Written Testimony of

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before the
The Senate Committee on Health, Education, Labor and Pensions

on

"Why Does the United States Pay, by Far, the Highest Prices in the World for Prescription Drugs?"

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Chairman Sanders, Ranking Member Cassidy and Members of the Committee,

Thank you for the opportunity to testify today on the high prices Americans pay for prescription drugs. I am Peter Maybarduk, Access to Medicines Director of Public Citizen. Public Citizen is a national public interest organization with more than 500,000 members and supporters. For more than 50 years, we have advocated for stronger health, safety and consumer protections; for corporate and government accountability; and in more recent years, for affordable access to essential medicines and biomedical technologies.

I. THE DRUG PRICING CRISIS AT THE HANDS OF THE PHARMACEUTICAL INDUSTRY

This hearing unfolds against the backdrop of a drug pricing crisis in the United States. The Centers for Disease Control and Prevention's (CDC) data from 2021 shows approximately 9.2 million Americans aged18-64 are unable to take medications as prescribed due to costs.[1] 2023 Kaiser data on all adults shows that three in 10 Americans have not taken their medications as prescribed due to costs, 82% of Americans say the cost of prescription drugs is unreasonable, and 73% say that the government is not doing enough to regulate drug prices.[2] People with disabilities are three times more likely not to take medications as prescribed due to cost barriers.[3]

Americans also confront the highest drug prices in the world, paying nearly three times more for the same drugs than other countries.[4] For the 20 top-selling drugs worldwide, drug corporations made more than $100 billion from sales to American patients in comparison to $57 billion from all other countries combined in 2020.[5] This pricing disparity is even more egregious considering significant taxpayer funded contributions to drug development. The taxpayer funded National Institutes of Health is the largest public funder of biomedical research in the world, investing nearly $45 billion in U.S. taxpayer dollars.[6] Much of this funding focuses on the foundational

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[1] Laryssa Mykyta, and Robin A. Cohen, Centers for Disease Control and Prevention, National Center for Health Statistics, *Characteristics of Adults Aged 18–64 Who Did Not Take Medication as Prescribed to Reduce Costs: United States, 2021*, NCHS DATA BRIEF NO. 470 (June 2023).
[2] Ashley Kirzinger, Alex Montero, Grace Sparks, Isabelle Valdes, & Liz Hamel, *Public Opinion Prescription Drugs and Their Prices*, KFF (Aug. 21, 2023), https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/.
[3] *Id*. at 2.
[4] ANDREW W. MULCAHY, DANIEL SCHWAM & SUSAN L. LOVEJOY, RAND, INTERNATIONAL PRESCRIPTION DRUG PRICE COMPARISONS: ESTIMATES USING 2022 DATA (2024), https://aspe.hhs.gov/sites/default/files/documents/277371265a705c356c968977e87446ae/international-price-comparisons.pdf
[5] RICK CLAYPOOL & ZAIN RIZVI, UNITED WE SPEND: FOR 20 TOP-SELLING DRUGS WORLDWIDE, BIG PHARMA REVENUE FROM U.S. SALES COMBINED EXCEEDED REVENUE FROM THE REST OF THE WORLD (Sept. 30, 2021).
[6] National Institutes of Health, *Serving Society, Direct Economic Contributions*, IMPACT OF NIH RESEARCH, https://www.nih.gov/about-nih/what-we-do/impact-nih-research/serving-society/direct-economic-contributions (last visited Feb. 1, 2024).

research on biological targets for drug action that drug development is based upon.[7] Further, recent estimates suggest that publicly supported research was critical to the late-stage development of one in four drugs.[8]

Drug pricing abuses also put an enormous strain on the coffers of public health programs, and consequently our tax dollars. Of the more than $400 billion spent on retail prescription drugs in 2022, almost $135 billion came from Medicare and $45 billion from Medicaid.[9]

Excessive drug prices and self-imposed rationing by American patients are the outgrowth of unregulated pharmaceutical monopoly power over drug prices. Prescription drug corporations receive government-granted patent protection on drug inventions and statutory exclusivities on medicines. In theory, this incentivizes innovation of new medicines, and it is critically important that we support research and development. But in practice, the rules have been written by or with the deep influence of drug corporations, to maximize their ability to extract rents from our healthcare system. Corporations extend their exclusive power over new drugs through an array of anticompetitive tactics to the detriment of American patients.[10] For example, many have abused the patent system to obtain subsequent patents over the same medicine with marginal differences or benefits to retain longer periods of exclusivity, sometimes decades.[11]

Pharmaceutical companies have exploited their monopoly power to accrue tremendous influence in our political system and protect their exceptional profits. The pharmaceutical industry expends hundreds of millions of dollars each year in lobbying efforts to advance its interests, outranking every other industry.[12] When Medicare Part D was established to cover prescription costs for seniors two decades ago, pharmaceutical companies successfully lobbied to deprive the program of the power to negotiate drug prices.[13] Federal law requires private insurers, Medicare, and Medicaid to cover FDA approved drugs, which effectively provides a government mandate to buy companies' monopolized drugs with absent or weak measures to contain costs.[14]

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[7] Ekaterina Galkina, Jennifer M. Beierlein, Navleen Surjit Khanuja, and Fred D. Ledley, *Contribution of NIH funding to new drug approvals 2010–2016*, 115 PNAS 2329 (2017).
[8] Rahul H. Nayak, Jerry Avorn, & Aaron S. Kesselheim, *Public sector financial support for late stage discovery of new drugs in the United States: cohort study*, 367 BMJ l5766 (2019).
[9] *NHE Fact*, CMS.GOV, https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/nhe-fact-sheet (last visited Feb. 5, 2024).
[10] *E.g.*, Aaron Kesselheim, Jerry Avorn, & Ameet Sarpatwari, *The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform*, 316 JAMA NETWORK 858 (2016).
[11] Other tactics they use to maintain their extraordinary pricing power over essential medicines include switching patients from branded medications with patent protection nearing expiry to new drugs with no added clinical benefit and longer patent protection. Drug corporations also pay generic companies to delay their competing products in order to extract more profits.
[12] Inci Sayki, *Despite record federal lobbying spending, the pharmaceutical and health product industry lost their biggest legislative bet in 2022*, OPEN SECRETS (Feb. 2, 2023), https://www.opensecrets.org/news/2023/02/despite-record-federal-lobbying-spending-the-pharmaceutical-and-health-product-industry-lost-their-biggest-legislative-bet-in-2022/.
[13] Amy Kapczynski, *The Political Economy of Market Power in Pharmaceuticals*, 48 J. HEALTH POL., POL'Y L. 215, 223 (2023).
[14] *Id*.

Other countries employ cost-containing measures to protect their residents from drug pricing abuses, which is why the price of prescriptions drugs in the United States is so excessive by comparison.[15] Drug companies have been happy to benefit from a slew of U.S. government actions and policies that have dramatically increased their profits in recent decades, but they balk at any attempt to implement drug pricing measures that already benefit wide swathes of the world.

Drugmakers' largely unregulated, and government-expanded, pricing power has rewarded them with exceptional profits. To protect these profits, pharma trade groups claim that any measure that could deliver drug pricing relief to Americans will restrict resources to invest in new medicines and help patients in the future.[16] That framing usefully erases the millions of Americans that currently self-ration their medicines and are harmed due to pricing abuses. It also erases the tens of billions of taxpayer dollars invested annually in research and development, and the hundreds of billions the industry spends on self-enrichment.

