AMERICAN COLLEGE of CARDIOLOGY

Heart House
2400 N Street, NW
Washington, DC 20037-1153
USA

202-375-6000
800-253-4636
Fax: 202-375-7000
www.ACC.org

July 31, 2018

Scott Gottlieb, MD
Commissioner of Food and Drugs
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: Medical Device Safety Action Plan: Protecting Patients, Promoting Public Health [FDA-2018-N-1315]

Dear Commissioner Gottlieb,

The American College of Cardiology (ACC) is pleased to submit comments to the Food and Drug Administration (FDA) it's Medical Device Safety Action Plan: Protecting Patients, Promoting Public Health [FDA-2018-N-1315]. The ACC is a 52,000-member medical society that is the professional home for the entire cardiovascular care team. The College's mission is to transform cardiovascular care and improve heart health. The ACC leads in health policy formation, 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.

Overview

Cardiovascular professionals rely on medical therapies approved by the FDA to furnish high quality care to patients on a daily basis. There have been impressive strides made in cardiovascular care that would not have occurred without medical device assistance, both therapeutic and diagnostic. The FDA has played a crucial role in bringing these new therapies to market. Innovations in care and treatment for cardiovascular disease are critical to continuing the decline in mortality. At the same time, it is equally important that the FDA protect the public health. The FDA's mission requires the government to strike a balance between protecting the public health and encouraging creativity and scientific advancement. The Medical Device Safety Action Plan provides a blueprint as to how the FDA plans to continue

enhancing programs and process to ensure the safety of medical devices throughout the total product life cycle (TPLC), provide timely communication and resolution of known safety issues, and continue to advance safer, more effective and innovative technologies. The ACC's comments specifically address the following areas:

- Establishing a robust medical device patient safety net in the United States
- Exploring regulatory options to streamline and modernize timely implementation of postmarket mitigations
- Spurring innovation towards safer medical devices
- Advancing medical device cybersecurity
- Integrating the Center for Devices and Radiological Health (CDRH) premarket and postmarket offices and activities

The FDA has introduced several initiatives intended to help achieve the aim of the Medical Device Safety Action Plan and the ACC has been actively involved in the development of many of these initiatives. Following the establishment of a unique device identification (UDI) system, the ACC joined the Pew Charitable Trust, the Society of Thoracic Surgeons (STS), Aetna, Geisinger, Intermountain Health and others in calling for CMS to include device identification information in claims forms as a method to detect adverse events and device failure quicker. The ACC continues to work with the FDA as stakeholders implement the National Evaluation System for Health Technology (NEST) and identify projects for data collection and analysis. As the FDA seeks to improve cybersecurity of medical devices and create a competitive marketplace for device quality through programs such as the digital health software pre-certification (pre-cert) program, the ACC will continue to provide input and expertise by remaining an active participant in FDA workshops regarding the development of the pre-cert program for digital health software. The ACC has participated in discussions with the Heart Rhythm Society (HRS), the Federal Bureau of Investigation (FBI), the FDA, and other interested parties regarding threats, solutions and communication strategies surrounding medical device cyber security and will continue to do so.

ACC principles

The FDA intends to implement the Medical Device Safety Action Plan while working to reduce the burdens and costs associated with the medical device approval and surveillance process. 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 and continues to refine oversight of medical device safety throughout the 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.

Specific comments

Establishing a robust medical device patient safety net in the United States

According to the Medical Device Safety Action Plan, the FDA intends to work collaboratively as a member of the NEST Coordinating Center (NESTcc) to help establish the capabilities for the NEST to perform active surveillance; perform timely, efficient postmarket safety studies; and develop, test, and apply new methods for enhanced safety signal detection and evaluation. Recent efforts, including provisions in the 21st Century Cures Act, have promoted the use of real-world evidence to bolster regulatory decision-making, The College has been pleased by the FDA's efforts in recent years to explore the use of cost-effective, reusable sources of data such as the ACC's National Cardiovascular Registry® (NCDR®) to supplement traditional sources of data in the decision-making process and encourages the Agency to continue doing so. Using data sources with standardized terminology such as clinical data registries can allow the FDA to monitor device performance, decreasing the time that it takes to approve new devices. By doing so, the FDA can help to improve patient outcomes, increase access to valuable clinical data, and reduce regulatory costs.

