

United States Senate  
WASHINGTON, DC 20510

July 28, 2021

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

Dear Secretary Becerra:

We write today to request an update on the Department of Health and Human Services' (HHS or the Department) plans to utilize administrative authorities—such as government patent use compulsory licensing under 28 U.S.C. § 1498 and march-in rights under the Bayh-Dole Act—to lower prescription drug prices.<sup>1</sup> Specifically, we are interested in details of the Department's efforts to conduct a review of the authorities; its anticipated timeline for utilizing these authorities; and the list of drugs it plans to target with these authorities to lower prices.

In the past 10 years, spending on retail prescription drugs in the United States increased by over \$100 billion—from \$244.3 billion in 2009 to \$369.7 billion in 2019, the most recent year for which data is available.<sup>2</sup> Americans pay more for prescription drugs than patients in any comparable country. Each year, people in the United States spend an average of over \$1,200 per person on prescription medicines,<sup>3</sup> leaving families unable to afford critical drugs and forcing many to ration medications.<sup>4</sup> In addition to harming individual patients, high drug prices also harm taxpayers. The Medicare Advisory Payment Commission (MedPAC), recently found that while Medicare's "unadjusted spending on services covered under the physician fee schedule remained flat" from 2013 to 2018, the program's "unadjusted spending on drugs...grew by 26 percent."<sup>5</sup> "Nearly all of the growth in drug spending," MedPAC found, "was due to higher

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<sup>1</sup> 28 U.S.C. § 1498 (online at <https://www.law.cornell.edu/uscode/text/28/1498>); 35 U.S.C. § 203 (online at <https://www.law.cornell.edu/uscode/text/35/203>).

<sup>2</sup> Centers for Medicare & Medicaid Services, "National Health Expenditure Fact Sheet," December 2020, <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical>.

<sup>3</sup> Organisation for Economic Co-operation and Development, "OECD Data: Pharmaceutical spending," <https://data.oecd.org/healthres/pharmaceutical-spending.htm>.

<sup>4</sup> CNBC, "Americans are skipping medically necessary prescriptions because of cost," Megan Leonhardt, February 27, 2020, <https://www.cnbc.com/2020/02/26/people-skipping-medically-necessary-drugs-because-they-cost-too-much.html>; Healthline, "1 in 8 People with Heart Conditions Avoid or Ration Meds Due to Cost," Shawn Radcliffe, November 25, 2019, <https://www.healthline.com/health-news/1-in-8-people-with-heart-disease-avoid-or-ration-meds-due-to-cost>; NPR, "Insulin's High Cost Leads to Lethal Rationing," Bram Sable-Smith, September 1, 2018, <https://www.npr.org/sections/health-shots/2018/09/01/641615877/insulins-high-cost-leads-to-lethal-rationing>.

<sup>5</sup> Medicare Advisory Payment Commission, "Report to the Congress: Medicare and the Health Care Delivery System," June 2021, [http://www.medpac.gov/docs/default-source/reports/jun21\\_medpac\\_report\\_to\\_congress\\_sec.pdf?sfvrsn=0](http://www.medpac.gov/docs/default-source/reports/jun21_medpac_report_to_congress_sec.pdf?sfvrsn=0), pg. xx.

prices and launches of new drugs, rather than an increase in the number of prescriptions filled by beneficiaries.”<sup>6</sup> In other words, taxpayers are bearing the brunt of high drug prices while pharmaceutical companies rake in profits.<sup>7</sup>

High drug prices should, in theory, be offset by a robust generic drug market. Under our current system, the federal government awards patents and other statutorily authorized exclusivities to pharmaceutical companies that produce new, brand-name drugs—creating a time-limited monopoly over parts of the drug market to incentivize innovation. Once those patents and exclusivities expire, other drug companies can begin producing generic drugs. On average, the cost of a generic drug is 85% lower than the brand name product, and in 2019 alone, generic drugs saved the U.S. an estimated \$313 billion in health care spending.<sup>8</sup>

Pharmaceutical companies, however, have learned to manipulate the nation’s patent and exclusivity system, allowing them to maintain monopolies and keep drug prices high long after generics should have entered the market. Some companies develop “patent thickets”—a web of secondary and tertiary patents that extend exclusivity periods—to block generic competitors<sup>9</sup>; others engage in “product hopping,” extending revenue streams on older drugs by seeking FDA approval of patented alternative formulations that are not, in practice, substantially different from preexisting products.<sup>10</sup>

In recent years, Congress has contemplated legislation that would systemically lower the cost of prescription drugs. Meanwhile, President Biden has expressed his support for legislation that would “give Medicare the power to save hundreds of billions of dollars by negotiating lower prices for prescription drugs,” which “won’t just help people on Medicare—it will lower prescription drug costs for everyone.”<sup>11</sup> Congress should develop and pass drug pricing legislation. But in the interim, HHS must do more to lower prescription drug costs—and it has pre-existing authorities and solutions at its fingertips to do just that.

