

n November 2010, the National Institutes of Health (NIH) in Washington DC announced a major breakthrough in the fight against the spread of AIDS. A study had found that the medication Truvada, taken in pill form, could protect someone from contracting HIV. Many fighting the disease were understandably elated at having a pill available to combat its spread. (The research team received a congratulatory phone call from President Barack Obama.) After all, more than 50,000 Americans still contract HIV every year, and the World Health Organization (WHO) in 2012 put the number of annual new infections worldwide at 2.3 million.

Across the globe, more than 35 million people are living with AIDS. Well known blogger Andrew Sullivan compared Truvada's arrival with that of the contraceptive pill in the 1960s. Why not? A daily dose of Truvada, readily available today, prevents the transmission of HIV in 99 per cent of cases.

But those hailing the drug's promise have found themselves disappointed. To say it has not caught on in the United States would be an understatement. Only 2300 Americans in the past two years have taken Truvada, according to the online paper SF Gate. Thousands more who are already HIV-positive are taking it but only as one part of their treatment regimen.

This use has helped give Truvada's manufacturer, Gilead Sciences, a California biopharmacology company based in Foster City, north of Silicon Valley, more than \$US3 billion in sales in 2103. But these numbers would grow considerably if those who were HIV-negative started to take Truvada prophylactically, especially in the numbers health officials would like.

Why has there been such resistance to Truvada? It starts with contemporary sexual behaviour: Truvada's early promoters failed to appreciate how much having sex with caution—and that means condoms—is now the norm. The idea of abandoning condom-based safe-sex practices seemed dangerous to many, especially since the use of condoms also protects against many other sexually transmitted diseases, not just HIV. Moreover, and this is very

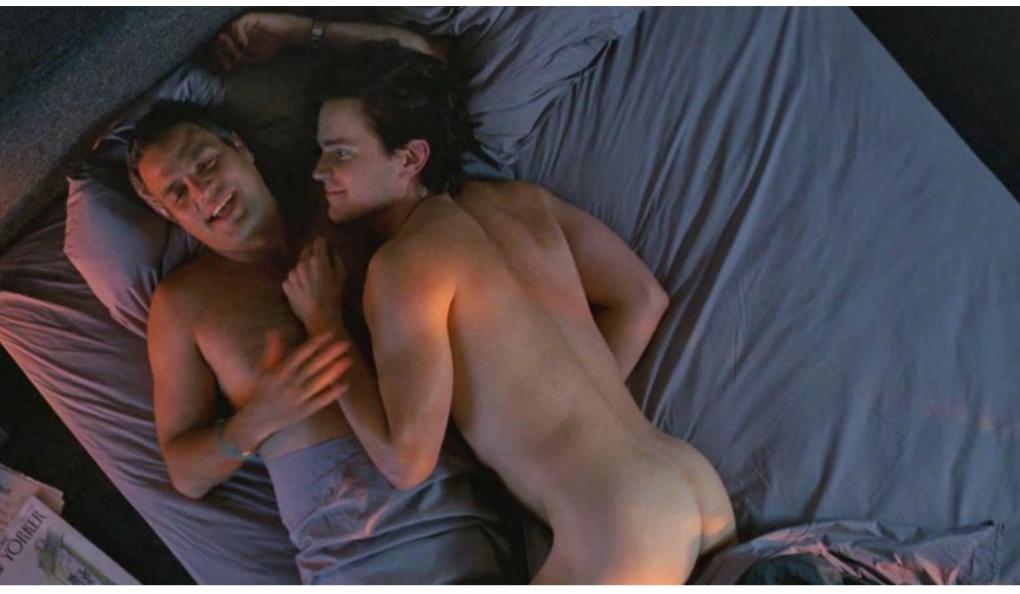


The AIDS Healthcare Foundation ran a concerted campaign to prevent Gilead Sciences obtaining FDA approval for Truvada as a pre-exposure prophylaxis (PrEP).

much the case in the gay community, taking Truvada and having sex with relative impunity, are being equated with a promiscuous lifestyle. And promiscuity is today widely held to be a bad thing.

Recently, Truvada's champions have started to fight back. They argue that, from a public health standpoint, its widespread acceptance is essential to combatting new infections. Going beyond getting the drug into the hands of the group currently most likely to become infected—young gay men of colour—they argue that Truvada further enhances the pleasure and security of thousands of serodiscordant couples: those where one partner is HIV-negative, the other positive.

