



# PHARMACEUTICAL PRICE CONTROLS

Impact of Drug Pricing Legislation on Access to  
Life-Enhancing Drugs

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The American Life Sciences Innovation Council (ALSIC) provided support for this work. ALSIC is a social welfare organization created in 2010 to support policies that foster an environment in which medical innovation can thrive. Its mission is to educate the public and policymakers about the effects of government regulation on key factors that drive life science innovation. The views expressed here are those of the authors.

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JULY 2022

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# Executive Summary

High and rising health care costs pose a perennial problem in America. Polling by Gallup consistently shows Americans name health care costs as one of the most important family financial problems.<sup>1</sup> As health care consumes a greater share of the economy, rising health care costs also consistently pose problems for state and federal budgets.

Lately, the cost control solutions offered by leaders in Washington have emphasized policies to bring down prescription drug prices. The Trump administration's health care agenda focused heavily on lowering drug prices.<sup>2</sup> More recently, Congress and the Biden administration's Build Back Better agenda relies on lowering drug prices to reduce federal Medicare spending and help fund the rest of the agenda. While the overall Build Back Better agenda stalled earlier this year, the Biden administration continues to prioritize lowering drug prices. In his State of the Union address, President Biden led off his plan to fight inflation with a call to cut drug prices, including a call to let Medicare negotiate lower prices.<sup>3</sup> Most recently, the Washington Post reported in late June that congressional Democrats are working to adopt a drug pricing plan similar to Build Back Better as part of a broader effort "to resurrect their agenda" in July.<sup>4</sup>

The Build Back Better approach to lowering drug prices focuses on creating a federal system of price setting and market limitations in the United States that applies to both the Medicare program as well as the private market. Specifically, these policies would allow Medicare to negotiate and effectively set prices for certain high-cost drugs, require drug manufacturers to pay the federal government rebates when price increases exceed inflation, and redesign the Medicare Part D prescription drug benefit to reduce cost-sharing.

There are clear tradeoffs to an approach that relies on price setting and market limitations to lower drug prices. While lower prices will lower

health care spending, they are also expected to make investments in research and development (R&D) less attractive and reduce the development of innovative new drugs. It would also negatively impact the U.S. drug industry's global leadership position, giving China the opportunity to control a greater share of the market and undermine U.S. foreign policy interests.

This report examines these tradeoffs and concludes, overall, the loss of new, life-enhancing drugs and the negative impact on U.S. interests outweigh the possible benefits of Build Back Better's drug pricing policies. This conclusion draws from the following key findings:

- » **The authority to "negotiate" drug prices in Build Back Better is in fact the authority to set and control prices.** While Build Back Better authorizes the Secretary of the Department of Health and Human Services (HHS) to negotiate drug prices, the bill also includes a punitive excise tax escalating up to 95 percent of the total sales of the drugs subject to "negotiation" if the manufacturer refuses to negotiate or fails to agree to a price. Combined with other federal taxes, this excise tax would likely result in a loss. As such, this tax creates an offer that cannot be refused and, therefore, cannot reasonably be construed as a negotiation. Instead, the negotiation provision functions as a price control.
- » **Build Back Better price controls will make R&D investments less attractive and, as a result, reduce the number of new drugs.** By design, Build Back Better's price controls—both the HHS price setting and inflation rebates—will reduce drug manufacturers' expected lifetime revenue from a new drug. Lower revenues will reduce the expected return on R&D

investments, which will make the investments less attractive and, in turn, lower spending on R&D. Less spending on R&D will naturally result in the development of fewer new drugs. Estimates on how many fewer new drugs vary widely. On the low end, the Congressional Budget Office (CBO) estimates the latest Build Back Better legislation will result in just one less new drug over the first decade, four fewer over the next decade, and another five fewer during the decade after that. University of Chicago economists estimate a much larger reduction amounting to 107 fewer new drugs over the first 20 years.

- » **Fewer new drugs will undoubtedly harm global health and well-being.** Overall, lower prices can improve health to some degree by increasing the use of existing drugs while, in the long run, fewer new drugs will lower the quality of life and life expectancy for people who would later benefit from new drugs. However, under the structure of Build Back Better's price controls, price reductions are not expected to lead to a measurable increase in utilization. The CBO assumes that low cost-sharing requirements that insulate people from drug prices will mean most of the savings accrue to the federal taxpayer and, therefore, will have only limited impact on individual utilization. Thus, on net, the negative health impacts from fewer new drugs which is fully borne by consumers can be expected to far outweigh any health benefits from increased utilization.
- » **A focus on prescription drug prices is not an effective strategy to control the overall cost of health care because drug prices are not responsible for the recent growth in health care costs.** A review of the most recent 10 years of National Health Expenditure (NHE) data from the Centers for Medicare & Medicaid Services (CMS) for 2010 to 2020 shows retail prescription drug expenditures represent only a small portion of the recent rise in health

care costs. Over this decade, prescription drug expenditures grew at a 3.2 percent average annual rate which is substantially less than the 4.8 percent average annual growth for NHE overall. NHE data suggests utilization increases, not higher drug prices, account for about 60 percent of this growth. This reflects the fact that the NHE's retail drug price index began to decline in 2018 for the first time since 1973 and have now declined for three straight years.

- » **Price Controls on prescription drugs will weaken the U.S. biopharma industry's global leadership.** International data on new drug development and R&D expenditures clearly show how Europe and the U.S. traded global leadership positions over the course of three decades. In the early nineties, the number of new chemical and biological drug entities developed in Europe were substantially higher in both Europe and Japan compared to the U.S. By contrast, in the recent five-year period covering 2016 to 2020, the U.S. developed more new drug entities than Europe and Japan combined. Research shows price controls do impact decisions on where biopharma companies choose to locate. Therefore, by adopting price controls in line with other countries, the U.S. would be giving up this competitive advantage.
- » **China is well positioned to take advantage and take market share if price controls weaken the U.S. position in the global biopharma market.** The U.S. has both strong economic and national security interests in maintaining global leadership in the biopharma and other advanced industries, especially in relation to China and their growing authoritarian influence. Toward that goal, the U.S. Senate passed the Endless Frontier Act on a bipartisan basis in 2021, which included "biotechnology, medical technology, genomics, and synthetic biology" in the initial list of key technology

focus areas. Yet, while the Endless Frontier Act works to strengthen the U.S. Biopharma industry's global leadership position, Build Back Better would weaken it and accelerate industry movement to other growth markets. Being one of the leading growth markets, China is possibly the best positioned to take market share from the U.S. for several reasons.

While every country relies on public investments in biopharma R&D, China's communist government has more power to increase these public investments to give the industry an edge over other countries if they make gaining market share a priority. Another factor giving China an advantage is the country's growing share of the pharmaceutical market. Medicine spending in China grew from \$68 billion in 2011 to \$169 billion in 2021, which accounts for 11.9 percent of global spending. China has also proven a willingness to steal intellectual property, which gives it an ongoing advantage over other countries.

- » **Larger market share will give China diplomatic leverage and may restrict U.S. access to new drugs.** The substantial investments China made in developing COVID-19 vaccines made China the world's top vaccine exporter in 2021. China successfully used access to the

vaccine to push Nicaragua to sever ties with Taiwan. These actions demonstrate China's willingness to use access to lifesaving and life-enhancing drugs to achieve diplomatic goals. Greater Chinese market share resulting from U.S. price controls and, consequently, greater dependence on China for drugs may also restrict access to new drugs. The need to protect U.S. access to critical resources like steel and energy has long influenced industrial policy. Access to drugs and other advanced technologies is likewise important to consider.

Considering lower drug prices will not lead to appreciably higher drug utilization, there's little health benefit to Build Back Better and the net impact on global health and well-being will almost certainly be negative and substantially so. Fewer new drugs and, in particular, fewer new drugs to treat the sickest populations will result in a lower quality of life and a lower life expectancy for people in the U.S. and worldwide. Access for people in the U.S. may be further restricted if other countries like China control a greater share of new drugs. The impact of allowing China to gain a greater share of new drugs will also undermine America's national interests, which deserves more attention. These considerations strongly weigh against adopting the type of price controls included in the Build Back Better agenda. ■

# Introduction

Health care costs consistently rise faster than inflation and consume a greater share of the economy. Prior to the COVID-19 pandemic, health spending had reached nearly 18 percent of GDP and is projected to continue rising to nearly 20 percent by the end of the decade.<sup>5</sup> This means individuals, families, and federal and state governments in the U.S. will have less to spend on other goods and services. However, efforts in Congress have largely focused on a relatively small fraction of health care spending represented by prescription drugs rather than looking at ways to make the entire system more efficient. This focus persists even though the fraction of prescription drug spending to overall health care spending has been declining in recent years as spending in other major health sectors grows at a greater rate.

Following this trend, the Build Back Better Act—passed in the House in November 2021—includes three main strategies to reduce the price of prescription drugs for consumers. This includes allowing Medicare to negotiate and effectively set prices for certain high-cost drugs, requiring drug manufacturers to pay rebates to the federal government when price increases exceed inflation, and redesigning the Medicare Part D prescription drug benefit to reduce cost-sharing.

