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October 25, 2016

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
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Submitted electronically via regulations.gov

Re: Docket No: FDA-2016-D-2153: Use of Real-World Evidence to Support Regulatory Decision-making for Medical Devices; Draft Guidance for Industry and Food and Drug Administration Staff.

Thank you for the opportunity to submit comments on the Food and Drug Administration (FDA) proposal to use real-world evidence for regulatory decision-making, including expediting patient access to new technologies and detecting safety problems with marketed devices. Achieving FDA's vision for the use of real-world evidence requires two policy changes: incorporation of unique device identifiers (UDIs) into the relevant data and development of a national device evaluation system that links information sources.

The Pew Charitable Trusts is an independent, non-profit research and public policy organization. Pew seeks to improve the data available on medical device safety and performance to improve patient care and facilitate innovation.

Traditional medical device trials conducted both before and after product marketing are often small and lack detailed clinical information over extended periods of time. For example, Pew research has found that even for devices deemed innovative by FDA and granted priority status, the median length of pivotal clinical trials was three years, and studies contained a mean enrollment of less than 297 patients.[1] Similarly, Pew research has found that that post-approval studies required by FDA often are not initiated or completed in a timely manner.[2] These postmarket studies can also be expensive; researchers found that they cost the device industry $1.2 billion over eight years.[3]

As FDA emphasizes in the proposed guidance, the use of real-world evidence—collected from electronic health records, insurance claims and registries—can, in some cases, supplement or provide similar information than the data obtained through a traditional study or via other means. Unlike data collected through traditional studies, real-world evidence could help obtain data on thousands—even millions—of patients using information that is already routinely collected. These data may help researchers study medical devices in a manner that is more efficient and cheaper than they could with traditional studies.

However, the use of real-world evidence requires two policy changes to ensure the utility of these data to better evaluate device safety and performance.

- First, real-world information should include the devices used in care by adding UDIs—which indicate the manufacturer and model of a product—to these data sources.
- Second, FDA, manufacturers, healthcare providers and other stakeholders should establish a national medical device evaluation system to collect better data on device performance.

Incorporation of UDI in Real-World Data Sources, Including Claims

Real-world data sources today often lack standardized information on the devices used in care. However, documenting the UDIs of medical devices—particularly implants, such as cardiac stents and artificial joints—in these sources can fill that gap and ensure that researchers have the data they need to study the performance and safety of specific products.[4]

Progress is already underway to incorporate UDIs in some real-world data sources. Registries are increasingly adding capabilities to collect the UDIs of products used, and, as a result of recent federal regulations, electronic health records will soon have standard fields for this information as well.[5]

Despite the progress in some real-world data sources, additional work is needed to advance the incorporation of UDI data into claims. Unlike other forms of real-world evidence, claims contain data for nearly every encounter with the healthcare system for a specific individual. For example, claims information collected over many years may contain data showing that a patient received a specific prescription drug, had surgery and visited the emergency department.

Claims can't be used to help study medical devices for one simple reason: claims currently list only the procedure—such as hip replacement surgery—and lack any specific information about the product implanted in the patient. Adding device identifiers to claims would provide that specificity, and allow researchers to use this data to assess devices more effectively.

Adding UDIs to patients' health records cannot provide the same benefits as claims. Electronic health records (EHRs) store information in varying ways and cannot easily exchange information. As a result, researchers face many challenges in combining EHR data across providers to understand quality and value. Claims, on the other hand, are already standardized for providers and payers, resulting in easier aggregation of information across the healthcare system. Adding UDI to claims would allow regulators and researchers to use claims to evaluate devices in the same way they already evaluate drugs and procedures.

Many organizations, including Pew, FDA, the Centers for Medicare & Medicaid Services, clinical societies, registries, health plans and other groups have all called for the addition of device information to claims to help generate better data on device performance.[6] A private-sector organization responsible for managing the standard, national claims form has not yet announced whether and how it will add device information to claims. As part of FDA's efforts to utilize real-world data, the agency should continue to advocate for the addition of device

identifiers to claims forms to ensure that this critical piece of information is usable by the agency and researchers.

Establishment of a National Evaluation System

In addition to ensuring that real-world data contain information about the devices used, FDA should also ensure that researchers can leverage and integrate these sources with one another to conduct more powerful and efficient analyses of product safety and performance. Two expert advisory organizations to FDA have advocated for the development of this integrated system, which has recently been referred to as the National Evaluation System for Health Technology, or NEST.[7]

This integrated system will link health records, claims data, registries, and other sources to evaluate device performance and safety. Through this approach, researchers at FDA, manufacturers or health plans could pull data from multiple locations to obtain more comprehensive information on patient outcomes, with different data sources alleviating the deficiencies of other data sources. For example, while EHRs contain detailed clinical information, they often lack data on patient outcomes across providers. Supplementing EHRs with claims data will make cross-provider and longitudinal data available for analyses.

Establishment of this system requires a coordinating center to develop needed guidance for the use of the integrated data network. Specifically, the coordinating center must ensure that the appropriate policies are in place so that researchers can effectively use data from these real-world sources. For example, the coordinating center should prioritize policies that will help identify and integrate the same patient's information from multiple locations—known as patient matching—and that the data are sufficiently standardized so that researchers can make meaningful inferences when extracting data from multiple locations.

The first steps to establish this system are already underway, as medical device manufacturers and FDA agreed to erect a coordinating center with funding from medical device user fees.[8] FDA, manufacturers, Congress and other stakeholders should ensure that the coordinating center has sufficient resources to effectively link the disparate data sources and oversee the development of needed policies.

Conclusion

The creation of an integrated device evaluation system and the inclusion of device identifiers in various information sources—particularly claims—will help realize the vision articulated by FDA in this guidance document to enhance patient safety and facilitate innovation. Through better use of real-world data sources, patients and clinicians can have enhanced information on the devices they use, FDA can more quickly detect safety problems and manufacturers can better study their products to develop the next generation of life-saving and life-changing devices.

Should you have any questions, please contact me at jrising@pewtrusts.org or 202-540-6761.

Sincerely,

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