

President-elect Biden
1401 Constitution Ave., NW
Washington, DC 20230

January 12, 2020

Dear President-elect Biden:

Congratulations on your recent electoral victory to become the next President of the United States of America. Our organizations represent diverse constituencies including patients, consumers, health care providers, public health experts, union members, and many more. We are eager and excited to work with you on an array of initiatives to advance social, economic, and racial justice. We write to you today to urge you to take rapid, bold action to deliver relief from prescription drug price gouging, using executive authorities that do not require congressional authorization, and to offer our knowledge and resources to help make those efforts a success.

Even before the pandemic, people across the United States were struggling to access the medicines they need to lead happy, healthy lives. Three-in-ten Americans reported not taking their medicine as prescribed due to costs.¹ High prices of medicines and hormones like insulin that millions of people throughout the country need to stay alive have led to rationing, and ultimately death.² Drug corporation price gouging disproportionately impacts people of color, who face higher rates of diabetes and other conditions requiring expensive medicines. Pandemic-related economic strains have only made our drug pricing and access to medicines crisis more acute.

While legislation is required to provide comprehensive reform, including by reversing the corrupt “noninterference clause” prohibition on Medicare drug price negotiation, the President and his agencies are equipped with many powerful legal authorities to lower drug prices and can start helping patients immediately upon taking office, even in the absence of congressional action.

For the people across the nation who are making difficult choices about paying for food and rent or paying to fill their prescriptions, the access to medicines crisis could not be more urgent, and so nor can our response. On Day 1 upon taking office, your Administration can use the following policy tools to tangibly improve the lives of millions of Americans:

- Authorizing generic competition through patent licensing pursuant to 28 U.S. Code § 1498 and 35 U.S. Code § 203 and otherwise empower the President and agencies to bring down prices substantially.³ For example, the government could use its § 1498 authority to enable state and local authorities to purchase low-price generic naloxone autoinjectors to help combat the opioid addiction crisis, or to finally put an end to Humira profiteering. The U.S. government uses § 1498 routinely to procure energy and defense technologies without permission of patentholders, in

¹ <https://www.kff.org/slideshow/public-opinion-on-prescription-drugs-and-their-prices/>

² <https://www.npr.org/sections/health-shots/2018/09/01/641615877/insulins-high-cost-leads-to-lethal-rationing>

³ In addition to nonvoluntary licensing, further upstream, adopting policy changes at the U.S. Patent and Trademark Office that prevent and remedy erroneous approval of low-quality patents, such as strengthening *Inter Partes* Review and rejecting and revising the Trump Administration interpretation of subject matter eligibility under 35 U.S. Code § 101 can help weed out bad patents that fuel monopoly pricing and prevent them from being granted in the first place.

exchange for reasonable compensation. In 2001, Secretary of Health and Human Services Tommy Thompson publicly explored using § 1498 to help stockpile Cipro, the anthrax antidote. While Secretary Thompson did not ultimately use § 1498, raising its prospect quickly led Bayer (the Cipro patentholder) to cut its price for the U.S. government in half.

- Establishing a reasonable pricing requirement in technology transfer and funding arrangements can help ensure that taxpayers don't pay twice for medicine developed with public funds – first funding research and development, and again through excessive prices. Such a policy could require that any commercialized medicine developed with taxpayer dollars be made available at a price commensurate with its therapeutic benefit and that recognizes the public contribution to biomedical R&D. The National Institutes of Health and other federal funders contribute more than \$40 billion dollars toward biomedical research and development annually. Adopting a reasonable pricing requirement would help ensure that these medicines are accessible and affordable.
- Launching a demonstration project under Center for Medicare & Medicaid Innovation authority established under the Affordable Care Act can be used to lower prices for some prescription drugs under both Medicare Part B and Part D to the median price paid in large countries with similar income per capita as the United States. Such a model should be advanced through notice and comment rulemaking and ensure beneficiary access to medicines is protected through measures such as putting in place a dedicated ombudsman program to monitor patient experiences, close and timely monitoring of claims data, and other measures. Compulsory licensing remedies could be utilized when prescription drug corporations threaten access to medicines implicated by the model.
- Prosecuting to the fullest extent of the law anti-competitive behavior in the pharmaceutical sector can help rein in monopoly abuses like pay-for-delay reverse patent settlements and patent thicketing, in lieu of additional legislative authority. Launching a Federal Trade Commission investigation into the “Big 3” insulin manufacturers could shine a spotlight on their cartel-like behavior and illuminate avenues for further enforcement.

We look forward to working with you and your administration to improve the lives of patients and families by lowering drug prices and making medicines affordable.

Sincerely,

Public Citizen

Social Security Works

Indivisible

Accountable.US

AIDS Healthcare Foundation

American Family Voices

American Federation of Teachers

AMSA

Center for Popular Democracy Action

Congregation of Our Lady of Charity of the Good Shepherd, US Provinces

Consumer Action

Doctors for America

Families USA

Health Care Voices

Health GAP

Just Care USA

National Advocacy Center for the Sisters of the Good Shepherd

NETWORK Lobby for Catholic Social Justice

Other98

Partners In Health

People's Action

PrEP4All

R2H Action [Right to Health], USA

T1International

U.S. PIRG

CC: The Honorable Xavier Becerra, Secretary-designate, Health and Human Services