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The mission of the American College of Cardiology and the American College of Cardiology Foundation is to transform cardiovascular care and improve heart health.

November 28, 2016

Robert M. Califf, MD, MACC
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 Commissioner Califf:

The American College of Cardiology (ACC) is pleased to submit comments to the Food and Drug Administration (FDA) on its draft agreement with industry for the reauthorization of the Medical Device User Fee Amendments (MDUFA) for Fiscal Years 2018 through 2022. The ACC is a 52,000-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 its response to the draft MDUFA agreement.

On a daily basis, cardiovascular professionals rely 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 devices to computed tomography and magnetic resonance imaging, the impressive strides made in cardiovascular care over the last thirty years could not have occurred without the assistance of medical devices, both therapeutic and diagnostic. The FDA has placed a crucial role in bringing these new therapies to market. Critical to continuing the decline in deaths from cardiovascular disease are innovations in care and treatments for those conditions. At the same time, it is equally important that the FDA protect the public health. 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.

When the College submitted its comments in August 2015 on items to include in the MDUFA agreement, the comments focused on three primary goals:

- A stable, predictable approval pathway
- Utilization of stakeholder expertise
- Development of a medical device evaluation system

It is clear from the draft agreement, as well as the stakeholder engagement process that these concerns were heard and considered.

Stable, predictable approval pathway

The main goal of MDUFA III was to create a stable, predictable pathway to approval for medical devices. While 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, it does appear that MDUFA IV seeks to build on that, providing additional plans for improving the processes even further.

Utilize expertise from external stakeholders

The draft agreement clearly recognizes the importance that external stakeholders play in the device development process. Section F addresses the need to include input from patients and their caregivers, including the development of relevant regulatory science, that will be essential to the creation of the next generation of therapies. **The ACC urges the FDA and industry to include clinicians in the discussions regarding the development of the relevant regulatory science.** Clinicians have been engaged in the study and development of measurement tools for many years and have a great deal of experience to offer regarding best practices. Additionally, the reference to the Network of Experts identifies clinicians as stakeholders in this process and singles them out for their expertise as scientists, as well as patient caregivers. **The College urges the Agency to build upon its existing programs and to use them, particularly in situations where FDA does not have the internal expertise.** The College and other medical specialty societies will be more than willing to work with the Agency to provide access to world-class experts. Reaching out to organizations through their government affairs teams will allow the FDA to establish points of contact with each organization for these and other efforts involving clinicians and reduce the resources the FDA will need to expend in order to connect with experts and other stakeholders.

Device evaluation system

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. More recently, 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 also, 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. Going forward, the FDA will need to evaluate the relevant statutes, regulations and guidance documents to determine if the current legal framework is sufficient to accommodate this change in approach or whether there will need to be revisions to it to enable a continuous learning environment. Additionally, steps will need to be taken to ensure that postmarket surveillance data is used for just that

– learning and improving technology, techniques, patient selection criteria and related measures of performance. Reporting of adverse events in the real world cannot lead to the automatic suspicion of liability on the part of the clinician.

The draft agreement takes its first tentative steps towards adoption of the TPLC approach, including acknowledging the potential for real world evidence (RWE) to play a role in regulatory decision-making on the premarket side of the equation. While it is disappointing that the draft agreement focuses so heavily on the premarket side, the College believes that industry will be convinced of its use as they see its benefit. According to the FDA, companies that have used clinical data registries to house their post approval studies have experienced savings of approximately 40 to 60 percent. That is a significant return on investment and will provide substantial benefit to patients in the long run because of the availability of the data for research purposes beyond post approval needs. The College is pleased to see that MDUFA funds will also be allocated for a coordinating center for the National Evaluation System for health Technology (NEST).

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. The College hopes that, despite the lack of MDUFA funding for postmarket activities, FDA will continue to fund such efforts and to engage with Congress and external stakeholders to identify additional funding sources for the postmarket efforts. These include:

- **Implementation of the National Medical Device Postmarket Surveillance System Planning Board Recommendations 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**
- **Streamlining informed consent with robust protection of research participants**
- **Standardization of clinical vocabularies, common data elements and outcome definitions**
- **Establishment of linkages across disparate data sources**
- **Support for a prospective registry embedded trial of a new device**
- **Development of efficient and feasible approaches to randomized clinical trials based on RWE**

Conclusion

The College appreciates the FDA's openness to stakeholder input throughout the MDUFA IV negotiation process and welcomes the opportunity to provide further input as needed. The ACC looks forward to working with the FDA on passage of the essential legislation required to implement this

draft agreement and other important issues. Please direct any questions or concerns to Lisa P. Goldstein, ACC Director, Research and Innovation Policy, at (202) 375-6527 or lgoldstein@acc.org.

Sincerely,

Richard A. Chazal, MD, FACC
President