PrEP in 2019

News You Can Use

NCHTEC

North Carolina HIV Training & Education Center
at the UNC School of Medicine

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Site PI, Ryan White HIV/AIDS Program Part D, UNC ID Clinic
Co-Leader, UNC CFAR PrEP Scientific Working Group

Institute for Global Health & Infectious Diseases
University of North Carolina at Chapel Hill
School of Medicine

As of 1 Oct 2018, Dr. Hurt serves as UNC site PI for a Gilead-funded study of PrEP (DISCOVER, comparing FTC/TAF vs FTC/TDF).

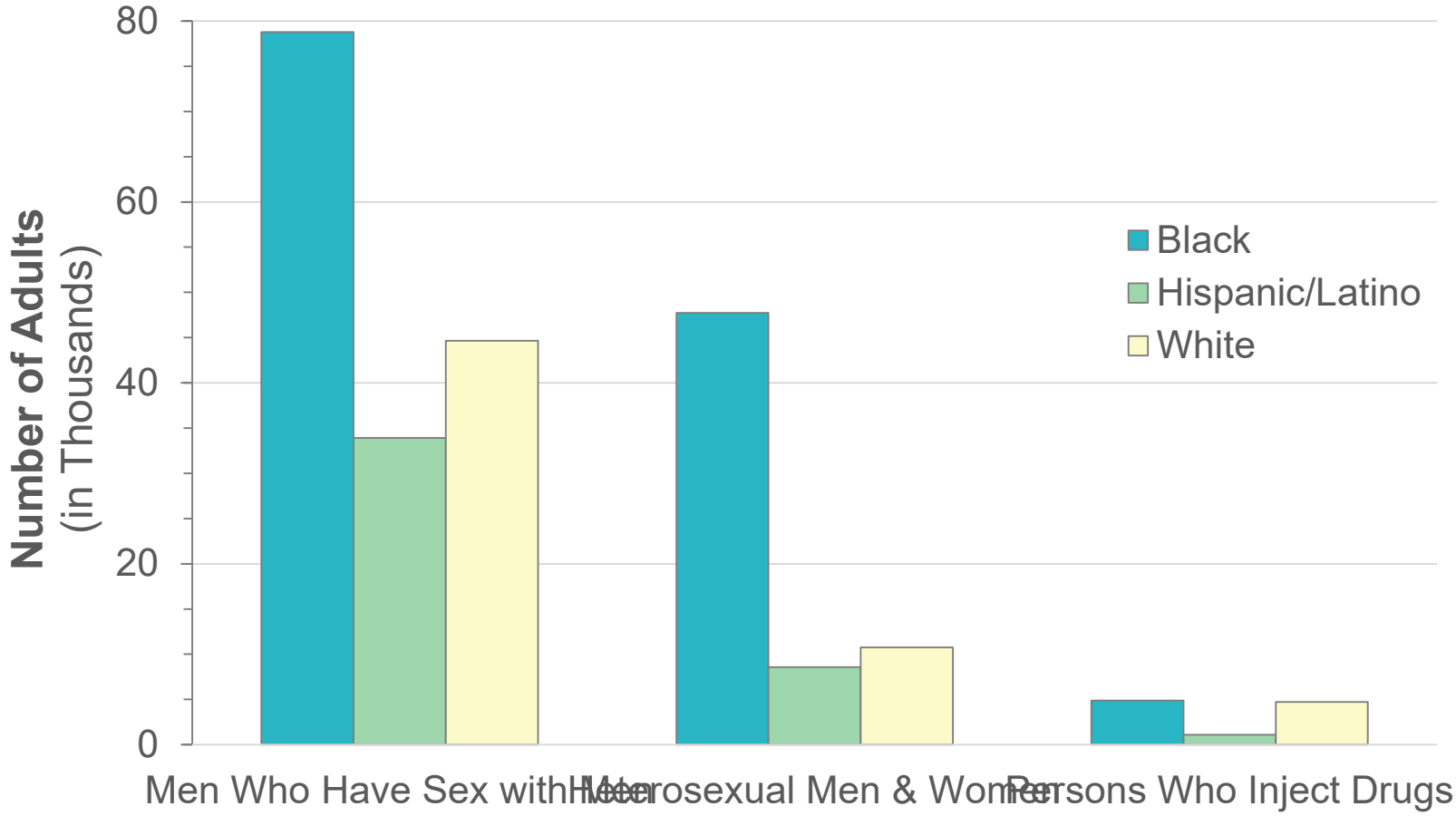
Dr. Hurt is supported by the Centers for Disease Control and Prevention (ELC-2017-J3), Health Resources and Services Administration (U1OHA30535), Eunice Kennedy Shriver National Institute of Child Health & Human Development (U19HD089881), the National Institute on Drug Abuse (UG3DA044823), and the National Institute of Allergy and Infectious Diseases (P30AI50410, UM1AI069423, UM1AI068619).

The views expressed are not necessarily those of CDC, HRSA, or the NIH.

Learning objectives

- Outline some of the new data on PrEP from scientific conferences in 2019
- Compare and contrast FTC/TDF and FTC/TAF for PrEP
- Discuss how HIV prevention advocates have approached issues related to pricing and availability of PrEP in the US
- Explain the controversy over patents for PrEP and the meaning of the Truvada lawsuits
- Describe the potential impact of the US Preventive Services Task Force's new recommendation for PrEP

How many adults across SE AETC states are candidates for PrEP?



As of 2015

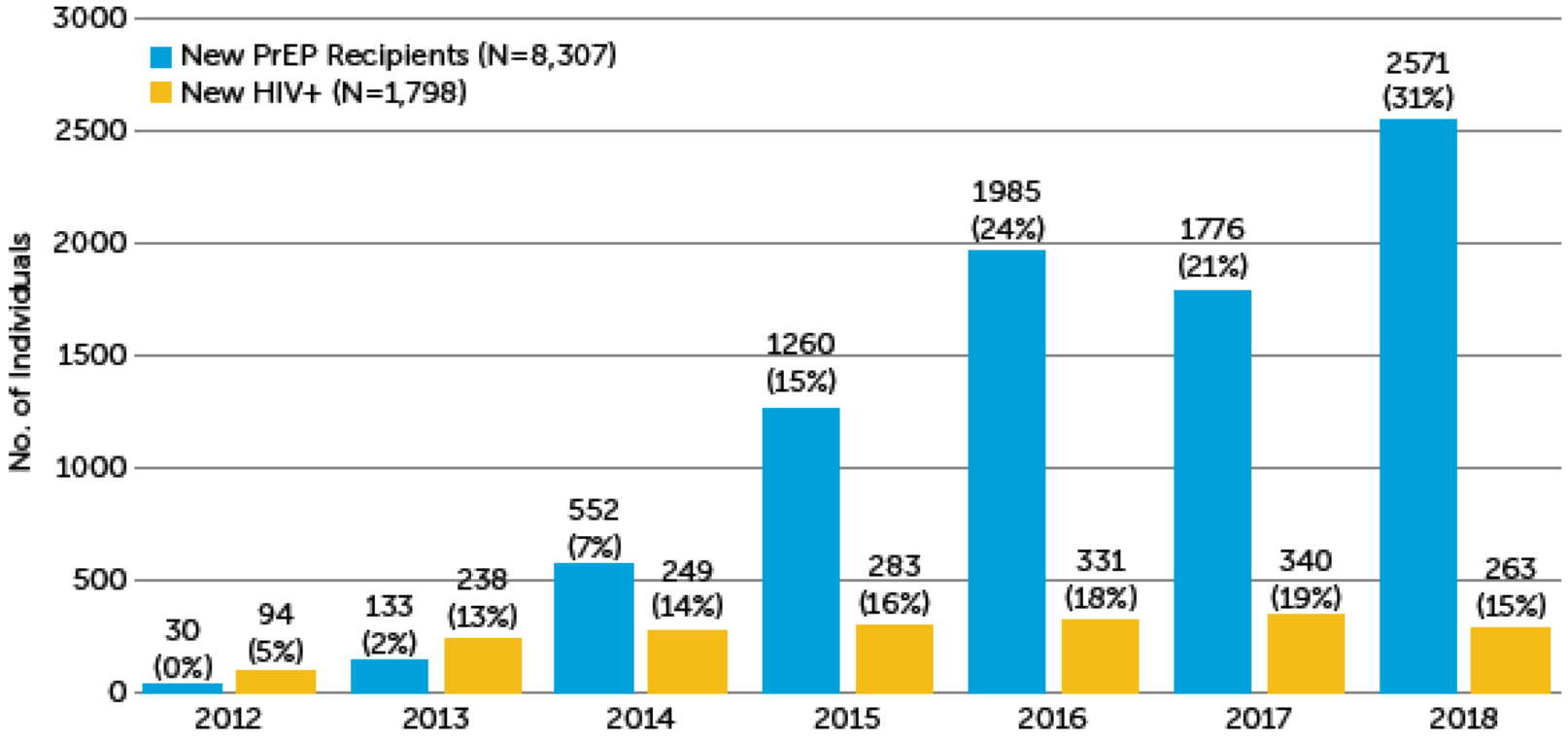
Smith DK et al., Annals of Epidemiology 28(12):850-857. 2018
Extracted data from Table 3 for AL, FL, GA, KY, MS, NC, SC, and TN

PrEP in the OPERA Cohort

Observational Pharmaco-Epidemiology Research & Analysis

OPERA®
The Longitudinal Cohort

Figure 1. Calendar year of PrEP initiation or HIV diagnosis



http://programme.ias2019.org/Abstract/Abstract/1387
http://www.natap.org/2019/IAS/IAS_111.htm

PrEP in the OPERA Cohort

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Table 2. Baseline demographic characteristics

		PrEP (n = 8,307)	New HIV+ (n = 1,798)
Age	Median (IQR)	33.1 (26.8, 42.9)	29.9 (25.1, 40.1)*
Sex	Female	538 (6.5%)	157 (8.7%)*
Gender	Transgender	96 (1.2%)	28 (1.6%)
Race†	Black	1488 (17.9%)	586 (32.6%)*
Ethnicity‡	Hispanic	1774 (21.4%)	619 (34.4%)*
Region**	Northeast	1934 (23.3%)	60 (3.3%)*
	South	3024 (36.4%)	1032 (57.4%)
	Midwest	146 (1.8%)	75 (4.2%)
	West	3203 (38.6%)	631 (35.1%)

*p-value <0.05

†Unknown race: 1081 PrEP recipients, 141 new HIV+; ‡Unknown ethnicity: 1185 PrEP, 43 new HIV+

**Northeast: CT, MA, ME, NH, NJ, NY, PA, RI, VT; South: AL, AR, DC, DE, FL, GA, KY, LA, MD, MS, NC, OK, SC, TN, TX, VA, WV; Midwest: IA, IL, IN, KS, MI, MN, MO, ND, NE, OH, SD, WI; West: AK, AZ, CA, CO, HI, ID, MT, NM, MT, OR, UT, WA, WY

- 59% of PrEP initiators returned for a follow-up visit 60-120 days later; 11% never returned for follow-up
- 42% discontinued PrEP with median time to discontinuation 12 months (IQR 11, 19)

