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December 9, 2015

The Honorable Susan M. Collins
Chairman
Special Committee on Aging
United States Senate
G31 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Claire McCaskill
Ranking Member
Special Committee on Aging
United States Senate
628 Hart Senate Office Building
Washington, DC 20510

Dear Chairman Collins and Ranking Member McCaskill,

Last year, Americans spent nearly $374 billion on prescription drugs, a 13.1 percent increase over 2013.[1] Specialty drugs – including those used to treat conditions such as cancer and hepatitis C – represent a significant portion of this spending. However, some off-patent drugs have also been increasing in price – some markedly – even when there have been no changes made to the drugs themselves to confer additional benefit to the patient. These cases raise significant concerns for the patients who rely on these important medications and the doctors who prescribe them. Polls show that the affordability of prescription drugs is a top concern for the public.[2]

Payers and policymakers must evaluate a variety of tools to manage drug costs, including improved utilization management, mechanisms to increase competition, faster market access for generic and biosimilar drugs, outcomes- and value-based frameworks and other options. Any such analysis should take into account the public benefit of Food and Drug Administration (FDA) approval, which includes review of safety and efficacy data for new products, bioequivalence data for generic products, and manufacturing quality standards for all products.

The Food, Drug and Cosmetic Act also allows pharmacies to make customized medications for individual patients when commercially available products are not available. It is important to note that compounded drugs do not meet the same approval standards outlined above and, as such, compounding cannot become an alternative to the protections of FDA-approved manufacturing.

After well publicized safety problems in 2012 that injured hundreds and led to scores of the deaths, the FDA increased its oversight of compounding facilities conducting over 200 inspections and issuing approximately 60 warning letters.[3] Indeed, while FDA visits to drug

[1] IMS Institute for Healthcare Informatics, "Medicines Use and Spending Shifts: A Review of the Use of Medicines in the US in 2014." April 2015. Available at: http://www.theimsinstitute.org/en/thought-leadership/ims-institute/reports/medicines-use-in-the-us-2014
[2] http://kff.org/health-costs/poll-finding/kaiser-health-tracking-poll-october-2015/
[3] U.S. Food and Drug Administration, "Compounding: Inspections, Recalls, and other Actions." http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339771.htm

production plants far exceed compounding inspections,[4] warning letters to the latter facilities exceed those to the former in FY 2014 (25 versus 20).[5]

As you consider mechanisms to ensure that patients have access to essential medicines at sustainable prices, we urge you to consider the importance of bioequivalence testing and manufacturing quality in protecting patient safety and drug efficacy, and to recognize the long-term importance of ensuring that manufacturers continue to take their products through the FDA approval process.

Sincerely,

Allan Coukell
The Pew Charitable Trusts

CC: Members of the Senate Special Committee on Aging

[4] U.S. Food and Drug Administration, FY 2016 Budget Justification, Field Human Drugs Program Activity. http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/UCM388309.pdf
[5] Joanne S. Eglovitch, The Gold Sheet, "FDA's Blizzard of Enforcement at Compounding Pharmacies Evident in GMP Warning Letters for FY 2014" February 26, 2015