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Societal innovation is frequently triggered by need. Year after year, novel technologies are created by entrepreneurs who seek to find a more effective, efficient, or less dangerous way of accomplishing a specific goal. Oftentimes, these new technologies enter the marketplace bringing with them a host of uncertainties concerning both their performance and effect on consumer activity. Despite these inevitable uncertainties, new technologies play a vital role in advancing society when appropriately controlled. Indeed, while the appropriate levels of control may vary across industries and technologies, one principal remains constant amongst them all: the obligation to balance risk with reward.

The need for such a delicate balancing act is no more evident than in the case of e-cigarettes and vaporizer products. Over the last two decades, innovators and entrepreneurs alike have sought to develop healthier solutions aimed at reducing the overwhelming number of fatalities and life-threatening illnesses associated with one of America's most prevalent killers, the consumption of traditional tobacco cigarettes. While the undeniable benefits of these innovations have been formally acknowledged by both the FDA and Congress, the current federal regulatory framework that

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controls their availability to consumers operates as a hindrance to innovation and industry growth rather than an effective means of protecting the public's health.

This Note sets out to analyze the turbulent rise and fall of government and consumer sentiment surrounding these products and evaluates the effectiveness of the current FDA regulatory framework, which functions to constrain the diffusion of what may be one of the next substantial public health benefits. Specifically, this Note explores the potential for a more effective and elastic regulatory framework which incorporates the dual use of federal and state regulatory measures to strike an optimal middle ground position between minimizing uncertain public health risks while simultaneously not discouraging innovation and industry growth. In the final analysis, officials tasked with developing sufficient regulatory measures should seek to take calculated risks in the interests of promoting innovation. After all, it should come as no surprise that the most promising technological tobacco alternative emerged from an unregulated environment.

INTRODUCTION

The "leading cause of preventable death" in the United States is attributable to the consumption of traditional tobacco cigarettes.[1] Shockingly, nearly 500,000 people in the United States die each year as a result of cigarette-related illnesses.[2] "This is about one in five deaths annually, or 1,300 deaths every day."[3] That said, after making strides to reduce cigarette consumption, and thus minimizing their associated medical ramifications, society is once again faced with the task of combating yet another slew of tobacco-related illnesses.[4] Although this task, a true 21st-century problem, arises in the technological age and concerns uncertain health risks associated with the use of e-cigarettes and vaporizers. E-cigarettes and vaporizer devices, also known as "electronic nicotine delivery systems" ("ENDS"), were developed with the primary intention of providing a more safe and effective way of assisting traditional cigarette smokers in their efforts to kick a deadly habit.[5] What was once thought to be an innovative technological advancement aimed at improving societal health, however, has begun to rear its ugly head as a potential Loch Ness monster of sorts imposing, in some cases, fatal consequences for its users.[6] As the volume of injuries increases day by day, researchers, scientists, and even the United States government remain unsure as to the precise cause of these recent fatalities and serious lung injuries affecting users of e-cigarette and vaporizer devices.[7]

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[1] *Smoking & Tobacco Use: Fast Facts*, CDC (Nov. 15, 2019), https://www.cdc.gov/tobacco/data_statistics/fact_sheets/fast_facts/index.htm.

[2] *Id*.

[3] *Id*.

[4] *Cigarette Smoking Among U.S. Adults Lowest Ever Recorded: 14% in 2017*, CDC (Nov. 8, 2018, 1:00 PM), https://www.cdc.gov/media/releases/2018/p1108-cigarette-smoking-adults.html.

[5] U.S. DEP'T HEALTH & HUMAN SERVS., E-CIGARETTE USE AMONG YOUTH AND YOUNG ADULTS: A REPORT OF THE SURGEON GENERAL, CDC 1, 8, 10, 201 (2016), https://e-cigarettes.surgeongeneral.gov/documents/2016_SGR_Full_Report_non-508.pdf.

[6] *See* Hannah Knowles & Lena H. Sun, *What We Know About the Mysterious Vaping-Linked Illnesses and Deaths*, WASH. POST (Jan. 10, 2020, 3:11 PM), https://www.washingtonpost.com/health/2019/09/07/what-we-know-about-mysterious-vaping-linked-illnesses-deaths/.

[7] *See id*.

Sudden and serious medical illnesses arising in various users of e-cigarette and vaporizer products has motivated the federal government to respond through the enforcement of regulatory measures created to prevent individuals from exposure to potentially dangerous tobacco-related products.[8] The federal government's regulatory response, however, enforced in the wake of serious but uncertain dangers, is likely to impose significant impediments to the innovation of healthier alternative tobacco products created for the primary purpose of deterring individuals from smoking lethal cigarettes.[9] As a result, this problem presents interesting questions concerning the federal government's regulatory approach in protecting the public health of its citizens from products that may possess uncertain dangers in addition to potentially significant public health benefits.[10] Accordingly, this Note will investigate these issues and, in doing so, seek to analyze a flexible regulatory framework most effective for dealing with these types of products.

This Note first begins in Part I by examining the historical rise of vaporizer and e-cigarette devices. Part I then summarizes the main arguments and rationales of public health officials who support a softer approach to the regulation of these devices, in addition to those who favor a strict approach to regulation. With these regulatory rationales in hand, Part II explains the recent news surrounding the nationwide outbreaks of vaping-related injuries. It further provides statistical data concerning the outbreaks, in addition to the conclusions drawn by the CDC as to the primary cause of those outbreaks. Next, Part III reviews the historical progression of United States tobacco regulation, focusing on FDA regulatory measures designed to regulate traditional cigarettes. Part III then goes on to analyze the significant impediments to the growth and longevity of the e-cigarette and vaporizer industries as a result of the FDA's promulgation of the Deeming Rule, which seeks to regulate these devices under the same framework currently utilized for traditional tobacco

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[8] *See id*.

[9] *See* Jonathan H. Adler, *Why FDA Regulations Limiting E-Cigarette Marketing May Cost Lives and Violate the Constitution*, WASH. POST (Dec. 12, 2017 at 8:06 AM), https://www.washingtonpost.com/news/volokh-conspiracy/wp/2017/12/12/why-fda-regulations-limiting-e-cigarette-marketing-may-cost-lives-and-violate-the-constitution/.

[10] *See id*.

cigarettes. After analyzing the challenges underlying the current FDA regulatory regime, Part IV begins by explaining the need for a more flexible regulatory approach that is capable of building in adjustment as the facts change. Specifically, Part IV proposes the implementation of certain federal regulatory measures to be coupled with the use of state tort law as a means of providing an elastic regulatory framework best suited to manage products that may possess uncertain dangers but which may also have significant public health benefits.

I. THE RISE OF VAPORIZER AND E-CIGARETTE TECHNOLOGY

As the demand for solutions to reduce the consumption of traditional cigarettes increased, Herbert Gilbert was successful in acquiring a patent for the first "smokeless nontobacco cigarette" in 1965.[11] By 2004, the device gained significant popularity among Chinese smokers "as a potential cessation device or an alternative cigarette product" and was later introduced into the U.S. market by the mid-2000s.[12] Today, e-cigarettes are electronically powered devices, which "operate by heating a liquid solution to a high enough temperature so that it produces an aerosol [vapor] that is inhaled."[13] The vapor ingested by the user is comprised mainly of concentrated amounts of nicotine, chemical flavoring, and various additional chemicals "such as glycol, to retain moisture and create the aerosol when heated."[14] Since their inception, e-cigarettes have caused a threatening disruption to the traditional cigarette market as studies have shown that "cigarette smokers [are] 28 percent more likely to

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[11] U.S. DEP'T HEALTH & HUMAN SERVS., *supra* note, 5, at 10; T.R. Goldman, *E-Cigarettes and Federal Regulation*, HEALTH AFFAIRS (July 18, 2014), https://www.healthaffairs.org/do/10.1377/hpb20140718.423628/full/; *see* Lauren H. Greenberg, *The "Deeming Rule": The FDA's Destruction of the Vaping Industry*, 83 BROOKLYN L. REV. 777, 783 (2017).

[12] *See* U.S. DEP'T HEALTH & HUMAN SERVS., *supra* note 5, at 10.

[13] *E-Cigarettes: Facts, Stats and Regulations*, TRUTH INITIATIVE (Nov. 11, 2019), https://truthinitiative.org/research-resources/emerging-tobacco-products/e-cigarettes-facts-stats-and-regulations.

[14] *Id.*; *see* Erin Coleman, *Health Risks of Vaping: What You Need to Know*, BENEFITS BRIDGE UNITED CONCORDIA DENTAL (Jul. 6, 2018), https://benefitsbridge.unitedconcordia.com/health-risks-of-vaping-what-you-need-to-know/.

stop smoking if they use[] e-cigarettes."[15] Further, the majority of adult e-cigarette users are comprised of former or current traditional cigarette smokers.[16] By 2018, the global e-cigarette and vaporizer industry was valued at roughly $14.05 billion.[17] This was a major increase from 2017, when the global industry was valued at $9.39 billion.[18] Moreover, some analysts project that by 2026 the market could reach upwards of $58 billion.[19] Perhaps one of the main reasons for the significant and rapid growth of the e-cigarette and vaporizer industry relative to other Nicotine Replacement Therapies ("NRTs") is because, unlike other NRTs, e-cigarettes and vaporizers imitate the act of smoking, thus having "both pharmacologic and behavioral components of [traditional] cigarette addiction."[20]

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[15] ROBERT J. SHAPIRO & SIDDHARTHA ANEJA, THE IMPACT OF ELECTRONIC CIGARETTES ON CIGARETTE SMOKING BY AMERICANS AND ITS HEALTH AND ECONOMIC IMPLICATIONS P22 (2019), https://www.progressivepolicy.org/wp-content/uploads/2019/08/ECigaretteStudy.pdf; Jonathan H. Adler et al., *Baptists, Bootleggers & Electronic Cigarettes*, 33 YALE J. REG. 313, 334 (2016) (discussing e-cigarettes threatening disruption).

