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# THE AIDS ACTION BULLETIN

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▼ "IF ANYTHING IS SACRED THE HUMAN BODY IS SACRED." – WALT WHITMAN ▼

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## AAB PREVENTION UPDATE

### NEW PREP DATA ON TRANSGENDER WOMEN FROM THE IPREX STUDY

By LYNDA DEE

**R**esearchers from the University of California in San Francisco (UCSF) unearthed new information about PrEP usage in transgender women by taking an innovative look at the new IPREX study data. The IPREX study was a 2010 French Canadian study in mostly negative gay and bisexual men that was the first to show the positive effect of emtricitabine plus tenofovir fumarate, which is combined in one pill known as Truvada, for HIV prevention. No such efficacy was found in transgender women because their initial numbers were too small to make any definitive findings. Only 29 people were initially identified as transgender women.

This new data is the first separate analysis of transgender women that has ever occurred in a PrEP trial. Before IPREX, no other randomized controlled trial, the gold standard for making definitive conclusions, has ever specifically looked at PrEP in transgender women. This is a large step forward for transgender women who have one of the highest rates of HIV infection. A re-

view of 22 studies indicated that approximately 28% of transgender women are HIV infected in the United States.

The IPREX study enrolled 2,499 gay and bisexual men (men who have sex with men or MSM), and transgender women in Brazil, Ecuador, Peru, South Africa, Thailand and the United States between 2007 and 2009. Because the initial results of the IPREX randomized study demonstrated that once daily Truvada prevented the risk of HIV prevention by 92% in people who actually took Truvada regularly, IPREX was extended to a non-randomized, an open label extension study that was ended in 2013. This means that everyone who wanted Truvada in the open label study received it. Blood levels of Truvada were measured to prove adherence. No one in the open label study who took Truvada at least four times per week became HIV infected during the study.

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**The Wyden-Grassley  
US Senate bipartisan  
Sovaldi Investigation**

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## Note from the President

This issue is devoted to the new and exciting IPREX PrEP study results in trans women. This new data is the first separate analysis of trans women that has ever occurred in a PrEP trial. Before IPREX, no other randomized controlled trial has ever specifically looked at PrEP in trans women. This is a large step forward for trans women who have 28% rates of HIV infection in the United States.

The good news is that just like men who have sex with men (MSM), trans women who had blood levels indicating that they took Truvada four times per week did not become HIV infected. Truvada was generally well-tolerated with moderate or severe side effects rarely reported. There was no difference in adverse events in trans women who took Truvada versus those who did not. Decreases in bone mineral density that may occur with Truvada use were less apparent in trans women than in MSM. Researchers surmised that this may be the result of less Truvada use or a protective effect of feminizing hormones.

It is perfectly clear from the new findings that we need much further study in this arena. When trans women use PrEP, it appears to work, but to increase awareness, encourage continued PrEP use programs and foster research participation, interactions need to take place in safe, gender-affirming environments. The integration of PrEP and gender affirming services, including feminizing hormone services as well as the development of distinct PrEP delivery programs for trans women that are specifically designed to support trans women, and that do not lump them together with MSM programs and studies are essential to PrEP use and adherence.

We are also highlighting AAB's advocacy work with the Fair Pricing Coalition (FPC) with respect to HCV drug pricing and access. AAB has been working with the FPC since it was founded by Martin Delaney and Linda Grinberg in 1999. Murray Penner, Executive Director of NASTAD (the National Alliance of State and Territorial AIDS Directors), and I are the co-chairs of the FPC.

The FPC negotiates new drugs prices with HIV and HCV drug companies, badgers them about drug price increases and ensures that they makes their antiretroviral drugs (ARVs) available to those who cannot afford them either through co-pay programs for people with insufficient insurance coverage or patient assistance programs for people with no insurance. We also work with the AIDS Crisis Task Force to ensure that AIDS Drug Assistance Programs (ADAPs) that ensure access to prescriptions for the working poor across the nation receive generous rebates for all drugs purchased for people with HIV. This type of advocacy does not happen in any other disease field.

The FPC worked with the Wyden-Grassley US Senate Finance Committee to shine a light on the astronomical pricing of Gilead's new HCV drugs. I'm sure many of you have heard of the \$1,000 per pill drug Sovaldi. Sovaldi is the object of the Committee's 144 page Senate report. You will be amazed at the access barriers and budget busting results the cost of Sovaldi has occasioned for people with HCV.