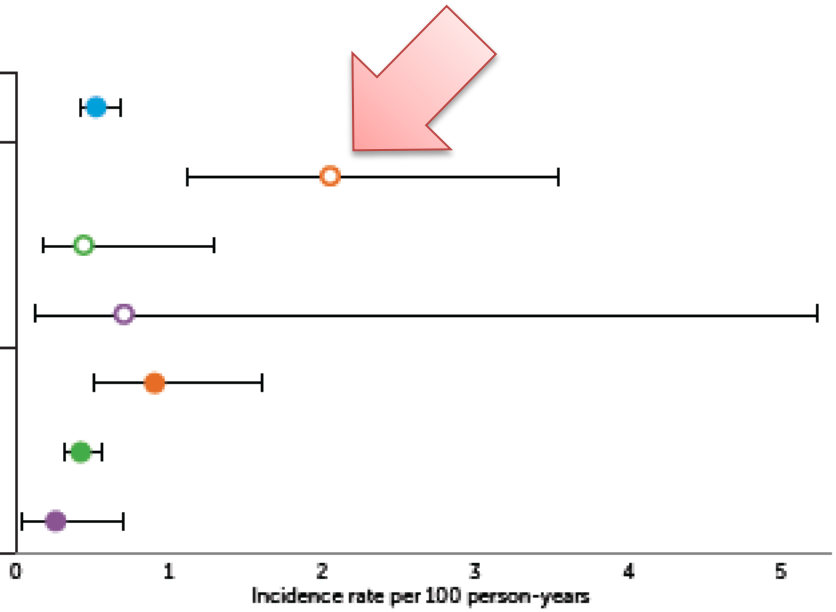
PrEP in the OPERA Cohort

Observational Pharmaco-Epidemiology Research & Analysis

OPERA®
The Longitudinal Cohort

Figure 2. Incidence rates of new HIV infection among PrEP recipients (N=8,307)

		# HIV	Person-Years	IR (95% CI) per 100 py
	Overall	58	10711.1	0.54 (0.42, 0.70)
Black	13-25 y.o.	12	584	2.05 (1.17, 3.62)
Black	26-49 y.o.	4	846.1	0.47 (0.18, 1.26)
Black	>50 y.o.	1	134.8	0.74 (0.10, 5.26)
Non-Black	13-25 y.o.	11	1215.9	0.90 (0.50, 1.63)
Non-Black	26-49 y.o.	27	6637.9	0.41 (0.28, 0.59)
Non-Black	>50 y.o.	3	1292.3	0.23 (0.07, 0.72)



http://programme.ias2019.org/Abstract/Abstract/1387
http://www.natap.org/2019/IAS/IAS_111.htm

HIV incidence relatively high after stopping PrEP

986 starting PrEP in SF Primary Care Clinics,
7/2012 – 11/2018 (15 centers for publicly-insured & uninsured persons)

66%
MSM

12%
TGW

37%
White

8

HIV seroconversions

- 7 after stopping
- 1 on 2-1-1 PrEP

50%

didn't discuss stopping with their provider

http://programme.ias2019.org/Abstract/Abstract/1769 http://www.natap.org/2019/IAS/IAS_23.htm

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- 7 after stopping
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Themes among seroconverters:

- Adherence challenges due to housing, substance use, or mental health (7/8)
- Competing priorities given cost and effort (5/8)
- Difficulty assessing benefits and risks (5/8)
- Conflict with partners over trust/intimacy (3/8)

http://programme.ias2019.org/Abstract/Abstract/1769 http://www.natap.org/2019/IAS/IAS_23.htm

DISCOVER

RCT of FTC/TAF vs FTC/TDF

Sept 2016 – Sept 2020 (May 2019)

Adult MSM/TGW at high risk for HIV infection

(N = 5387)

5313 MSM

74 transgender women

FTC/TDF
with placebo FTC/TAF

FTC/TAF
with placebo FTC/TDF

92 sites across US, Canada, Europe

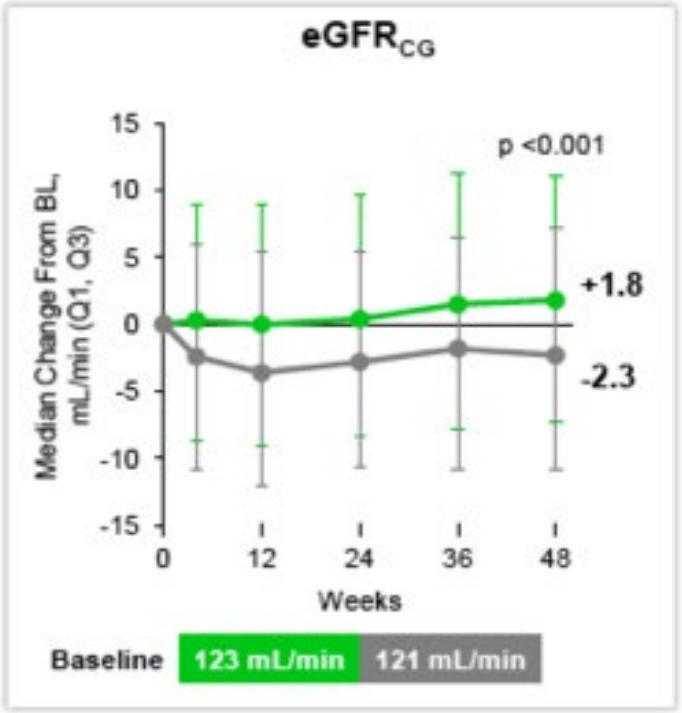
96 weeks of f/u planned w/**48 wk FTC/TAF open-label extension**

https://clinicaltrials.gov/ct2/show/NCT02842086

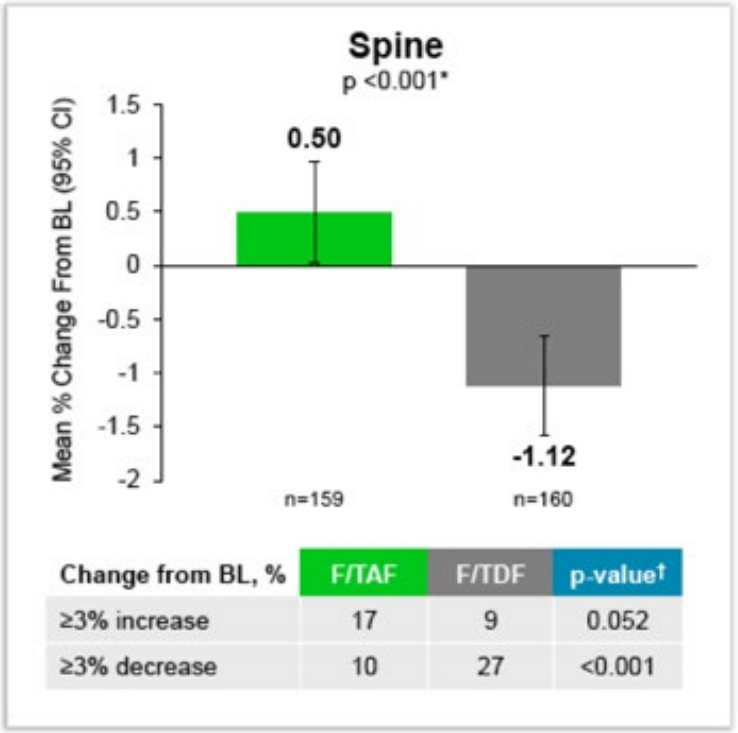
FTC/TAF had fewer kidney, bone issues…

emtricitabine /
tenofovir alafenamide

emtricitabine /
tenofovir disoproxil



F/TAF **F/TDF**



Change from BL, %	F/TAF	F/TDF	p-value†
≥3% increase	17	9	0.052
≥3% decrease	10	27	<0.001

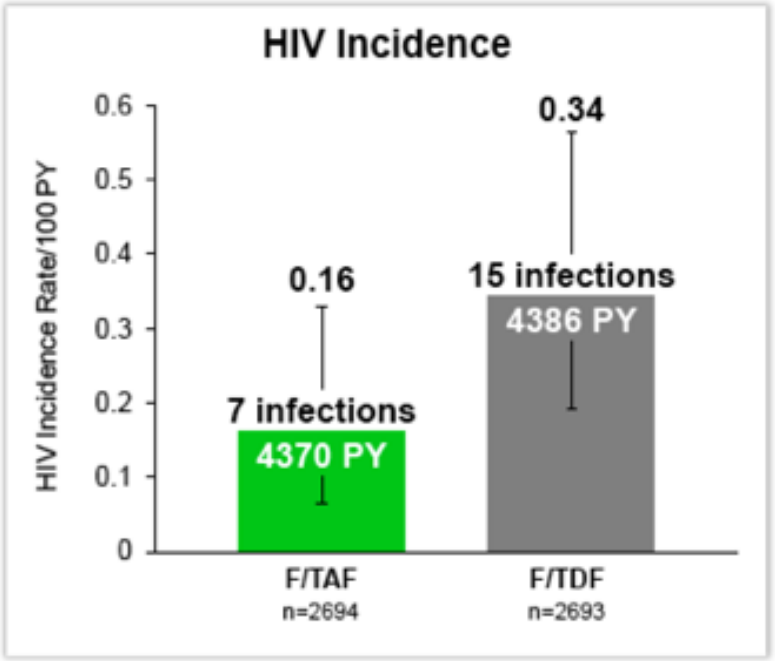
BMD
Baseline vs. Week 48

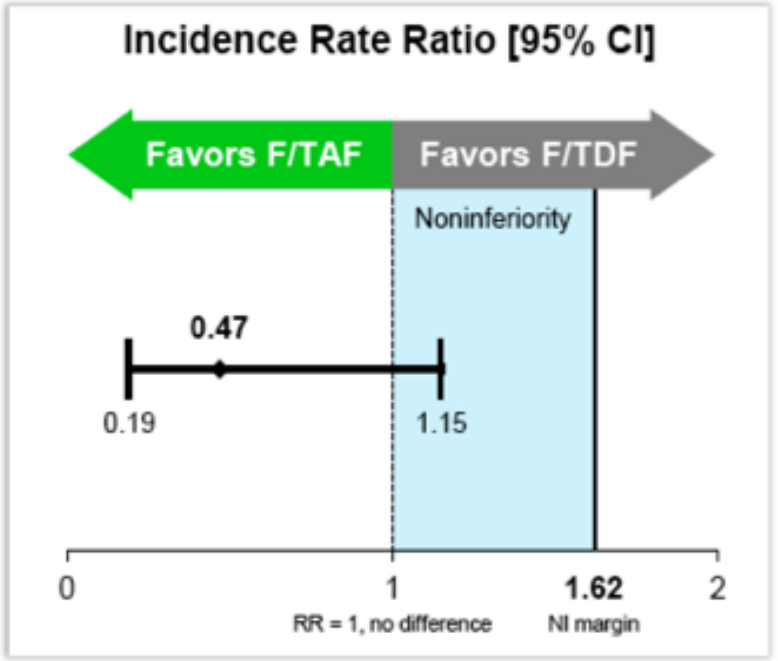
http://www.natap.org/2019/CROI/croi_21.htm

