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## The “Deeming Rule”: The FDA’s Destruction of the Vaping Industry

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# The “Deeming Rule”

## THE FDA’S DESTRUCTION OF THE VAPING INDUSTRY

“I currently work alone to build [devices that power atomizers in e-cigarettes] for my local community. It took me years to find a hobby that I excelled at and thoroughly enjoy. Business has been steadily increasing and [I] have plans to expand and hire employees. But at the proposed fees, I would have no choice but to stop.”<sup>1</sup>

### INTRODUCTION

The Food and Drug Administration (FDA) is the oldest consumer protection agency in the United States, officially created in 1930.<sup>2</sup> The agency is tasked with the responsibility of “protecting the public health by ensuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices . . . our nation’s food supply, cosmetics, and products that emit radiation.”<sup>3</sup> It has regulated the tobacco industry since researchers discovered that cigarettes were detrimental to human health.<sup>4</sup> According to the FDA, tobacco use kills more than 480,000 people in the United States each year, and each day about 600 youth become daily smokers.<sup>5</sup> About 42.1 million Americans smoke cigarettes.<sup>6</sup>

The FDA’s new “Deeming Rule,” an amendment to President Barack Obama’s 2009 Family Smoking Prevention and

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<sup>1</sup> Brief of Amicus Curiae Smoke-Free Alternatives Trade Association in Support of Plaintiffs’ Motions for Summary Judgment at 7, *Nicopure Labs, LLC v. Food and Drug Administration*, 266 F. Supp. 3d 360 (D.D.C. 2017) (No. 16-0878), 2016 WL 6355070 (survey response from an artisan in the business of crafting hand-engraved box mod units for vaping use).

<sup>2</sup> *U.S. Food & Drug Administration: History*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/WhatWeDo/History/default.htm> [https://perma.cc/34LZ-AVCE].

<sup>3</sup> *U.S. Food & Drug Administration: What We Do*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/WhatWeDo/> [https://perma.cc/CH9C-4LL3].

<sup>4</sup> Kristi Keck, *Big Tobacco: A History of its Decline*, CNN (June 19, 2009) <http://edition.cnn.com/2009/POLITICS/06/19/tobacco.decline/> [https://perma.cc/YP2T-U6GT].

<sup>5</sup> *Overview of the Family Smoking Prevention and Tobacco Control Act*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm246129.htm> [https://perma.cc/9Z46-A7VD].

<sup>6</sup> *Id.*

Tobacco Control Act (the Tobacco Control Act),<sup>7</sup> expands the FDA's authority from only regulating traditional tobacco cigarettes based on their negative health effects, to now regulating all other categories of "tobacco products," like e-cigarettes and vaporizers.<sup>8</sup> The Deeming Rule, a series of regulations, states that once the FDA has deemed a product to be a tobacco product, it can be subsequently restricted in sale, distribution, and advertising by the FDA. The purpose of the Deeming Rule is

(1) [t]o deem all products that meet the definition of 'tobacco product' under the law . . . and subject them to the tobacco control authorities in chapter IX of the FD&C Act and FDA's implementing regulations; and (2) to establish specific restrictions that are appropriate for the protection of the public health for the newly deemed tobacco products.<sup>9</sup>

Specifically, the regulation deems e-cigarettes and similar products to be tobacco products, subjecting them to the same intense regulatory treatment as traditional cigarettes.<sup>10</sup>

The FDA has concluded that these other tobacco products pose health risks to society, so must be subject to rigorous approval processes and heavily regulated by the government before such products are allowed to be sold in the marketplace. In effect, this regulation's approval processes place burdensome monetary and time barriers on e-cigarette companies, threatening their demise by forcing them to comply. The FDA derives its authority to pass this new regulation from the Tobacco Control Act.<sup>11</sup> As of August 8, 2016, the Tobacco Control

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<sup>7</sup> Family Smoking Prevention and Tobacco Control Act of 2009, Pub. L. No. 111-31, § 3(8), 123 Stat. 1776, 1783 (codified as amended at 21 U.S.C. § 387 (2012)).

<sup>8</sup> 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; Final Rule, 81 Fed. Reg. 28975 (May 10, 2016) (to be codified at 21 C.F.R. pts. 1100, 1140, 1143) [hereinafter Deeming Rule]. A typical e-cigarette looks almost identical to a traditional cigarette in terms of size, shape, and weight, and delivers "flavored smoke-like vapor." *Differences Between E-Cigarettes and Vaporizers*, <https://www.vaporfi.com/learn/e-cigarettes-vs-vaporizers.html> [<https://perma.cc/T46W-KKN9>]. They contain a "battery, the cartomizer (a combination of the cartridge and the atomizer) and a silicone mouthpiece. An LED light on the end of the battery glows when the user inhales, resembling the burning tip of a cigarette. The cartridge within the cartomizer holds the e-liquid and is usually disposable once empty." *Id.* On the other hand, vaporizers are both more advanced and customizable by consumers. The device has a "large battery on one end, a clear reservoir tank in the middle and a mouthpiece. By pressing a small button on the side of the battery, the user engages the heating element which vaporizes the e-juice and releases tasty vapor." *Id.* A vaporizer is larger than an e-cigarette, less traditional looking, delivers nicotine more smoothly and is consistently refillable, whereas e-cigarettes are mostly disposable and provide more limited flavor experimentation. *Id.*

<sup>9</sup> Deeming Rule, 81 Fed. Reg. 28975.

<sup>10</sup> *Id.*

<sup>11</sup> *Overview of the Family Smoking Prevention and Tobacco Control Act*, *supra* note 5.

Act has granted the FDA broad authority to regulate the tobacco market, including e-cigarettes and vaporizers.<sup>12</sup> The Tobacco Control Act allows the FDA to impose strict standards and require companies to pay high fees with mandatory product applications for market entry.<sup>13</sup> Since the act’s May 2016 announcement, numerous e-cigarette and vaporizer companies have filed lawsuits against the FDA, claiming this broad grant of authority is unconstitutional.<sup>14</sup> The high fees and burdensome regulatory scheme threaten to put small, previously booming businesses and vapor shops out of business for good.<sup>15</sup>

While nicotine-tobacco products have been heavily regulated since Obama’s 2009 legislation, this abrupt addition to the law to include some tobacco-free products is an unauthorized extension of congressional authority.<sup>16</sup> The FDA, under the Administrative Procedure Act (APA), unjustifiably concludes that vaping devices, including components of the devices, are “tobacco products”<sup>17</sup> under the Deeming Rule,<sup>18</sup> a ruling that is both “arbitrary [and] capricious,” and “unsupported by substantial evidence.”<sup>19</sup> The Deeming Rule specifically violates the APA because the FDA failed to perform the thorough cost-benefit analysis that the APA requires, and instead passed arbitrary, burdensome legislation without considering alternative avenues of regulation.<sup>20</sup> The FDA neglected to consider less burdensome alternatives that would be more fair to tobacco

<sup>12</sup> Deeming Rule, 81 Fed. Reg. 28975.

<sup>13</sup> *Id.*

<sup>14</sup> TOBACCO CONTROL LEGAL CONSORTIUM, LAWSUITS CHALLENGING THE FDA’S DEEMING RULE (2016), <http://publichealthlawcenter.org/sites/default/files/resources/FDA-Tobacco-Deeming-Lawsuits-as-of-June-2016.pdf> [<https://perma.cc/Y3PS-ZWJP>].

<sup>15</sup> *See id.*

<sup>16</sup> Complaint at 10, *Nicopure Labs, LLC v. FDA*, 266 F. Supp. 3d. 360 (D.D.C. 2017) (No. 16-00878) 2016 WL 2730789 [hereinafter *Nicopure Labs Complaint*]. The Deeming Rule regulates tobacco products as well as tobacco-free products, which include individual component parts that eventually assemble to create e-cigarettes and vaporizers.

<sup>17</sup> *See* 21 U.S.C. § 387j (2012).

<sup>18</sup> Deeming Rule, 81 Fed. Reg. at 29015.

<sup>19</sup> 5 U.S.C. § 706(2)(a), (2)(e) (2012). Under this section, courts must

hold unlawful and set aside agency action, findings, and conclusions found to be . . . (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law . . . [or] (E) unsupported by substantial evidence in a case subject to [5 U.S.C. §§ 556 and 557] or otherwise reviewed on the record of an agency hearing provided by statute.

*Id.* While the duty to perform a cost-benefit analysis is not written into the text of the APA, courts have interpreted this section to recognize the need for cost-benefit analysis “as an appropriate and possibly even necessary part of the regulatory process.” Eric Posner, *Controlling Agencies with Cost-Benefit Analysis: A Positive Political Theory Perspective*, 68 U. CHI. L. REV. 1137, 1138 (2001).

<sup>20</sup> 21 U.S.C. § 387j.

companies, while still prioritizing the health of Americans, making the Deeming Rule an unauthorized congressional action.

Part I of this note provides a brief history of tobacco regulation and the Tobacco Control Act. This Part also explains the lack of conclusive scientific evidence of e-cigarettes' harmful effects, especially relative to traditional cigarettes. Part II describes the Deeming Rule and its burdensome registration requirements, highlighting recent litigation. Part III recounts the purpose of the APA and analyzes the act in light of the new FDA regulations on e-cigarettes. Specifically, this Part argues that the Deeming Rule is a clear violation of the APA because the rule is arbitrary and lacks substantial evidence to support its passage, as legislators failed to adequately perform a cost-benefit analysis when they created the guidelines that lack merit. Finally, Part IV proposes alternative solutions to the over-inclusive law that would comply with the APA by adequately accounting for both costs and benefits. E-cigarettes and other electronic nicotine delivery systems (ENDS) products should be treated as consumer products instead of tobacco products. The FDA must either weaken or eliminate the stringent premarket authorization requirements and change the date by which new companies would have to file in order to avoid the burdensome regulations.

