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April 11, 2012

The Honorable Margaret A. Hamburg, MD
Commissioner
Food and Drug Administration
5630 Fishers Lane, room 1061
Rockville, MD 20852

RE: Medical Device User Fee Act; Public Meeting [FDA-2010-N-0389]

Dear Commissioner Hamburg:

The American College of Cardiology (ACC) is pleased to submit comments to the Food and Drug Administration (FDA) on the draft Medical Device User Fee Act (MDUFA) Reauthorization Performance Goals and Procedures for Fiscal Years 2013 through 2017. The College is a 40,000-member nonprofit medical society composed of physicians, nurses, nurse practitioners, physician assistants, pharmacists and practice managers and bestows credentials upon cardiovascular specialists who meet its stringent qualifications. The ACC is a leader in the formulation of health policy, standards and guidelines, and is a staunch supporter of cardiovascular research. The College provides professional education and operates national registries for the measurement and improvement of quality care. We appreciate the opportunity to provide input on the draft MDUFA agreement.

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 intention behind the Medical Device User Fee Program is to furnish the FDA with funding to do just that.

Negotiations between the FDA and medical device industry reportedly have been quite contentious, with neither side accomplishing all that they set out to do through these discussions. Part of the problem throughout these discussions appears to have been ongoing disagreements since the passage of MDUFA about

the exact definitions of those goals set forth during the last reauthorization and the success of the FDA at meeting them. The ACC urges the FDA and industry to meet regularly throughout the period of the next reauthorization to resolve disagreements early and on an ongoing basis. This will hopefully lay the groundwork for a smoother, more productive and more timely reauthorization process for MDUFA IV.

For many years, stakeholders in the development of medical devices have been identified as falling into one of two camps: industry and patients/consumers. It is only in more recent times that physicians have also been considered stakeholders in this arena, although they are still generally considered to have less at stake than the other two parties. While this may be true in some respects, this commonly held view ignores the key reason why most physicians enter the field of medicine: to help patients. Given this, physicians should not be ignored and should be critical to this process. Patients rely on their physicians to assist them in making decisions regarding their care, including their determination to use and selection of medical device. The training physicians receive, in addition to the role they play in the care delivery systems, makes their input critical. As such, the ACC urges the FDA to engage physician groups in the implementation of a newly reauthorized MDUFA. Additionally, the College requests that, as the process for the next reauthorization is developed and incorporated into statute, physicians be recognized as key stakeholders in their own right and be specifically included in that process.

Performance goals and procedures

The agreement as drafted demonstrates attention to clearly defined performance goals and procedures. Given that clinicians are generally not party to those meetings, the ACC declines to comment on the specific goals and meeting timelines. That said, the College is supportive of clear and achievable goals with reasonable timelines and requirements imposed upon the FDA. In return, the ACC urges the medical device industry to ensure that its submissions are complete upon submission and responses timely to reduce burdens on both parties and to ensure the efficient functioning of the application processes. This will enable patients to have access to critical new medical devices.

While the ACC does not offer an opinion on the meeting specifications and timelines outlined in the agreement, the College and its members do believe that medical specialty societies do have an important role to play in this arena. Cardiovascular specialists are experts in the management of cardiovascular diseases and conditions, and the ACC welcomes the opportunity to work with the FDA to provide expert opinions on cardiovascular-related issues. Already, the ACC is working with the FDA's Centers for Devices and Radiological Health to pilot its new Network of Experts program. In less than one week following receipt of a request from CDRH, the ACC was able to identify almost 20 cardiologists willing to assist the FDA in better understanding new technology under review. This influx of expertise to the FDA will enable the Agency to process medical device applications more quickly.

As described above, cardiovascular specialists have a crucial role to play in the development of medical devices and technologies. The College would also welcome the opportunity to work with the Agency to develop education for reviewers. The ACC regularly conducts educational programming for its members and works with experts in the field to identify emerging areas for such programming. As such, the ACC would be happy to assist the FDA in developing its

curriculum, identifying emerging issues, locating experts on cardiovascular topics, or in related capacities as needed.

MDUFA Reauthorization Goals

At the outset of this reauthorization process, the College identified five key goals of the Medical Device User Fee Act (MDUFA) reauthorization process: engagement of stakeholders in a transparent process; development of a rigorous, data driven process; facilitation of innovation and protection of patient safety; provision of increased access to devices for pediatric patients; and creation of a strengthened post-market surveillance program. While the FDA did engage in a transparent and open process, the ACC believes that the draft agreement fails to succeed in accomplishing many of the other goals.

