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November 16, 2012

Thomas Gross, MD, MPH  
Director, Office of Surveillance and Biometrics  
Center for Devices and Radiologic Health  
Food and Drug Administration  
Department of Health and Human Services  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

RE: *Strengthening Our National System for Medical Device Postmarket Surveillance*

Dear Dr. Gross:

The Medical Device Initiative of The Pew Charitable Trusts welcomes the opportunity to submit comments regarding the U.S. Food and Drug Administration's (FDA) National Medical Device Postmarket Surveillance Plan, "*Strengthening Our National System for Medical Device Postmarket Surveillance.*"

The Pew Charitable Trusts is an independent, non-profit organization that applies a rigorous, analytical approach to improve public policy, inform the public and stimulate civic life. The Medical Device Initiative seeks to improve the safety of medical devices and to foster innovation that benefits patients through streamlined device approvals.

The 2011 Institute of Medicine (IOM) report "*Medical Devices and the Public's Health: The FDA 510(k) Clearance Process at 35 Years*" recommended that FDA "develop and implement a comprehensive medical device postmarket surveillance strategy to collect, analyze, and act on medical device postmarket performance information." We are pleased that the FDA is working toward establishing a strategy to address the IOM's recommendation. This national strategy is an important step in the process to build a robust infrastructure to monitor and ensure device safety. Once the strategy is finalized and implemented, the strengthened postmarket surveillance system has the potential to significantly benefit public health.

Overall, we agree that the four priority areas identified in the document are critical to the effectiveness of the overall postmarket program. We have the following comments on the four areas:

**1. Unique Device Identifier (UDI)**

The FDA issued a proposed rule on a UDI system in July 2012. Once implemented by the FDA and utilized by healthcare providers, the UDI system will be the cornerstone for significant improvements in postmarketing surveillance of medical devices. As laid out by the agency, the UDI will benefit patients and public health by: providing for more rapid identification of medical

devices associated with adverse events; assisting with more rapid and efficient resolution of device recalls; and delivering an easily-accessible source of definitive device identification.

UDI will also allow medical devices to be incorporated into the Sentinel Initiative, an important postmarketing surveillance system for medical products. By proactively monitoring data from electronic health records and other sources rather than relying on spontaneous reporting from manufacturers and health care providers, Sentinel can more quickly identify safety issues. However, the system was designed initially to track drugs in the marketplace and it has been difficult to adapt Sentinel to track medical devices due to the challenge of identifying specific devices in the available electronic health records and insurance claims.

A UDI system will address this problem by allowing information about specific medical devices to be integrated into patient health records and health insurance claims, two of Sentinel's main data sources. UDI also has the potential to improve other types of postmarketing surveillance, such as registries, by facilitating the use of electronic records to provide data to these important surveillance systems.

We have submitted formal comments on the proposed rule to the FDA and look forward to publication of the final rule by the statutory deadline of May 7, 2013. Rather than restate all of our comments here, we will highlight two points most relevant to National Strategy for Postmarketing Surveillance.

- The FDA has proposed the creation of a Global Unique Device Identification Database (GUDID), a publicly accessible database that would hold information about each medical device marketed in the United States, as an integral part of the UDI system. We believe that this database will be a reference tool for both clinicians and patients. As such, the database should provide seamless linkage to sources of information about a medical device from the postmarket setting, such as adverse event reports and required postmarketing surveillance studies. Most importantly, the database should clearly indicate if the device is the subject of a recall. The FDA should work in a transparent manner with consumer and clinical groups to ensure that the GUDID database is user friendly and contains links to important safety information.
- Labeling a device with a UDI and linking the device to the GUDID database is a necessary but not sufficient step to realize the public health gains identified above. Additionally, the identifier must be incorporated into records at the facility and provider levels, such as inventory logs, electronic health records, and claims data. For example, the Sentinel system will only be able to incorporate medical device data if the UDI is included in electronic health records or insurance claims data. We applaud the agency for taking proactive steps in this area through its work with the Brookings Institution and other parties.

In particular, we urge the agency to coordinate with the Office of the National Coordinator for Health Information Technology (ONC). Specifically, the FDA should encourage the ONC to include the presence of a UDI field as a criterion for certification of electronic health records. The National Strategy document should go further than this,

though, and clearly identify the strategies that the agency will pursue to encourage uptake of the UDI by the healthcare system.

## 2. Registries

A medical device registry is a database that captures prespecified observational data from patients exposed to a selected device. We agree that registries are an important tool to understanding the postmarket safety and effectiveness of some devices. Medical device registries can provide information useful for many purposes, including safety and performance in “real-world” clinical practice, long-term device safety and performance, comparative device assessments, and evaluation of performance in subgroups. Of note, the FDA has emphasized that it does not intend to control or operate device registries; successful models of registries today include ones run by the American College of Cardiology, Kaiser Permanente, and the Veterans Health Administration.

