CSRxP: Bipartisan Policy Solutions to Make Prescription Drugs More Affordable for Patients and Taxpayers

Prescription drug price trends are not sustainable for American patients, families, taxpayers, businesses, and our economy as whole. Twenty-two cents of every health care dollar go toward prescription drugs – with drugs contributing more to health care costs and growing at a rate faster than any other type of health care service.[1] [2]

Big Pharma – and Big Pharma alone – is driving the rapid growth in prescription drug prices. Drug companies set excessively high launch prices for new drugs and raise those prices every year, even though far too many Americans already cannot afford their medications. The median annual list price among new FDA-approved drugs in 2023 was more than $300,000 – roughly $80,000 higher than the median price of $222,000 in 2022.[3] For one-time gene therapy treatments, list prices were even higher in 2023 ranging from $2.2 million to $3.2 million.[4] Meanwhile, drug makers increased prices on 775 drugs to start 2024, following decades of raising drug prices in the new year.[5]

Excessively high drug prices threaten the financial security, health, and well-being of patients and their families every day. They also financially strain federal and state health budgets and the taxpayers who fund them, as well as the many employers who seek to offer affordable health insurance to their employees.[6] **We simply cannot continue to pay for unjustifiably high-priced drugs that increase the bottom lines and profitability of Big Pharma at the expense of patients and taxpayers.**

That's why the Campaign for Sustainable Rx Pricing (CSRxP), a nonpartisan coalition of organizations, is committed to fostering an informed discussion on sustainable prescription drug pricing. CSRxP members represent consumers, hospitals, physicians, nurses, pharmacists, employers, pharmacy benefit companies and insurance providers who have joined together to put forward bipartisan, market-based solutions that promote **competition, affordability, and transparency** to help restore a functioning prescription drug market for all American consumers and taxpayers.

Competition

A truly competitive U.S. prescription drug market is possible, but right now the market is broken. Drug companies often employ anti-competitive tactics to game the system and block competition from more affordable generics and biosimilars, forcing consumers and taxpayers to spend billions of dollars on high-

[1] AHIP. Where Does Your Health Care Dollar Go? September 6, 2022.
[2] Centers for Medicare and Medicaid Services. NHE Fact Sheet. Accessed December 20, 2023.
[3].Beasley, D. "Prices for new US drugs rose 35% in 2023, more than previous year." Reuters. February 23, 2024.
[4] *Ibid*.
[5] Calfas, J. Drug Makers Raise Prices of Ozempic, Mounjaro, and Hundreds of Other Drugs. *The Wall Street Journal.* January 18, 2024.
[6] American Academy of Actuaries. "Prescription Drug Spending in the U.S. Health Care System." March 2018.

priced drugs without competition.[7] [8] [9] These tactics cost consumers more than $40 billion in just one year, amounting to each American paying an additional $120 on prescription drugs annually, according to analysis from the Initiative for Medicines, Access, and Knowledge (I-MAK) and American Economic Liberties Project.[10]

Generics and biosimilars saved the U.S. healthcare market more than $400 billion in 2022 and estimates suggest that use of biosimilars could save at least $38 billion and as much as more than $120 billion over 5 years.[11] [12] It is therefore imperative for actions to be taken to prevent Big Pharma from engaging in anti-competitive behavior.

- **Address patent "thickets".** One of the most common strategies that drug makers employ to abuse the system is the construction of so-called patent "thickets." Under this practice, drug companies apply for and obtain dozens or even hundreds of patents for their branded biologic drugs *after* FDA approval to prevent and delay market entry from less costly generics and biosimilars. Secondary, often non-innovative, patents covering additional indications, dosing and delivery, manufacturing and packaging, and patient safety protocols are obtained to create a "thicket" of patents. These patent "thickets" create a nearly insurmountable barrier to competition from lower cost biosimilars for years and, in some cases, decades due to the threat of lengthy, costly, and time-intensive litigation. Research from I-MAK found that on average 66% of patent applications for the top 10 selling drugs in 2021 were filed *after* FDA approval to build up their patent "thickets" and delay competition.[13]

