



Statement for the Record
American College of Physicians
Hearing before the Senate Committee on the Judiciary,
Subcommittee on Antitrust, Competition Policy and Consumer Rights
On
The CREATES Act: Ending Regulatory Abuse, Protecting Consumers and Ensuring Drug Price
Competition
June 21, 2016

My name is Nitin Damle. I am the President of the American College of Physicians (ACP), the nation's largest medical specialty organization, representing 143,000 internal medicine physicians who specialize in primary and comprehensive care of adolescents and adults, internal medicine subspecialists, and medical students who are considering a career in internal medicine. I am a practicing physician in Wakefield, RI, and the founding and managing partner of South County Internal Medicine. I am Clinical Associate Professor of Medicine at the Alpert Medical School of Brown University. I am past president of the Rhode Island Medical Society and a past President of the Medical Staff of the South County Hospital and a member of the Board of Trustees I have been a Fellow (FACP) of the ACP since 1992, serving on its Board of Regents, as Governor of the Rhode Island Chapter, and as Chairman of ACP's Medical Practice and Quality Committee. Today, I am pleased to share with you the College's perspective on the escalating cost of prescription drugs, the impact of these costs on internal medicine physicians and their patients, and strong support of the goal of ending anti-competitive practices that keep less expensive drugs off the market, including preventing manufacturers from abusing the Risk Evaluation and Mitigation Strategies (REMS) process, something the bipartisan Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act of 2016, S. 3056, would do.

On behalf of the College, I want to express our appreciation to Chairman Lee and Ranking Member Klobuchar for convening this hearing and for your shared commitment in wanting to ensure that patients have access to lower-cost alternatives of prescription drugs and biologics. We also appreciate the Subcommittee inviting input from the physician community during the introduction of the CREATES Act. As physicians, we know that prescription drugs are a key component in the doctor's toolkit to prevent and treat disease as well as avoiding costlier health care interventions. Our testimony today will focus on the impact that the rise in prescription drug prices has on patients and the importance of access to affordable medications for patients.

OVERVIEW OF ACP VIEWS ON RISING DRUG COSTS

The reasons for the rise in drug prices are complex, with many overlapping and interconnected moving parts. Therefore various components have been mentioned as contributing to the rise in prescription drug costs, including lack of pricing transparency, regulatory barriers, a shortage of comparative clinical data between the cost-effectiveness and value of a drug, health plan benefit structures, and loopholes that allow companies to extend monopolies on brand-name drugs to keep lower-cost alternatives out of the market. These issues must be dealt with 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 from 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.

ACP recognizes that ensuring and improving patient access to prescription drugs and biologics is a growing need. Over the past several years, we have seen a dramatic rise in the cost of prescription drugs in this country. These increases apply 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 our everyday conversations, including among those in Congress.¹ The Subcommittee's hearing today being an example. Accordingly, prescription drugs' share of total health costs has risen. In 2013, prescription drug costs accounted for 9.3% of the United States' total health

¹ DiJulio B, Firth J, Brodie M. Kaiser health tracking poll: August 2015. Kaiser Family Foundation. Accessed at kff.org/health-costs/poll-finding/kaiser-health-tracking-poll-august-2015/ on 17 September 2015.

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.² That is significant, considering a majority of Americans take at least one prescription drug.³ Clearly, these increasing costs impact the majority of patients of internal medicine physicians.

However, addressing the many issues surrounding prescription drug pricing may not be as straightforward as unilateral action by a single actor. There is no magic wand. The research, development, regulatory, and payment systems for prescription medication are deeply intertwined, and the pressing issue of drug pricing and payment will require comprehensive efforts—not only by Congress, but by manufacturers, insurers, physicians, and other entities—to increase transparency, accountability, and stewardship. The intent of the CREATES Act is one approach—facilitating increased competition through the development of lower-cost alternatives—that can be part of this overall effort.

IMPACT ON PATIENTS AND THE HEALTHCARE SYSTEM

Every day, internal medicine physicians see how prescription drugs affect the lives of their patients. While the benefits associated with prescription drugs cannot be ignored, unfortunately not all patients can absorb the out-of-pocket costs for these drugs. Approximately 18 percent of retail prescription drugs were paid for out of pocket in 2012, and patients used various techniques to reduce costs, including not taking a medication as prescribed (7.8%), asking the doctor for a lower-cost medication (15.1%), purchasing drugs from another country (1.6%), or using alternative therapies.⁴

² **IMS Institute for Healthcare Informatics.** Medicines use and pending shifts: a review of the use of medicines in the U.S. in 2014. April 2015. Accessed at www.imshealth.com/en/thought-leadership/ims-institute/reports/medicines-use-in-the-us-2014 on 14 March 2016.

