

Court ruling on PrEP could lead to more than 2,000 HIV infections in the next year, say researchers

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A recent U.S. federal court ruling that removes a requirement for employers to provide insurance coverage for the HIV prevention

medications known as Pre-Exposure Prophylaxis, or PrEP, could result in more than 2,000 entirely preventable HIV infections in the coming year, according to a new study led by researchers at the Yale School of Public Health.

The work is published in *Open Forum Infectious Diseases*.

The study addresses the potential consequences of a September 2022 decision by U.S. District Judge Reed O'Connor of Texas in a case known as *Braidwood Management v. Becerra*. O'Connor ruled in favor of the plaintiffs, a group of Christian business owners who claimed that federal mandates requiring private insurance policies to cover PrEP violated their religious freedoms.

PrEP is a scientifically proven medicine and is considered a cost-effective cornerstone of the federal government's approach to ending the HIV epidemic. Since 2019, the U.S. Preventive Services Task Force, an independent volunteer panel of experts in [disease prevention](#), has assigned PrEP a Grade A rating for the prevention of HIV in persons at high risk of infection. Federal law requires employers and insurers to provide full coverage without cost sharing for all preventive interventions that attain such a rating.

For the new study, a team of investigators led by Yale School of Public Health Professor A. David Paltiel assembled U.S.-based data on the epidemiology of HIV infection, current rates of PrEP coverage and effectiveness, and the estimated reduction in coverage if access to private [health](#) insurance benefits were curtailed. Focusing on men who have sex with men (MSM), they estimated that for every 1% decrease in the number of PrEP-eligible MSM receiving PrEP treatment, 114 new HIV infections would occur in the following year.

"Because our aim was to obtain a conservative estimate of the adverse

effects of decreasing access to HIV prevention services, we deliberately tipped the scales to understate the potential consequences of the Braidwood ruling," said Paltiel. "We estimate that at a minimum, the Braidwood ruling will result in more than 2,000 entirely preventable primary HIV infections among MSM—and many more infections in other populations at high risk of HIV transmission—in one year alone."

Researchers from Massachusetts General Hospital and Harvard Medical School contributed to the study, which applied rapid response modeling analysis to predict potential outcomes related to the decision. Scientific modeling is increasingly being used to inform lawmakers and policymakers of the impact of health care policies and practices.

The authors note that they did not address the racial, ethnic, and socioeconomic disparities that magnify the adverse consequences of restricted access to prevention services for sub-populations at elevated risk for HIV infection.

"The harms of the Braidwood ruling will be borne disproportionately by racial and ethnic socio-demographic groups at particularly high risk for HIV infection," said senior study author Dr. Meredith McNamara, an assistant professor of pediatrics at the Yale School of Medicine. "The burden of new restrictions on access to PrEP will fall on Black and Latino gay and bisexual men, as well as transgender women, who already face significant barriers to HIV prevention and care. The harms felt by indirect beneficiaries of PrEP, including children, must not be ignored."

The study supplements an earlier in-depth analysis by medical, legal, and public health experts at Yale, the University of Alabama-Birmingham, and the University of Texas-Austin challenging the [federal court](#) decision. That report, "[Braidwood Misreads the Science: the PrEP Mandate Promotes Public Health for the Entire Community](#)," was issued on Feb. 13, 2023.

The final outcome of the Braidwood case remains unclear. Judge O'Connor has yet to rule on a request by the plaintiffs for a nationwide injunction against the PrEP mandate as well as a religious exemption for PrEP [insurance coverage](#). A decision on those elements of the case is expected in the coming weeks. Potential remedies could narrowly apply to the plaintiffs alone, or in more sweeping terms, apply to all U.S. health plans.

"In the most worrisome potential outcome, the judge could strike down the Preventive Services Task Force's authority to issue binding recommendations on a range of preventive health services far beyond PrEP," said senior study author Dr. Anne M. Neilan, an infectious disease specialist with Massachusetts General Hospital. "This analysis suggests that by removing the requirement of insurers to cover PrEP, the court's ruling will have dramatic and injurious consequences for both individuals and public health, undermining years of effort and investment to end the HIV epidemic in the United States."

Other authors contributing to the study were Associate Professor Gregg Gonsalves from the Yale School of Public Health; and Ali Ahmed, Dr. Kenneth Freedberg and Elena Jin, all of Massachusetts General Hospital and Harvard Medical School.

More information: A David Paltiel et al, Increased HIV transmissions with reduced insurance coverage for HIV pre-exposure prophylaxis: Potential consequences of Braidwood Management v. Becerra, *Open Forum Infectious Diseases* (2023). [DOI: 10.1093/ofid/ofad139](https://doi.org/10.1093/ofid/ofad139)

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