device and whether the device has been marked by the OEM.

COMPLIANCE ACTIVITIES
FDA's inspectional program serves as a bridge between pre- and post-market activities. Since 2000, on average, FDA has conducted inspections of reprocessor firms once every two years, a rate considerably higher than the one inspection in four years for OEMs. Of the seven firms currently known to be reprocessing, all have been inspected within the last two years. FDA continues to evaluate newly registered firms to confirm whether they are performing SUD reprocessing and updates its inspectional plan as required.

POST-MARKET SURVEILLANCE FOR REPROCESSED SUDs
Post-market monitoring of device-related adverse events (AEs) and product problems is accomplished through the Medical Device Reporting (MDR) system. MDR reports include deaths, serious injuries, and device malfunctions. Healthcare facilities are required to report deaths suspected to be device-related to both FDA and the manufacturer/reprocessor. They are required to report serious injuries to the manufacturer/reprocessor. ... The final analysis of the reports found that the types of adverse events reported to be associated with the use of SUDs were the same types of events that also are being reported for new, non-reprocessed devices.

FEEDBACK FROM A SAMPLING OF MEDSUN HOSPITAL FACILITIES THAT USE REPROCESSED SUDs
FDA's Medical Product Safety Device Network (MedSun) is comprised of over 350 hospitals that have been recruited and specifically trained to identify and report device problems. ... None of the participants we spoke with reported specific problems with SUD-related infections. ... It also is interesting to note that the participants did not report a greater concern with mechanical problems associated with reprocessed SUDs compared to un-reprocessed SUDs. In general, the participants had a favorable view of reprocessed SUDs used in their facilities.

CONCLUSION
Available data show that SUDs can be reprocessed with a reasonable assurance of safety and effectiveness. FDA believes that reprocessed SUDs that meet FDA's regulatory requirements are as safe and effective as a new device. The law and regulations in place are designed to protect the public health by assuring that the practice of reprocessing and reusing SUDs is based on sound science. FDA continues to monitor the performance of these devices and to assess and refine our ability to regulate these devices appropriately.

Full transcript can be found on the FDA's website at http://www.fda.gov/ola/2006/suds0926.html

AMDR Overview of January 2008 Government Accountability Office report:

Reprocessed Single-Use Medical Devices -- FDA Oversight Has Increased, and Available Information Does Not Indicate That Use Presents an Elevated Health Risk

A. Background:

In a document made public on March 3, 2008, the United States Government Accountability Office (GAO), provided a report to the Committee on Oversight and Government Reform of the U.S. House of Representatives titled, *"Reprocessed Single-Use Medical Devices: FDA Oversight Has Increased, and Available Information Does Not Indicate That Use Presents an Elevated Health Risk."*

The report came as a follow-up to a GAO report in June 2000 titled, *"Single Use Medical Devices: Little Available Evidence of Harm From Reuse, but Oversight Warranted."* Since publication of the 2000 report, Congress has strengthened FDA oversight through The Medical Device User Fee and Modernization Act of 2002 (MDUFMA.)

B. Key Points of the 2008 GAO Report:

The report attempts to answer three questions:

- What is known about the reprocessing industry?
- What steps has FDA taken to strengthen its oversight of reprocessed devices?
- How does the safety of reprocessed devices compare to the safety of original "single use" devices (SUDs)?

1. What is known about the industry?

- FDA surveyed more than 5,000 hospitals in 2002 and found that nearly half with more than 250 beds reported using reprocessed devices
- GAO found that 11 companies are actively reprocessing more than 100 different types of SUDs in the US. Of these 11, GAO estimated that 3 companies account for approximately 90 percent of the total reprocessing business in the U.S.

- GAO found that reprocessed devices are being used across a wide spectrum of the nation's hospitals, including military hospitals

2. FDA oversight

- Since 2000, the Food and Drug Administration (FDA), the agency responsible for reviewing the safety and effectiveness of medical devices, has stepped up its regulation of reprocessed medical devices, both prior to going to market and through oversight after the product goes to market
- Additional tools were provided to FDA through the Medical Device User Fee and Modernization Act (MDUFMA)
- FDA has strengthened its oversight by requiring additional pre-market data submissions for 72 types of SUDs and by conducting additional post-market activities such as inspections and other surveillance
- Hospital participants in FDA focus groups (Medical Product Safety Network/MedSun) generally expressed confidence in reprocessed SUDs and believed that reprocessed establishments are more stringently regulated by FDA than are the original manufacturers and this provided them with a sense of confidence in the reprocessing process
- FDA has clarified that post-market inspections for reprocessing facilities are the same as for other device manufacturers

3. Safety comparison

- GAO found that available information does <u>not</u> indicate that use of reprocessed SUDs presents greater risk to patients than use of new devices
- Hospital participants in FDA focus groups (MedSun) said that there were actually fewer performance problems with reprocessed devices than with new devices
- FDA analysis of adverse events related to SUDs shows there is no "causative link between a reprocessed SUD and reported patient injury or death"
- FDA has concluded that the cost of conducting additional testing is not warranted, especially since the available data do not indicate that reprocessed SUDs present an elevated health risk

- GAO found that FDA's processes for monitoring and investigating data are sound, and sees no reason to question the FDA analysis of the safety issue

C. What This Means: the Reprocessing Industry Perspective

- The GAO report confirms AMDR's long-held position that there is no increased risk to patients with the use of reprocessed devices, there is no evidence linking SUD reuse with higher risks to patients, and there is no reason to question the FDA's analysis of these facts
- FDA-regulation of reprocessing is stringent. Third-party reprocessors are more stringently-regulated than original equipment manufacturers and have a history of more FDA-inspections than the overall medical device industry
- In this time of increased demand for FDA oversight on such issues as the safety of our food supply and the oversight of devices and drugs that ARE causing patient injury and deaths, AMDR agrees with FDA that it would be unreasonable to divert more time and resources toward the reprocessing segment of the device industry
- The safety of reprocessing some types of devices has been established by well-developed clinical studies
- Adverse event reporting, as documented in the GAO report, shows a tiny rate (65 reports in 4 years for reprocessed devices and 320,000 reports alone filed in 2006 for original devices) of all adverse events possibly involved a reprocessed device.
- Further, FDA found that the types of adverse events reported to be associated with the use of reprocessed devices were the same types of events that are reported for new, non-reprocessed devices
- Third party re-processors in the U.S. are the only segment of the device industry actually reducing the costs associated with medical devices, reducing medical waste and still providing the highest quality of medical care possible. We are pleased that the GAO report validates reprocessing as a critical tool for modern health care cost containment

United States Government Accountability Office

GAO

Report to the Committee on Oversight and Government Reform, House of Representatives

January 2008

REPROCESSED SINGLE-USE MEDICAL DEVICES

FDA Oversight Has Increased, and Available Information Does Not Indicate That Use Presents an Elevated Health Risk

G A O

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GAO-08-147

January 2008

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Highlights

Highlights of , a report to the Committee on Oversight and Government Reform, House of Representatives

REPROCESSED SINGLE-USE MEDICAL DEVICES

FDA Oversight Has Increased, and Available Information Does Not Indicate That Use Presents an Elevated Health Risk

Why GAO Did This Study

Within the Department of Health and Human Services (HHS), the Food and Drug Administration (FDA) is responsible for reviewing the safety and effectiveness of medical devices. The decision to label a device as single-use or reusable rests with the manufacturer. To market a reusable device, a manufacturer must provide data demonstrating to FDA's satisfaction that the device can be cleaned and sterilized without impairing its function. Alternatively, a single-use device (SUD) may be marketed without such data after demonstrating to FDA that the device is safe and effective if used once. Even though labeled for single-use, some SUDs are reprocessed for reuse with FDA clearance. This report addresses (1) the SUD reprocessing industry—the number of reprocessing establishments, the types of devices reprocessed, and the extent to which hospitals use reprocessed SUDs, (2) the steps FDA has taken to strengthen oversight of reprocessed SUDs, both on its own and in response to legislative requirements, and (3) the safety of reprocessed SUDs compared with other types of medical devices.

GAO reviewed FDA data on reprocessors, reprocessed SUDs, and device-related adverse events, as well as FDA documents and inspection reports, studies published in peer-reviewed journals, and relevant statutes and regulations. GAO interviewed FDA officials and officials from associations of manufacturers, reprocessors, and providers.

To view the full product, including the scope and methodology, click on . For more information, contact Randall B. Williamson at (202) 512-7114 or williamsonr@gao.gov.

What GAO Found

FDA has information on domestic reprocessing establishments, but it does not have data on the extent of actual production or on where the devices are being used. FDA officials identified 11 establishments that reported planning to market or actively marketing more than 100 types of reprocessed SUDs in the United States as of July 2007. Reprocessed SUDs ranged from devices used external to the body, such as blood pressure cuffs, to surgical devices used to repair joints. While many hospitals were believed to be reprocessing their own SUDs in 2000, FDA identified only one hospital in 2007 that was reprocessing SUDs. Reprocessed SUDs are being used in a variety of hospitals throughout the nation, including military hospitals. However, the Department of Veterans Affairs, which operates one of the nation's largest health care systems, prohibits their use entirely.

Since 2000, FDA has taken a number of steps—on its own and in response to legislation—to enhance its regulation of reprocessed SUDs both before they go to market (called premarket review) and afterwards (called postmarket oversight). In 2000, FDA published guidance that clarified its policies on the regulation of reprocessed SUDs. This guidance was directed at third-party entities and hospitals engaged in reprocessing SUDs for reuse. Following legislation passed in 2002, FDA imposed additional requirements for about 70 types of reprocessed devices and implemented new labeling requirements so that users would recognize those devices that had been reprocessed. In terms of postmarket review, FDA now inspects reprocessors and monitors reports of adverse events involving reprocessed SUDs. Seven of the 10 reprocessing establishments that FDA inspected in the last 3 years had problems requiring corrective actions. Regarding adverse event reporting, FDA modified its reporting forms in 2003 to enable FDA to better identify and analyze those adverse events involving reprocessed SUDs.

