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August 12, 2014

The Honorable Ron Wyden  
Chairman  
Committee on Finance  
United States Senate  
219 Dirksen Senate Office Building  
Washington, DC 20510

The Honorable Chuck Grassley  
Senator  
United States Senate  
135 Hart Senate Office Building  
Washington, DC 20510

Chairman Wyden and Senator Grassley:

Thank you for the opportunity to submit comments on the use of health data to better understand the effect of new medical products on patient outcomes.

The Pew Charitable Trusts is an independent, nonpartisan research and public policy organization dedicated to serving the public. Our medical device initiative seeks to enhance device safety and facilitate innovation that benefits patients.

One area where patients and physicians need better information is the performance of medical devices after they receive approval or clearance from the Food and Drug Administration (FDA). Recent examples—such as the failures of metal-on-metal hips and implantable defibrillator leads—demonstrate that it takes us too long to identify problems. Additionally, it is virtually impossible for patients, physicians, manufacturers and payers—including the Center for Medicare & Medicaid Services (CMS)—to assess the performance of different devices and determine the right product for each patient.

Recent technological innovations have the potential to provide this important information. One new tool is registries, which are large databases that collect information on patients with a certain medical condition. Additionally, the new unique device identifier (UDI) system makes it possible to assess the performance of specific medical devices. Several reforms are needed, though, to realize the potential of these new tools, including:

- the regular, public release of findings from registries—particularly those used to fulfill FDA and CMS requirements;
- improved interoperability of electronic health records (EHRs), allowing the more efficient extraction of data to registries; and

- the incorporation of UDI into electronic health data sources, including EHRs and health insurance claims, such as those submitted to Medicare and Medicaid.

### ***Registries can collect vital information***

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<sup>1</sup> but typically require only two years of clinical data for FDA approval.<sup>2</sup>

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,<sup>3</sup> leading to a worldwide recall. Registries are a central pillar in FDA’s national medical device postmarket surveillance plan.<sup>4</sup>

### ***Registry barriers must be overcome***

Pew, the Blue Cross and Blue Shield Association and the Medical Device Epidemiology Network Infrastructure Center at Weill Cornell Medical College will soon 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.

Based on input from medical device manufacturers, FDA, clinical societies, payers and patients groups, we 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 released on a regular basis, and that the governance, operations, and financing should be made publicly available. CMS, FDA and other stakeholders should encourage the use of registries that meet these criteria.

There are also a number of other 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 assess the status of interoperability efforts by the Office of the National Coordinator for Health Information Technology and elsewhere and lend assistance as needed.<sup>5</sup>

Additionally, many registries have sought clarity on when their studies are considered research or quality improvement efforts.<sup>6</sup> This confusion has slowed their use by hospitals and their ability to make a meaningful contribution.

### ***UDI will soon identify devices for postmarket surveillance***

In addition to registries, the new UDI system, established by the FDA at the direction of Congress, will support the development of new information on device performance for patients, physicians, payers and FDA. The UDI system will provide each medical device with a standardized, unique code corresponding to its make and model to facilitate recall resolution, enhance care coordination and generate new data on device performance.<sup>7</sup> Medical device manufacturers are now assigning this code to their products, and the highest-risk devices will have UDIs by this fall. Achieving the UDI system's benefits requires its integration into electronic health information—particularly EHRs and health insurance claims.

UDI incorporation into patients' health records will allow provide patients, physicians and hospitals with information that they currently lack on the devices used in care. This information will also enable patients and providers to submit more precise adverse event reports that identify the make and model—and in some cases the lot number—of a potentially malfunctioning device. Additionally, the inclusion of UDIs in EHRs will provide physicians to make more informed patient care decisions based on the devices implanted in patients. This information is especially critical when patients switch providers or see multiple physicians, all of whom may need information on the specific device. Finally, UDI information can provide hospitals with the necessary data to examine outcomes associated with different devices and better understand data on how physicians use certain products.

The Office of the National Coordinator for Health Information Technology (ONC) recognized these benefits by recently proposing the creation of a standardized field in EHRs to list the UDIs of implanted devices. Additionally, the Health Information Technology Policy Committee—a federal advisory panel that includes representatives from hospitals, EHR vendors and other stakeholders—recommended the creation of financial incentives for hospitals and providers to include UDI information in patients' health records.

### ***UDI capture in claims is needed***

In addition to EHRs, documenting UDI in claims can also provide additional data on device performance. Claims—which are already used by payers, FDA and others to evaluate drug Performance—lack information on the specific devices used in care.

Incorporating UDI in claims will provide payers—including CMS—with the necessary data unavailable elsewhere to evaluate outcomes for patients with devices.<sup>8</sup> 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 based on patient outcomes.

UDI data in claims can also enable FDA’s Sentinel Initiative—a postmarket surveillance monitoring program that relies almost exclusively on claims—to evaluate the safety of medical devices. Congress instructed FDA to create the 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.<sup>9</sup>

Given Sentinel’s successes, Congress instructed FDA in 2012 to expand this system to medical devices. However, due to Sentinel’s reliance on data derived from health insurance claims that currently lack information on the devices used in care, this system cannot efficiently assess device performance until claims include UDI data. To resolve this problem, claims should also include the UDI for procedures involving implanted medical devices.

