

March 8, 2022

The Honorable Elizabeth Warren
309 Hart Senate Office Building
United States Senate
Washington, DC 20510

Dear Senator Warren:

The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to submit this response to your March 1, 2022 letter. PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. Since 2000, PhRMA member companies have invested nearly \$1 trillion in the search for new treatments and cures, including \$91.1 billion in 2020.ⁱ Additionally, America's biopharmaceutical companies have successfully researched, developed, and delivered multiple vaccines and therapeutics to help halt the spread and mitigate the effects of COVID-19. The introduction of COVID-19 vaccines is estimated to have saved more than 275,000 lives and averted up to 1.25 million hospitalizations in the United States alone.ⁱⁱ

PhRMA and its members share many of the same goals as you and your colleagues, including lowering health care costs and endeavoring to make medicines more accessible to all Americans. We would welcome the opportunity to work together with you to identify solutions that will do what we can all agree is a priority: lower medicine costs for Americans at the pharmacy counter. We detail a series of ideas to accomplish this goal in our response and would like to have a discussion with you about these issues.

The questions in your letter raise competitively sensitive topics and our response is limited by antitrust laws and PhRMA's antitrust compliance policy. As a trade association, PhRMA does not permit any discussion about members' current and future drug pricing strategies and we are not privy to proprietary information about individual companies' business practices. PhRMA does not have any information about individual company pricing decisions and cannot comment on individual company pricing decisions or offer insight into those decisions. Our response has been prepared with these guidelines in mind and in compliance with the antitrust laws.

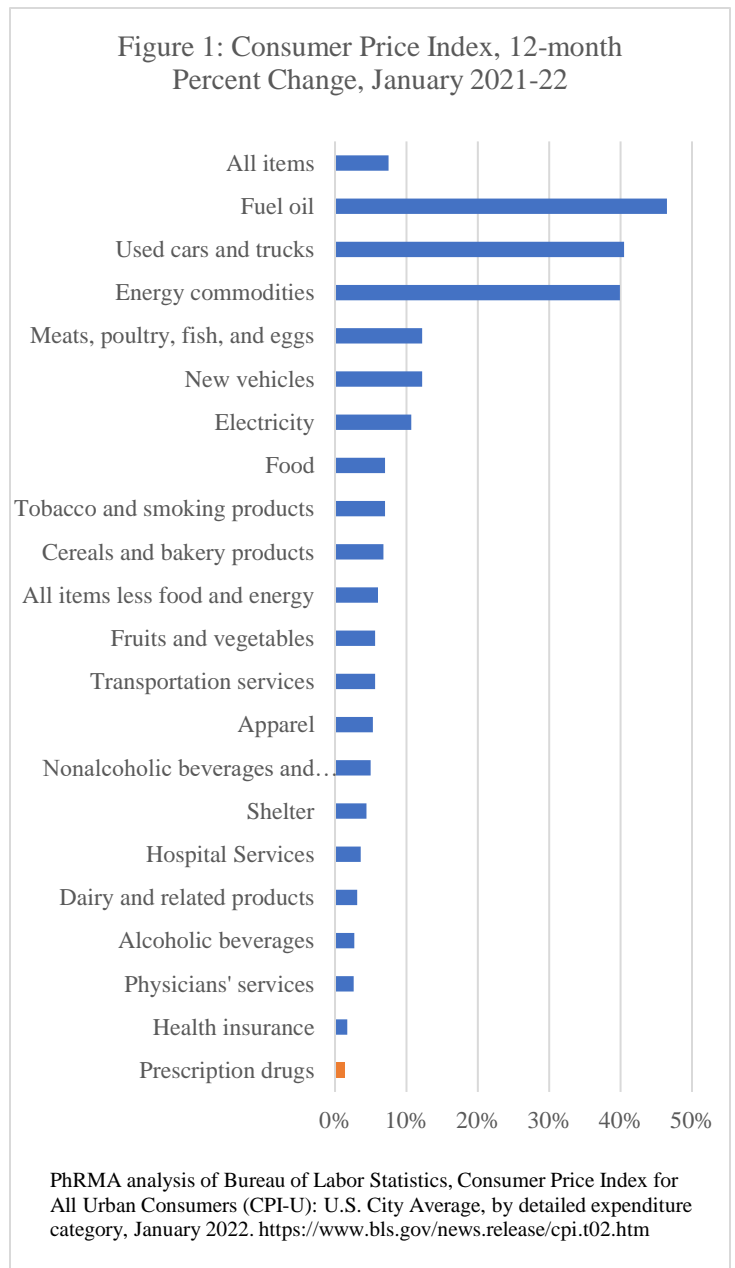
To have a productive dialogue, there needs to be agreement on the true causes of the fundamental problem at hand. Unfortunately, your letter refers to the findings of two recent studies that do not reflect the reality of the prescription drug market. Both analyses rely on flawed data that focus primarily on wholesale acquisition costs (WAC) or list prices and fail to account for the many rebates, discounts, and other payments from manufacturers that impact a manufacturer's net pricing, which leads to fundamentally misleading conclusions about the