We also hope you will join us for our new **ART FOR LIFE** benefit which will take place at the very hip Gallery 788, 3602 Hickory Avenue, Baltimore, MD 21211, in Hampden, from April 8 to April 17, 2016. Gallery 788 owner Eduardo Rodriguez has graciously agreed to host the art show and help obtain donated art from many local Baltimore *boho* artists. We will also be having quite a few surprise performing artists that will make the show even more edgy. Hope you can join us. Please see our Facebook event page for more information and scheduled events during the show at:

<https://www.facebook.com/events/537442829757623/> or  
<https://www.facebook.com/events/1111888865509809/>

Lynda Dee



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A new, more sophisticated method for determining who was transgender identified 339 transgender women which was 310 more than was originally indicated in the first IPREX study report. Fourteen percent of the 339 transgender study participants were classified as transgender women. Of this number 29 (1%) identified as women, 296 (12%) identified as trans or travesti and 14 (1%) identified as men, but reported taking feminizing hormones. Of this number, 192 participated in the open label extension, 79% of whom opted to take Truvada.

The study showed that when compared to MSM, transgender women reported much higher rates of sex work (64% v 38%), condomless receptive anal sex (86% v 55%), sexually transmitted diseases during the past six months (38% v 24%), and over five sex partners during the past three months. Transgender women had lower Truvada blood levels and were less likely to take Truvada consistently. Unlike results in MSM, there was no correlation in the consistency of Truvada use for transgender women who engaged in condomless anal sex. In the MSM population, those who engaged in condomless anal sex were more adherent to PrEP. None of the 11 transgender women who became HIV infected during the initial trial had Truvada blood levels which means they were not taking their PrEP. Two transgender women who received PrEP during the open label extension became HIV infected. In the open label study, transgender women were half as likely as MSM to have Truvada blood levels that indicated that they took Truvada at least four times per week (18% v 36%).

Transgender women who took feminizing hormones were less likely to have either detectable or sufficient Truvada blood levels.

The good news is that just like MSM, transgender women who had blood levels indicating that they took Truvada four times per week did not become HIV infected. Truvada was generally well-tolerated with moderate or severe side effects rarely reported. There was no difference in adverse events in transgender women who took Truvada versus those who did not. Decreases in bone mineral density that may occur with Truvada use were less apparent in transgender women than in MSM. Researchers surmised that this may be the result of less Truvada use or a protective effect of feminizing hormones. There was also no evidence of liver toxicity.

Transgender women with consistent Truvada drug levels appeared to be protected, according to UCSF investigator Robert M. Grant, MD. Grant who stated that while the numbers of transgender study participants were still too small to draw firm conclusions, there was strong evidence pointing to PrEP efficacy.

As the trans community has long known, researchers surmised that even though PrEP seems to be effective in trans women, they have more and different barriers to PrEP use. Thus, PrEP studies for trans women should be specifically designed and tailored to their needs, rather than simply using the same studies that are designed for MSM or simply including trans women within the MSM studies as if they had the same issues

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and risk factors. UCSF researcher Madeline B. Deutsch, MD also acknowledged that transgender women face institutional barriers like the lack of legal protections against discrimination resulting in difficulties in employment and income inequality that cause lack of adequate food and housing. She further stated that transgender women definitely need an HIV prevention tool that they can control and which they can use without their partners' knowledge or consent. Dr. Deutsch also explained that one of the important reasons transgender women do not take their PrEP is because they are afraid it will interfere with their gender affirming hormones. She pointed out that feminizing hormones are a higher priority than PrEP.

It is perfectly clear from the UCSF findings that we need much further study in this arena. When trans women use PrEP, it appears to work, but to increase awareness, encourage continued PrEP use programs and foster research participation, interactions need to take place in safe, gender-affirming environments. The integration of PrEP and gender affirming services, including feminizing hormone services as well as the development of distinct PrEP delivery programs for trans women that are specifically designed to support trans women, and that do not lump them together with MSM programs and studies are essential to PrEP use and adherence.