… and was non-inferior to FTC/TDF …

emtricitabine /
tenofovir alafenamide

emtricitabine /
tenofovir disoproxil



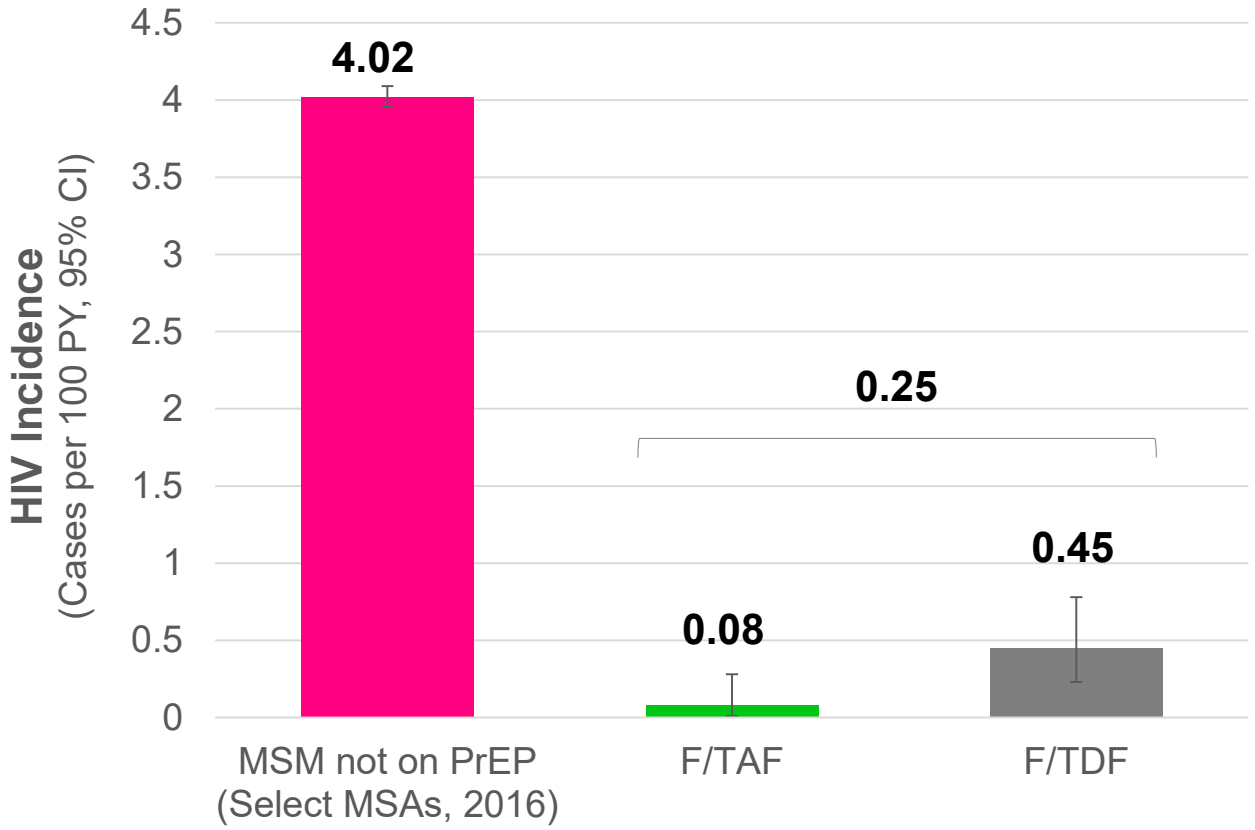


5313 MSM
74 transgender women

Hare B. et al. CROI 2019, abstract 104
http://www.natap.org/2019/CROI/croi_21.htm

… but there were comparatively few infections

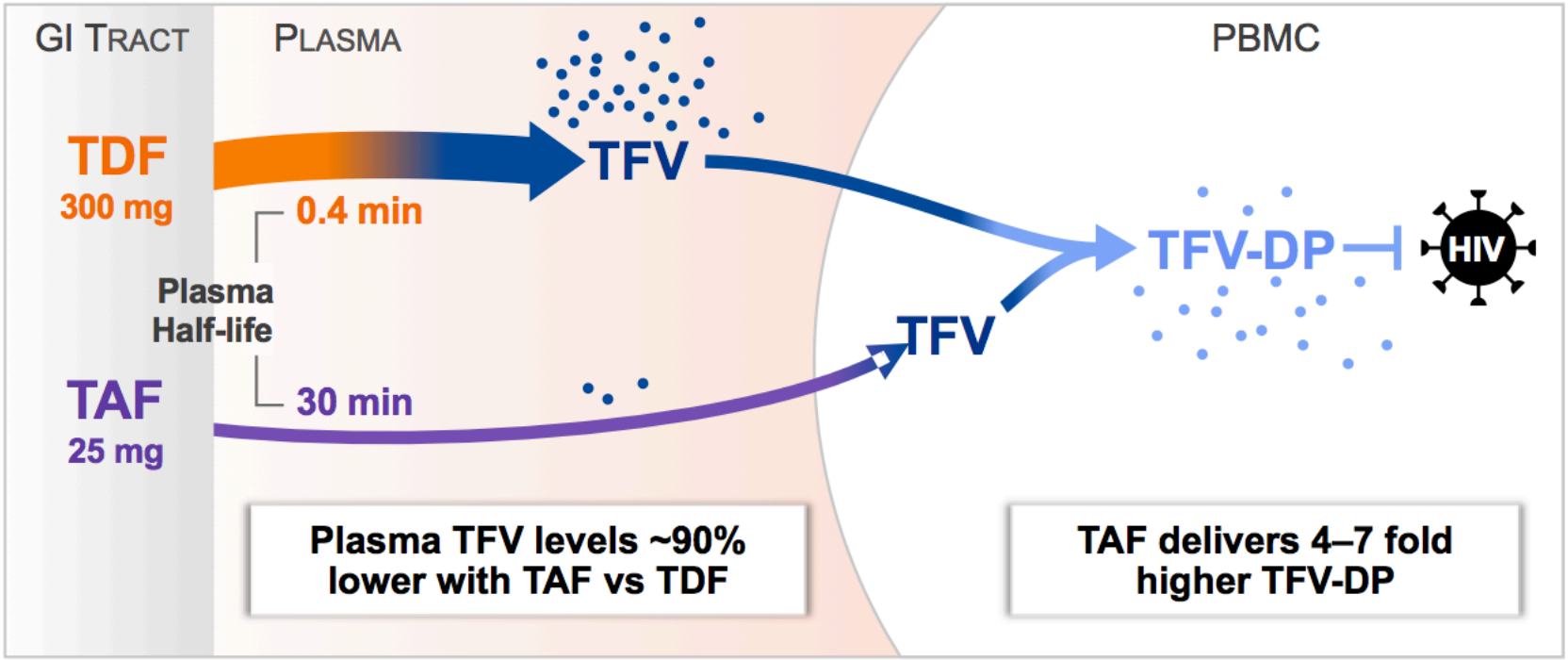
Comparison of HIV Incidence: MSM from Metropolitan Statistical Areas Overlapping DISCOVER Sites (2016) against Participants in DISCOVER



5313 MSM
74 transgender women

Hare B. et al. CROI 2019, abstract 104
http://www.natap.org/2019/CROI/croi_21.htm

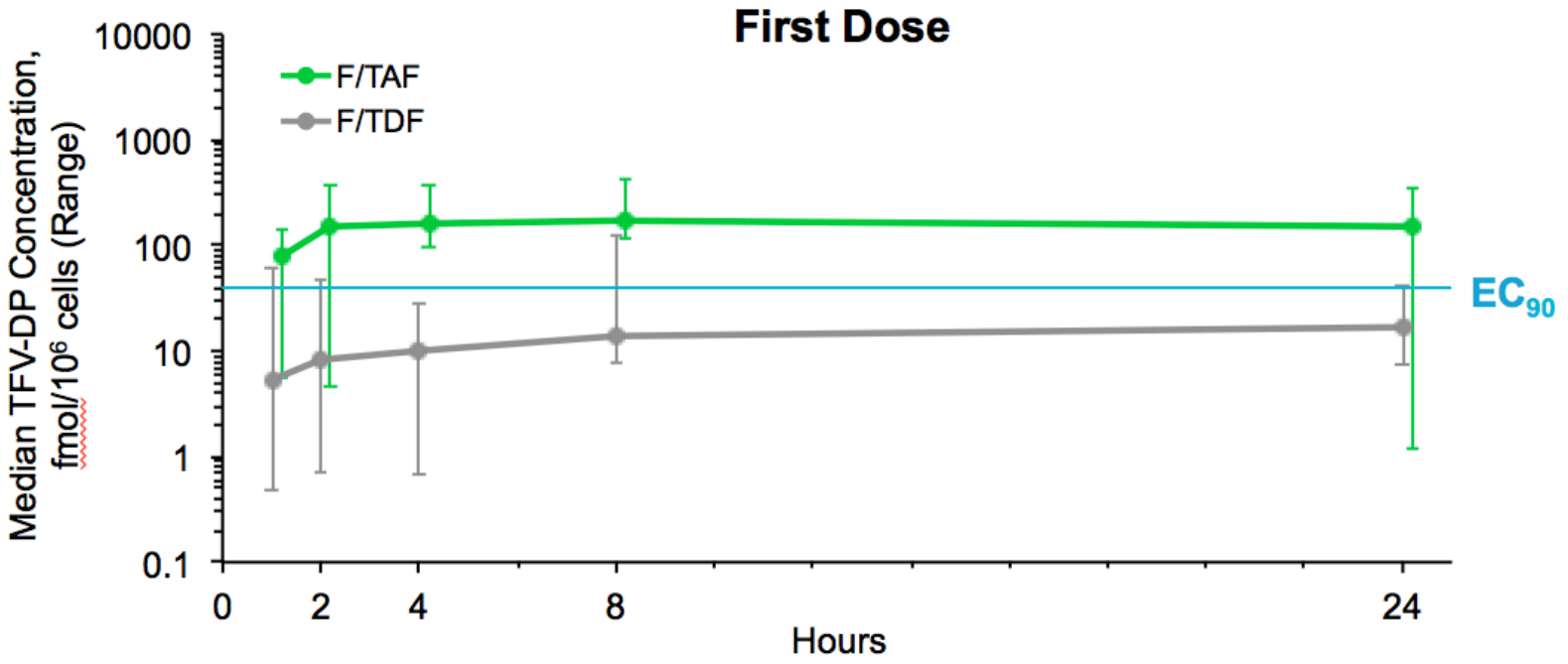
TAF has special pharmacological properties



GI, gastrointestinal.
Lee W, et al. Antimicr Agents Chemo 2005;49:1898-1906; Birkus G, et al. Antimicr Agents Chemo 2007;51:543-50; Babusis D, et al. Mol Pharm 2013;10:459-66; Ruane P, et al. J Acquir Immune Defic Syndr 2013; 63:449-5l; Sax P, et al. JAIDS 2014;67:52-8; Sax P, et al. Lancet 2015;385:2606-15.

