

Congress of the United States
Washington, DC 20515

June 23, 2022

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services
200 Independent Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Becerra:

We write to you today to urge you to utilize administrative authorities, including government patent use compulsory licensing under 28 U.S.C. 1498 and march-in and royalty-free rights under the *Bayh-Dole Act*, to lower prescription drug prices.

Americans pay more than two-and-a-half times as much for prescription drugs as people in other countries.¹ This is especially perverse and upsetting, given that U.S. taxpayers drive biomedical research through more than \$40 billion in annual investments through the National Institutes of Health.² High U.S. medicine prices are the result of prescription drug corporations using their monopoly power to hike prices and pad their bottom lines. Meanwhile, U.S. law forbids direct government negotiations and other restrictions on pharmaceutical pricing.³ This uniquely American combination of rules has led to pharmaceutical companies making more money in the U.S. than the rest of the world combined for the 20 top-selling drugs.⁴

Sky-high prices for medicines can be devastating for Americans' finances and health, leading to hardships and personal tragedies for families across the nation.

One in four Americans report they have been unable to afford their medicines, with Black and brown communities disproportionately bearing this suffering.⁵ Patients confronted with exorbitant prices are forced to make difficult decisions between filling prescriptions and putting food on the table or paying rent. And people with chronic illnesses who are forced to skip or

¹ RAND, "Prescription Drug Prices in the United States Are 2.56 Times Those in Other Countries," press release, January 28, 2021, <https://www.rand.org/news/press/2021/01/28.html>.

² National Institutes of Health, "Budget," <https://www.nih.gov/about-nih/what-we-do/budget#note>.

³ Kaiser Family Foundation, "Drug Price Negotiation Doesn't Mean the Government Will Restrict Access to Medicines," Juliette Cubanski and Larry Levitt, October 7, 2021, <https://www.kff.org/policy-watch/drug-price-negotiation-doesnt-mean-the-government-will-restrict-access-to-medicines/>.

⁴ Public Citizen, "United We Spend," Rick Claypool and Zain Rizvi, September 30, 2021, <https://www.citizen.org/article/united-we-spend-big-pharma-us-international-revenue-report/>.

⁵ Gallup, "In U.S., Large Racial Divide in COVID-19 Cost Concerns," Dan Witters, July 29, 2020, <https://news.gallup.com/poll/316052/large-racial-divide-covid-cost-concerns.aspx>; U.S. Department of Health and Human Services, "Prescription Drug Affordability among Medicare Beneficiaries," January 2022, p. 1, <https://aspe.hhs.gov/sites/default/files/documents/1e2879846aa54939c56efec9c6f96f0/prescription-drug-affordability.pdf>.

delay medication due to cost are more likely to experience adverse health events, including death.⁶

We thank you and President Biden for your leadership in seeking relief for many of these patients by calling for Congress to finally allow Medicare to negotiate drug prices for a selection of high-priced, brand-name drugs and to prevent prices for all drugs from rising faster than the rate of inflation.⁷ We stand committed to delivering on these vital legislative priorities. But to provide the urgent relief that Americans demand, including patients who would not initially benefit from Medicare drug price negotiations, you must simultaneously use the executive tools readily at your disposal.

Exercising these authorities would be extraordinarily popular – about 80 percent of voters favor breaking patent monopolies to reduce drug prices.⁸ Moreover, using executive tools to lower drug prices while also supporting robust drug pricing legislation is the policy of the administration as expressed by President Biden in the executive order he signed last summer, *Promoting Competition in the American Economy*.⁹ The order directs the Department of Health and Human Services to ensure that the patent system does not “unjustifiably delay generic drug and biosimilar competition,” while also expressing support for “aggressive” legislative reforms.¹⁰ It also directs the National Institute of Standards and Technology to consider not finalizing a Trump-era regulation that would prevent the government from exercising certain rights under the *Bayh-Dole Act* to lower drug prices on medicines invented with taxpayer funds.¹¹

Utilizing patent licensing authorities under these statutes could introduce generic or biosimilar competition and dramatic price relief in a matter of months. In your report released in September 2021, you recognized that the federal government holds government use patent licensing rights under 28 U.S.C. 1498 and march-in rights under the *Bayh-Dole Act*.¹² The report concludes that legislative and administrative actions presented in its pages “...will protect American patients and improve their access and adherence to medications by lowering drug prices through increased competition throughout the health care system.”¹³

⁶ Centers for Disease Control and Prevention, “Cost-Related Nonadherence and Mortality in Patients With Chronic Disease: A Multiyear Investigation, National Health Interview Survey, 2000-2014,” Sarah C. Van Alsten, Jenine K. Harris, December 3, 2020, https://www.cdc.gov/pcd/issues/2020/20_0244.htm.