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, AHIP, 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.<sup>10</sup> Secretary of Health and Human Services Sylvia Burwell also articulated some of these benefits during the Senate confirmation process.<sup>11</sup>

***Data is critical to innovation and improved patient care***

New data collection and analysis tools—such as registries, UDI and Sentinel—on the safety and performance of medical devices provide the health system with a key opportunity to improve patient care. The utility of these new tools relies on the dissemination of findings to patients, providers, regulators, payers, manufacturers and researchers. These data will provide patients and physicians with information on the safety and effectiveness of medical products, enable payers to assess the quality of product used by beneficiaries, and give manufacturers information to improve the next generation of products.

Thank you for considering our comments, and we look forward to working with you on this important public health issue.

Should you have any questions or if we can be of assistance, please contact Josh Rising, director of medical devices at The Pew Charitable Trusts, at 202-540-6761 or [jrising@pewtrusts.org](mailto:jrising@pewtrusts.org).

Sincerely,



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

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- <sup>1</sup> National Institutes of Health, National Institute of Arthritis and Musculoskeletal and Skin Diseases, “Questions and Answers about Hip Replacement,” accessed April 1, 2014, [http://www.niams.nih.gov/health\\_info/Hip\\_Replacement](http://www.niams.nih.gov/health_info/Hip_Replacement).
  - <sup>2</sup> American Academy of Orthopaedic Surgeons, “FDA Orders Postmarket Studies on MOM Hip Implants” (2011), accessed Feb. 14, 2014, <http://www.aaos.org/news/aaosnow/jun11/clinical1.asp>.
  - <sup>3</sup> A.J. Smith et al., “Failure Rates of Stemmed Metal-on-Metal Hip Replacements: Analysis of Data From the National Joint Registry of England and Wales,” *Lancet* 379, no. 9822 (2012): 1199–204, accessed May 28, 2014, <http://www.ncbi.nlm.nih.gov/pubmed/22417410>.
  - <sup>4</sup> Food and Drug Administration, Center for Devices and Radiological Health, “Strengthening Our National System for Medical Device Postmarket Surveillance” (2012), accessed Feb. 19, 2014, <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM301924.pdf>.
  - <sup>5</sup> Office of the National Coordinator for Health Information Technology, “Connecting Health and Care for the Nation: A 10-Year Vision to Achieve an Interoperable Health IT Infrastructure,” (June 5, 2014) accessed July 18, 2014, <http://healthit.gov/sites/default/files/ONC10yearInteroperabilityConceptPaper.pdf>.
  - <sup>6</sup> R.M. Portman, letter to Jerry A. Menikoff at Health and Human Services’ Office for Human Research Protections, Sept. 23, 2013, accessed Feb. 20, 2014, <http://www.sts.org/sites/default/files/documents/Registry%20Coalition%20-%20Letter%20to%20J%20Menikoff%20OHRP%20Sept%20%202013.pdf>.
  - <sup>7</sup> Food and Drug Administration, “Unique Device Identification (UDI),” (2014) accessed July 18, 2014, [http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/default.htm?utm\\_source=Members-Only%20Updates](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/default.htm?utm_source=Members-Only%20Updates).
  - <sup>8</sup> The WEDI Foundation, “Unique Device Identifiers: Facilitating the Capture and Transmission of UDI,” white paper, April 7, 2014, accessed July 18, 2014, [http://www.pharmamedtechbi.com/~media/Supporting%20Documents/The%20Gray%20Sheet/40/15/WEDI\\_UDI\\_White\\_Paper\\_04072014%20Final.pdf](http://www.pharmamedtechbi.com/~media/Supporting%20Documents/The%20Gray%20Sheet/40/15/WEDI_UDI_White_Paper_04072014%20Final.pdf).
  - <sup>9</sup> Food and Drug Administration, “FDA Drug Safety Communication: FDA approves label changes to include intestinal problems (sprue-like enteropathy) linked to blood pressure medicine olmesartan medoxomil” (July 3, 2013), accessed July 18, 2014, <http://www.fda.gov/Drugs/DrugSafety/ucm359477.htm>.
  - <sup>10</sup> AARP et al., letter to Margaret Weiker at The Accredited Standards Committee X12, April 7, 2014, accessed July 18, 2014, <http://www.ncvhs.hhs.gov/140610p49.pdf>; American College of Cardiology et al., letter to the National Coordinator for Health Information Technology, Food and Drug Administration, Centers for Medicare & Medicaid Services, May 29, 2014, accessed July 18, 2014, <http://www.ncvhs.hhs.gov/140610p54.pdf>; S. Kilpinen, testimony to the National Committee on Vital and Health Statistics, Subcommittee on Standards, June 10, 2014, accessed July 18, 2014, <http://www.ncvhs.hhs.gov/140610p26.pdf>.
  - <sup>11</sup> Hearing on the nomination of the Secretary of Health and Human Services-Designate Sylvia Mathews Burwell, Before the Senate Committee on Health, Education, Labor, and Pensions, 113<sup>th</sup> Cong. (May 8, 2014) (statement of Sylvia Mathews Burwell, Secretary of Health and Human Services-Designate).