Neither existing FDA data nor studies performed by others are sufficient to draw definitive conclusions about the safety of reprocessed SUDs compared to similar original devices. While FDA has made changes to its data collection process regarding reprocessed SUD-related adverse events, the data are not suitable for a rigorous comparison of the safety of reprocessed SUDs compared to similar original SUDs. The other studies published since 2000 that GAO identified are likewise insufficient to support a comprehensive conclusion on the relative safety of reprocessed SUDs. FDA officials have concluded that the cost of conducting rigorous testing would not be an efficient use of resources, especially given that the available data, while limited, do not indicate that reprocessed SUDs present an elevated health risk. FDA has analyzed its data on reported adverse events related to reprocessed SUDs and has concluded that there are no patterns that point to these devices creating such risks. After reviewing FDA's processes for monitoring and investigating its adverse event data, we found no reason to question FDA's analysis. HHS provided language to clarify several sentences of a draft of this report which GAO generally incorporated.

GAO
Accountability * Integrity * Reliability

United States Government Accountability Office
Washington, DC 20548

January 31, 2008

The Honorable Henry A. Waxman
Chairman
The Honorable Tom Davis
Ranking Member
Committee on Oversight and Government Reform
House of Representatives

The federal government, through the Food and Drug Administration (FDA) within the Department of Health and Human Services (HHS), takes the lead in ensuring that the thousands of types of medical devices sold for use in surgeries and other medical procedures are reasonably safe and effective and do not pose a threat to public health.[1] These devices range from bandages and surgical clamps to complicated devices such as heart pacemakers. Unless exempt, all devices are subject to FDA review—referred to as premarket review—before they may be legally marketed in the United States.

Using many types of devices, such as tongue depressors, a second time is not feasible, while others, such as stethoscopes, are specifically designed and sold to be used more than once. The decision to label a device as single-use or reusable rests with the manufacturer. If a manufacturer intends to label a device as reusable, it must provide data demonstrating to FDA's satisfaction that the device can be cleaned and sterilized without impairing its function. Thus, a device may be labeled as 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 demonstrate that the device can be labeled as reusable.

Some devices fall into another category—they are labeled and marketed by the original manufacturer as single-use devices (SUD), but with clearance from FDA are marketed after being reprocessed for reuse—that is, they are cleaned, sterilized, and performance-tested by one of numerous entities that are in business to reprocess them for reuse. These

[1]Generally, a medical device includes items used for the diagnosis, cure, mitigation, treatment, or prevention of a disease or other condition. 21 U.S.C. § 321(h). Throughout this report, the term *device* refers to a medical device that is not being regulated as a drug or a biological product.

reprocessed SUDs[2] can range from relatively simple items for external use, such as inflatable sleeves to improve blood circulation, to complex items placed inside the body, such as catheters inserted into the heart to monitor cardiac function.

For more than two decades, establishments such as hospitals and private companies have reprocessed various types of SUDs, citing lower purchasing and in-house sterilization costs and reduced medical waste. This development followed an increase in the number of devices labeled as single-use. Because these devices were intended to be discarded after one use, manufacturers did not develop appropriate cleaning, sterilization, and testing methods or provide instructions to health care providers about how to clean and sterilize them while still maintaining performance.

Concerns have been raised by the committee and others about the potential risks of infection from reprocessed SUDs or their failure to function properly. The original manufacturers of the SUDs, in particular, have objected to SUD reprocessing, saying that the reprocessed SUDs are inherently unsafe because these devices are not designed to facilitate cleaning and sterilization. Reprocessing firms, on the other hand, contend that reprocessed SUDs are indeed safe, citing a lack of data that show otherwise. In a June 2000 report on SUD reprocessing, we found that although there was little available evidence of harm from the use of reprocessed SUDs, FDA oversight of SUD reprocessing was inconsistent.[3] Since that time, Congress has acted to strengthen oversight requirements. The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) required that the labeling of all reprocessed SUDs specifically state that they are reprocessed SUDs as well as identify the reprocessor. The act also directed FDA to increase its oversight of these devices by identifying reprocessed SUDs that should not be marketed unless the reprocessing

[2]The term *reprocessed*, with respect to a SUD, means an original SUD that has previously been used on a patient and has been subjected to additional processing and manufacturing for the purpose of an additional single use on a patient. 21 U.S.C. § 321(ll)(2).

[3]GAO, *Single-Use Medical Devices: Little Available Evidence of Harm From Reuse, but Oversight Warranted,* (Washington, D.C.: June 20, 2000).

establishment first provided data demonstrating effective cleaning, sterilization, and functional performance.[4]

In light of action taken since our last report, you asked us to review how the reprocessing industry and FDA's oversight of reprocessed SUDs had changed since June 2000. Specifically, our report addresses the following three questions:

- What is known about the reprocessing industry—the number of reprocessing establishments, the types of devices they are reprocessing, and the extent to which hospitals are using reprocessed SUDs?
- What steps has FDA taken to strengthen oversight of reprocessed SUDs on its own initiative and to implement requirements set forth in MDUFMA?
- What is known about the extent to which the safety of reprocessed SUDs compares favorably or unfavorably with the safety of similar original SUDs?

To address these questions, we examined and evaluated available information on the SUD reprocessing industry in the United States and FDA's oversight of this industry. In conducting our work, we (1) reviewed available data on the types and characteristics of, FDA guidance and standards pertaining to, and FDA inspection reports on, SUD reprocessing establishments; (2) reviewed FDA-generated data and analyses on reported adverse events involving reprocessed SUDs; (3) interviewed FDA officials, representatives of the device reprocessing and manufacturing industry, including professional associations representing device manufacturing establishments[5] and the Association of Medical Device Reprocessors (AMDR), which represents two firms that operate three

[4]Pub. L. No. 107-250, § 302, 116 Stat. 1588, 1616-20. For additional information on other provisions of MDUFMA, see GAO, *Food and Drug Administration: Methodologies for Identifying and Allocating Costs of Reviewing Medical Device Applications Are Consistent with Federal Cost Accounting Standards, and Staffing Levels for Reviews Have Generally Increased in Recent Years,* (Washington, D.C.: June 25, 2007).

[5]These associations included the Advanced Medical Technology Association and the Medical Device Manufacturers Association.

large reprocessing establishments in the United States,[6] and officials representing provider associations and medical facilities of the Departments of Veterans Affairs and Defense; (4) reviewed relevant statutes, regulations, and *Federal Register* notices; and (5) conducted a literature search of peer-reviewed periodicals and reviewed other information to determine what is known about the safety of reprocessed SUDs.

In some cases, FDA data were not available or sufficiently reliable to allow us to develop detailed information or perform analyses. For example, we determined that FDA's data were not sufficiently reliable to determine the number of domestic establishments reprocessing SUDs prior to July 2007 or the number of foreign establishments reprocessing SUDs. As a result, we were unable to analyze trends in the number of reprocessing establishments or the types of devices they were reprocessing since 2000 and we were limited to reporting on domestic reprocessing establishments. Also, neither industry nor FDA representatives were able to provide comprehensive information on the size of the reprocessed SUDs market in the United States—in terms of volume and value—compared to the overall U.S. market for medical devices. See appendix I for additional information on our methodology and data limitations.

We conducted our work between November 2006 and January 2008 in accordance with generally accepted government auditing standards.

Results in Brief

FDA has information on domestic reprocessing establishments, but it does not have data on the extent of actual production or where the reprocessed SUDs are being used. According to FDA officials, as of July 2007, 11 establishments reported they were planning to market or actively marketing more than 100 types of reprocessed SUDs in the United States. The types of reprocessed SUDs ranged from compression sleeves used externally to maintain circulation during and after surgery to invasive devices used to lift and stabilize the heart during open-heart surgery. In terms of relative volume among the reprocessing establishments, 3 of the establishments account for about 90 percent of the SUD reprocessing business, according to AMDR. The extent of actual production of

[6]FDA defines a device establishment as a place of business under one management at one general physical location at which a device is manufactured, assembled, or otherwise processed. 21 C.F.R. § 807.3 (2007). Medical device manufacturers may have more than one establishment. FDA considers reprocessing of SUDs to be manufacturing.

reprocessed SUDs by the 11 establishments is largely unknown, however, because FDA does not gather these data and because many reprocessing establishments, for business reasons, treat their production numbers as proprietary information. When we last reported on the reprocessing industry in 2000, many hospitals were believed to be reprocessing their own SUDs, but FDA identified only one hospital that was reprocessing SUDs in July 2007. Our inquiries with representatives of private and federal hospitals indicated that reprocessed SUDs are being used across a wide spectrum of the nation's hospitals, including military hospitals. The Department of Veterans Affairs, one of the nation's largest health care providers, prohibits their use entirely however.

FDA has taken a number of steps to increase its oversight of reprocessed SUDs since 2000, both on its own initiative and in response to requirements established by MDUFMA in 2002. FDA has changed its approach to premarket review and postmarket surveillance:

- Premarket review. This aspect of oversight involves FDA's review of manufacturer submissions related to specifications, proposed labeling, and other information about a device to assess its safety and effectiveness before allowing it to be marketed. Shortly after our June 2000 report, FDA issued guidance clarifying its policies on the regulation of reprocessed SUDs, which was directed at hospitals and third-party reprocessing establishments. Also, in response to MDUFMA's requirements for increased oversight, FDA identified more than 70 types of reprocessed SUDs that would be subject to additional premarket submission requirements. For example, to obtain FDA clearance to market many types of reprocessed SUDs, such as scalpel blades and drill bits, reprocessing establishments must submit additional data to FDA on the processes used to clean, sterilize, and test the devices. Also in response to MDUFMA, FDA began reviewing the labeling accompanying reprocessed SUDs as well as the markings on the devices themselves for compliance with new requirements that they clearly indicated the device was reprocessed and identified the reprocessing establishment.

