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

Submitted electronically via regulations.gov

Re: Docket ID: FDA-2010-N-0389: Medical Device User Fee Amendments; Public Meeting; Request for Comments

Thank you for the opportunity to comment on the reauthorization of the medical device user fee program for fiscal years 2018 to 2022. Medical device user fees have successfully addressed delays in the Food and Drug Administration's (FDA's) review of new products. The agency now has opportunities to further utilize this program to strengthen its efforts to enhance the collection of robust and timely data on device performance and safety—both before and after the marketing of a new product.

The Pew Charitable Trusts is an independent, non-profit research and public policy organization. Pew seeks to enhance medical device safety and foster device innovation that benefits patients.

Medical device user fees—since their inception in 2002 as part of the Medical Device User Fee and Modernization Act—have provided FDA with additional resources for product reviews, enabling the agency to meet and exceed its goals for the timely evaluation of product submissions.[1] In addition, the premarket approval rate for devices has increased from 59% in fiscal year 2010 to 86% in fiscal year 2014, helping to facilitate more prompt patient access to life-saving and life-changing medical technologies.

As part of the evolving regulation of medical devices, there are currently efforts aimed at even faster development and approval of innovative new technologies. FDA's Expedited Access Premarket Approval (EAP) program[2] and the breakthrough devices provision of the 21st Century Cures Act passed by the House of Representatives[3] would shift data collection from the premarket to the postmarket setting to accelerate the delivery of innovative devices into clinical care. The prompt collection of data in the postmarket setting is critical to these efforts.

To ensure the success of the EAP and other programs, FDA and manufacturers should consider utilizing the user fee program to support the development of a better infrastructure that can collect more robust postmarket data on medical devices that are marketed with less certainty on their full risks and benefits.

In addition, the user fee program offers another opportunity to further enhance the predictability and consistency of FDA review. The user fees should support the use of common data standards

that would enhance the efficiency of FDA reviews and support the analysis of data across devices in a product class.

Utilizing user fees in these ways aligns with the precedent established in the prescription drug user fee program. For example, in 2012 FDA and drug manufacturers agreed to utilize user fees to support better postmarket surveillance—such as through the development of methodologies to conduct meta-analyses of data—and the implementation of mandatory clinical data standards.[4]

Improvements to postmarket surveillance system

As emphasized in FDA's EAP guidance and in a report issued by the National Medical Device Postmarket Surveillance Planning Board, the development of better data on devices after approval—such as through implementation of the agency's postmarket surveillance plan[5]—are essential to efforts to shift the collection of some information to after the marketing of the product. In addition to more quickly detecting problems with products that are approved with less certainty on their performance, postmarket data can also inform manufacturers as they develop the next generation of a product.

To improve postmarket surveillance—and thus support device innovation efforts—several advances are needed, including:

- The establishment of a national medical device evaluation system;
- Pilots to support implementation of the unique device identifier (UDI) system; and
- Prompt completion of post-approval studies.

Development of a national medical device evaluation system

Data on the performance of medical devices are collected by various healthcare stakeholders—including health plans, registries, FDA, individual hospitals and other organizations that conduct research. However, these organizations often work in silos, without the ability to leverage each other's information. Similarly, these organizations often do not coordinate priorities to improve the efficiency and utility of medical device data collection.

To avoid the duplication of efforts, identify information gaps, and leverage data generated throughout the healthcare system, better coordination of activities is essential to more quickly discover problems with devices and reduce the costs of postmarket surveillance. Recognizing the need for better data on devices, the National Medical Device Postmarket Surveillance Planning Board recommended the development of a new entity to coordinate and drive improvements in device data collection.

While this new center would not conduct postmarket surveillance itself, it would take the lead in developing the standards and infrastructure needed to efficiently collect data. Among its first priorities, the coordinating center should: 1) help develop or drive adoption of common data standards—such as core pieces of information that need to be recorded for specific conditions or devices; 2) facilitate the sharing of data on medical devices from EHRs, claims and registries across the health care system; and 3) support standards for the capture and exchange of UDI in various clinical, administrative and financial systems.

