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Micah L. Berman

The Ohio State University College of Public Health, berman.31@osu.edu

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THE FALTERING PROMISE OF FDA TOBACCO REGULATION

MICAH L. BERMAN*

ABSTRACT

Congress passed the Tobacco Control Act (TCA) in 2009, giving the FDA the authority to regulate tobacco products for the first time. Ten years later, the promise that the TCA's enactment would be a transformative moment for public health has not materialized. To the contrary, the FDA's most notable regulatory effort—requiring graphic warnings on cigarette packages and advertisements—has been struck down in court, and the FDA is now scrambling to address a youth e-cigarette epidemic that caught it off guard. This Article provides a brief review of TCA implementation during the Obama administration, and it reviews the Trump administration's "comprehensive plan" for nicotine regulation. It concludes with a discussion of the structural obstacles to more robust FDA tobacco regulation.

* Associate Professor of Public Health and Law, The Ohio State University. Thanks to Rob Gattter and the participants at the 2018 St. Louis University Health Law Symposium on "Public Health in the Era of Alternative Facts, Isolationism, and the One Percent"; Lindsay Wiley, Marc Scheineson, and the participants at American University Washington College of Law's "FDA: Past, Present, and Future" symposium; and my colleagues who participated in the Moritz College of Law junior faculty workshop and the Health Services Management and Policy works-in-progress series.

I. INTRODUCTION

In 2009, Congress passed the Family Smoking Prevention and Tobacco Control Act (TCA) with overwhelming bipartisan majorities,¹ giving the Food and Drug Administration (FDA), for the first time, comprehensive regulatory authority over tobacco products.² At the signing ceremony, President Obama triumphantly declared, “Thanks to the work of Democrats and Republicans . . . the decades-long effort to protect our children from the harmful effects of tobacco has emerged victorious.”³

Ten years later, the promise that the TCA’s enactment would be a transformative moment for public health has not been fulfilled. Smoking rates, for the most part, have continued their slight year-to-year declines, but implementation of the TCA has so far failed to impact this overall trend in any perceptible way.⁴ E-cigarette use among youth, which was essentially a non-issue in 2009, has become an “epidemic” that threatens to produce “a whole generation of young people . . . addicted to nicotine.”⁵ The FDA’s most notable regulatory effort—requiring large, graphic warnings on cigarette packages and advertisements—was struck down in court on First Amendment grounds.⁶ And

1. Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009). The Act was approved in the Senate by a 79-19 margin. *H.R.1256 - Family Smoking Prevention and Tobacco Control Act*, CONGRESS.GOV, https://www.senate.gov/legislative/LIS/roll_call_lists/roll_call_vote_cfm.cfm?congress=111&session=1&vote=00207 (last visited Mar. 29, 2019). The Act was approved by the House of Representatives by a 307-97 vote. *Id.*

2. The history leading up to the enactment of the TCA is beyond the scope of this paper. For a detailed review of the FDA’s unsuccessful first attempt to regulate tobacco products in the 1990s, *see generally* DAVID KESSLER, *A QUESTION OF INTENT* 383–84 (2001).

3. Barack Obama, Remarks regarding the Signing of the Family Smoking Prevention and Tobacco Control Act (June 22, 2009) (transcript available at <https://obamawhitehouse.archives.gov/video/President-Obama-Signs-Kids-Tobacco-Legislation/#transcript>).

4. *See* Ahmed Jamal et al., *Current Cigarette Smoking Among Adults — United States, 2005–2014*, 64 *MORBIDITY & MORTALITY WKLY. REP.* 1233, 1233, 1235 (2015).

5. FDA Statement, FDA, Statement from FDA Commissioner Scott Gottlieb, M.D., on New Steps to Address Epidemic of Youth E-cigarette Use (Sept. 12, 2018), <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-steps-address-epidemic-youth-e-cigarette-use>. Counting e-cigarette use as a form of tobacco use (as the FDA does), the rate of past-30-day tobacco use among high school students was higher in 2018 (at 27.1%) than in any year since 2002. Press Release, Ctrs. for Disease Control & Prevention, 4.9 Million Middle and High School Students Used Tobacco Products in 2018 (Feb. 11, 2019), <https://www.cdc.gov/media/releases/2019/p0211-youth-tobacco-use-increased.html>; René A. Arrazola et al., *Patterns of Current Use of Tobacco Products Among US High School Students for 2000–2012—Findings from the National Youth Tobacco Survey*, 54 *J. ADOLESCENT HEALTH* 54, 56 tbl.1 (2014).

6. *R.J. Reynolds Tobacco Co. v. Food & Drug Admin.*, 696 F.3d 1205, 1208, 1222 (D.C. Cir. 2012).

policies within the FDA's authority that could save tens of thousands of lives, such as prohibiting the sale of menthol cigarettes, have not been put in place.⁷

What happened? Why has the TCA, at least to this point, failed to deliver on its promise? In search of answers, this Article reviews some of the key developments in the ten years the FDA has had regulatory authority over tobacco products. From the outset, there have been competing visions of what the TCA was designed to do and how it might be implemented. Tobacco companies expected that the law would essentially lock in the status quo and protect their market positions, while public health groups intended for the FDA to aggressively reshape the industry in order to sharply reduce smoking rates. It was impossible for these conflicting views to simultaneously be correct. Under the Obama administration, the tobacco industry's view of how the law would function was far closer to the reality. And although the FDA under the Trump administration has proposed surprisingly strong tobacco control measures (such as reducing the level of nicotine in cigarettes), a combination of structural factors makes it unlikely that these measures will be implemented anytime soon. Part II of this Article reviews the competing perspectives of what the TCA was intended to accomplish. Part III describes how some key battles over the TCA's implementation played out during the Obama administration. Part IV then describes the Trump administration's "comprehensive plan" for nicotine regulation, its status to date, and its future prospects. The Article concludes with a brief discussion of the structural challenges that prevent the FDA from being a more aggressive tobacco control agency and calls for a renewed focus on progress at the state and local level.

II. COMPETING VISIONS OF THE TCA

The TCA passed as a bipartisan, compromise bill, with support from all of the major public health and tobacco control groups (the Campaign for Tobacco-Free Kids, the American Lung Association, the American Cancer Society, etc.) *and* from the nation's largest tobacco company, Altria Group. This odd bedfellows partnership was possible because the two sides had very different visions of how the law would be implemented.⁸

7. The Tobacco Products Scientific Advisory Committee—the body set up by the TCA to advise the FDA on tobacco-related matters—estimated in 2011 that a rule prohibiting the sale of menthol cigarettes would save more than 300,000 lives by the year 2050. TOBACCO PRODS. SCI. ADVISORY COMM., MENTHOL CIGARETTES AND PUBLIC HEALTH: REVIEW OF THE SCIENTIFIC EVIDENCE AND RECOMMENDATIONS 205 tbl.1 (2011), <https://wayback.archive-it.org/7993/20170405201750/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM247689.pdf>.

8. See Michael Givel, *Philip Morris' FDA Gambit: Good for Public Health?*, 26 J. PUB. HEALTH POL'Y 450 (2005) (analyzing earlier version of the TCA and discussing the interests of both the public health community and Philip Morris in pursuing FDA regulation).

From the tobacco industry's side, the law established that tobacco products, and cigarettes in particular, would be subject to regulation, but that they were here to stay as legitimate, regulated products. The purpose of the TCA, from the industry's perspective, was to educate the public, prevent the introduction of new products that would harm public health *more*, and get rid of "bad actors" (e.g., those selling counterfeit cigarettes or allowing sales to minors)—but otherwise to let people make their own decisions about whether to smoke. Indeed, the law's "purpose" section states that one goal of the TCA was to "continue to permit the sale of tobacco products to adults in conjunction with measures to ensure that they are not sold or accessible to underage purchasers[.]"⁹ This framing amounted to a congressional stamp of approval for two of the industry's key talking points: that smoking is an "adult choice" and that the industry has no interest in selling to minors.¹⁰

On a more practical level, the law also provided concrete advantages to the major tobacco companies.¹¹ For one, the law's "grandfathering" provision exempted products that were commercially available as of February 15, 2007 from the Act's premarket review requirements, but it required expensive and cumbersome marketing applications for products introduced after that date.¹² This naturally favored the companies that dominated the market as of 2007 and

9. Family Smoking Prevention and Tobacco Control Act § 3.

10. Edith D. Balbach et al., *How the Health Belief Model Helps the Tobacco Industry: Individuals, Choice, and "Information"*, 15 TOBACCO CONTROL iv37, iv38 (2006). ("The view presented by [tobacco industry] executives . . . is that the responsibility of cigarette manufacturers is simply to support the individuals' right to choose to smoke and to offer them more choices among products. Moral agency is lodged only within individual consumers, who can choose to exercise those 'rights'. If the consumer makes unfortunate choices, the industry and its products are not to blame."). It is important to note that these two talking points are demonstrably false. The vast majority of current smokers started smoking as minors, not as adults, and the industry has a long history of marketing to youth. *United States v. Philip Morris USA, Inc.*, 449 F. Supp. 2d 1 (D.D.C. 2006) (detailing industry practices of marketing to youth).

