THE SECRETARY OF HEALTH AND HUMAN SERVICES

WASHINGTON, D.C. 20201

November 15, 2021

The Honorable Elizabeth Warren
United States Senate
Washington, DC 20510

Dear Senator Warren:

Thank you for your letter regarding the Department of Health and Human Services' (HHS) efforts to lower prescription drug prices. As referenced in your letter, President Biden's Executive Order 14036, "Promoting Competition in the American Economy" (the Competition Executive Order), identifies a lack of competition as a key driver for problems across economic sectors.

As part of the Competition Executive Order, HHS has drafted a comprehensive plan (the Plan) for addressing high drug prices 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. The Plan presents the Biden-Harris Administration's principles for equitable drug pricing reform through competition, innovation, and transparency; describes promising legislative approaches; and summarizes actions already underway or under consideration across HHS. The Plan (available at: https://aspe.hhs.gov/reports/comprehensive-plan-addressing-high-drug-prices) was released on September 9th and presents the Administration's comprehensive steps to tackle high drug prices.

The information below outlines the Administration's views on the specific topics mentioned in your letter.

HHS understands that the patent system plays an essential role in incentivizing drug development while also affecting prescription drug costs. Brand drug manufacturers sometimes exploit the patents and exclusivities that are intended to promote innovation with "patent thickets," "product hopping," "pay-for-delay," and other anti-competitive practices to keep cheaper generics and biosimilars off the market. The number of patents on pharmaceutical products has grown over time, resulting in the development of patent thickets surrounding a given product. For example, among the 100 best-selling drugs from 2005 to 2015, more than 70 percent had their patent protection extended at least once, with almost 50 percent having patent protection extended more than once. Over this time period, 78 percent of the drugs associated with new patents were existing drugs already on the market. These groups of patents make it harder to introduce biosimilars and generics into the market, even if the patents are ultimately deemed invalid, unenforceable, or are not infringed upon by the competitor. At the extreme, manufacturers can "evergreen" their patents, in which their originator drugs obtain patent protection for each subsequent, minor change, helping to continuously avoid facing competition.

The Biden-Harris Administration supports action to ensure that drug manufacturers cannot unfairly use the patent system to discourage competition. The Food and Drug Administration (FDA) and the U.S. Patent and Trademark Office (USPTO) are working together to develop solutions as requested in the Competition Executive Order. An important component of this collaboration is FDA's transmission of a letter[1] to the Under Secretary of Commerce for Intellectual Property and Director of the USPTO regarding ways in which the patent system can continue to incentivize innovation and more rapid availability of biosimilars and generic drugs. Increased engagement between FDA and USPTO can facilitate greater awareness of their complementary work and introduce efficiency into their respective workstreams.

Another area of concern for HHS related to patents are pay-for-delay agreements. Pay-for-delay agreements occur when follow-on product manufacturers agree to delay market entry in exchange for monetary payment (or payment-in-kind) from brand-name firms. The Federal Trade Commission (FTC) has authorities to investigate some forms of anti-competitive agreements and has made substantial progress challenging these practices in court. This includes the landmark 2013 Supreme Court decision in Federal Trade Commission vs. Actavis, Inc., et al., which allowed the government and private parties to proceed with antitrust lawsuits against drug companies. However, certain challenges remain, as patent settlements increasingly favor non-cash business transactions, which limits the FTC's ability to file antitrust suits. HHS will support the FTC in its mission to ensure that any settlements do not infringe on competition and will remain vigilant to combat all forms of anticompetitive behavior by working with federal and state partners on enforcement.

HHS will also continue to give petitions for the use of march-in rights due consideration. The Bayh-Dole Act, which establishes march-in rights, was designed to address the absence of incentives to commercialize government-funded inventions by allowing small businesses or nonprofit organizations, such as universities, to claim title to inventions generated during performance of a federal grant or contract. Before the Bayh-Dole Act became law in 1980, the federal government owned any inventions it funded and none of them were used to develop therapeutics or vaccines; since then, 245 therapeutics and vaccines have been brought to market using university and federal laboratory patents. With regard to §1498, HHS will consider how this authority fits into its multi-prong effort to address high drug prices. HHS will also engage other government agencies to address barriers to accessing government-funded inventions as emphasized in the Competition Executive Order, which directs the Director of the National Institute of Standards and Technology to consider not finalizing any provisions on march-in rights and product pricing in the proposed rule, "Rights to Federally Funded Inventions and Licensing of Government Owned Inventions".

In sum, HHS is committed to ensuring all Americans have access to affordable, innovative therapies. The Competition Executive Order provides a number of options to address the significant issue of increasing drug prices, and HHS is already pursuing or considering a number of these options to support its mission to enhance the health and well-being of all Americans. Thank you again for your letter and taking the time to share your views. Should you or your staff have additional comments or questions, please contact the Acting Assistant Secretary for Legislation at (202) 690-7627. I will also provide this response to the co-signers of your letter.

Sincerely,

Xavier Becerra
Secretary

Cc: Hon. Amy Klobuchar
Hon. Lloyd Doggett

[1] *See* FDA's letter to USPTO in hope to further developing its engagement with USPTO; https://www.fda.gov/media/152086/download.