August 11, 2021

The Honorable Xavier Becerra Secretary of Health and Human Services U.S. Department of Health and Human Services 200 Independence Ave. SW Washington, D.C. 20201

Dear Secretary Becerra,

The undersigned organizations represent health care providers, public health experts, and consumer and taxpayer advocates who work to advance public health and promote access to affordable medicines. We welcome President Biden's groundbreaking new effort to promote competition in the American economy. We ask that the plan you develop to combat high prescription drug prices mirrors this ambition. As an integral part of this effort, we urge you to outline how you will use your power, under existing law, to authorize generic competition when drug corporations abuse government-granted monopolies to set excessive prices that harm patients. Any plan developed by the Department of Health and Human Services to combat excessive drug prices that does not call for the use of competitive licensing remedies would be incomplete.

High drug prices are rooted in monopoly power. Patents and other government-granted exclusivities give corporations the power to set high prices. The federal government does not regulate or by and large even negotiate for the monopoly price. As a result, Americans pay more than two-and-a-half times as much for prescription drugs than people in other countries. One-infour Americans report they have been unable to afford their medicines. Black and Brown communities disproportionately bear this suffering.

Our letter today follows a January 12 letter sent by many of our organizations to then-Presidentelect Biden, which outlined several key actions to lower drug prices and make medicines affordable that could be taken immediately by the President upon taking office.⁴ Most important among the policy options for executive action our groups provided in the January letter are those that directly challenge the monopoly power drug corporations abuse to charge excessive prices: government patent use and Bayh-Dole rights to march-in or use patents royalty-free.

The federal government has the power under existing law to increase competition and lower drug prices. Under 28 U.S. Code §1498, the federal government can use patents to authorize generic competitors in exchange for reasonable compensation. The government used the law repeatedly in the 1960s to buy low-cost generic versions of patented drugs.⁵ The government still

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

² Gallup, Medication Insecurity by Race and Political Identity, https://news.gallup.com/poll/316052/large-racial-divide-covid-cost-concerns.aspx

³ *Id*.

⁴ Letter to President-elect Biden Calling for Executive Action to Lower Drug Prices, https://www.citizen.org/article/letter-to-president-elect-biden-calling-for-executive-action-to-lower-drug-prices-january-2021/

⁵ Hannah Brennan et al., A Prescription for Excessive Drug Pricing, 18 Yale J. of Law & Tech 1 (2017).

routinely uses §1498 for other technologies, like passports and military equipment. In addition, the Bayh–Dole Act allows the federal government to "march-in" on drug patents developed with federal funding, or to use such patents royalty-free on behalf of the United States.⁶ These actions can help introduce additional producers. Generic competition, the Food and Drug Administration has found, can lead to price reductions of 95 percent.⁷

Americans support addressing patent monopoly abuse. Eight-in-ten voters favor breaking patent monopolies to reduce drug prices. Authorizing generic competition can rapidly lower prices for medicines used by many Americans, including medicines to prevent HIV (emtricitabine/tenofovir alafenamide), treat autoimmune disorders (adalimumab) and cure hepatitis C (ledipasvir/sofosbuvir). Your decisive action can help address the root cause of excessive medicine prices, and improve the lives of millions of Americans.

Sincerely,

Public Citizen

American Economic Liberties Project

Americans for Democratic Action, Southern California

Arkansas #insulin4all

Center for Popular Democracy Action

Citizen Action of Wisconsin

Connecticut #insulin4all

Consumer Action

Doctors for America

Down Home North Carolina

Florida #insulin4all

Global Health Justice Partnership at Yale

Health Care Voices

HealthGAP

Hometown Action

I-MAK

Indivisible

JustCare USA

Kentucky#insulin4all

Maine People's Alliance

Minnesota #insulin4all

NETWORK Lobby for Catholic Social Justice

North Carolina #insulin4all

Office of the Health Care Advocate, Vermont Legal Aid

ONE Northside

People's Action

⁶ KEI, KEI Briefing Note 2017:1. Bayh-Dole Act and difference between March-In Rights and the world wide royalty free rights in patents, https://www.keionline.org/24132

⁷ FDA, Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices, https://tinyurl.com/uxdc9.

⁸ Executive Summary of Arnold Ventures March 2019 Drug Pricing Polling, https://tinyurl.com/amhrukzf

PrEP4All

Progressive Leadership Alliance of Nevada

Progressive Maryland

Right to Health Action

Rights & Democracy New Hampshire

Rights & Democracy Vermont

Social Security Works

T1 International

The Democracy Collaborative

Treatment Action Group

U.S. PIRG

United Vision for Idaho

Universal Health Care Foundation of Connecticut

Universities Allied for Essential Medicines

Utah #insulin4all

Wisconsin #insulin4all

cc: President Joe Biden

The Honorable Dr. Francis Collins, Director, National Institutes of Health The Honorable Susan Rice, Director of the Domestic Policy Council

The Honorable Chiquita Brooks-LaSure, Administrator, Centers for Medicare & Medicaid Services

The Honorable Tim Wu, Special Assistant to the President for Technology and Competition Policy