⁷ The White House, “FACT SHEET: President Biden Calls on Congress to Lower Prescription Drug Prices,” press release, August 12, 2021, <https://www.whitehouse.gov/briefing-room/statements-releases/2021/08/12/fact-sheet-president-biden-calls-on-congress-to-lower-prescription-drug-prices/>.

⁸ Arnold Ventures, “Prescription Drug Prices: The Voters Speak,” March 2019, https://craftmediabucket.s3.amazonaws.com/uploads/AV-Summary-of-Polling-Project_052119_FINAL.pdf.

⁹ The White House, “Executive Order on Promoting Competition in the American Economy,” July 9, 2021, <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/07/09/executive-order-on-promoting-competition-in-the-american-economy/>.

¹⁰ *Id.*

¹¹ *Id.*

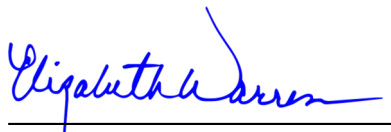
¹² U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, “Comprehensive Plan for Addressing High Drug Prices,” September 9, 2021, <https://aspe.hhs.gov/sites/default/files/2021-09/Competition%20EO%2045-Day%20Drug%20Pricing%20Report%209-8-2021.pdf>.

¹³ *Id.*

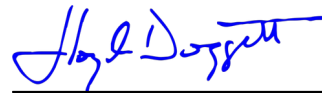
You personally understand the value that these authorities can provide to American patients. We appreciate that as California's attorney general, you led a bipartisan initiative of state attorneys general in urging the prior administration to use its licensing authorities to ensure access to and secure a fair price for the drug remdesivir.¹⁴ As a member of Congress, you also called on the Obama administration to use competitive licensing to lower drug prices.¹⁵

Now, you have the power to take on the monopoly abuses of the pharmaceutical industry and the responsibility to ensure Americans have affordable access to the medicines they need. We respectfully request a meeting with you by July 15, 2022 to discuss the Department's efforts to urgently lower drug prices for Americans using these authorities. You can provide immediate relief for millions of patients from Big Pharma's price gouging and show millions more Americans that you, President Biden, and his administration are on their side. Please do so without delay.

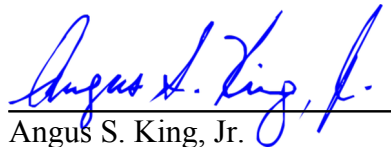
Sincerely,



Elizabeth Warren
United States Senator



Lloyd Doggett
Member of Congress




Angus S. King, Jr.
United States Senator



Joaquin Castro
Member of Congress

¹⁴ State of California Department of Justice, "Attorneys General Becerra and Landry Lead Bipartisan Coalition Urging Federal Government Action to Increase Access and Affordability for Remdesivir," press release, August 4, 2020, <https://oag.ca.gov/news/press-releases/attorneys-general-becerra-and-landry-lead-bipartisan-coalition-urging-federal>.

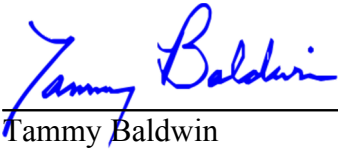
¹⁵ Knowledge Ecology International, "2016: 51 members of Congress have asked the NIH to use March-In rights to rein in high drug prices," James Love, January 11, 2016, <https://www.keionline.org/22983>.



