The Regulatory Capture of FDA's Tobacco Policy—And How to Reverse It

JEFFREY WEISS*

ABSTRACT

Smoking is the leading cause of preventable death in the United States. Passage of the 2009 Family Smoking Prevention and Tobacco Control Act (TCA) placed regulatory oversight for tobacco products with the Federal Food and Drug Administration (FDA). However, the newly formed Center for Tobacco Products (CTP) has not met expectations for significant tobacco harm reduction. A formal review has recommended that FDA establish a five-year Strategic Plan to refocus on the public health goals of the TCA. This Article explores the path of the CTP and interest group involvement and proposes elements for FDA to consider in formulating that plan.

I. INTRODUCTION

Tobacco use continues to be the leading cause of preventable death and disease in the United States.[1] Cigarettes are responsible for the vast majority of all tobacco-related disease and death in the United States.[2] According to the Centers for Disease Control and Prevention (CDC), each year 480,000 American adults die prematurely from smoking-related illnesses, or about one in five deaths.[3] This incidence places the estimated annual U.S. smoking-related death rate above that from COVID-19 in each of the years 2020–2022.[4]

Passage of the 2009 Family Smoking Prevention and Tobacco Control Act (TCA) was a milestone in the decades-long fight against smoking-related death and disease.

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* From 2012 to 2017, Jeffrey worked for NJOY, Inc. as its General Counsel, during 2016–2017 as its Interim President, and from 2010 to 2015, he was a member of its Board of Directors. From 2017 to 2020, he worked for NJOY, LLC as its General Counsel and from 2020 to May 2023 as its Chief Engagement Officer and Principal Deputy General Counsel. NJOY, LLC holds six of the twenty-three marketing granted orders issued by FDA for ENDS products. Jeffrey is currently a partner in Flagstaff Ventures, a venture capital firm with no connection to the nicotine or tobacco industries.

1 *See The Health Consequences of Smoking—50 Years of Progress. A Report of the Surgeon General*, CTRS. FOR DISEASE CONTROL & PREVENTION (2014), https://www.ncbi.nlm.nih.gov/books/NBK179276/ (last visited May 10, 2024).

2 *See A Report of the Surgeon General: How Tobacco Smoke Causes Disease: What It Means to You*, CTRS. FOR DISEASE CONTROL & PREVENTION (2010), https://stacks.cdc.gov/view/cdc/12057 (last visited May 10, 2024).

3 *See, e.g.*, *Smoking and Tobacco Use: Diseases and Death*, CTRS. FOR DISEASE CONTROL & PREVENTION (July 19, 2022), https://archive.cdc.gov/www_cdc_gov/tobacco/data_statistics/fact_sheets/fast_facts/diseases-and-death.html (last visited July 29, 2022).

4 Farid B. Ahmad, Jodi A. Cisewski, Jiaquan Xu & Robert N. Anderson, *COVID-19 Mortality Update—United States, 2022*, 72 MORBIDITY & MORTALITY WKLY. REP. 493 (May 5, 2023) at Table 1, https://www.cdc.gov/mmwr/volumes/72/wr/mm7218a4.htm#T1_down (last visited May 4, 2023).

It fulfilled the long-sought public health goal of U.S. Food and Drug Administration (FDA) oversight over all tobacco products. Among other things, the statute formally integrated tobacco harm reduction into the fight against smoking by creating a Center for Tobacco Products (CTP) and giving the new Center review authority over the introduction of new tobacco products that have the potential to reduce harm to smokers who switch. In providing this authority, Congress recognized that harm reduction was a needed tool in the fight against smoking-related illness and death for those smokers unable or unwilling to quit all use of nicotine—but also that industry could not be trusted to do this without FDA oversight given the disastrous experience with light and low-tar cigarettes. This framework for FDA-supervised harm reduction was the culmination of nearly fifteen years of consensus building among tobacco control and public health experts—as reflected in three major government reports on smoking and a historic, four-year "strategic dialogue."[5]

Nearly fifteen years after passage of the TCA, its promise remains unfulfilled. CTP has become a troubled center, leading FDA Commissioner Dr. Robert Califf to ask the independent Reagan-Udall Foundation (Reagan-Udall) to conduct an operational review. That review, completed at the end of 2022, included fifteen recommendations. First among these—and foundational to all of them—was the need for CTP to craft a five-year Strategic Plan with input from stakeholders. The plan would allow CTP to get out of its current "reactive mode" in which it finds itself "moving from one challenge to the next, mainly provoked by . . . outside forces," namely, "public health advocates and the regulated industry."[6]

A new Strategic Plan as envisioned by Reagan-Udall gives FDA an opportunity for a reset—to chart a new path forward that has the historic potential to impact public health positively and change forever the arc of smoking-related illness and death. To craft and subsequently implement a proper plan, however, the agency first needs to recognize the extent to which it has succumbed to what is known in the literature as "regulatory capture"—where a regulator's agenda has been co-opted by industry or interest groups.[7] In the case of FDA's tobacco policy, capture has occurred at the hands of certain key tobacco control advocacy groups who are acting in contravention of the TCA, the historic harm reduction consensus, and the agency's own better judgment. In formulating a new five-year Strategic Plan within the spirit of the Reagan-Udall recommendation, FDA must have as its initial goal the reclaiming of its independence in the implementation of its legislative prerogatives under the TCA, as informed by the science and in the spirit of the historic harm reduction consensus, ending the regulatory capture that time and again has distorted agency decision-making and precipitated much of CTP's ongoing struggle.

Part II of this Article introduces the concept of regulatory capture. Part II also presents the historic background essential to an understanding of the present policy environment, including the road to the 1998 Master Settlement Agreement, the evolution of harm reduction in the tobacco context, the development of a harm reduction consensus, passage of the TCA in 2009, and the controversial emergence of e-cigarettes. Part III describes the evolving position of the major tobacco control advocacy groups toward e-cigarettes, from the landmark *Sottera* litigation through

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5 *See infra* notes 48, 52, 62, 73 and accompanying text.

6 *See infra* note 250, at 5.

7 *See infra* notes 8–10 and accompanying text.

the 2019 Bloomberg Philanthropies-funded flavors initiative. Part IV presents the contrasting approach of the United Kingdom (UK), a leader in traditional tobacco-control policies, to e-cigarettes. Part V demonstrates capture by a coalition of tobacco control advisory groups (TCAGs) of FDA's tobacco policy through seven illustrative events. Part VI addresses the Reagan-Udall operational review and its key recommendation that FDA develop a five-year strategic plan. Part VII proposes seventeen key considerations that FDA should take into account in crafting that plan.

II. BACKGROUND

A. The Concept of Regulatory Capture

Nobel laureate George Stigler is generally credited with identifying what has come to be known as regulatory capture.[8] It is a phenomenon in which a regulatory agency becomes captured by outside forces—typically the industry that the agency is supposed to be regulating. According to Stigler, the goals of capture by industry may be, for example, to reduce entry by potential competitors, restrict the growth of new firms, affect production of substitutes and complements (e.g., butter producers seeking to suppress margarine and to encourage bread production), or enact price controls.[9]

The regulated industry, however, is not the only actor capable of accomplishing regulatory capture. Scholars have also identified political interest groups as potential capturers. In that scenario, an interest group may act on its own or in collusion with industry—what regulatory economist and former Federal Trade Commission (FTC) Executive Director Bruce Yandle has called the "bootlegger and Baptist" theory of regulation.[10]

As will be discussed below, through more than a half-dozen examples dating back to the passage of the TCA in 2009, FDA's tobacco policy has been effectively captured by a coalition of TCAGs. These groups include the Campaign for Tobacco-Free Kids (CTFK), the Truth Initiative, the American Cancer Society Cancer Action Network, the American Lung Association, the American Heart Association, and the American Academy of Pediatrics. TCAG have accepted millions of dollars, directly or indirectly, from Bloomberg Philanthropies (BP).[11] Through that funding, BP has emerged as the primary guardian of TCAG's policies—having driven multiple profound policy shifts on the part of TCAG members themselves. The capture of FDA's tobacco policy by established TCAGs has itself become derivative of the capture of those same groups by BP. As will be shown, the regulatory capture of FDA's tobacco policy has significantly contributed to the myriad legal and operational challenges faced by the agency.

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[8] *See* George J. Stigler, *The Theory of Economic Regulation*, 2 BELL J. ECON. & MGMT. SCI. 3 (1971).

[9] *Id.* at 5–6.

[10] Bruce Yandle, *Bootleggers and Baptists—The Education of a Regulatory Economist*, REGULATION, May/June 1983. The name comes from the phenomenon of Baptists who want to see liquor stores closed on Sundays for religious reasons, joining forces with bootleggers, who want to be able to sell liquor on a day when stores are closed, joining forces to support the passage of so-called Sunday "blue laws."

[11] *See infra* notes 110, 172 and accompanying text.

B. From the "Tobacco Wars" to the Master Settlement Agreement

1. The 20th Century "Tobacco Wars"

A brief history of the 20th century "tobacco wars"[12] will be helpful to understand how a special relationship between FDA and TCAGs was first created, ultimately leading to agency capture. Increasingly during the first half of the 20th century, as lung cancer rates climbed, there was a growing suspicion that cigarette smoking may be the culprit. The first studies to make the case compellingly for a link between smoking and lung cancer came in the early 1950s from A. Bradford Hill and Richard Doll in the UK[13] and Ernst Wynder in the United States.[14] Over the ensuing decade, the strength of the case against smoking grew to the point of scientific consensus, culminating in landmark reports by Britain's Royal College of Physicians in 1962[15] and the U.S. Surgeon General in 1964.[16]

In response, the tobacco industry—on the advice of public relations experts[17]—sought aggressively to deny the existence of a link between cigarettes and lung cancer. The beginning of that campaign is generally regarded to have been "A Frank Statement to Cigarette Smokers" (Frank Statement), published in hundreds of newspapers across the United States in 1954 by a coalition of cigarette manufacturers.[18] The Frank Statement asserted that there are "many possible causes of lung cancer," that "there is no agreement among the authorities" regarding the cause, and that "there is no proof that cigarette smoking is one of the causes."[19]

The Frank Statement was emblematic of a tobacco industry tactic to create uncertainty about whether cigarettes were in fact dangerous. Industry denials of the link between smoking and serious illness continued unabated for the next four decades. Science historians Naomi Oreskes and Erik Conway have dubbed the

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[12] For a complete, masterful telling of the story of the "tobacco wars," see RICHARD KLUGER, ASHES TO ASHES: AMERICA'S HUNDRED-YEAR CIGARETTE WAR, THE PUBLIC HEALTH, AND THE UNABASHED TRIUMPH OF PHILIP MORRIS (1996).

[13] Richard Doll & A. Bradford Hill, *Smoking and Carcinoma of the Lung*, 2 BRIT. MED. J. 739 (1950); Richard Doll & A. Bradford Hill, *Study of the Aetiology of Carcinoma of the Lung*, 2 BRIT. MED. J. 1271 (1952).

[14] Ernst L. Wynder, *Tobacco Smoking as a Possible Etiologic Factor in Bronchiogenic Carcinoma, A Study of Six Hundred and Eighty-Four Proved Cases*, 143 JAMA 329 (1950); Ernst L. Wynder, *Tobacco as a Cause of Lung Cancer: With Special Reference to the Infrequency of Lung Cancer Among Nonsmokers*, 57 PENN. MED. J. 1073 (1954); *See also supra* note 40; Ernst L. Wynder, Evarts A. Graham & Adele B. Croninger, *Experimental Production of Carcinoma with Cigarette Tar*, 13 CANCER RSCH. 855 (1953).

[15] *See* ROYAL COLLEGE OF PHYSICIANS, SMOKING AND HEALTH: A REPORT OF THE ROYAL COLLEGE OF PHYSICIANS OF LONDON ON SMOKING IN RELATION TO CANCER OF THE LUNG AND OTHER DISEASES (Pitman Med. Pub. Co. 1962).

[16] PUB. HEALTH SERV., U.S. DEP'T OF HEALTH, EDUC. & WELFARE, PUB. NO. 1103, SMOKING AND HEALTH: REPORT OF THE ADVISORY COMMITTEE TO THE SURGEON GENERAL OF THE UNITED STATES (1964), https://www.govinfo.gov/content/pkg/GPO-SMOKINGANDHEALTH/pdf/GPO-SMOKINGANDHEALTH.pdf.

[17] KLUGER, *supra* note 12, at 163–64.

[18] *Id.*

[19] *Id.*

practitioners of this tactic "Merchants of Doubt."[20] If the Frank Statement can be regarded as the beginning of the campaign of information and doubt-sowing—the ugly climax was perhaps an April 14, 1994 hearing of the House Subcommittee on Energy and Commerce, at which the heads of all of the major cigarette companies denied, under oath, that nicotine was addictive.[21]

Starting in the 1960's, several voluntary health associations that would become pillars of the tobacco control movement—primarily the American Cancer Society, the American Lung Association, and the American Heart Association—became progressively more outspoken on the smoking issue. They sounded the alarm about the health risks to the individual smoker from mainstream cigarette smoke and to bystanders from secondhand smoke. They developed campaigns that were intended to prevent young people from ever taking that first puff, in recognition of the fact that nearly all smokers began smoking before the age of eighteen. Politically, they lobbied at the city, state, and federal levels for a variety of measures that would become known as the "tobacco control toolkit"—including cigarette taxes, bans on indoor smoking, and restrictions on advertising.[22]

2. The 1996 FDA Rule

As the public's anxiety about the dangers of smoking increased, the cigarette companies looked at changes to their products as a way to restore confidence. By the 1950s, more of the leading brands were fitted with filters that were supposed to remove harmful ingredients.[23] In the 1970s, as discussed in more detail below, manufacturers introduced to the market so-called "light" and "low-tar" cigarettes that were also claimed to provide a safer smoking experience.[24] Over time, it became clear that none of these innovations reduced risk, and instead they came to be seen as nothing more than cynical ploys to keep people smoking.

In the 1980s and 1990s two of the leading manufacturers—R.J. Reynolds (with Premier) and Philip Morris (with Accord)—released to the market more seriously engineered cigarette alternatives that they claimed reduced toxicant production.[25] These were what might be thought of today as first-generation heated tobacco products. Though for decades FDA had steadfastly disclaimed any jurisdiction over conventionally marketed tobacco products, the release of these new products provided the voluntary health associations with an opening. They petitioned FDA to assert jurisdiction over the new heated products based on the claims of reduced toxicant exposure.[26] In 1994, then-Commissioner David Kessler responded to the petitions by saying that he would revisit FDA's authority to regulate tobacco

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[20] NAOMI ORESKES & ERIK CONWAY, MERCHANTS OF DOUBT: HOW A HANDFUL OF SCIENTISTS OBSCURED THE TRUTH ON ISSUES FROM TOBACCO SMOKE TO GLOBAL WARMING (2010).

[21] *Tobacco CEO's Statement to Congress 1994 News Clip "Nicotine is not Addictive."*, U. OF CALIF. SAN FRANCISCO (1994), https://senate.ucsf.edu/tobacco-ceo-statement-to-congress.

[22] *See generally* KLUGER, *supra* note 12.

[23] *Id.* at 182–83.

[24] *Id.* at 377–81.

[25] *See* United States v. Philip Morris USA, 449 F. Supp. 2d 1, 399, ¶¶ 1857–1865, 403-406 ¶¶ 1884–1904 (D.D.C. 2006), *aff'd in part, vacated in part by* United States v. Philip Morris USA Inc. (D.C. Cir., May 22, 2009).

[26] *Id.* at 407 ¶ 1907.

products under the agency's drug and device authority, based on evidence that the cigarette companies were controlling nicotine levels to sustain addiction.[27]

A year after the Kessler response, FDA issued a proposed rule (FDA Rule) asserting jurisdiction over the cigarette industry[28]—despite decades of precedent in which prior FDA Commissioners had rejected the argument that the agency had legislative authority to regulate cigarettes. The sole focus of the proposed FDA Rule was the imposition of restrictions on the marketing of cigarettes. Though FDA's investigation had looked at the feasibility of removing carcinogens to make smoking less dangerous[29] and at reducing nicotine content below the level necessary to sustain addiction,[30] the final FDA Rule made no effort to target the cigarette for change. The final FDA Rule explained the logic of FDA's approach—it would "inhibit the spread of smoking behavior from one generation to the next."[31] As for current smokers—they would "either quit or die."[32]

As anticipated, FDA's effort to regulate tobacco was challenged in court by the cigarette companies—culminating in a 2000 Supreme Court decision (*FDA v. Brown & Williamson*) that struck down the FDA Rule.[33] The essence of the *Brown & Williamson* decision was that FDA lacked authority from Congress to regulate cigarettes under the agency's drug jurisdiction, in the absence of some type of therapeutic claim for the product. For FDA to be able to regulate tobacco products as customarily marketed, the Court held, it would need an express grant of jurisdiction from Congress.

3. State Attorney General Lawsuits Against the Tobacco Industry

Beginning in 1994, a new front opened in the tobacco wars in the form of litigation against the industry by state attorneys general. The goal of these cases was to recoup health care costs incurred by the states in treating citizens harmed by cigarette smoking—a legal theory that side-stepped the industry's long-successful defense in liability lawsuits that individual smokers had voluntarily assumed the risk of disease and premature death by choosing to smoke. The first case was filed by Mississippi Attorney General Mike Moore and, by 1998, nearly all states had an active lawsuit against the cigarette companies.

In 1998, a resolution of all the state cases was achieved in what became known as the "Master Settlement Agreement" (MSA). The MSA called for substantial cash payments from industry including both initial and annual continuing payments—which to date has resulted in nearly $160 billion in payments to the states.[34] It also

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[27] DAVID KESSLER, A QUESTION OF INTENT: A GREAT AMERICAN BATTLE WITH A DEADLY INDUSTRY 91 (2001).

[28] Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. 44,396 (Aug. 28, 1996) (codified at 21 C.F.R. pts. 801, 803, 804, 807, 820, and 897) [hereinafter FDA Rule].

[29] KESSLER, *supra* note 27, at 237–38.

[30] *Id.* at 263.

[31] FDA Rule, *supra* note 28, at 44,419.

[32] *Id.*

[33] *See generally* FDA v. Brown & Williamson, 529 U.S. 120 (2000).

[34] NAT'L ASS'N OF ATT'YS GEN., MASTER SETTLEMENT AGREEMENT (1998), https://www.naag.org/wp-content/uploads/2020/09/2019-01-MSA-and-Exhibits-Final.pdf (as of Apr. 20, 2023) [hereinafter MSA]. NAT'L ASS'N OF ATT'YS GEN., PAYMENTS TO DATE (as of Apr. 20, 2023),

imposed advertising restrictions on cigarette sales, including bans on youth targeting, a prohibition against the use of cartoons, the elimination of outdoor and transit advertising, a ban on tobacco-branded merchandise, and a ban on youth access to free samples.[35] During the MSA negotiations, the cigarette companies agreed to discontinue the Marlboro Man and Joe Camel—marketing images that had become lightning rods for tobacco control criticism.[36] The MSA also targeted the decades-long misinformation campaign about smoking and serious illness—dismantling the notorious Tobacco Institute and other industry mouthpieces who were among the main "Merchants of Doubt." It replaced these actors with a new entity—the American Legacy Foundation (later renamed the Truth Initiative)—which was initially capitalized with more than $1 billion from the industry's MSA payments.[37] The public health provisions of the MSA were negotiated by Matt Myers of CTFK.[38]

C. Harm Reduction

1. Prior to Light/Low-Tar

Beginning with the publication of the original studies in the 1950s that persuasively linked cigarette smoking and lung cancer, the argument was advanced that the focus should turn to identifying and removing the dangerous ingredients in cigarette smoking. The editors of the *British Medical Journal* put it as follows in a 1952 editorial that appeared together with the publication of the second major Hill and Doll study:

> Intensive research on the chemical constituents of tobacco and of tobacco-smoke is now needed, and it is surely incumbent upon the tobacco manufacturers to do this. It is a reasonable expectation that if the carcinogenic agent can be isolated it can also be removed, so that smoking will become a less dangerous occupation than it is now.[39]

In a 1953 article reporting on the results of a groundbreaking study in which he and colleagues had painted the backs of mice with cigarette tar to determine if cancerous tumors would be created, American Ernst Wynder wrote: "The actual carcinogenic agent or agents in tobacco remain to be identified . . . . Should one be able to identify definite carcinogens and succeed in removing them, or at least in reducing their quantity in tobacco, proper preventive methods would be at hand."[40] At the 1967 World Conference on Smoking and Health, Wynder chaired three sessions devoted to the subject: "Toward a less harmful cigarette."[41] The National Cancer Institute (NCI) published a compilation of the papers delivered during the

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https://www.naag.org/wp-content/uploads/2023/04/2023-04-26-Payments_to_States_since_Inception_through_April_20_2023.pdf.

[35] MSA, *supra* note 34, at 18–29.

[36] MICHAEL PERTSCHUK, SMOKE IN THEIR EYES: LESSONS IN MOVEMENT LEADERSHIP FROM THE TOBACCO WARS 78 (2001).

[37] MSA, *supra* note 34, at 41–44.

[38] *See* PERTSCHUK, *supra* note 36, at 78–82.

[39] *Smoking and Lung Cancer*, 2 BRIT. MED. J. 1299, 1300 (1952).

[40] Wynder et al., *supra* note 14, at 863.

[41] TOWARD A LESS HARMFUL CIGARETTE: A WORKSHOP HELD AT THE WORLD CONFERENCE ON SMOKING AND HEALTH, SEPTEMBER 11–13, 1967 Monograph 28 (Ernst L. Wynder et al. eds., June 1968).

sessions, with a Preface by Surgeon General William Stewart that issued a clarion call for action to reduce the harmfulness of smoking: "Knowledge on the hazard to health of cigarette smoking has reached the stage where the emphasis can now shift from efforts aimed at determining the degree of hazard to those aimed at reducing or eliminating the hazard."[42] The Surgeon General cautioned against the lack of action on this front, in words that are chilling when read well over half a century later: "Thirty years ago, if we had had today's knowledge about the hazards of smoking and had acted upon it, thousands of those that are dying of cigarette-related diseases could have been saved. Thirty years from now there must be no need for such expression of regret."[43]

2. The Light/Low-Tar Debacle

The impulse to make the cigarette less dangerous led, in the 1970s, to the creation of the low tar cigarette. The NCI worked with the cigarette industry to help develop cigarettes with lower levels of tar, with claims relating to tar content to be validated by a test method that had been developed by the FTC.[44] In a 1976 article, NCI head Gio Gori wrote enthusiastically of the potential of the low tar cigarette to save lives, calling it "the single most important and potentially successful disease prevention opportunity in contemporary society."[45]

Instead of saving lives, the low tar cigarette would become one of the greatest public health fiascos of all time. The FTC's test method was unrealistic and not reflective of real-world smoking—as the industry knew—with the result that laboratory findings that certain products delivered lower levels of tar were not actually consistent with a typical smoker's experience.[46] To compound matters, people who now believed they were reducing their risk were led by the cigarette companies to believe that they didn't need to quit smoking, since they now had a "safe" or at least "safer" alternative that would allow them to keep lighting up.[47]

3. Subsequent to Light/Low Tar

i. The Institute of Medicine Reports

The idea that the risks associated with smoking should be reduced for those who could not or would not quit all use of nicotine was a powerful one, consistent as it was with the legal and regulatory attitude toward improving the safety of all consumer products. In 1994, the Institute of Medicine (IOM) (now the National Academies of Sciences, Engineering, and Medicine) produced a report (1994 Report)

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[42] *Id.* at ix.

[43] *Id.*

[44] Mark Parascandola, *Lessons from the History of Tobacco Harm Reduction: The National Cancer Institute's Smoking and Health Program and the "Less Hazardous Cigarette,"* 7 NICOTINE & TOBACCO RSCH. 779 (2005).

[45] Gio B. Gori, *Low Risk Cigarettes: A Prescription*, 194 SCIENCE 1243 (1976).

[46] *See, e.g.*, INSTITUTE OF MEDICINE, CLEARING THE SMOKE: ASSESSING THE SCIENCE BASE FOR TOBACCO HARM REDUCTION 317–19 (Kathleen Stratton, Padma Shetty, Robert Wallace & Stuart Bondurant eds., 2001), http://www.nap.edu/catalog/10029.html [hereinafter CLEARING THE SMOKE]; KLUGER, *supra* note 12, at 453–54.

[47] CLEARING THE SMOKE, *supra* note 46, at 25–27.

on reducing the health burdens of smoking.[48] While its primary focus was on preventing youth uptake—indeed the report was titled *Growing Up Tobacco Free*—the authors cautioned against ignoring harm reduction:

> [I]t must also be remembered, however, that the social burdens of tobacco use are not associated with nicotine per se. Nicotine dependence is problematic because it causes use of tobacco, which in turn causes disease and dysfunction, and the nation's regulatory strategy must ultimately maintain a clear focus on the adverse health effects of using tobacco.[49]

It was therefore imperative, according to the report, that "the focus should be on reducing harm related to use of tobacco"—not on "winning a 'war' against nicotine."[50] However, the authors of the 1994 Report were mindful of the low tar debacle and emphasized that harm reduction would need to occur within a proper regulatory framework: "Congress should confer upon an administrative agency the authority to regulate the design and constituents of tobacco products whenever it determines that such regulation would reduce the prevalence of dependence or disease associated with use of the product or would otherwise promote the public health."[51]

The idea underwent further development in the ensuing years. In 1999, at the behest of Mitch Zeller, then the Director of FDA's Office for Tobacco Programs and later the Director of the CTP, the IOM prepared a report that looked very specifically at "tobacco harm reduction" and the role that it might play in the fight against smoking-related death and disease.[52] The IOM appointed a twelve-person committee, made up of experts in fields including addiction and substance abuse, cancer, smoking cessation, epidemiology, public policy, and toxicology.[53]

The final 657-page report released in 2001 (2001 IOM Report) provided a clear endorsement of the potential for tobacco harm reduction, writing that "manufacturers of tobacco products and pharmaceuticals should be encouraged to develop and introduce new products that will reduce the burden of tobacco-related disease."[54] But, cognizant of the painful history of the low-tar cigarette, the authors made it clear that harm reduction in the cigarette context could only work if it was implemented in accordance with a number of "regulatory principles," one of which was that "[m]anufacturers should be permitted to market tobacco-related products with exposure-reduction or risk-reduction claims only after prior agency approval

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[48] INSTITUTE OF MEDICINE, GROWING UP TOBACCO FREE: PREVENTING NICOTINE ADDICTION IN CHILDREN AND YOUTHS (Barbara S. Lynch & Richard J. Bonnie eds., 1994), http://www.nap.edu/catalog/4757.html.

