

ISSUE BRIEF: THE EVIDENCE BASE ON THE IMPACT
OF PRICE CONTROLS ON MEDICAL INNOVATION
SEPTEMBER 2021

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Issue Brief:
**The Evidence Base on The Impact of Price Controls
on Medical Innovation**

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September 14, 2021

Executive Summary

This issue brief reviews the evidence on the impact of price controls on biopharmaceutical innovation and calibrates what this evidence implies for recent price control proposals in the US. A large academic literature estimates the effect of future drug revenues on R&D spending with a mid-range effect of a 1 percent reduction in revenue leading to a 1.5 percent reduction in R&D activity. Using the range of such effects found in the literature we find the proposed price controls of US bill HR3, the Lower Drug Costs Now Act, would lead to a 29 to 60 percent reduction in R&D from 2021 to 2039 which translates into 167 to 342 fewer new drug approvals during that period. The mid-range effect of the evidence implies a 44.6 percent decline in R&D and 254 fewer new drug approvals. We argue this is a conservatively low estimate of the impact of such proposals even though it is as much as a ten times larger reduction in new drugs compared to a recent [CBO](#) analysis.

Section 1: Introduction

A national debate has emerged again about the effect of price controls on pharmaceutical innovation. Many proponents of price controls for pharmaceutical drugs argue that they do not impact innovation while opponents argue they will lead to fewer new drugs. This issue brief attempts to provide insight into the likely effects of recent price control proposals by analyzing how the debate can be informed by basic economics and the prevailing empirical evidence.

While the United States has less stringent price regulations when compared to other nations, the Biden Administration has recently announced [plans](#) to lower drug prices through policies similar to those outlined in a recent bill referred to as the [Lower Drug Costs Now Act \(H.R.3\)](#) that passed the House of Representatives in December 2019 and was reintroduced in April 2021. This proposal would create price controls for the government's highest expenditure drugs and then apply price controls to firms conducting private sector transactions. This issue brief reviews the evidence on how sensitive innovation is to changes in revenues and applies the evidence to estimate the effect of proposed price controls.

Section 2: Evidence Base on Revenue Effects on Innovation

Biopharmaceutical companies routinely project future market size and profits for their products to determine the rate of return on investment (ROI) from R&D. A large body of evidence suggests that these market practices translate into a predictable positive relationship between realized revenues and R&D spending in the economy in general and for biomedical innovation in particular.

A rich academic literature quantifies this relationship between future revenues and pharmaceutical innovation. For assessing evidence related to revenue effects on R&D, it is important to recognize that global profits drive innovation and that revenues from different countries have different effects on those global profits because of different profit margins across countries. Expected earnings, not revenues, drive R&D investments. Therefore, decreases in US revenue will have larger effects on global profits than revenue losses in price-controlled markets in Europe due to higher profit margins in the US. [Goldman and Lakdawalla](#) (2018) find that pharmaceutical profits in the United States accounts for 64 to 78 percent of global profits, similar to an estimate from the Council of Economic Advisers ([CEA](#)) (2018). Consequently, the evidence finds that studies focusing on US revenue losses show larger R&D effects than those studying revenue losses in Europe.

In particular, a set of papers looks at the expansion of the Medicare prescription drug benefit, Medicare Part D, which provides the most relevant evidence for assessing the revenue effects of Medicare policy changes. They find that companies recognized this expansion and increased innovation in drugs treating diseases prevalent in the elderly population more so than innovation in non-elderly diseases ([Blume-Kohout and Sood](#) 2013).¹ Quantifying that relationship, a 1 percent increase in market size due to Medicare Part D leads to a 2.8 percent

¹ They also discuss how the highly regulated and price controlled pharmaceutical industry in the European Union leads to lower expected profits.

increase in early-stage clinical trials.² Another often cited paper finds a 1 percent increase in potential market size leads to a 4-6 percent increase in the entry of new drugs ([Acemoglu and Linn](#) 2004) in the US. Though other studies have found lower effects in Europe of the relationship between potential market size and the number of new treatments, a clear strong positive relationship exists ([Dubois et al](#) 2015).³ Other studies show that a 1 percent increase in price leads to a 0.22-1.33 percent increase in innovation.⁴ Another extensive literature illustrates how companies change their investments in lower quality drugs due to price controls and other regulations that decrease how much can be charged for high-quality drugs.⁵

