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Chairman Pitts, Ranking Member Pallone, and members of the Committee, thank you for the opportunity to provide testimony. My name is Josh Rising. I am a pediatrician, and I direct medical device work at The Pew Charitable Trusts, an independent, nonpartisan research and public policy organization dedicated to serving the public.

We have an exciting opportunity today to talk about the future of health care—a future where we can harness electronic data to improve patient care through a better understanding of how medical products impact health outcomes and more rapid cycles of product development. Technological advances allow us to consider evidence development as a continuous cycle that begins before a product is approved and continues as the product is used by patients.

This process begins during the product development and approval phase. The Food and Drug Administration (FDA) reviews data on drugs and medical devices to ensure that the benefits of new products outweigh risks. But the collection of data hardly stops when FDA approves a new medicine, implant or other technology used to treat, cure or prevent disease. Manufacturers, health plans, FDA and researchers all need information after approval to better understand the performance of new products.

This total life-cycle approach supports the development of the next generation of products while ensuring that sufficient data is collected both before and after approval. New electronic tools have the potential to improve the quality of the data and the efficiency of information collection throughout products' life cycles.

In particular, the expansion of health information technology and increased adoption of electronic health records (EHRs) have the potential to dramatically decrease the costs and time it takes to bring products to market.

Clinical trials are the gold standard of medical evidence. They are also the single largest contributor to the cost and length of product development. The key to facilitating innovation of new drugs and devices is to collect the information faster and cheaper, and ensure patients, providers, regulators and payers have the data they need. Registries, large databases that collect information over time on a group of patients treated for a particular medical condition, are one way to accomplish this.

We should seek to conduct clinical trials of the sort done by researchers in Europe studying heart attacks. They conducted a "registry-based randomized clinical trial" involving more than 7,000 patients, and—in unprecedented fashion—were able to keep track of every patient throughout

the course of the research. This study (the TASTE trial) only cost $300,000, roughly $50 per patient. Conducting such a study outside of a registry in the United States would cost hundreds of millions of dollars, if not more.[1]

Similarly, registries are used to identify problems with approved products. Registries can assess the real-world performance and long-term outcomes of medical devices that may not be detected in the clinical trial settings. Hip implants, for example, are expected to last 15-20 years[2] but typically require only two years of clinical data for FDA approval.[3] Demonstrating the ability of registries to detect problems, the Australian Orthopaedic Association National Joint Replacement Registry showed in 2007 that metal-on-metal hips—introduced in 2003 for younger patients needing hip replacements—failed at a rate more than two times higher than conventional hips,[4] leading to a worldwide recall. Registries are a central pillar in FDA's national medical device postmarket surveillance plan.[5]

Registry barriers must be overcome

Within the next few weeks, Pew will release the findings of a series of meetings that brought together medical device stakeholders to better define the role of device registries in our healthcare system. These meetings—hosted jointly by Pew, the Blue Cross and Blue Shield Association and the Medical Device Epidemiology Network Infrastructure Center at Weill Cornell Medical College—included representatives from device companies, FDA, clinical societies, payers and patients groups.

We concluded that registries should be established to collect evidence for those devices for which we do not have good data on their long-term performance, those where physicians and patients have a variety of choices, and those where the outcome may be dependent on surgical technique.

We also developed recommendations on necessary conditions to ensure that registries deliver timely, actionable information to all stakeholders, including the public. We recommend that registry findings and reports should be publicly released on a regular basis, and that the governance, operations, and financing should be made publicly available. FDA, the Centers for Medicare & Medicaid Services (CMS) and other stakeholders should encourage the use of registries that meet these criteria.

There are a number of challenges that must be overcome to enhance the use of registries in the United States today.

First, despite the dramatic uptake of electronic health information sources, these systems cannot easily transmit data among one another. This lack of interoperability, for example, hinders the ability for registries to extract clinical and outcomes data from EHRs. Instead, registries must develop the ability to extract information from the EHR systems at each facility, or require manual entry from providers. We urge the Committee to lend its full support to interoperability efforts by the Office of the National Coordinator for Health Information Technology and elsewhere.[6]

Additionally, many registries have sought clarity on when their studies are considered research or quality improvement efforts.[7] This confusion has slowed their use by hospitals and their ability to make a meaningful contribution.