## I. TOBACCO REGULATION

### A. *History*

Startling public health research prompted Congress to regulate the tobacco market to keep consumers completely informed and knowledgeable about the health risks of tobacco product use. According to the FDA, “[t]obacco use is the single largest preventable cause of disease and death in the United States.”<sup>21</sup> In 1965, the Federal Cigarette Labeling and Advertising Act sought to increase consumer knowledge of nicotine-related health risks by requiring a warning label on cigarette packaging reading: “Caution: Cigarette Smoking May Be Hazardous to Your Health.”<sup>22</sup> While this legislation required labels and Federal Trade Commission reports to Congress on the effectiveness of this

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<sup>21</sup> *FDA's New Regulations for E-Cigarettes, Cigars, and All Other Tobacco Products*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm394909.htm> [<https://perma.cc/9BTG-HLZT>].

<sup>22</sup> *Selected Actions of the U.S. Government Regarding the Regulation of Tobacco Sales, Marketing, and Use, Legislation*, CTRS. FOR DISEASE CONTROL & PREVENTION, [https://www.cdc.gov/tobacco/data\\_statistics/by\\_topic/policy/legislation/](https://www.cdc.gov/tobacco/data_statistics/by_topic/policy/legislation/) [<https://perma.cc/FPC7-J6KT>].

labeling, it fell short in regulating all types of cigarette advertising, especially targeted to the youth population.

In the 1990s, private litigation changed the landscape of tobacco regulation. The Master Settlement Agreement (MSA) resulted from a private tort liability suit and became the “largest civil litigation settlement in U.S. history.”<sup>23</sup> In 1994, four different states came together to sue large tobacco companies, demanding compensation for Medicaid and other medical costs for smoking-related diseases and damage.<sup>24</sup> The cigarette manufacturers defended themselves in the litigation, claiming contributory negligence<sup>25</sup> and asserting that smokers were responsible for their own health and well-being.<sup>26</sup> Four years, later in 1998, the four largest cigarette companies at the time—Philip Morris USA, R. J. Reynolds, Brown & Williamson, and Lorillard—entered into a settlement agreement with forty-six states, called the Master Settlement Agreement.<sup>27</sup> In exchange for Medicaid lawsuit settlements and a release of private tort liability, cigarette manufacturers agreed to pay about \$10 billion annually to the states in perpetuity, and agreed to strict restrictions on the sale and marketing of cigarettes.<sup>28</sup>

In the years following the MSA, to fill a variety of legislative gaps, Congress passed and President Obama signed into law the 2009 Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act).<sup>29</sup> This legislation went beyond simple labeling requirements and disclosure by ensuring that certain tobacco products complied with federal

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<sup>23</sup> TOBACCO CONTROL LEGAL CONSORTIUM, MASTER SETTLEMENT AGREEMENT: AN OVERVIEW (2015), <http://publichealthlawcenter.org/sites/default/files/resources/tclcf-m-sa-overview-2015.pdf> [https://perma.cc/N5KS-M8ZB].

<sup>24</sup> *Id.*

<sup>25</sup> Under the tort law idea of contributory negligence, “a plaintiff was totally barred from recovery if they were in any way negligent in causing the accident, even if the negligence of the defendant was much more serious.” *Contributory Negligence*, CORNELL UNIVERSITY LAW SCHOOL, LEGAL INFORMATION INSTITUTE, [https://www.law.cornell.edu/wex/contributory\\_negligence](https://www.law.cornell.edu/wex/contributory_negligence) [https://perma.cc/4UD8-VM7A].

<sup>26</sup> TOBACCO CONTROL LEGAL CONSORTIUM, *supra* note 23.

<sup>27</sup> *Id.*

<sup>28</sup> *Master Settlement Agreement*, PUBLIC HEALTH L. CTR., <http://publichealthlawcenter.org/topics/tobacco-control/tobacco-control-litigation/master-settlement-agreement> [https://perma.cc/F58W-94PR]. The MSA also restricted the targeting of youth in tobacco advertising, banned brand name sponsorships and free tobacco product samples except in certain facilities, prohibited companies from hiding negative health-related information, and more. TOBACCO CONTROL LEGAL CONSORTIUM, *supra* note 23.

<sup>29</sup> *Overview of the Family Smoking Prevention and Tobacco Control Act*, *supra* note 5.

and state regulations and were not sold to minors.<sup>30</sup> Before signing the legislation into effect, President Obama noted in a speech that children are “aggressively targeted as customers by the tobacco industry” and are “exposed to a constant and insidious barrage of advertising where they live, where they learn, and where they play,” tempting them to experiment with tobacco products.<sup>31</sup>

The Tobacco Control Act also required much stricter product warning labels on both tobacco products and their advertisements.<sup>32</sup> Under the new legislation, if a company wanted to make a claim that their product specifically was of modified risk or reduced harm to the public relative to other dangerous nicotine products, it had to support the claim with sufficient scientific evidence in order to secure FDA approval.<sup>33</sup> The Tobacco Control Act also required extensive disclosure of ingredients to the FDA in all tobacco products, but still left it to state authorities to regulate the industry in certain categories.<sup>34</sup> Congress intended for the Tobacco Control Act to give the FDA authority “to impose appropriate regulatory controls on the tobacco industry.”<sup>35</sup> Calling this legislation a “bipartisan victory” because it was overwhelmingly passed in both houses of

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<sup>30</sup> *Family Smoking Prevention and Tobacco Control Act—An Overview*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm246129.htm> [https://perma.cc/2TDM-E9SX].

<sup>31</sup> Barack Obama, XLIV President of the United States of America: 2009–2017, Remarks on Signing the Family Smoking Prevention and Tobacco Control Act of 2009, AM. PRESIDENCY PROJECT (June 22, 2009) <http://www.presidency.ucsb.edu/ws/index.php?pid=86316> [https://perma.cc/64ZF-EJWS]. President Obama also noted that this legislation was crucial because

[o]ne out of every five children in our country are now current smokers by the time they leave high school. Each day, 1,000 young people under the age of 18 become new, regular, daily smokers. And almost 90 percent of all smokers began at or before their 18th birthday. . . . And I also know that kids today don't just start smoking for no reason.

*Id.*

<sup>32</sup> Family Smoking Prevention and Tobacco Control Act of 2009, Pub. L. No. 111–31, 123 Stat. 1776 (codified as amended at 21 U.S.C. § 387 (2012)) Specifically, these labels included the following: “WARNING: This product can cause mouth cancer. WARNING: This product can cause gum disease and tooth loss. WARNING: This product is not a safe alternative to cigarettes. WARNING: Smokeless tobacco is addictive.” *Id.*

<sup>33</sup> *Section 911 of the Federal Food, Drug, and Cosmetic Act—Modified Risk Tobacco Products*, U.S. FOOD & DRUG ADMIN., [https://www.fda.gov/tobaccoproducts/guidancecomplianceregulatoryinformation/ucm262077.htm#Postmarket\\_Surveillance\\_and\\_Studies](https://www.fda.gov/tobaccoproducts/guidancecomplianceregulatoryinformation/ucm262077.htm#Postmarket_Surveillance_and_Studies) [https://perma.cc/7AE8-N46C].

<sup>34</sup> *Id.*

<sup>35</sup> Family Smoking Prevention and Tobacco Control Act of 2009, 123 Stat. 1776, 1783.

Congress, President Obama noted the new regulations would surely be “a step that will save lives and dollars.”<sup>36</sup>

The Tobacco Control Act did not, however, address every class of tobacco product, namely those that were relatively new to the market.<sup>37</sup> This created a major gap in regulation. While part of the Tobacco Control Act applied to a variety of different groups of tobacco products, like cigarettes, menthol, and chewing tobacco,<sup>38</sup> the general restrictions failed to include products like cigars, hookah tobacco, and e-cigarettes, which became popular in the years following the passage of the act because of the gap in regulation and technological innovation. The large unregulated marketplace for e-cigarettes, as one regulator put it, created an environment similar to the “Wild, Wild West.”<sup>39</sup>

### B. *Emergence of the E-Cigarette and Research on Its Health Effects*

In 1965, Herbert Gilbert received a patent for the first smokeless non-tobacco cigarette, and the patent was approved two years later.<sup>40</sup> Though he failed to commercialize his design, others helped bring his ideas to fruition years later.<sup>41</sup> Specifically, Chinese pharmacist and inventor Hon Lik created the first commercial electronic cigarette in 2003, which was eventually introduced to the U. S. market between 2006 and 2007.<sup>42</sup> Modern day e-cigarettes are battery-operated devices that contain a liquid solution sometimes made up of nicotine, flavoring chemicals, and other chemicals.<sup>43</sup> While there are

<sup>36</sup> Barack Obama, XLIV President of the United States of America: 2009–2017, Remarks on Signing the Family Smoking Prevention and Tobacco Control Act of 2009, *supra* note 31.

<sup>37</sup> Family Smoking Prevention and Tobacco Control Act of 2009, 123 Stat. 1776, 1827.

<sup>38</sup> *See id.*

<sup>39</sup> Mitch Zeller, *Protecting the Public and Especially Kids from the Dangers of Tobacco Products, Including E-Cigarettes, Cigars and Hookah Tobacco*, U.S. FOOD & DRUG ADMIN. (Aug. 8, 2016), <http://blogs.fda.gov/fdavoices/index.php/2016/08/protecting-the-public-and-especially-kids-from-the-dangers-of-tobacco-products-including-e-cigarettes-cigars-and-hookah-tobacco/> [<https://perma.cc/MA76-A63Z>].

<sup>40</sup> P.H., *A Case of the Vapers*, THE ECONOMIST (Mar. 17, 2014), <http://www.economist.com/blogs/schumpeter/2014/03/e-cigarette-patent-wars> [<https://perma.cc/BD6E-K6M9>].