http://programme.ias2019.org/Abstract/Abstract/4898
http://www.natap.org/2019/IAS/IAS_08.htm

More from DISCOVER: up to speed faster



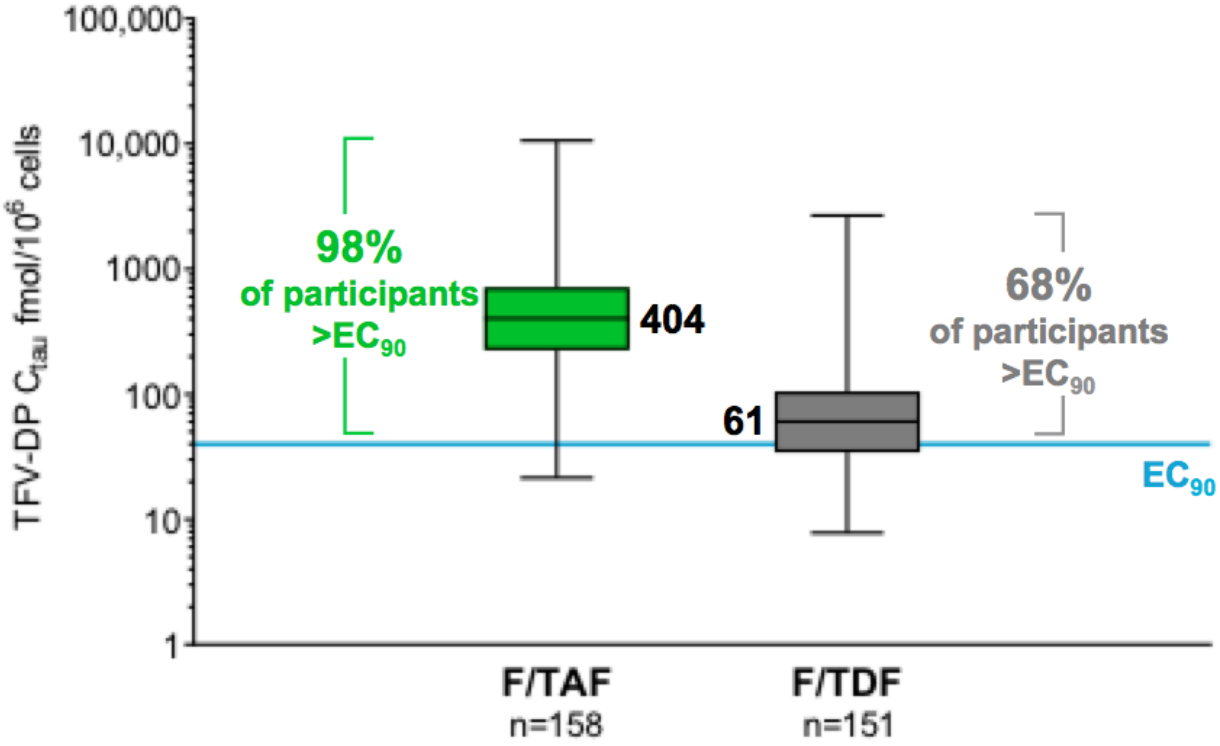
- With F/TAF, median TFV-DP concentrations exceeded EC_{90} within 1-2 h, all within 4 h, consistent with 2 prior studies[1-3]
- In contrast, 3 daily doses of F/TDF are needed to achieve EC_{90} in PBMCs[4]

EC_{90}, 90% effective concentration.

1. Schwartz JL, et al. R4P 2018.; 2. data on file; 3. Cottrell ML, et al. J Antimicrob Chemother 2017; 4. Anderson PL, et al. CROI 2012

http://programme.ias2019.org/Abstract/Abstract/4898
http://www.natap.org/2019/IAS/IAS_08.htm

More from DISCOVER: higher level over time



- Steady-state TFV-DP levels in PBMCs were 6.3-fold higher with F/TAF vs F/TDF

C_{tau}, concentration 20–28 h postdose. Box median, IQR, whiskers min, max

http://programme.ias2019.org/Abstract/Abstract/4898
http://www.natap.org/2019/IAS/IAS_08.htm

Affordability has become a clear issue

per month if paid
totally out-of-pocket

(excluding lab costs & provider fees)

Break the Patent → https://slate.com/human-interest/2018/05/act-up-is-challenging-gilead-to-make-truvada-more-accessible.html

TAF lawsuits → https://www.latimes.com/business/la-fi-gilead-hiv-drug-lawsuit-20180509-story.html
TAF patent → https://www.i-mak.org/wp-content/uploads/2018/12/Roadmap-SE-Report-on-TAF-2018-05-07F.pdf

2018

L to R: Cameron Kinker
(Prevention Access Campaign)
and two of PrEP4All's co-founders:
James Krellenstein & Nick Faust

THE PREP 4ALL COLLABORATON

#BREAKTHEPATENT

The drug Truvada has the ability to reduce the risk of HIV transmission by more than 99%, but it's being withheld from the American public because of the greed of its manufacturer.

Gilead Sciences has inflated the cost from $6 to more than $1,600 per month, despite the US taxpayer paying for almost the full cost of its development. If we could lower the price of the drug, we could end the HIV epidemic without a vaccine. **Drug companies have held the American people hostage for too long. Join the campaign to #BreakThePatent.**

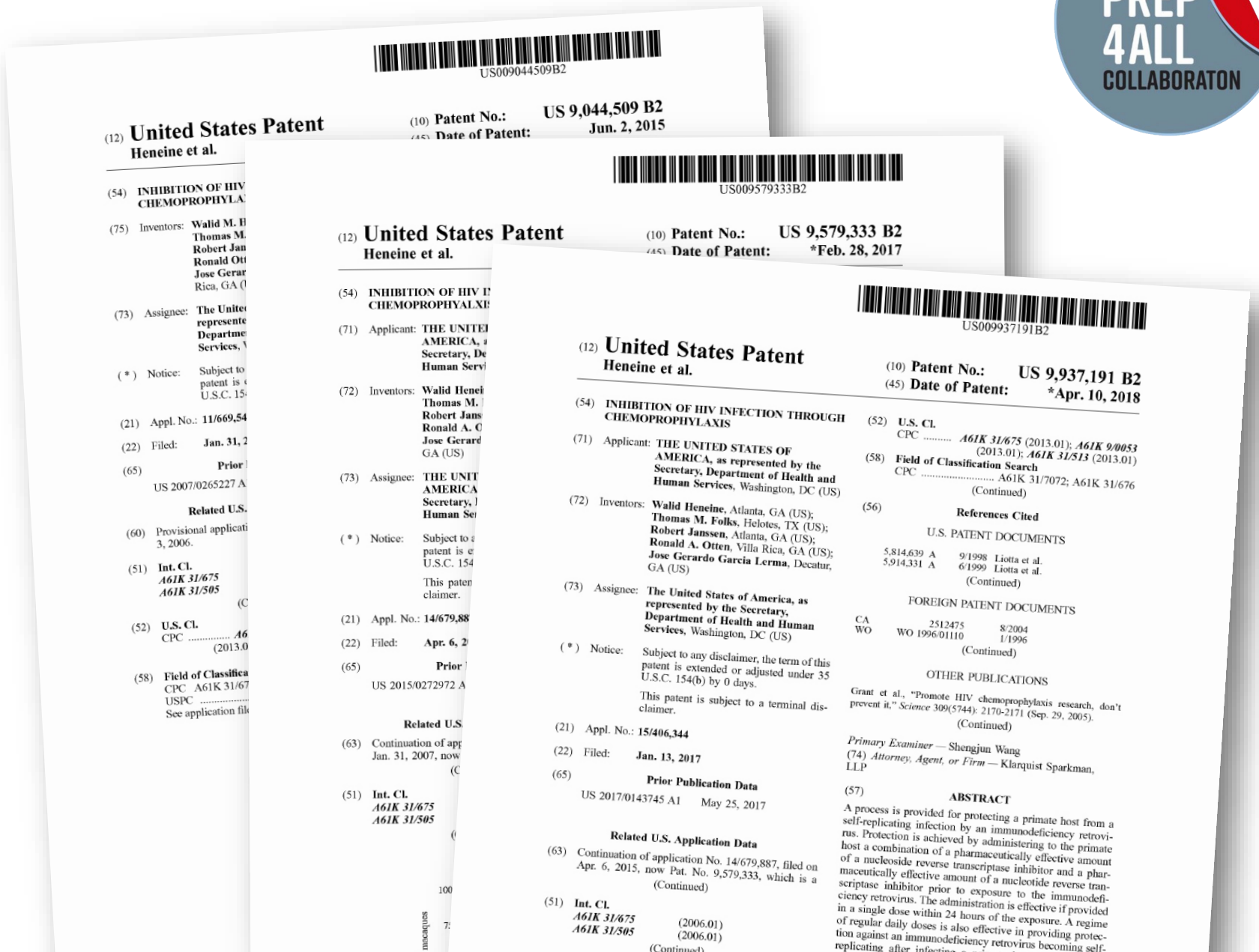
TAKE ACTION

HELP SPREAD THE WORD

SIGN THE PETITION TO #BREAKTHEPATENT
AND LOWER THE PRICE OF PREP

2018

THE PREP 4ALL COLLABORATON



US009044509B2

(12) **United States Patent**
Heneine et al.

(10) **Patent No.: US 9,044,509 B2**
(45) **Date of Patent: Jun. 2, 2015**

(54) INHIBITION OF HIV
CHEMOPROPHYLA

(75) Inventors: **Walid M. H**
Thomas M.
Robert Jan
Ronald Ott
Jose Gerar
Rica, GA (

(73) Assignee: **The Unite**
represente
Departme
Services,

(*) Notice: Subject to
patent is
U.S.C. 15

(21) Appl. No.: **11/669,54**

(22) Filed: **Jan. 31, 2**

(65) **Prior**
US 2007/0265227 A

Related U.S.

(60) Provisional applicati
3, 2006.

(51) **Int. Cl.**
A61K 31/675
A61K 31/505
(C

(52) **U.S. Cl.**
CPC ***A6***
(2013.0

(58) **Field of Classifica**
CPC A61K 31/67
USPC .....
See application fil

US009579333B2

(12) **United States Patent**
Heneine et al.

(10) **Patent No.: US 9,579,333 B2**
(45) **Date of Patent: *Feb. 28, 2017**

(54) INHIBITION OF HIV I
CHEMOPROPHYLAXIS

(71) Applicant: **THE UNITE**
AMERICA,
Secretary, De
Human Servi

(72) Inventors: **Walid Henei**
Thomas M.
Robert Jans
Ronald A. O
Jose Gerard
GA (US)

(73) Assignee: **THE UNIT**
AMERICA
Secretary,
Human Se

(*) Notice: Subject to
patent is e
U.S.C. 154

This paten
claimer.

(21) Appl. No.: **14/679,88**

(22) Filed: **Apr. 6, 2**

(65) **Prior**
US 2015/0272972 A

Related U.S.

