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Taking Aim at Contraceptive Coverage — The Trump Administration's Attacks on Reproductive Rights

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On November 15, 2018, the Trump administration took an aggressive stand against reproductive rights by publishing two final rules that would broadly allow employers to deny contraceptive coverage to their employees on the basis of religious or moral objections.[1,2] The rules, which aimed to erode the Affordable Care Act (ACA) requirement that private health plans cover contraception and contraceptive counseling without patient cost sharing, were temporarily blocked from implementation on January 14, 2019, when a federal court in Pennsylvania issued a nationwide injunction on the day the rules had been scheduled to take effect. The administration is expected to appeal the decision and extend the legal battle over the rules, which we believe undermine women's reproductive autonomy and could lead to an increase in rates of unintended pregnancies, unintended births, and abortions.

The ACA required most private health plans to cover at least one form of each of the 18 FDA-approved contraceptive methods for women and related services without cost sharing. Only grandfathered plans (those that were in place before March 2010 and haven't changed their benefits or costs) and employee plans offered by houses of worship are exempt from the requirement.

Religiously affiliated nonprofits have since been granted the right to an "accommodation" from the contraceptive mandate. Accommodations differ from exemptions in that employees and their dependents still receive no-cost contraceptive coverage, but the cost is shifted to the insurer or third-party administrator, thereby relieving the employer from paying for the benefit. As of 2015, an accommodation was requested by 1 in 10 large nonprofits, according to an analysis by the Kaiser Family Foundation. In 2014, the U.S. Supreme Court ruled in *Burwell v. Hobby Lobby Stores* that the contraceptive mandate violated employers' religious freedoms. The Obama administration subsequently revised the regulations to also allow closely held (usually small, family-owned) for-profit corporations to seek an accommodation from the mandate if their owners claimed a religious objection to contraception.

Although 29 states and Washington, D.C., have contraceptive-coverage laws, only 11 states and Washington, D.C., require that all types of contraceptives be covered without cost sharing. What's more, states don't have jurisdiction over self-insured plans (in which employers collect premiums and pay medical claims themselves), which

cover an estimated 60% of insured workers.

The final rules would allow a broader range of nonprofit and for-profit employers, insurers, and private colleges or universities that issue student insurance plans to be exempted from the contraceptive-coverage requirement if they cite religious or moral objections. Employers could voluntarily opt to maintain the contraceptive benefit at the health plan's expense, but they aren't required to do so. Employers also wouldn't be required to apply for an exemption or accommodation but would simply have to notify the insurer or third-party administrator of their decision. Therefore, although the final rules state that relatively few women would be affected by exemptions, the lack of a reporting mechanism would make it difficult to monitor the rules' effects.

In October 2017, the Trump administration issued nearly identical interim rules, which were blocked from going into effect nationwide by federal district courts in Pennsylvania and California. Testifying in *Commonwealth of Pennsylvania v. Trump et al.*, we disputed the administration's unsubstantiated claims that contraception is not effective at preventing pregnancy and promotes sexual promiscuity, and we argued that women and their families would be harmed if no-cost access to contraception were denied. Judge Wendy Beetlestone decided that the rules violated the Administrative Procedure Act because of the lack of the usual notice-and-comment period and that the Commonwealth would most likely suffer serious and irreparable harm because of them. A week later, California Judge Haywood S. Gilliam, Jr., delivered the opinion that "for a substantial number of women," the rules would "transform contraceptive coverage from a legal entitlement to an essentially gratuitous benefit wholly subject to their employer's discretion."

Claiming that the rules are necessary to protect the religious beliefs of certain people and entities, the Trump administration subsequently published final versions that largely maintain the interim rules and supersede them.[1,2] Twelve states and Washington, D.C., joined California's request for a preliminary injunction against the final rules, which was granted by Judge Gilliam on January 13, 2019, but the injunction protected only the states that signed on to the request. The next day, Judge Beetlestone imposed a broader injunction that temporarily blocks the rules from going into effect nationwide.

