December 16, 2005

Andrew C. von Eschenbach, MD
Acting Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Dr. von Eschenbach:

We are writing to request information regarding the Food and Drug Administration's (FDA) oversight over reprocessed single-use medical devices. According to a December 11, 2005, Washington Post article, *Hospitals Save Money, But Safety Is Questioned*, and a second article on December 12, 2005, *Reused Devices Attract Entrepreneurs, Scrutiny*, many hospitals are reusing medical devices designated for one-time use in an attempt to reduce costs. The original device manufacturers have said they cannot guarantee the safety of their single-use device once it is reprocessed and reused. Reprocessors, however, contend insufficient credible data and evidence exist to demonstrate that the use of reprocessed medical devices is riskier than the use of new ones.

While FDA is responsible for approving these devices, the manufacturers choose to submit applications for single-use only designation as opposed to a multi-use designation. The FDA does, however, allow reprocessed single-use devices to be marketed if they are "substantially equivalent" to the original device. The Washington Post articles, though, raise serious concerns regarding certification and use of reprocessed single-use medical devices and question whether these devices are safe and efficacious.

To better understand FDA's oversight and regulation of the industry for reprocessed single-use medical devices, we request that you provide the following information listed below by January 3, 2006:

1. What specific steps is FDA taking to ensure that reprocessed single-use medical devices are safe and efficacious?

2. Has FDA received complaints through the MedWatch adverse event reporting system of illnesses or injuries resulting from reprocessed medical devices that were designated for single-use?
    a. If so, please provide a list of the types of illnesses and injuries reported correlating with the type of device and the name of the reprocessing company.
    b. Please provide the specific action taken by FDA in response to each reported illness or injury to ensure the malfunction of the reprocessed medical device in question was not reflective of a systemic problem.
    c. Who is required to submit reports of such adverse events to FDA? Are both the hospital and the reprocessor responsible for reporting adverse events to FDA?

3. Please provide information on the number of adverse events reported for the original (first) use of single-use devices:
    a. Including any information about the comparative rates of injury from original use vs. reuse.
    b. If comparative information is unavailable, what actions would be necessary to develop such information?

4. What is the current Good Manufacturing Process (cGMP) for the reprocessing of single-use medical devices?
    a. What are the consequences for reprocessors if they violate the cGMP?
    b. In total, how many violations has FDA documented since the enactment of the Medical Device User Fee and Modernization Act (MDUFMA) in 2002?

5. Please provide a list of any enforcement action taken against reprocessors since the enactment of MDUFMA in 2002. This list should include the name of the company, type of device, date of the enforcement action, and reason for violation.

6. Under the MDUFMA, reprocessing firms seeking 510(k) approval must demonstrate that the reprocessed single-use device will remain "substantially equivalent" to the predicate device after the maximum reprocesses as proposed by the company filing the application.
    a. How often has FDA issued a "Not Substantially Equivalent" letter to firms seeking to legally market a reprocessed single-use medical device?

7. Does FDA have limits on how many times a medical device can be reprocessed?
    a. If so, how does FDA enforce compliance to ensure that a device is not reprocessed beyond the set number of times?

8. Please provide a list (separated by class) of all reprocessed single-use devices along with a correlating list of companies who reprocess those devices.

9. Not all reprocessed single-use medical devices are required to obtain 510(k) approval before being marketed; how does FDA determine which medical devices require approval and which do not?

If you have any questions regarding this request, please contact Susie Schulte, Majority Professional Staff, at (202) 225-5074 or Sarah Despres, Minority Professional Staff, at (202) 225-5051. In addition, we ask that you make your staff available to brief Committee staff on these issues at such time that is requested.

Sincerely,

Tom Davis
Chairman

Henry A. Waxman
Ranking Member

ONE HUNDRED NINTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON GOVERNMENT REFORM

2157 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515–6143

MAJORITY (202) 225–5074
FACSIMILE (202) 225–3974
MINORITY (202) 225–5051
TTY (202) 225–6852

http://reform.house.gov

December 16, 2005

The Honorable David W. Walker
Comptroller General of the United States
U.S. Government Accountability Office
441 G Street, NW
Washington, DC 20548

Dear Mr. Walker:

In recent years, many hospitals and other health care providers have used reprocessed "single-use" medical devices—devices that were approved for marketing by the Food and Drug Administration for one use only. These hospitals and other proponents of this practice argue that they can achieve significant cost savings by reprocessing and reusing many types of single-use devices without compromising patient safety. The widespread adoption of device reprocessing has led to the development of an industry of third-party device reprocessing companies. Within the last five years, FDA has developed standards for device reprocessing and has regulated third-party reprocessing firms in the same manner as the original manufacturers of medical devices. The GAO issued a report on this topic in June 2000 (*Single-Use Medical Devices: Little Available Evidence of Harm From Reuse, but Oversight Warranted*, GAO/HEHS-00-123), just before FDA's regulatory initiative took effect.

However, a recent series of articles in the Washington Post reported many instances of patient injuries associated with the use of defective or unsterile reprocessed single-use medical devices. In the articles, representatives of device reprocessing firms acknowledged those problems, but claimed that reprocessed devices failed no more frequently than original single-use devices.

We are alarmed by the incidents described in the Post, but we are also concerned about the lack of independent information available about the safety of the reprocessing of single-use medical

devices. For these reasons, we are writing to request that GAO update its 2000 report on single-use medical devices. In particular, we would like GAO to examine the safety of single-use device reprocessing and the adequacy of FDA's oversight of reprocessing. In addition, we would like GAO to examine how the safety and oversight of reprocessed devices compares to the safety and oversight of single-use devices.

Thank you for your attention to this important public health issue. Should you have any questions about this request, please contact Susie Schulte, Majority Professional Staff, at (202) 225-5074 or Sarah Despres, Minority Professional Staff, at (202) 225-5051.

Sincerely,

Tom Davis
Chairman

Henry A. Waxman
Ranking Member