



December 21, 2023

Honorable Jodey Arrington
Chairman
Committee on the Budget
U.S. House of Representatives
Washington, DC 20515

Honorable Michael C. Burgess
U.S. House of Representatives
Washington, DC 20515

*Re: Additional Information About Drug Price Negotiation and
CBO's Simulation Model of Drug Development*

Dear Chairman Arrington and Congressman Burgess:

This letter provides additional information that you and your colleagues requested about the Congressional Budget Office's analysis and model related to federal policies that affect the development of new drugs in the United States. In particular, you asked:

- How CBO's estimates of the budgetary effects of prescription drug provisions in the 2022 reconciliation act account for which drugs will be selected for price negotiation and for the effects on prices of competing drugs in the same therapeutic class as those selected for negotiation;
- How CBO's simulation model of drug development assesses potential changes in demand attributable to increases in the initial price of drugs when they come to market;
- Whether CBO's model accounts for changes in the indications (that is, the medical conditions that drugs are used to treat) that companies target when developing new drugs; and
- What changes to the model CBO may consider making to account for several factors, including ongoing trends in investment in early-stage drug development by venture capital firms, the law's effects on companies' decisions about which indications to target, and new research and data that could be used to refine and enhance the model.

Background

Under the 2022 reconciliation act (Public Law 117-169), the Secretary of Health and Human Services will negotiate prices for certain prescription drugs covered under Medicare Part B and Part D. To be selected for negotiation, a Part D drug must be among the 50 top-selling drugs without an approved generic equivalent or biosimilar competition in Part D. When Part B drugs become eligible for negotiation in 2026, those selected must likewise be among the 50 top-selling drugs in Part B. Selected drugs must meet other criteria as well.

CBO estimated that price negotiation will lower average drug prices paid by Medicare and will reduce the budget deficit by \$25 billion in 2031.¹ The agency further estimated that average drug prices in 2031 will be 9 percent lower in Part B and 8 percent lower in Part D (net of rebates and discounts) because of negotiation.²

The 2022 reconciliation act also requires drug manufacturers to pay an inflation rebate to Medicare for each unit of a drug that is sold to a Medicare beneficiary, if the drug's reference price exceeds its inflation-adjusted benchmark in any given year. (In Part B, the reference price is the drug's average sales price; in Part D, it is the average manufacturer price.) CBO estimated that average net prices of drugs in both Part B and Part D will be 2 percent lower in 2031 than they would have been without the inflation-rebate provisions and that overall, those provisions will reduce the federal budget deficit by \$8 billion in that year.

CBO's cost estimate for the 2022 reconciliation act accounts for how the law will affect companies' decisions about whether to develop new drugs. The agency used a simulation model to estimate the law's impact on the number of new drugs coming to market and how legislation could affect that number over time. CBO estimated that over the next 30 years, 13 fewer new drugs (of 1,300 estimated new drugs) will come to market as a result of the law.

¹ Congressional Budget Office, estimated budgetary effects of Public Law 117-169, an act to provide for reconciliation pursuant to title II of S. Con. Res. 14 (September 7, 2022), www.cbo.gov/publication/58455.

² Congressional Budget Office, "How CBO Estimated the Budgetary Impact of Key Prescription Drug Provisions in the 2022 Reconciliation Act" (February 2023), www.cbo.gov/publication/58850.

Additional Information About CBO's Estimates of the Budgetary Effects of Drug Provisions in the 2022 Reconciliation Act

CBO's estimates of the budgetary effects of drug provisions in the 2022 reconciliation act incorporate certain expectations about how the law will be implemented. To date, decisions made by the Centers for Medicare & Medicaid Services (CMS) have been largely consistent with those expectations.

For example, you asked whether the selection of certain drugs for price negotiation—namely, those about to face competition from biosimilar or generic drugs—has changed CBO's assessment of the budgetary effects of the law's drug provisions. CBO's estimates took that factor into account. The agency's assessment of the effects of those provisions incorporates the expectation that some drugs selected for negotiation would never be subjected to price reductions as a result of negotiation, because generic or biosimilar drugs would enter the market before the selected drugs' negotiated prices take effect.

CBO's assessment also incorporates the expectation that CMS will negotiate drug prices on the basis of a drug's active ingredient instead of its trade name or approval date; in practice, that is how CMS has approached negotiations thus far. CBO will continue to monitor the implementation of the 2022 reconciliation act's prescription drug provisions to understand how it may affect the federal budget.