(63) Continuation of app
Jan. 31, 2007, now
(C

(51) **Int. Cl.**
A61K 31/675
A61K 31/505
(

100

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macaques

US00937191B2

(12) **United States Patent**
Heneine et al.

(10) **Patent No.: US 9,937,191 B2**
(45) **Date of Patent: *Apr. 10, 2018**

(54) **INHIBITION OF HIV INFECTION THROUGH CHEMOPROPHYLAXIS**

(71) Applicant: **THE UNITED STATES OF AMERICA, as represented by the Secretary, Department of Health and Human Services**, Washington, DC (US)

(72) Inventors: **Walid Heneine**, Atlanta, GA (US); **Thomas M. Folks**, Helotes, TX (US); **Robert Janssen**, Atlanta, GA (US); **Ronald A. Otten**, Villa Rica, GA (US); **Jose Gerardo Garcia Lerma**, Decatur, GA (US)

(73) Assignee: **The United States of America, as represented by the Secretary, Department of Health and Human Services**, Washington, DC (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **15/406,344**

(22) Filed: **Jan. 13, 2017**

(65) **Prior Publication Data**
US 2017/0143745 A1 May 25, 2017

Related U.S. Application Data

(63) Continuation of application No. 14/679,887, filed on Apr. 6, 2015, now Pat. No. 9,579,333, which is a (Continued)

(51) **Int. Cl.**
A61K 31/675 (2006.01)
A61K 31/505 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ***A61K 31/675*** (2013.01); ***A61K 9/0053*** (2013.01); ***A61K 31/513*** (2013.01)

(58) **Field of Classification Search**
CPC A61K 31/7072; A61K 31/676
(Continued)

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5,914,331 A 6/1999 Liotta et al.
(Continued)

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CA 2512475 8/2004
WO WO 1996/01110 1/1996
(Continued)

OTHER PUBLICATIONS

Grant et al., "Promote HIV chemoprophylaxis research, don't prevent it," *Science* 309(5744): 2170-2171 (Sep. 29, 2005).
(Continued)

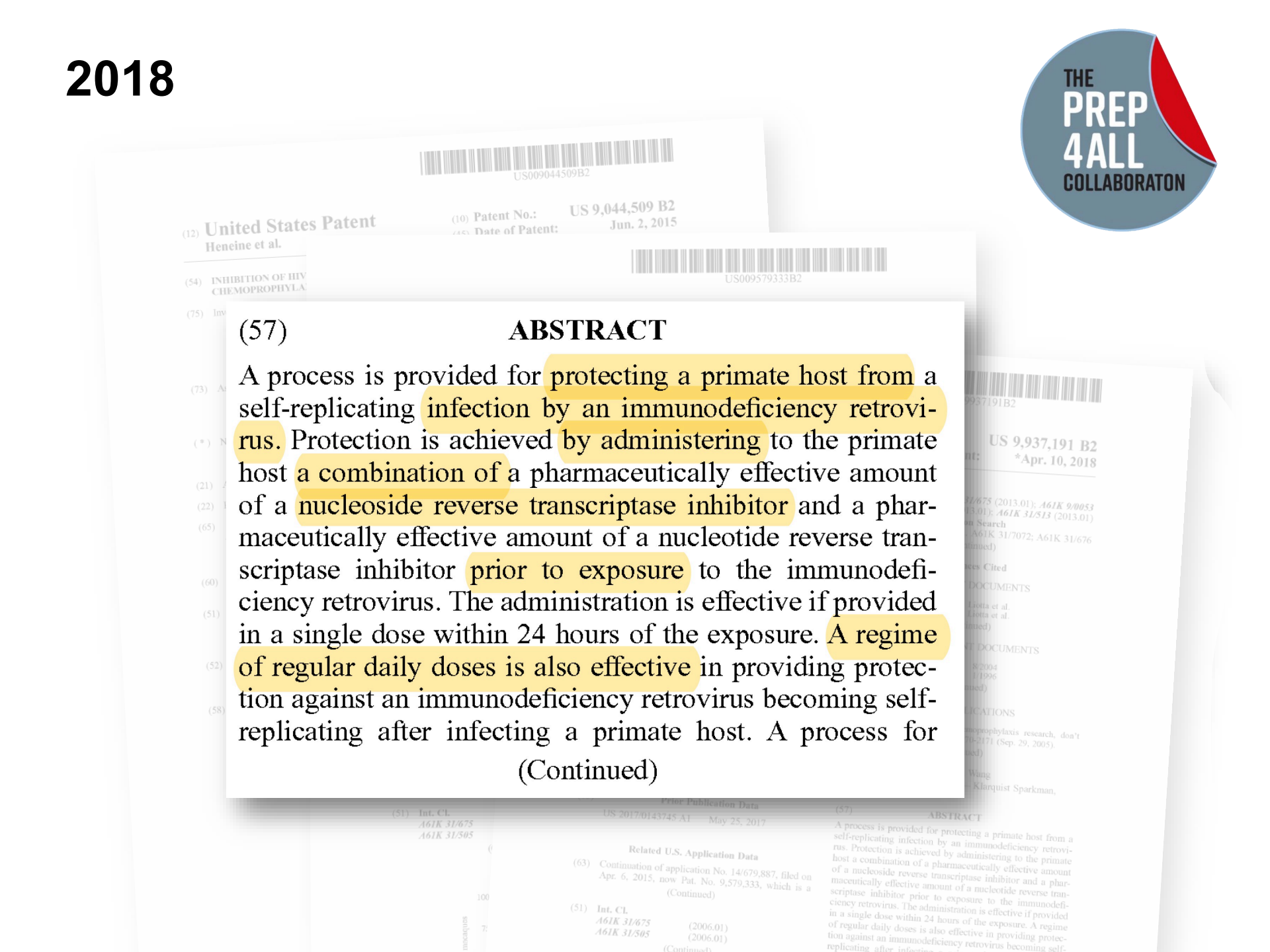
Primary Examiner — Shengjun Wang
(74) *Attorney, Agent, or Firm* — Klarquist Sparkman, LLP

(57) **ABSTRACT**

A process is provided for protecting a primate host from a self-replicating infection by an immunodeficiency retrovirus. Protection is achieved by administering to the primate host a combination of a pharmaceutically effective amount of a nucleoside reverse transcriptase inhibitor and a pharmaceutically effective amount of a nucleotide reverse transcriptase inhibitor prior to exposure to the immunodeficiency retrovirus. The administration is effective if provided in a single dose within 24 hours of the exposure. A regime of regular daily doses is also effective in providing protection against an immunodeficiency retrovirus becoming self-replicating after infecting

2018

THE PREP 4ALL COLLABORATON



US009044509B2

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US009579333B2

US 9,937,191 B2
*Apr. 10, 2018

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(Continued)

Prior Publication Data

US 2017/0143745 A1 May 25, 2017

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A61K 31/675 (2006.01)
A61K 31/505 (2006.01)

(Continued)

2018

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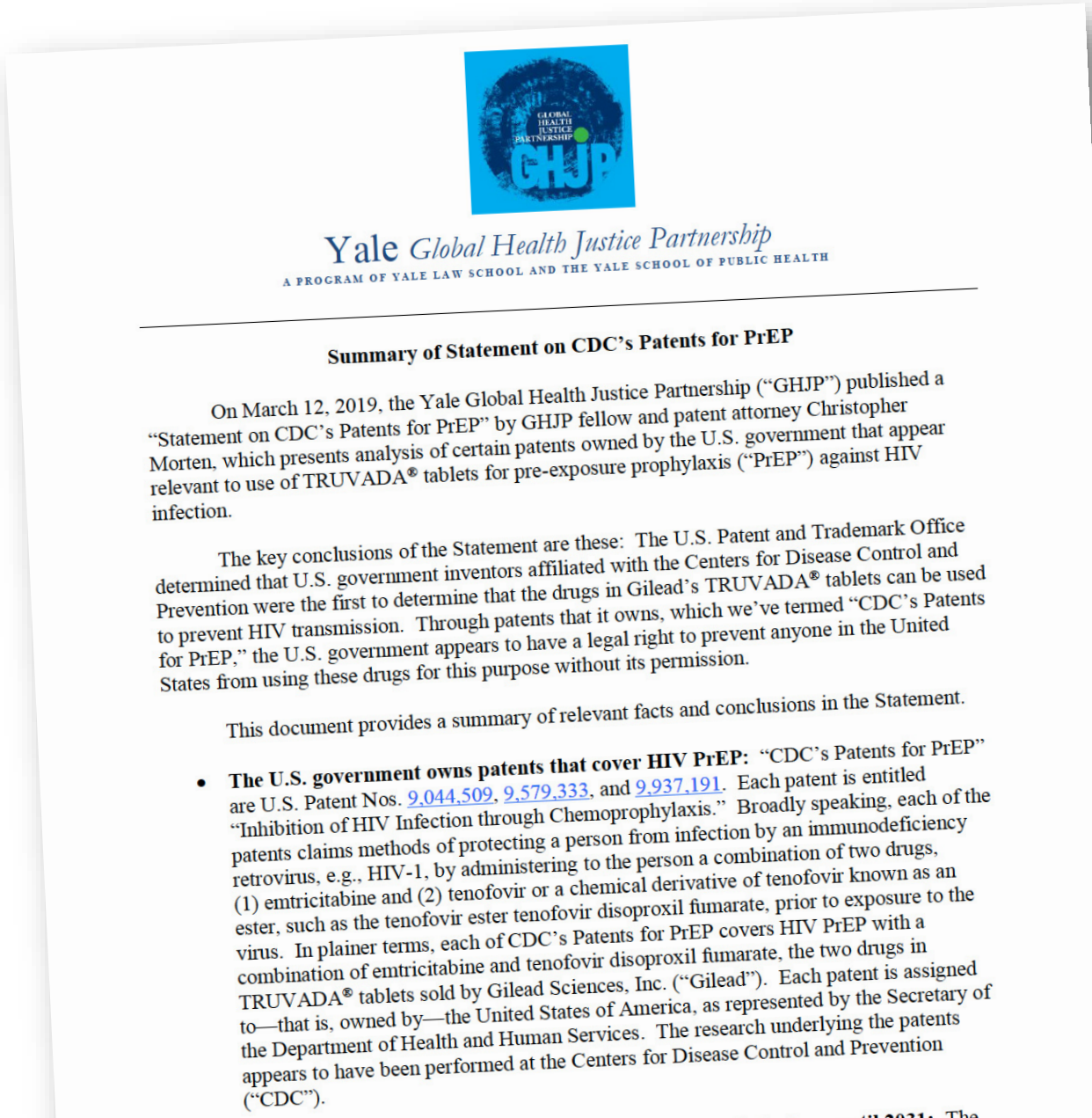
US 9,937,191 B2
*Apr. 10, 2018