Sara Jacobs
Member of Congress



Katie Porter
Member of Congress



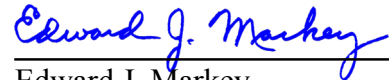
Tammy Baldwin
United States Senator




Sherrod Brown
United States Senator



Cory A. Booker
United States Senator



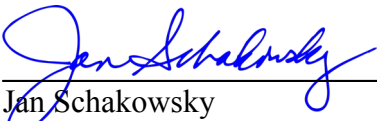
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United States Senator



Jeffrey A. Merkley
United States Senator



Bernard Sanders
United States Senator



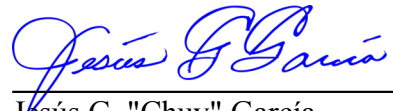
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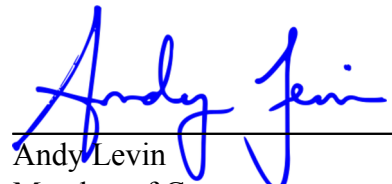
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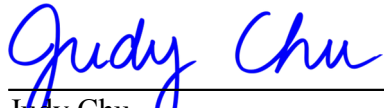
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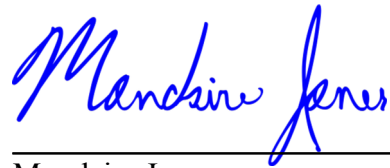
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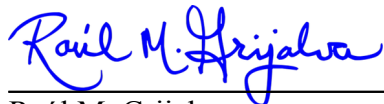
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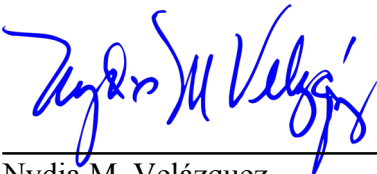
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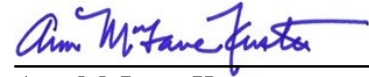
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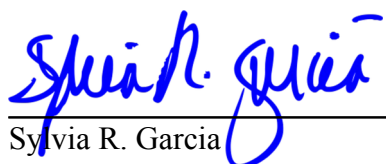
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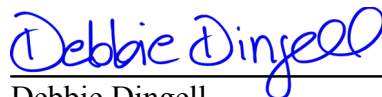
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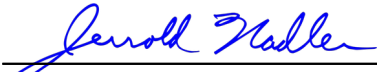
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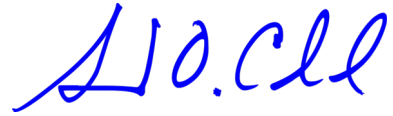
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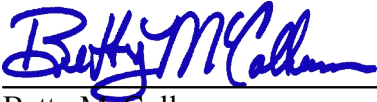
Karen Bass
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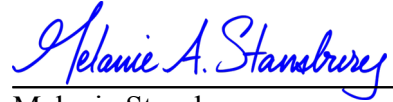
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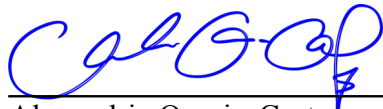
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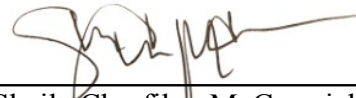
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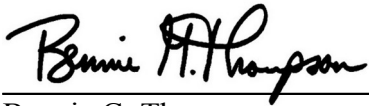
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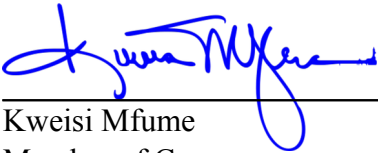
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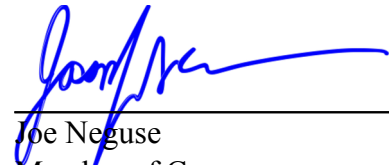
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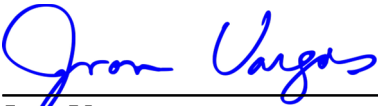
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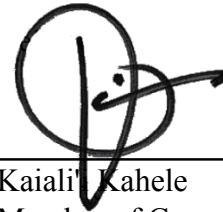
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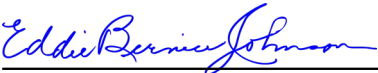
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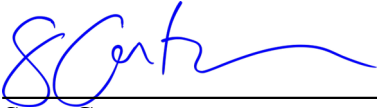
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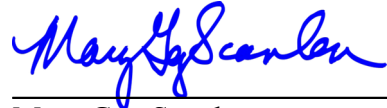
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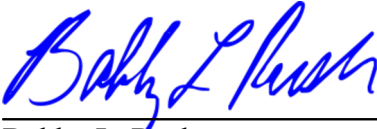
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