



**Science, Health &
Information Clinic**

The Honorable Merrick Garland
Attorney General of the United States
U.S. Department of Justice
950 Pennsylvania Avenue, NW
Washington, DC 20530-0001

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

May 30, 2023

Dear Attorney General Garland and Secretary Becerra,

[PrEP4All](#) and the [Public Interest Patent Law Institute](#) (PIPLI) write along with their legal representatives at Columbia Law School's [Science, Health, and Information Clinic](#) and the undersigned 32 organizations. We commend the decision by the Department of Justice (DOJ) and the Department of Health & Human Services (HHS) [to continue litigating](#) following [the unexpected jury verdict](#) in *United States v. Gilead*.

Advocates from communities who have been affected for over a decade by Gilead's price gouging and profiteering off of government-owned HIV PrEP technology [were deeply disappointed](#) in the unexpected May 9th jury verdict. Gilead Sciences must be held accountable for its long-running infringement of the government's patents on PrEP in order to deter future exploitation of government-funded discoveries. Long-overdue royalties paid by Gilead for its infringement would also provide resources to mitigate the significant harms caused by Gilead's wanton and flagrant disregard of the wellbeing and health of marginalized communities, including [delaying access to a drug that by its own estimates could have saved 16,200 lives](#) had it not been delayed.

As you know, the *United States v. Gilead* case creates an opportunity to correct a decade-long injustice that led to hundreds of thousands of new HIV infections. The [US government invested at least \\$143M in HIV PrEP research](#) that served as the primary basis for FDA approval of the first PrEP product in 2012. In the years since, Gilead has profited on this groundbreaking public science. For many years now, the company has charged American patients an obscene

price for PrEP—over \$20,000 per patient per year. Gilead’s high prices have [limited access to PrEP](#), perpetuating the HIV epidemic. And, for many years now, Gilead infringed on publicly owned patents on PrEP that emerged from groundbreaking research at the Centers for Disease Control & Prevention (CDC).

If the verdict stands, American taxpayers will be robbed once again. Gilead—a multi-billion dollar pharmaceutical company that has needlessly caused immense human suffering—will get away without paying a dime to the public despite its billions in profits and years of infringement.

The consequences here could be even bigger than Gilead and HIV/AIDS: If HHS and DOJ do not vigorously enforce these patents, they may encourage other drug companies to privatize and profit from publicly developed technology, without license and with impunity.

We strongly support HHS’s and DOJ’s decision to contest the surprising verdict. The government’s case is fundamentally strong. Taxpayers paid for CDC’s and NIH’s invention and development of HIV PrEP, and CDC scientists patented their work. The government attempted, for years, to negotiate with Gilead a reasonable license to these patents. Gilead refused. The government’s patents have withstood validity challenges that Gilead brought at the Patent Trial and Appeal Board. The European Patent Office also upheld validity after a challenge by Mylan.

As DOJ seeks a new trial, we strongly advocate that you involve community PrEP advocates as much as possible. Representatives from affected communities, including people living with HIV, can be assets to the government’s case and serve as witnesses to describe the non-economic harm that Gilead caused.

If the government prevails and obtains a royalty from Gilead, the [proceeds could provide badly-needed funding](#) to expand access to PrEP, HIV testing, and related care. Gilead’s effort to exploit public research and set PrEP at a luxury price is the single most significant reason why PrEP has only reached a quarter of Americans who would benefit most from it, with only 9% and 16% of Black and Latinx individuals in greatest need gaining access. For years, advocates have called for a [National PrEP Program](#) that empowers the federal government to secure fair public health prices for PrEP medications and related laboratory tests for uninsured persons; builds capacity throughout a PrEP-provider network, which encompasses clinical care providers as well as nonclinical community-based organizations and other partners that can reach people who aren’t accessing traditional health care sites; and invests in community education efforts. These funds could make that vision a reality.

Gilead has a long, sordid history of gamesmanship, exploitation of the American public, and profiteering at the expense of communities affected by infectious disease: not only HIV, but also hepatitis C (HCV). In 2015, Gilead was the subject of a [bipartisan Senate report](#) that found that

the company set egregious prices of over \$90,000 for its HCV cures despite having not invented them, knowing that those prices would place exceptional burden on public payers, and knowing that those prices would limit access. According to that bipartisan report, while Gilead “asserted that its primary concern in developing and marketing [its drug] was to treat the largest number of HCV patients possible,” “[i]n reality, Gilead’s marketing, pricing, and contracting strategies were focused on maximizing revenue—even as the company’s analysis showed a lower price would allow more people to be treated.” The company’s decision continues to have repercussions as 15,000 Americans still die of HCV each year. Presently Gilead is facing [another lawsuit](#) for its decision to delay, for years, research into a newer form of tenofovir (TAF) for the treatment of HIV in order to maximize profits; in 2018 the [company’s own modeling](#) concluded that delaying access to TAF could lead to 16,200 additional deaths and over 150,000 additional injuries over a nine year period for people living with HIV.

The *United States v. Gilead* case is a crucial opportunity to finally hold Gilead responsible for its corporate culture of exploitation and abuse. We cannot allow Gilead to once again buy its way out of accountability.

The government must continue to press its case on behalf of the American people, including an appeal (as necessary). We demand that Gilead pay for years of infringement of publicly owned patents, for years of profiteering on PrEP, and for the toll its profiteering has taken on the health of the American public.

Sincerely,



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Organizations:

Beta Cell Action

VOCAL-NY

UFC-NYC

Health Care Voices

Freedom Oklahoma

Prism Health North Texas

AIDS Foundation Chicago

AIDS Action Baltimore

CAEAR Coalition

International Planned Parenthood Federation - IPPF

Proactive Community Services

Chicago Women's AIDS Project

African American Office of Gay Concerns

Five Horizons Health Services

The Democracy Collaborative

Doctors for America

Public Citizen

Caracole Inc.

Interior AIDS Association

T1International USA

Treatment Action Group (TAG)

Oneheart Foundation

LIAN

UCSF

Safer Together

HIV + Aging Research Project--Palm Springs

GPS INVESTMENTS

Let's Kick ASS Palm Springs (AIDS Survivor Syndrome)

ICHANGE

Nola Safe And Sound Project

NAHEWD (National Alliance for HIV Education and Workforce)

LAAN

CC (*via email*):

Executive Officials:

The Honorable Admiral Rachel Levine, Assistant Secretary for Health, Department of Health and Human Services

The Honorable Kaye Hayes, Director, Office of Infectious Disease and HIV/AIDS Policy

The Honorable Rochelle Walensky, Director, Centers for Disease Control and Prevention

The Honorable Harold Phillips, Director, Office of National AIDS Policy

The Honorable Dr. Jonathan Mermin, Director, National Center for HIV, Viral Hepatitis, STD, and TB Prevention

The Honorable Dr. Demetre Daskalkis, Director, Division of HIV/AIDS Prevention

The Honorable Dr. Robyn Neblett Fanfair, Acting Director, Division of HIV/AIDS Prevention

The Honorable Maura Calsyn, Deputy Assistant Secretary for Health Policy, Office of the Assistant Secretary for Health

The Honorable Samuel Bagenstos, General Counsel, Department of Health and Human Services

The Honorable Michael Kades, Deputy Assistant Attorney General, Department of Justice

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