The Biden administration is making significant progress in addressing our nation's drug pricing crisis through implementation of Medicare drug price negotiation, inflationary rebates, the cap on out-of-pocket costs for insulin at $35 per month for Medicare enrollees, the caps on annual out-of-pocket expenses for prescription drugs in the catastrophic phase of Medicare Part D that will be set at $2,000 next year, and other provisions of the Inflation Reduction Act. Bipartisan reforms which this committee has considered and advanced can build on that progress.[17] However, far more is necessary to provide material relief to all patients facing unbearably high prescription drug prices, including people with private insurance and those without insurance.[18]

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[15] *Id*. at 223; Aaron Kesselheim, Jerry Avorn, & Ameet Sarpatwari, *The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform*, 316 JAMA NETWORK 858, 860 (2016).

[16] *See* PhRMA, *States Can Help Patients Pay Less for Their Medicines*, STATE POLICIES AND ISSUES, https://phrma.org/en/States (last visited Jan. 11, 2023); PhRMA, INFLATION REDUCTION ACT'S UNINTENDED CONSEQUENCES,https://phrma.org/inflation-reduction-act?utm_campaign=2024-q1-pri-v6&utm_medium=pai_srh_cpc-ggl-adf&utm_source=ggl&utm_content=clk-pat-v6-v6-v6-all-pai_srh_cpc-ggl-adf-IRAEvergreenSearchWCNational1-evg-v6-v6-lrm-soc_txt-v6-vra-adf&utm_term=inflation%20reduction%20act&utm_campaign=&utm_source=adwords&utm_medium=ppc&hsa_acc=8523309176&hsa_cam=20882819512&hsa_grp=158617381844&hsa_ad=685220095153&hsa_src=g&hsa_tgt=kwd-1705916798609&hsa_kw=inflation%20reduction%20act&hsa_mt=b&hsa_net=adwords&hsa_ver=3&gad_source=1&gclid=Cj0KCQiAwP6sBhDAARIsAPfK_wZ3PhDU-6cvBxNUI9JVXtfl-nZch3LOEQIJQA2j_rY2LRRBqHdL7fQaAkKjEALw_wcB (last visited Jan. 11, 2024); *PhRMA Statement on Proposed March-In Framework* , PHRMA (Dec. 6, 2023), https://phrma.org/resource-center/Topics/Access-to-Medicines/PhRMA-Statement-on-Proposed-March-In-Framework.

[17] Specifically, Public Citizen supports legislation to promote generic competition and lower drug prices through taking on drug corporation citizen petition abuse and exclusivity "parking", clarifying the scope of orphan drug exclusivity, and providing greater transparency for generic applicants. Additionally, Public Citizen has supported bipartisan measures advanced through the Judiciary Committee that address pay-for-delay, product hopping and citizen petition abuses.

[18] Public Citizen also supports legislation to build on the Inflation Reduction Act, through expanding the number of drugs negotiated, who benefits from negotiated prices, and reducing and removing the negotiation delay periods currently mandated. Public Citizen has also supported legislation reducing the biologics exclusivity period to 5 years, in parity with that afforded small molecule drugs, and legislation to require reasonable pricing of federally-

To highlight the need for stronger measures to deliver drug pricing relief to millions of Americans, this testimony focuses on the drug pricing abuses of Merck, Johnson & Johnson, and Bristol Myers Squibb. In our view, these corporations have taken advantage of weaknesses in our health system to price gouge Americans and used suspect patenting practices to unfairly extend their monopoly power.

II. MERCK, JOHNSON & JOHNSON, AND BRISTOL MYERS SQUIBB ENGAGE IN PRICING ABUSES OF LIFE-SAVING MEDICINES

Merck

Merck takes advantage of its monopoly power to excessively price its blockbuster drug, Keytruda, which treats many different cancer types,[19] and Januvia, a widely used drug to treat diabetes.[20] Additionally, Merck exploits its monopoly protections to price gouge Americans on the federally funded COVID-19 treatment, Lagevrio, that cuts the risk of hospitalization.[21] For Keytruda and Januvia, Merck has been granted patent protection beyond their active ingredient or mechanism, which helps prolong its monopoly control over these drugs by deterring manufacturers from bringing more affordable alternatives to market.

Keytruda

First, Merck exploits its monopoly protections in Keytruda to price the drug outrageously. The price of Keytruda for just three weeks is over $11,000,[22] and some patients may need to adhere to Keytruda for one to two years.[23] The extraordinary list price of the drug, amounting to over $190,000 a year, means that insured patients routinely hit their out-of-pocket limits, which can be thousands of dollars every year.[24] In 2023, Merck made **$25 billion** off of Keytruda according to its latest filing with the Securities Exchange Commission.[25] Of the $18 billion in sales of the drug globally in the first nine months of 2023, Merck extracted $11 billion in revenue from

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funded medical inventions. Public Citizen has repeatedly called on Congress to advance insulin access reform to ensure people without insurance and with private insurance can access affordable insulin. Public Citizen also strongly supports additional solutions to address patent thicketing suggested by the Initiative for Medicines, Access and Knowledge (I-MAK). *See* IMAK, ADDRESSING PATENT THICKETS TO IMPROVE COMPETITION AND LOWER PRESCRIPTION DRUG PRICES: A BLUEPRINT FOR REFORM (2023), https://www.i-mak.org/wp-content/uploads/2023/12/Addressing-Patent-Thickets-Blueprint_2023.pdf) .

[19] I-MAK, OVERPATENTED, OVERPRICED: KEYTRUDA'S PATENT WALL 3 (2021).

[20] ASSISTANT SECRETARY FOR HEALTH AND PLANNING, HHS, INFLATION REDUCTION ACT RESEARCH SERIES: JANUVIA: MEDICARE ENROLLEE USE AND SPENDING (Nov. 13, 2023), https://aspe.hhs.gov/reports/ira-research-series-medicare-drug-price-negotiation-program.

[21] Sharon Lerner, *Merck Sells Federally Financed Covid Pill to U.S. for 40 times What It Costs to Make*, THE INTERCEPT (Oct. 5, 2021), https://theintercept.com/2021/10/05/covid-pill-drug-pricing-merck-ridgeback/.

[22] *Cost Info and Financial Help*, KEYTRUDA, https://www.keytruda.com/financial-support/#:~:text=The%20list%20price%20for%20each,out%2Dof%2Dpocket%20costs. (last visited Feb. 1, 2024).

[23] *What Do I Need to Know About My Treatment Schedule?*, STARTING KEYTRUDA (last visited Feb. 1, 2024).

[24] Bob Herman, *The Keytruda Boom*, AXIOS (Oct. 19, 2021), https://www.axios.com/2021/10/29/keytruda-sales-merck-drug-prices.

[25] MERCK & CO., INC., FORM 8-K, EXHIBIT 99.1 (Feb. 1, 2024), https://www.sec.gov/ixviewer/ix.html?doc=/Archives/edgar/data/0000310158/000110465924009109/tm244517d1_8k.htm.