Accepting now that its introduction has been controversial, these advocates have started publicly promoting Truvada's benefits. But the jury is still out as to whether Truvada will be the breakthrough



Larry Kramer's play The Normal Heart, about the early AIDS crisis, is now a film starring Mark Ruffalo and Matt Bomer.

drug its supporters first claimed it would be, or relegated to the role of just another foot soldier in the continuing fight against the spread of AIDS.

RUVADA IS A COMBINATION of two nucleoside reverse transcriptase inhibitors (NRTI): Emtricitabine (brand name Emtriva) and Tenofovir disoproxil fumarate (brand name Viread). NRTIs block an HIV enzyme called reverse transcriptase (an enzyme is a protein that starts or increases the speed of a chemical reaction). By doing so, the two drugs in combination prevent HIV from multiplying and can reduce the volume of HIV in the body. And there is no doubt Truvada works. It can used as part of ongoing treatment for those who are HIV-positive and also as a barrier drug for those who are negative.

In the US, clinicians break down HIV treatment and prevention into two categories: post-exposure prophylaxis (PEP) and PrEP, or pre-exposure prophylaxis. PEP is offered by STD clinics across New York State to HIV-negative clients who, possibly during a wild night, had unprotected sex with a positive partner. If they are treated within 72 hours, the transmission rate is reduced to almost zero. A full course of PEP treatment takes 28 days.

Truvada, however, is also being prescribed for people who want to be permanently protected against HIV. One major study—the so-called iPrEx study—found it to be 99 per cent effective in halting the transmission of the virus. While the methodology of this study has been challenged, even doubters concede Truvada is effective in preventing transmission 92 per cent of the time.

A new study in July by the iPrEx researchers found Truvada was 90 per cent effective even if not taken only two or three times a week.

"The science is clear: this drug is the future of HIV prevention," said <u>Mark Joseph Stern</u>, *Slate*'s science contributor.

LOVE YOU

Truvada critic

The science may paint a rosy view of Truvada but it has not quietened Truvada's many critics. Dr Maurizio Bonacini, director of the HIV Liver program at California Pacific Medical Center,

recently told Sandra Levy, a writer for the website Healthline, that he found it appalling that Truvada was approved to prevent HIV: "So now we will have people that have high-risk sex taking a tablet with questionable adherence, and placing themselves at risk for HBV [hepatitis B], HCV [hepatitis C], HAV [hepatitis A], HSV [herpes simplex virus], HPV [human papillomavirus] and whatever other acronym that will spell health trouble."

(Worried about such attacks, Gilead Michael Weinstein. is now stating on its website that prescribing doctors must "counsel that Truvada routing should be used only as part of a comprehensive "Other prevention strategy", and they must further such a "educate on practising safer sex consistently and died in using condoms correctly".)

N EVEN MORE vociferous critic has been Michael Weinstein, president of the AIDS Healthcare Foundation, a powerful care and treatment lobbying group in Los Angeles. "If something comes along that's better than condoms, I'm all for it, but Truvada is not that," he wrote in the *Huffington Post*. "Let's be honest: <u>It's a party drug</u>."

Perhaps predictably, Larry Kramer, the writer who first warned the world about the apocalyptic dangers of AIDS in the 1980s, agrees.

"Anybody who voluntarily takes an antiviral every day has got to have rocks in their heads," Kramer, now in poor health, said in a May interview with The New York Times about the HBO version of his 1985 play The Normal Heart. "There's something to me cowardly about taking Truvada instead of using a condom. You're taking a drug that is poison to you, and it has lessened your energy to fight, to get involved, to do anything."

A more subtle but perhaps more pervasive strike against the pill has taken the form of a guilt campaign whereby someone taking Truvada is portrayed as, rightly or wrongly, indulging in

lots of sex. According to Tim Murphy, whose long feature "Sex Without Fear"

for New York Magazine argued that some who are taking it are so concerned that they will be viewed as "sluts" that they take the pill secretly, being labelled a "Truvada whore" is just one factor underlying their guilt.

"[S]ome gay men wonder how Truvada will play in the straight world; it sends a strikingly different message from the one in the 'Sunday Styles' wedding announcements [where mentions of same-sex weddings are

routine]," writes Murphy.

"Other gay men worry that the very existence of such a drug is a kind of betrayal: of those who've died in the epidemic; of fealty to the condom, an object alternately evoking fear and resilience, hot

Abandoning condombased safe-sex practices seemed dangerous to many, especially since the use of condoms also protects against many other sexually transmitted diseases.



