

May 22-23, 2018

The Rise in Prescription Drug Costs

Senators and House members should introduce, co-sponsor and pass legislation to establish greater transparency in drug pricing, remove anti-competitive industry practices that create barriers to generics coming to market, take into account value in payment and coverage for prescriptions, and provide authority to the federal government to negotiate drug discounts under the Medicare Part D program, as described below in the "What is ACP Asking of Congress" section.

What's it all about?

Over the past several years, there has been a dramatic rise in the cost of many prescription drugs in this country. This applies not only to specialty drugs that treat life-threatening illness like cancer, but also common drugs like antibiotics that treat bacterial infections. That, coupled with several recent high-profile "price gouging" cases, has vaulted the issue of rising prescription drug costs into the forefront of public concern, with voters across the partisan spectrum supporting action by Congress to lower Rx prices. (View a Kaiser Family Foundation poll on prescription drug costs). In 2016, prescription drug costs accounted for 10 percent of the United States' total health expenditure with a growth rate of 1.3 percent over the previous year, or approximately \$328.6 billion. In 2014, prescription drug spending grew 12.4 percent to \$297.7 billion and accounted for 9.9 percent of total health expenditures. In 2015, prescription drug spending grew 9 percent to \$324.6 billion and accounted for 10 percent of total health expenditures. That is significant, considering 7 out of 10 Americans take at least one prescription drug.

The advent and continued development of prescription drugs has improved the quality of life for millions of patients worldwide who depend on prescription drugs; efforts to address unsustainable and unjustified price increases must not stifle the discovery of new drugs. However, if steps are not taken now to address the problem of rising and unsustainable drug pricing, both by the federal government and manufacturers alike, the very life-saving benefit these drugs were designed to provide could be lost to many, who simply will not be able to afford them. Rising and unsustainable drug prices also will put a strain on Medicare, Medicaid, and other payers' expenditures, forcing trade-offs as more dollars need to be allocated to support excessively priced medication at the expense of reduced benefits for other needed services, higher premiums, and higher taxes.

✓ View CMS National Health Expenditures Projections 2017-2026

What's the current status?

Last year unfortunately, when Congress reauthorized the Food and Drug Administration (FDA) to collect user fees from manufacturers of prescription brand drugs, medical devices, generic drugs and biosimilars, it chose not to address the problem of rising prescription drug prices as part of that bill, the Food and Drug Administration Reauthorization Act (FDARA). Congress did take some action in the Bipartisan Budget Act of 2018 to help seniors enrolled in the Medicare Part D prescription drug program: 1) to make lower-cost biosimilars eligible (they were excluded) for the same 50 percent discount as name-brand biologics are when a beneficiary enters the Part D program coverage gap, known as the "donut hole"; and 2) accelerated the closing of the "donut hole" so beneficiaries are responsible for a lesser portion of their prescription drug costs. However, Congress declined to take any further concrete action during the legislative session to develop, debate, or pass any reforms that could help bring down the high cost of prescription drugs. The Trump Administration has expressed a willingness and intention to address high drug costs, and included as part of its fiscal year 2019 budget proposal, a Medicaid drug coverage demonstration program, making more rebates available to seniors under Part D, and getting rid of generic cost sharing and capping out of pockets costs for seniors under Part D. On May 11, the President unveiled a plan to help bring down drug costs, which ACP is currently evaluating.

Why and how should Congress address this issue?

Federal and state governments, as both a major source of prescription drug coverage (Medicare, Medicaid, other public programs) and as a regulator (FDA), has an obligation to be part of the solution to the rising cost of prescription drugs. However, there is no one solution to this problem. The research, development, regulatory, and payment systems for prescription medication are deeply intertwined, and addressing the pressing issue of drug pricing and payment will take comprehensive efforts to increase transparency, accountability, and stewardship. Various components have been mentioned as contributing to the rise in prescription drug costs, including lack of pricing transparency; regulatory barriers; health plan benefit structures; and loopholes that may keep lower cost drugs shut out of the market. All of these issues must be addressed in order to achieve meaningful change, and it will take an act of Congress to do it. With drug pricing escalating as it has been and public support for Congress to address this growing issue, the time is ripe now for Congress to step up and do its part to enact reforms that reverse this growing trend of price increases.

What is ACP asking of Congress?

Senators and Representative should increase transparency and accountability in prescription drug pricing and improve access to lower-cost generic medications by cosponsoring or introducing the following bills and urging their enactment:

The Drug Price Transparency in Communications Act, (S. 2157 in the Senate, no House version). This bill would require drug companies to disclose the Wholesale Acquisition Cost of an Rx in Direct-to-Consumer Advertising. Senators should cosponsor S. 2157 and representatives should introduce the companion bill in the House.

The Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act of 2017, (S. 974 in the Senate and H.R. **2212 in the House).** This bill would improve patient access to alternative low-cost prescription drugs and biological products by preventing prescription drug manufacturers from misusing the FDA's Risk Evaluation and Mitigation Strategies (REMS) process to make it difficult for competing generics to be brought to the market. Senators and representatives should cosponsor the bill in their respective chambers.

The Medicare Prescription Drug Price Negotiation Act of 2017, (S. 41 in the Senate and H.R. 242 in the House). This bill would grant authority to the Secretary of HHS to negotiate prescription drug prices with manufacturers for high-cost drugs and biologics covered under Part D of the Medicare program. Senators and representatives should cosponsor the bill in their respective chambers.

The Fair Accountability and Innovative Research (FAIR) Pricing Act, (S. 1131 in the Senate and H.R. 2439 in the House), would require drug manufacturers to disclose and provide more information about planned drug price increases, including research and development costs. Senators and representatives should cosponsor the bill in their respective chambers.

Consider incorporating the <u>recommendations</u> of the Campaign for Sustainable Drug Pricing, of which ACP is a member, in any legislation to address rising prescription drug prices. ACP has endorsed the Campaign's call for greater transparency, competition, and consideration of value.

- ✓ <u>View</u> ACP's 2016 policy paper on *Stemming the Escalating Cost of Prescription Drugs*
- ✓ View ACP's support letter on S. 41, the Medicare Prescription Drug Price Negotiation Act of 2017
- ✓ View ACP's support letters for <u>S. 974</u> and <u>H.R. 2212</u>, the CREATES Act

Who can I contact to learn more?

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