TOBACCO LITIGATION, E-CIGARETTES, AND THE CIGARETTE ENDGAME

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INTRODUCTION

Professor Richard Daynard[1] was an early proponent of the view that tort litigation could lead to the "undoing of the tobacco industry," just as litigation had helped drive asbestos and other dangerous products from the market.[2] Despite some notable litigation successes—and litigation's crucial role in revealing the tobacco industry's previously-hidden misconduct—this outcome has not materialized. To the contrary, in many cases courts have instead distorted legal doctrine in order *not* to hold the tobacco industry accountable for its wrongdoing, in part because judges viewed it as beyond their proper role to effectively put the tobacco industry out of business.[3] These distortions in legal doctrine have, in turn, catalyzed legal developments that have "severely weakened the ability of personal injury litigation to effectively deter corporate misconduct and protect public health" more generally.[4] Thus, the decades of tobacco litigation—often described as occurring in three separate "waves"[5]—have shown that despite its promise, tobacco litigation is a public health tool to be used with caution.[6]

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1 The "Public Health Litigation: Possibilities and Pitfalls" symposium at which this paper was presented was held in honor of Professor Daynard's groundbreaking scholarship and activism in his many years as a professor of law at Northeastern and as the President of the Public Health Advocacy Institute. Professor Daynard has been a role model to me in demonstrating that scholarship and activism can go hand in hand and in showing the importance of questioning conventional thinking in service of justice and public health.

2 Graham E. Kelder Jr. & Richard A. Daynard, *Judicial Approaches to Tobacco Control: The Third Wave of Tobacco Litigation as a Tobacco Control Mechanism*, 53 J. SOC. ISSUES 169, 183 (1997); *see also* Richard A. Daynard, *Tobacco Liability Litigation as a Cancer Control Strategy*, 80 J. NAT'L CANCER INST. 9, 9 (1988) (predicting that "[s]uccessful products liability suits against cigarette manufacturers on behalf of diseased smokers and their families would be likely to reduce future cigarette consumption dramatically" because of the cascading effects on the industry such liability would trigger).

3 *See generally* Micah L. Berman, *Smoking Out the Impact of Tobacco-Related Decisions on Public Health Law*, 75 BROOK. L. REV. 1 (2009). As discussed in this article, a contributing factor was that the courts *didn't* want a replay of the asbestos litigation, *id.* at 58, which the Supreme Court described as an "elephantine mass [that] defies . . . customary judicial administration and calls for national legislation." Ortiz v. Fibreboard Corp., 527 U.S. 815, 821 (1999). And unlike asbestos, cigarette litigation involved tens of millions of consumers who were addicted to the product, making courts even more reticent to issue decisions that could jeopardize the product's availability. Berman, *supra* note 3, at 45–46.

4 Berman, *supra* note 3, at 58.

5 *See, e.g.*, Robert L. Rabin, *The Third Wave of Tobacco Tort Litigation*, *in* REGULATING TOBACCO 176, 176–77 (Robert L. Rabin & Stephen D. Sugarman eds., 2001).

6 This is not to say that tobacco litigation has not also had positive results, many of which have been cataloged by Professor Daynard. *See, e.g.*, Richard A. Daynard, *Why*

Although continuing to think strategically about the use of litigation where appropriate, Daynard and others have more recently argued for legislative policies that would do what was once "unthinkable": prohibit the sale of cigarettes.[7] Daynard wrote in 2009:

> Cigarettes are the dirty needles of nicotine delivery devices. Addicts who get their nicotine from cigarettes are at least 10 times as likely to die from their nicotine delivery device as those who get it from non-smoked nicotine products. Phase out the cigarettes, while permitting non-smoked nicotine delivery devices to remain on the market, and the great majority of tobacco-caused diseases and deaths will disappear . . . [8]

Though suggesting the phase-out of cigarette sales may have been radical in 2009, it is now a much more widely (though by no means universally) accepted goal among tobacco policy scholars and advocates—and even among the general public.[9] Academic discussion and debate about possible "endgame" approaches has been extensive,[10] and two communities in California, Beverly Hills and Manhattan Beach, recently adopted ordinances that, as of January 2021, will prohibit the sale of nearly all tobacco products

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Tobacco Litigation?, 12 Tobacco Control 1, 1 (2003) (noting, for example, the important role litigation played in forcing the disclosure of previously secret industry documents, which has reshaped public and policymaker perceptions of the industry).

7 Richard A. Daynard, *Doing the Unthinkable (and Saving Millions of Lives)*, 18 Tobacco Control 2, 2 (2009); *see also* Kenneth E. Warner, *An Endgame for Tobacco?*, 22 Tobacco Control (Supplement 1) i3 (2013) (summarizing various "endgame" policy proposals); Marita Hefler, *The Changing Nicotine Products Landscape: Time to Outlaw Sales of Combustible Tobacco Products?*, 27 Tobacco Control 1, 2 (2018) ("The new continuum of nicotine products presents an opportunity to end the exceptionalism of combustible tobacco, and allow the most dangerous end of the nicotine product continuum to be rapidly, and completely, phased out.").

8 Daynard, *supra* note 7, at 2.

9 *See* Elizabeth A. Smith & Ruth E. Malone, *An Argument for Phasing Out Sales of Cigarettes*, Tobacco Control, Sept. 21, 2019, at 1, 3–5, https://tobaccocontrol.bmj.com/content/early/2019/09/27/tobaccocontrol-2019-055079.info ("Polling data from various regions and countries indicate that, even in the absence of any campaigns for ending cigarette sales, majorities of non-smokers (and 12%–46% of smokers) support the idea."). Referencing Professor Daynard's 2009 article, the authors note that "[w]hile the work to accomplish [a phase-out of cigarette sales] will be daunting, it is not impossible, nor is it any longer so 'unthinkable.'" *Id.*

10 This includes a 2014 conference hosted by Professor Daynard and the Public Health Advocacy Institute at Northeastern University School of Law. For an already-outdated synthesis of the literature, see generally Patricia A. McDaniel, Elizabeth A. Smith & Ruth E. Malone, *The Tobacco Endgame: A Qualitative Review and Synthesis*, 25 Tobacco Control 594 (2016).

within their borders.[11] Other communities are considering similar measures.[12]

Perhaps surprisingly, the tobacco industry itself is now engaging in "endgame" rhetoric. The website of Philip Morris International (PMI) prominently declares its commitment to a "smoke-free future" (though it calls it a "long-term vision"),[13] while British American Tobacco (the parent company of R.J. Reynolds Tobacco Company)[14] states that it "aim[s] to generate an increasingly greater proportion of [its] revenue from products other than cigarettes and so reduce the health impact of [its] business."[15] While one should be skeptical of the companies' true degree of commitment to a "smoke-free future," these statements reflect the fact that all of the major tobacco companies are now engaged in selling e-cigarettes and other non-combustible nicotine products, which they (likely accurately) assert are less harmful nicotine-delivery devices than conventional cigarettes.[16] This enables them to contemplate operating in a future tobacco market without conventional cigarettes—however far off they may privately wish that future to be.

The tobacco companies' acknowledgement that a "smoke-free future" is coming makes it easier to argue that "endgame" policies are within

11 *Los Angeles Region Is the Epicenter of a Global Revolution in Public Health*, ACTION ON SMOKING & HEALTH (Feb. 19, 2020), https://ash.org/la-region-is-the-epicenter/.

12 *See, e.g.*, Kevin Uhrich, *Pasadena Officials to Look at Outlawing Tobacco Sales in City*, PASADENA WKLY. (Feb. 5, 2020), https://pasadenaweekly.com/pasadena-officials-to-look-at-outlawing-tobacco-sales-in-the-city/.

13 *Delivering a Smoke-Free Future*, PHILIP MORRIS INT'L (July 31, 2019), https://www.pmi.com/our-transformation/delivering-a-smoke-free-future. PMI also funded the non-profit "Foundation for a Smoke-Free World," which claims that "[o]ur mission is to end smoking in this generation." *Our Mission*, FOUND. FOR SMOKE-FREE WORLD, https://www.smokefreeworld.org/our-vision/ (last visited Aug. 9, 2020). Public health experts have generally dismissed the foundation as "a public relations ploy to boost PMI's corporate image and possibly produce misleading science, while PMI continues to attack effective tobacco control policies and profit from cigarette sales." Yvette van der Eijk et al., *Philip Morris International-Funded 'Foundation for a Smoke-Free World': Analysing its Claims of Independence*, 28 TOBACCO CONTROL 712, 712 (2018).

14 *BAT Completes Acquisition of Reynolds*, BRIT. AM. TOBACCO (July 25, 2017), https://www.bat.com/group/sites/uk__9d9kcy.nsf/vwPagesWebLive/DOAPKCXS.

15 *Our Purpose and Strategy,* BRIT. AM. TOBACCO, https://www.bat.com/group/sites/UK__9D9KCY.nsf/vwPagesWebLive/DO9DEM4L (last visited Aug. 9, 2020).

16 If an individual switched to using e-cigarettes instead of conventional cigarettes, there is wide consensus that there would be health benefits to that individual, though the extent of such benefits is contested. KATHLEEN STRATTON ET AL., NAT'L ACADS. OF SCI., ENG'G, MED., PUBLIC HEALTH CONSEQUENCES OF E-CIGARETTES 11 (2018) (concluding that "[t]he evidence about harm reduction suggests that across a range of studies and outcomes, e-cigarettes pose less risk to an individual than combustible tobacco cigarettes."). Whether e-cigarettes benefit public health at the broader population level is far less clear, as discussed in Section I.B, *infra*.

the realm of possibility and not an ill-fated rerun of Prohibition. It also raises an obvious question that relates back to tobacco litigation: if tobacco companies themselves acknowledge that non-combustible products are less harmful alternatives to conventional cigarettes, *why are they still permitted to sell cigarettes*? Usually, under general principles of tort law, if a less harmful "reasonable alternative design" of a product is available, then the more harmful version is deemed to be defectively designed and cannot be sold without liability for the harm it causes.[17] Are e-cigarettes such a "reasonable alternative design" for cigarettes?

This article suggests that it is worth seriously considering whether litigation proposing e-cigarettes as a "reasonable alternative design" to cigarettes should be attempted. Though, as mentioned, tobacco litigation should be approached with caution, recent scholarship and analysis of newly uncovered tobacco industry documents may influence the calculus in this instance. These findings suggest that the tobacco industry has long seen precursors of modern e-cigarettes as potentially viable alternatives to cigarettes and that it suppressed the development of such products for exactly that reason.[18] For reasons explained in Professor Daynard's scholarship, litigation pressing on this point—and seeking the disclosure of additional documents—might end up benefitting public health even if the litigation itself is ultimately unsuccessful.[19]

Part I provides background by briefly reviewing the history of tobacco litigation, the emergence of e-cigarettes, and the tobacco industry's rhetorical endorsement of "harm reduction." Part II details historical efforts by the tobacco industry to develop e-cigarette-like products, starting in the 1960s. The historical record suggests that tobacco companies likely could have developed products similar to modern e-cigarettes decades ago, but they decided to abandon and hide these efforts in order to protect cigarette sales and minimize cigarette-related regulation and litigation. Part III reviews products liability doctrine and assesses whether plaintiffs could

17 As discussed in Part III, tort doctrine varies by state, but this is the general position endorsed by the Restatement (Third) of Torts: Products Liability, which explains that "[a] product . . . is defective in design when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design . . . and the omission of the alternative design renders the product not reasonably safe[.]" Restatement (Third) of Torts: Prods. Liab. § 2 (Am. Law. Inst. 1998).

18 *See infra* Part II.

19 *See, e.g.*, Daynard, *supra* note 6 (explaining that even if ultimately unsuccessful, the benefits of tobacco litigation may include obtaining documents that demonstrate the industry's misconduct, pressuring the industry to behave more responsibly, deterring future misconduct, and informing the public).

plausibly assert that e-cigarettes constitute a "reasonable alternative design" to cigarettes. Finally, Part IV discusses how litigation presenting e-cigarettes as a "reasonable alternative design" to cigarettes—and using the industry's own words against it—could play a role in reshaping tobacco control discourse and building momentum towards phasing out the most harmful forms of nicotine delivery, as Daynard proposed in 2009.

