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Tobacco Product Warnings in the Mist of Vaping: A Retrospective on the Public Health Cigarette Smoking Act

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Tobacco Product Warnings in the Mist of Vaping: A Retrospective on the Public Health Cigarette Smoking Act

*John D. Blum**

I. INTRODUCTION

With the 2020 presidential election looming, healthcare reform is emerging as a major campaign issue. Numerous ideas, from creation of a national single payer system, to major overhauls of Medicare/Medicaid, to significantly revising coverage requirements mandated under the Affordable Care Act, are in play. While the scope and details of health reform proposals are highly variable, the underlying issues, which any significant reform initiative will face, are universal and constant. Undoubtedly, the biggest challenge all health reform proposals confront concerns crafting innovative and meaningful approaches to addressing the pervasive fiscal pressures faced by government programs. There is a long history of attempts to "bend the cost curve," but this complex task remains elusive in the face of evolving demand and supply side pressures.[1] One large point of consensus in the complex arena of cost containment policy is a

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1 *See* Ehsan U. Syed, *Will We Ever Bend the Cost Curve in Healthcare?*, AM. HEALTH & DRUG BENEFITS (July 2019), http://www.ahdbonline.com/issues/2019/june-july-2019-vol-12-no-4/2789-will-we-ever-bend-the-cost-curve-in-healthcare [http://perma.cc/ABN5-LY8Z].

general agreement that there must be a direct assault on chronic health diseases, such as obesity, heart disease, and cancer. It is estimated by the Centers for Disease Control and Prevention ("CDC") that six in ten adults suffer from at least one chronic disease, and that this category of illnesses is a major driver of our nation's $3.3 trillion in healthcare costs.[2] No comprehensive health reform can succeed unless it promotes strategies to effectively mitigate the burden of chronic diseases.

Few chronic diseases have a greater impact on health costs than substance use disorders. While opioid addiction may be the most current and visible form of substance use disorders, it is part of a broader, ongoing epidemic that includes the abuse of licit and illicit drugs, as well as alcohol.[3] One of our nation's oldest substance use disorders is cigarette smoking—a behavior that is driven by nicotine, the highly addictive chemical found in tobacco.[4] Cigarette consumption is widely recognized as leading to multiple, serious health problems.[5] It is an ongoing public health epidemic and has been the focus of regulators and health organizations since the release of the U.S. Surgeon General's Report on Smoking in 1964.[6] In the many years in which a war against tobacco has been waged by public and private actors, great progress has been made in reducing the number of smokers in the U.S. from 43% in 1965 to less than 16% currently.[7] But even in the face of progress, cigarette smoking remains our most preventable cause of death—higher than AIDS, alcoholism,

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2 *Chronic Diseases in America*, NAT'L CTR. FOR CHRONIC DISEASE PREVENTION & HEALTH PROMOTION, http://www.cdc.gov/chronicdisease/pdf/infographics/chronic-disease-H.pdf [http://perma.cc/SKU5-WKLF] (last updated Sept. 12, 2019). It has also been estimated that four in ten adults suffer from two or more chronic health conditions. *Id.*

3 *See Trends & Statistics*, NAT'L INST. ON DRUG ABUSE, http://www.drugabuse.gov/related-topics/trends-statistics [http:perma.cc/2Y3F-TZJQ] (last updated Apr. 2017) (estimating the health costs of substance use disorders to be as high as $250 billion annually). For further details on the opioid epidemic, see *What is the U.S. Opioid Epidemic?*, U.S. DEP'T OF HEALTH & HUMAN SERVS., http://www.hhs.gov/opioids/about-the-epidemic/index.html [http://perma.cc/4MGT-YLUL] (last updated Sept. 4, 2019).

4 *See Is nicotine addictive?*, NAT'L INST. ON DRUG ABUSE, http://www.drugabuse.gov/publications/research-reports/tobacco-nicotine-e-cigarettes/nicotine-addictive [http://perma.cc/5VQU-B74A] (last updated Oct. 2019) (discussing the addictive properties of nicotine).

5 *See* Kayla Ruble, *Read the Surgeon General's 1964 Report on Smoking and Health*, PBS (Jan. 12, 2014, 2:00 PM), http://www.pbs.org/newshour/health/first-surgeon-general-report-on-smokings-health-effects-marks-50-year-anniversary [http://perma.cc/8P85-ELVR].

6 *See id.*

7 *See Smoking is down, but almost 38 Million American adults still smoke*, CTRS. FOR DISEASE CONTROL & PREVENTION (Jan. 18, 2018), http://www.cdc.gov/media/releases/2018/p0118-smoking-rates-declining.html [http://perma.cc/YEG8-YE8E]; *Smoking in America: Why more Americans are kicking the habit*, AM. HEART ASS'N (Aug. 30, 2018), http://www.heart.org/en/news/2018/08/29/smoking-in-america-why-more-americans-are-kicking-the-habit [http://perma.cc/EYR8-EB9E].

murder, suicide, and use of illegal drugs combined.[8] According to the CDC, smoking-related illnesses cost more than $300 billion a year in direct medical expenses and lost productivity; it is an addiction that accounts for 8.7% of healthcare spending, of which 60% is paid for by public sources.[9] The burdens of smoking on our health delivery system continue to be profound and any success we may have in containing healthcare costs will be realized only by continuation of the decades-long struggle to mitigate the tobacco epidemic.

The so-called war against tobacco has a long, detailed, and well-documented history that spans the second half of the twentieth century and continues to the present.[10] This robust history of regulation reveals an assortment of abatement strategies that pit public health actors against individual smokers, powerful manufacturers, retailers, and agricultural interests. Central to this history is the role of law as a basic tool to implement an array of public policies and interventions on both domestic and international levels.[11] The ubiquitous presence of law in the struggle against tobacco products has been divided into two distinct periods: the first being a long period in which the focus of regulation rests on tobacco as an agricultural product, and the second characterized by public protection, in which preventing and reducing the health impacts of consumption is dominant.[12] These two periods—private market regulation and public health oversight—are not sequential, but coexist as major focal points of activity.[13]

For decades, the regulation of tobacco as a private product has focused on farming policies, product taxation, and various attempts to promote market competition through antitrust law.[14]

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8 *See* U.S. DEP'T HEALTH & HUMAN SERVS., THE HEALTH CONSEQUENCES OF SMOKING—50 YEARS OF PROGRESS: A REPORT OF THE SURGEON GENERAL 678–79 (2014); *Smoking and Death*, CTRS. FOR DISEASE CONTROL & PREVENTION (Jan. 17, 2018), http://www.cdc.gov/tobacco/data_statistics/fact_sheets/health_effects/effects_cig_smoking/index.htm [http://perma.cc/D7HP-UNVD].

9 *Fast facts,* CTRS. FOR DISEASE CONTROL & PREVENTION, http://www.cdc.gov/tobacco/data_statistics/fact_sheets/fast_facts/index.htm [http://perma.cc/N5Q8-GZDF] (last updated Feb. 6, 2019); Xin Xu et al., *Annual Healthcare Spending Attributable to Cigarette Smoking*, 48 AM. J. PREVENTATIVE MED. 326, 331 (2015).

10 *See* Helene M. Cole & Michael C. Fiore, *The War Against Tobacco: 50 Years and Counting*, 311 JAMA 131–32 (2014) (providing a summary of the turn of public health policy against tobacco).

11 For an overview of the long history of tobacco regulation, see NAT'L COMM'N ON MARIHUANA & DRUG ABUSE, *History of Tobacco Regulation*, 1 APPENDIX: MARIHUANA: A SIGNAL OF MISUNDERSTANDING 514 (1972), http://hdl.handle.net/2027/umn.31951d03118410v [http://perma.cc/J8ND-T8KP].

12 *See id.*

13 *See* GIDEON DORON, THE SMOKING PARADOX 5 (Michael Connolly et al. eds., 1979).

14 *See id.* at 5–12.

The focus on public health regulation can be traced to a growing awareness of the correlations between smoking and disease that has gone from anecdotal speculation to scientific certainty.[15] Public good regulations are characterized by a host of mandates, from labeling and advertisement requirements, to age restrictions, to product content oversight.[16] The legal system's impact on smoking has arisen from a mélange of statutory directives at all levels of government, in addition to litigation—particularly the 1998 Master Settlement Agreement that promoted widespread adoption of restrictions on tobacco products.[17]

A central feature in any consideration of tobacco control concerns the response of the regulated. The growing, manufacturing, and selling of tobacco products is a large, sophisticated, and profitable industry, and even in the face of long-term scrutiny, this sector has been able to adjust to regulations by adopting strategies of aggression and accommodation as needed. Paradoxically, the tobacco companies that adamantly denied that smoking caused health problems during the twentieth century, now caution against this behavior, positing smoking as a matter of adult choice and advocating that smokers switch to their newest product line, e-cigarettes.[18]

This Article offers commentary on one legal strategy that has been used in the long-term struggle to control tobacco: the use of package warning labels. First introduced in 1965 in the Federal Cigarette Labeling and Advertising Act ("FCLAA," also referred to as the Cigarette Act), a label-warning mandate has since become a basic feature of tobacco regulation.[19] It is the second piece of federal legislation enacted during the 91st Congress, the Public Health Cigarette Smoking Act ("PHCSA"),[20] that modified cigarette label warning requirements and which will be the springboard for analysis in this Article. This piece will explore the evolution and changes in the law concerning federal cigarette package warnings, tracing legislative iterations in the area from a basic textual requirement originating in the 1960s,[21] to the

15 *See id.* at 12–15.

16 *See id.* at 14–19.

17 *See* Pete Levin, *The ABCs of the Tobacco Master Settlement Agreement*, 2 NAAG, Nov. 6, 2007, at 1–2, http://www.naag.org/assets/files/pdf/gazette/1.2.Gazette.pdf [http://perma.cc/U49K-7PEL].

18 *See E-Cigarettes: Facts, stats and regulations*, TRUTH INITIATIVE (July 19, 2018), http://truthinitiative.org/research-resources/emerging-tobacco-products/e-cigarettes-facts-stats-and-regulations [http:perma.cc/TR9S-SSEC].

19 Federal Cigarette Labeling and Advertising Act, Pub. L. No. 89–92, 79 Stat. 282 (codified in 15 U.S.C. §§ 1331–1336, 1338–1340 (2012)).

20 Public Health Cigarette Smoking Act of 1969, Pub. L. No. 91–222, 84 Stat. 87 (codified in 15 U.S.C. § 1340 (2012)).

21 *See id.*

much more complex requirement to add graphic health warnings enacted in 2009.[22] Undoubtedly the issue of tobacco warning labels is only one of many threads in the larger context of cigarette regulation, but it is one which provides a helpful window into the exploration of policies to address the public health epidemic of smoking. The adoption and changes to warning labels reflect the historic environments in which such anti-smoking policies were developed and demonstrate an ongoing tension between regulators and industry. While tobacco control is a pillar of public health, it is not an exact science, as best practices, such as warnings, are difficult to measure and uncertain in the face of evolving smoking practices, like the use of e-cigarettes. As in other areas of smoking policy, political and legal impediments abound in the warning arena, compromising government capabilities to find an endgame to this persistent epidemic. The goal of this Article is to identify lessons that can be garnered from a review of the law concerning cigarette-package warnings to both improve that process and, more broadly, confront the ongoing challenges smoking poses to our healthcare system.

II. BACKGROUND

The rise and fall of cigarettes is a story ingrained in the twentieth century. The combination of mass production and skillful marketing moved the cigarette from relative obscurity in 1900 to a central place in American life by the 1930s.[23] While tobacco use exploded both domestically and internationally, it was cigarette consumption that dominated and became the epicenter of this behavior.[24] Cigarettes were marketed as highly desirable products, and ads depicting smoking as tasteful, healthy, and refreshing were seen for years in all forms of advertising media.[25] The advertisements were diverse in character, with various brands arguing that their products were

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22 *See* Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111–31, 123 Stat. 1776 (codified in 21 U.S.C. §§ 387, 387a–387u, 387a–1, 387f–1 (2012)).

23 *See* ALLAN M. BRANDT, THE CIGARETTE CENTURY: THE RISE, FALL AND DEADLY PERSISTENCE OF THE PRODUCT THAT DEFINED AMERICA 2–3 (2007).

24 *See id.* at 97.

25 *See Cigarette Advertising Themes*, STAN. UNIV., http://tobacco.stanford.edu/tobacco_main/main.php [http://perma.cc/E8QZ-N36L] (last visited Sept. 18, 2019). Cigarette advertisements are iconic symbols of American life, often depicting well-known personalities of the day touting the attractiveness of smoking as healthful and refreshing. *See id.* A prime example of characteristic advertising can be found on the pages of America's most popular weekly magazine, Life Magazine; the back-cover page of the magazine was often devoted to full page, artful tobacco advertisements that are reflective of the culture surrounding cigarettes. *See* Stuart Elliot, *Once a Mainstay of Magazines, Cigarette Makers Drop Print Ads*, N.Y. TIMES (Nov. 29, 2007), http://www.nytimes.com/2007/11/29/business/media/29adco.html [http://perma.cc/8YR8-UGTG].

less irritating to the smoker's throat, thereby cloaking themselves in the imprimatur of medical endorsements.[26]

At the time cigarette smoking was reaching its zenith, seeds of concern about the health implications had been widely sown. In the early part of the twentieth century, criticism of cigarettes on moral grounds was as common as concerns over health, which somewhat paralleled reactions against alcohol use.[27] The public health case against cigarettes evolved over a considerable period of time as the epidemiological proof linking smoking with cancer became more convincing and spilled over from scientific literature into every day parlance.[28] Tobacco companies vigorously fought back, orchestrating a massive public relations effort to empathize with health concerns, while simultaneously calling into question the validity of the science linking cigarette consumption to disease.[29]

In the 1940s and 1950s, the tobacco industry challenged the validity of anti-smoking studies, and even financed its own research that called into question claims that the product was a gateway to serious health problems.[30] In addition to adopting a posture of aggressive denials over health claims, tobacco manufacturers began to introduce filtered cigarettes to reduce harmful tar and nicotine content, which paradoxically should not have been necessary had these products not been potentially harmful to begin with.[31] Another popular strategy used to market cigarettes was for manufacturers to make claims about the low levels of tar and nicotine in a given brand, arguing the result was less throat irritation, and, by implication, constituted a healthier product.[32] As more scientific research about the ills of smoking unfolded, the industry shifted from a rejection of causation to arguments that there was simply inadequate proof about the dangers of smoking to reach a definitive conclusion.[33] Through much of the twentieth century, cigarettes were largely

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26 *See* Martha M. Gardner & Allan M. Brandt, *"The Doctors' Choice Is America's Choice": The Physician in U.S. Cigarette Advertisements, 1930–1953*, 96 AM. J. PUBLIC HEALTH 222, 223–24 (2006).

