



# POLICY BRIEF



## BIDEN'S LIFE-THREATENING DRUG PRICE CONTROLS

The Biden administration is implementing price controls over the U.S. drug market which will harm and cost American lives. President Biden's so-called Inflation Reduction Act (IRA) imposed new price control mandates,<sup>1</sup> including statutory authorities for "drug price negotiation" with select private sector drug manufacturers, which has already forced companies to divest from critical drug development and increase prices on new drugs. Government price mandates will stifle innovation and reduce the financial viability for private sector companies to develop new life-enhancing medical drugs accessible to Americans.

- **Biden's Inflation Reduction Act drug pricing controls**

- As part of a new federal "drug pricing negotiation program," the Department of Health and Human Services (HHS) will impose price controls on select medical drugs that, once finalized, could take effect in 2026.<sup>2</sup>
  - HHS issued orders to companies as part of its "negotiating" process to establish final "maximum fair prices" on selected drugs as authorized under the 2022 IRA.<sup>3</sup>
  - The government-imposed "discounts" will range from 25 percent on drugs on the market less than 12 years ("short-monopoly" drugs and vaccines) and up to 60 percent for drugs that have been offered on the market for more than 16 years ("long-monopoly" drugs and vaccines).
  - Companies with selected drugs that refuse to participate in the HHS government-price control program will incur noncompliance penalties with a minimum penalty of 65 percent of drug sales and up to a maximum 95 percent.
- The threat of government price controls has already forced companies to hike prices.
  - For those consumers that maintain access as the HHS implements the drug pricing regulation, the regulation aims to artificially bring down prices directly faced by consumers of selected "high price" drugs.
  - The economics of Biden's drug pricing controls have resulted so far in the opposite effect, with companies making decisions to divest from development in drugs<sup>4,5</sup> and increase prices on new drugs that will not fall under the administration's pricing control scheme.<sup>6</sup>
  - Prices on new drugs brought to market by pharmaceutical companies increased 35 percent in 2023 compared to the previous year,<sup>7</sup> while prescription prices generally increased about 6 percent in 2023, up from 2 percent under the Trump administration.<sup>8</sup>

- **Private sector innovation, not government mandates, produces new life-enhancing medical drugs**

- The supposed narrow benefit of artificially "lower" prices paid by select consumers, however, misses the broader ramifications that will unfold as companies make ongoing cuts to research, development, and production.<sup>9</sup>
  - Some companies with drugs selected under the new pricing regulation have sued the federal government claiming that the program, if allowed to go into effect, violates certain constitutional rights,<sup>10,11</sup> including the "taking of property without just compensation" under the Fifth Amendment, and "excessive fines" under the Eighth Amendment.<sup>12,13</sup>

- Crucially, as companies make business decisions to disengage from ongoing research and production of drugs under current development, fewer new drugs would make it to market.<sup>14,15</sup> This is already occurring in the market even before the price control regime takes effect, where companies have decided to end certain drug development programs, from drugs that could be future cancer treatments to those addressing other rare and life-threatening diseases, because of cost uncertainty and the reduced financial viability.<sup>16</sup>
- In late 2022, for example, Alnylam Pharmaceuticals announced that it had suspended the phase 3 study of its “Stargardt disease” treatment,<sup>17</sup> and last year Eli Lilly halted its research into “a promising small-molecule blood cancer treatment, due to the market changes wrought by the Inflation Reduction Act.”<sup>18</sup>
- The U.S. leads the world in the development of new medical drugs, partly due to the ability for private companies to charge high prices that cannot be done elsewhere in the world.<sup>19</sup>
  - Prices on some drugs are higher in the U.S. market because many new drugs with high upfront development costs will only benefit a small, concentrated population of patients.<sup>20</sup>
  - The economics of “price-discriminating” monopolies over drugs, with the ability to charge different prices in different parts of the world, reduce what economists call “deadweight loss” and allow more consumers to benefit, both in the U.S and other countries.<sup>21,22</sup>
- Medical innovation, not government mandates, results in the production of new drugs that have, over time, dramatically improved and saved lives.<sup>23</sup>
  - One widely-cited economic study demonstrates that government price controls stifle medical innovation and drug development and estimates that regulatory constraints on drug development could result in up to 20 times greater impact on “life years lost” than the loss from Covid-19.<sup>24</sup>
  - Companies that no longer have financial incentives to invest in drug research and development will have less innovation.<sup>25</sup> This will result in more “life years lost,” which would cut life expectancy rates and longevity.<sup>26</sup>
- Any government “fixes” in the U.S. medical drug market must focus on ways to remove regulations and unleash supply-side incentives to boost production instead of the repeated focus on using demand-side government mandates and price controls.

Publ. March 21, 2024

<sup>1</sup> H.R. 5376 – Inflation Reduction Act of 2022. <https://www.congress.gov/bill/117th-congress/house-bill/5376/text>

<sup>2</sup> <https://www.cms.gov/files/document/medicare-drug-price-negotiation-program-initial-guidance.pdf>

<sup>3</sup> <https://www.hhs.gov/about/news/2024/02/01/biden-harris-administration-make-first-offer-drug-price-negotiation-program-launches-new-resource-hub-help-people-access-lower-cost-drugs.html>

<sup>4</sup> Joseph Grogan. The Inflation Reduction Act Is Already Killing Potential Cures. Wall Street Journal. November 3, 2022. <https://www.wsj.com/articles/the-inflation-reduction-act-killing-potential-cures-pharmaceutical-companies-treatment-patients-drugs-prescriptions-ira-manufacturers-11667508291>

<sup>5</sup> The Editorial Board. Drug Price Controls Mean Slower Cures. Wall Street Journal. August 29, 2023. <https://www.wsj.com/articles/drug-price-controls-medicare-joe-biden-inflation-reduction-act-pharma-8a38c333>