11. Due to post-TCA consolidation, there are now only two major tobacco companies that control roughly 90% of the U.S. cigarette market: Altria (which owns Philip Morris USA), and Reynolds American (which owns R.J. Reynolds). Reynolds American is in turn owned by British American Tobacco, one of the world's largest international tobacco companies. In addition to the practical advantages provided by regulation, there is substantial evidence that Altria/Philip Morris supported FDA regulation in order to boost its public image. See Patricia A. McDaniel & Ruth E. Malone, *Understanding Philip Morris's Pursuit of US Government Regulation of Tobacco*, 14 TOBACCO CONTROL 193 (2005); Stanton A. Glantz et al., *Compromise or Capitulation? US Food and Drug Administration Jurisdiction over Tobacco Products*, PLOS MED., July 2009, at 1, 2; Reynolds, Altria Lead Smokers Toward Tobacco's New Era, YAHOO! FIN.: INV'R'S BUS. DAILY (Aug. 1, 2014), <https://finance.yahoo.com/news/reynolds-altria-lead-smokers-toward-212600434.html>; Leo Sun, *A Foolish Take: Which Companies Control the U.S. Tobacco Market?*, MOTLEY FOOL (May 9, 2017), <https://www.fool.com/investing/2017/05/01/a-foolish-take-which-companies-control-the-us-toba.aspx>.

12. Family Smoking Prevention and Tobacco Control Act § 910.

made it difficult for new rivals to emerge.¹³ Relatedly, large companies like Altria and Reynolds American can easily absorb substantial new compliance-related costs (like the requirement to engage in product testing and report levels of “harmful and potentially harmful constituents”¹⁴), but smaller companies cannot. Again, this reinforced the incumbent advantage these companies already possessed. Finally, it is likely that Altria—perhaps with a wink to its more litigious rival, Reynolds American—thought that any aggressive moves by the FDA could be defeated either through the courts or by lobbying the administration or Congress.¹⁵ Indeed, immediately after the law was passed, R.J. Reynolds (and other tobacco companies and retailers) prevailed in a legal challenge that knocked out what would likely have been one of the TCA’s most effective measures—limits on the use of colors and graphics in advertising for cigarettes and smokeless tobacco.¹⁶ This provision was invalidated on First Amendment grounds by the Sixth Circuit Court of Appeals, and the FDA did not appeal to the Supreme Court.¹⁷

Meanwhile, public health groups had a very different view of the law and what the FDA would do with its newfound authority. When the law was signed by President Obama, the Campaign for Tobacco-Free Kids called it a “historic blow against the greatest public health menace of our time,” and said, “[w]e look forward to the FDA effectively implementing this law and using the strong authority it has been given to *fundamentally change* how tobacco products are manufactured, marketed and sold in the United States.”¹⁸ Indeed, the law did grant the FDA tremendous regulatory powers, including the ability to:

- Set “product standards” to reduce the addictiveness, toxicity, or appeal of tobacco products (including, for example, by reducing nicotine levels or prohibiting the use of certain flavors)¹⁹;

13. See Lawrence O. Gostin, *FDA Regulation of Tobacco: Politics, Law, and the Public’s Health*, 302 J. AM. MED. ASS’N 1459, 1460 (2009) (noting that “the [TCA] is a way of solidifying Altria’s market dominance, with regulatory hurdles dampening competition, particularly the introduction of ‘safer’ cigarettes.”).

14. Family Smoking Prevention and Tobacco Control Act § 914.

15. See Letter from Michael E. Szymanczyk, Chairman & CEO, Altria Group, Inc. to the President of the United States (June 12, 2009) (on file with author) (stating that Altria supported the Tobacco Control Act, but noting that it opposed some provisions, “including those that we believe cross constitutional limits”).

16. Disc. *Tobacco City & Lottery, Inc. v. U.S.*, 674 F.3d 509, 518, 569 (6th Cir. 2012).

17. *Id.* at 518; *Am. Snuff Co., LLC v. U.S.*, 569 U.S. 946, 946 (2013) (showing that the tobacco companies appealed other elements of the case to the Supreme Court, but their petition for review was denied).

18. Press Release, Campaign for Tobacco-Free Kids, President Obama Delivers Historic Victory for America’s Kids and Health Over Tobacco (June 23, 2009), https://www.tobaccofreekids.org/press-releases/id_1161 (emphasis added).

19. Product standards apply even to “grandfathered” products that were available as of February 15, 2007. Family Smoking Prevention and Tobacco Control Act § 907.

- Require larger, graphic warning labels on cigarette products and advertisements;
- Restrict the sales, advertising, or promotion of tobacco products “to [the] full extent permitted by the [F]irst [A]mendment”;
- Conduct premarket review any new tobacco products to ensure that they are “substantially equivalent” to grandfathered products (those on the market as of February 15, 2007) or that their sale would be “appropriate for the protection of the public health”;
- Prohibit health-related (“modified risk”) claims that have not been reviewed and authorized by the FDA; and
- Engage in public health education, including efforts to prevent youth tobacco use.²⁰

Public health groups reasoned that even if the FDA was not able to take full advantage of these powers due to tobacco industry interference or other political pressures, FDA regulation would still be, on balance, a vast improvement over the unregulated status quo.²¹

III. THE OBAMA YEARS

During the Obama administration, it appeared that the tobacco industry had the more accurate assessment of how the TCA would play out in practice. The FDA implemented the mandatory provisions put in the place by the TCA, but, with the exception of the Deeming Rule (discussed below), the FDA engaged in *no* discretionary rulemaking to further the TCA’s goals. Not one product standard was issued during the Obama administration, and, apart from the Deeming Rule and the TCA’s mandatory provisions, not one restriction on the sales, promotion, or marketing of tobacco products was put in place. Moreover, FDA’s implementation of its premarket review authorities was deeply flawed, and, at least in some cases, ignored entirely by the industry without any consequences.²²

20. *Id.* §§ 3, 201, 906, 907, 910, 911. This is by no means an exhaustive list. Among other provisions, the TCA also prohibited sales to minors, limited tobacco marketing, and prohibited flavored cigarettes (with the exception of menthol and tobacco flavors). *See id.* §§ 103, 907, 910. As discussed below, the TCA originally limited the FDA’s regulatory authority to cigarettes, smokeless tobacco, and roll-your-own tobacco, but it authorized the FDA to extend its authority to other products meeting the statutory definition of a “tobacco product” through administrative rulemaking. *Id.* § 901.

21. Some within the public health community were more skeptical. *See, e.g.*, Glantz et al., *supra* note 11, at 1.

22. *See generally* Desmond Jenson et al., *FDA’s Misplaced Priorities: Premarket Review under the Family Smoking Prevention and Tobacco Control Act*, 25 TOBACCO CONTROL 246 (2016).

A few brief case studies will illustrate how some key issues played out during the Obama administration.

