

PrEP Pricing + Access 101

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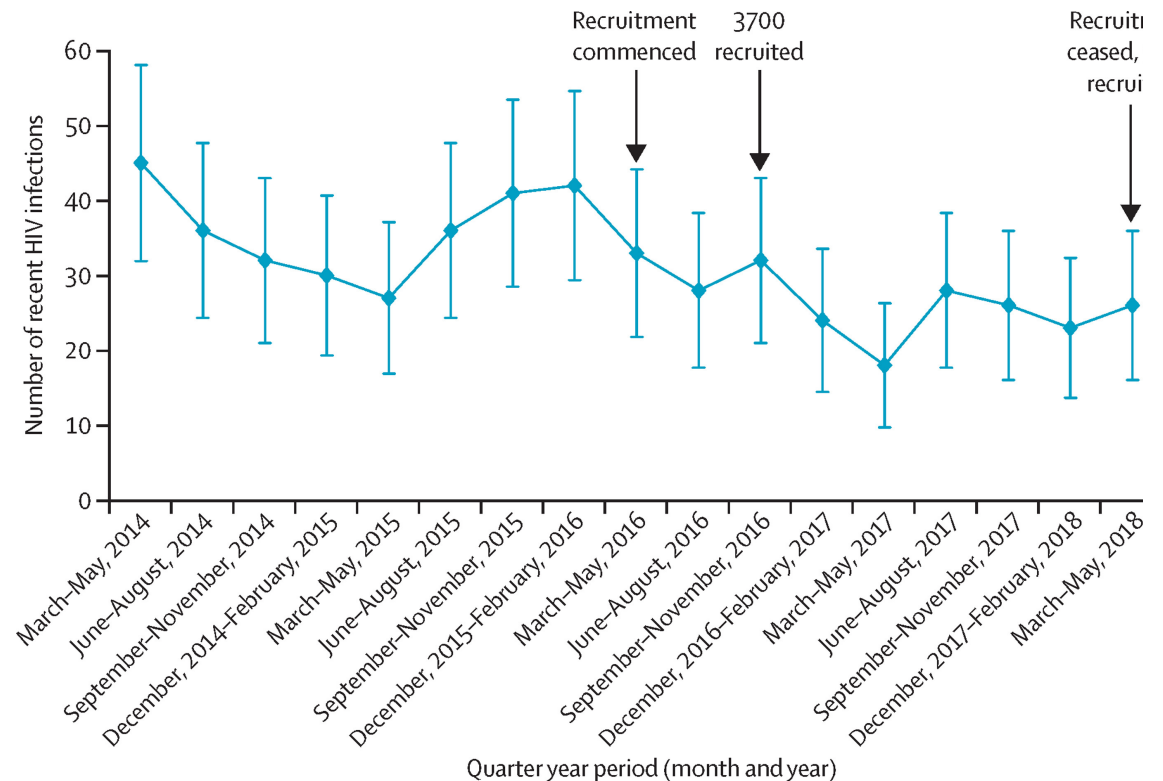
The Scientific Context

- This decade (2010-2020) has seen extraordinary progress in the *science* of HIV prevention.
 - **Treatment as Prevention \ Undetectable = Untransmittable (“U=U”)**
 - Consensus that effective anti-HIV therapy resulting in durable viral load suppression (*i.e.* <50 HIV RNA copies per mL of blood\plasma) makes forward transmission effectively **impossible**.
 - **Invention and FDA Approval of TDF\FTC PrEP**
 - If taken daily, reduces risk of HIV acquisition by at least 99%



