

May 23-24, 2017

## The Rise in Prescription Drug Costs

**Congress should take action to introduce, co-sponsor and enact 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. The pending legislation to reauthorize and fund the Food and Drug Administration (FDA)'s "user fee" program offers an opportunity to include such policies, 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 2013, prescription drug costs accounted for 9.3 percent of the United States' total health expenditure with a growth rate of 2.4 percent over the previous year, or approximately \$263.5 billion. In 2014, prescription drug spending grew 12.2 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 2015 Highlights

### What's the current status?

The current statutory authority for the Food and Drug Administration (FDA) to collect user fees from manufacturers of prescription brand drugs, medical devices, generic drugs and biosimilars will expire on September 30<sup>th</sup>. Congress must reauthorize the prescription drug user fee amendments (PDUFA), the medical device user fee amendments (MDUFA), the generic drug user fee amendments (GDUFA), and the biosimilar user fee amendments (BsUFA) or the FDA will no longer have the resources to approve these products in a timely manner. Reauthorization of these programs has long had bipartisan support in Congress. Currently, the House Energy and Commerce and the Senate Health, Education, Labor and Pension Committees have released draft legislation, the Food and Drug Administration (FDA) Reauthorization Act of 2017, that rolls up together the reauthorization of PDUFA, MDUFA, GDUFA, and BsUFA, and have held hearings and "markups" on this bill. Actions taken by Congress on this legislation this year will reshape the way prescription drugs move through the drug approval process for the next five years, until the next reauthorizations of the UFAs, creating opportunities to address the problem of rising prescription drug prices in the final bill.

President Trump has [expressed a desire](#) "to work in a bipartisan fashion to ensure prescription drug prices are more affordable for all Americans, especially those who need lifesaving prescription medications. Reforming the Food and

Drug Administration and reducing the regulatory burdens on drug manufacturers so as to enhance competition will help accomplish those goals.”

### Why should the 115<sup>th</sup> Congress address it?

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?

**Increase transparency in drug pricing by requiring pharmaceutical manufacturers to publically disclose production costs including research and development investments for specific high-cost drugs as identified by the HHS Secretary through regulation, as contained in the Fair Accountability and Innovative Research (FAIR) Drug Pricing Act, S. 1131.** Unlike many other industrialized and developed countries, the United States lacks regulatory authority to control the price of drugs or devices. As a result, pharmaceutical companies may price drugs at will and there is very little transparency or understanding of how companies arrive at the price of a drug.

**Senators and Representatives should cosponsor 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, which 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.** Samples are needed by low-cost manufacturers in order to collect enough data to develop and produce generics and low-cost alternatives and sometimes prescription drug manufacturers abuse the REMS process by not providing these samples. The CREATES Act attempts to stop these anti-competitive actions by determining when the denial of adequate samples have occurred and establishes a pathway for the lower-cost manufacturer to bring a cause of action in federal court for injunctive relief.

**Senators and Representatives should cosponsor the Medicare Prescription Drug Price Negotiation Act of 2017, S. 41 and H.R. 242, which 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.** The ACP has longstanding policy advocating for the ability of Medicare Part D to negotiate drug prices and rebates directly with pharmaceutical manufacturers as a way to lower prescription drug prices and make them more affordable to beneficiaries and the program.

**Consider incorporating the [recommendations](#) 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.**

**Incorporate the above recommendations into the FDA Reauthorization Act of 2017.**

- ✓ [View](#) 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 [S. 974](#) and [H.R. 2212](#), the CREATES Act
- ✓ [View](#) support letter from the Campaign for Sustainable Drug Pricing

### Who can I contact to learn more?

[advocacy@acponline.org](mailto:advocacy@acponline.org)

Digital version of this issue brief can be found at: <https://www.acpservices.org/leadership-day/policy-priority-issues>