<sup>6</sup> Joseph Grogan. The Inflation Reduction Act’s Harms Go Beyond Drug Pricing – They’re Threatening Your Medicare. USC. Schaefer School. December 23, 2023. <https://healthpolicy.usc.edu/article/the-inflation-reduction-acts-harms-go-beyond-drug-pricing-theyre-threatening-your-medicare/>

<sup>7</sup> Deena Beasley. Prices for new US drugs rose 35% in 2023, more than the previous year. Reuters. February 23, 2024. <https://www.reuters.com/business/healthcare-pharmaceuticals/prices-new-us-drugs-rose-35-2023-more-than-previous-year-2024-02-23/>

<sup>8</sup> This is, in part, due to provisions under the IRA that requires drug manufacturers to rebate to Medicare the difference between the list price and the rate of inflation. The Editorial Board. Biden’s Drug-Price Boomerang. Wall Street Journal. December 17, 2023. <https://www.wsj.com/articles/bidens-drug-price-boomerang-630d284d>

<sup>9</sup> Joel Zinberg. A Solution in Search of a Problem. City Journal. March 13, 2024. <https://www.city-journal.org/article/a-solution-in-search-of-a-problem>

<sup>10</sup> Daniel E. Troy. An Unconstitutional Offer Drug Companies Can’t Refuse. Wall Street Journal. June 8, 2023. <https://www.wsj.com/articles/an-unconstitutional-offer-drug-companies-cant-refuse-merck-ira-innovation-5dba27e0>

<sup>11</sup> Hannah-Alise Rogers. Constitutional Challenges to the Medicare Drug Price Negotiation Program. Congressional Research Service. September 6, 2023. <https://crsreports.congress.gov/product/pdf/R/R47682>

<sup>12</sup> Joseph Walker. Merck Challenges U.S. Government’s New Powers to Negotiate Drug Prices. Wall Street Journal. June 6, 2023. <https://www.wsj.com/health/pharma/merck-challenges-u-s-governments-new-powers-to-negotiate-drug-prices-127d4b0c>

<sup>13</sup> David Wainer. Big Pharma’s Battle With the Biden Administration Could Have Legs. Wall Street Journal. September 9, 2023. <https://www.wsj.com/health/pharma/big-pharmas-battle-with-the-biden-administration-could-have-legs-a0524692>

- 
- <sup>14</sup> Daniel Gassull, Harry Bowen, and Duane Schulthess. IRA's Impact on the US Biopharma Ecosystem. VitalTransformation. June 1, 2023. <https://vitaltransformation.com/2023/05/iras-impact-on-the-us-biopharma-ecosystem/>
- <sup>15</sup> Rob Davis. et al. The Inflation Reduction Act's Negative Impact on Patient-Focused Innovation, Value and Access. Merck. June 6, 2023. <https://www.merck.com/news/the-inflation-reduction-acts-negative-impact-on-patient-focused-innovation-value-and-access/>
- <sup>16</sup> <https://www.wsj.com/articles/the-inflation-reduction-act-killing-potential-cures-pharmaceutical-companies-treatment-patients-drugs-prescriptions-ira-manufacturers-11667508291>
- <sup>17</sup> Alnylam Pharmaceuticals Reports Third Quarter 2022 Financial Results and Highlights Recent Period Activity. Alnylam Pharmaceuticals, Inc. October 27, 2022. <https://investors.alnylam.com/press-release?id=27046>
- <sup>18</sup> Sally Pipes. Small-Molecule Price Controls Are a Big Mistake. Forbes. May 8, 2023. <https://www.forbes.com/sites/sallypipes/2023/05/08/small-molecule-price-controls-are-a-big-mistake/?sh=4cc89393acd0>
- <sup>19</sup> David R. Henderson and Charles L. Hooper. Be Thankful for High Drug Prices. Wall Street Journal. February 4, 2024. <https://www.wsj.com/articles/be-thankful-for-high-drug-prices-healthcare-policy-research-and-development-3e603ca8>
- <sup>20</sup> Robert Graboyes. Bad Ways to Lower Drug Prices. Mercatus Center. August 19, 2019. <https://www.mercatus.org/economic-insights/expert-commentary/bad-ways-lower-drug-prices>
- <sup>21</sup> *Id.*
- <sup>22</sup> Kofi Ampaabeng. Rich countries should pay their fair share for American drugs. The Hill. March 7, 2023. <https://thehill.com/opinion/international/3885103-rich-countries-should-pay-their-fair-share-for-american-drugs/>
- <sup>23</sup> Tomas J. Philipson. The Deadly Side Effects of Drug Price Controls. Wall Street Journal. April 5, 2023. <https://www.wsj.com/articles/medicare-drug-price-controls-will-make-america-sicker-research-innovation-negotiations-private-insurers-b503b4ba>
- <sup>24</sup> Tomas J. Philipson and Troy Durie. The Evidence Base on the Impact of Price Controls on Medical Innovation. Becker Friedman Institute for Economics at University of Chicago. September 14, 2021. [https://bfi.uchicago.edu/wp-content/uploads/2021/09/BFI\\_WP\\_2021-108.pdf](https://bfi.uchicago.edu/wp-content/uploads/2021/09/BFI_WP_2021-108.pdf)
- <sup>25</sup> <https://www.city-journal.org/article/a-solution-in-search-of-a-problem>
- <sup>26</sup> Frank R. Lichtenberg. Pharmaceutical Innovation and Longevity Growth in 30 Developing and High-income Countries, 2000-2009. National Bureau of Economic Research. 2012. <https://www.nber.org/papers/w18235>