  Data show that particularly outrageous patent "thickets" on only 5 brand drugs cost consumers and taxpayers more than $16 billion in a single year.[14] For example, Merck's blockbuster cancer drug *Keytruda* reached $25 billion in sales in 2023.[15] Merck filed 129 patent applications for *Keytruda* and 53 have been granted; 50% were filed after *Keytruda* approval and reporting from Reuters suggests that Merck is seeking "to patent a new formulation of its $20 billion cancer immunotherapy *Keytruda* that can be injected under the skin, allowing it to protect its best-selling drug from competition expected as soon as 2028."[16] [17] I-MAK estimates the cost of delayed competition for *Keytruda* could be at least $137 billion.[18]

---

[7] CBO. Prices for and Spending on Specialty Drugs in Medicare Part D and Medicaid: An In-Depth Analysis. Working Paper 2019-02. March 2019.
[8] HHS Assistant Secretary for Planning. Trends in Prescription Drug Spending, 2016 – 2021. September 2022.
[9] The IQVIA Institute. Biosimilars in the United States 2023 – 2027: Competition Savings, and Sustainability. January 31, 2023.
[10] I-MAK and the American Economic Liberties Project. The Costs of Pharma Cheating. May 16, 2023.
[11] Association for Accessible Medicines. The U.S. Generic & Biosimilar Medicines Savings Report. September 2023.
[12] RAND Corporation. Biosimilar Drug Could Generate $38.4 Billion in Savings over Five Years. January 10, 2022.
[13] I-MAK and the American Economic Liberties Project. The Costs of Pharma Cheating. May 16, 2023.
[14] Matrix Global Advisors. Patent Thickets and Lost Drug Savings. January 26, 2023.
[15] Dunleavy, Kevin. Who's No. 1? With $25B in sales, Merck's Keytruda looks to be the top-selling drug of 2023. Fierce Pharma. February 1, 2024.
[16] I-MAK. Overpatented, Overpriced: Keytruda's Patent Wall. May 2021.
[17] Erman, Michael. Focus: Merck could keep its patent edge by shifting Keytruda cancer drug to a simple shot. *Reuters*. December 2, 2022.
[18] I-MAK. Overpatented, Overpriced: Keytruda's Patent Wall. May 2021.

Likewise, in another highly problematic case impacting potentially millions of Americans who have obesity, the makers of the high-cost glucagon-like peptide 1 (GLP-1) class of weight loss drugs are not only obtaining drug patents – but also device patents – to build patent "thickets" that block competition from more affordable generics for years well beyond original market exclusivity protections. The manufacturers have constructed patent thickets for these combination drug-device products despite the fact that GLP-1s are simply repackaged versions of older diabetes medications that have been on the market for years. An analysis in *JAMA* found that out of the 188 patents for GLP-1 products, 107 (57%) were for device patents and 81 (43%) were for non-device patents; if the device patents were removed, the size of the patent "thickets" would decrease from a median of 20.5 patents to a median of 6 patents and lower the duration of expected patent protection for two products in particular by 1.5 years and 2.6 years, respectively, so that consumers could have earlier access to lower cost generic therapies.[19]

To curb Big Pharma's anti-competitive abuse of the patent system that harms patients and payers alike:

- **Limit the number of patents a single biologic can use to stave off biosimilar competition.** Congress should enact the *Affordable Prescriptions for Patients Through Promoting Competition Act*, which places limits on the number of patents a biologic manufacturer can use to thwart competition and thus lower barriers to market entry for biosimilars.

- **Foster USPTO and FDA coordination to improve patent quality.** Congress should enact the *Interagency Patent Coordination and Improvement Act of 2023* to improve coordination over patent-related activities between FDA and U.S. Patent and Trademark Office (USPTO). The USPTO and FDA should receive additional funding and resources and have all authorities necessary to carry out work targeting Big Pharma's intellectual property and patent abuses. As part of these efforts, Congress should enact the *Patent Examination and Improvement Act* of the 117th Congress and the *Medication Affordability and Patent Integrity Act* of the 118th Congress to further these goals.

- **Strengthen USPTO's Patent and Trial Appeals Board (PTAB) *inter partes review* (IPR) process**. The American Invents Act of 2011 established the IPR process with the goals of improving patent quality and serving as a quicker and less expensive alternative to district court patent litigation. To promote greater generic and biosimilar competition, Congress should enact the *Restoring America Invents Act* of the 117th Congress.