³ **Rocca WA, Boyd CM, Grossardt BR, Bobo WV, FinneyRutten LJ, Roger VL, et al.** Prevalence of multimorbidity in a geographically defined American population: patterns by age, sex, and race/ethnicity. *Mayo Clin Proc.* 2014; 89:1336-49. [PubMed](#) [CrossRef](#)

⁴ **Cohen RA, Villarroel MA.** Strategies used by adults to reduce their prescription drug costs: United States, 2013. *NCHS Data Brief.* 2015; (184):1-8. [PubMed](#)

The advent and continued development of prescription drugs has undoubtedly improved the quality of life for millions of patients worldwide who depend on prescription drugs. And efforts to address unsustainable and often unjustified price increases must be balanced in their approach in order not to 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 of our patients, 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.

In my own experience and at my practice in Rhode Island, which could be representative of anywhere in the country, I see firsthand the choices that patients must make about their health. A 67-year-old patient with diabetes, hypertension and heart disease can no longer afford his medications, as he has fallen into the "doughnut hole" of drug coverage. He must take brand-name drugs due to lack of cheaper generic alternatives to control his diabetes and prevent another heart attack. A 40-year-old patient with asthma cannot afford his preventive and rescue inhalers because of the high cost and his high deductible plan. There are again no generic alternatives. His non-compliance with medication will lead to an asthma exacerbation that may lead to an emergency room visit and even admission to the hospital. A third patient with rheumatoid arthritis cannot afford the immune modulating medications that are the standard of care due to the cost of the brand name medication with no generic alternatives. The inability to treat early rheumatoid arthritis with these medications will lead to more serious joint problems including joint replacement surgery and other medical complications of the disease.

These examples from just one day in my office are repeated day in and day out. Advances in medicine have been life saving but they need to be affordable to society. Non-compliance with medication regimens can lead to more serious health complications, more patients suffering from disease and more costs to society. The pharmaceutical industry needs a reasonable return on investment but there

needs to be a balance between profits and the service they provide in treating and maintaining the health of our patients.

ACP'S POSITIONS, RECOMMENDATIONS, AND ACTIVITIES REGARDING RISING DRUG PRICES

Recently, the College, by careful and considerate analysis and review through its Health and Public Policy Committee, and with final approval by its Board of Regents, developed a series of specific positions and recommendations that were published in its most recent position paper⁵ regarding escalating drug prices. The American College of Physicians (ACP) supports policies and proposals that give patients the best available information and access to prescription medications at the lowest cost possible, while acknowledging the need for a strong pharmaceutical market that fosters investment in and development of new treatments. These recommendations include ways to increase transparency and competition, leverage the purchasing power of public programs, and assessment of value as ways to lower prices. A more detailed discussion of these positions and recommendations can be found by reviewing the position paper which can be found here:

<http://annals.org/article.aspx?articleid=2506848> .

Our testimony today focuses on one element: anticompetitive practices that keep less expensive and equally effective drugs—particularly generics—off the market.

The College, along with over 80 other organizations, is a member of the Campaign for Sustainable Rx Pricing. The objective of the Campaign is to start a national and broadly-based discussion about the increasing costs of drugs. In addition to bringing attention the issue, the Campaign is interested in finding policy approaches widely-supported across the spectrum of stakeholders that can reduce drug costs. Among the Campaign's proposals for change endorsed by ACP are recommendations that foster competition and market-based solutions, including the curbing of the misuse of the Risk Evaluation and Mitigation Strategies (REMS) that can prevent lower-cost alternatives from coming to market sooner, something that the CREATES Act seeks to address.

⁵ Daniel, Hilary, Stemming the Escalating Cost of Prescription Drugs: A Position Paper of the American College of Physicians, *Ann. Intern. Med.* 2016; 165:2

COMPETITION CAN REDUCE COSTS; IMPROVE PATIENT ACCESS

The College also believes that establishing policies or programs that may increase competition for brand-name and generic drugs and biologics should be implemented.⁶ Generic drugs in the past have traditionally encouraged competition and driven costs down. When the patent protection for many branded drugs expired in 2012, resulting in a flood of new generic drugs entering the marketplace, there were considerable savings. The savings from the use of generic drugs increased 14% between 2012 and 2013, for about \$30 billion in additional savings.⁷ In January 2015, the Clinical Guidelines Committee of the ACP published best practice guidelines for the prescribing of generic medications, acknowledging that the use of generic substitutes may present the opportunity for additional cost savings to the health care system and that, “clinicians should prescribe generic medications, if possible, rather than more expensive brand-name medications.”⁸ However the ability of clinicians to prescribe safe, lower-cost alternatives to brand-name drugs is limited when there are few, if any, alternatives on the market they can prescribe.