American patients.[26] Evidence suggests the price of Keytruda is not keyed to its research and development costs. Merck itself did not make the original research and development contributions critical to the drug's discovery: it obtained ownership of the drug, and many others, via a corporate acquisition in 2009 for $41 billion.[27] In just two years, Merck has more than made up for those costs with $46 billion in sales for the drug.[28]

Second, Merck appears to be engaging in patenting practices designed to unfairly extend exclusivity over this biologic drug to prevent more affordable biosimilars from coming to market.[29] The Initiative for Medicines, Access and Knowledge (I-MAK) found that 129 patent applications have been filed to cover Keytruda, and 50% of these applications were filed after the drug's FDA approval in 2014, cutting against claims that these patent applications furthered innovation incentives for the drug's discovery.[30] Fifty-three patent applications have been granted to date, and the primary patents covering the antibody that's considered the main component of the drug were filed in 2008 and will expire in 2028.[31]

The other patents protect, among other things, methods of producing the drug and its use to treat different cancer types.[32] But method of production patents are more critical to biologics like Keytruda than small molecule drugs because the techniques for producing these drugs are more challenging.[33] As such, it's more difficult for manufacturers to work around these patents to create more affordable biosimilar alternatives.[34] Additionally, once the mechanism of action is known for a biologic in addressing one condition, testing its use for other similar indications becomes obvious.[35] Therefore, obtaining multiple patents for different clinical indications for these drugs appears problematic. The secondary patents on Keytruda grant an additional eight years of Merck's monopolistic pricing power over the drug, and as a consequence of this exclusivity, it is estimated that Americans will spend $137 billion on Keytruda.[36]

In sum, Merck appears to be unfairly extending its exclusivity over Keytruda, which will cost American patients billions in the coming years, in light of the filing pattern of patent applications on Keytruda particularly after its FDA approval, and the granted patent protection to deter biosimilar competitors after the expiry of primary patents.

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[26] MERCK & CO., INC., FORM 10-Q FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2023, at 29, https://www.sec.gov/ixviewer/ix.html?doc=/Archives/edgar/data/0000310158/000162828023036717/mrk-20230930.htm.
[27] I-MAK, OVERPATENTED, OVERPRICED: KEYTRUDA'S PATENT WALL 3 (2021).
[28] MERCK & CO., INC., FORM 8-K, EXHIBIT 99.1 (Feb. 1, 2024), https://www.sec.gov/ixviewer/ix.html?doc=/Archives/edgar/data/0000310158/000110465924009109/tm244517d1_8k.htm.
[29] I-MAK, OVERPATENTED, OVERPRICED: KEYTRUDA'S PATENT WALL 5-6 (2021).
[30] *Id.* at 1.
[31] *Id.*
[32] *Id.* at 3.
[33] *Id.*
[34] *Id.*
[35] *Id.*
[36] *Id.* at 4.

Januvia

Merck's pricing of Januvia, which treats diabetes, also exemplifies the pricing abuses rampant to the pharmaceutical industry. Merck charges Americans as much as $6,900 per year for Januvia, while the same drug can be purchased for $900 in Canada and $200 in France.[37] Medicare Part D spent more than $4 billion on just this one drug between June 2022 and May 2023,[38] and the drug has been selected by CMS for the first round of Medicare price negotiation. The drug on average costs Medicare nearly $5,000 annually per enrollee, with out-of-pocket costs amounting to more than $500 each year for enrollees who do not receive the low-income subsidy.[39] On Januvia, and the related product Janumet, Merck made $4.5 billion and $3.4 billion in 2022 and 2023, respectively.[40]

Merck has managed to extend its monopoly pricing power over Januvia through unfair patenting practices. Januvia was first approved by the FDA in 2006,[41] and the original patent covering Januvia's active ingredient, filed in 2002, expired in 2023.[42] Americans already should have access to lower cost generics. Indeed, Merck lost exclusivity for the drug in 2023 in Europe.[43] However, according to the FDA's Orange Book, one patent set to expire in 2027 stands in the way of low-cost generics for American patients.[44] That patent covers a specific salt form of the active ingredient created from a reaction with phosphoric acid.[45] According to Merck, innovating

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[37] Bernie Sanders: U.S. Senator for Vermont, *PREPARED REMARKS: Sanders Ahead of Vote to Subpoena CEOs to Testify on Outrageously High Prices of Prescription Drugs in America*, PRESS RELEASES (Jan. 25, 2024), https://www.sanders.senate.gov/press-releases/prepared-remarks-sanders-ahead-of-vote-to-subpoena-ceos-to-testify-on-outrageously-high-prices-of-prescription-drugs-in-america/.

[38] The White House, *FACT SHEET: Biden-Harris Administration Announces First Ten Drugs Selected for Medicare Price Negotiation*, BRIEFING ROOM: STATEMENTS & RELEASES (Aug. 29, 2023), https://www.whitehouse.gov/briefing-room/statements-releases/2023/08/29/fact-sheet-biden-harris-administration-announces-first-ten-drugs-selected-for-medicare-price-negotiation/.

[39] *Id*.

[40] MERCK & CO., INC., FORM 8-K, EXHIBIT 99.1 (Feb. 1, 2024), https://www.sec.gov/ixviewer/ix.html?doc=/Archives/edgar/data/0000310158/000110465924009109/tm244517d1_8k.htm.

[41] Merck Sharp & Dohme, LLC v. Mylan Pharm., No. 1:19CV101 4-5 (N.D.W. Va. Sep. 21, 2022); HIGHLIGHTS OF PRESCRIBING INFORMATION, https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/021995s019lbl.pdf (last visited Jan. 29, 2024).

[42] Merck Sharp & Dohme, LLC v. Mylan Pharm., No. 1:19CV101 16-17 (N.D.W. Va. Sep. 21, 2022); U.S. Patent No. US 6,699,871 Claim 17.

[43] MERCK & CO., INC., FORM 10-K, at 27 (Feb. 24 2023), https://www.sec.GOV/ixviewer/ix.html?doc=/Archives/edgar/data/310158/000162828023005061/mrk-20221231.htm.

[44] *Product Details for NDA 021995*, ORANGE BOOK: APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, https://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=N&Appl_No=021995#23300 (last visited Feb. 2, 2024).

[45] Merck Sharp & Dohme, LLC v. Mylan Pharm., No. 1:19CV101 12-13, 77 (N.D.W. Va. Sep. 21, 2022).

patents after the filing of the primary patent "enhance[s] the benefits and convenience of treatments for patients."[46]

The validity of the patent and Merck's argument that these secondary patents, at least for Januvia, benefit patients are belied by the litigation surrounding this patent. Although a district court ultimately upheld the patent based on technical legal rules, it noted that the earlier patent claimed salt forms of Januvia's active ingredient, and most egregiously, the earlier patent disclosed that a salt could be formed using phosphoric acid and even lists it as one of eight preferred acids for creating such salts.[47] The second patent simply covers the salt form product formed by a reaction of phosphoric acid with the active ingredient.[48] In essence, Merck was able to extend its monopolistic pricing power over Januvia by claiming something it had basically previously disclosed, and what many would consider an obvious variation of the active ingredient. Further, Merck's claim that there is some corollary benefit to patients that arises from its salt patent is contradicted by the record: to reject the generic manufacturer's challenge to the patent's validity, the district court found that the active ingredient by itself was fine and did not need to be reacted with a salt.[49]

Lagevrio

A five-day-course of Lagevrio, which cuts the risk of hospitalization from COVID-19, costs $17.74 to produce, but Merck charged the federal government $712, or over 40 times more, for the drug in 2021.[50] The government had contracted with Merck to supply 1.7 million courses of treatment at this price for a total of $1.2 billion.[51] The pricing of Lagevrio was particularly egregious because the federal government invested an estimated $29-35 million in the development of the drug.[52] In 2023, Merck's sales of the drug brought in $1.4 billion, but in the previous year, Merck made nearly $6 billion off of the treatment.[53]

In sum, Merck has been engaging in excessive pricing abuses with respect to Keytruda, Januvia, and Lagevrio, which bring in billions every year for the company. Additionally, it has sought to

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[46] Andrew Seidman, *How Merck extended its monopoly on a blockbuster diabetes drug*, PHILADELPHIA INQUIRER (Dec. 20, 2023), https://www.inquirer.com/business/merck-patent-januvia-medicare-price-negotiations-20231220.html.