The stakes for affordable access to modern contraception are high. In the United States, 45% of pregnancies are unintended.[3] Since the ACA contraceptive-coverage requirement went into effect, there has been a substantial reduction in out-of-pocket costs for contraception and increased use of the most effective methods of reversible contraception.[4]

We believe the new rules would directly harm U.S. women and impede our ability as health care professionals to care for them in several ways. First, the rules degrade 2011 recommendations from the Institute of Medicine (IOM; now the National Academy of Medicine) and the Department of Health and Human Services that the full range of FDA-approved contraceptives and contraceptive counseling be considered preventive health care services for women and covered without cost sharing. These recommendations were reconfirmed and updated 5 years later by the Women's Preventive Services Initiative. The administration's rules suggest that since pregnancy isn't a disease, contraception doesn't need to be considered a preventive service. However, the IOM committee that made the recommendations, on which one of us served, documented that the condition prevented by contraception is unintended pregnancy, which has substantial health implications for women and babies.

Second, we believe that the government's effort to protect the religious and moral liberties of business entities infringes on the health and personal autonomy of patients. The administration has stated that women denied contraceptive coverage can obtain contraceptive services at Title X federally funded family-planning clinics, but funding for these clinics is under threat, and the clinics don't have the capacity to meet increased patient demand.[5] A new proposed regulation could further limit the number of Title X providers in many states by disqualifying Planned Parenthood from receiving federal funding through the program. Moreover, Title X clinics aren't required to provide the full range of contraceptive methods.

Third, the rules allow entities to deny coverage of contraceptives to which they have a religious or moral objection, including certain contraceptive services "which they consider to be abortifacients." By definition, contraceptives prevent pregnancy and are not abortifacients. Allowing employers to determine which contraceptives they consider to be abortifacients, rather than relying on medical definitions and evidence, promotes the spread of misinformation.

Finally, the rules could lead to further disparities in contraceptive care. By returning the cost burden of contraception to women, they would disproportionately affect women who are least able to pay for contraception, including young women, poor women, and women of color.

Eroding the ACA's contraceptive mandate is just one of several attacks the Trump administration is waging on family planning. In addition to threatening to limit Title X funding, the administration supports programs that promote abstinence until marriage, despite overwhelming evidence that they are ineffective and harmful. Physicians can advocate for their patients' right to make their own reproductive decisions and against the government's attempts to prioritize the interests of a select group of businesses over women's health.

An audio interview with Dr. Chuang is available at NEJM.org

Disclosure forms provided by the authors are available at NEJM.org.

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The FDA's Proposed Ban on Menthol Cigarettes

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In November 2018, the Food and Drug Administration (FDA) proposed issuing a ban on menthol-flavored cigarettes, which, noted FDA Commissioner Scott Gottlieb, "represent one of the most common and pernicious routes by which kids initiate on combustible cigarettes" and "disproportionately and adversely affect underserved communities."[1] The tobacco industry responded that the proposal lacked scientific justification and predicted that it would not withstand a court challenge. The battle over banning menthols is not new. But the announcement marks a new chapter in a decades-long debate over the science of menthol and addiction, the public health costs, the marketing practices of tobacco companies, the politics of tobacco control in vulnerable populations, and the FDA's authority.

The FDA's jurisdiction over menthol-flavored cigarettes dates back to June 2009, when President Barack Obama signed into law the Family Smoking Prevention and Tobacco Control Act. The law granted the agency new powers to regulate tobacco products and banned almost all flavored tobacco products, which were known to entice young people to begin smoking. But menthols won a reprieve. Instead of an immediate ban, the law created the FDA's Tobacco Products Scientific Advisory Committee (TPSAC) to study "the impact of the use of menthol in cigarettes on the public health, including such use among children, African-Americans, Hispanics, and other racial and ethnic minorities," and to make recommendations.[2]

The menthol exemption reflected the tobacco industry's power to protect its lucrative menthol market, which it had spent decades cultivating along lines of sex, race, age, and economic status, even as Congress enacted broad reforms. Just as Philip Morris built Marlboro's working-class masculine image, and Virginia Slims branded itself with appeals to women, Brown & Williamson pitched the mentholated Kools to black smokers in the 1960s, while R.J. Reynolds aimed its Salem mild menthols at women. These appeals, which the industry nurtured through advertising and support for community and civic causes, proved highly effective in attracting women and black people as customers; today, those groups remain more likely than other smokers to smoke menthols.

On health matters, the marketing of menthol cigarettes has always walked a dangerous line between shrewd and deceitful. Long before the FDA's involvement, federal regulators struggled to rein