
# Pharmaceutical Price Controls Are Bad Medicine

**NOVEMBER 2021**

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## About CAGW

Citizens Against Government Waste (CAGW) is a private, nonprofit, nonpartisan organization dedicated to educating the American public about waste, mismanagement, and inefficiency in government.

CAGW was founded in 1984 by J. Peter Grace and nationally syndicated columnist Jack Anderson to build public support for implementation of the Grace Commission recommendations and other waste-cutting proposals. Since its inception, CAGW has been at the forefront of the fight for efficiency, economy, and accountability in government.

CAGW has more than 1 million members and supporters nationwide. Since 1984, CAGW and its members have helped save taxpayers more than $2.3 trillion. CAGW publishes special reports, including the *Congressional Pig Book* and *Prime Cuts*, as well as its official newsletter *Government WasteWatch* and blog *The WasteWatcher*, to expose government waste and educate the American people on what they can do to stop the abuse of their hard-earned money. Internet, print, radio, and television news outlets regularly feature CAGW's publications and experts.

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## Introduction

The U.S. Congress is embarking on a dangerous journey that will result in dramatic changes in the size, scope, power, and control of the federal government. If it is approved by the House and Senate, H.R. 5376, President Biden's Build Back Better (BBB) Act,[1] will cost at least $1.75 trillion, bringing the total amount approved by Congress since the beginning of the pandemic in March 2020 to more than $8.6 trillion, including the $1.2 trillion infrastructure bill that he signed into law on November 16.[2]

This legislation will create more than 150 new government programs, give electric vehicle subsidies for couples making more than $500,000 annually, and spend $19 million evenly divided for butterflies, desert fish, endangered plants, and freshwater mussels. The BBB Act will increase the national debt by more than $3 trillion, according to a report from House Budget Committee Republicans, and add to inflationary economic pressure.[3]

But the worst provisions are not directly related to more spending. The BBA Act would implement big government policies that have been pushed for years, including price controls on pharmaceuticals that are included in bills like H.R. 3, the Elijah E. Cummings Lower Drug Costs Now Act, which would be extremely unhealthy for the American people and the economy.[4]

The United States biopharmaceutical industry has provided cures and treatments for thousands of diseases, which has dramatically improved the quality of life, health, and well-being of people around the world. These achievements are the result of substantial annual investments in research and development.

The pharmaceutical industry accounts for 3.4 percent of the gross domestic product,[5] yet it conducts 17 percent of all business-funded research and development (R&D) investment. It spent nearly $1 trillion on research and development between 1999 and 2020,[6] with an increase of more than 50 percent between 2015 and 2020, when that total reached $91 billion.[7] The increased R&D was accompanied by a 60 percent increase in Food and Drug Administration (FDA) annual average drug approval between 2010 and 2019 compared to the annual average

[1] Build Back Better Act, H.R. 5376, 117th Congress (2021), https://www.congress.gov/bill/117th-congress/house-bill/5376.
[2] Infrastructure and Investment Jobs Act, Pub. L. No. 117-58, 117th Congress (2021), https://www.congress.gov/bill/117th-congress/house-bill/3684.
[3] House Budget Committee Republicans, "The Three Bs of the Biden Agenda," https://republicans-budget.house.gov/wp-content/uploads/2021/11/The-Three-Bs-of-Bidens-Agenda-Reconciliation.pdf.
[4] Elijah E. Cummings Lower Drug Costs Now Act, H.R. 3, 117th Congress (2021), https://www.congress.gov/bill/117th-congress/house-bill/3.
[5] PhRMA, TECONOMY Partners, LLC., "The Economic Impact of the U.S. Biopharmaceutical Industry: 2017 National and State Estimates," December 2019, p. 11, https://gabio.org/wp-content/uploads/2020/01/Teconomy-THE-ECONOMIC-IMPACT-OF-THE-U.S.-BIOPHARMACEUTICAL-INDUSTRY-2017-National-and-State-Estimates-12.2019-min.pdf.
[6] National Association of Manufacturers (NAM), "Ensuring a Healthy Future: The Impact and Importance of Pharmaceutical Manufacturing, p. 2, https://www.nam.org/wp-content/uploads/2021/09/ENSURING-A-HEALTHY-FUTURE.pdf.
[7] *The Wall Street Journal*, "The Political Raid on Future Cures," September 16, 2021, https://www.wsj.com/articles/the-political-raid-on-future-cures-drug-price-controls-house-democrats-pharmaceutical-companies-11631828137.

during the prior decade.[8] In addition, the pharmaceutical industry reinvests 27.7 percent of its sales into R&D, approximately six times higher than similar investments in other industries.[9]

The economic impact of the pharmaceutical industry goes beyond the 811,000 direct employees, who have good jobs at high wages and include the highest percentage of STEM workers, by supporting another 4 million jobs.[10] And of course, the industry created safe and effective COVID-19 vaccines in an extraordinarily short period of time, along with new treatments, which have saved and will save millions of lives.

Given the industry's value and importance to the United States, and indeed the world, taxpayers, consumers, and patients would think that it should be left alone to continue its successful endeavors and life-saving activities. Yet many members of Congress and the Biden administration believe the industry is the embodiment of evil capitalist greed and must be strictly regulated, including with the imposition of price controls.

The desire to regulate the industry is such a top priority for the Democratic majority in Congress that the third bill introduced in the 117th Congress, H.R. 3 is composed of a series of price controls that in the long run will cause shortages, raise costs, significantly destroy U.S. leadership in pharmaceutical research and development, and create a pathway for the government to take over private healthcare with Medicare for All.[11]

Trying to utilize price controls on drugs is nothing new for Congress. Price control legislation, often deceptively described as allowing the Department of Health and Human Services (HHS) secretary to enter "negotiations" for Medicare Part D drug coverage, has been introduced in every Congress since the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) was signed into law in 2003.