I. Tobacco Litigation, E-Cigarettes, and the Tobacco Industry's Rhetorical Shift

A. *Tobacco Litigation*

Tobacco litigation is often described as having occurred in three distinct "waves."[20] The first began soon after the initial revelations about the connection between smoking and lung cancer in the 1950s, and it lasted until the 1980s. The plaintiffs were almost all lung cancer victims or their families, and they grounded their claims "in varying theories of negligence, misrepresentation and breach of warranty."[21] Due to the tobacco industry's early adoption of an aggressive "scorched earth" strategy, few of these cases made it to trial.[22] Of those that did, the industry's argument that the connection between smoking and lung cancer had not been conclusively established successfully defeated all claims of liability.[23]

When the causation defense became untenable in the 1980s, the tobacco industry shifted its argument to defend against the "second wave" of tobacco litigation. For years it had denied that cigarettes were unsafe. Now it insisted that despite the industry's past (and, in some cases, ongoing) denials, these risks were "in fact 'common knowledge'—so much so that people who chose to smoke 'assumed the risk' of death and disease."[24] As with all of the first wave cases, the hundreds of second wave plaintiffs were similarly unable to win a case against the tobacco industry—until a federal court jury in New Jersey finally found for the plaintiff in *Cipollone v. Liggett Group, Inc.* in 1988.[25] What tipped the balance in *Cipollone* was the discovery of tobacco company documents and the testimony of former employees

20 Rabin, *supra* note 5, at 176.

21 D. Douglas Blanke, *Towards Health with Justice: Litigation and Public Inquiries as Tools for Tobacco Control*, World Health Org. 1, 16 (2002), https://www.publichealthlawcenter.org/sites/default/files/resources/who-tobacco-litigation-2002.pdf.

22 Jess Alderman & Richard A. Daynard, *Applying Lessons from Tobacco Litigation to Obesity Lawsuits*, 30 Am. J. Preventative Med. 82, 82-83 (2006) (summarizing the industry's "scorched earth" approach to litigation).

23 Graham E. Kelder Jr. & Richard A. Daynard, *The Role of Litigation in the Effective Control of the Sale and Use of Tobacco*, 8 Stan. L. & Pol'y Rev. 63, 71 (1997) ("Plaintiffs in the first wave were hampered by the paucity of medical studies establishing the link between smoking and disease, leading to difficulties in establishing proximate cause."). For a detailed discussion of "first wave" cases, see Robert L. Rabin, *Institutional and Historical Perspectives on Tobacco Tort Liability*, *in* Smoking Policy: Law, Politics, and Culture 110, 111–18 (Robert L. Rabin & Stephen D. Sugarman eds., 1993).

24 Blanke, *supra* note 21, at 17.

25 Rabin, *supra* note 5, at 178; Cipollone v. Liggett Grp., 893 F.2d 541, 541 (3d Cir. 1990) (reinstating 1988 jury verdict on appeal), *aff'd in part and rev'd in part*, 505 U.S. 504 (1992).

indicating the industry had hidden its knowledge of smoking's health risks and—critically for the discussion in this article—had suppressed internal efforts to develop a safer cigarette.[26]

The *Cipollone* verdict was voided by a 1992 U.S. Supreme Court decision ruling that failure to warn claims against cigarette manufacturers were preempted by the Federal Cigarette Labeling and Advertising Act (FCLAA), a 1965 federal law requiring warning labels on cigarette packaging and advertising[27] (notably, though, the Supreme Court's ruling did not extend to products liability claims, which were—and are—still permitted[28]). The plaintiff could not afford the cost of a new trial and therefore dropped the suit, but the jury verdict in *Cipollone*, and the documents uncovered in that case, opened the door to the new "third wave" of tobacco litigation.[29]

The "third wave," which started in the early 1990s and is arguably still ongoing, was composed of several different types of cases, all built on the foundation of the industry's own incriminating documents. First, there were individual lawsuits premised on smoking-caused disease or death that proceeded within the bounds set by the Supreme Court's *Cipollone* decision.[30] As a result of differences in tort law doctrine, outcomes varied tremendously by state.[31] But unlike the first two waves, plaintiffs in some jurisdictions were able to win, cumulatively resulting in the industry paying out hundreds of millions of dollars in damages.[32] Second, in the mid-1990s, the attorneys

26 Kelder & Daynard, *supra* note 2, at 182 ("The documents in *Cipollone* included evidence that . . . Liggett & Myers (L&M) knew by the early 1970s how to make a safer cigarette, but suppressed it, for fear that implicit in marketing it would be the admission that L&M's other cigarettes were unsafe[.]").

27 Cipollone v. Liggett Grp., 505 U.S. 504, 504–05 (1992).

28 *Id.* at 523 (noting that FCLAA "does not generally 'pre-empt state-law obligations to avoid marketing cigarettes with manufacturing defects or to use a demonstrably safer alternative design for cigarettes'") (citations omitted).

29 Blanke, *supra* note 21, at 20–21.

30 *Id.* at 29–31.

31 *Compare, e.g.*, Evans v. Lorillard Tobacco Co., 990 N.E.2d 997, 1006 (Mass. 2013) (upholding wrongful death jury verdict against tobacco company) *with* Brown *ex rel.* Estate of Brown v. Philip Morris Inc., 228 F. Supp. 2d 506, 506 (D.N.J. 2002) (applying New Jersey law and dismissing wrongful death claims against tobacco company based on analysis of the New Jersey Product Liability Act).

32 *See* Noreen Marcus, *Florida Still a Dismal Swamp for Cigarette Makers Fighting Death and Injury Claims*, FAIRWARNING (July 25, 2018), https://www.fairwarning.org/2018/07/florida-cigarette-death-injury-claims/ (reporting that the tobacco industry had paid out "close to $800 million in damage awards and settlements" in Florida alone). Because of some unique legal context in Florida, plaintiffs against the tobacco industry start on more favorable ground in Florida than elsewhere, and much of the nation's personal injury tobacco litigation is, therefore, taking place in that state. For additional background, see *What is the "Engle Progeny" Litigation?*, TOBACCO CONTROL LEGAL CONSORTIUM 2–3

general of nearly every state sued the tobacco industry to recover smoking-related costs.[33] These lawsuits culminated in the 1998 Master Settlement Agreement (MSA), in which the major tobacco companies agreed to pay more than $200 billion to the states and limit their marketing in various ways.[34] The MSA also required further disclosure of industry documents.[35] In return, the states (and their political subdivisions) gave up their legal claims against the cigarette manufacturers, including the right to sue the industry for smoking-related costs in the future.[36] Other third-wave suits included lawsuits premised on secondhand smoke exposure[37] and violations of consumer protection laws.[38] While all of these lawsuits imposed some costs on the industry, the tobacco companies were able to absorb the costs and, in some respects, emerge even stronger.[39] The costs of the MSA, for example, were quickly shifted to individual smokers by raising prices, while the agreement itself provided the companies with protection from future litigation risk.[40]

In the last couple of years, states and plaintiffs' attorneys have increasingly turned their attention away from cigarette litigation and towards e-cigarette litigation. In particular, "market leader JUUL Labs, Inc., and its largest shareholder, Altria Group (the parent company of Philip Morris USA), have been the subject of mounting litigation, including multiple class

(Sept. 2015), https://www.publichealthlawcenter.org/sites/default/files/resources/tclc-fs-engle-progeny-2015.pdf. Nonetheless, litigation against the industry remains difficult and expensive, even in Florida, as the industry continues to engage in the same "scorched earth" tactics it developed in the first two waves of litigation. Blanke, *supra* note 21, at 18.

33 Blanke, *supra* note 21, at 25.

34 *Master Settlement Agreement*, Nat'l Ass'n Attorneys Gen. (1998) https://www.naag.org/assets/redesign/files/msa-tobacco/MSA.pdf. The MSA was an agreement between the major tobacco companies and forty-six states. Blanke, *supra* note 21, at 25. The four other states—Florida, Minnesota, Mississippi, and Texas—had previously reached their own separate settlement agreements that roughly paralleled the MSA. *Id.*

35 Blanke, *supra* note 21, at 36.

36 *Id.* at 110–20.

37 *See* Patrick Luff, *Regulating Tobacco Through Litigation*, 47 Ariz. St. L.J. 125, 153 (2015).

38 *See, e.g.*, Altria Group v. Good, 555 U.S. 70 (2008). Third wave suits also included a concerted effort to pursue class action lawsuits against the tobacco industry, but these were generally unsuccessful. *See* Berman, *supra* note 3, at 42–47.

39 *See, e.g.*, F.A. Sloan et al., *Impacts of the Master Settlement Agreement on the Tobacco Industry*, 13 Tobacco Control 356, 358-59 (2004) (finding that in the years following the MSA, "participating manufacturers maintained or improved performance in terms of investor stock returns and profit from domestic tobacco sales").

40 For a discussion of the mixed legacy of MSA, see generally Micah L. Berman, *Using Opioid Settlement Proceeds for Public Health: Lessons from the Tobacco Experience*, 67 U. Kan. L. Rev. 1029 (2019).

actions, individual lawsuits and . . . suits filed by state attorneys general."[41] These are largely based on allegations that JUUL marketed to youth and "misled its customers to believe its e-cigarettes were less addictive than traditional cigarettes."[42]

B. *E-Cigarettes*

E-cigarettes come in a wide variety of forms, but they all "deliver nicotine by heating (not burning) a nicotine-containing liquid until it aerosolizes."[43] The theory behind e-cigarettes is that if people "smoke for nicotine but they die from the tar"—as tobacco researcher Michael Russell famously suggested in 1976[44]—an alternative product for smokers

41 *The E-Cigarette Industry's Legal Troubles*, LEXISNEXIS (Jan. 14, 2020), https://www.lexisnexis.com/community/lexis-legal-advantage/b/trends/posts/the-e-cigarette-industry-s-legal-troubles. Federal lawsuits from around the country have been transferred to a Multi-District Litigation proceeding in the Northern District of California. *See In re* Juul Labs, Inc., Mktg., Sales Practices, & Prods. Liab. Litig., No. 19-md-02913-WHO, 2020 WL 1487301, at *1 (N.D. Cal. Mar. 27, 2020).

42 *The E-Cigarette Industry's Legal Troubles*, *supra* note 41.

43 Patricia J. Zettler et al., *Closing the Regulatory Gap for Synthetic Nicotine Products*, 59 B.C. L. REV. 1933, 1947–48 (2018). *See id*. at 1948 n.87 for a discussion of how e-cigarette products "have evolved over time." To define terminology, "cigarettes," "traditional cigarettes," "conventional cigarettes" and "combustible cigarettes" all refer to the same familiar product: processed tobacco leaf wrapped in paper that is ignited on one end by the consumer. Note that, although the description of this product is simple, cigarettes are, in fact, a highly engineered product. *See How a Cigarette Is Engineered*, FDA., https://www.fda.gov/media/101198/download (last updated Oct. 2016). "E-cigarettes" go by many different names, including "[v]apes, vaporizers, vape pens, hookah pens . . . and e-pipes[,]" and they come in many shapes, sizes, and flavors. *Vaporizers, E-Cigarettes, and Other Electronic Nicotine Delivery Systems (ENDS)*, FDA, https://www.fda.gov/tobacco-products/products-ingredients-components/vaporizers-e-cigarettes-and-other-elctronic-nicotine-delivery-systems-ends (last updated June 3, 2020). As the term is used in this article, these devices all heat a liquid (referred to as an "e-liquid") containing nicotine, which is heated and aerosolized using battery power and then inhaled by the consumer. *Id.* The nicotine is usually extracted from tobacco leaves, but the product does not otherwise contain any tobacco, unless tobacco extract is also used as a flavoring agent. Finally, "heat-not-burn" products or "heated tobacco products" are a cross between these two previous product categories. *How are Non-Combusted, Sometimes Called Heat-Not-Burn Products, Different from E-Cigarettes?*, FDA, https://www.fda.gov/tobacco-products/products-ingredients-components/how-are-non-combusted-cigarettes-sometimes-called-heat-not-burn-products-different-e-cigarettes-and (last updated May 1, 2020). These products heat—but do not burn—processed tobacco leaf, producing an aerosol that is inhaled by the consumer. *See Heated Tobacco Products*, CDC, https://www.cdc.gov/tobacco/basic_information/heated-tobacco-products/index.html (last updated July 17, 2020).

44 M.A.H. Russell, *Low-Tar Medium-Nicotine Cigarettes: A New Approach to Safer Smoking*,

that delivers nicotine in a "cleaner" way, while still satisfying one's nicotine addiction, could save millions of lives.[45] In other words, it is the nicotine in cigarettes that creates and sustains addiction, but it is the other aspects of the cigarette smoke that more proximately cause most smoking-related disease and death. Accordingly, though nicotine itself poses some health-related risks,[46] replacing cigarettes with a device that delivers nicotine without the toxic smoke could, at least in theory, dramatically reduce the death toll of tobacco products.[47]

The use of e-cigarettes in the United States has risen exponentially, especially among youth, since their introduction in 2007.[48] In 2019, 27.5% of high school students reported using an e-cigarette in the past 30 days, far more than the 5.8% who reported using traditional (combustible) cigarettes.[49] Only 3.2% of adults reported regular use of e-cigarettes in 2018,[50] but adult use is much more common among both current smokers engaging in "dual

1976:1 Brit. Med. J. 1430, 1431 (1976) (citation omitted) ("[S]mokers cannot easily stop smoking because they are addicted to nicotine, and to expect people who cannot stop smoking to smoke cigarettes that have hardly any nicotine is illogical. . . . Their risk of lung cancer and bronchitis might be more quickly and effectively reduced if attention were focused on how to reduce their tar intake, irrespective of nicotine intake.").

