NATIONAL TAXPAYERS UNION

May 4, 2021

The Honorable Anna Eshoo
Chair, House Energy and Commerce Subcommittee on Health
2125 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Brett Guthrie
Ranking Member, House Energy and Commerce Subcommittee on Health
2322-A Rayburn House Office Building
Washington, D.C. 20515

Dear Chair Eshoo, Ranking Member Guthrie, and Members of the Subcommittee:

On behalf of National Taxpayers Union (NTU), the nation's oldest taxpayer advocacy organization, I wish to submit comments for the record for your May 4 hearing, "Negotiating a Better Deal: Legislation to Lower the Cost of Prescription Drugs." NTU has significant concerns with some provisions of the legislation the Subcommittee plans to discuss at this hearing. We wish to offer our perspective on bills like the Lower Drug Costs Now Act (H.R. 3) and the Bringing Low-cost Options and Competition while Keeping Incentives for New Generics (BLOCKING) Act (H.R. 2853), while also sharing taxpayer- and market-oriented alternatives that can 1) lower prescription drug costs for patients most at need of assistance and 2) retain the robust private sector incentives that make America the world's leader in prescription drug development.

NTU's Stake in Prescription Drug Policy

NTU has engaged on prescription drug policy both in Congress and in state legislatures across the country for decades. There are several reasons the nation's taxpayers can and should be concerned about federal and state prescription drug policy:

1. Federal taxpayers pay for a significant portion of the nation's prescriptions directly through the Medicaid and Medicare programs, not to mention through indirect subsidies such as premium tax credits for Affordable Care Act plans;
2. To the extent that prescription drugs save patients from more expensive medical care delivered in hospitals, clinics, and physicians' offices, proper utilization of prescription drugs (along with ongoing research and development in the private and public sectors) can actually *save* taxpayers and consumers money in the long run; and
3. America's world-leading biopharmaceutical sector creates jobs and economic growth, while offering enhanced access to new innovations and cures, that might be centered elsewhere in the world if policymakers had not so meticulously paved the way for a decades-long, productive public-private partnership that brings new treatments to American patients every year.

Unfortunately, some of the proposals the Subcommittee is discussing at this hearing would threaten all of the positive outcomes outlined above.

H.R. 3 Could Destroy Private-Sector Biopharmaceutical Innovation

The punitive taxes and one-sided "negotiation" process outlined in H.R. 3, the Lower Drug Costs Now Act, could destroy the private biopharmaceutical sector in the U.S., which currently leads the world. According to the Government Accountability Office (GAO): "[a]mong OECD member countries with available data, nearly two-thirds of pharmaceutical research and development [R&D] expenditures occur in the United States."[1]

The U.S. pharmaceutical industry is particularly R&D-intensive, meaning R&D expenditures make up a disproportionately large slice of the industry's net revenues. According to the Congressional Budget Office (CBO):

> In the early 2000s, when drug industry revenues were rising sharply, the industry's R&D intensity—that is, its R&D spending as a share of net revenues—averaged about 13 percent each year. Over the decade from 2005 to 2014, the industry's R&D intensity averaged 18 percent to 20 percent each year. That ratio has been trending upward since 2012, and it exceeded 25 percent in 2018 and 2019, the highest R&D intensities recorded by the pharmaceutical industry as a whole since at least 2000.[2]

This is many multiples the average R&D intensity across all industries in the U.S. Surely, one explanation for this R&D intensity is that the drugs that fail to eventually receive Food and Drug Administration (FDA) approval greatly outnumber the drugs that do receive approval. According to CBO, "[s]ome drugs developed in the preclinical phase never enter clinical trials, and of those that do, only about 12 percent reach the market (recent estimates range from 10 percent to 14 percent)."[3]

The existing policy and regulatory environment for prescription drug R&D is surely not perfect, but has by and large paved the way for a thriving, successful system that delivers new innovations to American patients on a regular basis. It has also paved the way for a large pipeline of generic alternatives to brand-name drugs, which have increased competition and lowered costs for U.S. consumers and taxpayers, all while *avoiding* harm to the numerous financial and intellectual property incentives in place for brand-name manufacturers. Indeed, nearly nine in ten prescriptions filled in the Medicare Part D program are for generic drugs.[4]

Unfortunately, H.R. 3 threatens to unravel the above system. Among the provisions that cause us deep concern are:

- Forcing the federal government to negotiate prescription drug prices for dozens of brand-name products on a nationwide basis, disrupting the current Part D system that allows privately-managed prescription drug plans and manufacturers to negotiate prices using existing tools like formulary placement, tiering, and utilization management;

