GUIDE TO THE ISSUES

HOUSE REPUBLICAN POLICY COMMITTEE
ESTABLISHED 1949

REDUCE PRESCRIPTION DRUG COSTS FOR AMERICANS

According to polling from the Kaiser Family Foundation, more than three quarters of Americans say the cost of prescription drugs is unreasonable.[1] Americans also pay higher prices for drugs than patients around the world.[2] Congress must ensure that the drug marketplace is competitive in a manner that rewards innovation and benefits consumers.

Quick Take

Policymakers must balance the marketplace incentive for innovation with the need for competition that benefits consumers.

Congress must create patent certainty, ensure the ability of generic manufacturers to compete when patents and exclusivity periods expire, and allow safe reimportation of drugs.

BACKGROUND

As of 2018, 90 percent of prescriptions filled in the United States are low-cost generics which account for roughly 22 percent of total drug spending.[3] Most increases in prescription drug spending are driven by brand-name drugs, biologics, and specialty drugs.[4] One of the greatest challenges facing drug innovators is recovering the cost of developing a specific drug or biologic and generating a profit while they have a temporary government-sanctioned monopoly.

As such, brand-name market focus tends to be on drugs that will reach a relatively large number of patients with chronic conditions which require ongoing prescriptions. For example, Humira,[5] a biologic which treats conditions such as rheumatoid arthritis, Crohn's disease, and psoriasis, accounted for $18.3 billion in non-discounted prescription drug spending in 2018 alone.[6] Even a therapy as well-known as Humira treats a relatively small portion of the U.S. population (4.2 million prescriptions in 2016) when compared to a drug like Metformin HCL which treats high blood sugar (81.3 million prescriptions in 2016).[7]

On the other end of the volume spectrum are so-called "orphan" drugs which treat illnesses in a relatively small population, usually less than 200,000 individuals. Federal law provides several incentives for manufacturers of orphan drugs through the Orphan Drug Act of 1983 and subsequent amendments.[8] Even so, the median cost of orphan drugs in 2017 was "more than $46,800 per year."[9] On a more positive note, "the median annual cost for the top ten rare disease therapies used by the greatest number of patients was much lower at $1,216."[10] These cost figures effectively demonstrate the challenge of balancing the marketplace incentive for innovation with the need for competition that benefits consumers.

Once a drug manufacturer's patent or exclusivity period expires, generic manufacturers produce the same or similar medication at a radically reduced cost. As such drug innovators have every incentive to protect their monopoly pricing power for as long as possible. This has led to the so-called creation of patent thickets where manufacturers seek to patent process numerous technical or process aspects of drug or biologic production that effectively extend patent protection long after a patent expires on the drug itself. For example, Humira's primary patent expired in 2016, but related patents extend to "2034—providing more than double the protection span a drug such as Humira might normally expect."[11] Delaying the opportunity for generics directly leads to higher drug costs.

CONSTITUTIONAL AUTHORITY AND REPUBLICAN PRINCIPLES

The Constitution authorizes Congress to promote the general welfare of the United States.[12] Congress must protect a competitive drug marketplace which will reduce costs for consumers.

POLICY SOLUTIONS

All prescriptions are not created equally. Some have been around for decades, are effective treatments, and are affordable in generic form. Others represent cutting-edge biotechnology, treat relatively small populations, and are exceptionally expensive branded drugs and biologics. Congress has several tools at its disposal to address drug prices:

- Allow reimportation of drugs that meet FDA standards. Significant price differences for the same drugs and biologics sold inside and outside of the United States are well-established.[13] Allowing for the safe reimportation of drugs purchased from foreign countries would likely result in cost savings for consumers. Currently, four states enacted laws to promote federal importation of prescription drugs in 2019.[14]

- Address practices that unnecessarily delay generic alternatives coming to market. Congress has many options to make lower-cost generic drugs and biologics available as soon as patents expire.[15] Options include streamlining unnecessary regulatory requirements, limiting frivolous petitions against generic drug approvals, ensuring generic manufacturers' access to drug samples, or curbing reverse-payment settlements which delay generics coming to market.

- Reduce the so-called "patent thicket" in the area of pharmaceuticals by considering a "one-and-done" approach to patents and market exclusivities in coordination with the Food and Drug Administration's approval process.[16] Doing so acknowledges the unique intellectual property issues attendant to pharmaceuticals.

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[1] Kaiser Family Foundation, *Public Opinion on Prescription Drugs and Their Prices* (Nov. 20, 2019), https://www.kff.org/slideshow/public-opinion-on-prescription-drugs-and-their-prices/.

[2]Assistant Secretary for Planning and Evaluation, U.S. Dept. of Health and Human Services, *Comparison of U.S. and International Prices for Top Medicare Part B Drugs by Total Expenditures* (Oct. 25, 2018), https://aspe.hhs.gov/system/files/pdf/259996/ComparisonUSInternationalPricesTopSpendingPartBDrugs.pdf

[3] Association for Affordable Medicine, *The Case for Competition: 2019 Generic Drug & Biosimilars Access & Savings in the U.S. Report* 4 (2019), https://accessiblemeds.org/sites/default/files/2019-09/AAM-2019-Generic-Biosimilars-Access-and-Savings-US-Report-WEB.pdf.

[4] Suzanne M. Kirchhoff, Judith A. Johnson, and Susan Thaul, Cong. Research Serv., R44832, *Frequently Asked Questions About Prescription Drug Pricing and Policy* 9 (2018), https://fas.org/sgp/crs/misc/R44832.pdf.

[5] Adalimumab is the generic name.

[6] Murray Aitken and Michael Kleinrock, *Medicine Use and Spending in the U.S.: A Review of 2018 and Outlook to 2023* (2019), IQVIA Institute for Human Data Science, https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/medicine-use-and-spending-in-the-us---a-review-of-2018-outlook-to-2023.pdf?_=1573664654948.

[7] ClinCalc.com, *The Top 300 of 2016* (2016), https://clincalc.com/DrugStats/Top300Drugs.aspx.

[8] PL 97-414 (1983) and 21 CFR 360c.

[9] Murray Aitken and Michael Kleinrock*, Orphan Drugs in the United States: Growth Trends in Rare Disease Treatments* (2018), IQVIA Institute for Human Data Science, https://www.iqvia.com/insights/the-iqvia-institute/reports/orphan-drugs-in-the-united-states-growth-trends-in-rare-disease-treatments.

[10] *Id.*
[11] Cynthia Koons, *This Shield of Patents Protects the World's Best-Selling Drug*, Bloomberg Business, Sept. 7, 2017, https://www.bloomberg.com/news/articles/2017-09-07/this-shield-of-patents-protects-the-world-s-best-selling-drug.
[12] U.S. Const. art. 1, § 8.
[13] Assistant Secretary for Planning and Evaluation, *supra*, note 2.
[14] Steven Findlay, *States Pass Record Number of Laws to Reel In Drug Prices,* Kaiser Health News, Sept. 9, 2019, https://khn.org/news/states-pass-record-number-of-laws-to-reel-in-drug-prices/.
[15] *See generally*, Aaron S. Kesselheim, *Strategies That Delay Market Entry of Generic Drugs*, The Commonwealth Fund, Sept. 18, 2017, https://www.commonwealthfund.org/publications/journal-article/2017/sep/strategies-delay-market-entry-generic-drugs.
[16] https://www.statnews.com/2019/02/11/drug-patent-protection-one-done/