The pros and cons to this approach present clear tradeoffs. On the pro side, lower drug prices

are expected to, on net, lower health care spending for the federal government and consumers. More affordable prices could also increase medication adherence and improve health. On the other hand, lower prices are expected to make investments in R&D less attractive and result in the development of fewer new drugs that would otherwise improve global health and well-being in the future. It's hard to overstate this risk to global health. Because the U.S. pharmaceutical market is the largest in the world, U.S. price controls will have an outsized impact on global drug development. At the same time, this dramatic change to the industry is likely to deliver only small reductions in the overall cost of health care in the U.S. as drug prices presently account for only a small portion of rising costs.

Moreover, adopting similar government price controls as the rest of the world will likely undermine the U.S. drug industry's global leadership position, as well as U.S. national security interests and democratic influence abroad. China is well-positioned to control a greater share of new drugs if U.S. leadership falters and has already used access to new COVID vaccines to advance their own national interests. This report takes a closer look at these tradeoffs and finds, overall, the loss of new, life-enhancing drugs and the negative impact on U.S. interests outweigh the possible benefits of Build Back Better's drug pricing policies. ■





## History of Congressional Action

Whether the federal government should use its influence and power to negotiate or set drug prices for the Medicare program has been heavily debated for decades. President Clinton's 1993 health care reform effort proposed requiring drug manufacturers to agree to rebates for brand-name drugs and allowed HHS to negotiate pricing for new drugs that were deemed overpriced.<sup>6</sup> The Medicare Modernization Act of 2003 was built around competing private sector purchasers negotiating prices with manufacturers and specifically prohibited the government from negotiating drug prices when it established the Medicare Part D prescription drug benefit.<sup>7</sup> This prohibition is referred to as the "noninterference provision."

Legislative proposals to allow negotiation soon emerged after the Medicare Part D program began in 2006. The Medicare Prescription Drug Price Negotiation Act of 2007 proposed to require the HHS Secretary to negotiate drug prices that drug manufacturers could charge to Part D prescription drug plans, which proponents

argued would result in significant savings.<sup>8</sup> However, the Congressional Budget Office (CBO) estimated this change to the noninterference provision "would have a negligible effect on federal spending."<sup>9</sup> As the CBO explained, Part D plans can

set formularies to steer people to preferred drugs and bear financial risk which gives them a strong financial incentive to negotiate. Thus, Part D plans already had the tools and incentives to negotiate better pricing.

This CBO perspective is supported by empirical research which shows Part D plan negotiations do, in fact, result in lower prices. For instance, an early review of the program by economists Mark Duggan and Fiona Scott Morton assessed prices in the first year of the

program and found prices for previously uninsured Medicare recipients dropped by more than 20 percent from 2003 to 2006 compared to what they would have been.<sup>10</sup> Later research by the authors found this lower pricing persisted to 2009, showing "the Part D plans succeeded in

**"Whether the federal government should use its influence and power to negotiate or set drug prices for the Medicare program has been heavily debated for decades."**

negotiating substantially lower prices for Medicare recipients through the first four years of the program.”<sup>11</sup> Research also shows how successful negotiations in Part D plans spill over to reduce drug prices in private plans.<sup>12</sup> In 2019, the HHS inspector general issued a proposed rule to prohibit drug manufacturers from paying rebates to Part D plans.<sup>13</sup> In another acknowledgement that negotiations work, CBO projected this would increase Part D premiums by \$170 billion over ten years.<sup>14</sup> This is, in part, because drug manufacturers could no longer reward pharmacy benefit managers for hitting certain targets and, as a result, they could not translate these rewards into lower premiums for consumers and taxpayers.<sup>15</sup>

In 2019, Senator Chuck Grassley asked the CBO if the conclusions they reached in 2007 still held true, to which the CBO replied that they continue “to stand by those conclusions.”<sup>16</sup> They explained negotiating authority would only work if it were “accompanied by some source of pressure on drug manufacturers to secure price concessions.” Later that year Rep. Frank Pallone introduced H.R.

3, The Elijah E. Cummings Lower Drug Costs Now Act, which added the sort of pressure necessary to leverage price concessions. Specifically, the bill imposed a substantial excise tax—up to 95 percent of the sales of drugs subject to negotiation—on drug manufacturers that refused to participate or failed to negotiate a price. Though the bill still used the term “negotiation,” the failure to agree to the price set by the HHS Secretary was considered a failure to negotiate. Thus, instead of a negotiation, the power of the HHS Secretary to set the price and the exceedingly punitive excise tax on not agreeing to the price functions as a mandate to accept the price set by the government. Therefore, the bill marks a dramatic shift from allowing government negotiation to allowing government price controls. H.R. 3 was eventually included in the Build Back Better Act, the \$1.75 trillion social spending and climate bill that passed the House last November. Senate versions of Build Back Better modified parts of H.R. 3, but still rely on the basic structure of allowing the HHS Secretary to set prices. ■



## Background on Build Back Better Drug Policies

In late December, Sen. Joe Manchin said he could not vote for the Build Back Better legislation. While this ended the prospects for enacting the bill as it passed in the House, a smaller spending package remains possible. This package would likely include Build Back Better's drug pricing provisions considering Sen. Manchin's consistent support for them and how they would deliver savings to help fund other provisions.<sup>17</sup> Therefore, these provisions remain the leading approach to control the cost of drugs still under consideration in Congress. To control drug costs, the legislation relies on three main strategies: allowing HHS to set prices for certain drugs covered by Medicare, requiring rebates if drug prices increase more than inflation, and redesigning Part D cost sharing.

**Price setting:** As noted previously, the non-interference provision included in the Medicare Modernization Act restricts the HHS Secretary from interfering with negotiations between drug manufacturers and pharmacies and Part D plans.

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The Secretary also does not negotiate prices for physician administered drugs under Medicare Part B, the part of Medicare that funds physician services and outpatient care. These prices are based on manufacturers' average sales price plus a fixed percentage mark-up, which reflects commercial pricing.

Build Back Better would add an exception to the noninterference provision to allow HHS to set prices for a limited number of high-cost single-source brand-name drugs or biologics covered by Part D and Part B, subject to certain criteria. To be included, a small-molecule drug must be at least 9 years and a biologic at least 13 years from their FDA approval or licensure date. Orphan drugs and drugs with an annual Medicare expenditure of less than \$200 million are exempt. In addition, small biotech drugs are exempt, but only for the first three years.

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manufacturer to an excise tax penalty escalating up to 95 percent of the total sales of the drugs subject to “negotiation” if the manufacturer refuses to negotiate or fails to agree to a price. This punitive excise tax when combined with a drug manufacturer’s income tax might exceed the sale price and result in a loss if they choose to sell the drug in the U.S.<sup>18</sup> As the CMS Office of the Actuary explains: “The penalty ... is so significant that we assumed that all brand-name manufacturers would participate in the negotiations.”<sup>19</sup> As such, this tax creates an offer that cannot be refused and, therefore, cannot reasonably be construed as a negotiation.

The proposal would also set a cap on the price HHS may set called the maximum fair price (MFP). This cap would be based on a percent of the non-federal average manufacturer price (AMP) which is a measure of what wholesalers pay for drugs. A civil penalty applies to manufacturers that charge more than the HHS price equal to 10 times the difference between the price charged and the MFP.

**Inflation rebates:** On top of the new authority for HHS to set drug prices, the legislation requires

manufacturers to pay rebates to the federal government equal to the amount a price increase for Medicare Part B and D covered drugs exceeds the general rate of inflation, as measured by the consumer price index for all urban consumers. Unlike prices set by HHS for Medicare reimbursement, this price cap impacts both Medicare and the private market. That’s because the calculation of the rebate equals the amount in excess of inflation multiplied by all units sold outside Medicaid, which includes the privately insured and the uninsured. Moreover, the benchmark price—the base price for which price increases are measured against inflation—is based on commercial market pricing. Thus, this combination effectively caps drug price increases to inflation for both Medicare and private payers.

**Part D redesign:** The legislation also redesigns Medicare part D to lower enrollee cost sharing largely by capping out-of-pocket spending at \$2,000. In addition, it requires Part D plans to pay more in the catastrophic phase of coverage and reduces government reinsurance subsidies to plans. ■



## Price Controls Will Reduce the Number of New Drugs

By design, Build Back Better’s price controls—both the HHS price setting and inflation rebates—will reduce drug manufacturers’ expected lifetime revenue from a new drug. Lower revenues will reduce the expected return on R&D investments, which will make the investments less attractive and, in turn, lower spending on R&D. Less spending on R&D will naturally result in the development of fewer new drugs. This natural progression to fewer new drugs is the tradeoff for lower drug prices. A substantial body of research maps the steps to this outcome.