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[1] Government Accountability Office. (March 2021). "Prescription Drugs: U.S. Prices for Selected Brand Drugs Were Higher on Average than Prices in Australia, Canada, and France." GAO-21-282. Retrieved from: https://www.gao.gov/assets/gao-21-282.pdf
[2] Congressional Budget Office. (April 2021). "Research and Development in the Pharmaceutical Industry." Retrieved from: https://www.cbo.gov/system/files/2021-04/57025-Rx-RnD.pdf
[3] *Id*.
[4] Medicare Payment Advisory Commission. (March 2019). "The Medicare prescription drug program (Part D): Status report." Retrieved from: http://medpac.gov/docs/default-source/reports/mar19_medpac_ch14_sec.pdf?sfvrsn=0

- Making the negotiation process severely one-sided, by punishing manufacturers with an up to 95-percent excise tax on *gross sales* of a given product should they fail to agree to the government-set price for a drug; this effectively turns the so-called "negotiation" between Medicare and manufacturers into an extortion by the federal government;
- Rigging the "negotiation" from the start with a maximum price that is tied to the average pricing for a prescription drug in foreign countries that, by and large, have centralized, government-set prices; and
- Allowing private payers, such as health insurers and self-funded plans, automatic access to the government-set price, rather than retaining the existing system where manufacturers and payers negotiate prices as market actors; and
- Punishing *all* manufacturers, brand and generic, with a mandatory rebate -- which could fairly be called a tax -- if they raise prices faster than inflation.

For all these reasons and more, we believe that Congress should not pass H.R. 3 under any circumstances. While portions of the legislation, such as Medicare Part D redesign and an out-of-pocket cap for seniors, are worthy of further consideration, those worthy provisions cannot and should not be considered in tandem with the punitive taxes that dominate the Lower Drug Costs Now Act.

The Protecting Consumer Access to Generic Drugs Act and the BLOCKING Act Are Also Counterproductive to Patients and Taxpayers

As mentioned above, the advent of the U.S. generic drug pipeline has been a significant boon to patients and taxpayers, both saving money and increasing competition in the biopharmaceutical industry at large. As GAO noted in March:

> Studies have found that use of generic drugs is more prevalent in the United States than in other countries, and the prices for generic drugs in the United States are often lower than prices for these drugs in other countries.[5]

Or, as NTU President Pete Sepp put it in 2019:

> Costly innovator drugs have been shown to reduce other expenses in government health programs over the long term, such as surgeries or long hospital stays. On the other hand, generics deliver massive savings over the nearer term to those same programs as well. No other country in the world can boast of such a successful policy environment that both encourages discoveries to reach patients (nearly 90 percent of newly launched drugs worldwide are available here) and controls costs (over 90 percent of prescriptions written in the U.S. are for generics).[6]

The Protecting Consumer Access to Generic Drugs Act and the BLOCKING Act, even if well-intentioned, could reverse America's 35-plus year progress on cultivating a robust generic drug pipeline.

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[5] Government Accountability Office. (March 2021). "Prescription Drugs: U.S. Prices for Selected Brand Drugs Were Higher on Average than Prices in Australia, Canada, and France." GAO-21-282. Retrieved from: https://www.gao.gov/assets/gao-21-282.pdf

[6] Sepp, Pete. "Hatch-Waxman Drug Patent Law Meets Middle Age – and Taxpayers Can Celebrate." National Taxpayers Union, April 1, 2019. Retrieved from: https://www.ntu.org/publications/detail/hatch-waxman-drug-patent-law-meets-middle-age-and-taxpayers-can-celebrate

The former legislation, from Rep. Bobby Rush (D-IL), would "prohibit the practice of 'pay-for-delay,' in which brand name drug companies compensate generics to delay the entry of generic drugs into the market."[7] We have warned at NTU that the proposal "would take a sledgehammer to biopharmaceutical innovation around the country in order to treat a 'pay-for-delay' problem that is limited in size and scope."[8]

A recent Federal Trade Commission (FTC) review revealed that nearly 90 percent of agreements between generic and brand-name manufacturers do not involve "explicit compensation from a brand manufacturer to a generic manufacturer and a restriction on the generic manufacturer's ability to market its product."[9] Federal and state legislation banning 'pay-for-delay,' though, could end up banning some of the private-sector agreements that bring benefits to consumers, taxpayers, brand manufacturers, and generic manufacturers, especially if the agreements bring other generics to market faster.