- **Increase information available in FDA's Purple Book for biological patents.** Congress should enact the *Biologic Patent Transparency Act* of the 116th Congress and improve the quality of patent information available to biosimilar developers.

- **Stop drug makers' anti-competitive "product hopping" practices**. Drug companies extend their monopolies by seeking approving of "new" products that are essentially the same as the

[19] Alhiary R et al. Delivery Device Patents on GLP-1 Receptor Agonists. *JAMA*. 2024;331(9):794-796. doi:10.1001/jama.2024.0919

original brands but with minor changes – an abusive tactic commonly known as "product hopping."[20] An investigation from the *New York Times* found, for example, that drug maker Gilead employed an egregious "product hopping" strategy around a pair of blockbuster HIV treatments to maximize profits while blocking access to newer versions of those treatments proven to be safer for patients.[21] Congress should enact the *Affordable Prescriptions for Patients Through Promoting Competition Act*, which targets abusive "product hopping" practices, as well as the *Reforming Evergreening and Manipulation that Extends Drug Years (REMEDY) Act* of the 116th Congress, which targets anti-competitive "evergreening" practices.

- **Reduce the market exclusivity period for brand biologics.** The overly generous 12-year market exclusivity period that brand biologics currently have should be reduced to 7 years to reflect the appropriate balance of incentives for pharmaceutical companies to continue innovating while also alleviating cost pressures for consumers and taxpayers. Bipartisan legislation – the PRICED Act – has been introduced in previous sessions to do so.

- **Promote policies that increase uptake of more affordable biosimilars.** Congress should enact the *Biosimilar Red Tape Elimination Act* of the 118th Congress, which would increase biosimilar substitution. Congress should also enact the *Increasing Access to Biosimilars Act* of the 118th Congress, which would establish a Medicare demonstration project to expand access to biosimilars. The FDA should incentivize outcome reporting on patients who switch from brand biologics to biosimilars in clinical trials and post-market surveillance programs and educate patients and providers on the results of these studies and programs. Medicare and Medicaid should continue and expand upon administrative policies that foster and promote biosimilar uptake.

- **Curb abuse of FDA's "citizen petition" process and help streamline generic drug approvals.** Brand drug companies exploit FDA's "citizen petition" process to file sham petitions that delay and prevent approval of generics and biosimilars. Congress should enact the *Stop Significant and Time-wasting Abuse Limiting Legitimate Innovation of New Generics (Stop STALLING) Act*, which would provide the Federal Trade Commission (FTC) with enhanced authority to stop this anti-competitive practice, as well as the *Ensuring Timely Access to Generics Act of 2023*, which gives FDA new oversight authority to reject sham citizen petitions. Congress also should enact the *Increasing Transparency in Generic Drug Applications Act*, to streamline the FDA approval process for generic drugs.

- **Curtail anticompetitive patent settlements.** Federal law currently requires all patent settlement agreements to be filed with the Federal Trade Commission (FTC) and in its most recent report noted a "continued decline" in the types of agreements most likely to harm consumers. At the same time, Congress could require the FTC to issue an annual report on patent settlement agreements and to do so in a timely manner. FTC should also be given more

[20] Matrix Global Advisors. The Cost of Brand Drug Product Hopping. September 2020.
[21] Robbins R and Stolberg S. How a Drugmaker Profited by Slow-Walking a Promising H.I.V. Therapy. *The New York Times.* July 23, 2023.

authority, as proposed in the *Preserving Access to Affordable Generics and Biosimilars Act of 2023* to ensure patent settlement agreements facilitate timely patient access to more affordable generics and biosimilars.

- **Target orphan drug incentives to truly rare disease products**. While FDA has approved hundreds of orphan drugs that have helped patients suffering from rare diseases, drug companies have abused the Orphan Drug Act in many instances to generate billions of dollars in sales for orphan drugs with "non-orphan" indications.[22] Policies should maintain the integrity of the Orphan Drug Program by requiring that any subsequent orphan indications a product receives to have shorter periods of market exclusivity than the 7 years of exclusivity awarded for the first orphan indication. Congress also should enact the *Retaining Access and Restoring Exclusivity (RARE) Act*, which would protect the scope of orphan drug exclusivity from abuse by drug makers.