27 *Id.* at 222; *see* U.S. DEP'T HEALTH & HUMAN SERVS., THE HEALTH CONSEQUENCES OF SMOKING—50 YEARS OF PROGRESS: A REPORT OF THE SURGEON GENERAL 19 (2014).

28 *See* Gardner & Brandt, *supra* note 26, at 222–23.

29 *See id.* at 223.

30 *See* Allan M. Brandt, *Inventing Conflicts of Interest: A History of Tobacco Industry Tactics*, 102 AM. J. PUBLIC HEALTH 63, 63–64 (2012).

31 *See* Gardner & Brandt, *supra* note 26, at 229–30.

32 Joel B. Cohen, *Smokers' Knowledge and Understanding of Advertised Tar Numbers: Health Policy Implications*, 86 AM. J. PUBLIC HEALTH 18, 19 (1996).

33 *See* STANTON A. GLANTZ ET AL., THE CIGARETTE PAPERS 25 (1996) ("After millions of dollars and over twenty years of research, the question about smoking and health is still open.").

unregulated, with the exception of Federal Trade Commission ("FTC") oversight, which had control over unfair trade practices.[34] The FTC did issue a number of cease and desist orders involving various advertising claims made in particular cigarette brand ad campaigns, but it lacked the capacity to contain an industry that was able to nimbly adjust advertising strategies to circumvent regulatory challenges.[35] Following Congressional tobacco hearings in 1957 that highlighted the deceptive nature of tobacco advertising, a movement to attach warning labels to cigarette packaging developed.[36]

Eventually the weight of science pressured the government to take action to evaluate the accumulating evidence linking smoking and illness, and a government commission was created in 1962 under the auspices of the U.S. Surgeon General to look into the matter.[37] In early January of 1964, the U.S. Surgeon General's Advisory Committee on Smoking and Health issued what has become a seminal report in the history of tobacco control.[38] It was a catalyst in the design of multidisciplinary health studies, which also sparked subsequent Surgeon General smoking evaluations.[39]

The Surgeon General's Report, based on review of over 7,000 articles on smoking and health, concluded "that cigarette smoking is—[a] cause of lung and laryngeal cancers in men[,] a probable cause of lung cancer in women[,]" as well as a "cause of

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34 *See* Federal Trade Commission Act, 15 U.S.C. § 49 (Supp. IV 1970) (using the subpoena power to investigate instances of unfair methods of competition).

35 *See* Statement of Basis and Purpose for the Cigarette Advertising and Labeling Trade Regulation Rule, 29 Fed. Reg. 8325 (July 2, 1964). On September 15, 1955, the FTC issued cigarette-advertising guides. 1960 FTC ANN. REP. at 82. Among other things, they prohibit representations in cigarette advertising or labeling which refer to the presence or absence of any physical effects from cigarette smoking or which make any unsubstantiated claims respecting nicotine, tar or any other components of cigarette smoke, or in any other respects contain misleading implications concerning the health consequences or the advertised brand. *See id.* at 83. In 1960, the Commission obtained the agreement of the leading cigarette manufacturers to discontinue the misleading and unsubstantiated representations of tar and nicotine content which had characterized the so-called tar derby. *See id.* The FTC was limited in its regulatory authority over tobacco as the additional authority granted to the FTC in 1938 through the Food, Drug, and Cosmetic Act did not include tobacco; it took time for the Commission to ban tar and nicotine content, as unsubstantiated health claims, lacking in proof or uniform testing. Federal Food, Drug, and Cosmetic Act, ch. 675, 52 Stat. 1040 (Supp. IV 1930) (codified as amended in scattered sections of 21 U.S.C.).

36 *See* BRANDT, *supra* note 23, at 246.

37 *See id.* at 219.

38 U.S. DEP'T HEALTH, EDUC., & WELFARE, PUB. HEALTH SERV. PUB. NO. 1103, SMOKING AND HEALTH: REPORT OF THE ADVISORY COMMITTEE TO THE SURGEON GENERAL OF THE PUBLIC HEALTH SERVICE (1964).

39 *Id.*

chronic bronchitis."[40] The report did not end scientific issues concerning cigarette smoking, but did resolve any uncertainty about whether there was a link between tobacco and illness, and as such, created an avenue for government to more forcefully address the smoking problem directly.

The Surgeon General's Report emerged in a period where smoking rates were high and, as noted, product regulation over cigarette content and manufacturing processes was largely non-existent. With cigarettes established as a type of disease vector by the Surgeon General, the initial focus of federal regulatory activity was centered on addressing the myths spawned by aggressive and misleading ad claims.[41] The challenge of moving the report from a scientific analysis to remedial action fell to the FTC, which quickly unveiled a new set of regulations that mandated warnings about the dangers of smoking under the Commission's authority to safeguard against unfair and deceptive trade practices.[42] The FTC issued a proposed rule, which, in part, specified that one of two prescribed warnings be prominently displayed in all advertisements and on every cigarette pack, box, or container, as well as in advertisements.[43] This FTC rulemaking sparked a national debate on cigarette regulation that shifted the issue from a question of science to one of politics, and raised questions about the scope of regulatory authority in this arena. While the FTC proposal to add powerful warnings concerning the dangers of smoking garnered strong support from most public health groups, surprisingly the American Medical Association ("AMA") did not endorse tobacco warning labels, but instead, for political reasons, called for increasing research into the public health implications of smoking, rather than adoption of warnings that the AMA felt would likely be ignored.[44]

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40 *History of the Surgeon General's Reports on Smoking and Health*, CTR. FOR DISEASE CONTROL & PREVENTION, http://www.cdc.gov/tobacco/data_statistics/sgr/history/index.htm [http://perma.cc/2M8P-49UD] (last updated Dec. 18, 2018). The Report concluded that the death rates for male smokers from lung cancer were 1,000% higher than male nonsmokers. BRANDT, *supra* note 23, at 224.

41 *See* Advertising and Labeling of Cigarettes, 29 Fed. Reg. 530, 530–32 (Jan. 22, 1964).

42 *See id.*

43 M. JOYCELYN ELDERS, PREVENTING TOBACCO USE AMONG YOUNG PEOPLE: A REPORT OF THE SURGEON GENERAL 257 (1994) (stating, caution: (a) "The Surgeon General's Advisory Committee on Smoking and Health has found that cigarette smoking contributes substantially to mortality from certain specific diseases and to the overall death rate"; or (b) "Cigarette smoking is dangerous to health. It may cause death from cancer and other diseases.").

44 It has been suggested that the AMA was caught up in its fights against Medicare and Medicaid legislation and did not want to alienate tobacco state members of Congress. BRANDT, *supra* note 23, at 249. In a *JAMA* editorial, the Executive Director of the AMA argued that tobacco had such large and multi-faceted implications that Congress, and not

While the science linking smoking to disease was advanced by the Surgeon General's Report, the tobacco war quickly took on a strong public policy cast as the tobacco lobby, shifted its efforts to the political arena, and waged its battles in Congress. Tobacco had powerful allies in Congress, led by members from tobacco growing states who had close ties to President Lyndon B. Johnson.[45] While the FTC was pushing for greater regulatory control over cigarettes, the tobacco industry went on the offensive by threatening litigation to block the Commission's expansion of tobacco regulations and proposing its own legislative fixes, which were reflected in Senate Bill 559.[46] Striking testimony in Congressional tobacco hearings was provided by some of the nation's leading cancer specialists who argued that the statistical link between smoking and health was not powerful enough to discount other multiple causes that might underlie lung cancer.[47]

At this point, the tobacco lobby recognized that the pendulum of science and public opinion about smoking had shifted, thereby making warnings inevitable. So, rather than fight this development, it supported a very diluted warning: "Caution: Cigarette Smoking May Be Hazardous to Your Health."[48] Ironically, while the smoking lobby continued to question the science around this behavior as uncertain, it supported a warning label as a mechanism to notify consumers about the dangers of smoking, and as a strategy to mitigate potential liability, thus creating an assumption of risk on the part of the smoker.[49] In addition, the industry sought to restrict FTC regulation and supported placing future labeling and advertising regulations in Congressional control, preempting state and local activities in this area.[50] On another front, a Tobacco Industry Code of Advertising was adopted in 1964.[51] The Code was a form of self-regulation, directed at prohibiting ads geared toward youth smoking, ensuring accuracy in health

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a regulatory agency, should control labeling and advertising. F.J.L. Blasingame, *Full Text of AMA Letter of Testimony to FTC*, *in* 188 JAMA 31, 31 (1964). In addition, the Tobacco Research Industry Committee in 1964 (renamed the Council for Tobacco Research) had pledged $10 million to the AMA Education and Research Foundation to conduct research into the possible association between smoking and health. *See* 21 CONG. Q. SERV., *Health Warning Required on Cigarette Packs*, *in* XXI CONG. Q. ALMANAC 344 (Henrietta Poynter et al. eds., 1965).

45 *See* CONG. Q. SERV.*, supra* note 44, at 344.

46 *See id.* at 344–45.

47 *See id.* at 348.

48 *See id.* at 345.

49 *See* BRANDT, *supra* note 23, at 254.

50 *Id.*

51 John W. Richards, Jr. et al., *The Tobacco Industry's Code of Advertising in the United States: Myth and Reality*, 5 TOBACCO CONTROL 295, 295 (1996).

claims, and creating an administrative mechanism to vet advertisements based on the first two objectives noted.[52]

In July of 1965, the FLCAA was signed into law by President Lyndon B. Johnson, despite the White House failing to endorse this bill and a lack of unanimity in the Executive branch about how tobacco control should be developed.[53] Opposition from key members of Congress, who feared any federal legislation that might adversely impact the economics of tobacco growing and product taxation, certainly played a critical role in what was contained in this legislation.[54] The tobacco lobby heavily influenced this federal law, and the conditions noted above (warning labels, preemptions, regulatory agency limitations) were incorporated into this statute, making it a very pro-industry enactment.[55] Nonetheless, even if the law was highly compromised, The Cigarette Act remains significant, as it was the first of several pieces of federal legislation enacted to regulate tobacco products, and represents a foundation on which subsequent tobacco legislation rests. The Cigarette Act required a conspicuous package-warning label that codified the explicit language to be included, by January 1966, on all domestic and imported cigarette packaging.[56] The warning mandate was a step towards the legal recognition of the dangers of smoking that had been endorsed by the U.S. Surgeon General as a matter of public education, even if it was much less stringent than what health advocates had hoped for.[57] The Cigarette Act placed a four-year moratorium on any additional federal, state, or local agency regulation of advertisements, as well as restricted federal agencies from requiring language in warning labels beyond what was specified in the statute.[58] While the FTC still retained its general powers to regulate cigarettes under its authority over unfair and deceptive trade practices, the FCLAA moratorium shifted power to Congress and struck a blow against agency autonomy in this field.[59] The law required that the Department of Health, Education, and Welfare ("DHEW") submit regular reports to Congress about the health consequences of smoking,

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52 *Id.*

53 Federal Cigarette Labeling and Advertising Act, 15 U.S.C. §§ 1331–1341 (1966).

54 *See* CONG. Q. SERV., *supra* note 44, at 346.

55 *See id.* at 345–46.

56 *Id.* at 345.

57 *See* NAT'L COMM'N ON MARIHUANA & DRUG ABUSE, *supra* note 11, at 523.

58 *Id.* The law prohibited the FTC from requiring that the warning be placed in tobacco advertisements. For a discussion of the preemption question that was later dealt with by the U.S. Court, see CONG. RESEARCH SERV., R40639, THE FEDERAL CIGARETTE LABELING AND ADVERTISING ACT AND PREEMPTION REVISITED: AN ANALYSIS OF THE SUPREME COURT CASE *ALTRIA GROUP, INC. V. GOOD* AND CURRENT LEGISLATION 14–16 (2009).

59 *See* NAT'L COMM'N ON MARIHUANA & DRUG ABUSE, *supra* note 11, at 523.

and that the FTC submit reports on the effectiveness of labeling and the impacts of advertising on smoking.[60]

III. THE PUBLIC HEALTH CIGARETTE SMOKING ACT AND THE 91ST CONGRESS

Through ongoing research in the 1960s, it became clearer that smoking causes multiple health problems and that this awareness was taking root in the public consciousness.[61] On the other hand, tobacco sales were at their zenith and smoking rates even increased in 1966 after mandated package-warning labels were legislated in the FCLAA.[62] The economic power of the tobacco industry and the success of cigarette advertising made smoking a difficult target for public health advocates.[63] But there were broader societal health concerns beyond smoking—such as increasing cancer rates generally and growing fears over illnesses caused by environmental toxins—that affected the regulatory climate of the 1960s.[64] In addition, it was during this time that the country experienced the growth of the consumer movement, in which an emphasis on safety, information, choice, and redress emerged as legal levers to empower individuals in the face of large corporate interests.[65] These broad societal forces came together during the Nixon administration and it was in this period that the 91st Congress was confronted with deciding what should be included in a new tobacco law in light of the sunset of key portions of FCLAA—particularly those concerning agency authority and package warning requirements.

The concerns about the ill effects of cigarettes did not subside after the passage of the FCLAA, but continued into the late 1960s, driven to a considerable extent on the political side by the Nixon administration's U.S. Surgeon General, Jesse Steinfeld.[66] Dr. Steinfeld, a cancer researcher from the National Cancer Institute, was a very strong anti-smoking advocate who used his position as Surgeon General as a bully pulpit to attack the tobacco industry; he argued that tobacco companies were

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60 *See id.*

61 *See id.*

62 *See id.*

63 *See id.*

64 *See* Robert Lichter, *Stop the Fearmongering Over Cancer*, FORBES (June 1, 2010, 11:24 AM), http://www.forbes.com/2010/06/01/cancer-hysteria-health-media-opinions-columnists-robert-lichter.html#163564cc3348 [http://perma.cc/M99L-24UH].

65 *See* Richard L. Worsnop, *Directions of the Consumer Movement*, *in* CQ RESEARCHER 3–4 (1972).

