July 22, 2011

Malcolm Bertoni, MS
Office of the Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Stakeholder response to FDA and industry MDUFA III Proposals

Dear Mr. Bertoni,

We want to thank you and your staff for the frank discussions about the Medical Device User Fee Act (MDUFA III) reauthorization process. We greatly appreciate CDRH's proactive and transparent approach to the stakeholder meetings and solicitation of our input. This letter provides our comments and suggestions regarding the MDUFA III proposals put forth by industry and the FDA. It also includes a request for additional information about specific FDA proposals.

Reject Short-Term Reauthorization and Inadequate Funding

We urge that MDUFA III be reauthorized for the full five years. Based on the June 1, 2011 negotiation meeting minutes, we know that industry has suggested reauthorizing MDUFA for only two years at the FY2012 user fee levels while simultaneously increasing CDRH responsibilities. Although we have significant concerns with the user fee program, we recognize that it was intended to supplement FDA funding and enable the agency to get safe and effective devices to patients as quickly as possible. However, based on the terms of industry's proposed two-year reauthorization, CDRH would have to review devices more quickly without additional resources.[1] This would undermine the Center's ability to collect and assess the information it needs to make a scientific determination about the safety and efficacy of medical devices.

Furthermore, a short-term MDUFA III would waste time and resources by requiring the FDA, industry, stakeholders, HHS, OMB, and Congress to go through the reauthorization process again in just two years. It would also negatively affect long-term initiatives, such as those addressing patient safety, scientific capacity, and management infrastructure, which require the certainty of long-term funding.

[1] Industry's proposed 4% increase in resources actually amounts to a decrease (FDA estimates about an 11% decrease in user fee *resources*). The is due to MDUFA II's spending plan that includes user fee *collections* that are higher than user fee *obligations* in the first two years, and obligations that are higher than collections in the last few years. So industry's 4% increase is based on collections in FY 2011, which are lower than the actual obligations.

For years, the agency has been under-resourced and has struggled to manage expanded demand with inadequate appropriations. The user fee program was designed to provide supplemental funding to the agency for specific services and outcomes, but it was never intended to supplant public funding to meet FDA's mission and statutory responsibilities. Indeed many of us object in principal to user fees because they erode the "arms length" transactional relationship between the regulator and the regulated. However, FDA appropriations have been historically less than adequate as the volume and complexity of their responsibilities increases. So we recognize the pragmatic reality that user fee revenues are necessary for the Agency to meaningfully exercise its authority and protect the public health.

However, an unfortunate provision to reduce device user fees in the last MDUFA negotiations has resulted in an enormous gap between user fees provided to the FDA and the FDA's costs of the review processes for PMA and 510(k) reviews, according to GAO[2]. The gap is very obvious when the device user fees are compared to prescription drug user fees for the largest, comparably-sized companies. The decision to lower fees has left CDRH without adequate resources, making it impossible for the FDA to review new devices as quickly as companies have demanded. This situation would be exacerbated in ways that harm patients if a reauthorization merely continued the current user fee structure or made more demands on speed and performance without substantial increases in resources for the FDA.

Therefore, until such time as Congress funds FDA at levels sufficient to adequately support it in carrying out its assigned responsibilities, user fees are a critically important revenue source and failure to optimize their potential contribution to FDA operations is, in our opinion, a mistake and would threaten the public's health. That said, we will continue to advocate with Congress for increased appropriations for the FDA.

Patient and Consumer Safety Proposals

While some of the proposals put forth by the FDA at the April 27, 2011 stakeholder meeting have the potential to improve and support medical device safety and effectiveness, we have outlined below key proposals that are critical priorities for the patient, consumer, and public health constituencies that we represent.

- *Unique ID System:* To improve patient and consumer safety, it is essential that all devices have a unique identifier. Currently, when there is a safety problem with a device, it is impossible for the FDA to inform the affected consumers, patients, and healthcare providers because there is no tracking system – people often don't know the model or

[2] GAO-09-190 http://gao.gov/new.items/d09190.pdf

manufacturer of the device implanted in their bodies. A unique ID system would also allow for better post-market safety surveillance of devices. Industry, FDA, and public health experts agree on the need for a unique ID system, but resources are needed to implement it.

- *Improvements to the MAUDE database:* Adverse event reports from consumers and clinicians may be the first indication of safety problems with a device – either because the problem was not identified in the trial population or because clinical data was not required prior to approval. The MedWatch system, however, is cumbersome to use and largely unfamiliar to the public. Most important, the data provided by the MedWatch system are rarely used because of shortcomings in IT capabilities at FDA. More resources are needed to improve MedWatch and the MAUDE database, so that this system will have the capacity to serve an important early warning function in the successful operation of a larger post market safety surveillance system.