A. *Menthol*

Menthol is a mint-derived additive that reduces the harshness of cigarette smoking. Menthol cigarettes increase youth initiation of smoking, deepen nicotine dependence, and inhibit smoking cessation.²³ “Menthol also has a disproportionate impact on vulnerable populations including youth, African Americans, Hispanics, the Lesbian, Gay, Bisexual and Transgender (LGBT) community, Asian-Americans, and women.”²⁴ The TCA prohibited the sale of cigarettes with “characterizing flavor[s],” but included an exception for menthol flavored-cigarettes. The TCA, however, gave the FDA the authority to limit or prohibit the use of menthol in cigarettes, and it instructed the FDA’s tobacco advisory committee, the Tobacco Products Scientific Advisory Committee (TPSAC), to take up the issue of menthol regulation as its first item of business.²⁵ In March 2011, TPSAC approved an extensive 249-page review of the evidence on the topic, concluding that “[r]emoval of menthol cigarettes from the marketplace would benefit public health in the United States.”²⁶ Before the report was even issued, however, Lorillard Tobacco Company and R.J. Reynolds filed a lawsuit in federal court asserting that several members of TPSAC should have been disqualified from TPSAC participation for serving as expert witnesses against tobacco companies, consulting for pharmaceutical companies, or possessing “pre-existing, well-defined anti-tobacco stances”—and that the FDA should therefore be barred from relying on TPSAC’s menthol report.²⁷ The FDA responded by dismissing the complained-about members from TPSAC,²⁸ even though the FDA ultimately prevailed in the litigation.²⁹

The FDA then decided to conduct its own review of the science surrounding menthol (perhaps out of concern that a court would block it from relying on TPSAC’s menthol report). Though this review did not make as direct a policy recommendation, it too concluded that “adequate data suggest that menthol use

23. Andrea C. Villanti et al., *Menthol Cigarettes and the Public Health Standard: A Systematic Review*, 18 BMC PUB. HEALTH 983 (2017).

24. Joelle M. Lester & Stacey Younger Gagosian, *Finished with Menthol: An Evidence-Based Policy Option That Will Save Lives*, 45 J. L., MED. & ETHICS 41, 41 (Supp. I 2017).

25. Family Smoking Prevention and Tobacco Control Act §§ 3, 907.

26. TOBACCO PRODS. SCI. ADVISORY COMM., *supra* note 7, at 225.

27. Third Amended Complaint for Declaratory and Injunctive Relief at 58, 124, Lorillard, Inc. v. Food & Drug Admin., No. 1:110cv000440 (D.D.C. Apr. 25, 2013).

28. Statement from Mitch Zeller, FDA (Mar. 5, 2015), <https://web.archive.org/web/20150308205058/http://www.fda.gov/TobaccoProducts/NewsEvents/ucm436783.htm>.

29. R.J. Reynolds Tobacco Co. v. Food & Drug Admin., 810 F.3d 827, 832 (D.C. Cir. 2016) (holding that the plaintiffs lacked standing, and thus, the court did not address the merits of the plaintiffs’ claims).

is likely associated with increased smoking initiation by youth and young adults,” that “menthol in cigarettes is likely associated with greater addiction,” and that “it [is] likely that menthol cigarettes pose a public health risk above that seen with nonmenthol cigarettes.”³⁰ Instead of initiating regulatory action, however, the FDA then took the further step of sending out its analysis for peer review. The public health community started to grumble that the FDA was dragging its feet. In 2013, when the FDA still had not taken any action, several public health groups filed a citizen petition asking the FDA to “prohibit menthol as a characterizing flavor in cigarettes.”³¹

The FDA’s response to the Citizen Petition consisted of a three-part announcement: (1) it issued an advance notice of proposed rulemaking (ANPRM), stating that it was considering regulatory options regarding menthol in cigarettes and inviting public comments; (2) it announced that it would fund additional research on menthol in cigarettes; and (3) it stated that it was developing a public education campaign “focused on preventing and reducing tobacco use, including menthol cigarettes.”³² The ANPRM garnered more than 174,000 comments, but during the remaining three years of the Obama administration, the FDA took no further action to address the issue of menthol in cigarettes.

B. *Graphic Health Warnings*

The TCA instructed the FDA to require new, graphic warnings for cigarette packages and advertisements that would cover the top 50% of the front and rear panels of cigarette packages and the top 20% of cigarette advertisements.³³ Extensive research has demonstrated that such graphic warnings “increase knowledge about tobacco use harms and perceptions of risk and promote smoking cessation.”³⁴ Accordingly, such warnings are standard practice

30. FOOD & DRUG ADMIN., PRELIMINARY SCIENTIFIC EVALUATION OF THE POSSIBLE PUBLIC HEALTH EFFECTS OF MENTHOL VERSUS NONMENTHOL CIGARETTES 6 (2013).

31. *See generally* TOBACCO CONTROL LEGAL CONSORTIUM ET AL., CITIZEN PETITION: ASKING THE U.S. FOOD AND DRUG ADMINISTRATION TO PROHIBIT MENTHOL AS A CHARACTERIZING FLAVOR IN CIGARETTES (2013).

32. News Release, FDA, FDA Invites Public Input on Menthol in Cigarettes (July 23, 2013), <https://web.archive.org/web/20130725191928/http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm361966.htm>.

33. Family Smoking Prevention and Tobacco Control Act § 201.

34. CAMPAIGN FOR TOBACCO-FREE KIDS, TOBACCO HEALTH WARNINGS: EVIDENCE OF EFFECTIVENESS 2 (2018).

internationally,³⁵ but in the U.S., cigarette packages still have the small, text-only warnings that have been on the side of cigarette packages since 1965.³⁶

The TCA gave the FDA two years to issue a regulation proposing new warnings. Two years to the day after the TCA's enactment (June 22, 2011), the FDA did so, proposing nine images to pair with the nine textual warnings outlined in the statute. Eight of those images are shown in Figure 1.

FIGURE 1: FDA PROPOSED WARNING IMAGES³⁷



The rule was immediately challenged in federal court by R.J. Reynolds and joined by other tobacco companies, which asserted that the rule violated the companies' First Amendment rights.³⁸

The tobacco companies ultimately prevailed on the First Amendment challenge, with the United States Court of Appeals for the District of Columbia concluding in a two-to-one ruling that the images were improper because they were "primarily intended to evoke an emotional response" rather than to inform consumers.³⁹ The court further wrote that the FDA had failed to show the

35. CANADIAN CANCER SOC'Y, CIGARETTE PACKAGE HEALTH WARNINGS: INTERNATIONAL STATUS REPORT 2, 6 (5th ed. 2016).

36. See Ellen Peters et al., *Emotion in the Law and the Lab: The Case of Graphic Cigarette Warnings*, 2 TOBACCO REG. SCI. 404, 405 (2016) ("The text of the warnings has changed somewhat over time whereas their size and placement have remained similar for more than 50 years." The FDA has also acknowledged that the current warnings are "'invisible' and fail to convey relevant information in an effective way."). See also Required Warnings for Cigarette Packages and Advertisements, 75 Fed. Reg. 69,524, 69,525 (Nov. 12, 2010) (to be codified at 12 C.F.R. pt. 1141).

37. FDA, <https://www.fda.gov/>.

38. R.J. Reynolds Tobacco Co. v. Food & Drug Admin., 696 F.3d 1205, 1211 (D.C. Cir. 2012), *overruled in part by* Am. Meat Inst. v. Dep't of Agric., 760 F.3d 18 (D.C. Cir. 2014).

39. *Id.* at 1216, 1222. Earlier, the tobacco industry had challenged, on First Amendment grounds, the portion of the TCA that required graphic warnings. This challenge was rejected by the Sixth Circuit Court of Appeals. *Disc. Tobacco City & Lottery, Inc. v. U.S.*, 674 F.3d 509, 569 (6th Cir. 2012), *cert. denied*, *Am. Snuff Co., LLC v. United States*, 569 U.S. 946 (2013) ("Because graphics can present factual information regarding the health risks of using tobacco, and because

warnings would further the government's interest in reducing smoking, because it "offer[ed] no evidence showing that such warnings have *directly caused* a material decrease in smoking rates in any of the countries that now require them."⁴⁰

With respect to the latter point, the FDA's loss may have been partially self-inflicted. The court repeatedly cited the FDA's own regulatory impact analysis (RIA), which estimated that the rule would reduce the U.S. smoking rate by only 0.088%, a number that was "not statistically distinguishable from zero."⁴¹ The conclusions of this RIA have been extensively critiqued and undermined by subsequent scholarship. The RIA relied on analysis of the effects of graphic warning labels (GWLs) in Canada, but leading scholars have demonstrated that "GWLs adopted in Canada decreased adult smoking prevalence by 12–20%, 33–53 times larger than FDA's estimates."⁴²

The court's conclusions were troubling, and its loose grip on both psychology⁴³ and epidemiology⁴⁴ have been appropriately criticized elsewhere—but the decision invalidated only the specific images the FDA had proposed, not the underlying requirement for the FDA to implement graphic warnings for cigarettes. In March 2013, following the court's decision, the FDA decided not to appeal the case to the Supreme Court. Instead, the FDA stated that it would "undertake [new] research to support a new rulemaking."⁴⁵ Though the FDA has subsequently funded a considerable amount of research relating to graphic warnings, it still has not initiated any formal steps to start a new rulemaking process. Several major public health groups lost patience in October 2016 and filed a lawsuit against the FDA, arguing the FDA had "unlawfully withheld and unreasonably delayed action on a rule" required by the TCA and

this information alleviates the possibility of consumer confusion, the Act's graphic-warning requirement is constitutional. . ."). Nonetheless, the D.C. Circuit's ruling on the as-applied challenge to the FDA's regulation nullified the FDA's warning requirement.

