

PrEP Justice

Updates on the
US v. Gilead Case

and the Fight for Equitable PrEP Access

JULY 17, 2024

12:00 PM ET - 1:15 PM ET

Join The Choice Agenda and PrEP4All to discuss the origin of US v. Gilead, the reasons for the government appeal, and what the case means for PrEP users in the United States.

Moderator:

Michael Chancley,
Communications and
Mobilization Manager,
PrEP4All

Speakers:

Chris Morten,
Columbia Law School
Jeremiah Johnson,
Executive Director,
PrEP4All



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for advocacy on the latest



HIV prevention research - a new forum
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avac.org/project/choice-agenda



Today's playlist

Why?

Bronski Beat

Somebody Save Me

Eminem & Jelly Roll

Mamushi

Megan Thee Stallion feat: Yuki Chiba

Got to Give it Up

Marvin Gaye



Columbia
Law School

Science, Health & Information Clinic

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Roadmap

1. Quick introduction, Part 1: Theory and goals of *United States v. Gilead*
2. Quick introduction, Part 2: Why the appeal matters
3. History of *United States v. Gilead*: How we got here
4. The appeal ahead: What to expect
5. Reconnecting the HIV/AIDS community: How to get involved

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Who Owns H.I.V.-Prevention Drugs? The Taxpayers, U.S. Says

In an unexpected lawsuit, federal officials claim that Gilead Sciences willfully disregarded government patents on medicines necessary to end the AIDS epidemic.

The Justice Department, which filed the suit on behalf of the Department of Health and Human Services, could seek billions of dollars in royalties, not only on previous sales of Truvada but also on future sales of Descovy.

Alternatively, the government could use the suit as leverage to force Gilead to lower the price of Descovy as part of any settlement.

NATIONAL PREP PROGRAM

Our goal has always been the same: create a National PrEP Program to make HIV prevention medication accessible to everyone who needs it.



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Alleged Price Gouging of PrEP Investigated by Justice Dept., Senate

PrEP4All, a coalition of activist groups, has **sent its own letter** to the CDC demanding action. Fewer than 10 percent of the people who need PrEP are using it, largely due to the cost, the coalition said.

"The CDC must license its patents protecting the use of Truvada as PrEP for maximum access and competition to benefit people living in the United States," the group wrote. "Any licensing agreement must require that Gilead dramatically reduce the price of Truvada, provide the drug at cost to public health programs, provide high quality data regarding PrEP utilization, and utilize royalty revenue for a National PrEP Access Program. This program must explicitly focus on increasing access in communities where PrEP is underutilized, including but not limited to communities of color and communities in the South, and fund existing community health centers providing HIV prevention services."

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U.S. Loses Key Case on Rights to H.I.V.-Prevention Drugs

A jury sided with Gilead Sciences in a dispute over whether the government could claim a share of profits from drugs seen as crucial to ending the H.I.V. epidemic.



By [Rebecca Robbins](#)

Rebecca Robbins reported from federal court in Wilmington, Del.

May 9, 2023

STAT

Biotech Pharma Public Health Health Tech Policy Science

PHARMALOT

Biden administration appeals jury finding in battle over patents for HIV prevention pills



By [Ed Silverman](#) July 8, 2024

PHARMALOT

Biden administration appeals jury finding in battle over patents for HIV prevention pills



By [Ed Silverman](#)  July 8, 2024

The Biden administration has [appealed a decision](#) in which a federal court jury last year [sided](#) with Gilead Sciences over the rights to a pair of groundbreaking HIV pills — and at least \$1 billion in royalties may be at stake.

At issue is a battle over patents for Truvada and a newer, upgraded version called Descovy — two highly effective and lucrative medications — as well as the role played by the federal government in making it possible to prevent transmission of a highly infectious disease that plagued the American public for decades.

