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An Analysis of the Effect of Drug Pricing Provisions in the Build Back Better Act on Pharmaceutical Innovation

A Report for PhRMA

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Executive Summary

Charles River Associates (CRA) has previously assessed the implications of proposals to implement international reference pricing in the U.S. and found they would reduce and skew investment in research and new drug development.[1] This report assesses the potential effects of two alternative approaches to regulating drug prices, government price setting and inflation penalties, on pharmaceutical innovation. These policies are part of the Build Back Better Act (BBB), which passed the House of Representatives in November 2021 and is currently under consideration for passage by the Senate.[2]

- **Government price setting:** After a certain period of time on the market, prices for selected drugs are set by the Secretary of Health and Human Services and may not exceed a pre-determined price ceiling. Biopharmaceutical companies must accept the government-set price or face an excise tax of up to 95%.
- **Inflation penalties:** In general, if a drug's price as of 2021 increases faster than the rate of inflation, biopharmaceutical companies must refund the difference in the form of a rebate to Medicare.

Approach

The analysis was based on a review of the published literature on price controls. Drawing on this literature, we assessed the drug pricing provisions in the BBB on: (1) R&D investment and innovation, (2) shifts in type of R&D (for instance, transformational vs. incremental or away from certain therapeutic areas), and (3) other unintended consequences. The analysis represents CRA's assessment of the legislative text as passed by the House of Representatives on November 19, 2021.

Conclusions

As summarized in Executive Summary Table 1, we find that the government price setting and inflation penalty provisions in the BBB would reduce and skew R&D investment, resulting in fewer new medicines. As of November 2021, the Congressional Budget Office (CBO) found that drug price controls in BBB would result in fewer new drugs: one fewer from 2022–2031, four fewer in the next decade, and five fewer in the following decade.[3] However, the CBO's methodology lacks consideration of the shift in incentives and investment behavior, which indicates that its score is unlikely to capture the full impact of price controls on innovation of new medicines. The results of our assessment imply that the CBO's score of BBB is likely an underestimate.

Executive Summary Table 1: Impact of drug pricing provisions in the Build Back Better Act

Impact on R&D Investment and Innovation
1. Negative effect on investment in R&D due to lower expected returns and cash flow
2. Added risk to the expected revenues of drugs, even for drugs that are not subject to price setting
Shift in Type of R&D
3. Investment shifts away from riskier R&D in transformational medicines to more predictable investments in lower risk innovation
4. Less incentive for investment in R&D that occurs after product approval in post market studies, including in pediatric populations
5. Potential shift away from investing in disease areas where demonstrating the clinical benefits of a drug would be more costly or challenging
Unintended Consequences
6. Undermining of generic and biosimilar markets due to uncertainty and lower expected revenues
7. Part D inflation penalty would unnecessarily apply to medicines where market competition is already working to limit net price growth

Source: CRA analysis

This report was developed at the request of, and received funding from, the Pharmaceutical Research and Manufacturers of America (PhRMA).

Introduction and Approach

Over the past decade there have been dozens of proposals to control drug pricing in the U.S. One example, the "Elijah E. Cummings Lower Drug Costs Now Act" (H.R.3), which the U.S. House of Representatives passed in 2019, and which CRA has previously analysed, would regulate prices of medicines principally by applying an international reference pricing approach, and could deter investment in biopharmaceutical R&D with potentially serious consequences.[4]

In November 2021, the Build Back Better Act (BBB) (H.R. 5736) was passed by the U.S. House of Representatives.[5] BBB includes two approaches to regulating drug prices, government price setting and inflation penalties, which are examined in this paper.[6]

The purpose of this paper is to draw on the existing literature on price controls to determine the impact of BBB proposals on innovation. Below, we summarize these provisions as specified by BBB:

Government Price Setting

- The BBB would allow the Secretary of Health and Human Services (HHS) to set the price of certain prescription drugs with the highest gross spending in Medicare Part B or D.
- Although the proposal describes the pricing process as a negotiation, the BBB establishes a maximum ceiling price equal to a set percentage of a drug's non-Federal Average Manufacturer Price (non-FAMP).[7] Biopharmaceutical companies must accept the government-set price or face an excise tax of up to 95% of the medicine's sales.
- Maximum prices are anchored to a percentage of the non-FAMP. For top selling drugs in 2017, the non-FAMP was estimated to be 68% of the Average Wholesale Price (AWP).[8] The government set price would apply in the Medicare Part B and Part D programs, as well as Medicare Advantage. Part D plans would be allowed to negotiate additional discounts below the federally set price.
- The products eligible for the government price setting process are small molecule or biological innovator drugs that have been on the market for at least 7 years and 11 years, respectively; do not have approved and marketed generics or biosimilars; and have Medicare Parts B and D expenditures greater than $200 million.[9,10] From that list, the HHS Secretary will negotiate prices for up to 10 drugs in 2025, 15 drugs in 2026 and 2027, and up to 20 drugs annually thereafter. All approved or licensed insulins that are marketed are also subject to price setting starting in 2025.

Depending on whether a drug eligible for negotiation is considered a "short-monopoly," "long-monopoly," or "post-exclusivity" drug, the Secretary would consider certain information for price setting.[11] For "long monopoly" and "post-exclusivity" drugs, the Secretary would consider the drug's costs of production, distribution and market data (including the distribution of sales across different programs and purchasers, and projected future revenues for the drug). For "short monopoly" drugs, the Secretary would also consider additional manufacturer specific data, including the drug's R&D costs and public funding received, as well as information on alternative treatment options, including comparative effectiveness data and the extent to which the drug addresses an unmet need.

Inflation Penalties

- Starting in 2023, and subject to certain statutory exceptions, for a Part B or D drug whose price growth from 2021 exceeds inflation,[12] biopharmaceutical companies would be required to pay a rebate to the federal government equivalent to the value of the current price minus the inflation-adjusted price for units sold with respect to the Part B or D drug.
- Drugs subject to government price setting would be excluded from the inflation penalties while their price is set by Medicare. Biopharmaceutical companies would be assessed a penalty of 125% of the required rebate for failure to comply.

The government price setting and inflation penalties envisioned in the BBB would be a substantial departure from current U.S. pharmaceutical market dynamics, where most brand drug prices are determined through private negotiation between insurers and biopharmaceutical firms.[13] Federal price setting is currently limited to programs designed primarily for lower income people and certain federal employees including the military.[14]

However, if BBB is passed into law, over time the number of drugs impacted by government price setting could grow, potentially to 100 or more drugs within ten years. The spillover effects of these mandated price concessions would also extend to medicines competing in therapeutic classes with one or more price-controlled drugs.[15]

In today's biopharmaceutical market, list prices and price increases are often reduced by discounts offered by biopharmaceutical manufacturers to payors.[16] These discounts are offered in exchange for formulary placement, which can mean a lower co-pay or reduction in other hurdles to access for a patient. For most medicines covered under Part D, the inflation penalty relies on a drug's standard average manufacturer price (AMP), which does not reflect discounts or rebates negotiated between payors and manufacturers.

Approach

To evaluate the impact of BBB on innovation, we conducted a review of published literature and economic analysis. We focused on academic literature to identify the incentives created by each BBB pricing policy and outline their implications on investment in pharmaceutical R&D, as suggested by economic theory. We used key word searches to identify the literature on economic theory of price control on innovation. The search used combinations of "price cap", "price regulation", "innovation", "R&D incentives", and "generics and biosimilar". We structured our assessment in three areas: (1) The impact on the level of R&D investment and innovation, (2) shifts in the type of R&D (for instance, transformational vs. incremental or away from certain therapeutic areas), and (3) other unintended consequences. Our review focused on research published in the last 10 years, including (among others) 21 peer-reviewed studies and 17 non-government and industry association reports.

Assessing the impacts of drug pricing provisions in the Build Back Better Act

Having described the government price setting and inflation penalties proposed in BBB, we next assess the extent to which both drug pricing proposals could affect innovation. Specifically, in this section, we consider the potential impact of BBB on investment in R&D, distortions to the type of R&D pursued, and potential unintended consequences of the policies.