First, HHS should consider using its government patent use compulsory licensing authority to lower prescription drug costs when drugs face limited competition or market practices have failed to ensure an affordable price. Codified at 28 U.S.C. § 1498, this authority allows the government to “manufacture, import, and use” products protected by active patents, as long as it provides patent holders with “reasonable and entire compensation for such use and

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<sup>6</sup> *Id.*

<sup>7</sup> Newsweek, “Big Pharma Companies Earn More Profits Than Most Other Industries, Study Suggests,” Rosie McCall, March 4, 2020, <https://www.newsweek.com/big-pharma-companies-profits-industries-study-1490407>.

<sup>8</sup> Association for Accessible Medicines, “Generic Drug Access and Savings in the U.S.,” 2018, pp 10, [https://accessiblemeds.org/sites/default/files/2018\\_aam\\_generic\\_drug\\_access\\_and\\_savings\\_report.pdf](https://accessiblemeds.org/sites/default/files/2018_aam_generic_drug_access_and_savings_report.pdf); Association for Accessible Medicines, “2020 Generic Drug and Biosimilars Access and Savings in the U.S. Report,” <https://accessiblemeds.org/resources/reports/2020-generic-drug-biosimilars-access-and-savings-us-report>.

<sup>9</sup> U.S. PIRG, “Hacking through thickets of drug patents to get to affordable medicine,” Patricia Kelmar, March 31, 2021, <https://usp.org/blogs/blog/usp/hacking-through-thickets-drug-patents-get-affordable-medicine>.

<sup>10</sup> Pharma News Intelligence, “Brand Drug Product Hopping Costs U.S. \$4.7B Annually,” Samantha McGrail, September 17, 2020, <https://pharmanewsintel.com/news/brand-drug-product-hopping-costs-us-4.7b-annually>.

<sup>11</sup> USA Today, “Read the full transcript from President Joe Biden’s address to a joint session of Congress,” April 29, 2020, <https://www.usatoday.com/story/news/politics/2021/04/28/joe-bidens-speech-congress-read-full-transcript/4883244001/>.

manufacture.”<sup>12</sup> The government could use this compulsory licensing authority to contract with third parties to begin the manufacture of highly-priced prescription drugs, regardless of whether those drugs are patent protected. The government does not need to seek prior approval from a patent holder to invoke this compulsory licensing authority—it can act quickly and flexibly as the situation demands. Patent holders can then bring a claim to the U.S. Court of Federal Claims, where an independent judge will determine the appropriate compensation amount owed by the federal government.<sup>13</sup> Section 1498 guarantees that any affected patent holder will be awarded “reasonable and entire” compensation proportionate to the scale of the government’s use of their patents. Compulsory licensing authority under § 1498 is broad and could apply to many drugs, devices, and associated products. The government has frequently used the authority, particularly around national defense, since it was created in 1910.<sup>14</sup>

Second, HHS should consider using march-in rights when drugs face limited competition or market practices have failed to ensure an affordable price, ensuring that prescription drugs invented with taxpayer dollars are reasonably priced and affordable. March-in rights were established under the Bayh-Dole Act, are codified at 35 U.S.C. § 203, and allow the government, in certain cases, to nonexclusively license patents without the permission of the rights holder.<sup>15</sup> Bayh-Dole gave federal contractors—like small businesses and universities—the right to exclusively manufacture and sell products developed with federal support, in an effort to ensure federally-funded research would be commercialized to benefit the American people.<sup>16</sup> However, in exchange for relinquishing title to the inventions developed with government funding, Bayh-Dole protected the public interest by allowing the federal government to retain “nonexclusive, nontransferable, irrevocable, paid-up” licenses for products developed with government funds.<sup>17</sup> This license permits the U.S. government itself to manufacture, distribute, sell, and otherwise use the patented invention without permission from or compensation to the patent holder. In certain cases, such as when health or safety needs have not been reasonably satisfied by the original licensee, the federal government can “march-in” and direct other licensees to produce products.<sup>18</sup> At the end of the march-in rights process, the federal government can contract with third parties to manufacture desired products.<sup>19</sup> In the past decade, federally-funded research has contributed

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<sup>12</sup> 28 U.S.C. § 1498 (online at <https://www.law.cornell.edu/uscode/text/28/1498>); Health Affairs, “March-In Rights and Compulsory Licensing—Safety Nets for Access To A COVID-19 Vaccine,” Michael Liu, William B. Feldman, Jerry Avorn, and Aaron S. Kesselheim, May 6, 2020, <https://www.healthaffairs.org/doi/10.1377/hblog20200501.798711/full/>.