66 *See* Alison Snyder, *Jesse Steinfeld*, 384 LANCET 1258, 1258 (Oct. 4, 2014), http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(14)61760-8/fulltext [http://perma.cc/6FD7-BUHA].

responsible for millions of related deaths.[67] Particularly noteworthy was Steinfeld's campaign that cautioned women about the dangers of smoking while pregnant or near children, and his pioneering work in raising concern about the dangers of secondhand smoke that underpinned a call to ban smoking in public places.[68] Steinfeld's vigorous advocacy proved controversial and unpopular with key political operatives in the Nixon administration who feared backlash from the tobacco industry and political fallout in states that were heavily dependent on this crop as a mainstay of their agricultural economies.[69] It was also argued that the Surgeon General was overly concerned with the health impacts of smoking, at the expense of taking action to combat other health hazards.[70]

In the period following the FCLAA, a number of important smoking-related developments occurred beyond the vigorous anti-smoking advocacy of the Surgeon General. In 1966, a request was made to television station WCBS to broadcast anti-smoking announcements under the equal time provisions of the fairness doctrine.[71] During this era, cigarettes were the leading product advertised on television, accounting for 8% of advertising time.[72] The argument was made that the law governing broadcast media required that airtime also be allotted to public health advocates to present information about the health risks of smoking to counter the false representations made in cigarette commercials.[73] The Federal Communications Commission ("FCC") supported the use of the fairness doctrine to counteract cigarette ads as a matter of public interest.[74] Later use of this doctrine was upheld in the federal courts where the argument that it violated First Amendment commercial speech protections was rejected.[75] While "equal time" was not required for anti-tobacco ads, broadcasters were required to devote a "significant amount of time" to free messages that educated the

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67 *Id.*

68 *Id.*

69 "Any attacks on tobacco are counter-productive in Kentucky, North Carolina and Virginia, where tobacco-growing and manufacturing are vital to the economy. The same is true to a lesser, but still significant, extent in Tennessee, Georgia, South Carolina, Florida and Maryland." Memorandum for the Att'y Gen. from Lee R. Nunn, Comm. for the Re-Election of the President (Jan. 18, 1972).

70 *See id.* at Attachment C.

71 NAT'L COMM'N ON MARIHUANA & DRUG ABUSE, *supra* note 11, at 524.

72 SUSAN WAGNER, CIGARETTE COUNTRY: TOBACCO IN AMERICAN HISTORY & POLITICS 166 (1971).

73 *See* Banzhaf v. FCC, 405 F.2d 1082, 1086 (D.C. Cir. 1968).

74 *See id.* at 1087.

75 *See id.* at 1100–01.

public about the hazards of smoking, and as such, frequent anti-tobacco spot ads began to populate the broadcast airwaves.[76]

Under the dictates of the FCLAA, the FTC was temporarily prevented from implementing any requirement that tar and nicotine content be listed on cigarette packages.[77] Still, the FTC, after many years of rejecting industry claims concerning cigarette content, reached a private agreement with tobacco manufacturers in 1966 to allow tar and nicotine content to be advertised.[78] The Commission had convened a panel of scientists to explore the tar and nicotine issue.[79] This panel concluded that there was sufficient evidence to support the claim that cigarette smoke that contained lower amounts of these two substances was less harmful and that recommendations should be made to the Surgeon General to support reduction of these harmful chemicals in cigarette smoke.[80] Cigarette manufacturers were not required to include tar and nicotine content in advertisements, but could choose to do so without facing a regulatory penalty.[81] The FTC required that advertised ingredients be based on accepted smoke testing procedures, even endorsing a particular testing method, and creating its own laboratory to conduct smoke tests.[82]

In 1967, the FTC released a report on cigarette labeling and advertising, required under FCLAA.[83] This report, based on survey data collected from public health professionals and consumers, concluded there was no evidence that the current label warning required in 1965 had any effect on cigarette consumption.[84] In fact, in the first two months after the warning appeared, product sales actually increased.[85] Survey respondents overwhelmingly reported that they felt that the current warning label language was insufficient to inform the public of the general hazards of smoking, particularly in the face of massive

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76 *Id.* at 1086–87.

77 NAT'L COMM'N ON MARIHUANA & DRUG ABUSE, *supra* note 11, at 523.

78 *See* Vanessa K. Burrows, CONG. RESEARCH SERV., RS22944, FEDERAL TRADE COMMISSION GUIDANCE REGARDING TAR AND NICOTINE YIELDS IN CIGARETTES (2008). For FTC guidance on tar and nicotine, see FTC, *FTC to Begin Cigarette Testing*, NEWS SUMMARY (Aug. 18, 1967), http://hdl.handle.net/2027/uiug.30112104343899 [http://perma.cc/P8YT-34QR].

79 *Cigarette Controls: A Sick Joke So Far*, 33 CONSUMER REPS. 97, 102 (1968).

80 *Id.* The tar and nicotine measures were also seen as a helpful tool to dispel the belief that filtered cigarettes were effective in reducing harmful chemicals in smoke, as filtered cigarettes seen as healthier dominated the cigarette market. *Id.*

81 *See* Burrows, *supra* note 78.

82 *See* Jeffrey Wigand, *What is the FTC Method of Cigarette Analysis?*, http://jeffreywigand.com/FTCmethod.pdf [http://perma.cc/X9MK-YTPE] (last visited Feb. 27, 2020); Burrows, *supra* note 78.

83 FTC ANN. REP. at 18–19, 78–79 (1967).

84 *Cigarette Controls: A Sick Joke So Far*, *supra* note 79, at 98.

85 *Id.*

industry advertising.[86] The Commission expressed concern about the impacts of advertising on teenagers who appeared to be a prime target of television cigarette promotions.[87] Tobacco ads depicted smoking as a relatively safe and fashionable behavior, never pointing out the addictive nature of the product.[88] The FTC noted that the industry did not appear to be following its own self-regulatory guidelines—particularly evident in its promotion of filtered cigarettes and its failure to mention the increasing evidence of the growing health hazards linked to smoking.[89] The Commission report recommended that package warnings be more stringent, using language that reads, "Cigarette Smoking Is Dangerous to Health and May Cause Death From Cancer and Other Diseases," and that such warning be expanded from packages to all product advertising, and mandate specific tar and nicotine content information.[90] In addition, the FTC called for appropriations of funds to support anti-smoking programs, especially for children, as well as support for the development of a "safer" cigarette.[91]

The broad health concerns over cancer and environmental pollution became legislative drivers of the 91st Congress and, within this context, the ongoing battle over how tobacco was to be regulated unfolded. Within the cigarette-smoking arena, the aggressive posture of the Surgeon General and the FTC, together with the use of the fairness doctrine mandated by the FCC, drove government's executive branch smoking activism. A Congressional showdown on tobacco in 1969 was sparked by the sunset provision in the FCLAA concerning warning language and advertisement regulation.[92] Numerous tobacco bills were introduced in the U.S. House of Representatives in 1969 that posited several primary approaches for ongoing regulation, including a stronger warning label, the inclusion of tar and nicotine levels on packaging and advertisements, prohibition of broadcast cigarette ads, as well as extension of provisions of the 1965 FCLAA.[93] During the time period the 91st Congress was deliberating new cigarette legislation, the FCC began rule-making processes to ban the broadcast of cigarette ads on

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86 *See id.*

87 *Id.*

88 *See id.* at 98, 100.

89 *See id.* at 100.

90 *Id.*

91 *See id.*

92 *See* S. REP. NO. 91-566, at 1–2 (1969), *as reprinted in* 1970 U.S.C.C.A.N. 2652, 2652–53.

93 Edward Klebe, CONG. RESEARCH SERV., 79-219EPW, ACTIONS OF THE CONGRESS AND THE FEDERAL GOVERNMENT ON SMOKING AND HEALTH 19–24 (1979).

radio and television and the FTC announced an even more stringent package warning than had been suggested in its 1967 Report to Congress.[94] In the Senate, the focus of their tobacco hearings was centered on industry self-regulation.[95] As a result of regulatory pressure and the growing impacts of the fairness doctrine pressure, the tobacco industry voluntarily offered to discontinue broadcast advertising—a strategic move to mitigate other legislative initiatives.[96] In turn, the FTC offered to suspend its efforts to require health warnings in cigarette advertisements until 1971 if broadcasters voluntarily withdrew cigarette ads.[97]

After a long process of hearings and debate, the 91st Congress enacted the second major piece of federal tobacco legislation: the PHCSA of 1969.[98] The legislation contained five key parts: (1) the suspension of broadcast media cigarette advertising; (2) a change in package label warnings; (3) a prohibition on state and local government regulation of tobacco advertising; (4) the suspension of FTC action on print advertising until July 1, 1971; and (5) a requirement that the FTC and DHEW report annually to Congress on the consequences of smoking, the effectiveness of labeling, and advertising practices.[99] While the PHCSA was somewhat more rigorous than the FCLAA, the final bill was the product of significant compromise and was, no doubt, heavily influenced by the strong hand of the tobacco lobby.[100] As was the case with the FCLAA, the White House appeared to distance itself from the PHCSA. The strong support from the public health community, and the drive to eradicate cancer that led to the National Cancer Act in the following year, marked a political climate that resulted in President Nixon signing the new cigarette act on April 1, 1970.[101]

On January 1, 1971 at 11:50 p.m., the last cigarette ad ran on network television, as what was arguably the most significant provision of the PHCSA of 1969 went into effect.[102] Television cigarette advertising was a hallmark of broadcast media, and

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94 *See id.* at 21.

95 *Id.* at 23.

96 *See id.*

97 *Id.* at 24.

98 Public Health Cigarette Smoking Act of 1969, Pub. L. No. 91-222, 84 Stat. 87 (codified as amended at 15 U.S.C. §§ 1331–1340 (2012)).

99 *See id.* at 87–89.

100 NAT'L COMM'N ON MARIHUANA & DRUG ABUSE, *supra* note 11, at 525.

101 ANNA D. BARKER & HAMILTON JORDAN, *Legislative History of the National Cancer Program*, *in* HOLLAND-FREI CANCER MEDICINE (Donald W. Kufe et al. eds., 6th ed. 2003), http://www.ncbi.nlm.nih.gov/books/NBK13873/ [http://perma.cc/K2XB-FESB].

102 *Nixon signs legislation banning cigarette ads on TV and radio*, HISTORY, http://www.history.com/this-day-in-history/nixon-signs-legislation-banning-cigarette-ads-on-tv-and-radio [http://perma.cc/9JZ3-DH4U] (last updated July 28, 2019).

was seen as a major influence on children.[103] In 1970, their final year on the airwaves, tobacco manufacturers spent over $200 million on TV ads.[104] But even prior to the U.S. ad ban, strict regulation of broadcast tobacco ads in several European countries, and an outright prohibition in the UK, appeared to have little impact on smoking rates in those countries.[105] Curiously, with the ban on cigarette advertising in place, the FCC mandate to require broadcasters to run free public health anti-smoking ads was no longer necessary, thereby abrogating the use of the fairness doctrine.[106] While television ads were eliminated, tobacco manufacturers continued their vigorous marketing elsewhere.[107] They shifted to print media and point of sale promotions, as well as various types of product sponsorships.[108]

Broadcasters, on the other hand, were faced with significant revenue losses and challenged the PHCSA ad ban in court, as being in violation of First Amendment commercial speech protections, and Fifth Amendment due process rights.[109] A three judge panel in *Capital Broadcasting Co. v. Mitchell* disagreed with the broadcasters' legal claims and ruled that commercial speech protections were more limited than other forms of speech.[110] Congress had the power to ban broadcast media cigarette advertising based on either its authority over regulatory agencies or interstate commerce. The court in *Mitchell* found that the broadcasters' rights to free speech were not violated, as their revenue loss from cigarette ads did not prohibit them from commenting on the issue of smoking and public health.[111] In a dissenting opinion in *Mitchell*, Judge Skelly Wright argued that the ban on cigarette advertising was a matter of public importance that should receive full constitutional speech protections.[112] Judge Wright was particularly concerned that the ban on TV and radio advertising took the issue off the airwaves and, in so doing, denied the use of the fairness doctrine to spark a more balanced discussion of the health impacts of cigarettes.[113]

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103 Lee Lescaze, *Cigarette Advertising*, WASH. POST (Jan. 15, 1979), http://www.washingtonpost.com/archive/politics/1979/01/15/cigarette-advertising/a46e78bd-85e1-4d2a-90d1-e0cbc4c7b8fd/?noredirect&utm_term=.074621ddf8f7 [http://perma.cc/EGQ9-XSJB].

104 *Id.*

105 *See* BRANDT, *supra* note 23, at 271.

106 *See id.* at 271–72.

107 *See id.* at 272.

108 *See id.*

109 Capital Broad. Co. v. Mitchell, 333 F. Supp. 582, 583 (D.D.C. 1971).

110 *See id.* at 583, 585–86.

111 *See id.* at 586.

112 *See id.* at 587 (Wright, J., dissenting).

113 *See id.* at 589 (Wright, J., dissenting).

The package warning label requirement in the PHCSA was not a novel legislative provision as the cigarette ad ban was, but rather offered a modest extension of the warning requirement in the FCLAA, with the inclusion of language that added the gravitas of the U.S. Surgeon General to the package label. The original 1965 warning label requirement did not succeed in reducing cigarette consumption, but rather than abandoning the idea of a consumer warning, subsequent legislative initiatives, starting with the 1969 PHCSA, amended the mandatory language to make the warnings more detailed.[114] The PHCSA prohibited the FTC from requiring the cigarette warnings apply beyond package labels, but that limitation was only in place until July 1, 1971, and once this moratorium had expired, the Commission, which was strongly committed to use of consumer warnings, expanded the requirement to include all tobacco advertising.[115]

The use of a product warning has a dual objective of both educating the public about the risks posed by a given product, as well as deterring use of the product. Clearly the goal of use deterrence was not one that was welcomed by cigarette manufacturers and sellers, and so the industry struggled to meet the legal warning requirements in ways that minimized their impact on sales. On the government side, even with ongoing mitigation efforts, there was no centralized voice for tobacco control in either the Executive branch or Congress.[116] Pockets of strong opposition to regulation were sparked by pressure from heavy lobbying by tobacco manufacturers and agricultural interests.[117] The cigarette warning label requirement in the PHCSA demonstrated underlying tensions in government ranks.[118] The regulators in the Executive branch were strong supporters of comprehensive oversight, in opposition to views sparked by economic concerns in Congress and the White House that resulted in favoring more limited approaches to cigarette regulation, including minimal package warnings.[119]

As previously noted, during the Nixon Administration, Surgeon General Steinfeld was an ardent anti-tobacco advocate, and specific to tobacco warnings, his views aligned with the FTC's position for much more stringent oversight than what was

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114 *See* Public Health Cigarette Smoking Act of 1969, Pub. L. No. 91-222, 84 Stat. 87, 88 (1970).

115 *See* Klebe, *supra* note 93, at 29.

116 *See* BRANDT, *supra* note 23, at 277.

117 *See id.*

118 *See* Memorandum for the Att'y Gen., *supra* note 69, at 1–6.