GLOBAL HEALTH JUSTICE PARTNERSHIP

GHJP

March 2019



Yale *Global Health Justice Partnership*

A PROGRAM OF YALE LAW SCHOOL AND THE YALE SCHOOL OF PUBLIC HEALTH

Summary of Statement on CDC's Patents for PrEP

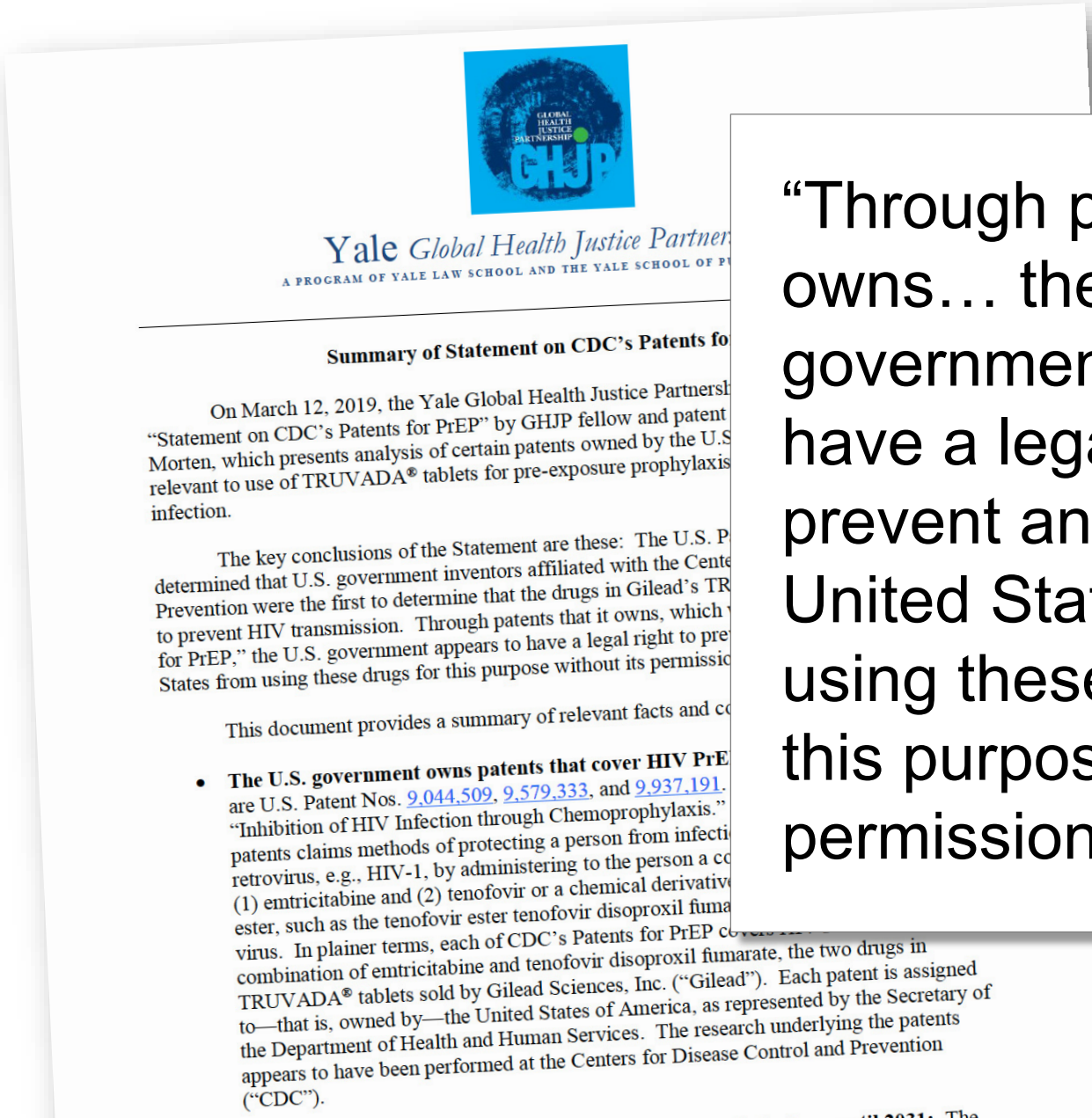
On March 12, 2019, the Yale Global Health Justice Partnership ("GHJP") published a "Statement on CDC's Patents for PrEP" by GHJP fellow and patent attorney Christopher Morten, which presents analysis of certain patents owned by the U.S. government that appear relevant to use of TRUVADA® tablets for pre-exposure prophylaxis ("PrEP") against HIV infection.

The key conclusions of the Statement are these: The U.S. Patent and Trademark Office determined that U.S. government inventors affiliated with the Centers for Disease Control and Prevention were the first to determine that the drugs in Gilead's TRUVADA® tablets can be used to prevent HIV transmission. Through patents that it owns, which we've termed "CDC's Patents for PrEP," the U.S. government appears to have a legal right to prevent anyone in the United States from using these drugs for this purpose without its permission.

This document provides a summary of relevant facts and conclusions in the Statement.

- **The U.S. government owns patents that cover HIV PrEP:** "CDC's Patents for PrEP" are U.S. Patent Nos. 9,044,509, 9,579,333, and 9,937,191. Each patent is entitled "Inhibition of HIV Infection through Chemoprophylaxis." Broadly speaking, each of the patents claims methods of protecting a person from infection by an immunodeficiency retrovirus, e.g., HIV-1, by administering to the person a combination of two drugs, (1) emtricitabine and (2) tenofovir or a chemical derivative of tenofovir known as an ester, such as the tenofovir ester tenofovir disoproxil fumarate, prior to exposure to the virus. In plainer terms, each of CDC's Patents for PrEP covers HIV PrEP with a combination of emtricitabine and tenofovir disoproxil fumarate, the two drugs in TRUVADA® tablets sold by Gilead Sciences, Inc. ("Gilead"). Each patent is assigned to—that is, owned by—the United States of America, as represented by the Secretary of the Department of Health and Human Services. The research underlying the patents appears to have been performed at the Centers for Disease Control and Prevention ("CDC").

March 2019



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The key conclusions of the Statement are these: The U.S. P determined that U.S. government inventors affiliated with the Cente Prevention were the first to determine that the drugs in Gilead's TR to prevent HIV transmission. Through patents that it owns, which for PrEP," the U.S. government appears to have a legal right to pre States from using these drugs for this purpose without its permissio

This document provides a summary of relevant facts and co

- **The U.S. government owns patents that cover HIV PrE** are U.S. Patent Nos. 9,044,509, 9,579,333, and 9,937,191. "Inhibition of HIV Infection through Chemoprophylaxis." patents claims methods of protecting a person from infecti retrovirus, e.g., HIV-1, by administering to the person a co (1) emtricitabine and (2) tenofovir or a chemical derivative ester, such as the tenofovir ester tenofovir disoproxil fuma virus. In plainer terms, each of CDC's Patents for PrEP co combination of emtricitabine and tenofovir disoproxil fumarate, the two drugs in TRUVADA® tablets sold by Gilead Sciences, Inc. ("Gilead"). Each patent is assigned to—that is, owned by—the United States of America, as represented by the Secretary of the Department of Health and Human Services. The research underlying the patents appears to have been performed at the Centers for Disease Control and Prevention ("CDC").

"Through patents that it owns… the U.S. government appears to have a legal right to prevent anyone in the United States from using these drugs for this purpose without its permission."

March 2019

The Washington Post
Democracy Dies in Darkness

Business

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

April 2019

GILEAD

Press Releases

April 05, 2019

Gilead Submits Supplemental New Drug Application to U.S. Food and Drug Administration for Once-Daily Descovy® for HIV Pre-Exposure Prophylaxis

- Filing Supported by Data Demonstrating Non-inferiority Compared to Truvada® Coupled with Bone and Renal Safety Advantages in People at Risk of Sexually Acquired HIV Infection -

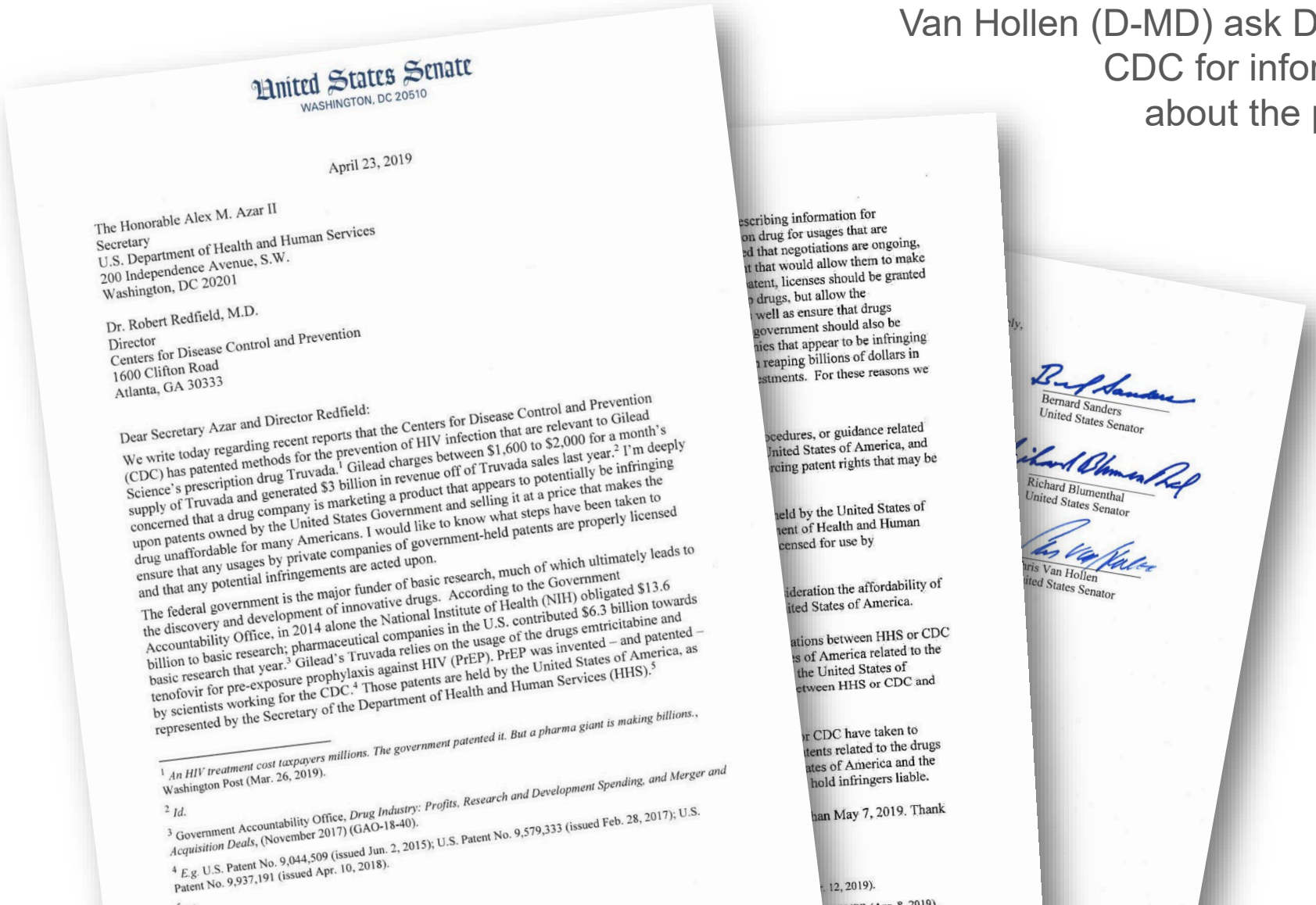
FOSTER CITY, Calif.--(BUSINESS WIRE)--Apr. 5, 2019-- Gilead Sciences, Inc. (NASDAQ: GILD) announced today that the company has submitted a supplemental New Drug Application (sNDA) to the U.S. Food and Drug Administration (FDA) for Descovy® (emtricitabine 200 mg and tenofovir alafenamide 25 mg tablets) for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection among individuals who are HIV-negative and at risk for HIV. A Priority Review voucher was submitted with the filing, leading to an anticipated review time of six months.