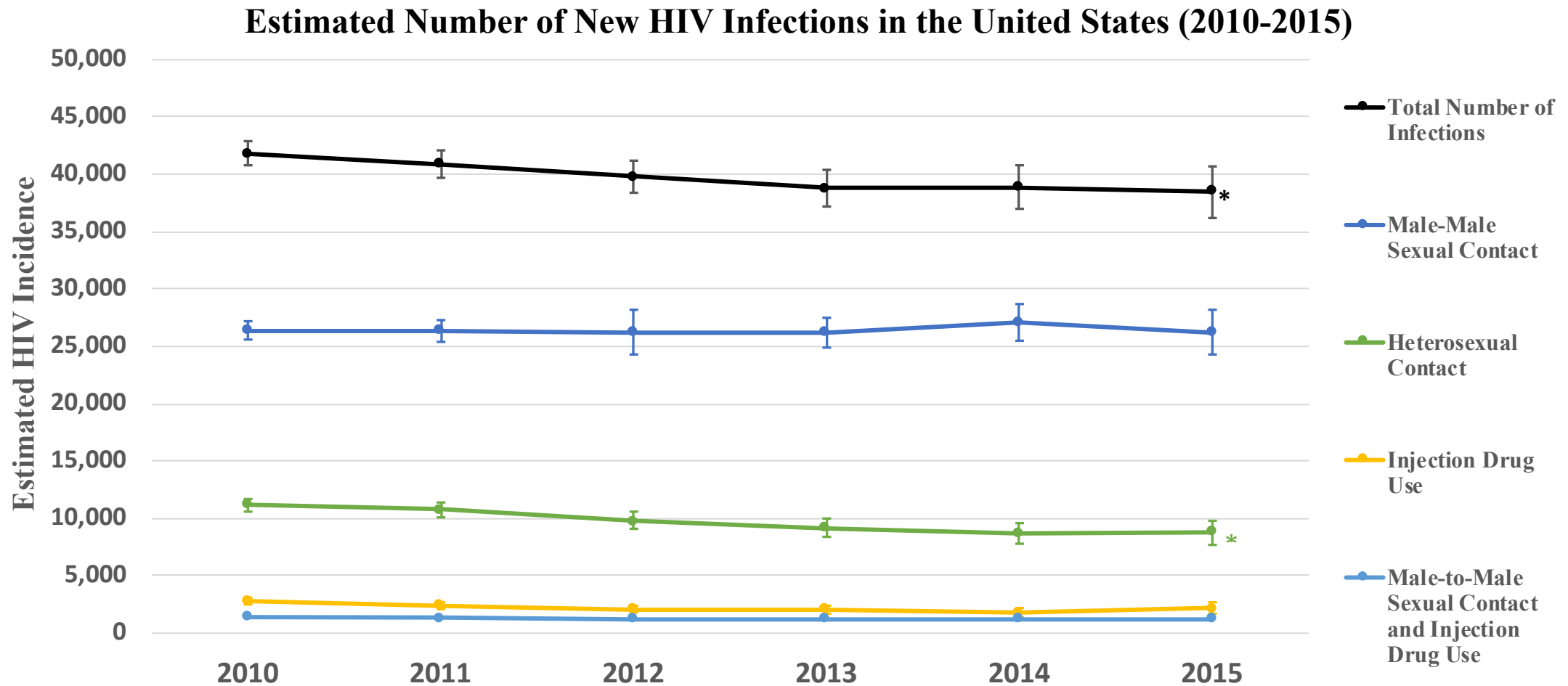
TasP and PrEP are Highly Effective at Population Scale -- *If* Effectively Implemented

- The Expanded PrEP Implementation in Communities New South Wales (EPIC-NSW) explored the *public health impact* of rapid scale up of PrEP in highly vulnerable communities (primarily gay + bisexual men).
- New South Wales had already exceeded UNAIDs 90-90-90 targets for rates of HIV diagnoses, linkage to care, and viral suppression by 2016.
- **Results were dramatic – number of recent infections in targeted communities dropped by 31.5% statewide in the year following roll out.**



So, how are we doing?