40. *R.J. Reynolds*, 696 F.3d at 1219 (emphasis added).

41. *Id.* at 1220.

42. Jidong Huang et al., *Cigarette Graphic Warning Labels and Smoking Prevalence in Canada: A Critical Examination and Reformulation of the FDA Regulatory Impact Analysis*, TOBACCO CONTROL, Mar. 2014 at 4 (emphasis added) ("[O]ur estimates imply that if similar [graphic warning labels] had been implemented in the USA in 2012, this would have led to a reduction of 5.3–8.6 million adult smokers in the USA in 2013.").

43. Peters et al., *supra* note 36, at 409 ("The courts in the R.J. Reynolds case . . . in trying to distinguish between 'factual' and 'emotional' messages, applied a simplistic model of the human mind and how it processes information that is out of sync with current behavioral research.").

44. Wendy E. Parmet & Peter D. Jacobson, *The Courts and Public Health: Caught in a Pincer Movement*, 104 AM. J. PUB. HEALTH 392, 394 (2014) ("The majority's disdain for the FDA's evidence shows a fundamental misunderstanding of the science behind epidemiology.").

45. Letter from Eric H. Holder, Att'y Gen., to John Boehner, Speaker of the House (Mar. 15, 2013), <https://tobacco.ucsf.edu/sites/tobacco.ucsf.edu/files/u9/Ltr%20to%20Speaker%20re%20Reynolds%20v%20FDA.PDF>.

asking the court to order the FDA to issue a new rule.⁴⁶ In March 2019, the district court judge ruled in favor of the plaintiffs, ordering the FDA to complete a new rulemaking by March 2020.⁴⁷ Even if the FDA meets that deadline, however, it is likely to give the tobacco companies eighteen months (until November 2021) to comply with the new warning requirements, and the industry is certain to challenge any new mandate in court, likely causing further delays. Additionally, the general legal landscape for mandated warnings has only become more challenging for the FDA in the meantime, and thus the FDA's prospects for success in another legal battle are uncertain.⁴⁸

C. *The Deeming Rule*

The TCA gave the FDA immediate authority over cigarettes, cigarette tobacco, smokeless tobacco, and roll-your-own tobacco. However, it also authorized the agency to regulate “any other tobacco products that the Secretary by regulation deems” subject to its jurisdiction.⁴⁹

Around the time the TCA was passed, the FDA started to realize that e-cigarettes (which are not mentioned in the text of the TCA at all) raised potential public health concerns. In 2009, it tried to bar certain e-cigarettes from being imported into the country, claiming that they were “unapproved drug-device combinations.”⁵⁰ E-cigarette manufacturers challenged this action in court, arguing that their products should instead be regulated as tobacco products under the newly-enacted TCA because they contained nicotine derived from tobacco. The D.C. Circuit Court of Appeals agreed with this argument and told the FDA that e-cigarettes could only be regulated as tobacco products, provided they were

46. Complaint at 25, *Am. Acad. of Pediatrics v. United States Food & Drug Admin.*, 330 F. Supp. 3d 367 (D. Mass. 2018) (No. 1:16-cv-11985-IT).

47. Memorandum & Order Granting Injunctive Relief at 6, *Am. Acad. of Pediatrics v. Food & Drug Admin.*, 330 F. Supp. 3d 657 (D. Mass. 2018) (No. 1:16-cv-11985-IT), 2019 WL 1047149, at *3.

48. See, e.g., Wendy E. Parmet et al., *The Supreme Court's Crisis Pregnancy Center Case—Implications for Health Law*, 379 NEW ENG. J. MED. 1489, 1490 (2018) (discussing the Supreme Court's 2018 decision in *National Institute of Family and Life Advocates (NIFLA) v. Becerra* and predicting that “NIFLA may . . . threaten a wide range of commercial-disclosure requirements and warning laws, despite the Court's assurances to the contrary.”). Citing the *NIFLA* decision, a federal district court judge later enjoined implementation of the FDA's planned *textual* warnings for cigars. *Cigar Ass'n v. U.S. Food & Drug Admin.*, 317 F. Supp. 3d 555, 558 (D.D.C. 2018).

49. Family Smoking Prevention and Tobacco Control Act § 901.

50. *Sottera, Inc. v. Food & Drug Admin.*, 627 F.3d 891, at 893, 897 (D.C. Cir. 2010). The FDA claimed these products were unapproved drug-delivery devices because it appeared that they were being sold for the purpose of helping to treat the withdrawal symptoms of nicotine addiction. The FDA argued that the products needed go through the drug approval process before they could be legally marketed. *Id.*

not making therapeutic claims (which would lead them to be classified as drugs or drug-delivery devices).⁵¹

In 2011, the FDA announced that it would not appeal the court's decision to the Supreme Court and would instead issue a "Deeming Rule" to bring e-cigarettes under its TCA-based regulatory authority.⁵² But while the public health community waited for the FDA to follow through on this pledge, e-cigarette use, particularly, among youth, skyrocketed. Current e-cigarette use (defined as use within the past thirty days) by high school students increased from 1.5% in 2011 to 16% in 2015, a more than 900% increase.⁵³ Youth use of e-cigarettes is particularly concerning because of nicotine's ability to induce structural changes in the brain that enhance the risk of deep, long-lasting nicotine addiction.⁵⁴ Additionally, "[o]ther consequences of early nicotine exposure include changes to the developing limbic system (the emotional core of the brain), which increases the likelihood of developing mood disorders, attention and cognition disorders, and drug-seeking behaviors."⁵⁵ In 2013, forty attorneys general joined in asking the FDA to move quickly to regulate e-cigarettes, noting that "e-cigarettes are being marketed to children through cartoon-like advertising characters and by offering fruit and candy flavors, much like cigarettes were once marketed to hook new smokers."⁵⁶ Beyond marketing to youth, other problems resulting from the lack of regulation included a lack of basic quality control;⁵⁷ counterfeit, mislabeled, and contaminated products;⁵⁸ use of potentially dangerous flavorants and additives;⁵⁹ and false and misleading

51. *Id.* at 898-99 ("The FDA has authority to regulate customarily marketed tobacco products—including e-cigarettes—under the [Tobacco Control Act]. It has authority to regulate therapeutically marketed tobacco products under the FDCA's drug/device provisions.").

52. Joyce Frieden, *FDA Will Regulate E-Cigarettes as Tobacco*, MEDPAGE TODAY (Apr. 26, 2011), <https://www.medpagetoday.com/Washington-Watch/FDAGeneral/26131>.

53. See AHMED JAMAL ET AL., CTRS. FOR DISEASE CONTROL & PREVENTION, TOBACCO USE AMONG MIDDLE AND HIGH SCHOOL STUDENTS — UNITED STATES, 2011–2016 2 (2017), <https://www.cdc.gov/mmwr/volumes/66/wr/mm6623a1.htm>.

54. Patricia J. Zettler et al., *Closing the Regulatory Gap for Synthetic Nicotine Products*, 59 B.C.L. REV. 1934, 1949 (2018).

55. *Id.* at 1941.

56. *Regulate E-Cigarettes Like Tobacco Products, 40 Attorneys General Urge FDA*, CBS NEWS (Sept. 24, 2013), <https://www.cbsnews.com/news/regulate-e-cigarettes-like-tobacco-products-40-attorneys-general-urge-fda/>.

57. Nathan K. Cobb et al., *Novel Nicotine Delivery Systems and Public Health: The Rise of the "E-Cigarette"*, 100 AM. J. PUB. HEALTH 2340, 2341 (2010).

58. Esther E. Omaiye et al., *Counterfeit Electronic Cigarette Products with Mislabeled Nicotine Concentrations*, 3 TOBACCO REG. SCI. 347, 353 (2017).