<sup>41</sup> *Historical Timeline of Electronic Cigarettes*, CONSUMER ADVOCATES FOR SMOKE FREE ALTERNATIVES ASSOCIATION, <http://casaa.org/historical-timeline-of-electronic-cigarettes/> [<https://perma.cc/765S-SCLT>].

<sup>42</sup> *Id.*

<sup>43</sup> *Electronic Cigarettes (E-Cigarettes)*, NATIONAL INSTITUTE OF DRUG ABUSE, (June 2017), <https://www.drugabuse.gov/publications/drugfacts/electronic-cigarettes-e-cigarettes> [<https://perma.cc/DU39-4AWM>].

many variations of e-cigarettes, the general technology and anatomy of an e-cigarettes is consistent across brands.<sup>44</sup>

Despite the FDA's decision to treat e-cigarettes as traditional cigarettes, the agency has also acknowledged that e-cigarettes have certain qualities making them less harmful relative to other tobacco products.<sup>45</sup> Although there is little research on the health effects of e-cigarettes,<sup>46</sup> the FDA has passed regulations treating e-cigarettes the same way that traditional cigarettes are treated. At the same time, the agency "recognizes that some tobacco products have the potential to be less harmful than others."<sup>47</sup> The FDA maintains that e-cigarettes have both risks and benefits, like the fact that e-cigarettes have a reduced toxicity content relative to conventional cigarettes, and some individuals use e-cigarettes to quit smoking conventional cigarettes.<sup>48</sup> While the FDA has not conducted or funded research of its own to investigate the health benefits and risks of the product, the FDA nevertheless "encourages manufacturers to explore product innovations that would maximize potential benefits and minimize risks."<sup>49</sup>

A series of negative health studies likely informed the FDA's attitude toward regulating the e-cigarette industry. The American Lung Association contends that a 2009 study found "detectable levels of toxic cancer-causing chemicals, including an ingredient used in anti-freeze, in two leading brands of e-cigarettes and [eighteen] various cartridges."<sup>50</sup> A study conducted in 2014 found that "aerosol from e-cigarettes with a higher voltage level contains more formaldehyde, another carcinogen with the potential to cause cancer."<sup>51</sup> Other studies also found e-cigarettes to contain chemicals like diacetyl, a flavored chemical often added to popcorn for a buttery flavor. This chemical is said to be linked to an irreversible lung condition called "popcorn lung."<sup>52</sup> This series of negative health studies likely prompted the FDA to reconsider its monitoring of the e-cigarette industry, and in turn broaden its regulatory reach.

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<sup>44</sup> *Id.*

<sup>45</sup> *The Facts on the FDA's New Tobacco Rule*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm506676.htm> [<https://perma.cc/F93X-KUZG>].

<sup>46</sup> *Id.*

<sup>47</sup> *Id.*

<sup>48</sup> *Id.*

<sup>49</sup> *Id.*

<sup>50</sup> *E-cigarettes and Lung Health*, AM. LUNG ASS'N, <http://www.lung.org/stop-smoking/smoking-facts/e-cigarettes-and-lung-health.html> [<https://perma.cc/VR3S-ZUNV>].

<sup>51</sup> *Id.*

<sup>52</sup> *Id.* (footnote omitted).

Other studies show that e-cigarettes create positive health benefits in comparison to traditional cigarettes. The Royal College of Physicians in London, United Kingdom recently reported that the use of e-cigarettes among adults who have never been smokers is quite rare.<sup>53</sup> That being said, e-cigarettes are most effective when used by smokers to assist them in quitting smoking. The Royal College of Physicians reported that the "hazard to health arising from long-term vapour inhalation from the e-cigarettes available today is unlikely to exceed 5% of the harm from smoking tobacco."<sup>54</sup> This staggering statistic illustrates the practical need for modified risk alternatives to conventional cigarette smoking. The study concludes that although "there is a need for regulation to reduce direct and indirect adverse effects of e-cigarette use," in the interest of public health, the regulation should be prohibited from significantly inhibiting the "development and use of harm-reduction products by smokers."<sup>55</sup> John Britton, the director of the U.K. Center for Tobacco and Alcohol Studies at the University of Nottingham, helped produce the report and believes that e-cigarettes are the "first genuinely new way of helping people stop smoking that has come along in decades."<sup>56</sup>

A study conducted by the Cleveland Clinic also points to evidence that e-cigarettes may even be a safer alternative to regularly smoking conventional cigarettes. One study comparing the toxicants in e-cigarettes with regular cigarettes found that "[e]-liquids and aerosols have toxicant levels much lower than those observed with tobacco smoke, and their carcinogen content is 'negligible.'"<sup>57</sup> In reviewing twelve e-cigarette brands, Roswell Park Cancer Institute researchers found that toxicant levels

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<sup>53</sup> ROYAL COLLEGE OF PHYSICIANS, NICOTINE WITHOUT SMOKE: TOBACCO HARM REDUCTION 186 (2016), <https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction-0> [<https://perma.cc/3MLH-3NDP>] (PDF available for download from site).

<sup>54</sup> *Id.* at 189.

<sup>55</sup> *Id.* at 190.

<sup>56</sup> Sabrina Tavernise, *Smokers Urged to Switch to E-Cigarettes by British Medical Group*, N.Y. TIMES (Apr. 27, 2016), [http://www.nytimes.com/2016/04/28/health/e-cigarettes-vaping-quitting-smoking-royal-college-of-physicians.html?\\_r=0](http://www.nytimes.com/2016/04/28/health/e-cigarettes-vaping-quitting-smoking-royal-college-of-physicians.html?_r=0) [<https://perma.cc/G2FL-R8P6>]. John Britton also stated that e-cigarettes "have the potential to help half or more of all smokers get off cigarettes. That's a huge health benefit, bigger than just about any medical intervention." *Id.*

<sup>57</sup> Amy Orciari Herman, *E-Cigarettes Safer Alternative to Regular Cigarettes* (July 31, 2014), <http://www.jwatch.org/fw109119/2014/07/31/e-cigarettes-safer-alternative-regular-cigarettes?query=pfw> [<https://perma.cc/HG9Y-8835>]; see also Raul Seballos, *New Research: E-Cigs Safer Alternative to Regular Cigarettes*, CLEVELAND CLINIC (Aug. 22, 2014), <https://health.clevelandclinic.org/2014/08/new-research-e-cigs-safer-alternative-to-regular-cigarettes/> [<https://perma.cc/65YG-EH5Q>].

“were 9 [to] 450 times lower [in e-cigarettes] than in cigarette smoke.”<sup>58</sup> The conflicting evidence and lack of conclusive studies throughout the United States and beyond on this topic illustrates the practical need for additional substantive research and evidence to support the FDA’s conclusion in the Deeming Rule that e-cigarettes are equally as dangerous as conventional cigarettes, and therefore should be regulated in the same exact manner. The FDA’s position—creating outright regulations that treat e-cigarettes the same way as traditional cigarettes—is not only an unauthorized extension of congressional power, but also threatens to wipe out an industry that could have a positive impact on American health.

## II. THE “DEEMING RULE”

Because the Tobacco Control Act gave the FDA significant power to regulate the tobacco industry, the agency subsequently promulgated the Deeming Rule, a series of regulations imposing strict standards and requiring companies to pay high fees with mandatory product applications in order to obtain market approval.<sup>59</sup> The Tobacco Control Act gives the FDA authority to “provide new and flexible enforcement authority to ensure that there is effective oversight of the tobacco industry’s efforts to develop, introduce, and promote less harmful tobacco products.”<sup>60</sup> In formulating the Deeming Rule, the FDA decided to regulate the previously unregulated markets of e-cigarettes, hookah tobacco, and cigars to ensure consumer knowledge of health risks and prevent another public health crisis like that of traditional cigarettes, which were widely used to the detriment of an unknowing public.<sup>61</sup> This broad grant of authority under the Tobacco Control Act applies to the creation and enforcement of the Deeming Rule.

### A. Overview

The Deeming Rule extends the FDA’s authority over all tobacco products, as well as their component parts. The new rule

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<sup>58</sup> Maciej Lukasz Goniewicz et al., *Levels of Selected Carcinogens and Toxicants in Vapour from Electronic Cigarettes*, BMJ JOURNALS (Mar. 6, 2013) <http://tobaccocontrol.bmj.com/content/early/2013/03/05/tobaccocontrol-2012-050859.abstract> [<https://perma.cc/LPC4-X9T2>]; see also Seballos, *supra* note 57.

<sup>59</sup> *Overview of the Family Smoking Prevention and Tobacco Control Act*, *supra* note 5.

<sup>60</sup> H.R. REP. NO. 110-762, at 6 (2008).

<sup>61</sup> *Achievements in Public Health, 1900-1999: Tobacco Use—United States, 1900-1999*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm4843a2.htm> [<https://perma.cc/98JX-P6TQ>].