Affordability

Far too often patients must choose between purchasing the medications they need to get well and stay healthy and paying for other necessities like food and housing. Patients and their families should never be presented with this choice. Three in 10 adults reported not taking their medications as prescribed due to cost and 82% say the cost is unreasonable in a recent Kaiser Family Foundation survey.[23] Nearly 4 in 10 adults taking 4 or more drugs reported facing challenges affording their prescriptions, as did lower income adults living in households with annual incomes of less than $40,000.[24]

Taxpayers also bear the significant burden on Big Pharma's pricing practices. Spending on drugs in Medicare, Medicaid, and other health programs continues to grow at unsustainable rates, capturing greater shares of federal and state budgets each year.[25] [26] This trend only will continue with more expensive biologic medicines with little to no competition, widely used and questionably priced weight loss drugs, and increasing numbers of cell and gene therapies with multi-million dollar price tags.[27] [28] To improve prescription drug affordability for consumers and taxpayers, policymakers should:

- **Scrutinize drug companies' anti-competitive lockstep "shadow pricing" practices.** Drug companies have long used lockstep "shadow pricing" to set prices whereby would-be competitor drug makers raise their prices in lockstep to maintain price "parity" and use their competitors' price increases as justification for their own price increases – with the impact most hurting patients and taxpayers who pay billions of excess dollars in unjustified price increases. Scrutiny should be applied to therapeutic drug markets with the greatest potential for anti-competitive

[22] Tribble S and Lupkin S. Drugmakers Manipulate Orphan Drug Rules To Create Prized Monopolies. *KFF Health News*. January 17, 2017.
[23] Kaiser Family Foundation. Public Opinion and Prescription Drugs and Their Prices. August 21, 2023.
[24] Kaiser Family Foundation. Public Opinion and Prescription Drugs and Their Prices. August 21, 2023.
[25] CMS. NHE Fact Sheet. Accessed December 20, 2023.
[26] Cubanski et al. FAQs on Health Spending, the Federal Budget, and Budget Enforcement Tools. *Kaiser Family Foundation.* March 20, 2023.
[27] Reuters. Vertex/CRISPR price sickle cell disease gene therapy at $2.2 mln. December 8, 2023.
[28] KFF. Drugs Used for Weight Loss Could Cost Americans Much More Than People in Peer Countries. August 17, 2023.

"shadow pricing" practices. Some of the drug companies making the new weight loss drugs, for example, are the very same drug companies that make insulin – a therapeutic drug class where separate investigations by the Senate Finance Committee[29] and House Oversight and Investigations Committee[30] found that "shadow pricing" significantly raised prices on the cost of this life-saving drug for diabetes patients over the course of many years.

In the case of insulin, "[r]ather than seeking to undercut its competitors' pricing, from 2014 on Novo Nordisk engaged in a cat-and-mouse strategy of pricing that followed Sanofi's price increases closely, sometimes mirroring them within days or even hours" without any significant advances in efficacy.[31] The impact of "shadow pricing" on insulin has been significant: data from AARP show that several Medicare Part D products with the greatest percentage price increases since entering the market have been diabetes drugs, including Sanofi's Lantus up 739%, Novo Nordisk's Novolog up 628%, and Merck's Januvia up 275%.[32] Drug makers have imposed these unjustified price hikes on insulin despite an estimated 1.3 million Americans – or 16% of diabetes patients – reporting not taking life-sustaining insulin as prescribed due to cost.[33] In addition to the harmful impact on patients, the costs to taxpayers of lockstep "shadow pricing" for insulin also have been enormous with the growth of Medicare spending on insulin significantly surpassing the growth rate of Medicare beneficiaries using insulin from 2010 to 2019.[34] And insulin is just one example, as investigations also have uncovered anti-competitive "shadow pricing" practices in the other prescription drug markets such as multiple sclerosis drugs.[35] [36] Hence, to curb this anti-competitive pricing behavior going forward, scrutiny should be applied to prescription drug markets where anti-competitive "shadow pricing" practices are most likely to arise.