Especially as more data on device performance is gathered in the postmarket setting to reduce premarket development times, FDA and manufacturers should consider whether user fees could support the development of a national medical device evaluation system to coordinate and improve data collection after product approval. The user fees could, for example, support the development of a business plan for this system so that various stakeholders, including manufacturers, invested in better device data could support ongoing advances in this area.

Pilots to support UDI adoption

In 2007, Congress instructed FDA to develop a unique device identifier (UDI) system to provide each medical device with a code corresponding to its manufacturer and model. This new UDI system—which took effect last year—has the potential to significantly improve healthcare by allowing FDA, researchers, clinicians and other stakeholders to:

- More quickly collect device performance to detect safety problems;
- Help track down recalled products that are either on hospital shelves or implanted in patients;
- Enhance clinical decision support for physicians to know what devices their patients use;
- Improve adverse event reports, which often include incomplete or incorrect information; and
- Enrich the information available to registries, which are large databases used to evaluate outcomes for patients with similar medical conditions.

However, to fully achieve the potential of this new system, UDI must be included in health information sources, particularly patients' electronic medical records and insurance claims submitted by hospitals to health plans.

There is already significant momentum toward the incorporation of UDI in patients' electronic health records (EHRs). Specifically, the Office of the National Coordinator for Health Information Technology (ONC) has proposed to require that EHRs: 1) include a dedicated field for the UDIs of implanted devices; 2) link with FDA's Global Unique Device Identification Database (GUDID) to extract human-readable information about the device into the EHR; and 3) incorporate the UDIs of implanted devices into summary of care documents, known as the common clinical data set (CCDS).[6]

Similarly, there is also considerable support across the healthcare system—from surgeons, large hospital systems, health plans, accountable care organizations, health plan sponsors, device safety experts, public health groups, patients and consumers—to incorporate the UDIs of implanted products into insurance claims, which are already used to evaluate the safety of drugs. Claims, though, only contain information on the procedures that a patient undergoes but not which device was implanted, hindering their utility for device surveillance.

For UDI capture in EHRs and claims, there remains significant uncertainty on how best to document this information in electronic databases and transmit it both within a hospital and to external data sources, such as health plans or registries. While FDA has funded some pilot projects—such as the incorporation of UDI into the electronic databases used in the cardiac

catheterization laboratories of the multi-state Mercy health system[7]—additional pilot projects are needed to demonstrate both the feasibility and benefits to hospitals, clinicians, health plans and patients for the capture and documentation of UDI, including as part of EHRs and claims.

In addition, FDA and manufacturers should consider utilizing user fees to support the inclusion of UDIs in the agency's postmarket surveillance Sentinel program, which relies on claims data to evaluate the safety of drugs. Even though Congress required FDA to expand Sentinel to devices in 2012, the lack of product-specific information in claims hinders the agency's ability to utilize this system for medical implants. FDA should develop methodologies to utilize Sentinel to evaluate medical device safety.

FDA has also indicated that it will assess the expansion of the Sentinel program to allow other stakeholders access to its infrastructure to conduct research on medical product performance and quality improvement.[8] With UDI information added to claims, manufacturers—as well as health plans and other researchers—could utilize the Sentinel system to evaluate product performance and conduct other research to enhance device safety and quality. FDA's user fee programs could support the development of the necessary infrastructure and policies—such as around data access and use—needed to support Sentinel's expansion as a national resource, which would help it become self-sustaining through multi-stakeholder funding and less reliant on FDA resources.

Postmarket study completion

The prompt initiation and completion of post-approval studies are also essential to a robust postmarket surveillance system. Research conducted by Pew has shown that approximately half of all required post-approval and postmarket surveillance studies do not have an agreed upon test protocol at the time of approval; in those cases it took a median of 180 days before the manufacturer and FDA agreed to study procedures.[9]

Given challenges with the initiation and completion of post-approval studies, FDA as part of the EAP program indicated that the postmarket trials should commence within six months of approval and conclude within three years.