Impact on R&D Investment and Innovation

There is substantial empirical support for the connection between expected pharmaceutical revenues and investment in R&D.[17,18,19] Even though the **government price setting** in BBB is imposed several years into a drug's lifecycle, companies consider expected lifetime returns when making R&D investment decisions. The economic literature thus predicts that the drug pricing provisions in the BBB could lead to decreased investment in the development of new drugs. Since government price setting in BBB focuses on some of the most commercially successful drugs in Medicare, the policy may discourage investment in blockbuster innovation.[20]

Though the price controls in BBB would directly affect a relatively small number of drugs initially, at the time an investment decision is made, it is not known whether the drug will be included in the scope of the price setting policy, which adds uncertainty to investment decisions. As a result, the policy may impact revenue expectations of drugs beyond those whose revenue will be reduced directly by government price setting. This may lead investment, especially early-stage investment, to shift to sectors other than biopharmaceuticals that provide more certain returns.[21]

Economic research also suggests that pharmaceutical firm cash flow is a determinant of R&D spending because internal capital is less costly than external debt.[22] Firms base their investment decisions not only on expected revenues but also on how much internal capital they have, choosing to invest internal capital before turning to external sources.[23] Government price setting would affect current profit margins and decrease firm cash flow, which is associated with lower spending on R&D.

Shift in Type of R&D

Investment in R&D is risky but there are additional risks in investing in transformational therapies because the science is often less established. Historically, these higher risks have been offset by higher expectations for revenue on transformational medicines. The literature suggests companies trade-off expected revenues, costs, and risks when investing in R&D.[24,25] As a result, price controls, which have a disproportionate impact on transformational medicines, may shift efforts toward lower-risk drug development.[26]

The products eligible for **government price setting** proposed by BBB are focused on the largest selling medicines in Medicare that have been on the market for seven or more years (11 years for biologics). This type of policy may have distortionary effects such as discouraging further investment in innovation for drugs that have been in the market for several years. For example, traditional regulatory approval processes target adult patient populations and may not include children. Pediatric studies are often conducted after approval, and in addition to certain studies that FDA may require, the Pediatric Exclusivity statute includes an incentive allowing FDA to request pediatric studies, which if conducted, qualify for an additional 6 months of exclusivity.[27] Similarly, there would be less incentive to invest in testing new indications for existing products. Important innovation often takes place after a molecule is approved, e.g., discovering it is effective for other conditions, at earlier stages in disease, or can improve patient adherence. If prices are controlled for drugs before this research can be conducted, the incentive to invest in gathering data for products currently on the market is reduced; in fact, just the prospect of price control would be expected to have a cooling effect on R&D.

While BBB indicates that comparative efficacy data or therapeutic impact may be considered for price setting, it is not clear how the federal government would use this information or how disease areas without well-understood or tangible clinical endpoints would be impacted. For example, there has been disagreement on what constitutes a clinically meaningful outcome for patients with dementia.[28,29] This approach to pricing may lead some patients to be disproportionately affected by shifts in R&D away from certain disease areas.

Furthermore, BBB likely would characterize biologic medicines as long-monopoly drugs.[30] Therefore, BBB would require that information on market data, including information on sales and costs of production and distribution, be considered in price setting for qualifying biologic drugs. Setting prices based on market data and production costs alone, however, would ignore the full cost of developing medicines. Most significantly, it would ignore the cost of the many failures that are an inevitable feature of the drug discovery process. In its 2020 guideline on country pharmaceutical pricing policies, a development-cost plus pricing model was the only policy the World Health Organization (WHO) issued a conditional recommendation against,[31] in part due to feasibility concerns and possible negative effects to innovation. Specifically, the WHO noted that "an undesirable effect of cost-plus pricing might be reduced incentive for manufacturers to invest in R&D, as only investments in a small proportion of pharmaceuticals actually reaching the market would be recovered, whereas costs of failed R&D efforts would not be compensated."[32] As such, investors are likely to invest less in biologic innovation given the expectation of pricing based on costs plus a fixed margin.