119 *See id.*

legislated in the PHCSA.[120] On the other hand, as evidenced in a 1972 Republican memorandum to the attorney general on tobacco regulation, concerns were voiced about anti-smoking measures that were having a negative impact on political support for President Nixon in southern states.[121] In the noted memorandum, the tobacco industry was praised for its willingness to self-regulate and pursue objective scientific research into the health aspects of cigarettes.[122] Surgeon General Steinfeld was characterized as an anti-smoking zealot with a vendetta against tobacco that was pursued at the expense of dealing with other hazardous substances.[123] The warning provision in the PHCSA balances countervailing pressures, as the package label requirement was driven by a regulatory commitment to educate the public about the hazards of smoking, a culture of individualism, and a strong desire not to disrupt the economic status quo.[124]

In his 1968 presidential campaign, President Nixon was asked about his opinion on tobacco warnings. The President characterized the studies concerning smoking and health as controversial, and noted that all the federal government could do concerning cigarettes was provide information about smoking hazards to the public, and let individuals choose.[125] He expressed skepticism about whether warnings would have any impact on consumer behavior.[126] Like the prior Kennedy and Johnson administrations, the Nixon White House was very guarded in its support of anti-smoking measures, and while Nixon signed the PHCSA into law, no fanfare accompanied this signing.[127]

IV. BEYOND THE PHCSA: THE TRAJECTORY OF WARNINGS

At first blush, it appears that the legacy of the PHCSA sinks into the sea of laws, regulations, and litigation that developed in the area of tobacco control since 1970. Still, the major components of the 1969 law—the advertising ban, revised warning labels, and preemption of local/state law on advertising—were significant steps in the history of tobacco use abatement measures that remain relevant in the current smoking landscape. Indeed, as the smoking question has

120 *See* Snyder, *supra* note 66, at 1258.
121 Memorandum for the Att'y Gen., *supra* note 69, at 1.
122 *Id.* at 4–5.
123 *Id.* at 1–2.
124 *See id.* at 1–6.
125 *Id.* at Attachment A.
126 *Id.*
127 *See Nixon signs legislation banning cigarette ads on TV and radio*, *supra* note 102.

expanded into new and different forms of nicotine delivery devices beyond traditional cigarettes, the fundamental and long-standing regulatory controls found in the PHCSA remain viable public health tools in the face of the growing use of e-cigarettes and a heightened awareness of the need to control health care costs through more effective prevention.

There are three developments post-1969 concerning smoking mitigation that should be noted in tracking the evolution of tobacco regulation, dealing directly and indirectly with warning labels. First, from the mid-1970s, a major catalyst for ongoing smoking regulation was the growing public concern over the dangers of cigarette smoking, fueled by an awareness of the impacts of secondhand smoke.[128] With the emergence of solid evidence that non-smokers exposed to cigarette smoke were at risk for numerous medical conditions, the public health focus over smoking broadened.[129] Smoking abatement was no longer limited to concerns about individual behavior that centered on questions of personal choice, but expanded into a population wide problem.[130] Numerous laws enacted, at all levels of government, prohibited smoking in various indoor and outdoor spaces.[131] With them came ubiquitous signage declaring no smoking policies.[132] There was also a growing awareness and concern about nicotine content in cigarettes, as science emerged that cautioned about the addictive nature of this chemical.[133]

A second development that affected the direction of warnings occurred in 1972 when cigarettes and other tobacco products were excluded from the jurisdiction of the Consumer Products Safety Commission ("CPSC"), thereby closing an avenue for possibly more impactful regulation by another regulatory actor.[134] In 1973, a request was made to the CPSC to set a maximum level of twenty-one milligrams of tar in cigarettes and ban any cigarettes exceeding that amount from interstate commerce, drawing on the Federal Hazardous Substances Act

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128 *See* BRANDT, *supra* note 23, at 292–93.

129 *See* Melissa Conrad Stoppler, *Secondhand Smoke*, MEDICINENET, http://www.medicinenet.com/secondhand_smoke/article.htm#secondhand_smoke_facts [http://perma.cc/JC5Q-4DVA] (last updated Nov. 13, 2018).

130 *See id.*

131 *See* Dustin Heap, *No Smoking Laws For All Fifty States*, SIGNS.COM (May 20, 2014), http://www.signs.com/blog/no-smoking-laws-for-all-fifty-states/ [http://perma.cc/H5TH-YRKS].

132 *See id.*

133 *See* U.S. DEP'T OF HEALTH & HUMAN SERVS., THE HEALTH CONSEQUENCES OF SMOKING: NICOTINE ADDICTION: A REPORT OF THE SURGEON GENERAL 6 (1988), http://profiles.nlm.nih.gov/spotlight/nn/catalog/nlm:nlmuid-101584932X426-doc [http://perma.cc/XK7B-YXMK].

134 Consumer Product Safety Act, Pub. L. No. 92-573, 86 Stat. 1207, 1207–08 (1972).

("FHSA") as supporting law.[135] According to the General Accounting Office ("GAO"), who had been referred the matter by the U.S. Comptroller General, the FHSA did not extend to cigarettes, and while the CPSC could regulate matters under the FHSA generally, tobacco oversight was limited to Congress.[136] Concern about CPSC regulation was great enough to result in legislative action that explicitly excluded tobacco regulation from the FHSA.[137] In addition, tobacco was further excluded from inclusion in both the Controlled Substances Act ("CSA"), as well as the Toxic Substances Control Act ("TSCA"), in essence leaving cigarettes exempt from the oversight of significant consumer and worker protection regulatory schemes.[138]

A third major development in tobacco control can be found in the evolution of smoking litigation that escalated throughout the second half of the twentieth century. Often, liability claims at state levels raised questions about the impacts of mandated warning labels; but, starting with the FCLAA, such state claims were preempted, spawning a reliance on alternative causes of action.[139] It would take several decades, but eventually consolidated tobacco litigation culminated in a master settlement between states' attorney generals in 1998.[140] The settlement resulted in historic payments by the manufacturers to individual states and adoption of an array of measures, particularly oriented to youth, that restricted cigarette advertising and marketing, as well as prohibited industry practices designed to hide health information about the dangers of smoking.[141]

While the cigarette smoking challenge continued to spark new approaches to regulation, the use of warning labels that came out of the FCLAA and the PHCSA in the 1960s was not abandoned, even in the face of skepticism about the effectiveness of warnings on education and prevention.[142] A review of the

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135 Klebe, *supra* note 93, at 33–34.

136 *Id.* at 34–35. The Consumer Products Safety Commission validated the conclusions of the GAO concerning the Federal Hazardous Substances Act in a three to two vote on May 17, 1974 that the Commission lacked the authority to regulate tar in cigarettes. *Id.* at 35.

137 James T. O'Reilly*, A Consistent Ethic of Safety Regulation: The Case for Improving Regulation of Tobacco Products*, 3 ADMIN. L.J. 215, 245 (1989). *See also* 15 U.S.C. § 1262(f)(2).

138 O'Reilly, *supra* note 137, at 230.

139 *See* Controlled Substances Act, 21 U.S.C. § 802 (1982 & Supp. V 1987); Toxic Substances Controlled Act, 15 U.S.C. § 2602 (1988). These statutes can serve as alternative causes of action.

140 *See The Master Settlement Agreement: An Overview*, PUB. HEALTH L. CTR. (Jan. 2019), http://www.publichealthlawcenter.org/sites/default/files/resources/MSA-Overview-2019.pdf [http://perma.cc/6WGG-VCFP].

141 *See id.*

142 *See* Deborah M. Scharf & William G. Shadel, *Graphic Warning Labels on Cigarettes Are Scary, but Do They Work?*, RAND CORP. (Sept. 30, 2014),

legislative history of tobacco in the 1970s demonstrates that there were ongoing efforts to strengthen warning labels in a number of proposed federal bills, as well as a recommendation by the FTC to expand warnings to include tar and nicotine content in both packaging and advertising.[143] The FCLAA was amended in 1973 to expand package-warning requirements to include little cigars.[144] In 1981, the FTC, in a report to Congress, concluded that the PHCSA health warning language was no longer impactful on public knowledge and attitudes about smoking, spurring Congress to revisit the labeling issue.[145] In 1984, the Comprehensive Smoking Education Act ("CSEA," also known as the Rotational Warning Act) was passed.[146] This law required cigarette packages and advertising to use one of four health warnings that included much more explicit language about the adverse health effects of smoking.[147] The four rotational warnings were mandatory for not only packaging, but for all advertisements and outdoor billboards.[148] The 1984 statute contained explicit details about the format of labeling, and required that manufacturers and importers submit advertising plans for approval to the FTC for each brand of cigarettes.[149] CSEA was an attempt to refocus cigarette control efforts, not only by expanding warnings labels, but also by extending anti-tobacco educational efforts, tracking cigarette ingredients, and facilitating interagency coordination of anti-smoking efforts.[150] Not long after CSEA was enacted, mandatory package warnings were extended to smokeless tobacco products.[151]

The rotational warnings on both cigarettes and smokeless tobacco became a fixture on cigarette packages. Despite a whirlwind of legal and policy developments concerning smoking abatement, this regulatory mandate—a vestige from the

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http://www.rand.org/blog/2014/09/graphic-warning-labels-on-cigarettes-are-scary-but.html [http://perma.cc/3NC2-BX59].

143 Klebe, *supra* note 93, at 36–40. *See also* Smoker and Nonsmoker Health Protection Act, H.R. 10748, 94th Cong. (1975) (showing an example of proposed federal legislation that included expansion of cigarette warnings); H.R. 3827, 93d Cong. (1973) (requiring a package label reading, "Cigarette Smoking Is Dangerous to Health and May Cause Death From Cancer, Coronary Heart Disease, Chronic Bronchitis, Pulmonary Emphysema, or Other Diseases").

144 Little Cigar Act, Pub. L. No. 93-109, 87 Stat. 352, 352 (1973).

145 *See* 1981 FTC ANN. REP. 6.

146 Comprehensive Smoking Education Act, Pub. L. No. 98-474, 98 Stat. 2200, 2201–02 (1984).

147 *Id.*

148 *Id.*

149 15 U.S.C. § 1333 (1982), *amended by* 15 U.S.C. § 1333 (Supp. IV 1982).

150 Comprehensive Smoking Education Act, H.R. 3979, 98th Cong. (1984).

151 Comprehensive Smokeless Tobacco Health Education Act, Pub. L. No. 99-252, 100 Stat. 30, 30–31 (1986).

1960s—held firm. The skepticism, noted above, about the efficacy of cigarette label warnings remained a persistent undertone in this area. In a landmark report on tobacco control in 2007, the Institute of Medicine ("IOM") voiced support for the use of packaging as an effective vehicle for health communications, but concluded that the warnings stemming from CSEA were inadequate.[152] The IOM called for revised warnings to foster greater public awareness of health risks, as well as to discourage consumption.[153]

The 2007 IOM report was a harbinger of the Family Smoking Prevention and Tobacco Control Act of 2009 ("TCA"), the most comprehensive federal legislation in the tobacco control area to date.[154] Congress crafted the TCA based on key evidence drawn over several decades.[155] Major drivers of the law included reducing smoking among children and adolescents, recognizing the strong link between smoking and addiction to nicotine, and continuing public educational efforts to counter tobacco-marketing efforts.[156] The TCA established a broad framework for ongoing regulation—drawing together in one bill an array of measures posited for some time.[157] In particular, the law designated the federal Food and Drug Administration ("FDA") as the central authority in this area, giving the Administration the power to regulate the manufacture, distribution, and marketing of cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco, and any other tobacco product the Administration deems by regulation to be considered a "tobacco product."[158] The 2009 law provides three pathways for approval of new tobacco products by the FDA in conjunction with its general powers under the Food, Drug, and Cosmetic Act.[159] The three regulatory pathways include a pre-market approval order for all new tobacco products; secondly, a modified risk tobacco product

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152 *See* INST. OF MED., ENDING THE TOBACCO PROBLEM: A BLUEPRINT FOR THE NATION 289–96 (Richard J. Bonnie et al. eds., 2007).

153 *See id.*

154 *See* Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009).

155 *See id.* at 1777–81.

156 *See* Nicopure Labs, L.L.C. v. FDA, 266 F. Supp. 3d 360, 371 (D.C. Cir. 2017).

157 *See Family Smoking Prevention and Tobacco Control Act—An Overview*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/tobacco-products/rules-regulations-and-guidance/family-smoking-prevention-and-tobacco-control-act-overview [http://perma.cc/EW6G-K37F] (last updated Jan. 17, 2018).

158 *See* Federal Food, Drug, and Cosmetic Act, ch. 675, 52 Stat. 1040 (1938) (codified as amended in scattered sections of 21 U.S.C.); *see also* 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, 79 Fed. Reg. 23,142, 23,142 (2014).

159 *See* Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 387j, 387k (2012).

category that applies to single products that have been altered to modify health considerations; and thirdly, a substantial equivalence plan for predicate products that came on the market prior to March 2011.[160] It is noteworthy that tobacco products that were unchanged since entering the market prior to 2007—while subject to FDA regulation—are treated as grandfathered brands, not requiring specific Administration approval.[161] Another noteworthy feature of the Act is the requirement that cigarette companies disclose all product ingredients, and stop using descriptive words like "light" and "ultra-light" to create the impression that a particular product is a healthy smoking alternative.[162] Critics of the TCA voiced concern that the legislation comes up short.[163] For example, it allows the FDA to mandate lower nicotine levels in cigarettes, but by not banning this chemical outright, it results in addicted smokers inhaling more deeply and increased consumption by these smokers to feed their nicotine craving.[164]

Perhaps the most significant feature of the TCA is that the law, for the first time in twenty-five years, imposes new labels and warnings on tobacco packages and on advertisements.[165] The combined influence of the IOM report's critique of warnings, along with the adoption of more detailed textual warnings, and startling graphic depictions of illnesses caused by smoking in countries across the globe, spurred a renewed American regulatory effort to invigorate the warning process. The 2006 World Health Organization ("WHO") Framework Convention on Tobacco Control ("FCTC") called for the use of packaging warnings that are rotating, "large, clear, visible and legible,"

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160 *See Premarket Tobacco Product Applications*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/premarket-tobacco-product-applications [http://perma.cc/RQ8K-KJX6] (last updated Oct. 25, 2019); *Modified Risk Tobacco Products*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/tobacco-products/advertising-and-promotion/modified-risk-tobacco-products [http://perma.cc/9746-TVYP] (last updated Oct. 22, 2019); FOOD & DRUG ADMIN., DEMONSTRATING THE SUBSTANTIAL EQUIVALENCE OF A NEW TOBACCO PRODUCT: RESPONSES TO FREQUENTLY ASKED QUESTIONS (3d ed. Dec. 2016), http://www.fda.gov/media/90811/download [http://perma.cc/E76U-D22D].

161 For an interesting discussion of the deeming rule, see *Introducing the FDA Deeming Authority Clarification Act of 2015*, 114th Cong. 5694 (Apr. 28, 2015) (statement of Hon. Tom Cole).

162 *See* Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776, 1780 (2009).

