House Committee on Energy and Commerce Hearing

"FDA User Fee Reauthorization: Ensuring Safe and Effective Medical Devices"

Written Testimony By: Dr. Richard Kovacs, Chief Medical Officer and past President of the American College of Cardiology

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WELCOME AND INTRODUCTION

Chairwoman Eshoo, Ranking Member Guthrie, and distinguished members of the House Energy and Commerce Committee's Health Subcommittee, I am Dr. Richard Kovacs, Chief Medical Officer and past President of the American College of Cardiology (ACC). I am a practicing cardiologist, a Professor at the Indiana University School of Medicine, and served as the service line leader for Indiana University Health Physicians. My research has focused on three topics: quality and measurement of quality, drug safety, and sports cardiology. I appear before you today on behalf of ACC, the professional home for cardiovascular care team members working to improve heart health worldwide.

The American College of Cardiology 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 54,000 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 cardiovascular data registries (NCDR) to measure and improve care, and offers cardiovascular accreditation to hospitals and institutions. For more, visit ACC.org.

Thank you for the opportunity to discuss the reauthorization of the Medical Device User Fee Act (MDUFA) and the importance of passing this legislation before the current authorization expires. I appreciate that the Food and Drug Administration (FDA) announced the agreement with industry leaders last week and hope this will allow the process of reauthorization to proceed swiftly and expeditiously to prevent any lapse in patient access and care. 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 FDA commitment for the identification of novel methods of obtaining data that may prove or disprove safety and efficacy, it does appear that MDUFA V seeks to build on that commitment, providing plans for further improving these processes. My comments below will focus on the continued importance of the patient voice within the device development process, regulating the total product life cycle, utilizing real-world evidence throughout, and the ongoing development of regulatory science. Ultimately, it is my honor to offer the ACC's continued commitment to its longstanding, successful partnership with FDA, Congress, and all stakeholders to improve patient care.

On a daily basis, cardiovascular professionals rely on medical devices approved by the FDA to furnish high quality patient care. From catheters, heart valves and stents to pacemakers, internal cardiac defibrillators and remote monitoring devices to ultrasound, computed tomography and magnetic resonance imaging, the impressive advances in cardiovascular care

over the last thirty years could not have occurred without medical devices, both therapeutic and diagnostic. The FDA has played a crucial role in bringing these new therapies to market. The ability to further decrease deaths and debility from cardiovascular disease depends upon innovations in care and treatments. At the same time, it is equally important that the FDA protect the public health in performing its mission of assessing and assuring the safety and efficacy of devices. The MDUFA Program furnishes the FDA with the necessary funding to meet the objectives of promoting innovation and protecting public health. On behalf of the ACC, its members, and their patients, I applaud FDA, Congress, and industry stakeholders for coming forward to advance this critically important work.

PATIENT VOICE

We use medical devices to serve and heal our patients. Clinicians ask patients what is important to them and listen carefully. Before I flew to Washington last night, I saw Richard, an 84-year-old man from Northwestern Indiana in my clinic. He likes to work in the yard. He suffered from aortic stenosis, a severe narrowing of the main outlet valve of the heart. 3 weeks ago, he could not walk 50 feet from his car to the hospital door because of shortness of breath. He received a transcatheter valve replacement (TAVR), left the hospital within 48 hours with no chest incision, and is now ready to work in his garden.

Care for patients with medical devices does not stop with a device implant. A few weeks ago, I had to say goodbye to Carlos, a 70-year-old man from Northeastern Indiana. I met Carlos in 1989, when he needed to have his aortic valve replaced. We selected a mechanical valve that performed flawlessly until he died from another disease.

Ensuring that MDUFA reauthorization occurs is vital because our patients' lives depend on it. But in the development of new devices, we must listen to the voice of the patient.

The College encourages continued emphasis on *Patient Engagement & the Science of Patient Input.* While the American public is an audience for the FDA, the individual patients affected by medical product approval should be invited to contribute to the process. Section F of MDUFA IV 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. MDUFA IV made improvements in this field, but more work needs to be done. We urge:

- Expanding clinical, statistical, and other scientific expertise and staff capacity to respond to submissions containing patient preference information (PPI), voluntary patient reported outcomes (PROs) and/or patient-generated health data.
- Guidance on best practices for incorporating clinical outcomes assessments into premarket studies, including their use as primary or co-primary endpoints. How a patient functions or feels is an important observation in clinical trials.
- Use patient input to inform clinical study design and conduct, reducing barriers to participation in clinical trials and facilitating recruitment and retention of a diverse patient sample.
- Advance remote data collection of patient generated health information in clinical trials.