The MMA requires the HHS secretary to follow section 1860D-11(i) [42 U.S.C. 1395w-111], the "noninterference clause," which states: "In order to promote competition under this part and in carrying out this part, the Secretary (1) may not interfere with the negotiations between drug manufacturers and pharmacies and PDP [prescription drug plan] sponsors; and (2) may not require a particular formulary or institute a price structure for the reimbursement of covered part D drugs."[12]

This language echoes S. 2541, the Medicare Expansion for Needed Drugs (MEND) Act of 2000, which was introduced by then-Senate Minority Leader Tom Daschle (D-S.D.). The legislation was cosponsored by current Sens. Dick Durbin (D-Ill.), Diane Feinstein (D-Calif.), Patrick Leahy (D-Vt.), Patty Murray (D-Wash.), Chuck Schumer (D-N.Y.) and then-senator, now President Joe Biden. The bill would have established a voluntary insurance program that would provide a drug benefit for Medicare beneficiaries, the disabled, or those with end-stage

[8] Congressional Budget Office, "Research and Development in the Pharmaceutical Industry," Summary, April 2021, https://www.cbo.gov/publication/57126.
[9] Nam D. Pham, "The Importance of IP-Intensive Manufacturing Industries to the U.S. Economy," October 2021, p. 8, https://ndpanalytics.com/wp-content/uploads/IP-Intensive-Industries-Report-October-2021.pdf.
[10] PhRMA, TECONOMY Partners, LLC., pp. 9, 12.
[11] Ibid., H.R. 3, Elijah E. Cummings Lower Drug Costs Now Act.
[12] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 108th Congress (2003), pp. 117 STAT. 2098-2099, https://www.govinfo.gov/content/pkg/PLAW-108publ173/pdf/PLAW-108publ173.pdf.

renal disease. It included a noninterference clause, which stated, that the secretary of Health and Human Services could not administer the drug benefit in a manner that would require a particular price structure or formulary or interfere in private negotiations on pricing, or any other competitive activities related to providing prescription drug benefits.[13]

The ongoing efforts by these Democrats to repeal the noninterference clause are diametrically opposed to their original position, which turned out to be correct, because the private sector negotiations that are protected by the Part D noninterference clause have worked well. In 2005, the cost of Part D by 2012 was estimated to be approximately $126.8 billion; its cost was $55 billion.[14] A government program ended up costing less than was predicted is practically unheard of in Washington, D.C.

Part D is also extremely popular with seniors. The Healthcare Leadership Council's 2021 Medicare Part D Recipients' Perception of Care Survey showed that 84 percent said they can afford their monthly premiums, 76 percent said they have reasonable out-of-pocket costs, and 75 percent have coverage of all their prescribed medications. The average overall satisfaction rate for prescription drug coverage between 2020 and 2021, when the survey was taken, was at 90 percent.[15] When asked about potential impact of the government setting prices of medicines and deciding which ones could be covered under Medicare, 50 percent of seniors said the current law should be kept to prevent the government from deciding which drugs are available, compared to 30 percent who said the law should be changed to allow the government to negotiate prices.[16]

Supporters of permitting the HHS secretary to "negotiate" drug prices are discounting the successful negotiations that occur among pharmaceutical manufacturers, insurers, pharmacy benefit managers (PBMs), and pharmacists, as well as the high rate of support for Part D among beneficiaries. They simply continue to push for H.R. 3 and variants thereof to allow the government to directly "negotiate" prices, and establish a price ceiling, which would abrogate the noninterference clause with a lot of interference and undoubtedly lead to fewer drugs and higher costs.

The government does not negotiate. It tells suppliers what it will pay for a product. The "discounts" are written into law, like Medicaid drug rebates, which vary depending on the type of drug. The Medicaid rebate is mandatory and ranges from 13 percent of the average manufacturer's price (AMP) for generics to 23.1 percent for brand name drugs. Similarly, under H.R. 3, the statutory set ceiling price and a mandated discount is not a negotiation.

A pharmaceutical manufacturer cannot participate in the government drug benefit programs unless they agree to the mandated discount or rebate. In the Medicare Part D coverage gap, or "donut hole," the government mandates that manufacturers pay 70 percent of the cost of

[13] Medicare Expansion for Needed Drugs (MEND) Act of 2000, S. 2541, 106th Congress (2000), https://www.congress.gov/bill/106th-congress/senate-bill/2541/text.
[14] Douglas Holtz-Eakin, Robert Book, "Competition and the Medicare Part D Program," American Action Forum, September 11, 2013, https://www.americanactionforum.org/research/competition-and-the-medicare-part-d-program.
[15] Healthcare Leadership Council, "Medicare Part D Recipients' Perceptions of Care Survey," July 2, 2021, http://medicaretoday.org/wp-content/uploads/2021/07/2106179_HLC_Medicare-Part-D_Satisfaction_7.27.21_final.pdf.
[16] Healthcare Leadership Council, "Medicare Part D Recipients' Perceptions of Medicare Negotiations," July 2021, http://medicaretoday.org/wp-content/uploads/2021/07/2106179_HLC_Medicare-Part-D-Policy_7.27.21_final.pdf.

their drugs for Medicare beneficiaries; the Department of Veterans Affairs uses statutorily mandated prices and discounts of 24 percent plus an inflation penalty, in addition to having fixed formulary that covers fewer drugs than Part D;[17] and the 340B drug discount program that is supposed to assist certain safety net providers that serve vulnerable or underserved populations and is calculated to match Medicaid prices but has been compromised over the years,[18] becoming a convenient program for hospitals and for-profit pharmacies to make large profits. All the government price controls in drug benefit plans have distorted the entire U.S. pharmaceutical marketplace, driving up costs in the private market.

But this does not stop efforts to increase government control over Medicare beneficiaries' drug benefit even though the price controls that have been used throughout history failed to solve the problem they were created to fix, and in the end made matters far worse.

