

September 14, 2010  
The Marriott Inn and Conference Center,  
UMUC, 3501 University Blvd E, Hyattsville, MD 20783, Phone: 301-985-7300  
Patient Perspective Panel is scheduled from 11:00am - noon.

The purpose of the meeting is to hear stakeholder views on medical device user fee reauthorization as FDA considers the features to propose in the next medical device user fee program are considered by FDA. FDA is interested in responses to the following two general questions and welcomes any other pertinent information stakeholders would like to share:

1. What is your assessment of the overall performance of the medical device user fee program thus far?
2. What aspects of the medical device user fee program should be retained, changed, or discontinued to further strengthen and improve the program?

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II. Question 1: Revenue from the program appears to have resulted in increased resources for the FDA to review and approve medical devices in a faster time period than prior to enactment, but speed is only meritorious if the device approved is safe and effective for women.

III. Statement about the value and importance of medical devices for women with heart disease

Women represent only one-third of all recipients of implantable defibrillators, pacemakers, high-risk PCI procedures, coronary bypass grafts, heart transplants, ventricular assist devices, and long-term artificial hearts. Women are less aggressively identified and diagnosed with heart disease. Delay in identification of proper device support results in poor outcomes. "Time is muscle" in sustaining the proper function of the heart's pumping function and ability to adequately perfuse vital organs such as brain, kidneys, and liver.

IV. Aspects of the medical device user fee program that need to be changed to strengthen or improve the program:

There is a basic need to increase the number of women in clinical trials. The MDUFA program can impact participation rates of women in clinical trials by the following:

- Require PMA applicants to set protocols/trial designs that have gender parity whenever possible
- Ensure that when a device reaches panel that gender use, applicability and effectiveness is examined
- Ensure that studies reviewed are sufficiently powered at the onset to allow statistical influences and identification of sex-specific outcomes
- Do not approve devices for use in women unless there are data showing safety and efficacy in women
- Provide more sex specific data regarding outcome of trials because the small number of women in a study can make it difficult to draw conclusions regarding differences in safety profile of a device between men and women

- Report all data stratified by race, ethnicity and gender, as described in the HEART for Women Act (S. 422/HR 1032).

We offer the following recommendations for the medical device approval process that impact the MDUFA reauthorization. It is our goal to improve access to safe and effective medical devices for women with heart disease without stifling innovation through unnecessary delays in the FDA approval process. It is critical that women with heart disease get the information they need to make prudent decisions about the safety, efficacy and comparative effectiveness of their medical care.

- We recommend that the reauthorization of MDUFA build in safety and efficacy improvements by requiring that the quality of evidence supporting PMAs for devices be based on more scientifically rigorous studies, including more randomized trials with blinding and sham controls and clinical (not surrogate) endpoints.
- We concur with the GAO and HHS that FDA expeditiously take steps to issue regulations for class III devices types currently allowed to enter the market via the 510 (k) process by requiring PMAs or by reclassifying them to a lower class.
- In the interim, we recommend that FDA continue monitoring and reporting on the percentage and type of devices that bypass the PMA process and are approved by the 510k clearance process.
- We recommend a careful review of the recommendations of the IOM Report on the use of the 510(k) clearance expected in Spring /Summer2011
- We recommend that FDA establish publicly available post approval registries to collect data on outcomes of medical device use including information on sex of device recipients to evaluate effectiveness for typical patients over a longer period of time combined with FDA action to withdraw device approvals if indicated
- We recommend there be rigorous scientific standards to demonstrate evidence of net benefit and lack of harm in women before FDA approval for devices implanted in critically ill patients ( because risks for adverse effects such as bleeding or stroke may be worthwhile if the device has proven benefit, but maybe not if it does not meet certain predetermined criteria for success.
- We recommend that physicians and health professionals in addition to as well as companies be required to report to the FDA to all cases in which a patient has an adverse outcome with a Class III device. These reports should be public and easily accessible,
- We recommend that companies be required to report to the FDA all cases in which a patient has an adverse outcome with a Class III device.
- We strongly recommend that the FDA increase the budget for the Center for Devices and Radiological Health (CDRH) and that Congress increase the appropriation to the FDA.
- We recommend that FDA follow through with public meetings and deliberations aimed at increasing gender representation in cardiac device clinical trials and publish guidance documents by Spring 2011