[16] *Electronic Cigarettes: What's The Bottom Line*, CDC, https://www.cdc.gov/tobacco/basic_information/e-cigarettes/pdfs/Electronic-Cigarettes-Infographic-508.pdf; *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. 28974, 29036 (May 10, 2016) (codified at 21 C.F.R. §§ 110; 1140; 1143) [hereinafter Deeming Rule]; Jonathan H. Adler, *Regulatory Obstacles to Harm Reduction: The Case of Smoking*, N.Y.U. J.L. & LIBERTY 712, 722 (2017) [hereinafter *Regulatory Obstacles to Harm Reduction*].

[17] *See Vaping Market to Reach a Value $29.39 Billion at a CAGR of 20.3% From 2018-2022 | a Report From TBRC*, PRNEWSWIRE (Aug. 21, 2019, 9:10 AM), https://www.prnewswire.com/news-releases/vaping-market-to-reach-a-value-29-39-billion-at-a-cagr-of-20-3-from-2018-2022--a-report-from-tbrc-300904265.html.

[18] *See Global Electronic Cigarette Market Outlook Report 2017 – 2019 & 2026*, PRNEWSWIRE (Sept. 2, 2019, 1:30 PM), https://www.prnewswire.com/news-releases/global-electronic-cigarette-market-outlook-report-2017-2019--2026-300910267.html.

[19] *See id*.

[20] *Regulatory Obstacles to Harm Reduction*, *supra* note 16, at 722–23 (citing Zachary Cahn & Michael Siegel, *Electronic Cigarettes as a Harm Reduction Strategy for Tobacco Control: A Step Forward or a Repeat of Past Mistakes?*, 32 J. PUB. HEALTH POL'Y. 16, 17 (2011)); *see* Caroline Franck et. al, *Electronic*

Supporters of e-cigarette and vaporizer products advocate that these devices may provide a safer nicotine alternative for individuals addicted to smoking traditional cigarettes.[21] Various studies focusing on the health risks associated with e-cigarette consumption have bolstered this argument. For example, the National Academies of Sciences, Engineering, and Medicine (the "NAS") recently released a study, "mandated by Congress," in which researchers concluded that "switching to e-cigarettes reduces the exposure to many toxins and cancer-causing substances in regular cigarettes."[22] Moreover, the FDA has agreed with these findings stating that, "the inhalation of nicotine (e.g., nicotine without the products of combustion) is of less risk to the user than the inhalation of nicotine delivered by smoke from combusted tobacco products."[23] The prevailing reason behind this rationale is that, unlike traditional cigarettes, e-cigarette and vaporizer products are not operated through combustion, and thus these products do not release the numerous carcinogens that are present in traditional cigarettes.[24] Furthermore, studies have also revealed that the vapor released from e-cigarette usage does not present the equivalent threats of second-hand smoke to bystanders as traditional cigarettes do.[25]

Such studies have bolstered the credibility of various public health experts who advocate for a soft approach in regulating these

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Cigarettes in North America History, Use, and Implications for Smoking Cessation, 129 CIRCULATION 1945, 1946 (2014).

[21] *See* Goldman, *supra* note 11.

[22] Stacy Simon, *Report: What's Known About the Harms and Benefits of E-Cigarettes*, AM. CANCER SOC'Y (Feb. 8, 2018), https://www.cancer.org/latest-news/report-whats-known-about-the-harms-and-benefits-of-e-cigarettes.html.

[23] Deeming Rule, *supra* note 16, at 28981.

[24] *See* Julia Belluz, *4 Big Takeaways from the Most Comprehensive Report on E-Cigarettes Yet,* VOX (Jan. 23, 2018, 2:18 PM), https://www.vox.com/science-and-health/2018/1/23/16923070/nas-report-e-cigarettes-health-risks. ("There is conclusive evidence . . . that completely substituting e-cigarettes for combustible tobacco cigarettes reduces users' exposure to numerous toxicants and carcinogens present in combustible tobacco cigarettes.").

[25] *See* Ashley Turner, *Juul-sponsored Study Shows Secondhand Vaping Emissions Are Much Less Toxic Than Cigarette Smoke*, CNBC (June 14, 2019, 10:06 AM), https://www.cnbc.com/2019/06/13/juul-study-shows-secondhand-vaping-emissions-are-less-toxic-than-cigarette-smoke.html; *Regulatory Obstacles to Harm Reduction*, *supra* note 16, at 725–26.

alternative tobacco products.[26] Advocates of a soft regulatory approach seek to minimize the extent to which e-cigarette regulation may impede the ability of traditional cigarette smokers to use e-cigarettes as a means of aiding them in their efforts to quit smoking combustible cigarettes.[27] This is because research surrounding these products indicates the potential for significant public health benefits for cigarette smokers who transition to e-cigarettes instead.[28] In a May 2014 study, researchers conducted interviews with "nearly 6000 smokers trying to quit on their own and found that about one in five using e-cigarettes had stopped smoking at the time of the survey, while only half that number—about one in 10—had been able to stop using conventional nicotine patches and gum."[29] Thus, supporters contend that overly strict regulation of e-cigarettes may prevent individuals from utilizing a less harmful means of nicotine consumption.[30]

By contrast, advocates for strict regulatory frameworks contend that the scientific uncertainty surrounding the potential long-term health effects of e-cigarette and vaping products may render these devices to be dangerous.[31] Moreover, many fear that e-cigarette marketing may prompt smokers to engage in the dual use of both e-cigarettes and traditional cigarettes rather than having the intended effect of assisting individuals to quit tobacco and nicotine

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[26] *See, e.g.*, ST. GEORGE'S UNIVERSITY OF LONDON, *E-Cigarettes Research Shows Clear Benefits of Switching from Tobacco*, MED. PRESS (Oct. 10, 2018), https://medicalxpress.com/news/2018-10-e-cigarettes-benefits-tobacco.html; *see also* Adler et al., *supra* note 15, at 339 n.153 (citing ROYAL COLLEGE OF PHYSICIANS. NICOTINE WITHOUT SMOKED: TOBACCO HARM REDUCTION (2016) (encouraging consumption of e-cigarettes in order to curb smoking).

[27] *See* Goldman, *supra* note, 11.

[28] *See, e.g.*, ST. GEORGE'S UNIVERSITY OF LONDON, *supra* note 26; Adler et al., *supra* note 15, at 339.

[29] Goldman, *supra* note 11.

[30] *See id*.; Sabrina Tavernise, *F.D.A. Imposes Rules for E-Cigarettes in a Landmark Move*, N.Y. TIMES (May 5, 2016), https://www.nytimes.com/2016/05/06/science/fda-rules-electronic-cigarettes.html?smid=pl-share.

[31] *See* SHAPIRO & ANEJA, *supra* note 15, at P7, P40; Mitchell Zeller et al., *The Strategic Dialogue on Tobacco Harm Reduction: A Vision and Blueprint for Action in the US*, 18 TOB CONTROL 324, 325–26, 331 (2009).

altogether.[32] Furthermore, many public officials express serious concerns regarding e-cigarette marketing serving as a catalyst for increased youth nicotine addictions, as e-cigarette usage amongst our nation's youth has significantly increased.[33] In fact, Health and Human Services Secretary, Alex Azar, has noted that "[t]he United States has never seen an epidemic of substance use arise as quickly as our current epidemic of youth use of e-cigarettes."[34] In November 2019, a report conducted by the Journal of the American Medical Association revealed "that more than 1 in 4 high school students (more than 5 million teens nationwide) now use flavored e-cigarettes monthly, a significant increase from last year . . . ."[35] This astronomical figure is even more concerning when coupled with the opinions of medical professionals such as Dr. Tom Frieden of the Centers for Disease Control and Prevention (the "CDC"), who believes that increased use of e-cigarette products by the nation's youth will likely lead them to become addicted to traditional cigarettes as well.[36] As a result, public officials have been met with significant pressure to take measures to reduce youth exposure to e-cigarettes.[37]

While e-cigarettes and vaporizer products remained largely unregulated for many years following their introduction into the U.S.

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[32] *See* Janine K. Cataldo et. al, *E-Cigarette Marketing and Older Smokers: Road to Renormalization*, AM. J. HEALTH BEHAV. 361, 369 (2015), https://www.bhthechange.org/wp-content/uploads/2019/07/Handout5-E-Cigarettes-and-Older-Adults.pdf. ("[E]-cigarette advertising promotes dual use and may contribute to the renormalization of smoking."); *Regulatory Obstacles to Harm Reduction*, *supra* note 16, at 752 (citing David B. Abrams, *Promise and Peril of E-Cigarettes: Can Disruptive Technology Make Cigarettes Obsolete?,* 311 JAMA 135 (2014)).

[33] *See* Matt Richtel, *Use of E-Cigarettes by Young People Is Major Concern, Surgeon General Declares*, N.Y. TIMES (Dec. 8, 2016), https://www.nytimes.com/2016/12/08/health/ecigarettes-united-states.html.

[34] *See* Dan Vergano, *Trump Just Announced a Nationwide Ban of All Vape Flavors Except Tobacco and Menthol*, BUZZFEED NEWS (Jan 2, 2020, 5:17 PM), https://www.buzzfeednews.com/article/danvergano/trump-juul-flavor-ban.

[35] *Id.*

[36] *See* Karen Kaplan, *CDC Director Explains What He Hates About Electronic Cigarettes*, L.A. TIMES (Apr. 29, 2014), https://www.latimes.com/science/sciencenow/la-sci-sn-why-tom-frieden-hates-electronic-cigarettes-cdc-20140429-story.html.

