October 16, 2019

The Honorable Frank Pallone, Chairman
The Honorable Greg Walden, Ranking Member
House Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington D.C. 20515

Dear Chairman Pallone, Ranking Member Walden, and Members of the Committee:

On behalf of the National Taxpayers Union, I write urging you to make substantial modifications to H.R. 3, the Lower Drug Costs Now Act of 2019, or reject this misguided legislation and instead pursue market-oriented proposals that will lower costs for patients and taxpayers.

Drug prices are a real concern for many Americans, especially those taking prescription drugs or relying on new, expensive, or innovative treatments. According to a February 2019 Kaiser Family Foundation poll, more than one-third of Americans taking four or more prescription drugs said that it is difficult to afford their medicine.[1] Complex biologics, which cost tens of billions of dollars to bring to market and have higher list prices than many other drugs, lack the robust biosimilar competition that would drive down costs for patients.[2]

However, the prescription drug market is working for many Americans. According to the same Kaiser poll, almost three-quarters of Americans currently taking prescription drugs say that affording them is easy.[3] Average monthly premiums for Medicare's prescription drug benefit, Part D, are $29.20 in 2019, the lowest they have been since 2009.[4] And thanks in large part to the bipartisan Hatch-Waxman drug patent law, over 90 percent of prescriptions written in the U.S. are for generics that often cost significantly less than their reference product.[5]

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[1] "Public Opinion on Prescription Drugs and Their Prices." Kaiser Family Foundation, July 15, 2019. Retrieved from: https://www.kff.org/slideshow/public-opinion-on-prescription-drugs-and-their-prices/

[2] Only 23 biosimilars have been approved by the U.S. Food and Drug Administration (FDA), compared to 69 approved by the European Medicines Agency. See: "Biosimilar Product Information." FDA, Accessed October 10, 2019. Retrieved from: https://www.fda.gov/drugs/biosimilars/biosimilar-product-information; "Search results." European Medicines Agency, Accessed October 10, 2019. Retrieved from: https://www.ema.europa.eu/en/medicines/field_ema_web_categories%253Aname_field/Human/ema_group_types/ema_medicine/field_ema_med_status/authorised-36/ema_medicine_types/field_ema_med_biosimilar/search_api_aggregation_ema_medicine_types/field_ema_med_biosimilar

[3] Ibid., 1.

[4] Cubanski, Juliette; Damico, Anthony; Neuman, Tricia. "10 Things to Know About Medicare Part D Coverage and Costs in 2019." Kaiser Family Foundation, June 4, 2019. Retrieved from: https://www.kff.org/medicare/issue-brief/10-things-to-know-about-medicare-part-d-coverage-and-costs-in-2019/

[5] 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

We commend the Committee's attention to how policymakers can lower costs for the portion of Americans who struggle to pay for prescription drugs. The Lower Drug Costs Now Act, though, is a deeply flawed piece of legislation that will ultimately harm patients, consumers, and taxpayers. H.R. 3 will make significant, irreversible disruptions to a market that has worked for the majority of Americans, in order to correct problems that would better be fixed by increasing market competition for expensive brand-name drugs and biologics.

The provision of the Lower Drug Costs Nows Act that is perhaps most disruptive to the free market is the retroactive, up to 95 percent tax on biopharmaceutical companies who cannot come to a price agreement with the federal government. The draft version of Speaker Pelosi's drug proposal claimed that this process would be "voluntary" and "bi-lateral," but the terms here suggest negotiations are anything but voluntary.

The ceiling for prescription drug companies is already set, and is pegged to prices set by foreign governments.[6] Companies who take issue with the government's preferred price have little to no recourse to enter into a true negotiation. It is difficult to see what incentive the federal government would have to budge from its preferred price, since the penalty on companies for failing to reach an agreement is astronomical.[7] To make matters worse, biopharmaceutical companies forced to sell their product at below cost have no way to make up their losses in the private sector - the Lower Drug Costs Now Act forces companies to offer the same, government-mandated price to all purchasers.[8]

What H.R. 3 amounts to is the government using aggressive price controls to place significant financial pressure on biopharmaceutical companies. We believe this will harm several constituencies, large and small, but especially patients suffering from rare and complex diseases. Treatments for these rare ailments, which are often more expensive to research and develop, may be significantly hampered by the Lower Drug Costs Now Act's steep taxes and mandates.

This legislation will also harm emerging, small, and mid-sized biopharmaceutical companies, who lately are responsible for a majority of the new therapies approved by the FDA. According to Iqvia, in 2018 "so-called emerging biopharma companies developed 38 of the 59 therapies OK'd in 2018," despite having much smaller research and development budgets than large biopharmaceutical companies.[9] While these larger companies may be able to survive despite the onerous taxes in H.R. 3, emerging biopharmaceutical companies will likely be thrust into bankruptcy by the Lower Drug Costs Now Act.

We share the Committee's broad goal of lowering drug costs. When costs go up, patients pay higher premiums in their individual, employer-sponsored, or Part D plans, and they often have higher out-of-pocket costs in their respective plans. Taxpayers pay more to sustain Medicare Parts B and D, state-administered Medicaid programs, and the Affordable Care Act's insurance subsidies. That is why we have outlined several alternative approaches that we believe would lower drug costs for patients and taxpayers, without destroying the market forces that have brought new treatments and cures - along with lower-priced generic drugs - to Americans for decades.