[49] *Id.* at 251.

[50] *Id.*

[51] *Id.* at 286.

[52] CLEARING THE SMOKE, *supra* note 46.

[53] *Id.* at v, x.

[54] *Id.* at 205.

based on scientific evidence . . . ."[55] Elsewhere the report made it clear that the "agency" that the IOM had in mind was, preferably, FDA.[56]

As the sole representative of tobacco control in the negotiations that led to the MSA, Matt Myers had sought the inclusion in the settlement of provisions that would lead to comprehensive federal oversight of tobacco by FDA, including a mechanism for the review and approval of proposed reduced harm products.[57] In 1998, Arizona Senator John McCain introduced a bill that had these elements. Support for the McCain bill was broad and bi-partisan and it advanced rapidly, passing out of the Senate Commerce Committee by an astonishing 19–1 vote.[58] Then three of the most admired figures within the tobacco control movement—former Surgeon General C. Everett Koop, former FDA Chairman David Kessler, and liberal Senator Henry Waxman of California—insisted that it was too lenient toward industry, because it would protect "Big Tobacco"[59] from lawsuits over past bad actions and because it failed to sufficiently raise tobacco taxes. They demanded changes that would have made it easier to sue the cigarette companies and, in the end, industry declared its opposition and the McCain bill died.[60]

Matt Myers did not give up on the goal of achieving FDA jurisdiction over tobacco. He spent the next eleven years fighting to resurrect the bill—later renamed the Family Smoking Prevention and Tobacco Control Act. There was a flurry of activity in 2007—a slightly revised version of the McCain bill stripped of its poison pill provisions passed the Senate by an overwhelming majority and there were hearings in both the Senate and the House.[61] That year, the IOM released yet another major report on tobacco titled *Ending the Tobacco Problem: A Blueprint for the Nation* (2007 IOM Report)—this time focused specifically on the pending bill.[62]

The 2007 IOM Report reaffirmed the harm reduction recommendations contained in the 2001 IOM Report—that harm reduction was needed and could work, but only if implemented through comprehensive federal regulation that included FDA review of reduced harm claims.[63] This was now at hand, the 2007 IOM Report noted, in the form of the revised legislation then pending before Congress: "[T]he proposed

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[55] *Id.* at 10.

[56] *Id.* at 207.

[57] PERTSCHUK, *supra* note 36, at 126–29.

[58] *Id.* at 214; Saundra Torry & Helen Dewar, *Senate GOP Kills McCain Bill*, WASH. POST (June 18, 1988), https://www.washingtonpost.com/archive/politics/1998/06/18/senate-gop-kills-mccain-tobacco-bill/084c2008-b308-4321-8574-205d37bacc22/.

[59] The label "Big Tobacco" is generally used to refer to the largest tobacco companies. *See, e.g.*, Maggie Fox, *Big Tobacco Finally Tells the Truth in Court-Ordered Ad Campaign*, NBC NEWS (Nov. 26, 2017), https://www.nbcnews.com/health/health-news/big-tobacco-finally-tells-truth-court-ordered-ad-campaign-n823136.

[60] PERTSCHUK, *supra* note 36, at 213, 218–21.

[61] *The Need for FDA Regulation of Tobacco: Hearing Before the Comm. on Health, Educ., Labor and Pensions*, 110th Congress (2007) [hereinafter 2007 Senate Hearing]; *The Family Smoking Prevention and Tobacco Control Act: Hearing Before the Subcomm. on Energy and Comm.*, 110th Congress (2007) [hereinafter 2007 House Hearing].

[62] INSTITUTE OF MEDICINE, ENDING THE TOBACCO PROBLEM: A BLUEPRINT FOR THE NATION (Richard J. Bonnie, Kathleen Stratton & Robert B. Wallace eds., 2007), https://nap.nationalacademies.org/catalog/11795/ending-the-tobacco-problem-a-blueprint-for-the-nation [hereinafter 2007 IOM REPORT].

[63] *Id.* at 279.

Tobacco Control legislation would grant FDA the authority to regulate tobacco products. FDA was selected because it is the only existing regulatory agency with expertise both in scientific and health issues and in product regulation."[64] This would allow FDA to "'protect the public health' by reducing initiation, promoting cessation, preventing relapse, reducing consumption, and reducing product hazards."[65]

ii. Judge Kessler Opinion

A perhaps unexpected source for the recognition that harm reduction was needed came from the federal government's Racketeer Influenced and Corrupt Organizations (RICO) litigation against the major cigarette companies before Judge Gladys Kessler of the United States District Court for the District of Columbia, filed in 1999. Judge Kessler's 1,653-page Final Opinion,[66] issued in 2006, was a comprehensive presentation of the history of big tobacco misconduct throughout the decades of the tobacco wars. Judge Kessler ruled that the government had substantiated its allegations that the defendants had violated the RICO statute and entered a remedial order to prevent and restrain such violations in the future.

In her Final Opinion, Judge Kessler held that the government had met its burden with respect to most of its allegations—though not, notably, with respect to one of them. The government had alleged that the defendants "deliberately chose not to develop, market, and profit from less hazardous cigarettes in order to insulate their existing brands from competition and reduce their litigation exposure."[67] After a thorough analysis of the record with respect to the research and expenditures related to, among other products, R.J. Reynolds' (RJR) Premier (1988) and Eclipse (2000)[68] and Philip Morris's Accord (1998),[69] Judge Kessler rejected the government's argument, finding that the companies had in fact devoted considerable resources to the development of less harmful products:

> [T]he Court concludes that the Government has failed to carry its burden of proving, by a preponderance of the evidence, that Defendants deliberately chose to sabotage the successful marketing and production of less hazardous cigarettes. As these Facts demonstrate, Philip Morris and RJR . . . spent many years, enormous amounts of money, and the creative energies of their top scientists to investigate different approaches to production of cigarettes which would present fewer health risks to the public.[70]

None of the products analyzed by Judge Kessler succeeded in the marketplace. On that point, the government had argued that "more effective marketing and advertising

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64 *Id.*

65 *Id.*

66 *See* United States v. Philip Morris USA, Inc., 449 F. Supp. 2d 1, pt. 3, 385 (D.D.C. 2006), *aff'd in part, vacated in part*, 449 F. Supp. 2d 1, pt. 3, 385 (D.D.C. 2006), *aff'd in part, vacated in part*, 566 F.3d 1095 (D.C. Cir., May 22, 2009).

67 *Id.* at 385, ¶ 1765.

68 *Id.* at 403–415, ¶¶ 1884–1949.

69 *Id.* at 399–400, ¶¶ 1857–1865.

70 *Id.* at 429, ¶ 2018.

which focused on the health benefits of these newly developed cigarettes could have overcome the consumer resistance to them."[71] In response, Judge Kessler pointed to the government and advocacy groups as being responsible for cigarette company reluctance to promote the products in this fashion:

> Defendants were operating in a regulatory climate where their fears of litigation with the Federal Trade Commission were by no means unreasonable given cases which the Commission had actually brought and won. Moreover, Defendants faced petitions filed with the FTC by advocacy groups which believed that cessation of all smoking was the only effective answer to the public health problem, and therefore opposed introduction of any new cigarette, no matter how much less risk it might pose to health.[72]

iii. The Strategic Dialogue

During the same period that the battle for FDA regulatory oversight of tobacco was reaching its climax, prominent members of the tobacco control community were taking part in a years-long effort to establish the contours of a consensus approach to tobacco harm reduction. Co-chaired by Mitch Zeller, what came to be known as the "Strategic Dialogue" consisted of two years of meetings involving some twenty-five leading experts.[73] Participants included the heads of both CTFK and the American Legacy Foundation as well as individuals from the CDC and the NCI.[74] The effort culminated in a 2009 article that was written over a two-year period and then published only months before the signing into law of the TCA.[75] The article made clear that the participants unanimously supported the idea that "the intelligent application of harm reduction principles has the potential to achieve public health gains."[76] This was because, according to the participants:

> There is a very pronounced continuum of risk depending upon how toxicants and nicotine, the major addictive substance in tobacco, are delivered. Cigarette smoking is undoubtedly a more hazardous nicotine delivery system than various forms of non-combustible tobacco products for those who continue to use tobacco, which in turn are more hazardous than pharmaceutical nicotine products.[77]

The Strategic Dialogue participants achieved consensus on the potential public health benefit to tobacco harm reduction based on the continuum of risk, within a proper regulatory framework:

> The tobacco harm reduction approach that will lead to the greatest reduction in tobacco-related morbidity and mortality is cessation of use

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[71] *Id.* at 430, ¶ 2020.

[72] *Id.*

[73] Mitchell Zeller & Dorothy Hatsukami, *The Strategic Dialogue on Tobacco Harm Reduction: A Vision and Blueprint for Action in the US*, 18 TOBACCO CONTROL 324 (2009).

[74] *Id.*

[75] *Id.*

[76] *Id.* at 3.

[77] *Id.*

> of all tobacco products. Short of this goal, shifting from combustible tobacco products to the long-term and exclusive use of non-combustible products, particularly therapeutic products, with the right controls and post-market surveillance is likely to create less harm among continuing users. This shifting of product use should[ ]be part of a comprehensive approach that includes the regulation of all nicotine products, whether or not they contain tobacco.[78]

The Strategic Dialogue stressed the need for accurate communication of risk, concluding that: "In a regulated environment . . . [c]onsumers should be accurately informed and educated about relative risks of the use of different types of nicotine-containing products."[79] This was consistent with the 2007 IOM Report's prescription on harm reduction, which included the need for accurate risk communication, to "educat[e] users about the risks and benefits of novel products."[80] It was also in line with the government's own allegations and Judge Kessler's findings in *United States v. Philip Morris*. The need for accurate risk communication was obvious—otherwise it would be difficult to drive science-based decision-making by adults trying to choose among different nicotine-containing products. This would be particularly so where the reduced harm product was less consumer-satisfying than the cigarette that it was seeking to replace.

D. The 2009 Family Smoking Prevention and Tobacco Control Act

On June 22, 2009, within months of the publication of the results of the Strategic Dialogue, the long fight for establishing FDA jurisdiction over tobacco products reached its successful climax when Congress passed and President Obama signed into law the TCA.[81] A central focus of the TCA was to place restrictions on the marketing of traditional cigarettes—the continued sale of which was expressly permitted by the statute, provided they were on the market as of February 15, 2007.[82] These restrictions included a ban on vending machine, self-service, and mail order sales; a minimum pack size of twenty cigarettes; a prohibition against putting a tobacco trade or brand name on a non-tobacco item; a ban on free samples; and restrictions on print advertising.[83] Justification for the imposition of advertising restrictions was provided by a number of congressional "Findings," including:

> Tobacco advertising and promotion play a crucial role in the decision of . . . minors to begin using tobacco products . . . . The reasonable restrictions on the advertising and promotion of tobacco products

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[78] *Id.* at 10–11.

[79] Zeller & Hatsukami, *supra* note 73, at 17. *See also id.* at 15 (noting "the principle that consumers deserve accurate and evidence-based information on the toxicity and relative risk for disease of different products").

[80] 2007 IOM Report, *supra* note 62, at 282.

[81] Family Smoking Prevention and Tobacco Control Act, 21 U.S.C. § 387, et seq. (2009) [hereinafter TCA].

[82] *Id.* § 910(a)(1)(A), 21 U.S.C. § 387j(a)(1)(A).

[83] Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents, 21 C.F.R. § 1140.16 (Mar. 19, 2010).

> contained in such regulations will lead to a significant decrease in the number of minors using and becoming addicted to those products.[84]

The TCA provided a mechanism for FDA authorization, following pre-market review, of putative reduced-risk products based on a public health standard that looked at impacts both on current users of tobacco products and on non-users (especially youth).[85] Under the statute, FDA would authorize products that it determines are "appropriate for the protection of public health."[86] The TCA's review process for potential reduced risk products—allowing sale only following FDA review based on application of a public health standard—was consistent with the recommendations by the IOM in its 1994, 2001, and 2007 Reports and with the Strategic Dialogue. As explained by Congress in the "Findings" section of the TCA:

> The Food and Drug Administration is a regulatory agency with the scientific expertise to identify harmful substances in products to which consumers are exposed, to design standards to limit exposure to those substances, to evaluate scientific studies supporting claims about the safety of products, and to evaluate the impact of labels, labeling, and advertising on consumer behavior in order to reduce the risk of harm and promote understanding of the impact of the product on health.[87]

The TCA gave FDA exclusive authority over product reviews and the promulgation of product standards for regulated "tobacco products," preempting any additional or conflicting efforts at the state or local level. That preemption was critically important, as Matt Myers explained in testimony before the Senate in 2007:

> The legislation achieves a reasonable balance between Federal and State or local authority over tobacco. It allows the States to continue to regulate the sale, distribution, and possession of tobacco products and would expand State authority to regulate tobacco product marketing. To ensure consistent product standards nationally, however, the legislation reserves to the Federal Government the right to regulate the product itself, which is consistent with the way the FDA regulates other products under its jurisdiction.[88]

The TCAG enthusiastically embraced President Obama's signing of the TCA into law. Passage of the statute had the support of more than 1,000 "public health, faith and other organizations" in what CTFK called "one of the strongest coalitions ever to unite behind public health legislation." [89] The Campaign called the TCA "an historic blow against the greatest public health menace of our time" and "the strongest action

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[84] TCA, § 2(31), 21 U.S.C. § 387, (31). *See also* §§ 2(5, 6, 12, 25, 26, 27), 21 U.S.C. § 387(5, 6, 12, 25, 26, 27), https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/section-2-tobacco-control-act-findings.

[85] TCA, § 910(c)(4), 21 U.S.C. § 387j(c)(4).

[86] *Id.*

[87] TCA, § 2(44), 21 U.S.C. § 387(44).

[88] 2007 Senate Hearing, *supra* note 61, at 13–19, 18 (Prepared Statement of Matthew L. Myers); *see generally* 2007 House Hearing, *supra* note 61, at 86–104 (Prepared Statement of William Corr).

[89] *President Obama Delivers Historic Victory for America's Kids and Health over Tobacco*, CAMPAIGN FOR TOBACCO-FREE KIDS (June 22, 2009), https://www.tobaccofreekids.org/press-releases/id_1161.

the federal government has ever taken to reduce tobacco use, the leading preventable cause of death in the United States."[90]

E. E-Cigarettes

1. The Technology

In the years immediately preceding passage of the TCA, electronic cigarettes began to appear in the U.S. marketplace.[91] These consisted of a battery; a cartridge containing a supply of "e-liquid" with nicotine, propylene glycol, and flavoring; and a heating element or atomizer that vaporized the e-liquid when the user inhaled on the device.[92] The vaporized e-liquid, due to the presence of propylene glycol, formed a visible aerosol that, when exhaled by the user, had the visual aspect of cigarette smoke.[93] Because e-cigarettes did not combust tobacco, it was believed that they did not produce the same toxic cocktail that was a byproduct of smoking cigarettes.[94]

The goal of those early e-cigarettes was to provide adults who smoke an alternative that delivered nicotine through an inhalation route of administration like a cigarette and that replicated the habits of smoking such as the hand-to-mouth ritual.[95] However, unlike medicinal nicotine replacement therapy products, which were to be used temporarily to induce both the quitting of smoking *and* treatment of the underlying nicotine addiction, e-cigarettes were intended to be a replacement for cigarettes by those people unable or unwilling to quit all use of nicotine.[96]

2. Sottera, Inc. dba NJOY v. FDA

Shortly prior to passage of the TCA, FDA began to look at e-cigarettes. In the latter part of 2008 and early 2009, FDA blocked the importation of products by two companies—Smoking Everywhere and NJOY, Inc. FDA's action was based on the same nicotine-as-a-drug theory that had been unsuccessful in the *Brown & Williamson* case. On April 28, 2009, Smoking Everywhere filed suit against FDA in the U.S. District Court for the District of Columbia, seeking a preliminary injunction against further product seizures.[97] On May 15, 2009, NJOY (listed in the court's caption as "Sottera, Inc. d/b/a NJOY") (Sottera/NJOY) was permitted to join the lawsuit as an additional plaintiff.[98]

After oral argument on the injunction motion but prior to a decision by the court, President Obama signed the TCA into law. The parties then briefed the significance,

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[90] *Id.*

[91] Memorandum Opinion, Smoking Everywhere v. FDA, No. 09-00771 (D.D.C. Jan. 14, 2010), ECF No. 54, at 5 [hereinafter *Smoking Everywhere v. FDA*].

[92] *Id.* at 2–3.

[93] Jean-François Bertholon, Marie-Hélène Becquemin, Isabella Annesi-Maesano & Bertrand Dautzenberg, *Electronic Cigarettes: A Short Review*, 86 RESPIRATION 433 (2013).

[94] *Smoking Everywhere v. FDA*, *supra* note 91, at 2–3.

[95] Pasquale Caponnetto, Riccardo Polosa, Cristina Russo, Carmelo Leotta & Davide Campagna, *Successful Smoking Cessation with Electronic Cigarettes in Smokers with a Documented History of Recurring Relapses: A Case Series*, 5 J. MED. CASE REPS. 585 (2011).

[96] *Smoking Everywhere v. FDA*, *supra* note 91, at 21–24.

[97] Complaint, Smoking Everywhere v. FDA, No. 09-00771 (D.D.C. Apr. 28, 2009), ECF No. 1.

[98] Minute Entry, Smoking Everywhere v. FDA, No. 09-00771 (D.D.C. May 15, 2009) (see court docket text entry).

if any, of the new law to the pending lawsuit.[99] The plaintiffs argued that because the nicotine in e-cigarettes was physically "derived" from the tobacco leaf, the products met the definition of a "tobacco product" in the TCA, which included "any product made or derived from tobacco that is intended for human consumption." Thus, according to plaintiffs, FDA had the legal authority under the TCA to assert jurisdiction over them through a regulatory process known as "deeming" and to thereby bring them under FDA's tobacco oversight. Plaintiffs contended that, absent therapeutic claims—for example that the products would aid in smoking cessation—they could not be regulated by FDA as drug delivery devices, consistent with the Supreme Court's ruling in *Brown & Williamson*. FDA rejected Plaintiffs' argument and pressed its attempt to ban the products as unapproved drug delivery devices.[100]

On January 14, 2010, Judge Richard Leon issued his ruling, dismissing FDA's arguments that it could treat e-cigarettes as unapproved drug delivery devices, notwithstanding passage of the TCA and its conferring of FDA authority over "tobacco products." The court accepted Sottera/NJOY's arguments that electronic nicotine delivery systems (ENDS) fit the definition of "tobacco product" in the TCA and that through that statute "Congress . . . confer[red] FDA jurisdiction over any tobacco product—whether traditional or not—that is sold for customary recreational use, as opposed to therapeutic use."[101]

FDA appealed Judge Leon's decision to the D.C. Circuit.[102] The D.C. Circuit ruled in favor of Sottera/NJOY, holding: "Together, *Brown & Williamson* and the Tobacco Act establish that the FDA cannot regulate customarily marketed tobacco products under the FDCA's drug/device provisions, that it can regulate tobacco products marketed for therapeutic purposes under those provisions, and that it can regulate customarily marketed tobacco products under the Tobacco Act."[103]

On April 25, 2011, FDA issued a letter to stakeholders (2011 Letter to Stakeholders), announcing that it had "decided not to seek further review" of the D.C. Circuit's decision and instead would "comply with the jurisdictional lines established by *Sottera*."[104] To do so, FDA intended to issue a "deeming rule" that would subject the affected products "to general controls, such as registration, product

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[99] Smoking Everywhere v. FDA, No. 09-00771 (D.D.C. 2009), Motion for Leave to File Instanter a Brief of Supp. Authority in Support of its Motion for Preliminary Injunction by Smoking Everywhere at 8, ECF No. 35, Smoking Everywhere's Supplemental Memorandum in Support of 24 Motion for Preliminary Injunction, ECF 36, Sottera, Inc.'s Motion for Leave to File Supplemental Brief in Support of Motion for Preliminary Injunction, ECF No. 37, Supplemental Memorandum to re 2 Motion for Temporary Restraining Order, 24 MOTION for Preliminary Injunction in Opposition to Motions for Preliminary Injunction, ECF No. 41, Smoking Everywhere's Reply Supplemental Memorandum, ECF No. 44, Smoking Everywhere's Reply Supplemental Memorandum, ECF No. 45.

[100] *Id.*

[101] *Smoking Everywhere v. FDA*, *supra* note 91, at 20.

[102] *See generally* Sottera, Inc. dba NJOY v. FDA, 627 F.3d 891, 893 (D.C. Cir. 2010). During the pendency of the appeal, Smoking Everywhere voluntarily dismissed its complaint against FDA, leaving Sottera/NJOY as the sole remaining plaintiff.

[103] *Id.* at 898.

[104] Lawrence R. Deyton & Janet Woodcock, *FDA Tobacco Determination Email*, AM. ASS'N OF PUB. HEALTH PHYSICIANS (Apr. 25, 2011), https://www.aaphp.org/Determination. A deeming rule was needed because, as explained in the letter: "Although the statute places certain 'tobacco products' immediately under the general controls and premarket review requirements in Chapter IX (i.e., cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco), it also permits FDA, by regulation, to extend those controls to other categories of 'tobacco products.'" *Id.*

listing, ingredient listing, good manufacturing practice requirements, user fees for certain products, and the adulteration and misbranding provisions, as well as to the premarket review requirements for 'new tobacco products' and 'modified risk tobacco products.'"[105]

3. The Deeming Rule

On April 25, 2014, slightly more than three years after the 2011 Letter to Stakeholders, FDA issued a proposed deeming rule to expand agency jurisdiction to cover electronic cigarettes and other products meeting the definition of "tobacco products" in the statute.[106] The proposed deeming rule also sought to bring so-called "little cigars" under the statute. With respect to "premium cigars," the proposed deeming rule explained that the agency was trying to decide between an Option 1, pursuant to which premium cigars would be exempted from deeming, and an Option 2, under which they would be included within the scope of the new rule. As explained further in Part V.A below, during the public comment period, TCAG strongly urged FDA to select Option 2 and include premium cigars in the final deeming rule.

On May 10, 2016, two years after publication of the proposed deeming rule and five years after the 2011 Letter to Stakeholders, FDA published the final deeming rule.[107] It brought electronic cigarettes and other products meeting the definition of "tobacco product" under CTP's jurisdiction. Consistent with the position taken by TCAG, FDA selected Option 2 and included premium cigars within the scope of deeming.

Because the final deeming rule subjected the newly deemed products to, among other things, the premarket review requirements of the TCA, FDA confronted a dilemma with respect to e-cigarettes and other newly deemed products already on the market. A strict application of the premarket review requirement would have required all products on the market—many of which had been sold for years—to be immediately withdrawn from further sale, pending the preparation, filing, and successful pursuit of a premarket tobacco product application (PMTA). As set forth in both the proposed and final deeming rules, FDA's alternative solution was to announce the exercise of "enforcement discretion," pursuant to which products on the market as of August 8, 2016, the effective date of the final deeming rule, would be allowed to remain—provided that a PMTA was filed by the deadline. The PMTA deadline, pursuant to the final deeming rule, was initially set for August 8, 2018.

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[105] *Id.*

[106] Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 21 C.F.R., pts. 1100, 1140, and 1143 (proposed Apr. 25, 2014).

[107] Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 21 C.F.R. pts. 1100, 1140, and 1143, (final rule May 10, 2016).

4. Emerging Science on Relative Safety, Quitting Efficacy, and Flavors

In the years following *Sottera* and the 2011 Letter to Stakeholders, the science began to accumulate regarding ENDS products. Among other things, it became increasingly clear that ENDS products, because they did not combust tobacco, did not produce toxic and carcinogenic compounds at the levels seen for combustion cigarettes. In 2013, shortly before his appointment as CTP Director, Mitch Zeller wrote that: "Along the path of the continuum of risk are products that pose less harm to the individual than cigarettes but for which less is known about their population-level health impacts. Here, we would place smokeless and dissolvable tobacco products as well as the 'e-cigarette.'"[108] One widely cited 2014 study found that "the levels of potentially toxic compounds in e-cigarette vapor is from 9- to 450-fold lower than those in the smoke from conventional cigarette, and in many cases comparable to the trace amounts present in pharmaceutical preparation."[109]

The year 2014 also saw the publication of two meta-analyses of ENDS research, one of which was co-authored by long-time ENDS skeptic Stan Glantz. Though differing in their level of optimism about the impact of the technology given youth, dual use, and indoor air concerns, both concluded that the aerosol was less toxic than cigarette smoke and that the products had potential public health benefit as a reduced harm alternative for people who switched completely. According to the analysis co-authorized by Glantz: "E-cigarettes deliver lower levels of some of the toxins found in cigarette smoke."[110] As a consequence, Glantz and his co-authors wrote that "it is reasonable to assume that, if existing smokers switched completely from conventional cigarettes (with no other changes in use patterns) to e-cigarettes, there would be a lower disease burden caused by nicotine addiction[.]"[111] Thus, "[i]f a patient has failed initial treatment, has been intolerant of or refuses to use conventional smoking cessation medication, and wishes to use e-cigarettes to aid quitting, it is reasonable to support the attempt."[112]

The conclusions of the 2014 meta-analyses regarding a lower harm profile for ENDS as compared to traditional e-cigarettes held up in the ensuing years. Four years later, in 2018, the National Academies of Science, Engineering, and Medicine (NASEM), formerly the IOM, issued a report at the request of FDA, on "the current state of knowledge about the health risks and benefits of e-cigarette use."[113] Based on

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[108] Mitchell Zeller, *Reflections on the 'Endgame' for Tobacco Control*, 22 TOBACCO CONTROL i40, i40 (2013).