“extends the FDA’s regulatory authority to all tobacco products, including e-cigarettes<sup>62</sup> . . . all cigars (including premium ones), hookah (also called waterpipe tobacco), pipe tobacco, nicotine gels, and dissolvables that did not previously fall under the FDA’s authority.”<sup>63</sup> The products now regulated—beyond typical tobacco products—also include components and parts of newly deemed products, e-liquids, atomizers, batteries, cartomizers, cartridges, tank systems, flavors for e-liquids, vials that contain e-liquids, programmable software, digital display or lights, and more.<sup>64</sup> The FDA defines “Component or Part” to mean “any software or assembly of materials intended or reasonably expected: (1) To alter or affect the tobacco product’s performance, composition, constituents or characteristics; or (2) to be used with or for the human consumption of a tobacco product.”<sup>65</sup> In essence, the FDA created a “one-size-fits-all” regulatory regime to encompass a broad variety of tobacco and non-tobacco products in the agency’s strict tobacco regulation.<sup>66</sup>

Beyond including these new categories of tobacco products, the Deeming Rule requires “manufacturers of newly regulated tobacco products that were not on the market as of February 15, 2007 . . . to show that products meet the applicable public health standard set by the law. And those manufacturers will have to receive marketing authorization from the FDA.”<sup>67</sup> Because e-cigarettes are relatively new products in the tobacco market throughout the United States, this requirement will effectively apply to almost every company and product in the industry. The new rule also provides a broad grant of authority to the FDA, by enabling the agency to “issue further regulations related to such products that are appropriate for the protection to the public health.”<sup>68</sup>

### *B. Registration Requirements: Burdensome PMTA Pathway*

Because manufacturers of these newly regulated categories of tobacco products must register their products with

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<sup>62</sup> E-cigarettes “are also called electronic cigarettes or electronic nicotine delivery systems (ENDS).” *The Facts on the FDA’s New Tobacco Rule*, *supra* note 45.

<sup>63</sup> *Id.*

<sup>64</sup> *Vaporizers, E-Cigarettes, and other Electronic Nicotine Delivery Systems (ENDS)*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm456610.htm> [<https://perma.cc/T59L-GWEM>].

<sup>65</sup> Deeming Rule, 81 Fed. Reg. 28975.

<sup>66</sup> Complaint of Right To Be Smoke-Free Coalition at 13, No. 16-01210, 2016 WL 3586148, *consolidated as* Nicopure Labs, LLC v. FDA, 266 F. Supp. 3d 360 (D.D.C. 2017) [hereinafter Right To Be Smoke-Free Coalition Complaint].

<sup>67</sup> *The Facts on the FDA’s New Tobacco Rule*, *supra* note 45.

<sup>68</sup> Deeming Rule, 81 Fed. Reg. at 29075.

the FDA, there are three avenues for approval: substantial equivalence (SE),<sup>69</sup> substantial equivalence exemption (SE exemption),<sup>70</sup> and premarket tobacco application (PMTA).<sup>71</sup> The PMTA pathway is by far the most complex and burdensome path for approval and, for most new products, the PMTA pathway for market approval is inevitable. The FDA-imposed grandfather date of February 15, 2007 poses a threat to ENDS manufacturers because the majority of these products did not enter the commercial marketplace until after this date and so would not qualify for the simpler SE route.<sup>72</sup> For ENDS, this almost always requires a PMTA for sellers.

The process of filing a PMTA for a product currently on the market is quite tedious and financially burdensome, especially as it must occur within twenty-four months of the date the Deeming Rule was passed: August 8, 2016.<sup>73</sup> For products that are not yet on the market, sellers must receive market approval before any commercial sale.<sup>74</sup> The process first requires “full reports of all information, published or known to, or which should reasonably be known to, the applicant, concerning investigations which have been made to show the health risks of such tobacco product and whether such tobacco product presents less risk than other tobacco products.”<sup>75</sup> These reports include both clinical and nonclinical investigations and studies “assessing constituents of tobacco or tobacco smoke, toxicology, consumer exposure, and consumer use profiles.”<sup>76</sup> The FDA explicitly requires each PMTA to include a full investigation of health risks for each individual product application, and intends for those applications to include extensive studies proving their safety or modified risk to society.<sup>77</sup>

A PMTA also requires sellers to disclose the ingredients and properties of the tobacco product and a description of the

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<sup>69</sup> The SE pathway is the simplest and requires a manufacturer selling tobacco products only to show that the new tobacco product is substantially equivalent to a tobacco product that was commercially available before or as of February 15, 2007. 21 U.S.C. § 387j(a) (2012).

<sup>70</sup> The SE exemption pathway, the second route for approval, allows the FDA to approve tobacco products for the commercial market that only make minor changes to existing tobacco products. *Id.* § 387e(j).

<sup>71</sup> Deeming Rule, 81 Fed. Reg. at 28990–91.

<sup>72</sup> *Historical Timeline of Electronic Cigarettes*, *supra* note 41.

<sup>73</sup> Deeming Rule, 81 Fed. Reg. at 28978.

<sup>74</sup> *Id.*

<sup>75</sup> 21 U.S.C. § 387j(b)(1)(A).

<sup>76</sup> U.S. FOOD & DRUG ADMIN., APPLICATIONS FOR PREMARKET REVIEW OF NEW TOBACCO PRODUCTS: DRAFT GUIDANCE 9 (2011), <http://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM273425.pdf> [<https://perma.cc/7HXX-MWB7>].

<sup>77</sup> 21 U.S.C. § 387j(b)(1)(A).

manufacturing, processing, and packing facilities. It requires manufacturers to submit “information to show that such aspect of such tobacco product fully meets such tobacco product standard or adequate information to justify any deviation from such standard,”<sup>78</sup> as well as samples of the tobacco product and components and proposed labeling.<sup>79</sup>

In July 2017, the FDA announced a delay in its plan for e-cigarette regulation that would subsequently delay the timeline for the PMTA process and other approval avenues for newly regulated products on the market.<sup>80</sup> Specifically, newly regulated combustibles on the market as of August 8, 2016, now have until August 8, 2021, to submit applications, while newly regulated non-combustibles on the market as of August 8, 2016, will have until August 8, 2022.<sup>81</sup> The FDA announced its desire to take this additional time to “make certain that the [agency] is striking an appropriate balance between regulation and encouraging development of innovative tobacco products that may be less dangerous than cigarettes.”<sup>82</sup> Though the FDA has extended this deadline, it is nevertheless committed to the regulatory scheme.<sup>83</sup> The mere act of delaying the process to pursue additional research and analysis is a concession to e-cigarette companies, illustrating that the Deeming Rule is in fact burdensome and may not adequately assess the costs to companies manufacturing and selling these products.

While the FDA does not disclose a specific fee for the PMTA application, the FDA has estimated that the process will require 1,500 hours per product, in turn costing several thousand dollars per application.<sup>84</sup> This means that each individual product, even those that are similar, that a

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<sup>78</sup> *Id.* § 387j(b)(1)(D).

<sup>79</sup> *Id.* § 387j(b)(1)(C), (E).

<sup>80</sup> Sheila Kaplan, *F.D.A. Delays Rules That Would Have Limited E-Cigarettes on Market*, N.Y. TIMES (July 28, 2017), <https://www.nytimes.com/2017/07/28/health/electronic-cigarette-tobacco-nicotine-fda.html> [<https://perma.cc/FVG6-K5T5>].

<sup>81</sup> *FDA Announces Comprehensive Regulatory Plan to Shift Trajectory of Tobacco-related Disease, Death*, FOOD & DRUG ADMIN. (July 28, 2017), <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm568923.htm> [<https://perma.cc/M273-YLKX>].

<sup>82</sup> *Id.*

<sup>83</sup> *Id.* Additionally, the FDA noted on May 3, 2017 that this delay “will allow new leadership at the FDA and the Department of Health and Human Services additional time to more fully consider issues raised by the final rule that are now the subject of multiple lawsuits in federal court.” *May 2017: Web Statement*, U.S. FOOD & DRUG ADMIN. (May 3, 2017), <https://www.fda.gov/TobaccoProducts/NewsEvents/ucm556562.htm> [<https://perma.cc/9586-GK4Q>].

<sup>84</sup> Kaleigh Rogers, *Five Ways the FDA’s New Regulations Will Transform the Vaping Industry*, MOTHERBOARD (May 5, 2016, 4:50 PM), <http://motherboard.vice.com/read/five-ways-the-fdas-new-regulations-with-transform-the-vaping-industry-e-cigarettes> [<https://perma.cc/LQ89-M8UG>].

manufacturer makes and sells will require about 1,500 hours spent to obtain FDA approval.<sup>85</sup> Moreover, “[t]he FDA estimates it will only receive about 750 PMTAs each year and since companies only have the next two years to apply for their existing products, that works out to about 1,500 PMTAs.”<sup>86</sup> Because PMTAs are filed per product and not per company, the more than 4,000 vape manufacturers in the United States will not be able to afford filing fees of PMTAs, which the FDA clearly anticipates in its low total PMTA estimation.<sup>87</sup>

Because the PMTA process requires an application for each product—even for every flavor and every nicotine level of e-liquid—the process will surely burden companies’ time and revenue. Based on its Regulatory Impact Analysis, the FDA predicted that the rule would cost between \$66 and \$77 million per year for the PMTA of newly deemed products.<sup>88</sup> For example, Apollo Electronic Cigarettes, a California-based fine electronic vaping company, makes twelve different varieties of fruit flavors, each with five different nicotine level options.<sup>89</sup> Based on the company’s product variation, the Deeming Rule requires Apollo submit sixty different PMTAs to the FDA for approval. If each PMTA will cost them 1,500 hours, Apollo will spend a total of 90,000 hours just on this one product variation. Although Apollo is a large manufacturer and may not go out of business due to the costly regulation, these requirements would likely destroy smaller companies that operate by manufacturing similar product varieties. The FDA admits that the Deeming Rule would accelerate the consolidation of the e-cigarette industry, which would then cause smaller, poorer e-cigarette and component manufacturers to forgo the PMTA process altogether, changing their business models<sup>90</sup> and reducing the market.<sup>91</sup> An application denial would inevitably crush

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<sup>85</sup> *Id.*

<sup>86</sup> *Id.*

<sup>87</sup> *Id.*

<sup>88</sup> DEPT OF HEALTH AND HUMAN SERVS., DEEMING TOBACCO PRODUCTS TO BE SUBJECT TO THE FOOD, DRUG, AND COSMETIC ACT, AS AMENDED BY THE FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT; REGULATIONS RESTRICTING THE SALE AND DISTRIBUTION OF TOBACCO PRODUCTS AND REQUIRED WARNING STATEMENTS FOR TOBACCO PRODUCT PACKAGES AND ADVERTISEMENTS 114–16 (2016) <https://www.fda.gov/downloads/AboutFD/UCM394933.pdf> [<https://perma.cc/642X-PJLX>].