MDUFA IV clearly recognized the important role external stakeholders play in the device development process. The College encourages that this effort be expanded upon in MDUFA V to include additional opportunities for patient input. The ACC is studying further expansion of patient-reported outcomes into all its NCDR programs like those already incorporated in the STS/ACC TVT Registry and the NCDR Cath PCI Registry. In addition, synergies across the outcomes reported in clinical trials for registration and outcomes in clinical practice - real world evidence - should be explored. Furthermore, the FDA should study best methods to communicate these data to patients and to incorporate them into future clinical trials.

TOTAL PRODUCT LIFE CYCLE (TPLC) AND REAL-WORLD EVIDENCE (RWE)

In my role as a cardiologist, I use medical devices regularly with patients and continue to care for these patients over decades. Our particular specialty tends to experience rapid innovation among medical devices, which benefits our patients in the long run. The College supports the FDA's efforts to advance the regulation of products throughout the total product life cycle (TPLC). We support the TPLC Advisory Program, and efforts to facilitate early involvement of clinicians in finding solutions to development issues. We applaud the Center for Devices and Radiological Health's (CDRH) 2019 reorganization, integrating premarket and post-market program functions along product lines to leverage knowledge and optimize decision-making across the TPLC. It is impossible to know everything about a medical device from a single pivotal trial (which as a scientist is something I fully understand); a device's full capabilities and problems may not be identified until it is used and observed in the real world. As such, the medical device approval process must include data collection in both the pre-market and post-market phases. This post-market data can be used not only to ensure a device's safety, but also its effectiveness and potential improvements to the device. After all, the word safety comes before efficacy in the FDA's mission statement.

As clinicians, we are responsible for the long-term care of our patients and can provide longitudinal data that are relevant to the development of real-world evidence (RWE). This is based on credible data from the clinicians using devices in the field, and ideally collated into high quality registries such as the NCDR, a major effort of the ACC. We can also engage the entire breadth of our clinical and scientific community, including clinicians who treat under-represented minority patients and those who practice in underserved communities. Real-world evidence is crucial to improve care for patients, particularly for populations who have historically been underrepresented in clinical trials.

The use of real-world evidence collected during post-market surveillance is beneficial to patients, scientists, regulatory agencies, and device manufacturers. Sponsors that have used clinical data registries to house their post-approval studies have experienced financial savings of approximately 40 to 60 percent along with the acceleration of patient data available for evaluation due to the widespread US hospital registry participation. That is a significant return on investment and provides substantial benefit to patients in the long run. Innovative collaborations have identified new methods for accelerating spread of new technologies. This includes the employment of clinical data registries, such as the Transcatheter Valve Therapy Registry (TVT) operated by The Society of Thoracic Surgeons and the ACC.

REGULATORY SCIENCE

The College also supports the ongoing development of regulatory science. Success in the development of drugs with less risk for QT prolongation and the Cardiac Safety Research Consortium are examples of a regulatory/academic/industry partnership moving toward a common goal of good science. Clinicians have been engaged in the study and development of measurement tools for many years and have experience to offer regarding best practices. The FDA has already developed the Network of Experts Program, in which the ACC currently has a standing agreement, that allows it to work with medical specialty societies to identify clinical experts. The ACC sees further opportunities for stakeholders to better leverage medical specialty societies and other similar organizations that can provide the agency with access to world-class experts in all these fields when MDUFA funds are allocated towards identification of the best methods and any associated infrastructure. The College and other medical specialty societies stand willing to work with the Committee and the FDA to provide access to world-class experts.

NEW LEGISLATION

The College has reviewed two pieces of legislation that are also being considered at this hearing with regards to electronic cybersecurity and adding an advisory panel at the FDA focused on diagnostics.

- Introduced by Congressman Michael Burgess, MD (R-TX), HR 7084, the Protecting and Transforming Cyber Health Care (PATCH) would implement cybersecurity protocols and procedures for manufacturers applying for premarket approval through the FDA to ensure the US is properly equipped to deal with foreign or domestic ransomware attacks.
- Introduced by Congresswoman Kim Schrier, MD (D-WA), HR 7192, the Diagnostic Device Advisory Committee Act would create an advisory committee—similar to others in the MDAC—to discuss diagnostic devices specifically.

After a complete examination by staff and member experts, the College is pleased to support the inclusion of both bills in the MDUFA package.

CONCLUSION

ACC appreciates this committee's openness to stakeholder feedback throughout the MDUFA V reauthorization process and welcomes the opportunity to provide further input as needed. We thank the FDA, medical device manufacturers, and other stakeholders who helped negotiate this agreement for coming together and putting forth a framework that aims to better the lives of the patients we serve. We constantly strive to improve and refine our efforts to better achieve our mission of transforming cardiovascular care and improving heart health. The ACC looks forward to working with the members of this committee on the passage of the essential legislation required to implement future agreements and other important issues that are so vital to patient access and care.