While the use of existing data sources, such as clinical data registries, to develop a safety net has promise, it is important for the FDA to harmonize efforts to capture this data. The Center for Devices and Radiological Health (CDRH) has multiple device surveillance programs currently underway including but not limited to the Medical Device Epidemiology Network Initiative (MdEpiNet), NEST, and the Cardiac Device Coordinated Research Network (CDCRN). These programs have similar missions and intend to utilize analogous data sources, threatening to duplicate efforts and compound challenges clinical data registries face when participating in FDA surveillance programs. As the FDA seeks to reduce the administrative and financial burdens associated with medical device surveillance and development, the FDA must consider these same burdens placed on medical societies that own and operate registries. The FDA must also ensure coordination between surveillance programs and prevent duplication of efforts across projects. Streamlined surveillance programs will more effectively provide the robust medical device patient safety net the FDA aims to produce.

According to the plan, the Agency intends to seek additional funding to assure active surveillance capabilities are developed and ensure that the NEST is financially self-sustaining. The ACC appreciates efforts to ensure the NEST is adequately funded and sustainable and encourages the FDA to continue to seek additional funding sources to ensure the long-term sustainability of NEST and other active surveillance programs.

Exploring Regulatory Options to Streamline and Modernize Timely Implementation of Postmarket Mitigations

Standardized, accurate, and reusable data sources, such as clinical data registries, promise to provide clinicians, patients, and regulators with postmarket device surveillance in a more efficient, timely and cost-effective manner. These surveillance programs will allow the FDA to more quickly work with manufactures to develop postmarket mitigations should adverse events occur. Additionally, the FDA intends to consider taking other actions to mitigate and address new or increased known risks as part of the Action Plan, possibly including special controls using current statutory authority or potential new authorities to allow for additional actions. Protecting the public health is the number one mission for the FDA, and it should continue to explore all options to ensure clinicians and patients can work together to mitigate adverse events and risks. While doing so, the FDA should also continue to provide patients with access to novel therapies developed and approved by the highest standards for safety and effectiveness.

A 2017 Office of the Inspector General (OIG) report found that claims data lacked the necessary information to detect device failures and subsequently recommended adding device identifier to claims to indicate the brand and model of device used. The ACC strongly supports this recommendation. Inclusion of device identifiers on claims forms will allow the FDA to use this data in conjunction with other data sources, such as registries, to track devices and provide robust data on product performance and detect device failures in a more timely manner. Postmarket surveillance for devices relies on a broad range of data, including clinical trial databases, adverse event reports, registries and other data sources. Each of these data sources has its strengths and its limitations. One of the strengths of claims data is that they provide longitudinal information (such as revision surgery to remove an implant) on patient outcomes in ways that other data sources may not be able to provide. Incorporating device identifiers in claims would enable them to supplement—not replace—other sources of information for postmarket surveillance and would

fill critical gaps in the availability of longitudinal data on large numbers of individuals. The FDA should work with CMS to develop a comprehensive device identifier strategy available on claims as a method of streamlining and modernizing postmarket mitigation strategies.

Spurring Innovation towards safer medical devices

Under the Medical Device Safety Action Plan, the FDA intends to provide both regulatory incentives and scientific expertise to help drive the marketplace to develop safer technologies, in addition to the development of medical devices that address unmet medical needs. Actions to facilitate this include establishing a voluntary, modified 510(k) pathway, pilot use of an evaluation process for organizational excellence through the digital health software pre-certification (pre-cert) program, and increased interactions between FDA staff and developers during development and pre-market review. The FDA's efforts to develop novel approaches to regulatory decision-making to encourage the development of innovative medical therapies are encouraging, and the ACC strongly believes the FDA should work to provide patients with access to novel therapies while maintaining the high standard for safety and effectiveness.