45 *See, e.g.*, Riccardo Polosa et al., *A Fresh Look at Tobacco Harm Reduction: The Case for the Electronic Cigarette*, Harm Reduction J., Oct. 4, 2013, at 7, https://harmreductionjournal.biomedcentral.com/track/pdf/10.1186%2F1477-7517-10-19 ("E-cigs may contain nicotine, which contributes to nicotine addiction and helps sustain tobacco use. However, if sufficient numbers of smokers can transfer their nicotine dependence to a less-harmful delivery method, millions of lives could be saved.").

46 Conference of the Parties to the WHO Framework Convention on Tobacco Control, *Electronic Nicotine Delivery Systems*, World Health Org. 3 (July 21, 2014), http://apps.who.int/gb/fctc/PDF/cop6/FCTC_COP6_10-en.pdf (noting that nicotine, in addition to being addictive, "can have adverse effects during pregnancy and may contribute to cardiovascular disease" and "may function as a 'tumour promoter'" even though it is not a carcinogen itself).

47 This is of course the theory behind nicotine replacement therapies (NRTs) like nicotine patches and gums. The problem with NRTs has been their low rate of efficacy. *See, e.g.,* Eric C. Leas et al., *Effectiveness of Pharmaceutical Smoking Cessation Aids in a Nationally Representative Cohort of American Smokers*, 110 J. Nat'l Cancer Inst. 581, 582, 585–86 (2018) ("[P]harmaceutical aids for smoking cessation, despite strong evidence for efficacy from randomized trials, have not been effective at increasing successful quitting in the United States."). This may be because NRTs, in order to obtain FDA approval as pharmaceuticals, have been deliberately calibrated *not* to create and sustain nicotine dependence. Zettler, *supra* note 43, at 1944 n.62.

48 Zettler et al., *supra* note 43, at 1948.

49 Karen A. Cullen et al., *E-Cigarette Use Among Youth in the United States, 2019*, 322 JAMA 2095 (2019).

50 MeLisa R. Creamer et al., *Tobacco Product Use and Cessation Indicators Among Adults—United States, 2018*, 68 Morbidity & Mortality Wkly. Rep. 1013, 1014 (2019).

use" and former smokers, some of whom may have used e-cigarettes as a smoking cessation tool.[51]

On a product-to-product basis, e-cigarettes are almost certainly less toxic than conventional cigarettes, even though the full extent to which they pose health risks is still unknown.[52] This is not to suggest that e-cigarettes are harmless.[53] Though e-cigarettes likely pose a dramatically lower risk of cancer,[54] emerging evidence suggests that e-cigarette use contributes to cardiovascular disease (perhaps as much as smoking),[55] impairs respiratory health (to a still-unknown degree),[56] and harms oral health.[57] And nicotine exposure, from any source, is harmful to adolescent brain development.[58] But

51 Hongying Dai & Adam M. Leventhal, *Prevalence of E-Cigarette Use Among Adults in the United States*, *2014-2018*, 322 JAMA 1824, 1826 (2019).

52 NAT'L ACADS. OF SCI., ENG'G, MED., *supra* note 16, at 15–16 (conducting a comprehensive review of the scientific literature on e-cigarettes and concluding that e-cigarettes "contain fewer toxicants" than conventional cigarettes, but that the long-term health effects of e-cigarettes are unknown).

53 *See* OFFICE ON SMOKING & HEALTH, U.S. DEP'T OF HEALTH & HUMAN SERVS., E-CIGARETTE USE AMONG YOUTH AND YOUNG ADULTS: A REPORT OF THE SURGEON GENERAL (2016) (describing the risks that e-cigarette use poses to youth and young adults).

54 Maciej Lukasz Goniewicz et al., *Levels of Selected Carcinogens and Toxicants in Vapour from Electronic Cigarettes*, 23 TOBACCO CONTROL 133, 138 (2014) (finding that "the levels of potentially toxic compounds in e-cigarette vapour are [between 9 and] 450-fold lower than those in the smoke from conventional cigarettes, and in many cases comparable with the trace amounts present in pharmaceutical preparation").

55 Jessica L. Fetterman et al., *Alterations in Vascular Function Associated with the Use of Combustible and Electronic Cigarettes*, J. AM. HEART ASS'N (Apr. 29, 2020), https://www.ahajournals.org/doi/full/10.1161/JAHA.119.014570.

56 Jeffrey E. Gotts et al., *What Are the Respiratory Effects of E-cigarettes?*, BRIT. MED. J., Sept. 30, 2019, at 11, https://www.bmj.com/content/bmj/366/bmj.l5275.full.pdf (concluding that "e-cigarettes will likely prove to have at least some pulmonary toxicity with chronic and possibly even short term use" and that without long-term studies, "saying with certainty that e-cigarettes are safer than combustible cigarettes is impossible").

57 Sukirth M. Ganesan et al., *Adverse Effects of Electronic Cigarettes on the Disease-Naive Oral Microbiome*, SCI. ADVANCES, May 27, 2020, at 9, https://advances.sciencemag.org/content/advances/6/22/eaaz0108.full.pdf (finding that "e-cigarettes exert a powerful, detrimental effect on the subgingival ecosystem"). In 2019, e-cigarettes were also associated with an outbreak of an acute lung disease termed E-cigarette or Vaping Associated Lung Injury (EVALI). *Outbreak of Lung Injury Associated with the Use of E-Cigarette or Vaping Products*, CDC, https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html (last updated Feb. 25, 2020). As of February 2020, EVALI had been identified as the cause of 68 deaths and nearly 3000 hospitalizations in the U.S. The primary cause, however, appears to have been vitamin E acetate, an additive used in THC vaping products. At least in the vast majority of cases, nicotine e-cigarettes (the focus of this article), as opposed to THC-containing or mixed nicotine and THC-containing e-cigarettes, do not appear to have been implicated. *Id.*

58 Zettler et al., *supra* note 43, at 1941.

when compared to cigarettes—"the single most deadly consumer product ever made"[59]—there is wide consensus among experts that e-cigarettes are less harmful.[60] The scientific debate is about *how much* less harmful they will prove to be.[61]

But the fact that e-cigarettes are likely less harmful than cigarettes when compared product-to-product does not mean that the availability of e-cigarettes is necessarily beneficial for public health at the population level. As Zettler et al. summarize:

> If current smokers switched completely from smoking to e-cigarette use that would likely produce enormous public health gains. Currently, however, the majority of people who use e-cigarettes are also smoking. Youth e-cigarette use is additionally a concern, both because of the effects of nicotine on the developing brain, and because of accumulating evidence that e-cigarette use is a gateway to smoking. Moreover, the history of tobacco product marketing suggests that the industry has economic incentives to target the youth population in its marketing, and is likely to do so.[62]

In short, e-cigarettes hold the potential to improve public health because they are likely a far safer way to consume nicotine than conventional cigarettes. But it is unclear that they will deliver on that promise as long as conventional cigarettes are still for sale, both because (a) most adult e-cigarette users are also *dual users* of cigarettes, and thus not necessarily reducing harm,[63] and

59 Ruth Malone, Patricia McDaniel & Elizabeth Smith, *It Is Time to Plan the Tobacco Endgame*, Brit. Med. J., Feb. 11, 2014, at 1, https://www.bmj.com/content/348/bmj.g1453.

60 Nat'l Acads. of Sci., Eng'g, Med., *supra* note 16, at 11 (expert consensus report concluding that "[t]he evidence about harm reduction suggests that across a range of studies and outcomes, e-cigarettes pose less risk to an individual than combustible tobacco cigarettes").

61 For a window into this debate, see sources cited in Eric N. Lindblom, *Should FDA Try to Move Smokers to E-Cigarettes and Other Less-Harmful Tobacco Products and, If So, How?*, 73 Food & Drug L.J. 276, 281 n.18 (2018).

62 Zettler et al., *supra* note 43, at 1948–49 (2018) (citations omitted). E-cigarette companies could seek to have their products approved as smoking cessation therapies by the FDA. To date, however, no e-cigarette has been approved as a smoking cessation therapy, and there is no evidence that any e-cigarette company has sought such approval. *Cf.* Elizabeth G. Klein et al., *Online E-Cigarette Marketing Claims: A Systematic Content and Legal Analysis*, 2 Tobacco Regulatory Sci. 252, 258 (2016) ("Because the FDA has not approved any [e-cigarette] products for sale as a drug or device, any [e-cigarette] products making cessation or health-benefit claims are violating the law by marketing unapproved products.").

63 Lindblom, *supra* note 61, at 283 ("Switching to dual use from smoking is not less harmful to users than just smoking and could be somewhat more harmful—unless

(b) youth e-cigarette use may serve as a "gateway" to conventional cigarette use,[64] potentially undermining decades of tobacco control progress.

Adding to the concern about youth use is the runaway success of JUUL, a rechargeable e-cigarette shaped like a USB drive that uses nicotine salts in place of the free-base nicotine used by earlier e-cigarettes.[65] Each JUUL pod contains nicotine "equivalent to approximately 20 combustible cigarettes" (a full pack), and the use of nicotine salts allows for much higher levels of nicotine delivery "without an aversive user experience."[66] As Tackett et al. noted in 2020, "[i]t was not until the proliferation of nicotine-

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the dual use reduces smoking levels substantially, to very low levels."); *see also* Simon Chapman, *E-Cigarettes: The Best and the Worst Case Scenarios for Public Health*, BRIT. MED. J., Sept. 9, 2014, at 2, https://www.bmj.com/content/349/bmj.g5512 (suggesting that "[o]nly the most naive or captured advocates for vaping could fail to acknowledge that the tobacco industry wants people who vape to smoke and vape, not vape instead of smoking").

64 NAT'L ACADS. OF SCI., ENG'G, MED., *supra* note 16, at 10 ("There is substantial evidence that e-cigarette use increases risk of ever using combustible tobacco cigarettes among youth and young adults."). While the National Academies report "refers to this potential effect of e-cigarette use on increased smoking initiation as the 'catalyst' hypothesis" rather than a "gateway" effect because of the "colloquial" connotations of the latter term, the underlying idea remains the same: although youth and young adults may initially choose e-cigarettes over tobacco cigarettes because e-cigarettes are perceived as less dangerous, their continued exposure to e-cigarettes may eventually result in an "increase[d] proclivity" to try tobacco cigarettes. *Id.* at 496–97 n.1; *see also* Jasmine N. Khouja, et al., *Is E-Cigarette Use in Non-Smoking Young Adults Associated with Later Smoking? A Systematic Review and Meta-Analysis*, TOBACCO CONTROL, Mar. 10, 2020, at 7 https://tobaccocontrol.bmj.com/content/tobaccocontrol/early/2020/03/01/tobaccocontrol-2019-055433.full.pdf (finding "a strong consistent association in observational studies between e-cigarette use among non-smokers and later smoking," though noting that "findings from published studies do not provide clear evidence that this is explained by a gateway effect rather than shared common causes of both e-cigarette use and smoking").

65 Minal Patel et al., *JUUL Use and Reasons for Initiation Among Adult Tobacco Users,* 28 TOBACCO CONTROL 681, 681 (2019) (noting that by "April 2019, JUUL comprised 74.6% of the [e-cigarette] market"). The relevant difference between nicotine salts and freebase nicotine is that freebase nicotine "is harsh and difficult to inhale at high concentrations," whereas "Juul virtually eliminated the harsh side effects" by using nicotine salts. Chris Kirkham, *Addictive Nicotine in Juul Nearly Identical to a Marlboro: Study*, REUTERS (Dec. 17, 2019), https://www.reuters.com/article/us-juul-ecigarettes-study/addictive-nicotine-in-juul-nearly-identical-to-a-marlboro-study-idUSKBN1YL26R.

66 Jessica L. Barrington-Trimis & Adam M. Leventhal, *Adolescents' Use of "Pod Mod" E-Cigarettes – Urgent Concerns*, 379 NEW ENG. J. MED. 1099, 1100 (2018); *see also* Robert K. Jackler & Divya Ramamurthi, *Nicotine Arms Race: JUUL and the High-Nicotine Product Market,* 28 TOBACCO CONTROL 623, 626 (2019) ("The threshold for addiction of a young person has been estimated at 5mg/day, or about 4–5 traditional cigarettes. A youth would reach the addictive threshold by inhaling the aerosol generated by merely ¼ of a JUUL pod per day.").

salt-based, pod-style e-cigarette devices, of which the most well-known is JUUL, that youth e-cigarette use increased by 135% to the current record high."[67] The elevated levels of nicotine delivery that make JUUL and other pod-based devices highly addictive to youth could, in theory, also make them safer and more acceptable alternative products for current adult smokers.[68] To date, however, it appears that most adult tobacco users who also use JUUL do so "infrequently and concurrently with other products," which is unlikely to reduce tobacco-related health risks.[69]

C. *The Tobacco Industry's New Rhetoric*

The discussion in the previous subsection suggests that e-cigarettes are likely far less harmful, on a product-to-product basis, than cigarettes. Therefore, *if cigarettes were no longer sold*, death and disease from tobacco and nicotine would drop dramatically, even with widespread uptake of e-cigarettes. In the current environment, however, it is far less clear that e-cigarettes are contributing to improved population health. Glossing over these population-level concerns, the major tobacco companies[70]—all of which are either directly selling e-cigarettes or are heavily invested in

67 Alayna P. Tackett et al., Editorial, *E-Cigarette Regulation: A Delicate Balance for Public Health*, Addiction, Apr. 19, 2020, at 1, https://onlinelibrary.wiley.com/doi/10.1111/add.15092.