[47] Merck Sharp & Dohme, LLC v. Mylan Pharm., No. 1:19CV101 73, 76-77 (N.D.W. Va. Sep. 21, 2022).

[48] *Id*. at 12-13, 77.

[49] *Id*. at 85. The district court's reasoning may have been flawed, as it noted earlier that Merck had been motivated to find a salt form of the compound because it proved unsuitable for making pharmaceutical tablets and was unstable. *Id*. at 7. Even if this were true, this should have provided the motivation for a person to arrive at this salt version of the active ingredient, rendering the patent claim obvious and invalid.

[50] Sharon Lerner, *Merck Sells Federally Financed Covid Pill to U.S. for 40 times What It Costs to Make*, THE INTERCEPT (Oct. 5, 2021), https://theintercept.com/2021/10/05/covid-pill-drug-pricing-merck-ridgeback/.

[51] *Id*.

[52] *Id*; Luis Gil Abinader, *US government rights in patents on Molnupiravir, based upon funding of R&D at Emory University*, KNOWLEDGE ECOLOGY INTERNATIONAL BLOG (Oct. 4, 2021), https://www.keionline.org/36648.

[53] MERCK & CO., INC., FORM 8-K, EXHIBIT 99.1 (Feb. 1, 2024), https://www.sec.gov/ixviewer/ix.html?doc=/Archives/edgar/data/0000310158/000110465924009109/tm244517d1_8k.htm.

extend its monopolistic pricing power over Keytruda and Januvia using patenting practices we should deem unfair.

Johnson & Johnson

Like Merck, Johnson & Johnson benefits from monopoly protections to price gouge American patients on vital medicines. These drugs include (1) Stelara, which helps treat psoriasis, psoriatic arthritis, Crohn's disease, and ulcerative colitis;[54] (2) Xarelto, which prevents and treats blood clots and reduces health risks for patients with coronary or peripheral heart disease, and is licensed for sale in the U.S. from Bayer AG;[55] and (3) Darzalex, which treats multiple myeloma.[56] Imbruvica is another possible example of Johnson & Johnson's drug pricing abuses. Johnson & Johnson commercializes Imbruvica, which treats blood cancers,[57] outside the United States and has co-exclusive rights with AbbVie to commercialize the drug in the United States, though AbbVie states it is "the principal in the end-customer product sales."[58] The companies share profits and losses equally from the commercialization of the drug.[59] Even if Johnson & Johnson does not ultimately control the prices of drugs in the United States, it profits equally from the abuses of its commercial partner.

Johnson & Johnson also benefits from unfair patenting practices extending exclusivity over Xarelto and Imbruvica, which will incur billions in costs to U.S. patients.

Stelara

Johnson & Johnson prices Stelara exorbitantly in comparison to other high-income markets. The drug is priced at $79,000 in the United States when it can be purchased for a fifth of the price in the United Kingdom.[60] Even considering rebates, the price of Stelara is between 28%-81% lower

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[54] ASSISTANT SECRETARY FOR HEALTH AND PLANNING, HHS, INFLATION REDUCTION ACT RESEARCH SERIES: STELARA: MEDICARE ENROLLEE USE AND SPENDING (Nov. 13, 2023), https://aspe.hhs.gov/reports/ira-research-series-medicare-drug-price-negotiation-program.

[55] ASSISTANT SECRETARY FOR HEALTH AND PLANNING, HHS, INFLATION REDUCTION ACT RESEARCH SERIES: XARELTO: MEDICARE ENROLLEE USE AND SPENDING (Nov. 13, 2023), https://aspe.hhs.gov/reports/ira-research-series-medicare-drug-price-negotiation-program; BAYER ANNUAL REPORT 2022 97 (2023), https://www.bayer.com/en/investors/integrated-annual-reports,

[56] DAVID RIND, FOLUSO AGBOOLA, DMITRIY NIKTIN, AVERY MCKENNA, EMILY NHAN, MATT SEIDNER, & STEVEN D. PEARSON, INSTITUTE FOR CLINICAL AND ECONOMIC REVIEW, UNSUPPORTED PRICE INCREASE REPORT: UNSUPPORTED PRICE INCREASES OCCURRING IN 2022 10 (Dec. 11, 2023), UPI_2023_Report_121123.pdf (icer.org).

[57] ASSISTANT SECRETARY FOR HEALTH AND PLANNING, HHS, INFLATION REDUCTION ACT RESEARCH SERIES: IMBRUVICA: MEDICARE ENROLLEE USE AND SPENDING (Nov. 13, 2023), https://aspe.hhs.gov/reports/ira-research-series-medicare-drug-price-negotiation-program.

[58] ABBVIE INC., FORM 10-K FOR THE FISCAL YEAR ENDED DECEMBER 31, 2022, at 66-67, https://www.sec.gov/ixviewer/ix.html?doc=/Archives/edgar/data/1551152/000155115223000011/abbv-20221231.htm#i8aa2d13e9ab74474a8ce0ca02e5f47bc_97.

[59] *Id*.

[60] Bernie Sanders: U.S. Senator for Vermont, *PREPARED REMARKS: Sanders Ahead of Vote to Subpoena CEOs to Testify on Outrageously High Prices of Prescription Drugs in America*, PRESS RELEASES (Jan. 25, 2024), https://www.sanders.senate.gov/press-releases/prepared-remarks-sanders-ahead-of-vote-to-subpoena-ceos-to-testify-on-outrageously-high-prices-of-prescription-drugs-in-america/; The White House, *FACT SHEET: Biden-Harris Administration Announces First Ten Drugs Selected for Medicare Price Negotiation*, BRIEFING ROOM: STATEMENTS

in Canada, Switzerland, Germany, Australia, the United Kingdom, France, and Australia.[61] In 2023, Johnson & Johnson made nearly $11 billion in sales from the drug, almost $7 billion of which came from U.S. patients.[62]

The drug has been selected for the first round of Medicare price negotiation, and between June 2022 and May 2023, Medicare Part D spent over $2.6 billion on the drug. Further, Stelara had incurred over $4,000 in out-of-pocket costs annually for enrollees who did not receive the low-income subsidy.

There is reason to believe that Johnson & Johnson has engaged in unfair patenting practices to maintain its monopoly power over Stelara. Hagens Berman filed a class action lawsuit on Dec. 7, 2023 for health benefit providers on the basis that Johnson & Johnson illegally delayed the entry of biosimilar competitors to Stelara.[63] Their complaint alleges that Johnson & Johnson defrauded the Patent and Trademark Office by intentionally misleading the examiner on the patentability of a subject patent in Stelara, purchased a manufacturer that had patents in the methods of producing biosimilar alternatives to Stelara, and used these fraudulently and unlawfully obtained patents to delay alternatives that would have been more affordable to patients.[64]

Darzalex

In 2022, the Institute for Clinical and Economic Review found that Johnson & Johnson's 6.8% price hike of Darzalex was unsupported by new clinical evidence, increasing spending by an estimated $248 million in the United States.[65] In 2023, Johnson & Johnson made nearly $10 billion on the drug, of which more than $5 billion derived from the U.S. market.[66]

Xarelto

Johnson & Johnson prices Xarelto at $542 for a 30-day supply, which is nearly $7,000 a year in the United States.[67] Even considering rebates, Xarelto is two to four times more expensive in the United States compared to Canada, Switzerland, Germany, Australia, the United Kingdom,

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& RELEASES (Aug. 29, 2023), https://www.whitehouse.gov/briefing-room/statements-releases/2023/08/29/fact-sheet-biden-harris-administration-announces-first-ten-drugs-selected-for-medicare-price-negotiation/.