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Prevention of Rectal SHIV Transmission in Macaques by Daily or Intermittent Prophylaxis with Emtricitabine and Tenofovir

J. Gerardo García-Lerma^{1*}, Ron A. Otten¹, Shoukat H. Qari¹, Eddie Jackson², Mian-er Cong¹, Silvina Masciotra¹, Wei Luo¹, Caryn Kim¹, Debra R. Adams¹, Michael Monsour¹, Jonathan Lipscomb¹, Jeffrey A. Johnson¹, David Delinsky³, Raymond F. Schinazi³, Robert Janssen¹, Thomas M. Folks¹, Walid Heneine^{1*}

¹ Division of HIV/AIDS Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention, Atlanta, Georgia, United States of America, ² Division of Scientific Resources, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, Atlanta, Georgia, United States of America, ³ Emory University School of Medicine, Atlanta, Georgia, United States of America

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812

DECEMBER 30, 2010

VOL. 363 NO. 27

Preexposure Chemoprophylaxis for HIV Prevention in Men Who Have Sex with Men

CONCLUSIONS

Oral FTC–TDF provided protection against the acquisition of HIV infection among the subjects. Detectable blood levels strongly correlated with the prophylactic effect.

BUSINESS

An HIV treatment cost taxpayers millions. The government patented it. But a pharma giant is making billions.



By [Christopher Rowland](#)

March 26, 2019 at 7:26 p.m. EDT

The Washington Post
Democracy Dies in Darkness

“Activists want the government to take a more aggressive stance against Gilead. Their complaints are part of a broader wave of anger over drug companies reaping hefty financial rewards by capitalizing on taxpayer-funded research. ‘The CDC has all these patents and is allowing Gilead to rip off the American people at the expense of public health,’ said James Krellenstein, an HIV/AIDS activist and co-founder of the PrEP4All Collaboration, who has spent months digging into the government patents. Instead of enforcing the patent, Krellenstein said, CDC officials are ‘twiddling their thumbs.’”

The Washington Post

Business

Gilead defied a government HIV patent. The Justice Department has opened a review.

By [Christopher Rowland](#)

April 24



Alleged Price Gouging of PrEP Investigated by Justice Dept., Senate



GETTY IMAGE

The call for action comes because the government developed the use of Truvada as PrEP but Gilead Sciences is making all the money from it.

BY TRUDY RING

APRIL 24 2019 3:19 PM EST



Alleged Price Gouging of PrEP Investigated by Justice Dept., Senate



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BY TRUDY RING

APRIL 24 2019 3:19 PM EST



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HIV Prevention Drug: Billions in Corporate Profits after Millions in Taxpayer Investments

Meeting Status: [Schedule](#) | [Hearing](#)
d

Date: Thu, 05/16/2019 - 10:00 AM

Location: Capitol Complex, 2154 RHOB, Washington, DC, 20515, USA



PRESS RELEASE

United States Files Complaint against Pharmaceutical Company Gilead for Patent Infringement Related to Truvada[®] and Descovy[®] For Pre- Exposure Prophylaxis of HIV

Thursday, November 7, 2019

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For Immediate Release

Office of Public Affairs

PRESS RELEASE

United States Files Complaint against Pharmaceutical Company Gilead for

“Gilead has received billions of dollars in revenue from HIV prevention regimens invented by HHS researchers and patented by the United States,” said Assistant Attorney General Jody Hunt of the Department of Justice’s Civil Division. “This lawsuit demonstrates the Department’s commitment to protect the government’s intellectual property and hold accountable those who seek to unfairly gain from the government’s research without paying reasonable royalties as the law requires.”

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Office of Public Affairs



By Rebecca Robbins

Rebecca Robbins reported from federal court in Wilmington, Del.

May 9, 2023

U.S. Loses Key Case on Rights to H.I.V.-Prevention Drugs

A jury sided with Gilead Sciences in a dispute over whether the government could claim a share of profits from drugs seen as crucial to ending the H.I.V. epidemic.

But the jury found that Gilead had not violated any of those patents and that they were invalid. The government had been seeking more than \$1 billion in damages from Gilead, equivalent to the C.D.C.'s [annual budget for preventing H.I.V.](#) in the United States.

Jeremiah Johnson, executive director of the advocacy organization PrEP4All, on Tuesday urged the government to appeal the verdict, saying that it risked “encouraging other drug companies to privatize and profit from publicly developed technology with impunity.”