[109] Maciej Lukasz Goniewicz, Jakub Knysak, Michal Gawron, Leon Kosmider, Andrzej Sobczak, Jolanta Kurek, Adam Prokopowicz, Magdalena Jablonska-Czapla, Czeslawa Rosik-Dulewska, Christopher Havel, Peyton Jacob III & Neal Benowitz, *Levels of Selected Carcinogens and Toxicants in Vapor from Electronic Cigarettes*, 23 TOBACCO CONTROL 133 (2014).

[110] Rachel Grana, Neal Benowitz & Stanton A. Glantz, *E-Cigarettes: A Scientific Review*, 129 CIRCULATION 1972, 1981 (2014); Peter Hajek, Jean-François Etter, Neal Benowitz, Thomas Eissenberg & Hayden McRobbie, *Electronic Cigarettes: Review of Use, Content, Safety, Effects on Smokers, and Potential for Harm and Benefit*, 109 ADDICTION 1801 (2014).

[111] Grana et al., *supra* note 110, at 1983.

[112] *Id.* at 1981.

[113] NAT'L ACADEMIES OF SCIS. ENG'G & MED., PUBLIC HEALTH CONSEQUENCES OF E-CIGARETTES Preface x (Kathleen Stratton, Leslie Y. Kwan & David L. Eaton eds., 2018), https://nap.national

a review of "more than 800 peer-reviewed scientific studies,"[114] NASEM concluded: "There is **conclusive evidence** that completely substituting e-cigarettes for combustible tobacco cigarettes reduces users' exposure to numerous toxicants and carcinogens present in combustible tobacco cigarettes."[115] This essential finding—as applied to specific ENDS products reviewed by FDA—would become foundational to its Marketing Granted Orders.[116]

Evidence regarding the ability of ENDS products to help people quit also began to accumulate—both from population studies and randomized controlled trials (RCTs). With respect to the former, a 2017 CDC study revealed that, for the years 2014–2016: "Substituting some cigarettes with e-cigarettes was used by a greater percentage of smokers than the nicotine patch, nicotine gum, or other cessation aids approved by the US Food and Drug Administration."[117] A 2017 study, which analyzed data from the government's 2014–2015 Current Population Survey-Tobacco Use Supplement, concluded:

> [E]-cigarette use was associated with an increased smoking cessation rate at the level of subgroup analysis and at the overall population level. It is remarkable, considering that this is the kind of data pattern that has been predicted but not observed at the population level for cessation medication, such as nicotine replacement therapy and varenicline. This is the first statistically significant increase observed in population smoking cessation among US adults in nearly a quarter of a century.[118]

With respect to RCTs, the Cochrane Reviews—long regarded as the gold standard for meta-analytic reviews—has since 2014 consistently found that ENDS help people quit. The strength of Cochrane's confidence in this finding went from "low certainty" in 2014[119] and 2016,[120] to "moderate certainty" in 2020[121] and 2021,[122] and

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academies.org/catalog/24952/public-health-consequences-of-e-cigarettes [hereinafter 2018 NASEM REPORT].

[114] *Id.*

[115] *Id.* at 18 (emphasis in original).

[116] *See, e.g.*, *FDA Issues Marketing Decisions on NJOY Ace E-Cigarette Products*, U.S. FOOD & DRUG ADMIN. (Apr. 26, 2022), https://www.fda.gov/tobacco-products/ctp-newsroom/fda-issues-marketing-decisions-njoy-ace-e-cigarette-products ("The authorized NJOY products were found to meet this standard because, among several key considerations, chemical testing was sufficient to determine that overall harmful and potentially harmful constituent (HPHC) levels in the aerosol of these products is lower than in combusted cigarette smoke. . . . Therefore, these products have the potential to benefit adult smokers who switch completely or significantly reduce their cigarette consumption.").

[117] Ralph S. Caraballo, Paul R. Shafer, Deesha Patel, Kevin C. Davis & Timothy A. McAfee, *Quit Methods Used by US Adult Cigarette Smokers*, 14 PREVENTING CHRONIC DISEASE 2014 (2017). It does not appear that CDC has repeated this study in the six years since its publication.

[118] Shu-Hong Zhu, Yue-Lin Zhuang, Shiushing Wong, Sharon E. Cummins & Gary J. Tedeschi, *E-Cigarette Use and Associated Changes in Population Smoking Cessation: Evidence from US Current Population Surveys*, 358 BMJ j3262 (2017). Varenicline is an FDA-approved medicine sold in tablet form for quitting smoking. *See, e.g.*, *Tips from Former Smokers: How to Use Varenicline*, CTRS. FOR DISEASE CONTROL & PREVENTION (Nov. 28, 2022), https://www.cdc.gov/tobacco/campaign/tips/quit-smoking/quit-smoking-medications/how-to-use-quit-smoking-medicines/how-to-use-varenicline.html.

[119] Hayden McRobbie, Chris Bullen, Jamie Hartmann-Boyce & Peter Hajek, *Electronic Cigarettes for Smoking Cessation and Reduction*, 12 COCHRANE DATABASE SYSTEMATIC REVS., Dec. 17, 2014, https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD010216.pub2/full.

finally to "high certainty" in 2022. According to the 2022 review, which was based on seventy-eight studies in over 22,000 participants: "New evidence published today in the Cochrane Library finds high certainty evidence that people are more likely to stop smoking for at least six months using nicotine e-cigarettes, or 'vapes', than using nicotine replacement therapies, such as patches and gums."[123]

In a 2021 essay in the *American Journal of Public Health*, fifteen former Presidents of the Society for Research in Nicotine and Tobacco (SRNT) co-authored a "Research & Analysis" essay titled "Balancing Consideration of the Risks and Benefits of E-Cigarettes." The authors reviewed all the hot-button issues regarding ENDS—including safety, switching efficacy, and risk to youth. They concluded: "Because evidence indicates that e-cigarette use can increase the odds of quitting smoking, many scientists, including this essay's authors, encourage the health community, media, and policymakers to more carefully weigh vaping's potential to reduce adult smoking-attributable mortality."[124] The authors' former leadership of SRNT made the essay particularly worthy of attention, given the TCA's express call-out of SRNT as one of the "scientific, medical and public health experts" that the Department of Health and Human Services (HHS) should consult on "how best to regulate, promote, and encourage the development of innovative products and treatments."[125]

5. The 2017 Comprehensive Nicotine and Tobacco Policy

On July 28, 2017, FDA Commissioner Dr. Scott Gottlieb announced FDA's new "Comprehensive Approach to Nicotine and Tobacco" (2017 Comprehensive Plan).[126] Dr. Gottlieb's speech began by outlining the basics of the problem. He explained that "[t]he overwhelming amount of the death and disease attributable to tobacco is

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[120] Jamie Hartmann-Boyce, Hayden McRobbie, Chris Bullen, Rachna Begh, Lindsay F. Stead & Peter Hajek, *Electronic Cigarettes for Smoking Cessation*, 9 COCHRANE DATABASE SYSTEMATIC REVS., Sept. 13, 2016, https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD010216.pub3/full.

[121] Jamie Hartman-Boyce, Hayden McRobbie, Nicola Lindson, Chris Bullen, Rachna Begh, Annika Theodoulou, Caitlin Notley, Nancy A. Rigotti, Tari Turner, Ailsa R. Butler, Thomas R. Fanshawe & Peter Hajek, *Electronic Cigarettes for Smoking Cessation*, 10 COCHRANE DATABASE SYSTEMATIC REVS., Oct. 14, 2020, https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD010216.pub4/full?cookiesEnabled.

[122] Jamie Hartman-Boyce, Hayden McRobbie, Ailsa R. Butler, Nicola Lindson, Chris Bullen, Rachna Begh, Annika Theodoulou, Caitlin Notley, Nancy A. Rigotti, Tari Turner, Thomas R. Fanshawe & Peter Hajek, *Electronic Cigarettes for Smoking Cessation*, 9 COCHRANE DATABASE SYSTEMATIC REVS., Sept. 14, 2021, https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD010216.pub6/full.

[123] *Latest Cochrane Review Finds High Certainty Evidence that Nicotine E-Cigarettes are More Effective than Traditional Nicotine-Replacement Therapy (NRT) in Helping People Quit Smoking*, COCHRANE (Nov. 17, 2022), https://www.cochrane.org/news/latest-cochrane-review-finds-high-certainty-evidence-nicotine-e-cigarettes-are-more-effective [hereinafter 2022 Cochrane Review].

[124] David J.K. Balfour, Neal L. Benowitz, Suzanne M. Colby, Dorothy K. Hatsukami, Harry A. Lando, Scott J. Leischow, Caryn Lerman, Robin J. Mermelstein, Raymond Niaura, Kenneth A. Perkins, Ovide F. Pomerleau, Nancy A. Rigotti, Gary E. Swan, Kenneth E. Warner & Robert West, *Balancing Consideration of the Risks and Benefits of E-Cigarettes*, 111 AM. J. PUB. HEALTH 1661, 1661 (2021).

[125] Family Smoking Prevention and Tobacco Control Act, § 918(b)(1), 21 U.S.C. § 387r(b)(1).

[126] *Protecting American Families: Comprehensive Approach to Nicotine and Tobacco*, U.S. FOOD & DRUG ADMIN. (July 28, 2017), https://www.fda.gov/news-events/speeches-fda-officials/protecting-american-families-comprehensive-approach-nicotine-and-tobacco-06282017 [hereinafter *2017 Comprehensive Plan*].

caused by addiction to cigarettes."[127] However, "the nicotine in cigarettes is not directly responsible for the cancer, lung disease, and heart disease that kill hundreds of thousands of Americans each year."[128] Instead, "it's the other chemical compounds in tobacco, and in the smoke created by setting tobacco on fire, that directly and primarily cause the illness and death, not the nicotine."[129]

Having identified the problem—distinguishing clearly between the harmful and addictive components of smoking—Dr. Gottlieb moved on to a key part of FDA's new approach to tobacco and nicotine: "[W]e must recognize the potential for innovation to lead to less harmful products, which, under FDA's oversight, could be part of a solution."[130] His approach was premised on the acknowledgment of a pillar of harm reduction thinking going back to the Strategic Dialogue: "For starters, given everything I just said about the vital role of the delivery mechanism, we must acknowledge that there's a continuum of risk for nicotine delivery. That continuum ranges from combustible cigarettes at one end, to medicinal nicotine products at the other."[131]

The 2017 Comprehensive Plan announced by Dr. Gottlieb also prominently included a proposal to mandate the reduction of nicotine levels in combustion cigarettes to render them non-addictive.[132] This would close off the pipeline of new smokers and prevent the development of smoking-related illnesses down the road.[133] A final pillar of the 2017 Comprehensive Plan was to ask FDA's "Center for Drug Evaluation and Research to examine possible steps we can take to address the performance of medicinal nicotine products, including the speed with which the nicotine is delivered, and other possible innovations in treatments that could help more smokers use FDA-approved products to quit smoking."[134]

One aspect of Dr. Gottlieb's historic announcement was its handling of the deadline for PMTA filings—which, in the final deeming rule, was August 8, 2018. Because the new Commissioner wanted to see some additional FDA regulations and guidance documents put into place—among other things, with little more than a year to go before the deadline, FDA had not yet finalized a PMTA guidance or a PMTA rule—Gottlieb announced that he was moving the PMTA deadline back by four years, to August 2022. As discussed in Part III.C below, as a result of litigation by TCAG, the PMTA deadline was later moved forward from August 2022 to September 2020.

6. FDA's Declaration of a Youth Vaping Epidemic

Slightly over a year after Dr. Gottlieb's dramatic announcement, the trajectory of FDA's tobacco and nicotine policy—and in particular its attitude toward ENDS—abruptly changed. On September 11, 2018, with preliminary National Youth Tobacco Survey (NYTS) data in hand, Dr. Gottlieb announced that there had been a

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[127] *Id.*

[128] *Id.*

[129] *Id.*

[130] *Id.*

[131] *Id.*

[132] *Id.*

[133] *Id.*

[134] *Id.*

precipitous rise in youth vaping. There was, he declared, "an epidemic of e-cigarette use among teenagers."[135] When official NYTS numbers were released a few months later, they would show that, from 2017 to 2018, "current" (at least once in the prior thirty days) use among high school students had climbed from 11.7% to 20.8%, and among middle school students from 3.3% to 4.9%.[136]

FDA retained its use of the word "epidemic" in 2019, with the release of NYTS data showing further significant increases in both high school and middle school vaping.[137] That year's survey saw current high school vaping increase from 20.8% to 27.5% and current middle school vaping from 4.9% to 10.5%. High school and middle school current vaping began to decline in 2020, returning to 2018 levels.[138] The trend continued in 2021, with levels (current high school vaping of 11.3% and current middle school vaping of 2.8%) falling below those seen in 2016.[139] In announcing the 2020 NYTS results, which it called "[e]ncouraging," FDA discontinued use of the term "epidemic."[140] In 2021 and 2022, it moved to a characterization of youth vaping as a "serious public health concern."[141] In 2023, CTP Director Brian King confirmed that CTP no longer uses the term "epidemic" in regard to youth vaping.[142]

7. The EVALI Outbreak

Beginning in August 2019, there was a sudden surge in cases of mostly young people presenting at hospital emergency rooms with serious lung injuries. Over the

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[135] *Statement from FDA Commissioner Scott Gottlieb, M.D., on New Steps to Address Epidemic of Youth E-Cigarette Use*, U.S. FOOD & DRUG ADMIN. (Sept. 11, 2018), https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-steps-address-epidemic-youth-e-cigarette-use.

[136] Karen A. Cullen, Bridget K. Ambrose, Andrea S. Gentzke, Benjamin J. Apelberg, Ahmed Jamal & Brian A. King, *Notes from the Field*: *Use of Electronic Cigarettes and Any Tobacco Product Among Middle and High School Students—United States, 2011–2018*, 67 MORBIDITY & MORTALITY WKLY. REP. 1276 (2018), https://www.cdc.gov/mmwr/volumes/67/wr/mm6745a5.htm?s_cid=mm6745a5_w.

[137] *Trump Administration Combating Epidemic of Youth E-Cigarette Use with Plan to Clear Market of Unauthorized, Non-Tobacco-Flavored E-Cigarette Products*, U.S. FOOD & DRUG ADMIN. (Sept. 11, 2019), https://www.fda.gov/news-events/press-announcements/trump-administration-combating-epidemic-youth-e-cigarette-use-plan-clear-market-unauthorized-non.

[138] *National Survey Shows Encouraging Decline in Overall Youth E-Cigarette Use, Concerning Uptick in Use of Disposable Products*, U.S. FOOD & DRUG ADMIN. (Sept. 9, 2020), https://www.fda.gov/news-events/press-announcements/national-survey-shows-encouraging-decline-overall-youth-e-cigarette-use-concerning-uptick-use.

[139] *Youth E-cigarette Use Remains Serious Public Health Concern Amid COVID-19 Pandemic*, U.S. FOOD & DRUG ADMIN. (Sept. 30, 2021), https://www.fda.gov/news-events/press-announcements/youth-e-cigarette-use-remains-serious-public-health-concern-amid-covid-19-pandemic.

[140] Cullen et al., *supra* note 136.

[141] *Trump Administration Combating Epidemic of Youth E-Cigarette Use*, *supra* note 137; Press Release, U.S. Food & Drug Admin., New Data Show More Than 2.5 Million U.S. Youth Currently Use E-Cigarettes (Oct. 6, 2022), https://www.fda.gov/news-events/press-announcements/new-data-show-more-25-million-us-youth-currently-use-e-cigarettes.

[142] American Vapor Manufacturers, *The Future of Vaping in the US: A Conversation with FDA's Dr. Brian King*, YOUTUBE, at 24:55 (Feb. 24, 2023), https://www.youtube.com/watch?v=zfQ8u59z8Ac. Brian King succeeded Mitch Zeller as CTP Director, taking over from Michele Mital who had held the position on an acting basis. Hannah Hammond, *FDA's Center for Tobacco Products Hires Director: King Previously Worked in the CDC's Office on Smoking and Health*, CSP DAILY NEWS (May 24, 2022), https://www.cspdailynews.com/tobacco/fdas-center-tobacco-products-hires-director.

course of just a few months, there were over 2,800 cases and nearly seventy deaths. Almost immediately, FDA identified the potential culprit—a chemical additive found in certain marijuana vaping products. As reported by *Washington Post* health reporter Lena Sun on September 6, 2019: "The chemical is an oil derived from vitamin E [Vitamin E Acetate]. Investigators at the U.S. Food and Drug Administration found the oil in cannabis products in samples collected from patients who fell ill across the United States."[143]

Initially, CDC declined to rule out other possible chemical causes for these acute episodes—and indeed specifically refused to rule out a connection to nicotine vaping.[144] It justified its resistance by pointing to statements of patients who denied using THC and who had claimed only to have vaped nicotine—despite the fact that toxicology results and other data for many of these same individuals showed that they had in fact used THC.[145] It appeared that patients were either deceptive about their actions, perhaps because THC was illegal in their jurisdiction or because they did not want their parents to know they were using THC, or they were genuinely unaware that they had used a product that contained THC. CDC's apparent determination to maintain an aura of suspicion around nicotine vaping products was also reflected in the name that it chose for the syndrome—"electronic-cigarette (e-cigarette), or vaping, product use-associated lung injury (EVALI)."[146] The new name replaced Vaping-Associated Pulmonary Injury (VAPI) that had previously been in use.[147]

It was not until February 2020, some five months after the crisis had begun and with an end to additional case reports, that CDC finally declared: "Laboratory data show that vitamin E acetate, an additive in some THC-containing e-cigarette, or vaping, products, is strongly linked to the EVALI outbreak."[148]

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[143] Lena H. Sun, *Contaminant Found in Marijuana Vaping Products Linked to Deadly Lung Illnesses, Tests Show*, WASH. POST (Sept. 5, 2019), https://www.washingtonpost.com/health/2019/09/05/contaminant-found-vaping-products-linked-deadly-lung-illnesses-state-federal-labs-show/.

[144] Joshua G. Schier et al., *Severe Pulmonary Disease Associated with Electronic-Cigarette-Product Use—Interim Guidance*, 68 MORBIDITY & MORTALITY WKLY. REP. 787 (2019), https://www.cdc.gov/mmwr/volumes/68/wr/mm6836e2.htm?s_cid=mm6836e2_w.

[145] *Id.*; Isaac Ghinai, Ian W. Pray, Livia Navon, Kevin O'Laughlin, Lori Saathoff-Huber, Brooke Hoots, Anne Kimball, Mark W. Tenforde, Jennifer R. Chevinsky, Mark Layer, Ngozi Ezike, Jonathan Meiman & Jennifer E. Layden, *E-cigarette Product Use, or Vaping, Among Persons with Associated Lung Injury—Illinois and Wisconsin, April–September 2019*, 68 MORBIDITY & MORTALITY WKLY. REP. 865, 865–68 (2019), https://www.cdc.gov/mmwr/volumes/68/wr/pdfs/mm6839e2-H.pdf.

[146] Erin Moritz et al., *Update: Characteristics of Patients in a National Outbreak of E-cigarette, or Vaping, Product Use-Associated Lung Injuries—United States, October 2019*, 68 MORBIDITY & MORTALITY WKLY. REP. 985 (2019), https://www.cdc.gov/mmwr/volumes/68/wr/mm6843e1.htm?s_cid=mm6843e1_w.

[147] *See, e.g.*, *CDC Urges Clinicians to Report Possible Cases of Unexplained Vaping-associated Pulmonary Illness to their State/Local Health Department*, CTRS. FOR DISEASE CONTROL & PREVENTION (Aug. 16, 2019), https://emergency.cdc.gov/newsletters/coca/081619.htm.

[148] *Outbreak of Lung Injury Associated with the Use of E-Cigarette, or Vaping, Products*, CTRS. FOR DISEASE CONTROL & PREVENTION (last updated Aug. 3, 2021), https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html.

III. TCAG AND E-CIGARETTES

A. TCAG and Sottera*—Opposition*

TCAG supported FDA's efforts in the *Sottera* litigation to ban all ENDS products as unapproved drug delivery devices. In a July 23, 2009, press release titled "FDA Acts To Protect Public Health From Electronic Cigarettes," CTFK wrote: "The U.S. Food and Drug Administration has acted to protect public health from so-called electronic cigarettes by seeking to block importation of these products. . . . We look forward to the FDA taking additional action to stop the marketing and sale of these unapproved products."[149] TCAG filed an amicus brief in support of FDA's position at the D.C. Circuit. [150]

B. Prior to the Declaration of a Youth Vaping Epidemic and EVALI—Partial Acceptance

Within a few years of the D.C. Circuit's decision in *Sottera*, as the science began to accumulate regarding the reduced toxicity of ENDS as compared to traditional cigarettes and their increasingly successful use as a quit aid, there were signs of acknowledgment among TCAG of the potential public health benefit from the new products for adults otherwise unable or unwilling to quit all use of nicotine. In a 2014 policy statement, for example, the American Heart Association acknowledged that "e-cigarette aerosol is likely to be much less toxic than cigarette smoking" and that, as a consequence: "If a patient has failed initial treatment, has been intolerant to or refused to use conventional smoking cessation medication, and wishes to use e-cigarettes to aid quitting, it is reasonable to support the attempt."[151] The recommendation came with the caveats that ENDS "may contain low levels of toxic chemicals," "have not been proven as cessation devices," and "there are as yet no long-term safety studies of e-cigarette use."[152]

The following year, the Truth Initiative issued a statement titled "The Truth About Electronic Nicotine Delivery Systems." In a section of the document captioned "WHERE WE STAND: ENDS" Truth declared:

> Regulation of Electronic Nicotine Delivery Systems (ENDS) is essential to ensure they are as safe as possible, that individual and population benefits are maximized while harms are minimized, and that youth do not use ENDS. . . . If prudently regulated, we believe ENDS hold promise as one means to move smokers to a less harmful product and reduce the devastating death and disease burden caused by combustible tobacco products such as cigarettes, cigars or hookah.[153]

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[149] *FDA Acts to Protect Public Health from Electronic Cigarettes*, CAMPAIGN FOR TOBACCO-FREE KIDS (July 23, 2009), https://www.tobaccofreekids.org/press-releases/id_1166.

[150] Amicus Brief, Sottera v. FDA, No. 10-532 (D.C. Cir. Dec. 28, 2010), ECF No. 1285116.

[151] Aruni Bhatnagar, Laurie P. Whitsel, Kurt M. Ribisl, Chris Bullen, Frank Chaloupka, Mariann R. Piano, Rose Marie Robertson, Timothy McAuley, David Goff & Neal Benowitz, *Electronic Cigarettes: A Policy Statement From the American Heart Association*, 130 CIRCULATION 1418 (2014).

[152] *Id.*

[153] *The Truth About: Electronic Nicotine Delivery Systems*, TRUTH INITIATIVE (Dec. 2015), https://cdn.ymaws.com/www.naquitline.org/resource/resmgr/newsroom_/dec8ENDS_Fact_Sheet_-_1_4_16.pdf.

In early 2018, following the publication of the NASEM report on ENDS, the American Cancer Society issued a "Position Statement on Electronic Cigarettes," which included the following "Clinical Recommendation":

> Some smokers, despite firm clinician advice, will not attempt to quit smoking cigarettes and will not use FDA approved cessation medications. These individuals should be encouraged to switch to the least harmful form of tobacco product possible; switching to the exclusive use of e-cigarettes is preferable to continuing to smoke combustible products.[154]

For its part, the CTFK took a position more in line with that of the Strategic Dialogue, namely, that it favored harm reduction, provided it was implemented under FDA oversight and pursuant to its scientific review within the framework established by the TCA. For example, at a presentation at the May 2017 E-Cigarette Summit in Washington, DC,[155] CTFK President Matt Myers stated: "I happen to believe that responsible harm reduction is an absolutely essential and critical component to the battle to reduce the death and disease from tobacco use as we move forward."[156] He explained further that "I believe a well-regulated e-cigarette inevitably will be safer and if marketed to smokers who can't or won't quit has the potential to dramatically and rapidly reduce tobacco use in our country."[157]

But, as Myers explained, the anchoring of all of this in an FDA review process was critical:

> Smokers have the right to know which of these products are designed in such a way to deliver nicotine in a way that the best available minds believe have a reasonable chance of assisting them in either reducing or quitting to a degree necessary. And there is no other way to do that unless you have a science based, evidence based, objectively and independently determined set of mechanisms for doing so.[158]

Thus, a slide accompanying his presentation stated: "The Current FDA Authority Is Necessary to Both Protect the Public and Fulfill the Potential of New Products to Reduce Harm."[159] FDA is, Myers explained, the "independent arbitrator" when it comes to putative reduced harm products.[160] In a speech at the same conference the following year,[161] Myers made many of the same points. He argued that there is a need for a "trusted arbiter" when it came to harm reduction, explaining that "[t]he Current FDA Authority Is Necessary to Both Protect the Public and Fulfill Any

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[154] *American Cancer Society Position Statement on Electronic Cigarettes*, AM. CANCER SOC'Y (Feb. 15, 2018), https://www.casaa.org/wp-content/uploads/American-Cancer-Society-Position-Statement-on-Electronic-Cigarettes.pdf.

[155] 2017 E-Cigarette Summit, *Matthew Myers Presentation*, VIMEO (2017), https://vimeo.com/219506484.