[37] *See* Vergano, *supra* note 34.

marketplace,[38] health studies highlighting the potentially dangerous effects of these devices provided the federal government with significant motivation to more closely examine the need for a stricter regulatory approach in the interest of protecting public health.[39] In a 2009 study conducted by the FDA, researchers discovered "detectable levels of toxic cancer-causing chemicals, including an ingredient used in antifreeze, in two leading brands of e-cigarettes and 18 various cartridges."[40] Additionally, a 2014 study revealed that "aerosol from e-cigarettes with a higher voltage level contains more formaldehyde, another carcinogen with the potential to cause cancer."[41] Moreover, in 2016, researchers determined that "people who use[] e-cigarettes [are] 30 percent more likely to . . . develop[] a chronic lung disease, including asthma, bronchitis and emphysema, than nonusers."[42] Most recently, in 2019, the American Journal of Preventive Medicine assessed the impact of e-cigarettes on the human respiratory system and concluded that "people who use only e-cigarettes increase their risk of developing lung disease by about 30% compared with nonusers."[43] Despite these medical findings, however, strict regulatory measures for ENDS products remained

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[38] *See* Goldman, *supra* note 11.

[39] *See FDA Warns of Health Risks Posed by E-Cigarettes*, FDA (July 2009), https://www.casaa.org/wp-content/uploads/FDA-Press-Release-2009.pdf; Greenberg, *supra* note 11, at 784.

[40] Dieter Holger, *7 Reasons E-Cigarettes Are Bad*, INQUISITR (Aug. 30, 2015), https://www.inquisitr.com/2378144/7-reasons-e-cigarettes-are-bad/; *Are Electronic Cigarettes Safe?*, PIEDMONT HEALTHCARE, https://www.piedmont.org/living-better/are-electronic-cigarettes-safe.

[41] Mary Brophy Marcus, *E-Cigarette Flavorings Linked With Lung Disease*, CBS NEWS (Dec. 8, 2015, 5:21 PM), https://www.cbsnews.com/news/e-cigarette-flavorings-linked-with-lung-disease/; Greenberg, *supra* note 11, at 784 (quoting *E-Cigarettes and Lung Health*, AM. LUNG ASS'N, http://eee.lung.org./stop-smoking/smoking/smoking-facts/e-cigarettes-and-lung-health.html [https://perma.cc/VR3S-ZUNV].).

[42] Erika Edwards, *E-Cigarettes Linked to Lung Problems, First Long-term Study on Vaping Finds*, NBC NEWS (Dec. 16, 2019, 6:36 AM), https://www.nbcnews.com/health/vaping/e-cigarettes-linked-lung-problems-first-long-term-study-vaping-n1101641.

[43] Kathleen Raven, *Teen Vaping Linked to More Health Risks*, YALE MED. (Dec. 18, 2019), https://www.yalemedicine.org/stories/teen-vaping/ (citing Dharma N. Bhatta & Stanton A. Glantz, *Association of E-Cigarette Use with Respiratory Disease Among Adults: A Longitudinal Analysis*, 58 AM. J. PREVENTATIVE MED. 182, 182–90 (2019)).

largely unenforced by the federal government until a nationwide "outbreak" of severe lung injuries took the public by storm.[44]

II. THE FALL: RECENT OUTBREAKS

The sale of e-cigarettes and vaporizers in the United States market has steadily increased for nearly a decade.[45] Widely publicized reports of serious vaping-related illnesses beginning in 2019, however, set the stage for what some public health officials consider to be our most recent "public health crisis."[46] The highly-publicized outbreaks of vaping-linked lung illnesses were first brought to the nation's attention by the Illinois and Wisconsin state health departments in April 2019.[47] Those departments tracked 53 patients, mostly young adult males, who were hospitalized after having reported serious "coughing, chest pain or shortness of breath."[48] Since April 2019, there have been over 2,000 cases of vaping-linked illnesses arising in every state in the nation.[49] Of those 2,000 + cases, the CDC has confirmed at least 57 deaths in 27 states.[50] Further, many victims who were fortunate to have escaped death "have ended up with acute respiratory distress syndrome, a life-threatening condition in which fluid builds up in the lungs and prevents [] oxygen . . . from circulating in the bloodstream."[51] While these mysterious vaping-linked illnesses perplexed medical officials for months,

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[44] Matthew Sprankle & Audrey Davis, *Up in Smoke: The Countdown on Vape Enforcement Discretion Begins*, EPSTEIN BECKER GREEN: HEALTH L. ADVISOR BLOG (Aug. 13, 2019), https://www.healthlawadvisor.com/2019/08/13/up-in-smoke-the-countdown-on-vape-enforcement-discretion-begins/; *see* Vergano, *supra* note 34.

[45] *See* Knowles & Sun, *supra* note 6.

[46] *Is a Vaping-Linked Lung Illness a Public Health Crisis? That Depends On Who You Ask*, PBS NEWS HOUR (Oct. 8, 2019, 2:54 PM), https://www.pbs.org/newshour/health/is-a-vaping-linked-lung-illness-a-public-health-crisis-that-depends-on-who-you-ask; *Outbreak of Lung Injury Associated with the Use of E-Cigarette, or Vaping, Products*, CDC (Feb. 25, 2020, 1:00 PM), https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html.

[47] *See* Knowles & Sun, *supra* note 6.

[48] *See id*.

[49] *Id*.

[50] *Id*.

[51] *Id.*

on November 8, 2019, "CDC officials announced a 'breakthrough' discovery" in their efforts to identify the precise cause of this newly identified lung disease formally named EVALI (the acronym stands for e-cigarette or vaping product use-associated lung injury).[52]

The CDC stated that vitamin E acetate, a chemical commonly found in some THC products, appeared to be the likely culprit causing the recent EVALI outbreaks.[53] That said, CDC officials noted that their discoveries were "inconclusive," stating that "more than one chemical could be contributing" to the vaping-linked illnesses.[54] Although inconclusive, data collected by the CDC surrounding EVALI outbreaks shows a strong correlation between the presence of vitamin E acetate in the bodies of victims and the inhalation of vaporized THC products.[55] In fact, the CDC announced that "nearly 83 percent of 1,184 patients for whom relevant data is available reported using THC-containing products, [the psychoactive component of marijuana], in the three months before [developing] their symptoms."[56] That said, 13% of victims reported to have only vaped nicotine-containing products.[57] Of that 13%, however, doctors have noted that some of the patients who stated that they had only vaped nicotine products tested positive for THC in their urine.[58] Given this inconsistency, some doctors believe that patients are unwilling to admit having used marijuana, likely because the substance is illegal under federal law.[59] Thus, with no conclusively identified singular cause of EVALI, the CDC has continued to actively compel those at higher risk, including young adults, to refrain from using all e-cigarette and vaping-related products.[60] Moreover, in the interest of

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[52] *Id*.; Raven, *supra* note 43; *E-Cigarette or Vaping Product Use-Associated Lung Injury (EVALI)*, YALE MED, https://www.yalemedicine.org/conditions/evali.

[53] Raven, *supra* note 43.

[54] *Id*.

[55] *See* Knowles & Sun, *supra* note 6.

[56] *Id*.; *see Marijuana Research Report: How does marijuana produce its effects?*, NAT'L INST. DRUG ABUSE, https://www.drugabuse.gov/publications/research-reports/marijuana/how-does-marijuana-produce-its-effects.

[57] Knowles & Sun, *supra* note 6.

[58] *Id*.

[59] *See id*.

[60] *Outbreak of Lung Injury Associated with the Use of E-Cigarette, or Vaping, Products*, *supra* note 46.

protecting the public health of their citizens, various state and local officials have taken regulatory matters into their own hands.[61]

On September 24, 2019, in response to the suspected link between the use of e-cigarette and vaping products and EVALI, "Massachusetts Governor Charlie Baker declared a public health emergency . . . call[ing] for a ban on the sale of all flavored and non-flavored vaping products and devices, including tobacco and marijuana."[62] This public health emergency enforced a four-month ban on the sale of all vaping-related products both online and in retail stores.[63] The decision to fully restrict the sale of these devices arose, in some part, because of "the absence of strong federal action by the FDA that is forcing states to have to make choices like this on how they are going to protect from e-cigarettes," said Governor Baker.[64] That said, the seemingly abrupt and strict regulatory measures taken by Governor Baker were met with significant pushback from local retailers and consumers contending, among other things, that the governor's decision would "push[] people into the illicit market—precisely where the dangerous products are—[the decision] goes against every principle of public health and harm reduction."[65] Further, in addition to opposition at the state level, the federal government has also been faced with strong challenges regarding its current regulatory framework for e-cigarette and vaping products.[66]

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[61] *See, e.g.*, Matt Stout, *Baker Declares Public Health Emergency, Orders 4-month Ban on All Vaping Products*, BOSTON GLOBE (Sept. 24, 2019, 2:13 PM), https://www.bostonglobe.com/news/marijuana/2019/09/24/governor-baker-make-vaping-announcement-amid-spate-lung-illnesses/o8sO6mf3GOmX4mOpLLtcEL/story.html.

[62] *States and Tribes Stepping in to Protect Communities from the Dangers of E-Cigarettes: Actions and Options (2020),* PUB. HEALTH L. CTR. (Feb. 25, 2020), https://www.publichealthlawcenter.org/resources/states-and-tribes-stepping-protect-communities-dangers-e-cigarettes-actions-and-options.

[63] Mark Fortier et al., *Sale of Vaping Products Temporarily Banned in Massachusetts as Gov. Baker Declares Public Health Emergency*, NBC BOSTON (Sept. 25, 2019, 6:11 PM), https://www.nbcboston.com/news/local/gov-charlie-baker-to-make-announcement-about-vaping-in-massachusetts/115821/.

[64] *Id*.

[65] *See* Stout, *supra* note 61.

[66] *See, e.g.*, Nicopure Labs, LLC v. FDA, 266 F. Supp. 3d. 360, 366 (D.D.C. 2017).

