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The Rise in Prescription Drug Costs

Senators and House members should develop legislation that addresses the rising cost of prescription drugs, including elements that will increase vital funding for the Food and Drug Administration (FDA), provide authority to the federal government to negotiate drug discounts, and establish greater transparency in drug pricing, as described below in the “What’s ACP’s view” 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, including among those in Congress. ([View here](#) a Kaiser Family Foundation poll on prescription drug costs). In 2013, prescription drug costs accounted for 9.3% of the United States’ total health expenditure with a growth rate of 2.4% over the previous year, or approximately \$263.5 billion. In 2014, prescription drug spending grew 12.2% to \$297.7 billion and accounted for 9.9% of total health expenditures. That is significant, considering seven 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 here](#) CMS National Health Expenditures 2014 Highlights

What’s the current status?

In the 114th Congress, a special task force on prescription drugs in the House, stemming from the Energy & Commerce Committee, was created to examine the issue of prescription drugs. The House Oversight Committee conducted a hearing on drug pricing on Feb. 4 where the focal point was the conduct of Turing Pharmaceuticals and its price increase for a 62-year old drug called Daraprim (treatment for parasitic infections) from \$13.50 a tablet to \$750. The Senate Committee on Aging has also been investigating the impact of rising prescription drug prices.

In the Administration’s FY2017 budget, the President included measures intended to combat rising prescription drug prices. The budget calls for an increase in discretionary spending for the FDA, which can be used to support and expedite the review of new and generic drug applications. It accelerates manufacturer drug discounts to provide relief to Medicare beneficiaries in the coverage gap, and it allows the Secretary of Health and Human Services (HHS) to negotiate prices for biologics and high cost prescription drugs.

Why should the 114th 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 stakeholders 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's ACP's view?

Legislation should be developed and introduced in both chambers that will include the following elements:

Increase transparency in drug pricing by requiring pharmaceutical manufacturers to publically disclose production costs including research and development investments for specific high-cost drugs that the Secretary identifies through regulation. Unlike many other 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.

Authorize and appropriate \$2.74 billion in discretionary spending for the FDA to expedite, through fast-track approval, new drugs that address unmet medical need in the treatment of a serious or life threatening condition, as well as to address the back-log of pending generic drug applications. The median approval times for standard and priority review drugs in fiscal year 2013 dropped to 12 months and 7.9 months. Drugs can move through the regulatory approval process more rapidly if they qualify for fast track designation, accelerated approval, priority review, or breakthrough therapy designation. While we are encouraged by a recent FDA report that shows the agency is approaching targets and commitments made by the agency to improve review times, we continue to advocate for additional resources for the FDA so that progress can continue on clearing the backlog. ACP also supports robust oversight and enforcement of restrictions on product-hopping, evergreening, and pay-for-delay practices as a way to increase marketability and availability of competitor products. In these practices, companies prevent generic competition from entering the market by making small adjustments to a drug with no real therapeutic value that grant the company longer patent protection, or they remove the drug from market, forcing patients to switch to a reformulated version of the same drug.

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. Medicare Part D pays on average more than other federal health care programs - 73% more than Medicaid and 80% more than the Veteran's Health Administration (VA). The VA operates as a closed system and provides care directly to veterans. They purchase drugs and other pharmaceuticals directly from manufacturers, and have a national formulary which does not exist in Medicare or Medicaid. 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 keep costs to the system down. Although the Congressional Budget Office, in a 2007 [letter](#) to Senator Wyden, contended that the savings would be negligible, other recent [estimates](#) show Medicare Part D could save \$15-16 billion a year if it were allowed to negotiate drug prices.

- [View](#) ACP's 2016 paper on Stemming the Escalating Cost of Prescription Drugs

Who can I contact to learn more?

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