- *CDRH Labeling Initiative:* CDRH has begun work on an initiative that would make device labels available on the FDA's website. We strongly agree that placing all device labels on a common site is a simple, commonsense step that can help consumers who have lost or misplaced instructions, or in cases where the manufacturer has moved or gone out of business and a replacement booklet is difficult to find. It will also help doctors and patients make better choices by making it easier to compare device features.

<u>FDA Enhancing Capacity Proposals</u>

Strengthen Scientific Infrastructure: We have previously expressed several concerns with the use of external consults and third-party reviewers. Conflicts of interest are inherently difficult to minimize or manage in those arrangements. Additionally, CDRH should not have to depend as a routine matter on external sources to assess the safety and efficacy of devices under review. We recognize that the increasing complexity of device submissions creates a need for reviewers with new skills and expertise to review applications. For these reasons, we support:

- Hiring additional review staff and providing them with enhanced training
- Providing professional and technical expertise development for experienced reviewers
- Building teams of experts within and across the Center to ensure back-up expertise

As part of the *Strengthening Scientific Infrastructure* proposal, FDA recommended "facilitat[ing] improved incorporation of post-market information into pre-market decision-making." Post-market data should not replace solid pre-market clinical trials. However, due to the inherent limitations of pre-market clinical data, strong post-market surveillance can inform and improve device safety. We strongly support CDRH using the results of post-market approval studies and

safety surveillance to establish safety initiatives such as those described by Dr. Ron Yustein at the March 22, 2011 MDUFA stakeholder meeting; in particular:

- *Updating device labeling* to reflect safety and effectiveness information obtained from use of the device in the general population that may not have been identified in the pre-market trial population. This information should not replace the need for pre-market clinical trials, but would be especially valuable for low-risk devices that are cleared without clinical data.

- *Assisting in reclassification decisions* about devices that either have not yet been classified (grandfathered devices) or need to be up or downgraded based on additional safety and effectiveness information.

- *Changing the device design* to swiftly resolve safety problems that were the result of an unsuccessful product innovation. For example, if a device approved through the 510(k) pathway was the same as its predicate except that it used a new material that caused safety problems, the manufacturer could change the design to use the original material with its established safety profile.

FDA Managing Workload Proposals

Increase efficiency of the guidance process: We urge the FDA to ensure patient, consumer, and scientific stakeholders are included in the guidance document development process to improve efficiency of the process.

Efficient Use of Resources: We support the FDA's intent to develop and apply objective criteria for "refuse to accept" checklists. The Center cannot responsibly assess the safety and effectiveness of devices with incomplete or poor submissions.

FDA Fostering Innovation Proposals

Improving U.S. clinical trial infrastructure: We support the development and publication of a clinical investigator list, as well as additional training for clinical investigators. With regard to accrediting academic medical centers and research institutions as part of the clinical research infrastructure, we urge the FDA to take the necessary steps to protect against conflicts of interest and ensure the scientific integrity of clinical trial sites and staff.

Questions: FDA Fostering Innovation Proposals

Clinical Trial Registries: We support strengthening the post-approval study infrastructure. Registry studies provide necessary information about safety and effectiveness. We request that CDRH provide us with additional information, specifically:

- How will registries be used as part of the required post-approval study infrastructure?
- What role will MDEpiNet play in the assessment of registries as a means of speeding up the initiation of post-approval studies?

Questions: FDA Improving Interaction Proposals

One of the Improving Interaction proposals calls for "yearly public meetings with stakeholders at the division level" to provide feedback on product-specific issues. We request that CDRH provide us with additional information, specifically:

- Who is meant by "stakeholders?" Does this refer to industry, academic institutions, other agencies or nonprofit organizations?
- Will patient, consumer and scientific representatives be included on an equal basis with other stakeholders?

We appreciate working with CDRH throughout the reauthorization process and look forward to hearing from the agency regarding our comments, concerns and questions.

Sincerely,

Annie Appleseed Project
Breast Cancer Action
Center for Medical Consumers
Consumer Union
Government Accountability Project
National Physicians Alliance
National Research Center for Women & Families/Cancer Prevention and Treatment Fund
National Women's Health Network
Our Bodies, Ourselves
The TMJ Association, Ltd.
Truth in Medicine, Inc.
Union of Concerned Scientists, Scientific Integrity Program
Woody Matters
U.S. PIRG