Other Unintended Consequences

Government price setting for drugs before the end of patent life would reduce the price differentials that encourage generic and biosimilar entry, undermining both a thriving generics market that already works to control drug spending and a growing biosimilars market that is beginning to drive prices down.[33]

Biosimilar market entry is particularly dependent on expected market size. After entry, off-patent manufacturers may struggle to compete at lower, government-set prices and may withdraw from the market, limiting the potential for price competition. In other words, the uncertainty of expected market size could put at risk the competitive effects of the biosimilar market. For example, it is estimated that biosimilars enter the market at prices as much as 45% below the innovator, generated more than $6 billion in savings in 2020 alone, and are projected to produce savings exceeding $100 billion between 2020 and 2024.[34]

As for the **Part D inflation penalty**, there is evidence that pharmacy benefit managers (PBMs) and other distribution system intermediaries may have incentives to prefer medicines with higher list prices and larger rebate percentages from manufacturers.[35] Biopharmaceutical company revenues are governed not by list prices, but rather by net prices, which take into account these rebates and discounts that payers receive. In recent years, it has been reported that net prices for brand medicines have grown more slowly than inflation and in 2020, net brand prices declined by 2.9%.[36] The standard average manufacturer price (AMP) on which the Part D inflation penalty is based doesn't reflect most negotiated discounts or rebates and does not represent the actual net prices paid by Part D plan sponsors. To the extent that current increases in AMP do not reflect declining net price trends, the BBB could be unnecessarily applied to medicines where market competition is already working well to keep net price growth low. In doing so, the BBB risks a reduction in revenues (and consequently in R&D investment) possibly beyond the reductions intended by the policy.

Conclusion

A fundamental issue in pharmaceutical policy is the conflict between the short-term goal of affordable access to current medications and the long-term goal of access to future, yet-to-be developed ones. Although the debate on price regulation focuses on impact in terms of savings today, it is paramount to understand the long-term implications of potential pricing regulation including the government price setting and inflation penalty provisions included in BBB. In addition to the impact on the level of investment in R&D and number of medicines, the impact on the type of pharmaceutical innovation must not be ignored.

Our conclusions on the likely impacts of the drug pricing provisions in the BBB are summarized in Table 1. We find that government price setting and inflation penalties would skew investment incentives. As of November 2021, the Congressional Budget Office (CBO) found that drug price controls in BBB will result in fewer new drugs: one fewer from 2022–2031, four fewer in the next decade, and five fewer in the following decade.[37] However, their methodology lacks consideration of the shift in incentives and investment behaviour, which indicates that the CBO's score is unlikely to capture the full impact of price controls on innovation of new medicines. The results of our assessment imply that the CBO's score of BBB is likely an underestimate.

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Shift in Type of R&D
3. Investment away from riskier R&D in transformational medicines to more predictable investments in lower risk innovation
4. Less incentives for investment in R&D that occurs after product approval in post market studies, including in pediatric populations
5. Since comparison to therapeutic alternatives is considered in price setting, R&D may shift away from disease areas where demonstrating the clinical benefits of a drug would be costly or challenging
Other Unintended Consequences
6. Undermining of generic and biosimilar markets due to uncertainty and lower expected revenues
7. Part D inflation penalty would unnecessarily apply to medicines where market competition is already working well to keep limit net price growth low

Source: CRA analysis

[1] Axelsen, K. and Jayasuriya, R. (2021) Government Scorekeepers Likely Underestimate the Impact of Lower Drug Costs Now Act (H.R.3) on Investment in Innovative Medicines. Retrieved from: https://media.crai.com/wp-content/uploads/2021/05/07124312/Review-of-CBO-Assessment-of-HR3-5-3-2021-FINAL.pdf.

[2] 117th Congress (2021-2022) H.R.5376 - Build Back Better Act. Retrieved from: https://www.congress.gov/bill/117th-congress/house-bill/5376.