Transparency

As required by the President's Executive Order, the FDA has made remarkable strides in making its decision-making process more open and transparent. Additionally, the Food and Drug Administration Amendments Act (FDAAA) required inclusivity in the MDUFA reauthorization process, and the monthly stakeholder meetings demonstrated the FDA's attempt to comply with that requirement. While these meetings did bring more openness and transparency to the process, the ACC believes that there is more to be done. The College encourages the FDA to continue to educate the public and stakeholders on the reauthorization process, the purpose of MDUFA and its goals. Public input to the Agency and to Congress will be far more meaningful and a more fluid dialogue can occur if the public is appropriately educated on this issue. Education on device approval processes and the various tracks is a crucial component of ensuring a transparent and open reauthorization process. Additionally, the College supports optimizing the public availability of data on regulated devices. Device manufacturers are required to collect and submit data on their devices as part of the approval processes. The public should have the same access to that data as does the FDA to instill trust and confidence in the FDA approval processes.

Also a key component of transparency is the finalization and publication of guidance documents. The FDA has increased the number of guidance documents released for comment within the last year, including the very recently released guidance on factors to consider when making benefit-risk determinations in medical device premarket approval and *de novo* classifications. These guidance documents provide critical information to regulated industry and healthcare professionals regarding FDA's expectations and review processes. The latest guidance will go a long way towards answering unresolved industry questions pertaining to benefit-risk determinations. The ACC is encouraged by the FDA's demonstrated commitment to publication of long-awaited guidance documents that will assist industry in understanding review procedures and Agency intentions. The College looks forward to reviewing the plans for improving the guidance document development process even further, along with the regular publication of the guidance priorities. Releasing this information will provide the public with information necessary for reducing application review times and increasing patient access to care by allowing innovative devices and technologies to move through the application process more rapidly. Clear guidance will assist industry in submitting better, more complete applications, reducing wasted time and resources for both the FDA and industry. Additionally, publication of guidance documents allows the broader public to have a clearer understanding of

the FDA's decision-making process. This improved understanding will lead to better, more informed decision-making about use of medical devices.

Importance of data

The ACC is a strong supporter of evidence-based medicine. This basic principle does not apply only to the methods of treatment used for cardiovascular diseases or conditions; it also applies to the medical devices and pharmaceuticals used as part of those treatments. Thus, we strongly support the development and maintenance of high standards for evidence and the experts who review that evidence. As a component of the strengthened review process, evidentiary standards must be developed for data collection. The data can then be studied by subject matter experts as a component of additional review. To minimize potential bias, the College also urges the FDA to improve access to the data used as part of the medical device approval process.

Once the standards for evidence collection have been developed, ensuring that the FDA has appropriate levels of staffing and continuous education for that staff will be critical. The ACC strongly supports the use of user fees to fund the hiring of additional personnel through a streamlined process. Additionally, the College also supports spending user fees to provide education to FDA review managers and reviewers. This additional education reviewers and their managers receive will help to improve the quality and consistency of reviews, as well as contribute to decreases in review times.

Innovation facilitation

The FDA has the critical role of facilitating innovation in the development of medical devices, while simultaneously protecting the public. This requires a delicate balancing act and continuous evaluation of exactly where the line should be drawn. The introduction of novel technologies can create incredible ripples in accepted standards for patient care, but the introduction needs to be done carefully and only after appropriate study. Additionally, continued study after introduction needs to occur to ensure there are no unintended consequences or results that were not identified during pre-market study. However, too much delay in introduction will result in delays in the ability of patients to access these new treatments. It is especially critical to ensure that devices designed to address unmet needs or rare diseases are available as quickly as appropriate.

As part of its mission, the FDA is responsible for advancing the public health by helping to speed product innovations. As such, the ACC supports the efforts of the FDA's Critical Path Initiative to foster research and collaboration between the private and public sectors, as well as between government agencies. Lessons learned as part of this program that can be translated to the medical device industry should be incorporated into the MDUFA reauthorization process.

The ACC is disappointed to note that the draft MDUFA agreement does not attempt to address unmet needs identified by the FDA's Council on Medical Device Innovation. As part of the 2008 reauthorization, Congress specifically recognized the failure of industry to address the unique needs of the pediatric patient population by including provisions aimed at remedying this problem. To date, a number of those provisions still have not been implemented. The ACC urges the FDA to move quickly to remedy this situation, so devices can be developed specifically for

children suffering from life-threatening conditions. Children are not simply small adults; their medical issues are unique and must be addressed by special devices designed to accommodate their unique issues. Instead, today, physicians are forced to adapt devices designed for adults for use in children, despite the lack of testing of these devices in children. The FDA has an important role to play in fostering innovation in areas such as pediatric cardiology where the development of appropriate devices is crucial, and user fees should assist the FDA in achieving this goal.