“cost” of medicines. Manufacturer rebates and other payments have more than doubled since 2012, reaching \$187 billion in 2020.ⁱⁱⁱ As a result, the net price of brand medicines was, on average, 44% lower than the WAC or list price in 2020.^{iv}

According to government, pharmacy benefit manager (PBM), and market analyst data, medicine prices have been growing in line with or below the rate of inflation over the past five years.^v The most recent data (Figure 1) from the Bureau of Labor Statistics (BLS) show that prices for prescription medicines are growing significantly more slowly than overall inflation (1.3% vs. 7.5%) and more slowly than health insurance, hospital services, and physicians’ services.^{vi} Importantly, these BLS data do not account for rebates, discounts and other manufacturer payments. Data sources that do account for these factors show that net prices for brand medicines *declined* by 2.9%, on average, in 2020.^{vii} These sources also project that annual net price growth for brand medicines will be limited to -3% to 0% through 2025.^{viii}

Other government data indicate that the average price of medicines has fallen over the past decade. The Congressional Budget Office (CBO) recently examined nationwide trends in medicine prices and found that the average net price per prescription in Medicare Part D and Medicaid declined between 2009 and 2018, even though this period saw the introduction of many new treatments and cures.^{ix} These savings are the result of a unique system of cost containment built into the prescription medicine lifecycle. Over time, new medicines help to reduce overall health care costs and lead to lower-cost generics and biosimilars that bring long-term value to patients and the health care system.^x Similar cost containment mechanisms do not exist for other health care services.^{xi}

Brand medicines face competition from generic drugs, biosimilars, and other brand medicines, which payers leverage to further drive down prices.^{xii} For example, less than a year after market



entry of the first breakthrough treatment for hepatitis C, multiple other products entered the market, some offering improved cure rates for patients. The resulting competition was so fierce that the average net daily cost for this class today is nearly 80% lower than the first product's launch price.^{xiii} Moreover, hepatitis C is now largely cured in the United States, saving costs from avoided health care treatments and reducing lost workdays and lost productivity.^{xiv} In 2019, only a small number of brand medicines – accounting for less than 1% of Part D spending – did not yet have a competing brand or generic medicine in their therapeutic class.^{xv} Looking forward, despite the introduction of many new treatments expected to transform patient care, the share of total health care spending attributable to medicines over the next decade is projected to remain at 14%, exactly the same as today.^{xvi}

Today, more than 50% of spending on brand medicines goes to others in the supply chain, like insurers and PBMs, government, hospitals and other stakeholders – not the companies that research, develop and manufacture the novel medicines.^{xvii} In fact, in recent years more of the increase in spending on brand medicines goes to payers, including insurers and PBMs, than manufacturers.^{xviii} Contrary to your letter's claim that providers have been hurt by rising prescription costs, medicines represent a significant source of profit for many hospitals that mark up the cost of medicines to private insurers by 250% or more.^{xix} The amount a hospital receives for administering a medicine often far exceeds the net revenue earned by the manufacturer who researched and developed it.

These figures demonstrate the true barrier to affordable patient access to life saving medicines – payer incentives in the current system are misaligned. Government agencies, economists, and other experts have noted that PBMs may favor medicines with high list prices and larger rebates to maximize their revenue.^{xx} According to a recent Senate Finance Committee report, “PBMs have an incentive for manufacturers to keep list prices high, since the rebates, discounts, and fees PBMs negotiate are based on a percentage of a drug's list price—and PBMs retain at least a portion of what they negotiate.”^{xxi} Public sources have noted that manufacturer efforts to reduce list prices have been met with significant headwinds, including letters from PBMs dissuading such actions and formulary exclusions of lower list priced alternatives.^{xxii}

We share your concern that, although brand medicine prices and spending are growing more slowly than inflation, it often does not feel that way for patients because such a large – and growing – share of the rebates and discounts negotiated with manufacturers is going to middlemen and not to reduce patient costs. It is health insurers and PBMs, not manufacturers, that ultimately determine how much patients pay out-of-pocket for their medicines and choose to distort the purpose of insurance by shifting more and more of the cost of care to the sickest and most vulnerable patients.