[61] Evan D. Gumas, Paige Huffman, Irene Papanicolas, & Reginald D. Williams II, *How Prices for the First 10 Drugs Up for U.S. Medicare Price Negotiations Compare Internationally, Controlling Health Care Costs*, THE COMMOWEALTH FUND (Jan. 4, 2024), https://www.commonwealthfund.org/publications/2024/jan/how-prices-first-10-drugs-medicare-negotiations-compare-internationally.

[62] JOHNSON & JOHNSON, FORM 8-K, EXHIBIT 99.2 (Jan. 23, 2024), https://www.sec.gov/ixviewer/ix.html?doc=/Archives/edgar/data/200406/000020040624000004/jnj-20240123.htm.

[63] *Stelara Antitrust*, HAGENS BERMAN, https://www.hbsslaw.com/cases/stelara-antitrust (last visited Feb. 4, 2024).

[64] *Id.*

[65] DAVID RIND, FOLUSO AGBOOLA, DMITRIY NIKTIN, AVERY MCKENNA, EMILY NHAN, MATT SEIDNER, & STEVEN D. PEARSON, INSTITUTE FOR CLINICAL AND ECONOMIC REVIEW, UNSUPPORTED PRICE INCREASE REPORT: UNSUPPORTED PRICE INCREASES OCCURRING IN 2022 10 (Dec. 11, 2023), UPI_2023_Report_121123.pdf (icer.org).

[66] *Id.*

[67] HOW MUCH SHOULD I EXPECT TO PAY FOR XARELTO®?, https://www.xarelto-us.com/cost (last visited Feb. 3, 2024).

France, and Australia.[68] Xarelto has been selected for the first round of Medicare price negotiation, and between June 2022 and May 2023, Medicare Part D spent over $6 billion on Xarelto, with over $600 in out-of-pocket costs per year for enrollees who did not receive the low-income subsidy.[69]

Johnson & Johnson benefits from the unfair patenting practices of another company to prolong its exclusive authority to price and sell Xarelto in the United States. Johnson & Johnson licenses Xarelto from Bayer AG, a German company that owns the patents in the drug.[70] Johnson & Johnson received FDA approval for Xarelto in 2011,[71] and the patent protection for two of three patents listed for the drug in the Orange Book expire in 2025.[72] But the protection of a third patent covering the 10 mg, 15 mg, and 20-mg tablets of the drug expires in 2034.[73] Bayer AG describes that the patents covering the active ingredient of Xarelto in the U.S. expire in 2025.[74] Thus, the secondary patent expiring in 2034 for the drug prolongs Johnson & Johnson's monopolistic pricing power over these Xarelto tablets by almost a decade in excess of the protection afforded by the primary patents. This secondary patent appears to be a significant barrier to generic entry, as Johnson & Johnson and Bayer are relying solely on this patent's claims in lawsuits seeking to prevent at least three, and likely more, manufacturers from selling generics of the 10, 15 and 20-mg doses of Xarelto.[75]

While the earlier patents cover the active ingredient, its combination with other substances to form the drug, the process of preparing the drug, a solid oral version of the drug, and its use for preventing or treating cardiovascular issues, the primary marginal benefit claimed by the later-expiring patent appears to be its protection over a once-daily tablet version of the drug.[76] Bayer

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[68] Evan D. Gumas, Paige Huffman, Irene Papanicolas, & Reginald D. Williams II, *How Prices for the First 10 Drugs Up for U.S. Medicare Price Negotiations Compare Internationally, Controlling Health Care Costs*, THE COMMOWEALTH FUND (Jan. 4, 2024), https://www.commonwealthfund.org/publications/2024/jan/how-prices-first-10-drugs-medicare-negotiations-compare-internationally.

[69] The White House, *FACT SHEET: Biden-Harris Administration Announces First Ten Drugs Selected for Medicare Price Negotiation*, BRIEFING ROOM: STATEMENTS & RELEASES (Aug. 29, 2023), https://www.whitehouse.gov/briefing-room/statements-releases/2023/08/29/fact-sheet-biden-harris-administration-announces-first-ten-drugs-selected-for-medicare-price-negotiation/.

[70] BAYER ANNUAL REPORT 2022 65 (2023), https://www.bayer.com/sites/default/files/2023-02/Bayer-Annual-Report-2022.pdf.

[71] *Xarelto (rivaroxaban) 10 mg immediate release Tablets*, DRUG APPROVAL PACKAGE, https://www.accessdata.fda.gov/drugsatfda_docs/nda/2011/022406Orig1s000TOC.cfm (last visited Jan. 29, 2024).

[72] *Product Details for NDA 022406*, ORANGE BOOK: APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, https://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=N&Appl_No=022406#36514 (last visited Jan. 29, 2024).

[73] *Id*.

[74] BAYER ANNUAL REPORT 2022 65 (2023), https://www.bayer.com/sites/default/files/2023-02/Bayer-Annual-Report-2022.pdf.

[75] JOHNSON & JOHNSON, FORM 10-K FOR THE FISCAL YEAR ENDED JANUARY 1, 2023, at 91-92, https://www.sec.gov/ixviewer/ix.html?doc=/Archives/edgar/data/200406/000020040623000016/jnj-20230101.htm. The patent's claims are likely barring the entry of even more generic manufacturers according to a more recent SEC filing. *See* JOHNSON & JOHNSON, FORM 10-Q FOR THE QUARTERLY PERIOD ENDED OCTOBER 1, 2023, at 35, https://www.sec.gov/ixviewer/ix.html?doc=/Archives/edgar/data/200406/000020040623000102/jnj-20231001.htm.

[76] *Compare* U.S. Patent No. US 9,539,218 *with* US 7,157,456 & US 9.415,053.

itself states in its annual corporate statements that the patent covering 10, 15, and 20-mg once-daily tablets in Europe is set to expire in 2026.[77] If this patent survives litigation in the U.S., it will likely be another instance in which Americans are uniquely deprived of more affordable generic medications.

Imbruvica

Imbruvica was priced at over $180,000 in 2021, nearly double its launch price in 2013.[78] The net price of the drug is higher than in Switzerland, Germany, the United Kingdom, France, Canada, Japan, and Australia.[79] Excluding Switzerland, Imbruvica is priced two to four times more in the U.S. compared to these high-income nations.[80] In 2023, Johnson & Johnson made $3.26 billion in sales from the drug, with over $1 billion coming from U.S. patients.[81] Additionally, the drug has been selected for the first round of Medicare price negotiation, and Medicare Part D spent over 2.6 billion on the drug between June 2022 and May 2023.[82] Imbruvica exacted the highest financial toll on Medicare enrollees of the drugs selected for Medicare price negotiation, with an average annual out-of-pocket cost of $6,497 per enrollee who did not receive the low-income subsidy.[83] The price of Imbruvica is even more unreasonable in light of the preclinical research support from government and nonprofit sources that led to the drug's development and FDA approval, as described by Knowledge Ecology International.[84]

Like Xarelto, Johnson & Johnson profits from patent abuses on Imbruvica committed by its collaborator, AbbVie. There is a massive patent thicket depriving U.S. patients of more affordable alternatives of the drug, with 88 patents granted to date.[85] The House Oversight & Reform Committee reported that the initial patent in Imbruvica's active ingredient was filed in 2006 and was expected to expire in 2026.[86] Citing I-MAK, the Committee detailed how a "drip-