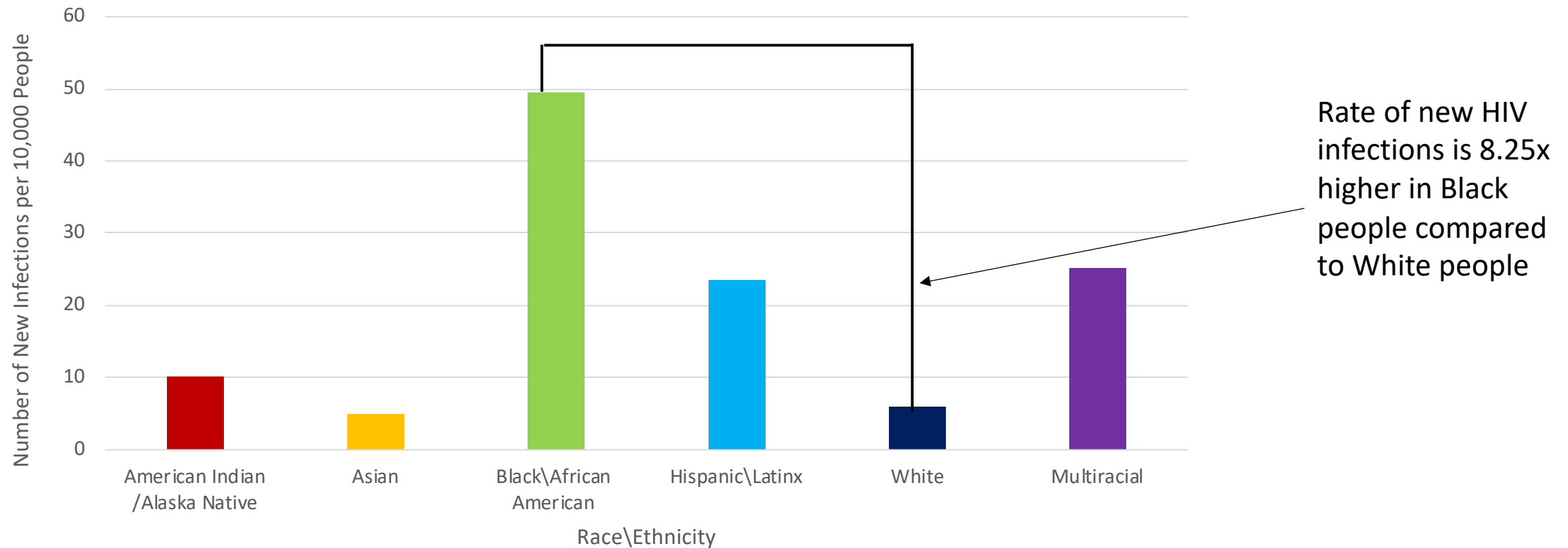
HIV Prevention Has Stalled in the United States



Source: *HIV Surveillance Supplemental Report 23[1]* (CDC)

