

# MEDICAL STUDENT ADVOCACY AND REGION CONFERENCE 2019

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## ISSUE BRIEF: PRESCRIPTION DRUGS

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### Prescription Drug Pricing and Cost – The Facts

The rising cost of prescription medication has continued to grow inexorably from year to year. Physicians experience and see first-hand the difficulty and burden high pharmaceutical costs have imposed on our patients, on physician practices, and the broader health care system. When patients delay, forgo, or ration their medication, their health status may deteriorate. *Here are some of the facts:*

- Between 2013 and 2015, net spending on prescription medication increased by 20 percent.
- Federal payments for brand-name drugs in Part D, utilized by Medicare beneficiaries, increased 62% between 2011 and 2015 — and that's after accounting for rebates that offer discounts on drugs sticker prices, while the number of actual prescriptions fell 17% over the same period.
- More than 300 generic drugs had at least one “extraordinary” price increase of 100% or more, according to a Government Accountability Office (GAO) report in 2017.
- Health plans respond to high prescription medication costs by imposing administrative barriers, such as frequently changing formularies, step therapy and prior authorization requirements. A recent AMA survey showed that the average physician completes 29 prior authorization requests per week, an average of 14.6 hours.
- In a 2018 national survey, 32% of respondents reported that they had not filled a prescription or have taken less than the prescribed dose of medicine.
- Pay-for-delay agrees, a practice in which drug companies pay a generic company not to launch a cheaper version of a drug, costs U.S. consumers and taxpayers \$3.5 billion in high drug costs each year.

### Advocacy in Action – AMA Principles on Drug Cost, Price, and Transparency

The AMA recently submitted comments to the U.S. House of Representatives Committee on Oversight and Government Reform for the hearing, *Examining the Actions of Drug Companies in Raising Prescription Drug Prices*. In our comments to Congress we call for the following policy in legislative solutions moving forward.

#### Increase pharmaceutical market competition and combat anticompetitive practices

The AMA continues to vigorously support expanded authority and funding for the [Federal Trade Commission](#) (FTC) in a number of areas to address anticompetitive practices as well as to advance consumer protections. The AMA strongly supports increased resources and direction to:

- Stop patent [pay-for-delay settlements](#)
- Limit efforts by pharmaceutical companies attempting to reduce competition from generic manufacturers through manipulation of patent protections.
- More rigorously evaluate the impact of mergers and consolidations among pharmaceutical companies on competition as well as consumer access by, among other things, expanding clinical expertise within the FTC and consulting with the relevant national medical specialty societies. The AMA's work on consolidation in health care can be found [here](#) and [here](#).
- Recommend enforcement action against manufacturers that engage in anticompetitive actions to the U.S. Department of Justice.

The AMA also continues to support measures to address the misuse of Food, Drug, and Cosmetic Act (FDCA) provisions for anti-competitive purposes while at the same time advocating for modifications to FDCA to increase access to some of the most-costly prescription medications: [biologics](#). The AMA strongly urges action to:

- End the ability of generic manufacturers to indefinitely “park” the [180-day exclusivity period](#) authorized by the FDCA by delaying final approval of their application by the U.S. Food and Drug Administration (FDA) as part of a settlement agreement with a brand manufacturer.

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- Shorten the exclusivity period for biological products. The AMA was an early and strong supporter of establishing a pathway for follow-on biologicals. The reduction in the exclusivity period is warranted to spur competition while not decreasing the impetus to innovate.

## Require pharmaceutical supply chain transparency

The second component of AMA advocacy has been to encourage transparency throughout the pharmaceutical supply chain, so patients and physicians have the information they need to make key decisions regarding medication, and policymakers can craft viable solutions to high and escalating pharmaceutical costs. The practices and policies of pharmaceutical manufacturers, [pharmacy benefit managers](#) (PBMs), and health insurers warrant steps by Congress to interject much needed transparency. To that end the AMA strongly supports:

- Requiring pharmaceutical manufacturers to provide public notice before increasing the price of any drug by 10 percent or more each year or per course of treatment and provide justification for the price increase.
- Requiring pharmaceutical manufacturers to publicly disclose a variety of information, which could include research and development costs, expenditures on clinical trials, total costs incurred in production, and marketing and advertising costs.
- Requiring PBMs to apply manufacturer rebates and pharmacy price concessions to drug prices at the point-of-sale to ensure that patients benefit from discounts as well as eliminate some incentives for higher drug list prices.
- Requiring insurers to provide increased transparency in formularies, prescription drug cost-sharing, and utilization management requirements for patients and physicians at the point-of-prescribing as well as when beneficiaries make annual enrollment elections.
- Prohibiting removal of drugs from a formulary or moving to a higher cost tier during the duration of the patient's plan year unless a change is made for safety reasons.

## **Tackling the High Cost of Prescription Drugs – A Step in the Right Direction**

### The Creating and Restoring Equal Access to Equivalent Samples (CREATES) of 2019" (S. 340/H.R. 965)

A key driver of affordability in prescription drugs is competition from generics once the market exclusivity has expired on a brand-name medication. However, some brand name pharmaceutical companies have abused regulatory rules to deny generic manufacturers the ability to purchase the samples they need to bring more affordable FDA-approved drugs to market – keeping the price of prescription drugs unnecessarily elevated.

The CREATES Act ([S. 340/H.R. 965](#)), introduced by Senator Patrick Leahy (D-VT) in the Senate, and Representative David Cicilline (D-RI) in the House of Representatives is a step towards restoring the balance between providing incentive for innovation through exclusivity while providing for affordability through generic competition. The bill would accomplish the following:

- Allow generic drug manufacturers facing anticompetitive delay tactics – such as failing to provide sufficient quantities of branded product samples for premarket testing - to bring an action in federal court for injunctive relief.
- Expedite the market introduction of generic drugs (including biosimilar versions of biologics) faster compared to current law.
- Reduce direct spending by \$3.3 billion over 10-year timeframe.

## **THE ASK**

- Help reduce the cost of life-saving prescription drugs by supporting or considering sponsorship of the "*Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act of 2019*" (S. 340/H.R. 965)
- Consider the AMA's call for increased pharmaceutical market competition, pharmaceutical supply chain transparency, and efforts to combat anticompetitive practices amongst pharmaceutical manufacturers, pharmacy benefit managers (PBMs), and health insurers.