[156] *Id.* beginning at about 1:05.

[157] *Id.* beginning at about 4:01.

[158] *Id.* beginning at about 7:16.

[159] *Id.* at about 1:55 (slide).

[160] *Id.* at about 10:45.

[161] 2018 E-Cigarette Summit, *Matthew Myers Presentation*, VIMEO (2018), https://vimeo.com/showcase/5155140/video/268311497.

Potential of New Products to Reduce Harm."[162] He also argued that this was "not a debate about kids v. adults"—that "FDA regulation protects both."[163]

C. Am. Acad. of Pediatrics v. FDA

In March 2018, TCAG filed suit in U.S. District Court for the District of Maryland, challenging FDA's decision—as part of the 2017 Comprehensive Nicotine and Tobacco Policy—to extend the PMTA deadline by four years, to August 2022.[164] They argued that any such extension could only have been implemented pursuant to notice and comment rulemaking and that the extension was therefore invalid.

The complaint included, for each of the TCAG Plaintiffs, a description of the organization—in each instance touting its track record of anti-smoking advocacy.[165] None of the plaintiffs disclosed—whether in the complaint or elsewhere—any information regarding its financial donors (e.g., pharmaceutical companies who sell medicinal nicotine replacement products) and, by extension, the potential economic interests that could be inferred from such relationships.

FDA moved to dismiss the complaint based on a lack of standing. As part of their opposition to the motion, the plaintiffs each presented declarations that sought to explain their particular interest in the outcome.[166] Consistent with the Strategic Dialogue, plaintiffs emphasized the value in getting products under FDA review and the benefits that would flow from being able to rely on the results of such review—including to assist adults who smoke and who may be interested in using an authorized ENDS product. The Truth Initiative's Declaration was particularly clear on this point. According to its general counsel: "[T]he absence of premarket review prevents Truth Initiative from helping users make decisions regarding e-cigarettes, including making informed choices between e-cigarettes. Truth Initiative is committed to harm reduction and would identify products that appeared to carry the least risks in its materials, but simply cannot do so without data from FDA."[167] Neither the complaint nor any of the declarations submitted in support of the opposition to the motion to dismiss argued that FDA would be required to deny authorization to any particular category of ENDS—for example all flavored variants.

On May 15, 2019, the court ruled in favor of plaintiffs, vacating the August 2022 PMTA deadline.[168] In a separate remedies order, the court set a new PMTA deadline

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[162] *Id.* at about 0:10 (slide), at about 17:40 (slide), and beginning at about 20:22 ("FDA has a unique opportunity to be the trusted objective arbiter and rule maker, to bring people together and not separate them apart with regard to these issues.").

[163] *Id.* at about 15:40 (slide).

[164] Complaint, Am. Acad. of Pediatrics v. FDA, No. 18-00883 (D. Md. Mar. 27, 2018), ECF No. 1.

[165] *Id.* at ¶¶ 8–18.

[166] *See generally* Am. Acad. of Pediatrics v. FDA, No. 18-00883, Exhibits to the Memorandum in Opposition to Motion to Dismiss at, Declaration of Matthew L. Myers, ECF No. 39-1 (CTFK), Declaration of Timothy B. Phillips, ECF No. 39-3 (ACS-CAN), Declaration of Mark A. Schoeberl, ECF No. 39-4 (AHA), Declaration of Harold P. Wimmer, ECF No. 39-5 (ALA), Declaration of Robert N. Falk, ECF No. 39-6 (Truth), Declaration of Jonathan Winickoff, ECF No. 39-10 (AAP).

[167] *See supra* note 166, at ECF No. 39-6, ¶¶ 10.

[168] Memorandum Opinion, Am. Acad. of Pediatrics v. FDA, No. 18-00883 (D. Md. May 15, 2019), ECF No. 73.

of March 9, 2020[169]—later extended to September 9, 2020, based on the disruptions caused by COVID-19 closures.[170] The remedies order also set a twelve-month limit for FDA's exercise of enforcement discretion during the pendency of FDA's PMTA review.[171]

D. The 2019 Bloomberg Flavor Initiative

In September 2019, a year after Dr. Gottlieb's declaration of a youth vaping epidemic and a month after the first reports of EVALI cases, billionaire Michael Bloomberg, on behalf of Bloomberg Philanthropies, announced a $160 million initiative called "Protect Kids: Fight Flavored E-Cigarettes" (2019 Bloomberg Flavor Initiative).[172] The goal of the initiative was the "banning of all flavored e-cigarettes."[173]

In announcing the initiative, Bloomberg took direct aim at FDA, explicitly positioning the initiative as a means of sidestepping the agency, including through legislative efforts at the state and local level to ban flavors: "The federal government has the responsibility to protect children from harm, but it has failed—so the rest of us are taking action. I look forward to partnering with advocates in cities and states across the country on legislative actions that protect our kids' health."[174] Specifically, the initiative set as a goal helping "at least 20 cities and states pass laws banning all flavored tobacco and e-cigarettes."[175] The initiative called for the $160 million program to be "led by the Campaign for Tobacco-Free Kids, which will partner with other leading organizations including parent and community groups concerned about the nation's kids and health." The partner organizations, the leaders of which provided supporting quotes in the official announcement, included all of the TCAG members as well as the CDC Foundation.

Bloomberg and CTFK justified the initiative based on the youth vaping epidemic declared the prior year and on the EVALI cases. With respect to the latter, the official press announcement was titled "New initiative launches on heels of 33 states investigating more than 450 cases of lung illnesses associated with vaping, many of which involve teens and young adults."[176] The launch of the new initiative also included a joint appearance by Michael Bloomberg and the CTFK President on CBS

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[169] Memorandum Opinion and Order, Am. Acad. of Pediatrics v. FDA, No. 18-00883 (D. Md. July 12, 2019), ECF No. 127.

[170] Indicative Ruling, Am. Acad. of Pediatrics v. FDA, No. 18-00883 (D. Md. Apr. 3, 2020), ECF No. 179.

[171] *Supra* note 169.

[172] *Bloomberg Philanthropies Launches New $160 Million Program to End the Youth E-Cigarette Epidemic*, BLOOMBERG PHILANTHROPIES (Sept. 10, 2019), https://www.bloomberg.org/press/bloomberg-philanthropies-launches-new-160-million-program-end-youth-e-cigarette-epidemic/.

[173] *Id.*

[174] *Id.*

[175] Michael Bloomberg & Mathew Myers, *Ban Flavored E-Cigarettes to Protect Our Children: We Know Big Tobacco's Playbook: It is Targeting Kids—And Putting Them in Serious Danger*, N.Y. TIMES (Sept. 10, 2019), https://www.nytimes.com/2019/09/10/opinion/vape-deaths-children-bloomberg.html#:~:text=Banning%20flavored%20e%2Dcigarettes%20is,to%20ban%20flavored%20e%2Dcigarettes.

[176] *Bloomberg Philanthropies Launches*, *supra* note 172.

This Morning.[177] During the segment, Bloomberg referenced the EVALI crisis, informing the hosts that "people are dying now."[178] He dismissed claims that ENDS products may be safer than cigarettes or that they can assist adults in switching away from cigarettes, adding: "Just think if your kid was doing this and winds up with an IQ [intelligence quotient] 10 or 15 points lower than he or she would have had for the rest of her life."[179]

In early 2023, Bloomberg Philanthropies announced the commitment of an additional $420 million for ""global tobacco reduction efforts," of which "$140 million will target reducing e-cigarette use among teenagers in the United States."[180] The announcement referred back to the 2019 Bloomberg Flavor Initiative, and pointed to its successful support of "the passage of 55 state and local flavor bans."[181] CTFK is a partner in the continued initiative as are, presumably, the other TCAG groups from 2019.[182]

E. TCAG Post the 2019 Bloomberg Flavor Initiative—Reversion to Opposition

Following the launch of the 2019 Bloomberg Flavor Initiative, TCAG uniformly aligned their advocacy around the central message that all flavored ENDS must be banned. More broadly, to strengthen the case for a flavor ban, TCAG aggressively promoted the arguments that vaping does not help people quit and that the products are unsafe.

The call for an across-the-board ENDS flavor ban—without regard to the quantum of evidence that may be submitted as part of a PMTA to establish adult benefit and without regard to marketing restrictions that could limit youth exposure and use—was a repudiation of the fundamental and consensus principle that FDA should be the "trusted arbiter" of the potential benefit of putative reduced harm products based on a public health standard that looks at impacts on *both* adults and youth. Moreover, the term "flavored" ENDS, in TCAG usage, was expanded to include menthol, despite the fact that menthol cigarettes remain lawfully on the market throughout most of the United States. For example, though promoted as part of an effort to ban all "flavored tobacco products," in multiple states (including New York, New Jersey, and Rhode Island), TCAG supported final legislation that outlawed flavored ENDS while leaving menthol cigarettes untouched[183]—an advocacy position that turns the

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[177] *See* CBS Mornings, *Michael Bloomberg Blames FDA for Teen Vaping Epidemic*, YOUTUBE (Sept. 10, 2019), https://youtu.be/Gx2p-NraM2s.

[178] *Id.* at about 1:25.

[179] *Id.* at about 3:21.

[180] *Bloomberg Philanthropies Commits Additional $420 Million to Reduce Tobacco Use Globally*, BLOOMBERG PHILANTHROPIES (Feb. 2, 2023), https://www.bloomberg.org/press/bloomberg-philanthropies-commits-additional-420-million-to-reduce-tobacco-use-globally/.

[181] *Id.*

[182] *Michael Bloomberg and Bloomberg Philanthropies Continue Their Lifesaving Leadership in the Global Fight Against Tobacco*, CAMPAIGN FOR TOBACCO-FREE KIDS (Feb. 2, 2023), https://www.tobaccofreekids.org/press-releases/2023_02_02_bloomberg.

[183] *New Jersey Takes Historic Action to Tackle Youth E-Cigarette Epidemic, Needs to Crack Down on Menthol Cigarettes Next*, CAMPAIGN FOR TOBACCO-FREE KIDS (Jan. 14, 2020), https://www.tobaccofreekids.org/press-releases/2020_01_14_newjersey; *Gov. Raimondo's Actions to End the Sale of Flavored E-Cigarettes Will Protect Rhode Island Kids; New Poll Shows Two-Thirds of Voters Support the Move*, CAMPAIGN FOR TOBACCO-FREE KIDS (Mar. 25, 2020), https://www.tobaccofreekids.

continuum of risk on its head by favoring a combustion cigarette over an identically flavored non-combustible product. And, consistent with the flavor initiative's goal of sidelining FDA, TCAG opposed statutory language at the state level that would exempt flavored ENDS that had received PMTA authorization from FDA, regarding it as a "loophole."[184]

A second consistent talking point has been that ENDS products do not help adults quit smoking. For example, according to congressional testimony by CTFK's president: "the evidence is insufficient to conclude that e-cigarettes are a safe and effective smoking cessation device."[185] The American Lung Association uses identical language in dismissing the quitting efficacy of ENDS.[186] However, statements of this type are referring to medicinal cessation as defined by FDA, which is restricted to products that claim to induce *both* quitting cigarettes and all use of nicotine.[187] The use of medicinal approval language avoids a discussion of the benefits of ENDS in inducing the quitting of smoking without eliminating all nicotine use—which FDA *has* found in the ENDS products it has authorized through the PMTA pathway. It also ignores multiple years of Cochrane Review findings that ENDS promote quitting of cigarettes more effectively than NRT. And it can only confuse people who smoke and are interested in finding a way to stop using cigarettes—while unable or unwilling to quit all use of nicotine.

The third main plank of the campaign has been to tarnish all ENDS products as unsafe. Symbolic of this portion of the new advocacy was a November 2019 statement by the American Cancer Society, withdrawing the 2018 policy statement that had supported the potential beneficial use of ENDS. According to the replacement statement:

> [A]dults who smoke who switch to using e-cigarettes expose themselves to potentially serious ongoing health risks. Thus, people who smoked formerly who are currently using e-cigarettes, whether alone or in combination with combustible tobacco products, should be encouraged and assisted to stop using all tobacco products, including e-cigarettes, as

org/press-releases/2020_03_25_raimondo_rhodeisland; *New York Takes Historic Action to Tackle Youth E-Cigarette Use by Ending the Sale of All Flavored E-Cigarettes*, CAMPAIGN FOR TOBACCO-FREE KIDS (Apr. 2, 2020), https://www.tobaccofreekids.org/press-releases/2020_04_02_ny-flavored-ecigs.

184 *Id.*

185 *Legislation to Reverse the Youth Tobacco Epidemic: Hearing Before the H. Comm. on Energy and Comm. Subcomm. on Health*, 116th Congress (2019), Written Testimony of Matthew L. Myers, President, Campaign for Tobacco-Free Kids, at 3 (Oct. 16, 2019), https://www.congress.gov/116/meeting/house/110091/witnesses/HHRG-116-IF14-Wstate-MyersM-20191016.pdf.

186 *E-Cigarettes*, AM. LUNG ASS'N (last updated May 31, 2023), https://www.lung.org/quit-smoking/e-cigarettes-vaping/lung-health ("The Food and Drug Administration has not found any e-cigarette to be safe and effective in helping smokers quit.").

187 Clarification of When Products Made or Derived From Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding "Intended Uses," 21 C.F.R. pts. 201, 801, 1100 (2017) ("FDA has approved a number of drug products made or derived from tobacco as nicotine replacement therapies with indications to reduce withdrawal symptoms, including nicotine craving, associated with quitting smoking."), https://www.govinfo.gov/content/pkg/FR-2017-01-09/pdf/2016-31950.pdf.

> soon as possible both to eliminate their exposure to ongoing health risks and avoid perpetuating addiction.[188]

Among other things, as part of the attack on the relative safety of ENDS, TCAG continued to link nicotine vaping with EVALI or EVALI-like harm.[189] Indeed, TCAG leveraged the EVALI crisis to obtain emergency orders in eight states banning all e-cigarette flavors other than tobacco—on the implicit ground that menthol and non-traditional flavors caused EVALI symptoms while tobacco flavored products did not.[190] In addition to the sustained campaign to link EVALI and ENDS, from the beginning of the COVID-19 pandemic, TCAG advanced the claim that ENDS use increased COVID-19 risk.[191] This argument would later be based on a single small-scale survey that promoted the biologically implausible conclusion that "former" ENDS users were at increased COVID-19 risk but "current" users were not. The survey implicitly assumed that 64% of all COVID-19 testing in the first months of the pandemic was in individuals aged 13–24, which was clearly implausible.[192] Ultimately, CDC did not adopt ENDS use as a COVID-19 risk factor.[193]

Concurrent with the TCAG campaign against ENDS post the launch of the 2019 Bloomberg Flavor Initiative—which featured baseless claims based on EVALI and COVID-19 risk—the perception of the relative harmfulness of ENDS as compared to combustion cigarettes has deviated ever farther from the scientific reality. As reported by researchers from the American Cancer Society: "[P]erceptions that E-cigarettes are more harmful than cigarettes increased between 2019 and 2020 but more steeply than between previous years. This finding suggests that communication

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188 *American Cancer Society Position Statement on Electronic Cigarettes*, AM. CANCER SOC'Y, https://www.cancer.org/cancer/risk-prevention/tobacco/e-cigarettes-vaping/e-cigarette-position-statement.html (last visited June 22, 2023).

189 *The Impact of E-Cigarettes on the Lung*, AM. LUNG ASS'N (last updated May 31, 2023) ("The Inhalation of Harmful Chemicals Can Cause Irreversible Lung Damage and Lung Disease."), https://www.lung.org/quit-smoking/e-cigarettes-vaping/impact-of-e-cigarettes-on-lung.

190 The eight states were Massachusetts, Michigan, Montana, New York, Oregon, Rhode Island, Utah, and Washington. *STATES & LOCALITIES THAT HAVE RESTRICTED THE SALE OF FLAVORED TOBACCO PRODUCTS*, CAMPAIGN FOR TOBACCO-FREE KIDS, https://www.tobaccofreekids.org/assets/factsheets/0398.pdf.

191 *See, e.g.*, *COVID-19: Never has it Been More Important for Smokers to Quit and for Individuals to Avoid Damaging their Lungs by Vaping*, CAMPAIGN FOR TOBACCO-FREE KIDS (Mar. 20, 2020), https://www.tobaccofreekids.org/press-releases/2020_03_20_covid-19 ("The coronavirus (COVID-19) attacks the lungs, and behaviors that weaken the lungs put individuals at greater risk. The harmful impact of smoking on the lungs is well documented, and there is a growing body of evidence that e-cigarette use (vaping) can also harm lung health."); *What You Need to Know About Smoking, Vaping and COVID-19*, AM. LUNG ASS'N (Mar. 27, 2020), https://www.lung.org/blog/smoking-and-covid19 ("According to American Lung Association's Chief Medical Officer Albert Rizzo, M.D., an important step to immediately improve your health and possibly avoid the most serious symptoms of this scary disease is to consider quitting smoking and vaping.").

192 Shivani Mathur Gaiha, Jing Cheng & Bonnie Halpern-Felsher, *Association Between Youth Smoking, Electronic Cigarette Use, and COVID-19*, 67 J. ADOLESCENT HEALTH 519 (2020); Konstantinos Farsalinos & Raymond Niaura, *E-Cigarette Use and COVID-19: Questioning Data Reliability*, 68 J. ADOLESCENT HEALTH 213 (2021).

193 *Underlying Medical Conditions Associated with Higher Risk for Severe COVID-19: Information for Healthcare Professionals*, CTRS. FOR DISEASE CONTROL & PREVENTION (last updated Feb. 9, 2023), https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/underlyingconditions.html#anchor_1618433687270.

(media coverage, social media, health communiques) of EVALI and COVID-19 risks potentially played a role in shaping relative harm perceptions."[194] These misperceptions had, according to the study authors, real-world impact on switching: "[I]ncreases in exclusive cigarette smoking and exclusive E-cigarette use were restricted to persons who perceived their preferred product as relatively less harmful, and dual use increases were observed in those perceiving these products to be equally harmful. This suggests that changes were potentially guided by product-specific relative harm perceptions."[195] The authors ended with the recommendation that, "[i]n the context of pervasive health misinformation that has circulated after COVID-19[,] these findings highlight the need for accurate and tailored messaging of relative and absolute product risks."[196] Even doctors have been affected by the misinformation—according to a 2020 survey, 80% of physician respondents strongly but incorrectly agreed that nicotine causes cancer, cardiovascular disease, and chronic obstructive pulmonary disease.[197]

IV. THE UNITED KINGDOM APPROACH

A. Traditional Tobacco Control Measures

The United States and the United Kingdom have gone down parallel roads with respect to the formulation and implementation of tobacco-control policies in response to the increasing recognition of the link between cigarette smoking and lung cancer and other serious health risks. The UK's health report linking cigarette smoking and lung cancer—*Smoking and Health*, prepared by the Royal College of Physicians—came out in 1962,[198] two years earlier than the U.S. Surgeon General's 1964 report. Consistently, in the sixty years since the 1962/1964 reports and continuing to this very day, the UK has outpaced the United States when it comes to the speed of adoption and scope of anti-smoking and anti-tobacco measures. For example: a) the UK banned cigarette television advertising in 1965,[199] five years earlier than the United States[200]; b) the UK banned the display of cigarette logos at televised sporting events in 1972,[201] more than two decades earlier than the United States[202]; c) since 2008, UK law requires cigarette packages to carry pictorial health warnings, and since 2017, the UK has mandated standardized packaging for

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[194] Priti Bandi, Samuel Asare, Anuja Majmundar, Nigar Nargis, Ahmedin Jemal & Stacey A. Fedewa, *Relative Harm Perceptions of E-Cigarettes Versus Cigarettes, U.S. Adults, 2018–2020*, 68 AM. J. PREVENTIVE MED. 186 (2022).

[195] *Id.* at 192.

[196] *Id.* at 192.

[197] Michael B. Steinberg, Michelle T. Bover Manderski, Olivia A. Wackowski, Binu Singh, Andrew A. Strasser & Cristine D. Delnevo, *Nicotine Risk Misperception Among US Physicians*, 36 J. GEN. INTERNAL MED. 3888 (2021).

[198] *See* ROYAL COLLEGE OF PHYSICIANS, SMOKING AND HEALTH, *supra* note 15.

[199] *See Key Dates in Tobacco Regulation 1962–2020*, ACTION ON SMOKING & HEALTH (Apr. 2022), https://ash.org.uk/uploads/Key-Dates.pdf.

[200] The U.S. television ban became effective on January 1, 1971, pursuant to the Public Health Cigarette Smoking Act of 1969, 15 U.S.C. §§ 1331, 1335 et seq.

[201] *See supra* note 199.

[202] MSA, *supra* note 34, at 19.

cigarettes,[203] which required the removal of all brand images, colors, and promotions from tobacco product packaging—none of which is required in the United States; d) the UK bans the display of tobacco products at the point of sale—something not in contemplation within the United States[204]; e) since 2020, menthol cigarettes have been banned in the UK,[205] yet they remain lawfully on the market in the United States, despite more than a decade of effort to remove them; and f) the UK, but not the United States, has signed the WHO's Framework Convention on Tobacco Control.[206]

B. UK E-Cigarette Consensus

Electronic cigarettes began to appear in the UK around the same time as they did in the United States. British tobacco experts initially reacted to the new products with skepticism, in much the same way that their American colleagues did. But they withheld full judgment until they had a better sense of the data—namely, the relative safety of the products as compared to smoking, their effectiveness at helping smokers switch, and their acceptability to smokers.

In 2014, Public Health England, an "executive agency" of the Department of Health, which had been established a year earlier to protect and improve the nation's health and wellbeing and reduce health inequalities, issued its first report on electronic cigarettes.[207] After reviewing the available evidence, the report concluded with a strong endorsement of the "vast potential health benefits" for the products: "The emergence of electronic cigarettes and the likely arrival of more effective nicotine-containing devices currently in development provides a radical alternative to tobacco, and evidence to date suggests that smokers are willing to use these products in substantial numbers."[208]

In 2016, leading UK health and tobacco control groups (including Action on Smoking and Health, Cancer Research UK, the Royal College of Physicians, and the British Lung Foundation) joined with Public Health England in releasing a consensus statement on e-cigarettes. The consensus statement included the declaration: "We all agree that e-cigarettes are significantly less harmful than smoking."[209] That same year, the Royal College of Physicians issued a 206-page report that found that "[e]-cigarettes appear to be effective when used by smokers as an aid to quitting

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[203] *See supra* note 199.

[204] *Id.*

[205] Press Release, Action on Smoking & Health, Media Advisory: Ban on Menthol Flavoured Cigarettes Comes Into Force on 20 May 2020 (May 12, 2020), https://ash.org.uk/media-centre/news/press-releases/advisorymentholban2020.

[206] *WHO Framework Convention on Tobacco Control (WHO FCTC)*, WORLD HEALTH ORG., https://www.who.int/europe/teams/tobacco/who-framework-convention-on-tobacco-control-(who-fctc) (last visited June 22, 2023).

[207] John Britton & Ilze Bogdanovica, *Electronic Cigarettes: A Report Commissioned by Public Health England* (May 2014), https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/311887/Ecigarettes_report.pdf.

[208] *Id.*

[209] *E-Cigarettes: A Developing Public Health Consensus: Joint Statement on E-Cigarettes by Public Health England and Other UK Public Health Organisations*, PUB. HEALTH ENG. (2016), https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/534708/E-cigarettes_joint_consensus_statement_2016.pdf.

smoking" and that "[p]rovision of the nicotine that smokers are addicted to without the harmful components of tobacco smoke can prevent most of the harm from smoking."[210]

Public Health England provided updates to its prior reports in 2015,[211] 2018,[212] 2019,[213] 2020,[214] 2021,[215] and 2022[216]—in each instance exhaustively reviewing the additional scientific evidence on e-cigarettes published subsequent to the prior update. The updates have found continued validity for the findings that e-cigarettes are likely substantially safer than traditional cigarettes, that they aid in quitting, and that their use should be recommended for smokers otherwise unable or unwilling to quit nicotine use.

C. From the Kahn Report to Swap to Stop

In 2019, the UK government announced the objective of achieving an adult smoking rate below 5% by 2030, what has become known as "Smokefree 2030."[217] In 2022, the Secretary of State for Health and Social Care appointed Dr. Javed Kahn to conduct a review that would look at ways the government could do more to help achieve its smokefree goal. In the spring of 2022, Kahn issued his report, titled *Making Smoking Obsolete*.[218] The Kahn report included "critical recommendation" 3, labeled "Promote Vaping," which states: "The government must embrace the promotion of vaping as an effective tool to help people to quit smoking tobacco. We know vapes are not a 'silver bullet' nor are they totally risk-free, but the alternative is far worse."[219] In April 2023, the UK government announced a "world-first" program called "swap to stop" to "improve the health of the nation and cut smoking

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[210] *Nicotine Without Smoke: Tobacco Harm Reduction*, ROYAL COLL. OF PHYSICIANS (2016), https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction.

[211] *E-Cigarettes: An Evidence update, August 2015*, PUB. HEALTH ENG. (2015), https://www.gov.uk/government/publications/e-cigarettes-an-evidence-update.

[212] *E-Cigarettes and Heated Tobacco Products: Evidence Review February 2018*, PUB. HEALTH ENG. (2018), https://www.gov.uk/government/publications/e-cigarettes-and-heated-tobacco-products-evidence-review.

[213] *Vaping in England: An Evidence Update February 2019*, PUB. HEALTH ENG. (Feb. 27, 2019), https://www.gov.uk/government/publications/vaping-in-england-an-evidence-update-february-2019.

[214] *Vaping in England: Evidence Update March 2020*, PUB. HEALTH ENG. (Mar. 4, 2020), https://www.gov.uk/government/publications/vaping-in-england-evidence-update-march-2020.

[215] *Vaping in England: Evidence Update February 2021*, PUB. HEALTH ENG. (Feb. 23, 2021), https://www.gov.uk/government/publications/vaping-in-england-evidence-update-february-2021.