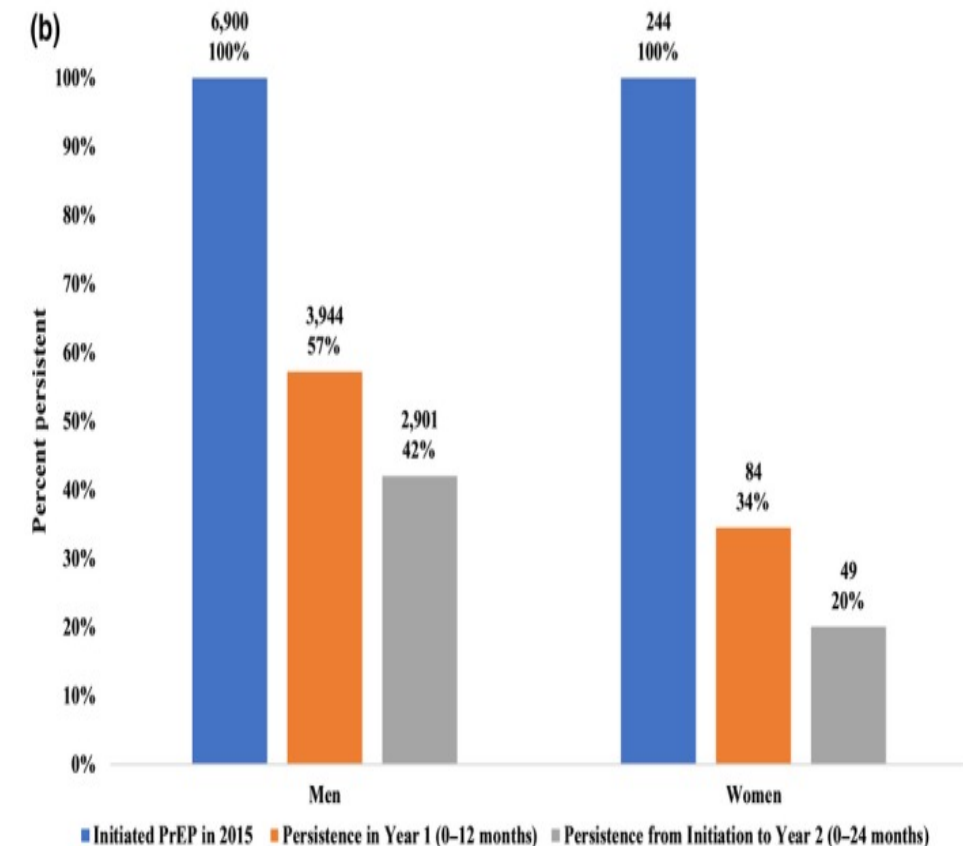


New HIV Infections are Disproportionately Concentrated in People of Color, Despite No Evidence of Increased Risk Behavior (USA, 2015)



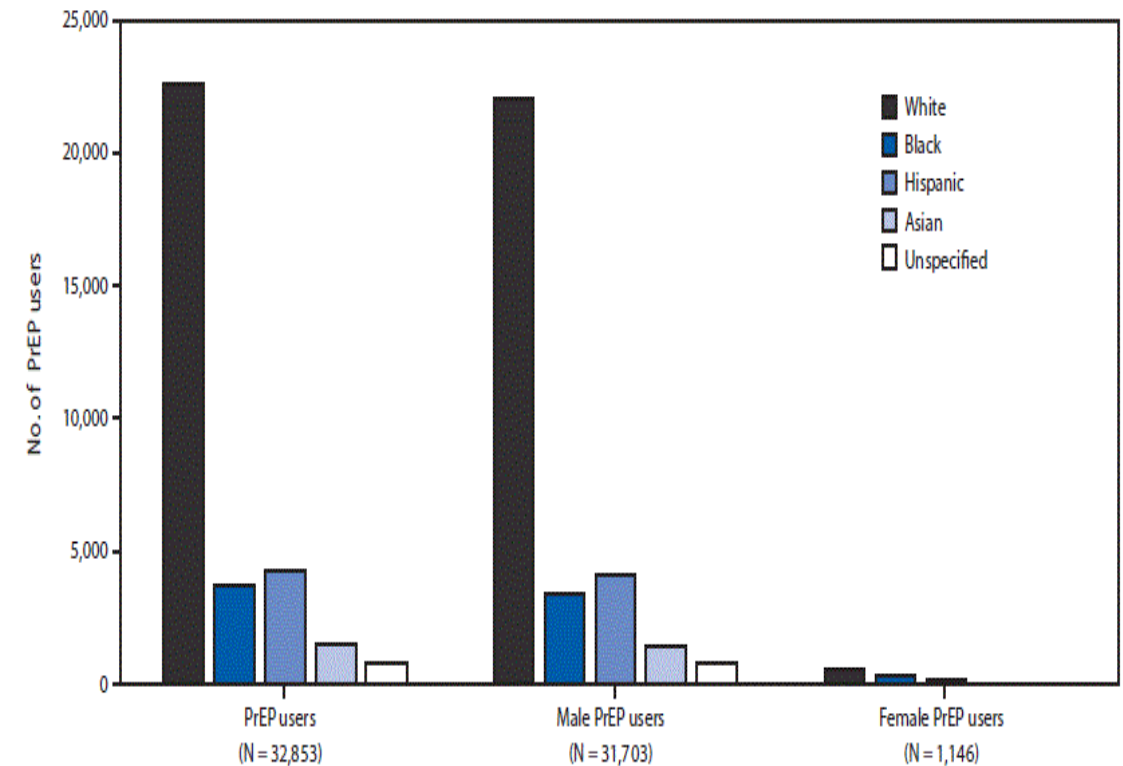
Not Enough People are Accessing PrEP in the U.S.