Price and Demand Responses to the Law's Drug Provisions. CBO expects that the prescription drug provisions in the 2022 reconciliation act will affect the prices of drugs in several ways. For example, in the agency's assessment, drug companies will increase the list price of drugs entering the market as a response to the law's inflation-rebate provisions and, to a much lesser extent, its negotiation provision.³

Nevertheless, the agency expects that, net of rebates and discounts, drug prices in the commercial and Medicare Part D segments of the market will be affected only slightly, if at all, by those higher list prices. That is because drug manufacturers will raise rebates to offset increases in list prices and maintain net prices to maximize revenues in those market segments. (CBO's estimates of the 2022 reconciliation act's impact on overall drug prices account for that behavior.) Considering the limited

³ For a more detailed discussion, see Congressional Budget Office, letter to the Honorable Jason Smith providing additional information about prescription drug legislation (August 4, 2022), www.cbo.gov/publication/58355.

changes in net prices of new drugs, CBO expects that the demand for those drugs will be largely unaffected.

CBO's estimates of the budgetary effects of the 2022 reconciliation act also account for the impact of the law's negotiation provision on the prices of drugs that are therapeutic competitors to those chosen for price negotiation. The agency expects that prices will decrease for drugs that do not have negotiated prices but that are therapeutic competitors to those selected for negotiation. The savings from those reduced prices account for less than 5 percent of the estimated budgetary savings attributable to the law's negotiation policy.

Effects of the Law's Drug Provisions on Drug Availability and Health

Outcomes. A key factor in CBO's estimate of the number of new drugs that would come to market is the projected size of the law's effect on companies' expected revenues. In the case of the 2022 reconciliation act, the agency estimated that global revenues from sales of new drugs would fall by 1 percent to 3 percent. The effect on revenues reflects three key factors: first, that manufacturers can adjust their pricing strategy for future drugs to account for the law's provisions governing price negotiation and the inflation rebate; second, that reductions in prices attributable to the negotiation provision would occur only after a drug has been on the market for about a decade; and third, that the negotiation provision applies only to drugs in the Medicare program.

Although CBO's estimates of the effects of the law's drug provisions account for how companies make broad decisions about whether to develop new drugs, the agency has not assessed how the provisions might affect companies' strategies for developing specific drugs or which indications are targeted for a given drug. CBO has also not assessed how those strategies or choices would affect the timing of drugs' availability or patients' health outcomes.

Trends in Venture Capital Investment in Drug Development

Using data from the business-information provider Crunchbase, CBO has examined how the share of venture capital firms' investment that goes to pharmaceutical companies has changed since the 2022 reconciliation act became law in August of that year. (The available data from Crunchbase relate to firms' overall investment in pharmaceutical companies rather than their specific investment in early-stage drug development.)

Although investments vary from month to month, there is currently no evidence of a systematic decrease in the percentage of venture capital

flowing to pharmaceutical companies after August 2022—or in the period immediately preceding the law’s enactment (when there was probably some public awareness of its provisions). In fact, the share of venture capital reaching pharmaceutical companies has been trending upward (see [Figure 1 on page 7](#)). That trend is consistent with estimates developed using CBO’s current model, as is other recent evidence on industry-wide behavior since the 2022 reconciliation act became law.⁴ CBO will continue to work to understand how investments in drug development may evolve and will update its model on the basis of any new evidence.

CBO’s Transparency Efforts and Planned Future Work

Transparency is a top priority for CBO. The agency’s initial version of its simulation model of drug development was described in a technical paper published on its website in August 2021.⁵ CBO revised the model after receiving feedback from various stakeholders, including Congressional staff, representatives from the pharmaceutical industry, and academic experts. The revisions, which included a change in the way the model accounts for the effects of federal policies on early-stage drug development, are described in a slide deck that the agency published in January 2022.⁶

In addition to publishing that working paper and slide deck, CBO has presented and described its drug development model at an annual conference of the American Society of Health Economists, the Dartmouth Institute for Health Policy & Clinical Practice, and a health economics seminar cosponsored by Boston University, Harvard University, and the Massachusetts Institute of Technology.⁷

CBO will continue to improve its simulation model of new drug development. For example, the agency will explore ways to expand the model to estimate how the effects of policies may vary for drugs with different characteristics, such as small- or large-molecule drugs or those

⁴ See Richard G. Frank and Ro W. Huang, “Early Claims and M&A Behavior Following Enactment of the Drug Provisions in the IRA” (Brookings Institution, August 23, 2023), <http://tinyurl.com/2bzx8r5x>; and ATI Advisory, *Pharmaceutical Innovation and the Inflation Reduction Act: What Can We Learn From the First Half of 2023?* (November 2023), <http://tinyurl.com/3fyr9knr>.