68 Anna K. Duell et al., *Nicotine in Tobacco Product Aerosols: 'It's Déjà Vu All Over Again'*, Tobacco Control, Dec. 17, 2019, at 6, https://tobaccocontrol.bmj.com/content/tobaccocontrol/early/2019/12/16/tobaccocontrol-2019-055275.full.pdf ("De-freebasing has undoubtedly made e-cigarettes more effective as substitutes to get smokers off combustibles. However, as with smoked tobacco, it is likely that e-cigarettes have also been made vastly more addictive for never-smokers.").

69 Patel et al., *supra* note 65, at 682 (recognizing that some dual users may transition to exclusive JUUL use over time but finding that most adults using JUUL did not report using the product in order to quit use of combustible tobacco products).

70 The major tobacco companies' organizational structures and inter-corporate relationships are exceedingly complex and frequently changing. *See generally*, David T. Levy et al., *The US Cigarette Industry: An Economic and Marketing Perspective*, 5 Tobacco Reg. Sci. 156 (2019). Currently, in the United States, the two major cigarette producers are (1) Philip Morris USA, a subsidiary of Altria (formerly known as Philip Morris), which sells Marlboro and other brands, and (2) R.J. Reynolds Tobacco Company, a subsidiary of British American Tobacco (BAT), which sells Camel, Newport, and other brands. *Id.* at 156-58, 164. For convenience, those two companies are referred to in this article as "Philip Morris" and "R.J. Reynolds." In 2008, Altria spun off Philip Morris International (PMI), which sells Marlboro and other Altria brands outside of the U.S. Though the focus of this article is on the U.S. market, PMI is also discussed, as "close association exists between [PMI and Altria] and the brand[s] they market," despite the fact that they are separate legal entities. Annalise Mathers et al., *Transnational Tobacco Companies and New Nicotine Delivery Systems*, 109 Am. J. Pub. Health 227, 228 (2019).

e-cigarette distribution—have enthusiastically embraced the language of "tobacco harm reduction," that is, the idea that current smokers should be encouraged "to move themselves down the risk spectrum by choosing safer alternatives to smoking – without demanding abstinence."[71]

Under the 2009 Tobacco Control Act (TCA), companies cannot promote a specific tobacco product as being less harmful than others unless that claim is reviewed and authorized by the FDA.[72] But the major tobacco companies are now quite clear that, in their view, e-cigarettes and heat-not-burn products are, in general terms, far less harmful than conventional cigarettes. As R.J. Reynolds states on its website,

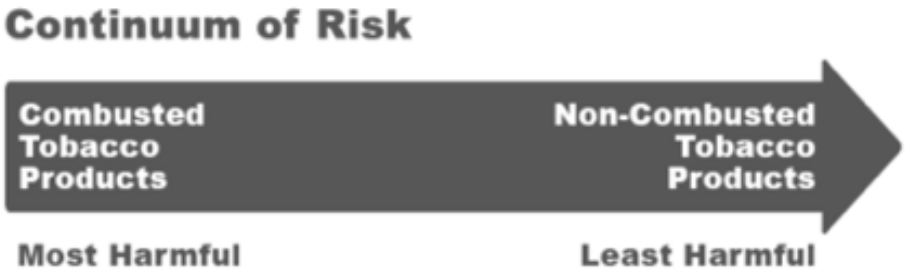
> "there is a growing body of scientific evidence that vapor and other noncombustible tobacco products may present significantly less risk than smoking. While some studies report that there may be health risks associated with these products, we believe those risks are lower than the risks of smoking cigarettes."[73]

71 David Sweanor et al., *Tobacco Harm Reduction: How Rational Public Policy Could Transform a Pandemic*, 18 INT'L. J. DRUG POL'Y 70, 70 (2007).

72 Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, § 911, 123 Stat. 1776, 1812 (codified at 21 U.S.C. § 387(k) (2018)). Nor can they make claims that their products are effective for smoking cessation without obtaining approval for sale as a drug or drug-delivery device. Clarification of When Products Made or Derived from Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding "Intended Uses," 82 Fed. Reg. 2193, 2198 (Jan. 9, 2017) (to be codified at 21 CFR pt. 201, pt. 801, pt. 1100) ("FDA has long considered claims related to smoking cessation in the context of curing or treating nicotine addiction and its symptoms to bring products within FDA's 'disease prong' jurisdiction."). Implementation of this FDA rule has been delayed, but the underlying statutory scheme it describes still applies. *See* "Intended Uses"; Partial Delay of Effective Date, 83 Fed. Reg. 11,639, 11,639 (Mar. 16, 2018).

73 *Transforming Tobacco*, R.J. REYNOLDS TOBACCO, https://www.rjrt.com/transforming-tobacco/guiding-principles-and-beliefs/ (last visited May 26, 2020). General statements like this do not violate the TCA because they are not in reference to the marketing for any particular product. 21 U.S.C. § 387k.

Altria even makes this clear in visual form on its website:[74]



Why have these companies shifted their position to embrace the concept of tobacco harm reduction? Presumably because, while continuing to sell cigarettes, they have all started selling e-cigarettes (and other non-combustible products) as well—and they are seeking to market these products as less harmful alternatives for current smokers. Philip Morris recently received FDA authorization to market a "heat-not-burn" product named IQOS[75] with claims that it "significantly reduces the production of harmful and potentially harmful chemicals" compared to conventional cigarettes.[76] In order to avoid the TCA's required review of health-related claims, most e-cigarette ads more subtly suggest that e-cigarettes reduce health-related risks without stating so explicitly.[77] For example, ads for blu e-cigarettes state: "Why quit? Switch to blu[.] blu is the smart choice for smokers wanting a

74 *Our Approach to Harm Reduction*, Altria, https://www.altria.com/harm-reduction/our-approach-to-harm-reduction (last visited May 26, 2020) ("A strong public health consensus has formed that not all tobacco products present the same risk. Public health authorities agree that there is a broad continuum of risk among tobacco products, with cigarettes at the highest end of that spectrum. This continuum recognizes that most of the harm caused by tobacco results from the burning of tobacco.").

75 *FDA Authorizes Marketing of IQOS Tobacco Heating System with 'Reduced Exposure' Information*, FDA (July 7, 2020), https://www.fda.gov/news-events/press-announcements/fda-authorizes-marketing-iqos-tobacco-heating-system-reduced-exposure-information. A "heat-not-burn" product like IQOS is essentially a cross between a conventional cigarette and an e-cigarette; it uses cigarette-like sticks that contain tobacco, but the tobacco is heated to produce an inhalable aerosol, instead of combusted as in conventional cigarettes. *See* PHILIP MORRIS PRODUCTS S.A., PMI Research & Development, MRTPA Executive Summary 9–21 (2017), https://www.fda.gov/media/105437/download (detailing PMI's research toward "modified risk tobacco products applications," or "MRTPA").

76 *FDA Authorizes Marketing of IQOS Tobacco Heating System with 'Reduced Exposure' Information*, *supra* note 75.

77 *See*, *e.g.*, Kimberly G. Wagoner et al., *Health Claims Made in Vape Shops: An Observational Study and Content Analysis*, 28 TOBACCO CONTROL e119, e121–e123 (2019) (cataloging health-related claims made in vape shops and finding claims such as a testimonial from a smoker-turned-vaper stating: "'I breathe better. I smell better. I feel better.'").

change. . . . blu is everything you enjoy about smoking and nothing else."[78]

The idea that policy should reflect the "continuum of risk" concept featured on Altria's website is, in general terms, widely accepted by health experts.[79] But as stated above, the fact that a product is less harmful on a product-to-product basis does not mean that its availability will improve population-level health outcomes in the absence of corporate behaviors and regulatory measures directed towards that result. Though they claim to support harm reduction and a move toward a "smoke-free world," tobacco companies undermine their credibility when they advertise to youth, promote dual use, continue investing heavily in promotion of cigarettes, and fight against any efforts to regulate cigarette sales.[80] For instance, underscoring the depth of the industry's continued opposition to even minimal tobacco control measures, when the governor of Virginia—the state with *the lowest* cigarette tax in the nation—recently proposed a modest cigarette tax increase

78 *Why Quit? Switch to Blu*, TOBACCO.STANFORD.EDU, http://tobacco.stanford.edu/tobacco_main/images_ecigs.php?token2=fm_ecigs_st372.php&token1=fm_ecigs_img16975.php&theme_file=fm_ecigs_mt043.php&theme_name=Helps%20You%20Quit&subtheme_name=Quit (last visited May 26, 2020). The ad also seems to directly *discourage* complete cessation, adding "[n]obody likes a quitter, so make the switch today." *Id.* These ads ran in 2013, when blu was a subsidiary of Lorillard, Inc. *See* Brian Solomon, *Reynolds, Lorillard Dump Blu E-Cigarettes in $27 Billion Merger,* FORBES (July 15, 2014) https://www.forbes.com/sites/briansolomon/2014/07/15/reynolds-lorillard-dump-blu-e-cigarettes-in-27-billion-merger/#32f922dd1699. Lorillard was subsequently purchased by R.J. Reynolds, and the blu brand was transferred to Imperial Tobacco, a multinational tobacco company. *Id.*

79 *See, e.g.*, Mitchell Zeller & Dorothy Hatsukami, *The Strategic Dialogue on Tobacco Harm Reduction: A Vision and Blueprint for Action in the US*, 18 TOBACCO CONTROL 324, 327 (2009) (summarizing the findings of an expert workgroup as reporting that "there was a consensus about the value and the concept of this continuum of risk," though disagreement about the harm-reducing prospects of particular products). The "continuum of risk" concept was the theoretical basis for the FDA's 2017 "Comprehensive Plan for Tobacco and Nicotine Regulation," which suggested reducing nicotine levels in combustible tobacco products while delaying the regulation of e-cigarettes. That plan has now largely been abandoned by the FDA. *See* Micah L. Berman, *The Faltering Promise of FDA Tobacco Regulation*, 12 ST. LOUIS U.J. HEALTH L. & POL'Y 145, 159–65 (2018).

80 Tobacco companies continue to do all of these things. *See, e.g.,* Madlen Davies et al., *The 'Unsmoke' Screen: The Truth Behind PMI's Cigarette-Free Future*, BUREAU INVESTIGATIVE JOURNALISM (Feb. 24, 2020), https://www.thebureauinvestigates.com/stories/2020-02-24/the-unsmoke-screen-the-truth-behind-pmis-cigarette-free-future (discussing PMI's youth marketing and its plans to continue leading in cigarette sales); *Spinning a New Tobacco Industry*, TRUTH INITIATIVE 2–3, 15 (Nov. 2009), https://truthinitiative.org/sites/default/files/media/files/2019/11/Tobacco%20Industry%20Interference%20Report_final111919.pdf (discussing industry efforts to undermine and block regulations).

(which would have exempted e-cigarettes) Altria immediately objected.[81]

Developing and promoting a less harmful alternative to a dangerous product is, in most cases, a social good. What makes this situation unusual is that tobacco companies claim to offer the solution to a problem that they created and continue to sustain. Corporate statements make it clear that despite their rhetoric, the companies are in no rush to stop selling cigarettes—the deadliest, but clearly the most profitable, tobacco product. For example, when pressed on *exactly when* they would stop selling cigarettes, PMI leadership is deeply evasive. CEO André Calantzopoulos says, "[n]ot in my time as chief executive, but in my lifetime, I do hope."[82] Ignoring PMI's active promotion of cigarettes, the company's vice president of communications suggests that the timeline for achieving the company's stated "smoke-free" goal is out of its hands, stating: "[o]ur vision is that one day smoke-free products will replace cigarettes. The sooner the world transitions away from cigarettes, the sooner we can stop making them."[83]

81 Michael Martz, *Northam Wants to Boost Tobacco and Fuel Taxes, End Vehicle Inspections, Slash Registration Fees,* Richmond Times-Dispatch (Dec. 17, 2019), https://www.richmond.com/news/virginia/northam-wants-to-boost-tobacco-and-fuel-taxes-end-vehicle-inspections-slash-registration-fees/article_30f6bc9c-b0ad-5b0a-a270-e1931a1e72f9.html. The proposed measure, which has not been enacted as of this writing, would raise the state's cigarette tax from 30 cents per pack to 60 cents per pack. *Id.* This would still leave Virginia's cigarette tax lower than nearly all other states. *State Cigarette Tax Rates*, Tax Pol'y Ctr. (Jan. 27, 2020) https://www.taxpolicycenter.org/statistics/state-cigarette-tax-rates.

