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Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061,
Rockville, MD 20852

**Re: Medical Device De Novo Classification Process [FDA-2018-N-0236]**

Dear Commissioner Scott Gottlieb, MD,

The American College of Cardiology (ACC) appreciates the opportunity to provide input on the on the Food and Drug Administration's (FDA) proposed rule on the medical device De Novo classification process. Transparency is critical to the medical device approval process. The College thanks the FDA for using the formal rulemaking process and allowing interested individuals and organizations to comment.

The ACC envisions a world where innovation and knowledge optimize cardiovascular care and outcomes. As the professional home for the entire cardiovascular care team, the mission of the College and its more than 52,000 members is to transform cardiovascular care and to improve heart health. The ACC bestows credentials upon cardiovascular professionals who meet stringent qualifications and leads in the formation of health policy, standards and guidelines. The College also provides professional medical education, disseminates cardiovascular research through its world-renowned JACC journals, operates national registries to measure and improve care, and offers cardiovascular accreditation to hospitals and institutions.

**ACC Policy Principles**

In 2018, the FDA published the Medical Device Safety Action Plan, outlining a process to reduce the burdens and costs associated with the medical device approval and surveillance process without compromising patient safety. The FDA's stated vision is for a "medical device ecosystem [which] is inherently focused on device features and manufacturing practices that have the greatest impact on product quality and patient safety." While pursuing this vision, it is important for the FDA to balance the reduction of regulatory burdens that inflate the cost and time associated with new therapy development with the need for regulatory decisions that protect patient interests and public health through rigorous scientific merit.

As the FDA expands upon numerous initiatives listed in the Medical Device Safety Action Plan, including modifications to the De Novo process, and continues to refine oversight of medical device safety throughout the total product life cycle (TPLC), the FDA must retain patient safety as its number one priority. The medical device ecosystem must also promote innovation and ensure novel medical devices are safe and effective. As the FDA works to encourage these aims, the ACC has developed principles intended to serve as a guide to evaluate regulatory efforts, including that the FDA should:

- Ensure regulatory decisions are patient centered and based on scientific merit
- Protect public health while fostering innovation
- Reduce the costs of new therapies and regulatory review through increased harmonization of regulations across federal agencies, as well as standardization of best practices and data collection internationally
- Encourage the use of standardized, accurate, and reusable data sources, such as the National Cardiovascular Data Registry (NCDR) and other clinical data registries, to improve patient outcomes, increase access to valuable clinical data, and reduce regulatory costs
- Allow for flexibility in regulatory decision-making processes to accommodate the potential for rapid therapeutic advancements
- Provide patients with access to novel therapies while maintaining the high standard for safety and effectiveness
- Take steps to ensure data used for regulatory decision-making is representative of the affected patient population, as well as to communicate the availability of data on the effects of therapies on demographic subpopulations
- Encourage development of medical therapies designed for historically underrepresented patient populations
- Regularly monitor the impact of decisions to minimize adverse effects on drug supply
- Collaborate with other federal agencies to monitor the landscape affecting drug pricing and supply and address concerns
- Strengthen relationships with professional medical societies, public, private and academic partners, and other stakeholders to further the field of regulatory science through regular consultation and communication

It is important for the FDA to balance the reduction of regulatory burdens that inflate the cost and time associated with new therapy development with the need for regulatory decisions that protect patient interests and public health through rigorous scientific merit. Reductions in regulatory burdens and costs must not come at the expense of patients or the safety and effectiveness of the drugs and devices they rely upon for safe, effective care.

**De Novo Classification Process**

On a daily basis, cardiovascular professionals rely on medical devices approved by the FDA to furnish high quality care to patients. The ACC is a strong supporter of innovations in care and treatments for cardiovascular 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 innovation and scientific advancement. The College urges the FDA to continue to move carefully in this arena and engage in extensive consultation with industry when evaluating changes to the device approval process.

The College has a strong commitment to evidence-based medicine, and this applies to approvals for medical devices, as well. Science must be the foundation of all approved medical devices. Any changes to the De Novo medical device approval process must not stray from this fundamental principle. Medical devices unsupported by scientific evidence should not be approved, and the approval process must protect against this. The ACC urges the FDA to ensure that any changes to the approval process are supported by science and that any decisions made through the approval process will also be required to be supported by science. Overall, the ACC supports efforts by the FDA to find the appropriate balance between fostering innovation and ingenuity and protecting the public health.

The ACC has consistently encouraged the FDA to ensure that the medical device approval process for all classes of medical devices is clear and predictable and the path for navigating it is publicly available and easily understood. This will allow medical device manufacturers to understand their objectives in the early stages of product development. It will also prevent delays in the approval process that create additional work for both the FDA and industry when requirements are misunderstood, causing the submission of incomplete applications. Ultimately, unnecessary resource usage is minimized when all parties understand initially what is expected of them, benefiting all concerned.

The proposed classification process intends to codify minimum content requirements to allow industry to better anticipate necessary information for De Novo classification and approval. The ACC commends the FDA for clearly listing content requirements for the De Novo classification process, providing a transparent method ensuring applicants are aware of requirements. By clearly spelling out content requirements for applicants and criteria for acceptance for review of a De Novo application, the FDA decreases the chances of incorrect or missing application content. Additionally, the ACC applauds the FDA's encouragement for early and continued communication between potential applicants and FDA staff to ensure all parties are clear on what information should be submitted when seeking a path to market via the De Novo classification process.

Recently, the FDA convened a meeting to discuss the content of premarket submissions for management of cybersecurity in medical devices. The College was heartened to see the FDA take stakeholder comments into consideration and convene stakeholders to discuss methods for incorporating cybersecurity management into the premarket process. The ACC encourages the FDA to continue this commitment to cybersecurity by ensuring cybersecurity mitigation capabilities are incorporated into the De Novo medical device approval process. Integrating cybersecurity into the approval process will ensure medical device manufacturers keep pace with emerging threats and vulnerabilities.

**Conclusion**

The ACC is committed to working with the FDA to ensure the medical device process remains a transparent, evidence-based process while still encouraging innovation and scientific advancement and

looks forward to continued collaboration on this and other issues. If you have any questions or would like additional information regarding any recommendations in this letter, please contact Joseph Cody, Associate Director, Research and Innovation Policy, at (202) 375-6251 or jcody@acc.org.

Sincerely,

C. Michael Valentine, MD, FACC
President