[216] *Nicotine Vaping in England: 2022 Evidence Update September 2022*, PUB. HEALTH ENG. (Sept. 29, 2022), https://www.gov.uk/government/publications/nicotine-vaping-in-england-2022-evidence-update/nicotine-vaping-in-england-2022-evidence-update-main-findings.

[217] *The Smokefree 2030 Ambition*, ACTION ON SMOKING & HEALTH, https://ash.org.uk/health-inequalities/the-smokefree-2030-ambition (last visited June 22, 2023).

[218] *Independent Report, The Khan Review: Making Smoking Obsolete: Independent Review by Dr Javed Khan OBE Into the Government's Ambition to Make England Smokefree by 2030*, OFF. FOR HEALTH IMPROVEMENT & DISPARITIES (2022), https://www.gov.uk/government/publications/the-khan-review-making-smoking-obsolete/.

[219] *Id.* at 10.

rates."[220] It called for the provision of a vape starter kit, together with behavioral support, to one million UK smokers.[221]

V. TCAG'S CAPTURE OF FDA'S TOBACCO POLICY

FDA's CTP came into existence in 2009, following passage of the TCA. As will be shown through seven different examples, TCAG have effectively captured CTP's policy prerogatives. TCAG have successfully driven CTP's priorities, its policies, its major product review decisions, and even its communications strategy. The results of that capture have brought CTP into conflict with both the statute itself and the historic consensus around harm reduction. They have left FDA with its tobacco policy in disarray—presiding over a landscape characterized by an ever-proliferating black-market; an ongoing campaign of misinformation that has confused even physicians; and an almost complete absence of authorized products, including not a single authorized menthol ENDS. All of this leaves accomplishment of the lofty visions of the 2017 Comprehensive Plan seemingly farther away than ever.

A prerequisite for agency capture by an interest group is political power. TCAG has acquired that power in several ways. During the decades-long tobacco wars, TCAG built strong relationships with politicians from both parties—leveraging anti-big business sentiment typically identified with the political left and moralistic impulses typically associated with the political right. Over time TCAG was able to largely overcome the traditional power of politicians from tobacco-producing states to defend industry and block legislation—culminating in the passage of the TCA with strong support from both sides of the aisle. In recent years, its most vocal supporter has been Senate Democrat and Majority Whip Richard Durbin of Illinois. The senator has developed his own direct communication pipeline to both the FDA commissioner and the director of the CTP, calling on the former directly to demand TCAG-favored action[222] and on one occasion summoning the latter to his Capitol Hill office "to discuss FDA's long-standing failure to use its authority to effectively and efficiently regulate the e-cigarette and synthetic nicotine marketplace."[223] In the most recent example of a years-long congressional letter-writing campaign directed at FDA's ENDS policies, in June of this year—with the explicit endorsement of TCAG—a group of more than fifty members of Congress wrote to the FDA commissioner to, among other things, demand that the agency "deny applications for all non-tobacco flavored e-cigarettes, including menthol."[224]

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[220] Press Release, Dep't of Health & Soc. Care, Smokers Urged to Swap Cigarettes for Vapes in World First Scheme (Apr. 11, 2023), https://www.gov.uk/government/news/smokers-urged-to-swap-cigarettes-for-vapes-in-world-first-scheme.

[221] *Id.*

[222] Press Release, Senator Dick Durbin, On Senate Floor, Durbin Announces Support for Biden FDA Commissioner Nominee, But Urges Immediate Action on Vaping Epidemic (Feb. 2, 2022), https://www.durbin.senate.gov/newsroom/press-releases/on-senate-floor-durbin-announces-support-for-biden-fda-commissioner-nominee-but-urges-immediate-action-on-vaping-epidemic.

[223] Press Release, Senator Dick Durbin, Durbin Meets With New Director of FDA's Center for Tobacco Products (Sept. 29, 2022), https://www.durbin.senate.gov/newsroom/press-releases/durbin-meets-with-new-director-of-fdas-center-for-tobacco-products.

[224] Press Release, Representative Debbie Wasserman Schultz, Wasserman Schultz, DeGette Lead Congressional Call for Overdue Review, Enforcement of E-Cigs Still on Market (June 12, 2023), https://wassermanschultz.house.gov/news/documentsingle.aspx?DocumentID=3020.

In recent years, the most significant source of TCAG political power has been Bloomberg money. Bloomberg Philanthropies has spent over $1.5 billion to support anti-tobacco and ENDS measures consistent with its policy prerogatives. Since 2019, it has earmarked $300 million for the fight against flavored ENDS. An undisclosed but presumably sizable portion of that amount has gone to the CDC Foundation, which gives BP access to CDC's Office on Smoking and Health, the "lead federal agency for comprehensive tobacco prevention and control."[225] As the Office on Smoking and Health's own website declares: "CDC's global tobacco work is supported by the CDC Foundation through donations from the Bloomberg Initiative to Reduce Tobacco Use and The Bill and Melinda Gates Foundation."[226] As a complement to the substantial funding of TCAG and the CDC Foundation, Bloomberg has been a powerful benefactor to politicians. *The New York Times*, in a lengthy investigation of his political and philanthropic giving, has described him as "the single most important political donor to the Democratic Party and its causes."[227] In 2020, Bloomberg committed $100 million dollars in an effort to win Florida for Joe Biden.[228]

Bloomberg has openly linked his giving with an effort to influence government policy. As he explained it in a 2015 letter on his charity philosophy:

> In so many areas, governments represent our best hope for making the broad-based societal changes that philanthropic organizations are devoted to bringing about. Governments have the authority to drive change in ways that philanthropic organizations cannot. By leveraging our resources, and forming partnerships with government, philanthropic organizations can help push those changes forward. That mindset may be untraditional, but it is at the heart of nearly everything Bloomberg Philanthropies does.[229]

David Callahan, founder and editor of the media site *Inside Philanthropy*, has written: "Bloomberg . . . understands that influencing government is often the best way to get things done and focuses much of his giving on leveraging changes in public policy."[230] Callahan has characterized this as "rather unnerving," explaining: "One of the world's wealthiest men has openly said that he plans to spend the bulk of

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[225] *Office on Smoking and Health at a Glance*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/chronicdisease/resources/publications/aag/tobacco-use.htm (last visited Aug. 31, 2023).

[226] *Office on Smoking and Health (OSH)*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/tobacco/about/osh/index.htm (last visited Jan. 10, 2024).

[227] Nichlas Kulish & Alexander Burns, *Bloomberg's Billions: How the Candidate Built an Empire of Influence*, N.Y. TIMES (Feb. 15, 2020), https://www.nytimes.com/interactive/2020/02/15/us/politics/michael-bloomberg-spending.html.

[228] Michael Scherer, *Mike Bloomberg to Spend at Least $100 Million in Florida to Benefit Joe Biden*, WASH. POST (Sept. 13, 2020), https://www.washingtonpost.com/politics/bloomberg-money-florida-biden/2020/09/12/af51bb50-f511-11ea-bc45-e5d48ab44b9f_story.html.

[229] BLOOMBERG PHILANTHROPIES, ANNUAL UPDATE (Apr. 2015), https://assets.bbhub.io/dotorg/sites/2/2015/04/2014-Annual-Update.pdf.

[230] DAVID CALLAHAN, THE GIVERS: WEALTH, POWER, AND PHILANTHROPY IN A NEW GILDED AGE 14 (2017).

his fortune to influence government policies, not just in America but around the planet."[231]

The following are primary examples of TCAG's capture of FDA's tobacco policy.

A. The Premium Cigar Diversion

As noted above, after FDA announced in 2011 that it would forego an attempt to seek Supreme Court review of *Sottera* and would, instead, issue a deeming rule, FDA stated that it was considering excluding premium cigars given the lack of data showing that youth used these products. In response, TCAG argued: "There is no justification for exempting any cigars from FDA regulation. . . . All cigars are harmful and potentially addictive to users."[232]

FDA acquiesced to TCAG's advocacy and included premium cigars in the 2016 final deeming rule. By 2017, it was clear that FDA was having second thoughts. During the announcement of the Comprehensive Nicotine and Tobacco Policy, the FDA Commissioner stated that he wanted the agency to look at "whether and how we would exempt premium cigars from regulation."[233] Despite this, FDA failed to reverse course, leaving it locked in years of ultimately pointless litigation with the premium cigar industry. That litigation resulted first in a 2020 district court ruling enjoining FDA from enforcing the premarket review provisions against premium cigars.[234] Thereafter, in 2022, the same court ruled that "FDA's decision not to exempt premium cigars altogether from regulation under the Final Deeming Rule was arbitrary and capricious."[235] Finally, on August 9, 2023, the court issued its remedies order, vacating FDA's decision to deem premium cigars.[236]

The disruption caused to FDA's tobacco policy by the premium cigar litigation went far beyond FDA's loss of its ability to regulate premium cigars under the TCA and the lost opportunity cost represented by limited regulatory resources that could have been put to productive use. The very fight over the scope of deeming, in the five years between FDA's announced intent to deem and the issuance of a final deeming rule, contributed to the substantial delay in bringing ENDS under FDA's oversight. As *Time Magazine* health correspondent and author Jamie Ducharme has written in her history of JUUL:

> This [decision to include premium cigars in deeming] proved problematic, because the cigar industry was lobbying hard for exclusions, arguing to the Obama administration that premium cigars should be exempted from the FDA's regulations. Those conversations, and the political considerations they raised, kept delaying the process.

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[231] *Id.* at 14–15.

[232] *Comment from the American Academy of Family Physicians, et al*, Docket No. FDA-2014-N-0189, REGULATIONS.GOV (Aug. 8, 2014), https://www.regulations.gov/comment/FDA-2014-N-0189-79772.

[233] *2017 Comprehensive Plan*, *supra* note 126.

[234] Memorandum Opinion and Order, Cigar Ass'n of Am. v. FDA, No. 16-01460 (D.D.C. Aug. 19, 2020), ECF No. 214.

[235] Memorandum Opinion and Order, Cigar Ass'n of Am. v. FDA, No. 16-01460 (D.D.C. July 5, 2022), ECF No. 268.

[236] Memorandum Opinion and Order, Cigar Ass'n of Am. v. FDA, No. 16-01460 (D.D.C. Aug. 9, 2023), ECF No. 276.

> The FDA could have written a deeming rule just for e-cigarettes, but its leadership chose to wait and do it all at once.[237]

B. PMTA Prioritization

As noted above, the *American Academy of Pediatrics v. FDA* remedies order advanced the PMTA deadline to September 9, 2020, and set a twelve-month limit on FDA's continuing enforcement discretion for products covered by still-pending PMTAs. Those requirements, taken together, created an expectation that the PMTA review process for essentially all ENDS products on the market would be completed by September 9, 2021.

In August 2020, a month prior to the filing deadline, FDA announced that it was unlikely to be able to meet the September 9, 2021 deadline for the completion of all PMTA reviews given the substantial volume of expected filings.[238] Because of its anticipated inability to complete all PMTA reviews within a twelve-month period, FDA announced a prioritization approach, according to which FDA would first examine the applications for the largest market share products, so as to maximize the public health impact of its decision-making: "**To ensure the greatest public health impact,** transforming the current tobacco landscape into a fully regulated marketplace is our foremost priority. This means providing adequate review resources for reviewing those products currently on the market that have the greatest chance, either positively or negatively, of impacting public health."[239] FDA reiterated its prioritization approach, to transform the marketplace as rapidly as possible to a fully regulated one, in February 2021.[240]

That prioritization plan apparently was not acceptable to TCAG, who wanted to see more rapid decision-making and, in particular, an advance commitment by FDA to deny peremptorily all applications for flavored (including menthol) ENDS. TCAG supporters in Congress summoned Acting FDA Commissioner Janet Woodcock to a hearing titled *An Epidemic Continues: Youth Vaping in America*. The hearing took place on June 23, 2021—some two and a half months before the twelve-month anniversary of the PMTA filing deadline. Its purpose, it became immediately clear, was to criticize the acting commissioner over the lack of PMTA denials and to explicitly demand that she commit in advance to deny every application for a flavored product, including for menthol ENDS. Senator Durbin was invited to open the hearing with prepared remarks, and he strongly attacked FDA for its failure to simply deny all applications for flavored ENDS.[241]

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[237] JAMIE DUCHARME, BIG VAPE: THE INCENDIARY RISE OF JUUL 59 (2021).

[238] Mitch Zeller, *Perspective: FDA's Preparations for the September 9 Submission Deadline*, U.S. FOOD & DRUG ADMIN. (Aug. 31, 2020), https://public4.pagefreezer.com/content/FDA/16-06-2022T13:39/https://www.fda.gov/tobacco-products/ctp-newsroom/perspective-fdas-preparations-september-9-submission-deadline.

[239] *Id.* at 6 (emphasis in original).

[240] Mitch Zeller, *Perspective: FDA's Progress on Review of Tobacco Product Applications Submitted by the Sept. 9, 2020 Deadline*, U.S. FOOD & DRUG ADMIN. (Feb. 16, 2021), https://www.fda.gov/tobacco-products/ctp-newsroom/perspective-fdas-progress-review-tobacco-product-applications-submitted-sept-9-2020-deadline?utm_campaign=ctp-sept9&utm_content=landingpage&utm_medium=email&utm_source=govdelivery&utm_term=stratcomms.

[241] *An Epidemic Continues: Youth Vaping in America: Hearing Before the H. Oversight & Gov. Reform Subcomm. on Econ. and Consum. Policy*, 117th Congress (2021), https://docs.house.gov/meetings/GO/GO05/20210623/112808/HHRG-117-GO05-Wstate-DurbinR-20210623.pdf (statement of

Senator Durbin's call for automatic flavor denials was repeated throughout the hearing. According to Chairman Krishnamoorthi: "FDA has the opportunity to step up and finish the fight against the youth vaping epidemic. Don't let any flavored products from any e-cigarette company stay on the market, not mango and not menthol. If you leave a single flavor on the market, kids will use it . . . ."[242] Representative Katie Porter was equally explicit: "The only way to protect our kids is to deny premarket tobacco product applications for every flavored e-cigarette other than tobacco flavor. Will you [speaking to Acting Commissioner Woodcock] commit to doing that?"[243]

Within little more than two weeks after the June 23 House Hearing, Acting Commissioner Woodcock put in motion a change to the August 2020/February 2021 prioritization scheme—pursuant to a July 9, 2021 "Fatal Flaw" memo that was intended to facilitate "final action on as many applications as possible by September 10, 2021."[244] Application of the Fatal Flaw memo approach led to the rapid denial of applications representing millions of product combinations, positioning Acting Commissioner Woodcock to be able to announce, on the one-year anniversary of the PMTA filing deadline and thus the presumptive deadline for processing all PMTAs, that:

> We've made significant progress in the months since, working diligently to better understand these products and, as of today, taking action on about 93% of the total timely-submitted applications. This includes issuing Marketing Denial Orders (MDO) for more than 946,000 flavored ENDS products because their applications lacked sufficient evidence that they have a benefit to adult smokers sufficient to overcome the public health threat posed by the well-documented, alarming levels of youth use of such products.[245]

These MDOs precipitated the filing of more than thirty petitions for review in federal circuit courts around the country.[246] In response, FDA fought some of these appeals, resolved others by putting applications back under review,[247] won multiple

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Sen. Richard J. Durbin: "It's quite simple: any product with a history of increasing youth use must be rejected by FDA—especially flavored products that we know are meant to hook kids, and, sadly, do an effective job of it. This is the Super Bowl for the FDA's tobacco effort. I worry they are not up for this primetime challenge.").

[242] *An Epidemic Continues: Youth Vaping in America: Hearing Before the H. Oversight & Gov. Reform Subcomm. on Econ. and Consum. Policy*, 117th Congress, Hearing Transcript, at 2 (2021), https://docs.house.gov/meetings/GO/GO05/20210623/112808/HHRG-117-GO05-Transcript-20210623.pdf [hereinafter 2021 House Hearing].

[243] *Id.* at 18.

[244] Wages & White Lion Invs. v. FDA, 41 F.4th 427, 427 (5th Cir. July 18, 2022) (Judge Jones dissenting), *reh'g en banc granted, vacated*, Wages & White Lion Invs. v. FDA, No. 21-60766 (5th Cir. Jan. 19, 2023).

[245] Press Release, U.S. Food & Drug Admin., FDA Makes Significant Progress in Science-Based Public Health Application Review, Taking Action on Over 90% of More Than 6.5 Million 'Deemed' New Tobacco Products Submitted (Sept. 9, 2021), https://www.fda.gov/news-events/press-announcements/fda-makes-significant-progress-science-based-public-health-application-review-taking-action-over-90.

[246] Jim McDonald, *Vape Companies vs FDA: Appeals and Legal Actions*, VAPING360 (July 7, 2023), https://vaping360.com/vape-news/111563/vape-companies-challenging-fda-marketing-denials/.

[247] *See Marketing Denied Orders*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/media/168105/download.

cases, and lost three.[248] Its most recent loss was at the hands of the Fifth Circuit acting en banc—which criticized fundamental aspects of FDA's approach to PMTA reviews.[249] With its far-reaching ruling, the Fifth Circuit decision, unless reversed by the Supreme Court, should profoundly alter the PMTA review process going forward.

The shift in PMTA prioritization set in motion by the June 2021 House Hearing—which moved FDA away from taking up first the applications pertaining to the most-sold products and precipitating the fastest possible transformation to a fully regulated marketplace—has set CTP on a consistent course of measuring PMTA progress based on an essentially meaningless statistic, i.e., the number of pending "applications" that it has resolved. When FDA announced in September 2021 that it had taken action "on about 93% of the total timely-submitted applications," it created an impression that much of the PMTA work had been completed. FDA has continued to publicly measure progress against "total timely-submitted applications," allowing the agency to announce for some time, and most recently in May 2023,[250] that it has taken action on 99% of PMTAs.

This performance metric is, regrettably, illusory. First, the practical reality is that a single PMTA filing, consisting of all of the modules contemplated by the statute (as clarified in the agency's PMTA guidance and later its PMTA rule), may contain multiple product combinations (e.g., different-sized bottles of the same e-liquid, multiple nicotine concentrations of an otherwise identical e-liquid, different flavor formulations, etc.)—with CTP treating each individual combination as a separate PMTA.[251] By focusing on the technical number of "applications"—now up to twenty-six million—the agency has created an impression of an almost unimaginable administrative task against which it is making real progress. Yet more than 21 million of the 26 million applications came from only *two* PMTA filings—one with 4.5 million combinations and one with 17 million combinations.[252] With presumably

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[248] Bidi Vapor, LLC. v. FDA, No. 21-13340 (11th Cir. Aug. 23, 2022); Fontem US v. FDA, No. 22-1076 (D.C. Cir. Aug. 29, 2023); *Wages & White Lion Invs.*, 41 F.4th.

[249] In vacating the MDOs issued to Triton and the other appellants, the Fifth Circuit held that FDA: a) improperly failed to review or consider submitted marketing plans despite having advised applicants that these were "critical"; b) imposed new testing requirements without notice; c) imposed, without notice (much less notice and comment rulemaking) "an across-the-board ban on flavored products"; d) failed to give applicants "fair notice" of the agency's expectations; and e) failed to consider applicants' good faith reliance on the agency's pre-MDO guidance on PMTA expectations. *Wages & White Lion Invs.*, 41 F.4th at 3, 13–14, 30, 42–43.

[250] *FDA Denies Marketing of 250+ Flavored and Tobacco-Flavored E-Liquids: Multidisciplinary Scientific Review Finds Products Do Not Meet the Necessary Public Health Standard*, U.S. FOOD & DRUG ADMIN. (May 18, 2023), https://www.fda.gov/tobacco-products/ctp-newsroom/fda-denies-marketing-250-flavored-and-tobacco-flavored-e-liquids.

[251] OPERATIONAL REVIEW OF CERTAIN COMPONENTS OF FDA'S TOBACCO PROGRAM, REAGAN-UDALL FOUND. 8 (Dec. 2022) (citations omitted), https://reaganudall.org/sites/default/files/2022-12/Tobacco%20report%20210pm.pdf ("FDA regulations establishing the requirements for PMTAs specify that a PMTA is required for every individual tobacco product, which CTP has interpreted to mean each individual flavor or flavor combination of a product and certain other properties that uniquely identify the products. Although the regulations permit manufacturers to bundle or group submissions, the preamble to the regulations says that when FDA receives a premarket submission that covers multiple new tobacco products, it intends to consider the information on each individual product as a separate individual PMTA.") [hereinafter REAGAN-UDALL REPORT].

[252] *FDA Issues Refuse to File (RTF) Letter to JD Nova Group LLC: As a Result of This RTF Action, the Company Must Remove Approximately 4.5 Million Products From the Market or Risk Enforcement*

little administrative effort, FDA disposed of the first with a simple "refuse to file" letter and the second a "refuse to accept" letter—given that each applicant had failed to include the required Environmental Assessment for each individual product combination. In neither instance was the agency required to perform a substantive PMTA review to determine if any individual product combination met the "appropriate for the protection of public health" standard.

A perhaps unanticipated consequence of FDA's application counting methodology was the Fifth Circuit's use of that approach, against the agency, to support its conclusion that FDA's PMTA expectations were clearly unreasonable because "one million" applicants understood them differently:

> FDA received over one million PMTAs for flavored e-cigarette products—and not a single one of them contained the scientific studies that FDA now requires and that (it says) any reasonable manufacturer would have known *ex ante* were required. It is perhaps possible that FDA did its part to give the regulated community clear guidance and that one million out of one million not only got it wrong but got it *unreasonably* wrong. But administrative law does not turn on such infinitesimal possibilities.[253]

Moreover, the sheer number of PMTA applications presented in a single, bundled filing does not correlate with what is actually going on in the marketplace. Rather than the number of PMTAs, progress should be measured—consistent with the August 2020 and February 2021 prioritization policy—based on the disposition of applications representing the most-used products, so as to most rapidly transform the marketplace to a fully regulated one. As judged against this, based on FDA's most recent status report in the *American Academy of Pediatrics v. FDA* case, filed October 23, 2023, the agency has resolved only 69% of the PMTAs filed by the large manufacturers and served notice that it was no longer committed to deciding all applications by the end of 2023.[254]

C. Flavored (Including Menthol) ENDS

As noted above, TCAG directly and through its political patrons in Congress have since 2019 maintained constant pressure on FDA to deny summarily all PMTAs for flavored ENDS, including menthol. FDA is being pressured to deny applications without regard to the quantum of supporting evidence (i.e., to not act as the "trusted arbiter"); without regard to evidence that adult ENDS users overwhelmingly prefer

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Action by FDA, U.S. FOOD & DRUG ADMIN. (Aug. 9, 2021), https://www.fda.gov/tobacco-products/ctp-newsroom/fda-issues-refuse-file-rtf-letter-jd-nova-group-llc; *FDA Makes Determinations on More Than 99% of the 26 Million Tobacco Products For Which Applications Were Submitted*, U.S. FOOD & DRUG ADMIN. (Mar. 15, 2023), https://www.fda.gov/tobacco-products/ctp-newsroom/fda-makes-determinations-more-99-26-million-tobacco-products-which-applications-were-submitted.

[253] *Wages & White Lion Invs.*, 41 F.4th at 44 (citation omitted). The court appears to have derived the "one million" number from FDA's August 26 and September 9, 2021 press releases, which referenced the denials of 55,000 and 946,000 "applications," respectively. *Id.* at 16.

[254] Status Report, Am. Acad. of Pediatrics. v. FDA, No. 18-00883 (D. Md. Oct. 23, 2023), ECF No. 216 ("In its prior status report, FDA estimated completing review of 100% of Covered Applications by December 31, 2023 . . . . That estimate may change as the agency considers the D.C. Circuit's opinion in *Fontem US, LLC v. FDA* . . . .").

non-tobacco flavors;[255] and, in the case of menthol in particular, without regard to the continued lawful availability of menthol cigarettes in forty-eight of fifty states.

To this point, CTP has surrendered to the pressure. It has consistently denied *all* applications for ENDS in non-tobacco flavors. In the case of menthol, under its prior director, CTP deferred decisions, citing "unique considerations"—i.e., the continued lawful presence of menthol cigarettes in the marketplace.[256] Subsequently, CTP has started to consistently deny applications for menthol ENDS—including high profile denials issued to Logic, Fontem, and R.J. Reynolds. In its announcement of these denials, CTP has introduced a "no-menthol" logo that creates the unmistakable expression that there is now a de facto product standard banning all menthol ENDS:

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The impression that CTP is now implementing a "no flavors" (including menthol) product standard—precisely as demanded by TCAG—was further strengthened by the revelation in Logic's PMTA appeal that CTP's Office of Science had recommended the authorization of Logic's menthol products—a decision that the incoming director reversed.[258] In its en banc ruling in *Triton*, the Fifth Circuit

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[255] A recent review, co-authored by Joanna Cohen, the Bloomberg Professor of Disease Prevention and the Director of the Institute for Global Tobacco Control at the Johns Hopkins Bloomberg School of Public Health, found the following regarding adults and flavors: "The most reported primary flavor category was fruit among all age groups in all [PATH] waves. Candy/desserts in waves two, three, four, and menthol/mint in wave five were the second most reported flavor in all age groups." Bekir Kaplan, Jeffrey J. Hardesty, Kevin Welding, Alison B. Breland, Thomas Eissenberg & Joanna E. Cohen, *Electronic Nicotine Delivery System Flavor Use Over Time by Age Group in the US: A Longitudinal Analysis*, 21 TOBACCO INDUCED DISEASES 67 (2023).

[256] Press Release, U.S. Food & Drug Admin., FDA Denies Marketing Applications for About 55,000 Flavored E- Cigarette Products for Failing to Provide Evidence They Appropriately Protect Public Health (Aug. 26, 2021), https://www.fda.gov/news-events/press-announcements/fda-denies-marketing-applications-about-55000-flavored-e-cigarette-products-failing-provide-evidence.