- Less than 120,000 people accessed a single or more doses of Truvada PrEP in the U.S. in Q4 2017 -- <10% of CDC estimated need. ([Ann Epidemiol.](#) 2018 Dec;28(12):841-849.)
- Only two out of five PrEP users persisted on PrEP after two years of follow-up in the U.S. Significantly higher rates of non-persistence were found in people:
 - **Who were non-male identifying**
 - **Had a drug copay over \$20**
 - **Having non-commercial insurance**
 - **Did not access PrEP at a community-based specialty pharmacy**



Current Patterns of PrEP Utilization may *Exacerbate* rather than Mitigate Disparities in HIV

- In 2016, PrEP use was highly unequal
 - 68.7% of PrEP users were white,
 - 11.2% were black
 - 13.1% were Hispanic\Latinx
 - 4.5% were Asian
 - Only 4.7% of PrEP users were women
- Contrast that with HIV diagnosis data in 2016:
 - 25% of new diagnoses were in white people
 - 44% of new diagnoses were in black people
 - 25% of new diagnoses were in Hispanic\Latinx people
 - 2.5% were in Asian people.
 - 19% were in women



Let's Talk About Money

At Gilead's current prices, Truvada is more than twice as expensive as Gold

- Truvada is an extraordinary cheap drug to manufacture
 - FDA approved generics are available for <\$4.50 per 30 day supply.
- Despite this, Gilead charges over \$1,600 (WAC) per month for the drug
 - More expensive than Gold (200 mg FTC + 300 mg TDF = \$55.88 for 500 mg API, vs. \$21.45 for 500 mg of Gold)



Gilead's extremely high price fundamentally alters where resources are allocated in HIV prevention

Description	Cost (USD)	Units per Year	Annual Cost (USD) per person w. generic PrEP	Annual Cost (USD) per person w. Gilead Truvada
30-Day Supply TDF/FTC	~\$15 (Generic) \$2011 (AWP for Truvada)	12	\$180	\$24,132
4 th Generation HIV Test (CPT 87389)	\$29.38	4	\$117.52	\$117.52
Renal Function Test (CPT 80069)	\$10.72	2	\$21.44	\$21.44
STI Tests (RPR, 3-site testing for G\C NAAT) (CPT 86593, 87491, 87591)	\$259.80	2	\$519.66	\$519.66
Pregnancy Tests (CPT 81025)	\$8.61	4	\$4.79	\$4.79
Physician Visit Cost (CPT 99214)	\$111.95	4	\$447.80	\$447.80
<u>TOTAL COST</u> <u>per year per</u> <u>user</u>			\$1,291.31	\$25,243.31

Gilead's Price Prevents Universal Access

- Price is not the only barrier to PrEP use in the United States
- But by inflating the price of Truvada so dramatically, Gilead misdirects resources that could be used to mitigate the myriad of other barriers that prevent PrEP access
- The U.S. Healthcare System spends approx. \$2 billion per year on procuring Truvada for PrEP (excluding clinical and other costs), to cover less than 10% of people who need it.
 - If we had access to comp. priced generics, we could spend the *same* amount of money we spend currently, but ensure *free* access to drug and clinical care for 1.2 million people, as well as approx. \$500 million left over to mitigate other barriers

An example budget for mitigating some barriers

- **Providing non-emergency medical transportation for routine clinical visits for 10% (120,000) of patients at avg. cost of \$40 per trip. Budget: \$20 Million**
- **Fund a national physician education campaign, educating prescribers on PrEP. Budget: \$131 million (\$500 per PCP in the entire country)**
- **Dramatically increasing awareness of PrEP among vulnerable populations using advertising campaigns. Budget: \$50 million**
- **Increase funding for organizations that directly engage with impacted communities, in order to increase capacity for patient centered advocacy, as well as national engagement with PrEP priorities. Budget: \$250 million**

The CDC's Patents on PrEP

- CDC basic science research paved the way for the discovery of TDF/FTC and TAF/FTC PrEP
- CDC owns three U.S. patents on PrEP, that Gilead is on infringing on.
 - CDC already enforces these patents, and receives monetary royalties, on generic TDF/FTC sales overseas
 - CDC is owed billions of dollars in back royalties from Gilead, that could be used to fund a national PrEP program

