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## Legislative Priorities to Reduce Prescription Drug Prices in the 115th Congress

### [Leveraging Negotiating Power](#)

#### **The Medicare Negotiation and Competitive Licensing Act of 2018 ([H.R.6505](#))**

The Medicare Negotiation and Competitive Licensing Act of 2018 would allow the Department of Health and Human Services to negotiate directly with pharmaceutical companies to attain lower prescription drug prices for Medicare Part D. When negotiations fail to arrive at an appropriate price, the bill licenses generic and biosimilar competition with brand name drugs. The threat of competition would provide strong leverage to the government in conducting negotiation, and ensure Medicare Part D beneficiaries have access to the medicines they need, even if prescription drug corporations don't offer a reasonable price in negotiations.

#### **Medicare Drug Savings Act of 2017 ([S. 252](#))**

Also found in Sec. 205 of the Affordable Meds Act Prior to the creation of Medicare Part D, low-income Medicare beneficiaries who were also eligible for Medicaid (dual-eligible beneficiaries) received prescription drug coverage through Medicaid, including the Medicaid statutory discount of 23.1 percent and rebates for price increases exceeding inflation. After Part D became law, low-income beneficiaries received subsidies, but drug manufacturers no longer were required to provide Medicaid-level discounts. The Medicare Drug Savings Act would restore those discounts and help bring down Part D prescription drug spending. The Congressional Budget Office [estimated](#) that it would provide \$145 billion in savings over 10 years.

### [Stopping Price Spikes](#)

#### **Stop Price Gouging Act ([S. 1369](#), [H.R. 2974](#))**

Prescription drug corporations routinely price gouge patients by sharply increasing the prices of lifesaving medicines without justification, and there is nothing in current law to prevent this practice. The Stop Price Gouging Act, also reflected in Sec. 202 of the Affordable Meds Act, would put an end to steep, unfair prescription drug price spikes by imposing penalties on corporations that price gouge proportionate to the severity of the abuse. An analysis by Harvard Medical School researchers estimated that this bill could save [several billion in taxpayer dollars annually](#) through Medicare alone.

### [Curbing Monopoly Abuses](#)

#### **PRICED Act ([H.R.6577](#))**

Biologic medicines, which include many new treatments for cancer and other serious diseases and conditions, are currently protected by a 12-year marketing exclusivity protection that extends monopolies and delays cost-lowering competition. The PRICED Act would reduce this monopoly protection to seven years, savings consumers and health programs billions of dollars.

#### **Preserve Access to Affordable Generics Act ([S. 124](#)) and Competitive DRUGS Act of 2017 ([H.R. 4117](#))**

Brand name prescription drug corporations and generic firms sometimes enter into patent settlements wherein brand-name companies pay generic firms not to bring low-price generic versions of their brand-name prescription drug product on the market for a certain period of time, also known as "pay-for-delay".



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The Federal Trade Commission (FTC) [estimates](#) that this practice costs U.S. consumers \$3.5 billion in higher drug costs each year. The Preserve Access to Affordable Generics Act would provide the FTC with the legal tools it needs to curtail this practice.

#### **[CREATES Act of 2017 \(S. 974, H.R. 2212\)](#) and [FAST Generics Act of 2017 \(H.R. 2051\)](#)**

The FDA has the authority to ask for risk evaluation and mitigation strategy (REMS) requirements from manufacturers to ensure that the benefits of a drug or biologic outweigh any risks. However, certain brand-name pharmaceutical companies abuse REMS requirements by denying manufacturers of generics and biosimilars access to product samples they need to obtain FDA approval and market entry. This practice delays the introduction of price-lowering generic and biosimilar competition, and the brand-name manufacturers inappropriately extend their monopolies. The CREATES Act and the FAST Generics Act would curb REMS abuses and promote drug price competition. The CREATES Act has been scored to save more than \$3 billion over the next ten years.

#### **[Medical Innovation and Prize Fund Act \(S. 495\)](#)**

Providing incentive for innovation through a prize fund is a market-based approach that has been endorsed by experts and lauded by [proponents of delinking](#) the costs of research and development from the prices of medicines. The Medical Innovation Prize Fund Act denies any person the exclusive right to manufacture, distribute, sell, or use in interstate commerce a drug or biologic, or the product's manufacturing process. In lieu of market exclusivity, it provides a prize payment from a Fund for Medical Innovation Prizes as an alternative incentive. It also requires the Government Accountability Office to conduct an audit to determine the Fund's effectiveness in bringing to market new medicines in a cost-effective manner to address society's global medical needs.

#### **[FAIR Drug Pricing Act \(S. 1131, H.R. 2439\)](#) and [Transparent Drug Pricing Act of 2017 \(H.R. 4116\)](#)**

Drug manufacturers often claim that high prices are necessary to support research and development (R&D). Yet these companies are not required to publish information about research and development costs, including product-specific information on government subsidies as well as spending on clinical trials by all parties involved. The public and healthcare providers should also have greater access to comparative effectiveness research to determine if high-priced drugs are better than alternative options. The FAIR Drug Pricing Act is a significant step toward advancing drug pricing transparency requirements for drugs that are the subject of a price spike. The Transparent Drug Pricing Act of 2017 is even stronger, requiring public reporting requirements for all drugs, including more granular data on R&D spending by clinical trials phase, and more, largely similar to the language included in Sec. 101 of the Affordable Meds Act.

#### **[Comprehensive Legislation](#)**

##### **[Improving Access to Affordable Prescription Drugs Act \(H.R. 1776\)](#) and [Affordable Medications Act \(S.3411\)](#)**

The Improving Access to Affordable Prescription Drugs Act and the Affordable Medications Act, are comprehensive, landmark legislative packages to lower drug prices and hold pharmaceutical companies accountable for abuses. They include an array of policies to lower prices and make medicines affordable, including by letting Medicare negotiate lower medicine prices for seniors, bringing transparency to drug development, curbing monopoly abuses of prescription drug corporations and limiting out-of-pocket costs.