82 James Ashton, *One Day I Hope We Won't Sell Cigarettes, Says Marlboro Boss*, Sunday Times (Oct. 23, 2016), https://www.thetimes.co.uk/article/one-day-i-hope-we-wont-sell-cigarettes-says-marlboro-boss-zfclkx5dt.

83 Davies et al., *supra* note 80. PMI recently added, "[t]he Company will be ready to support an industry-wide gradual phase-out of cigarettes as soon as a majority of smokers in a country have switched to scientifically substantiated smoke-free products. PMI believes that with the right regulatory encouragement and support from civil society, cigarette sales can end within 10 to 15 years in many countries." *PMI's Statement of Purpose: Excerpt from PMI's Integrated Report 2019*, Philip Morris Int'l, https://www.pmi.com/integrated-report-2019/pmi's-statement-of-purpose (last visited July 24, 2020). Whether or not PMI is sincere about this commitment is a matter of judgment, but it is notable that the company is asking for immediate and concrete deregulatory actions from governments in return for a longer-term (and unenforceable) pledge to support a future phase-out of cigarettes.

II. TOBACCO INDUSTRY E-CIGARETTE RESEARCH

Though they only started selling and promoting e-cigarettes within the past decade, tobacco companies have been studying e-cigarette technology—and worrying about its potential to undermine their cigarette business—for much longer. Chinese pharmacist Hon Lik is generally credited with inventing the e-cigarette in 2003,[84] but tobacco companies have been working on some version of an e-cigarette since the 1960s, as the examples discussed below will illustrate.[85] Tobacco companies abandoned these projects, at least in part, because they viewed these inventions as potentially viable alternatives to (or replacements for) cigarettes, and they did not want to compete with their own highly profitable product. They also worried about triggering a new wave of cigarette-related litigation[86] or further regulatory oversight. Taken together, these examples suggest that although the tobacco companies have long had the ability to bring an e-cigarette (or e-cigarette-like) product to the market as a less harmful alternative to conventional cigarettes, they made a deliberate choice not to do so until independent companies demonstrated the commercial viability of e-cigarettes.[87]

84 *See, e.g.*, Martinne Geller, *E-Cigs a 'Consumer-Driven' Revolution Born from a Bad Dream*, REUTERS (June 9, 2015), https://www.reuters.com/article/us-ecigarettes-inventor/e-cigs-a-consumer-driven-revolution-born-from-a-bad-dream-idUSKBN0OP1YV20150609 ("Hon Lik invented the e-cigarette, a device now shaking up the Big Tobacco industry."). Lik later sold his invention to Imperial Tobacco Group. *Id*.

85 *See infra* Sections II(A)–II(C).

86 *See* Daniel Givelber, *Cigarette Law*, 73 IND. L.J. 876, 888, 891 (1998) ("Collusion, not competition, ensured that the companies [did not work] strenuously to bring to market a demonstrably safer product . . . [T]he existence of a safer cigarette would undermine the effective legal immunity flowing from the industry's insistence that it was not possible to make such a product.").

87 These independent companies also demonstrated that an e-cigarette market could exist without destroying the profitability of cigarettes. *See* Chapman, *supra* note 63 (suggesting that that tobacco companies are content to have many current smokers "smoke *and* vape" concurrently, while at the same time e-cigarette marketing can recruit new customers to long-term nicotine consumption) (emphasis added); Jennifer Maloney & Saabira Chaudhuri, *Against All Odds, the U.S. Tobacco Industry Is Rolling in Money*, WALL ST. J. (Apr. 23, 2017, 1:31 PM), https://www.wsj.com/articles/u-s-tobacco-industry-rebounds-from-its-near-death-experience-1492968698 (explaining how the tobacco industry has been able to increase its profitability by raising the price of cigarettes, despite declining cigarette consumption).

A. *BAT's Project Ariel*

British American Tobacco (BAT) developed the essential concept of e-cigarettes in the early 1960s through a research effort called "Project Ariel."[88] This project was a response to the "widely publicized epidemiological studies link[ing] smoking to lung cancer."[89] BAT, despite its public denials, already knew that the addictive power of nicotine drove tobacco use, so the goal of Project Ariel was to "make a space-age cigarette that would deliver nicotine 'satisfaction' without the 'unattractive side effects' of cancer and emphysema."[90]

By 1962, BAT had developed a working model that "vaporize[d] nicotine without burning it."[91] Two years later, it added citric acid to reduce the pH and make the aerosol easier to inhale, and it filed a series of patents to protect its invention.[92] Though the resulting prototype was still more irritating than products available today, BAT had, in essence, assembled a product with the key design features of a modern e-cigarette.[93] In 1965, as it prepared to commercialize the device, the project leader reported that despite some technical obstacles, BAT's work "show[ed] clearly that the original objective [was] *feasible* and achievable."[94] But company leadership slowed the project's development before ultimately canceling it altogether in 1969.[95] Researcher Stephen Risi suggests that the project was abandoned not because of any technical shortcomings, but because "the industry was highly successful in blocking any effective antitobacco regulation," and, contrary to what the industry had feared, "[c]igarettes were clearly not on their way out."[96] As a result, Project Ariel posed a potential threat to BAT's own most profitable product and had to be hidden. Risi writes:

88 Stephan Risi, *On the Origins of the Electronic Cigarette: British American Tobacco's Project Ariel (1962–1967)*, 107 Am. J. Pub. Health 1060, 1060 (2017).

89 *Id.*

90 Robert N. Proctor, *Acting Now Is Urgent: Commentary on Zeller*, 21 Nicotine & Tobacco Res. 340, 340 (2019). For background on BAT's efforts to mislead the public about the addictiveness and harms of cigarettes, see, e.g., Stanton A. Glantz et al., *Looking Through a Keyhole at the Tobacco Industry: The Brown and Williamson Documents*, 274 JAMA 219, 223 (1995) (finding that the company's internal documents showed that "BAT recognized more than 30 years ago that nicotine is addictive and that tobacco smoke is 'biologically active' (eg [sic], carcinogenic)").

91 Risi, *supra* note 88, at 1063.

92 *Id.* at 1064. The patents were filed by the Battelle Memorial Institute "to avoid associating BAT with this new device." *Id.*

93 *Id.* at 1063, 1065.

94 *Id.* at 1064 (emphasis added).

95 *Id.*

96 *Id.*

> BAT hid Ariel not because it was fraudulent but precisely because it worked: unlike other tobacco industry gimmicks, such as light cigarettes, the Ariel device was genuinely designed to be healthier and the developed prototypes showed tar deliveries far below those of filter cigarettes. . . . [I]nternal documents show that BAT presumably shut down Ariel precisely because it worked—it was threatening because it permitted one to think of a future when cigarettes could be replaced with a healthier way of administering nicotine.[97]

B. *Philip Morris's Capillary Aerosol Generator*

Philip Morris did not get to the same idea as early as BAT, but in the early 1990s it developed a Capillary Aerosol Generator (CAG), which was likewise built around the same basic concept as modern e-cigarettes: extracting nicotine from tobacco and heating it into an inhalable aerosol.[98] And like BAT, it chose not to commercialize the project, instead, shelving the project because of its "reluctance to develop and introduce products that would compete with tobacco cigarettes."[99]

Internal documents suggest that from the start, the CAG was intended as a "defensive strategy," to be commercialized "only if necessitated by competition or regulation, rather than by health concerns."[100] As William Farone, former Director of Applied Research for Philip Morris, explained:

> All of our research was done for defensive reasons . . . Philip Morris was preparing for a time when they were forced—by the government or by competitors in the marketplace—to make meaningful changes to their products . . . These techniques were put "on the shelf" until they might become needed, unless they

97 *Id.* at 1065. Instead, the industry focused on promoting "light" and "low-tar" cigarettes that created the perception of reduced risk but instead likely *increased* tobacco-related harms. Min-Ae Song et al., *Cigarette Filter Ventilation and Its Relationship to Increasing Rates of Lung Adenocarcinoma*, 109 J. NAT'L CANCER INST., Dec. 2017, at 1–2, 4, 12 (finding strong evidence that "the inclusion of ventilation in cigarette filters"—the main design feature of "light" and "low-tar" cigarettes—"contributed to increased lung adenocarcinomas among smokers").

98 Because Philip Morris did not develop an e-cigarette prototype until decades after BAT did, the products liability theory discussed in Part IV, *infra*, would only be available to smokers who purchased Philip Morris cigarettes as of the early 1990s, while suits against BAT could potentially reach back all the way to the late 1960s.

99 Zachary Cahn & Lindsay Eckhaus, *Explaining the Discontinuation of a Non-Tobacco Nicotine Project at Philip Morris: Obstacles to Innovation*, 39 J. PUB. HEALTH POL'Y 131, 133 (2018).

100 *Id.* at 136.

> could lead to an immediate profit.[101]

Philip Morris was also worried (for good reason) that marketing a nicotine aerosol device would undermine its public positions—maintained in both litigation and congressional testimony—that nicotine was not addictive and that it was not manipulating nicotine levels in cigarettes.[102]

Though Philip Morris was not "sitting on a finished version of an e-cigarette-like product" when it abandoned the CAG effort, research examining Philip Morris's internal documents (released as a result of litigation) suggests that "[t]he most important obstacles to CAG development appear to [have been] regulatory and business 'bottom-line' concerns," *not* technological feasibility concerns.[103] An internal 1998 Philip Morris report stated that the company "determined it was not in our business interests to continue to pursue research on this device," even though it "recognized the potential advantages this invention could have to the pharmaceutical and medical community."[104]

C. *R.J. Reynolds's Nicotine Salts*

In the early 1970s, cigarette giant R.J. Reynolds—as part of an effort to "get [its] share of the youth market"—started experimenting with nicotine salts.[105] Nicotine salts are formed by combining nicotine with a low-pH acid.[106] The resulting compound has a much lower pH than nicotine alone, making it more palatable for users.[107]

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101 *Id.* at 133, 136–37 (quoting Farone). Putting it more bluntly, Farone also stated that Philip Morris "always worried in the ultimate about losing the damn gold mine they have." *Id.* at 139.

102 *Id.* at 135. These positions were knowingly fraudulent, and a federal court later ordered the major cigarette manufacturers (including Philip Morris) to issue public "corrective statements" that, *inter alia*, specifically referenced both of these falsehoods. United States v. Philip Morris USA, Inc., 449 F. Supp. 2d 1, 27, 852 (D.D.C. 2006).

103 Cahn & Eckhaus, *supra* note 99, at 133, 139.

104 Lauren M. Dutra et al., *Philip Morris Research on Precursors to the Modern E-Cigarette Since 1990*, 26 Tobacco Control e97, e100 (2017) (quoting Philip Morris Int'l Inc., *Message Points: Aerosol Patent* (1998), https://www.industrydocuments.ucsf.edu/docs/#id=pynd0064). Philip Morris sought to further suppress cigarette alternatives by pressuring Merrell Dow Pharmaceuticals to limit its marketing of Nicorette. Robert N. Proctor, Golden Holocaust: Origins of the Cigarette Catastrophe and the Case for Abolition 524–26 (2011).

105 Emily Baumgaertner, *Juul Took a Page from Big Tobacco to Revolutionize Vaping*, L.A. Times (Nov. 19, 2019), https://www.latimes.com/politics/story/2019-11-19/juul-vaping-chemical-formulas-based-in-big-tobacco. At the time of the developmental research discussed here, R.J. Reynolds was not a subsidiary of BAT.

106 *Id.*

107 *Id.* As discussed above, JUUL's use of nicotine salts enabled its e-cigarettes to pack a

According to recently-released R.J. Reynolds documents, the company synthesized and heated various nicotine salt combinations "in pursuit of the 'maximum release of nicotine.'"[108] It also "tested the salts' ability to dissolve into a liquid—a trait that would decades later become central to vaping products like JUUL."[109] Some of the resulting nicotine salts were later patented by R.J. Reynolds.[110] When confronted with these documents, a company spokesperson stated that they were part of an experimental effort by the company to "'reduce the risks' of smoking while 'maintaining nicotine delivery.'"[111]

Though R.J. Reynolds could have combined this nicotine salt breakthrough with other early vaping-like technologies it developed, it never did.[112] The reasons it dropped this line of research and product development is unclear, but it is likely similar to the reasons BAT and Philip Morris abandoned their early e-cigarettes: it did not want to undermine its false public statements about nicotine and invite additional regulatory scrutiny, nor did it want to cannibalize its own cigarette sales.

Decades later, the founders of JUUL carefully studied R.J. Reynolds's nicotine salt research, even referencing R.J. Reynolds's patent in their own patent application.[113] The ability of JUUL's founders—two Stanford graduate students—to develop a phenomenally successful vaping device using nicotine salts suggests that R.J. Reynolds would have had the technical capacity to do the same at a much earlier date, had it chosen to do so.