As your letter acknowledges, the result is that half of commercially insured patients' out-of-pocket spending for brand medicines is now based on the undiscounted list price.^{xxiii} This has to

stop. If health insurance companies and middlemen don't pay the full price for medicines, patients shouldn't either.

There are ways to fix this problem. PhRMA has long advocated for requiring PBMs and health plans to share the savings they receive on medicines directly with patients at the pharmacy counter.^{xxiv} However, efforts to share those savings with patients have been met with resistance and opposition in Congress. In fact, Congress has chosen to delay and is considering withdrawing regulations that would have helped ensure that the rebates and discounts negotiated on medicines are used to lower patients' out-of-pocket costs.

In addition to policies that would ensure patients benefit from rebates and discounts at the pharmacy counter, Congress should pursue other common-sense reforms to improve patient access to medicines, including:

- **Cover more medicines from day one.** Insurers increasingly require patients to pay high deductibles before their medicines are covered. As a result, patients may ration or never fill their prescriptions, leading to worse health outcomes and costly hospitalizations. Policymakers can immediately improve patient access and affordability by requiring that some medicines, such as those used to treat certain chronic conditions, be covered by all insurance from day one – without being subject to a deductible.
- **Make cost sharing more predictable.** High and unpredictable cost sharing is a barrier to prescription medicine access, especially for patients with chronic, disabling or life-threatening conditions. Insurers' increasing use of coinsurance and deductibles can leave patients with sticker shock at the pharmacy counter. One potential solution is to encourage the use of fixed-dollar copays instead of coinsurance. Placing a limit on the maximum amount a patient will be asked to pay for medicines per prescription, per month and/or annually would also help.
- **Make coupons count.** Due to high out-of-pocket costs, patients with commercial insurance are increasingly turning to manufacturer cost-sharing assistance to help them afford their medicines. In some cases, commercial insurers do not allow the assistance manufacturers provide to patients to count toward deductibles or a patient's annual out-of-pocket limit, meaning patients could be paying thousands more at the pharmacy than they should be. We need to end this practice so that patients with commercial insurance get the full benefit of the programs meant to help them afford their medicines.
- **Require standardized plans.** On the health insurance exchanges, standardized plans often have lower and more predictable cost sharing for critical items and services than non-standardized plans and can make health care more accessible and affordable. They also aid consumer choice by allowing for apples-to-apples comparisons across health plans. These kinds of plans should be required on health insurance exchanges.

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As we have long said, we want to work with Congress on these ideas and others that will solve the real problems facing patients – a system that does not work for them and puts the highest costs on the sickest patients. We need to make insurance work like insurance. We need to make sure patients are front and center in all of our policy discussions. And we need to ensure that all patients have access to the medicines they need to survive and thrive.

Sincerely,

A handwritten signature in black ink, appearing to read "Stephen J. Ubl". The signature is written in a cursive, flowing style.

Stephen J. Ubl
President and CEO

ⁱ PhRMA. “2021 PhRMA Annual Membership Survey,” July 2021. <https://phrma.org/research-and-development/2021-phrma-annual-membership-survey>

ⁱⁱ Galvani A, et al. “Deaths and Hospitalizations Averted by Rapid U.S. Vaccination Rollout,” Commonwealth Fund, July 2021. <https://www.commonwealthfund.org/publications/issue-briefs/2021/jul/deaths-and-hospitalizations-averted-rapid-us-vaccination-rollout>

ⁱⁱⁱ Fein A. “Gross-to-Net Bubble Update: Net Prices Drop (Again) at Six Top Drugmakers,” Drug Channels, April 2021. <https://www.drugchannels.net/2021/04/gross-to-net-bubble-update-net-prices.html>

^{iv} IQVIA. “The Use of Medicines in the U.S.: Spending and Usage Trends and Outlook to 2025,” May 2021. <https://www.iqvia.com/insights/the-iqvia-institute/reports/the-use-of-medicines-in-the-us>

^v SSR Health. “3Q21 List and net price trends for US Rx brands,” December 2021.; CVS Health. “The Drug Trend Report,” April 2022. https://insightslp.cvshealth.com/rs/161-LXO-491/images/CVS-Drug-Trend-Report_PDF_2.23.22.pdf; IQVIA. “The Use of Medicines in the U.S.: Spending and Usage Trends and Outlook to 2025,” May 2021. <https://www.iqvia.com/insights/the-iqvia-institute/reports/the-use-of-medicines-in-the-us>; BLS.

