

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 inef-



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

fective 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.

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

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This article was published on January 30, 2019, at NEJM.org.

1. Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services. Religious exemptions and

accommodations for coverage of certain preventive services under the Affordable Care Act. Final rules. Fed Regist 2018; 83(221):57536-90.

2. Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services. Moral exemptions and accommodations for coverage of certain preventive services under the Affordable Care Act. Final rules. Fed Regist 2018;83(221):57592-631.

3. Finer LB, Zolna MR. Declines in unintended pregnancy in the United States, 2008–2011. N Engl J Med 2016;374:843-52.

4. Snyder AH, Weisman CS, Liu G, Leslie D, Chuang CH. The impact of the Affordable Care Act on contraceptive use and costs among privately insured women. Womens Health Issues 2018;28:219-23.

5. Rosenbaum S, Wood S, Strasser J, Sharac J, Wylie J, Tran T-C. The Title X family planning proposed rule: what's at stake for community health centers? Health Affairs Blog. June 25, 2018 (<https://www.healthaffairs.org/doi/10.1377/hblog20180621.675764/full/>).

DOI: 10.1056/NEJMp1815738

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The FDA's Proposed Ban on Menthol Cigarettes

Keith Wailoo, Ph.D.

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.

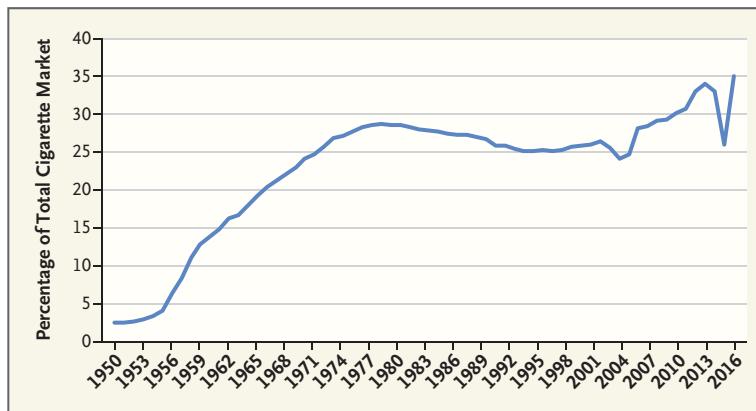
The FDA's jurisdiction over

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



Menthol Cigarettes as a Percentage of the Total Cigarette Market, 1950–2016.

in the promotion of menthols. In 1942, for example, the Federal Trade Commission ordered Brown & Williamson to “cease and desist” from trying to link its product to health by claiming that “doctors know the beneficial head-clearing quality of menthol.”³ By the time such explicit campaigns were ended, the industry had created enduring associations between menthol and health, and menthol-cigarette consumption continued to increase even after the Surgeon General’s report on smoking was issued in 1964 and after Congress banned television and radio advertising of cigarettes in 1970. By the 1980s, menthol-flavored cigarettes represented nearly 30% of the total market, a level that has held steady through recent decades (see graph).

In the 1990s, public and legal scrutiny of menthol intensified, thanks to lawsuits brought against cigarette companies by private litigants, state attorneys general, and the U.S. Department of Justice. The cases highlighted the industry’s history of denying links between smoking and cancer and other diseases, as well as its methods of targeting customers on the basis of their age, class, and race. Critics saw the use of the cartoon figure Joe Camel, the

rise of urban billboards, and the crafty use of gender and ethnic imagery as particularly egregious examples of industry tactics. Yet the companies pushed forward. In 1990, R.J. Reynolds announced that Uptown, a new menthol-heavy brand, would be test-marketed primarily in black neighborhoods in Philadelphia, provoking a fierce backlash. Louis Sullivan, Secretary of Health and Human Services under President George H.W. Bush, labeled the company “slick and sinister,” joining grassroots activists in denouncing the scheme.⁴ The backlash halted Uptown’s rollout and fueled calls for banning all menthol cigarettes.

These battles increased pressure on officials to regulate tobacco, a goal that often transcended party lines. Tobacco products had long been shielded from FDA oversight, but David Kessler, FDA commissioner under President George H.W. Bush and President Bill Clinton, sought to classify nicotine as a drug in order to assert FDA authority over tobacco products. In response, the industry launched a vigorous defense of its multibillion-dollar product. After years of litigation, the Supreme Court sided with industry, affirming that Congress had “created a distinct regulatory

scheme for tobacco products [that] squarely rejected proposals to give the FDA jurisdiction.” Without federal legislation, then, the FDA could not regulate cigarettes or nicotine, let alone menthol.

Even after the industry admitted that smoking posed enormous disease risks in the 1998 Master Settlement Agreement and abided by the agreement’s ban on cigarette-ad billboards, it continued forcefully defending nicotine and menthol. When critics marshaled evidence that menthol cigarettes resulted in deeper inhalation, made quitting more difficult, and were disproportionately used by minorities, the industry insisted that menthol did not increase the dangers of smoking.