- **Ensure launch prices are justified.** The median annual launch price for new drugs approved by the FDA in 2022 was more than $220,000 – a median launch price markedly higher than the already sky high median of $180,000 in 2021.[37] Further, an analysis from the *Wall Street Journal* found that the median monthly price for a newly approved drug nearly tripled from 2011 to 2022 – increasing from $2,624 to $7,034.[38] It is therefore no surprise that the Congressional Budget Office (CBO) deemed escalating launch prices as one of the two main

[29] U.S. Senate Finance Committee. Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug Staff Report.
[30] House Committee on Oversight and Reform. Drug Pricing Investigation Majority Staff Report. December 2021.
[31] *Ibid*.
[32] AARP. Prices for Top Medicare Part D Drugs Have More Than Tripled Since Entering the Market. August 2023.
[33] Alltucker, K. More than 1.3M Americans ration life-saving insulin due to cost. This is 'very worrisome' to doctors. USA Today. October 17, 2022.
[34] U.S. Senate Finance Committee. Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug Staff Report.
[35] House Committee on Oversight and Accountability. Press Release: Cummings and Welch Launch Investigation of Drug Companies' Skyrocketing Prices for MS Drugs. August 17, 2017.
[36] House Committee on Oversight and Reform. Drug Pricing Investigation Majority Staff Report. December 2021.
[37] Beasley, D. "U.S. new drug price exceeds $200,000 median in 2022." Reuters. January 5, 2023.
[38] Loftus, Peter. New Drugs for Cancer, Rare Disease Can Now Cost More Than $20,000 a Month. The Wall Street Journal. March 9, 2023.

reasons for the average price of a brand drug more than doubling in Medicare Part D and increasing by 50% in Medicaid over the 2009 to 2018 period.[39]

To curb unjustifiable growth in launch prices, additional funding should be given to private and public efforts engaged in comparative effectiveness work, such as the Institute for Clinical and Economic Review (ICER), and drug makers should be required to conduct comparative effectiveness studies comparing their new drugs to existing drugs on the market. The U.S. Department of Health and Human Services (HHS) should issue an annual report on launch prices and launch price trends to systematically monitor their impacts on consumers and taxpayers. In addition, the Patient-Centered Outcomes Research Institute (PCORI) and Agency for Healthcare Research and Quality (AHRQ) should be empowered with the resources and authorities necessary to conduct cost-effectiveness work – in addition to their ongoing work on clinical effectiveness work – to assess whether launch prices, and ongoing price increases, align with value to patients.

- **Curb drug makers' outrageous price-gouging of weight loss drugs for U.S. consumers.** Approximately 42% of American adults are obese according to the Centers for Disease Control and Prevention (CDC) and there are numerous adverse health effects associated with the condition, making the potential demand for weight loss drugs significant.[40] [41] [42] Drug makers have headed into the new "gold rush" of this emerging class of weight loss medications, GLP-1 drugs, by price-gouging American consumers and setting list prices at nearly $1,000 or more per month – U.S. list prices that far exceed list prices in other countries.[43] [44] Drug maker Novo Nordisk, for example, set the U.S. list price for a monthly supply of *Ozempic* at $936 versus $169 in Japan – meaning the company is charging patients 5.5 times more in the U.S. than in Japan for the same drug. Because data indicate that patients must take these medications consistently and long-term to maintain weight loss, estimates suggest that the annual costs of taking these weight loss drugs per patient in perpetuity range from roughly $12,000 to $17,000.[45]

  Moreover, while Medicare currently does not provide coverage for weight loss drugs, recently published research in the *New England Journal of Medicine* suggests that if just 10% of Medicare beneficiaries took one new weight loss drug, Novo Nordisk's *Wegovy*, the annual cost to Medicare could range from $13.6 billion to $26.8 billion – and as the Kaiser Family Foundation notes, higher take-up rates of weight loss drugs would mean even higher Medicare spending.[46] [47]

