# Getting Practical About PrEP

May 23, 2012 By David Evans

Time to bring in the referees: a U.S. Food and Drug Administration (FDA) panel has voted to approve the first HIV prevention medication for adults in the history of the epidemic--and some people are not at all happy about it.

On May 10, 2012, an FDA advisory panel recommended with near unanimity that the antiretroviral (ARV) drug Truvada (tenofovir plus emtricitabine) may be used not only by HIV-positive people to treat their HIV, but also by some HIV-negative people to prevent them from acquiring the virus. The panel's recommendation, which the FDA will likely follow, should have been an occasion for great joy--the triumph of the first new prevention tool in the 30-year history of the epidemic--but the hearing, just like the public discussions that led up it, was marred by apprehension, misinformation and controversy.

In my capacity as Director of Research Advocacy for Project Inform I attended the marathon twelve-and-a-half hour FDA advisory meeting, one that highlighted a schism among the audience members and some of the panelists, and suggests contentious public discussions about resource allocation and on PrEP's efficacy and safety are still to come.

Since the vote, several prominent activists and researchers have expressed their displeasure, citing concerns about side effects and drug resistance and worries that people will throw out their condoms. While it's understandable that tempers are running hot as we dissect the science, pragmatism, from all sides, is what's truly needed.

AIDSmeds' very own Tim Horn gives an excellent overview of the full hearing and its outcome here (so I won't go into a blow-by-blow account), but I do want to draw attention to a presentation given at the beginning of the hearing by Susan Buchbinder of the San Francisco Department of Public Health, who made one of the most compelling cases for PrEP that I've heard yet.

Buchbinder described how condoms and behavior change alone have failed to put even a small dent in the epidemic for some time. There are myriad reasons for this, but at the heart of it is that lots of people struggle to use condoms consistently for vaginal or anal sex and our efforts to fix that have been only modestly successful. We are going on 16 years of flat HIV numbers overall--more than 50,000 new cases per year in the United States--and HIV rates are rising in young men who have sex with men (MSM), particularly young MSM of color. In fact, in some cities nearly 80 percent of young black men could become infected by the age of 60 if something doesn't change--not because of greater risk-taking behavior, but simply because HIV is so prevalent among their

sex partners that even one or two slip-ups can have devastating consequences.

On top of that, Buchbinder explained, our best interventions to help reduce HIV risk through behavior change have rarely demonstrated long-lasting effects in most people, nor have those studies ever documented an actual reduction in new HIV infections. Lastly, for many people condom use means risking the loss of a relationship or safe housing, or in some cases physical violence. Such people desperately need prevention tools that take such risks into account and that don't require the consent and cooperation of their sex partners. PrEP fully meets those conditions.

Given the stigma and emotional hardship of an HIV diagnosis, the risk of discrimination and prosecution, the reduced life expectancy and astronomical cost of health care, allowing 50,000 more people to become infected each year is an unfolding moral and financial catastrophe.

Like condoms, PrEP can be a highly effective technology--more than 90 percent effective when used correctly. And just like condoms, PrEP only works if it is used. Unlike condoms, however, which are cheap, abundant and safe, Truvada for PrEP is expensive, and carries the risk of side effects and of causing those who become infected while taking Truvada to develop drug resistance. This is a substantial point of controversy. But as Buchbinder and others have pointed out so eloquently, for tens of thousands of people each year the choice won't be one of PrEP versus condoms, but PrEP versus nothing at all.

It's fair to assume that most people share the same goal at heart: to end the AIDS epidemic in a way that respects the rights and wellbeing of those living with HIV and those at risk for becoming infected. PrEP, I believe, is a critical step toward that aim, if we apply it properly. Here's how:

**Give people the facts--the whole picture--and let them decide whether PrEP is right for them**

Let's tell people how effective the drug is when they actually take it as prescribed--over 90 percent effective--and stop quoting statistics from the clinical trials where they averaged all of the people together whether or not they were actually taking the drugs. People are going to need motivation to adhere well to PrEP and telling them that it will only cut their chance of becoming infected by 42 percent (the iPrEx study) or 75 percent (Partners PrEP) is not only dishonest, it could significantly undercut their willingness to take a pill every day. How would people feel if we said that condoms were only 30 or 40 percent effective and never revealed that this figure is true only because we counted all of the people who never used condoms in the first place?

Let's also stress that in the clinical studies, PrEP was used with condoms, at least some of the time by some of the participants, and that it shouldn't be seen as a complete substitute. That said, the fear that people will forgo condoms for PrEP is a reasonable one. Therefore, I believe strongly that we should be targeting PrEP to those who are struggling most with condom use, for whatever reason.

Let's also emphasize that while side effects were rare, and not immediately serious in the vast majority of PrEP-takers in trials, we honestly don't know what long-term side effects will look like.

People who ultimately end up taking PrEP for more than two years are entering new territory, as are people who might have greater underlying risks for kidney or bone disease.