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[77] BAYER ANNUAL REPORT 2022 65 (2023), https://www.bayer.com/sites/default/files/2023-02/Bayer-Annual-Report-2022.pdf.
[78] U.S. HOUSE OF REPRESENTATIVES' COMMITTEE ON OVERSIGHT & REFORM, STAFF REPORT: DRUG PRICING INVESTIGATION: ABBVIE—HUMIRA AND IMBRUVICA 3 (May 2021).
[79] *Id.*
[80] *Id.*
[81] JOHNSON & JOHNSON, FORM 8-K, EXHIBIT 99.2 (Jan. 23, 2024), https://www.sec.gov/ixviewer/ix.html?doc=/Archives/edgar/data/200406/000020040624000004/jnj-20240123.htm.
[82] The White House, *FACT SHEET: Biden-Harris Administration Announces First Ten Drugs Selected for Medicare Price Negotiation*, BRIEFING ROOM: STATEMENTS & RELEASES (Aug. 29, 2023), https://www.whitehouse.gov/briefing-room/statements-releases/2023/08/29/fact-sheet-biden-harris-administration-announces-first-ten-drugs-selected-for-medicare-price-negotiation/.
[83] ASSISTANT SECRETARY FOR PLANNING AND EVALUATION, OFFICE OF HEALTH POLICY, DEPARTMENT OF HEALTH AND HUMAN SERVICES, INFLATION REDUCTION ACT RESEARCH SERIES— MEDICARE ENROLLEES' USE AND OUT-OF-POCKET EXPENDITURES FOR DRUGS SELECTED FOR NEGOTIATION UNDER THE MEDICARE DRUG PRICE NEGOTIATION PROGRAM 5 (Aug. 29, 2023), https://aspe.hhs.gov/sites/default/files/documents/9a34d00483a47aee03703bfc565ffee9/ASPE-IRA-Drug-Negotiation-Fact-Sheet-9-13-2023.pdf .
[84] ARIANNA SCHOUTEN, NOTES ON THE PRECLINICAL DEVELOPMENT OF IMBRUVICA (IBRUTINIB) (2023), https://www.keionline.org/wp-content/uploads/KEI-BN-2023-4.pdf.
[85] I-MAK, OVERPATENTED, OVERPRICED: IMBRUVICA'S PATENT Wall 2 (July 2020).
[86] *Id.*

feed" patent strategy was employed to prolong monopoly power over Imbruvica.[87] Under this strategy, multiple additional patents were filed covering aspects of Imbruvica that had already been disclosed in earlier patents but with more specificity.[88] The sheer number of patents providing protection on the drug is designed to discourage generic competition against the drug. Even then, the Committee reports that nearly a dozen generic manufacturers sought FDA approval of generics, but most entered confidential agreements to delay generic entry until 2032, six years after the primary patent was expected to expire.[89]

In sum, Johnson & Johnson price gouges American patients on several critical medicines. Moreover, the unregulated drug pricing power of the company will be unfairly extended by abuses of the United States' patent system.

Bristol Myers Squibb

Bristol Myers Squibb, like Merck and Johnson & Johnson, has engaged in pricing abuses of several drugs to the detriment of American patients, including Breyanzi, a cell therapy for B-cell lymphoma; Pomalyst, which is used to treat multiple myeloma;[90] and Revlimid, which treats the same.[91] This is also true of (1) Abecma, a cell therapy for treating multiple myeloma, that BMS licensed from the company, 2seventy bio, and for which BMS shares profits and losses equally with its commercial partner, and (2) Eliquis, which is a small molecule drug used to prevent and treat blood clots, that BMS developed with Pfizer.[92] Profits and losses are largely shared equally by the companies on a global scale, but BMS "is the principal in the end customer product sales in the U.S., significant countries in Europe, as well as Canada, Australia, China, Japan and South Korea."[93]

Eliquis

Bristol Myers Squibb abuses its monopoly protections to charge Americans over $7,000 for Eliquis while pricing the same drug for just $900 in Canada and just $650 in France.[94] Even with rebates, the price of Eliquis is between 35-70% lower in the high-income nations of Switzerland,

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[87] U.S. HOUSE OF REPRESENTATIVES' COMMITTEE ON OVERSIGHT & REFORM, STAFF REPORT: DRUG PRICING INVESTIGATION: ABBVIE—HUMIRA AND IMBRUVICA 36 (May 2021).
[88] *Id.*
[89] *Id.* at 37.
[90] BRISTOL-MYERS SQUIBB, FORM 10-K FOR THE FISCAL YEAR ENDED DECEMBER 31, 2022, at 2, https://www.sec.gov/ixviewer/ix.html?doc=/Archives/edgar/data/14272/000001427223000046/bmy-20221231.htm.
[91] *Id.* at 3.
[92] ASSISTANT SECRETARY FOR HEALTH AND PLANNING, HHS, INFLATION REDUCTION ACT RESEARCH SERIES: ELIQUIS: MEDICARE ENROLLEE USE AND SPENDING (Nov. 13, 2023), https://aspe.hhs.gov/reports/ira-research-series-medicare-drug-price-negotiation-program; BRISTOL-MYERS SQUIBB, FORM 10-K FOR THE FISCAL YEAR ENDED DECEMBER 31, 2022, at 77. https://www.sec.gov/ixviewer/ix.html?doc=/Archives/edgar/data/14272/000001427223000046/bmy-20221231.htm.
[93] *Id.*
[94] Bernie Sanders: U.S. Senator for Vermont, *PREPARED REMARKS: Sanders Ahead of Vote to Subpoena CEOs to Testify on Outrageously High Prices of Prescription Drugs in America,* PRESS RELEASES (Jan. 25, 2024), https://www.sanders.senate.gov/press-releases/prepared-remarks-sanders-ahead-of-vote-to-subpoena-ceos-to-testify-on-outrageously-high-prices-of-prescription-drugs-in-america/.

Germany, the United Kingdom, France, Canada, Japan, and Australia.[95] Eliquis was selected for the first round of Medicare price negotiation. Between June 2022 and May 2023, Eliquis was the top spend among the 10 drugs selected for price negotiation, costing Medicare Part D over $16 billion.[96] Medicare enrollees who did not receive the low-income subsidy paid over $600 in annual out-of-pocket costs just for this one drug.[97]

Bristol Myers Squibb has sought to extend its monopoly protections over Eliquis using unjust patenting practices. Although generics received FDA approval in 2019,[98] none will come to market until 2026, with some alternatives prohibited until 2031 due to patent litigation and settlements.[99] The company's patent for the active ingredient of Eliquis was filed in September 2002, and was set to expire in February 2023.[100] But BMS received an extension of its patent term until November 2026 using a federal law that can provide extensions for time lost in the premarket government approval process.[101]

On top of its extension on the primary patent, BMS and Pfizer obtained a patent on a pharmaceutical composition with a particular crystalline form of the active ingredient that expires in 2031.[102] In patent litigation, a generic manufacturer argued the claim was obvious because someone would have been motivated to develop the same claim based on what was known at the time. While American courts upheld the patent claim based on a finding that there was no need that would have motivated someone else to pursue this invention, the UK courts

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[95] Evan D. Gumas, Paige Huffman, Irene Papanicolas, & Reginald D. Williams II, *How Prices for the First 10 Drugs Up for U.S. Medicare Price Negotiations Compare Internationally, Controlling Health Care Costs*, THE COMMOWEALTH FUND (Jan. 4, 2024), https://www.commonwealthfund.org/publications/2024/jan/how-prices-first-10-drugs-medicare-negotiations-compare-internationally.

[96] The White House, *FACT SHEET: Biden-Harris Administration Announces First Ten Drugs Selected for Medicare Price Negotiation*, BRIEFING ROOM: STATEMENTS & RELEASES (Aug. 29, 2023), https://www.whitehouse.gov/briefing-room/statements-releases/2023/08/29/fact-sheet-biden-harris-administration-announces-first-ten-drugs-selected-for-medicare-price-negotiation/.