### Price controls reduce revenue

In their evaluation of H.R. 3 as introduced in 2019, the CBO estimated the legislation would reduce future global revenue from new drugs by 19 percent.<sup>20</sup> Several other independent analyses suggest this estimate underestimates the revenue impact of H.R. 3. An analysis by Avalere, funded by PhRMA, estimates H.R. 3 as released in 2019 would reduce manufacturer revenues by \$1,275 billion to \$1,655 billion over the 2020 to 2029 period.<sup>21</sup> This represents a 34 to 44 percent reduction in revenue for brand-name drug manufacturers. Similarly, a report by Vital Transformation estimates the policy would reduce revenues by \$102 billion per year.<sup>22</sup>

Because the latest version of the Build Back Better legislation reduces the number of drugs subject to HHS price setting, the loss of revenue will be less. Nonetheless, Tomas Philipson and Troy Durie, economists at the University of Chicago, still estimate that it would reduce revenues by \$2.9 trillion through 2039—a 12 percent drop.<sup>23</sup> A majority of this drop—61 percent—stems from the inflation rebate provision. The “negotiation” provision accounts for 34 percent and the Part D redesign accounts for the remaining 5 percent. This estimate is substantially higher than the CBO. Lawmakers can dial the revenue impact up or down, but by design, there must be a drop in revenue to attain lower drug prices.

These revenue losses will not be restricted to U.S. companies. In the global biopharma market, companies headquartered in foreign countries rely on access to the more profitable U.S. market just the same as companies headquartered in the U.S. As one of the last countries without price controls, biopharma sales in the U.S.—accounting for 41 percent of global spending<sup>24</sup>—provide a massive share of the additional revenues above cost necessary to support global R&D investments in new drugs.

While these revenue estimates project an overall drop in revenue, drug manufacturers are expect-

ed to take steps to mitigate revenue losses which could lead to higher prices in certain circumstances. For instance, under H.R. 3, both CBO and the CMS Chief Actuary assumed drug manufacturers would increase international list prices to increase this reference price and it's possible they would similarly increase the non-federal AMP under the latest legislation.<sup>25</sup> However, there's a long running debate among economists as to whether the costs of lower Medicare and Medicaid prices can be shifted to higher prices on private payers<sup>26</sup> and international markets<sup>27</sup> as the CBO and CMS assume.

## Less revenue reduces R&D

Less revenue will mean drug manufacturers spend less on R&D. As the CBO explained in their analysis of H.R. 3, "the prospect of lower revenues would make investments in research and development less attractive to pharmaceutical companies."<sup>28</sup> It will also make outside investment in the drug manufacturers less attractive to venture capitalists and institutional investors who regularly reallocate investments from lower to higher expected returns.

Research shows a strong connection between expected returns and R&D spending. After Medicare Part D expanded the prescription drug benefit, research shows that drug companies increased R&D spending on drugs to treat conditions that are more prevalent among the older, Medicare-eligible population.<sup>29</sup> Research also shows R&D spending is higher in companies with a higher proportion of sales in the more profitable U.S. market where prices are largely market-based versus non-U.S. markets with government price regulations.<sup>30</sup> Similarly, research shows a higher percentage of sales to European countries with price controls is associated with lower R&D investments.<sup>31</sup>

Philipson and Durie synthesized the evidence from the leading research and calculated an aver-

age impact that a change in drug company revenue has on R&D spending.<sup>32</sup> They find, on average, that a one percent reduction in revenue leads to a 1.5 percent reduction in R&D spending. Using this data, they estimate even the more modest Build Back Better legislation will reduce R&D spending by 18.5 percent through 2039—a \$663 billion decline.

## Less R&D reduces the number of new drugs

With less spending and activity devoted to researching and developing new drugs, there will naturally be fewer new drugs. Estimates on how many fewer new drugs vary widely. On the low end, the CBO estimated that H.R. 3 as introduced would result in eight to 15 fewer new drugs over 10 years.<sup>33</sup> By contrast, the White House Council of Economic Advisers estimated H.R. 3 could lead to as many as 100 fewer drugs over the same time.<sup>34</sup> Vital Transformation estimates H.R. 3 would reduce the number of medicines developed by small and emerging biotech companies by 90-plus percent, resulting in 61 fewer new medicines.<sup>35</sup> CBO estimates the latest Build Back Better legislation will result in just one less new drug over the first decade, four fewer over the next decade, and another five fewer during the decade after that.<sup>36</sup> Philipson and Durie estimate a much larger reduction amounting to 135 fewer new drugs through 2039.<sup>37</sup>

In a report for PhRMA, Charles River Associates (CRA) concluded the CBO estimates of H.R. 3, including estimates on revenue and R&D, likely understate its impact due to "outdated evidence and simplified modeling."<sup>38</sup> Understandably, any projection on how Build Back Better will impact new drug development is highly speculative. Given the wide range of estimates, policymakers would benefit from additional information and more rigorous assessments. ■



## Impact on Global Health

The consequences of passing the legislation and thereby eliminating 60 to 100 or more new drugs would be disastrous. Fewer new drugs will undoubtedly harm global health and well-being. In 2009, Arthur Daemrich explained in a paper for the Harvard Business School how “[t]he ‘pharmacy to the world,’ once located at the intersection of Germany, Switzerland, and France, today is found in the United States.”<sup>39</sup> Since then, the U.S. position has only strengthened. As the pharmacy to the world, the impact of U.S. price controls will be felt globally. Life expectancies and quality of life can be expected to decline all else being equal. Moreover, the loss of new drugs will likely impact the sickest populations who need drugs the most.

Overall, lower prices can improve health to some degree by increasing the use of existing drugs while, in the long run, fewer new drugs will lower the quality of life and life expectancy for people who would later benefit from new drugs. This represents an important tradeoff to consider. However, under the structure of Build Back Better’s price controls, price reductions are not expected to lead to a

**“The loss of new drugs will likely impact the sickest populations who need drug innovations the most.”**

measurable increase in utilization. Low cost-sharing requirements already tend to insulate beneficiaries from the full price of drugs which means their utilization behavior under the legislation won’t change much with a change in the negotiated price.<sup>40</sup> Instead, the savings from price reductions largely accrue to the federal taxpayer in the form of lower Medicare spending. Thus, on net, the negative health impacts from fewer new drugs which is fully borne by consumers can be expected to far outweigh any health benefits from increased utilization.

Philipson and Durie predict the latest version of Build Back Better would result in a loss of 331.5 million life years just in the U.S.<sup>41</sup> That’s 31 times larger than the loss of life due to COVID-19 at the time of their publication. Globally, the loss of life years would be substantially higher. Research assessing the impact of tighter price controls in Europe found a 20 percent reduction in prices similarly projected a reduction in life expectancy.<sup>42</sup> Demonstrating the global impact of a price reduction in one region, life expectancies were estimated to drop by similar

amounts in the U.S. compared to Europe due to Europe's price tightening.

The loss of new drugs will likely impact the sickest populations who need drug innovations the most. As the FDA explains, developing drugs for rare diseases is challenging due to the complex biology and the difficulty in conducting clinical trials for an inherently small patient population.<sup>43</sup> The inherently small population also means there is a smaller market, which may limit the return on investment.<sup>44</sup> Considering these challenges in the face of a decline in R&D spending due to Build Back Better's price controls, drug manufacturers are likely to cut investment here first versus investments in drugs for less complex conditions that reach broader markets. This is consistent with modeling from Vital Transformation that finds H.R. 3 would "disproportionately impact new treatments in rare diseases, oncology, and neurology."<sup>45</sup>

To better understand the impact of Build Back Better on drug development, CRA studied the potential impact on the number of clinical trials run to develop for potential treatments. They estimate Build Back Better's price controls would reduce future revenues from HIV medicines by approxi-

mately 17 percent, resulting in up to a 22 percent drop in R&D spending.<sup>46</sup> The decline in R&D investments in HIV medicines would lead to "537 to 551 fewer clinical trials between 2022-2035."<sup>47</sup> This represents an enormous impact on HIV drug development considering only 610 HIV trials are currently ongoing.<sup>48</sup>

The latest version of Build Back Better focuses HHS price setting on drugs with the highest total spending in Medicare Part B and D. While a drug with high spending can be a lower cost drug with high utilization, the thrust of the legislation is to target high-cost drugs that have been on the market for several years without competition.<sup>49</sup> While drugs for rare conditions defined as "orphan" drugs may be exempt from these price setting provisions, new drugs that target smaller patient populations, like many anti-cancer drugs, would risk being targeted for HHS price setting. Because the smaller market size combined with a high therapeutic value command a higher price, drugs that uniquely benefit these sicker populations may be the prime targets of Build Back Better's price setting provision. Accounting for this risk will lower the expected returns on investments in these drugs even further. ■





## Impact on U.S. Health Care Costs

The previous discussion outlines the clear tradeoffs to giving HHS the power to control drug prices. U.S. health care costs will decline, but global health will suffer from fewer new drugs due to less R&D funding. To better understand this tradeoff, it's important to consider how this strategy to lower drug prices fits in the context of the broader problem with rising U.S. health care costs. If the growth of prescription drug expenditures represented a major portion of the rising cost of health care, then Build Back Better's focus on drug pricing may justify the tradeoffs. However, a review of the most recent 10 years of National Health Expenditure (NHE) data from CMS for 2010 to 2020 shows retail prescription drug expenditures and, in particular, prescription drug pricing, represent only a small portion of the recent growth in health care costs.