<sup>89</sup> Rogers, *supra* note 84.

<sup>90</sup> Deeming Rule, 81 Fed. Reg. 28975, 28990. If products do not receive FDA approval, either because the company fails to file a PMTA in time or the product is rejected post-filing, the products are not allowed to be sold in the market. *Id.* at 28978.

<sup>91</sup> DEPT OF HEALTH AND HUMAN SERVS., *supra* note 88, at 78. The FDA expands on the likelihood of product consolidation, noting “[i]t may not be profitable for firms to bear the per-product costs of this final rule for all products currently marketed. Given the

large portions of a company’s revenue, forcing it to spend money to achieve compliance or completely exit the market in that particular space.

### C. *Influx of Litigation*

Since the FDA’s May 2016 announcement of its plan to release the Deeming Rule, many e-cigarette and vaping companies filed suit against the FDA. Nicopure Labs LLC, a Florida manufacturer of e-cigarette devices and liquid nicotine, filed suit on May 10, 2016.<sup>92</sup> On June 20, 2016, the Right To Be Smoke-Free Coalition, along with many other vaping advocacy groups across America, filed a complaint against the FDA, the FDA’s Commissioner of Food and Drugs Robert Califf, and the Secretary of Health and Human Services Sylvia Burwell.<sup>93</sup> A few weeks later, Judge Amy Berman Jackson, a judge sitting in the United States District Court for the District of Columbia, consolidated the lawsuits with Nicopure’s most recent complaint because both groups filed suit in the same federal court.<sup>94</sup> The groups together argued, among other things, that (1) the FDA’s Deeming Rule violates the First Amendment by prohibiting truthful, non-misleading product statements; (2) that the FDA overstates the benefits and understates the costs of the rule,<sup>95</sup> and (3) the APA makes it “unlawful and unreasonable” for the FDA to define electronic nicotine delivery systems as a “tobacco product.”<sup>96</sup> In July 2017, Judge Berman Jackson ruled in favor of the FDA, stating that the agency acted within the scope of its authority under the Tobacco Control Act and APA in classifying e-cigarettes and nicotine-free liquids and

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potential compliance costs, we assume that 5 percent of baseline newly deemed combusted products . . . will exit from the market rather than submit a marketing application.” *Id.* Additionally, the FDA’s “analysis reflects a significant degree of product exit and consolidation . . . . [T]his will be accompanied by changes in the composition of products available on the market, given the requirements of premarket review.” *Id.* at 80.

<sup>92</sup> Nicopure Labs Complaint, *supra* note 16.

<sup>93</sup> Right To Be Smoke-Free Coalition Complaint, *supra* note 66, at 1 (groups included American E-Liquid Manufacturing Standards Association (AEMSA), American Vaping Association (AVA), Electronic Vaping Coalition of America, Georgia Smoke Free Association, Kentucky Vaping Retailers Association/Kentucky Smoke Free Association, Louisiana Vaping Association, Maryland Vape Professionals, Ohio Vapor Trade Association, New Jersey Vapor Retailers Coalition, and Tennessee Smoke Free Association).

<sup>94</sup> Lydia Wheeler, *Lawsuits Mount Against FDA Regs on E-cigarettes*, HILL, (July 10, 2016 8:00 AM ET) <http://thehill.com/regulation/court-battles/287056-lawsuits-mount-against-fda-regs-on-e-cigarettes> [https://perma.cc/M3YE-PVZB]. See Nicopure Labs, LLC v. Food and Drug Admin., 266 F. Supp. 3d 360 (D.D.C. 2017).

<sup>95</sup> Wheeler, *supra* note 94.

<sup>96</sup> *Id.*

components to be tobacco products.<sup>97</sup> In supporting her finding, Judge Berman Jackson stated that the regulation only subjects the products to “heightened regulation, but the deeming decision does not—and could not—completely ban those products from the market.”<sup>98</sup>

A number of other companies have since filed suit, claiming violations of federal statutes, as well as constitutional rights. Altria Group, Inc., the parent company of both John Middleton and Philip Morris USA, also filed suit.<sup>99</sup> Lost Art Liquids LLC, a California manufacturer of e-cigarette devices and liquid nicotine, filed a lawsuit against the FDA, claiming the FDA “failed to consider the impact its rule would have on small businesses in violation of the Regulatory Flexibility Act. (RFA).”<sup>100</sup> In its complaint, Lost Art Liquids LLC also discussed the FDA’s failure to consider the obviously large costs to companies in its cost-benefit analysis of the rule, and the company further claimed violations of both the First and Fifth Amendments.<sup>101</sup> Several cigar companies and associations have also filed suit against the FDA for similar reasons.<sup>102</sup>

Beyond companies, outspoken politician Larry Faircloth, a Republican in the West Virginia House of Delegates, is also suing the FDA over the new rules. In his complaint, Faircloth claims that “he used e-cigarettes and other vaping devices to quit smoking and will ‘likely return to the unhealthy habit of using tobacco products’ as a result of the rule.”<sup>103</sup> He notes that the premarket review process is burdensome, especially in light of the arbitrary grandfather date, and believes the new regulations will stifle innovation in the tobacco industry.<sup>104</sup>

These lawsuits are sure to give the FDA a run for its money, challenging the agency’s federal constitutional authority to pass the Deeming Rule and claiming a failure by the FDA to adequately provide evidentiary support to back the new regulations. Because

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<sup>97</sup> *Nicopure Labs, LLC*, 266 F. Supp. 3d at 367–68.

<sup>98</sup> *Id.* at 391.

<sup>99</sup> Mike Esterl, *Altria Sues U.S. to Keep ‘Black & Mild’ Cigar Name*, WALL ST. J., (May 26, 2016) <https://www.wsj.com/articles/altria-sues-u-s-to-keep-black-mild-cigar-name-1464282368> [<https://perma.cc/35CU-EJZH>].

<sup>100</sup> Wheeler, *supra* note 94.

<sup>101</sup> TOBACCO CONTROL LEGAL CONSORTIUM, *supra* note 14, at 3 (“[T]he rule’s prohibition on using modified risk descriptors and the requirement that products bear warning labels violate the First Amendment’s protection of free speech and the Fifth Amendment’s protection from unlawful governmental takings.”).

<sup>102</sup> Wheeler, *supra* note 94.

<sup>103</sup> *Id.*

<sup>104</sup> Larry W. Faircloth v. U.S. Food & Drug Administration, *Public Health and Tobacco Policy Center*, <http://tobaccopolicycenter.org/tobacco-control/recent-cases/fda-deeming-rule/larry-w-faircloth/> [<https://perma.cc/2GFV-HY8B>].

the FDA failed to consider alternative methods of regulation that were less invasive given inconclusive science, the agency is now in violation of the Administrative Procedure Act.

### III. VIOLATION OF THE ADMINISTRATIVE PROCEDURE ACT

#### A. *Purpose of the Administrative Procedure Act*

Congress passed the Administrative Procedure Act (APA) in 1946,<sup>105</sup> to create comprehensive procedures for government agencies to follow when performing regulatory activities, including rulemaking.<sup>106</sup> Section 553 of the APA details the requirements for rulemaking.<sup>107</sup> Specifically, it requires the rulemaking agency to allow interested parties to participate in the process through “submission of written data, views, or arguments with or without opportunity for oral presentation.”<sup>108</sup> The inclusion of this provision illustrates Congress’s intention to ensure a democratic process for an interested party that chooses to challenge a regulation.

If an interested party files suit against a federal agency claiming that the agency acted in violation of the APA, the claims will be reviewed using mandatory guidelines that apply to the scope of federal agency actions.<sup>109</sup> In reviewing a challenge, a court is authorized to set aside a law it deems an arbitrary abuse of discretion or unsupported by substantial evidence.<sup>110</sup> An agency rule is considered arbitrary and capricious if the agency has relied too heavily on specific factors, failed to consider a crucial point, explained a decision in a manner that disregards agency evidence, or “is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.”<sup>111</sup> The reviewing court cannot itself create a reasonable basis for the agency’s action that the agency has not already submitted to the court for review.<sup>112</sup>

Particularly, the reviewing court must determine whether the agency has both examined data and explained a

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<sup>105</sup> Administrative Procedure Act, 79 Pub. L. 404, 60 Stat. 237, 79 Cong. Ch. 324, 79 Pub. L. 404, 60 Stat. 237, 79 Cong. Ch. 324 (June 11, 1946).

<sup>106</sup> See, e.g., 5 U.S.C. § 553 (2012).

<sup>107</sup> See *id.*

<sup>108</sup> *Id.* § 553(c).

<sup>109</sup> 5 U.S.C. § 706 (2012).

<sup>110</sup> *Id.* § 706(2)(a), (e).

<sup>111</sup> *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (quoting *Secs. & Exch. Comm’n v. Chenery Corp.*, 332 U.S. 194, 196 (1947)).

<sup>112</sup> *Motor Vehicle Mfrs. Ass’n*, 463 U.S. at 43.

rational reason for its action.<sup>113</sup> An agency's discretion is not without boundaries, and the agency must have sufficiently investigated and considered data and facts,<sup>114</sup> and "articulated a satisfactory explanation for its action based upon the record."<sup>115</sup> If the agency fails to recognize a critical part of the issue or offers an explanation that contradicts agency evidence, the reviewing court can vacate the regulation.<sup>116</sup> When a party claims an agency action is arbitrary, a reviewing court must engage in substantial inquiry to determine the viability of the claim.<sup>117</sup> Though courts afford much deference to federal agencies and the burden is on the challenging party,<sup>118</sup> there are nevertheless narrow opportunities for parties to critically challenge federal regulations.