III. FDA REGULATION: THE DEEMING RULE & PRE-MARKET APPROVAL

The federal government has regulated the tobacco industry since 1965 when Congress first passed the Cigarette Labeling and Advertising Act (the "CLAA").[67] This legislation came on the heels of the 1964 Surgeon General's report, which first brought significant attention to the serious health risks caused by smoking cigarettes.[68] As a result, the passage of the 1965 CLAA imposed new rules requiring warning labels to be placed on all cigarette packages in order to increase the public's knowledge regarding the serious health risks associated with cigarettes.[69] Since then, a myriad of tobacco control laws have been implemented at the federal level relating to youth access, labeling, and marketing.[70] The inherent structure of tobacco regulation, however, remained largely unaltered until a series of litigation arose in the 1990s, resulting in "the largest privately negotiated transfer of wealth arising out of litigation in world history."[71] During that decade, a compilation of states' attorneys generals worked together to sue the largest tobacco companies in a tort liability suit, seeking compensation for health care costs incurred as a result of "treating sick and dying cigarette smokers."[72] By 1998, the four largest cigarette manufacturers entered into "The Master Settlement Agreement" (the "MSA") with forty-six states, which required, among other things, that the companies pay roughly $12.75

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[67] *See* Federal Cigarette Labeling and Advertising Act, 15 U.S.C. §§ 1331-39 (1965); *see also* Matthew R. Herington, *Tobacco Regulation in the United States: New Opportunities and Challenges*, 23 HEALTH L. 13, 13–15 (2010).

[68] CDC, *History of the Surgeon General's Reports on Smoking and Health*, https://www.cdc.gov/tobacco/data_statistics/sgr/history/index.htm; *Regulatory Obstacles to Harm Reduction: The Case of Smoking*, *supra* note 16, at 715.

[69] *See* Kelly A. Moore, *Federal Cigarette Labeling and Advertising Act of 1965*, CENGAGE (Jan. 16, 2020), https://www.encyclopedia.com/history/encyclopedias-almanacs-transcripts-and-maps/federal-cigarette-labeling-and-advertising-act-1965; Greenberg, *supra* note 11, at 780.

[70] *See* Herington, *supra* note 67, at 13–15.

[71] *See* Bruce Yandle et al., *Bootleggers, Baptists & Televangelists: Regulating Tobacco by Litigation*, 2008 U. ILL. L. REV. 1225, 1227 (2008); *Regulatory Obstacles to Harm Reduction*, *supra* note 16, at 716; Greenberg, *supra* note 11, at 781.

[72] *Master Settlement Agreement: An Overview*, PUB. HEALTH LAW CENTER, https://www.publichealthlawcenter.org/sites/default/files/resources/tclc-fs-msa-overview-2015.pdf; *see* Greenberg, *supra* note 11, at 781.

billion annually to the states, agree to increased restrictions on their marketing and advertising practices in addition to an imposed tax that would increase the price of cigarettes.[73] Although, before the MSA, lawsuits against tobacco manufacturers were primarily initiated by private individuals seeking compensation for their injuries derived from cigarette usage.[74] Much of this private litigation, however, proved to be unsuccessful as plaintiffs encountered challenging hurdles surrounding their claims of deceptive marketing practices because, by then, all cigarette packages had provided "government-mandated warning[s]."[75] As a result, this reinforced the large tobacco companies successful defenses in claiming that the plaintiffs had assumed the risk of using cigarettes.[76] That being said, unlike the private lawsuits, the lawsuits initiated by the states' attorneys general were more powerful because the assumption of risk defense did not apply in the states' suits.[77] As one attorney general explained, "[t]his time, the industry cannot claim that a smoker knew full well what risks he took each time he lit up. The state of Mississippi never smoked a cigarette. Yet it has paid the medical expenses of thousands of indigent smokers who did."[78] As a result, the tobacco companies both recognized and appreciated the lurking threat of being faced with aggressive lawsuits by upwards of 50 states, and thus they agreed to a revolutionary settlement deal with the states, paving the way for progressive tobacco regulation to come.[79]

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[73] *Master Settlement Agreement: An Overview*, *supra* note 72, at 2–3; *see* Greenberg, *supra* note 11, at 781; Yandle et al., *supra* note 71, at 1227.

[74] *See* Adler et al., *supra* note 15, at 327 (citing Yandle et al., *supra* note 71, at 1259–63.).

[75] *See id*.

[76] *See* Stephen D. Sugarman, *Mixed Results From Recent United States Tobacco Litigation*, 10 TORT REV. 1, 3 (2002); Lynn Mather, *Theorizing about Trial Courts: Lawyers, Policymaking, and Tobacco Litigation*, 23 L. & SOC. INQUIRY 897, 904 (1998).

[77] *See* Adler et al., *supra* note 15, at 327; Michael DeBow, *The State Tobacco Litigation and the Separation of Powers in State Governments. Repairing the Damage*, 31 SETON HALL L. REV. 563, 571–72 (2001).

[78] Mike Moore, *The States Are Just Trying to Take Care of Sick Citizens and Protect Children*, 83 A.B.A. J, 53, 53 (1997); *see* DeBow, *supra* note 77, at 572.

[79] *See* Jess Alderman & Richard A. Daynard, *Applying Lessons from Tobacco Litigation to Obesity Lawsuits*, 30 AM. J. PREV. MED., 82, 83 (2006); Adler et al.,

While the MSA laid the groundwork for cigarette regulatory measures, it did not possess "the force of federal law."[80] Years after the MSA, however, Congress passed the 2009 Family Smoking Prevention and Tobacco Control Act ("The Tobacco Control Act" or "The Act"), which gave the FDA significant power to regulate tobacco products in various ways.[81] Specifically, the Tobacco Control Act enabled the FDA to require cigarette manufacturers to disclose all of the "health information, including lists of ingredients by brand and sub-brand, descriptions of nicotine delivery [content], and documentation of the health effects of each product" they sold.[82] Perhaps most notably, the Act also imposed significant regulations on the marketing and advertising of modified risk products.[83] Under the 2009 legislation, a modified risk product constitutes "any tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products."[84] Thus, if a cigarette manufacturer seeks to market their product as being less harmful compared to other tobacco products, they are required "to support that claim with scientific evidence" that "demonstrate[s] that the product will or is expected to benefit the health of the population as a whole," before they can receive FDA approval.[85] The Tobacco Control Act, however, when initially signed into law, did not extend its regulatory power over all types of tobacco-related products.[86]

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supra note 15, at 327–28; DeBow, *supra* note 77, at 567–68; Greenberg, *supra* note 11, at 781.

[80] *See* Adler et al., *supra* note 15, at 330.

[81] 21 U.S.C. § 387a–1; *see* Greenberg, *supra* note 11, at 781; Adler et al., *supra* note 15, at 332.

[82] *A Deeming Regulation: What is Possible Under the Law*, PUB. HEALTH L. CENTER https://www.publichealthlawcenter.org/sites/default/files/resources/tclc-fs-deeming-reg-what-is-possible-2014.pdf.

[83] *Id.*; *see* Adler et al., *supra* note 15, at 332.

[84] 21 U.S.C. § 387k(b)(1).

[85] *See Modified Risk Tobacco Products*, FDA (Sept. 17, 2020), https://www.fda.gov/tobacco-products/advertising-and-promotion/modified-risk-tobacco-products; Greenberg, *supra* note 11, at 782.

[86] *See* Goldman *supra* note 11; Greenberg, *supra* note 11, at 783.

A. *Introducing: The Deeming Rule*

Non-tobacco nicotine delivery products such as vaporizers and e-cigarettes, remained unregulated by the Tobacco Control Act at the time of its passage.[87] Thus, the "major gap in regulation"[88] presented policymakers with difficult questions regarding how to fit these new electronic nicotine delivery systems into the previously existing tobacco regulatory regime.[89] Because the Tobacco Control Act granted the FDA regulatory authority over "cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and to any other tobacco products that the Secretary by regulation *deems* to be subject to this subchapter," however, the agency was granted the legislative discretion to *deem* e-cigarettes and numerous other devices as "tobacco products" subject to the Act.[90]

Despite this broad grant of authority by Congress in 2009, the FDA refrained from taking any action to deem previously unregulated tobacco products to be subject to the Tobacco Control Act until 2016.[91] In May of 2016, the FDA acted on its authority to impose a new rule that would deem e-cigarettes and other previously unregulated tobacco products to be subject to all of the Tobacco Control Act's requirements and to even further FDA product regulation.[92] The primary basis for the agency's decision was to learn more about the potential for harm to public health.[93] Not only did the Deeming Rule subject e-cigarettes and other vaporizer devices to new regulations, the rule was also extended to include, among other things,

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[87] *See* Greenberg, *supra* note 11, at 783.

[88] *Id*.

[89] *See* Wendy E. Parmet, *Paternalism, Self-Governance, and Public Health: The Case of E-Cigarettes*, 70 U. MIA. L. REV. 879, 883 (2016).

[90] *See* 21 U.S.C. § 387a(b) (emphasis added); Adler et al., *supra* note 15, at 332–33.

[91] *See* Deeming Rule, *supra* note 16, at 28974; Katelyn Newman, *Vaping and E-Cigarettes: The New Public Health Problem*, US NEWS (Sept. 30, 2019 at 9:00 AM), https://www.usnews.com/news/healthiest-communities/articles/2019-09-30/vaping-and-e-cigarettes-a-new-public-health-problem.

[92] *See* Newman, *supra* note 91.