Although the FDA has identified a number of key issues related to registries in the National Strategy, the agency did not discuss how these issues will be prioritized, the processes that will be used to develop solutions and the timeline for doing so. Following are some of the issues that FDA should prioritize and suggestions on how to address them.

- Prioritizing devices and criteria for future device registry establishment: No consensus currently exists regarding which devices should be included in registries. We recommend the establishment of generalizable criteria outlining when a device should be captured in a registry as a condition of approval. We urge the FDA to work with stakeholders over the next twelve months to establish these criteria and then to publish the criteria in a guidance document by the spring of 2014. As part of this process, we also suggest that the agency and other stakeholders identify the specific devices for which the greatest public health benefit would be achieved by participation in a registry so that initial efforts could be focused on those devices.
- Registries Forum: Most medical device registries in the United States are still early in their life-cycle and face common challenges around issues such as sustainability and ensuring patient privacy. Given the reliance by FDA on external registries in the National Strategy, we encourage the agency to work with registries and other governmental agencies such as the Agency for Healthcare Research and Quality to provide a forum for sharing best practices. The first convening should be held within one year in order to maximize the benefit to registries that are new or in early stages of development. Participation in the forum should be especially encouraged for registries that capture devices previously identified as public health priorities.
- Standards for registries: FDA’s reliance on external registries in the National Strategy raises questions about how to ensure that valuable data captured by registries can be used by clinicians, patients and other stakeholders in decisions around which medical devices have the most benefit for public health and for specific individuals. Establishing basic standards for the governance of registries and transparency around data analysis and results would ensure that registries achieve these goals. The National Strategy should describe how the agency intends to establish these standards. We recommend that the

agency partner with external stakeholders to establish these criteria and finish the work within the next twelve months. By the summer of 2014, the agency should issue a guidance outlining the criteria that a registry would need to meet in order to be eligible to host an FDA-required post-approval study.

### **3. Modernizing MDR and analysis**

Medical Device Reporting (MDR) is the program through which FDA is notified of medical device adverse events so device problems can be quickly detected and addressed. One barrier to the effectiveness of MDR has been uncertainty about which specific device or device model is involved in an adverse event. FDA has taken the first steps in improving MDR by issuing the proposed rule for UDI and pursuing the electronic infrastructure upgrades necessary to make MDR a useful postmarket tool. We encourage FDA to require electronic submission of adverse event reports to allow more efficient and timely analysis and eliminate the significant cost of adding paper reports to the MDR database. In addition, the agency should make available additional adverse event data, such as those contained in Alternative Summary Reporting submissions, so long as those data are not redundant to the reports in the MAUDE database.

The final strategy document should describe specific goals for the new MDR system, including how the increased volume of electronic reports will be handled, how FDA plans to identify “signals” through analysis and communicate that information, and how manufacturers and others submitting adverse event reports will be involved. We encourage FDA to establish a transparent process for addressing these issues, including publication of recommendations within two years.

### **4. New Methods for Evidence Generation, Synthesis and Appraisal**

The agency’s initial work to establish new research methods under the MDEpiNet umbrella has shown promise, such as with the establishment of the International Consortium of Orthopedic Registries, which has developed new techniques that allow data on implantable orthopedic devices from registries around the world to be aggregated. Recognizing the interest that many stakeholders have in this line of research, the agency intends to utilize a public-private partnership (PPP) for this effort going forward. We support this effort and urge the agency to describe this plan in more detail in the final document, including the timeline for moving forward with the PPP. Additionally, we urge the agency to discuss how it will ensure adequate public representation in the governance of the PPP.

### **5. Other considerations**

#### Post-approval studies

Although this area is not identified as part of the strategy document, postmarket trials are still necessary at times to provide important safety and effectiveness information for some devices. We encourage FDA as part of the national strategy to restate the importance of these trials and to monitor these trials more closely to ensure that they are conducted in a timely manner and to take action when they are delayed. Recently enacted statute requires manufacturers to submit plans for “522” studies (which can be ordered by the FDA when a potential problem with a device on the marketplace is identified) within 30 days of the FDA order and to initiate the studies within 15 months of the order. FDA should use enforcement tools to ensure that manufacturers meet these milestones. In addition, the information available on completed post-approval studies and

522 studies on FDA's website should be expanded by the FDA to provide users a more comprehensive and accessible view of the trial results.

**Summary**

Pew believes that this document provides a solid framework for future improvements in medical device monitoring. We urge the agency to provide more detail in the areas identified above and to establish a timeline for all of the proposed elements of the strategy. Having such a timeline will be useful for all stakeholders in ensuring that the vision of the National Strategy is achieved. We look forward to working with the agency to achieve our common goals.

Thank you for your consideration of our comments. Should you have any questions, please contact Josh Rising at 202-540-6761 or [jrising@pewtrusts.org](mailto:jrising@pewtrusts.org).

Sincerely,

A handwritten signature in black ink, appearing to read "Josh Rising". The signature is fluid and cursive, with a large, sweeping flourish at the end.

Josh Rising  
Director, Medical Device Initiative  
The Pew Charitable Trusts