These requirements imply, but do not explicitly require, a cost-benefit analysis, though many courts have read the APA to require this type of analysis. Specifically, the APA requires an agency to publicly submit a description of the proposed regulation, leaving the agency vulnerable to criticism both by a reviewing court and public.<sup>119</sup> Recent case law suggests that upon reviewing challenged laws, courts favor a cost-benefit analysis, but a rule is not necessarily vacated just because it fails a cost-benefit analysis.<sup>120</sup>

The Deeming Rule should be vacated due to an unreasonable cost-benefit analysis and the FDA's failure to consider alternative measures of regulation that would inform the public, while preserving a successful industry. The Supreme Court, in *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, found that the National Highway Traffic Safety Administration's (NHTSA) rule eliminating the requirement that new motor vehicles produced after a certain date have automatic seatbelts or airbags to protect the safety of vehicle occupants<sup>121</sup> was

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<sup>113</sup> *Id.* at 48 (holding "an agency must cogently explain why it has exercised its discretion in a given manner"). A reviewing court must determine whether "the decision was based on a consideration of . . . relevant factors [or if] there [was] a clear error of judgment." *Id.* at 43.

<sup>114</sup> *Michigan v. Env'tl. Prot. Agency*, 135 S. Ct. 2699, 2706 (2015) (quoting *Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 43).

<sup>115</sup> *California v. Fed. Comm'n Comm'n*, 905 F.2d 1217, 1230 (9th Cir. 1990).

<sup>116</sup> *Id.* at 1230 (citing *Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 43).

<sup>117</sup> *Citizens to Preserve Overton Park Inc. v. Volpe*, 401 US 402, 415 (1971).

<sup>118</sup> *See Balt. Gas & Elec. Co. v. Nat'l Res. Defense Council, Inc.*, 462 U.S. 87, 103 (1983).

<sup>119</sup> 5 U.S.C. § 552 (2012).

<sup>120</sup> Yifan Zhou, *Is Quantified Cost-Benefit Analysis a Requirement for Rulemaking?*, THE REGULATORY REVIEW (June 1, 2016), <https://www.theregreview.org/2016/06/01/zhou-quantified-cost-benefit-rulemaking/> [<https://perma.cc/LY4X-Z2CW>].

<sup>121</sup> *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 56–57 (1983). The NHTSA stated that it no longer found the automatic restraint requirement to produce safety benefits, which was the basis for its rescission of the rule. *Id.* at 38. Soon after,

arbitrary and capricious, and that the agency failed to conduct a fair cost-benefit analysis. In analyzing the scope of review, the Court noted that "the 'arbitrary and capricious' standard is narrow," as a court is not meant to substitute its judgment for the judgment of the applicable agency.<sup>122</sup> Though difficult to prove, if the court finds that the agency failed to consider a crucial aspect of the issue or relied on factors it should not have considered, the rule will be deemed arbitrary and capricious under Section 706 of the APA.<sup>123</sup> Under NHTSA rules, the agency had to consider all relevant safety information and data before passing and implementing a new regulation. Upon performing a cost-benefit analysis, the agency concluded that "incremental costs of the requirements were no longer reasonable."<sup>124</sup> Justice White, writing for the Court, held "that the agency failed to present an adequate basis and explanation for rescinding the . . . requirement and . . . must either consider the matter further or adhere to or amend [the] Standard along lines which its analysis supports."<sup>125</sup> The Court held that the NHTSA "was too quick to dismiss the safety benefits of automatic seatbelts,"<sup>126</sup> and vacated the agency's rescission altogether.

Likewise, the Supreme Court, in *Michigan v. Env'tl. Prot. Agency* found that the Environmental Protection Agency (EPA) failed to adequately consider the costs of amendments to the Clean Air Act.<sup>127</sup> In 2012, the EPA announced that electric utility steam generating units were emitting mercury, a chemical hazardous to public health, and regulation was therefore "appropriate and necessary."<sup>128</sup> State and industry labor groups challenged the regulations, citing the high costs of compliance with the regulations that the EPA failed to consider. In his opinion, Justice Scalia stated that it was unreasonable for the EPA to decline to consider the cost to power plants, though the agency was not required to do a full, formal cost-benefit analysis prior to passing the regulations.<sup>129</sup> He noted, however, that a court cannot uphold a regulation merely because there are ancillary benefits that outweigh the costs.<sup>130</sup> Though courts

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insurance companies sued the NHTSA, claiming there was a clear safety need for automatic seatbelts and airbags and arguing that the agency's new regulation was arbitrary and capricious because it failed to consider the evidence. *Id.* at 39–40.

<sup>122</sup> *Id.* at 43.

<sup>123</sup> *Id.*

<sup>124</sup> *Id.* at 54.

<sup>125</sup> *Id.* at 34.

<sup>126</sup> *Id.* at 51.

<sup>127</sup> *Michigan v. Env'tl. Prot. Agency*, 135 S. Ct. 2699, 2712 (2015).

<sup>128</sup> *Id.* at 2716.

<sup>129</sup> *Id.* at 2711.

<sup>130</sup> *Id.*

provide much deference to agencies that consider both costs and benefits in their analyses of a regulation before it is applied to the market, costs cannot be deemed irrelevant.

*B. Violation of the Administrative Procedure Act*

A reviewing court should analyze the costs relative to the benefits of the Deeming Rule to determine whether its passage is arbitrary under the APA. Of its many purposes, the Tobacco Control Act gives the FDA authority “to provide new and flexible enforcement authority to ensure that there is effective oversight of the tobacco industry’s efforts to develop, introduce, and promote less harmful tobacco products.”<sup>131</sup> This broad statement gives the FDA discretion to determine ultimate goals and the necessary steps to implement President Obama’s goal of reducing tobacco-related deaths.<sup>132</sup> Under the Deeming Rule, the FDA has decided to regulate any product that is “made or derived from tobacco that is intended for human consumption.”<sup>133</sup> Within this regulatory sphere, the FDA proposes to regulate both tobacco products and non-tobacco components all in an identical manner. This is unjustified, as the effects of each product vastly differ, warranting diverse regulations tailored to each product.

*C. Failure to Assess Costs*

The FDA’s failure to adequately assess the costs of the regulatory scheme in place violates the APA. Federal agencies “must consider cost—including, most importantly, cost of compliance—before deciding whether regulation is appropriate and necessary.”<sup>134</sup> In publishing the Deeming Rule, the FDA applied a cost-benefit analysis and concluded in its final rule that “the benefits of the final rule justify the costs,”<sup>135</sup> primarily because of the health benefits associated with the regulation. The FDA stated that the reduction of e-cigarette users would in turn reduce the amount of smoking overall, including usage of traditional, combustible cigarettes.<sup>136</sup> Specifically, the 2014 Surgeon General Report stated that “the promotion of noncombustible products is much more likely to provide public

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<sup>131</sup> 21 U.S.C. § 387a (2012).

<sup>132</sup> *Id.* at 1777.

<sup>133</sup> *Id.* § 101(a) (codified as amended at 21 U.S.C. § 321(rr)(1)).

<sup>134</sup> *Michigan v. Env’tl. Prot. Agency*, 135 S. Ct. at 2711–12 (holding that the “EPA interpreted § 7412(n)(1)(A) unreasonably when it deemed cost irrelevant to the decision to regulate power plants”).

<sup>135</sup> Deeming Rule, 81 Fed. Reg. 28975, 29075.

<sup>136</sup> *Id.* at 28985.

health benefits only in an environment where the appeal, accessibility, promotion, and use of cigarettes and other combusted tobacco products are being rapidly reduced.”<sup>137</sup> The report, as summarized in the final rule, went on to say that in a situation where a larger category of products is proven to be beneficial to the public, regulation is warranted if individual products within that larger, overarching category raise health concerns.<sup>138</sup> Despite this blanket conclusion, the FDA was nevertheless unable to quantify the potential benefits of the Deeming Rule.<sup>139</sup> Specifically, the FDA noted that the “direct benefits of making each of the newly deemed tobacco products subject to the requirements of chapter IX of the [Food, Drug and Cosmetic] Act are difficult to quantify, and [the FDA] cannot predict the size of these benefits at this time.”<sup>140</sup> Though the agency attempted to sketch the anticipated costs of the regulation, it nevertheless conceded that costs could be exorbitantly higher than quoted.

The FDA’s failure to adequately conduct research on the actual cost of compliance *prior* to imposing strict regulations illustrates an error in APA compliance. By “entirely fail[ing] to consider an important aspect of the problem,”<sup>141</sup> the FDA acted in violation of the APA and must reconsider the high costs and unknown benefits of the regulation.

#### D. *Total Disregard of Benefits*

The FDA also disregarded the potential health benefits of ENDS products relative to traditional cigarettes. In essence, the agency concedes that e-cigarettes are less harmful than traditional cigarettes, yet still regulates the two products in the same manner.<sup>142</sup> The FDA notes that “[r]esearchers recognize that the effects from nicotine exposure by inhalation . . . are likely not responsible for the high prevalence of tobacco-related death and disease in this country.”<sup>143</sup> Nicopure, one of the many vaping companies that has filed suit against the FDA, consistently tells

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<sup>137</sup> *Id.* at 28984.

<sup>138</sup> *Id.*

<sup>139</sup> *Id.* at 28981.

<sup>140</sup> *Id.*

<sup>141</sup> That problem being the high, understated costs and unknown health benefits. See *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

<sup>142</sup> Michael Siegel, *POV: New FDA Regulations on Vaping Products a Failure*, BU TODAY (July 13, 2016), <https://www.bu.edu/today/2016/fda-vaping-regulations/> [<https://perma.cc/63MJ-RCF9>].