Retail prescription drug expenditures accounted for 8.4 percent of NHE in 2020. Note that NHE data do not separately account for non-retail prescription drug expenditures, such as drugs administered in a physician's office, hospital, or nursing home. Estimates of non-retail prescription drug expenditures increase total prescription drug expenditures by around 50 percent, which

puts total drug expenditures at approximately 13 to 14 percent of NHE.<sup>50</sup> By contrast, hospital care accounted for about 30 percent and physician and clinical services account for about 17 percent of NHE in 2020 after subtracting non-retail prescription drug expenditures.<sup>51</sup>

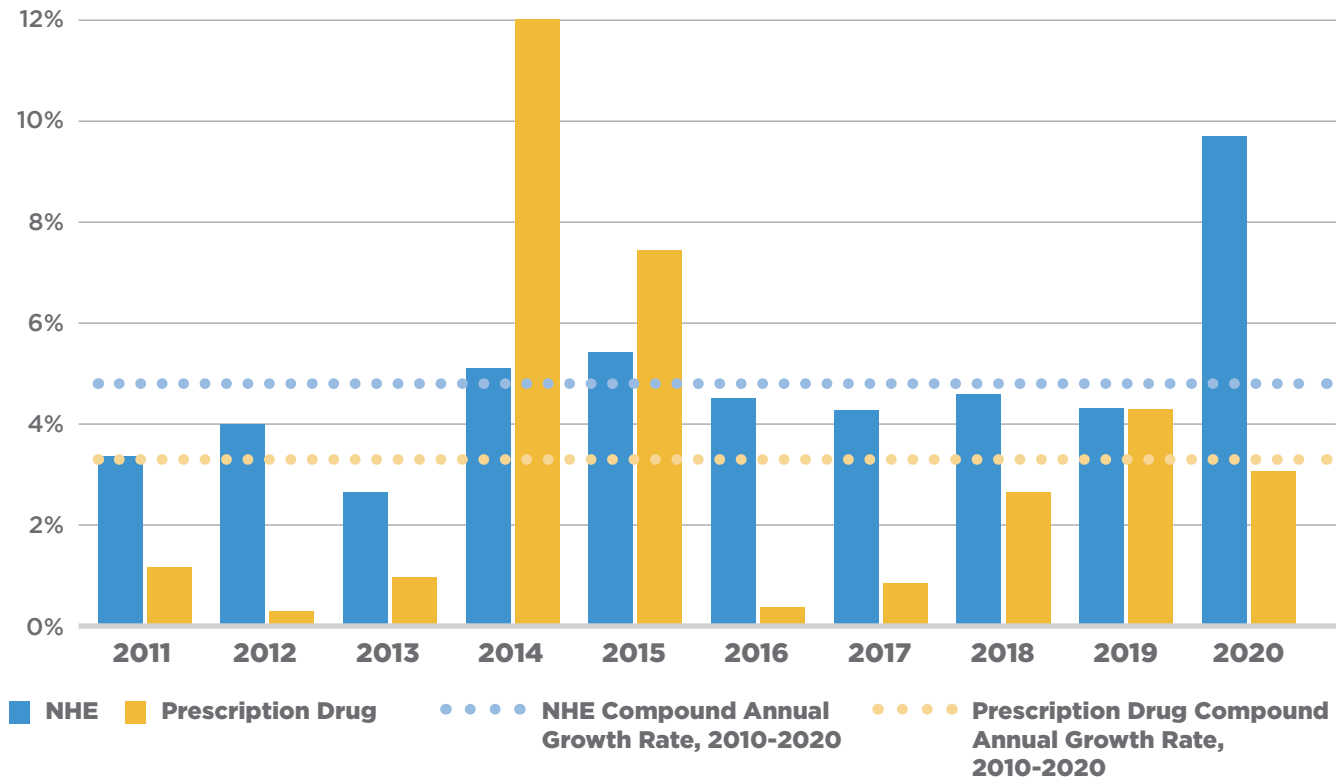
While prescription drug expenditures account for a reasonable share of NHE, the growth in prescription drug expenditures has trailed far behind other major health expenditures in recent years. From 2010 to 2020, prescription drug expenditures grew by 37 percent. However, this is substantially less than expenditure growth in hospital care (57 percent),

physician and clinician services (58 percent), other professional services (68 percent), and other health, residential and personal care (63 percent). From 2010 to 2020, Figure 1 shows prescription drug expenditures grew at a 3.2 percent compound annual growth rate which is substantially less than the 4.8 percent annual growth for NHE overall. As a result of this lower growth rate, the proportion of prescription drug expenditures to total expenditures dropped from 9.8 percent in 2010 to 8.4 percent in 2020.

**“Retail prescription drug expenditures accounted for 8.4 percent of NHE in 2020.”**

FIGURE 1

## Annual Growth in Total National Health Expenditures and Retail Prescription Drug Expenditures



**NOTE:** PRESCRIPTION DRUG EXPENDITURE GREW AT SLOWER RATE DESPITE A SUBSTANTIAL INCREASE IN EXPENDITURES IN 2014 AND 2015 THAT WAS LARGELY DRIVEN BY THE INTRODUCTION OF EXPENSIVE TREATMENTS TO CURE HEPATITIS C AND MAJOR COVERAGE EXPANSIONS UNDER THE AFFORDABLE CARE ACT. CENTERS FOR MEDICARE & MEDICAID SERVICES, PROJECTIONS OF NATIONAL HEALTH EXPENDITURES AND HEALTH INSURANCE ENROLLMENT: METHODOLOGY AND MODEL SPECIFICATION (MARCH 24, 2020), AVAILABLE AT [HTTPS://WWW.CMS.GOV/RESEARCH-STATISTICS-DATA-AND-SYSTEMS/STATISTICS-TRENDS-AND-REPORTS/NATIONALHEALTHEXPENDDATA/DOWNLOADS/PROJECTIONSMETHODOLOGY.PDF](https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/downloads/projectionmethodology.pdf). ALSO, REMOVE THE 2020 SPIKE IN NHE RELATED TO COVID-19 AND AVERAGE ANNUAL GROWTH IN PRESCRIPTION DRUG EXPENDITURES REMAINS NEARLY 1 PERCENTAGE POINT LOWER THAN NHE OVERALL.

**SOURCE:** CENTERS FOR MEDICARE & MEDICAID SERVICES, NATIONAL HEALTH EXPENDITURES DATA.

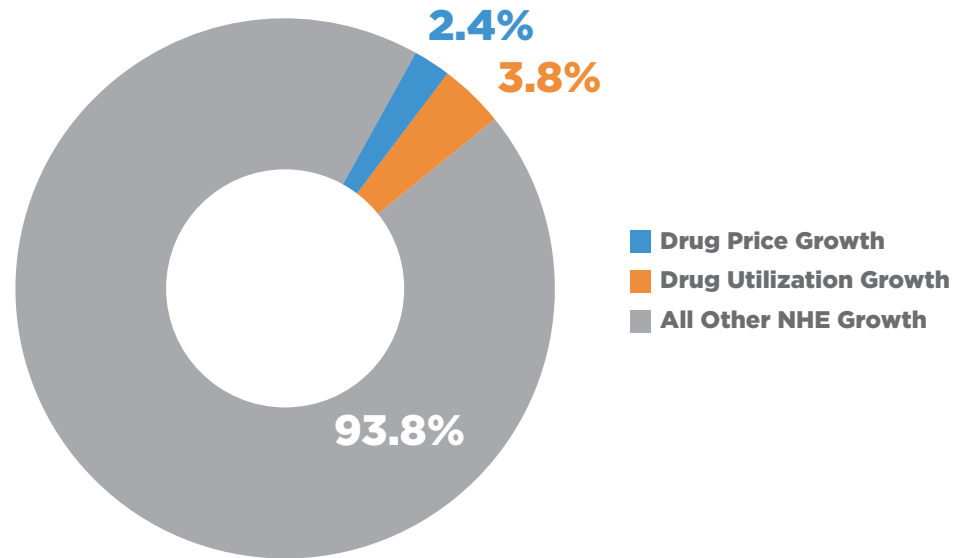
This lower rate of growth also means retail prescription drugs contributed much less to the total increase in health care spending from 2010 to 2020. NHE grew by \$1.5 trillion over that time while prescription drug expenditures grew by \$95 billion, representing just 6.2 percent of the growth in NHE. By contrast, hospital care represented \$461 billion—30.1 percent—of the rise in NHE over this period.