- Postmarket surveillance. This aspect of oversight involves inspecting establishments that reprocess SUDs and collecting and analyzing data about device-related adverse events that occur when a device is used, such as infections, injuries to patients or providers, or breakage. With the issuance of its August 2000 guidance, FDA intended to make clear its plans to subject hospitals and other third-party establishments that reprocess SUDs to FDA inspection for compliance with applicable regulatory requirements just like other establishments manufacturing medical devices. According to FDA, 10 of the 11 establishments it identified as

engaged in reprocessing in the United States in July 2007 were inspected during the period August 2004 through October 2007; the remaining establishment registered with FDA in 2006 as a reprocessing establishment and is scheduled for inspection in 2008. During inspections at 7 of the establishments, FDA identified compliance issues that required corrective action. For example, one inspection revealed that the establishment had reprocessed two models of a type of SUD before it had received FDA clearance to market those particular models of reprocessed SUDs. However, the establishment had stopped reprocessing these models of SUDs prior to FDA's inspection and FDA inspectors determined that the establishment had voluntarily taken the corrective actions that were required. With respect to adverse event data, FDA modified its forms in 2003 for reporting device-related adverse events to indicate whether a reprocessed SUD was involved. This change, required by MDUFMA, was designed to enable FDA to differentiate those adverse events involving reprocessed SUDs from those involving other devices. In addition, an FDA workgroup is studying whether refinements, such as additional instructions, could further improve the device-related adverse event reports involving reprocessed SUDs.

Neither existing FDA data nor studies performed by others are sufficient to draw definitive conclusions about the safety of reprocessed SUDs compared to similar original devices. While FDA has made changes to its data collection process regarding reprocessed SUD-related adverse events, the data are not suitable for a rigorous comparison of the safety of reprocessed SUDs compared to similar original SUDs. For such a comparison to be definitive, FDA would have to collect additional data that would identify the type of device and adverse event, the number of original and reprocessed SUDs of that type in use, the number of times each reprocessed SUD was used, and the rate of adverse events associated with the original devices. With regard to safety-related data outside of FDA, the limited number of peer-reviewed studies related to reprocessing published since 2000 was insufficient to support a comprehensive conclusion on the relative safety of reprocessed SUDs. FDA officials have concluded that the cost of conducting rigorous testing would not be an efficient use of resources, especially given that the available data, while limited, do not indicate that reprocessed SUDs present an elevated health risk. FDA has analyzed its data on reported adverse events related to reprocessed SUDs and has concluded that there are no patterns that point to these devices creating such risks. After reviewing FDA's processes for monitoring and investigating its adverse event data, we found no reason to question FDA's analysis.

In commenting on a draft of this report, HHS provided language to clarify several sentences which we generally incorporated. We also incorporated HHS's technical comments as appropriate.

Background

Under the Federal Food, Drug, and Cosmetic Act (FDCA), FDA is responsible for reviewing the safety and effectiveness of medical devices before they go to market (premarket review) and ensuring that they remain safe and effective afterwards (postmarket oversight). Manufacturers intending to sell medical devices in the United States, including reprocessed SUDs, must register with FDA and provide information listing the devices they intend to market.[7] FDA considers establishments engaged in reprocessing (that is, any activity needed to render a used SUD ready for use on a subsequent patient) to be the manufacturers of those reprocessed SUDs.[8] Establishments, including reprocessing establishments, are required to update their registrations annually and their device listings twice each year.

FDA's premarket review activities for devices—that is, for reusable devices, for originally manufactured SUDs, and for reprocessed SUDs—mainly involve analyzing information submitted by those establishments that plan to market devices, including clinical or engineering documents and proposed labeling and instructions for use. Devices encompass a wide range of complexity and potential risk, and higher-risk or innovative devices require a more rigorous level of premarket review than lower-risk devices. For example, many relatively simple, low-risk devices, such as scissors used for medical purposes, are exempt from premarket review requirements. For other devices, such as catheters, manufacturers are

[7]When establishments register with FDA, they indicate which of several FDA-regulated activities they plan to engage in, such as manufacturing, importing, relabeling and repackaging devices, or reprocessing SUDs. When establishments identify their devices—a process known as medical device listing—establishments indicate which devices are associated with each activity, in order to allow FDA to determine which devices are manufactured or imported and which are reprocessed, for example. By listing a device with FDA, an establishment does not necessarily mean it is commercially distributing that device. For example, some listed devices may not yet be available, but are being considered for the future or are awaiting premarket clearance, if required.

[8]FDA does not consider the activity of resterilizing unused devices to be reprocessing. The need to resterilize such "open but unused" devices may arise when a surgical procedure is cancelled after the devices had been removed from their sterile packaging, and a hospital may send these devices out to be resterilized and repackaged by an outside establishment.

required to submit documentation for FDA's review and receive clearance before they may be marketed.

For all devices, FDA has assigned about 1,700 device types[9] into one of three classes based on the level of risk posed and controls necessary to ensure their safety and effectiveness.[10] Class I (low-risk) devices include such things as elastic bandages. Class II (medium-risk) devices include items like powered bone drills. Class III (high-risk) devices include those that support or sustain human life such as balloon angioplasty catheters. Most class I devices are exempt from premarket submission requirements set forth in Section 510(k) of the FDCA (premarket notification).[11] For most class II devices, manufacturers are required to submit a premarket notification report. The premarket notification report must provide evidence that the device is substantially equivalent to a device already on the market before FDA will allow it to be marketed.[12] For class III devices, manufacturers are required to submit an application for premarket

[9]Throughout this report we refer to *type of device* or *device type* to indicate a generic category of device. Each FDA-identified device type has a particular intended use (for example, a scalpel is intended to cut tissue) and may have more specialized "indications for use" (for example, a scalpel designed to make incisions on the cornea). Each device type may include a variety of models made by different manufacturers. Accessories used along with a particular device may have their own product code or be included in the same product code as the main device.

[10]Device classifications and exemptions from premarket review are codified in parts 862 through 892 of title 21 of the Code of Federal Regulations; in addition, FDA's Web site provides searchable databases at www.fda.gov/cdrh/databases.html. Class I devices are those for which compliance with the *general controls*, such as basic manufacturing requirements specified in FDA's quality system regulation, are sufficient to ensure safety and effectiveness. Class II devices are subject to both the general controls and *special controls*, such as postmarket surveillance, to ensure safety and effectiveness. Class III devices, in addition to going through premarket approval, which is the most rigorous premarket review, are subject to general controls and may be subject to special controls as well.

[11]21 U.S.C. § 360(k).

[12]*Substantially equivalent* or *substantial equivalence* means the device has the same intended use as another legally marketed device and the same technical characteristics, or different technical characteristics that are found to be as safe and effective as the marketed device and do not raise different questions of safety or effectiveness. 21 U.S.C. § 360(c)(i). Most devices enter the market by demonstrating their substantial equivalence. New devices are automatically classified as class III devices and must go through premarket approval before they may be marketed. Manufacturers of new devices automatically classified into class III can petition FDA for reclassification. 21 U.S.C. § 360c(e).

approval, which must provide evidence, including clinical data, demonstrating that the device is safe and effective.[13]

FDA's postmarket surveillance activities mainly involve inspecting device establishments and collecting and analyzing reports about device safety. FDA inspects registered device establishments, including reprocessing establishments, to assess compliance with applicable quality control and adverse event reporting regulations, among others.[14] In addition to inspecting device establishments, FDA's postmarket activities include collecting and analyzing reports of device-related adverse events to ensure that devices already on the market remain safe and effective. Manufacturers are required to report device-related deaths, serious injuries, and certain malfunctions to FDA. In addition, user facilities, such as hospitals and nursing homes, are required to report device-related deaths to FDA and to the device manufacturer, and to report serious injuries to the manufacturer or, if the manufacturer is unknown, to FDA. Both manufacturers and user facilities may also voluntarily report to FDA less-serious device-related events that are not likely to result in subsequent serious injuries if the malfunction were to recur.[15] FDA maintains databases that include both mandatory and voluntary reports of device-related adverse events, which agency officials can search to conduct research on trends or emerging problems with device safety. FDA scientists review these reports, request follow-up investigations, and

[13]21 U.S.C. § 360e.

[14]FDA's quality system regulation specifies quality control processes that all device manufacturers, including reprocessing establishments, must follow to ensure that devices are safe and effective for their intended use and otherwise in compliance with the FDCA. See 21 C.F.R. pt. 820 (2007). FDA inspectors document instances where establishments are not in compliance with the regulation but generally do not indicate a specific corrective action. FDA also conducts premarket inspections of establishments. Premarket inspections are conducted prior to the introduction of devices into the U.S. market. Postmarket inspections occur after a device has already been marketed.

