

# Would House and Senate Bills to Lower Drugs Costs Achieve Savings or Affect Innovation?

*\*See 12/13/19 Update: [House Passes the Elijah Cummings Lower Drug Costs Now Act \(H.R. 3\)](#)*

Increasing the affordability of prescription drugs is of primary importance to Congress and to the nation. In this post, we review two of the federal bills receiving substantial press coverage - the Lower Drug Costs Now Act, introduced in the House by Speaker Pelosi and the Prescription Drug Pricing Reduction Act, introduced in the Senate by Senator Grassley. While the current bills may have [a bumpy road to approval](#), we analyze the proposals in the bills to assess whether they are likely to reduce spending on prescription drugs or reduce investment in research and development.

## **The Lower Drug Costs Now Act of 2019**

The House bill, the Lower Drug Costs Now Act of 2019 ([H.R. 3](#)), introduced by Speaker Nancy Pelosi, limits the annual out-of-pocket costs for Medicare Part D beneficiaries to \$2,000 and requires the Secretary of Health and Human Services (HHS) to negotiate with drug manufacturers and sets a price ceiling, or “maximum fair price,” for some single-source drugs.

Under this bill, HHS selects and publishes a list of drugs subject to the negotiation process. The original bill set the minimum number of negotiation-eligible drugs at 25, but the Energy and Commerce Committee [increased](#) that number to 35 during their review. The list is limited to single-source drugs that are among the 125 drugs with the greatest net expenditures and must include any insulin product approved by the Food and Drug Administration (FDA).[1] The bill states that the maximum fair

price may not exceed 120% of the average international price (AIM).[2] In the case where an AIM cannot be calculated, for example when the drug is first released in the United States, the negotiated rate may not exceed 85% of the average manufacturer price (AMP) of the drug.[3] This price ceiling is the starting point for a negotiation between HHS and the manufacturer, although it is unclear what incentive a manufacturer has for agreeing to a price below that ceiling. This maximum price applies to all Medicare plans, and, perhaps more importantly, manufacturers must offer the maximum fair price to health plans in the commercial market, although private commercial plans may opt not to accept the negotiated price (e.g. if they think their pharmacy benefit manager can negotiate a lower price through formulary management).

If the manufacturer and HHS are unable to agree on a maximum fair price (i.e. if the manufacturer refuses to accept 120% of the AIM), then the manufacturer will be assessed an escalating mandatory rebate levied on the manufacturer's annual gross sales - starting at 65 percent and increasing by 10 percent every quarter the manufacturer is out of compliance, up to a maximum of 95 percent.[4] As a result, if a manufacturer cannot come to terms with the Secretary, it could lose all revenue for that drug. Furthermore, because this rebate is not deductible for income tax calculations, the manufacturer [could actually lose money](#) by selling a drug for which it cannot reach a pricing agreement with the Secretary.

## **The Prescription Drug Pricing Reduction Act of 2019**

The Senate Bill, the Prescription Drug Pricing Reduction Act of 2019 (PDPRA, [S. 2543](#)), introduced by Senator Chuck Grassley, makes major revisions to payments for pharmaceuticals in the Medicare Part B and D programs.[5] In contrast to the Lower Drug Costs Now Act, the PDPRA does not extend any of these changes to private plans. The reforms to the Medicare Part D program - the stand-alone prescription drug coverage - include capping out-of-pocket costs for beneficiaries at \$3,100 annually and requiring manufacturers to pay an additional 20% rebate for drugs used by beneficiaries who have reached the out-of-pocket maximum. The reforms to the Medicare Part B program - the Medicare program that includes

coverage for outpatient drugs administered by a physician – include refining the calculation of the Average Sales Price (ASP) to more accurately establish fair Medicare payment rates for physician-administered drugs.[6] Furthermore, [the PDPRA mandates](#) that manufacturers pay additional rebates to the government for any amount that occurs when an increase in the wholesale acquisition cost for a drug covered under Medicare Part B or D exceeds the rate of inflation.

## **Budget Implications of the Bills**

The Congressional Budget Office (CBO) published a preliminary report of the effects of H.R. 3 on federal direct spending, estimating that the provisions of H.R. 3 would reduce Medicare spending by \$345 billion between 2023 and 2029, with the largest savings coming from lower prices for drugs that are sold internationally.[7] The CBO anticipates that prices for drugs in other countries would rise in response to the link between prices in the U.S. and foreign markets. Preliminary calculations by the CBO anticipate reductions in revenues to drug manufacturers of \$0.5 to \$1 trillion over the next ten years.

The CBO also estimates that the PDPRA would decrease the federal deficit by \$100 billion over the 2020-2029 period. Additionally, [the CBO estimates](#) modest savings to commercial prescription drug spending due to spillover effects from the Part D inflation rebate policy. In short, the CBO calculates savings to the government of H.R. 3 to be about three times that of the PDPRA and the savings in prescription drug spending to be about five to ten times greater for H.R. 3 than PDPRA.

## **What Do the Savings Mean for Drug Innovation?**

Not surprisingly, the pharmaceutical industry [vehemently opposes](#) these bills and more than 100 CEOs of small drug companies [signed a letter](#) in opposition to H.R. 3. Perhaps the most vigorous opposition to these bills argues that the reduction in revenue for drug manufacturers will result in lower spending on research and development and fewer medications coming to market. Specifically, the Council of

Economic Advisors issued a [report](#) on December 3, 2019, estimating that H.R. 3 could lead to about 10 fewer drugs entering the United States market annually. Although this estimate relies on the upper limit of the CBO's estimate and a highly criticized estimate of the cost of developing a new drug at \$2 billion, we examine in more detail the idea that a reduction in drug manufacturer revenue may lead to a reduction in pharmaceutical development.