FDA and manufacturers should consider evaluating the common causes of delays commencing and completing post-approval studies and identify ways to ensure that the data are more quickly and efficiently collected. For example, FDA and manufacturer should consider shared metrics on the finalization of postmarket study plans at the time the device is approved or within a certain timeframe after product approval if there are valid scientific reasons that the protocol cannot be finalized at the time of device approval.

Use of common clinical language for pre- and postmarket analyses

Along with establishing a better infrastructure to collect information on medical device performance, the development of common standards can help ensure that the data collected are useful across many applications. Information from different sources—such as electronic health records, premarket submissions to FDA and registries—cannot be automatically aggregated because data elements could have different definitions or units of measure. Even seemingly

simple data—from whether a patient had a stroke or demographic information—are often not described, defined or documented in a uniform manner across health information sources.

Given this reality, the implementation of a common data model for devices could ensure that patient data is defined and documented in standard ways in electronic health information systems.

The use of a common data model could facilitate innovation and reduce both the costs and time associated with bringing new devices to market. As part of the prescription drug user fee program, FDA and manufacturers agreed to utilize common standards from the Clinical Data Interchange Standards Consortium (CDISC) as part of regulatory submissions to the agency. CDISC, a not-for-profit standards development organization that supports the acquisition, exchange, submission and archive of clinical research data, has already developed a core set of standards for use in regulatory submissions for devices.[10]

CDISC has indicated that the use of its standards can save between 70 to 90 percent of time and resources spent before patient enrollment begins, and—when manufacturers submit data electronically—reduce costs by $180 million, or 18 percent, per submission.[11] For drugs with an average of 12-year clinical development time, CDISC also estimates that it could reduce time-to-market by two years, thus expediting patient access to new medicines while improving the data collected.

The use of CDISC standards could also support FDA review of applications by improving the transparency and predictability of medical device application reviews. These standards can help resolve common problems that delay product evaluations, like missing data and protocol deviations. Additionally, FDA reviewers would be familiar with the terminology and data elements included in submissions, thus improving the predictability of review.

Finally, the use of common clinical data standards as part of submissions to FDA could allow the agency to aggregate the information and search for common issues across devices classes. For example, the agency could analyze the same questions on safety or performance across premarket submissions from multiple devices.

Given the demonstrated value of common clinical data models for drugs, extending these standards to devices could reduce clinical trial time and costs, enhance FDA review of products and facilitate better analyses across applications. As part of the user fee negotiations, FDA and device manufacturers should consider requirements to utilize common data standards as part of premarket submissions to parallel provisions of the prescription drug user fee agreement. FDA should also consider what exemptions from these criteria are needed to ensure that the requirements do not suppress innovation from manufacturers—such as small companies—that may not be familiar with or able to implement these standards.

Conclusion

Over the past 13 years, the medical device user fee program has provided FDA with critical resources to improve the efficiency of its reviews of product applications. As FDA consistently

meets and exceeds the user fee performance goals and shifts product regulation to a total product life cycle approach, the agency and manufacturers should leverage this program to further improve the efficiency of data collection—both before and after product marketing.

As part of the next iteration of the user fee program, improvements to the postmarket surveillance infrastructure will support effective implementation of efforts to shift data collection until after approval. Similarly, the development and use of common data models as part of FDA submissions can enhance the predictability and consistency of the agency's review process while also supporting better analyses on classes of products. These changes would benefit manufacturers, FDA and patients through more efficient data collection to help encourage innovation and ensure that devices on the market are safe and effective.

Thank you for considering our comments. Should you have any questions or if we can be of assistance on ways to better collect medical device data both before and after approval, please contact Josh Rising, Director, Healthcare Programs, at 202-540-6761 or jrising@pewtrusts.org.

Sincerely,

Josh Rising, MD
Director, Healthcare Programs
The Pew Charitable Trusts

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