## Price Controls Throughout History

Monarchies, dictators, and elected leaders throughout the world have tried to control prices and services by various methods for centuries. But the controls do not fix the problem they were created to solve and end up hurting their citizenry. In their 1978 book, *Forty Centuries of Wage and Price Controls*, authors Robert Scheuttinger and Eamonn Butler did an admirable job of showing how price controls cause severe damage, whether applied in 2150 B.C. or 1971 A.D. From the Babylonian Code of Hammurabi to President Richard Nixon's Economic Stabilization Act, to rent control in New York City, the authors laid out how price controls interfered with the marketplace, caused shortages, and hurt the very population they were intended to help.[19]

And no matter how brilliant or sophisticated our elected leaders are in the 21st Century, they will not be able to devise a system in which price controls work. Economist Gary North wrote in a May 1, 1974, article, "The Puritan Experiment with Price Controls," that even as early as 1630 colonial America, price controls were implemented and failed. The Massachusetts Bay Company passed a law that, "established wage ceilings for carpenters, joiners, bricklayers, sawyers, and thatchers. Common laborers were limited to twelve shillings a day, or six if meat and drink were provided by the employer. Any artisan violating this statute was to be assessed a ten shilling fine. The effect of these wage ceilings must have presented itself almost immediately: an excess of demand for the services of artisans over the available supply. Under such conditions, it is always difficult to recruit labor. Within six months, these wage ceilings were repealed, leaving wages 'free and at liberty as men shall reasonably agree.'"[20] Unfortunately, the New England forefathers did not learn that such meddling in the free market

[17] Xcenda, "Comparing the Generosity of Drug Coverage in the Medicare Part D and Veterans Affairs Programs," AmerisourceBergan, July 2020, https://www.xcenda.com/-/media/assets/xcenda/english/content-assets/white-papers-issue-briefs-studies-pdf/comparing-the-generosity-of-drug-coverage-in-the-medicare-part-d-and-veterans-affairs-programs.pdf.
[18] House Energy and Commerce Committee, "Review of the 340B Drug Pricing Program," January 18, 2018, https://republicans-energycommerce.house.gov/news/press-release/new-ec-report-examines-340b-drug-pricing-program.
[19] Robert Schuettinger and Eamonn Butler, *Forty Centuries of Wage and Price Controls – How Not to Fight Inflation*, The Heritage Foundation, Washington, D.C., 1978.
[20] Gary North, "The Puritan Experiment with Price Controls," Foundation for Economic Freedom, FEE.org, May 1, 1974, https://fee.org/articles/the-puritan-experiment-with-price-controls.

was destructive and reimposed the price controls several times to halt "excess profits," whatever that meant to anyone, creating ongoing confusion and uncertainty in the marketplace.[21]

A more recent example of the destruction that wage and price controls create occurred under President Richard Nixon. Out-of-control spending in the mid-to-late 1960s on new social programs and the Vietnam War led to high inflation and a weakening of the dollar. As inflation rose, President Nixon made an ill-fated mistake. Under the authority of the Economic Stabilization Act of 1970, he issued Executive Order (EO) 11615 on August 15, 1971, to "stabilize prices, rents, wages, and salaries in order to improve our competitive position in world trade and to protect the purchasing power of the dollar."[22] The conditions at that time are sounding eerily familiar now.

Although the EO was only supposed to last 90 days, it went from August 15, 1971, to April 30, 1974. Secretary of the Treasury George Schultz announced the goal was to reduce inflation to 3 percent per year or less. But during that period, the Wholesale Price Index (WPI) and the Consumer Price Index (CPI) increased at annual rates of 12 percent and 7.2 percent, respectively. In the 12 months prior to implementing price controls, the WPI and CPI had annual rate increases of 3.3 percent and 4.3 percent, respectively.[23]

Numerous evasive and shrewd actions by businesses took place during that period to avoid the price controls, like butchers changing the name of standard cuts of beefs to new ones like "watermelon roast," which did not fall under the government requirements. Since imported lumber was not price controlled, lumber producers exported wood to Canada and then re-imported it back into the U.S.[24]

Most emblematic of that era was the gas shortages. Domestic oil was under price controls while foreign oil prices rose and fell based on market forces. The price controls led to distortions in the domestic marketplace and government regulators developed complex rules to address the irrational behavior the government had caused. U.S. refiners had access to domestic and foreign oil in different proportions and the Nixon administration sought to equalize their costs with a two-tier pricing system. Prices for foreign oil and domestic oil from "new" wells were allowed to rise while prices for oil from "old" domestic wells were controlled. The government intrusion into the allocation of oil supplies caused Americans in various regions of the country to line up for hours to get access to gasoline.[25]

The U.S. also became more reliant on foreign oil, particularly from less reliable sources in unstable parts of the world. When the Organization of the Petroleum Exporting Countries (OPEC) announced an oil embargo on countries, like the United States, that assisted Israel in the

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[21] Ibid.
[22] Richard M. Nixon, Executive Order 11615, "Providing for the Stabilization of Prices, Rents, Wages, and Salaries," The American Presidency Project, August 15, 1971, https://www.presidency.ucsb.edu/documents/executive-order-11615-providing-for-stabilization-prices-rents-wages-and-salaries.
[23] Schuettinger and Butler, pp. 107-108.
[24] Steve Mufson, "Price Controls: Past as Health Care Prologue; Clinton Would Find a History of Failure, Unintended Effects," *The Washington Post*, March 14, 1993, p. H1, https://www.washingtonpost.com/archive/business/1993/03/14/price-controls-past-as-health-care-prologue/bcf61ebd-5549-492a-a210-08c3fe54bc7b.
[25] Herbert Stein, *Presidential Economics: The Making of Economic Policy from Roosevelt to Clinton*, American Enterprise Institute, Washington, D.C., 1994, p. 186.