25

Q. **And if the United States were to prevail in this case**

151

Mermin - cross

1 **and the jury awarded damages for infringement, what would**
2 **CDC do with the funds?**

3 A. **We will do exactly that, we would put it back into**
4 **our programs, our research, and try to implement strategies**
5 **that improves the nation's health.**

Jonathan Mermin, MD, MPH, (RADM, USPHS, RET) is the Director of the National Center for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), and a retired two-star Rear Admiral in the U.S. Public Health Service.



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.

March 25, 2024, 4:10 PM EDT

Gilead Win on US HIV-Drug Patents Survives, But New Risk Rises



Christopher Yasiejko

Senior correspondent



A federal judge mostly upheld Gilead Sciences Inc.'s 2023 trial win in which the US sought \$1 billion from the bioscience giant for allegedly using joint research to develop an HIV-prevention drug regimen without compensation.

Judge Maryellen Noreika granted the government's [renewed request](#) for a judgment that Truvada and Descovy directly infringe three of its patents, but she left intact jurors' findings that the patents are invalid, according to an [opinion](#) issued March 22 in the US District Court for the District of Delaware. The ruling sets the stage for any potential appeals of a verdict [Gilead won](#) last May.

Documents

- [Opinion](#)
- [US v. Gilead Sciences Inc. \(D. Del., 19-cv-2103\)](#)

Bloomberg Law[®]

PHARMALOT

Biden administration appeals jury finding in battle over patents for HIV prevention pills



By [Ed Silverman](#)  July 8, 2024

The Biden administration has [appealed a decision](#) in which a federal court jury last year [sided](#) with Gilead Sciences over the rights to a pair of groundbreaking HIV pills — and at least \$1 billion in royalties may be at stake.

At issue is a battle over patents for Truvada and a newer, upgraded version called Descovy — two highly effective and lucrative medications — as well as the role played by the federal government in making it possible to prevent transmission of a highly infectious disease that plagued the American public for decades.

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07/12/2024 [1](#) Appeal docketed. Received: 07/08/2024. [1017360]
Entry of Appearance due 07/26/2024. Certificate of Interest is due on 07/26/2024. Docketing Statement due 08/12/2024. Appellant's brief is due 09/10/2024. [MMA] [Entered: 07/12/2024 12:40 PM]



“This has been an unprecedented, landmark case from the very beginning and the government’s appeal opens an important new chapter,” said Christopher Morten, an associate clinical professor at Columbia Law School who directs the Science, Health & Information Clinic, and works with AIDS activists monitoring the case.

“Last year’s jury trial went well for Gilead and badly for the government. But, earlier this year, the government won a major victory on infringement. Now, the only thing standing between the government and a new trial is this appeal on patent validity. If the government wins this appeal, it could very well win in a new trial and win the entire case... The stakes remain as high as ever.”

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Community Stakes in US v. Gilead

Jeremiah Johnson
Executive Director
PrEP4All



A Brief History of Advocacy in US v. Gilead

- **July 16, 2018**– NYTimes op-ed by Krellenstein, Lord, Staley: [Why Don't More Americans Use PrEP?](#)
- **March 12, 2019**– Yale Global Health Justice Partnership's Statement on CDC Patents
- **March 26, 2019**– Washington Post article: [An HIV treatment cost taxpayers millions. The government patented it. But a pharma giant is making billions.](#)
- **May 16, 2019**– House Committee on Oversight and Reform hearing including Gilead CEO Daniel O'Day, PrEP4All co-founder Aaron Lord. [WaPo piece](#) mentions the role activists played in unearthing the patents in 2018
- **June 2019**– Senator Stabenow (MI) and the late Rep. Elijah Cummings (MD) asked GAO to investigate why HHS had not enforced its patents against Gilead
- **August 2019**– [Financial Times](#) estimates that the gov't could reasonably claim \$1B in back royalties. If Gilead's infringement was "willful," it could trigger a provision for enhanced damages- \$3B.