163 Michael Siegel, *Tobacco regulations are no regulations at all*, L.A. TIMES (June 3, 2009), http://web.archive.org/web/20161226015412/http://articles.latimes.com/2009/jun/03/opinion/oe-siegel3 [http://perma.cc/7JW7-K79Y].

164 *Id.*

165 *See* Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776, 1842–43.

and includes pictures or pictograms.[166] Under the TCA, the FDA was empowered to require that cigarette packages and advertisements bear one of nine new health warnings and that the warnings, with graphics, comprise 50% of the front and rear panels of cigarette packages.[167] The new label warnings are linked to the FDA requirements under the Administration's misbranding provisions, which require that a regulated product include proper labeling.[168] In the case of cigarettes, the product would be considered misbranded if it failed to comport with the necessary language, placement, typography, and graphics.[169] Congress legislated the nine rotational warnings that were to be used, but left the selection of accompanying graphics in the hands of the FDA.[170] The law allows the FDA to adjust the type size, text, and format of cigarette health warnings to ensure that the graphics and accompanying text are clear, conspicuous, legible, and adequately sized.[171]

In deciding which graphic warnings to be used, the FDA was tasked with balancing a strategy to discourage nonsmokers, especially children, from initiating cigarette use and to encourage current smokers to change their behavior in order to reduce health risks.[172] The Administration analyzed thirty-six graphic images drawn from consumer research on health communications, considering cognitive and emotional reactions.[173] The FDA concluded that risk information was best communicated through emotional messages, because such messages are more likely to garner a reaction from smokers.[174] The Administration settled on nine graphic images to accompany each of the new mandated warning statements, together with a phone number from the National Cancer Institute's "Network of Tobacco Cessation Quitlines."[175] Selection of the graphic images was based on an 18,000-person Internet survey that focused on

166 WORLD HEALTH ORG., WHO FRAMEWORK CONVENTION ON TOBACCO CONTROL, Art. 11.1(b) (Feb. 27, 2005).

167 15 U.S.C. § 1333 (2012) (The warnings include: "[c]igarettes are addictive"; "[t]obacco smoke can harm your children"; "[c]igarettes cause fatal lung disease"; "[c]igarettes cause cancer"; "[c]igarettes cause strokes and heart disease"; "[s]moking during pregnancy can harm your baby"; "[s]moking can kill you"; "[t]obacco smoke causes fatal lung disease in nonsmokers"; and "[q]uitting smoking now greatly reduces serious risks to your health").

168 *See* Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 387c (2012).

169 *See id.* § 321(n).

170 *See* 15 U.S.C. § 1333.

171 *See id.*

172 *See* Required Packaging Warnings for Cigarette Packages and Advertisements, 75 Fed. Reg. 69,525 (Nov. 12, 2010).

173 *See* Required Warnings for Cigarette Packages and Advertisements, 76 Fed. Reg. 36,637–38 (June 11, 2011).

174 *Id.* at 36,639.

175 *Id.* at 36,681.

whether the proposed graphic increased the consumer's desire to quit or refrain from smoking, expanded knowledge about the risks of smoking and secondhand smoke, and sparked a negative reaction.[176] In its response to criticisms about the new graphic labels, the FDA acknowledged that its study did not permit the Administration to reach firm conclusions about long-term effects of the proposed warnings, but justified the new regulation based on scientific literature and the widespread use of graphic warning labels in other countries.[177]

Following the issuance of the final rule implementing the FDA's new graphic cigarette package warnings, the tobacco companies filed two separate lawsuits. In a suit brought in the Western District of Kentucky in *Discount Tobacco & Lottery v. United S*tates, five tobacco companies and one retailer challenged the legality of the 2009 Tobacco Control Act on several grounds.[178] One such ground claimed that the new labeling requirements violated commercial speech rights under the First Amendment.[179] In overturning a district court grant of summary judgment to the corporate plaintiffs resting on the use of a First Amendment strict scrutiny standard, the court of appeals in the Kentucky case applied a more liberal approach to commercial speech that rested on the state's interest in preventing consumer deception.[180] The court found that the new graphic warnings constituted a form of commercial speech that was accurate, salient, and reasonably related to health protection.[181] Further, it found that the labeling requirement did not infringe on the plaintiffs' speech rights, as either an undue burden or an unjustified consumer protection.[182]

Another suit was filed by the tobacco industry that challenged the legality of the FDA graphic warning label regulation, rather than the statutory challenge against the TCA

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176 *See id.* at 36,637.

177 R.J. Reynolds Tobacco Co. v. FDA, 696 F.3d 1205, 1210 (D.C. Cir. 2012), *overruled on other grounds by* Am. Meat Inst. v. U.S. Dep't of Agric., 760 F.3d 18, 22–23 (D.C. Cir. 2014).

178 Disc. Tobacco City & Lottery, Inc. v. United States, 674 F.3d 509, 518 (6th Cir. 2012).

179 *Id.*

180 *See id.* at 522. The court relied on the commercial speech test articulated by the U.S. Supreme Court in *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*. *Id.* at 523–24 (citing 471 U.S. 626, 627 (1985)).

181 *See id.* at 522–23, 531.

182 *See id.* at 530–31. The court of appeals found that the requirement to include a "quit" number on cigarette labels did not fall under the *Zauderer* standard but should be subjected to a more stringent standard of review as it was not designed to directly inform consumers, but rather constitutes a smoking mitigation measure. *See id.* at 522–23. Under the more rigorous *Central Hudson* test, the "quit" number needed greater justification to demonstrate it is the most viable mechanism to meet a government goal; on its face, the "quit" number contradicts the tobacco company message at the point of sale, imposing a significant burden on commercial speech. *See id.* at 522–23, 544.

raised in *Discount Tobacco & Lottery*. The corporate plaintiffs in the D.C. circuit case of *R.J. Reynolds v. FDA* argued that the graphic warning regulation infringed on their First Amendment commercial speech rights.[183] Unlike the court in *Discount Tobacco & Lottery*, the *R.J. Reynolds* court applied a First Amendment review based on precedents from *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, and a more challenging commercial speech analysis drawn from the case of *Central Hudson Gas & Electric v. Public Service Commission*.[184] The D.C. court reasoned that purely factual and uncontroversial required disclosures per *Zauderer* were allowed under the First Amendment, provided such disclosures were justified and not overly burdensome.[185] The court's analysis next included the application of elements drawn from *Central Hudson*, which required that in order to restrain free speech, the government must demonstrate a valid interest, the advancement of that interest in its exertion of regulatory authority, and a showing that the regulation in question was narrowly cast.[186] The D.C. court concluded that the FDA failed to present any data that enacting the proposed graphic warnings would accomplish the objectives of reducing smoking rates.[187] The court found that consumers could misinterpret some of the required images, and that others failed to convey any warning language at all.[188] The *R.J. Reynolds* court vacated the rule and remanded it back to the Administration. Following the decision, the FDA withdrew the graphic warning rule, even though, as noted, the Western District of Kentucky had supported the constitutionality of the TCA.[189] Shortly after the D.C. decision, the Attorney General of the United States notified Congress that the FDA would undertake research to support a new rulemaking effort consistent with the Tobacco Control Act.[190] In the interim, the warning label requirements that required a textual warning—which had been in place since 1984—remained in force.

The FDA moved very slowly in developing a new tobacco-labeling rule, even in the face of its statutory obligation

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183 *See R.J. Reynolds*, 696 F.3d at 1211.
184 *See id.* at 1217.
185 *See id.* at 1216.
186 *See id.* at 1217.
187 *Id.* at 1219.
188 *See id.* at 1216–17.
189 *See id.* at 1222.
190 Letter from Eric Holder Jr., Att'y Gen., to the Honorable John Boehner, Speaker, U.S. H.R. (Mar. 15, 2013) (on file with the Univ. of Cal. S.F. Ctr. for Tobacco Control Res. & Educ.), http://tobacco.ucsf.edu/sites/tobacco.ucsf.edu/files/u9/Ltr%20to%20Speaker%20re%20Reynolds%20v%20FDA.PDF [http://perma.cc/6HDL-QF7N].

under the TCA and a 2012 court decision compelling action in this area.[191] Frustration with Administration inaction on the part of public health advocates resulted in a legal challenge in the United States District Court for the District of Massachusetts, which alleged that the Administration was unlawfully withholding action in its failings to issue new graphic warning labels.[192] The action sought a court order to compel rulemaking.[193]

The Massachusetts Federal District Court in *American Pediatrics v. FDA* ruled in favor of the plaintiff health care associations, holding that the Administration unlawfully withheld and unreasonably delayed issuing graphic warning labels.[194] The court found that the Administration failed to justify its delay in the face of public health and welfare interests, and absent a showing of competing priorities.[195] The judge ordered the FDA to issue a new proposed rule on graphic cigarette warnings in compliance with the TCA by August 15, 2019, with a final rule to be completed by March 15, 2020.[196]

In August of 2019, eight years after the first notice of proposed rulemaking was issued to implement the graphic warning provisions of the TCA, the FDA issued a new proposed rule in compliance with the federal court order in *American Pediatrics*.[197] The Administration proposed thirteen new textual health warning label statements "accompanied by color graphics depicting the negative health consequences of smoking."[198] These new color graphics are required to "appear prominently on packages and in advertisements, occupying the top 50 percent of the area of the front and rear panels of cigarette packages and at least 20 percent of the area at the top of cigarette advertisements."[199] The warnings and graphics focus on well-known health risks caused by smoking, such as lung cancer and heart disease, but also include lesser-known risks, like

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191 *See R.J. Reynolds*, 696 F.3d at 1222.

192 *Court Orders FDA to Issue Proposed Graphic Cigarette Warning Rule This Year*, TROUTMAN SANDERS: TOBACCO L. BLOG (Apr. 24, 2019), http://www.tobaccolawblog.com/2019/04/court-orders-fda-to-issue-proposed-graphic-cigarette-warnings-rule-this-year/ [http://perma.cc/BRR7-UF8G].

193 *Id.*

194 Am. Acad. of Pediatrics v. FDA, 330 F. Supp. 3d 657, 667 (D. Mass. 2018).

195 *Id.*

196 *Federal court orders FDA to issue final rule requiring graphic cigarette warnings*, TRUTH INITIATIVE (Mar. 6, 2019), http://www.truthinitiative.org/press/press-release/federal-court-orders-fda-issue-final-rule-requiring-graphic-cigarette-warnings [http://perma.cc/N555-EW4Y].

197 *See* Tobacco Products; Required Warnings for Cigarette Packages and Advertisements, 84 Fed. Reg. 42,754, 42,754 (Aug. 16, 2019).

198 *Id.* at 42,757.

199 *Id.*

bladder cancer and diabetes.[200] The FDA developed the new rule in the wake of the *R.J. Reynolds* case, so the commercial speech elements in *Zauderer* and *Central Hudson* became essential parameters in the development of the rulemaking process.[201] The new rule, driven by the court critiques in *R.J. Reynolds*, was the product of extensive legal, scientific, and regulatory analysis resting on an iterative research process that was much more detailed than the case made for the 2011 rule.[202] The FDA regulators posit that the new rule advances a substantial government interest and is no more extensive than is necessary.[203] The Administration believes that its original and expansive research provides a basis for the revised cigarette warnings that offer consumers' new information, sparking greater understanding about the health risks of smoking, and is both more understandable and memorable than prior Surgeon General warnings.[204] In addition, the FDA was very conscious of not mandating warnings that are purely emotional in character, but rather took pains to develop labels which simultaneously garner attention and convey substantive messages.[205] Under the dictates of the proposed rule, product manufacturers, distributors, and retailers must submit a plan to the FDA for the random display and distribution of required warnings on packages.[206] The thirteen new warning labels and the twelve accompanying picture graphics are set to take effect fifteen months after the final FDA warning label regulation is in place, which may occur in 2021.[207] It is conceivable that a new commercial speech challenge may be mounted, as the tobacco industry is unlikely to cede the marketing benefits of its packaging without a fight.

V. WARNINGS AND THE DEEMING RULE

While most of the developments concerning tobacco warnings, dating back to the 1970s' FCLAA and PHCSA, center on cigarette packages and advertisements, such mandates also extend to other tobacco products and were motivated by evolving health concerns. As noted earlier, special textual warning requirements for smokeless tobacco products have been in place

200 *See id.* at 42,773–76.
201 *See id.* at 42,778–79.
202 *See id.* at 42,778.
203 *See id.* at 42,777–79.
204 *See id.* at 42,772.
205 *See id.* at 42,778.
206 *Id.* at 42,755.
207 *See id.* at 42,784.

since 1986.[208] In a 2000 FTC settlement, the seven largest American cigar manufacturers agreed to include health warnings on packaging and in advertisements.[209] The settlement led to the adoption of one of five textual cigar-smoking warnings.[210] The most significant expansion of tobacco product warning label requirements emerges from the 2009 TCA. Under the TCA, the FDA is granted authority to regulate all tobacco products which includes cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco, and, very significantly, *any other product it deems, by regulation, to be a tobacco product*.[211] The FDA under its "deeming" authority is able to apply a very broad definition of what a tobacco product is, including "any product made or derived from tobacco . . . including any component, part, or accessory of a tobacco product . . . ."[212] To date, the expanded regulatory power includes electronic nicotine delivery systems (e-cigarettes and e-liquid), cigars, hookah, and pipe tobacco.[213] The TCA scheme allows tobacco products that were on the market prior to 2007 to continue being sold without Administration approval, but other tobacco products are subject to regulation, either as equivalent to pre-2007 smoking implements or ones that must obtain a new tobacco marketing order.[214]

In May 2016, under the auspices of the TCA, the FDA issued a final deeming rule that established a regulatory floor for control of so-called "other tobacco products" ("OTP"), with a particular emphasis on electronic nicotine delivery systems.[215] Under the deeming rule, the Administration may use its power to restrict the sale, distribution, and promotion of OTPs, provided such actions are for public health purposes.[216] A key feature of this final rule is its focus on the issue of warning

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208 *See* Comprehensive Smokeless Tobacco Health Education Act of 1986, Pub. L. No. 99-252, 100 Stat. 30 (codified as amended at 15 U.S.C. §§ 4401–4406, 4408 (2012)). This law requires smokeless tobacco product packages and advertisements to include health related warning labels on a rotational basis. *Id.* at 31–32.

209 *FTC Announces Settlements Requiring Disclosure of Cigar Health Risks*, FTC (June 26, 2000), http://www.ftc.gov/news-events/press-releases/2000/06/ftc-announces-settlements-requiring-disclosure-cigar-health-risks [http://perma.cc/S9XY-8KZ3].

210 *Id.*

211 21 C.F.R. § 1100.1 (2019).

212 21 U.S.C. § 321(rr)(1) (2012).