“Table 2. Consumer Price Index for All Urban Consumers (CPI-U): U. S. city average, by detailed expenditure category,” January 2022. <https://www.bls.gov/news.release/cpi.t02.htm>

^{vi} Over this period, inflation was 1.7% for health insurance, 3.6% for hospital services, and 2.6% for physicians’ services; BLS. “Table 2. Consumer Price Index for All Urban Consumers (CPI-U): U. S. city average, by detailed expenditure category,” January 2022. <https://www.bls.gov/news.release/cpi.t02.htm>

^{vii} IQVIA. “The Use of Medicines in the U.S.: Spending and Usage Trends and Outlook to 2025,” May 2021. <https://www.iqvia.com/insights/the-iqvia-institute/reports/the-use-of-medicines-in-the-us>

^{viii} *Ibid.*

^{ix} Congressional Budget Office. “Prescription Drugs: Spending, Use, and Prices,” January 2022. <https://www.cbo.gov/publication/57772>

^x IQVIA. “The Use of Medicines in the U.S.: Spending and Usage Trends and Outlook to 2025,” May 2021. <https://www.iqvia.com/insights/the-iqvia-institute/reports/the-use-of-medicines-in-the-us>

^{xi} PhRMA analysis of Healthcare Cost and Utilization Project (HCUP). National (Nationwide) Inpatient Sample (NIS) database. 2007, 2017. Accessed July 2020. <https://www.ahrq.gov/research/data/hcup/index.html>

^{xii} IQVIA. “Biosimilars in the United States 2020 – 2024,” September 2020. <https://www.iqvia.com/insights/the-iqvia-institute/reports/biosimilars-in-the-united-states-2020-2024>

^{xiii} Silseth S, Shaw H. “Analysis of prescription drugs for the treatment of hepatitis C in the United States.” Milliman, June 2021. <https://www.milliman.com/en/insight/analysis-of-prescription-drugs-for-the-treatment-of-hepatitis-c-in-the-united-states>

^{xiv} Sulkowski M, Ionescu-Ittu R, Macaulay D, et al. “The Economic Value of Improved Productivity from Treatment of Chronic Hepatitis C Virus Infection: A Retrospective Analysis of Earnings, Work Loss, and Health Insurance Data.” *Adv Ther.* 2020;37(11):4709-4719. <https://link.springer.com/article/10.1007/s12325-020-01492-x>

^{xv} Avalere. “Majority of Part D Spending Is on Brand Drugs in Classes with Generics,” March 2021. <https://avalere.com/insights/majority-of-part-d-spending-is-on-brand-drugs-in-classes-with-generics>

^{xvi} Altarum Institute. “Projections of the Non-Retail Prescription Drug Share of National Health Expenditures,” September 2020. <https://altarum.org/publications/projections-non-retail-prescription-drug-share-national-health-expenditures>

^{xvii} Brownlee A. “The Pharmaceutical Supply Chain, 2013-2020,” Berkeley Research Group, January 2022. <https://www.thinkbrg.com/insights/publications/pharmaceutical-supply-chain-2013-2020/>

^{xviii} *Ibid.*

^{xix} Silverman E. “How much? Hospitals mark up some medicines by 250% on average,” STAT, 2021. <https://www.statnews.com/pharmalot/2021/01/20/hospitals-biosimilars-drug-prices/>

^{xx} PBM Accountability Project. “Understanding the Evolving Business Models and Revenues of Pharmacy Benefit Managers,” December 2021. https://www.pbmaccountability.org/files/ugd/b11210_264612f6b98e47b3a8502054f66bb2a1.pdf?index=true

^{xxi} Senate Finance Committee. “Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug,” 2021. [https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20\(FINAL%201\).pdf](https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf)

^{xxii} Sagonowsky E. “UnitedHealthcare demands drug rebates even if pharma cuts list prices: analyst,” February 2019. <https://www.fiercepharma.com/pharma/letter-to-pharmas-unitedhealthcare-seeks-to-protect-drug-rebates-from-price-reductions>; Xcenda. “Skyrocketing Growth in PBM Formulary Exclusions Raises Concerns About Patient Access,” September 2020. <https://www.xcenda.com/insights/skyrocketing-growth-in-pbm-formulary-exclusions-raises-concerns-about-patient-access>

^{xxiii} IQVIA. “Medicine Spending and Affordability in the U.S.” August 2020. <https://www.iqvia.com/insights/the-iqvia-institute/reports/medicine-spending-and-affordability-in-the-us>

^{xxiv} PhRMA. Comment Letter on Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program. January 2017. https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/P-R/PhRMA-Comment-Letter-on-CMS-Proposed-Rule_FINAL.pdf