The filing is based on the results of the Phase 3 DISCOVER trial which evaluated the safety and efficacy of Descovy compared to Truvada in men and transgender women who have sex with men at high-risk for sexually acquired HIV infection. Truvada® (emtricitabine 200 mg and tenofovir

Despite MSM (&TGW) focus of DISCOVER, application was to expand the indication to include PrEP *for all persons at risk*

April 2019

4/23: Sens. Stabenow (D-MI), Cardin (D-MD), Baldwin (D-MN), Duckworth (D-IL), Sanders (I-VT), Blumenthal (D-CT), and Van Hollen (D-MD) ask DHHS & CDC for information about the patents



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).

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han May 7, 2019. Thank

12, 2019).

ly,

Bernard Sanders
United States Senator

Richard Blumenthal
United States Senator

ris Van Hollen
ited States Senator

May 2019

5/8: Gilead announces it's voluntarily shortening patent by a year
(FTC expires in 2021)

CNBC

MARKETS BUSINESS INVESTING TECH POLITICS CNBC TV SEARCH QUOTES

BIOTECH AND PHARMA

Generic HIV prevention drug coming in 2020, Gilead says

PUBLISHED WED, MAY 8 2019 • 1:53 PM EDT

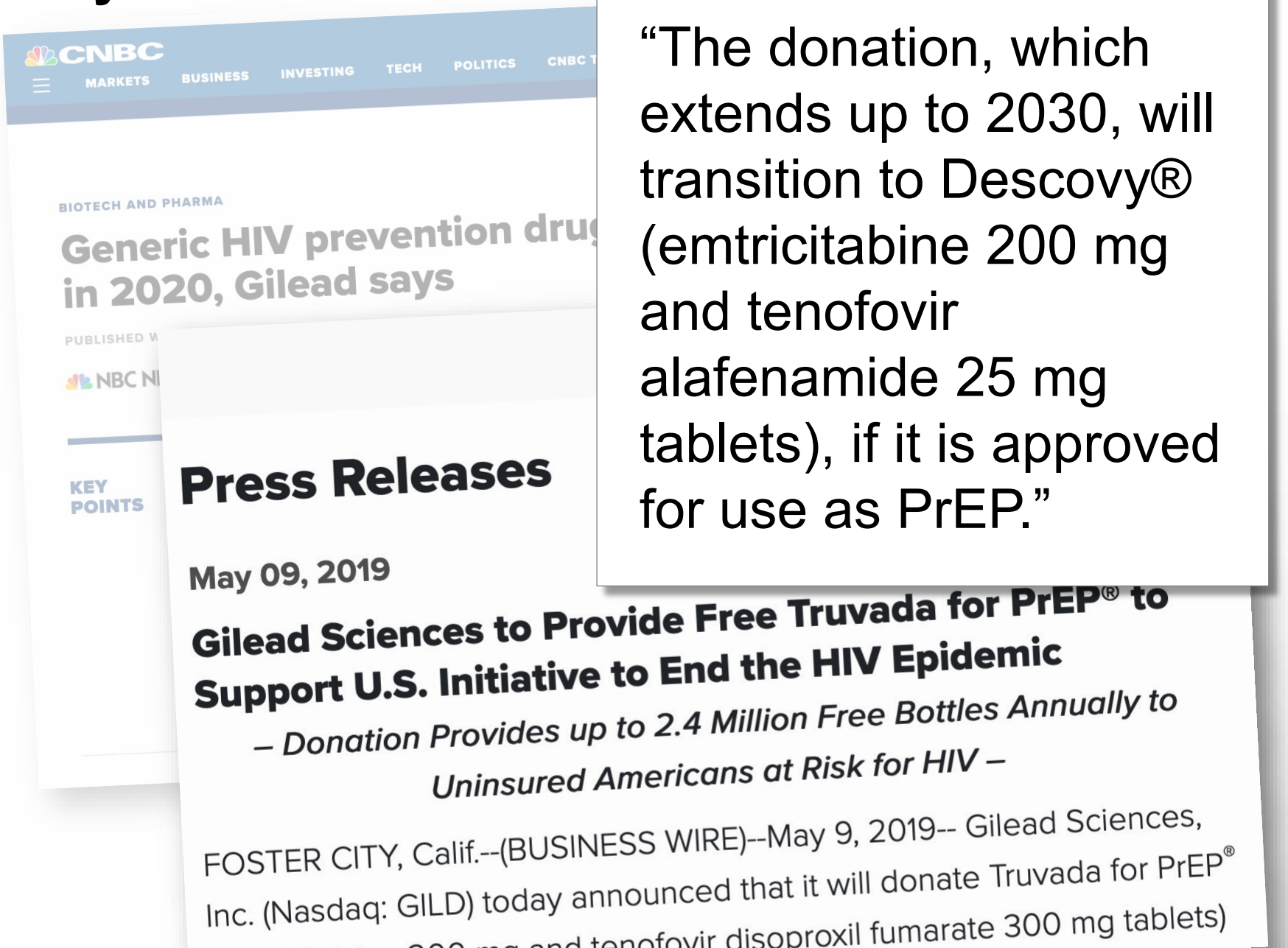
NBC NEWS | Tim Fitzsimons

SHARE

KEY POINTS

- Gilead Sciences announced Wednesday that a generic version of Truvada will be available in September 2020, one year earlier than expected.
- When taken daily, Truvada prevents HIV transmission.
- In the United States a month's supply sells for $1,600 to $2,000, and activists have mounted a pressure campaign to force Gilead to make the drug more widely available in order to curb the global HIV epidemic.

May 2019



"The donation, which extends up to 2030, will transition to Descovy® (emtricitabine 200 mg and tenofovir alafenamide 25 mg tablets), if it is approved for use as PrEP."

May 2019

The New York Times

Opinion

A Million Americans Need This Drug. Trump's Deal Won't Help Enough of Them.

A donation of H.I.V.-prevention drugs from the pharmaceutical giant Gilead could benefit shareholders more than patients.

By The Editorial Board

The editorial board represents the opinions of the board, its editor and the publisher. It is separate from the newsroom and the Op-Ed section.

May 13, 2019

182

Federica Bordoni

May 2019

Roll Call

Congress

Ocasio-Cortez grills CEO of pharma company making billions on government-patented HIV drug

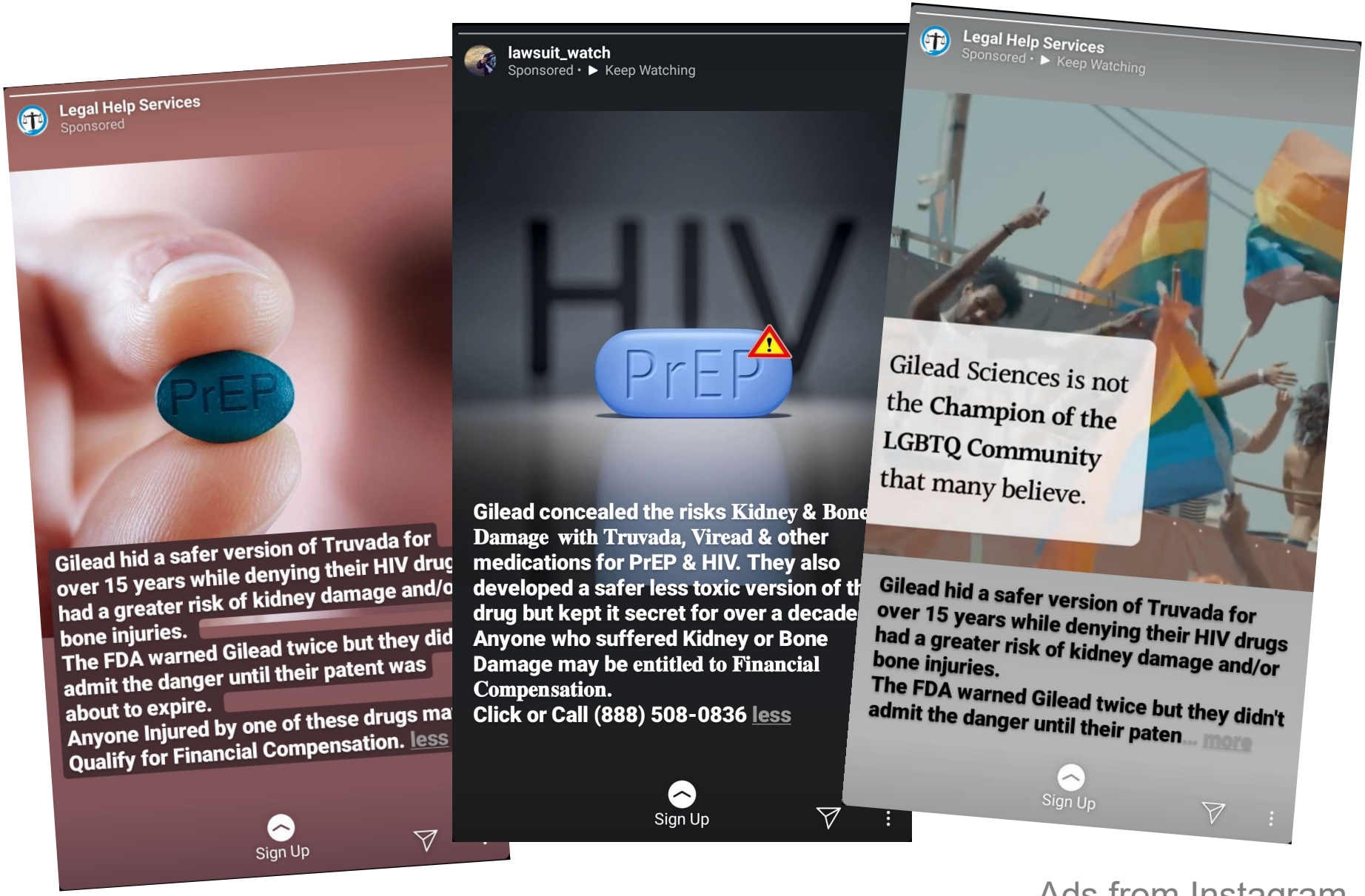
Daniel O'Day faced scathing questions over taxpayers funding research and development for blockbuster drug

Rep. Alexandria Ocasio-Cortez, D-N.Y., was among the Democrats on the House Oversight Committee grilling Gilead CEO Daniel O'Day on Thursday over the high price of the HIV prevention drug, Truvada. (Tom Williams/CQ Roll Call)