59. Raquel Rutledge, *Lab Tests Reveal Popular E-Cigarette Liquids Contain Harmful Chemicals*, J. SENTINEL (Oct. 20, 2015), <http://archive.jsonline.com/watchdog/watchdogreports/lab-tests-reveal-popular-e-cigarette-liquids-contain-harmful-chemicals-b99583582z1-334833961.html/>.

claims.⁶⁰ Indeed, knowing that potentially onerous FDA regulation was on its way quite plausibly led some e-cigarette companies to try to make as much money as possible in a short period of time, without regard to product safety.⁶¹

In 2014, the FDA finally issued a proposed Deeming Rule.⁶² After receiving and reviewing more than 135,000 comments, it issued a final rule that took effect on August 8, 2016, deeming itself to have regulatory authority over all “products meeting the [TCA’s] statutory definition of ‘tobacco product.’”⁶³

The Deeming Rule extended the FDA’s tobacco-related jurisdiction not only to e-cigarettes, but also to cigars, cigarillos, pipe tobacco, hookah tobacco, and other previously unregulated tobacco products. Among other provisions, the Deeming Rule (1) prohibited sales of the newly-deemed products to minors, (2) mandated text-only warning labels, and (3) applied the TCA’s general regulatory framework to the newly-deemed products, including requirements relating to premarket review and pre-approval of modified risk claims.⁶⁴ Industry associations and individual businesses filed at least a dozen lawsuits challenging various aspects of the Deeming Rule; as of March 2019, several of those lawsuits remain pending.⁶⁵

The public health community generally welcomed the finalization of the Deeming Rule, but because the rule had been so extensively delayed, it had a bit of a “closing the stable door after the horse has bolted” feel to it.⁶⁶ Because the newly-deemed products were subject to the same regulatory structure as cigarettes and smokeless tobacco, finalization of the rule meant that any product introduced after February 15, 2007 was required to retroactively go through the premarket review process. The FDA recognized that it would be unfair and impractical to remove all of the thousands of newly-deemed products from the

60. Elizabeth G. Klein et al., *Online E-cigarette Marketing Claims: A Systematic Content and Legal Analysis*, 2 TOBACCO REG. SCI. 252, 259 (2016).

61. This could help explain the problem of exploding e-cigarettes. See, e.g., Susan F. Rudy & Elizabeth L. Durmowicz, *Electronic Nicotine Delivery Systems: Overheating, Fires and Explosions*, 26 TOBACCO CONTROL 10, 14 (2017).

62. Deeming Tobacco Products to be Subject to FDCA, 79 Fed. Reg. 23,142, 23,142–43 (Apr. 25, 2014) (to be codified at 21 C.F.R. pt. 1100, 1140, 1143).

63. See generally 81 Fed. Reg. 28,973, 28,974–29,020 (May 10, 2016) (to be codified at 21 C.F.R. pt. 1100, 1140, 1143).

64. *Id.*

65. For a list on ongoing lawsuits, see *Lawsuits Challenging the FDA’s Deeming Rule (2019)*, PUB. HEALTH L. CTR., <https://publichealthlawcenter.org/resources/lawsuits-challenging-fda-deeming-rule> (last updated Mar. 5, 2019).

66. See, e.g., Lawrence Gostin, *The FDA’s E-Cigarette Rule Isn’t Enough*, U.S. NEWS & WORLD REP. (May 6, 2016), <https://www.usnews.com/opinion/articles/2016-05-06/curbing-e-cigarettes-and-tobacco-use-would-be-obamas-real-moonshot> (“... At long last, the Food and Drug Administration finalized its ‘deeming’ rule, putting cigars, pipe tobacco, hookah, e-cigarettes and other nondrug nicotine products under FDA’s extensive tobacco control authority. But it is too little and too late.”).

marketplace while they underwent premarket review.⁶⁷ It therefore stated that products that had been introduced after February 15, 2007, but before the Deeming Rule was finalized, could stay on the market until they submitted such applications (which they were required to do within two years) and for another year thereafter—up to three years in total.⁶⁸ But because of Deeming Rule was not finalized until 2016, this provision—as well as most of the rest of the Deeming Rule’s requirements—was left for the Trump administration to implement.

For tobacco control advocates, the Obama years began with the excitement of the TCA’s passage and ended largely in disappointment. This section reviewed only a few of the key issues the FDA considered during this period, but the pattern is clear. Any significant FDA action (or even potential action) was met with litigation. And while the market continued to rapidly evolve, the FDA moved forward—if at all—at an exceedingly slow pace, adding unnecessary procedural steps to its deliberative processes, and at times producing questionable analyses that undermined its own litigation position.⁶⁹

IV. THE TRUMP ADMINISTRATION AND THE FUTURE

When the Trump administration came into office, there was reason for public health advocates to be concerned about the future direction of FDA tobacco regulation.⁷⁰ But Scott Gottlieb, appointed by President Trump as FDA

67. It would have been unfair, because the companies had no ability to submit a premarket review application before the Deeming Rule was finalized and thus would have had no ability to keep their products from being removed from the market even if they could meet the applicable standards.

68. 81 Fed. Reg. 28,973, 28,978. Smaller e-cigarette manufacturers and retailers complained that this premarket review requirement would, when fully implemented, put them out of business because they could not afford the expense of submitting premarket review applications. Andrew Siddons, *E-Cigarette Regulations Could Stymie Small Shops*, ROLL CALL (May 5, 2016), <https://www.rollcall.com/news/policy/fda-issues-long-awaited-e-cigarette-regulations> (quoting Gregory Conley, president of the American Vaping Association, as saying, “If the FDA’s rule is not changed by Congress or the courts, thousands of small businesses will close in two to three years.”).

69. For discussion of another example of questionable FDA analysis, see Frank J. Chaloupka et al., *Accounting for “Lost Pleasure” in a Cost–Benefit Analysis of Government Regulation: The Case of the Food and Drug Administration’s Proposed Cigarette Labeling Regulation*, 162 ANNALS INTERNAL MED. 64, 65 (2015).

70. Among other reasons, President Trump had previously partnered with Philip Morris to promote cigarettes at his casino. Adam Shapiro, *Trump’s Taj Mahal Tobacco Proposal Shows His Willingness to Put Profit over People*, NBC NEWS (July 6, 2018), <https://www.nbcnews.com/think/opinion/trump-s-taj-mahal-tobacco-proposal-shows-his-willingness-put-ncna889121>. He had also invested in tobacco companies, “including Philip Morris International, its American spinoff Altria Group, and Reynolds American Inc.” Jessica Glenza, *Tobacco Companies Tighten Hold on Washington Under Trump*, GUARDIAN (July 13, 2017), <https://www.theguardian.com/world/2017/jul/13/tobacco-industry-trump-administration-ties>. And for Secretary of Health and Human

Commissioner, immediately took a personal interest in tobacco regulation and proposed surprisingly aggressive regulatory action. On July 28, 2017, Commissioner Gottlieb announced that the FDA was pursuing a “Comprehensive Plan for Tobacco and Nicotine Regulation,” including exploring the potentially game-changing option of reducing nicotine levels in cigarettes to non-addictive levels.⁷¹

A. *The FDA’s “Comprehensive Plan for Tobacco and Nicotine Regulation”*

The FDA’s July 2017 announcement included three components.⁷² The first—and the one that drew the lion’s share of press attention—was its plan to consider lowering nicotine levels in cigarettes (and, potentially, other tobacco products) to “minimally-addictive or non-addictive levels.” If the FDA eventually implements such a regulation, it could have a transformative public health impact. It is no exaggeration to say that the tobacco industry’s entire business model is built around the addictiveness of cigarettes (and, in once-secret internal documents, the industry has admitted as much).⁷³ Young kids, who believe they will not become addicted to cigarettes, experiment with smoking, and then a significant portion of them ultimately become addicted, long-term cigarette smokers. If cigarettes were not addictive, the business model of recruiting young “replacement smokers” would fall apart.⁷⁴ Modeling by FDA researchers suggests that if cigarettes were made non-addictive, the smoking rate would fall from roughly 15% today to 2% by 2040, as the next generation escapes the trap of addiction to cigarettes.⁷⁵

Services (the cabinet official to whom the FDA Commissioner reports), President Trump appointed Tom Price, a well-established ally of the tobacco industry. Patrick Caldwell, *Of Course Trump’s Health Secretary Is a Friend of Big Tobacco*, MOTHER JONES (Feb. 10, 2017), <https://www.motherjones.com/politics/2017/02/tom-price-hhs-tobacco/> (noting Price’s history of investing in tobacco companies and receiving tobacco industry political contributions). Price has since left the administration.