[3] Congressional Budget Office, Summary of Cost Estimate for H.R. 5376, the Build Back Better Act. Retrieved from: https://www.cbo.gov/publication/57627.

[4] Axelsen, K. and Jayasuriya, R. (2021) Government Scorekeepers Likely Underestimate the Impact of Lower Drug Costs Now Act (H.R.3) on Investment in Innovative Medicines. Retrieved from: https://media.crai.com/wp-content/uploads/2021/05/07124312/Review-of-CBO-Assessment-of-HR3-5-3-2021-FINAL.pdf.

[5] The BBB is currently under consideration for passage by the Senate. Just prior to publication, Senate Committees began releasing modified legislative text for their respective sections of the BBB. Those modifications are not considered in this paper.

[6] 117th Congress (2021-2022) H.R.5376 - Build Back Better Act. Retrieved from: https://www.congress.gov/bill/117th-congress/house-bill/5376.

[7] See Congressional Budget Office (2021) “A Comparison of Brand-Name Drug Prices Among Selected Federal Programs” at Table 2. Retrieved from: https://www.cbo.gov/system/files/2021-02/56978-Drug-Prices.pdf. The Non-FAMP is the average amount paid per unit for drugs by non-federal purchasers, such as wholesalers, to pharmaceutical companies for their medicines. The non-FAMP includes discounts to the wholesalers such as those for prompt-payment, but it does not include the rebates pharmaceutical companies pay to health insurers or other entities for formulary coverage, nor does it include the price paid for units to government payors and special low-income programs such as Medicaid or the Veterans Administration. The Non-FAMP is not publicly released at present.

[8] The AWP is a published list of pharmaceutical prices.

[9] Some categories of medicines are exempt from government price setting, including certain drugs treating rare diseases and drugs produced by small biotechs.

[10] Extended from 12 to 13 years in House Managers Amendment November 4, 2021, accessed at https://rules.house.gov/sites/democrats.rules.house.gov/files/BILLS-117HR5376-RCP117-19.pdf.

[11] Per the text in BBB, a short-monopoly drug is defined as being within 12 years from its approval by the FDA. A post-exclusivity drug is defined as being at least 12 years but fewer than 16 years since approval. A long-monopoly drug is defined as being at least 16 years since approval. See 117th Congress (2021-2022) H.R.5376 - Build Back Better Act. Retrieved from: https://www.congress.gov/bill/117th-congress/house-bill/5376.

[12] For medicines covered under Part B, price is defined as the average sales price (ASP) plus the 6 percent add-on payment. For medicines covered under Part D, price is defined as the annual average of quarterly reported average manufacturer prices (AMP).

[13] Commercial insurers construct drug formularies by engaging in selective contracting with pharmaceutical firms. Pharmaceutical firms compete for formulary placement, which drives volume, by negotiating discounts and rebates with commercial insurers. Net pricing reflects the price after rebates and discounts. Biopharmaceutical firms are free to set a list price then privately contract with insurers for discounts from that list price.

[14] Medicaid, the Department of Defense, qualifying 340B hospitals and certain federal grantees, and Tribal Organizations can purchase drugs at prices that reflect maximum discounts to other payors as well as additional discounts that these payors can negotiate with biopharmaceutical firms for formulary access.

[15] Hayden Consulting Group. Controlling Competition: The Impact of Government Price Controls on Competition and the Market - #1. November 16, 2020. https://www.haydencg.com/post/controlling-competition-the-impact-of-government-price-controls-on-competition-and-the-market-1.

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[29] Budish, Eric, Benjamin Roin, and Heidi Williams. 2015a. "Do Firms Under-invest in Long-Term Research? Evidence from Cancer Clinical Trials." American Economic Review 105 (7): 2044–85.

[30] Biologics are more likely to be characterized as post-exclusivity or long-monopoly drugs under the BBB, given average times on the market prior to biosimilar entry. These categorizations mean that in determining their price, the Secretary of Health and Human Services would consider market data for the drug, including the distribution of sales across different programs and purchasers, projected revenues for the drug, and the unit costs of production and distribution of the drug.

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