[15]User facilities must also submit to FDA an annual report of device-related deaths and serious injuries that they have filed each year. Manufacturers must submit a supplemental or follow-up report for an adverse event within 1 month after receiving information that is required to be reported but that was not included in the initial adverse event report because it was either not known or not available at the time. Manufacturers can request alternative summary reporting under 21 C.F.R. § 803.19(b). In addition, health care professionals, consumers, and others may also voluntarily report device-related product problems as well as device-related adverse events. See app. IV for additional information on specific device-related adverse event reporting requirements, including the time frames in which manufacturers and user facilities are required to submit reports.

determine whether further action is needed to ensure patient safety.[16] Such action may include product recalls, public health advisories to notify health care providers and the public of potential device-related health and safety concerns, or requiring a manufacturer to change the instructions in its device labeling. FDA officials told us that the vast majority of reports involve a device malfunction that has the potential to cause a death or serious injury if the malfunction were to recur, even though there was no death or serious injury in the reported event.[17]

Varied Information Available on Reprocessed SUD Industry

FDA has information on domestic reprocessing establishments and the devices they are reprocessing or considering for reprocessing, but it does not have data on the extent of actual production or on where the devices are being used. Collectively, according to FDA, 11 establishments were actively reprocessing or planning to reprocess more than 100 different types of SUDs in the United States as of July 2007.[18] (See app. II for a list of the types of SUDs that have been listed by reprocessing establishments.) While definitive information on the size of the reprocessed SUD market is not available, representatives of the reprocessing industry estimate that 3 of the 11 registered reprocessing establishments (2 of which are owned by the same firm) account for the vast majority of the total reprocessing business in the United States. Only one hospital was included among the

[16]FDA officials told us that, while the agency reviews all adverse event reports, it places the highest priority on reports involving pediatric deaths, multiple deaths or serious injuries from a single device, fires, burns, or highly unusual events such as radiation exposure, over- or underdosing of radiation, radiation being delivered to the wrong site, and severe allergic reactions (anaphylaxis).

[17]However, FDA officials told us that, taken as a whole, even less-serious reports can provide valuable information. The review of malfunction reports can lead to identification of significant problems with devices that have the potential for serious injuries or deaths. FDA conducts ongoing analyses to identify emerging trends in the type or volume of problems that could warrant further review, for example, if FDA receives similar reports of user-error associated with a particular device.

[18]FDA data indicated that more than 40 establishments were registered as reprocessing establishments as of March 2007, including 13 located outside the United States. However, upon our request, FDA officials determined that many of these establishments had registered as reprocessing establishments in error, and FDA officials identified 11 establishments in the United States that were engaged in reprocessing SUDs as of July 2007. As of October 2007, FDA officials were in the process of determining whether the 13 registered establishments located outside of the United States were actively engaged in reprocessing, and if so, whether they were marketing reprocessed SUDs in this country. The officials stated that the agency plans to issue assignments by March 2008 for the inspection of foreign establishments it identifies as actively reprocessing SUDs for the U.S. market but they did not specify a date by which the inspections would be completed.

11 active reprocessing establishments identified by FDA. Our inquiries with hospital representatives and federal agencies that administer hospitals, such as the Department of Veterans Affairs, indicated use of reprocessed SUDs among hospitals varies.

Eleven Active Reprocessing Establishments Collectively May Be Reprocessing More than 100 Types of SUDs

FDA identified 11 establishments actively reprocessing SUDs in the United States as of July 2007, 1 of which was a hospital. Seven establishments engaged exclusively in reprocessing or in reprocessing and one other activity, such as contract sterilizer. According to representatives of the reprocessing industry, 3 of these 7 account for about 90 percent of all SUD reprocessing. Four of the 11 reprocessing establishments registered with FDA to undertake three or more FDA-regulated activities including distribution or manufacturing. For example, 1 reprocessing establishment manufactures over 80 different types of medical devices but reprocesses only one type of SUD that it also manufactures. Four of the 11 establishments, including the hospital, have each listed only one type of reprocessed SUD.[19]

The more than 100 types of devices that reprocessing establishments reported actively reprocessing or planning to reprocess represent devices with a range of intended uses, some more invasive than others. For example, compression sleeves, which are used to provide intermittent compression to a patient's limbs to help prevent postoperative blood clots from forming, are intended to make contact with patients' skin only, not to enter the body. In contrast, surgical devices such as orthopedic drill bits or surgical saw blades are intended for use in internal parts of the body. Electrophysiology catheters are inserted into the heart to measure cardiac rhythm and have been reprocessed for over 20 years. While we found no reliable data on the volume of reprocessed SUDs by device type, representatives of 3 large reprocessing establishments have stated that noninvasive devices such as compression sleeves account for the greatest volume of their overall business, with surgical devices representing a much smaller share of their business.

[19]By listing a device with FDA, an establishment does not necessarily mean it is actively reprocessing and commercially distributing that device. For example, some listed devices may not yet be available, but are being considered for the future or are awaiting premarket clearance, if required. Therefore the listed devices we report represent both those SUDs that are currently available as reprocessed and those that were being considered for reprocessing.

Information on the Size of the Reprocessed SUD Market Is Not Available

Data on the exact size of the SUD reprocessing industry—in terms of the volume or value of reprocessed SUDs sold—and how it compares to the original SUD industry or the overall medical device industry are not available. FDA neither collects nor reports on the volume or value of reprocessed SUDs sold; the agency also does not maintain data on the volume or value of original SUDs or on all medical devices sold. Regarding private sector data sources, we found that data on the SUD reprocessing industry were either not available or were considered proprietary by industry sources. Similarly, representatives of trade associations that represent establishments that manufacture original SUDs and reusable devices could not provide data on the proportion of the overall medical device industry that consists of devices labeled for single-use and could be reprocessed.

Hospital Use of Reprocessed SUDs Varies

Two FDA studies indicate that hospital use of reprocessed SUDs varies. In 2002, FDA reported that about one-fourth of U.S. hospitals used at least one type of reprocessed SUD, with larger hospitals being more likely to do so.[20] To develop this estimate, FDA surveyed more than 5,000 hospitals.[21] Nearly half of responding hospitals with more than 250 beds reported using reprocessed SUDs, compared with 12 percent of responding hospitals with fewer than 50 beds.[22] This information was supplemented by a more recent study in 2005. In this study, which focused on hospitals' level of satisfaction with reprocessed SUDs, FDA received information from 102 representatives of hospitals across the nation. About 40 percent indicated they used a third party to reprocess SUDs. FDA followed up with

[20]U.S. Food and Drug Administration, *Final Report: Survey on the Reuse and Reprocessing of Single-Use Devices (SUDs) in U.S. Hospitals* (Rockville, Md., 2002). Prepared for FDA by Eastern Research Group, Inc., Lexington, Mass., Contract 223-98-8002.

[21]The survey response rate was 79.4 percent, which included both complete and partial responses.

[22]Most of the hospitals reported contracting with other establishments to perform the reprocessing, but the initial results of the survey indicated that about 13 percent of those that used reprocessed SUDs reported doing their own reprocessing. FDA informed us that, to enforce the requirement that hospitals that do their own reprocessing register with FDA and comply with appropriate quality control regulations, inspectors visited all of the hospitals that reported performing their own reprocessing and a statistical sample of about 200 of the approximately 900 hospitals that did not respond to the survey. According to FDA officials, the inspectors who visited these hospitals determined that most were not involved in reprocessing and had responded to the survey question in error. FDA officials told us that all of the hospitals that FDA's inspectors determined were reprocessing SUDs indicated that they planned to stop the practice after the FDA inspectors' visits.

focus groups to obtain more detailed information on the differing perspectives of various types of hospital personnel about the hospitals' use of reprocessed SUDs. In general, participating hospitals that reported using reprocessed SUDs indicated their facilities had specific policies regarding reprocessing, used a variety of types of reprocessed SUDs, and believed that reprocessing provides substantial cost savings.

In our discussions with representatives of reprocessing establishments and a managed care organization that runs several hospitals, we were told that hospitals or hospital systems generally set their own policies regarding whether to use reprocessed SUDs, which reprocessing establishment to use, and which reprocessed SUDs are acceptable to the hospitals' physicians and other clinical personnel. This holds true for some federal hospitals as well. The Department of Defense, for example, allows individual medical facilities the option of using SUDs that are reprocessed by establishments that are registered with FDA as reprocessors.[23] According to Department of Defense officials, as of October 2007

- 3 of the Navy's 22 medical centers and hospitals reported using reprocessed SUDs;
- 4 of the Army's 26 medical centers and hospitals reported using, or planning to use, reprocessed SUDs; and
- 1 of the Air Force's 17 medical centers and hospitals reported using reprocessed SUDs.

In contrast to the Department of Defense policy, the Department of Veterans Affairs has had an agencywide policy prohibiting the use of reprocessed SUDs in any of its medical centers since at least 1991. According to Department of Veterans Affairs officials, the agency could not determine whether reprocessed SUDs are safe or not. However, the agency does not allow the use of reprocessed SUDs because manufacturers did not design SUDs to be used more than once and, as a consequence, do not provide instructions on cleaning and sterilizing these devices. These officials told us that the department's policy has remained

[23]Department of Defense medical facilities are not obligated to use reprocessed SUDs. Medical facilities that choose to use reprocessed SUDs must follow Department of Defense and service-level policy, which is based on current FDA guidance, and can not reprocess SUDs internally but must utilize a third-party reprocessor registered with FDA as a reprocessor.

largely unchanged, although the agency has reconsidered it at various times.

FDA Has Increased Its Oversight of SUD Reprocessing

FDA has taken actions, both on its own initiative and in response to legislation, to strengthen the agency's oversight of reprocessed SUDs. These actions include (1) requiring additional premarket data submissions for 72 types of reprocessed SUDs and (2) conducting postmarket activities such as inspections of reprocessing establishments to ensure compliance with regulatory requirements and other surveillance to assess whether reprocessing is associated with an increased public health risk.

FDA Identified More than 70 Types of SUDs That Require Additional Premarket Review

FDA's premarket oversight of reprocessed SUDs has increased, beginning with actions FDA took on its own initiative in 2000. In August of that year, FDA issued guidance that clarified its policies on the regulation of reprocessed SUDs. This guidance was directed at hospitals and third-party entities engaged in reprocessing SUDs for reuse. At the time, a sizeable minority of U.S. hospitals were thought to be reprocessing their own SUDs without FDA oversight.[24] FDA recognized that hospitals were not likely to be familiar with its regulations, so the guidance included time frames for these reprocessing establishments to comply.[25] According to FDA officials, the agency intended to subject each type of reprocessed SUD to the same level of premarket review as required of original SUDs. For example, if the SUD was exempt from premarket requirements before it was used for the first time, the reprocessed SUD would also be exempt.

