

United States Senate

WASHINGTON, DC 20510

April 23, 2019

The Honorable Alex M. Azar II
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dr. Robert Redfield, M.D.
Director
Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30333

Dear Secretary Azar and Director Redfield:

We write today regarding recent reports that the Centers for Disease Control and Prevention (CDC) has patented methods for the prevention of HIV infection that are relevant to Gilead Science's prescription drug Truvada.¹ Gilead charges between \$1,600 to \$2,000 for a month's supply of Truvada and generated \$3 billion in revenue off of Truvada sales last year.² I'm deeply concerned that a drug company is marketing a product that appears to potentially be infringing upon patents owned by the United States Government and selling it at a price that makes the drug unaffordable for many Americans. I would like to know what steps have been taken to ensure that any usages by private companies of government-held patents are properly licensed and that any potential infringements are acted upon.

The federal government is the major funder of basic research, much of which ultimately leads to the discovery and development of innovative drugs. According to the Government Accountability Office, in 2014 alone the National Institute of Health (NIH) obligated \$13.6 billion to basic research; pharmaceutical companies in the U.S. contributed \$6.3 billion towards basic research that year.³ Gilead's Truvada relies on the usage of the drugs emtricitabine and tenofovir for pre-exposure prophylaxis against HIV (PrEP). PrEP was invented – and patented – by scientists working for the CDC.⁴ Those patents are held by the United States of America, as represented by the Secretary of the Department of Health and Human Services (HHS).⁵

¹ *An HIV treatment cost taxpayers millions. The government patented it. But a pharma giant is making billions.*, Washington Post (Mar. 26, 2019).

² *Id.*

³ Government Accountability Office, *Drug Industry: Profits, Research and Development Spending, and Merger and Acquisition Deals*, (November 2017) (GAO-18-40).

⁴ *E.g.* U.S. Patent No. 9,044,509 (issued Jun. 2, 2015); U.S. Patent No. 9,579,333 (issued Feb. 28, 2017); U.S. Patent No. 9,937,191 (issued Apr. 10, 2018).

⁵ *Id.*

Based on an analysis of these patents and the FDA-approved prescribing information for Truvada, Gilead appears to potentially be marketing a prescription drug for usages that are patented by the government.⁶ Although Secretary Azar has stated that negotiations are ongoing, Gilead has reportedly reached no agreement with the government that would allow them to make use of these patented methods.⁷ When the government holds a patent, licenses should be granted on terms that make it economically viable for industry to develop drugs, but allow the government to recoup its investment and fund further research as well as ensure that drugs developed using government-owned patents are affordable. The government should also be willing to enforce its patents and take legal action against companies that appear to be infringing on their patents, in order to prevent multinational companies from reaping billions of dollars in profits without properly compensating the government for its investments. For these reasons we ask that you provide us with the following:

1. Please provide copies of any HHS or CDC policies, procedures, or guidance related to the filing for a patent, licensing patents held by the United States of America, and for identifying cases of potential infringement and enforcing patent rights that may be subject to such infringement.
2. Please provide us with the number of patents currently held by the United States of America, as represented by the Secretary of the Department of Health and Human Services, and of those, how many have currently been licensed for use by pharmaceutical companies.
3. Please document for us how HHS or CDC take into consideration the affordability of prescription drugs when licensing patents held by the United States of America.
4. Please provide a detailed summary of the status of negotiations between HHS or CDC and Gilead regarding any patents held by the United States of America related to the use of drugs emtricitabine and tenofovir for PrEP held by the United States of America. Please include a summary of communications between HHS or CDC and Gilead.
5. Please provide a detailed summary of the steps that HHS or CDC have taken to identify any specific instances of infringement upon the patents related to the drugs emtricitabine and tenofovir for PrEP held by the United States of America and the steps HHS or CDC have taken to enforce its patents and to hold infringers liable.

Please provide us with a complete response to these requests no later than May 7, 2019. Thank you for your prompt attention to this matter.

⁶ Yale Global Health Justice Partnership, *Statement on CDC's Patents for PrEP* (Mar. 12, 2019).

⁷ *How HHS Secretary Reconciles Proposed Medicaid Cuts, Stopping The Spread Of HIV*, NPR (Apr. 8, 2019).

Sincerely,



Debbie Stabenow
United States Senator



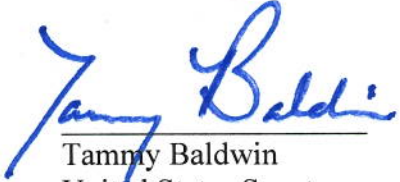
Bernard Sanders
United States Senator



Benjamin L. Cardin
United States Senator



Richard Blumenthal
United States Senator



Tammy Baldwin
United States Senator



Chris Van Hollen
United States Senator



Tammy Duckworth
United States Senator