We synthesized the evidence base by computing the average R&D elasticity with respect to revenue estimated from 10 different studies looking at the effect of a price change, expected market, and overall revenue on R&D ([Acemoglu and Linn](#) 2004; [Dubois et al](#) 2015; [Blume-Kohout and Sood](#) 2013; [Giacotto, Santerre, and Vernon](#) 2005; [Civan and Maloney](#) 2009; [Abbott and Vernon](#) 2007; [Vernon](#) 2015; [Finkelstein](#) 2004; [Filson](#) 2012; and [Lichtenberg](#) 2005). The average elasticity across these 10 studies is 1.54.

To assess the impact on the number of new drugs from reductions in R&D spending, a common approach is to divide the reduction in R&D spending by an estimate of the costs of bringing a drug to market. This is a useful approach and implies a proportional reduction in new drugs to the reduction in R&D spending regardless of the particular cost per drug. In other words, using this methodology, a 10 percent reduction in R&D spending leads to 10 percent fewer drugs regardless of the cost per drug estimate used. The elasticity of R&D spending with respect to revenue in this case therefore also represents the elasticity of new drugs to revenue.

Despite the evidence, there is some debate among law makers concerning whether revenue or price controls affect innovation at all. However, the evidence is consistent with common market practices of biopharmaceutical innovation—a positive relationship between investment and earnings. Such market practices include the use of net present value (NPV) calculations to determine a new drug’s ROI. Biopharmaceutical companies determine the demand for new drug therapies by analyzing the prevalence of disease, insurance coverage of the population affected by the disease, and reimbursement by payers managing patients’ care. The pharmaceutical industry spent more than \$91 billion on R&D in 2020.⁶ In obtaining such R&D funding, companies have relied on venture capital funding, licensing agreements, or mergers and acquisitions as well as their own revenue. All rely on ROI assessments to evaluate R&D investments. Indeed, markets routinely assess

² [Finkelstein](#) (2004) finds a similar effect of a 1 percent increase in the utilization of preexisting vaccines through public policy increases new clinical trials for new vaccines by 2.5 percent.

³ They find a 1 percent change in the expected market size to increase innovation by 0.23 percent. They also conduct a comprehensive literature review on this topic.

⁴ [Giacotto, Santerre, and Vernon](#) (2005) look at drug prices and R&D spending, [Vernon](#) (2015) look at potential cash flow and R&D spending, [Civan and Maloney](#) (2009) look at entry price and drugs in the pipeline, and [Abbott and Vernon](#) (2007) look at price and R&D projects undertaken.

⁵ Further discussions can be found at [Sood et al](#) (2008), [Kyle](#) (2007), [Hassett](#) (2004), [Koenig and MacGarvie](#) (2011), and [Doran and Henry](#) (2008).

⁶ [PhRMA’s](#) 2021 Membership Survey.

the enterprise value of firms by estimating the present value of expected cash flows across all business lines and projects.⁷

Section 3: Calibration of the Impact on Innovation of Proposed US Price Controls

This section evaluates what the evidence implies for the innovation effects of proposed US price controls. We calibrate that the price controls implemented in the United States would lead to a 29.2 to 60.0 percent reduction in R&D from 2021 to 2039. This equates to \$952.2 billion to \$2.0 trillion in lost R&D spending and 167 to 342 fewer new drug approvals during this period. This means annual new drug approvals will be 11.7 to 24.0 percent lower per year from 2021 to 2029 and 45.0 to 92.4 percent lower from 2030 to 2039. We discuss how these findings, as well as findings from other studies, differ from [CBO](#) (2019), which finds only 37 fewer new drug approvals over this time period, which is 550.2 to 1,024 percent lower than our estimates.⁸ Our estimates are conservative as the entire evidence base is considered and not only the evidence base for the more R&D sensitive US market.

