THE PEW CHARITABLE TRUSTS

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January 28, 2016

The Honorable Lamar Alexander
Chairman
Senate Committee on Help,
Education, Labor and Pensions
428 Senate Dirksen Office Building
Washington, DC 20510

The Honorable Patty Murray
Ranking Member
Senate Committee on Help,
Education, Labor and Pensions
428 Senate Dirksen Office Building
Washington, DC 20510

Dear Chairman Alexander and Ranking Member Murray,

As you convene the Health, Education, Labor and Pensions hearing on "Generic Drug User Fee Amendments: Accelerating Patient Access to Generic Drugs" on January 28, 2016, we write to urge that when considering measures 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 – drugs made by pharmacies – 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.

Generic competition for off-patent drugs can keep price increases in check. To function well, the generic market depends on timely FDA approvals. But it also depends on the presence of generic

[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

drug companies that wish to compete. Allowing compounded drugs – which do not go through approvals – to enter the market runs the risk of undermining incentives for drug companies to develop generic drugs. Moreover, it exposes patients to drugs that have not met the bioequivalence standards or manufacturing quality standards required for FDA-approved products.

An approved drug is more than the active ingredient: it is a combination of active and inert ingredients, as well as a specific formulation (e.g. tablet, capsule, injection, cream) – all factors that affect the potency and stability of the drug, and how well it is absorbed by the body. This means a new ingredient combination, or a new formulation, can affect a drug's safety and effectiveness. Indeed, any manufacturer that wishes to create a new combination or formulation must secure additional FDA approval.

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 Committee on Health, Education, Labor and Pensions