NHE data also includes a prescription drug price index that measures and isolates the annual

change in drug prices. This allows for a rough approximation of the proportion of rising prescription drug expenditures that can be attributed to changes in drug prices versus utilization. These data show higher drug prices accounted for \$37 billion and changes in utilization accounted for \$58 billion of the total \$95 billion growth in prescription drug expenditures from 2010 to 2020. Therefore, drug pricing, as shown in Figure 2, amounts to just 2.4 percent of the growth in NHE over this ten-year period. This reflects the fact that drug prices began

FIGURE 2

## Contribution of Higher Retail Drug Prices and Utilization to NHE Growth, 2010 to 2020



**NOTE:** THE GROWTH OF ANNUAL PRESCRIPTION DRUG EXPENDITURE DUE TO CHANGES IN DRUG PRICES IS CALCULATED BY MULTIPLYING THE PRIOR YEAR'S PRESCRIPTION DRUG EXPENDITURES BY THE PERCENTAGE CHANGE IN THE DRUG PRICE INDEX. THE PROPORTION OF GROWTH DUE TO CHANGES IN UTILIZATION IS CALCULATED BY SUBTRACTING THE EXPENDITURE GROWTH DUE TO PRICE CHANGES FROM THE TOTAL CHANGE IN PRESCRIPTION DRUG EXPENDITURES. THIS OFFERS ONLY A ROUGH ESTIMATE AS IT ASSUMES PRICE INCREASES BASED ON UTILIZATION FROM THE PRIOR YEAR.

**SOURCE:** AUTHORS' CALCULATIONS FROM CMS NHE DATA.

to decline in 2018 for the first time since 1973 and have now declined for three straight years.<sup>52</sup>

Unique competitive dynamics within the drug industry help explain lower growth rates in drug pricing. The CBO credits the growing use of generics with the recent downward pressure on pricing.<sup>53</sup> Similar to generics, biosimilars are biologic drugs with no meaningful difference from a licensed originator biologic drug that compete with the originator. The Biologics Price Competition and Innovation Act enacted with the Affordable Care Act in 2010 provided a shortcut for developing and gaining FDA approval for biosimilars. The law has yet to fully deliver the expected boost in competition.<sup>54</sup> However, competition is growing. Biologic drugs representing 19 percent of biologic spending faced a biosimilar competitor by 2019.<sup>55</sup> Even when a

generic or biosimilar is not available, a brand-name drug protected within an exclusivity period can still have competition from a therapeutic equivalent. Formularies set by health plans and pharmacy benefit managers (PBMs) also help steer people to these lower cost, higher value therapeutic equivalents. When there is no therapeutic equivalent for a brand-name drug, PBMs can use their buying power to negotiate lower pricing.<sup>56</sup>

While any comprehensive approach to address the high and rising cost of care should not neglect drug pricing, the fact that drug pricing represents just 2.4 percent of the cost problem over the past 10 years makes it hard to justify including drug pricing as the main cost control strategy in Build Back Better when the risk to innovation and new drug development is so clear. ■



## Price Controls Will Weaken U.S. Biopharma's Global Leadership

Europe's biologic and pharmaceutical industry used to be the global leader, but their leadership position substantially eroded over the past three decades. The U.S. biopharma industry now stands as the clear global leader. European price controls are regularly cited as one factor contributing to their decline. If the U.S. begins emulating the price controls imposed in Europe, Japan, and elsewhere, then the U.S. biopharma industry can expect its global leadership to weaken as well.

International data on new drug development and R&D expenditures clearly show how Europe and the U.S. traded global leadership positions over the course of three decades. As Figure 3 shows, the number of new chemical and biological drug entities developed in Europe were substantially higher in both Europe and Japan compared to the U.S. over the 1991 to 1995 period. A decade later, the U.S. biopharma industry took the lead and has held it ever since. In the most recent five-year period, U.S. drug development has now more than doubled that of Europe. This recent boost happened at the same time U.S. R&D expenditures leapt ahead of Europe. Figure 4 shows R&D expenditures in the U.S. and Europe remained roughly the same from 2011 to 2014, but began to increase in the U.S. in 2015 while remaining flat in Europe. By 2020, R&D

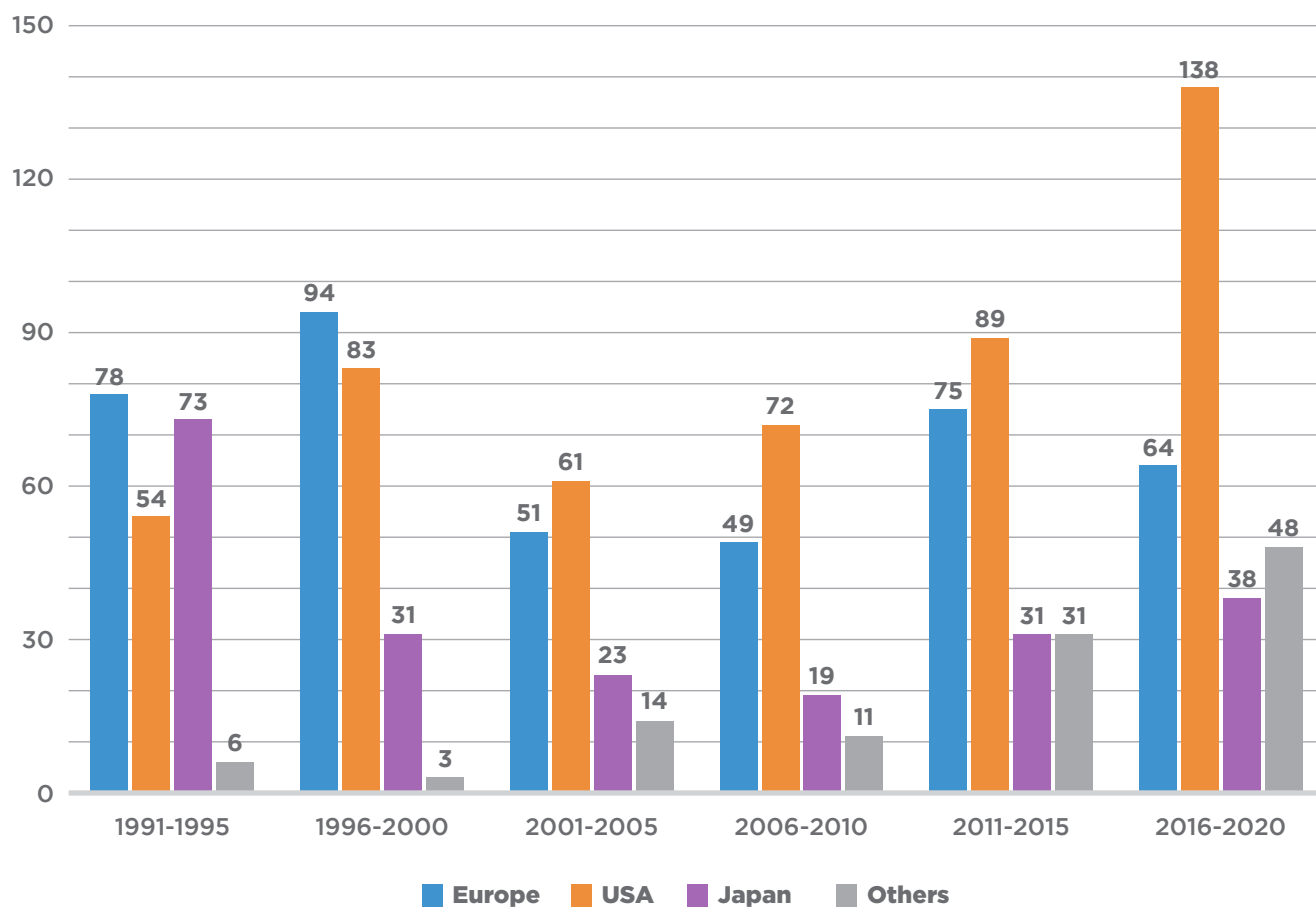
expenditures in the U.S. rose to be 63 percent higher than Europe.

It is not immediately obvious how European price controls contribute to less R&D spending and fewer new drugs in Europe compared to the U.S. The market for selling biologics and pharmaceutical drugs is global and European-based companies retain access to the more profitable U.S. market. Nonetheless, research comparing investment in European countries between 2002 and 2009 shows a 59.7 percent lower probability of investment in countries that implemented stricter price controls during that time.<sup>57</sup> Similarly, research by Margaret Kyle, an economics professor at MINES ParisTech, finds that "drugs invented by firms headquartered in countries that use price controls reach fewer markets and with longer delays than products that originate in countries without price controls."<sup>58</sup>

Kyle posits two possible explanations for this finding. First, the domestic market is generally the easiest and lowest cost place to gain regulatory approval and, therefore, the first place to launch. If the domestic market has price controls, then the initial launch price will likely be set relatively low. This limits opportunities to profitably launch in more foreign markets because the initial low domestic price will lead to lower launch prices elsewhere be-

FIGURE 3

## Number of New Chemical and Biological Drug Entities, 1991-2020



**SOURCE:** EUROPEAN FEDERATION OF PHARMACEUTICAL INDUSTRIES AND ASSOCIATIONS, THE PHARMACEUTICAL INDUSTRY IN FIGURES: KEY DATA (2021); AND EUROPEAN FEDERATION OF PHARMACEUTICAL INDUSTRIES AND ASSOCIATIONS, THE PHARMACEUTICAL INDUSTRY IN FIGURES: KEY DATA (2009 UPDATE).