71. *FDA Announces Comprehensive Regulatory Plan to Shift Trajectory of Tobacco-Related Disease, Death*, FDA (July 28, 2017), <https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm568923.htm>.

72. For collected documents outlining the various components of this comprehensive plan, see *FDA’s Comprehensive Plan for Tobacco and Nicotine Regulation*, FDA, <https://www.fda.gov/tobaccoproducts/newsevents/ucm568425.htm> (last visited Dec. 31, 2018).

73. See, e.g., *United States v. Philip Morris USA, Inc.*, 449 F.Supp.2d 1, 562 (D.D.C. 2006) (“In internal documents, Defendants admit that stimulating youth smoking initiation and retaining and increasing their share of the youth market is crucial to the success of their businesses.”).

74. *Philip Morris*, F.Supp.2d, at 562, 565 (“The only way Defendants can sustain themselves is by bringing in large numbers of replacement smokers each year.”).

75. Benjamin J. Apelberg et al., *Potential Public Health Effects of Reducing Nicotine Levels in Cigarettes in the United States*, 378 NEW ENG. J. MED. 1725, 1725, 1727–30 (2018). This estimate is based on an “expert elicitation” of the likely effects of nicotine reduction on smoking cessation, initiation, and dual use. Expert elicitation is helpful to demonstrate the possible impact

The second prong of the FDA's plan was to "encourage innovations" by "extend[ing] timelines to submit tobacco product review applications for newly regulated tobacco products that were on the market as of August 8, 2016."⁷⁶ This delay was framed as a way to ensure that if the FDA reduces nicotine levels in cigarettes, there will be other, less harmful nicotine-delivery alternatives available to current smokers. In theory, this approach makes sense. As Commissioner Gottlieb emphasized in his announcement, nicotine makes cigarettes addictive, but it is the byproducts of combustion that make them deadly.⁷⁷ If current smokers could fully transition to non-combustible nicotine delivery products, including e-cigarettes, that could be a huge win for public health. But this prong of the "comprehensive plan" was problematic from the start for two reasons. First, the FDA delayed until 2021 the requirement to submit premarket review applications for newly-deemed *combustible* tobacco products, including cigars, pipe tobacco, and hookah tobacco. Delaying review of these products is wholly contrary to the goal of moving current smokers to less harmful products. Second, it delayed until 2022 the requirement to submit premarket review applications for newly-deemed non-combustible products, including e-cigarettes, but *only for products that were on the market as of August 8, 2016* (the effective date of the Deeming Rule).⁷⁸ By definition, delaying review of products that are already being sold does nothing to promote innovation.⁷⁹ Other steps—like providing for expedited premarket review of e-

of a nicotine reduction policy in general terms, but the specifics of the model output cannot be viewed as reliable.

76. *FDA Announces Comprehensive Regulatory Plan to Shift Trajectory of Tobacco-Related Disease*, *supra* note 71.

77. Scott Gottlieb, Comm'r, Food & Drug Admin., Protecting American Families: Comprehensive Approach to Nicotine and Tobacco (July 28, 2017).

78. Unlike the Deeming Rule, the revised guidance did not provide an end date by which these products would be removed from the market if not authorized for sale by the FDA. This provided an incentive for companies to avoid submitting their premarket review applications until the last possible date.

79. In September 2018, Commissioner Gottlieb stated that, given the evidence of surging e-cigarette use, the FDA would "re-visit the compliance policy that we announced last summer to extend the application compliance periods for certain deemed products, including and especially the e-cigarettes that were on the market as of Aug. 8, 2016." Press Release, Scott Gottlieb, Comm'r, FDA, New Steps to Address Epidemic of Youth E-cigarette Use (Sept. 12, 2018), <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm620185.htm>. In doing so, the Commissioner suggested that the deadline for premarket review had been extended in 2017 because "we wanted to allow time for FDA to establish and more clearly explain the series of appropriate regulatory gates – and for companies to prepare quality applications for new products like e-cigarettes" in order to ensure that "there was a clear, viable pathway to seek FDA authorization to market alternative products for adult smokers who still sought access to nicotine." *Id.* This statement altered the FDA's previous explanation for the delayed implementation date. It suggested that the delayed enforcement was not due to a desire to "encourage innovation," but was instead due to the FDA's failure to adequately prepare itself and e-cigarette companies for the

cigarette products that meet certain criteria, as others have suggested,⁸⁰ might have been more logical ways to promote innovation.⁸¹

As the final prong of the plan, the FDA announced that it would seek public comment on three issues to “help ensure the agency has the proper science-based policies in place to meaningfully reduce the harms caused by tobacco use.”⁸² The three topics were: (1) regulation of flavors—including menthol—in tobacco products; (2) regulation of “premium” cigars; and (3) increasing access to medicinal nicotine (such as gums and patches).⁸³ As noted above, if nicotine levels are reduced in cigarettes, then it is important that current smokers have access to other, safer forms of nicotine. Accordingly, increasing access to medicinal nicotine, and potentially reformulating the products to make them more effective, is important.⁸⁴ The other two points, however, can hardly be considered part of a true “comprehensive plan.” The FDA had already studied these issues in depth, and the FDA’s new call for comments only provided an opportunity to the opposing sides to revise and resubmit comments they submitted numerous times before. As discussed above, the FDA already has all the information it needs to take action on menthol. The new announcement extended the FDA’s track record of finding additional ways to study the issue

Deeming Rule’s implementation. Given the fact that the Deeming Rule had been in the works for roughly six years before it was finalized, this is an astounding admission.

80. Eric N. Lindblom, *Effectively Regulating E-Cigarettes and Their Advertising—And the First Amendment*, 70 *FOOD & DRUG L. J.* 55, 79 (2015).

81. In March 2018, a coalition of public health groups filed a lawsuit against the FDA, claiming the delay in enforcing the Deeming Rule’s premarket review requirement was unlawful. That litigation is pending as of this writing. Laurie McGinley, *FDA Sued for Delaying E-Cigarette, Cigar Regulations*, *WASH. POST* (Mar. 27, 2018), https://www.washingtonpost.com/news/to-your-health/wp/2018/03/27/fda-sued-for-delaying-e-cigarette-cigar-regulations/?utm_term=.ba2e7abc419f.

82. *FDA Announces Comprehensive Regulatory Plan to Shift Trajectory of Tobacco-Related Disease*, *supra* note 71.

83. *Id.* Though not mentioned in its announcement, the FDA also opened a docket to “stimulate dialogue around the subject of possible illicit trade in connection with tobacco product standards.” Draft Concept Paper: Illicit Trade in Tobacco Products After Implementation of a Food and Drug Administration Product Standard; Availability; Request for Comments, 83 *Fed. Reg.* 11,754, 11,754 (Mar. 16, 2018). This feeds into one of the tobacco companies’ key talking points against any proposed nicotine standard. Andrew Rowell et al., *Tobacco Industry Manipulation of Data on and Press Coverage of the Illicit Tobacco Trade in the UK*, 23 *TOBACCO CONTROL*, May 2014, at e35, e35 (“Despite historical involvement in the illicit trade and recent evidence of complicity, [tobacco companies] continue to use the threat of illicit tobacco to argue against key tobacco control policies.”).

84. With regard to increasing access to medicinal nicotine products, this is something public health groups have been calling upon the FDA to do for years and is something the FDA has already studied and reported upon. *See, e.g., Nicotine-Containing Products*, FDA, <https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm345928.htm> (last visited Oct. 7, 2018) (reporting on FDA’s TCA-mandated report to Congress on increasing access to medicinal nicotine and its response to a citizen petition from public health groups on the same topic).

without taking action. Likewise, the FDA had already sought input on both flavored products and premium cigars.⁸⁵ With respect to premium cigars, the additional request for comments seems to have been a way to deflect some pressure from Congress to reconsider its decision (during the Obama administration) to include such products within the Deeming Rule.⁸⁶

After the explosive popularity of JUUL e-cigarettes led youth e-cigarette use to spike yet again in 2018—prompting Commissioner Gottlieb to refer to use e-cigarette use as an “epidemic”⁸⁷—the FDA added additional prong entitled “Youth Tobacco Prevention Plan,” which was absent from the its original plan.⁸⁸ The FDA has now also proposed (but not yet finalized) guidance to restrict the sale of flavored e-cigarettes and move the premarket review date for e-cigarettes back to 2021.⁸⁹

B. *The Future*

The future of the FDA’s tobacco-related plans were thrown into question in March 2019, when Commissioner Gottlieb announced that he was leaving the FDA.⁹⁰ Though his acting replacement, Ned Sharpless, has voiced support for continuing to pursue the same approach, it is unknown how actively or quickly he will be able to move it forward—or how long he will even be in that position.