[93] Deeming Rule, *supra* note 16, at 28983; *see Regulatory Obstacles to Harm Reduction*, *supra* note 16, at 733–34.

various components and parts of e-cigarettes and vaporizers such as their batteries, cartridges, e-liquids, and even device software.[94]

Further, FDA enforcement of the Deeming Rule also required that e-cigarette and vaporizer manufacturers be subjected to a "mandatory approval process that could hamstring all but the largest e-cigarette producers."[95] Specifically, the Rule requires all "manufacturers of newly regulated tobacco products, that were not on the market as of February 15, 2007, . . . to show that [their] products meet the applicable public health standard set by the law. And those manufacturers will have to receive marketing authorization from the FDA."[96] In order to meet the applicable public health standards, manufacturers must submit an application to the FDA sufficiently demonstrating that its brand of e-cigarette is substantially equivalent to a product that was on the market in 2007.[97] Given the recency of e-cigarette innovations, however, there were little to no commercially marketed e-cigarettes as of February 15, 2007.[98] Therefore, many industry leaders and even the FDA has acknowledged that nearly every e-cigarette company and product on the market will be unable to meet this required showing of substantial equivalence, and, as a result, companies will need to go through a procedure of premarket review prior to being permitted to lawfully sell their products in the U.S. marketplace.[99]

B. *Pre-market Tobacco Applications ("PMTAs")*

Acquiring premarket approval, in most cases, poses significant challenges for the vast majority of e-cigarette and vaporizer

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[94] Deeming Rule *supra* note 16, at 28975; Greenberg, *supra* note 11, at 786–87; *see* Adler, *supra* note 16, at 739.

[95] Adler et al., *supra* note 15, at 314 (citing Tavernise, *supra* note 30.).

[96] *The Facts on the FDA's New Tobacco Rule*, FDA (Jun. 16, 2016), https://www.fda.gov/consumers/consumer-updates/facts-fdas-new-tobacco-rule; *see* Greenberg, *supra* note 11, at 787.

[97] *See* 21 U.S.C. § 387j(a).

[98] *See Historical Timeline of Electronic Cigarettes*, CASAA, http://www.casaa.org/historical-timeline-of-electronic-cigarettes/; Greenberg, *supra* note 11, at 787; Parmet, *supra* note 89, at 941.

[99] *See* Jacob Sullum, *'Tobacco Products' That Aren't*, REASON (May 5, 2014, 8:30 AM), https://reason.com/2014/05/05/tobacco-products-that-arent/; Parmet, *supra* note 89, at 941 (citing *The FDA & Deeming Regulations of E-Cigarettes*, CASAA (Mar. 3, 2013), http://casaa.org/deeming_ regulations.html.).

manufacturers who seek to lawfully sell their products in the U.S. marketplace.[100] In April of 2020, a U.S. District Court judge in Maryland issued a revised order requiring that companies engaged in the sale of e-cigarette devices prior to the August 8, 2016, passage of the Deeming Rule submit applications for market approval by September 9, 2020, in order to continue selling their products.[101] Companies that did not have products on the market prior to the August 8, 2016, passage of the Deeming Rule must submit a PMTA and receive FDA approval before being permitted to engage in the lawful sale of their products.[102] Furthermore, the rule exempts traditional tobacco products from the PMTA requirements because nearly all traditional cigarettes were marketed prior to 2007, grandfathering those products in.[103] Such a rule of construction provides a windfall to the big tobacco companies because if e-cigarette manufacturers are forced out of business due to an inability to meet the financial burdens of the PMTA requirements, then the big tobacco companies would have less competition.[104]

PMTAs require that manufacturers begin by providing samples of their products along with "descriptive information" about their product's "formulation and design, the nicotine strength, [and] instructions for its use."[105] Further, manufacturers must also include "detailed scientific studies and analyses of research findings,"[106]

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[100] *See* Tavernise, *supra* note 30.

[101] Azim Chowdhury & Eric Gotting, *Maryland District Court Extends Premarket Application Submission Deadline to September 9, 2020 in Light of Coronavirus Outbreak; Appeal of the Merits Continues with the Fourth Circuit*, CONTINUUM RISK (Apr. 29, 2020), https://www.thecontinuumofrisk.com/2020/04/maryland-district-court-extends-pmta-submission-deadline-to-september-9-2020-in-light-of-coronavirus-outbreak-appeal-of-the-merits-continues-with-the-fourth-circuit/; *see* American Academy of Pediatrics, et al. v. FDA, et al., No. 8:18-cv-00883, Docket No. 182 (D. Md. Apr. 22, 2020) (modifying a remedy order).

[102] *See* Sprankle & Davis, *supra* note 44.

[103] *See* Sullum, *supra* note 99.

[104] *See Regulatory Obstacles to Harm Reduction*, *supra* note 16, at 740–41 (citing Tavernise, *supra* note 30); 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.

[105] Sprankle & Davis, *supra* note 44.

[106] *Id*.

which "show the health risks of such tobacco product and whether such tobacco product presents less risk than other tobacco products."[107] Finally, each PMTA must also include "information on how to minimize the risks associated with ENDS batteries and to address the likelihood of use and misuse leading to overheating, fire, and explosion."[108]

Before a manufacturer submits their PMTA and receives FDA approval, the manufacturer is prohibited from making any commercial statements that "explicitly or implicitly" state that a product "presents a lower risk of tobacco-related disease or is less harmful than one or more other commercially marketed tobacco products, . . . contains a reduced level of a substance or presents a reduced exposure to a substance, . . . or does not contain or is free of a substance."[109] Interestingly, manufacturers are even prohibited from repeating the FDA's own statements regarding the health risks of e-cigarettes relative to traditional cigarettes.[110] Thus, despite the fact that FDA has publicly stated that "the inhalation of nicotine (e.g., nicotine without the products of combustion) is of less risk to the user than the inhalation of nicotine delivered by smoke from combusted tobacco products," manufacturers are prohibited from including this statement in any form of product advertising without first having their PMTA approved by the FDA.[111] Furthermore, prior to receiving the FDA's blessing, "[a]n electronic cigarette company cannot even inform consumers that the[ir] product does not produce smoke."[112]

Acquiring PMTA approval poses significant challenges for manufacturers because of how expensive and time-consuming the process is.[113] The FDA has estimated that the research costs associated with gathering the required data for a single product to be

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107 Greenberg, *supra* note 11, at 788; *see* 21 U.S.C. § 387j(b)(1)(A).

108 Sprankle & Davis, *supra* note 44.

109 *See* Adler, *supra* note 9.

110 *Id.*

111 *Id*.

112 *See* Sullum, *supra* note 99.

113 *See* Tavernise, *supra* note 30; Susan Adams, *E-Cigarette Manufacturers Say New Regulations Will Devastate The Industry*, FORBES (May 5, 2016, 3:01 PM), https://www.forbes.com/sites/susanadams/2016/05/05/e-cigarette-manufacturers-say-new-regulations-will-devastate-the-industry/#4a9ea62266d4.

between $117,000 and $466,000.[114] The magnitude of these costs is extreme given that manufacturers are required to submit a PMTA for each individual product, which includes each "differing flavor variant" and each level of "nicotine strength" offered.[115] All alterations in product design and packaging, are also treated as a different product.[116] Thus, because most manufacturers of e-cigarettes and vaping products produce numerous different flavors and varying levels of nicotine content, the total cost of filing applications for all of a manufacturer's products may cost millions of dollars.[117] For example, Apollo Electronic Cigarettes, one of the more popular manufacturers in the vaping industry,[118] produces over a dozen different flavors of vaping liquid, each of which are available in five varying levels of nicotine content.[119] The company would be required to submit 60 individual PMTAs in order to keep producing and selling their flavor options after the May 2020 deadline,.[120] Thus, Apollo Electronic Cigarettes' total costs for filling applications for all of its products would run the company between roughly $7,000,000 and $28,000,000 with no guarantee that their product applications will even receive FDA approval.[121] In addition to the costly prices, PMTAs are also significantly time-consuming as the FDA estimates that the process for filing a PMTA "will require 1,500 hours per

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[114] *See* FDA, *Commonly Asked Questions: About the Center for Tobacco Products* (Jun. 11, 2019), https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp/commonly-asked-questions-about-center-tobacco-products.

[115] *Id.*; *see* Kaleigh Rogers, *Five Ways the FDA's New Regulations Will Transform the Vaping Industry*, VICE (May 5, 2016, 4:50 PM), https://www.vice.com/en_us/article/4xa3kq/five-ways-the-fdas-new-regulations-with-transform-the-vaping-industry-e-cigarettes; *Regulatory Hurdles to Harm Reduction*, *supra* note 16, at 738; Greenberg, *supra* note 11, at 790.

[116] *See* FDA, GUIDANCE FOR INDUSTRY: DEMONSTRATING THE SUBSTANTIAL EQUIVALENCE OF A NEW TOBACCO PRODUCT: RESPONSES TO FREQUENTLY ASKED QUESTIONS (EDITION 3) 3 (2016), http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM436468.pdf; *Regulatory Obstacles to Harm Reduction*, *supra* note 16, at 738.

[117] *See* Rogers, *supra* note 114.

[118] *See Apollo E-Cigarette and E-Liquids – Popular, Reliable,* Affordable, BEST E-CIGARETTE GUIDE (Jan. 24, 2020), https://best-e-cigarette-guide.com/e-cigarette-reviews/apollo-ecigarette-and-e-liquids-popular-reliable-affordable/.

[119] *Id.*; *see* Greenberg, *supra* note 11, at 790 (analyzing impact on time-consumption for Apollo e-cigarettes to submit 60 PMTAs).

[120] Greenberg, *supra* note 11, at 790.