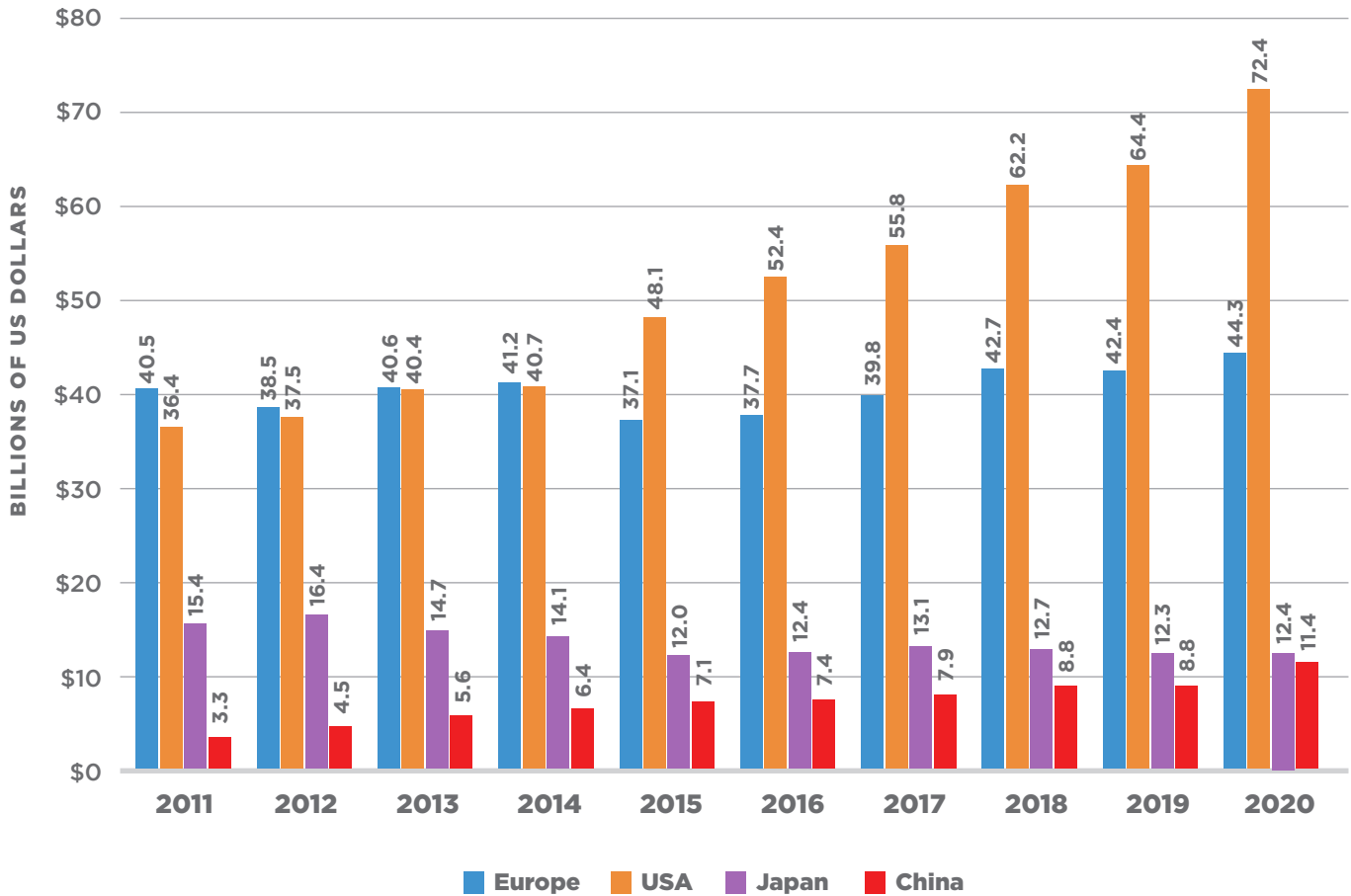
cause of parallel trade and international reference pricing. Second, countries with price controls may try to provide domestic companies with more favorable pricing, which creates an incentive for the domestic companies to produce drugs primarily for their home market versus producing higher-quality drugs that can better compete in foreign markets.

While there are many factors that contribute to where biopharma companies decide to locate

and invest, this research shows price controls do impact these location decisions. Therefore, by adopting price controls in line with other countries, the U.S. would be giving up this competitive advantage. Looking to the future, this would mean that the U.S. biopharma industry's annual rate of growth would fall relative to other countries and give them greater opportunity to take market share away from the U.S. ■

FIGURE 4

## Pharmaceutical R&D Expenditure in Europe, USA, Japan, and China



**SOURCE:** PHRMA, 2021 ANNUAL MEMBERSHIP SURVEY, JULY 22, 2021; EUROPEAN FEDERATION OF PHARMACEUTICAL INDUSTRIES AND ASSOCIATIONS, THE PHARMACEUTICAL INDUSTRY IN FIGURES, VARIOUS YEARS; JAPAN PHARMACEUTICAL MANUFACTURERS ASSOCIATION, DATA BOOK 2022; AND NATIONAL BUREAU OF STATISTICS OF CHINA, CHINA STATISTICAL YEARBOOK, VARIOUS YEARS. CURRENCIES CONVERTED TO USA DOLLARS USING INTERNATIONAL MONETARY FUND ANNUAL EXCHANGE RATES.



## China is Well Positioned to Take Advantage and Take Market Share

The U.S. has both strong economic and national security interests in maintaining global leadership in the biopharma and other advanced industries, especially in relationship to China and their growing authoritarian influence. Toward that goal, the U.S. Senate passed the Endless Frontier Act on a bipartisan basis in 2021. A press release from Sen. Todd Young called it “a landmark bill to out-compete China in key emerging technology areas critical to our national security.”<sup>59</sup> Senate Majority Leader Chuck Schumer summarized the global stakes if China gains the edge this way:

*Technology firms currently make up a quarter—a quarter—of the global stock market. Whoever wins the race to the technologies of the future is going to be the global economic leader, with profound consequences for foreign policy and national security as well. Whoever harnesses the technologies like AI, quantum computing, and innovations yet unseen, will shape the world in their image.*

*Do we want that image to be a democratic image? Or do we want it to be an authoritarian image, like the one President Xi would like to impose on the world?<sup>60</sup>*

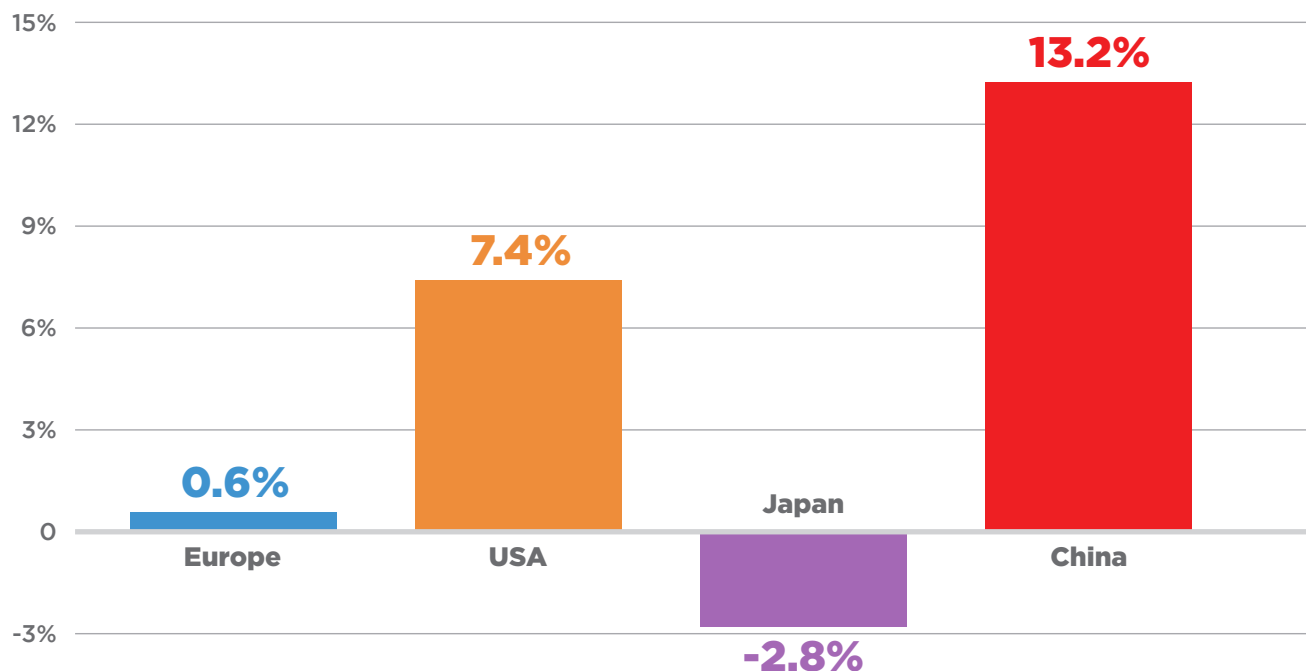
Recognizing pharmaceutical drugs and biologics are an important technology of the future, the Endless Frontier Act included “biotechnology, medical technology, genomics, and synthetic biology” in the initial list of key technology focus areas.<sup>61</sup>

Yet, while the Endless Frontier Act works to strengthen the U.S. biopharma industry’s global leadership position, Build Back Better would weaken it. If Build Back Better became law, Vital Transformation’s analysis finds the “industry likely would accelerate movements towards China, Singapore, Korea, and other growth markets.”<sup>62</sup> Being one of the leading growth markets, China is maybe the best positioned to take market share from the U.S. for several reasons.

