

## **Government Scorekeepers Likely Underestimate the Impact of Lower Drug Costs Now Act (H.R.3) on Investment in Innovative Medicines: Brief**

A study for the Pharmaceutical Research and  
Manufacturers of America (PhRMA)

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In 2019, the US House of Representatives passed the “Lower Drug Costs Now Act” (H.R.3), which would require the federal government to set the price of many prescription medicines.<sup>1</sup> The Congressional Budget Office (CBO), which is charged with calculating the costs of potential legislation to guide policymaking, estimated that if H.R.3 were enacted, government-set prices for medicines would reduce direct federal spending by nearly \$500 billion between 2023 and 2029.<sup>2</sup> H.R.3 would also have a significant impact on biopharmaceutical industry revenues. Other research suggests that industry revenues could decline by \$1,275 billion to \$1,655 billion between 2020 and 2029, which translates to a reduction in US brand drug revenue of 34% to 44% across the Medicare and commercial markets.<sup>3</sup>

Despite H.R.3’s unprecedented impact on the US market, the world’s leading market for biopharmaceuticals, CBO projected that only 8 to 15 fewer new medicines would be developed over the next 10 years, with an additional 30 new medicines failing to reach the market in the following decade. Given the challenges inherent in forecasting the impact of a policy change of this magnitude on future innovation—and the potentially serious implications for drug development and consequently the health of the US population—Charles River Associates (CRA) was retained by the Pharmaceutical Research and Manufacturers of America (PhRMA) to review the CBO approach to estimating the impact of H.R.3. Overall, CRA concludes that there is no sufficient analogue to estimate the effect of this policy and the CBO likely underestimates the true impact of H.R.3 on future incentives for innovation. Therefore, policymakers have not been provided with sufficiently reliable estimates to adequately assess the risk of such a decision.

CBO’s estimate of a modest innovation impact from H.R.3 stems partly from its likely understated estimate of H.R.3’s impact on biopharmaceutical company revenues. For example, CBO assumes that the “reference price” is most likely to be set at the upper end of the range of possible prices, when it could also be set at the lower end of the range.<sup>4,5</sup> Also, CBO assumes companies can increase their prices outside the US when in reality payers outside of the US are unlikely to accept a higher price and those payers have policies in place such as Health Technology Assessment that may not allow a price increase or support significantly higher launch prices.

The focus of CRA’s review, however, is on CBO’s assessment of the future **innovation impacts** that result from H.R.3’s revenue reductions. Following a review of the methods and related literature along with expert interviews, CRA concludes that the CBO likely understates the impact of H.R.3 on the development of new medicines. In particular, the CBO estimate:

- **Undervalues the impact of the US market as the single largest source of industry revenue due to lack of reliable, analogous evidence:** The US represents 41% of global biopharmaceutical revenue<sup>6</sup> and is a significant force for stimulating investment in new medicines. CBO relies on estimates of the effect of a change in market size on investment in new medicines from countries with far smaller market sizes. In contrast, investors and developers are significantly more likely to be responsive to changes in US demand. For example, Blume-Kohout and Sood (2013) explain that pharmaceutical revenues in the European Union are highly regulated, with regulations subject to rapid changes over time and prices are controlled, which fosters lower expected profits and greater uncertainty

about future profits.<sup>7</sup> Extrapolation from smaller, price-regulated markets may underestimate the effects of a policy change on a market such as the US.

- **Ignores the likely disproportionate impact of the policy on high risk, high unmet need disease areas:** CBO computes an average effect across all drugs and fails to recognize the differentially large impact of the policy on particular disease states, specifically oncology and rare disease, which would be de-facto targets of the policy. These drugs have distinct development cost profiles and challenges and would treat many diseases for which there are no current options.
- **Underestimates the impact of industry revenue reductions on R&D incentives by failing to make needed mathematical adjustments:** CBO applies a revenue impact estimate from an academic study which is dependent on a specific magnitude of change in revenue.<sup>8</sup> To accurately estimate the impact of a policy change as large as H.R.3, the impact estimate must be adjusted for market size before being applied. In other words, CBO should have replicated the academic study's model to compute an impact estimate that is relevant to H.R.3, rather than simply applying an average estimate, which would understate the impact.
- **Ignores the complexity and mobility of the investor market which could readily shift to more profitable industries:** In relying on studies which use old data, CBO fails to consider that drug investment is increasingly dynamic and capital is mobile. Today, smaller biotechnology firms make a sizeable contribution to the development of new medicines.<sup>9</sup> These smaller firms rely to a large extent on venture capital (VC) and on deals and partnerships with large biopharmaceutical companies. In the face of an expectation of lower returns on what are typically highly uncertain investments, venture capital could easily shift to other portfolios offering greater expected returns such as the renewable energy or technology sector. At the same time, large biopharmaceutical companies with significantly reduced free cash flow will have less to invest in acquiring or partnering with venture-backed start-ups. These dynamics are ignored in evidence relied on by CBO, which are reflective of an era less reliant on small biotechs and outside investors.

