DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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STATEMENT OF

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS
COMMITTEE ON VETERANS AFFAIRS
HOUSE OF REPRESENTATIVES

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INTRODUCTION

Mr. Chairman and Members of the Committee, I am Dr. Daniel Schultz, Director, Center for Devices and Radiological Health (CDRH) at the Food and Drug Administration (FDA or the Agency). I consider device safety and sterility to be of utmost importance and appreciate your invitation and the opportunity to discuss this issue.

BACKGROUND

Let me begin with a brief overview of our regulatory authorities regarding medical devices. As defined by Federal law, the term "medical device" encompasses several thousand health products, from simple articles such as tongue depressors and heating pads, to cutting-edge and complex devices such as pacemakers, lasers, and imaging technologies.

The Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic (FD&C) Act gave FDA specific authority to regulate the safety and effectiveness of medical devices. The FD&C Act prescribes a variety of mechanisms to achieve this goal. These include our general controls: quality system requirements for manufacturing; prohibition against adulterated or misbranded devices; pre-market notification (510[k]) requirements; the ability to ban device types; registration of manufacturing facilities; listing of device types; and record keeping, repair, replacement and refund.

Devices on the market at the time the 1976 Amendments passed, were assigned to one of three "classes." Devices posing the lowest risk, such as elastic bandages, were placed in Class I, subject to the "general controls" I just outlined. Class II devices, such as laparoscopes and powered wheelchairs, which pose incrementally greater risk and whose safety and effectiveness cannot be adequately controlled solely with Class I requirements, are subject to "special controls." These special controls include guidance documents, patient registries, post-market surveillance studies, and mandatory performance standards. The riskiest devices, such as some implants and life-supporting or life-sustaining devices, are placed in Class III. Class III devices undergo pre-market evaluation, including clinical studies, and must be found to be safe and effective for their intended use before manufacturers can introduce them into commerce.

MEDICAL DEVICE POSTMARKET TRANSFORMATION INITIATIVE

FDA's post-market programs for medical device safety include recalls, the Medical Device Reporting Program, and the Medical Device Safety Network of 300 hospitals and other facilities trained to recognize and report device-related adverse events.

As part of the Center's Medical Device Post-market Transformation Initiative, CDRH is currently working to increase its ability to identify, analyze, and act on post-market information in order to improve the safety and effectiveness of medical devices and radiation-emitting products. In 2005, the Center conducted a comprehensive inventory of its post-market safety programs, looking at successes and challenges in implementing effective programs.

The post-market safety program inventory considered:

- how we identify post-market problems;
- how we assess the information we obtain; and
- how we respond to that information through both stakeholder communication and enforcement action.

The Center's plan to strengthen its post-market program focuses on:

- developing a "culture of collaboration" for post-market safety within the Center;
- developing world-class data sources and systems to quickly and accurately collect, analyze, and disseminate information about potential risks;
- enhancing risk communication efforts; and
- improving coordination with the FDA field staff.

A senior-level team, comprised of CDRH management and outside consultants experienced in medical device safety and product regulation, will help guide the Center in this effort. This team plans to complete its work this summer.

CDRH has prepared a report, "Ensuring the Safety of Marketed Medical Devices: CDRH's Medical Device Post-market Safety Program," which documents the post-market inventory and discusses the CDRH post-market program. A separate Synopsis and Recommendations document provides a list of initial action steps the Center will take to strengthen post-market effectiveness. We would like to submit these items for the record.

STERILITY ISSUES RAISED BY THE DEPARTMENT OF VETERANS AFFAIRS

As you know, FDA is in the process of addressing issues raised by the Department of Veterans Affairs (VA) regarding sterility of medical devices. We take these events very seriously, as they represent a serious breach in patient safety.

In the first case, the VA reported to FDA's MedWatch System an incident involving the potential implantation of a non-sterile cranial prosthesis into a patient at the James A. Haley Department of Veterans Affairs Medical Center in Tampa, Florida. A cranial implant, or cranioplasty device, is a Class II device that is implanted into the skull to repair head injuries. Our Manufacturer and User Device Experience database contained two reports from the device manufacturer, Stryker Leibinger, one of which was linked to the VA report. The second report from Stryker described an incident, apparently at the same VA facility, in which a non-sterile cranioplasty device was actually implanted into a patient. The manufacturer characterized both of these adverse events as "Use Error" and did not indicate that further follow-up was warranted. A search of the FDA adverse events database did not turn up any other reports of this nature for this type of device. There is no information in the adverse events database to indicate that the rate of infection associated with this type of device is abnormal or is trending upward. FDA conducted a review of the device labeling for this product and found that the device is non-sterile when it is shipped, consistent with industry practice. The labeling states that the device should be "sterilized by steam sterilization (autoclaving)" prior to use. FDA's Office of Surveillance and Biometrics (OSB) concluded that the events were attributable

to user error and that the adverse events database should be actively monitored for similar events.

In the other case, the VA informed CDRH staff that it had determined some of its hospitals were improperly cleaning and sterilizing reusable transrectal ultrasound transducer devices manufactured by B-K Medical Systems, Inc. Transrectal ultrasound transducers are Class II devices used to perform prostate biopsies. The lumen of a needle guide was found to be soiled. Upon investigation, it was discovered that the brushes were not being used to clean the lumen of the needle guide. FDA provided comments on the VA's draft Patient Safety Alert, which the VA subsequently issued on April 3, 2006. FDA and the VA have been working together to ensure that users have clear and accurate instructions for cleaning and sterilizing the device.

In addition, FDA assembled a Post Market Issue (PMI) Action Team to investigate this matter. PMI Action Teams, staffed with appropriate clinical, scientific, technical, and regulatory expertise, are convened to develop recommendations for actions that will address public health issues. The PMI Action Team for this device is continuing to work with the VA. The PMI Action Team is preparing a Public Health Notification to further reinforce for the user community recommendations of safe practices in reprocessing invasive ultrasound devices. I am pleased to report a draft copy of the Public Health Notification is undergoing final review by both internal and external experts in this issue. We hope to post the Public Health Notification on its webpage within the next week. The Notification focuses on a broad range of reusable ultrasound transducers used for

biopsy procedures. It will remind users of the importance of properly cleaning and disinfecting these devices between patient uses and reiterate how critical it is to comply with individual manufacturer's instructions for reprocessing the transducer assemblies because each brand and model of device may require different cleaning and sterilization procedures. The Notification will automatically be forwarded to over 45,000 subscribers on our list server. This will ensure that the message will be widely disseminated to healthcare providers and hospitals.

NEXT STEPS

For the incidents involving the cranioplasty devices, FDA has determined that the events were attributable to user error and the devices are labeled appropriately by the manufacturer. Thus, FDA will monitor the adverse events database for any further reports, and, if safety concerns arise, will respond accordingly. In addition, FDA is working on revising labeling guidance for manufacturers and will consider including recommendations that implantable devices supplied non-sterile are labeled "non-sterile."

With respect to the transrectal ultrasound transducer devices, the Agency's actions will depend upon the results of the investigation and analysis of the team of experts participating in the PMI Action Team. In addition, FDA will collaborate with the VA health care system to ensure the delivery of safe and optimal health care.

CONCLUSION

We applaud the VA's proactive stance and their efforts to prevent further incidents involving these devices. We also appreciate the good work of the VA's Office of Inspector General, who investigated the non-sterile cranial prosthesis event, and whose conclusions and recommendations provide value for us all. We will work with the VA on both of these issues and take whatever corrective actions may be necessary to ensure the safety of medical devices.