Gilead CEO
Daniel O'Day

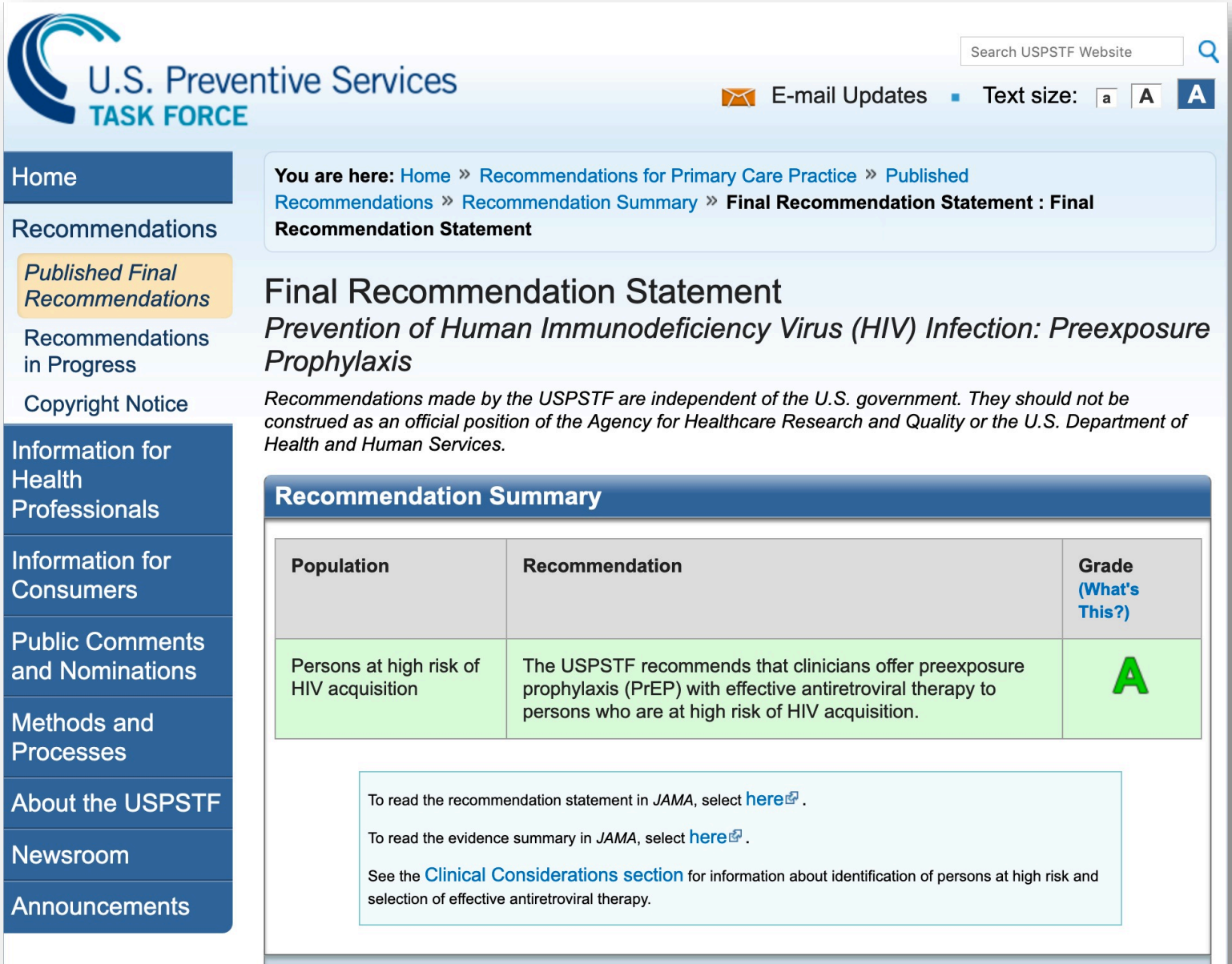
May 16

Spring & early Summer 2019



Ads from Instagram

June 2019



U.S. Preventive Services TASK FORCE

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Final Recommendation Statement

Prevention of Human Immunodeficiency Virus (HIV) Infection: Preexposure Prophylaxis

Recommendations made by the USPSTF are independent of the U.S. government. They should not be construed as an official position of the Agency for Healthcare Research and Quality or the U.S. Department of Health and Human Services.

Recommendation Summary

Population	Recommendation	Grade (What's This?)
Persons at high risk of HIV acquisition	The USPSTF recommends that clinicians offer preexposure prophylaxis (PrEP) with effective antiretroviral therapy to persons who are at high risk of HIV acquisition.	A

To read the recommendation statement in *JAMA*, select here.

To read the evidence summary in *JAMA*, select here.

See the Clinical Considerations section for information about identification of persons at high risk and selection of effective antiretroviral therapy.

THE HENRY J. KAISER FAMILY FOUNDATION

Filling the need for trusted information on national health issues...

August 2015 | Fact Sheet

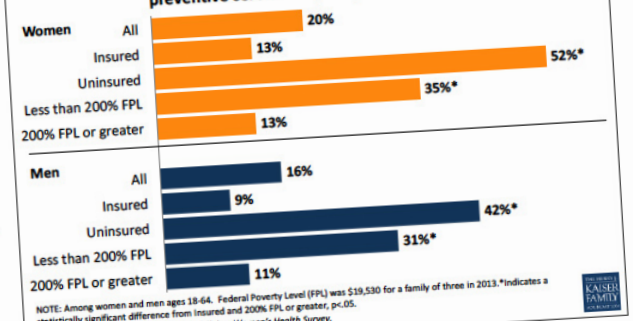
Preventive Services Covered by Private Health Plans under the Affordable Care Act

A key provision of the Affordable Care Act (ACA) is the requirement that private insurance plans cover recommended preventive services without any patient cost-sharing.[1] Research has shown that evidence-based preventive services can save lives and improve health by identifying illnesses earlier, managing them more effectively, and treating them before they develop into more complicated, debilitating conditions, and that some services are also cost-effective.[2] However, costs do prevent some individuals from obtaining preventive services **(Figure 1)**. The coverage requirement aims to remove cost barriers.

Figure 1

Cost barriers to use of preventive services for women and men

Share of women and men reporting they put off or postponed preventive services in past year due to cost



NOTE: Among women and men ages 18-64. Federal Poverty Level (FPL) was $19,530 for a family of three in 2013.*Indicates a statistically significant difference from insured and 200% FPL or greater, p<.05.
SOURCE: Kaiser Family Foundation, *2013 Kaiser Women's Health Survey*.

ACA Requirements for Coverage of Preventive Services

Under Section 2713 of the ACA, private health plans must provide coverage for a range of preventive services and may not impose cost-sharing (such as copayments, deductibles, or co-insurance) on patients receiving these services.[3] These requirements apply to all private plans – including individual, small group, large group, and self-insured plans in which employers contract administrative services to a third party payer – with the exception of those plans that maintain "grandfathered" status. In order to have been classified as "grandfathered," plans must have been in existence prior to March 23, 2010, and cannot make significant changes to their coverage (for example, increasing patient cost-sharing, cutting benefits, or reducing employer contributions). In 2014, 26% of workers covered in employer sponsored plans were still in grandfathered plans,[4] and it is expected that over time almost all plans will lose their grandfathered status.

The required preventive services come from recommendations made by four expert medical and scientific bodies – the U.S. Preventive Services Task Force (USPSTF), the Advisory Committee on Immunization Practices (ACIP), the Health Resources and Services Administration's (HRSA's) Bright Futures Project, and HRSA and the Institute of Medicine (IOM) committee on women's clinical preventive services. The [illegible] that insurers cover preventive services recommended by the USPSTF, ACIP, and Bright Futures [illegible] beginning on or after September 23,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Filling the need for trusted information on national health issues...

August 2015 | Fact Sheet

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Figure 1

Cost barriers t… men

Share of w… p…

Women	All	
	Insured	
	Uninsured	
Less than 200% FPL		
200% FPL or greater		
Men	All	
	Insured	
	Uninsured	
Less than 200% FPL		
200% FPL or greater		

NOTE: Among women and m… statistically significant differe…
SOURCE: Kaiser Family Found…

ACA Requirements for Coverage of Pre…

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"A key provision of the Affordable Care Act (ACA) is … private insurance plans cover recommended preventive services without any patient cost-sharing. … **Insurers now must cover evidence-based services for adults that have a rating of "A" or "B"** in the current recommendations of the [USPSTF]"

June 2019

"Donating the Truvada costs them almost nothing because we know that it costs less than $60 a year to make, so the activists estimate that that donation is costing them less than $10 million a year. But they're taking a tax deduction for something like the retail cost, not the cost of making it. That's how donations work for the pharmaceutical industry. You donate something that costs you pennies to make, and you take the tax deduction for the dollars that you sell it for."

– Donald G. McNeil
Science & Health Reporter
The New York Times
June 5, 2019

July 2019

August 2019

October 7
(MSM & TGW only)

P25Z

FDA Advisers Give Descovy PrEP Mixed Reviews

Evidence supports new PrEP option for gay men and trans women, but there's no consensus for other groups.

August 8, 2019 By Liz Highleyman

There is ample evidence that Descovy (tenofovir alafenamide/emtricitabine) is a safe and effective new HIV prevention option for gay and bisexual men and transgender women, but the jury is still out regarding other groups, according to a Food and Drug Administration (FDA) advisory committee.

At a hearing on August 7, the panel of independent experts voted 16 to 2 in favor of FDA approval of Descovy for pre-exposure prophylaxis (PrEP) for men who have sex with men (MSM) and trans women, based on findings from the DISCOVER study. But the panel was split—8 in favor and 10 opposed—over whether this recommendation should extend to cisgender (non-trans) women.

Gilead Sciences' Descovy contains tenofovir alafenamide (TAF), an updated version of the tenofovir disoproxil fumarate (TDF) in the Truvada combination pill. The FDA approved Truvada for HIV prevention in 2012, and this indication includes adults and adolescents at risk for sexually acquired HIV regardless of sex, gender or sexual orientation.

Compared with TDF, TAF produces higher levels of the active drug (known as tenofovir diphosphate) in immune cells that are susceptible to HIV. This means TAF can be given at lower doses, leading to less drug exposure for the kidneys, bones and other organs. Studies have shown

August 2019

The Washington Post
Democracy Dies in Darkness

Business

Gilead files challenge to government patents for HIV prevention pill

August 21, 2019

Take home messages

- Plenty of linkage and retention challenges remain for PrEP… but when it's taken consistently, it works well
- FTC/TAF was non-inferior to FTC/TDF for HIV prevention among MSM and TGW... approval as PrEP pending
- FTC/TAF gets up to speed faster than FTC/TDF and lingers for longer period… both beneficial for prevention
- USPSTF's recommendation means greater access to PrEP… but does "PrEP" mean the service or the drug?
- Stay tuned to see what happens with ongoing patent disputes and advocacy efforts!

Questions?

Please email me!

Christopher Hurt, MD

churt@med.unc.edu