The growth in R&D expenditures in China’s biopharma industry already consistently exceeds the U.S., Europe, and Japan. Figure 5 shows the average annual growth in R&D spending for the eight years leading up to the COVID-19 pandemic. Growth in Europe and Japan remained sluggish, rising by just 0.6 percent, and dropping by 2.8 percent respectively. U.S. R&D expenditures grew by a more substantial 7.4 percent, reflecting the country’s global leadership position. However, China outpaced them all at a 13.2 percent average annual rate of growth.

FIGURE 5

## Compound Average Annual Growth in R&D Expenditures, 2011-2019 (U.S. Dollars)



**SOURCE:** AUTHORS' CALCULATIONS FROM PHRMA, 2021 ANNUAL MEMBERSHIP SURVEY, JULY 22, 2021; EUROPEAN FEDERATION OF PHARMACEUTICAL INDUSTRIES AND ASSOCIATIONS, THE PHARMACEUTICAL INDUSTRY IN FIGURES, VARIOUS YEARS; JAPAN PHARMACEUTICAL MANUFACTURERS ASSOCIATION, DATA BOOK 2021; AND NATIONAL BUREAU OF STATISTICS OF CHINA, CHINA STATISTICAL YEARBOOK, VARIOUS YEARS.

China also showed the ability to significantly increase investments in response to the pandemic. In 2020, the U.S. increased R&D expenditures by 12.5 percent, an \$8.1 billion increase. By comparison, China boosted R&D expenditures by 28.9 percent representing a \$2.5 billion increase. Europe and Japan failed to keep pace and increased R&D expenditures by just 4.5 percent and 0.8 percent, respectively. As a result of these growing R&D investments, products from China-headquartered companies represented 12 percent of the of the R&D pipeline in 2021, up from 4 percent in 2016.<sup>63</sup> This boost pushed China ahead of Japan, which dropped from 11 percent to 6 percent of the R&D pipeline over this period.<sup>64</sup>

China's larger percentage increase in R&D spending off a smaller base is exactly what to ex-

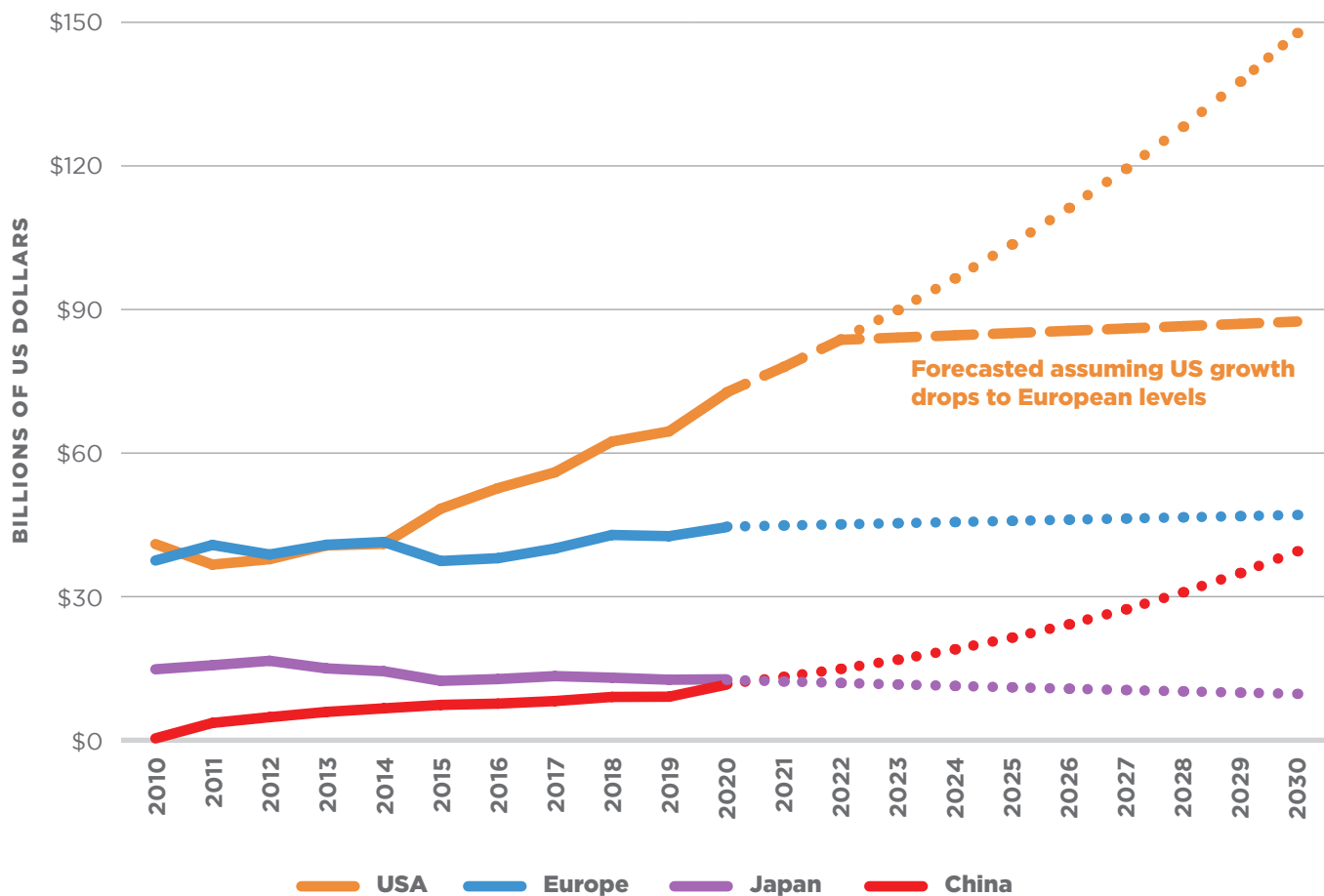
pect from a growth market versus an established market. Over time this excess growth will take market share away from the U.S. regardless of whether the U.S. adopts price controls. However, by adopting price controls and losing this competitive advantage, growth in U.S. R&D expenditures will be slower relative to China by a larger amount. In turn, this will give China a larger market share of new drugs.

Figure 6 forecasts what this might look like assuming pre-pandemic compound annual growth rates from 2011 to 2019 persist through 2030. There are several moving parts that influence the trajectory of R&D investment, so this is only a rough estimate for illustrative purposes. Under the current law scenario, China's share of R&D expenditures grows from 8.1 percent in 2020 to 16.2



FIGURE 6

## Pharmaceutical R&D Expenditure in Europe, USA, Japan, and China



**NOTE:** DOTTED LINES REFLECT PROJECTED GROWTH ASSUMING 2011 TO 2019 COMPOUND ANNUAL AVERAGE GROWTH RATES PERSIST TO 2030. THE DASHED ORANGE LINE REPRESENTS WHAT U.S. GROWTH WOULD LOOK LIKE UNDER PRICE CONTROLS.

**SOURCE:** AUTHORS' CALCULATIONS FROM PHRMA, 2021 ANNUAL MEMBERSHIP SURVEY, JULY 22, 2021; EUROPEAN FEDERATION OF PHARMACEUTICAL INDUSTRIES AND ASSOCIATIONS, THE PHARMACEUTICAL INDUSTRY IN FIGURES, VARIOUS YEARS; JAPAN PHARMACEUTICAL MANUFACTURERS ASSOCIATION, DATA BOOK 2021; AND NATIONAL BUREAU OF STATISTICS OF CHINA, CHINA STATISTICAL YEARBOOK, VARIOUS YEARS.

percent in 2030. Without price controls, the U.S. share continues to grow from 51.5 percent to 60.7 percent. The orange dashed line illustrates how U.S. growth would look after the implementation of price controls, assuming growth in U.S. R&D expenditures drops to European levels in 2023. In this scenario, the U.S. share of R&D drops to 47.8 percent in 2030—a 13.0 percentage point drop

from the current law projection. China's share increases from 16.2 percent to 21.5 percent. Together this represents a 18.3 percentage point reduction in the U.S. advantage over China. This larger share of global R&D investment will eventually translate to China winning a larger share of the global market for new drugs.

While every country relies on public invest-

ments in biopharma R&D to some degree, China's communist government has more power to increase these public investments to give the industry an edge over other countries if they make gaining market share a priority. Thus, even if growth in private investment declines as China's industry becomes larger and more established, the Chinese government will have the ability to maintain higher growth rates if it chooses to prioritize the industry.