New regulatory approaches such as the pre-cert program and a voluntary, modified 510(k) pathway offer developers of novel therapies the promise of flexibility to allow for iterative improvements as technology rapidly improves. However, as previously noted, it is vital that the FDA develop sufficient safety nets through surveillance programs that can accurately and rapidly track medical devices and mitigate new or known risks. Without the development of surveillance programs and tracking strategies, decreased regulatory scrutiny in the pre-market approval process can result in insufficiently understood and vetted medical devices reaching patients and threaten their wellbeing. Therefore, the development of any new regulatory approaches which reduce pre-market testing must be accompanied with robust post-market surveillance.

Advancing Medical Device Cybersecurity

New cyber capabilities in medical devices present unique opportunities for patients and clinicians to access and transmit personal health information. However, these access and transmission capabilities also present unique cybersecurity threats and vulnerabilities. Increasingly, health systems and their information technology (IT) infrastructure are targets of cyberattacks, which threaten patient health information, as well as the wellbeing of patients. These attacks attempt to cripple systems, harvest valuable protected personal data, and hold hostage vital medical systems. The FDA must continue to push medical device manufacturers to keep pace with these emerging threats and vulnerabilities.

As part of the Medical Device Safety Action Plan, the FDA intends to evaluate requiring manufactures to build in cyber risk mitigation capabilities into a product's design. The College believes it is critical for the FDA to implement this approach to protect patients and clinicians. In addition to embedding these capabilities into a product's design, the ACC also believes that it is important that the FDA continuously monitor medical devices in the postmarket setting to ensure manufacturers are continuing to keep devices up-to-date to protect against new cyber threats as they emerge. It is equally important that manufacturers incorporate methods for clinicians and their staff to quickly and easily update medical devices without special effort. The College urges the FDA to work alongside manufacturers to ensure updates, patches and necessary security

actions are effortlessly and rapidly undertaken.

Additionally, the FDA proposes the development of a CyberMed Safety (Expert) Analysis Board (CYMSAB) as a public-private partnership that will provide vulnerability assessment, serve as an expert panel resource for device manufactures, assess proposed mitigations, and assist in the investigation of suspected device compromise. In addition to service as an expert panel resource, the CYMSAB should also work to promote awareness and provide education to patients about potential cybersecurity threats to their devices. The ACC supports the founding and funding of the CYMSAB. The FDA, manufacturers, and providers have a shared responsibility to ensure medical devices are safe and effective, and the CYMSAB would provide invaluable expertise and assets to the FDA, industry, and health care facilities.

Integrating the CDRH's premarket and postmarket offices and activities to advance the use of a TPLC approach to device safety

To facilitate the implementation of a TPLC approach to medical device safety, the Safety Plan discusses a strategic reorganization of the FDA's medical device center, CDRH, into one large office composed of seven smaller device-specific offices that would each be responsible for premarket review, postmarket surveillance, manufacturing and device quality, and enforcement. The ACC fully supports efforts to streamline efforts and allow CDRH staff to take a more universal view of device oversight. Pre-and postmarket office integration would ideally allow the FDA to fulfill the Safety Plan's goal of increased collaboration and more frequent conversations between staff and manufacturers through the TPLC. The College urges the FDA to ensure that any reorganization streamlines efforts to monitor medical devices through postmarket surveillance, taking into consideration and reducing the administrative and financial burdens placed on surveillance networks such as clinical data registries and ensuring surveillance projects do not duplicate efforts. Additionally, any reorganization efforts should seek to 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. The ACC has developed a trusted relationship with FDA officials, regularly meeting to discuss concerns and solutions for issues that arise. The ACC hopes this relationship would not only continue, but flourish, under a strategic reorganization.

Conclusion

The ACC thanks the FDA for allowing it to provide comments on the Medical Device Safety Action Plan. The College looks forward to continuing to work with the FDA as the Agency moves forward implementing components of this plan. To address these comments or additional questions, please contact Joseph Cody, Associate Director, Research and Innovation Policy, at jcody@acc.org.

Sincerely,

C. Michael Valentine, MD, FACC
President

AMERICAN COLLEGE of CARDIOLOGY
2400 N Street, NW
Washington, DC 20037-1153 USA
202-375-6000
800-253-4636
Fax: 202-375-7000
www.ACC.org