D. *Cigarette Companies in the E-Cigarette Business*

Starting in the 1960s, the tobacco companies developed and patented the technologies discussed in this section,[114] but all of them made

much larger nicotine punch than other e-cigarettes, fueling its meteoric rise. *Id.*

108 *Id.* These R.J. Reynolds papers were part of JUUL's internal documents that were turned over to the FDA as part of its investigation into the company's marketing activities. *Id.*

109 *Id.*

110 *Id.*

111 *Id.*

112 *Id.* (noting that R.J. Reynolds developed one of the first heat-not-burn cigarettes, indicating that it was exploring the aerosolization of nicotine in the same time frame).

113 *Id.*

114 The examples discussed in Sections II(A)–II(C) were just some of the tobacco industry's forays into "safer cigarette research"). *See* Givelber, *supra* note 86, at 891–93 (1998) (providing other examples). Professor Givelber, a long-time colleague and co-author of Professor Daynard, summarizes: "There were concerns that the safer cigarette would undermine the market for normal, unsafe cigarettes. These concerns melded with fear

the deliberate choice *not* to sell and instead conceal[115] their own e-cigarette products until decades later when independent companies began selling e-cigarettes. When it became clear that e-cigarettes were both attracting customers and clearing potential regulatory hurdles, the major tobacco companies quickly entered and took control of the e-cigarette market.[116] The cigarette companies acquired independent e-cigarette brands and quickly rolled out their own products,[117] in some cases with marked similarities to the prototypes discussed above.[118] In the case of JUUL, Altria acquired a 35% minority stake in the company, and a former Altria executive was installed as JUUL's new CEO.[119] The timing of these investments—especially when combined with "continu[ing] to aggressively market conventional cigarettes and challenge all attempts to . . . reduce smoking"—suggests that the companies are playing a largely defensive game (as the earlier Philip Morris documents indicated), rather than sincerely pursuing the goal of phasing out cigarette smoking.[120]

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of liability once it became clear that cigarette companies, if they wished to do so, could in fact make a healthier product." *Id.* at 892.

115 Kelder and Daynard provide a vivid example:

> [Former Vice President for Research at Brown & Williamson] Dr. Wigand also testified that, following a meeting of top scientists from B&W and its affiliates in Vancouver, British Columbia, in 1989, [B&W attorney J. Kendrick] Wells eliminated roughly twelve pages of the meeting's minutes. Wigand said that the missing pages detailed "the company's research on a safer cigarette and on nonaddictive nicotine alternatives[.]"
>
> Shortly after the 1989 Vancouver meeting, Wigand testified that he was summoned to [B&W President Thomas] Sandefur's office and told "there would be no further discussion or efforts on any issues related to a safer cigarette." Wigand also testified that Mr. Sandefur told him "that there can be no research on a safer cigarette. Any research on a safer cigarette would clearly expose every other product as unsafe and, therefore, present a liability issue in terms of any type of litigation."

Kelder & Daynard, *supra* note 2, at 177 (citations omitted).

116 Mathers et al., *supra* note 70, at 233.

117 *Id.* (detailing how the major tobacco companies "focused on acquiring independent cigalike manufacturers, thereby gaining intellectual property, market share, and distribution networks," and then also pursued the "internal development of additional branded e-cigarettes").

118 Dutra et al., *supra* note 104, at e102 (noting the "strong similarities and parallels" between the CAG and the e-cigarette design Philip Morris patented in 2009).

119 Baumgaertner, *supra* note 105.

120 Mathers et al., *supra* note 70, at 233. Tobacco companies may have also found that involvement in the e-cigarette sector provides them with other strategic and public relations advantages. *See* Chapman, *supra* note 63 ("E-cigarettes also promise hope of new respectability to tobacco companies. The same tobacco company staff who

III. ARE E-CIGARETTES A "REASONABLE ALTERNATIVE DESIGN"?

If a company sells a dangerous and deadly product when there are safer alternative designs for that product available, that is often grounds for liability under state tort law.[121] Importantly, whether or not such a "reasonable alternative design" should have been used is evaluated *as of the time of sale*, not at the time of litigation.[122] At first, this might seem to be a dead end for lawsuits seeking to hold up e-cigarette products as a "reasonable alternative design" for conventional cigarettes. But, as summarized in this section, the historical record suggests that, in fact, the major tobacco companies may have long had the capacity to create and market e-cigarette products like the ones they are now touting as less harmful—but for decades they chose not to. This section turns to the question of whether this historical evidence

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scheme to attack effective tobacco control and bust open low income, high illiteracy markets with cigarette promotions, suddenly have opportunities to present themselves as the harm reducing solution to the 'terrible' health problems that arise because of their work.").

121 Though this section focuses on the "reasonable alternative design" element of a design defect lawsuit, the plaintiff must always establish all of the other elements of a *prima facie* case as well, including causation, and defeat any affirmative defenses (such as assumption of risk) raised by the tobacco companies. Causation was fatal to the plaintiff's design defect claim in *Cipollone*. Cipollone v. Liggett Grp., Inc., 683 F. Supp. 1487, 1495 (D.N.J. 1988). The court concluded that even if the plaintiff had used the proffered alternative product—a palladium cigarette—instead of conventional cigarettes, it would have only marginally reduced the plaintiff's likelihood of developing cancer, which was not sufficient to establish causation. *Id.* The theory behind palladium cigarettes was that "incorporat[ing] palladium nitrate into tobacco . . . made combustion of the tobacco more thorough and complete, resulting in smoke containing less harmful byproducts." *Project XA*, SOURCEWATCH, https://www.sourcewatch.org/index.php/Project_XA (last modified Dec. 25, 2019). Liggett conducted extensive research on palladium cigarettes, but was ultimately pressured by other tobacco companies to abandon the research because of the fear that "[p]romoting one cigarette as 'safer' than others 'would be an indictment of the tobacco industry and its longstanding position that conventional cigarettes are not unsafe.'" *Id.* Another barrier may be that the plaintiff must be able to show that a reasonable alternative design was available to *the defendant company.* If a developmental e-cigarette is being introduced as the proposed alternative, the plaintiff must show that the defendant company possessed the technology to commercialize that product. *See* RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2, cmt. d. (AM. LAW. INST. 1998) ("[T]he plaintiff must prove that such a reasonable alternative was, or reasonably could have been, available at time of sale or distribution"). Thus the evidence summarized in Part II may only be relevant in litigation against those particular companies.

122 *See, e.g.*, Brown v. R.J. Reynolds Tobacco Co., 852 F. Supp. 8, 10 (E.D. La. 1994), ("[A] necessary element of proof for defective design is that an alternative design existed at the time the product left the manufacturer's control…."), *aff'd*, 52 F.3d 524 (5th Cir. 1995).

could be used in court to show that there were less harmful "reasonable alternative designs" for cigarettes that the tobacco companies could have—and, as a matter of law, should have—pursued.

A. *What Is a "Reasonable Alternative Design"*

Under *Cipollone* and its progeny, failure to warn claims against cigarette companies are preempted by federal law, but claims premised on a product's defective or negligent design are not. Whether or not a product's design is defective is evaluated through a *consumer expectations test* (whether or not a product conforms to a consumer's "reasonable expectations with regard to safety"), a *risk-utility* test (whether or not the manufacturer has employed available cost-effective measures to reduce harm), or some combination thereof.[123] Historically, pursuing defective design theories has not been fruitful for plaintiffs in cigarette-related litigation because (a) under the consumer expectations test, consumers arguably expect cigarettes to be harmful;[124] and (b) under the risk-utility test, defendants have successfully argued that cigarettes are simply "inherently dangerous," and no less harmful alternative designs are possible.[125]

123 *See* Restatement (Third) of Torts: Prods. Liab. § 2 cmt. d (Am. Law. Inst. 1998) (providing state-by-state review of approaches to design defects and concluding that the "overwhelming majority of American jurisdictions" require proof of a "reasonable alternative design" in design defect cases). The Restatement (Third) adopts such a "reasonable alternative design" requirement. *Id.*

124 The influential Restatement (Second) of Torts used a consumer expectations approach. Restatement (Second) of Torts § 402A cmt. i (Am. Law. Inst. 1965) Comment *i* to Section 402A of the Restatement provided, "[t]he article sold must be dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics." *Id.* This was historically a major obstacle to products liability lawsuits, particularly because another part of Comment *i* specifically provided that "[g]ood tobacco is not unreasonably dangerous merely because the effects of smoking may be harmful[.]" The tobacco industry attorneys "were deeply involved in drafting this document." Proctor, *supra* note 104, at 332; *see also* Givelber, *supra* note 86, at 880 (detailing the history of this provision). The Third Restatement preserves the rule that the sale of dangerous but "[c]ommon and widely distributed products such as alcoholic beverages, firearms, and above-ground swimming pools" is generally not grounds for liability. Restatement (Third) of Torts: Prods. Liab. § 2 cmt. d (Am. Law Inst. 1998). However, it notably excludes tobacco products from this list, and it also provides that liability for a design defect can attach—even to the listed products—"if reasonable alternative designs could have been adopted." *Id.*

125 *See, e.g.*, American Tobacco Co. v. Grinnell, 951 S.W.2d 420, 433 (Tex. 1997) ("Because American [Tobacco Co.] conclusively proved that no reasonably safer alternative design exists for its cigarettes, we hold that summary judgment was proper on all of the Grinnells' design defect claims.").

The risk-utility test seeks to "balance the risks of the product as designed against the costs of making the product safer[,]" factoring in any loss of utility to consumers as a cost.[126] In most jurisdictions using the risk-utility test, it is a required part of the plaintiff's *prima facie* case to present a "reasonable alternative design" (sometimes called a "safer alternative design" or a "feasible alternative design") that the defendant should have employed.[127] Co-Reporters of the Products Liability section of the Restatement (Third) of Torts Aaron Twerski and James Henderson summarize that in risk-utility design defect cases, plaintiffs "live or die by their ability to establish a reasonable alternative design."[128] Past lawsuits against cigarette companies have often foundered on this point.[129] Indeed, leading products liability scholars have suggested that "[a]lthough production of addictive and lethal cigarettes might be negligent or worse, it may be difficult to imagine a reasonable alternative design."[130]

Where a reasonable alternative design for cigarettes has been proffered by the plaintiffs, courts have been reluctant to even send the question to the jury, often noting that "feasibility" involves more than technical capacity. For example, in *Tompkins v. R.J. Reynolds*, the plaintiffs suggested that earlier versions of heat-not-burn products would have been feasible alternatives available to R.J. Reynolds.[131] The court granted summary judgment to the tobacco company, concluding that "Plaintiffs have failed to meet their burden pertaining to evidence of a *feasible*, alternative design" because "Plaintiffs [failed to] discuss the cost of manufacturing or marketing an alternative design, or whether an alternative product would be profitable

126 DAN B. DOBBS ET AL., DOBBS' LAW OF TORTS § 456 (2d ed. 2020 Update), Westlaw DOBBLOT 456. The risk-utility test is a balancing test. On the "risk" side, one considers "not only the likelihood of harm but also its magnitude." *Id.* The risk-utility test may therefore suggest that the immense harms caused by conventional cigarettes justifies requiring the use of a less harmful alternative, even if the alternative product offers somewhat lower "utility" (a concept difficult to apply in this context).

127 *See* RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. §§ 2, 14, 24–25, 50 (AM. LAW INST. 1998) ("To establish a prima facie case of defect, the plaintiff must prove the availability of a technologically feasible and practical alternative design that would have reduced or prevented the plaintiff's harm."). Critically, this alternative must have been available to the manufacturer "at the time of sale or distribution." *Id.* § 14.

128 Aaron D. Twerski & James A. Henderson, Jr., *Manufacturers' Liability for Defective Product Designs: The Triumph of Risk-Utility*, 74 BROOK. L. REV. 1061, 1108 (2009).

129 *See, e.g.*, *Grinnell*, 951 S.W.2d at 433; Miller v. Brown & Williamson Tobacco Corp., 679 F. Supp. 485, 488 (E.D. Pa. 1988) ("Plaintiff has the burden of proving defective design. On this record, plaintiff will not be able to demonstrate that there is something wrong with the design of cigarettes or how the design could be improved.").

130 DOBBS ET AL., *supra* note 126.

131 Tompkins v. R.J. Reynolds Tobacco Co., 92 F. Supp. 2d 70, 84–85 (N.D.N.Y. 2000).

for any company."[132] Even if they could clear this bar, courts may also require the plaintiff to show that consumers would have considered the alternative product to have been an acceptable substitute. For example, in *Adamo v. Brown & Williamson Tobacco Co.*, the New York Court of Appeals wrote that, even if plaintiffs could show that reduced-tar cigarettes were a safer alternative, they "did not show that cigarettes from which much of the tar and nicotine has been removed remain 'functional'" in the sense that they are "as satisfying as regular cigarettes" to current smokers.[133] Put together, this suggests a very high bar for plaintiffs to establish the availability of a "reasonable alternative design": they must show not only that defendant tobacco company had the technical ability to develop a less harmful alternative, but also that it would have been able to successfully commercialize the product and that consumers would have found it to be an acceptable replacement.[134]

132 *Id.* at 85.

