THE PEW CHARITABLE TRUSTS

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February 3, 2016

Congressman Jason E. Chaffetz
Chairman
House Committee on Oversight
and Government Reform
2157 Rayburn House Office Building
Washington, DC 20515

Congressman Elijah E. Cummings
Ranking Member
House Committee on Oversight
and Government Reform
2471 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Chaffetz and Ranking Member Cummings,

As you convene the Government Reform Committee hearing on "Developments in the Prescription Drug Market: Oversight" on February 4, 2016, we write to urge that when exploring tools to ensure that patients have access to affordable drugs, you also recognize the importance of ensuring the safety and effectiveness of those medications. Proposals to rely on compounded drugs to address pricing concerns dangerously circumvent the Food and Drug Administration approval process, which is essential to ensuring that the benefits of medications outweigh their risks.

The Pew Charitable Trusts is a national nonprofit dedicated to advancing research and policy in the interest of the public. We have longstanding areas of work in the areas of drug quality, safety, and access.

Polls show that the affordability of prescription drugs is a top concern for the public.[1] Last year, Americans spent nearly $374 billion on prescription drugs, a 13.1 percent increase over 2013.[2] 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.

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.

We are concerned about proposed solutions that could significantly compromise patient safety, specifically: relying on pharmacy compounding to produce alternate supplies of Food and Drug Administration (FDA) approved drugs. Compounding drugs solely for the purpose of creating a low-

[1] http://kff.org/health-costs/poll-finding/kaiser-health-tracking-poll-october-2015/
[2] 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

cost alternative to FDA approved products may expose patients to unknown risks, and threatens to undermine the critical protections built into the drug-approval system.

The Food, Drug and Cosmetic Act allows pharmacies to make customized medications for individual patients when commercially offered products are not available. But compounded drugs are not equivalent to approved drugs. They 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 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 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]

Quality is not the only issue. Allowing compounded drugs — even if made at a regulated facility — to be a market alternative to FDA-approved products creates a disincentive to take products through the approval process. The approval process is essential to ensuring that drugs have been tested so that patients know that they drugs they are taking are safe and effective.

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. Patients with legitimate clinical needs for compounded drugs should receive those products. However, we should not rely on compounding as a solution to the challenges of managing high drug costs.

Sincerely,

Allan Coukell
The Pew Charitable Trusts

CC: Members of the House Committee on Oversight and Government Reform

[3] U.S. Food and Drug Administration, "Compounding: Inspections, Recalls, and other Actions." http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339771.htm
[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