213 *See* 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, 81 Fed. Reg. 28,974, 29,028 (May 10, 2016) (to be codified at 21 C.F.R. pts. 1100, 1140, and 1143).

214 *See* 21 U.S.C. § 387j (2012).

215 Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act, 81 Fed. Reg. at 28,974–75.

216 *Id.* at 28,975.

labels.[217] The warning requirements in the rule are centered on the dangers of nicotine, requiring language that states, "This product contains nicotine. Nicotine is an addictive chemical."[218] Packaging and advertising for cigars must continue to use one of five warnings, as well as an addictiveness warning.[219] Under the deeming rule, health warnings need to appear on at least 30% of each of the two principal display panels of packaging or 20% of print advertisements.[220]

In its notice of proposed rulemaking for the deeming rule, the FDA makes a detailed case in support of tobacco health warnings in both packaging and advertisements, to assist current and future smokers in understanding the serious adverse health consequences of smoking.[221] The Administration voices concerns it has about consumers' erroneous and unsubstantiated beliefs that tobacco products, other than cigarettes, are less addictive or not addictive at all.[222] According to the Administration, warnings ought to be directed to adolescents, whose lack of knowledge about the risks of cigarettes and other tobacco products, particularly e-cigarettes, make them very susceptible to resultant health risks.[223] The FDA strategy encompasses OTPs, which pose novel and unfolding health risks, as the products have changed in the short time since their introduction into the market in 2007.[224] The Administration's support of package warnings rests on the frequency of exposure to such messages, as warnings are present at the point of purchase, time of use, and impacts are likely to extend beyond vapers to the public at large.[225] Formatting of warning labels and ads is a major issue for the Administration, as research shows that warnings that are made in small font sizes have a much

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217 *See id.* at 28,988.

218 *Id.* at 28,979.

219 *See FTC Announces Settlements Requiring Disclosure of Cigar Health Risks*, *supra* note 209. The deeming rule adopted the cigar warnings that the FTC agreed to in its 2000 settlement with manufacturers. *See* Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act, 81 Fed. Reg. at 29061. The 2016 final rule contained a new cigar warning directed to pregnant women, "[c]igar use while pregnant can harm you and your baby." *See id.*

220 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, 79 Fed. Reg. 23142, 23205 (Apr. 25, 2014).

221 *Id.* at 23,142.

222 *Id.* at 23,166.

223 *See id.* at 23,146.

224 *See id.* at 23,144.

225 *Id.* at 23,164.

lower impact on general consumer awareness than those in larger font.[226]

Cigar companies and e-cigarette manufacturers pushed back against the deeming rule, claiming in a number of lawsuits that the regulation was unconstitutional.[227] As the Administrative Procedures Act and the Regulatory Flexibility Act govern the actions of the FDA, typically challenges against the Administration rest on allegations of a violation of one or both statutes.[228]

In *Nicopure Labs, L.L.C. v. FDA*, a Florida e-cigarette manufacturer alleged in the District Court for the District of Columbia that the FDA interpretation of a tobacco product that includes e-cigarettes was too broad, and as such, not in accordance with the Administrative Procedures Act.[229] The e-cigarette company argued that premarket certification, validation of health benefits, and nicotine warnings were all unnecessary.[230] A separate challenge in the same district court brought by eleven e-cigarette trade groups, including an allegation that the deeming rule violated free speech rights because of its prohibition on free sample distribution, was consolidated with *Nicopure*.[231] In ruling in favor of the FDA, the district court concluded that the allegations did not concern the details of the deeming rule, but rather focused on statutory requirements in the TCA.[232] Under the auspices of the TCA, the Administration had the necessary statutory authority to subject e-cigarette and liquid manufacturers to tobacco product regulation, and such action could not be characterized as arbitrary and capricious.[233] In using the *Central Hudson* commercial speech test noted earlier, the court in *Nicopure* found that the distribution of free samples of e-cigarette products is not sufficiently expressive

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226 *See id.* at 23,165. The FDA was very influenced by a 2001 European Directive (2001/37/EC) requiring that health warnings consume 30% on the front of the packaging and 40% on the back of the packaging. *Id.*

227 *See Lawsuits Challenging the FDA's Deeming Rule (2019)*, PUB. HEALTH L. CTR., http://www.publichealthlawcenter.org/resources/lawsuits-challenging-fda-deeming-rule [http://perma.cc/V9QG-U6YP] (last updated Mar. 5, 2020).

228 Administrative Procedures Act, Pub. L. No. 116-56, 60 Stat. 238 (1946) (codified as amended in scattered sections of 5 U.S.C.); Regulatory Flexibility Act, 5 U.S.C. §§ 601–612 (2018).

229 Nicopure Labs, L.L.C. v. FDA, 266 F. Supp. 3d 360, 366, 391 (D.D.C. 2017).

230 *Id.* at 367–68 ("This case does not pose the question—which is better left to the scientific community in any event—of whether e-cigarettes are more or less safe than traditional cigarettes. The Rule did not purport to take the choice to use e-cigarettes away from former smokers or other adult consumers; the issue is whether the FDA has the authority to require that the choice be an informed one.").

231 *Id.* at 366.

232 *Id.* at 368.

233 *Id.* at 393.

to constitute speech, and thus the FDA has the power, under the auspices of the TCA, to restrict such conduct.[234]

In July of 2017, the FDA announced a new comprehensive plan for tobacco and nicotine regulation to provide a multi-year roadmap—specifically to protect children and reduce tobacco related disease and death.[235] The Administration's goal is to strike a better balance between appropriate oversight of smoking, while encouraging development of innovative tobacco products that may be less dangerous than cigarettes.[236] As part of its regulatory effort, the FDA rolled back the implementation of the deeming rule to August 2021 for newly regulated tobacco products (cigars, pipe tobacco, and hookah tobacco) and to August 2022 for non-combustible products ("END").[237] As a result of litigation challenging the FDA rollback, the new tobacco product applications deadline was accelerated to 2020.[238] In 2018, the Administration issued three advanced notices of proposed rulemaking ("ANPR") dealing with nicotine levels, regulation of flavors, and regulation of premium cigars.[239] In the case of cigars, the ANPR solicited ideas about how current product warnings can be strengthened by adding any additional or alternative language.[240] A major focus of the ANPRs concerns the FDA's interest in establishing maximum nicotine levels that would make tobacco products less addictive, or even non-addictive, demonstrating that future tobacco abatement efforts will center on combating long-term product dependence.[241]

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234 *Id.* at 411.

235 *FDA announces comprehensive regulatory plan to shift trajectory of tobacco-related disease, death*, U.S. FOOD & DRUG ADMIN. (July 27, 2017), http://www.fda.gov/news-events/press-announcements/fda-announces-comprehensive-regulatory-plan-shift-trajectory-tobacco-related-disease-death [http://perma.cc/DJ5H-ZA7D].

236 *Id.*

237 *Id.*

238 *See* Am. Acad. of Pediatrics v. FDA, 379 F. Supp. 3d 461, 468, 498 (D. Md. 2019), *appeal docketed*, No. 19-2130 (4th Cir. Oct. 16, 2019). The original deadline of 2021 was challenged by the Vapor Technology Association ("VTA"), which filed suit on August 14, 2019, seeking to enjoin the FDA from enforcing its new deadline of 2020. *See* Verified Complaint (Preliminary Injunction Requested) at 2, Vapor Tech. Ass'n v. U.S. Food & Drug Admin., No. 5:19-cv-00330-KKC (E.D. Ky. Aug. 14, 2019). The VTA suit was subsequently dismissed for lack of standing and causation.

239 *See* Tobacco Product Standard for Nicotine Level of Combusted Cigarettes, 83 Fed. Reg. 11,818 (Mar. 16, 2018); Regulation of Flavors in Tobacco Products, 83 Fed. Reg. 12,294 (Mar. 21, 2018); Regulation of Premium Cigars, 83 Fed. Reg. 12,901 (Mar. 26, 2018).

240 *See* Regulation of Premium Cigars, 83 Fed. Reg. at 12,903.

241 *See* Tobacco Product Standard for Nicotine Level of Combusted Cigarettes, 83 Fed. Reg. at 11,819.

VI. WARNINGS AND VAPING

Cigarette labeling requirements are part of the universe of increasingly ubiquitous consumer product warnings, driven both by general product liability concerns and statutory health mandates.[242] Since their inception in the 1960s, cigarette label and advertisement regulations have been a core element of the tobacco use mitigation strategy. With the emergence of OTPs (e-cigarettes, heat not burn) in recent years, subject to the FDA's expanded authority through the deeming rule, the issue of product warnings arises not as a historical curiosity, but rather as a matter of immediate policy concern. Unlike cigarettes, the newer ENDs products use an e-liquid, varying compositions of chemical flavorings, propylene glycol, as well as vegetable glycerin.[243] Typically these products contain some level of nicotine and come in a dizzying assortment of flavors.[244] OTPs are not a single product, but are multiple devices that allow users to inhale an aerosol that simulates cigarette smoke.[245] Proponents of e-cigarettes advocate for their use as a safer choice than cigarettes, and promote ENDs as smoking cessation devices.[246] Taking a page from big tobacco, e-cigarette companies have combined clever marketing and use of sweet flavor additives to make these products extremely popular with school-aged children.[247] The rapid rise in adolescent vaping that may result in a new generation of nicotine addiction—reversing progress in

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242 *See* Thomas Whiteside, *Cutting Down*, NEW YORKER (Dec. 11, 1970), http://www.newyorker.com/magazine/1970/12/19/the-fight-to-ban-smoking-ads [http://perma.cc/K2F7-H2RG].

243 *See Vaporizers, E-Cigarettes, and other Electronic Nicotine Delivery Systems (ENDS)*, U.S. FOOD & DRUG ADMIN. (Sept. 12, 2019), http://www.fda.gov/tobacco-products/products-ingredients-components/vaporizers-e-cigarettes-and-other-electronic-nicotine-delivery-systems-ends [http://perma.cc/2PC4-MFL6].

244 *But see Do E-Cigs Contain Nicotine?*, VAPEMOUNTAIN.COM (Apr. 20, 2016), http://www.vapemountain.com/news/do-e-cigs-contain-nicotine.html [http://perma.cc/Q6JJ-BMVV] (noting that varying levels of nicotine are available in these products).

245 *See What Do We Know About E-cigarettes?*, AM. CANCER SOC'Y, http://www.cancer.org/cancer/cancer-causes/tobacco-and-cancer/e-cigarettes.html [http://perma.cc/4V3A-XSH4] (last updated Sept. 26, 2019).

246 *See* Michael Joseph Blaha, *5 Vaping Facts You Need to Know*, JOHNS HOPKINS MED., http://www.hopkinsmedicine.org/health/wellness-and-prevention/5-truths-you-need-to-know-about-vaping [http://perma.cc/QU3V-KB93] (last visited Oct. 13, 2019).

247 *See id.* The CDC estimated that between 2011 and 2015 the use of e-cigarettes among high school and middle school children increased by 900%. *Surgeon General's Advisory on E-cigarette Use Among Youth*, CTRS. FOR DISEASE CONTROL & PREVENTION, http://www.cdc.gov/tobacco/basic_information/e-cigarettes/surgeon-general-advisory/index.html [http://perma.cc/Y8UW-L5VP] (last reviewed Apr. 9, 2019). Several states are suing e-cigarette manufacturers for targeting children through deceptive marketing practices. *See* Naomi Martin, *Healey files lawsuit against JUUL, alleging a campaign to lure underage teens*, BOS. GLOBE, http://www.bostonglobe.com/2020/02/12/metro/ag-files-lawsuit-against-juul-alleging-campaign-lure-underage-teens/ [http://perma.cc/3A7E-ZMTT] (last updated Feb. 12, 2020, 12:16 PM).

smoking abatement—is a driving force in public health prevention, underpinning FDA action in the OTP arena.[248]

This growing concern over youth vaping escalated in 2019 as the CDC reported 1,604 lung injury cases in forty-nine states, which included thirty-four deaths in twenty-four states, with the common denominator linking these cases being the inhalation of vapors from ENDs products.[249] The vaping-related hospitalizations triggered heightened government scrutiny of e-cigarettes, led by both the FDA and the Centers for Disease Control and Prevention ("CDC").[250] A few local and state governments, following San Francisco's lead, have placed an outright ban on the sale of e-cigarettes in light of the mysterious outbreaks of serious pulmonary injury.[251] A more common regulatory reaction against ENDs is likely to result in comprehensive bans on the use of flavor additives such as menthol; both the White House and the FDA are supporting flavor bans.[252]

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248 *See id.*

249 *Outbreak of Lung Injury Associated with E-Cigarette Use or Vaping, Products*, CTRS. FOR DISEASE CONTROL & PREVENTION, http://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html [http://perma.cc/HJY4-7CTF] (last visited Nov. 10, 2019); *see also* Sydney Lupkin & Anna Maria Barry-Jester, *Mysterious Vaping Lung Injuries May Have Flown Under Regulatory Radar*, KAISER HEALTH NEWS (Aug. 27, 2019), http://khn.org/news/mysterious-vaping-lung-injuries-may-have-flown-under-regulatory-radar/ [http://perma.cc/783P-PZ5T]. In October 2019, the CDC issued new guidelines for vaping related lung injuries, classifying the condition as EVALI (e-cigarette or vaping product use associated lung injury). *See* 68 Morbidity and Mortality Weekly Report 919–27 (2019).

250 *See CDC, FDA, States Continue to Investigate Severe Pulmonary Disease Among People Who Use E-cigarettes*, CTRS. FOR DISEASE CONTROL & PREVENTION (Aug. 21, 2019), http://www.cdc.gov/media/releases/2019/s0821-cdc-fda-states-e-cigarettes.html [http://perma.cc/A8AP-ZF3Q].

251 *See* Victoria Colliver, *In California, Juul's problems are only beginning*, POLITICO (Sept. 17, 2019, 5:01 AM), http://www.politico.com/story/2019/09/17/juul-cigarettes-trump-california-san-francisco-1730095 [http://perma.cc/Z2XA-MSFD]; *see also* CNN NEWSOURCE, *Vape store owners are suing to stop the product bans in New York and Massachusetts*, NEWS CHANNEL 5 NASHVILLE (Oct. 7, 2019, 9:58 AM), http://www.newschannel5.com/news/national/vape-store-owners-are-suing-to-stop-the-product-bans-in-new-york-and-massachusetts [http://perma.cc/E9KY-5CJN]; *Vapor Technology Association Files Lawsuit Against New York Department of Health and Public Health and Health Planning Council to Stop Ill-Considered Flavor Ban*, CISION: PR NEWSWIRE (Sept. 25, 2019), http://www.prnewswire.com/news-releases/vapor-technology-association-files-lawsuit-against-new-york-department-of-health-and-public-health-and-health-planning-council-to-stop-ill-considered-flavor-ban-300925566.html [http://perma.cc/N2VS-2K2D]; *Read the Lawsuit: Vape Shops Sue to Overturn Gov. Charlie Baker's Four-Month Ban on Sale of Vaping Products*, MASSLIVE (Oct. 2, 2019), http://www.masslive.com/news/2019/10/read-the-lawsuit-vape-shops-sue-to-overturn-gov-charlie-bakers-four-month-ban-on-sale-of-vaping-products.html [http://perma.cc/RJ23-J4H8].