[121] *See id*. at 789–90.

product."[122] As a result, Apollo Electronic Cigarettes would likely need to spend approximately 90,000 hours in order to obtain FDA approval for all the variations of their product.[123] What this demonstrates is that manufacturers could potentially spend thousands of hours and millions of dollars in preparation for PMTA filings without the guarantee that their applications are even going to be approved. In fact, as of November 2019, the FDA had received 389 PMTAs.[124] Of those 389 applications, only one has been granted FDA approval for an e-cigarette product.[125] The application was submitted by Philip Morris, one of the largest and most profitable cigarette manufacturers in the tobacco industry.[126] Thus, in the eyes of the American Vaping Association, this regulatory procedure "is not regulation—it is prohibition."[127]

Given the infancy of the vaping industry, it is important to note that the majority of manufacturers are not entities such as Big Pharma or Big Tobacco, which have the resources to take on these extreme PMTA requirements.[128] Instead, the burdensome PMTA requirements threaten to eviscerate smaller businesses who simply do not have the financial resources to conduct sufficient research in order to have their applications approved.[129] Furthermore, assuming that a manufacturer does have the necessary resources to receive

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122 *Id.* at 789–90 (citing Rogers, *supra* note 115).

123 *Id.*

124 Tara Lin Couch & Mark J. Vaders, *FDA Holds Public Meeting on PMTAs for Deemed Products Meeting Summary*, FOOD & DRUG L. INST. (Nov. 2019), https://www.fdli.org/2019/11/fda-holds-public-meeting-on-pmtas-for-deemed-products-meeting-summary/.

125 *Id*.

126 *Id.*; *see The Facts about Philip Morris International: Company Is Cause of the Tobacco Problem, Not the Solution,* TOBACCO-FREE KIDS, https://www.tobaccofreekids.org/what-we-do/industry-watch/pmi-foundation/bad-acts (last visited May 15, 2021); Press Release, FDA, FDA permits sale of IQOS Tobacco Heating System Through Premarket Tobacco Product Application Pathway (Apr. 30, 2019); Tomi Kilgore, *Philip Morris's Stock Gains After Profit, Revenue Beat Expectations* (Oct. 20, 2020, 7:11 AM), https://www.marketwatch.com/story/philip-morriss-stock-gains-after-profit-revenue-beat-expectations-2020-10-20.

127 Tavernise, *supra* note 30.

128 *See* Adams, *supra* note 113.

129 *See id.*; Shari Rudavsky, *Indiana Vape Shop Owners Say New FDA Rule Will Crush Industry*, INDY STAR (May 9, 2016), https://www.indystar.com/story/news/2016/05/08/indiana-vape-shop-owners-say-new-fda-rule-crush-industry/84036264/.

application approval, the increased costs that the company will absorb from PMTA requirements will inevitably drive up the purchase price of their products for the consumer. Due to the heightened costs of production, companies will be forced to increase the price of their products in order to maintain their revenue figures.[130] As a result, this mark-up in price will likely have an adverse effect on consumers by compelling them to purchase deadly, traditional cigarettes as opposed to more expensive, but less harmful e-cigarettes.[131]

Moreover, one of the most serious concerns arising from this regulatory framework is "stifling innovation."[132] As a result of the immense costs, time, and research requirements, which are beyond the reach of most manufacturers, companies will have significantly less incentive to invest in innovative technologies to develop new safer alternatives to traditional cigarettes.[133] This serious disruption to the advancements of public health may very well reinvigorate a tobacco market dominated, once again, by traditional cigarettes scientifically proven to cause death and serious disease.[134]

Notwithstanding these legitimate concerns, the FDA has maintained its position that imposing the deeming regulations on e-cigarette and vaping products will aid in protecting public health.[135] The agency, however, failed to identify and quantify the specific health benefits that would result from such a broad extension of the Deeming Rule. Indeed, the FDA has even conceded 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

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130 *See* Rudavsky, *supra* note 129.

131 *See id.*; Greenberg, *supra* note 11, at 798–99.

132 *See* Gregory Conley, *Use Common Sense on E-Cigarettes*, U.S. NEWS & WORLD REP. (July 30, 2014), https://www.usnews.com/opinion/articles/2014/07/30/fda-should-not-classify-e-cigarettes-as-tobacco-products; Greenberg, *supra* note 11, at 798; Adler, *supra* note 16, at 752 (citing Abrams, *supra* note 32).

133 *See* Greenberg, *supra* note 11, at 799 (citing Michael Siegel, *POV: New FDA Regulations on Vaping Products a Failure*, BU TODAY (July 13, 2016), https://www.bu.edu/articles/2016/fda-vaping-regulations).

134 *See* Abrams, *supra* note 32, at 135; *Regulatory Obstacles to Harm Reduction* , *supra* note 16, at 752.

135 *See Regulatory Obstacles to Harm Reduction*, *supra* note 16, at 741 (citing *The Facts on the FDA's New Tobacco Rule*, *supra* note 96).

of these benefits at this time."[136] Thus, although the FDA has publicly affirmed their own findings regarding the lessened health risks of e-cigarettes relative to traditional cigarettes,[137] the agency remains committed to the proposition that the regulation of e-cigarettes as traditional cigarettes is necessary to "benefit public health," despite the fact that they are not certain as to how.[138]

Under the current FDA regulatory framework, the decision to regulate e-cigarettes in an identical fashion to that of traditional tobacco cigarettes poses undeniable constraints on innovation and threatens to undo the substantial progress made to reduce cigarette-related injuries.[139] As stated in the *Journal of the American Medical Association,*

> Applying overly burdensome, expensive regulatory hurdles to e-cigarettes could stifle innovation and favor the market domination of tobacco companies, which potentially promote dual use of cigarettes and e-cigarettes to minimize losing market share for their primary cigarette products. Independent e-cigarette companies . . . are more likely to have the goal of eliminating combusted cigarettes.[140]

While e-cigarettes are not free of all health risks, what is clear is that they have the potential to produce public health benefits by providing a less harmful alternative to a scientifically proven lethal product.[141] As such, this Note does not advocate for the proposition that e-cigarettes should go completely unregulated, but rather that society would benefit from an elastic regulatory framework capable of building in adjustment as the facts change. The remaining question becomes what type of regulatory framework is flexible enough to

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[136] Deeming Rule, *supra* note 16, at 28981; *see Regulatory Obstacles to Harm Reduction*, *supra* note 16, at 741; Greenberg, *supra* note 11, at 797.

[137] Deeming Rule, *supra* note 16, at 28984; *see* Adler, *supra* note 9.

[138] Deeming Rule, *supra* note 16, at 28984; *Regulatory Obstacles to Harm Reduction*, *supra* note 16, at 741.

[139] *See Regulatory Obstacles to Harm Reduction*, *supra* note 16, at 752.

[140] *Id.* (citing Abrams, *supra* note 32, at 135); Abrams, *supra* note 32, at 135 (citing Riccardo Polosa & Pasquale Caponnetto, *Time for Evidence-based E-Cigarette Regulation*, 14 LANCET 582, 582–83 (2013).

[141] *See, e.g.*, Simon, *supra* note 22; *Smoking and Tobacco Use: Fast Facts, supra* note 1.

minimize the risks of products that are not yet fully understood without hindering the development and industry growth of products with potentially large public health value. The answer may be found through the use of state tort law as "civil courts provide an alternative governmental arena for implementing and sometimes developing public polic[y] . . . ."[142]

IV. PRODUCTS LIABILITY: BALANCING DETERRENCE AND INCENTIVIZATION

Products liability theory serves to benefit both individual victims and society as a whole.[143] In general, tort law and products liability suits have three main goals.[144] The first goal, on the individual level, is to serve as a vehicle for injured victims to receive compensation for their product-related injuries.[145] This compensation may "include economic losses such as medical expenses or lost wages, and noneconomic losses such as pain and suffering."[146] Second, products liability suits serve a social function of deterring manufacturers from producing unsafe products.[147] This deterrence function occurs mainly by punishing product manufacturers "through [the] assessment of punitive damages."[148] Third, there are economic goals of products liability theory that also seek to provide a benefit to society. In general, tort law seeks to allocate resources efficiently "by attributing the social costs of accidents to those who cause them—for example, irresponsible corporations."[149] Thus, while products liability suits and federal regulation both serve to benefit the public health by preventing "the production [and] use of unsafe products,"

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[142] Mather, *supra* note 76, at 933 (citing Jacob Herbert, *Courts and Politics in the United States in* COURTS LAW AND POLITICS IN COMPARATIVE PERSPECTIVE 64 (1996)).

[143] *See* Susan Bartlett Foote, *Product Liability and Medical Device Regulation: Proposal for Reform* in NEW MEDICAL DEVICES: INVENTION, DEVELOPMENT, AND USE 73 (Karen B. Ekelman ed., 1988).

[144] *Id.* at 75.

[145] *Id*.

[146] *Id.*

[147] *Id*. at 73–74.

[148] *Id.* at 75; *see* Jane Mallor & Barry Roberts, *Punitive Damages: Toward a Principled Approach*, 31 HASTINGS L. J., 639, 641 (1980).

[149] Foote, s*upra* note 143, at 75.

products liability suits provide the added functions of victim compensation and social punishment.[150] Social deterrence and the threat of punishment through punitive damages can be strong motivating factors by which products are forced to be made safer.[151] In fact, in the case of Big Tobacco, R.J. Reynolds began engaging in measures to develop a safer traditional cigarette and desired to inform consumers about these plans.[152] Before the company could spread the news, however, their attorney swiftly warned Reynolds to refrain from taking such action "because of two words: product liability."[153]

In November 2019, Apple made the decision to remove "181 vaping apps from its online store."[154] Many of those now prohibited apps contain software that allows the user to configure various settings on their vape devices including the temperature at which vape fluids are vaporized.[155] Thus, following the lead of recent state and federal regulations, Apple has taken steps to "distance itself" from various manufacturing companies in the vaping industry.[156] This raises interesting questions as to whether intermediaries such as Apple are exposed to liability when they provide a marketplace for products that may or may not be dangerous. The answer to this question is likely no given that generally, under United States law, intermediaries that provide an online marketplace for mobile applications are protected against liability for the conduct of independent third-party app developers in a similar way to how online marketplace providers like Amazon are generally not liable for product defects arising in products manufactured by third-parties and sold

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150 *Id*. at 79.