Yom Kippur War in 1973, the result was price gouging and long lines at gas pumps. Americans looked for green flags outside gas stations that proclaimed they had gasoline and they could only buy gas on certain days depending on their license plate number.[26]

President Jimmy Carter was elected in 1977 and spent billions of dollars on alternative energy, including wasteful projects like coal gasification. Oil consumption continued to rise, and while Carter removed some gas price controls to encourage domestic production during the Iranian oil crisis, prices quickly rose causing sky-high inflation. It was not until President Ronald Reagan entered the White House and completely removed all price controls and approximately 200 energy regulations did oil consumption and prices begin to fall as production increased. It was the free market that helped improve conditions, not government intervention.[27]

## Destructive Effects of Price Controls Have Already Been Experienced in Pharmaceutical Marketplace

In 2019, according to the Centers for Medicare & Medicaid Services (CMS) National Health Expenditures, $369.7 billion was spent on retail prescription pharmaceuticals. Of that amount, $53.7 billion was spent out of pocket and $311.7 billion was spent by insurance. Breaking these statistics down further, $164.6 billion was spent under private insurance; $104.6 billion under Medicare; $31.4 billion under Medicaid; $11 billion by other insurance programs like the Children's Health Insurance Program (Title XIX and XXI), the Departments of Defense and Veterans Affairs; and, $4 billion by other third-party payers.[28] A back-of-the-envelope calculation shows that at minimum $147 billion was spent on pharmaceuticals under a government-run program that utilized price controls in some form, which means almost 40 percent of all retail pharmaceutical sales in the United States has a price control affecting it in some way – creating harmful distortions elsewhere in the market.

Price controls have distorted markets throughout history and clearly, they have done nothing to stabilize or lower drug prices in the United States. Former President Donald Trump, who eliminated dozens of unnecessary regulations and cut taxes, resulting in record low unemployment rates and salary gains until the COVID-19 pandemic,[29] steered off course when he supported a variety of pharmaceutical price controls and brought new life to a proven damaging policy.

A March 22, 2019, *Real Clear Politics* article by Doug Badger discussed the various price controls that have been implemented in U.S. government programs and how "extorting price concessions from manufacturers across a broad range of programs" has artificially driven up drug prices. Badger reviewed various studies, including a 2016 *New England Journal of*

[26] Ibid., pp. 191-193.
[27] Richard Miniter, "The Oil Shortage That Wasn't," *National Review*, April 15, 1991, p. 38.
[28] CMS National Health Expenditures, Table 16 Retail Prescription Drug Expenditures, December 16, 2020, https://www.cagw.org/sites/default/files/pdf/Copy%20of%20Table%2016%20Retail%20Prescription%20Drugs%20Expenditures_0.pdf.
[29] Ray Maurer, "BLS Reports Lowest Employment in 50 Years," Society for Human Resource Management, May 3, 2019, https://www.shrm.org/ResourcesAndTools/hr-topics/talent-acquisition/Pages/BLS-HR-Jobs-Unemployment-April-2019.aspx.

*Medicine* analysis that reported, "manufacturers can and do pass the costs of the 340B discounts to other programs" and a University of Pennsylvania paper which found that due to Medicaid rebates, "a 10 percent increase in Medicaid market share is associated with a 7 to 10 percent increase in a medicine's average price."[30]

**Foreign Price Controls are Nothing to Emulate**

Progressives in Congress have long desired to adopt foreign drug price controls. Avowed Socialist Sen. Bernie Sanders (I-Vt.) said in March 2021 when he introduced a package of legislation that he believed would lower drug prices, "The United States pays by far the highest prices in the world for prescription drugs. This is an immediate health crisis that must be addressed … That is why I am reintroducing legislation to drastically reduce prescription drug prices in the United States. The time is now to stand up to the pharmaceutical industry and say enough is enough. The greed of drug companies is out of control and the cost is human lives." Sen. Sander's package included S. 909, the Prescription Drug Price Relief Act, which pegged the price of U.S. prescription drugs to the median price in Canada, France, Germany, Japan, and the United Kingdom; S. 908, the Medicare Drug Price Negotiation Act, which directed the HHS secretary to directly negotiate lower prices on drugs in Medicare Part D; and S. 920, the Affordable and Safe Prescription Drug Importation Act, which would allow patients, pharmacists, and wholesalers to import drugs from Canada, among other countries.[31]

Those who promote importing "cheap" drugs from other countries, like Canada, conveniently forget to mention that these countries use price controls and rationing to keep drug prices artificially low and deny their citizens access to some of the newest and most innovative pharmaceuticals in the market. They do not talk about the fact that price controls have hurt foreign pharmaceutical innovation and countries rely on U.S. research and development dollars to supply their medicine cabinets. They also conveniently do not mention the fact that Canada has said repeatedly "no" to exporting their drugs to the U.S., as the country has its own drug shortages, which are harming its citizens.[32]

A March 2019 issue paper written by Doug Badger and released by the Galen Institute demonstrates how countries utilize a variety of non-market-based tools, like reference pricing, price caps, and comparative effectiveness studies to keep pharmaceutical costs down. As a result, citizens in these countries get access to new pharmaceuticals at much lower rates than Americans. For example, between 2011 and 2018, there were 290 active new pharmaceutical substances and Americans got access to 89 percent of them, while citizens in Austria, Denmark,

[30] Doug Badger, "Trump Blames the Wrong Government for High Drug Prices," *Real Clear Politics*, March 22, 2019, https://www.realclearhealth.com/articles/2019/03/22/trump_blames_the_wrong_government_for_high_drug_prices_110887.html.
[31] Sen. Bernie Sanders (I-Vt.), "NEWS: Sanders, Khanna, Doggett, Welch, Bush Introduce Sweeping Legislation to Lower Drug Prices," March 23, 2021, https://www.sanders.senate.gov/press-releases/news-sanders-khanna-doggett-welch-bush-introduce-sweeping-legislation-to-lower-drug-prices.
[32] Matthew Schwartz, "Canada Blocks Export of Medications in Short Supply in Response to Trump Plan," NPR WAMU 88.5, November 29, 2020, https://www.npr.org/2020/11/29/939890111/canada-blocks-export-of-medications-in-short-supply-in-response-to-trump-plan.