It should be noted, however, that making comparisons to CBO estimates is made more difficult due to the highly non-transparent discussion of their underlying analysis, which makes third-party replication of their results impossible. This “black-box” nature of analysis is often the case with government reports and raises larger issues with the difficulty for private parties and taxpayers - who funded the analysis - being able to assess their accuracy. In contrast, we believe the presentation of the evidence discussed above, and the innovation effects they directly imply, is highly transparent as it simply documents the findings of the studies and their implied effects.

3.1 The Proposed US Price Controls

The United States has fewer restrictions on price than other countries, but the Biden Administration has announced their [goal](#) to lower drug prices through greater price regulation, as set forth in a recent bill referred to as [H.R.3](#). This proposal would change the way certain single-source brand drugs are priced for Medicare beneficiaries by requiring drug manufacturers to “negotiate” drug prices with the Secretary of Health and Human Services. A prohibitive excise tax of 65 to 95 percent will be applied to a company’s annual gross sales if they refuse to negotiate, making the requirement largely equivalent to mandatory price controls. Drug prices set by the Secretary may not exceed the prices in specified countries by more than 20 percent and price increases would be capped at the rate of inflation ([CBO](#) 2021).⁹

In addition, these price controls would also be extended to private transactions by employer-based plans as stated on August 12, 2021 by President Biden and as implied by the proposed legislation. Private payers can choose the lower prices negotiated by the government, which they presumably will.

⁷ Enterprise value equals the market value of equity plus debt less cash.

⁸ We calculated the lost R&D spending using the 5 percent reduction reported from [York](#) (2021) and applying it to our methodology. CBO (2019) originally found 38 fewer new drug approvals from 2020 to 2039.

⁹ The specified countries are Australia, Canada, France, Germany, Japan, and the United Kingdom.

3.2 CBO's Estimated Effects and Alternative Estimated Effects of the Proposed Price Controls

CBO (2019) previously estimated that a drop in future revenues due to H.R.3 would lead to 8 fewer drugs from 2020 to 2029, which would then expand to 30 fewer drugs from 2030 to 2039.¹⁰ In August 2021, [CBO \(2021b\)](#) updated its estimated impact of price negotiations to be 2 fewer drugs in the first decade (0.5 percent), 23 fewer in the second decade (5 percent), and 34 fewer drugs in the third decade (8 percent). Since the development process takes about a decade, the long run effects of the bill will be larger than its short-run effects. To align these estimates with our time period of 2021-2039, we lower their estimate to 7 fewer drugs from 2021 to 2029 and keep the estimate of 30 fewer drugs from 2030 to 2039.¹¹

Consistent with our analysis, other analysts' assessments of CBO's 2019 analysis of H.R.3 conclude that [CBO \(2019\)](#) likely underestimates the impact of H.R.3. [Charles River Associates \(2021\)](#) finds the CBO study underestimates the company revenue impact by assuming companies will be able to set their price at the high end of the allowed price range, and that companies will be able to increase their non-U.S. price. Both assumptions may not be true due to uncertainty around behavioral responses in negotiations. Further, for the loss-of-revenue impact on R&D, CBO extrapolates price control effects from smaller markets, and they do not account for the larger impact on targeted disease groups most impacted by the policy like rare diseases and oncology. CBO's analysis relies on [Dubois et al \(2015\)](#) to estimate the effect of H.R.3 on R&D, but CRA notes that this estimated effect is smaller than most of the other literature, too dependent on specific assumptions, and may not be as relevant to a policy of H.R.3's magnitude.

Other analysts' estimates of the impact of the price controls introduced in H.R. 3 show a considerably larger impact on global revenues and R&D than assumed by CBO. [Stengel et al \(2020\)](#) estimate drug manufacturer revenues would fall 34 to 44 percent, which would equate to about \$1.3 to \$1.7 trillion in total lost global revenues from 2020-2029. [Vital Transformation \(2021\)](#) estimates annual earnings would fall 56 percent, or on average \$102 billion a year, starting in the year 2024. This fall in earnings when fitted to past data would have lowered new approved drug therapies in their sample from 68 new drugs to 7 new drugs, an 89.7 percent decline from 2010 to 2019.

3.3 Effects of the Proposed Price Controls Implied by the Evidence Base

In light of the reported shortcomings in the [CBO \(2019\)](#) report, we used the broader evidence base discussed in this issue brief to assess the effect H.R.3's proposed price controls would have on innovation. We create a range of the estimated drop in global drug manufacturer revenues by taking the CBO's lower estimate of 19 percent and the midpoint revenue effect of alternative studies, 39 percent, from [Stengel et al \(2020\)](#).