[257] *See, e.g.*, FDA Tobacco (@FDATobacco), TWITTER (Jan. 24, 2023, 6:31 PM), https://twitter.com/FDATobacco/status/1617923105191591936.

[258] Letter to the Court under FRAP 28(j), Logic Tech. Dev. v. FDA, No. 22-3030 (3d Cir. Dec. 12, 2022), ECF No. 34-1. In a 2–1 decision, the Third Circuit rejected Logic's arguments based on the menthol memos and affirmed the MDO: "Reasoned disagreement among civil servants is the stuff of good

specifically found that "FDA imposed an across-the-board ban on *all* flavored products, regardless of device type" and, further, that it failed to follow the TCA's "notice-and-comment obligations before imposing its de facto ban on flavored e-cigarettes."[259]

As with the change in course on PMTA prioritization, it is apparent that CTP is making flavor decisions generally and menthol ones specifically in response to outside pressures that are against its own better judgment. As regards menthol ENDS, the Logic memos reveal not just the reversal of an Office of Science recommendation to authorization—an action that deprives FDA of the ability to assert that it is merely "following the science"—but that it had previously treated menthol as a traditional cigarette flavor for which no special evidence of superior switching benefit would be needed, including in deficiency letters to applicants. CTP's prior position with respect to menthol ENDS was consistent with the Office of Science's exhaustive, 193-page review of the science around flavors, which showed substantial adult appeal for menthol.[260]

D. Marketing Restrictions

Fundamental to TCAG's demand that CTP deny all PMTAs for flavored and menthol ENDS is the view that any and all marketing restrictions are irrelevant to preventing youth access and use—in other words, that marketing restrictions are incapable of having sufficient beneficial impact on reducing risk to youth to ever tilt the public health balance in favor of authorization. Where flavored products are available, according to TCAG's logic, youth will find and use them—regardless of any marketing limitations FDA may impose. As CTFK recently put it: "FDA must deny marketing applications for ALL flavored e-cigs. As long as any are for sale, kids will migrate to them."[261]

The notion that marketing restrictions are irrelevant to reducing youth use of tobacco flies in the face of decades of tobacco control activism against cigarette advertising. And, as noted above, in enacting the TCA, Congress explicitly

government, not APA violations." Majority Opinion, Logic Tech. Dev. v. FDA, No. 22-3030 at 29 (3rd Cir. Oct. 19, 2023). The dissenting judge disagreed: "To survive the arbitrary and capricious standard of review, the FDA must first have acknowledged that it changed its menthol policy and then provided a reasoned analysis for the change that addressed Logic's reliance interests and considered available alternatives. It did not do so. Instead, [CTP Director] King overruled the OS divisions, changed the agency's menthol policy 'out of Logic's sight,' and then the agency denied Logic's menthol PMTAs because they failed to meet an undisclosed evidentiary standard. That is not 'good government.'" Dissenting Opinion, *Logic Tech. Dev.*, No. 22-3030 at 8 (3d Cir. Oct. 19, 2023). On December 3, 2023, Logic filed a petition for rehearing en banc. Logic Tech. Dev. v. FDA, No. 22-3030 (3d Cir. Dec. 3, 2023), ECF 118. In a stay ruling in a separate Fifth Circuit appeal, issued subsequent to the decision to grant en banc review in *Triton*, the court relied on the Logic menthol memos in ruling that the appellant in that case, R.J. Reynolds, was "[significantly] likely" to prevail on appeal in part because FDA appears to be enforcing a de facto product standard on flavors. Stay Order, R.J. Reynolds Vapor Co. v. FDA, No. 23-60037 (5th Cir. Mar. 23, 2023), ECF No. 121-1.

[259] *Wages & White Lion Invs.*, 41 F.4th, n.5.

[260] U.S. FOOD & DRUG ADMIN., INTERDISCIPLINARY OS STATE OF THE SCIENCE ON ELECTRONIC NICOTINE DELIVERY 120 (2020) https://static1.squarespace.com/static/5f6002fa681995196b0b45cc/t/640f47ea32ee6e4f40e6de02/16787230 ("Among adults, while some studies have found the most common or preferred ENDS flavor is fruit, often followed by candy and mint/menthol, others have found the most common or preferred ENDS flavor for adults is mint/menthol587 or tobacco.").

[261] Campaign for Tobacco-Free Kids (@TobaccoFreeKids), TWITTER (May 25, 2023, 10:11 PM), https://twitter.com/tobaccofreekids/status/1661812224170635264?s=12.

recognized the critical importance of marketing restrictions in reducing youth use of cigarettes. An FDA enforcement guidance, first issued in January 2020, also acknowledged the importance of marketing restrictions on reducing youth access, consistent with the TCA. It listed a number of "adequate measures" manufactures could take "to prevent minors' access" to ENDS products, including: 1) age-verification barriers for retail websites, 2) enforcement monitoring programs with retailers, 3) a limit on the number of ENDS that can be purchased at once or over a period of time, and 4) a mystery shopper program.[262] The guidance also listed common ways manufacturers improperly target minors, such as advertising with "social media influencers," "popular children's characters," and kid-friendly "cartoon or animated characters"[263]—implicitly guiding companies to avoid such practices in order to limit youth appeal and access.

TCAG,[264] state attorneys general,[265] private litigants,[266] and FDA[267] itself have long placed much of the blame for the 2018–2019 youth vaping epidemic on a single ENDS company, JUUL. A central justification for that blame was its marketing practices. These included its now notorious "Vaporized" ad campaign in 2015, its effective use of social media and social media influencers, its extensive use of free samples, its advertisements on youth-focused websites, and its launch parties.[268] Routinely, the company was alleged to have promoted its products in a manner that was right out of Big Tobacco's marketing "playbook."[269] Over forty states have now reached settlements with JUUL.[270] In each case, the focus of the settlements, consistent with the MSA model, has been cash payments combined with a laundry list of marketing restrictions.[271]

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[262] U.S. FOOD & DRUG ADMIN., ENFORCEMENT PRIORITIES FOR ELECTRONIC NICOTINE DELIVERY SYSTEM (ENDS) AND OTHER DEEMED PRODUCTS ON THE MARKET WITHOUT PREMARKET AUTHORIZATION—GUIDANCE FOR INDUSTRY 22 (2020), https://www.fda.gov/media/133880/download.

[263] *Id.* at 26–27.

[264] *See, e.g.*, Letter to Acting Commissioner Janet Woodcock from AAP, ACS-CAN, AHA, ALA, CTFK and the Truth Initiative Re: Premarket Tobacco Product Applications for JUUL 1 (Apr. 27, 2021), https://www.lung.org/getmedia/62d7a250-77d5-4bc1-9312-39c2b326c399/letter-on-juul-pmta-4-27-21.pdf ("JUUL's products have been largely responsible for the extraordinary growth in youth e-cigarette use and the growth in the percentage of youth who have become addicted to e-cigarettes . . . .").

[265] *See, e.g.*, *Oregon Leads $438 Million Agreement with JUUL Labs*, OR. DEP'T OF JUST. (Sept. 7, 2022), https://www.doj.state.or.us/media-home/news-media-releases/oregon-leads-438-million-agreement-with-juul-labs/; *Attorney General Bonta Announces $462 Million Multistate Settlement with E-Cigarette Maker JUUL*, CAL. ATT'Y GEN. (Apr. 11, 2023), https://oag.ca.gov/news/press-releases/attorney-general-bonta-announces-462-million-multistate-settlement-e-cigarette.

[266] Christina Jewett, *Vaping Settlement by Juul Is Said to Total $1.7 Billion: The Proposed Deal Would Resolve Thousands of Lawsuits in Multidistrict Litigation Based in Northern California*, N.Y. TIMES (Dec. 10, 2022), https://www.nytimes.com/2022/12/10/health/juul-settlement-teen-vaping.html.

[267] *See 2017 Comprehensive Plan*, *supra* note 126; *See also* Press Release, U.S. Food & Drug Admin., Statement from FDA Commissioner Scott Gottlieb, M.D., on New Enforcement Actions and a Youth Tobacco Prevention Plan to Stop Youth Use of, and Access to, JUUL and Other E-Cigarettes (Apr. 23, 2018), https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-enforcement-actions-and-youth-tobacco-prevention.

[268] *See, e.g.*, DUCHARME, *supra* note 237, at 74, 79–86; LAUREN ETTER, THE DEVIL'S PLAYBOOK: BIG TOBACCO, JUUL, AND THE ADDICTION OF A NEW GENERATION 149–52 (2021).

[269] *See, e.g.*, DUCHARME, *supra* note 237, at 2.

[270] *See supra* note 265.

[271] *Id.*

In bowing to TCAG pressure to ignore the importance of marketing restrictions in PMTA authorization decisions for flavored and menthol products, FDA has placed itself in the untenable position of arguing in PMTA appeals that marketing restrictions simply cannot work when it comes to restricting youth use of tobacco products and thus that FDA had no obligation even to review the marketing restrictions portion of PMTAs or weigh their expected effectiveness in making an APPH determination.[272] FDA's failure to review and consider marketing restrictions has been criticized by multiple circuit courts—and was a specific basis for MDO reversals in both the Fifth and Eleventh Circuits.

E. Graphic Warnings

Another area of TCAG pressure and interference with CTP decision-making has been to force FDA to devote resources to developing and then fighting for the ability to require the placement of pictorial warnings or "graphic warnings" on cigarette packages. These are intended to illustrate the "lesser-known" hazards associated with smoking.[273]

The fight for graphic warnings is an old one, beginning soon after passage of the TCA. On June 22, 2011, as required by the statute, FDA issued its first rule requiring graphic warnings on cigarette packs.[274] In response, cigarette manufacturers sued FDA.[275] In 2012, the U.S. Court of Appeals for the District of Columbia Circuit ruled that the graphic cigarette health warnings were unconstitutional because the government would be requiring private companies to advertise the government's anti-smoking message—remanding to FDA to allow it to change the graphic cigarette health warnings to conform to constitutional standards.[276]

When FDA failed to commit itself to resuming its efforts to impose graphic warnings, TCAG sued the agency in federal court in Massachusetts.[277] The aim of the lawsuit was to obtain a court order requiring FDA to proceed with a new graphic warning rulemaking. On September 5, 2018, the court ruled in favor of the TCAG plaintiffs, finding that FDA had "unlawfully withheld" and "unreasonably delayed" issuance of a graphic warnings rule.[278] The court ordered FDA to issue a graphic health warning proposed rule by August 15, 2019, and a final rule by March 15, 2020. In response, FDA published a final rule on March 18, 2020.[279] As it had done

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[272] *See*, *e.g.*, Stay Order, R.J. Reynolds Vapor Co. v. FDA, No. 23-60037, at 8–9 (5th Cir. Mar. 23, 2023), ECF No. 121-1.

[273] *Cigarette Labeling and Health Warning Requirements*, U.S. FOOD & DRUG ADMIN. (last updated Aug. 25, 2021), https://www.fda.gov/tobacco-products/labeling-and-warning-statements-tobacco-products/cigarette-labeling-and-health-warning-requirements.

[274] Required Warnings for Cigarette Packages and Advertisements, 21 C.F.R. pt. 1141 (2011).

[275] Complaint, R.J. Reynolds Tobacco Co. v. FDA, No. 11-01482 (D. D.C. 2011), ECF No. 1.

[276] R.J. Reynolds Tobacco Co. v. FDA, 696 F.3d 1205 (D.C. Cir. 2012), *overruled by* Am. Meat Inst. v. U.S. Dep't of Agric. (D.C. Cir. July 29, 2014).

[277] *See generally* Am. Acad. of Pediatrics v. FDA, 330 F. Supp. 3d 657 (D. Mass. 2016).

[278] *Id.*

[279] Tobacco Products; Required Warnings for Cigarette Packages and Advertisements, 21 C.F.R. pt. 1141 (2020).

the first time, the industry promptly filed suit on constitutional grounds. In December 2022, a district judge in Texas struck down the new graphic warnings rule.[280]

F. Menthol in Cigarettes

A priority initiative for TCAG following enactment of the TCA has been the issuance by FDA of a product standard that would ban menthol as a characterizing flavor in cigarettes. The main arguments in favor of a menthol ban have been: a) menthol cigarettes increase youth initiation of smoking and progression to regular use; b) menthol cigarettes are harder to quit; and c) menthol smoking is disproportionately higher among African Americans, a population that has been the subject of targeted advertising by industry going back decades, with the result that they suffer a disproportionate toll of the death and disease caused by menthol cigarettes.[281]

The TCA itself preserved the legality of menthol flavor in cigarettes, while also providing a mechanism for FDA to study the issue and, if appropriate, develop a product standard that would ban its use. For these purposes, the statute required FDA to refer the issue to the newly created Tobacco Products Scientific Advisory Committee (TPSAC) "for report and recommendation."[282] FDA duly made the referral required by the statute. In early 2011, several members of the cigarette industry sued to block the effort, alleging conflicts of interest on the part of certain TPSAC members.[283] While the litigation was pending, TPSAC completed its work and, in 2011, recommended that FDA promulgate a product standard banning menthol, citing "a concerning rise of menthol cigarette smoking among youth" and concluding that "the availability of menthol cigarettes has an adverse impact on public health by increasing the number of smokers with resulting premature death and avoidable mortality."[284]

In April of 2013, TCAG and other groups filed a citizen petition requesting that FDA issue a menthol product standard as recommended by TPSAC (2013 Citizen Petition).[285] Central to the 2013 Citizen Petition was concern about impacts on youth:

> Given the Tobacco Control Act's express purpose of reducing youth tobacco use and the substantial body of evidence indicating that menthol

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[280] Opinion and Order, R.J. Reynolds Tobacco Co. v. FDA, No. 20-00176 (E.D. Tex. Dec. 7, 2022), ECF No. 106.

[281] *See, e.g.*, U.S. FOOD & DRUG ADMIN., PRELIMINARY SCIENTIFIC EVALUATION OF THE POSSIBLE PUBLIC HEALTH EFFECTS OF MENTHOL VERSUS NONMENTHOL CIGARETTES (2011), https://www.fda.gov/media/86497/download.

[282] Family Smoking Prevention and Tobacco Control Act, § 907(e)(1), 21 U.S.C. § 387g(e)(1).

[283] In July 2014, a U.S. District Court judge ruled in favor of the plaintiffs in the menthol/TPSAC litigation, requiring FDA to reconstitute TPSAC's membership and barring the agency from using the report issued by the original committee. R.J. Reynolds Tobacco Co. v. FDA, No. 11-00440 (D. D.C. 2014), ECF No. 82. On appeal, the D.C. Circuit reversed, holding that the plaintiffs lacked standing to challenge TPSAC's composition. R.J. Reynolds Tobacco Co. v. FDA, No. 14-5226 (D.C. Cir. 2016), ECF No. 1593800.

[284] TOBACCO PRODS. SCI. ADVISORY COMM., CTR. FOR TOBACCO PRODS., U.S. FOOD & DRUG ADMIN., TPSAC MENTHOL REPORT (2011), https://www.lung.org/getmedia/a889275a-0aba-4cd6-bf0b-2deb2e979883/tpsac-report.pdf.

[285] *Tobacco Control Legal Consortium et al - Citizen Petition*, FDA-2013-P-0435-0001, REGULATIONS.GOV (May 14, 2013), https://www.regulations.gov/document?D=FDA-2013-P-0435-0001.

> facilitates experimentation and progression to regular smoking, the FDA must take action to regulate menthol in tobacco products. Failing to include menthol in the prohibition against characterizing flavors ignores the fact that menthol has the same gateway properties as other flavorings . . . .[286]

In the ensuing years, TCAG continued to pressure FDA to enact a menthol product standard as requested in the 2013 Citizen Petition. In 2020, two TCAG "partner" groups—the African American Tobacco Control Leadership Council and Action on Smoking and Health (US)—filed suit in the U.S. District Court for the Northern District of California, seeking an injunction requiring FDA to respond to the 2013 Citizen Petition and "to begin the rulemaking process for adding menthol to the list of characterizing flavors banned by the Tobacco Control Act within 60 days of" the court's order.[287] CTFK issued a press release several days later announcing that it "strongly supports the lawsuit."[288]

In 2021, the court agreed to place in abeyance an FDA motion to dismiss the lawsuit, to give FDA an opportunity to issue a notice of proposed rulemaking on menthol within one year.[289] FDA proceeded to issue a proposed menthol product standard within that timetable (Proposed Menthol Rule).[290] In it, FDA included the following findings relating to youth initiation and progression to regular smoking: "By prohibiting menthol as a characterizing flavor in cigarettes, FDA expects a significant reduction in the likelihood of youth and young adult initiation and progression to regular cigarette smoking, which is expected to prevent future cigarette-related disease and death."[291] Following issuance of the Proposed Menthol Rule, the agency successfully requested that the lawsuit be dismissed, since FDA had already given Plaintiffs the relief they had requested.[292]

Assuming the Proposed Menthol Rule proceeds to the issuance of a final rule, it is reasonable to assume that it will be challenged in court by one or more of the manufacturers of menthol cigarettes. In defending against such a challenge, FDA will need to show that its adoption of a menthol product standard is "appropriate for the protection of public health," based on "scientific evidence" regarding: a) "risks and benefits to the population as a whole, including users and nonusers of tobacco products, of the proposed standard"; b) "increased or decreased likelihood that existing users of tobacco products will stop using such products"; and c) "increased

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[286] *Id.* at 4 (internal citations omitted).

[287] Complaint, Afr. Am. Tobacco Control Leadership Consortium v. Dep't of Health & Hum. Servs., No. 20-04012 (N.D. Cal. June 17, 2020), ECF No. 1 at 44.

[288] *To Protect the Health of African Americans, FDA Must Act Now to Prohibit Menthol Cigarettes*, CAMPAIGN FOR TOBACCO-FREE KIDS (June 18, 2020), https://www.tobaccofreekids.org/press-releases/2020_06_18_menthol.

[289] Afr. Am. Tobacco Control Leadership Consortium v. Dep't of Health & Hum. Servs., No. 20-04012 (Nov. 17, 2021), ECF No. 73.

[290] Tobacco Product Standard for Menthol in Cigarettes, 21 C.F.R. pt. 1162 (2022), https://public-inspection.federalregister.gov/2022-08994.pdf.

[291] *Id.* (see Executive Summary, Purpose of the Proposed Rule).

[292] Third Joint Case Management Statement, Afr. Am. Tobacco Control Leadership Consortium v. Dep't of Health & Hum. Servs., No. 20-04012 (N.D. Cal. May 2, 2022), ECF No. 77.

or decreased likelihood that those who do not use tobacco products will start using such products."[293]

Fundamental to the first two prongs will be the impact on current menthol cigarette smokers, post institution of a ban. In this regard, the Proposed Menthol Rule shows that FDA's impact assessment relies primarily on a population model that identifies the following anticipated responses by current menthol cigarette smokers to a menthol cigarette ban: a) some will switch to non-menthol combustibles, b) some will switch to illicit menthol combustibles, c) some will switch to ENDS/Nicotine Vaping Products, and d) some will quit all tobacco product use.[294] More specifically, the primary study upon which FDA relies assumes that 17.3–24.2% of current menthol smokers will switch to an ENDS product. The study authors also considered the impact of a menthol ban that extended to ENDS products. They opined "that menthol smokers were less likely to switch out of menthol cigarette use (i.e., into NVPs [ENDS] or no regular use) in that scenario compared with a ban limited to cigarettes and cigars. This outcome is consistent with expectations that menthol smokers would be especially likely to switch to menthol NVPs [ENDS]."[295] Thus, in the view of the experts whose analysis critically underpins the population level benefit analysis in the Proposed Menthol Rule, the population level impact of a cigarette menthol ban in terms of prevention of premature deaths and life-years lost is expected to be greatest in a scenario in which a larger percentage of menthol smokers are able to switch to a menthol-flavored ENDS product, rather than continuing to smoke a combustible cigarette of any kind. Several of the authors of the population model submitted a docket comment to FDA on the Proposed Menthol Rule, emphasizing the importance to the model of the availability of menthol ENDS.[296]

The model's assessment of the importance of menthol ENDS in maximizing public health impact was recently validated in a study funded by FDA and NIH.[297] In that study, researchers conducted a qualitative study of possible behavior changes among menthol smokers in response to a menthol cigarette ban, using a simulated online store called an Experimental Tobacco Marketplace.[298] The researchers found that: "menthol-flavored e-cigarettes were the most commonly purchased product, with over two-thirds of participants buying them, followed by non-menthol cigarettes

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[293] Family Smoking Prevention and Tobacco Control Act, § 907(a)(3), 21 U.S.C. §387g(a)(3).

[294] David T. Levy, Rafael Meza, Zhe Yuan, Yameng Li, Christopher Cadham, Luz Maria Sanchez-Romero, Nargiz Travis, Marie Knoll, Alex C. Liber, Ritesh Mistry, Jana L. Hirschtick, Nancy L. Fleischer, Sarah Skolnick, Andrew F. Brouwer, Cliff Douglas, Jihyoun Jeon, Steven Cook & Kenneth E. Warner, *Public Health Impact of a US Ban on Menthol in Cigarettes and Cigars: A Simulation Study*, TOBACCO CONTROL (Sept. 2, 2021), doi:10.1136/tobaccocontrol-2021-056604. This study is the source of FDA's estimate of premature deaths prevented (650,000) and life years saved (11.3 million) that are at the heart of the public health justification for a menthol ban. *See supra* note 290, at 91.

[295] Levy et al., *supra* note 294, at 6.

[296] *Comment from Douglas, Clifford*, Docket No. FDA-2021-N-1349, REGULATIONS.GOV (Aug. 2, 2022), https://www.regulations.gov/comment/FDA-2021-N-1349-175692.

[297] Rachel L. Denlinger-Apte, Ashley E. Strahley, Darcy E. Lockhart, Kimberly D. Wiseman, Rachel N. Cassidy, Danielle R. Davis, Richard J. O'Connor & Jennifer W. Tidey, *Reactions to Using Other Nicotine and Tobacco Products Instead of Menthol Cigarettes: A Qualitative Study of People who Smoke Menthol Cigarettes in the United States*, 34 PREVENTIVE MED. REPS. 102228 (2023).

[298] *Id.*

as the second most purchased alternative product."[299] The authors concluded: "for people who are unwilling or unable to stop using nicotine, the availability of menthol-flavored e-cigarettes, which many participants in the current study said functioned as substitutes for menthol cigarette, may help to minimize switching to non-menthol cigarettes."[300]

If there are no authorized menthol ENDS on the market, the percentage of switching to ENDS will presumably be lower and a significant portion of the switching to ENDS that does occur will be to unauthorized and potentially illicit products—a clearly non-optimal public health outcome that fundamentally undermines the public health analysis contained in the Proposed Rule. This outcome has the significant potential to be a fatal flaw in the context of an industry challenge to the Proposed Menthol Rule—with the result that a menthol cigarette ban will ultimately *not* become enforceable law without authorized menthol ENDS.

Placing unnecessary impediments in the way of switching by menthol smokers would be particularly detrimental to the anticipated public health benefits of the proposed standard given the finding in Section IV(D) of the Proposed Menthol Rule that "menthol smokers have more difficulty quitting compared to non-menthol smokers." FDA Commissioner Dr. Califf recently reinforced this point during testimony before the House Appropriations Committee:

> [W]hen it comes to menthol, something I'm very concerned about going into next year is that when these rules are finalized and people that have been dependent are addicted, it's a fierce addiction to nicotine, who are dependent on menthol tobacco. If you just ask a question, where do they go to get help, coming off of a terrible addiction? Our health care systems are not set up to deal with that right now.[301]

The final prong of the public health standard, as noted above, will be the "increased or decreased likelihood that those who do not use tobacco products will start using such products"[302]—i.e., youth. Here, FDA has simply adopted the 2011–2013 arguments regarding menthol's role in inducing youth initiation and progression to regular smoking. However, though the arguments in favor of a menthol product standard have not evolved over the last decade—the population level data has not stood still. According to a new study, rates of past-thirty-day

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[299] *Id.*

[300] *Id.*

[301] *Budget Hearing—Fiscal Year 2024 Request for the Food and Drug Administration: Hearing Before the H. Appropriations Comm.*, 118th Cong. at 48:40–49:10 (Mar. 29, 2023), https://www.congress.gov/event/118th-congress/house-event/115588 (statement of Robert Califf, Commissioner of Food and Drugs); *See also Cancer Moonshot Smoking Cessation Forum*, THE WHITE HOUSE (June 1, 2023), https://www.whitehouse.gov/cancermoonshot/events-and-webinars/past-events (Califf remarks at 40:35–41:43: "Let's imagine when these rules [menthol and reduced nicotine product standards] go through, now you've got millions of people, they all know it's not cool to smoke. . . . [I]f you look at this population, it's very disproportionately disadvantaged in many ways that make it really tough. It's not that they don't want to quit, it's just really hard to do. Now we're going to take away the menthol . . . and we ask the question, what is the care package for these people as they try to quit? It's so important because your risk of dying, even if you are 50 or 60 years old and you quit, goes down dramatically . . . . I'm really here with a plea . . . we need a clinical care system that delivers the goods for people who need to quit, know they need to, and are having a hard time.").

[302] Family Smoking Prevention and Tobacco Control Act, § 910(c)(4)(B), 21 U.S.C. § 387j(c)(4)(B).

menthol smoking by youth dramatically declined between 2012 and 2020. That study, titled "Recent, National Trends in U.S. Adolescent Use of Menthol and Nonmenthol Cigarettes," was led by Richard A. Miech, the principal investigator on the NIDA-funded *Monitoring the Future* study.[303] Miech et al. found, based on an analysis of MTF data from 2012–2020, that past-thirty-day menthol smoking among "non-Hispanic black" youth was 0.95% and among "non-black" youth was 1.98%. According to the authors: "[F]or all time periods [2012–2014, 2015–2017, and 2018–2020] prevalence of menthol use was significantly lower for non-Hispanic black as compared with all other adolescents."[304] This means that on the third prong of the public health standard as well, FDA is going to be on the defensive in trying to persuade a court that implementation of a menthol cigarette ban is appropriate for the protection of public health.