<sup>13</sup> New York University School of Law Technology Law & Policy Clinic and Prep4All, “§ 1498: A Guide to Government Patent Use—A Path to Licensing and Distributing Generic Drugs,” Joseph Adamczyk, Adrienne Lewis, Shivani Morrison, Christopher Morten, March 2021, <https://static1.squarespace.com/static/5e937afbfd7a75746167b39c/t/60099e3582c53f4f1b6a4a57/1611243061897/P4A++1498+A+Guide+to+Government+Patent+Use.pdf>.

<sup>14</sup> Health Affairs, “‘Government Patent Use’: A Legal Approach To Reducing Drug Spending,” Amy Kapczynski and Aaron Kesselheim, May 2016, <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2015.1120>.

<sup>15</sup> Congressional Research Service, “March-In Rights Under the Bayh-Dole Act,” John R. Thomas, August 22, 2016, <https://fas.org/sgp/crs/misc/R44597.pdf>.

<sup>16</sup> *Id.*

<sup>17</sup> 35 U.S.C. § 202 (online at <https://www.law.cornell.edu/uscode/text/35/202>).

<sup>18</sup> 35 U.S.C. § 203 (online at <https://www.law.cornell.edu/uscode/text/35/203>).

<sup>19</sup> *Id.*

to the development of hundreds of drugs, some of which are protected by key patents that could be subject to march-in rights.<sup>20</sup>

The Biden Administration has the opportunity to lower the prices of key drugs using these authorities. Americans should not be forced to ration essential drugs because they cannot afford their medical bills, and people should not die of preventable causes because state and local governments cannot afford the drugs they need. HHS should consider use of administrative authorities to produce affordable insulin, ensuring that the over 7 million Americans who rely on it can stay healthy without going broke.<sup>21</sup> It should also consider targeting drugs to prevent and treat HIV/AIDS—like emtricitabine/tenofovir alafenamide (brand name Descovy)<sup>22</sup>—to ensure that the millions of Americans eligible for these treatments can access them.<sup>23</sup> It should explore how administrative authorities could be used to produce more affordable Hepatitis C drugs—like ledipasvir/sofosbuvir (Harvoni) and sofosbuvir (Sovaldi), which are protected by thickets of questionable patents<sup>24</sup>—to improve the health of the 2.4 million Americans estimated to be living with the virus.<sup>25</sup> HHS could identify additional drugs to target, like adalimumab (Humira), whose manufacturers have taken advantage of patent thickets and weak patents to extend their monopoly for decades<sup>26</sup> and bilked taxpayers for tens of billions of dollars through programs like Medicare,<sup>27</sup> and enzalutamide (Xtandi), a prostate cancer drug developed with federal funding.<sup>28</sup> Finally, it should examine the extent to which these authorities could be used to lower the prices of naloxone (ensuring that state and local governments can prevent avoidable drug overdoses<sup>29</sup> as substance use disorder increases amidst the COVID-19 pandemic<sup>30</sup>) and albuterol.

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<sup>20</sup> Bentley University, “Bentley University study shows NIH spent more than \$100 billion on basic science for new medicines,” Joanna Howarth, February 13, 2018, <https://www.bentley.edu/news/bentley-university-study-shows-nih-spent-more-100-billion-basic-science-new-medicines>.

<sup>21</sup> American Diabetes Association, “Insulin Access and Affordability Working Group: Conclusions and Recommendations,” June 2018, <https://care.diabetesjournals.org/content/41/6/1299>.

<sup>22</sup> New York University School of Law Technology Law & Policy Clinic and Prep4All, “§ 1498: A Guide to Government Patent Use—A Path to Licensing and Distributing Generic Drugs,” Joseph Adamczyk, Adrienne Lewis, Shivani Morrison, Christopher Morten, March 2021, <https://static1.squarespace.com/static/5e937afb7d7a75746167b39c/t/60099e3582c53f4f1b6a4a57/1611243061897/P4A++1498+A+Guide+to+Government+Patent+Use.pdf>.

<sup>23</sup> Reuters, “New brand-name HIV-prevention pill not worth the added cost: study,” Lisa Rapaport, March 9, 2020, <https://www.reuters.com/article/us-health-prep-costs/new-brand-name-hiv-prevention-pill-not-worth-the-added-cost-study-idUSKBN20W31V>.