[97] ASSISTANT SECRETARY FOR PLANNING AND EVALUATION, OFFICE OF HEALTH POLICY, DEPARTMENT OF HEALTH AND HUMAN SERVICES, INFLATION REDUCTION ACT RESEARCH SERIES— MEDICARE ENROLLEES' USE AND OUT-OF-POCKET EXPENDITURES FOR DRUGS SELECTED FOR NEGOTIATION UNDER THE MEDICARE DRUG PRICE NEGOTIATION PROGRAM 5 (Aug. 29, 2023), https://aspe.hhs.gov/sites/default/files/documents/9a34d00483a47aee03703bfc565ffee9/ASPE-IRA-Drug-Negotiation-Fact-Sheet-9-13-2023.pdf .

[98] *FDA approves first generics of Eliquis*, NEWS RELEASE (Dec. 23, 2019), https://www.fda.gov/news-events/press-announcements/fda-approves-first-generics-eliquis.

[99] *The Bristol-Myers Squibb-Pfizer Alliance is pleased with the U.S. District Court decision to uphold both the composition of matter (COM) patent (US 6,967,208) and formulation patent (US 9,326,945) covering Eliquis®*, PRESS RELEASE (Aug. 5, 2020), https://news.bms.com/news/details/2020/The-Bristol-Myers-Squibb-Pfizer-Alliance-is-pleased-with-the-U.S.-District-Court-decision-to-uphold-both-the-composition-of-matter-COM-patent-US-6967208-and-formulation-patent-US-9326945-covering-Eliquis/default.aspx.

[100] U.S. Patent No. US 6,967,208.

[101] *Applications for patent term extension and patent terms extended under 35 U.S.C. § 156*, UNITED STATES PATENT & TRADEMARK OFFICE, https://www.uspto.gov/patents/laws/patent-term-extension/patent-terms-extended-under-35-usc-156 (last visited Feb. 5, 2024); *Patent and Exclusivity for: N202155*, ORANGE BOOK: APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, https://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Product_No=001&Appl_No=202155&Appl_type=N (last visited Feb. 5, 2024).

[102] U.S Patent No. 9,326,945.

invalided the patent.[103] That court argued that it would have been obvious because someone in the field would have arrived at the invention, and if the court believed BMS's argument that there really was no need that would have driven the obvious invention, then the patent would have been invalid for lack of utility.[104] Ultimately, the patent appears to have marginal value given that it was not addressed to a particular issue at the time, but the consequences of five years of additional monopoly power over the drug will be enormous. American patients will continue to face hundreds of dollars in out-of-pocket costs and the coffers of public programs will be stretched in the absence of lower cost generics.

Abecma & Breyanzi

The list prices of Bristol Myers Squibb's cell therapies, Abecma and Breyanzi, were $419,500 and $410,300 *before* BMS hiked the price of Abecma by almost $38,000 and Breyanzi by almost $37,000 in 2023; these spikes were among the nine highest list price increases of that year.[105] The therapies reached a combined $836 million in sales in 2023, with nearly 80% of the sales deriving from American patients.[106]

Pomalyst & Revlimid

In 2022, Bristol Myers Squibb hiked the price of its drugs for treating multiple myeloma. It hiked the wholesale acquisition price of Pomalyst by over $4,000, increasing its price to $94,845 for 100 capsules. The company also hiked the price of Revlimid by over $3,500, increasing its price for 100 capsules to $83,322.[107] These price hikes were among the nine highest for 2022 in terms of total dollar amount. In 2023, Revlimid made BMS over $6 billion in sales, of which over $5 billion was earned from the U.S. market.[108] That same year, Pomalyst's sales were $3.4 billion, of which $2.36 billion was earned from U.S. patients.[109]

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[103] *Compare* Bristol Myers Squibb Co. v. Aurobindo Pharma U.S. Inc., 477 F. Supp. 3d 306, 356 (D. Del. 2020) *with* Sandoz Limited & Teva Pharmaceutical Industries Limited v. Bristol Myers-Squibb Holdings Ireland Unlimited Company & Pfizer Inc., [2022] EWHC 1831 (Pat) (Mead, J.) at 48.

[104] *Compare* Bristol Myers Squibb Co. v. Aurobindo Pharma U.S. Inc., 477 F. Supp. 3d 306, 356 (D. Del. 2020) *with* Sandoz Limited & Teva Pharmaceutical Industries Limited v. Bristol Myers-Squibb Holdings Ireland Unlimited Company & Pfizer Inc., [2022] EWHC 1831 (Pat) (Mead, J.) at 48.

[105] ASSISTANT SECRETARY FOR PLANNING AND EVALUATION, OFFICE OF HEALTH POLICY, HHS, ISSUE BRIEF: CHANGES IN THE LIST PRICES OF PRESCRIPTION DRUGS, 2017-2023 (Oct. 6, 2023), aspe-drug-price-tracking-brief.pdf (hhs.gov). Due to the opacity of drug pricing, it is difficult to discern the financial burden of this drug on the average patient. According to one source from 2021, a single dose of Abecma cost $419,500. *See* Eric Sagonowsky, *Bristol's new myeloma CAR-T needs a hefty discount to be cost-effective, watchdogs say while endorsing GSK's Blenrep*, FIERCE PHARMA (Apr. 7, 2021), https://www.fiercepharma.com/pharma/bristol-s-new-myeloma-car-t-needs-a-big-discount-to-be-cost-effective-watchdogs-say-while.

[106] BRISTOL MYERS SQUIBB, FORM 8-K, EXHIBIT 99.1 (Feb. 2, 2024), https://www.sec.gov/ixviewer/ix.html?doc=/Archives/edgar/data/14272/000001427224000020/bmy-20240202.htm.

[107] ASSISTANT SECRETARY FOR PLANNING AND EVALUATION, OFFICE OF HEALTH POLICY, HHS, ISSUE BRIEF: PRICE INCREASES FOR PRESCRIPTION DRUGS, 2016-2022, 2017-2023 (Sept. 30, 2023), Price Increases for Prescription Drugs, 2016-2022 (hhs.gov). Due to the lack of drug pricing transparency, it is difficult to determine the price for end users of the drug.

[108] BRISTOL MYERS SQUIBB, FORM 8-K, EXHIBIT 99.1 (Feb. 2, 2024), https://www.sec.gov/ixviewer/ix.html?doc=/Archives/edgar/data/14272/000001427224000020/bmy-20240202.htm.

[109] *Id.*

Thus, Bristol Myers Squibb's pricing practices are yet another example of how drug corporations price gouge American patients. Further, Bristol Myers Squibb engages in patenting practices of marginal value that appear to be widespread in the pharmaceutical industry to extend monopoly control over drug prices and unfairly deprive U.S. patients of lower cost generics.