G. "No Tobacco Product is Safe"

Consistent with TCAG anti-ENDS messaging subsequent to the launch of the 2019 Bloomberg Flavor Initiative, FDA continues to refrain from any public-facing messaging regarding the potential benefit of FDA-authorized ENDS products. FDA is not currently educating either adults who smoke or their health care providers about the continuum of risk and the positive role that an authorized "tobacco product" can play for the smoker who is unable or unwilling to quit all use of nicotine. Indeed, in its announcements of Marketing Granted Orders, FDA routinely includes the categoric statement that "no tobacco product is safe"—a message that fails to contextualize the risk of using an authorized ENDS product as compared to continuing to smoke combustion cigarettes. Though the announcements go on to state that FDA review has determined that the product poses less risk to the individual who switches completely or at least displaces most of his or her cigarette use—the mixture of messaging can only add to the rampant confusion that already predominates when it comes to a comparison of ENDS with cigarettes. It would be tantamount to FDA saying that "no COVID-19 vaccine is safe"—given that all vaccines present some potential side effects, some serious, to a small minority of recipients—instead of contextualizing the safety message to recognize the existence of side effects while properly educating the public and the health care community that, on balance, given the much greater risk to an unvaccinated individual who contracts COVID-19, getting vaccinated is the sensible and proper health choice for anyone without a recognized contraindication.

If there was any doubt about the impact of the "no tobacco product is safe" messaging, one need only look at this explanation promoted by Quit With Us, Louisiana, a "partner organization" to the members of TCAG,[305] citing FDA's own official announcement:

> The FDA authorized—not approved—the marketing of Vuse Solo and their tobacco-flavored e-liquid pods, meaning these particular products can be sold in the United States. The FDA said this is because these

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[303] Richard A. Miech, Adam M. Leventhal & Lloyd D. Johnson, *Recent, National Trends in US Adolescent Use of Menthol and Non-Menthol Cigarettes*, 32 TOBACCO CONTROL e10 (2023).

[304] *Id.*

[305] *Partner Organizations*, QUIT WITH US LA, , https://quitwithusla.org/partner-organizations/ (last visited Feb. 27, 2024).

> specific products might help adults quit smoking, but they are still unsafe—especially for all youth and people who do not use tobacco products.[306]

And federal circuit court judges hearing PMTA appeals have also not been immune to the negative effects of the "no tobacco product is safe" message, as evidenced by these extraordinary words to which five dissenting Fifth Circuit judges in *Triton* put their names: "[E]-cigarettes are *not* safe. Just as being shot in the stomach might be less likely to cause death than being shot in the head, but neither one is wanted, neither e-cigarettes nor cigarettes are safe."[307]

It is understandable that FDA does not want to engage in across-the-board messaging about *all* ENDS without regard to their review status—the U.S. system is founded on product-specific reviews—but the continued silence if not outright disparagement regarding *authorized* ENDS runs counter to the purpose of the statute, the 2017 Comprehensive Plan, and the harm reduction consensus which, as discussed above, always assumed accurate messaging to smokers about relative risk so as to inform sensible decision-making with respect to product use.

VI. THE REAGAN-UDALL OPERATIONAL REVIEW

September 9, 2021 came and passed without a single decision on a nationally distributed ENDS product—until a decision the following month on a tobacco-flavored version of a largely discontinued Reynolds product called the Vuse Solo.[308] The flurry of flavored e-liquid denials issued by FDA pursuant to the fatal flaw memorandum by September 9, 2021, at the request of the Acting FDA Commissioner following the June 2021 House hearing, triggered over thirty appeals in federal circuit courts around the country[309]—without in any apparent way contributing to the "transformation" of the actual e-cigarette marketplace to a fully regulated one. To the contrary, in the period after September 9, 2021, the marketplace became less rather than more regulated, with unauthorized flavored disposable ENDS products, left untouched by the January 2020 enforcement guidance, increasingly prevalent and becoming the dominant youth-used ENDS product. As well, flavored disposable and other manufacturers—including some of those affected by the flurry of FDA e-liquid denials—began turning to synthetic nicotine in order to avoid all FDA oversight, since jurisdiction over ENDS pursuant to the TCA required the presence of tobacco-derived nicotine.[310] As noted above, as

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[306] Quit With Us, La (@QuitWithUsLA), TWITTER (June 7, 2023, 7:14 PM) (linking to *Vapes*, UNFILTERED FACTS, https://unfilteredfacts.com/get-the-facts/vapes/ (last visited June 22, 2023)).

[307] Wages & White Lion Invs. v. FDA, No. 21-60766 (5th Cir. Jan. 3, 2024), ECF No. 353-1, at 54.

[308] *Key Concerns About FDA's First E-Cigarette Authorization for Vuse Solo*, TRUTH INITIATIVE (Oct. 18, 2021), https://truthinitiative.org/research-resources/emerging-tobacco-products/key-concerns-about-fdas-first-e-cigarette ("[I]t's important to note that Vuse Solo has no significant market share, according to Nielsen sales data as of June 2021.").

[309] 2021 House Hearing, *supra* note 242.

[310] Christina Jewett, *The Loophole That's Fueling a Return to Teenage Vaping: Sales are Rising of Flavored E-Cigarettes Using Synthetic Nicotine that Evades Regulatory Oversight, a Gap That Lawmakers are Now Trying to Close*, N.Y. TIMES (Mar. 8, 2022), https://www.nytimes.com/2022/03/08/health/vaping-fda-nicotine.html. Congress subsequently amended the TCA to incorporate synthetic nicotine products into the definition of "tobacco product." Family Smoking Prevention and Tobacco Control Act (TCA), § 101(a), 21 U.S.C. § 321 (rr)(1).

the months went by, past September 9, 2021, TCAG and their supporters in Congress excoriated FDA over the agency's failure to clear the market of all flavored ENDS products, including menthol.[311]

Recognizing the magnitude of the problem, in July 2022, FDA Commissioner Dr. Robert Califf asked the Reagan-Udall Foundation to conduct a comprehensive evaluation of the agency's tobacco program.[312] In making the request, Dr. Califf noted that "even greater challenges lie ahead as we determine how the agency will navigate complex policy issues and determine enforcement activities for an increasing number of novel products that could potentially have significant consequences for public health."[313] Reagan-Udall conducted its tobacco review over a 60-business day period—during which it interviewed CTP personnel and engaged stakeholders through public hearings and review of written comments—issuing a report in December of 2022.[314]

In providing its Report, Reagan-Udall noted the "enormous challenges" confronting CTP, which finds itself in a "pivotal place in its evolution."[315] In introducing its recommendations, Reagan-Udall noted that CTP's struggles were "in part due to some of its own policy choices."[316] The report observed that "CTP has been forced to operate primarily in a reactive mode, moving from one challenge to the next, mainly provoked by . . . outside forces"; namely, "public health advocates and the regulated industry."[317] A central focus of the panel's recommendations was for CTP to "transition to becoming a more proactive and strategic program."[318] To this end, Reagan-Udall recommended: "CTP must invest the time, now, with staff and public input, to create and implement a Strategic Plan that identifies the Center's strategic objectives and plots an operational roadmap of the steps CTP will take over the next five years to achieve those objectives."[319] Underscoring its importance, the development of a five-year Strategic Plan was the first of the panel's fifteen specific recommendations.

Following an initial review of the Report, CTP Director Dr. Brian King issued a statement that committed CTP to "initiat[ing] the development of a comprehensive 5-year strategic plan, building upon the foundation of the center's previous strategic plans."[320] In terms of timing, Dr. King stated: "[W]e intend to issue interim strategic goals by summer 2023. We anticipate soliciting stakeholder input on the plan by summer and intend to release the strategic plan to the public no later than December

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311 *See supra* notes 222–24 and accompanying text.

312 *FDA Conducting Evaluation of Key Agency Activities to Strengthen Operations*, U.S. FOOD & DRUG ADMIN. (July 19, 2022), https://www.fda.gov/news-events/press-announcements/fda-conducting-evaluation-key-agency-activities-strengthen-operations.

313 *Id.*

314 REAGAN-UDALL REPORT, *supra* note 251.

315 *Id.* at 1.

316 *Id.* at 3.

317 *Id.* at 3–4.

318 *Id.* at 4.

319 *Id.* at 13.

320 *An All-Center Approach: CTP's Response to the Reagan-Udall Foundation Evaluation Report*, U.S. FOOD & DRUG ADMIN. (Feb. 24, 2023), https://www.fda.gov/tobacco-products/ctp-newsroom/all-center-approach-ctps-response-reagan-udall-foundation-evaluation-report.

2023."[321] Consistent with this timetable, on December 18, 2023, CTP released that document.[322] Though it is labeled "Strategic Plan," it lacks any of the critical elements outlined by Reagan-Udall as part of this recommendation—including "strategic objectives," "an operational roadmap," "key metrics," or "performance indicators."[323] Indeed, other than a commitment to bring matters to TPSAC at least once per year, responsive to a separate Reagan-Udall recommendation, it lacks time deadlines of any kind. Rather, it consists of five "strategic goals" and four "cross-cutting themes"—none of which appear to be anything more than a continuing commitment to engaging in pre-existing, sound regulatory practices.[324] What FDA released in December 2023, ostensibly as its five-year plan, regrettably serves as further evidence of regulatory capture by "outside forces" (i.e., TCAG) rather than as a means for escaping it.

Given these shortcomings, the release of the December 2023 document should be regarded as a step in the Strategic Plan process rather than its conclusion. Reagan-Udall recommended that the Strategic Plan be "considered a living document reflecting Agency priorities for tobacco regulation, providing a roadmap that is revised and matures with the program."[325] In that spirit, and particularly in the wake of the subsequent rebuke of CTP contained in the Fifth Circuit's en banc *Triton* decision, a revision of the Strategic Plan is essential.

VII. REVERSING CAPTURE—CRAFTING THE NEW STRATEGIC PLAN

FDA's first step in reversing the capture of its tobacco policy must come in the new Strategic Plan, as revised consistent with the original Reagan-Udall recommendation following the Fifth Circuit's en banc ruling. This will be the roadmap for all FDA tobacco decision-making over the ensuing five years—and is the opportunity for FDA to chart a new, independent, science-driven course. An insufficient Strategic Plan, like the December 2023 document, virtually guarantees the continuation of a chaotic situation that satisfies no one other than the black marketeers, that leaves both opponents and supporters of harm reduction frustrated, and that keeps FDA mired in unnecessary litigation. A thoughtful Strategic Plan, founded on the historic harm reduction consensus and faithful to the dictates of the TCA, has the ability to put FDA on a sensible path forward with the potential for driving historic declines in smoking-related death and disease.

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[321] *Id.*

[322] *CTP Strategic Plan*, U.S. FOOD & DRUG ADMIN. (Dec. 18, 2023), https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp/ctp-strategic-plan.

[323] REAGAN-UDALL REPORT, *supra* note 251, at 14.

[324] The five goals are: "Develop, Advance, and Communicate Comprehensive and Impactful Tobacco Regulations and Guidance," "Ensure Timely, Clear, and Consistent Product Application Reviews," "Strengthen Compliance of Regulated Industry Utilizing All Available Tools, Including Robust Enforcement Actions," "Enhance Knowledge and Understanding of the Risks Associated with Tobacco Product Use," and "Advance Operational Excellence." *CTP Strategic Plan*, *supra* note 322.

[325] REAGAN-UDALL REPORT, *supra* note 251, at 14.

A. Process

The reversing of capture must begin with the very process by which the Strategic Plan is developed and, as a "living document," is revised from time to time. Reagan-Udall recommended that the plan be developed with input from all stakeholders—and FDA should of course follow that recommendation assiduously. In accepting outside input, FDA should not let the plan development and revision process be dominated by TCAG or, for that matter, industry. Input should be transparent and through the usual methods by which stakeholders engage with federal agencies—public hearings, docket comments, and the like.[326] Privileged, behind-closed-doors access should not be a feature of the process for developing or revising a Strategic Plan. Judging by the fact that TCAG held meetings with FDA literally the day the Reagan-Udall Report was delivered,[327] with the contents of the meetings unpublished—TCAG apparently has a different perspective. FDA cannot allow the Strategic Plan development/revision process to itself be captured by TCAG, as seemingly already occurred with the December 2023 document—and for these groups to effectively dictate how the agency should be devoting its resources moving forward.

B. FDA as Trusted Arbiter

The Strategic Plan development and revision process should begin, as a starting point, with a thorough review of the U.S. harm reduction consensus as reflected in the 1994, 2001, and 2007 IOM Reports and in the 2005–2009 Strategic Dialogue. These documents emphatically endorsed the need for FDA-regulated harm reduction as an important additional tool in the fight against smoking-related death and disease—and the benefit reduced harm products can uniquely provide in moving people who cannot or will not quit all use of nicotine down the "continuum of risk."[328]

Perhaps most importantly, the Strategic Plan should reflect FDA's commitment to truly wear the mantle of "trusted arbiter" when it comes to product authorizations. It should be prepared to make hard decisions and to communicate those forthrightly—without bending to pressure from outside advocacy groups that defy the historic consensus when they attempt to demand specific decision outcomes. When it comes to flavors, a categoric ban was never part of the harm reduction consensus. Rather, it was always anticipated that FDA would consider all product attributes in making a science-based decision based on the public health standard. FDA needs to restore

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[326] FDA sought stakeholder input prior to the release of the December 2023 Strategic Plan through a public Listening Session on August 22, 2023, and by opening a docket for the receipt of written comments. *See* Public Meeting and Listening Session for Developing the Food and Drug Administration's Center for Tobacco Products' Strategic Plan; Request for Comments, 88 Fed. Reg. 47509 (July 24, 2023). For the reasons discussed above (see *supra* notes 321–23 and accompanying text), it does not appear that the December 2023 document reflects the incorporation of any such input, other than that coming from TCAG.

[327] *Public Calendar: December 18–December 24, 2022*, U.S. FOOD & DRUG ADMIN. (last updated Jan. 3, 2023), https://www.fda.gov/news-events/public-calendar-meetings-fda-officials/public-calendar-december-18-december-24-2022 (showing meetings under the subject heading "Discussion of the Independent Panel of Experts Report on FDA's Tobacco Program" between FDA personnel and leaders of the Campaign for Tobacco-Free Kids, the American Lung Association, the American Heart Association, and the American Thoracic Society).

[328] *See supra* notes 48, 52, 62, 73 and accompanying text.

confidence that it actually is committed to following the science and that it is not using PMTA denials to implement the de facto flavor ban that TCAG has demanded and that the Fifth Circuit has held the agency has indeed imposed—contrary to the TCA's notice and comment requirements for product standards.

C. Attending to Both Prongs of the Public Health Authorization Standard

The Strategic Plan should further reflect FDA's strong commitment, in performing its role as "trusted arbiter," to give full weight to both prongs of the public health standard—to impacts on *both* youth and on adults. Under TCAG pressure, FDA has only been weighing the interests of youth. Looking only at youth prevention is contrary to the harm reduction consensus and violates the statute.[329] It is a return to the "quit or die" approach of the 1996 FDA Rule—which did not reflect the harm reduction consensus and which never achieved the force of law. The Strategic Plan should reflect a sincere commitment on FDA's part also to weigh seriously the interests of the 30 million adults who continue to smoke—and truly to engage with the scope of the toll (480,000 premature deaths each year caused by smoking-related disease[330]) that smoking continues to take. C. Everett Koop, the legendary Surgeon General who made the campaign against smoking a central feature of his tenure as "America's Family Doctor,"[331] admonished in a 1998 article titled "Don't Forget the Smokers": "We must not focus our efforts so narrowly on preventing tobacco use by youth that we send smokers the message that we have abandoned them—that their addiction is their own fault and that we don't care about them."[332] His message is as important and timely today as it was a quarter of a century ago—and it is imperative that FDA in particular heed it.

As it attends to the youth portion of the public health standard, FDA needs to forthrightly engage with the science and not allow itself to be pressured by TCAG into accepting the simplistic notion that "flavors hook kids."[333] It needs to consider seriously, for example, what the NYTS itself says about why kids vape—that conventional drivers of youth behavior like peer pressure are the primary causes, not the mere existence of flavors.[334] That the youth who use vapor products—like adult

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[329] *See* Family Smoking Prevention and Tobacco Control Act, § 910(c)(4)(A)–(B), 21 U.S.C. § 387j(c)(4)(A)–(B) ("[T[he finding as to whether the marketing of a tobacco product for which an application has been submitted is appropriate for the protection of the public health shall be determined with respect to the risks and benefits to the population as a whole.").

[330] *See supra* note 3.

[331] *See* C. EVERETT KOOP, KOOP: THE MEMOIRS OF AMERICA'S FAMILY DOCTOR (1991).

[332] C. Everett Koop, *Don't Forget the Smokers*, WASH. POST (Mar. 8, 1998), https://www.washingtonpost.com/archive/opinions/1998/03/08/dont-forget-the-smokers/3560fbed-880a-45ff-8669-110fd8b63509/.

[333] *See, e.g., U.S. State and Local Issues: Ending the Sale of Flavored Tobacco Products*, CAMPAIGN FOR TOBACCO FREE KIDS (last updated Dec. 12, 2022) (listing state and local "flavors hook kids" campaigns), https://www.tobaccofreekids.org/what-we-do/us/flavored-tobacco-products; *American Lung Association 'State of Tobacco Control' Report: Hawaii Has Opportunity to Prioritize Public Health over the Tobacco Industry in 2020*, AM. LUNG ASS'N (Jan. 29, 2020), https://www.lung.org/media/press-releases/american-lung-association-81 ("The Lung Association strongly supports the 'Flavors Hook Kids' campaign . . . .").

[334] According to the 2021 National Youth Tobacco Survey, among students who ever used e-cigarettes, the most common reasons for first use were "a friend used them" (57.8%), "I was curious about them" (47.6%), "I was feeling anxious, stressed, or depressed" (25.1%), and "to get a high or buzz from

vapers—overwhelmingly use flavored variants does not mean that flavors are *causing* youth initiation. It is a classic conflation of correlation and causation and, moving forward, FDA needs to be guided, on this as on all issues, by science rather than slogans.

D. The Importance of Marketing Restrictions

In protecting youth while also attending to the needs of adults, the Strategic Plan should reflect that FDA intends to take seriously the beneficial impact of marketing restrictions on restricting youth usage. The institution of marketing restrictions to successfully reduce youth smoking while continuing to permit adult access was a central feature of decades of successful tobacco control advocacy. FDA's current litigation contention in PMTA appeals—that marketing restrictions cannot possibly make a difference—disregards this larger history and has contributed to two MDO reversals (the Fifth and Eleventh Circuit decisions in *Triton* and *Bidi Vapor*, respectively). A refusal to weigh marketing restrictions also contradicts the statute itself—which makes clear that marketing restrictions emphatically do matter. The Strategic Plan should reflect a serious commitment to utilize marketing restrictions in PMTA authorizations as a fundamental tool to protect youth while serving the urgent needs of at-risk adults.

E. The Impact of Menthol Cigarette Availability

When it comes to adults, the Strategic Plan should reflect a commitment to engage pragmatically with the reality that menthol cigarettes are lawfully on the market in nearly all states. These products have defied every effort to ban them at the federal level dating back to the TCA itself. No serious observer can credibly argue that a legally enforceable menthol ban at the federal level is in prospect any time soon. A policy that favors combustion cigarettes over PMTA-authorized alternatives on the critical dimension of flavor violates the consensus and impairs a proper functioning of the continuum of risk. For the continuum to be appropriately leveraged by smokers, the less risky products should not be artificially forced to be less satisfying, from a flavor perspective, than lethal cigarettes. And, to the extent that FDA remains committed to pursuing a menthol cigarette ban regardless of the challenges—it should enhance its chances of success by providing current menthol smokers with authorized menthol ENDS to which they may switch—a development that could significantly improve the agency's prospects for sustaining a menthol ban against an industry-led legal challenge.

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nicotine" (23.3%). That they were "available in flavor, such as menthol, mint, candy, fruit or chocolate," was the seventh most common reason—selected by only 13.5% of respondents. With respect to "current users" as well, "flavors" was chosen as the reason for first use by only 13.2% of respondents—after "I was feeling anxious, stressed, or depressed" (43.4%), "to get a high or buzz from nicotine" (42.8%), "a friend used them" (28.3%), and I can "use them to do tricks" (20.0%). Andrea S. Gentzke, Teresa W. Wang, Monica Cornelius, Eunice Park-Lee, Chunfeng Ren, Michael D. Sawdey, Karen A. Cullen, Caitlin Loretan, Ahmed Jamal & David M. Homa, *Tobacco Product Use and Associated Factors Among Middle and High School Students—National Youth Tobacco Survey, United States, 2021*, 71 MORBIDITY & MORTALITY WKLY. REP. (Mar. 11, 2022), https://www.cdc.gov/mmwr/volumes/71/ss/ss7105a1.htm?s_cid=ss7105a1_w.

F. Flavors

Another reality that FDA must take into account under the Strategic Plan is how adult vapers behave in the real world. Overwhelmingly, adults who vape use flavored products—and this has been a persistent and unsurprising feature of the adult vaping market for years, as CTP's own exhaustive review of the literature confirms. Study after study tell us that adults prefer flavored vapor products and FDA needs to internalize this reality. Doing otherwise ensures a continuing black market and a continuation of the conflict and chaos that has marked FDA tobacco policy for years. It is remarkable that we still have to be reminded, more than 100 years after the passage of the Volstead Act,[335] that prohibition does not work. That does not, however, mean that anything goes—menthol and other flavored products should be authorized only if FDA determines that they are sufficiently safe relative to cigarette smoking based on product-specific toxicological and other evidence included in the PMTA, that they promote switching, and that they will be marketed in a restricted manner to limit youth use.

G. Adult Education

The Strategic Plan should also reflect a serious commitment on FDA's part to getting adult education right. Education matters—it was always fundamental to the harm reduction consensus that smokers would need to receive accurate information about the relative risk of different products in order to make reasoned decisions about reducing their risk. Maintaining essentially as a secret FDA's science-based findings that authorized products are safer than smoking violates the consensus and impedes progress toward reducing smoking-related death and disease. As Judge Kessler recognized in her RICO opinion, industry's inability to advertise early non-combustible products like Accord and Premier as safer than smoking helped doom those products.[336] Worse, purposefully confusing already-confused and misinformed smokers with statements like "no tobacco product is safe" guarantees bad outcomes when it comes to adult decision-making. Reduced harm products cannot displace cigarettes unless adults who smoke—and their healthcare providers—are alerted to the fact that the products are, in fact, less harmful—even if not *absolutely* safe as compared to using no nicotine-containing product at all.

Relatedly, the charge is often leveled that too much ENDS use is "dual use" rather than complete switching. Multiple studies have shown that daily ENDS use is associated with significantly higher rates of complete switching—including a recent study, co-authored by the PATH lead investigator, which found that daily vaping led to increased quitting even among people not planning to quit.[337] Yet the

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[335] The Volstead Act (41 Stat. 305 (1919)) implemented and provided an enforcement apparatus for the 18th Amendment, which prohibited "the manufacture, sale, or transportation of intoxicating liquors." *The Volstead Act*, NAT'L ARCHIVES, https://www.docsteach.org/documents/document/volstead-act (last visited July 17, 2023).

[336] *See supra* notes 71–72 and accompanying text.

[337] Karin A. Kasza, Kathryn C. Edwards, Heather L. Kimmel, Andrew Anesetti-Rothermel, K. Michael Cummings, Raymond S. Niaura, Akshika Sharma, Erin M. Ellis, Rebecca Jackson, Carlos Blanco, Marushka L. Silveira, Dorothy K. Hatsukami & Andrew Hyland, *Association of E-Cigarette Use With Discontinuation of Cigarette Smoking Among Adult Smokers Who Were Initially Never Planning to Quit*, JAMA NETWORK OPEN, Dec. 28, 2021, https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2787453.

unwillingness of FDA and CDC and the inability of manufacturers of PMTA-authorized products to inform adults about the difference between dual use and complete switching (and the disproportionate benefit of the latter), as well as one pathway for getting there (daily rather than occasional use), is an obvious part of the problem.

FDA has invested staggering resources in education when it comes to youth through "The Real Cost" and other programs.[338] No responsible actor argues that The Real Cost should be discontinued—programs to deter youth initiation have been foundational to tobacco control for decades, with demonstrably positive results. Yet it needs to be balanced by a commitment, at least as sincere and urgent, to educate adults who are dying at the rate of 480,000 a year.[339] Communications to schools about preventing youth use of any tobacco product (including e-cigarettes) should be balanced by communications to doctors, smoking cessation counselors, and similar adult-facing actors about the beneficial role that PMTA-authorized products can play for the adult smoker who cannot or will not quit all use of nicotine. Anti-vaping posters in high school bathrooms will only be seen by the youth who are their targets. Sensible adult messaging in equivalent adult-only locations like veterans hospitals and in-patient addiction treatment centers should also be an FDA focus, and the Strategic Plan should define a commitment to getting there with urgency. An excellent starting point would be a recent article providing detailed recommendations for communications by health care providers, to adults who smoke, about ENDS.[340]

H. Clearing the Backlog

When it comes to dealing with the backlog of PMTA applications, the Strategic Plan should reflect several FDA commitments. First, it should be based upon a restoration of the August 2020 and reiterated February 2021 prioritization approach to PMTA dispositions.[341] The goal should be to transform the e-cigarette marketplace as rapidly as possible to one in which all available products have been through an FDA review process and have been found to be appropriate for the protection of public health. Above all, FDA should not be measuring progress based on an artificial PMTA counting system that is unconnected with what is actually going on in the marketplace.

