January 2008

REPROCESSED SINGLE-USE MEDICAL DEVICES

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

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Highlights

Highlights of GAO-08-147, a report to the Committee on Oversight and Government Reform, House of Representatives

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 GAO-08-147. 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.