---

[39] CBO. "Prescription Drugs: Spending, Use, and Prices." January 2022, page 2.
[40] CDC. Obesity and Overweight. Accessed January 5, 2024.
[41] CDC. Health Effects of Overweight & Obesity. Accessed January 5, 2024.
[42] Chen and Herper. The Obesity Revolution. *Stat+.* March 5, 2023.
[43] Hopkins, J. Drugs Like Ozempic Created a Gold Rush. These Drugmakers Want In. *The Wall Street Journal.* July 16, 2023.
[44] Peterson-KFF Health System Tracker. How do prices of drugs for weight loss in the U.S. compare to peer nations' prices? August 17, 2023.
[45] Milliman. Payer strategies for GLP-1 medications for weight loss. August 2023.
[46] Baig et al. Medicare Part D Coverage of Antiobesity Medications – Challenges and Uncertainty Ahead. *New England Journal of Medicine.* March 16, 2023.
[47] KFF. What Could New Anti-Obesity Drugs Mean for Medicare? May 18, 2023.

For context, total Medicare Part D spending in just one year (2021) was $98 billion – so spending on just weight loss drugs alone could be as high as one-fourth of total Medicare Part D spending in a single year.[48] Indeed, CBO agrees that costs to Medicare would be "significant" if the program started providing coverage for weight loss drugs and, more broadly, CBO predicted that covering GLP-1 weight loss drugs "at their current prices, would cost the federal government more than it would save from reducing other health care spending."[49] [50] Policymakers must hold Big Pharma accountable for the egregious price-gouging of weight loss drugs and develop new payment strategies that expand access at lower costs so that consumers and taxpayers can actually afford them – but not in such a way that any potential novel multi-year payment approaches hide manufacturer price hikes and the true total cost of treatment.

- **Develop a sustainable approach to paying for multi-million-dollar cell and gene therapies.** FDA recently approved two cell and gene therapies with $3.1 million and $2.2 million price tags, respectively, and estimates suggest spending in this new therapeutic area could reach $25 billion annually and more than $300 billion over 15 years.[51] [52] While these treatments have the potential to meaningfully help patients suffering from severe and debilitating diseases, their record-setting prices make them entirely unaffordable for far too many patients and payers – including state Medicaid programs that must adhere to annual budgets.[53]

  Novel reimbursement approaches should require cell and gene therapy makers to have financial skin in the game, for example, with outcomes-based payment arrangements, and must ensure the fiscal sustainability of the Medicaid program. They should account for the fact that patients may change insurance providers over the course of treatment and should be designed to protect against manufacturers masking high prices through multi-year payment arrangements that effectively allow for excessive price hikes without full transparency about the entire cost of treatments. The long-term clinical and cost impacts of these therapies remain unknown, given that the FDA has approved many of these treatments based on clinical trials with very small numbers of patients. Recognizing that patients may switch insurance providers over time, Congress should support clinical registries to track patients on cell and gene therapies over many years to evaluate the impacts on patient outcomes and health care spending. Enforcement mechanisms also must be in place to ensure that CGT makers complete any required post-marketing studies in a timely manner. In addition, underserved low-income and uninsured patients should receive assistance in helping to pay for treatment costs.

- **Make drugs more affordable to Medicare beneficiaries.** Congress took steps toward holding drug manufacturers accountable for their harmful pricing practices, in part through

[48] *Ibid*.
[49] CBO. A Call for New Research in the Area of Obesity. October 5, 2023.
[50] CSRxP. Dose of Reality.
[51] *Reuters*. Vertex/CRISPR price sickle cell disease gene therapy at $2.2 mln. December 8, 2023.
[52] Wong et a. NBER Working Paper Series: Estimating the Financial Impact of Gene Therapy in the U.S. April 2021.
[53] CMS. CMS Innovation Center's One-Year Update on the Executive Order to Lower Prescription Drug Costs for Americans. October 11, 2023.

adopting policies long advocated for by CSRxP including keeping drug companies' price hikes for Medicare-covered drugs at rates below inflation, capping Medicare Part D out-of-pocket costs for beneficiaries, and ensuring that drug makers pay a portion of costs when Medicare Part D beneficiaries reach catastrophic coverage.[54] [55]

To build on these efforts, Medicare should maximize the use of drug value assessments from non-partisan, independent organizations like ICER in price negotiations – so long as those value assessments reflect the rights and needs of all patients and do not discriminate against the disabled, elderly, or terminally ill.[56] Medicare also should be as transparent as possible about its justification for negotiated prices, so that the public knows the negotiated prices represent the lowest possible prices that can be obtained.

