



**U.S. House of Representatives**  
COMMITTEE ON THE BUDGET  
Washington, DC 20515-6065

November 20, 2023

Phillip Swagel, Ph.D.  
Director  
Congressional Budget Office  
402 Ford House Office Building  
Washington, DC 20515

Dear Director Swagel:

We appreciate the work and economic analysis that the nonpartisan Congressional Budget Office (CBO) provides to lawmakers to understand the impact of proposed policies on the Federal budget. We also understand the inherent uncertainty and difficulty of projecting budgetary and other economic impacts of proposed policies. We write to follow up on your recent participation in the House Budget Committee Health Care Task Force roundtable in an effort to better understand CBO's analysis and model related to policies that impact new drug development in the United States.

As you know, the Inflation Reduction Act (IRA) created an exception to the Part D non-interference clause and instituted a framework for the "negotiation" of prescription drugs within both Part B and Part D of the Medicare program. This sweeping change is already having a profound impact on drug development decisions in the United States.<sup>1</sup>

CBO's analysis suggested that the IRA will result in one fewer drug coming to U.S. market over 2023-2032, about five the subsequent decade, and about seven over the decade after that, for a total of 13 fewer drugs coming to market over the next 30 years.<sup>2</sup> Independent assessments and related studies have suggested a significantly higher number of new drugs not being brought to the U.S. market as a result of the law's implementation, ranging from 139 fewer drugs coming to market over 10 years<sup>3</sup> to 135 fewer drugs over the next 20 years.<sup>4</sup>

With the growing impact of health spending on the Federal budget, we appreciate that CBO recognizes the power of innovation to reduce health care costs. Earlier this year, you noted that federal health spending was about \$1 trillion less than projected over the 2010-2020 period—largely from "reduced spending on patients with cardiovascular diseases" including

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<sup>1</sup> "The Inflation Reduction Act is Already Killing Potential Cures" [Wall Street Journal](#) (November 3, 2022)

<sup>2</sup> "Estimated Budgetary Effects of Public Law 117-169" [Congressional Budget Office](#) (September 7, 2022)

<sup>3</sup> "IRA's Impact to the US Biopharma Ecosystem" [Vital Transformation](#) (June 1, 2023)

<sup>4</sup> "The Impact of HR 5376 on Biopharmaceutical Innovation and Patient Health" [University of Chicago](#) (November 29, 2021)

from “greater use of medications to control risk factors.”<sup>5</sup> We fear that the loss of innovation and new treatments reaching patients because of the IRA’s price controls will lead to one less tool that could lower federal health care spending in the future.

President Biden and Congressional Democrats have expressed support for legislation that expands upon the drug price “negotiation” program initiated by the IRA. In fact, President Biden’s Fiscal Year 2024 Budget proposes to expand the IRA’s drug price controls by “negotiating more drugs and bringing drugs into negotiation sooner after they launch.” House Democrats have also introduced legislation that would increase the annual number of drugs subject to price controls in the Medicare program from 20 to 50.<sup>6</sup>

Accordingly, it is increasingly important that CBO’s analysis of policies that impact drug development in the U.S is incorporating the latest and most accurate information to ensure policymakers are fully aware of the impact legislation will have on patient access to new drugs.

In order to better understand CBO’s current approach to modeling policies that impact new drug development, we respectfully request answers to the following questions:

- 1) CBO has shared that the drug development model has been continually updated based on additional information and feedback from stakeholders and independent experts. Since passage of the IRA, numerous biopharmaceutical companies, investment funds, and financial institutions have made public statements on the impact of the IRA on clinical development decisions and investment strategies. Is CBO tracking trends in investments in early-stage drug development by venture capital firms following the passage of the IRA? Are there additional updates or changes CBO is currently considering to the drug development model?
- 2) Is CBO working, or willing to work, to expand the drug development model to forecast the impact of related policies on the total number of post-approval indications garnered by drugs that do come to market or the different impact on specific therapeutic areas? Does CBO intend to incorporate the impact not only to overall drug discovery, but the likelihood of firms moving away from small molecule indications, as well as the likelihood of firms moving to indications that will target a population outside of the mean Medicare age?
- 3) Has CBO shifted, or considered reevaluating their assessment of the IRA’s impact as a result of actions the Centers for Medicare and Medicaid Services (CMS) has taken to implement the law since enactment? Specifically, does the selection of drugs with forthcoming biosimilar and generic competition as part of the first ten drugs in the drug price negotiation program alter CBO’s expectations regarding the reductions in budget outlays attributable to the IRA?

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<sup>5</sup> “CBO’s Projections of Federal Health Care Spending” Letter to Senator Whitehouse, [Congressional Budget Office](#) (March 17, 2023)

<sup>6</sup> 118<sup>th</sup> Congress, [H.R. 4895](#) (Introduced July 26, 2023)

- 4) CBO has stated that it expects that drug companies will increase launch prices in response to the inflation rebate and negotiation provisions in the IRA. Independent economists have argued that companies are already expected to be pricing at the maximum price the market can bear. How does CBO's model assume the market will accept higher launch prices without a decrease in demand?
- 5) Some analyses have noted that the IRA will have implications on the pricing of therapeutic competitors of drugs selected for Medicare "negotiation." What, if any, assumptions did CBO make about the impact of the law on the pricing of products that are therapeutic competitors to selected drugs?
- 6) Since the timeline to selection for Medicare "negotiation" starts with a medicine's initial FDA approval or licensure, the IRA could create an incentive for innovator medicines to wait until they have developed clinical trial data for larger indications rather than move forward with indications to treat smaller populations with unmet needs for later lines of therapy, therefore delaying patient access to therapy. In its assessment of the IRA's effects on drug innovation, to what extent did CBO assess this factor as potentially affecting the timing of medicines' availability to American patients and subsequent impacts on patient health outcomes?
- 7) CBO recently issued a blog post soliciting feedback on new research on the use of anti-obesity medications to help inform the agency's analysis of relevant policies.<sup>7</sup> Will CBO commit to issuing a similar blog post that asks for independent feedback on new research and data to help inform potential refinements and improvements to the drug development model?

Thank you for your time and attention to this important matter. We look forward to your response.

Sincerely,



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MICHAEL C. BURGESS M.D.  
Chair of the Health Care Task Force  
House Budget Committee



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JODEY ARRINGTON  
Chairman  
House Budget Committee

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<sup>7</sup> "A Call for New Research in the Area of Obesity" [Congressional Budget Office](#) (October 5, 2023)



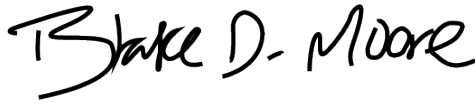
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LLOYD SMUCKER  
Member of Congress



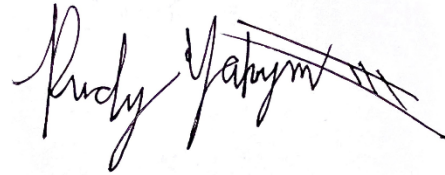
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EARL L. "BUDDY" CARTER  
Member of Congress



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BLAKE D. MOORE  
Member of Congress



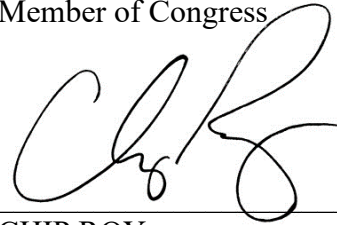
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