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May 30, 2013

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: Update to the National Medical Device Postmarket Surveillance Plan.

Dear Commissioner Hamburg:

We appreciate the commitment to improving medical device safety demonstrated in the recent update to the U.S. Food and Drug Administration (FDA) report "Strengthening Our National System for Postmarket Surveillance." We are writing to commend the FDA for highlighting the importance of a unique device identifier (UDI) system and medical device registries and to offer additional recommendations to further this plan.

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

Under the FDA's national postmarket surveillance plan, the agency has committed to obtain input from stakeholders via a planning board; establish an effective UDI system; promote the development of registries; modernize adverse event reporting; and establish new methods for evidence generation. The system outlined by the FDA will benefit all stakeholders by providing critical information on the real-world performance of medical devices. We applaud the FDA's inclusion of deliverable dates for each of the action items.

While we agree that an effective UDI system and more sophisticated medical device registries should serve as the foundation to an integrated, national postmarket surveillance system, this plan can only succeed through UDI capture in electronic health information and collaboration with other organizations that are identifying best practices for registry utilization. We also urge you to include a diverse group of stakeholders in the proposed multi-stakeholder postmarket surveillance planning board, and to ensure the timely completion of FDA-mandated post-approval studies.

UDI capture in electronic health information

We applaud the FDA for recognizing the importance of UDI capture in electronic formats. Incorporating these device identifiers in patient records and claims forms, though, can only occur once the FDA finalizes the UDI proposed rule—released nearly a year ago.

As the FDA acknowledges in the plan, Congress instructed the agency to incorporate medical devices into the postmarket surveillance Sentinel Initiative via section 615 of the Food and Drug Administration Safety and Innovation Act. The only way to comprehensively accomplish that directive involves the capture of UDI in claims data, which represent a major data source for the Sentinel system. The Sentinel system, which can examine data from more than 100 million patients, tracks the safety of medical products to more quickly identify problems.

The FDA should demonstrate to CMS, private payers, hospitals and other related organizations the importance of UDI capture in claims forms to improve patient outcomes and enhance the evaluation of medical device safety and performance. Claims forms can provide longitudinal data on patient outcomes across healthcare institutions that may not use interoperable electronic health records.

To ensure UDI capture in electronic health records, the FDA must collaborate with the Centers for Medicare & Medicaid Services (CMS) and the Office of the National Coordinator for Health Information Technology (ONC). The agencies intend to conduct rulemaking next year to update electronic health record standards as well as criteria for providers and hospitals to meet to demonstrate the meaningful use of electronic health records. In the interim, federal advisory committees to ONC are drafting recommendations on these topics; FDA engagement with these panels is critical to ensure that new electronic health record standards include the capability to document UDIs in addition to the establishment of a new meaningful use objective for the capture of UDIs for implanted devices.

National and international device registries

As emphasized by the FDA, national and international registries can provide additional data on the risks and benefits of medical devices beyond information collected through claims forms and electronic health records. These registries can evaluate health outcomes, identify patient subgroups affected differently than the general population, and enable more comprehensive long term follow-up.

To enhance medical device registry utilization, Pew is engaging a broad group of stakeholders—from the FDA, CMS, academia, industry, and elsewhere—to identify when registries are the best tool to evaluate device performance and what the appropriate standards are for these registries. This initiative, conducted in conjunction with the FDA's Medical Device Epidemiology Network (MDEpiNet) Program and the Blue Cross Blue Shield Association Technology Evaluation Center, can complement activities of the proposed Medical Device Registry Task Force, created under MDEpiNet. We look forward to closely collaborating with the FDA as the agency begins this important work.

FDA should work with other stakeholders—including manufacturers, CMS, private payers and other stakeholders—to implement appropriate reforms to support registries that will enable more comprehensive evaluations of medical device benefits and risks.

Additional areas for consideration

Pew supports many of the other elements in the update to the national medical device postmarket surveillance plan, but offers additional comments for consideration.

The new Medical Device Postmarket Surveillance System Planning Board can only succeed in improving patient outcomes if the proposed panel includes representatives from a diverse group of healthcare stakeholders, including consumers, patients, clinicians and manufacturers. As enhancing medical device postmarket surveillance may require new funding models, involving CMS and the payer community will be critical to the Planning Board's success.

Lastly, the updated national strategy does not emphasize the importance of timely completion of FDA-mandated post-approval studies. A preliminary Pew analysis suggests that nearly one-third of active post-approval studies listed on the FDA website are progressing inadequately. Pew also found that the study protocols for a significant number of devices were not finalized for more than a year after device approval. The FDA approves some medical devices with the condition that manufacturers will collect additional data on the product. Timely fulfillment of these data collection requirements is essential so that patients and clinicians are fully informed about the risks and benefits of medical devices.

Conclusion

A robust postmarket surveillance system will ensure that problems with medical devices are identified faster and that mechanisms exist to collect data on products approved with less information on their risks and benefits. Central to this system are UDIs and medical device registries, both of which the FDA rightly recognizes as pillars to improving postmarket surveillance.

Should you have any questions or if we can be of assistance to help realize these improvements to medical device postmarket surveillance, please contact Josh Rising, director of medical devices, at The Pew Charitable Trusts, at 202-540-6761 or jrising@pewtrusts.org.

Sincerely,

Josh Rising, MD
Director, Medical Devices
The Pew Charitable Trusts