



February 28, 2017

Senator Bernie Sanders
332 Dirksen Senate Office Building
Washington, DC 20510

Dear Senator Sanders,

The Pew Charitable Trusts is an independent, non-partisan research and policy organization with a health portfolio that includes initiatives on enhancing the security of drug manufacturing and supply chain and on addressing the rising costs of prescription medications.

Americans spent approximately \$310 billion on prescription drugs in 2015, after accounting for rebates and other price discounts.¹ This is projected to increase six to nine percent annually through 2021, faster than health care overall.^{2,3} Over three-quarters of Americans now believe the cost of prescription drugs is unreasonable, and most favor additional steps to keep prescription drug costs down.⁴

Multiple factors affect drug spending growth, but the largest contributors are spending on new, brand-name drugs and year-on-year increases in prices for existing branded drugs.⁵ Although these innovative products often deliver significant health benefits to patients compared with existing therapies, many have very high costs by historical standards.

Policymakers should consider a variety of tools to manage drug spending, and Pew has undertaken an analysis of many of these approaches, including policies to: increase generic competition; allow for price negotiation in Medicare Part D; and reform how Medicare pays for

¹ IMS Institute for Healthcare Informatics, "Medicines Use and Spending in the U.S.: A Review of 2015 and Outlook to 2020." April 2016. Available at: <http://www.imshealth.com/en/thought-leadership/quintilesims-institute/reports/medicines-use-and-spending-in-the-us-a-review-of-2015-and-outlook-to-2020>

² Centers for Medicare & Medicaid Services, "National Health Expenditure Projections 2016-2025." Available at: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/proj2016.pdf>

³ IMS Institute for Healthcare Informatics, "Outlook for Global Medicines through 2021." December 2016. Available at: http://www.imshealth.com/en/thought-leadership/quintilesims-institute/reports/outlook_for_global_medicines_through_2021

⁴ Kaiser Family Foundation, "Kaiser Health Tracking Poll: September 2016." September 2016. Available at: <http://kff.org/health-costs/report/kaiser-health-tracking-poll-september-2016/>

⁵ The Pew Charitable Trusts, "What's Driving Increased Pharmaceutical Spending?" May 2016. Available at: <http://www.pewtrusts.org/en/research-and-analysis/analysis/2016/05/26/whats-driving-increased-pharmaceutical-spending>

drugs in Part B, including biosimilars. These analyses are available at <http://www.pewtrusts.org/en/projects/drug-spending-research-initiative>.

Importation of prescription drugs from countries that limit drug prices may give Americans access to some medicines at lower prices. Competition from imports could also put long-term pressure on drug companies to reduce the price of their products in the U.S. However, large-scale importation could potentially strain the supply of pharmaceuticals in other countries. Foreign governments seeking to protect their own drug supply may limit export of drugs to the United States. It is difficult to estimate potential savings of such a program without knowing how many entities would participate, but the Congressional Budget Office (CBO) evaluated a 2003 proposal that would have required the Secretary of Health and Human Services to issue regulations permitting pharmacists, wholesalers, and individuals to import prescription drugs from 25 countries, including Canada.⁶ While acknowledging the difficulty in predicting the effects of drug importation, CBO estimated that the proposal would have produced “at most a modest reduction in prescription drug spending in the United States,” approximately \$40 billion over 10 years.⁷ In addition, CBO stated that permitting importation only from Canada would produce a negligible reduction in drug spending.

Against those potential savings, Congress must weigh the effect of importation on the pharmaceutical supply chain security provisions that Congress enacted in the Drug Quality and Security Act (DQSA) of 2013. This law protects public health by establishing a national drug supply chain security system that requires every package of drug product sold in the U.S. to carry a product identifier that will enable electronic tracing of that product throughout the drug supply. By 2023, all manufacturers, repackagers, wholesalers and pharmacies must participate in this system, creating an interoperable electronic drug security system that can track every unit of drug product, everywhere in the supply chain. This will make it easier to detect when counterfeit or illegal product is introduced into the system, and will significantly enhance the speed and accuracy of implementing product recalls.

The Affordable and Safe Prescription Drug Importation Act attempts to integrate importation provisions with the DQSA; however, significant gaps remain that would compromise the security of the U.S. supply chain. While in many circumstances foreign sellers would be required to purchase from FDA-registered facilities, it is unclear how that requirement would be enforceable, particularly given the profit potential for entities that purchase from illegal sources and sell to the U.S. market. Even if it were, product would be sold into the U.S. system without the product identifiers necessary to allow a fully electronic and interoperable drug security system, thus making it difficult for supply chain partners who encounter product that is not DQSA-compliant to determine which products are counterfeit or otherwise illegal, and which are legally imported.

This poses a safety risk with respect to imported product, but also undermines the entire system, which depends on being able to flag non-compliant product as being potentially counterfeit or otherwise illegal. With a steady supply of non-compliant product coming over the border, or through online pharmacies, it will be very difficult, and potentially impossible, to distinguish

⁶ H.R. Pharmaceutical Market Access Act of 2003.

⁷ Congressional Budget Office, “Would Prescription Drug Importation Reduce U.S. Drug Spending?” April 2004. Available at: <https://www.cbo.gov/sites/default/files/108th-congress-2003-2004/reports/04-29-prescriptiondrugs.pdf>

product that is non-compliant because it is authorized under this legislation from product that poses a risk to public health.

We appreciate your commitment to addressing the significant problem of increasing drug costs, and would welcome the opportunity to work with you going forward to address the rising price of drugs in a way that would not compromise the safety of the drug supply.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Allan Coukell', written in a cursive style.

Allan Coukell
Senior Director, Health Programs