PrEP is not benign, but neither is HIV; let's strive for balance and accuracy in describing both. We all have a responsibility to correct inaccurate information where we find it, whether in our community publications or blogs, local planning meetings or in our groups of friends. We can never know who's in most desperate need of PrEP and who might be swayed inappropriately one way or the other by misleading or cherry-picked information.

Speaking of correct information, let's also spread the message far and wide that "disco dosing," whereby people only take Truvada during sex, is completely untested and that there are reasons to fear it won't work. Misuse of PrEP is a realistic concern, and we should do what we can to discourage it, but prohibiting PrEP for everyone out of fear that some will misuse it is the worst kind of paternalism.

At the beginning of the AIDS epidemic a group of HIV-positive men and women assembled in Denver and produced what's called the Denver Principles: a manifesto that demands the rights of people with HIV to make their own healthcare decisions based on the best possible scientific knowledge available; that health care providers stop treating people with HIV like ignorant children who aren't capable of being full partners in their own health care.

We should afford the same rights and respect to HIV-negative men and women seeking to protect themselves from becoming infected.

**Advocate fiercely for demonstration projects, where we test how best to use PrEP in real-world settings**

We know how PrEP works in the artificial confines of a clinical trial (efficacy), but we don't yet know how it works in the real world (effectiveness). Understanding the difference is crucial and the only way we'll learn this will be in the multiple demonstration projects that will be slowly rolling out over the coming months and years. Yet, paradoxically, one prominent HIV organization tried to shut down two large demonstration projects in California this spring for reasons that were never entirely clear, but were apparently due to out-and-out opposition to PrEP altogether. Right-wingers spew enough anti-science rhetoric around HIV as it is (e.g. opposition to needle exchange and promotion of abstinence only education). We certainly don't need that coming from within our community.

Here are the things that each of us can do to support these demonstration projects:

- Insist that our local, state and federal AIDS organizations are advocating for demonstration projects in our communities. We'll never learn how to use PrEP safely and effectively if we don't. The AIDS Vaccine Advocacy Coalition (AVAC) will be helping us keep tabs on demonstration

projects and the target communities of those projects on their website (www.avac.org).

- Let's do what we can to reduce the stigma associated with participating in these kinds of trials. If we hear our peers or our community leaders denigrating HIV-negative people who struggle with safer sex or who might be considering PrEP, or claim that people can't be trusted with this technology let's call them on the carpet.

**Turn down the emotion on conversations regarding resources for PrEP**

At a time when we still have thousands of people with HIV who don't have health care, and when we still have waiting lists for the AIDS Drug Assistance Programs (ADAPs), it's completely understandable that people would fear anything that might further stretch resources. Still, we don't have to let that fear shut down reasonable and necessary discussions, or cause us to neglect the facts.

Some have expressed fears that if public or private health insurers choose to cover PrEP it will lead to a reduction in resources for people with HIV. Health insurance plans aren't generally set up that way, however, and extending services to one group rarely results in reduced services to another.

So if PrEP won't take resources away from HIV-positive people on Medicaid, Medicare or private health insurance, what about Ryan White or the AIDS Drug Assistance Programs, which provide healthcare and HIV drugs to low-income HIV-positive people who don't have insurance? By law, no money from these programs can ever be spent on HIV-negative individuals' health care. What's more, we have never had federal budget discussions where an increase in prevention funds at the CDC had to be offset by cuts to Ryan White, and that has been true throughout the last five years of extreme shortages in ADAP funding. At the state and local level, the reverse has actually been true.

Moreover, Truvada's maker, Gilead Sciences, has promised to offer PrEP for free to lower-income individuals who don't have health insurance, as well as to provide vouchers to cover HIV testing and condoms. That's a massive reduction in the likely costs for PrEP to cash-strapped state and local HIV prevention programs. We'll still need to find money from our HIV and STD prevention funds for doctor visits, adherence support and tests to monitor a person's bone and kidney health, but that's a more manageable task given that awareness of PrEP among those at high risk for HIV is quite low and so we aren't expecting a huge and immediate upswing in demand for it.

If PrEP uptake is as low and slow as many expect it to be, we will have plenty of time for the hoped-for demonstration projects to reveal how effective it is in real-world settings. Armed with that information a couple of years down the road, we can then have reasonable conversations about the resources required to reach those who need PrEP most. We can also figure out where PrEP will be most cost effective. Given that PrEP itself will be free to some of those who need it most, experts have already estimated that this will be incredibly cost saving when compared to a

lifetime spent on ARVS if they become infected.

HIV-positive and HIV-negative activists have partnered hand-in-hand for nearly thirty years to advocate for both care and treatment for people with HIV and prevention services for those not living with the virus. It’s been a winning, effective combination. I hope when it comes to PrEP we can overcome fear, suspicion and rancor and ensure that this partnership stays strong.

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