As discussed earlier, a conservatively low estimate of the elasticity of revenue on either R&D or the introduction of new drugs is 1.5 based on current evidence. We apply this elasticity to the 19 to 39 percent decline in revenues to derive a percentage reduction in R&D. This percentage reduction is thereafter used to calibrate

¹⁰ [York \(2021\)](#) explains how this is a 5 percent reduction in innovation and how it is likely a lower-bound estimate.

¹¹ Since they found 8 fewer drugs for the decade, this equates to almost one year. We shorten the time period by a year, so we adjust the result by 1 fewer drug.

the reduction in absolute R&D spending or number of approved drugs. by applying it to the CBO baseline trend in absolute values. In other words, the reduction in R&D spending and the number of new drug approvals during 2021 to 2039 is obtained by determining how much would be lost in each of those measures from CBOs baseline trends given the percent reduction in R&D.¹²

Table 2 illustrates our main findings. Using the average elasticity on the 19 to 39 percent drop in global revenues, innovation through R&D is expected to drop 29 to 60 percent. Using the middle of our range, this would equate to lost R&D spending of up to \$1.5 trillion. We find that this drop in spending will lead to 167 to 342 fewer new drug approvals.

Our estimates are therefore 550.2 percent to 1024.0 percent larger than [CBO](#) (2019)'s estimated 37 fewer new drug approvals, adjusted to our time period. [CBO](#) (2019) points out that lower R&D spending will take time to be reflected in new drug approvals due to the long development process, so the reduction in revenue results in 7 fewer new drug approval, 18.9 percent of their total estimate, in the first 9 years and 30 more in the following decade, 81.1 percent of their total estimate. We assume this breakdown as well, so new drug approvals will fall by 32 to 65 approvals from 2021 to 2029 and 135 to 277 approvals from 2030 to 2039. These significant drops in new drug approvals will lead to delays in needed drug therapies, resulting in worse health outcomes for patients.

Table 2. Impact of Price Controls on R&D, 2021-2039

	Lower End of Range	Middle	Upper End of Range	CBO (2019)
Assumed Fall in Global Revenues (%)	-19.0%	-29.0%	-39.0%	-19.0%
Impact on R&D (%)	-29.2%	-44.6%	-60.0%	-5.0%
Impact on R&D (billions of dollars)	-952.2	-1,453.3	-1,954.4	-162.9
Impact on New Drug Approvals	-167	-254	-342	-37*

¹² For the impact on R&D spending, we took a time series from [PhRMA's](#) 2020 Membership Survey showing pharmaceutical R&D spending from 2000-2019 and calculated the compound annual growth rate to get a trend for expected R&D spending through 2039. We then applied the impact on R&D to each year and summed these values to get a total. We take the about 30 new drug approvals baseline from [CBO](#) (2019). We assumed 30 new drugs annually moving forward to 2039 and applied the impact on R&D for each year and summed.

However, this may be a low baseline. From 2015-2020, the FDA has approved an average of 46 [New Molecular Entities and New Therapeutic Biologic Product Approvals](#). We could also reasonably assume a higher annual baseline for new drug approvals than [CBO](#) (2019), 46 annual approvals versus 30 approvals, which would increase the middle of our estimate to 390 fewer total drug approvals.

2021-2029	-32	-48	-65	-7
2030-2039	-135	-206	-277	-30

Sources: CBO (2019); PhRMA (2020); Papers cited in text; Author calculations.

Note: * CBO (2019)'s 2021 to 2029 new drug approval impact is adjusted to a shorter time-period than they initially reported.

Our analysis likely underestimates true innovation effects, which, if considered fully could make our findings even further away from the CBO estimates. This is because the average R&D elasticity of 1.5 used included studies of non-US markets with lower earnings effects than US markets. Given that the US has higher margins, price controls are expected to have a larger impact on earnings. Thus, only using the larger estimated elasticities from US markets, which would double the elasticity of 1.5, would yield proportionally larger differences between the evidence base and the CBO estimates.

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