

December 9, 2021

Dear Senators and Representatives:

On behalf of the undersigned organizations -- taxpayer, consumer, and free market advocates from across the country -- we write with significant concerns about the prescription drug pricing provisions included in the House's version of the Build Back Better Act, including the effect these provisions may have on drug and biologic development, as well as the availability of generics and biosimilars in both Medicare and the private health insurance marketplace.

As you know, there are three major prescription drug pricing proposals included in the most current language of the Build Back Better Act:

1. A requirement for Medicare to set the prices of certain prescription drugs in Parts B and D on a top-down basis, replacing the market-based negotiations and payments in Medicare, between the government, plans, and manufacturers, with a government-always-wins approach that emphasizes price caps and punitive excise tax penalties for failure to comply;
2. Inflation caps in Medicare Parts B and D that require manufacturers to pay a rebate to Medicare if they increase their prices faster than a broad measure of inflation; and
3. The redesign of the Part D benefit, which protects seniors with the first ever out-of-pocket cap for prescription drug expenses and adjusts patient, plan, and manufacturer liabilities throughout a patient's drug spending in Part D.<sup>1</sup>

It is the first two proposals that concern our organizations gravely. Many of us have a long list of reasons to oppose these two measures. These policies would replace private-sector negotiations in Part D and market-based pricing in Part B with government price controls, and levy an up to 1,900-percent tax on a manufacturer's gross product sales upon failure to accept the government's pricing terms. These price controls would push the cost bubble for researching, developing, manufacturing, and providing prescription drugs to millions of Medicare patients onto other payers, or lead to fewer innovations in the prescription drug market in future years, or, worse yet, both.

We are also deeply concerned about the impact these two proposals could have on generic drug and biosimilar development. The top-down negotiation requirement is structured in such a way that it will undermine the carefully balanced policy that provides space for generic drug and biosimilar manufacturers to develop products that offer lower-cost alternatives to popular brand-name drugs.

By requiring negotiation for certain products either nine or 13 years after they first reach the market, and effectively controlling the price of those drugs, generic and biosimilar manufacturers will have fewer financial incentives to develop low-cost alternatives that can provide a vibrant, competitive marketplace for patients and taxpayers.

Given it took the average generic drug about 14 years to come to market from 2017 through 2019 -- and 13 years for generic competitors to brand drugs with "sales greater than \$250 million ... the year before generic entry"<sup>2</sup> -- it seems clear that the timing and level of price controls proposed on Part D drugs in the Build Back Better Act could prevent some generic competitors from ever entering the market in the first place, undermining the significant price reductions that accompany significant generic competition.

Don't just take it from us, though. Former Sen. Orrin Hatch (R-UT), the co-author of the highly successful, bipartisan Hatch-Waxman Act, recently asserted that the prescription drug provisions proposed in the Build Back Better Act "would undermine the generic competition that is at the heart of Hatch-Waxman. Likewise, it could jeopardize the biopharmaceutical innovation incentivized by that competition."<sup>3</sup>

The inflation caps are also as damaging to generic manufacturers as they are to others, if not more so. Applying a broad-based measure of consumer price growth to the growth of a medical product is clunky at best, and could severely undermine manufacturers' ability to account for the cost growth of developing, manufacturing, and distributing their products at worst.

We write with these concerns in significant part because generic drugs save patients and taxpayers money. No other country in the world has so successfully created a prescription drug policy environment that permits innovation and affordability to coexist and reinforce each other.

As the Food and Drug Administration (FDA) has noted, "the generic [average manufacturer price] is 39% lower than the brand AMP before generic competition."<sup>4</sup> Once four competitors have entered a particular drug's market, "generic prices

<sup>1</sup> For more, see: Lautz, Andrew. "Analyzing the New Prescription Drug Pricing Proposal For Reconciliation." National Taxpayers Union, November 5, 2021. Retrieved from: <https://www.ntu.org/publications/detail/analyzing-the-new-prescription-drug-pricing-proposal-for-reconciliation>

<sup>2</sup> Grabowski, Henry; Long, Genia; Mortimer, Richard; and Bilginsoy, Mehmet. "Continuing trends in U.S. brand-name and generic drug competition." Journal of Medical Economics, Volume 24 Issue 1. Retrieved from: <https://www.tandfonline.com/doi/full/10.1080/13696998.2021.1952795> (Accessed November 30, 2021.)