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[6] "Lower Prescription Drug Costs Now." Speaker.gov, September 23, 2019. Retrieved from: https://www.speaker.gov/sites/speaker.house.gov/files/HR3%20Lower%20Drug%20Costs%20Now%20Act%20Backgrounder%209.23.19.pdf

[7] Ibid., 6.

[8] Ibid., 6.

[9] The researchers define "emerging biopharmas" as "those which spend less than $200 million a year on R&D or earn less than $500 million in annual revenue." See: Pagliarulo, Ned. "In R&D, small biotechs hold their own against big pharma." Biopharma Dive, July 26, 2019. Retrieved from: https://www.biopharmadive.com/news/in-rd-small-biotechs-hold-their-own-against-big-pharma/553260/

- **Restructure the catastrophic phase of Part D.** Under current law, taxpayers cover 80 percent of the bill for a Medicare beneficiary's drug costs beyond a catastrophic threshold. Proposals from the American Action Forum (AAF),[10] the Medicare Payment Advisory Commission,[11] and the Senate Finance Committee[12] all suggest drastically reducing taxpayer liability (to around 20 percent, in the case of AAF and Senate Finance). This restructuring would benefit taxpayers, and some of the savings could go to achieving desired outcomes for members of both parties - for example, lowering the catastrophic threshold for Part D beneficiaries or eliminating cost-sharing for patients after the threshold.
- **Increase the availability and uptake of biosimilars.** These products, which are similar to often-expensive reference biologics, could save the American health care system tens of billions of dollars over the next decade.[13] We recently outlined several measures Congress and federal regulators can take to achieve these goals, including: 1) streamline FDA review and approval of biosimilars; 2) allow for reciprocal drug approval; 3) increase practitioner and patient knowledge of biosimilars; 4) update the "Purple Book," and 5) as biosimilars come to market, monitor and evaluate federal reimbursement policies.[14]
- **Reduce the cost of prescription drugs with pro-market, pro-taxpayer reforms.** Last December, we shared seven ideas we had to reduce the cost of prescription drugs. They are: 1) negotiate and promulgate trade policies that prioritize savings; 2) reduce barriers within the FDA drug approval process; 3) repeal taxes and unnecessary regulations that raise medication costs; 4) have the private market take the lead to reduce drug costs; 5) reform government health programs that needlessly raise prices across the system; 6) enhance oversight measures of government health care programs; and 7) recognize the balance between intermediate and long-term cost savings for taxpayers.[15]
- **Let regulators work with the private sector to pursue unique, cost-saving solutions.** One recent example of this is with the drugs Repatha and Praluent, which combat high cholesterol. Amgen, the manufacturer of Repatha, was able to bring savings to both patients and taxpayers by introducing the same drug under a new National Drug Code (NDC), cutting the price by more than half. The company worked with the Centers for Medicare and Medicaid Services (CMS) to achieve this. This story is just one example of how market actors, in tandem with policymakers, can reach more efficient and effective solutions than government can on its own.

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[10] Hayes, Tara O'Neill. "Redesigning Medicare Part D to Realign Incentives." American Action Forum, August 14, 2018. Retrieved from: https://www.americanactionforum.org/research/redesigning-medicare-part-d-realign-incentives-1/

[11] "Restructuring Medicare Part D for the era of specialty drugs." Medicare Payment Advisory Commission, June 2019. Retrieved from: http://www.medpac.gov/docs/default-source/reports/jun19_ch2_medpac_reporttocongress_sec.pdf?sfvrsn=0

[12] "Description of the Chairman's Mark, The Prescription Drug Pricing Reduction Act (PDPRA) of 2019." Senate Committee on Finance, July 25, 2019. Retrieved from: https://www.finance.senate.gov/imo/media/doc/FINAL%20Description%20of%20the%20Chairman's%20Mark%20for%20the%20Prescription%20Drug%20Pricing%20Reduction%20Act%20of%202019.pdf

[13] Mulcahy, AW; Hlavka, JP; Case, SR. "Biosimilar Cost Savings in the United States: Initial Experience and Future Potential." RAND Health Quarterly, March 30, 2018. Retrieved from: https://www.ncbi.nlm.nih.gov/pubmed/30083415

[14] Lautz, Andrew. "Pro-Taxpayer Ways to Increase the Availability and Use of Biosimilars." National Taxpayers Union, September 16, 2019. Retrieved from: https://www.ntu.org/publications/detail/pro-taxpayer-ways-to-increase-the-availability-and-use-of-biosimilars

[15] 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

We stand ready to work with the Committee on any of the above solutions. Above all, we urge you to reject the Lower Drug Care Costs Act in its current form. If passed into law, the legislation will harm patients who rely on innovative treatments, emerging drugmakers who bring those treatments to the FDA for approval, and taxpayers, who ultimately foot the bill when the U.S. falls behind on treating rare, chronic, or expensive diseases.

Thank you for your time and consideration, and should you have any further questions I am at your service.

Sincerely,

Andrew Lautz
Policy and Government Affairs Associate
National Taxpayers Union