France, Germany, Switzerland, and the U.K. got access to 60, 57, 48, 62, 48, and 60 percent respectively.[33]

There is similar access (or lack thereof) for 82 new oncology drugs that have been on the market since 2011. Americans received access to 96 percent, while citizens in Austria, Denmark, France, Germany, Switzerland, and the U.K. got access to 70, 66, 66, 73, 62, and 71 percent respectively.[34]

In a November 2020 NDP Analytics report, researchers Nam D. Pham, Ph.D. and Mary Donovan wrote, "The positive and negative impacts that public policies can have on biopharmaceutical innovation can be seen in the movement in the balance of R&D investment from Europe to the U.S. in the late 1990s, and perhaps again with the rise of Asia as a biopharmaceutical innovation center very recently. Price controls and other interventions in the European medicines market decades ago – and the adoption in the U.S. of more market friendly drug policies – corresponded with the shift to the U.S. as the world leader in biopharmaceutical R&D."[35]

The researchers demonstrated that biopharmaceutical research and development in Europe was "consistently higher than R&D investment in the U.S. until the late 1990s." At that time total investment in research and development between the two regions was $16.7 billion, with the U.S. contributing 40.8 percent and Europe contributing 59.2 percent. By 2005, investment was shifting, when the U.S. contributed 53.1 percent and Europe contributed 46.9 percent for a total of $58.3 billion in biopharmaceutical research and development. By 2017, the U.S. contributed 58.3 percent and Europe contributed 41.7 percent of the total $95.7 billion in invested.[36]

According to Pham and Donovan, "price control policies are shown to be one of the crucial factors affecting the shift of biopharmaceutical R&D investment from Europe to the U.S. in the late-1990s and early-2000s. Since the 1980s, European governments imposed a wide range of policies to control drug prices, including price freezes, fixed pricing, profit controls, and reference pricing." They listed the various policies different countries adopted, like Germany's reference pricing for medications based on a "basket of other nation's reimbursement levels" and France adding over a period of years, "a variety of taxes, ad-hoc price cuts, spending caps and other policies that undercut incentives to conduct R&D and innovate medicines in that country." The U.K.'s National Institute for Health and Clinical Excellence, ironically called NICE, became a "gatekeeper" and assessed the value of drugs, often denying U.K. citizens access to many of the most innovative new drugs.[37]

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[33] Doug Badger, "Examination of International Drug Pricing Policies in Selected Countries Shows Prevalent Government Control over Pricing and Restrictions on Access," Galen Institute, March 2019, pp. 15, 20, https://galen.org/assets/Badger-Report-March-2019.pdf.
[34] Ibid.
[35] Nam D. Pham, Ph.D., Mary Donovan, "Will U.S. Leadership in Biopharmaceutical R&D Continue?: Consequences of Price Controls and Other Anti-Innovation Policies," NDP Analytics, November 2020, p. 1, https://ndpanalytics.com/wp-content/uploads/ImpactsofPublicPoliciesonRDFinal.pdf.
[36] Ibid., p. 3.
[37] Ibid., p. 6.

The authors also provided a stern warning that the U.S. should not take for granted its current biopharmaceutical leadership position. They noted that many Asian countries are moving forward with regulatory reforms, like more science-based reviews and approvals of new medicines and pricing changes to encourage home-grown research and development. Between 2008 and 2016, biopharmaceutical research and development in some Asian countries has grown at a rate of 19.3 percent annually, compared to the U.S. annual rate of 3.3 percent. The Chinese government, which has little respect for intellectual property rights, has modernized its drug reimbursement list for the first time and "is seeking to establish an innovative biopharmaceutical industry as a key development goal."[38] If Congress enacts H.R. 3 or variants thereof, it will destroy the U.S. lead in biopharmaceutical research and development and increase reliance on countries like China for the research and development of lifesaving medicines.

**H.R. 3 is Prolific with Putrid Policies**

If legislation could be written that would combine the worst government policies that stifle innovation, reduce growth, and destroy jobs, H.R. 3 would be the model. This bill contains price controls, inflation rebates, and excise taxes.

Citizens Against Government Waste (CAGW) laid out its concerns more than two years ago on H.R. 3 in a September 2019 blog, "Lenin, Stalin, and Capone Would be Proud of Pelosi's Drug Pricing Plan," noting, "The proposal laughably states the secretary of Health and Human Services would 'negotiate' with drug companies over the price of a drug. While up to 250 drugs that lack competition and have the greatest cost to Medicare and the commercial market would be identified as targets, the secretary would be required to negotiate at least 25 drugs annually. If a company refuses to accept the government's maximum fair price, it would be hit with up to a 95 percent excise tax on the previous year's annual gross sales of the drug in question … This is not negotiation; it is criminal enterprise-level extortion."[39]

CAGW has released dozens of other blog posts, letters, and comments on price controls, and this report is the third in a series of issue briefs that began with the October 30, 2000, "Price Controls on Drugs: Hazardous to Your Health,"[40] and continued with the November 1, 2016, "Pharmaceutical Price Controls: A Prescription for Disaster."[41]

H.R. 3 has little to do with lowering drug prices and everything to do with government control. Fifty current sitting U.S. Senators and 137 House members, or 31 percent of the caucus, are age 65 and older. They should have clear recollections on the harm price controls did to the U.S. economy in the 1970s, especially in creating long gas lines that led to more foreign dependence on oil. These members should understand that the Nixon and Carter

[38] Ibid., p. 2.
[39] Elizabeth Wright, "Lenin, Stalin, and Capone Would be Proud of Pelosi's Drug Pricing Plan," September 19, 2019, *The WasteWatcher*, Citizens Against Government Waste, https://www.cagw.org/thewastewatcher/lenin-stalin-and-capone-would-be-proud-pelosis-drug-pricing-plan.
[40] Elizabeth Wright, Assisted by Gerald Cox, "Price Controls on Drugs: Hazardous to Your Health," Citizens Against Government Waste, October 30, 2000, http://www.cagw.org/sites/default/files/pdf/CAGW_2000_Price_Controls_on_Drugs.pdf.
[41] Elizabeth Wright, "Pharmaceutical Price Controls: A Prescription for Disaster," Citizens Against Government Waste, November 1, 2016, https://www.cagw.org/reporting/pharmaceutical-price-controls.

administrations' destructive policies ushered in President Ronald Reagan because the American people were tired of government-created inflation rates, stagnation, and job losses.

