THE PEW CHARITABLE TRUSTS

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February 29, 2016

Dr. Robert Califf
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

Dear Commissioner Califf:

Congratulations on your confirmation as Commissioner of the U.S. Food and Drug Administration. As an independent, non-profit research and public policy organization with a number of initiatives focused on improving Americans' health, The Pew Charitable Trusts looks forward to working with you on concrete steps to address the critical public health issues of medical device safety, drug safety, food safety, and antibiotic resistance.

***Medical device safety***

We thank you for supporting a stronger national postmarket surveillance system for medical devices. We are pleased that improving FDA's ability to collect and analyze post-market data for medical products will be one of your priorities as Commissioner,[1] and that you have emphasized the importance of including unique device identification data in Medicare claims.[2] Including this information in claims is an essential component of the FDA's long-term medical device surveillance plan.[3]

As you know, millions of Americans rely on implanted medical devices, from pacemakers to artificial heart valves and joints, and their numbers will only grow as our population ages. Unfortunately, the FDA currently lacks the data it needs to actively identify safety problems with these products. We commend the FDA for recognizing this problem and implementing the unique device identification (UDI) system, which now assigns each product an identifying code. However, the promise of this system to allow active surveillance will not be realized until Medicare collects these codes, which will unlock the data for regulators and researchers. It will help us identify problem devices more quickly, lead to greater patient safety and help manufacturers improve device performance.

As you know, FDA's Sentinel Initiative allows for analysis of prescription drug safety signals in a dataset of well over 100 million individuals. Congress has required that FDA expand the Sentinel model to devices, but this has not been possible to date as insurance claims do not contain identifying information about devices, as they already do for drugs.

Your commitment to work with the Centers for Medicare & Medicaid Services (CMS) to include device codes in claims data is critical. We urge you to emphasize to CMS the importance of immediate action, as the standard insurance claims form is currently undergoing revisions. If

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UDI is not included in the current update cycle, it will be years until the next opportunity. Your leadership, in conjunction with action by CMS, will ensure that this important step toward device safety surveillance is achieved.

***Drug safety***

Pew supported the development of the Compounding Quality Act of 2013, which established important patient protections from contaminated or unsafe compounded drugs, as well as the Drug Supply Chain Security Act, which created a national system to improve drug distribution security. As the FDA implements these laws, Pew looks forward to supporting our shared goal of improving drug compounding oversight. In addition, we recognize the importance of effective state oversight of compounding, in ensuring full and effective implementation of the federal law. Last week, Pew issued two reports on state oversight of pharmacy compounding.[4]

***Food safety***

Pew has worked collaboratively with FDA staff to ensure the successful implementation of the landmark Food Safety Modernization Act (FSMA), which provided the most significant changes to food safety oversight since the Great Depression. We applaud the FDA's recent release of final rules governing the safety of fresh produce and food imports. For the first time, there will be mandatory, enforceable standards aimed at minimizing contamination of fruits and vegetables intended to be eaten raw. We look forward to continuing to assist the FDA as it works to build a powerful, prevention-based food safety system.

***Antibiotic resistance***

Antibiotic resistance is a grave threat to human health. Pew recognizes the need to preserve the effectiveness of current antibiotics by encouraging their judicious use in humans and on farms, as well as to facilitate the discovery and development of needed treatments. New antibiotics are necessary to treat the tens of thousands of Americans who die each year from antibiotic-resistant infections. We look forward to continuing our work with the FDA and Congress to create a limited population approval pathway to facilitate the development of antibiotics to treat serious and life threatening infections that meet an unmet medical need. In addition, we share your commitment to collecting data on antibiotics used for food animals in order to better understand the relationship between antibiotic usage patterns and resistance trends.

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We look forward to working with you on these shared priorities. Should you have any questions or if we can be of assistance, please contact me at acoukell@pewtrusts.org.

Sincerely,

Allan Coukell
Senior Director, Health Programs
The Pew Charitable Trusts

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[1] Nomination of Dr. Robert Califf to serve as FDA Commissioner: Hearing Before the Committee on Health, Education, Labor & Pensions, United States Senate, 114th Cong. 6 (2015) (statement of Robert Califf, Commissioner nominee, Food and Drug Administration), http://www.help.senate.gov/imo/media/doc/Califf.pdf.
[2] Thomas Burton, "Senate Confirms Cardiologist Robert Califf as FDA Commissioner," *Wall Street Journal*, Feb. 24, 2016, http://www.wsj.com/articles/senate-confirms-cardiologist-robert-califf-as-fda-commissioner-1456337667.
[3] Center for Devices and Radiological Health, Food and Drug Administration, "Strengthening our National System for Medical Device Postmarket Surveillance," Sept. 2012, http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM301924.pdf.
[4] The Pew Charitable Trusts, "National Assessment of State Oversight of Sterile Compounding," Feb. 2016, http://www.pewtrusts.org/~/media/assets/2016/02/national_assessment_of_state_oversight_of_sterile_drug_compounding.pdf; The Pew Charitable Trusts, "Best Practices for State Oversight of Drug Compounding," Feb. 2016, http://www.pewtrusts.org/~/media/assets/2016/02/best_practices_for-state_oversight_of_drug_compounding.pdf.