<sup>143</sup> Deeming Rule, 81 Fed. Reg. at 28981.

consumers that with vaping, “nothing is burned,” “no smoke is released,” and “no ash” is created.<sup>144</sup> Nicopure also contends that e-cigarettes release only “a fraction of the 4000 chemicals currently found in standard tobacco cigarettes.”<sup>145</sup>

By “arbitrarily discount[ing] the safety benefits offered by vaping devices and e-liquids”<sup>146</sup> and undermining the costs, the Deeming Rule ignores reality in favor of a burdensome approval process. The effect of a strict regulation like the Deeming Rule will not only disrupt the e-cigarette marketplace through financially burdensome processes, but it will also halt innovation. Though the FDA contends “the employment of the premarket authorities could create incentives for producers to develop products that are less dangerous when consumed, less likely to lead to initiation of tobacco use, and/or easier to quit,”<sup>147</sup> the agency has failed to consider the realities of the legislation as required by the APA. Some studies show that usage of e-cigarettes is linked to a decreased use of traditional cigarettes, predicting that “innovations are likely to improve the substitutability of e-cigarettes for cigarettes, unless there are major regulatory hurdles for introducing new products.”<sup>148</sup> Dr. Michael Siegel, a professor in the Department of Community Health Sciences at the Boston University School of Public Health and practicing doctor for over twenty-five years, noted that the FDA’s legislation will “prohibit[] manufacturers from making safety improvements to an e-cigarette if they do not undergo the multi-year, multi-million dollar approval process.”<sup>149</sup>

The Deeming Rule effectively eliminates an entire marketplace of activity that mitigates the effects of traditional cigarettes that are scientifically proven to be deadly. This will cause those who have previously turned to e-cigarettes as a mitigating alternative to traditional cigarettes to go back to traditional cigarettes, primarily because the e-cigarette marketplace will vastly diminish with these regulations. What’s more, the extremely expensive, burdensome PMTA requirements could also cause e-cigarettes to drastically rise in price so that

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<sup>144</sup> Jacob Sullum, *FDA E-Cigarette Regulations Give Smoking a Boost*, REASON (Aug. 15, 2016), <http://reason.com/archives/2016/08/15/fda-e-cigarette-regulations-give-smoking> [https://perma.cc/R9HJ-ZEM6].

<sup>145</sup> *Id.*

<sup>146</sup> Nicopure Labs Complaint, *supra* note 16, at 10.

<sup>147</sup> Deeming Rule, 81 Fed. Reg. 28975, 28983.

<sup>148</sup> Levy, et al., *Potential Deaths Averted In USA By Replacing Cigarettes with E-Cigarettes*, 27 TOBACCO CONTROL BMJ J., 18, 22 (2017), <http://tobaccocontrol.bmj.com/content/tobaccocontrol/27/1/18.full.pdf> [https://perma.cc/97VH-LVHM].

<sup>149</sup> Christopher Russell, *Unintended Consequences of the FDA’s E-cigarette Regulations*, HILL, (Aug. 25, 2016, 10:00 AM), <http://thehill.com/blogs/pundits-blog/healthcare/292542-unintended-consequences-of-the-fdas-e-cigarette-regulations> [https://perma.cc/32HK-E4FQ].

companies can keep up with growing costs associated with production. This would make the price of e-cigarettes to consumers much higher, thereby eliminating consumer ability to choose the less harmful alternative to smoking traditional cigarettes.

The Deeming Rule also disrupts innovations and “advances in public health while preserving the status quo that existed in 2007, i.e., a market dominated by cigarettes.”<sup>150</sup> In effect, the regulation blocks beneficial product developments of vaping systems and components that could make them easier and safer to use.<sup>151</sup> By intensely regulating a product that is not conclusively and scientifically linked to tobacco-related death the way traditional cigarettes are linked to death, entrepreneurs will not invest in technology and research to make e-cigarettes safer and healthier for the public.<sup>152</sup> The FDA’s failure to identify and further research these discrepancies prior to regulation shows a clear violation of the APA’s required cost-benefit analysis.

Despite the FDA’s July 2017 news release stating that it would revise the application timelines to facilitate “public dialogue about lowering nicotine levels in combustible cigarettes to non-addictive levels through achievable product standards,” the agency nevertheless maintains the rules currently put into place.<sup>153</sup> A mere timing extension without true analysis of each individual regulation and its effect on the industry does not survive a thorough cost-benefit analysis.

### *E. Arbitrary PMTA Process*

The PMTA process is arbitrary in that the FDA ignores the enormity of costs to vaping companies, threatening to destroy the livelihood of those invested in the industry and completely eliminating a safer alternative to smoking cigarettes. Though many argue e-cigarettes are dangerous in nature, the fact that the health risks are much less detrimental and deadly compared to traditional cigarettes provides a mitigating alternative. Additionally, given the lack of scientific research that conclusively categorizes e-cigarettes as an equal danger as traditional cigarettes, the FDA has no place burdening the public and industry stakeholders with regulations. The FDA

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<sup>150</sup> Nicopure Labs Complaint, *supra* note 16, at 11.

<sup>151</sup> Sullum, *supra* note 144. Additionally, “[i]t is in the interest of profit-seeking companies to constantly look for changes that make their products more appealing to consumers, which in this case means encouraging smokers to make a switch that could save their lives. The FDA’s response to such beneficial innovation: Cut it out.” *Id.*

<sup>152</sup> Siegel, *supra* note 142.

<sup>153</sup> FDA Announces Comprehensive Regulatory Plan to Shift Trajectory of Tobacco-related Disease, Death, *supra* note 82.

notes that one PMTA “will take more than 5,000 hours to complete and will cost a minimum of \$330,000 per product.”<sup>154</sup> Nicopure’s CEO Jeff Stamler says his company anticipates “each e-liquid PMTA [to cost] at least \$5 million, and each vaporizer (or vaporizer component) PMTA [to cost] at least \$3 million.”<sup>155</sup> This is significantly higher than the FDA’s conservative estimates.<sup>156</sup> While some of the largest companies will be able to shoulder this large financial investment in premarket approval, “it is highly likely that the vast majority of small and independent manufacturers will not, and so, will be put out of business.”<sup>157</sup>

This burdensome requirement alone threatens to destroy small businesses and “hand the e-cigarette market over to a small number of large companies, including the tobacco companies.”<sup>158</sup> Even if these large companies have more resources to comply with regulations, it is not fair to wipe small business owners out of a booming industry just because they do not have the money to comply with exorbitantly high administrative fees. These large companies will have a monopoly over the industry, affecting stakeholders and the wider economy.

Were the fees justified and backed by scientific evidence, however, the result may be different. While the FDA contends it has done an appropriate cost-benefit analysis, the FDA nevertheless expects that it will be difficult for manufacturers of ENDS hardware/apparatus components “to make the showing necessary to meet the statutory standard, given the great extent of possible variations in combinations of hardware components, if all are considered and sold separately.”<sup>159</sup> Because it is financially impossible for small manufacturers to collect the resources necessary to file a PMTA within the allotted time frame, and therein prove that their product is beneficial to public health and safer than traditional cigarettes, these companies will likely go out of business in any effort to comply with the Deeming Rule.

Nicopure likened the PMTA process to the new drug application (NDA) process promulgated by the FDA. American Bioscience, a pharmaceutical research company that developed a process to safely and effectively deliver Taxol, a chemotherapy drug, brought suit against the FDA claiming the agency’s drug

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<sup>154</sup> Michael B. Siegel, *The FDA’s Vaporous Thinking About E-Cigs*, WALL ST. J. (May 5, 2016, 6:34 PM), <http://www.wsj.com/articles/the-fdas-vaporous-thinking-about-e-cigs-1462487690> [<https://perma.cc/9DEK-CY3M>].

<sup>155</sup> Sullum, *supra* note 144.

<sup>156</sup> Russel, *supra* note 149.

<sup>157</sup> *Id.*

<sup>158</sup> Siegel, *supra* note 154.

<sup>159</sup> *Deeming Rule*, 81 Fed. Reg. 28975, 28992.

approval process was arbitrary and capricious.<sup>160</sup> The court described the NDA approval process as “expensive and time-consuming, requiring data from tests showing the drug’s safety and effectiveness.”<sup>161</sup> American Bioscience sought to enjoin the FDA from approving a competitor’s abbreviated NDA for a generic form of Taxol, which was already patented.<sup>162</sup> The court held that the FDA’s process as well as its intervention in the marketing of generic versions of Taxol was arbitrary and capricious.<sup>163</sup>

Similarly, the FDA’s failure to give significant weight to the large number of predicted hours<sup>164</sup> companies will be spending each year on PMTA’s—leading to the waste of millions of dollars of industry money, effective destruction of small companies in the industry, and halt to innovation that could provide future health benefits—is in violation of the APA. A cost-benefit analysis may indicate a much heavier cost for small businesses with regard to time and money required to get their products approved for the marketplace, relative to a much smaller overall health benefit for the population. Conceding a lack of conclusive statistical evidence, the FDA has not provided an adequate basis for its analysis and conclusion that the Deeming Rule should apply to ENDS products, a clear requirement under the APA before passing broad-reaching regulations.

Lastly, the grandfather date set forth in the Deeming Rule is arbitrary and will cause an undue burden to vaping companies across the country. The FDA has not demonstrated the purpose of imposing the PMTA pathway on manufacturers that brought products to market after the specific date of February 15, 2007. This date set by the FDA is arbitrary, as “the e-vapor industry was relatively nonexistent in 2007.”<sup>165</sup>

Because the date is wholly arbitrary and not reflective of the e-cigarette industry, policymakers are fighting for a date change. In early 2017, the House introduced the Agricultural Appropriation Bill,<sup>166</sup> which proposed to move the grandfather date from February 15, 2007, to the date the Deeming Rule went into effect, August 8, 2016.<sup>167</sup> This proposition would exempt

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<sup>160</sup> *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1078 (D.C. Cir. 2001).

