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April 22, 2022

The Honorable Xavier Becerra Secretary U.S. Department of Health & Human Services 200 Independence Avenue SW Washington, DC 20201

## Dear Secretary Becerra:

I write to bring to your attention to a new letter, sent to me by over 25 legal and public health experts, describing "three powerful tools that the [Biden Administration] can use to lower drug prices by breaking patent barriers and accelerating competition." <sup>1</sup>

According to the letter, which was led by experts from Yale Law School, Harvard Medical School, and Columbia Law School:

High prescription drug prices in the United States are a major problem today for both patients and the sustainability of our healthcare system. Importantly, these prices do not typically reflect material factors like supply shortages, manufacturing difficulties, or labor costs. Instead, drug prices are high primarily because brand-name drug companies use government-granted exclusivities, such as patents, to prevent competition and charge high prices.

Existing law gives the executive branch several tools to intervene when patients and public health are harmed by excessive drug prices. These tools can help the Administration break patent barriers, foster competition where currently there is none, and drive down prices. Critically, using them requires no additional congressional action.

This letter describes three of these tools: the "government patent use power" codified at 28 U.S.C. § 1498, and the Bayh-Dole Act's "royalty-free license" and "march-in rights." **These tools are integral, longstanding, and legitimate parts of our patent system.** Together, their directed use can help the government obtain fair prices for prescription drugs.

<sup>&</sup>lt;sup>1</sup> Letter from Legal and Public Health Experts to Senator Elizabeth Warren, April 20, 2022, <a href="https://www.warren.senate.gov/imo/media/doc/2022.4.20%20Letter%20to%20Warren%20on%20Drug%20Pricing%20Executive%20Authorities.pdf">https://www.warren.senate.gov/imo/media/doc/2022.4.20%20Letter%20to%20Warren%20on%20Drug%20Pricing%20Executive%20Authorities.pdf</a>.

I have repeatedly called upon the Administration to use its executive powers to lower drug prices,<sup>2</sup> as explicitly contemplated by the Department of Health and Human Service's Comprehensive Plan for Addressing High Drug Prices.<sup>3</sup> The attached letter affirms in extraordinary detail that you have the legal authority to do so. Consistent with these experts' conclusions, I urge you to move swiftly to use your existing authorities to give sorely needed relief to the millions of Americans paying far too much for their prescription drugs.

Thank you for your attention to this important matter.

Sincerely,

Warren

United States Senator

Enclosure

<sup>&</sup>lt;sup>2</sup> See, e.g., Letter from Senator Elizabeth Warren, Senator Angus King, and Congressman Lloyd Doggett to HHS Secretary Xavier Becerra, February 17, 2022,

https://www.warren.senate.gov/imo/media/doc/2022.02.17%20Letter%20to%20Sec.%20Becerra%20on%20Xtandi %20March-in%20Petition%20(2).pdf; Letter from Senator Elizabeth Warren, Senator Amy Klobuchar, and Congressman Lloyd Doggett to HHS Secretary Xavier Becerra, July 28, 2021,

https://www.warren.senate.gov/imo/media/doc/2021.07.28%20Letter%20to%20Secretary%20Becerra%20re%20Dr ug%20Pricing%20Authorities.pdf.

<sup>&</sup>lt;sup>3</sup> U.S. Department of Health & Human Services, Office of the Assistant Secretary for Planning and Evaluation, "Comprehensive Plan for Addressing High Drug Prices: A Report in Response to the Executive Order on Competition in the American Economy," September 9, 2021, p. 22, https://aspe.hhs.gov/sites/default/files/2021-09/Competition%20EO%2045-Day%20Drug%20Pricing%20Report%209-8-2021.pdf.