MDUFMA, enacted in 2002, directed FDA to review the premarket submission requirements for reprocessed SUDs and identify those devices for which FDA would require additional validation data to document cleanliness, sterility, and performance following reprocessing. This meant that reprocessing establishments had to submit additional premarket

[24]In our 2000 report, we referred to surveys in the late 1990s indicating that between 16 and 31 percent of hospitals reported using reprocessed SUDs, with at least one-third of those hospitals reporting contracting with independent reprocessing companies. at 8–9.

[25]See U.S. Food and Drug Administration, *Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals* (Rockville, Md., Aug. 14, 2000). Among other things, this guidance specified that hospitals and third-party establishments engaged in reprocessing must comply with registration and listing, quality system regulation, and applicable premarket requirements.

documentation for certain types of reprocessed SUDs to demonstrate that they remain safe and effective or substantially equivalent to another device already on the market. MDUFMA directed FDA to identify devices that fell into the following two categories and to determine whether additional information was needed to determine their continued marketability:

- The first category consisted of reprocessed SUDs that had been *exempt from* premarket notification at the time MDUFMA was enacted.[26] For these reprocessed SUDs, FDA was required to determine whether the devices' premarket notification exemptions should be terminated to provide reasonable assurance of their safety and effectiveness. Manufacturers of devices identified by FDA were required to provide premarket notification with validation data on cleaning, sterilization, and functional performance to ensure that the reprocessed SUDs remained safe and effective after the maximum number of reprocessing cycles.[27] FDA, in response, identified 20 types of reprocessed SUDs that met these criteria and revoked their premarket notification exemptions. Examples of types of reprocessed SUDs that had their exemptions terminated and that were required to submit the additional validation data included noncompression heart positioners (devices intended to move, lift, and stabilize the heart during open heart surgery), nonelectric biopsy forceps (devices used to remove a specimen of tissue for microscopic examination), and various surgical devices such as specialized needles and catheters.

- The second category consisted of reprocessed SUDs that were *already subject* to premarket notification at the time MDUFMA was enacted. FDA was required to determine whether additional documentation on cleaning, sterilization, and performance was necessary to ensure that the device remained safe and effective after the maximum number of reprocessing cycles. FDA, in response, identified 52 types of reprocessed SUDs that met those criteria and required that premarket submissions for them include such data. Examples of device types that were subject to the additional validation data requirement included electric biopsy forceps, surgical drills

[26]This provision of MDUFMA applied only to *critical* and *semicritical reprocessed SUDs*. Critical reprocessed SUDs are intended to contact normally sterile tissue or body spaces during use, and semicritical reprocessed SUDs are intended to contact intact mucous membranes and not penetrate normally sterile areas of the body. 21 U.S.C. § 321(mm)(1), (2).

[27]According to FDA officials, FDA does not set a limit on the number of times a device type may be reprocessed; the purpose of the validation data is to ensure that reprocessing establishments test, and document to FDA's satisfaction, that a SUD may be reprocessed for at least the number of times the establishment has designated.

and accessories, and oximeters (devices used to measure the level of oxygen in a patient's blood).

Appendix III summarizes FDA's methodology for identifying the 72 types of reprocessed SUDs for which the agency has required additional premarket data submissions in accordance with MDUFMA.[28]

As part of its premarket review, FDA evaluates not only the devices themselves but the accompanying labeling and instructions for use. MDUFMA required that the labeling of all reprocessed SUDs state that the device had been reprocessed and the name of the establishment that reprocessed it. This provision took effect in January 2004 and applies to devices marketed after that date. MDUFMA and subsequent legislation also required that reprocessed SUDs or an attachment to such devices "prominently and conspicuously" bear the reprocessing establishment's name, abbreviation, or symbol.[29] FDA issued guidance that first became effective on August 1, 2006, to help reprocessing establishments comply with this requirement.[30]

FDA Actions for Postmarket Oversight of Reprocessed SUDs Have Taken Several Forms

FDA's actions regarding its postmarket oversight of reprocessed SUDs have included (1) clarifying that SUD reprocessing establishments are subject to the same inspection requirements as other device manufacturing establishments and (2) updating reporting forms to better

[28]In addition to directing FDA to identify those reprocessed SUDs that should require additional validation data to document cleanliness, sterility, and performance following reprocessing, for class III reprocessed SUDs, MDUFMA created a new requirement. Those manufacturers marketing class III reprocessed SUDs would have to submit a premarket report, which requires among other things a full description of the methods used in, and the facilities and controls used for, the reprocessing and packaging of the device. According to FDA, the agency had received one premarket report for a class III reprocessed SUD as of July 2007, but the applicant subsequently withdrew it.

[29]Medical Device User Fee Stabilization Act of 2005, Pub. L. No. 109-43, § 2(c), 119 Stat. 439, 441 (2005). When MDUFMA was enacted this requirement applied to all devices, but subsequently Public Law 109-43 limited it to reprocessed SUDs only. In cases where the original SUD is not marked directly with the manufacturer's name, abbreviation, or symbol, the reprocessing establishment may provide a detachable identification label on the device's package that is intended to be attached to the patient's medical record.

[30]U.S. Food and Drug Administration, *Guidance for Industry and FDA Staff: Compliance with Section 301 of the Medical Device User Fee and Modernization Act of 2002, as amended – Prominent and Conspicuous Mark of Manufacturers on Single-Use Devices* (Rockville, Md., May 1, 2006).

identify those device-related adverse event reports involving reprocessed SUDs.

FDA Clarified Oversight Policies and Plans for Inspecting Reprocessing Establishments

With the issuance of its August 2000 guidance, FDA intended to make clear its plans to subject hospitals and other third-party establishments that reprocess SUDs to FDA inspection for compliance with applicable regulatory requirements just like other establishments manufacturing medical devices. For the 11 U.S. establishments actually reprocessing SUDs as of July 2007, FDA had inspected 10 at least once during the period August 2004 through October 2007. These included multiple inspections of the 3 reprocessing establishments that industry representatives estimate to account for about 90 percent of all U.S. SUD reprocessing. FDA had not inspected 1 of the 11 reprocessing establishments. This establishment was first registered as a reprocessing establishment in 2006, and FDA officials told us that the agency plans to inspect it in 2008.[31]

We reviewed FDA summaries and other documents related to inspections conducted from August 2004 through October 2007 for the 10 inspected reprocessing establishments. For 3 establishments, none of the inspections indicated that corrective actions were needed. That is, no objectionable conditions or practices were found during the inspection. For the remaining 7 reprocessing establishments, at least one FDA inspection for those establishments during this period found that corrective actions were needed. This means that the inspection identified objectionable conditions or practices through which the establishment failed to meet either regulatory or administrative requirements. In general, in cases like these, depending upon the severity of the objectionable conditions identified, FDA determined whether the establishments could take corrective actions voluntarily, or whether conditions warranted issuance of FDA warning letters or more severe enforcement actions such as product seizures or

[31]FDA instructs its district offices to select medical device establishments for inspection using the following priority order: (1) device manufacturers with a pending medical device premarket application for approval; (2) manufacturers of class III devices that have never been inspected; (3) follow-up inspections for previously conducted for-cause or compliance inspections; (4) manufacturers of high-risk devices identified by special assignment from FDA, such as manufacturers of devices with a higher frequency of recalls and adverse event reports or manufacturers of new devices that have not been manufactured and distributed for very long; and (5) SUD reprocessing establishments. See FDA guidance *Inspection of Medical Device Manufacturers* (June 15, 2006) (http://www.fda.gov/cdrh/comp/guidance/7382.845.html, downloaded Oct. 25, 2007).

injunctions.[32] In the cases we reviewed that involved corrective actions, we found the following:

- For 6 establishments, FDA investigators determined that actions taken by the establishments were adequate to address the deficiencies identified during the establishment inspections. FDA considers these inspections to be resolved. For example, one inspection revealed that the establishment had reprocessed two models of SUDs before it received FDA approval to reprocess them. The firm stopped reprocessing these models of SUDs prior to FDA's inspection and FDA inspectors determined that the establishment had voluntarily taken the corrective actions that were required. In another instance, FDA investigators found that the establishment had not maintained complaint files appropriately. Specifically, the establishment received a complaint from one hospital that five blood pressure cuffs reprocessed by that establishment did not function properly. However, the establishment listed all five devices as a single complaint rather than documenting each nonfunctioning device separately as required. At the end of the inspection, the establishment agreed to make each device a separate complaint rather than group several devices under one complaint number.

- The inspection for 1 establishment was open and under investigation as of November 2007. For this establishment, FDA inspectors identified a number of objectionable conditions, including instances in which the establishment did not adequately investigate reported problems associated with reprocessed SUDs or submit reports of device problems to FDA within the required time. In September 2007, FDA conducted a meeting with officials representing the establishment to discuss the inspection findings in detail. The establishment subsequently provided a written response to FDA containing the actions it proposed to take in order to correct the deficiencies identified by FDA investigators. FDA officials told us that the agency will not consider the inspection deficiencies to be resolved until FDA investigators reinspect the establishment. As of November 2007, FDA had not scheduled a reinspection of this establishment.