H.R. 3 includes these harmful policies:

- Requires the secretary of HHS to identify 250 brand-name drugs that have no generic or biosimilar competitor and are the greatest cost to Medicare and the entire U.S. healthcare system by determining Medicare, Medicaid, and private insurance costs in the aggregate. While the secretary will be required to "negotiate a maximum fair price" for at least 25 drugs in 2023 and 50 in 2024, this is a nebulous term. The bill specifically calls for a price no greater than 1.2 times the volume-weighted average of the drug price from six countries: Australia, Canada, France, Germany, Japan, and the United Kingdom. This will be an Average International Market Price.

    - These countries use price controls to determine drug prices in their country. While the HHS secretary is supposed to consider a company's research, development, and production costs, in the end, that will be an irrelevant requirement because the goal is control, not a lower price.

- If a pharmaceutical company should refuse the HHS secretary's "fair" price for a drug, then the manufacturer will face an ever-increasing excise tax, starting at 65 percent of the company's previous annual gross sales, rising 10 percent every quarter to a maximum of 95 percent if no agreement is reached. According to the Tax Foundation, the tax amounts to a 1,900 percent tax rate because of how H.R. 3 defines the tax base. For example, if a drug costs $100, it would incur a $1,900 tax.[42]

    - This is a tax on medicine. Supporters of the legislation claim this provision will provide a "powerful financial incentive" to negotiate. It is more like Al Capone holding a loaded gun at a victim's head and asking for cooperation in a crime. The only incentive it will provide is for investors to spend their dollars elsewhere.

- The legislation includes Medicare Part B and Part D inflation rebates or penalties. Every one of the more than 8,000 drugs under the two programs would be subject to an inflation rebate if its price should increase greater than the consumer price index, and the rebate would be retroactive to 2016, unless the price is lowered. Any inflation penalties would be paid to the Federal Supplemental Medicare Insurance Trust Fund, instead of lowering costs for patients. The penalty would also extend to the commercial marketplace.

    - The rebate policy does not consider the distortions already in the pharmaceutical market created by the government, like the 70 percent pharmaceutical manufacturer rebate in the Medicare Part D coverage gap or Medicaid's rebates. It focuses on list price and not what the patient pays at the pharmacy counter due

[42] Erica York, "Lawmakers' Tax Rate to Help Pay for Reconciliation is 1,900 Percent," Tax Foundation, August 31, 2021, https://taxfoundation.org/hr3-tax-pay-for-reconciliation.

to current price negotiations among manufacturers, insurers, pharmacy benefit managers (PBMs), and pharmacists. It ignores possible shortages of both active and excipient ingredients in a drug that manufacturers may have little to no control over.

The prices charged by a pharmaceutical manufacturer today recapture the investments made yesterday and for many prior years to invest in discoveries for tomorrow. Without these new investment dollars, there will be far fewer cures in the future, especially for complex diseases and those that affect smaller populations.

**Destruction of the U.S. Pharmaceutical Industry and Government Takeover of Healthcare**

H.R. 3 will destroy the vibrant U.S. biopharmaceutical industry and it will be a gateway for the government to take over the entire U.S. healthcare marketplace. After all, the politicians who favor price controls on drugs also want government-run healthcare, or Medicare for All. H.R. 3 accomplishes this by the provision that allows inflation rebates to be given to participants and beneficiaries in commercial group health plans. At first blush, healthcare entities and employers may think this will save them a lot of money, although these businesses would protest strongly if the government tried to price control their products.

But government bureaucrats and Congress will ultimately stick their noses into their private contracts as well under the bill's transparency requirements, collect data, and determine what should be considered fair prices among the drug companies, hospitals, insurers, PBMs, and employers. Eventually, there will be no need for insurers or PBMs to negotiate drug prices, or any price for a health product for that matter, because the government will be determining what is fair. The private sector role will diminish or disappear altogether.

For-profit hospitals have already realized the problem with Congress looking to implement price controls on pharmaceuticals, eventually leading to a government takeover of our nation's healthcare system. In a September 14, 2021, *Axios* article, reporter Caitlin Owens wrote, "Allowing government-negotiated drug prices to extend to the commercial market 'sets a very bad precedent when you have real negotiation on the private sector side, whether it's in drugs or for other providers,' Chip Kahn, president and CEO of the Federation of American Hospitals [FAH], told *Axios*. 'This sets a precedent that could lead to other public policy that might undermine private sector negotiation.'" The article pointed out that Medicare already has the power to determine what it will pay hospitals through price controls. Hospitals, as well as other healthcare entities, rely on private insurance, which pays more and carries the financial freight for government programs, to provide quality care.[43]

Some may think that the National Institutes of Health (NIH) could easily pick up the biopharmaceutical research mantle if pharmaceutical companies cut back on their research and development due to the implementation of H.R. 3. But according to an April 22, 2021, article by Zachary Brennan in *Regulatory Focus*, in FY 2018 the entire NIH budget was $34 billion to support more than 300,000 scientists and research personnel at more than 2,500 institutions

[43] Caitlin Owens, "What Hospitals Don't Like About Democrats' Drug Pricing Bill," *Axios*, September 14, 2021, https://www.axios.com/hospitals-democrats-prescription-drug-prices-congress-324851a0-e024-40c1-9fd6-8672c9b96723.html.

across the country for all research, not just biopharmaceutical. In 2019, the NIH appropriation was $39 billion.[44] But in those same years, U.S. biopharmaceutical industry expenditures on research were $79.6 billion and $83 billion respectively.[45] It is therefore not surprising that more than 90 percent of FDA-approved drugs are unrelated to patents supported by NIH, and even those that are NIH-related include other patents financed entirely by private investment.[46]

The April 2021 CBO report pointed out the following three factors that influence research and development spending:

- "The expected lifetime global revenues of a new drug depend on the prices that companies expect to charge for the drug in different markets around the world, the volume of sales they anticipate at those prices, and the likelihood the drug-development effort will succeed.