Other tools can provide key data

In addition to registries, several other new data collection tools can provide critical information on the performance of new drugs and medical devices.

One such tool is the Sentinel Initiative, which can be used to evaluate the safety of drugs and biologics used in patient care. Congress instructed FDA to create this Sentinel program in 2007, and it has since been used both to identify safety concerns with products and to disprove suspected problem. For example, FDA utilized the Sentinel program to identify a correlation between a blood pressure medicine and intestinal problems.[8]

Given Sentinel's successes, Congress instructed FDA in 2012 to expand this system to medical devices. However, Sentinel relies primarily on data derived from health insurance claims. These claims currently lack any information on the specific devices used in care.

To resolve this problem, claims should include information about the specific devices implanted in patients. A new unique device identifier (UDI) system established by the FDA at the direction of Congress was designed with this purpose in mind. In 2007, Congress ordered FDA to create this UDI system to provide each medical device with a unique code corresponding to its make and model.[9] Medical device makers are now adding this code to their products. However, to be effective, it is important that health insurance claims include this code.

Documenting UDI in claims can also bolster other efforts to utilize data to better understand device performance. For example, incorporating UDI in claims will also provide payers—including CMS—with the necessary data unavailable elsewhere to evaluate outcomes for patients with devices.[10] As Medicare and Medicaid pay billions annually for health services involving devices, they should know what products they are purchasing and have the information necessary to make better coverage and reimbursement decisions.

Adding a UDI field to claims has garnered support across the health system—including from hospitals, health plans, physicians, patients, and consumers. Aetna, Mercy, Geisinger Health System, the American College of Cardiology, the Society of Thoracic Surgeons, Premier, Trust for America's Health, AARP, and many other organizations have expressed their support for documenting UDI in claims.[11] Secretary of Health and Human Services Sylvia Burwell also articulated some of these benefits during the Senate confirmation process [12]

New initiatives can leverage these tools

Through the development of these new tools, FDA, patients and clinicians can have confidence that problems with new medical products will be quickly identified. As previously stated, this confidence can enable FDA to expedite patient access to new products, such as by shifting some of the data collected premarket to after approval for technologies that fill serious, unmet medical

needs. These principles are at the heart of recent FDA proposals intended to expedite patient access to new medical devices.[13,14]

The success of expediting access by shifting data relies on the prompt collection of postmarket information. Often, despite current FDA requirements for manufacturers to conduct postmarket trials, commencement of those studies is delayed. For example, in May 2011 FDA responded to concerns of high failure rates with metal-on-metal hip implants by ordering manufacturers to conduct postmarket studies assessing adverse events associated with the products. Despite that order, by June 2012 postmarket study plans for less than one-quarter of metal-on-metal hip products were in place.[15] These types of delays will undermine efforts to shift premarket data to the postmarket setting.

Additionally, FDA must have the ability to quickly withdraw approval for a device if the necessary postmarket data are either not collected or demonstrate that the product does not meet the agency's approval standards. While FDA has the ability to take administrative actions to withdraw approval, removing products from the market can still take several months—if not longer. In the interim, patients may continue to be exposed to products whose risks outweigh their benefits.

FDA—and Congress—should evaluate whether FDA has sufficient authorities to promptly withdraw product approvals if the necessary data are not promptly collected or suggest that the product benefits do not outweigh risks. Congress should also ensure that FDA can fully implement its medical device postmarket surveillance plan, including through the adoption of UDI across the health care system.

Should FDA lack any of these authorities, Congress should provide the agency with enhanced abilities to protect the public through robust postmarket surveillance.

Conclusion

Expediting patient access to new cures requires a holistic view of the product life cycle. New mechanisms to collect data both prior to and after FDA approval can help facilitate faster clinical trials and ensure that any problems are promptly identified.

Given the proven value of electronic health information and registries, Congress should work with the Administration to maximize the potential of these data sources to expedite patient access to safe and effective medical products.

Thank you again for the opportunity to testify, and I welcome your questions.

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