151 *See* Alderman & Daynard, *supra* note 79, at 86 (citing Daniel Givelber, *Pure Smoke: Product Liability, Innovation, and the Search for the Safe Cigarette*, 7 TULANE J. TECH. INTELL. PROP. 1–49 (2005)).

152 *Id*.

153 *Id*.

154 Jack Nicas & Amie Tsang, *Apple to Ban Vaping Apps From Its Store*, N.Y. TIMES (Nov. 17, 2019), https://www.nytimes.com/2019/11/15/business/apple-vaping-apps.html.

155 *See id*.

156 *See id*.

through Amazon's platform.[157] This remains true "even if the [intermediaries] take an active role in selecting the apps."[158]

Despite this legal protection for intermediaries like Apple, what seems implicit in the background is the notion that if and when dangerous products result in consumer injuries, companies fear threats of liability.[159] Thus, what seems relatively apparent is that federal regulation is not the only concern for e-cigarette and vaporizer manufactures who wish to profit from the sale of their products. Without access to large online marketplaces such as Apple and other equivalent business entities, various e-cigarette and vaporizer manufacturers face the danger of significant product marginalization.[160] Thus, Apple may have the leverage to presumably impose significant regulatory responses on e-cigarette and vaporizer manufacturers who wish to sell their products in online marketplaces even before the courts get involved. In an effort to carefully avoid liability, Apple may, however, risk being careless in looking closely at the governing bodies of law when determining if they truly could face exposure to liability for marketing these applications.

That being said, if Apple decides to preclude marketplace entry to a substantial portion of the vaping industry, it could potentially face impending lawsuits by the manufacturers. In the event that Apple proceeds with this course of action, small businesses are going to be denied access to a large online marketplace, which may cause some of the businesses to fail and could inevitably lead those

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[157] CTR. FOR DEMOCRACY & TECH., INTERMEDIARY LIABILITY: PROTECTING INTERNET PLATFORMS FOR EXPRESSION AND INNOVATION 6–7 (2010), https://www.cdt.org/paper/intermediary-liability-protecting-internet-platforms-expressionand-innovation (citing 47 U.S.C. 230(c)(1)); *see* John Severance, *Judge: Couple Can't Sue Amazon for Fire Caused by Hoverboard Purchased From Chinese Seller*, COOK CNTY. REC. (Apr. 2, 2019), https://cookcountyrecord.com/stories/512398611-judge-couple-can-t-sue-amazon-for-fire-caused-by-hoverboard-purchased-from-chinese-seller.

[158] CTR. FOR DEMOCRACY & TECH., MOBILE PLATFORMS AS INTERMEDIARIES: LIABILITY PROTECTIONS IN THE UNITED STATES, THE EUROPEAN UNION, AND CANADA 2–3 (2012), https://cdt.org/wp-content/uploads/pdfs/Mobile-Platforms-As-Intermediaries.pdf.

[159] *See* Thomas C. Galligan, *Deterrence: The Legitimate Function of the Public Tort*, 58 WASH. & LEE L. REV. 1019, 1031–32 (2001), https://scholarlycommons.law.wlu.edu/wlulr/vol58/iss3/6.

[160] *See Apple Bans Major Vaporizers*, TVAPE REV. BLOG, https://torontovaporizer.ca/blog/apple-bans-major-vaporizers/ (Sept. 29, 2020).

businesses to bring lawsuits against Apple claiming tortious interference.[161] This begs the question of whether those businesses would have a viable claim for tortious interference if Apple precludes them from a large online marketplace while lacking sufficient knowledge regarding whether e-cigarette and vaporizers actually pose a significant public health risk. Although not a topic for this Note, there seems to be a potential for valid claims of tortious interference with contractual relations under these circumstances.[162]

What this example demonstrates is that corporations have a significant interest in taking measures to avoid exposure to tort liability claims.[163] Thus, if there is truth to the notion that the threat of tort liability is capable of imposing self-regulation on the e-cigarette and vaping industries, it begs the question of what added benefit strict federal regulation provides in managing the potential uncertainties associated with these products. The Master Settlement Agreement, which was struck between the States and the largest cigarette manufacturers, is a prime example of how the threat of tort liability has the power to force regulatory measures upon large corporations.[164] Furthermore, even if FDA requirements are fulfilled, in most cases, "compliance with federal . . . regulations does not preclude a jury from concluding that the product is unsafe, either because the design is defective or the warnings inadequate."[165] Thus, courts may find that a product has a defective design or an inadequate warning even if the product contains the FDA mandated language in its warning labels and the agency has approved the product as being safe.[166] This is not an unusual occurrence as "one trial lawyer [has] asserted that

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[161] *See* Andrew Medal, *Assessing the Effects of Apple's Ban on Vaping Apps*, ENTREPRENEUR (Nov. 27, 2019), https://www.entrepreneur.com/article/342899; *see also Jamie Maggard et al.*, What Constitutes "Wrongful Conduct" in Interference with Contractual or Economic Relations?, ABA (May 6, 2019), https://www.americanbar.org/groups/litigation/committees/business-torts-unfair-competition/practice/2019/wrongful-conduct-interference-contractual-economic-relations/ (discussing the element of "improper conduct" in a tortious interference action).

[162] *See* Zachary G. Newman & Anthony P. Ellis, *Navigating the Nuances of Tortious Interference Claims,* BUS. TORTS J., Summer 2011, at 1, 20.

[163] *See, e.g.*, DeBow, *supra* note 77, at 580.

[164] *See Master Settlement Agreement: An Overview*, *supra* note 72.

[165] Foote, *supra* note 143, at 80 (citing Ferebee v. Chevron, 736 F.2d 1529, 1539 (D.C. Cir. 1984)).

[166] *Id*.

'an effective presentation can be made in court that the FDA's standards . . . do not preclude recovery since they are so ineffectual as to be virtually meaningless.'"[167] Therefore, perhaps the most flexible and efficient way of regulating innovative modified risk tobacco products can be achieved through product liability claims based on state tort law with some federal regulatory measures enforced. This contention finds its support by analyzing the historical reformation of the Big Tobacco industry, which demonstrates that while governmental legislation can, at times, lend itself to constructive regulation, "litigation is often necessary to affect industry practices at the national level."[168]

State tort law causes of action have historically provided consumers of tobacco-related products with remedies for injuries incurred as a result of deceptive or misleading product warnings.[169] Further, Congress has acknowledged that private litigation has played an essential role in exposing tobacco industry practices in addition to effective regulatory measures necessary to combat those practices.[170] It is the adversarial nature of litigation that is capable and arguably most effective for exposing both the dangers of specific products in addition to any deceptive or misleading claims, warnings, or product labeling.[171] Tort law liability suits do, however, have drawbacks as they may not always serve as an effective means by which to achieve information gathering regarding potentially dangerous products due to the fact that "over 90 percent of [tort law] suits are settled out of court."[172] There is an undeniable threat to information gathering in the products liability arena given the "pressure from individuals and their lawyers [to receive] compensation."[173] The desire for individuals to receive compensation may lead to most cases being settled, which can impede information

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[167] *Id.* (quoting Raney, M. B. 1986. Medical-device Defects. Trial (May): 39–42).

[168] Alderman & Daynard, *supra* note 79, at 82.

[169] *See* Debow, *supra* note 77, at 563–65.

[170] *See* 144 CONG. REC. 9793–96 .

[171] *See* Sam F. Halabi, *The Scope of Preemption under the 2009 Family Smoking Prevention and Tobacco Control Act*, 71 FOOD & DRUG L. J. 300, 306–07 (2016).

[172] Foote, *supra* note 143, at 76.

[173] *Id*. at 81.

gathering processes necessary to improve product safety.[174] Such a threat, however, may be neutralized by having states bring lawsuits on behalf of victims.[175]

State-initiated litigation occurred in the context of traditional cigarettes in which numerous states' attorneys general initiated lawsuits against some of the largest cigarette manufacturers in the industry.[176] This series of litigation revealed significant information about the tobacco industry by focusing "media and public attention on the plaintiffs' cigarette-induced suffering, as well as exciting widespread discussion and debate on the larger issues of personal and corporate responsibility."[177] Furthermore, the litigation also revealed substantial information through compelled disclosures, including "evidence of nicotine research within the industry," which assisted attorneys in developing legal arguments that the tobacco companies conspired to "hide scientific evidence about the [known] dangers of smoking . . . ."[178] In sum, tobacco litigation proved to be a significant instrument for advancing public health as it exposed damaging information about the tobacco industry and laid the foundation for subsequent governmental regulations.[179]

When trial court activities are covered by the media, as was the case with traditional cigarettes, this "may have similar effects to Supreme Court actions in increasing public awareness and legitimacy of [the] issues before them."[180] Therefore, if we believe that tort litigation is a capable vehicle for both generating and integrating expert knowledge in order to expose dangerous products without FDA intervention, then there seems to be no justifiable reason for the federal government to try and force-fit e-cigarette and vaporizer products into FDA regulatory processes like the Deeming Rule, which was not designed for them. This contention is further supported by

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174 *See id*. at 76.

175 *See* Mather, *supra* note 76, at 931.

176 *See* DeBow, *supra* note 77, at 566–70 (explaining the history of state-initiated lawsuits against major cigarette manufacturers).

177 Richard A. Daynard, *Tobacco Liability Litigation as a Cancer Control Strategy*, 80 J. NAT'L CANCER INST. 9, 10 (1998).

178 Mather, *supra* note 76, at 919, 931 (citing Graham E. Kelder & Richard A. Daynard, *Tobacco Litigation as a Public Health and Cancer Control Strategy*, 51 J. AM. MED. WOMEN'S ASS'N, 57–62 (1996)).

179 *See id.* at 912, 931–33.