133 Adamo v. Brown & Williamson Tobacco Corp., 900 N.E.2d 966, 968 (N.Y. 2008). In this case, the court was reviewing a jury verdict, not deciding whether to allow the case to go to the jury. But the standard the court set has been used to grant summary judgment for tobacco companies in subsequent design defect cases. *See, e.g.*, Fabiano v. Philip Morris Inc., 909 N.Y.S.2d 314, 319 (Sup. Ct. 2010). In *Adamo*, the plaintiffs presented "light" cigarettes as a reasonable alternative design, which should have been rejected not because "light" cigarettes are unacceptable to consumers, but because they are not, in fact, safer. Though they promoted them as less-harmful alternatives, the cigarette companies "were well aware that smokers of 'light' and 'low tar' cigarettes would 'compensate' for reduced nicotine levels by 'breathing more deeply, taking more puffs, or blocking the ventilation holes of cigarette filters,' thus negating any potential health benefits." Micah L. Berman, *Tobacco Litigation Without the Smoke? Cigarette Companies in the Smokeless Tobacco Industry,* 11 J. Health Care L. & Pol'y 7, 37 (2008). In any event, "consumer acceptability" is an odd standard to use (or to employ without defining it more precisely) in a context where consumer use is largely driven by the addictive power of nicotine, and most long-term consumers of cigarettes express a desire to quit.

134 The story of heat-not-burn products, including the Premier and Eclipse cigarettes discussed in *Tompkins*, complicates the historical record reviewed in Part II. These products were marketed by the tobacco industry starting in the 1990s as purportedly safer cigarettes and proved to be commercial flops. *See, e.g.*, Brown v. R.J. Reynolds Tobacco Co., 852 F. Supp. 8, 10 (E.D. La. 1994) (concluding that because "RJR's test market of the Premier cigarette was a failure, and . . . the product was withdrawn from the marketplace[,] plaintiff appears to be unable to establish the necessary element of alternative, feasible design"). The story of these product failures is more complicated than can be reviewed here, but in addition to being commercial flops, it is less clear that these products were substantially less harmful than cigarettes. For instance, R.J. Reynolds was forced to pay Vermont more than $8 million for making unsubstantiated health claims about its Eclipse cigarette, *State v. R.J. Reynolds Tobacco Co.*, No. S1087-05 CnC., 2013 WL 3184666, at *1 (Vt. Super. Ct. June 3, 2013); *State v. R.J. Reynolds Tobacco Co.*, No. S1087-05 CnC., 2010 WL 1323565, at *88 (Vt. Super. Ct. Mar. 10, 2010), and Eclipse was also criticized for having hazardous glass fibers in its filter. John L. Pauly et al., *Glass Fiber Contamination of Cigarette Filters: An Additional Health Risk*

As Daniel Givelber wrote back in 1998, requiring the plaintiff to establish the availability of a safer alternative seems to put the burden in the wrong place, at least in the context of cigarettes, as it requires "plaintiffs [to] establish as true that which the tobacco companies have gone to great lengths to keep secret," and "no one but the cigarette companies has the resources or expertise necessary to determine if cigarettes can be made safer." [135] Indeed, because the tobacco companies knew that developing a "safer cigarette" could potentially expose them to liability,

> they put lawyers rather than scientists or manufacturing executives in charge of the research that was conducted, and they withheld dissemination of the results of that research as privileged legal work product. Collusion, not competition, ensured that the companies neither discussed the relative safety of the various brands nor worked strenuously to bring to market a demonstrably safer product.[136]

Fear of legal liability is likely a key reason that the early e-cigarette projects discussed in Part II were hidden and then quashed by company leadership.

B. *What Is the Product?*

An additional major obstacle to arguing that e-cigarette products presented a "reasonable alternative design" for cigarettes is the question of whether such products are "alternative designs" or a different product altogether. In recent litigation, Philip Morris argued against other asserted alternative designs, writing:

> Any contention that PM USA should have made a nicotine-free or uninhalable "cigarette" suffers from exactly the same flaw. It is nothing more than a disguised claim that PM USA should have made an entirely different product. Courts across the country have consistently rejected such theories. Neither is a car an alternative safer design for a motorcycle, nor grape juice an alternative safer

to the Smoker?, 7 CANCER EPIDEMIOLOGY, BIOMARKERS & PREVENTION 967, 967 (1998). The commercial failure of these products, though, does raise an interesting conceptual question about how far producers of a dangerous product must go to find a consumer-acceptable safer alternative. As Robert Proctor suggests, the cigarette companies may have been happy to see these products flop and were perhaps not interested in making them more acceptable to consumers. PROCTOR, *supra* note 104, at 531. Instead, they could shift blame to smokers by arguing that they had tried to offer a safer alternative, but smokers were not interested. *Id.*

135 Givelber, *supra* note 86, at 882, 888–89.

136 *Id.* at 888–89.

> design for wine.[137]

Though correct that an "entirely different product" cannot be an "alternative design," Philip Morris may be overstating its case here. Indeed, in the very litigation it cites, *Kimball v. R.J. Reynolds*, the court allowed the question of "what is a cigarette?" to go to the jury, specially raising the possibility that a cigarette may be nothing more than a "Nicotine-Delivery Device."[138] And the notion that a cigarette is, at essence, a nicotine delivery device comes directly from the companies' files. A 1972 Philip Morris memo, for example, explained:

> The cigarette should be conceived not as a product but as a package. The product is nicotine . . . Think of the cigarette pack as a storage container for a day's supply of nicotine . . . Think of the cigarette as a dispenser for a dose unit of nicotine.[139]

Similar statements can be found in the files of the other major tobacco

137 Defendant's Motion for a Directed Verdict on Plaintiff's Strict Liability Design Defect and Negligent Design Claims, Capone v. R.J. Reynolds Tobacco Co., No. 08-1464 CA, 2018 WL 7287441 (Fla. Cir. Ct. Dec. 12, 2018) (citing Kimball *ex rel.* Kimball v. R.J. Reynolds Tobacco Co., No. C03-664JLR, 2006 WL 1148506, at *3 (W.D. Wash. Apr. 26, 2006) ("[A] plaintiff injured in a motorcycle accident cannot argue that if the manufacturer had installed four wheels on the motorcycle, it would have been safer. 'Two-wheeledness' is an essential characteristic of a motorcycle. What are the essential characteristics of a cigarette? . . . The jury will decide the issue, and will thus decide whether any alternative design that [plaintiff] proffers is a feasible alternative.")).

138 Kimball *ex rel*. Kimball v. R.J. Reynolds Tobacco Co., No. C03-664JLR, 2006 WL 1148506, at *3 (W.D. Wash. Apr. 26, 2006); Plaintiff's Response to Motion to Exclude or Limit Testimony of K. Michael Cummings at 11, Kimball *ex rel*. Kimball v. RJ Reynolds Tobacco Co., No. CV 03-0664 JLR, 2006 WL 1499592 (W.D. Wash. Apr. 10, 2006). The plaintiffs in Kimball sought to introduce heat-not-burn tobacco products (Premier and Eclipse) as the reasonable alternative designs for conventional cigarettes. Ultimately, this case resulted in a jury verdict in favor of the defendant. *R.J. Reynolds Prevails in Jury Trial Brought by Smoker's Widower*, Jones Day (May 15, 2006), https://www.jonesday.com/en/practices/experience/2009/08/rj-reynolds-prevails-in-jury-trial-brought-by-smoker39s-widower. Plaintiffs also failed to prevail in earlier cases seeking to use heat-not-burn projects as reasonable alternative designs for cigarettes. *See, e.g.*, Brown v. R.J. Reynolds Tobacco Co., 852 F. Supp. 8, 10 (E.D. La. 1994), *aff'd*, 52 F.3d 524 (5th Cir. 1995); Neri v. R.J. Reynolds Tobacco Co., No. 98-CV-371, 2000 WL 33911224, at *13 (N.D.N.Y. Sept. 28, 2000); Tompkins v. R.J. Reynolds Tobacco Co., 92 F. Supp. 2d 70, 85 (N.D.N.Y. 2000).

139 Memorandum re Motives and Incentives in Cigarette Smoking, William L. Dunn, Jr., Phillip Morris Research Ctr. 5 (July 1, 1972), https://www.industrydocuments.ucsf.edu/tobacco/docs/#id=tggp0125. This memo was uncovered through discovery in the *Cipollone* case. Myron Levin, *Key Smoker Death Trial Draws to Close; Jury Is First to See Company Documents*, L.A. Times (June 1, 1988), https://www.latimes.com/archives/la-xpm-1988-06-01-mn-3676-story.html.

companies as well.[140] They all recognized, long before they admitted it publicly, that cigarettes are, at their core, drug-delivery devices (as the FDA concluded in the 1990s).

A leading torts treatise, Dobbs' Law of Torts, suggests that this "functional" approach to what counts as a reasonable alternative design makes sense.[141] It notes that if you narrowly define "asbestos [as] asbestos[,]" then there is, by definition, no reasonable alternative to be used as a comparison.[142] But if you instead define the relevant product as "insulating material," "you can find very good substitutes that can easily count as reasonable alternative designs"—and that are much safer.[143] Dobbs suggests that although finding the precise boundaries of this concept may prove difficult, "[c]ourts should be permitted to characterize the product broadly or, much the same thing, to consider substitute products that have similar functions or those that would be accepted by consumers as substitutes."[144] The Third Restatement also endorses this functional approach, suggesting that "other products already available on the market may serve the same or very similar function at lower risk and at comparable cost" as the defendant's product, and "[s]uch products may serve as reasonable alternatives to the product in question."[145]

If the question then becomes *what is a reasonable substitute nicotine delivery device for a cigarette?*, the early e-cigarettes may fit the bill.[146] In at least one case, *Smith v. Brown & Williamson Tobacco Corp.*, the court agreed that the early e-cigarettes in BAT's Project Ariel could be presented to the jury as evidence of "specific design choices" made by the company that rendered conventional cigarettes "unreasonably dangerous."[147] This shows

140 *See generally Tobacco Company Quotes: Nicotine as a Drug*, CAMPAIGN FOR TOBACCO-FREE KIDS (1999), http://tobaccopolicycenter.org/wp-content/uploads/2017/11/161.pdf.

141 DOBBS ET AL., *supra* note 126, § 459.

142 *Id.*

143 *Id.*

144 *Id.*

145 RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2 cmt. f (AM. LAW INST. 1998).

146 NRTs like gums and lozenges could also be presented as potential alternatives. These products, though, are not really intended to be substitute nicotine delivery devices; rather, they are a mode of treatment for nicotine addiction. If the "product" is defined as a recreational nicotine delivery device, then NRTs would be outside of that definition, but e-cigarettes would be within it. E-cigarettes have the added advantage of replicating the hand-to-mouth action of smoking, which on its own has been shown to somewhat reduce the urge to smoke. Martijn Van Heel et al., *The Importance of Conditioned Stimuli in Cigarette and E-Cigarette Craving Reduction by E-Cigarettes*, INT'L J. ENVTL. RES. & PUB. HEALTH, Feb. 2017, at 14 (2017).

147 Smith v. Brown & Williamson Tobacco Corp., 275 S.W.3d 748, 796 (Mo. Ct. App. 2008). Twerski and Henderson note that "Missouri is an interesting example of a state

a willingness by at least one court to think of the early, developmental e-cigarettes as potentially "safer cigarette[s]," which is likely how the industry conceptualized them.[148] And the jury, which ruled in favor of plaintiff, was apparently convinced by this characterization as well.[149]

Highly relevant to this question is the issue raised in the Massachusetts case *Evans v. Lorillard* in 2013.[150] In this case, the state's highest court asked, *who is the consumer for whom the "reasonableness" of the alternative design question is analyzed?* The consumer considering whether or not to smoke his or her first cigarette, or the already-addicted smoker?[151] As the court noted, if the answer is the latter, then the more addictive a product is, the more it will be immunized from liability, because only a similarly-addictive product could be a reasonable alternative.[152] Analyzing the issue that way, the court concluded, "would eliminate any incentive for cigarette manufacturers to make safer perhaps the most dangerous product lawfully sold in the market through reasonable alternative designs."[153] Instead, it wrote that "we must determine whether the design alternative unduly interfered with the performance of

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that, while disavowing reliance on the *Products Liability Restatement*, nevertheless requires plaintiffs to establish a reasonable alternative design in order to make out a prima facie case of design defect." Twerski & Henderson, *supra* note 128, at 1077.