FDA Has Taken Steps to Improve Adverse Event Reports Related to Use of Reprocessed SUDs

MDUFMA directed FDA to modify its forms for mandatory and voluntary reporting of incidents involving devices to indicate when device-related adverse event reports involved reprocessed SUDs. Since fall 2003, FDA has included a check box in its mandatory and voluntary adverse event

[32]See app. II for additional information on the inspection results.

reporting forms to indicate whether the device associated with the adverse event was a reprocessed SUD.[33]

In addition to the change already made, an FDA workgroup is investigating whether further refinements in the device-related adverse event reporting forms, such as additional instructions, could further improve the accuracy of the adverse event reports associated with reprocessed SUDs. FDA officials told us that, while the new labeling and marking requirements for reprocessed SUDs, as well as the updated reporting forms, may eventually enhance their ability to identify device-related adverse event reports involving reprocessed SUDs, as of July 2007, agency officials had not detected an appreciable change in the reports submitted involving reprocessed SUDs.

Available Data Lack Rigor for Definitive Comparisons but Do Not Indicate That Reprocessed SUDs Pose an Elevated Health Risk

While FDA has made changes to its data collection process regarding reprocessed SUD-related adverse events, the data are not suitable for a rigorous comparison of the safety of reprocessed SUDs relative to original SUDs of the same type on their initial use. Such a comparison would require collecting additional data such as the type of device and adverse event and the number of original and reprocessed SUDs of that type in use. The limited number of peer-reviewed studies related to reprocessing that we identified were insufficient to support a comprehensive conclusion on the relative safety of reprocessed SUDs. Despite the limitations of available data, FDA's analysis of reported device-related adverse events does not show that reprocessed SUDs present an elevated health risk.

[33]The number of adverse event reports associated with all devices increased substantially from 2000 to 2006. In 2000, FDA received about 77,000 reports of adverse events associated with all devices. By 2006, this number had increased more than fourfold to about 320,000 reports.

Rigorous Safety Comparisons Not Possible through Current or Planned Adverse Event Reporting

While FDA's database of device-related adverse events is designed to provide information about trends such as infection outbreaks or common user error caused by inadequate instructions, it is not comprehensive. That is, the system cannot generate sufficient data on device performance that would be required to compare the safety of reprocessed SUDs with either original SUDs on their initial use or to other devices in general.[34] Such a study, at a minimum, would require data that would identify the type of device and adverse event, the number of original and reprocessed SUDs of that type in use, the number of times each reprocessed SUD was used, and the rate of adverse events associated with the original devices. FDA officials, including the Director of the Center for Devices and Radiological Health, have described the effort that would be required and acknowledged the shortcomings of the current adverse event reporting system to generate comparative safety data. FDA officials indicated to us, however, that such studies would not be an efficient use of agency resources given the existing level of FDA oversight.

To supplement our review of the safety information developed and analyzed by FDA, we conducted a review of the scientific literature related to SUD reprocessing published in peer-reviewed journals since 2000. We identified six studies that addressed the safety of reprocessed SUDs. On examination, none of the six studies were comprehensive enough to support an overall conclusion about the relative safety of reprocessed SUDs compared to SUDs on their initial use. They were limited in that they tested relatively few devices, and the reprocessing establishments had not been inspected by FDA.

FDA Has Found No Causative Link between a Reprocessed SUD and Reported Patient Injury or Death

FDA has reviewed available adverse event reports associated with reprocessed SUDs and has not identified a causative link between the adverse event and the fact that the devices involved were reprocessed. In September 2006, the Director of FDA's Center for Devices and Radiological Health testified that based on available adverse event data, FDA had identified 434 reports submitted from October 2003 to July 2006 in which reprocessed SUDs were identified on the reporting form. With respect to these reports, FDA determined that the majority of the reports,

[34]We have reported on the limitations of FDA's adverse event data. For example, in 2000, we reported that all adverse event reporting systems, such as FDA's, that rely on health care providers to take the initiative to make a report experience a high level of underreporting. See GAO, *Adverse Events: Surveillance Systems for Adverse Events and Medical Errors,* (Washington, D.C.: Feb. 9, 2000).

including all 15 of the reports involving deaths, did not involve a reprocessed SUD. For example, FDA determined that many of the reported events involved reusable devices such as magnetic resonance imaging machines or SUDs on their initial use. Of the 434 reports, FDA further reviewed the 65 events that it found actually involved or were suspected to involve a reprocessed SUD and that the reprocessed SUD was one of several possible causal factors in the adverse event. In reviewing these 65 reports, FDA found that the types of adverse events reported to be associated with the use of reprocessed SUDs were the same types of events that are reported for new, nonreprocessed devices.

In 2005, FDA consulted hospitals participating in the agency's Medical Product Safety Network (MedSun) about their experiences, including adverse events or safety concerns, with reprocessing.[35] None of the representatives of MedSun hospitals who participated in the FDA focus groups reported being aware of any infections related to the use of reprocessed SUDs. However, hospital representatives noted that if an infection occurred, it would be very difficult to discern if a reprocessed SUD was the cause. Similarly, none of the hospital representatives expressed significant concerns about potential malfunctions with reprocessed SUDs, even though some of them indicated that malfunctions of reprocessed SUDs occurred on occasion (for example, surgical blades and other tools sometimes may not have been sharpened properly).[36] Overall, however, participating hospital representatives generally expressed confidence in reprocessed SUDs, with some participants stating that there were actually fewer performance problems with reprocessed SUDs than with new SUDs. According to FDA, all participants believed that reprocessing establishments are more stringently regulated by FDA than are the manufacturers of the original devices, and this provided them a sense of confidence in the reprocessing process.

After reviewing the available evidence—including FDA's process for identifying and investigating device-related adverse events reported to involve reprocessed SUDs, peer-reviewed studies published since 2000,

[35]MedSun was launched in 2002 to collect more-detailed adverse event reports about devices from a network of approximately 350 large hospitals that report through an Internet-based system. Participating MedSun hospitals voluntarily provide detailed information related to the design and use of devices. MedSun also encourages reporting of "close calls" so that preventative action can be taken before patients are injured.

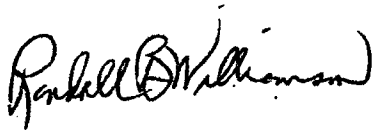
[36]One small hospital, for example, reported that it had discontinued the use of a reprocessed SUD after one broke during a procedure.

and the results of our and FDA's consultations with hospital representatives—we found no reason to question FDA's analysis indicating that no causative link has been established between reported injuries or deaths and reprocessed SUDs. That is, the available information regarding safety, while not providing a rigorous safety comparison between reprocessed SUDs and other devices, does not indicate that reprocessed SUDs currently in use pose an increased safety threat.

Agency Comments

In commenting on a draft of this report, HHS provided language to clarify several sentences which we generally incorporated. We also incorporated HHS's technical comments as appropriate. HHS's written comments appear in appendix V.

As arranged with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution of it until 30 days after its issue date. At that time, we will send copies of this report to the Secretary of Health and Human Services, the Commissioner of FDA, appropriate congressional committees, and other interested parties. We will also make copies available to others on request. In addition, this report is available at no charge on the GAO Web site at http://www.gao.gov. If you or your staff have questions about this report, please contact me at (202) 512-7114 or williamsonr@gao.gov. GAO staff who made major contributions to this report are listed in appendix VI.



Randall B. Williamson
Acting Director, Health Care

Appendix I: Scope and Methodology

To address the report objectives, we (1) reviewed relevant laws, regulations, and agency guidance; (2) interviewed Food and Drug Administration (FDA) officials, representatives of professional associations of manufacturing establishments,[1] and the Association of Medical Device Reprocessors (AMDR); (3) interviewed officials from a provider association, private hospitals, and the Departments of Defense and of Veterans Affairs regarding their policies on the use of reprocessed single-use devices (SUD); and (4) reviewed FDA data, market research, and peer-reviewed studies. We conducted our work between November 2006 and January 2008 in accordance with generally accepted government auditing standards.

We consulted a variety of sources, including FDA officials who track industry trends, professional associations representing device manufacturers and reprocessing establishments, and hospitals. We found that neither industry nor FDA representatives were able to provide comprehensive information on the number and volume of devices manufactured for the United States, or on the subset of devices that are SUDs or reprocessed SUDs.

To determine the number of reprocessing establishments, we reviewed FDA data on the number of registered reprocessing establishments. FDA data indicated that more than 40 establishments were registered as reprocessing establishments as of March 2007, including 13 located outside the United States. After we determined that the FDA list did not match information provided by two FDA district offices, FDA officials determined that many of the establishments had registered as reprocessing establishments in error and subsequently identified 11 establishments in the United States that, as of July 2007, were engaged in reprocessing SUDs. We determined FDA's information on the number of establishments reprocessing SUDs in the United States as of July 2007 was sufficiently reliable for our purposes. However, given the errors in the FDA list of registered reprocessing establishments in 2007 and the lack of information on foreign establishments registered as reprocessors, we determined that FDA's data were not sufficiently reliable to determine the number of establishments reprocessing SUDs prior to July 2007 or the

[1]These associations included the Advanced Medical Technology Association and the Medical Device Manufacturers Association.

number of foreign reprocessing establishments at any time.[2] As a result, we were unable to analyze trends in the number of reprocessing establishments or the types of devices being reprocessed since 2000, and we were limited to reporting on domestic reprocessing establishments.

Regarding the types of SUDs being reprocessed, our ability to provide precise information was limited because although FDA maintains databases of the types of devices the reprocessing establishments listed with FDA, it does not confirm that all listed devices are currently available. As a result, FDA's data may include types of SUDs that the reprocessing establishments no longer reprocess, types of SUDs they plan to reprocess, or types of SUDs they listed in error—in effect, overstating the types of SUDs the establishments are reprocessing or plan to reprocess.[3] In addition, representatives of one reprocessing establishment identified one device type listed in the FDA database that the establishment never reprocessed, but only resterilized and repackaged in unused form. While we were unable to determine their reliability, we used FDA's data listing the types of SUDs being reprocessed for the limited purpose of portraying the types of SUDs that the reprocessing establishments were reprocessing or planned to reprocess as of July 2007.