The rebate rule that increases Part D enrollee out-of-pocket costs without lowering drug prices and limits Part D plans and pharmacy benefit companies' ability to negotiate lower drug prices on behalf of Part D enrollees should be permanently rescinded.[57] Health plans should have more flexibility to manage high-cost Part D drugs, including drugs in the "protected classes," with meaningful, appropriate beneficiary protections in place. Medicare and Medicaid should continue developing novel value-based payment approaches to lower drug costs.[58]

Transparency

Drug manufacturers routinely justify their pricing decisions by citing industry-funded research, which claims that it costs $2.6 billion in research and development (R&D) to bring a new drug to market.[59] However, there is no way to independently verify this figure and published research in *JAMA* found there was no association between prices and estimated R&D costs.[60] Further, there is no way of knowing how much drug companies actually invest in true R&D versus other expensive business activities drive to help increase utilization like marketing and advertising. Therefore, it is critical to inject more transparency in drug companies' pricing practices so that consumers and taxpayers can determine whether a drug's price is, in fact, justifiable. To enhance transparency in drug pricing:

- **Make drug makers publicly justify high prices and report pricing information.** Congress should enact the *Fair Accountability and Innovative Research (FAIR) Drug Pricing Act* of the 118th Congress to apply basic transparency to drug pricing and require drug manufacturers to justify price increases. Consumers and taxpayers should have access to information on manufacturing

[54] HHS ASPE. Inflation Reduction Act Research Series – Medicare Part B Inflation Rebates in 2023. December 14, 2023.
[55] KFF. Changes to Medicare Part D in 2024 and 2025 Under the Inflation Reduction Act and How Enrollees Will Benefit. April 20, 2023.
[56] ICER. ICER Publishes Special Report on Eliquis and Xarelto Submitted to CMS as Part of Public Comment Process for Medicare Drug Price Negotiations. October 2, 2023.
[57] 85 FR 76666
[58] CMS. CMS Innovation Center's One-Year Update on the Executive Order to Lower Prescription Drug Costs for Americans. October 11, 2023.
[59] DiMasi et al. Innovation in the pharmaceutical industry: New estimates of R&D costs. *Journal of Health Economics.* Volume 47, May 2016, pages 20 – 33.
[60] Wouters et al. "Association of Research and Development Investments With Treatment Costs for New Drugs Approved From 2009 to 2018." *JAMA Netw Open.* 2022;5(9):e2218623. doi:10.1001/jamanetworkopen.2022.18623

and R&D costs, net profits, and marketing and advertising costs for expensive medications and drug companies should have to publicly justify price increases so they are held accountable for their pricing practices. Notably, transparency requirements applied to other healthcare providers are not without precedent and therefore could justifiably be applied to drug manufacturers; health plans, for example, must provide premium information to state insurance commissioners many months in advance of those premiums applied to plans in the market and issuers with rate increases in excess of 10% must submit a justification to the government for review and make summary information accessible to the public in an understandable format.

- **Mandate disclosure of drug prices in direct-to-consumer (DTC) advertising.** Big Pharma spent nearly $8.1 billion on DTC advertising pushing brand name drugs on consumers in 2022.[61] And in 2023, drug makers spent nearly $500 million just on DTC ads for diabetes and weight loss drugs – an increase of 20% over 2022, reflecting the "gold rush" for drug makers' to capture this new, burgeoning market.[62] Congress should enact the *Drug-Price Transparency for Consumers Act* of the 118th Congress, which would require drug makers to disclose list prices in DTC ads and provide disincentives for them to continue price-gouging patients.