San Francisco politician Scott Wiener announces he's taking Truvada in September. source: http://sfpublicpress.org/

sex and safe-sex fatigue; and of a mindset of sexual prudence that has governed gay-male life since the early 1980s."

If they were not prepared for the complex and sometimes vitriolic pushback against Truvada initially, the pill's supporters, including many public health officials, are very aware of it now. And they remain adamant its health advantages far outweigh some of the potential social consequences.

In July, as part of governor Andrew Cuomo's campaign to end AIDS, the New York State Department of Health announced it would begin heavily promoting Truvada's use. The department has negotiated agreements to make Truvada less expensive. This month, it begins an advertising campaign to educate high-risk groups, particularly young gay men of colour, about the benefits of PrEP, including taking Truvada.

In San Francisco, Truvada recently gained a highly public poster boy. Scott Wiener, a member of the San Francisco Board of Supervisors, stepped forward in September to announce he is taking the prophylactic medication. As reported on the New York Times website, Wiener, who represents the Castro district of the city, said, "a much larger segment of gay men should be taking a close look at PrEP. I hope that my being public about my use of PrEP can help."

NOTHER VERY OUTSPOKEN advocate has been Damon Jacobs, a New York-based marriage and family therapist, who writes frequently about his use of Truvada. (Still, Jacobs admitted to me that he, too, has been the target of considerable anger, and at one point was called "a Truvada murderer".) The psychotherapist, whose Truvada Facebook group now has more than 4000 followers, argues "it affords an opportunity to experience intimacy and sensual pleasure without a latex barrier".

Part of the resistance to Truvada's use and why the message about it has been hard to get out stems, according to this therapist, from "people being uncomfortable talking about anal sex. They—and this includes government officials—are happy to discuss PrEP in scientific terms but they shy away from its emotional and sensual advantages."

Andrew Sullivan is also urging its adoption. "I have to say I'm aghast by the attempt to stigmatize—yes, stigmatize—a medication that could prevent countless men from being infected with HIV," he wrote in a long plea on his website, *The Dish*, last April.

"Think about it: if it were 1990 and the news emerged that—just by taking one pill a day — you could avoid ever getting infected with HIV, do you think there would be any debate at all?

There would be lines around the block for it, huge publicity campaigns to get the amazing news out, celebrations in the streets, and huge relief for anyone not infected with the virus. Fast forward a quarter century, and those taking this medication are actually demonised as 'Truvada Whores'."

But even if Truvada's supporters are able to give it a better public image, and thus make it a more acceptable and necessary part of sexual relations, this anti-HIV treatment faces additional hurdles.

The first is cost. A monthly dose costs about \$US1300, close to \$US16,000 a year. (This compares to \$US9 a month for a generic contraceptive pill; the more expensive brands range from \$US90 to \$US1080 a year.) Most insurers in the US, including

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all Obamacare plans, will cover all, or nearly all, the costs of Truvada. Proponents such as Damon Jacobs argue it is a good investment for the insurance companies, since the monthly cost of HIV treatment is much higher at more than US\$3000.

There are now questions as to whether the Supreme Court's recent Hobby Lobby ruling, which allows private employers, on the grounds of their religious belief, to block contraceptive coverage for workers, might allow employers to block Truvada reimbursement on their plans.

It's easy to blame ignorance or fear or lack of effective marketing for this medication's

behaviour, especially when it comes to sex, and even harder when that person is healthy.

Look how long it took to convince people to use condoms, and even now condom usage is far from guaranteed. Asking them to shift gears again and take a pill a day will not be easy.

"Clinicians fundamentally have difficulty giving healthy people drugs," notes Salim Karim, director of the Centre for the AIDS Programme of Research in South Africa, "This is not unique to HIV."

The resistance to Truvada demonstrates how deeply the AIDS epidemic has altered our attitudes towards sex. AIDS turned sexual relations from an arena associated with pleasure—and perhaps on occasion procreation—into one filled with anxiety. The consequences of the sexual act, mostly ignored for the two decades since the arrival of the contraceptive pill, loomed large once again. Now that there is a means of prevention, it means trying to realign that complex set of fears.

It also means dealing with the fact that millions of people are engaging in risky sex and becoming infected. As Christopher Glasek, writing in *The New Yorker*, lamented last year, "despite repeated demonstrations that Truvada provides protection from HIV, another hundred and fifty thousand Americans, more than a third of whom are in their teens and twenties, have become infected with the virus since the results of the first NIH study were released four years ago".

Since then, 50,000 more Americans have contracted HIV. Unless Truvada's supporters can convince the public to start taking it, this looks to continue.