A Brief History of Advocacy in US v. Gilead

- **November 7, 2019**– USG (DOJ on behalf of HHS Secretary Alex M. Azar II) sues Gilead for infringing on patents. [PrEP4All issues a statement](#) calling for funds to be invested in National PrEP Program
- **November 8, 2019**– NYTimes covers the story with quotes from PrEP4All
<https://www.nytimes.com/2019/11/08/health/hiv-prevention-truvada-patents.html#>
- **January 20, 2022**– [PrEP4All sends a sign on letter calling for updates from DOJ](#). 25 organizations call once again for funding to be invested in a National PrEP Program.
- **May 9, 2023**– Jury issues a verdict against the government, saying the patents are invalid and infringement did not occur.
- **May 30, 2023**– PrEP4All, the Public Interest Patent Law Institute, Columbia Law School and 32 organizations press DOJ to keep fighting. [Letter to DOJ and HHS](#)



A brief reminder of Gilead's wealth

- **Gilead makes enormous profit on PrEP** with a gross margin of over 97% on PrEP. Company financial records indicated a 43.3% operating margin on all products between 2015 and 2023 “much higher than generic companies.” (D.Del., Jury Trial Transcript (Day 5), P. 1277).
- Between 2012 and 2021 Gilead made total revenue of \$35.6B for both Truvada and Descovy (D.Del., D.I. 446-19 (Ex. F to Exhibit 9D.2). **\$10B was for PrEP between 2015 and 2021.** (Fed. Cl., D.I. 172, P.13; Fed. Cl., D.I. 142, P.68)
- Paying a **4% royalty they would keep \$8.27B**, with a **10% royalty they would keep \$7.67B**. Gilead is already doing this for other products. CDC already makes generic companies pay royalties in other contexts. (D.Del., Jury Trial Transcript (Day 5), P. 1280).
- Government damages expert says Gilead spent **just 4.9% to 10.6% of its profit between 2011 and 2020 on reinvestment for R&D** (D.Del., Jury Trial Transcript (Day 5), P. 1279). In 2017 the LA Times noted that in 2016 effectively 100% of Gilead's profits went into stock buybacks and dividends.