85. *FDA’s Early Steps Under New Tobacco Regulatory Framework: Seeking Input, Shaping Policy*, FDA, [https://www.fda.gov/TobaccoProducts/News Events/ucm607551.htm#1](https://www.fda.gov/TobaccoProducts/News%20Events/ucm607551.htm#1) (last visited Oct. 7, 2018). Public comments on both these topics were collected in response to the proposed Deeming Rule. *Id.* Importantly, in the final Deeming Rule, the FDA intended to “use its enforcement discretion to take newly-deemed products with any flavor other than tobacco off the market – including menthol,” while allowing other newly-deemed products to stay on the market pending review of their premarket applications. Desmond Jenson & Joelle Lester, *FDA Overruled by White House on Removing Flavored Cigars and E-Cigarette Liquids from the Market*, PUB. HEALTH L. CTR. (June 2, 2016), <http://www.publichealthlawcenter.org/blogs/2016-06-02/fda-overruled-white-house-removing-flavored-cigars-and-e-cigarette-liquids-market>. However, the FDA was overruled by the White House’s Office of Management and Budget, which edited the Deeming Rule and “deleted 17 pages of evidence presented by the FDA supporting the need for immediate regulation of flavors in e-cigarettes and other tobacco products.” Micah L. Berman & Y. Tony Yang, *E-Cigarettes, Youth, and the US Food and Drug Administration’s “Deeming” Regulation*, 170 J. AM. MED. ASS’N PEDIATRICS 1039, 1040 (2016).

86. *See AAFP to House: Don’t Exempt Cigars from FDA Oversight*, AM. ACAD. FAM. PHYSICIANS (Feb. 23, 2017), <https://www.aafp.org/news/health-of-the-public/20170223houseci.html> (discussing congressional efforts to exempt premium cigars from FDA regulation).

87. Press Release, Scott Gottlieb, *supra* note 79.

88. *FDA’s Comprehensive Plan for Tobacco and Nicotine Regulation*, *supra* note 72.

89. FDA, MODIFICATIONS TO COMPLIANCE POLICY FOR CERTAIN DEEMED TOBACCO PRODUCTS: DRAFT GUIDANCE 14 (2019), <https://www.fda.gov/media/121384/download>.

90. Sheila Kaplan & Jan Hoffman, *F.D.A. Commissioner Scott Gottlieb, Who Fought Teenage Vaping, Resigns*, N.Y. TIMES (Mar. 5, 2019), <https://www.nytimes.com/2019/03/05/health/scott-gottlieb-resigns-fda.html>.

The challenges in implementing a nicotine reduction rule, however, go far beyond the question of who the commissioner is. For one, a rule to reduce nicotine levels in cigarettes must traverse a *long* road before it becomes a final regulation. In the medial products context, a 2014 review found that the average time for the FDA to finalize a significant rule was 7.3 years.⁹¹ And the long road to a final regulation makes numerous stops at the White House Office of Management and Budget (OMB), which has been quite hostile toward tobacco regulation (including during the Obama administration). Further, under the Trump administration, OMB is implementing measures like the “2-for-1 rule” and “regulatory budgets” that have significantly reduced the pace of federal administrative rulemaking across the board.⁹²

The FDA has moved forward with issuing an ANPRM on nicotine reduction, but an ANPRM is still a long way from a final rule. Indeed, the FDA Center for Tobacco Products has a poor track record of converting ANPRMs into final rules.⁹³ The likelihood that a nicotine rule will be finalized during the current presidential term is close to zero; the likelihood that it could be finalized during a potential second Trump administration term is also extremely low. Plus, at the end of the process, there is likely to be a lawsuit that could delay the implementation of a final rule even further.⁹⁴

Moreover, the tobacco industry—despite its rhetoric of wanting a “smoke-free future”—will not accept a nicotine reduction regulation without a fight and will certainly try to slow down the FDA’s progress as much as possible.⁹⁵ Already, the major tobacco companies have been reassuring investors that a nicotine rule is not coming anytime soon. Altria General Counsel Murray Garnick told investors that the FDA’s plan kicks off “a long-term process with multiple opportunities for stakeholders to provide perspective,” and he

91. Thomas J. Hwang et al., *Quantifying the Food and Drug Administration’s Rulemaking Delays Highlights the Need for Transparency*, 33 HEALTH AFF. 309, 311–12 (2014).

92. Roncevert Almond et al., *Regulatory Reform in the Trump Era: The First 100 Days*, 35 YALE J. ON REG. BULL. 29, 30, 46 (2017); CONNOR RASO, WHERE AND WHY HAS AGENCY RULEMAKING DECLINED UNDER TRUMP? (Brookings Inst. eds., 2018).

93. See Eric N. Lindblom, *Should FDA Try to Move Smokers to E-Cigarettes and Other Less-Harmful Tobacco Products and, if so, How*, 73 FOOD & DRUG L. J. 276, 294 (2018).

94. There is also likely to be a delay between the time that a rule is finalized (or finally upheld in court) and the date it goes into effect. The TCA provides that a product standard cannot take effect “before 1 year after the date of its publication unless the Secretary determines that an earlier effective date is necessary for the protection of the public health.” Family Smoking Prevention and Tobacco Control Act § 907(d)(2). If the FDA attempted to mandate an effective date less than a year from the time the rule is finalized, that would certainly trigger further litigation.

95. There seems to be unanimity among experts on this point. See David Lazarus, *White House Could be Blowing Smoke with Plan to Cut Nicotine in Cigarettes*, L.A. TIMES (Mar. 23, 2018), <http://www.latimes.com/business/lazarus/la-fi-lazarus-fda-cigarettes-nicotine-20180323-story.html> (reporting that “[n]ot one expert I spoke with said they think Big Tobacco will roll over and accept a reduction of nicotine in cigarettes”).

foreshadowed several potential lines of legal attack against a final rule.⁹⁶ Likewise, Reynolds American emphasized to investors that the FDA rulemaking process is a “multi-year” undertaking and that the company is “well prepared and will be actively engaged” in the process.⁹⁷ Besides lobbying the FDA and appealing to the courts, the industry also has other levels to pull. If the FDA does proceed in moving quickly towards a final rule reducing nicotine levels in cigarettes, the industry could seek to use its influence with Congress, the OMB, and the White House to prevent such a rule from being finalized (and, potentially, to revoke the FDA’s authority to issue such a product standard).

Thus, despite its massive public health potential, it is unlikely that a nicotine reduction rule is coming anytime soon. In the meantime, though, the FDA’s decision to delay the review of newly-deemed products *took effect immediately*. As noted above, the argument that this delay “encourage[s] innovation” does not hold up to scrutiny, as it only applies to products that were already on the market when the Deeming Rule was finalized.⁹⁸ Instead, e-cigarette companies were left with virtually free reign to continue promoting and selling their products in a largely unregulated environment that the FDA had previously referred to as the “wild, wild west.”⁹⁹ The result has been an unprecedented surge in youth e-

96. Remarks by Marty Barrington, and Other Members of Altria’s Senior Management Team at Altria’s Investor Day (Nov. 2, 2017), http://media.corporate-ir.net/media_files/IROL/80/80855/2017InvestorDay/Remarks_and_Reconciliations.pdf. For why these legal arguments are not convincing, see Micah L. Berman et al., *Anticipating Industry Arguments: The US Food and Drug Administration’s Authority to Reduce Nicotine Levels in Cigarettes*, 133 PUB. HEALTH REP. 502 (2018). There is nonetheless a high likelihood that litigation could succeed in delaying the implementation of any nicotine reduction rule.

97. Danny Herko, Exec. Vice President of Scientific & Regulatory Affairs, RAI Servs. Co., Presentation to British American Tobacco (2017).

