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# FDA panel backs first HIV drug

## Truvada protects healthy people from contracting virus

**SILVER SPRING (Maryland):** The first drug shown to prevent HIV infection has won the endorsement of a panel of US federal advisers, clearing the way for a landmark approval in the 30-year fight against the virus that causes AIDS.

In a series of votes, a Food and Drug Administration advisory panel recommended approval of the daily pill Truvada for healthy people who are at high risk of contracting HIV, including gay and bisexual men and heterosexual couples with one HIV-positive partner.

The FDA is not required to follow the panel's advice, though it usually does. A final decision is expected by June 15.

Gilead Sciences Inc, based in Foster City, California, has marketed Truvada since 2004 as a treatment for people who are infected with the virus. The medication is a combination of two older HIV drugs, Emtriva and Viread. Doctors usually prescribe it as part of a drug cocktail to repress the virus.

While panellists ultimately backed Truvada for prevention, Thursday's 12-hour meeting highlighted a number of concerns created by the first drug to prevent HIV. In particular, the panel debated whether Truvada might lead to reduced use of condoms, the most reliable defence against HIV.

The experts also questioned the drug's effectiveness in women, who have shown much lower rates of protection in studies.

Panellists struggled to outline steps that would ensure patients

take the pill daily. In clinical trials, patients who did not take their medication diligently were not protected, and patients in the real world are even more likely to forget taking it.

"The trouble is adherence, but I don't think it's our charge to judge whether people will take the medicine," said Dr Tom Giordano of Baylor College of Medicine, who voted in favour of the drug. "I think our charge is to judge whether it works when it's taken and whether the risks outweigh the benefits."

Panellists stressed that people should be tested to make sure they do not have HIV before starting therapy with Truvada.

Those who already have the virus and begin taking Truvada could develop a resistance to the drug, making it more difficult to treat.

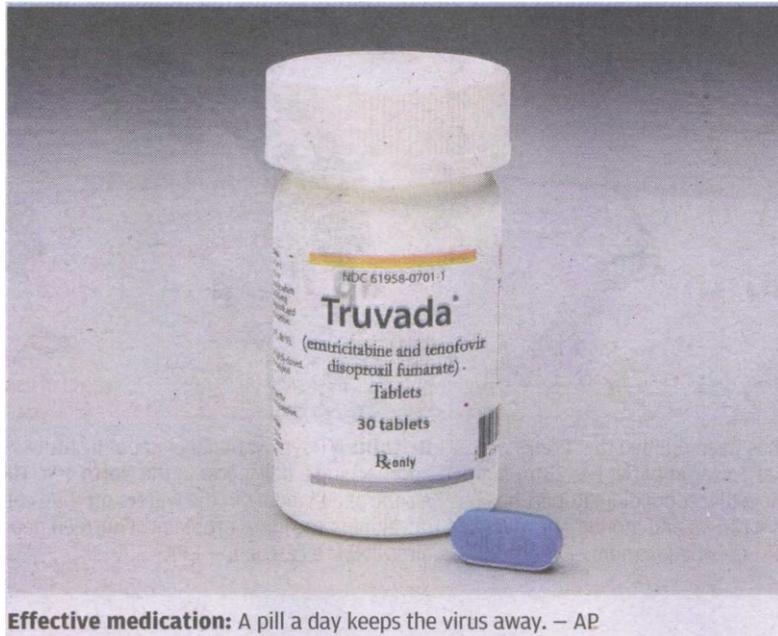
The experts grappled with how to protect patients while avoiding hurdles that could discourage them from seeking treatment.

"If we put up too many hoops to jump through, there will be people who don't make it through those hoops," said Daniel Raymond, the panel's patient representative.

Truvada first made headlines in 2010, when government researchers showed it could prevent people from contracting HIV. A three-year study found that daily doses cut the risk of infection in healthy gay and bisexual men by 42%, when accompanied by condoms and counselling. — AP

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— DR TOM GIORDANO

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**Effective medication:** A pill a day keeps the virus away. — AP