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August 11, 2015

Stephen Ostroff, MD
Acting Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: Medical Device User Fee Amendments Public Meeting; Request for Comments
[FDA-2010-N-0389

Dear Acting Commissioner Ostroff:

The American College of Cardiology (ACC) is pleased to submit comments to the Food and Drug Administration (FDA) on its recommendations regarding the reauthorization of the Medical Device User Fee Amendments (MDUFA) for Fiscal Years 2018 through 2022. The ACC is a 49,000-member medical society that is the professional home for the entire cardiovascular care team. The mission of the College is to transform cardiovascular care and improve heart health. The ACC leads in the formation of health policy, standards and guidelines. The College operates national registries to measure and improve care, provides professional medical education, promotes cardiovascular research and bestows credentials on cardiovascular specialists who meet stringent qualifications. The ACC appreciates the opportunity to provide input as the FDA begins the negotiation process.

On a daily basis, cardiovascular professionals rely heavily on medical devices approved by the FDA to furnish high quality care to patients. From catheters and stents to pacemakers, internal cardiac defibrillators and remote monitoring to computed tomography and magnetic resonance imaging, the impressive strides made in cardiovascular care over the last thirty years simply could not have occurred without the assistance of medical devices, both therapeutic and diagnostic. Given this and the desire to continue to decrease the number of deaths attributable to cardiovascular conditions, the ACC is a strong supporter of innovations in care and treatments for those conditions. At the same time, the ACC understands the mission of the FDA requires the government to strike a balance between protecting the public health and encouraging creativity and scientific advancement. The Medical Device User Fee Program furnishes the FDA with funding to do just that.

Stable, predictable approval pathway

The main goal of MDUFA III was to create a stable, predictable pathway to approval for medical devices. The College is generally not in a position to comment on the success or failure of the Agency with respect to this goal, other than an observed commitment to identification of novel methods of obtaining data that may prove or disprove safety and efficacy.

Utilize expertise from external stakeholders

Inherent within that first goal is a second goal of strengthening the infrastructure of the Center for Devices and Radiological Health (CDRH) through the hiring and training of the staff needed to implement the first goal. CDRH continues to face difficulties hiring, training and retaining staff with the appropriate expertise. Medical device regulation requires a variety of skill sets that are highly specialized and in demand, including clinical, research, engineering, statistics, epidemiology and others. Because of the high degree of specialization required and the demand, individuals with these skill sets command top dollar in the private sector, as well as flexible work environments. The FDA is limited to the resources provided to it by the federal government in Silver Spring, Maryland, making it difficult for the Agency to compete with the private sector.

One method for addressing ongoing education and training of FDA staff is to engage national medical specialty societies and other similarly situated organizations. The FDA has already developed the Network of Experts Program that allows it to work with medical specialty societies to identify clinical experts, although it has been underutilized since its inception. The College encourages the Agency to better promote this program to its staff and to provide it the necessary resources. Additionally, the ACC has worked with CDRH staff in the past to organize tours of nearby facilities and discussions with clinicians regarding their work. The College welcomes the opportunities to discuss the potential for ongoing collaborations that would assist in the educational development of FDA staff who work on matters pertaining to cardiovascular disease. As such, **the ACC urges the FDA to better leverage medical specialty societies and other similar organizations that can provide the Agency with access to world-class experts in all of these fields and that MDUFA funds be allocated towards identification of the best methods for doing so, as well as any necessary associated infrastructure.**

Postmarket surveillance

Additionally, Congress provided the Agency with a third goal when it passed the enabling legislation, the FDA Safety and Improvement Act (FDASIA), to improve the nation's postmarket surveillance capabilities for medical devices. All three of these goals contribute to the overarching goal of providing Americans with access to effective and safe novel medical devices that improve patient outcomes.

For many years, the Agency has approached its responsibilities with respect to oversight of medical devices by segmenting them into components and approaching them as individual components. However, in the past few years, Agency officials have advanced the notion of approaching medical device regulation from a total product lifecycle (TPLC) vantage point. The College supports the TPLC approach because it recognizes that the approval process should be a fluid one. It is impossible to know everything about a medical device from a randomized clinical trial; a device's full capabilities and problems will not be identified until it is used and observed in the real world. As such, the medical device approval process must include not only the collection of data during the pre-market phase, but must also include the collection and study of data during the postmarket phase. This postmarket data can be used not only to ensure a device's safety, but also its effectiveness and potential improvements to the device that may increase both.

The FDA has taken significant steps forward in the development of the postmarket surveillance system over the last three years and has demonstrated a clear commitment to using this system to improve the TPLC, rather than merely adding another level of complexity to the regulatory process. The Agency formed a partnership with external stakeholders to issue recommendations for the strategic development of a national medical device postmarket surveillance system, and it has issued guidance regarding the timing of the collection of certain types of data in order to make the regulatory process more efficient. Innovative collaborations among stakeholders have modeled new methods for accelerating access to new

technologies. This includes the employment of clinical data registries, such as the Transcatheter Valve Therapy Registry operated by The Society for Thoracic Surgeons and the ACC.

These efforts cannot end with the publication of these documents and new collaborations. The FDA must obtain the necessary funds to develop this system. The College has four specific recommendations with respect to the use of MDUFA funds for postmarket surveillance, namely that **MDUFA IV must include funding for:**

- **Implementation of the National Medical Device Postmarket Surveillance System Planning Board as issued by the Brookings Institute in February 2015**
- **Development and maintenance of medical device registries where appropriate to allow for the collection of real world data on novel technologies and streamlined post approval studies**
- **Identification and use of novel techniques for postmarket surveillance, such as DELTA pilot studies in the National Cardiovascular Data Registry® (NCDR®)**
- **Drafting and implementing regulations and guidance to address issues pertaining to the use of existing data sets for FDA-regulated activities.**

Given the clear benefits to the medical device industry of a well-developed TPLC approach to medical device regulation, it is fitting that user fees be allocated for the aforementioned purposes.

Conclusion

The College appreciates the opportunity to provide input to the FDA as it begins to negotiate with industry regarding the reauthorization of MDUFA and would welcome further discussion of this matter. The ACC looks forward to working with the FDA on this and other important issues. Please direct any questions or concerns to Lisa P. Goldstein, ACC Regulatory Policy Counsel, at (202) 375-6527 or lgoldstein@acc.org.

Sincerely,

Kim Allan Williams, Sr., MD, FACC, FAHA, FASNC