

Congress of the United States

Washington, DC 20515

February 27, 2025

President Donald J. Trump
The White House
1600 Pennsylvania Avenue, N.W.
Washington, DC 20500

Honorable Robert F. Kennedy
Secretary of Health & Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20001

Dear President Trump and Secretary Kennedy,

Thank you for your commitment to rooting out waste and reducing costs for all Americans. We stand with you on your promises to secure lower drug costs for patients and seniors at the pharmacy counter and are committed to working with your administration to do exactly that.

We are concerned about the impact of the Inflation Reduction Act (IRA) on patients' access to lifesaving and life-preserving medicines, advancements and cures for serious diseases. We ask that you take immediate executive action to pause the IRA's self-executing provisions consistent with your day one memo to halt many of Biden's last-minute actions. Many of Biden's IRA implementing guidance's were too broad and impact seniors' ability to access critical medications and discourage future research and investment for new cures. The IRA has self-executing deadlines that we believe you can pause before February 28, 2025, and allow your team time to ensure IRA guidance is consistent with statute and applied in a manner that does not stifle future innovation.

Pausing allows your team time to assess whether the drugs President Biden's Administration chose at the last minute for 2027 were done appropriately, or if as we suspect, they overreached. Their last minute 2027 list of drugs includes over 26 rather than the 15 required by the IRA. Their plans for implementing the 2026 price controls also do not appropriately consider issues independent pharmacies will have, and this could lead to a major lack of access for seniors.

Specifically, we urge your administration to adjust and quickly re-issue the guidance on what constitutes a "Qualified Single Source Drug (QSSD)." Adjusting the QSSD guidance to eliminate the Biden version that is in plain violation of the law is critical to making sure the right drugs are chosen for price setting. Biden's version of the QSSD guidance allows CMS to select drugs that have only been on the market for much less time than the seven years specified in IRA. One study estimated that over the next ten years, 139 drugs are at risk of not being developed because of the Biden Administration's definition of QSSD, amounting to 40 percent fewer new drugs being brought to market than if the program were not in effect.ⁱ Fixing the QSSD definition will preserve incentives for manufacturers to continue investing in post-approval research into new treatments and uses after receiving initial approval in a different indicated area.ⁱⁱ

The IRA drug price-control scheme also includes several troubling provisions, one of the worst being the so-called 9/13 "Biden pill penalty." This requires CMS to set prices on pills four years earlier than they do for injected biologics. There has been legislation introduced that would equalize these timelines. We know people prefer pills to injections: they are more convenient, and often the only type of medicine that can cross the blood-brain barrier to treat certain cancers. It is terribly misguided policy to discourage research into oral medications. We ask for your support of our legislation to fix the Biden pill penalty and get America back on the right track to Make America Healthy Again.

Republicans in Congress unanimously opposed the IRA's price control scheme because it would increase monthly premiums for seniors enrolled in Medicare Part D, reduce choice and competition among Medicare prescription drug plans, and stifle life-saving innovation. The promised savings are much lower than projected and we now expect an increase in federal spending of \$10 to \$20 billion in 2025. As your key staff takes office, we want to work with you to ensure seniors do not lose access to the most clinically effective and affordable prescription medications that best meet their needs.ⁱⁱⁱ Pursuing such policies will also help create new manufacturing jobs across the United States, a key priority of yours.

The American people chose you after you successfully ran for and were elected President on a platform that included a pledge to protect seniors on Medicare and ensure they receive the care they need without being burdened by excessive costs or lack of access. Yet the Biden Administration, only days before your inauguration, published an overly broad list of drugs and left you with a program that is failing to live up to its promises. We are glad to hear reports your administration is considering administrative changes and more transparency in the law and look forward to working with you on these vital matters. Thank you for your time and consideration of our request.

Most respectfully,



Richard Hudson



Dan Crenshaw



Neal P. Dunn, M.D.



Gregory F. Murphy, M.D.



Claudia Tenney



Chuck Fleischmann



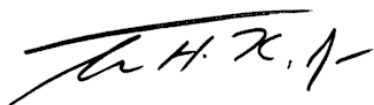
Mike Kelly




Tim Moore



Mike Carey



Tom Kean, Jr.



Rick Allen



August Pfluger



Carol Miller



Vern Buchanan



David Rouzer



Mariannette Miller-Meeks, M.D.



Robert Latta



Brad Knott



Randy Feenstra



Erin Houchin



Aaron Bean



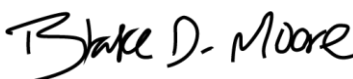
Craig Goldman



Rudy Yakym III



Russ Fulcher



Blake Moore



Pete Stauber



Robert B. Aderholt



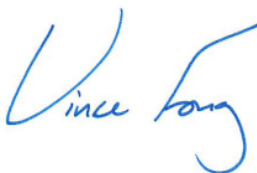
Kevin Hern



Adrian Smith



Dan Newhouse



Vince Fong



Gary Palmer



Nicole Malliotakis



Kat Cammack



Brian Fitzpatrick



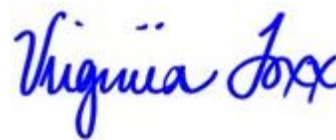
Ashley Hinson



Michelle Fischbach



Diana Harshbarger, Pharm.D.



Virginia Foxx



Dale W. Strong



Glenn Grothman



Rob Bresnahan, Jr.



James Comer

ⁱ Vital Transformation, "IRA's Impact on the US Biopharma Ecosystem,"

(https://www.bio.org/sites/default/files/2024-04/iras_impact_on_the_us_biopharma_ecosystem.pdf).

ⁱⁱ Stat, Medicare drug pricing rules will delay access to promising therapies, ([Medicare drug pricing rules may hinder new uses for existing drugs](#)).

ⁱⁱⁱ CMS, Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026 (<https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf>).