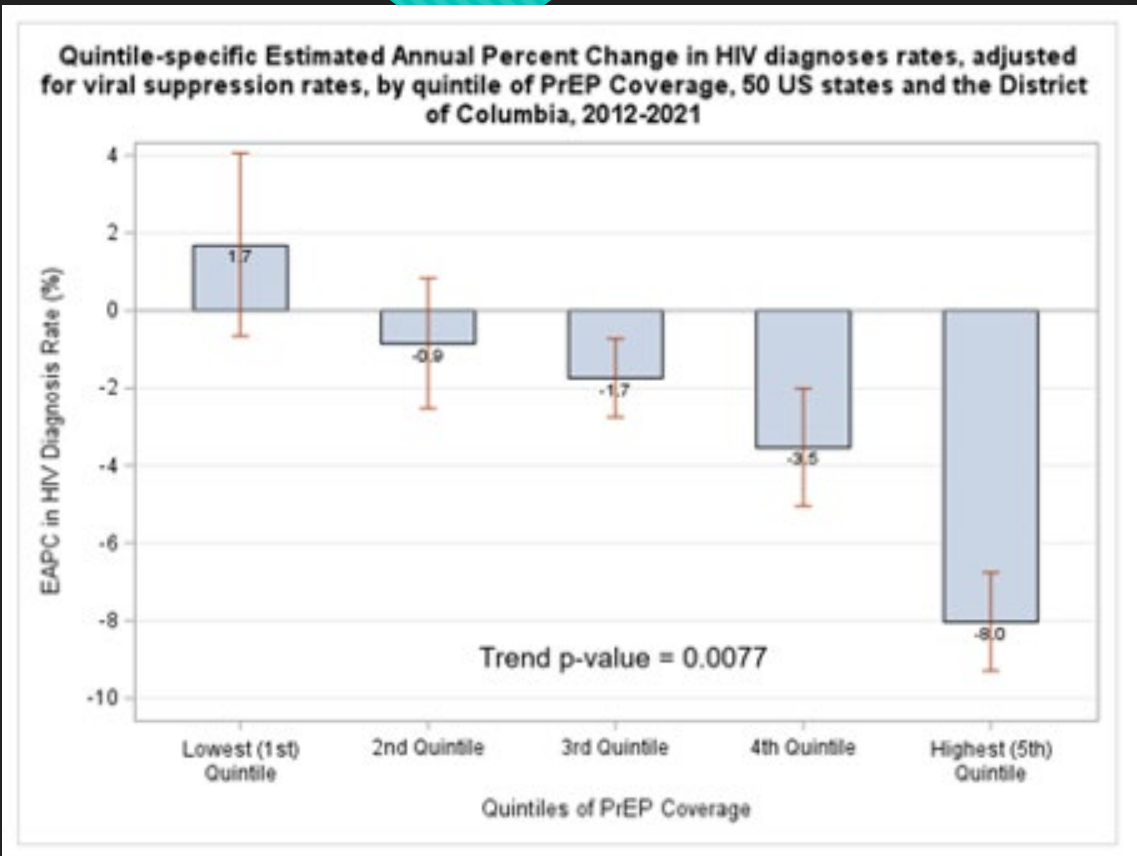


A brief reminder of Gilead's resistance to champion PrEP

- Estimate that Gilead contributed **a mere \$1.7M to original CDC PrEP research** based on manufacturing cost (*Fed. Cl., D.I. 142, P. 68*). Recent estimates have shown that the **government invested at least \$143M in PrEP research**. Gilead's refusal to do PrEP research impeded progress. (*Fed. Cl., D.I. 128, P. 1577*).
- FDA had to pressure Gilead to apply for the PrEP indication; told Gilead they were **unethically harming patients for not seeking an indication**. (*Fed. Cl., D.I. 117, P. 105*)
- Gregg Alton, Gilead's former Chief Patent Officer said Gilead **resisted promoting PrEP** to not "interfere with commercial business on treatment. (*Fed. Cl., D.I. 117, P. 113; Fed. Cl., DTX-37, P.13*). Government testimony that an unnamed Gilead employee had said Gilead did not want to promote a drug associated with "unprotected anal sex." (*Fed. Cl., D.I. 126, P. 1179*).
- Started to promote once the company saw a commercial opportunity but laments that the "treatment market...grew at a slower rate." (*Fed. Cl., DTX-50, P.40*).
- Testimony showing Gilead **putting pressure on government officials** over the case; saying that the dispute could have "negative consequences for industry government collaboration." (*Fed. Cl., PX-357*)



What are the Stakes for PrEP Access?



Funds from *US v. Gilead* could and should be used to get us back on track for equitable PrEP access:

- Enormous disparities in PrEP access that Gilead's pricing has directly contributed to
- Very behind on reaching 2030 Ending the HIV Epidemic targets
- Fewer resources for HIV/AIDS (enormous cuts proposed by House Republicans for FY24 and FY25; reduced 340B reimbursements from Gilead)
- Failure of Gilead's 2019 "donation" to the US government
- Need better infrastructure for PrEP and other key interventions for HIV negative communities



Investing in a National PrEP Program



- President Biden and community advocates have called for a National PrEP Program for un- and underinsured populations
 - Simple, comprehensive access to generic PrEP, labs, and provider visits w/o cost sharing
 - Expansion of community access points, including via telePrEP
 - Community-driven awareness/demand creation campaigns
- Funds can immediately go toward efforts to build a foundation
 - Creation of a comprehensive federal *PrEP Pass*
 - Investment in pilot initiative in a subset of jurisdictions
- Infrastructure that can set the stage for equitable access to long acting injectables, other key interventions for marginalized communities (doxy PEP, mpox vaccination, syphilis treatment, etc.)



Stay Involved

- Sign up at www.prep4all.org for our email list
- Donate: www.prep4all.org/donate
- For media, ideas on elevating awareness of the case, and other inquiries email Jeremiah@prep4all.org and Michael@prep4all.org