These challenges highlight that there remains insufficient information to adequately assess and present the risk-to-benefit profile of H.R.3, particularly the risk to the availability of new medicines for the thousands of serious diseases such as cancer and rare diseases with no current treatment options.<sup>10</sup> Even for an organization as sophisticated and adept as the CBO, forecasting the impact on innovation of a policy change of unprecedented magnitude, in the world's biggest market for medicines is impossible, as there are no relevant analogues for change on this scale.

Understanding the true impact of H.R.3 on future innovation is not an easy task, but CBO's implicit assumptions based on outdated evidence and simplified modeling could have dangerous unintended consequences if relied upon as conclusive. Given the lack of similar analogues and limitations in the CBO's computational approach to estimating H.R.3's impact on future innovation, we conclude that CBO likely underestimates the true impact of H.R.3 and that policymakers have not been provided with a sufficiently accurate estimate of the cost of the policy to adequately balance the risk of such a decision.

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## References

- <sup>1</sup> H.R.3 would require the government to establish a ceiling on the price of “selected” medicines used by Medicare beneficiaries. The upper limit for government-set prices would be determined by the prices charged in six designated foreign countries. Biopharmaceutical companies would face steep financial penalties if they failed to accept these prices, which would also be made available to payers in the commercial market. Medicines selected for government price-setting would disproportionately target the most innovative medicines, with a de-facto focus on treatments for complex conditions such as cancer and rare diseases.
- <sup>2</sup> Letter from Swagel, P.L to Honorable Frank Pallone Jr., Budgetary Effects of H.R.3, the Elijah E. Cummings Lower Drug Costs Now Act (as passed by the House of Representatives in December 2019).
- <sup>3</sup> Avalere, Impact of H.R.3 as Passed by the House on Federal Spending and Drug Manufacturer Revenues. Retrieved from <https://avalere.com/insights/impact-of-h-r-3-scenarios-on-federal-spending-and-drug-manufacturer-revenues>.
- <sup>4</sup> CBO’s application of the “Nash bargaining framework” is outside the scope of this paper but deserves further attention. The approach is described in: Adams C. and Herrnstadt E., *CBOs Model of Drug Price Negotiations Under the Elijah E. Cummings Lower Drug Costs Now Act*, Working Paper 2021-01, February 2021.
- <sup>5</sup> Kanavos, P., Fontrier, AM., Gill, J. et al. (2020) Does external reference pricing deliver what it promises? Evidence on its impact at national level. *European Journal Health Economics* 21, 129–151, <https://doi.org/10.1007/s10198-019-01116-4>.
- <sup>6</sup> IQVIA Institute. (2020). Global Medicine Spending and Usage Trends: Outlook to 2024. Retrieved from: [https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/global-medicine-spending-and-usage-trends.pdf?\\_=1597160672472](https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/global-medicine-spending-and-usage-trends.pdf?_=1597160672472).
- <sup>7</sup> Blume-Kohout, M. E., & Sood, N. (2013). Market Size and Innovation: Effects of Medicare Part D on Pharmaceutical Research and Development. *Journal of Public Economics*, 97, 327–336, <https://doi.org/10.1016/j.jpubeco.2012.10.003>.
- <sup>8</sup> Dubois, P., de Mouzon, O., and Scott-Morton, F. (2015). Market Size and Pharmaceutical Innovation. *RAND Journal of Economics*, 46(4), 844-871, <https://doi.org/10.1111/1756-2171.12113>.
- <sup>9</sup> IQVIA Institute (2019). *The Changing Landscape of Research and Development: Innovation, Drivers of Change, and Evolution of Clinical Trial Productivity*. Retrieved from: <https://www.iqvia.com/insights/the-iqvia-institute/reports/the-changing-landscape-of-research-and-development>.
- <sup>10</sup> US Department of Health and Human Services, National Center for Advancing Translational Sciences, Genetic and Rare Diseases Information Center (2017). FAQs About Rare Diseases. Retrieved from: <https://rarediseases.info.nih.gov/diseases/pages/31/faqs-about-rare-diseases>.