252 *See* Colliver, *supra* note 251; *see also* Andrew B. Meshnick et al., *How FDA Can Act On E-Cigarettes And Protect The Public Health*, HEALTH AFFAIRS (Sept. 17, 2019), http://www.healthaffairs.org/do/10.1377/hblog20190916.952475/full/ [http://perma.cc/FHZ7-U4FS]. The crackdown on vaping coming from the Executive branch narrowly focuses on reusable (rechargeable) vaping devices and does not cover cheaper disposable products which are readily available and come in an assortment of flavors. *See Matthew Perrone, FDA*

Two realities define the current public health efforts to combat the ills of smoking and reduce the resultant addiction to nicotine, combining to make this long-standing task a type of double bind for regulators. On one hand, health authorities face the ongoing challenge of traditional smoking health problems, and even in the face of significant reduction in this behavior, there is a seemingly intractable number of smokers who pursue this addiction, unmoved by long standing abatement strategies. On the other hand, public health authorities must now cope with the development of new tobacco products.[253] The rapid growth in use of e-cigarettes, particularly among young people, poses new and novel challenges for anti-smoking advocates.[254] Recent events underscore the lack of comprehensive scientific knowledge about the short and long-term physiological implications of ENDs use, underscoring the critical need for research in this area.[255] There is, however, enough evidence currently to conclude that e-cigarettes are a nicotine delivery device that can result in addiction and easily act as a gateway to more traditional cigarette smoking.[256] Compounding the challenge of e-cigarettes is their increasing use by adult smokers as a seemingly safer alternative to traditional cigarette[257]—an idea that is being endorsed with a dearth of evidence.[258] The power of a global tobacco industry as it moves into ENDs products, along with a host of new smoking options, present formable challenges to overtaxed public health regulators trying to keep up with the new developments and strength of the tobacco industry.[259] An already highly profitable

crackdown on vaping flavors has blindspot: disposables, AP NEWS (Feb. 7, 2020), http://apnews.com/600c4aa443dde043aad6f70a00251fa0 [http://perma.cc/H2ZE-7E8L].

253 *See* Ana Aceves, *Vaping May Lead Teens to Adopt Smoking Habits*, PBS SOCAL (Mar. 15, 2018), http://www.pbs.org/wgbh/nova/article/vaping-teen-smoking-habit/ [http://perma.cc/JEN3-Y6XJ].

254 *See id.*

255 *See Outbreak of Lung Disease Associated with the Use of E-Cigarette, or Vaping Products*, CTR. FOR DISEASE CONTROL & PREVENTION, http://www.cdc.gov/tobacco/ basic_information/e-cigarettes/severe-lung-disease.html [http://perma.cc/HJY4-7CTF] (last visited Oct. 13, 2019).

256 *See* Aceves, *supra* note 253.

257 *See id.*

258 *See id.*

259 The e-cigarette industry has taken a page from tobacco manufacturers, developing clever marketing strategies to attract youth to their products. *See E-Cigarette Marketing Continues to Mirror Cigarette Marketing*, CAMPAIGN FOR TOBACCO FREE KIDS: BLOG TOBACCO UNFILTERED (June 17, 2015), http://www.tobaccofreekids.org/blog/2015_06_17 _ecig [http://perma.cc/F73L-8Q7J]. A significant amount of e-cigarette marketing is done via social media sites geared toward children and young adults, in which product warnings and age restrictions are minimized. *See* Rick Nauert, *Aggressive Online Marketing of E-cigarettes May Target Teens*, PSYCHCENTRAL (Aug. 8, 2018), http://psychcentral.com/news/2015/10/05/aggressive-online-marketing-targets-teens-for-e-cigarettes/93128.html [http://perma.cc/CZH9-9T2L].

cigarette industry is reinventing itself, setting the stage for new chapters in smoking abatement battles.[260]

As noted in the beginning of this Article, effective health prevention and promotion is essential to the future of our health system. Addressing population health challenges, like smoking and accompanying nicotine addiction, have strong medical and economic implications. Unless more effective approaches are developed to reduce major preventable public health problems, no systemic reform, whatever its character, will find the elusive balance between cost and quality. To combat the ills of smoking in its traditional and evolving forms, health authorities will need to continue to apply established rules, as well as pursue new approaches to regulation that have the capacity to reduce and possibly eradicate this behavior.[261] As such, assessment of abatement tools, such as product warnings, should be ongoing as public health enforcement strategies must be adjusted to meet current challenges, particularly in fluid areas like smoking.

In reviewing the history of tobacco regulations over the past sixty years, mandatory product health warnings designed to educate and deter consumption can be characterized as a fundamental and lasting approach to smoking abatement. The review of cigarette warning labels in this piece demonstrates movement in regulation from modest textual warning requirements in the 1960 laws, such as the Public Health Cigarette Smoking Act, to the expansion of four rotational warnings in the 1984 CSEA, and, more recently, to further textual warnings and the addition of picture graphics in the 2009 TCA. While this movement is hardly rapid, it does reflect a deeper understanding of the array of tobacco research and expansion of knowledge about the physiological effects of smoking, with a greater current focus on nicotine exposure from OTPs, as well as a sustained commitment to the viability of warnings as a key public health measure.

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260 It is estimated that the e-cigarette market in 2018 in the United States was worth $11.26 billion and is estimated, by 2024, to grow to $18.12 billion, with an increase in online sales. *See E-Cigarette Market—Growth, Trends and Forecast (2019–2024)*, MORDOR INTELLIGENCE, http://www.mordorintelligence.com/industry-reports/global-e-cigarettes-market-industry [http://perma.cc/XE2Z-CQE7] (last visited Oct. 13, 2019); *see also* Josh Constine, *How Juul made vaping viral to become worth a dirty $38 billion*, TECH CRUNCH (Dec. 22, 2018, 10:58 AM), http://techcrunch.com/2018/12/22/juul-me-twice-shame-on-you/ [http://perma.cc/BQ5L-4RPA].

261 For a discussion on a British perspective on smoking eradication, a goal that transcends borders, see Jason Murugesu, *Will we ever stamp out smoking entirely?*, NEW STATESMAN AM. (Aug. 1, 2019), http://www.newstatesman.com/politics/health/2019/08/will-we-ever-stamp-out-smoking-entirely [http://perma.cc/RDW7-HE8M].

But nagging questions emerge from a review of tobacco product label warnings. Are tobacco-warning labels necessary? Are labels effective vehicles to inform and deter smoking? Can changes be made in tobacco product labels to make them more impactful? How should warnings be approached in the new landscape of OTPs? Concerning the question of whether there is a need to have warning labels, there are simply no voices of opposition to these warnings.[262] They have garnered universal domestic and international support as a core enforcement mechanism from public health policy makers and regulators alike.[263] While product manufacturers and sellers may not appreciate text warnings on packaging, there is no push back from this sector on this requirement—on the menu of possible controls, it does not impose a serious marketing impediment.[264] In fact, the e-cigarette manufacturers of their own accord, independent of government directives, added a nicotine-warning label in anticipation of the eventuality of such a mandate, and more importantly, as a mechanism to deter product liability litigation.[265]

The second question as to whether cigarette-warning labels actually work opens a more controversial line of inquiry. Perhaps President Nixon's guarded opinion about cigarette warnings, noted earlier in this piece, was noteworthy as to the government's responsibility to notify the public about known dangers and let individuals choose to smoke or not.[266] President Nixon characterized the science driving warnings as controversial, but currently, with the exception of e-cigarettes, the case against traditional tobacco is definitive, and the quest to avoid dangers to health through safe cigarette alternatives still remains a Sisyphean one.[267]

President Nixon's other observation expressing doubt about the effect of cigarette warnings on the public mirrors long standing opinions on both sides of the smoking issue. As noted in prior discussion, regulators, as early as 1967, frequently vented their frustrations about the textual package warnings, and in

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262 *See* Abby Ohlheiser, *Big tobacco companies are putting big warning labels on their e-cigarettes*, WASH. POST (Sept. 29, 2014, 10:21 AM), http://www.washingtonpost.com/news/to-your-health/wp/2014/09/29/big-tobacco-companies-are-putting-big-warning-labels-on-their-e-cigarettes/ [http://perma.cc/L55A-ZZHX].

263 *See id.*

264 *See id.*

265 *See id.*

266 *See* Whiteside, *supra* note 242.

267 *See* Laurie McGinley, *Forget Those Occasional Cigarettes: There is No Safe Smoking Level*, WASH. POST (Dec. 5, 2016, 8:00 AM), http://www.washingtonpost.com/news/to-your-health/wp/2016/12/05/forget-those-occasional-cigarettes-there-is-no-safe-smoking-level/ [http://perma.cc/R23E-JUUV].

fact, an outpouring of criticism about the ineffectiveness of such regulation preceded every major tobacco bill.[268] The U.S., once the leader in mandating tobacco warnings, fell behind in smoking controls as other nations implemented graphic warning label requirements, spurred by global tobacco abatement policies adopted in the WHO's Framework Convention on Tobacco Control.[269] Eventually in 2009, with the passage of the TCA, the U.S. joined the global community in finally requiring graphic warning labels.[270] However, as discussed, the regulatory efforts in the U.S. to implement graphic warnings have been stormy, unsettled, and delayed.

Confronting the analytical question of whether text only or graphic warnings work better to prevent and deter smoking behavior places one into the murky waters of behavioral economics. Some studies on the effectiveness of tobacco warnings on youth and adult smokers conclude that textual warnings may increase health knowledge and awareness of risk based on size and design, but, at best, the results are tepid.[271]

On the other hand, studies concerning the impacts of graphic package warning labels are more positive.[272] One mega analysis of the area concluded that graphic anti-smoking warnings could elicit "maladaptive psychological responses"—in other words, they could work.[273]

No doubt package-warning labels offer a relatively inexpensive mechanism to communicate with smokers at the point of purchase; however, isolating the impacts of pictorial warnings on behavior reduction, independent of other regulatory controls, is largely a matter of speculation. Support for warnings

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268 *See* Luca Paoletti et al., *Current Status of Tobacco Policy and Control*, 27 J. THORACIC IMAGING 213, 215 (2012) ("A 1967 FTC report concluded that 'the warning label on cigarette packages has not succeeded in overcoming the prevalent attitude toward cigarette smoking created and maintained by the cigarette companies through their advertisements, particularly the barrage of commercials on television, which portray smoking as a harmless and enjoyable activity that is not habit forming and involves no hazards to health.'").

269 WORLD HEALTH ORG., *supra* note 166, at 9–10.

270 *See* Family Smoking Prevention and Tobacco Control Act, Pub. L. 11, 123 Stat. 1776 (codified as amended in 21 U.S.C. §§ 387, 387a–387u, 387a–1, 387f–1 (2012)).

271 *See* David M. Erceg-Hurn & Lyndall G. Steed, *Does Exposure to Cigarette Health Warnings Elicit Psychological Reactance in Smokers?*, 41 J. APPLIED SOC. PSYCHOL. 219, 230 (2011); *see also* William G. Shadel et al., *Do Graphic Health Warning Labels on Cigarette Packages Deter Purchases at Point-of-Sale? An Experiment with Adult Smokers*, 34 HEALTH EDUC. RES. 321, 321–31 (2019). The Shadel article notes that various types of analyses on textual and pictorial tobacco warnings have found that pictorial warnings are recalled more readily, generate more negative cognitions about smoking, and have greater impacts on prevention and smoking reduction. *Id.*

272 *See* Erceg-Hurn & Steed, *supra* note 271, at 219.

273 *See id.*

rests as much on intuition as fact. Review of American regulatory history demonstrates that there is a long-standing belief that textual warnings have little effect overtime—the use of graphic labels has been delayed for almost ten years, so, as yet, there is no experience with graphics in the U.S. American cigarette marketplace. Perhaps a better gauge about the impacts of warnings can be drawn from the reactions to expanded warning labels on the part of the smoking industry. As text warnings are relatively benign, occupying a side panel of cigarette packs, displayed in similar fonts and colors blending with the overall container, they became predictable and easily ignored. Graphic warnings, on the other hand, featuring jarring images that essentially change the character of the product package, have not been met with industry acquiescence, but rather sparked vigorous legal challenges that have foiled this initiative for over a decade, which could be indicative of the fact that they may actually work.

It is possible to envision an even more stringent and detailed tobacco warning label requirement than the August 2019 graphic warnings proposed rule, akin to labeling mandates for over-the-counter drugs.[274] Another direction that could be taken is to adopt the approach of Australia and a number of other countries that requires cigarettes to be sold in plain packages, containing only a warning, without signature brand designs.[275] While plain packaging could be in our future, at this point, graphic warning labels need to be adopted and their effectiveness assessed over a number of years. Such regulatory impact assessments need to occur in a more regular and timely manner than was the case with prior warning label analyses and should be based on more grounded methodological determinations of costs and benefits. The fact that label warnings have been used for many years should not establish them as permanent regulatory strategies that are not frequently revisited and updated—or even abandoned if they have lost their efficacy.

It would be wrong to suggest that the FDA has been a totally absent regulator in the vaping arena.[276] Since issuing the

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274 *See The Over-the-Counter Medicine Label: Take a Look*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/drugs/resources-you-drugs/over-counter-medicine-label-take-look [http://perma.cc/T3L7-SYBA] (last reviewed Sept. 27, 2017).

275 *See* Thomas Parker, *From Uruguay to Saudi Arabia: 14 countries that have implemented plain tobacco packaging*, NS PACKAGING (May 28, 2019), http://www.nspackaging.com/analysis/plain-tobacco-packaging/ [http://perma.cc/8C8F-5HEH].