- "The expected cost to develop a new drug – including capital costs and expenditures on drugs that fail to reach the market – has been estimated to range from less than $1 billion to more than $2 billion.

- "The federal government influences the amount of private spending on R&D through programs (such as Medicare) that increase the demand for prescription drugs, through policies (such as spending for basic research and regulations on what must be demonstrated in clinical trials) that affect the supply of new drugs, and through policies (such as recommendations for vaccines) that affect both supply and demand."[47]

The CBO report also discussed how small biotech drug companies, with revenue less than $500 million, now account for more than 70 percent of nearly 3,000 drugs in phase III clinical trials. Larger drug companies, with revenue greater than $1 billion, account for more than half of new drugs approved by the FDA since 2009, but only 20 percent of these drugs were initiated by them. A common trend has been larger drug companies purchasing smaller firms or the rights to their inventions. The larger firm's "specialized knowledge" can increase the value of the acquisition, diversify its portfolio, bring a promising drug through FDA approval and into the marketplace much sooner and have a wider distribution than a small firm.[48]

Chris Edwards, director of tax policy studies at the Cato Institute, described the key role that wealthy individuals, or "angel investors," have played in expanding the American dream by investing in small, start-up businesses throughout U.S. history, from Henry Ford to George Eastman to Jeff Bezos. Angel investors typically put about 10 percent of their wealth into an

[44] Zachery Brennan, "How Biopharma Companies Use NIH and Vice Versa," *Regulatory Focus*, Regulatory Affairs Professionals Society, April 22, 2019, https://www.raps.org/news-and-articles/news-articles/2019/4/how-biopharma-companies-use-nih-and-vice-versa.
[45] Statista, "Research and Development Expenditure of Total U.S. Pharmaceutical Industry from 1995 to 2020," https://www.statista.com/statistics/265085/research-and-development-expenditure-us-pharmaceutical-industry.
[46] NAM, p. 6.
[47] Ibid., CBO "Research and Development in the Pharmaceutical Industry," p. At a Glance.
[48] Ibid., CBO "Research and Development in the Pharmaceutical Industry," p. 4.

investment.[49] Anti-capitalist members of Congress, like Sen. Elizabeth Warren (D-Mass.), are interested in destroying these avenues of private-sector success with high taxes, especially on capital gains, and restrictions on private equity investments.[50]

Edwards wrote, "In the United States, COVID-19 has been beaten back by vaccines developed by Moderna of Massachusetts and BioNTech of Germany. BioNTech teamed with American pharmaceutical giant Pfizer in manufacturing and distributing its vaccine. As of August 2021, about 360 million doses of the two vaccines had been delivered in the United States. The development of the technologies that enabled the two firms to respond quickly to the crisis was a product of scientific advances and large private investments over many years. Governments funded some of the research underlying the vaccines, and during the pandemic it funded production and distribution, but wealthy angels and venture capitalists played the crucial roles in the growth of the two companies." The research involved was very risky since harnessing mRNA, which was used in both vaccines, had been tried by pharmaceutical companies but it was extremely difficult to do without side effects and had been abandoned until Moderna and BioNTech took it up and were successful.[51]

Edwards noted that for more than four decades, the U.S. biotech industry has been fueled by risk capital and that venture capital created the biotechnology industry, starting with investments in Genentech, which created the first synthetic human insulin in 1978 and later the first genetically engineered insulin, Humulin,[52] which was licensed to Eli Lilly.

Angel investment was responsible for $25 billion in 2020, which was invested in 64,480 companies with an average investment of $392,025. According to Edwards, 36 percent of those investments went to healthcare and biotechnology, 23 percent went to software, and the rest went to energy, financial services, and retail.[53]

It is clear H.R. 3 would be very destructive, especially to smaller and innovative biotech firms due to less funding and private investment by venture capitalists and "angel investors" because of the enormous risk and time it takes for success. During drug development, of the thousands of investigational compounds tested, only about 12 percent make it into clinical trials, and after 10 to 15 years of testing, only one will be approved by the FDA.[54] If the entire biopharmaceutical market is price controlled, especially small companies that are on the precarious leading edge of science, investors have no reason to take an enormous risk on biotech companies. There are plenty of other areas private investors can risk their capital and receive a good return.

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[49] Chris Edwards, "How Wealth Fuels Growth," CATO Institute, Policy Analysis #921, September 29, 2021, pp. 2-7, https://www.cato.org/sites/cato.org/files/2021-09/policy-analysis-921-doi.pdf.
[50] Thomas Schatz, "Sen. Warren Continues to Display Disdain and Ignorance of Capital Markets," *The WasteWatcher*, Citizens Against Government Waste, October 21, 2021, https://www.cagw.org/thewastewatcher/sen-warren-continues-display-disdain-and-ignorance-capital-markets.
[51] Ibid., p.11.
[52] Ibid., p. 12.
[53] Ibid., p. 4.
[54] Genia Long, "The Biopharmaceutical Pipeline: Innovative Therapies in Clinical Development," Analysis Group, Inc., July 2017, Executive Summary, https://www.analysisgroup.com/globalassets/content/insights/publishing/the_biopharmaceutical_pipeline_report_2017.pdf.