To determine available research published about the safety of reprocessed SUDs since we last reported on the topic in 2000, we reviewed FDA documents related to adverse events involving reprocessed SUDs and an FDA-sponsored survey of the experience of some hospitals related to SUDs, reviewed summaries of, and other documents related to, FDA inspections of reprocessing establishments conducted from August 2004 through October 2007, and conducted a literature search of studies (which we call articles) published in peer-reviewed journals from January 2000 through January 2007. We performed the literature review of peer-

[2]FDA officials were unable to determine whether the 13 establishments located outside of the United States that were registered as reprocessing establishments in 2007 were actively engaged in reprocessing, and if so, whether they were marketing reprocessed SUDs in this country. According to FDA officials, the agency is actively working to determine whether any of the 13 foreign establishments registered as reprocessors, plus an additional foreign establishment that FDA officials identified as potentially reprocessing SUDs, have imported reprocessed SUDs into the United States in the 6 months prior to October 2007. The officials stated that the agency plans to issue assignments by March 2008 for the inspection of all foreign establishments it identifies as actively reprocessing SUDs for the U.S. market but they did not specify a date by which the inspections would be completed.

[3]For example, an establishment might list a device for which it intends to obtain premarket clearance but does not yet have such clearance.

reviewed articles by searching the following databases: BIOSIS, EMBASE, Medline, ProQuest, and the Science Citation Index.[4]

Of the more than 30 articles located through the literature search, we identified a total of 6 articles that were published in peer-reviewed journals and that addressed the safety of reprocessed SUDs.[5] These articles are listed below:

Colak, T.; Ersoz, G.; Akca, T.; Kanik, A.; Aydin, S. "Efficacy and Safety of Reuse of Disposable Laparoscopic Instruments in Laparoscopic Cholecytectomy: A Prospective Randomized Study." *Surgical Endoscopy* 18, no. 5 (2004): 727–731.

daSilva, M.; Ribeiro, A.; Pinto T. "Safety Evaluation of Single-Use Devices After Submission to Simulated Reutilization Cycles." *Journal of AOAC International* 88, no. 3 (2005): 823–829.

Fedel, M.; Tessarolo, F.; Ferrari, P.; et al. "Functional Properties and Performance of New and Reprocessed Coronary Angioplasty Balloon Catheters." *Journal of Biomedical Materials Research* 78, no. 2 (2006): 364–372.

Lipp, M.; Jaehnichen, G.; Golecki N.; et al. "Microbiological, Microstructure, and Material Science Examinations of Reprocessed Combitubes® After Multiple Reuse." *Anesthesia & Analgesia* 91 (2000): 693–397.

Roth, K.; Heeg, P.; Reichl, R. "Specific Hygiene Issues Relating to Reprocessing and Reuse of Single-Use Devices for Laparascopic Surgery." *Surgical Endoscopy* 16, no. 7 (2002): 1091–1097.

[4]We performed our search using the following key words: SUD, single-use, single-use devices, one use, disposable equipment, medical device(s), equipment, reprocess, reuse, use again, safety, infection, malfunction, contaminate, contamination, or injury. We also examined other articles published in peer-reviewed journals identified during the course of our review.

[5]We did not review letters of opinion, news articles, commentary, association position statements, federal government publications such as FDA informational news articles or guidance documents, and previous GAO reports. We also excluded articles if the periodical was published outside of the United States; we could not confirm that the publication was peer reviewed; if the authors were known or thought to be associated with device trade associations, reprocessing establishments, or manufacturers; or if the study was directly sponsored by a manufacturer.

Wilson, S.; Everts, R.; Kirkland, K.; et al. "A Pseudo-Outbreak of Aureobasidium Species Lower Respiratory Tract Infections Caused by Reuse of Single-Use Stopcocks During Bronchoscopy." *Infection Control and Hospital Epidemiology* 21, no. 7 (2000): 470–472.

On examination, none of these studies were comprehensive enough to support an overall conclusion about the relative safety of reprocessed SUDs compared to SUDs on their initial use. Several limitations in the articles we identified through our literature review make it difficult to support an overall statement comparing the safety of reprocessed SUDs with the safety of other devices. These limitations include the following:

- Five of the six articles described studies that were conducted outside of the United States, so we could not determine whether the reprocessing methods and facilities would have met FDA's approval. The remaining article, while conducted in the United States, was published prior to MDUFMA's enactment in 2002 and subsequent FDA actions to implement new requirements.

- The articles reported on studies that tested few types of devices. Because each study used different types of devices, it is not possible to compare and aggregate their results to support general conclusions regarding the relative safety of reprocessed SUDs.

Appendix II: Reprocessing Establishments, Types of Reprocessed Devices Listed, and FDA Inspection Results

Establishment	Number of device types listed[a, b]	Examples of types of devices[b]	Years of inspections conducted from August 2004 through October 2007	Inspection finding	Inspection finding status
A	20	Blood pressure cuff Cardiac stabilizer Laparoscopic instruments	2006 2005	Corrective action indicated Corrective action indicated	Open investigation Resolved
B	40	Curette External fixation device Electrophysiology catheter	2007 2005	Corrective action indicated No action indicated	Resolved
C	11	Tracheal tube stylet Protective restraint Bite block for endoscope	2006 2005	Corrective action indicated No action indicated	Resolved
D	43	Surgical saw blade Nonelectric biopsy forceps Orthopedic knife, burr	2007 2005	Corrective action indicated No action indicated	Resolved
E	11	Oxygen mask Oximeter Compression sleeve	2007 2005 2005	No action indicated No action indicated No action indicated	
F	29	Oxygen mask Nonelectric biopsy forceps Arthroscopic accessories Pneumatic tourniquet	2006 2005	No action indicated No action indicated	
G	1	External fixation clamp	2007 2006	Corrective action indicated Corrective action indicated	Resolved Resolved
H	14	Orthopedic cutting instrument, bone tap Reamer, burr, drill bit	[c]	n.a.	
I	1	Disposable surgical instrument kit	2007 2006 2005	No action indicated Corrective action indicated No action indicated	 Resolved
J	1	Disposable surgical instrument kit	2007 2006	Corrective action indicated Corrective action indicated	Resolved Resolved

Establishment	Number of device types listed[a, b]	Examples of types of devices[b]	Years of inspections conducted from August 2004 through October 2007	Inspection finding	Inspection finding status
K	1	Compression sleeve	2004	No action indicated	

Source: GAO analysis of Food and Drug Administration (FDA) data.

Notes: n.a. = not applicable.

[a]Device types indicate all devices assigned to a distinct product code by FDA. Each device type may include a variety of actual instruments, manufacturers, and models. For example, some device types include the device itself, such as a powered saw, and its accessories.

[b]These data are provided for illustrative purposes to show the types of devices FDA data indicated that the 11 reprocessing establishments were reprocessing or planned to reprocess as of July 2007. Available data were limited because the FDA data on listed devices are not regularly verified and, as a result, the data may include types of SUDs that the reprocessing establishments no longer reprocess or plan to reprocess or that reprocessing establishments listed in error—in effect, overstating the types of SUDs establishments are reprocessing or plan to reprocess.

[c]The establishment first registered as a reprocessing establishment in 2006; as of July 2007 no inspections had been conducted but FDA officials reported plans to inspect the establishment in 2008.

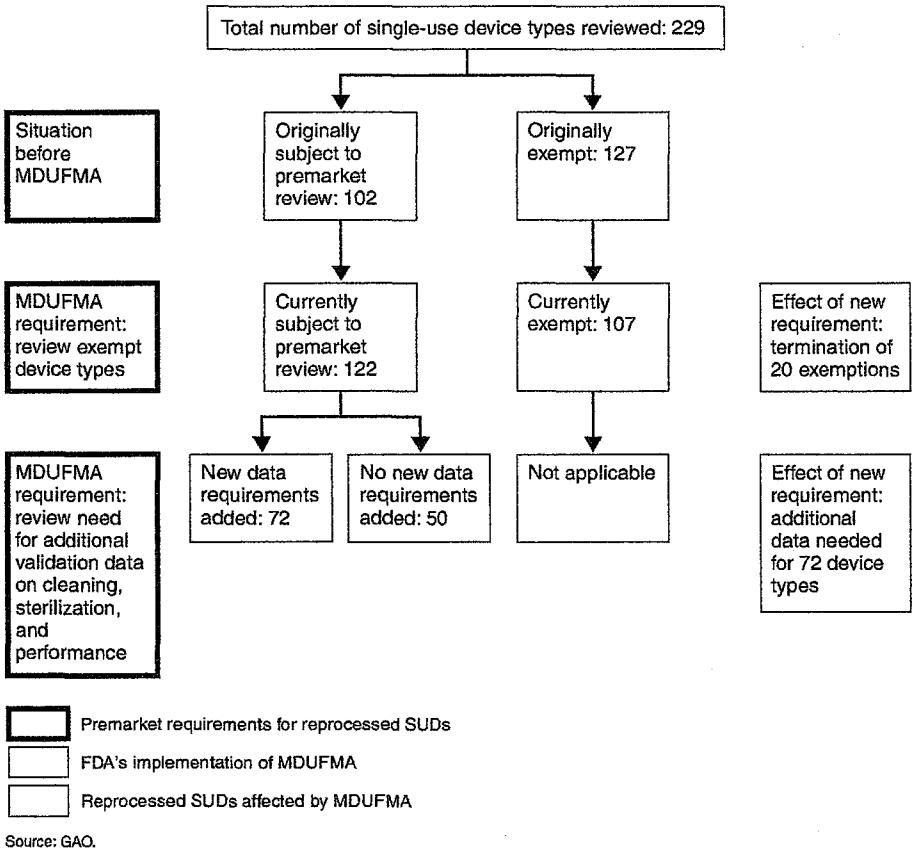
Appendix III: FDA's Review of Premarket Requirements for Reprocessed SUDs Following MDUFMA

The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) required the Food and Drug Administration (FDA) to identify reprocessed single-use devices (SUD) that should be subject to additional premarket data submission requirements to ensure their safety and effectiveness. To identify these reprocessed SUDs, FDA analyzed the risks of infection or inadequate performance for 229 types of SUDs that the agency identified as either actually or potentially being reprocessed. For purposes of implementing MDUFMA, FDA took into account such factors as the physical characteristics of each type of SUD, including coatings that could be damaged by reprocessing, the type of contamination associated with the type of SUD's intended use, and the severity of potential injuries that could result if that type of SUD fails after reprocessing. FDA published the results of its review in a series of *Federal Register* Notices between April 2003 and September 2005.[1] These devices were either: (1) previously exempt from premarket notification and have had their exemptions revoked, and now also require validation data on cleaning, sterilization, and functional performance; or (2) already subject to premarket notification and now also require the additional validation data.