The BLOCKING Act would also take a hammer to the incentives in place for generic manufacturers to bring drugs to market while attempting to tackle a problem that is limited in size and scope. As NTU wrote in 2019:

> The intent of the legislation is to prevent a small number of manufacturers from intentionally delaying final FDA approval, 'parking' their first-to-file applications and preventing subsequent generic manufacturers from entering the market. The House Energy and Commerce Committee reported that the FDA claims this happens "an average of five times each year, and each time delays competition an average of twelve months."
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> While generic 'parking' is a legitimate policy concern, either Section 205 [of the Lower Health Care Costs Act] or the BLOCKING Act would also punish many generic manufacturers who are simply caught up in a lengthy FDA approval process for their first-to-file applications. In 2017, the median FDA review time for generic drug applications was 37.26 months - seven months longer than the BLOCKING Act's trigger date and four months longer than Section 205's trigger date. Of course, 37.26 months is just the median review time - by definition, half of all applications took longer than 37.26 months in 2017.[10]

For the sake of taxpayers and consumers invested in a continual supply of generic drug competition, we respectfully ask you to reject the Protecting Consumer Access to Generic Drugs Act and the BLOCKING Act

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[7] United States Congressman Bobby Rush. (January 5, 2021). "Rush Announces His Legislative Priorities on the Opening of the 117th Congress." Retrieved from: https://rush.house.gov/media-center/press-releases/rush-announces-his-legislative-priorities-on-the-opening-of-the-117th (Accessed May 3, 2021.)

[8] Lautz, Andrew. "'Pay-for-Delay' Legislation in Minnesota Would Cause Drug Development Problems, Not Fix Them." National Taxpayers Union, April 9, 2020. Retrieved from: https://www.ntu.org/publications/detail/pay-for-delay-legislation-in-minnesota-would-cause-drug-problems-not-fix-them

[9] Federal Trade Commission. (2016). "Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003." Retrieved from: https://www.ftc.gov/system/files/documents/reports/agreements-filled-federal-trade-commission-under-medicare-prescription-drug-improvement/mma_report_fy2016.pdf (Accessed May 3, 2021.)

[10] Lautz, Andrew. "Generic Drugs Save Taxpayers and Patients Money. Congress Could Accidentally Hurt Them This Month." National Taxpayers Union, December 9, 2019. Retrieved from: https://www.ntu.org/publications/detail/generic-drugs-save-taxpayers-and-patients-money-congress-could-accidentally-hurt-them-this-month

Pro-Taxpayer and Pro-Market Alternatives

As the Subcommittee indicates in its hearing memo, many Americans still do struggle with their prescription drug costs. We recognize it is not enough to oppose several of the proposed policies the Subcommittee is considering at its hearing *without* offering up alternatives.

NTU offered its lengthy thoughts on this matter in a February issue brief, "A Taxpayer- and Market-Oriented Path Forward for Federal Prescription Drug Policy."[11] We humbly ask you to consider our policy alternatives, which we summarize below:

- Capping the amount seniors pay out of pocket in Part D for the first time (and paying for these changes by reducing taxpayer liability in the so-called "catastrophic" phase of the Part D benefit where drug spending is highest);
- Actually reducing distortionary rebates in the Medicaid, Part D, and 340B Drug Pricing programs, where steep, mandatory discounts on the cost of brand-name drugs push the cost bubble for prescription drugs onto other payers, like employers, private health insurers, and private plan sponsors in Part D;
- Using America's free trade negotiations with foreign partners to reduce price controls and price fixing in other countries; steep, mandatory discounts manufacturers must provide in other countries pushes the cost bubble for drug R&D, manufacturing, and distribution onto Americans; and
- Reducing regulatory barriers to competition and patient barriers to access; though the NTU team does not weigh in on the intricacies of Food and Drug Administration (FDA) policy, we are concerned by the numerous complaints from governmental and non-governmental stakeholders that the FDA drug approval process is too costly, too time-consuming, and too burdensome.[12]

Thank you for considering our viewpoints on these critical issues. Should you be interested in engaging on any of the above proposals or should you have any questions, we are at your disposal.

Sincerely,

Andrew Lautz
Director of Federal Policy

CC: The Honorable Frank Pallone, Chair, House Committee on Energy and Commerce
The Honorable Cathy McMorris Rodgers, Ranking Member, House Committee on Energy and Commerce
Members of the House Energy and Commerce Subcommittee on Health

[11] Lautz, Andrew. "A Taxpayer- and Market-Oriented Path Forward for Federal Prescription Drug Policy." National Taxpayers Union, February 25, 2021. Retrieved from: https://www.ntu.org/publications/detail/a-taxpayer-and-market-oriented-path-forward-for-federal-prescription-drug-policy

[12] Sepp, Pete. "Prescription Drug Costs: Better Ways to Help Patients and Taxpayers." National Taxpayers Union, December 6, 2018. Retrieved from: https://www.ntu.org/publications/detail/prescription-drug-costs-better-ways-to-help-patients-and-taxpayers