- **Guarantee a better return on taxpayer investments**. The U.S. Government funded research that led to some of the underlying technology behind Moderna's COVID-19 vaccine and taxpayers later provided an almost $10 billion investment to help develop and purchase Moderna's vaccine, which allowed the company to rake in massive profits.[63] [64] [65] Once reimbursement for COVID-19 vaccines shifted from the federal government to the commercial market, Moderna and Pfizer announced they were dramatically increasing the prices of their vaccines to between $120 and $130 – or a more than 500% price increase for Moderna and a nearly quadrupled price increase for Pfizer and both representing an estimated "10,000 percent markup" over what experts estimate are the costs borne by the drug makers of producing the vaccines.[66] [67]

  The COVID-19 vaccines are just one example of numerous drugs sold by drug makers founded on research paid for by the U.S. government. Indeed, data show that funding from the National Institutes of Health (NIH) contributed to almost every one of the 356 drugs approved by the FDA between 2010 and 2019.[68] Data also show that roughly 13% of NIH awardees did not

---

[61] Adams, Ben. The top 10 pharma drug ad spenders for 2022. *Fierce Pharma.* May 1, 2023.
[62] Constantino, A. Ad spending for obesity, diabetes drugs is soaring this year, as drug makers shell out nearly $500 million. *CNBC*. September 29, 2023.
[63] Lalani et al. US Taxpayers Heavily Funded the Discovery of COVID-19 Vaccines. Clin Pharmacol Thera. 2022 Mar; 111(3): 542-544. Published online 2021 Jul 9. doi: 10.1002/cpt.2344
[64] Stolberg S and Robbins R. Moderna and U.S. at Odds Over Vaccine Patent Rights. *The New York Times.* November 9, 2021.
[65] Lopez, Ian. Covid Vaccine 'Windfall' Profits Under Attack by Patent Holders. *Bloomberg Law.* August 17, 2022.
[66] Lim, David. Moderna expects updated Covid-19 vaccine to cost $110-$130. *Politico Pro.* May 4, 2023.
[67] Erman, Michael. Pfizer Covid vaccine price hike to boost revenue for years, rivals may follow. *Reuters*. October 21, 2022.
[68] Clearly et al. "Comparison of Research Spending on New Drug Approvals by the National Institutes of Health vs the Pharmaceutical Industry, 2010 – 2019." JAMA Health Forum. 2023 APR; 4(): e230511.

consistently disclose NIH support in patents awardees obtained that resulted from NIH-funded research during the period of 2012 – 2021.[69] Given the potentially enormous profits that drug manufacturers can make from research funded by taxpayers, drug makers should be required to disclose R&D costs for drugs, including identifying which portion of research they funded versus how much was funded by the NIH, along with research conducted by other academic entities, and/or by another pharmaceutical company (even if it is later acquired by the current manufacturer).

- **Limit third-party patient assistance schemes primarily paid for by Big Pharma that mask actual drug prices and raise costs.** Third-party patient assistance programs can help patients afford high-priced drugs – but in many cases are used by drug companies to shield patients from high prices and have health plans continue to bear the high costs. For example, the House Oversight and Investigations Committee found that "[p]atient assistance programs allowed Novartis to reduce patient price sensitivity, and Novartis used its co-payment programs to drive demand, particularly after loss of exclusivity" for the cancer treatment Gleevec.[70] Internal Novartis documents projected a potential rate of return on the Gleevec co-pay assistance program of $8.90 for every $1.00 invested at 6 months prior to loss of market exclusivity.[71]

  To increase transparency and lower costs, policymakers should require independent third-party patient assistance organizations to report their donors, amounts donated, and the total amount of payment assistance provided to individuals who are prescribed drugs manufactured by any contributor to these organizations. The HHS OIG should scrutinize third-party patient assistance programs to ensure that such programs do not inappropriately direct patients to certain therapies and do not increase federal spending on healthcare programs. Use of patient assistance programs funded by drug makers should be prohibited in commercial health insurance and the current regulatory ban on use of drug manufacturer assistance coupons in federal health programs should be codified. Co-pay accumulator programs that discourage inappropriate third-party assistance by drug makers should be explicitly permitted in federal health programs and commercial health plans.

[69] Government Accountability Office. National Institutes of Health: Better Data Will Improve Understanding of Federal Contributions to Drug Development. GAO-23-105656. May 4, 2023.
[70] U.S. House of Representatives House Committee on Oversight and Reform. "Staff Report: Drug Pricing Investigation Novartis – Gleevec." October 2020.
[71] *Ibid*.