III. THESE COMPANIES SPEND BILLIONS ON SELF-ENRICHING ACTIVITIES, OFTEN IN EXCESS OF RESEARCH AND DEVELOPMENT EXPENSES

All three companies have alleged that the Medicare price negotiation provisions of the Inflation Reduction Act would detract from the innovation of new life-saving medicines and sued to invalidate these measures.[110] But there is a wealth of evidence that contradicts claims that drug price regulation will impact the innovation of new medicines. First, experts, and even the Congressional Budget Office, conclude there is no connection between a drug's research and development cost and its future price.[111] Rather, the current price of drugs reflects the maximum that companies believe healthcare payers will pay for monopolized drugs with few if any adequate therapeutic alternatives.[112] More specifically, the Congressional Budget Office found that only 13 fewer drugs out of 1,300 (1%) would come to market over the next 30 years as a result of the Inflation Reduction Act.[113] Second, compared to the rest of the globe, the United States is an outlier that does little to protect its residents from the unfair pricing power of drug companies,[114] and bringing American policy into alignment with those of other countries, including other high-income peers, will not destroy the incentive to innovate new medicines. Finally, drug corporations spend in excess on executive compensation, share buybacks, and dividends which enrich their shareholders, cutting against the industry's mistaken impression that it is strapped for resources to research and develop new medicines.[115] For example, in just 2022,

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[110] Complaint, Janssen Pharmaceutical Inc. v. Beccera et al., No. 3:23-cv-03818, para. 40. (D. N.J. July 18, 2023); *The Inflation Reduction Act's Negative Impact on Patient-Focused Innovation, Value and Access*, MERCK: COMPANY STATEMENT (June 6, 2023), https://www.merck.com/news/the-inflation-reduction-acts-negative-impact-on-patient-focused-innovation-value-and-access/; *Impact of the inflation reduction act on innovative medicines for patients*, BRISTOL MYERS SQUIBB (June 16, 2023), https://www.bms.com/impact-of-the-inflation-reduction-act-on-innovative-medicines-for-patients.html; *Kevin Dunleavy, Johnson & Johnson becomes 4th drugmaker to file suit against IRA's drug price negotiations*, FIERCE PHARMA (July 18, 2023), https://www.fiercepharma.com/pharma/johnson-johnson-becomes-4th-big-pharma-file-suit-against-ira-drug-price-negotiations.

[111] CONGRESSIONAL BUDGET OFFICE, RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY (Aug. 2021) ("In CBO's assessment, current R&D spending does not influence the future prices of the drugs that result from that spending."); Aaron Kesselheim, Jerry Avorn, & Ameet Sarpatwari, *The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform*, 316 JAMA NETWORK 858 (2016); Vinay Prasad, Kevin De Jesus, Sham Mailankody, *The high price of anticancer drugs: origins, implications, barriers, solutions*, 14 NAT. REV. CLIN. ONC. 381 (2016).

[112] Aaron Kesselheim, Jerry Avorn, & Ameet Sarpatwari, *The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform*, 316 JAMA NETWORK 858 (2016).

[113] CONGRESSIONAL BUDGET OFFICE, ESTIMATED BUDGETARY EFFECTS OF PUBLIC LAW 117-169 (Sept. 7, 2022), https://www.cbo.gov/system/files/2022-09/PL117-169_9-7-22.pdf.

[114] Amy Kapczynski, *The Political Economy of Market Power in Pharmaceuticals*, 48 J. HEALTH POL., POL'Y & L. 215 (2023); S. Vincent Rajkumar, *The high cost of prescription drugs: causes and solution*s, 10 BLOOD & CANCER J. 381 (2020).

[115] Amy Kapczynski, *The Political Economy of Market Power in Pharmaceuticals*, 48 J. HEALTH POL., POL'Y & L. 215, 230 (2023) (citing Aaron Kesselheim & Jeffrey Avorn, *Letting the Government Negotiate Drug Prices Won't*

the manufacturers of the drugs selected for Medicare price negotiation spent $10 billion more on these self-enriching activities than research and development.[116]

Stock buybacks enrich investors by reducing the number of outstanding shares in a company. The fewer shares there are in investors' hands, the more each share is worth. When a company buys back and cancels 10% of its shares, that makes each share still held by an investor or insider rise in value, as it represents a greater claim on the company's earnings. Spending money this way allows companies to enrich shareholders silently, as well as the executives often paid in stock.[117] Stock buybacks are particularly problematic as they have historically increased stock value without raising taxable income, can provide a mistaken impression about the economic health of a company, and detract from more worthwhile investments in a company's own workers and productive capacity, such as research and development efforts. Dividends are another way of returning cash to investors. Each fiscal quarter, publicly traded companies typically issue fixed dividends to shareholders that rise when business is good and shrink or get suspended when business is bad.[118]

Looking at these self-enriching activities, Johnson & Johnson spent nearly $12 billion on dividends to shareholders, over $6 billion on stock buybacks, and $45 million on executive compensation in just the year 2022. In total, Johnson & Johnson spent nearly $18 billion on these self-enriching activities compared to $15 billion on research and development.[119] Similarly, Bristol Myers Squibb spent over $8 billion on stock buybacks, nearly $5 billion on dividends, and 48 million on executive compensation.[120] The company spent approximately $3 billion more on these self-enriching activities compared to research and development in 2022.[121] If we examine these spending patterns from 2012-2021, Johnson & Johnson spent $43 billion more on stock buybacks and dividends than research and development.[122] Similarly, Merck's spending on stock buybacks and dividends over this period exceeded its research and development costs by $3 billion.[123]

Hurt Innovation, WASH. POST (Sept. 27, 2021), https://www.washingtonpost.com/outlook/2021/09/22/drug-pricing-negotiation-biden-bill/); U.S. HOUSE OF REPRESENTATIVES' COMMITTEE ON OVERSIGHT & REFORM, DRUG PRICING INVESTIGATION: INDUSTRY SPENDING ON BUYBACKS, DIVIDENDS, & EXECUTIVE COMPENSATION (July 2021).

[116] JISHIAN RAVINTHIRAN, PUBLIC CITIZEN & PROTECT OUR CARE, PROFITS OVER PATIENTS: SPENDING ON SELF-ENRICHMENT EXCEEDS RESEARCH AND DEVELOPMENT COSTS FOR MANY MANUFACTURERS OF IRA DRUGS (Jan. 18, 2024).

[117] PUBLIC CITIZEN, BAILOUT WATCH, FRIENDS OF THE EARTH, BIG OIL'S WARTIME BONUS 2 (2022).

[118] *Id.* at 8.

[119] JISHIAN RAVINTHIRAN, PUBLIC CITIZEN & PROTECT OUR CARE, PROFITS OVER PATIENTS: SPENDING ON SELF-ENRICHMENT EXCEEDS RESEARCH AND DEVELOPMENT COSTS FOR MANY MANUFACTURERS OF IRA DRUGS (Jan. 18, 2024).

[120] *Id*.

[121] *Id*.

[122] WILLIAM LAZONICK & ÖNER TULUM, INSTITUTE FOR NEW ECONOMIC THINKING, SICK WITH "SHAREHOLDER VALUE": US PHARMA'S FINANCIALIZED BUSINESS MODEL DURING THE PANDEMIC (Dec. 6, 2022).

[123] *Id*.

In sum, the spending patterns of all three companies belies their impression to the public that their profits are re-invested in research and development capacities; instead, they reallocate their profits mostly to the benefit of their shareholders and executives. As such, there is no necessary relationship between providing drug pricing relief for millions and harming resources for innovating new medicines.

CONCLUSION

Supermajorities of Americans want decisive government action to rein in the price gouging tactics of the pharmaceutical industry. And though most drug corporations have been happy to benefit from an array of government policies that have expanded their monopoly power over drugs to the detriment of patients, many now fiercely resist any efforts to deliver material drug pricing relief to millions of Americans. The drug pricing tactics of Johnson & Johnson, Merck, and Bristol Myers Squibb are representative of the broader exploitative practices endemic to the pharmaceutical industry. They use their monopoly control to price life-saving medicines excessively, and either pursue, or benefit from, additional patents of marginal value to extend their power to exorbitantly price drugs. This profiteering demands greater action from the Biden administration and Congress, which would not tangibly impact the innovation of new life-saving medicines.