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Federal Court Ruling Endangers PrEP Coverage Under ACA

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By Arthur S. Leonard 0 comments Posted on September 7, 2022

A federal judge ruled that a company does not have to provide coverage for the HIV prevention medication known as PrEP.

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Judge Reed O'Connor, a conservative activist appointed by President George W. Bush to the federal district court in Texas, ruled on September 7 that Braidwood Management, Inc., which he describes as "a Christian for-profit corporation owned by Steven Hotze" with about 70 employees, does not have to provide coverage for PrEP as part of the company's self-insured health care plan because of Hotze's religious objections to non-marital sex and homosexuality.

O'Connor, whose longtime hostility to the Affordable Care Act has generated several controversial opinions, also ruled that there were unconstitutional appointments of members of the federal

advisory body that recommended classifying PrEP as a preventive medication that should be covered by insurance plans under the Affordable Care Act.

O'Connor's ruling responded to motions for summary judgment in a complex multi-plaintiff lawsuit challenging both the procedure by which the Department of Health and Human Services (HHS) determines coverage requirements under the Affordable Care Act (ACA) and whether objecting individuals and employers are stuck having to buy or provide insurance plans covering procedures to which they have religious objections or just that they believe are not necessary for them.

Several of the plaintiffs are individuals who complain that if they want to get insurance as required by the ACA, they are required to buy a package that includes coverage mandated by HHS in a procedure that involves various federal advisory bodies, including the US Preventive Services Task Force (PSTF), the Advisory Committee on Immunization Practices, and the Health Resources and Services Administration (HRSA).

None of the "experts" appointed to these bodies to recommend coverage requirements are appointed by the President and confirmed by the Senate, so a major part of the lawsuit contends that their policy-making role violates the constitutional separation of powers, violates the constitutional requirement that "officers of the United States" be appointed by the president and confirmed by the Senate, and violates the "non-delegation doctrine" that courts have used to bar executive branch agencies and bodies from engaging in legislative activity. This doctrine fell from favor during the last century with the emergence of "the administrative state," but has been gaining new life in decisions by the increasingly conservative Supreme Court.

O'Connor concluded that the non-delegation doctrine was not violated by the preventive services provisions of the ACA, which are at issue regarding the PrEP coverage requirement. However, Judge O'Connor held that the members of the PSTF, which had determined, among other things, that PrEP had an "A" rating, on the basis of which HHS required the coverage, were not constitutionally appointed. By his interpretation, they are "officers of the United States," which under the Constitution must be appointed by the president and confirmed by the Senate, but were actually appointed through an internal process at HHS that did not involve either the president or the Senate. This could mean that their decision to classify PrEP is potentially invalid, although

Judge O'Connor "reserved judgment" on what the remedy should be, so his order does not mean that insurers can immediately drop the very-expensive medication from their plans at this point. Further briefing and argument on remedy must take place.

O'Connor turned his attention to one of the plaintiffs, Braidwood Management, whose owner, Steve Hotze, argued that under the Religious Freedom Restoration Act (RFRA), a measure passed by Congress in the 1990s, his company does not have to comply with the PrEP coverage mandate because of his religious views about homosexuality and non-marital sex.

"The PrEP mandate substantially burdens the religious exercise of Braidwood's owners," wrote O'Connor. "Hotze objects to providing coverage for PrEP drugs because he believes that (1) the Bible is 'the authoritative and inerrant word of God,' (2) the 'Bible condemns sexual activity outside marriage between one man and one woman, including homosexual conduct,' (3) providing coverage of PrEP drugs 'facilitates and encourages homosexual behavior, intravenous drug use, and sexual activity outside of marriage between one man and one woman,' and (4) providing coverage of PrEP drugs in Braidwood's self-insured plan would make him complicit in those behaviors." Failing to provide the coverage would make his plan non-compliant with the ACA, subjecting him to financial penalties as the employer.

Applying the RFRA test, O'Connor found that the government had not shown that the PrEP mandate furthers a compelling governmental interest. The government argued that it has a "compelling interest in reducing the spread of HIV, a potentially fatal disease," and that PrEP substantially reduces the risk of HIV transmission. Although covering PrEP is expensive, the government argues that the mandate is cost-effective. But O'Connor insisted that the government had "framed the interest too broadly," because "RFRA requires the Government to demonstrate that the compelling interest test is satisfied through the application of the challenged law 'to the person' — the particular claimant whose sincere exercise of religion is being substantially burdened," which requires courts "to look to the marginal interest" in enforcing the government mandate in similar cases. (This is part of the legacy of the Supreme Court's notorious Hobby Lobby decision, which resulted in many people losing their contraceptive coverage if they worked for companies whose owners had religious objections to contraceptives.)

O'Connor pointed out that the PSTF classification of PrEP on its "A" list was, technically, a "recommendation," and that PSTF "does not articulate the position of the United States government." In fact, he wrote, "PSTF recommends PrEP drugs only 'to persons who are at high risk of HIV acquisition,'" so, in his view, "neither Congress nor PSTF expressed the compelling interest that Defendants now put forward."

"More importantly," he wrote, "Defendants do not show a compelling interest in forcing private, religious corporations to cover PrEP drugs with no cost-sharing and no religious exemptions. Defendants provide no evidence of the scope of religious exemptions, the effect such exemptions would have on the insurance market or PrEP coverage, the prevalence of HIV in those communities, or any other evidence relevant to 'the marginal interest' in enforcing the PrEP mandate in these cases." He also noted that the "compelling interest" argument was undermined by two statutory exemptions: employers of fewer than 50 workers are not required to comply with the insurance mandate, and plans in existence when ACA went into effect were "grandfathered" and did not have to adjust their coverage to comply.

Thus, he concluded, the defendants "outline a generalized policy to combat the spread of HIV, but they provide no evidence connecting that policy to employers such as Braidwood, nor do they provide evidence distinguishing potential religious exemptions from existing secular exemptions."

Furthermore, the burden on religious exercise is supposed to be the "least restrictive means" of furthering the government's interest. Taking a page from the lawsuits about contraceptive coverage, O'Connor pointed out that if the government had such a strong interest in prevent the spread of HIV, it could provide the benefit of PrEP directly for those falling within the PSTF recommendation, rather than requiring employers to cover it under their insurance plans. He quoted from a 2015 Supreme Court ruling in the contraceptive battles, which stated: "If a less restrictive means is available for the Government to achieve its goals, the Government must use it." O'Connor granted summary judgment to Braidwood on the claim that the PrEP mandate violates the company's right under RFRA.

Unfortunately, Texas is within the jurisdiction of the very conservative Fifth Circuit Court of Appeals, so an appeal by the government is unlikely to achieve a reversal of O'Connor's rulings, and how they would fare in the Supreme Court, where there is a majority that is hyper-sensitive to free exercise of religious claims, is not much better. Only Congress can cure this problem, but what are the odds of that happening?