⁵ Christopher Adams, *CBO’s Simulation Model of New Drug Development*, Working Paper 2021-09 (Congressional Budget Office, August 2021), www.cbo.gov/publication/57010.

⁶ Christopher Adams, “CBO’s Model of New Drug Development” (presentation to the Dartmouth Institute for Health Policy & Clinical Practice, January 13, 2022), www.cbo.gov/publication/57450.

⁷ Christopher Adams, “CBO’s Model of New Drug Development” (presentation to the Health Economics Seminar cosponsored by Boston University, Harvard University, and the Massachusetts Institute of Technology, February 2, 2022), www.cbo.gov/publication/57449.

that target certain diseases or patient populations (such as the elderly). As part of those efforts, the agency will also explore the possibility of expanding the model to allow for indication-specific estimates of drug development, as evidence permits.

Moreover, CBO continues to request and receive feedback to help inform potential refinements and improvements to its drug development model and its estimates of the budgetary effects of legislation that would affect the development of new drugs. The agency recently published a blog post highlighting its work in that area and calling for new research to further enhance that work.⁸

I hope this information is useful to you. Please contact me directly if you have further questions.

Sincerely,

A handwritten signature in black ink, appearing to read "Phillip Swagel", with a long, sweeping flourish extending to the right.

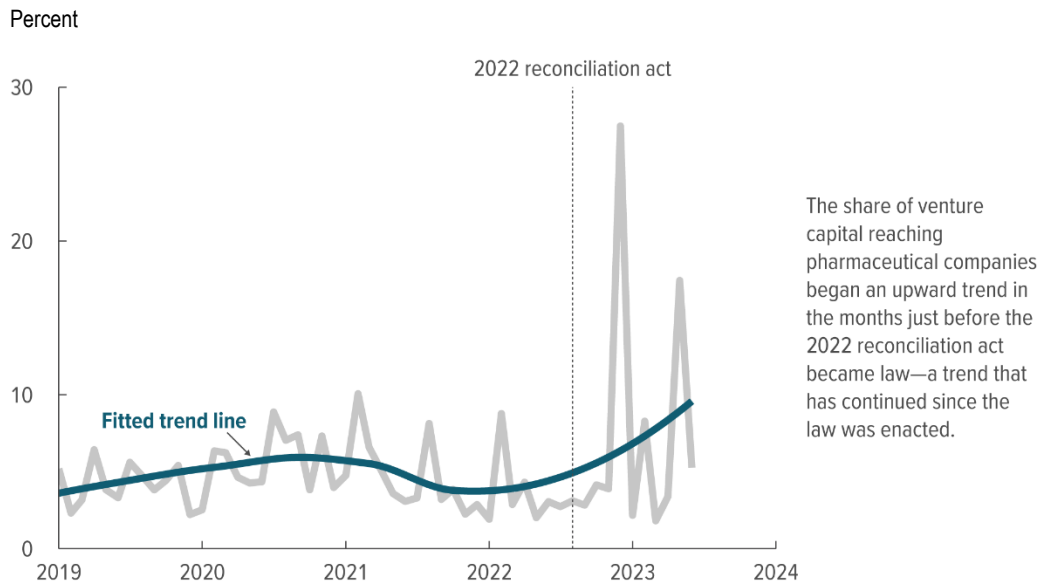
Phillip L. Swagel
Director

cc: Honorable Brendan Boyle, Ranking Member, Committee on the Budget; Honorable Earl L. “Buddy” Carter; Honorable A. Drew Ferguson IV; Honorable Blake D. Moore; Honorable Chip Roy; Honorable Lloyd Smucker; Honorable Rudy Yakym III

⁸ Congressional Budget Office, “A Call for New Research in the Area of New Drug Development,” *CBO Blog* (December 20, 2023), www.cbo.gov/publication/59818.

Figure 1.

Share of Venture Capital Flowing to Pharmaceutical Companies



Data source: Congressional Budget Office, using monthly data from the business-information provider Crunchbase.