<sup>3</sup> See: BioUtah. "Hatch Warns of Dangers to Generic Drug Market." November 18, 2021. Retrieved from: <https://bioutah.org/hatch-warns-of-dangers-to-the-generic-drug-market/> (Accessed November 30, 2021.); for more on the potential impacts Build Back Better provisions could have on prescription drug development, see: The University of Chicago Kenneth C. Griffin Department of Economics. "Issue Brief: The Impact of HR 5376 on Biopharmaceutical Innovation and Patient Health." November 30, 2021. Retrieved from: <https://ecchc.economics.uchicago.edu/2021/11/30/issue-brief-the-impact-of-hr-5376-on-biopharmaceutical-innovation-and-patient-health/> (Accessed December 6, 2021.)

<sup>4</sup> FDA. "New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices." December 13, 2019. Retrieved from: <https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/generic-competition-and-drug-prices> (Accessed November 16, 2021.)

are 79% less than the brand drug price before generic entry.”<sup>5</sup> At six competitors, “price reductions [are] more than 95% compared to brand prices.”<sup>6</sup>

Of note, the price benefits of generic competition -- for even one competitor to a brand-name drug -- are *greater* than the proposed price controls for small molecule drugs 12 to 16 years past exclusivity.<sup>7</sup> The price benefits of significant generic competition (four or more competitors) are greater than any price control proposed by policymakers in the Build Back Better Act.

Generics also save taxpayers money. According to the Medicare Payment Advisory Commission (MedPAC), Part D prices actually *declined* in 2019, “owing to increased generic competition.”<sup>8</sup> Today, nearly nine in every 10 prescriptions filled in Part D are for generic drugs.<sup>9</sup> This leads to more sustainable long-run costs in the Part D program for both patients and taxpayers.

Biosimilars have also shown some promise in reducing both biologic sales prices (through the introduction of competition) and offering patients lower-cost alternatives to expensive biological products, according to MedPAC.<sup>10</sup> This offers some hope for future taxpayer savings in the Part B program -- so long as biosimilar competition is not undermined, as it would be under the Build Back Better Act.

Lawmakers should be proposing policies that build on these strengths, rather than undermining them. Our organizations may differ on the ideal mix of policies to maximize innovator and generic drug development and use, however we all agree that the provisions in the Build Back Better Act will undoubtedly harm drug development and competition, as well as the patients and taxpayers who benefit from these unique attributes.

Our organizations urge you to oppose these harmful prescription drug provisions that will impact patients and taxpayers. Should you wish to discuss pro-taxpayer and pro-competitive alternatives to providing for increased generic drug development and utilization, we are at your service.

Sincerely,



National Taxpayers Union



60 Plus Association



Association of Mature American Citizens Action



American Consumer Institute



Americans for Prosperity



Americans for Tax Reform



Center for a Free Economy



Center for Freedom and Prosperity



Center for Individual Freedom



Competitive Enterprise Institute



Consumer Action for a Strong Economy



Council for Citizens Against Government Waste



Freedomworks



Institute for Liberty



Institute for Policy Innovation



R Street Institute



Small Business & Entrepreneurship Council (SBE Council)



Taxpayers Protection Alliance

Grace-Marie Turner, President, Galen Institute

James Edwards, Executive Director, Conservatives for Property Rights

Naomi Lopez, Director of Healthcare Policy, Goldwater Institute

\* Affiliations listed for identification purposes only

<sup>5</sup> *Ibid.*

<sup>6</sup> *Ibid.*

<sup>7</sup> Lawmakers propose a price cap of 65 percent of non-federal AMP for small molecule drugs 12 to 16 years past exclusivity under the Build Back Better Act, while according to the FDA one generic competitor’s price for a drug is typically 61 percent of the brand drug AMP before competition. For more, see the links in footnotes 1 and 2.

<sup>8</sup> MedPAC. “The Medicare prescription drug program (Part D): Status report.” February 13, 2021. Retrieved from: [http://www.medpac.gov/docs/default-source/reports/mar21\\_medpac\\_report\\_ch13\\_sec.pdf?sfvrsn=0](http://www.medpac.gov/docs/default-source/reports/mar21_medpac_report_ch13_sec.pdf?sfvrsn=0) (Accessed November 16, 2021.)

<sup>9</sup> *Ibid.*

<sup>10</sup> Medicare Payment Advisory Commission (MedPAC). “Section 10: Prescription drugs.” Retrieved from: [https://www.medpac.gov/wp-content/uploads/2021/10/July2021\\_MedPAC\\_DataBook\\_Sec10\\_SEC.pdf#page=10](https://www.medpac.gov/wp-content/uploads/2021/10/July2021_MedPAC_DataBook_Sec10_SEC.pdf#page=10) (Accessed December 1, 2021.)