Not only does China have more power to boost public investments in the biopharma sector, China is exercising that power. According to a recent report published by the Center for Strategic and International Studies, China spends far more to promote industrial policy when compared to Brazil, France, Germany, Japan, South Korea, Taiwan, and the United States.<sup>65</sup> In 2019, China spent up to 1.73 percent of GDP on industrial policy.<sup>66</sup> The next closest, South Korea, spent 0.67 percent of GDP and the U.S. spent 0.39 percent. In dollar terms, China spent up to \$248 billion while the U.S. spent \$84 billion.<sup>67</sup>

China has prioritized a portion of this spending on industrial policy to support the biopharma sector since at least the mid-2000s. When China set out a new industrial policy in 2006, it devoted two of 16 megaprojects to supporting the development of new drugs and treatments.<sup>68</sup> The first project focused on developing 30 to 40 market competitive new drugs with intellectual property protections and the second focused on developing new vaccines and treatments for infectious diseases.<sup>69</sup> China then announced a more formal industrial policy in late 2009 with the launch of its Strategic Emerging Industries initiative that set out preferential policies for key sectors, including biopharmaceuticals.<sup>70</sup> Next, in 2015 China issued the "Made in China 2025" plan to turn "China into a leading manufacturing power by the year 2049."<sup>71</sup> This new initiative included bio-medicine and high-end medical equipment among ten key

sectors for promoting breakthroughs.<sup>72</sup> Most recently, China issued new guidance on expanding investment in strategic emerging industries that listed the biotech industry as the number two area for focused investment.<sup>73</sup>

Another factor giving China an advantage is the country's growing share of the pharmaceutical market. Medicine spending in China grew from \$68 billion in 2011 to \$169 billion in 2021, which accounts for 11.9 percent of global spending.<sup>74</sup> Looking to 2026, China is projected to generate the largest absolute growth in medical spending among developing countries.<sup>75</sup> As noted previously, research shows domestic markets are easier and less costly to enter. With more domestic consumers in China, there will be more opportunities for companies headquartered in China to use this domestic advantage and increase their share of the global market. As drugs initially launched in countries with price controls tend to reach fewer foreign markets, U.S. drug manufacturers subject to price controls will be less likely to reach the growing Chinese market.

It's also worth noting that China has proven a willingness to steal intellectual property, which gives it an ongoing advantage over other countries. For instance, on January 3, 2022, the U.S. Department of Justice (DOJ) announced a third former GlaxoSmithKline (GSK) scientist pleaded guilty to stealing trade secrets to benefit a Chinese drug company that received financial support and subsidies from the government of China.<sup>76</sup> Lucy Xi and her co-defendants, Yu Xue, Tao Li and Yan Mei, established the Chinese company Renopharma to develop anti-cancer drugs, but instead, the company was used to collect stolen information from GSK. Three days later, in an entirely separate prosecution, DOJ announced that another Chinese national pleaded guilty to stealing trade secrets from Monsanto.<sup>77</sup> ■



## Larger Market Share Gives China Diplomatic Leverage

The substantial investments China made in developing COVID-19 vaccines made China the world's top vaccine exporter in 2021.<sup>78</sup> These exports supported China's "vaccine diplomacy" to curry favor from other countries by either donating the vaccine or making the vaccine available at competitive prices. Last September, President Xi announced at the United Nations that China was working to supply two billion vaccines to other countries and donating 100 million to developing countries by the end of the year.<sup>79</sup>

The Wilson Center reports that both China and Russia implemented their vaccine diplomacy efforts in Latin America quicker than the U.S., with Russia sending vaccines to Latin America in February 2021 and China in March 2021.<sup>80</sup> The U.S. didn't send its first vaccine donation to Latin America until June. The U.S. eventually began catching up, but Figure 7 shows Chinese vaccines still represented 40 percent of all doses administered in South America, Central America, and the Caribbean. U.S. vaccines represented 33 percent and Europe just 15 percent at the end of the year.<sup>81</sup>

**“Unlike other countries, China has directly tied the provision of vaccines to diplomacy.”**

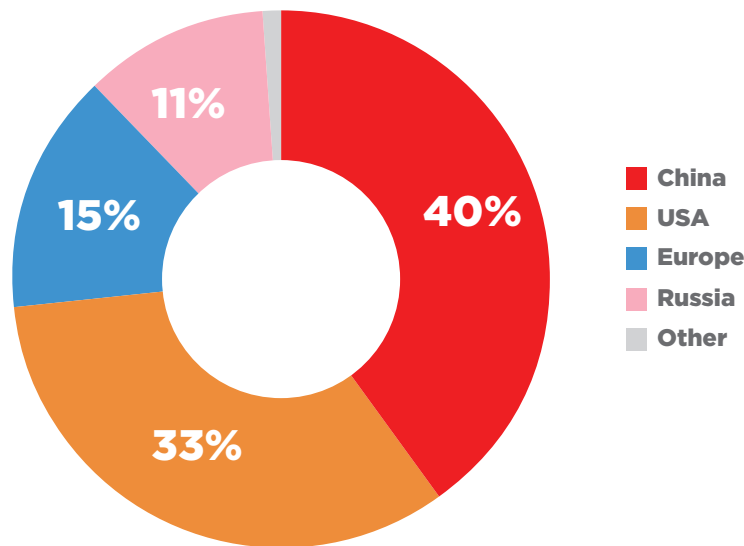
Unlike other countries, China has directly tied the provision of vaccines to diplomacy. Early in 2021, China told the people of Paraguay they would receive millions of doses of vaccines if the country severed ties with Taiwan.<sup>82</sup> Paraguay refused and, at the end of 2021, only five percent of vaccines administered in Paraguay were from China, according to data from the Pan American Health Organization. Likewise, this data shows other countries in the region with ties to Taiwan—including Belize, Guatemala, Haiti, Honduras, and St. Lucia<sup>83</sup>—are not receiving vaccines from China. Nicaragua, however, received vaccines after bending to China and severing ties with Taiwan in

December.<sup>84</sup>

These actions demonstrate China's willingness to use access to lifesaving and life-enhancing drugs to achieve diplomatic goals. As Paraguay's Ministry of Foreign Affairs urges, "a distressing humanitarian scenario ... should not be used to satisfy petty sectoral interests, nor to manipulate or force specific actions on the part of States."<sup>85</sup> This is clearly not China's position. As China controls a greater share

FIGURE 7

## Percent of Vaccine Doses Administered in South America, Central America, and the Caribbean by Source Country through 12/29/2021



**SOURCE:** PAN AMERICAN HEALTH ORGANIZATION WEBSITE AT [HTTPS://AIS.PAHO.ORG/IMM/IM\\_DOSISADMIN-VACUNACION.ASP](https://ais.paho.org/imm/im_dosisadmin-vacunacion.asp) (ACCESSED ON JANUARY 4, 2022).

of new drugs, they will increase their power to influence other countries. By adopting price controls, the U.S. would be giving up market share to China and, in turn, boosting China’s diplomatic power and influence.

Greater Chinese market share resulting from U.S. price controls and, consequently, greater dependence on China for drugs may also restrict access to new drugs. As Daemmrich explains, part of the reason nations compete for pharmaceutical industry research and manufacturing sites is “to

ensure access to the medicines they invent and manufacture.”<sup>86</sup> The need to protect U.S. access to critical resources like steel and energy has long influenced industrial policy. Access to drugs and other advanced technologies is likewise important to consider. Unlike most industrial policies that protect national interests by sacrificing free trade and market efficiency (e.g., tariffs), a decision to not set price controls on drugs both promotes national security interests and promotes free markets. ■

# Conclusion

Considering it is unlikely lower drug prices will lead to appreciably higher drug utilization and adherence, there's little health benefit to Build Back Better and, therefore, the net impact on global health and well-being will be overwhelmingly negative. Fewer new drugs and, in particular, fewer new drugs to treat the sickest populations in the most need will result in a lower quality of life and a lower life expectancy for people in the U.S. and worldwide. Access for people in the U.S. may be further restricted if other countries like China control a greater share of new drugs. The impact of allowing China to gain a greater share of new drugs will also undermine America's national interests, which deserves more attention.

As we look at the potential for material advancements in health care and patient outcomes, the life sciences industry holds the greatest potential to deliver the most impactful contributions. This has been illustrated over the past decade through the complete transformation of HIV and the eradication of Hepatitis C. New life sciences

innovation is the only segment of health care that has any potential to fight and win battles against complex diseases. Defeating Alzheimer's, diabetes, breast cancer, colon cancer, and the slate of auto-immune disorders all depend on the development of new drugs and biologics.

Higher quality hospitals, more physicians, and broader insurance coverage are all important aspects of achieving a better health care system in the U.S. But for people with complex diseases, these improvements will be meaningless if the therapies they are waiting on to be developed never get funded. Price controls will reduce funding which will shelve or delay the research necessary to develop these future therapies. These negative impacts far outweigh the benefits of lower federal spending. This is especially true considering government price controls are not the only policy option to lower drug prices. Instead of heavy-handed price setting, the federal government can introduce policies to drive efficiencies and lower prices through stronger competition. ■

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