In 2019, large pharmaceutical manufacturers spent about [20% of revenues](#) on research and development. Furthermore, a [2017 report](#) from the Government Accountability Office estimated that from 2006 to 2015, pharmaceutical and biotechnology sales revenue increased from \$534 billion to \$775 billion, and most drug companies saw an increase in their annual profit margins. Nonetheless, spending on research and development only increased slightly from 2008 to 2014 - from \$82 billion to \$89 billion. These data demonstrate that increase or reduction in revenues is not necessarily correlated to investment in research. A [report](#) written by West Health Policy Center found that large pharmaceutical manufacturers are the most profitable of any industry group.[8] Furthermore, these large pharmaceutical manufacturers could have realized 11% fewer profits and still maintained their position as the most profitable industry.

Since large pharmaceutical companies have a large profit margin, a reduced profit margin will not necessarily correlate to a reduced investment in R&D as companies will continue to invest in innovative treatments if they believe new drugs will bring additional future profits and a large return on investment. A [report](#) from the American Enterprise Institute written by former FDA Commissioner Scott Gottlieb and Research Fellow Institute Benedic Ippolito analyzed how the provisions of the PDPRA may change investment in specific drug categories by affecting the expected return on investment. Gottlieb and Ippolito calculate which drugs are likely to face larger rebates under the PDPRA and, therefore, how the bill may incentivize manufacturers to alter research spending away from specific diseases. They found that therapeutic classes with high net-priced drugs (e.g. cystic fibrosis, pulmonary arterial hypertension, and oncology) and disease areas where patients disproportionately receive low-income subsidies (e.g. hepatitis C, HIV, mental health and diabetes) were most likely to face additional rebates under the PDPRA. As a result, Gottlieb and Ippolito predict that investment for drugs on specialty tiers and

in these disease areas “are likely to moderate” under the PDPRA.

It appears that lowering drug company revenues will not necessarily reduce investment in research and development, but rather encourage pharmaceutical companies to invest in therapeutic classes that are likely to have the largest return on investment. If new laws are passed to incentivize innovation, companies will likely invest in innovation. Many countries, including those used to calculate the AIM in H.R. 3, use an assessment of cost-effectiveness as part of the approval or coverage determinations.[9] As a result, tying price ceilings to those standards would, at least indirectly, incentivize investment in treatments that could command high prices for their effectiveness. It remains unclear, therefore, whether passing H.R. 3 or the PDPRA would substantially lower the number of drugs released in the United States market.

## **Conclusion**

If passed, both H.R. 3 and the PDPRA will reduce expenditures by the federal government on prescription drugs. Furthermore, H.R. 3 will extend these savings to the private sector. While it is worth considering how the provisions of each bill will change incentives for investment in research and development by the pharmaceutical industry, it is far from certain that a reduction in pharmaceutical expenditures would lead to fewer new treatments. While both bills will reduce drug expenditures by the federal government, neither bill contains a cost-effectiveness analysis like that performed by many other countries. While H.R. 3 and PDPRA are commendable efforts by Congress, an ideal legislative solution to drug costs would ensure that cost-effectiveness is considered in both establishing an initial price and in any subsequent price increases.

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[1]H.R. 3 § 1192 (e).

[2]The bill defines the AIM as “the average price (which shall be the net average

price, if practicable, and volume-weighted, if practicable) for any dosage form and strength” for each drug sold in Australia, Canada, France, Germany, Japan, and The United Kingdom. (H.R. 3 § 1191 (c)(3)).

[3]H.R. 3 § 1194 (c)(2).

[4]H.R. 3 § 4192 (c).

[5]The bill also makes revisions to Medicaid prescription drug coverage and requires additional price transparency for services provided at physician offices (requires same reporting as ambulatory surgery clinics, ASCs) but those reforms are beyond the scope of this post.

[6] The bill requires manufacturer without a Medicaid drug rebate agreement to report ASP for those drug to Medicare, requires coupon amounts (only available to private plans) to be deducted from ASP, and narrows the definition of “bona fide service fees” to require more fees to be deducted from ASP price reported to HHS. All of these calculation changes will reduce the reported ASP and more accurately reflect the amount manufacturers receive for selling the drug. As a result, the Medicare payment rates for these drugs should be commensurately lower.

[7]Letter to the Honorable Frank Pallone Jr., Chairman Committee on Energy and Commerce, *Re: Effects of Drug Price Negotiation Stemming From Title 1 of H.R. 3, the Lower Drug Costs Now Act of 2019, on Spending and Revenues Related to Part D of Medicare*. October 11, 2019. Available from: <https://www.cbo.gov/system/files/2019-10/hr3ltr.pdf>.

[8]The West Health Policy Center report says that the Return on Invested Capital (ROIC) is higher for large pharmaceutical manufacturers than any other industry group.

[9]See e.g., [https://www.cadth.ca/sites/default/files/pdf/economic\\_guidelines\\_worked\\_example.pdf](https://www.cadth.ca/sites/default/files/pdf/economic_guidelines_worked_example.pdf), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4802685/> and <https://www.nice.org.uk/process/pmg6/chapter/assessing-cost-effectiveness>