276 *See* Katie Thomas & Sheila Kaplan, *E-Cigarettes Went Unchecked in 10 Years of Federal Inaction*, N.Y. TIMES (Oct. 14, 2019, 5:12 PM), http://www.nytimes.com/2019/10/14/health/vaping-e-cigarettes-fda.html [http://perma.cc/YT32-E7H3].

deeming rule in 2016,[277] the Administration's Center for Tobacco Products ("CTP") has moved on a number of fronts to address labeling, manufacturing, and marketing of ENDs products.[278] In particular, emphasis has been placed on preventing youth sales and use; conducting retailer and manufacturer checks; developing product premarket authorization policies; and sponsoring and promoting research.[279] In addition, the FTC is also involved in e-cigarettes, as it continues its traditional role in policing unfair and deceptive practices in the tobacco products arena.[280] However, the recent outbreaks of serious lung damage in vapers rightly calls into question the adequacy of the current regulatory structure.[281]

The question arises as to whether the centralized regulatory structure of the 2009 TCA is optimal to meet the challenges posed by vaping—a practice that was barely in existence when the TCA was enacted. Vaping-related lung disease, also known as EVALI, has cast a bright light on the potential hazards in e-liquids, sparking an awareness of both the complexity and lack of knowledge of the underlying health exposures.[282] While uniformity in federal regulatory approaches to e-cigarettes is ultimately desirable, given this lack of certainty about the safety of these diverse products and nicotine delivery devices, it may be desirable to consider involvement of other regulatory actors, and processes in framing warning labels in the ENDs area.[283] It is noteworthy that in the 2020 Trump-proposed federal budget there is a recommendation that a new tobacco control agency be created in the Department of Health and Human Services, stripping the FDA of this responsibility.[284]

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277 The decision to regulate combustible cigarettes as tobacco products, primarily under FDA auspices, is the result of many years of effort to centralize tobacco regulation that culminated in the 2009 TCA.

278 *See* Ned Sharpless, *How FDA is Regulating E-Cigarettes*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/news-events/fda-voices-perspectives-fda-leadership-and-experts/how-fda-regulating-e-cigarettes [http://perma.cc/ZB8P-LZ7J] (last updated Sept. 10, 2019).

279 *See id.*

280 *See* Jennifer Maloney, *Juul's Marketing Practices Under Investigation by FTC*, WALL STREET J. (Aug. 29, 2019), http://www.wsj.com/articles/juuls-marketing-practices-under-investigation-by-ftc-11567096073 [http://perma.cc/7F28-67EC].

281 *See* Michael Siegel, *POV: New FDA Regulations on Vaping Products a Failure*, BU TODAY (July 13, 2016), http://www.bu.edu/articles/2016/fda-vaping-regulations [http://perma.cc/VBB8-N7FG].

282 *See* Jennifer E. Layden et al., *Pulmonary Illness Related to E-Cigarette Use in Illinois and Wisconsin—Preliminary Report*, NEW ENG. J. MED. (Sept. 6, 2019), http://www.nejm.org/doi/full/10.1056/NEJMoa1911614 [http://perma.cc/K89Y-ND2L].

283 *See What is Vaping?*, VAPING, http://vaping.org/ [http://perma.cc/DD6P-8XSX] (last visited Oct. 13, 2019).

284 Nicholas Florko, *Trump Doesn't Want the FDA to Regulate Tobacco*, STAT (Feb. 10, 2020), http://www.statnews.com/2020/02/10/trump-doesnt-want-the-fda-to-regulate-tobacco/ [http://perma.cc/C68W-U62H]. It is difficult to pinpoint the motivations for this proposal with certainty. On the one hand, the FDA can be seen as a tepid regulator, slow

The FDA regulatory scheme for e-cigarette products follows the dictates of the 2009 TCA and is actualized through the Administration's deeming rule. Other regulatory avenues within the Food, Drug, and Cosmetic Act ("FDCA") have not been pursued since the Supreme Court decision in *FDA v. Brown & Williamson* that held that tobacco products, as marketed, could not be regulated under the FDCA, triggering the subsequent enactment of the TCA.[285] While the *Brown & Williamson* case appears to be superseded by the TCA, the 2009 regulatory scheme does not allow tobacco products, without therapeutic value, to be explicitly regulated as either a drug or medical device.[286] A federal court in *Sottera v. FDA* reiterated *Brown & Williamson* in upholding an e-cigarette manufacturer's argument that their products could not be regulated separate from the TCA.[287] At issue in *Sottera* was whether e-cigarettes could be regulated as unapproved drug device combinations.[288] It is noteworthy that a key factor in the *Sottera* analysis limiting the FDA's authority is that the product at issue was not being sold for therapeutic purposes, but rather recreational.[289] The conclusion can be made that a device sold for therapeutic purposes would fall within the ambit of Administration oversight as a drug/medical device.[290] It is evident that e-cigarettes are being promoted to adults for smoking cessation, and as such, may be regulated as a type of medical device.[291] This opens the door to another possibility, beyond the TCA scheme, for additional e-cigarette FDA action—such as

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to act against the threats posed by the explosion in e-cigarettes, and generally overwhelmed by its overall mandates. But on the other hand, the FDA tobacco regulatory structure is well developed and embodies the requisite authority to be a meaningful public health authority in the e-cigarette arena. Creating a new regulatory body may only serve to further delay necessary oversight at a time when both the products and their markets are far ahead of government control.

285 FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 143 (2000).

286 *See* Clarification of When Products Made or Derived From Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding "Intended Uses," 82 Fed. Reg. 2,193 (Jan. 9, 2017) (to be codified at 21 C.F.R. pts 201, 801, and 1100).

287 Solterra, Inc. v. FDA, 627 F.3d 891, 897–98 (D.C. Cir. 2010).

288 *See id.* at 892.

289 *See id.* at 898. Therapeutic purposes under the FDCA include use in the diagnosis, cure, mitigation, treatment, or prevention of disease, according to 21 U.S.C. § 321 (g)(1) (2018). *See id.* at 893–94.

290 *See* Clarification of When Products Made or Derived From Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding "Intended Uses," 82 Fed. Reg. 2,193.

291 *See* Esther Wang, *Juuling Is Fine, Actually (For Adults Who Want to Quit Smoking Cigarettes)*, JEZEBEL (Sept. 30, 2019, 2:05 PM), http://jezebel.com/juuling-is-fine-actually-for-adults-who-want-to-quit-1838622453 [http://perma.cc/Z9EU-FDZM]; s*ee also* Belinda Borrelli & George T. O'Connor, *E-Cigarettes to Assist with Smoking Cessation*, 380 NEW ENG. J. MED. 678, 678 (Feb. 14, 2019), http://www.nejm.org/doi/full/10.1056/NEJMe1816406 [http://perma.cc/8N52-4TUN].

regulating ENDs as over-the-counter medical devices. As an OTC device, it is comparable to other tobacco prevention products. ENDs devices and e-liquids would need to meet more detailed labeling requirements under FDA-OTC regulations.[292] Under device labeling mandates, the FDA can tailor an OTC product label to include additional information that is specific to a given health concern and make revisions as new research unfolds. Presently, the FDA can move closer to declaring an OTP as "safer" if the product undergoes a more rigorous review and demonstrates a lower risk to smokers ("MRTP," or modified risk tobacco product).[293] It is unclear, however, if an MRTP approval can allow the OTP manufacturer to claim that the ENDs device is actually a smoking cessation device.[294] Such a claim goes beyond a stipulation that the smoking product is "safer" into the realm of medical devices.[295]

Vaping entails igniting a chemical cocktail of ingredients, some of which may be quite harmful.[296] As such, regulatory oversight could benefit from expanding e-cigarettes into the purview of the Federal Hazardous Substances Act ("FHSA"), under the jurisdiction of the U.S. Consumer Products Safety Commission ("CPSC").[297] The current FDA deeming rule could be strengthened by inclusion of an additional warning mandate focused on chemical exposure; a joint agency-labeling scheme with input from the CPSC concerning hazardous chemicals content would be a more robust labeling scheme. It appears that vaping chemicals meet the criteria required for application of labeling mandates under the FHSA.[298] At the time cigarettes were excluded from FHSA jurisdiction by Congress, smoking products did not extend beyond use of plant-based medium, but now clearly fall into the realm of hazardous chemicals.[299] Broadening CPSC

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292 *See General Device Labeling Requirements*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/medical-devices/device-labeling/general-device-labeling-requirements [http://perma.cc/36ZE-WLUY] (last updated Mar. 27, 2018) (citing 21 C.F.R. § 801 (2018)).

293 *See Modified Risk Tobacco Products*, *supra* note 160.

294 *See id.*

295 *See id.*

296 *See* Carley Thompson, *Meet the 5 Chemicals You Didn't Know Were in Vaping Products*, PUB. HEALTH INSIDER (June 14, 2017), http://publichealthinsider.com/2017/06/14/meet-the-5-chemicals-you-didnt-know-were-in-vaping-products/ [http://perma.cc/FQ5X-ATG7]; *see also* Katelyn Newman, *Vaping and E-Cigarettes: The New Public Health Problem*, U.S. NEWS (Sept. 30, 2019, 9:00 AM), http://www.usnews.com/news/healthiest-communities/articles/2019-09-30/vaping-and-e-cigarettes-a-new-public-health-problem [http://perma.cc/QTZ2-CEJX].

297 *See* Federal Hazardous Substances Act, 15 U.S.C. § 1261 (2012).

298 *See Federal Hazardous Substances Act (FHSA) Requirements*, CPSC, http://www.cpsc.gov/Business--Manufacturing/Business-Education/Business-Guidance/FHSA-Requirements/ [http://perma.cc/D3EY-BWVX] (last visited Oct. 28, 2019).

299 Klebe, *supra* note 93, at v.

jurisdiction to include e-cigarette regulation builds on existing Commission authority to regulate e-liquid containers.[300]

Warning label jurisdiction should be expanded to the state level in keeping with the TCA, which generally carves out a greater role for state and local government involvement in tobacco regulation. During this period of uncertainty, it seems reasonable for states to have authority to add their own warning language to e-cigarette products, provided a given state can make the case that the additional information being added to a warning fosters public health interests. Unlike traditional cigarettes, where regulation is the byproduct of years of study, the uncertainties surrounding ENDs products could benefit from regulatory initiatives warranting experiments with use of a variety of OTP warning labels.

Warning labels are only one strategy that can be identified in the long history of cigarette abatement, and as noted in this piece, they are not foolproof and need to be continually assessed and amended to reflect changes in science and public response. However, in the face of e-cigarette triggered lung disease, warning labels take on a significant role in filling a regulatory void in the midst of a public health emergency. Unless these products are actually banned, it becomes critical to both strengthen e-cigarette warnings and expand the field of regulators and their responsibilities for crafting these new vaping warnings. E-cigarette and e-liquid warning labels should go beyond a brief statement about nicotine and also warn about the danger of inhaling chemical constituents of e-liquids that are carriers for the nicotine. The warnings should state that vaping products are dangerous and that it is recommended by medical authorities that individuals refrain from the recreational use of the product, as this practice may result in serious lung damage. Once e-cigarettes and e-liquids have undergone successful premarket review by the FDA, that should also be noted on the product label. In addition, like a food label, the chemical content in the e-cigarette ought to be disclosed, listed on the package, and jointly regulated by the CPSC.

The arguments made by this new industry that e-cigarettes can lead to smoking cessation should not be casually dismissed

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300 *See* Jim McDonald, *An Obscure Safety Rule Could Shut Down the Vaping Industry*, VAPING360 (Apr. 29, 2019), http://vaping360.com/vape-news/79053/an-obscure-federal-safety-rule-could-cripple-the-vaping-industry/ [http://perma.cc/R5N2-BPTE]; *see also* Letter from Mary F. Toro, Dir. of Regulatory Enf't Div., Office of Compliance & Field Operations (July 22, 2016), http://www.cpsc.gov/s3fs-public/pdfs/foia_CNPPA07222016revisedIndustryLetterFINAL.pdf [http://perma.cc/MPW9-P3NT].

but need to be verified through extensive scientific research. The newest entry into the OTP market, the Philip Morris I Quit Ordinary Smoking ("IQOS"), is a heat-not-burn cigarette device that has obtained an FDA Premarket Tobacco Application ("PMTA").[301] The IQOS approval was granted based on the conclusion that this heat-not-burn product produces fewer or lower levels of toxins than traditional cigarettes.[302] The FDA stresses that the award of the PMTA does not mean that the product is safe, and that the IQOS will be considered a cigarette, necessitating that they meet current labeling and advertising restrictions.[303] The FDA decision is not without controversy, as health advocates have pointed out the lack of research, beyond Philip Morris' own study, that the IQOS actually helps individuals either reduce smoking generally or that the product is any safer for an individual's lungs and immune system.[304]

VII. CONCLUSION

In the annals of public health, few issues have garnered as much attention as cigarette smoking. Although dramatic progress has been made in smoking abatement, the emergence and rapid proliferation of other tobacco products, especially e-cigarettes, results in new challenges emerging in this arena. Package label warnings continue to be a foundational regulation needed to both educate and deter, dating back to the 1970s—the period in which the 91st Congress enacted the Public Health Cigarette Smoking Act. As smoking sparked multiple regulatory interventions, it is difficult to isolate the singular contribution of package warnings in isolation from other abatement measures. The review of the legislative history of tobacco label regulations leads to the conclusion that text-only warnings appear to have had diminishing returns on smoking prevention and cessation. While graphic warnings have garnered global support, there is simply no American experience with this approach and judging their impact prior to implementation, even in the face of more

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301 *See FDA permits sale of IQOS Tobacco Heating System through premarket tobacco product application pathway*, FDA (Apr. 30, 2019), http://www.fda.gov/news-events/press-announcements/fda-permits-sale-iqos-tobacco-heating-system-through-premarket-tobacco-product-application-pathway [http://perma.cc/C7HH-KLMM]. For a deep dive into FDA policy concerning PMTA in the context of IQOS, see Eric N. Lindblom, *The Tobacco Control Act's PMTA & MRTP Provisions Mean to Protect the USA From Any New Tobacco Products That Will Not Reduce Health Harms—But FDA Isn't Cooperating*, J. HEALTH CARE L. & POL'Y, (forthcoming 2020).

302 *See id.*

303 *See id.*

304 *See* Lisa Rapaport, '*Heat-not-burn' cigarettes still damage lungs*, REUTERS (Sept. 18, 2018, 10:15 AM), http://www.reuters.com/article/us-health-iqos/heat-not-burn-cigarettes-still-damage-lungs-idUSKCN1M12CB [http://perma.cc/48NZ-S33W].

extensive research, is still a matter of speculation. On the other hand, it seems clear that current e-cigarette warnings need to be strengthened, and until the FDA engages in complete review of e-cigarette products, including e-liquids, multiple regulators should be encouraged to contribute to the development of more impactful product warnings.

President Nixon's reflection on cigarette warnings, a half century ago, which concluded that the government's role is to simply provide information about risks and let individuals choose, belies the need for vigilance in addressing this ongoing public health challenge. Our society has paid, and continues to pay, a very high price in placating economic and alleged liberty interests related to tobacco.[305] Both individual and population health demand maintenance of an aggressive posture in the smoking area, as this behavior has significant implications on the financial sustainability of the broader health system and the future of reforms in this sector.

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305 *See* Gallagher v. City of Clayton, 699 F.3d 1013, 1017–18 (8th Cir. 2002).