## Pharmaceutical Price Controls Are Bad Medicine

Some members of Congress may be skeptical that H.R. 3 would harm future investments in life changing drugs, but an August 2021 CBO study by Christopher Adams shows otherwise. The report shows that a "15 percent to 25 percent reduction in expected returns for drugs in the top quintile of expected returns is associated with a 0.5 percent average annual reduction in the number of new drugs entering the market in the first decade under the policy, increasing to an 8 percent annual average reduction in the third decade." or 34 fewer drugs. The CBO study also considered both a reduction of expected returns by 15 percent to 25 percent and reduced available cash to the industry by $900 billion. The result was 9 percent fewer new drugs in the third decade.[55]

A May 7, 2021, Charles River Associates report, noted that a December 10, 2019, CBO score of H.R. 3 undervalues the impact of the U.S. market, which represents 41 percent of global pharmaceutical revenue and is a "significant force for stimulating investment in new medicines." For example, the authors stated the CBO report looks at the average effect across all drugs, overlooking the disproportionate impact on high risk and unmet need disease areas, like oncology, rare diseases, and pediatric conditions which would be targets of the policy and "ignores the complexity and mobility of the investor market which could readily shift to more profitable industries."[56]

### H.R. 3 and its Variants Should Be Rejected Now and Into the Future

As of this writing, it is unclear if any of the provisions of H.R. 3 will be able to pass Congress as part of the BBB Act. As noted in a November 16, 2021 letter from House Energy and Commerce Committee Ranking Member Cathy McMorris Rogers (R-Wash.) and Ways and Means Committee Ranking Member Kevin Brady (R-Texas) to HHS Secretary Xavier Becerra and CMS Administrator Chiquita Brooks-LaSure, the impact of these provisions has not been fully considered by Congress.[57] They wrote that the provisions appear to give the secretary the ability to start price negotiations at $0 and wanted to know how the agencies will deal with companies that do not accept the ceiling price. The ranking members asked for any analysis of the number of generic drugs and biosimilars that would not enter the marketplace over the next 10-50 years, and how plans to implement the legislation would impact Americans with debilitating diseases and disabilities. They also wanted to know if the bill would lead to the use of Quality Adjusted Life Years (QALY) to price drugs and determine who would get treated.[58]

By assigning a monetary value to a life year, QALY reduces the value of life for those with a disability or chronic disease, as well as the elderly. This process is used to reduce overall healthcare costs in countries with single-payer or government-run healthcare. The "appropriate value" method would compare the value of treating a blind teenager with an elderly cancer

[55] Christopher Adams, "Simulation Model of New Drug Development," Congressional Budget Office, August 2021, Abstract, p. 1, https://www.cbo.gov/system/files/2021-08/57010-New-Drug-Development.pdf.
[56] Kirsten Axelsen and Rajini Jayasuriya, "Government Scorekeepers Likely Underestimate the Impact of Lower Drug Costs Now Act (H.R.3) on Investment in Innovative Medicines," Charles River Associates, May 7, 2021, pp. 1-7, https://media.crai.com/wp-content/uploads/2021/05/07124312/Review-of-CBO-Assessment-of-HR3-5-3-2021-FINAL.pdf.
[57] Reps. Cathy McMorris Rodgers (R-Wash.) and Kevin Brady (R-Texas), "Letter to HHS and CMS re Drug Pricing Implementation," November 16, 2021, https://republicans-energycommerce.house.gov/wp-content/uploads/2021/11/11.16.21-Letter-to-HHS-and-CMS-re-Drug-Pricing-Implementation.pdf, pp. 1-2.
[58] Ibid.

patient and come up with a lower value for the older person. This would mean rationing or restricted care for anyone whose "value" is lower than the person to whom they are being compared.[59]

Reps. McMorris-Rodgers and Brady also expressed concern over the cost of these provisions. They wanted to know if the CMS Office of the Actuary had updated its November 2018 analysis of H.R. 3, in which the actuary concluded that the inflation rebate penalty provisions would have increased spending on behalf of seniors by $30 billion, "including more $24 billion in increased premiums, over their initial 10-year period. The analysis also anticipated 'higher brand name prices associated with higher expected launch prices to partially offset the Medicare inflation rebate' in the private market." They requested an update of this analysis based on the new language in the BBA Act.

The provisions of the BBB Act, some of which are so-called "compromises," are nothing of the sort. They would further distort the U.S. pharmaceutical marketplace with more price controls and adopt the same method of operation that progressives have used before to institute government-controlled prices and socialized medicine small steps at a time.

Instead of enacting price controls of any kind, Congress should implement more free-market initiatives, like the Medicare Part D proposal offered by the American Action Forum (AAF) in its August 2018 issue paper. The proposal reverses some of the perverse incentives that were added under the Patient Protection and Affordable Care Act and the Bipartisan Balanced Budget Act, by removing the 70 percent rebate required of drug manufactures in the coverage gap, extending the initial coverage phase to the catastrophic phase, establishing a maximum out-of-pocket cost for beneficiaries, and putting insurers and PBMs more at risk in the coverage phase by covering 75 percent of the costs.[60] This will encourage more robust negotiations and the use of generic drugs. CAGW would prefer that pharmaceutical companies are not required to rebate 9 percent in the catastrophic phase that are in the AAF plan as this is a price control and will adversely influence the drug's list price and negotiations. But redesigning the plan in the AAF model will make Medicare Part D behave more like insurance and not like Medicaid.

CAGW also believes that the 340B discount program also needs reform. Adding a clear definition that a 340B patient is an uninsured, low-income person who is ineligible for Medicaid, would do more to reform the program and return it to its original purpose than any other action taken by Congress.[61]

Congress must stop looking to price controls to lower drug prices because history has demonstrated they only exacerbate the problem. Encouraging more competition among private entities by incentivizing the free market and faster FDA drug approvals will do more to lower

[59] Elizabeth Wright, "The Republic Is Safe, For Now," *The WasteWatcher*, Citizens Against Government Waste, November 12, 2021, https://www.cagw.org/thewastewatcher/republic-safe-now.
[60] Tara O'Neill Hayes, "Redesigning Medicare Part D to Realign Incentives," American Action Forum, August 9, 2018, https://www.americanactionforum.org/wp-content/uploads/2018/08/2018-08-09-Part-D-Benefit-Design-Reform-Proposal_FINAL.pdf.
[61] Elizabeth Wright, "340B Drug Discount Program Should Be on GAO's High-Risk List," *RealClear Health*, April 2, 2021, https://www.realclearhealth.com/articles/2021/04/02/340b_drug_discount_program_should_be_on_gaos_high-risk_list_111186.html.

drug prices than enacting stifling government regulation. That has always been the best medicine and will always be the answer to lowering costs.