We are finally headed in the right direction. Stay tuned for the latest on PrEP for HIV prevention. ▼

## **AAB ANTIRETROVIRALS REPORT**

### **The Wyden-Grassley US Senate bipartisan Sovaldi Investigation Spotlights a Revenue-Driven Pricing Strategy Behind Gilead's \$1,000 per pill Hepatitis Drug Launch**

By LYNDA DEE

**T**he US Senate Finance Committee chaired by Senators Ron Wyden, D-Oregon and Chuck Grassley, R-Iowa issued a scathing bipartisan investigative report on December 1, 2015, revealing a clearly intended pricing and marketing strategy undertaken by Gilead Sciences, Inc. with little concern for patient access or availability to its life-saving drug Sovaldi which has a 99% success cure rate for hepatitis C (HCV). The report which took 18 months to complete is amazingly thorough and comprehensive worthy of the US Senate and a Pulitzer Prize for investigative reporting.

The full report is available at:

<http://www.finance.senate.gov/newsroom/ranking/release/?id=3f693c73-0fc2-4a4c-ba92-562723ba5255>.

A press conference given by Senators Wyden and Grassley is also streaming at:

[https://www.youtube.com/watch?v=rxd\\_PTfoouo](https://www.youtube.com/watch?v=rxd_PTfoouo).

According to the Senate report, "HCV is the most common blood-borne virus in the United States, affecting as many as 5.2 million people." HCV is a life threatening disease that attacks the liver, causing inflammation and scar-

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ring that results in cirrhosis and substantially increases the risk of liver cancer.

Gilead's first HCV blockbuster drug Sovaldi was approved by the FDA on December 6, 2013. Sovaldi was the first in class of a new HCV regimen that would mark the eventual beginning of interferon and ribavirin free therapy for HCV. The HCV community was overwhelmed with absolute joy at the advent of a perfect new treatment scenario for people with HCV who had been waiting years for new more effective, less-toxic HCV treatments. The recommendations of the United States Preventive Services Task Force positioned HCV in a category that would ensure reimbursement for HCV testing. The Affordable Care Act would also provide medical insurance for millions of Americans who were previously unable to obtain insurance because of pre-existing conditions, and for the first time in history, Sovaldi represented a new HCV drug that was 99% effective in curing people with HCV, including even the most hard to treat patients who were mostly African-Americans and people in danger of death from cirrhosis. Finally, a treatment was available that would first end the need for interferon with the approval of Sovaldi and eventually end the need for interferon and ribavirin with the FDA approval of Gilead's one pill once a day blockbuster Harvoni on October 10, 2014. Finally, the ravages of interferon and ribavirin treatment would be a thing of the past.

Unfortunately, Gilead turned this long-awaited perfect treatment scenario into a perfect storm of near-impossible drug access, marked by public and private insurance road blocks in the form of prior approval requirements and cost-containment measures, instituted because government and industry insurance payers could not afford the unconscionable cost of first Sovaldi that alone cost \$1,000 per pill for a total of \$84,000 for a typical course of HCV treatment, and eventually Harvoni, the Gilead combination that would cost \$94,500 for a typical cost of HCV treatment. (Prices cited are the

Wholesale Acquisition Cost before any discounts.)

The Fair Pricing Coalition (FPC), a community group co-chaired by AIDS Action Baltimore (AAB), advocates for reasonable drug prices and price increases as well as access to drugs for those in need through drug company programs approval. AAB begged Gilead at their FDA approval hearing to price Sovaldi reasonably so that the hundreds of thousands of people who had been waiting so long for effective, less toxic HCV treatments would have access to Gilead's new miracle drug. The FPC also met with Gilead before their launch of both Sovaldi and Harvoni and urged them to set these new and exciting HCV drugs at a reasonable price to ensure patient accessibility to the drugs. Nevertheless, the Gilead drugs were astronomically priced with Sovaldi's WAC price being \$1,000 per pill.

Instead of the new wonder drugs being accessible to patients who had waited so long for highly effective treatments without the horrible side effects of the past, Gilead's unsustainable price created a prior approval firestorm with insurance companies and government payers like Medicaid and Medicare. Prior approval road blocks like requiring patients being required to have late stage liver fibrosis scores and to be drug free and able to prove it are some of the cost containment measures designed to prevent budget busting costs which are now the new normal for HCV drugs. This trend is now spilling over into the HIV arena as well. What was a dream scenario is currently a terrible nightmare of bureaucratic insurance barriers for people with HCV and their doctors who must navigate this now impossible and time consuming access mine field.