The FDA’s marginal role in these debates changed dramatically in June 2009, when an emboldened Democratic majority in Congress, led by Representative Henry Waxman (D-CA), passed comprehensive legislation regulating the tobacco industry, granting the FDA the regulatory authority it had long sought, and banning flavored cigarettes.

But menthol, the most popular flavor for cigarettes, was excluded from the ban. Big Tobacco’s strategy of supporting civic causes, organizations, cultural events, and politicians — especially in the black community — had worked well. In 2009, the Congressional Black Caucus was split on a menthol ban, with long-time beneficiaries of industry dollars opposing a ban and other caucus members deeply concerned about protecting the health of the black community. Waxman, the law’s chief architect, said he could not afford to lose any members of the caucus. “Congress punted the question of a menthol ban to the FDA,”

Waxman recently noted. Menthol remained legal, pending review by the newly created TPSAC.

In referring the issue to the FDA, Congress set the stage for a decade of litigation. In 2011, the TPSAC determined that evidence suggested that “removal of menthol from the marketplace would benefit public health in the United States” but made no recommendations about banning products.⁵ Tobacco companies quickly challenged the committee’s legitimacy, charging that some of its members harbored conflicts of interest. In 2014, a U.S. District Court agreed, but in 2016, a federal appeals court overturned this ruling. For the next 2 years, however, the FDA was reluctant to act on menthol.

Now, nearing the 10th anniversary of the 2009 legislation, Gottlieb seems poised to act, though the agency has yet to take the next crucial step by proposing the new rule. To date, no hearings on banning combustible menthol tobacco products have been scheduled. The industry has responded to the proposal with a familiar tactic: claiming that science does not support such a ban and threatening litigation.

If the past is prologue, any path to removing menthol cigarettes from shelves will be long,

winding, and uncertain. Opponents worry that a ban would create a black market for menthol cigarettes and profound difficulties in enforcement; proponents insist that the science and the law are on their side and that the public health benefits are overwhelming. Bans or restrictions have been instituted in Canada and in several U.S. cities, including Somerville, Massachusetts, and San Francisco. New York’s City Council recently began hearings on a ban. With billions of dollars at stake, it may take years of litigation for Gottlieb’s promise of better health to be realized.

The questions surrounding menthol are intertwined with the agency’s decisions regarding e-cigarettes. Although the industry argues that there’s no scientific evidence that menthol is hazardous or addictive, the health effects of menthol smoking are worrisome; similar concerns surround e-cigarettes. As the case is made against menthols, the scientific issues will be extensively debated: the likelihood of increased addiction, the question of added difficulty in quitting smoking, and the health consequences of deep inhalation. But the regulatory debates and legal challenges to come, regarding both menthol

and e-cigarettes, will also hinge on the history of marketing — how companies have used these products to encourage blacks, women, and young people to take up a behavior with serious public health consequences.

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

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This article was published on February 20, 2019, at NEJM.org.

1. Gottlieb S. Statement from FDA Commissioner Scott Gottlieb, M.D., on proposed new steps to protect youth by preventing access to flavored tobacco products and banning menthol in cigarettes. Silver Spring, MD: Food and Drug Administration, November 15, 2018 (<https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/UCM625884.htm>).
2. Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1804(e)(1) (111th Cong.) (<https://www.govinfo.gov/content/pkg/PLAW-111publ31/html/PLAW-111publ31.htm>).
3. Brown & Williamson Tobacco Corporation. Stipulation as to the Facts and Agreement to Cease and Desist, file no. 1-14737. 1942 May 22. Brown & Williamson Records; Minnesota Documents (<https://www.industrydocumentslibrary.ucsf.edu/tobacco/docs/mrdc0136>).
4. Quinn M. Don’t aim that pack at us. *Time*. January 29, 1990 (<http://content.time.com/time/magazine/article/0,9171,969261,00.html>).
5. Food and Drug Administration. Preliminary scientific evaluation of the possible public health effects of menthol versus nonmenthol cigarettes (<https://www.fda.gov/downloads/ucm361598.pdf>).

DOI: 10.1056/NEJMp1900204

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When Sparks Fly — Or How Birding Beat My Burnout

Joshua Schor, M.D.

A little more than a year ago, I took up birding as a hobby. As a child and into my 20s, I built model airplanes, shot rifles (don’t ask), and chased the planets. Since that time, I have not had a bona fide hobby. I have read about

the tragic disappearance of hobbies from young people’s lives, though given that I’m approaching 60, my adoption of a new hobby won’t really move the needle for the young. Nevertheless, I thought maybe it would preserve

my cognition and stave off other erosions by a few more years. What I’ve discovered is that a tiny part of me that long reveled in making a “great diagnosis” was burning out, and birding has helped me have some fun again.