<sup>161</sup> *Id.* at 1079.

<sup>162</sup> *Id.* at 1084.

<sup>163</sup> *Id.* at 1086.

<sup>164</sup> *See supra* Section II.B.

<sup>165</sup> Melissa Vonder Haar, *Grandfather Date Takes Center Stage in ‘Deeming’ Regs*, CSP DAILY NEWS (May 6, 2016), <http://www.cspdailynews.com/category-news/tobacco/articles/grandfather-date-takes-center-stage-deeming-regs> [https://perma.cc/C4UL-XWZY].

<sup>166</sup> *To Amend the Federal Food Drug and Cosmetic Act to Provide for a Certain Effective Date with Respect to Deemed Tobacco Products, and for Other Purposes: Hearing on H.R. 2058*, 114th Cong. (2015–2016).

<sup>167</sup> *Id.*

almost all e-cigarette manufacturers and component manufacturers from participating in the burdensome PMTA process, and allow them to utilize the SE pathway instead.<sup>168</sup> Mitch Zeller of the FDA, however, argued that this date change would have negative health effects, stating that “unreviewed products will be able to serve as predicates for new products coming down the road.”<sup>169</sup> Despite Zeller’s concerns, the FDA’s current system is flawed, forcing almost every ENDS manufacturer into the PMTA process, a process that is tedious, expensive, and will delay sales.

Without ample consideration of alternatives,<sup>170</sup> the FDA is threatening to wipe out an entire industry based on its arbitrary new regulation. It is quite easy for agencies and administrators to place a ban on many activities,<sup>171</sup> but “an artificial narrowing of the scope of the regulatory problem is itself arbitrary and capricious and is ground for reversal.”<sup>172</sup> Without considering the large costs to the industry and public health, overstating unknown benefits, and considering unintended consequences of the regulation—like a halt to innovation and the creation of a black market of ENDS products with “dubious manufacturing standards and unknowable toxicity”<sup>173</sup>—the FDA has not adequately shown an appropriate purpose for the legislation under the APA. While the ENDS market may require some regulation, the FDA’s Deeming Rule, which treats ENDS products and components—some of which do not even include tobacco-like traditional combustible cigarettes,

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<sup>168</sup> *Id.* This proposed bill provides that

A person introducing a tobacco product that is substantially similar to a marketed product less than [twenty-one] months after that type of product is deemed a tobacco product must submit a report to the FDA on the similar product not later than [twenty-one] months after that type of product is deemed a tobacco product.

*H.R. 2058 (114th): FDA Deeming Authority Clarification Act of 2015*, GOVTRACK (Apr. 28, 2015), <https://www.govtrack.us/congress/bills/114/hr2058/summary> [<https://perma.cc/NMJ6-498Z>].

<sup>169</sup> Haar, *supra* note 165.

<sup>170</sup> *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 46 (1983).

<sup>171</sup> *United States v. Nova Scotia Food Prods. Corp.*, 568 F.2d 240, 253 (2d Cir. 1977).

<sup>172</sup> *Home Box Office, Inc. v. FCC*, 567 F.2d 9, 36 (D.C. Cir. 1977).

<sup>173</sup> Russell, *supra* note 149 (“The FDA has indicated that the goal of the new regulations is to protect Americans from tobacco-related disease and death. Yet by rationalizing current users’ decisions to circumvent the rule by turning to black market e-cigarettes, or going back to smoking tobacco, the regulations risk creating harm where little, if any, currently exists for consumers. By beginning to buy e-cigarettes ‘off the books’ from black market traders, consumers will become effectively invisible to legitimate vendors and to health and regulatory authorities that wish to monitor use of e-cigarettes in the population. They will be entirely visible, however, to black market traders who will inevitably begin to offer these consumers more than just illegal e-cigarettes.”).

which have been proven to cause death—is wholly arbitrary and should be overturned under the APA.

#### IV. STEPPING OUT

The best way to minimize the negative effects of the Deeming Rule is for the FDA to step out of the regulation sphere with regard to e-cigarettes until the agency completes a true cost-benefit analysis. Because there is unsettled science, a lack of conclusive health research, and a need for additional studies, the FDA should not yet monitor the industry by imposing burdensome regulations that treat e-cigarettes like traditional tobacco cigarettes. Until then, consumers should assume the potential risk of smoking an e-cigarette, as intense regulation before any conclusive determination does not help society. But this result is unlikely: the FDA has convinced policymakers and politicians that the e-cigarette marketplace is in dire need of strict regulation to protect the health and safety of American citizens. Thus, at the very least, it is imperative for the FDA to alter the current Deeming Rule to ensure innovation and keep companies from going out of business.

While it is important to regulate the e-cigarette market due to its potential health risks, the FDA has exceeded its authority in subjecting e-cigarettes to the same regulatory scheme as traditional cigarettes without investigating the health effects more closely. Instead of placing the massive obstacle of PMTA fees in the way of small businesses without conclusive research to support the regulation, the FDA should try to make e-cigarettes safer by incentivizing innovation. The FDA should fund additional research of its own to be carried out by other government agencies.

Restricting the sale and marketing of ENDS products to youth is understandable to prevent young people from choosing to participate in an activity with unknown health consequences. Scientists and policymakers, however, still do not yet know enough about the health risks to justify the imposition of legislation that threatens to knock small vaping businesses out of the marketplace. As *The Hill* contributor Christopher Russell suggests, to create an incentive for companies to participate in research, the FDA should require manufacturers "to conduct research on the products they wish to market, and that the quality of this research should be assessed to determine whether the introduction of a product into the market is likely to cause more harm than benefit to the

public'[s] health.”<sup>174</sup> Companies submitting any new products after the grandfather date should be required to conduct generalized research. This would require companies to absorb the cost of research instead of the government, and provide a safety blanket for consumers wondering about potential health risks. The pathway for market approval should also apply to general categories rather than specific, individual products, in order to minimize costs. For example, each individual flavor of e-cigarette liquid should not require its own extensive research; instead, the base ingredients and recipes for flavor combinations should be submitted to the FDA for market approval based on a cost-benefit analysis. This would both save companies time and money, as well as FDA resources.

While some electronic cigarettes contain nicotine, non-tobacco products, such as component parts, should not be heavily regulated, as they do not pose a health risk sold alone. In this way, electronic cigarettes should be treated as consumer products, not as tobacco products. The FDA should set “uniform safety standards for these products—standards that address battery safety, overcharge protection, temperature control, safety of flavorings, and basic quality control and manufacturing safety.”<sup>175</sup> These uniform standards should apply to all products on the market regardless of the grandfather date.

The current effects of the Deeming Rule will cause small vaping companies to go out of business, leaving consumers to a black market of electronic cigarettes, or alternatively forcing them back into the traditional cigarette marketplace. To reduce consumption of traditional cigarettes, the most scientifically harmful product on the market, it's important not to “protect cigarettes from competition from a much safer alternative.”<sup>176</sup>

The grandfather date of the FDA's regulations should also be changed. Because this date is so crucial as to whether the PMTA process' burdensome requirements will impact small manufacturers and threaten to put them out of business, the Cole/Bishop Amendment or an alternative date change is necessary. According to Michael Siegel, a professor of Community Health Sciences at the Boston University School of Public Health, “[t]he only way out of this disaster would be for Congress to enact legislation that prevents the FDA from requiring PMTAs for vaping products and forces the FDA instead to develop actual

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<sup>174</sup> *Id.*

<sup>175</sup> Siegel, *supra* note 142.

<sup>176</sup> *Id.*

safety standards for these products.”<sup>177</sup> Siegel asserts that “the Cole/Bishop Amendment is a step in the right direction,” but is still problematic because any products under review after the grandfather date would be subject to the PMTA process.<sup>178</sup> Under this amendment, PMTAs would still be required for new products, which would in turn “stifle” innovation.<sup>179</sup> The grandfather date should be moved to the proposed grandfather date according to the Cole/Bishop Amendment: August 8, 2016. Additionally, imposing a strict two-year requirement on manufacturers to comply with the new regulation is a large burden as well: it requires significant costs for premarket approval within a short time frame where funding could pose a threat to the continuation of business efforts. This two-year frame is wholly arbitrary, especially in light of a lack of conclusive scientific evidence as to whether ENDS products actually pose significant harm. The FDA should consider expanding this time frame to better accommodate the financial needs of manufacturers.

In order to weaken the PMTA requirements to better reflect the health benefits of e-cigarettes as well as the FDA’s need to stay within the confines of the APA, it is important to limit regulation on components and parts, and require scientific research to be done on e-cigarette parts that contain chemicals and nicotine outright. It makes more sense to regulate potentially harmful substances than it does component parts that do not contain anything harmful.

## CONCLUSION

“An agency’s view of what is in the public interest may change, either with or without a change in circumstances. But an agency changing its course must supply a reasoned analysis . . . .”<sup>180</sup> E-cigarettes provide a reduced-risk alternative for cigarette-smokers that should not be regulated in the same manner as traditional tobacco cigarettes. The FDA reached beyond its scope of authority in passing the Deeming Rule, including a broad variety of what it defines as “tobacco products” to be heavily regulated, amounting to a burden threatening to send local shops out of business. This unauthorized, broad extension of authority runs contrary to the APA and must be

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<sup>177</sup> Haar, *supra* note 165.

<sup>178</sup> *Id.*

<sup>179</sup> *Id.*

<sup>180</sup> *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 57 (1983) (quoting *Greater Boston Television Corp. v. FCC*, 444 F.2d 841, 852 (D.C. Cir. 1970) (omission in original)).

vacated or amended to reflect the health benefits of e-cigarettes relative to traditional cigarettes.

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