Increasingly, the pharmaceutical marketplace is narrowing its focus to highly innovative, biologic, or specialty drugs for which there are few, if any, competitors, creating monopolies and limiting the cost-controlling power of competition. The focus on brand-name drugs and new biologics results in a greater desire for companies to protect the investments in these drugs and keeping them as profitable for as long as possible. However, limited competition—even in the generic market—can also drive up the cost of a medication. The generic manufacturing market is becoming more consolidated, and progressively some generics are being manufactured by a single company or are disappearing from the market. Limited competition – in almost any sector – limits the cost-containing power of competition. When there is no competition, patients have little choice. For example, if there is only one costly name brand drug for the patient, they really only have two options – either pay for the drug or forgo treatment and risk escalating their condition. Even the generic market is not immune to this

⁶ **Daniel, Hilary**, Stemming the Escalating Cost of Prescription Drugs: A Position Paper of the American College of Physicians, *Ann. Intern. Med.* 2016; 165:2

⁷ **Generic Pharmaceutical Association**. Generic drug savings in the U.S. Sixth annual edition: 2014. Accessed at www.gphaonline.org/media/cms/GPhA_Savings_Report.9.10.14_FINAL.pdf on 4 March 2016.

⁸ **Choudhry NK, Denberg TD, Qaseem A**. Improving Adherence to Therapy and Clinical Outcomes While Containing Costs: Opportunities From the Greater Use of Generic Medications: Best Practice Advice From the Clinical Guidelines Committee of the American College of Physicians. *Ann Intern Med.* 2016; 164(1):41-49. doi:10.7326/M14-2427

happening, single-source generics are more expensive than other generics; some health plans place these drugs in the preferred drug tier in absence of a competitor, resulting in higher costs to the patient.^{9 10} Therefore, ACP believes it is important that policies addressing the increase in prescription drug prices cover not only new entrants to the market, but also drugs that have been on the market and may be generic or single-source drugs.

There have also been anti-competitive practices by a few manufacturers of brand name drugs to prevent or delay other companies from developing alternative lower-cost products. These few brand-name manufacturers utilize the FDA's Risk Evaluation and Mitigation Strategies (REMS) process and its accompanying Elements to Assure Safe Use (ETASU) requirements in a manner that prevents development of lower-cost alternatives. In some instances, the REMS process and ETASU requirements have been used to deny availability of drug samples and participation in FDA safety protocols. Using the REMS process and ETASU requirements in this way by a few brand-name drug companies keeps lower-cost generics and biologicals off of the market, thereby decreasing patient access to lower-cost medications. As I discussed above, preventing even one manufacturer developing and supplying one lower-cost alternative to the market can have a considerable impact on patient access.

Congress has a unique role in establishing policies that may increase or restore needed competition for brand-name and generic drugs and biologics and should enact legislation to do so. The CREATES Act of 2016 attempts to stop these anti-competitive actions by determining when the denial of adequate samples and when participation in a joint-safety protocol have occurred and creates a pathway for the lower-cost manufacturer to bring a cause of action in federal court for injunctive relief. The federal court may also award damages for future deterrence of similar actions by the brand-name manufacturer. The Act will remove a delaying tactic used by a few name-brand manufacturers and

⁹ **Anthem Blue Cross Blue Shield.** Generic premium 3-tier prescription drug program Bluecare. 1 April 2011. Accessed at www.anthem.com/equote/CT/a102_14996.pdf on 4 March 2016.

¹⁰ **HMSA.** Single-source generic drugs. 14 May 2014. Accessed at <https://hmsa.com/help-center/single-source-generic-drugs/> on 4 March 2016.

make it easier and faster for other manufacturers to pursue bringing lower-cost alternatives to market and increase patient access by increasing competition.

CONCLUSION

The College would again like to sincerely thank Chairman Lee and Ranking Member Klobuchar for convening this hearing and for your shared bipartisan commitment to ensure that patients have access to lower-cost prescription drugs and biologic alternatives through this legislation. We appreciate the Committee inviting input from the physician community during introduction of the CREATES Act. Our hope is that the information shared today will provide the Subcommittee with a provider perspective on the important issue of prescription drug pricing and we stand ready to continue to serve as a resource and welcome the opportunity to work with you as you continue to advance this bill through the 114th Congress. Thank you.