Reprocessing establishments that did not provide the required premarket notification and validation data by the deadlines established in these notices could no longer legally market those devices. Figure 1 summarizes the results of FDA's review in chart form.

[1]70 Fed. Reg. 56911 (Sept. 29, 2005), 69 Fed. Reg. 19433 (Apr. 13, 2004), 68 Fed. Reg. 38071 (June 26, 2003), and 68 Fed. Reg. 23139 (Apr. 30, 2003).

Figure 1: Overview of FDA's Implementation of MDUFMA's Premarket Review Requirements for Reprocessed SUDs, April 2003 through September 2005



Source: GAO.

As of May 30, 2007, FDA had received a total of 6 premarket notification submissions with additional validation data for 2 types of reprocessed SUDs that had their exemptions revoked following enactment of MDUFMA. Of these 6 submissions, 4 were cleared by FDA and 2 were pending as of May 30, 2007. FDA also received 88 submissions of premarket validation data for 16 types of reprocessed SUDs that had not been exempt at the time MDUFMA was enacted but that were subsequently required to submit additional validation data. Of these 88 submissions, 74 were cleared by FDA, 4 were found not substantially equivalent and therefore not marketable, and 10 were either withdrawn or pending as of May 30, 2007.

Appendix IV: Reporting Requirements for Device-Related Adverse Events

The Food and Drug Administration's (FDA) reporting framework for device-related adverse events includes both mandatory and voluntary components, depending on who is doing the reporting. Under FDA's Medical Device Reporting (MDR) regulation, device user facilities (including hospitals and other providers)[1] and manufacturers (including reprocessing establishments) must report deaths and serious injuries that a device has caused or may have contributed to. User facilities must report deaths to FDA and the manufacturer, and serious injuries to the manufacturer, if known, otherwise to FDA, whenever they become aware of information that reasonably suggests that a device has or may have caused or contributed to the death or serious injury of a patient. Manufacturers must report device-related deaths and serious injuries to FDA whenever they become aware of information that reasonably suggests that one of their devices has or may have contributed to the event. Manufacturers are also required to submit device malfunction reports to FDA whenever they become aware of information that reasonably suggests that one of their marketed devices has malfunctioned and that the device or a similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. See table 1 for a summary of MDR mandatory reporting requirements.

[1]For purposes of device-related adverse event requirements, a device user facility is defined as a hospital, an ambulatory surgical facility, a nursing home, an outpatient treatment facility, or an outpatient diagnostic facility that is not a physician's office. 21 C.F.R. § 803.3 (2007).

Table 1: Summary of MDR Mandatory Reporting Requirements for Device-Related Adverse Events

Reporter	What	To whom	When
User facility	Deaths	FDA and manufacturer	Within 10 work days from becoming aware of relevant information
	Serious injuries[a]	Manufacturer (FDA if manufacturer unknown)	Within 10 work days from becoming aware of relevant information
	Annual report of deaths and serious injuries[a]	FDA	January 1
Manufacturer[b]	Deaths and serious injuries[a]	FDA	30 calendar days from becoming aware of relevant information
	Malfunctions[c]	FDA	30 calendar days from becoming aware of relevant information
	Events that require immediate remedial action to prevent an unreasonable risk of substantial harm to the public health.[d]	FDA	Within 5 work days of becoming aware of relevant information

Source: FDA.

Notes: This table does not include the medical device reporting responsibilities of device importers.

[a]FDA defines "serious injury" as an injury or illness that is life threatening; or results in permanent impairment of a body function or permanent damage to a body structure; or necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure. 21 C.F.R. § 803.3 (2007).

[b]Manufacturers are also required to submit supplemental and baseline reports. Supplemental reports include information that was not known or available when the original report was submitted. They must be filed within 1 month after the manufacturer becomes aware of new information. Baseline reports include information about the manufacturer and the device that is the subject of a reported adverse event. They are required when the manufacturer submits the adverse event report and must be updated annually.

[c]Malfunctions must be reported if the device or a similar device would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

[d]These reports must also be submitted when FDA notifies the manufacturer in writing that 5-day reports involving subsequent events of the same nature associated with a particular type of device or similar devices are needed.

In addition to its mandatory reporting component, FDA also has a voluntary component for reporting device-related adverse events, known as FDA's MedWatch program. Health care professionals can voluntarily report serious adverse events, product quality problems, or product use

errors that they suspect are associated with the devices they prescribe, dispense, or use. Consumers and others can also voluntarily report adverse events, product use errors, or quality problems, that they suspect are associated with the use of a device.

Appendix V: Comments from the Department of Health and Human Services

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Assistant Secretary for Legislation

Washington, D.C. 20201

JAN 7 2008

Randall B. Williamson
Acting Director, Health Care
U.S. Government Accountability Office
Washington, D.C. 20548

Dear Mr. Williamson:

Enclosed are the Department's comments on the U.S. Government Accountability Office's (GAO) draft report entitled, "Reprocessed Single-Use Medical Devices: FDA Oversight Has Increased and Available Information Does Not Indicate That Use Presents and Elevated health Risk (GAO 08-147).

The Department appreciates the opportunity to comment on this draft before its publication.

Sincerely,

Rebecca Hennard

for Vincent J. Ventimiglia
Assistant Secretary for Legislation

General Comments of the Department of Health and Human Services (HHS) on the Government Accountability Office's Draft Report Entitled, "Reprocessed Single-Use Medical Devices: FDA Oversight Has Increased and Available Information Does Not Indicate That Use Presents an Elevated Health Risk," (GAO-08-147)

General Comments

Page 1

footnote one: revise as follows:

Generally, a medical device includes items used for the diagnosis, cure, mitigation, treatment, or prevention of a disease or other condition. 21 U.S.C. § 321(h). Throughout this report, the term *device* refers to a medical device that is not being regulated as a drug or a biological product.

Page 5, 9th line from the bottom:

replace the sentence beginning with "Also, in response" with:

> Also, in response to MDUFMA's requirements for increased oversight, FDA identified more than 70 types of reprocessed SUDs that would be subject to additional premarket submission requirements.

Page 7, first sentence under Background:

replace "ensuring that all devices are reasonably safe and effective" with:

> reviewing the safety and effectiveness of nonexempt devices.

Page 9, footnote 14:

strike "and" in the last sentence and replace with:

> but generally do not

Appendix VI: GAO Contact and Staff Acknowledgments

GAO Contact

Randall B. Williamson, (202) 512-7114 or williamsonr@gao.gov

Acknowledgments

In addition to the contact named above, Kim Yamane, Assistant Director; Matt Byer; Julian Klazkin; Suzanne Rubins; Stan Stenersen; and Jennifer Wiley made key contributions to this report.

Related GAO Products

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Food and Drug Administration: Limited Available Data Indicate That FDA Has Been Meeting Some Goals for Review of Medical Device Applications. GAO-05-1042. Washington, D.C.: September 30, 2005.

Single-Use Medical Devices: Little Available Evidence of Harm From Reuse, but Oversight Warranted. GAO/HEHS-00-123. Washington, D.C.: June 20, 2000.

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Conference room: 016
Testifier position: oppose
Testifier will be present: Yes
Submitted by: Kerrie Lane Woodall
Organization: Ascent Healthcare Solutions
Address: 702 Hoopii Place Honolulu, HI 96825
Phone: 808-230-5577
E-mail: kwoodall@ascenths.com
Submitted on: 2/8/2009

Comments:
Testimony of Kerrie Lane Woodall/Ascent Healthcare Solutions

This is a bad bill and I strongly oppose it. Partnering with hospitals in Hawaii, Ascent has helped reduce the amount of medical waste generated to Hawaii's landfill by over 4410# in 2008. These same hospitals saved nearly $1 million dollars by using FDA approved remanufactured SUD's last year. Medical device reprocessing is safe, saves money and saves the environment.

Hawaii Medical Center is in bankruptcy, Wahiawa has been bailed out in the past, and HHSC continues to struggle financially. Before a hospital looks at laying off employees or reducing services, they need to look first at using reprocessed devices. Ironically, all three facilities do not use reprocessed devices in their OR's.

The Legislature should be considering a bill in support of reprocessing, which mandates that all hospitals in Hawaii, including HHSC, be encouraged to use remanufactured SUD's. SB361 would be detrimental to Hawaii's hospitals who rely on the use of reprocessed devices to help balance their budgets, as well as increase the amount of waste going into our landfills.

Please defeat Bill SB361. It is not good for our hospitals and it is not good for Hawaii. Thank you.