180 Mather, *supra* note 76, at 913.

the FDA's own statements noted above, in which the agency has unambiguously conceded that it is not exactly sure how to quantify the direct benefits of imposing the Deeming Rule on e-cigarettes and vaporizer products.[181]

At present, current FDA regulatory measures are ineffectively utilized. As discussed, the requirements for PMTA approval impose significant costs on many industry manufacturers who simply do not have the resources to meet those requirements.[182] As a result, such high costs will likely force many, especially smaller companies, out of the industry.[183] Further, for the select minority of companies that can meet the PMTA burdens, the imposition of these newly imposed costs will likely result in increased product pricing to fall on the shoulders of consumers, and thus potentially disincentivize them from purchasing a less dangerous, but more expensive tobacco alternative.[184] Lastly, the excessive requirements to receive PMTA approval also pose a serious threat to the "stifling [of] innovation" by disincentivizing investment in new technologies.[185] As such, there is a pressing need for a regulatory regime that strikes an appropriate middle ground between protecting the public health interest without imposing significant constraints on industry growth, product innovation, and consumer access to alternative harm reducing e-cigarette devices.

In order to accomplish this goal, e-cigarettes and vaporizers must not be subject to regulation in the same fashion as traditional cigarettes. There are two compelling reasons for this. First, traditional cigarettes are scientifically proven to be lethal killers whereas the harmful effects of e-cigarette and vaporizers remain largely inconclusive.[186] What is conclusive, however, is that e-cigarettes and vaporizers possess potential promise as a healthier alternative to

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[181] Deeming Rule, *supra* note 16, at 28981.

[182] *See* Adams, *supra* note 113.

[183] *See id*.

[184] *See* Rudavsky, *supra* note 129; Greenberg, *supra* note 11, at 798–99.

[185] *See* Conley, *supra* note 132; Greenberg, *supra* note 11, at 798–99; Adler, *supra* note 16, at 752; Abrams, *supra* note 32, at 135.

[186] *See Smoking & Tobacco Use: Fast Facts*, *supra* note 1; Simon, *supra* note 22; SHAPIRO & ANEJA, *supra* note 15, at P6–P7.

traditional cigarettes.[187] Thus, until there is conclusive science indicating that e-cigarettes and vaporizer products cause a substantial threat to public health, the current FDA regulatory framework lacks a rational basis and may, in the final analysis, "do more harm than good" in regards to protecting public health.[188] To be clear, this Note does not argue that the federal government should refrain from imposing any regulatory measures; rather, there needs to be an appropriate balance between state and federal regulatory means because solely utilizing rigid federal regulatory measures does not allow for adjustment to be built in as the facts change. That said, under tort law, adjustment can happen automatically as the facts change and suddenly the litigation looks different. As such, tort law may provide a flexible framework for regulation that can be utilized in conjunction with specific federal regulatory requirements.

One middle-ground position for a regulatory regime that incorporates both state tort law and federal regulatory measures may be that the federal government first imposes serious restrictions on marketing tactics aimed at the youth by, among other things, banning the sale of flavored e-cigarettes as President Donald Trump and other officials have sought to do.[189] The available data clearly reflects a heightened correlation between commercial sales of flavored e-cigarettes and increased use by minors as recent studies indicate that "[y]outh e-cigarette users cite flavors as a top reason they began using e-cigarettes."[190] Second, in light of the recent outbreaks of EVALI,[191] which have revealed the THC thickening agent, vitamin E acetate, to likely be the primary culprit attributable to the mysterious vape-related lung diseases, the federal government should also impose a complete ban on the use of this thickening agent in all vaporizer products.[192] Third, the FDA should implement restrictions on the voltage or temperature settings at which e-cigarette and vaporizer devices can heat their liquids, given evidence indicating that

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[187] *See* Michael Joseph Blaha, *5 Vaping Facts You Need to Know*, JOHNS HOPKINS MED., https://www.hopkinsmedicine.org/health/wellness-and-prevention/5-truths-you-need-to-know-about-vaping; Simon, *supra* note 22.

[188] *See* Adler, *supra* note 9.

[189] *See* Vergano, *supra* note 34.

[190] *E-Cigarettes: Facts, Stats and Regulations*, *supra* note 13.

[191] *Outbreak of Lung Injury Associated with the Use of E-Cigarette, or Vaping, Products*, *supra* note 46.

[192] Knowles & Sun, *supra* note 6.

sufficiently high temperatures may cause users to be exposed to increased levels of formaldehyde, but lower temperatures and voltages produce no exposure.[193] By restricting the sale of flavored e-cigarettes, prohibiting the use of vitamin e-acetate, and restricting device voltages, the FDA will retain its regulatory measures designed to protect the public health while eliminating most unintended adverse impacts of the current regulatory scheme. These FDA regulatory measures are appropriate because they address concrete and currently identifiable threats to public health.

Furthermore, to promote effective information gathering processes, the FDA should also implement an incentive system for manufacturers in order to increase the volume and quality of information provided to the agency.[194] Such an incentive system can be utilized to address the current burdens of the PMTA approval process. Instead of requiring that all e-cigarette and vaporizer manufacturers be subjected to the financial burdens of the PMTA approval process, the FDA should consider making PMTA requirements optional, but provide meaningful incentives for companies that do fulfill the PMTA requirements. In order to properly incentivize those companies that meet the PMTA requirements, the FDA could develop a rule of construction that would impose a defense or bar against products liability suits brought against those companies.[195] Thus, if a company's PMTA receives FDA approval, then the company would be insulated from tort liability.[196] If a company, however, decides not to apply for or does not receive PMTA approval for their product, then that company would not be provided insulation from tort liability suits based on defective design or inadequate warnings or labels.[197] Under this regulatory scheme, there will likely be consolidation of the industry given that there will inevitably be manufacturers that decide not to take advantage of the FDA incentives given a lack of resources, time, or otherwise, and thus will become exposed to lawsuits. That said, companies will have a strong incentive to comply with the PMTA requirements given that

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193 Paul R. Jensen et al., *Letters, Hidden Formaldehyde in E-Cigarette Aerosols*, 372 NEW ENG. J. MED. 392, 392 (2015).

194 *See* Foote, *supra* note 143, at 85.

195 *See id.* (utilizing a similar model in context of medical devices).

196 *See id*.

197 *See id*.

damages incurred as a result of product liability suits have historically forced manufacturers into bankruptcy.[198] Aside from these regulatory measures, however, the federal government should permit state tort law to manage the remaining though uncertain risks associated with e-cigarette and vaporizer products.

To effectuate the functions of social deterrence and punishment, product liability suits involving e-cigarette and vaporizer products should be brought by the states themselves on behalf of victims instead of by private individuals.[199] This type of public law regime would presumably decrease the number of cases that settle out of court, and thus increase the effectiveness of information gathering through litigation, which integrates the use of expert knowledge. Furthermore, such a regime may also protect private individuals against a "scorched earth" litigation strategy, whereby large companies utilize their immense resources to delay litigation proceedings and refuse to engage in settlement negotiations in an effort to "wear[] down plaintiffs financially and emotionally."[200] Such a public law regime, however, could raise the issue of whether states can be fully entrusted with the responsibility of initiating lawsuits against industries when such action is appropriate.[201] One mitigating factor on this issue may be that providing states with this right of action would allow for an entity to exercise a middle position judgment because while the states may have some political accountability, they also have real interests in money in addition to the beneficiaries who will vote for them.[202] That said, such a regime may also delay the time in which victims eventually receive compensation because the cases may not settle quickly, if at all. Nevertheless, the increase in information gathering through state-initiated litigation may outweigh this concern.[203]

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198 *See, e.g.*, Stuart Diamond, *Robins, In Bankruptcy Filing, Cites Dalkon Shield Claims,* N.Y. Times (Aug. 22, 1985), https://www.nytimes.com/1985/08/22/business/robins-in-bankruptcy-filing-cites-dalkon-shield-claims.html.

199 *See* DeBow, *supra* note 77, at 566–67.

200 Alderman & Daynard, *supra* note 79, at 82–83.

201 *See* Foote*, supra* note 143, at 89.

202 *See* DeBow, *supra* note 77, at 576–80.

203 *See* Daynard, *supra* note 177, at 10–11.

CONCLUSION

Products such as e-cigarette and vaporizers present uncertain health risks yet to be fully understood.[204] At the same time, these products also possess potentially significant public health benefits capable of improving societal health.[205] Thus, in some ways, these products can be thought of as valuable moving targets that are in need of more factual learning. As a result, these products and future ones like them require a flexible regulatory framework that is capable of building in adjustment as the facts develop. Striking a middle ground between minimizing uncertain public health risks, while at the same time not discouraging innovation and industry growth, should be the primary goal for regulation. Thus, for officials tasked with developing the most effective methods of regulation, perhaps this means that they should take calculated risks in the interest of promoting innovation as "[i]t is no accident that the most promising technological [tobacco] alternative [originally] emerged from an unregulated environment."[206]

The safety of our society is improved by the development of potentially "dangerous technologies."[207] Rather than imposing inequitable and overly burdensome regulatory regimes that discourage innovation and the diffusion of what may be the next significant public health benefit, the most effective means of regulation might be to embrace calculated risks in the pursuit of innovative technologies that advance society. In the final analysis, a products liability theory of regulation managed under state tort law that includes specific target-oriented federal restrictions may provide the most balanced regulatory framework for creating a habitable environment in which new innovations for public health can appropriately flourish.

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204 *See* SHAPIRO & ANEJA, *supra* note 15, at P7.

205 *See, e.g.*, Simon, *supra* note 22.

206 *Regulatory Obstacles to Harm Reduction* , *supra* note 16, at 752–53.

207 *See id*. at 753 (citing Fred L. Smith, *Assessing the Political Approach to Risk Management*, 16 ECON. AFFAIRS 11, 11–14 (1995)).