The FDA's mission encompasses a wide range of issues from fostering innovation to drug and device safety to food safety and beyond. In order to ensure the FDA has the resources to carry out its mission, a reauthorized MDUFA should also enhance the FDA's capability, capacity and authority to conduct that mission. When creativity and innovation are encouraged, it can lead to an increase in applications for product approvals. Without the additional resources for staff, the FDA will not have the capacity to review those applications in a timely fashion. The FDA is already struggling to find the capacity to enforce the crucial post-market surveillance provisions included in the previous reauthorization. Given the importance of such efforts, the College believes that it is important that the FDA has the resources, financial and otherwise, to carry out its mission as set forth by Congress. The reauthorization of MDUFA is an opportunity to ensure just that, and yet, the FDA has failed to capitalize on it.

One area in which the MDUFA agreement contains a clear commitment to fostering innovation is in the area of in vitro diagnostics (IVD). IVD is a relatively new area and there are constantly new diagnostic tests under development. Because this is a relatively new field, significant investments in approval processes and pathways have not yet been made. The draft MDUFA agreement makes a commitment to using user fees to support the development of a transitional approach to IVDs as a way of regulating emerging diagnostics in these early days. The ACC commends the FDA and industry for recognizing and acknowledging this need by including this reference in the draft agreement. The ACC looks forward to reviewing and providing input on a proposed transitional IVD approach.

Another method the agreement uses to demonstrate the commitment to innovation is the recognition that there are medical devices on the market that pose minimal safety risks to users. Already, there are certain medical devices that have been deemed to pose such an insignificant risk so as to be exempted from premarket notification. The FDA has committed to identifying and exempting additional such devices. In so doing, the FDA's workload will be reduced, enabling reviewers to focus their efforts on medical devices that potential pose more serious risks to patients and consumers. The ACC applauds this effort.

Post-market surveillance

In addition to reviewing device applications and information available before devices can be publicly available, the FDA has responsibility to ensure that additional evidence is gathered as use becomes more widespread and that the evidence does not raise new safety concerns. The FDA has a long way to go towards improving its post-market surveillance capabilities. Unfortunately, the draft agreement misses an important opportunity to provide additional support to this critical aspect of FDA's mission. The ACC is disappointed that the draft user agreement does not include using user fees to fund the development of a strong post-market surveillance infrastructure, as was done in the draft of the Prescription Drug User Fee

agreement. For instance, the agreement contains no mention of the prospect of expanding the Sentinel Initiative into the medical device arena. While the current legal mandate for the Sentinel Initiative only applies to pharmaceuticals, the FDA is not limited to this application. The College urges the FDA to strengthen the post-market surveillance system for medical devices with the support of user fees.

Additionally, the ACC urges the FDA to more fully incorporate the use of registries in the existing post-market surveillance infrastructure. Registries are a critical component of the data-gathering process. Data collected by registries, such as the National Cardiovascular Data Registry® (NCDR®) can be used to conduct comparative effectiveness research, adverse event and signal reporting, identifying device performance trends, inappropriate off-label use and hypotheses for follow-up studies. Registries assist in improving clinical care by providing the evidence for gap analyses, guideline development and adherence, and performance measure implementation and validation. Enhancing post-market surveillance capabilities by using existing registries will help to provide the confidence in safety and effectiveness necessary to provide patients with timely access to critical advances in medical device and pharmaceutical technology. The FDA has demonstrated support for the use of registries in other instances, such as through the approval order for the Edwards Sapien transcatheter aortic valve, but it continuously fails to formally recognize the critical role that registries can play in a strong post-market surveillance program. ACC believes that registries are crucial to ensuring patient safety and quality improvement efforts and supports their use as a component in the post-market surveillance infrastructure, leading to improved regulation of medical devices and the inclusion of physicians in that process.

Conclusion

While traditionally, clinicians are not viewed as stakeholders during discussions on medical devices and their development, the ACC believes that clinicians are critical partners in the process. Clinicians are frequently in the role of educators and advisors to patients, the ultimate decision-makers when it comes to medical care. Improving clinicians' understanding of medical devices and novel technologies and the associated approval processes can only lead to better educated patients who are able to take ownership over their healthcare, thereby leading to better and safer use of medical devices. Providing physicians and clinical staff with additional information pertaining to device safety can only serve to improve clinical care. As such, clinicians have an important role to play in the development and dissemination of new medical devices and technologies. The ACC appreciates the opportunity to comment on the draft MDUFA performance goals and procedures for fiscal years 2013 through 2017. The College looks forward to continuing to work with FDA to protect the interests of cardiovascular patients and would welcome the opportunity to discuss this input further. Please direct any questions or concerns to Lisa P. Goldstein at (202) 375-6527 or lgoldstein@acc.org.

Sincerely,

William A. Zoghbi, M.D., F.A.C.C.
President