<sup>24</sup> STAT, “European regulator amends some Gilead hep C patent claims,” Ed Silverman, October 5, 2016, <https://www.statnews.com/pharmalot/2016/10/05/gilead-sovalid-europe-invalidated/>.

<sup>25</sup> U.S. Department of Health and Human Services, “Viral hepatitis in the United States: Data and Trends,” <https://www.hhs.gov/hepatitis/learn-about-viral-hepatitis/data-and-trends/index.html>.

<sup>26</sup> Axios, “Higher prices drove up Medicare drug spending, advisers say,” Bob Herman, <https://www.axios.com/medpac-medicare-drug-spending-prices-9364a77d-079b-496f-b758-ea90b97e0f1f.html>.

<sup>27</sup> Washington Post, “Why price of Humira keeps rising despite FDA approval of generic competition,” Christopher Rowland, January 8, 2020, [https://www.washingtonpost.com/business/economy/why-humira-price-keeps-rising-despite-fda-approval-of-generic-competition/2020/01/07/549ed0ce-2e3a-11ea-bcb3-ac6482c4a92f\\_story.html](https://www.washingtonpost.com/business/economy/why-humira-price-keeps-rising-despite-fda-approval-of-generic-competition/2020/01/07/549ed0ce-2e3a-11ea-bcb3-ac6482c4a92f_story.html).

<sup>28</sup> Knowledge Ecology International, “Xtandi petition regarding Bayh-Dole remedies to excessive prices,” <https://www.keionline.org/xtandi>.

<sup>29</sup> See Letter from Baltimore City Health Department and Public Citizen to Kellyanne Conway, May 3, 2018, <https://www.citizen.org/wp-content/uploads/naloxone-product-government-use-request.pdf>.

<sup>30</sup> The Commonwealth Fund, “The Spike in Drug Overdose Deaths During the COVID-19 Pandemic and Policy Options to Move Forward,” March 25, 2021, <https://www.commonwealthfund.org/blog/2021/spike-drug-overdose-deaths-during-covid-19-pandemic-and-policy-options-move-forward>.


We write today to request an update on the review of the tools at HHS' disposal to reduce the prices of drugs and gather additional details on HHS' plans to utilize various administrative authorities and solutions to lower drug prices. We ask for answers to the following questions no later than August 11, 2021:

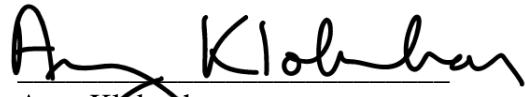
1. What steps has HHS taken to conduct a review of the tools at HHS' disposal to reduce the price of drugs and make treatments for affordable for the American people?  
Specifically:
  - a. What steps has HHS taken to review government patent use compulsory licensing as a tool to lower drug prices? What conclusions has HHS drawn?
  - b. What steps has HHS taken to review march-in rights as a tool to ensure reasonable prices for publicly funded medical inventions or to alleviate health and safety needs? What conclusions has HHS drawn?
  - c. What other administrative tools has HHS identified as possibilities that would allow the Administration to reduce the price of drugs?
2. When it comes to utilizing executive branch authorities to lower drug prices what drugs is HHS planning to target? Specifically, does HHS plan to target insulin, HIV/AIDS prevention and treatment drugs, Hepatitis C medication, Humira, Xtandi, naloxone, or albuterol? What other drugs is HHS considering, and what factors is HHS using to identify those drugs?
3. When does HHS plan to utilize march-in rights, compulsory licensing, and other executive branch tools to lower the price of drugs?
4. In his recent "Executive Order on Promoting Competition in the American Economy," President Biden directed you to, within 45 days, "submit a report...with a plan to continue the effort to combat excessive pricing of prescription drugs and enhance domestic pharmaceutical supply chains, to reduce the prices paid by the Federal Government for such drugs, and to address the recurrent problem of price gouging."<sup>31</sup>
  - a. Is HHS planning to include government patent use compulsory licensing in this report?
  - b. Is HHS planning to include march-in rights in this report?
  - c. What additional administrative tools, if any, does HHS plan to include in this report?

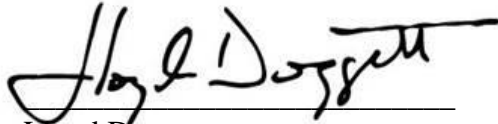
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<sup>31</sup> The White House, "Executive Order on Promoting Competition in the American Economy," July 9, 2021, <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/07/09/executive-order-on-promoting-competition-in-the-american-economy/>.

Sincerely,

  
Elizabeth Warren  
United States Senator

  
Amy Klobuchar  
United States Senator

  
Lloyd Doggett  
Member of Congress