98. Problematically, there is clear evidence that new products are being introduced illegally nonetheless, and the FDA has thus far failed to take any action to address them. Chris Kirkham, *Special Report-High Nicotine E-Cigarettes Flood Market Despite FDA Rule*, REUTERS (Sept. 24, 2018), <https://www.reuters.com/article/vaping-regulation-juul/special-report-high-nicotine-e-cigarettes-flood-market-despite-fda-rule-idUSL2N1WA017> (“[A] new wave of lower-priced Juul knock-offs is showing up at convenience stores, vape shops and online - despite a U.S. Food and Drug Administration rule banning the sale of new e-cigarette products after August 2016 without regulatory approval”).

99. Julia Belluz, *The Wild West of E-Cigarettes Just Ended with a New, Sweeping Federal Rule*, VOX (May 5, 2016), <https://www.vox.com/2016/5/5/11595784/fda-rule-e-cigarettes-tobacco> (quoting Mitch Zeller, the Director of the FDA’s Center for Tobacco Products). The FDA might disagree that these companies still operate in the “wild west,” but the FDA’s enforcement actions have been almost entirely limited to policing illegal sales to minors. With limited exceptions, it has not addressed the misleading and unauthorized claims that remain rampant in e-cigarette marketing.

cigarette use, driven by the explosive popularity of JUUL¹⁰⁰—a development the FDA is now belatedly scrambling to address.¹⁰¹

V. CONCLUSION

This largely pessimistic review of tobacco regulation under the TCA is not meant to question the efforts or intentions of those leading the FDA Center for Tobacco Products (CTP). Rather, it is to suggest that the optimistic vision that FDA regulation would “fundamentally change how tobacco products are manufactured, marketed and sold in the United States”¹⁰² was perhaps unrealistic (or at least unlikely) from the start. Even if its leadership wanted to push forward with a powerful tobacco control measure (prohibiting the sale of menthol cigarettes, for example), the structural challenges facing CTP are immense. A more rigorous analysis of those barriers is needed, but some of them can be briefly cataloged here.

As an initial matter, CTP is the newest of the FDA’s six centers and must compete with the interests of other centers when the FDA sets its priorities. Regulation of drugs and medical devices tends to dominate the FDA’s agenda, with former commissioner Gottlieb’s personal interest and involvement in tobacco regulation being the exception rather than the rule. The FDA is in turn just one agency within the Department of Health and Human Services (HHS), and so it must then compete with the other priorities of the Department. During the Obama administration, for example, HHS leadership was understandably preoccupied with implementing and defending the Affordable Care Act. And, for high-level decisions that require White House involvement, HHS is just one of the many cabinet agencies. Thus, what may look to the outside like wheel-spinning may reflect the difficulties inherent in pushing aggressive policy measures through so many levels of review.

Moreover, the rulemaking process provides many opportunities for public health initiatives to get derailed. In addition to lengthy and complex internal FDA processes and the well-established pathologies of the notice-and-comment

100. Andrea S. Gentzke et al., *Vital Signs: Tobacco Product Use Among Middle and High School Students—United States, 2011–2018*, 68 MORBIDITY & MORTALITY WKLY. REP. 157, 162 (2019).

101. Moreover, the FDA has, to date, failed to remove from the market the new e-cigarette products (largely JUUL copycats) that have been illegally introduced after the effective date of the Deeming Rule, tacitly giving the green light to companies to keep developing and introducing new products without going through the required FDA review. Kirkham, *supra* note 98. The FDA did send warning letters to some of these companies in October 2018, but no other action has been taken. Press Release, FDA, FDA Advances Investigation into Whether More Than 40 E-cigarette Products are Being Illegally Marketed and Outside Agency’s Compliance Policy (Oct. 12, 2018), <https://www.fda.gov/news-events/press-announcements/fda-advances-investigation-whether-more-40-e-cigarette-products-are-being-illegally-marketed-and>.

102. Press Release, Campaign for Tobacco-Free Kids, *supra* note 18.

process,¹⁰³ proposed rules must make repeated trips to OMB, where the tobacco industry can lobby for them to be delayed, weakened, or killed.¹⁰⁴ Members of Congress can also weigh in, threatening to take retaliatory action against the FDA if it proceeds. Indeed, the mere mention that the FDA was open to a prohibition on menthol cigarettes provoked a strong response from the two senators from North Carolina (the home state of R.J. Reynolds).¹⁰⁵ And all of these structural obstacles are without reference to the dynamics of the current administration, which has put policies in place that are designed to make it extremely difficult for any regulatory agency to issue new regulations.

Should the FDA nonetheless somehow succeed in finalizing a regulation that threatens the industry's interests, tobacco manufacturers, retailers, or trade associations will be standing by ready to litigate. And federal courts, as a general matter, are becoming less deferential towards regulatory agencies¹⁰⁶ and more receptive to the First Amendment claims of corporations.¹⁰⁷ In short, the TCA set up tobacco regulation to play out in arenas—the FDA, OMB, courts, and Congress—that tend to be challenging turf for public health groups to navigate.

Evaluating the impact of FDA tobacco regulation overall is complicated by the fact that it is impossible to say what would have happened in the absence of such regulation. Perhaps the mere fact of FDA tobacco regulation has thwarted some negative developments that might otherwise have occurred. But if public health advocates are relying on the FDA to proactively lead the way forward, they are likely to be disappointed. In the U.S., tobacco control has historically

103. Thomas O. McGarity, *Some Thoughts on "Deossifying" the Rulemaking Process*, 41 DUKE L. J. 1385, 1388 (1992) ("Important rulemaking initiatives grind along [through the notice-and-comment rulemaking process] at such a deliberate pace that they are often consigned to regulatory purgatory, never to be resurrected again.").

104. The current acting administrator of the OMB's Office of Information and Regulatory Affairs, which is the office that reviews agency rules, has said that one of his top priorities is to "ensur[e] that all relevant federal stakeholders are able to review a regulation and comment on it[.]" Cheryl Bolen, *Trump's New Regulations Chief to Oversee Major Rule Rollbacks*, BLOOMBERG GOV. (Apr. 15, 2019), <https://about.bgov.com/news/trumps-new-regulations-chief-oversee-major-rule-rollbacks/>. Protecting the public health policymaking process from the influence of the tobacco industry is key pillar of the World Health Organization's Framework Convention on Tobacco Control. *Guidelines for Implementation of Article 5.3 of the WHO Framework Convention on Tobacco Control*, WHO, https://www.who.int/fctc/guidelines/adopted/article_5_3/en/ (last visited May 1, 2019). The U.S., however, is not a party to that agreement.

105. Richard Craver, *Burr, Tillis Push Back Against Tighter FDA Tobacco Restrictions, Particularly Banning Menthol Cigarettes*, WINSTON-SALEM J. (Nov. 20, 2018), https://www.journalnow.com/business/burr-tillis-push-back-against-tighter-fda-tobacco-restrictions-particularly/article_6077f034-13c1-599e-ad3f-544848dbcd74.html.

106. Rex S. Heinke et al., *The Supreme Court Takes Aim at Deference to Administrative Agencies*, N.Y. L. J. (Apr. 5, 2019), <https://www.law.com/newyorklawjournal/2019/04/05/the-supreme-court-takes-aim-at-deference-to-administrative-agencies/>.

107. See generally Robert Post & Amanda Shanor, *Adam Smith's First Amendment*, 128 HARV. L. REV. F. 165 (2015).

been more innovative and effective at more local levels, where the tobacco industry tends to have less power and influence.¹⁰⁸ Despite the broad authority that the FDA now has, policymaking at the state and local levels is still likely to be the most effective pathway forward.

108. Heather Wipfli & Jonathan M. Samet, *One Hundred Years in the Making: The Global Tobacco Epidemic*, 37 ANN. REV. PUB. HEALTH 149, 153 (2016) (reviewing history and discussing how “[a]dvocates in the United States combated the tobacco industry primarily by focusing on state and local action.”). Of course, the tobacco industry has historically been quite influential in certain tobacco-growing regions. Amanda Fallin & Stanton A. Glantz, *Tobacco-Control Policies in Tobacco-Growing States: Where Tobacco Was King*, 93 MILBANK Q. 319, 321 (2015) (“The tobacco industry has been especially concerned about blocking tobacco taxes in tobacco states, has promoted a pro-tobacco social norm in these states, and has succeeded in winning state laws that preempt local clean indoor air laws in tobacco-growing states.”).

