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POLICY & ACTION FROM CONSUMER REPORTS

April 6, 2017

President Donald J. Trump
The White House
1600 Pennsylvania Avenue
Washington, D.C. 20500

Dear President Trump,

Consumers Union, the policy arm of Consumer Reports¹, writes to express our support for the request made by Congressman Doggett and 50 other Members of Congress in a letter sent to you on April 4, to use existing law to protect taxpayers' rights, frequently referred to as "march-in authority" to address the serious problem of high prescription drug prices. Unaffordable drug prices affect millions of consumers, leading to poor health outcomes and financial distress, and must be addressed by policymakers.

Currently, the National Institutes of Health (NIH) has the ability to address high prices for drugs developed with taxpayer money. Estimates are that nearly 40% of all basic science research is paid for with tax money through federal and state governments. When taxpayer dollars help fund research and result in a new drug patent, NIH can require drug patent holders to license these patents to third parties, in certain situations. For example, the prostate cancer drug Xtandi was developed at the University of California, Los Angeles with taxpayer money in the form of research grants and yet, Americans pay two to four times more for this drug than consumers in other high-income countries. Under the Bayh-Dole Act of 1980, NIH may instruct drug companies to license their patents to third parties when "action is necessary to alleviate the health and safety needs which are not reasonably satisfied" or when patent-protected drugs are not "available to the public on reasonable terms."²

Despite NIH having this authority, the agency has not exercised it to date. It has also not written clarifying guidelines on the circumstances which would trigger use of this authority. With skyrocketing prescription drug prices, market conditions now, more than ever, warrant NIH action and the development of guidelines to clarify in which situations it will exercise these

¹ Founded in 1936, *Consumer Reports* is an expert, independent, nonprofit organization whose mission is to work for a fair, just, and safe marketplace for all consumers, and to empower consumers to protect themselves. Using its more than 50 labs, auto test center, and survey research center, the nonprofit rates thousands of products and services annually. Consumer Reports has over 8 million subscribers to its magazine, website, and other publications. Its policy and advocacy division, Consumers Union, works for health reform, food and product safety, financial reform, and other consumer issues in Washington, D.C., the states, and the marketplace. This division employs a dedicated staff of policy analysts, lobbyists, grassroots organizers, and outreach specialists who work with the organization's more than 1 million online activists to change legislation and the marketplace in favor of the consumer interest.

² Respectively, 35 U.S.C. §203(a)(2) and 35 U.S.C. §201(f).

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rights, both for the protection of consumers' health and financial wellbeing, as well as the taxpayer investment in research and development.

Spikes in drug prices, as well as prices that are consistently too high, have been widely reported in the news and confirmed by Consumer Reports' own, nationally representative surveys. Our 2016 poll found that nearly one-third of people who regularly take at least one prescription drug experienced unexpected price spikes, averaging \$63 extra in their out-of-pocket drug costs in the prior 12 months. American consumers paid an estimated \$2 billion out of pocket for a drug they regularly take.³ High and rising drug prices are rightfully a major concern for the nearly 60% of adults who take a prescription drug.⁴

Our survey, as well as the research of others, show that when people are unable to afford their medications, they frequently cut corners in ways that could be harmful to their health.⁵ They might skip filling a prescription or take less of a medication than prescribed, which can lead to poor health outcomes and higher healthcare costs in the long run. The consequences of high drug prices are painful and real, both financially and in terms of the health of Americans, and must be addressed.

Consumers Union believes that the appropriate exercise by NIH of taxpayer protection rights would be an important step toward addressing the significant burden of high drug prices on consumers. Developing guidance on Bayh-Dole is a modest, but necessary, step toward that goal and we look forward to your supporting that approach.

Sincerely,



Betsy Imholz
Special Projects Director



Victoria Burack
Health Policy Analyst

Cc: Francis S. Collins, M.D., Ph.D.
Director, National Institutes of Health

³ Consumer Reports National Research Center poll of more than 2,000 adults, March 10-17, 2016, <http://www.consumerreports.org/drugs/as-drug-prices-increase-quality-of-life-goes-down/>

⁴ As of 2011-12, nearly 3 in 5 Americans over age 20 take at least one prescription drug. As of 2012, those taking five or more drugs has doubled since 1999-2000 to 15% of all Americans. Elizabeth D. Kantor et al. *Trends in Prescription Drug Use Among Adults in the United States From 1999-2012*. *JAMA*. 2015;314(17):1818-1830

⁵ For example, sixteen percent of diabetes patients in Medicare fail to fill at least one prescription a year because of the cost, according to Williams J, Steers WN, Ettner SL, Mangione CM, Duru OK. 2013. "Cost-related Nonadherence by Medication Type among Medicare Part D Beneficiaries with Diabetes". *Medical Care*. 2013; 51(2):193-198

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