The Strategic Plan needs to reflect FDA's recognition that creating a functioning lawful e-cigarette marketplace is a necessary precondition to clearing out unlawful products. Who today would buy moonshine when legally produced alcohol, sold in an age-restricted manner and the marketing of which is regulated, is readily available to adults who want to consume it? And, notably, the disappearance of illegal liquor

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[338] As of 2019, FDA had invested more than $250 million in The Real Cost. Press Release, U.S. Food & Drug Admin., Statement on New Results Demonstrating Continued Success of the Agency's Youth Smoking Prevention Efforts and Significant Public Health Cost Savings (Aug. 20, 2019), https://www.fda.gov/news-events/press-announcements/statement-new-results-demonstrating-continued-success-agencys-youth-smoking-prevention-efforts-and (Statement of Ned Sharpless, Acting Commissioner of Food and Drugs).

[339] *See supra* note 3.

[340] Kenneth E. Warner, Neal L. Benowitz, Ann McNeill & Nancy A. Rigotti, *Nicotine E-Cigarettes as a Tool for Smoking Cessation*, 29 NATURE MED. 520 (2023).

[341] *See supra* notes 237–39 and accompanying text.

from the American landscape naturally followed legalization[342]—its forced removal by law enforcement, something that years of determined effort had shown to be impossible, was not a *precondition* to legalization. A continued exclusive focus on "clearing the market" of illegal products—unbalanced by a complementary commitment to authorize products that adults who smoke will want to use and which by necessity includes well-characterized and responsibly marketed menthol and other flavored products—guarantees a continuation of the chaos.

I. The 2017 Comprehensive Plan

An additional feature of the Strategic Plan process should be to examine the extent to which the 2017 Comprehensive Plan[343] has continued vitality and relevance—and where it may not. Those elements that continue to resonate and that are consistent with the historic consensus should be retained. Elements that are not part of the consensus and, above all, that are no longer realistic, should be left out of the new plan. In this regard, the 2017 Comprehensive Plan's embrace of the continuum of risk and the beneficial role that regulated, authorized e-cigarettes and other products can play in improving the public health was squarely within the historic consensus. Indeed, particularly with respect to the very use of the phrase "continuum of risk," it seems to have come directly out of the Strategic Dialogue.

However, the "all or nothing" tethering of the regulated harm reduction component of the Strategic Plan to two other initiatives—reducing nicotine levels in combustion cigarettes and a reformation of the medicinal pathway—was not part of the historic consensus. Without regard to whether either is a good idea from a public health point of view, the practical reality is that neither has happened within the six years since the announcement of the 2017 Plan and responsible, non-ideological actors have to concede that there is no guarantee that either will ever occur. Also, in the particular case of nicotine reduction, it is worth noting that the idea has been under discussion for nearly thirty years.[344] In the meantime, the Strategic Plan should unlink cigarette nicotine reduction and medicinal reform on the one hand, from regulated harm reduction on the other. Progress on harm reduction should not be held hostage by other agency initiatives that were not part of the consensus and that have no guaranteed prospect of becoming a reality any time soon, if ever.

J. Medicinal Cessation Products

In a recent Viewpoint in *JAMA*, the FDA Commissioner and CTP Director wrote of the need for a "smoking cessation care package."[345] That article focused primarily on the need for increased efforts to improve awareness and use of existing medicinal cessation products, on the agency's menthol ban and reduced nicotine initiatives, and encouraging the development of "novel therapeutic approaches to smoking

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[342] Harry G. Levin & Craig Reinarman, *From Prohibition to Regulation: Lessons from Alcohol Policy for Drug Policy*, 69 MILBANK Q. 461 (1991) ("Within two years of repeal nearly every state had an agency to supervise the sale and distribution of alcoholic beverages, and alcohol had ceased to be a controversial and politically charged issue.").

[343] *2017 Comprehensive Plan*, *supra* note 126.

[344] *See* Neal Benowitz & Jack Henningfield, *Establishing a Nicotine Threshold for Addiction. The Implications for Tobacco Regulation*, 331 NEW ENG. J. MED. 123 (1994).

[345] Robert M. Califf & Brian King, *Viewpoint, The Need for a Smoking Cessation "Care Package"*, 329 JAMA 203 (2023).

cessation."[346] On e-cigarettes, while conceding that "growing evidence indicates that certain e-cigarettes may facilitate smoking cessation among adults," it regrettably repeats the TCAG talking points that "[n]o e-cigarette is currently approved by the FDA for smoking cessation" and that "further high-quality research on this issue, including on short- and long-term clinical outcomes, is needed."[347] The article does not acknowledge the existence of PMTA-authorized e-cigarette products.

A primary focus on medicinal cessation—and disregard of the role that FDA-authorized reduced harm products can play—violates the historic consensus, disregards a significant component of the statute, and should not be reflected in the Strategic Plan. Moreover, as the FDA Commissioner has lamented on multiple recent occasions, the pharmaceutical companies are simply not focused on developing new medicinal cessation products.[348] It should go without saying that existing medicinal cessation products like patches and gums, on the market for decades, have failed to fully solve the adult smoking problem. That means that those emphasizing a medicinal approach going forward must be counting on new medicinal products that are not actually in prospect, or on a radical transformation of decades-long usage and success patterns. The inability of medicinal products, alone, to solve the problem is yet another practical reality that the Strategic Plan needs to internalize, and which makes the successful implementation of regulated harm reduction all the more urgent.

K. The Healthy People 2030 Goal

As noted above, the UK government is making a determined effort in pursuit of Smokefree 2030—an adult smoking rate below 5%. Though one would be hard pressed to be aware of it given the lack of attention that it has received, the United States has the same goal. In a U.S. context, that ambition is reflected in the Healthy People 2030 objectives. As a group of experts put it in a recent article, this goal is "ambitious" but "attainable."[349] According to the authors, the ability to achieve a 5% adult smoking rate will depend on continuing increases in adult quitting.[350] Given that ENDS have become the commonly used quit aid—and in light of Cochrane's most recent determination that there is "high certainty evidence that people are more likely to stop smoking for at least six months using nicotine e-cigarettes, or 'vapes,' than using nicotine replacement therapies"[351]—this is the most promising focus for efforts to further increase quit rates and make good on the Healthy People 2030 objective for current adult smoking. The new Strategic Plan should reflect that reality.

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[346] *Id.* at 204.

[347] *Id.* at 203.

[348] *See, e.g.*, *Cancer Moonshot Smoking Cessation Forum*, *supra* note 301, at 1:10:05–1:10:17 ("[T]he industry I think could do a lot better in developing smoking cessation products, but the return on investment doesn't match what it can get from other areas.").

[349] David Méndez, Thuy T.T. Le & Kenneth E. Warner, *Monitoring the Increase in the U.S. Smoking Cessation Rate and Its Implication for Future Smoking Prevalence*, 24 NICOTINE & TOBACCO RSCH. 1727 (2022).

[350] *Id.*

[351] 2022 Cochrane Review, *supra* note 123.

L. The Art of the Possible

The Strategic Plan should, above all, focus on what is truly possible from a scientific, legal, and regulatory point of view. FDA should not be committing significant resources to things that are going nowhere, whether they are potentially good ideas or not. The legendary diplomat Otto Von Bismarck famously declared: "Politics is the art of the possible, the attainable—the art of the next best."[352] FDA is a public health agency that should be focused on responsibly delivering results in a science-driven way that benefits the public health. It is not an advocacy group that can afford to spend time on hopeless causes and that, indeed, may feel the need to do precisely that in order to justify continued operations and satisfy donors. The Strategic Plan should reflect FDA's recognition that tilting against windmills—like the imposition of a de facto ENDS flavor ban, repeated battles over graphic warnings, pursuit of a cigarette menthol ban without first authorizing menthol ENDS, and the deeming of premium cigars—is a drain on agency resources and credibility. FDA should husband its resources and credibility wisely—even in the face of possible future threats by TCAG to yet again take the agency to court.

M. Cancer Moonshot

A signature ambition of the Biden Administration is the Cancer Moonshot, which seeks to cut the death rate from cancer by at least 50% over the next twenty-five years.[353] That goal has real meaning only if a sincere effort to tackle smoking-related cancers—including primarily lung cancer—is a critical component. Lung cancer is the leading cause of cancer-related death in the United States.[354] According to the CDC, people who smoke are fifteen to thirty times more likely to develop lung cancer than non-smokers, and cigarette smoking is linked to about 80–90% of lung cancer deaths.[355] According to a recent study by researchers from the American Cancer Society and the University of Oxford, quitting smoking has enormous cancer-prevention impact: "[T]hose who quit smoking at ages 15 to 34, 35 to 44, 45 to 54, and 55 to 64 years avoided an estimated 100%, 89%, 78%, and 56% of the excess cancer mortality risk associated with continued smoking, respectively."[356]

The new Strategic Plan should derive inspiration from the lofty vision of the Cancer Moonshot. A determined effort to incorporate regulated harm reduction into the fight against smoking-caused lung cancer is critically important if we are to truly drive down the cancer death rate, given the extraordinary cancer prevention benefits

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[352] "*Die Politik ist die Lehre vom Moglichen*." Otto von Bismarck, Interview (11 August 1867) with Friedrich Meyer von Waldeck of the *St. Petersburgische Zeitung: Aus den Erinnerungen eines russischen Publicisten. 2. Ein Stündchen beim Kanzler des norddeutschen Bundes*. In: *Die Gartenlaube* (1876) p. 858 de.wikisource. Reprinted in *Fürst Bismarck: neue Tischgespräche und Interviews*, Vol. 1, p. 248.

[353] *Cancer Moonshot: Ending Cancer As We Know It*, THE WHITE HOUSE, https://www.whitehouse.gov/cancermoonshot/.

[354] *An Update on Cancer Deaths in the United States*, CTRS. FOR DISEASE CONTROL & PREVENTION (last updated Feb. 28, 2022), https://www.cdc.gov/cancer/dcpc/research/update-on-cancer-deaths/index.htm.

[355] *Lung Cancer Risk Factors*, CTRS. FOR DISEASE CONTROL & PREVENTION (last updated Nov. 7, 2023), https://www.cdc.gov/lung-cancer/risk-factors/index.html.

[356] Blake Thompson, Jonathan Emberson, Ben Lacey, Sarah Lewington, Richard Peto & Farhad Islami, *Association of Smoking Initiation and Cessation Across the Life Course and Cancer Mortality: Prospective Study of 410 000 US Adults*, 7 JAMA ONCOLOGY 1901 (2021).

associated with quitting smoking. There may be no single better way to change the arc of American lung cancer deaths dramatically—in the spirit of the Cancer Moonshot—than science-driven, determined leveraging of the continuum of risk for nicotine-containing products.

N. The Lessons of COVID-19

In the aftermath of the COVID-19 pandemic, there are important public health lessons that have direct application to FDA and how it should approach the fight against cigarette-related death and disease. Given that the estimated annual U.S. smoking-related death rate (480,000) was above that attributed to COVID-19 in each of the years 2020–2022,[357] it is imperative that the agency show that it has learned from its experience with the pandemic in dealing with the country's leading cause of preventable death and disease.

The devastating impact of misinformation has been a continuing legacy of COVID-19—as Commissioner Califf frequently and appropriately calls out.[358] The agency should have zero tolerance for groups that traffic in it—including those who claim to be defenders of the public health. And, even more important and under FDA's complete control—it should ensure that it is not engaging in any misinformation, whether by commission (distorting the science) or by omission (omitting facts).

FDA showed during the COVID-19 pandemic that it functions best when it stands up to political pressure. Emergency use authorizations for hydroxychloroquine and convalescent plasma to treat COVID-19—under political pressure and against the agency's own better scientific judgment—were low points in FDA's history.[359] Resisting outside pressure to rush the review process for COVID-19 vaccines represented one of its finest moments.[360] Perhaps the single greatest aspiration that has emerged from the response to COVID-19 has been the need to always "follow the science." That is no less important in dealing with tobacco-related death and disease than it has been with COVID-19.

O. The UK

The Strategic Plan should reflect that CTP has seriously pondered why the United States is approaching ENDS so differently than the UK. The UK has been and continues to be the world leader on traditional tobacco control—it has consistently moved faster and more aggressively than the United States, continuing to the present day. Moreover, the UK government and its tobacco control groups strictly adhere to Article 5.3 of the Framework Convention on Tobacco Control and have steered fully clear of financial or other entanglements with the cigarette industry. And yet, it has moved in a determined and consensus fashion to incorporate harm reduction into the fight against smoking-related illness, in remarkable contrast to what has been

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[357] *See supra* notes 3–4.

[358] *See, e.g.*, Dr. Robert M. Califf (@DrCaliff_FDA), TWITTER (Apr. 1, 2022, 10:24 PM), https://twitter.com/DrCaliff_FDA/status/1509975085117026311 ("Misinformation does enormous harm and contributes to poor health outcomes. That's why I've made combating misinformation one of my priorities. Providing factual info is key to helping people make the best health decisions.").

[359] *See* THE COVID CRISIS GROUP, LESSONS FROM THE COVID WAR: AN INVESTIGATIVE REPORT 214–16 (2023).

[360] *Id.* at 215–17.

happening in the United States. The conclusion is inescapable that much of the difference in approach is a function of U.S. regulatory capture—capture that the UK, none of whose leading tobacco control/public health groups have become Bloomberg Philanthropies partners, has avoided.[361]

The UK and United States have a long history of shared values and partnership—as reaffirmed in the New Atlantic Charter signed by President Biden and British Prime Minister Boris Johnson in 2021.[362] That document included the following provision: "[W]e recognise the catastrophic impact of health crises, and the global good in strengthening our collective defences against health threats. We commit to continuing to collaborate to strengthen health systems and advance our health protections, and to assist others to do the same."[363] In the spirit of the New Atlantic Charter, it is incumbent upon FDA to seriously engage with the UK position on tobacco harm reduction and ENDS.

P. Handling the "Outside Forces"

Reagan-Udall identified the central problem with FDA's tobacco product regulation when it pointed out that it has been operated primarily in a reactive mode, provoked by outside forces, i.e., public health advocates and the regulated industry.[364] Each has shown a willingness to sue the agency, dating back to passage of the TCA and continuing to the present.

In dealing with the ever-present threat of litigation, FDA should do several things. First, it should fortify itself with the knowledge that as between it and the "outside forces," FDA is the true custodian of public health. Protecting the public health through drug and other approvals and with tobacco product authorizations is its charge under the Federal Food, Drug, and Cosmetic Act (FDCA), as amended by the TCA. FDA should, first and foremost, be mindful of that responsibility. And, when challenged by TCAG's congressional allies, FDA leadership should be prepared to speak truth to power—something Dr. Califf demonstrated admirably in his recent testimony before the House Appropriations Committee and again at a White House Cancer Moonshot event, when he pointed out that the nation's health care systems are not set up to help menthol smokers, post implementation of a ban.[365]

FDA needs to also internalize the fact that regardless of the good work they may have done in past years fighting against cigarettes, TCAG have no legal mandate to represent or speak for public health. TCAG are, like any group that accepts outside funding, subject to potential conflicts of interest. Here that has come from the enormous sums distributed by Bloomberg Philanthropies with the goal of supporting the Bloomberg anti-ENDS agenda—funding that dramatically exceeds money that still comes in from pharmaceutical companies that manufacture NRT products and which creates its own conflict. Bloomberg funding—especially since the September 2019 Flavors Initiative—has triggered a demonstrable change in long-standing

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[361] *Global Initiatives—Bloomberg Initiative to Reduce Tobacco Use*, CAMPAIGN FOR TOBACCO-FREE KIDS, https://www.tobaccofreekids.org/what-we-do/global/bloomberg (last visited Feb. 27, 2024) (listing partner organizations).

[362] *The New Atlantic Charter*, THE WHITE HOUSE (June 10, 2021), https://www.whitehouse.gov/briefing-room/statements-releases/2021/06/10/the-new-atlantic-charter/.

[363] *Id.*

[364] REAGAN-UDALL REPORT, *supra* note 251, at 4.

[365] *See supra* note 301 and accompanying text.

TCAG positions on regulated harm reduction, on the primacy of and deference to FDA review, and on the agency's exclusive authority to develop product standards. The historic harm reduction consensus has been exchanged for a bald-faced pressure campaign on FDA to summarily deny all flavored applications—and efforts to persuade states and cities to undermine FDA by passing flavor bans that do not include a PMTA authorization exception. When it comes to TCAG, the capturer has itself been captured—and recognizing that can be the first step to neutralizing the litigation threat they represent. And, in any future TCAG litigation, FDA should ensure that the court is appropriately advised concerning TCAG's Bloomberg and pharmaceutical company funding so that it can consider the potential financial interests affecting their arguments. FDA should also take steps to try to ensure that any TCAG plaintiffs are held to account with respect to any standing-related representations that they make, along the lines of those in *American Academy of Pediatrics v. FDA* (i.e., that they will integrate PMTA-authorized products into their public messaging and programs).

Of course, industry also is not "public health." Companies that manufacture and sell ENDS can claim to act in a manner that is consistent with the public health—but they are not, like advocacy groups, public health itself. FDA needs to be ever mindful of the cigarette companies' decades-long campaign of misinformation in the decades prior to the 1998 MSA and the mendacity of the light/low-tar debacle—while also recognizing that the means for addressing that is faithful implementation of the TCA, based on product-specific FDA reviews that follow the science. Big Tobacco's 20th Century conduct is not a basis, in the third decade of the 21st Century, to artificially tilt the scales against industry's regulatory submissions and to disregard the actual science. Reviewing industry-funded science is what all centers in FDA do—that is how the system works—and CTP should not be any different. Certainly, that is what the historic harm reduction consensus and the TCA itself always contemplated.

In addition, when it comes to "industry," FDA should recognize that it is not a monolith. It includes companies whose products are nationally distributed, who have devoted resources to creating a regulatory and compliance infrastructure, and who have a demonstrated commitment to the regulatory process as evidenced by PMTA-authorizations that they have already received. The term "industry" also includes those vape shops that are engaged in on-premises blending and who have been on the receiving end of the bulk of FDA's "fatal flaw" rejections. Some of these entities, and the advocacy groups with whom they identify, have been extremely vocal on social media and elsewhere in criticizing FDA's tobacco policy and PMTA decision-making.[366] That criticism, which flouts the harm reduction consensus, is often

[366] *See, e.g.*, American Vapor Manufacturers (@VaporAmerican), TWITTER (June 2, 2022, 6:37 PM), https://twitter.com/VaporAmerican/status/1664657550460198912 ("Don't let the genteel Carolina drawl fool ya. In public remarks to @ReaganUdall last week, @DrCaliff_FDA said a few things that were truly bonkers. Well, a lot of things actually."); Jim McDonald, *Senate Vote on Synthetic Nicotine Likely to Happen by Friday*, VAPING360 (Mar. 8, 2022), https://vaping360.com/vape-news/113497/congress-ban-synthetic-nicotine/ (quoting from the President of the American Vapor Manufacturers Association: "At a time when the FDA is under scrutiny from multiple federal courts for unlawful regulatory overreach on nicotine, handing the agency even more powers to prevent Americans from switching to vaping is like handing car keys and a bottle opener to your drunk uncle.").

personal and insulting and FDA has understandably called it out.[367] As is the case with all manner of policy debates, the loudest and most aggressive voices on social media tend to be the ones that are most heard. But in this case, opposition to FDA regulation and a substantive, product-specific PMTA process is demonstrably not an "industry" position across-the-board.

When it comes to the "outside forces," there are no great mysteries—we know what they will do for the foreseeable future. TCAG will advocate for the same policies that they have consistently championed since the 2019 Bloomberg Flavor Initiative—including a ban on all flavored (including menthol) ENDS, a ban on menthol cigarettes, and graphic warnings on cigarette packs. Cigarette companies will oppose a menthol cigarette ban, a reduced nicotine standard, and graphic warnings. ENDS companies will oppose a de facto ban on flavored (including menthol) ENDS. The ENDS blending companies will continue to oppose a robust PMTA process that is product-specific and that has statutorily mandated rigor with respect to product safety and population-level effects. All of these are givens—and some of this will result in litigation, whether in the form of the continuation of existing cases or the filing of new ones.

It is beyond FDA's power to simply avoid all litigation. Indeed, efforts to assuage one stakeholder can and will cause one or more other stakeholders to sue. We have seen this multiple times with FDA tobacco policy—with the agency getting buffeted by countervailing lawsuits by TCAG and industry on menthol, graphic warnings, and PMTA policy.[368] The best protection against such willingness to litigate will always be for FDA to be able to persuasively show that it has followed the science and the FDCA without fear or favor. Where FDA has effectively done so, litigation will be deterred and, where brought, will be more effectively defended against. Decisions that reflect a surrender to political or legal pressure of any kind, contrary to FDA's own understanding of the science and the statute, increase the risk of litigation and put the agency in the worst possible position when it comes to dealing with actual lawsuits—as, for example, shown in the premium cigar litigation and in the potential Fifth Circuit defeat where the reversal of an Office of Science recommendation has drawn the court's attention.[369] The agency should not fear litigation if science and the interests of public health are on its side.

Q. History Matters

As CTP looks to re-set itself in the coming months in response to Reagan-Udall, it would do well to consider one additional step. There is a unique need in the tobacco context to learn and be ever mindful of the long history of the tobacco wars—the industry's doubt-sowing campaign beginning in the 1950s and continuing for more than four decades until the MSA, the failure of unregulated harm reduction in the form of light and low-tar cigarettes, the long campaign to incorporate regulated harm

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[367] *See, e.g.*, Benjamin Toll (@bentollphd), TWITTER (Mar. 1, 2023, 10:08 PM), https://twitter.com/bentollphd/status/1631023717688934406 (quoting from speech by CTP Director Brian King: "It's easy to criticize from a twitter handle in your mother's basement.").

[368] *See supra* notes 164–71 (TCAG PMTA litigation), 245–48 (industry PMTA appeals), 275–76, 280 (industry graphic warnings litigation), 277–78 (TCAG graphic warnings litigation), 283 (industry menthol litigation), 287, 289, 292 (TCAG menthol litigation) and accompanying text.

[369] *See supra* notes 234–36 (premium cigar litigation) and 248 (5th Circuit appeals) and accompanying text.

reduction under FDA oversight, and the painstaking development of a harm reduction consensus. Much of this occurred before the beginning of the careers of anyone who today is under the age of fifty—and it is not sufficiently studied or understood. TCAG have become masters at playing on two aspects of this history—the tobacco industry's decades-long Merchants of Doubt campaign and the light/low-tar disaster. Conveniently, though, they ignore the years-long effort to build a consensus around FDA-regulated harm reduction and the fundamental need for FDA to act as the "trusted arbiter" for product decisions that are guided by science, not politics. And, of course, they take no ownership of their own years-long doubt-sowing campaign against ENDS. CTP needs a tobacco/nicotine historian—one with an ability to translate this history into the confidence to push back equally against those who believe harm reduction doesn't require any regulation *and* those who seek to subvert the FDA review process by pressuring the agency to make product authorization decisions without considering the science.

FDA would also do well to consider how history, written years from now, will judge what the agency does today. This can be the FDA (and CTP) that once and for all puts the nation on a clear pathway to a smoke-free future, one in which fewer than 5% of adults currently smoke. It can get there by fairly and effectively utilizing all of the tools at its disposal—medicinal interventions, prevention, and regulated harm reduction for those who cannot or will not quit all use of nicotine. An FDA moving determinedly down that road, guided by the FDCA and unafraid of the criticism and even litigation that it will face in the near term, can truly make public health history. Nothing less than that should be its goal. Former FDA Commissioner Scott Gottlieb appealed to history in announcing the 2017 Comprehensive Plan, in words that continue to ring true:

> To miss the opportunity to build on everything that FDA has accomplished since the enactment of the Tobacco Control Act would be irresponsible. We have it within our grasp to use the tools of product regulation to dramatically reduce tobacco-caused disease and death. I can think of no more impactful action FDA could possibly take on my watch to help American families.[370]

VIII. CONCLUSION

FDA's tobacco policy has struggled since the passage of the TCA to find stable footing. It has been buffeted by outside pressure and lawsuits and has been understandably rattled by the youth vaping epidemic of 2018–2019. Today it struggles with a backlog of PMTA applications and a growing black market, including most prominently flavored disposables. It has lost the confidence of all stakeholders and no one—least of all the FDA commissioner—argues that it is currently on the right track.

With the Reagan-Udall Report in hand, and having received a major legal setback to its product review efforts at the hands of the Fifth Circuit, FDA is at a crossroads. It can chart a new path forward that brings it back to the FDCA and the historic consensus that led to its passage—and in so doing drive progress toward achievement of the ambitious Healthy People 2030 goal of an adult smoking rate

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[370] *2017 Comprehensive Plan*, *supra* note 126.

below 5%. The alternative is for FDA to continue down some version of its current path—driven by TCAG policy prerogatives of the moment, in regular conflict with all stakeholders, and with a continuing series of judicial decisions regularly disrupting agency operations and strategy.

FDA's first step in all of this must be to understand how its tobacco policy has been captured by TCAG in the years following passage of the TCA. In that context, it should recognize how TCAG, which participated in the formation of the historic harm reduction consensus and heroically brought about passage of the TCA, has itself been captured. In formulating a new five-year plan, FDA should methodically seek to reverse the capture of its prerogatives and put it on a path to properly function as the "trusted arbiter" of reduced harm products and their integration into the fight against smoking-related death and disease. It should at all times follow the science and avoid misinformation. The new Strategic Plan, in the form of a "living document" that is periodically revised, should be in harmony with the TCA and the historic harm reduction consensus—and should internalize the lessons from the COVID-19 pandemic. Finally, it should function in a way that is consonant with the lofty objectives of the Cancer Moonshot project.

FDA has an historic opportunity in its new Strategic Plan to reclaim control over its tobacco policy—and the administration and the Secretary of HHS should ensure that it does so. The lives of the 30 million current adult smokers demand nothing less.