"The FPC warned Gilead that unless they offered government payers supplemental rebates that the government would have no choice but to institute cost-containment measures to slow the demand for these exor-

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bitantly priced regimens. Now the poorest people in the country are the ones that face the most access barriers to all the new life-saving HCV regimens as a result of the unsustainable drug prices that Gilead initiated with their initial pricing of Sovaldi with an eye toward what the company would eventually make for the real prize interferon-ribavirin free Sovaldi containing Harvoni one pill combination in the future, said FPC co-chair Murray Penner.

The new Senate report provides clear evidence of Gilead's revenue intentions, stating, "Based on all of the information reviewed, it appears that in pricing its line of HCV drugs Gilead may have underestimated the warnings of patient groups, insurers, health care providers, and other organizations about the potential impact that price would have on access. Such warnings were made not only through the media, but directly to company officials, both in private correspondence and various public forums. While publicly saying it prioritized patient access, Gilead set Sovaldi's price at a level where ultimately many patients would not receive treatment. Sovaldi was on the market for almost a year without serious competitors, allowing Gilead to maintain a high effective price despite efforts by many payers to negotiate volume or treatment discounts or rebates."

Wyden-Grassley Report cites the landmark release of Medicaid Data requested by the Senate Committee that reveals that in 2014, more than \$1.3 Billion was spent by Medicaid Programs on Sovaldi, but that only 2.4% of Medicaid patients with HCV were actually treated because of the excessive price of Sovaldi.

According to the report, "In the 18 months that Gilead's drugs have been on the market, Medicare's monthly spending on HCV treatments increased more than six-fold from \$116.4 million in January 2014 (Sovaldi, 76%, Olysio, 9%, Other HCV drugs, 15%) to \$793.2 million in June 2015 (Harvoni, 82%; Sovaldi, 14%; Other HCV drugs, 4%). Medicare's average pre-rebate

monthly spending on HCV drugs grew to \$765 million during the first six months of 2015, more than double the average monthly spend of \$349.5 million.

Prisoners in the US Bureau of Prisons (BOP) system were also adversely affected. According to the report, "In fiscal year 2014, the year Sovaldi became available to treat prisoners infected with HCV, the BOP's spending on HCV drugs increased 14%, even though the number of patients treated decreased 52%. By comparison, in fiscal year 2012, before the Gilead pharmaceuticals had been introduced as a viable treatment option, the BOP spent \$4.4 million on treatment of 369 HCV cases... In fiscal year 2014, after the introduction of Sovaldi, the BOP spent \$5.9 million on the treatment of only 183 HCV inmates. Moreover, in fiscal year 2015 YTD with the use of both Sovaldi and Harvoni as HCV treatment, the BOP has spent nearly \$13.7 million to treat just 222 HCV-diagnosed inmates. In fiscal year 2014, Gilead's drugs accounted for 46% of the BOP's HCV spending; by fiscal year 2015, Gilead's drugs accounted for 91%.

This remarkable investigative report is an indictment against Gilead and the US drug pricing system which allows life-saving drugs to be priced at what the market will bear. At his press conference, Senator Wyden astutely observed that drugs for other diseases like Alzheimer, diabetes and cancer are in the pipeline. He noted that prices similar to Gilead's HCV drugs are clearly not sustainable by private insurance companies and government payers. AAB wishes to thank Senators Wyden and Grassley, the Minority Staff of the Senate Finance Committee and Senator Grassley's staff for their Herculean efforts in compiling this investigative bipartisan report on HCV drug pricing based on over 20,000 documents and was delighted to assist in this investigation. ▼

# GET PREPPED ON PrEP: A TOWN HALL MEETING ON PRE-EXPOSURE PROPHYLAXIS

Join us to learn about the latest exciting news on PrEP for men who have sex with men and for transgender people and hear from a panel of community members who are taking PrEP.

## DATE

MARCH 9TH, 2016

## TIME

6:30 P.M. TO 8 P.M.

## LOCATION

First and Franklin Presbyterian Church  
210 W. Madison St. (Enter on Park Avenue side)  
Baltimore, MD 21201

Food and refreshments will be provided

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May They Live Forever  
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Rest In Peace

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