148 *See Smith*, 275 S.W.3d at 821. Though the *Smith* court concluded that the plaintiffs had presented sufficient evidence to support a plaintiff's verdict on the design defect claim, it incongruously proceeded to say that the plaintiffs could not make out a negligent design claim. *Id.* at 748. The court wrote:

> [T]he conduct at issue for this claim is B & W designing cigarettes containing harmful constituents and failing to use ordinary care to design a safer cigarette. Viewed in the light most favorable to submissibility, the evidence establishes that B & W stopped trying to develop a safer cigarette for fear it would hurt the sales of its normal "non-safe" cigarette. Further, it attempted to persuade other tobacco companies not to pursue a safer cigarette for similar reasons. The implication is that B & W was more concerned with profits than with the development of a safe cigarette. Nonetheless, [the plaintiff's witnesses] testified that it is not possible to make a safe cigarette. The three brands currently on the market that may be characterized as "safer" have not been proven safer and still bear the Surgeon General's warning. This is not clear and convincing evidence that B & W's conduct was tantamount to intentional wrongdoing.

Id. at 821.

149 *Id.* at 759. A search by the author found that this is the only reported products liability case in which Project Ariel is mentioned.

150 Evans v. Lorillard Tobacco Co., 990 N.E.2d 997, 1018 (Mass. 2013).

151 *Id.* at 1018.

152 *Id.* at 1019–20. As the court noted, apart from cigarettes, there are few if any other consumer products for which this question would ever come up. *Id.*

153 *Id.* at 1019.

the product from the perspective of a rational, informed consumer, whose freedom of choice is not substantially impaired by addiction."[154]

This is important because most early e-cigarette products that the tobacco industry explored likely would not have delivered nicotine as effectively as cigarettes and thus would not have been as "satisfying" to current smokers. But if the product is reconceived as a recreational nicotine delivery device and viewed from the perspective of a nicotine-naïve potential consumer, an e-cigarette that is less toxic and less powerfully addictive might well be considered a *better* alternative. Approaching the issue in this way would undermine the industry's common talking point that any proposed alternative must have "large acceptance by a vast majority of the people who smoke."[155] The *Evans* court argues that the industry has it backwards; what is relevant is not what *current* smokers would view as an alternative, but what *potential* smokers would.

The approach taken by the *Evans* court has not been widely embraced beyond Massachusetts, and it stands in contrast to the view taken in the *Adamo* case discussed above and many others. But when combined with the "functional" approach to alternative designs endorsed by the Restatement, it does suggest a pathway, viable in at least some jurisdictions, for arguing that a proposed alternative product need not be *as* addictive as a conventional cigarette to be a reasonable alternative design.

C. *Public Policy Challenges*

Despite the glimmer of hope presented by cases like *Smith* and *Evans*, establishing that e-cigarettes present a reasonable alternative design for cigarettes is likely to be difficult in the vast majority of cases.[156] Even if a jury were inclined to accept such an argument (which may run contrary to jurors' general understanding of what a cigarette is), courts may reject such

154 *Id.* at 1019–20.

155 K. Michael Cummings et al., *Consumer Acceptable Risk: How Cigarette Companies Have Responded to Accusations That Their Products Are Defective*, 15 TOBACCO CONTROL (SUPP. IV) iv84, iv85, iv88 (2006) (quoting industry argument to jury and noting that similar argument was made in every case the authors reviewed).

156 *Smith* is not the only case in which a proposed "alternative design" for cigarettes has reached the jury. *See, e.g.*, Miele v. Am. Tobacco Co., 770 N.Y.S.2d 386, 392 (N.Y. App. Div. 2003) ("[Plaintiff's evidence] that the tobacco companies opted not to develop, pursue, or exploit available technologies to reduce the toxins in cigarettes which cause disease[] sufficed to raise an issue of fact as to whether the foreseeable risk of harm posed by cigarettes could have been reduced or avoided by the adoption of a reasonable alternative design by the manufacturer respondents."); Haglund v. Philip Morris, Inc., No. 012367C, 2009 WL 3839004, at *9-10 (Mass. Super. Ct. Oct. 20, 2009) (low-nicotine cigarette as proposed alternative product).

suits on the grounds that such determinations are better left to the political branches of government. Put differently, a court or jury's determination that e-cigarettes are a safer alternative design for cigarettes that the tobacco companies should have sold instead is a different way of saying that *all* conventional cigarettes are defectively designed.[157] This is a conclusion with obviously significant economic and political implications that many courts are likely to shy away from.[158]

Courts' reluctance to impugn all cigarettes as defectively designed relates to the torts concept of "category liability," that is, whether an entire category of products can be considered to have been defectively designed. Twerski and Henderson, who are opposed to the concept of category liability, write:

> American courts have never imposed category liability, mainly because they intuitively (and correctly) understand that it would constitute an abuse of judicial power to decide which broad categories of products should not be distributed at all. Such sweeping regulation, courts have concluded, should be left to legislatures to undertake.[159]

Twerski and Henderson, however, explain that the Third Restatement rejects category liability *because it insists on evidence of a reasonable alternative design*.[160] If

157 *Cf.* Clinton v. Brown & Williamson Holdings, Inc., 498 F. Supp. 2d 639, 648 (S.D.N.Y. 2007) ("A state law requirement that allows only cigarettes with no tar or no nicotine to be sold is a virtual ban on cigarettes, just as a requirement that allows only 'alcohol-free' liquor to be sold would be a ban on whiskey."). Note, though, that holding that a product is defective is not the same as a ban. *See infra* note 160. Additionally, if the product category is conceptualized as a nicotine delivery device, then the better analogy would be to prohibiting the most toxic form of whiskey, not to banning alcohol.

158 *See, e.g.*, Gunsalus v. Celotex Corp., 674 F. Supp. 1149, 1159 (E.D. Pa. 1987) ("Whether products should be banned or whether absolute liability should be imposed for their use are determinations more appropriately made by the legislative branch of government.").

159 Twerski & Henderson, *supra* note 128, at 1069 (noting that "alcoholic beverages must, almost by definition, contain alcohol to be attractive to those who desire to consume such products. Removing the alcohol does not merely make such beverages safer for those who [abuse them], it also destroys their utility for everyone, including the significant majority who do not abuse them"). The cigarette/e-cigarette example could be distinguished from this alcohol example. The "utility" of cigarette smoking, such as it is, comes primarily from the nicotine delivery, which e-cigarettes also provide.

160 *Id.* at 1070. Other torts scholars are not opposed to the concept of category liability. *See* Ellen Wertheimer, *The Smoke Gets in Their Eyes: Product Category Liability and Alternative Feasible Designs in the Third Restatement*, 61 Tenn. L. Rev. 1429, 1436 (1994) ("[P]roduct category liability and product abolition are two very different concepts. A product even with high dangers and no social utility will continue to exist as long as it turns a profit; strict liability exists simply to make sure that the profit is a true one and

there is a safer alternative design available for the same product, then, *ipso facto*, category liability is not being imposed. As such, the question becomes indistinguishable from the underlying issue of whether e-cigarettes are a reasonable alternative design for cigarettes or a different product altogether. Nonetheless, it seems likely the desire to avoid imposing what may look like a form of category liability may influence courts' conclusions about that underlying question.

not one created by exempting manufacturers from their responsibilities").

IV. The Intersection of Products Liability Litigation and Endgame Efforts

The discussion in Part III suggests that successfully establishing in court that e-cigarettes (or early versions thereof) present a reasonable alternative design for cigarettes may be possible in some cases, but doing so—much less prevailing on the entire lawsuit—will remain challenging. As briefly discussed in this section, though, pairing the lawsuit with a strategic public relations effort could help educate the public and build momentum for public policies designed to phase out the sale of combustible cigarettes.

As noted above, in any products liability lawsuit, the plaintiffs would have to show that an alternative was available *at the time the allegedly defective cigarettes were being sold* (which would vary by case), not at the present time.[161] Nonetheless, it is likely that the modern commercial success of e-cigarettes will shape the way courts and jurors receive and evaluate this historical evidence. The idea that a nicotine vaporizer could be a realistic alternative to cigarettes likely seemed wildly implausible to the average person fifteen or twenty years ago, when many of the third wave lawsuits were filed. It does not seem nearly so far-fetched now, in a world where leading Wall Street analysts have predicted that e-cigarette sales will eventually overtake and function as a substitute for cigarette sales.[162]

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161 This is because for a products liability (or other torts) suit to proceed, there must be an injury. The death and disease from cigarette use often does not manifest for years. Thus, the relevant time period to examine is when the injury-causing cigarettes were consumed, not the present day. Suits trying to accelerate the time point at which a plaintiff can file a lawsuit by noting that current cigarette use increases the *risk* of future harms have, for the most part, been unsuccessful. *See, e.g.*, Caronia v. Philip Morris USA, Inc., 5 N.E.3d. 11, 14, 22 (N.Y. 2013) (rejecting lawsuit seeking "medical monitoring" for current smokers); *In re* Tobacco Litig. (Med. Monitoring Cases), 215 W. Va. 476 (W. Va. 2004) (upholding jury verdict denying recovery for medical monitoring and noting the "extremely high bar" plaintiffs face in such cases); Lowe v. Philip Morris USA, Inc., 183 P.3d 181, 184 (Or. 2008) (similarly rejecting medical monitoring claim, writing that "the fact that a defendant's negligence poses a threat of future physical harm is not sufficient, standing alone, to constitute an actionable injury"). *But see* Donovan v. Philip Morris USA, Inc., 914 N.E.2d 891 (Mass. 2009) (recognizing cause of action for medical monitoring under Massachusetts law).

162 Investment analyst Bonnie Herzog said in 2013, "[w]e have increased conviction that consumption of e-cigs could surpass consumption of conventional cigs within the next decade." Dan Mangan, *E-Cigarette Sales Are Smoking Hot, Set to Hit $1.7 billion*, CNBC (Aug. 28, 2013) https://www.cnbc.com/id/100991511. She has since retreated from this position but still believes the e-cigarette market will continue to grow and that it will account for approximately 30% of all nicotine sales by 2025 (driving continued overall growth of nicotine sales, despite further declines in cigarette use). Bonnie Herzog, *Wall Street Tobacco Industry Update*, Nat'l Ass'n Tobacco Outlets 25 (Feb. 11, 2019), http://

Furthermore, now—again in contrast to fifteen or twenty years ago—*even the cigarette companies themselves* are arguing that e-cigarettes are the ideal substitute for cigarettes, that they are less harmful, and that they should eventually replace cigarettes. Though these industry statements may be inadmissible in court (because they relate to the present context, not the time period that would be relevant in a given lawsuit), they also undoubtedly shape the litigation context. And, if the industry continues to argue in court that e-cigarettes are not feasible alternatives to cigarettes, it could be confronted out of court (e.g., in the press) with the hypocrisy of arguing the exact opposite in its advertising.

If a "fourth wave" of tobacco litigation based on reasonable alternative design arguments is attempted, it should be coupled with such an out-of-court public communications campaign. Such a campaign could press the industry to live up to its disingenuous "smoke-free future" rhetoric by highlighting that:

- » the cigarette companies could have sold e-cigarettes decades ago, but deliberately chose not to, instead taking extreme measures to hide their research;[163]
- » the companies only reluctantly started selling e-cigarettes when forced to do so by competition from independent companies;[164]
- » the companies now assert that e-cigarettes are less harmful than cigarettes and a satisfying alternative product for current smokers, *but still*—despite their "smoke-free future" rhetoric—spend the bulk of their advertising dollars on combustible cigarettes and resist nearly all cigarette-focused regulation.[165]

Though the industry is likely to be unmoved by such a campaign, it could refocus legislators' and tobacco control advocates' attention on

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www.natocentral.org/uploads/Wall_Street_Update_Slide_Deck_February_2019.pdf.

163 *See supra* Sections II(A)–II(C).

164 *See supra* Section II(D).

165 *Is Reynolds American a Good Corporate Citizen? History and Recent Actions Say No*, CAMPAIGN FOR TOBACCO-FREE KIDS (Mar. 3, 2017), https://www.tobaccofreekids.org/assets/factsheets/0124.pdf (summarizing evidence that "the company remains focused on selling more cigarettes, despite claiming a commitment to reducing the harms of tobacco"); *see, e.g.*, Becky Freeman, *Is Big Tobacco Abandoning Smokes for E-cigarettes?*, CONVERSATION (July 8, 2014), https://theconversation.com/is-big-tobacco-abandoning-smokes-for-e-cigarettes-28328 ("Since acquiring e-cigarette brands, not one tobacco company has stepped out of the way of tobacco control policy makers working to reduce smoking."). For detailed information on the tobacco companies' marketing and lobbying campaigns, see generally *Tobacco Companies*, TOBACCO TACTICS, https://tobaccotactics.org/topics/tobacco-companies/ (last visited June 23, 2020).

conventional cigarettes, which (by far) remain the leading cause of tobacco-related disease and death.[166] Without discounting the very real harms caused by the surge in youth e-cigarette use, a renewed focus on the role of combustible tobacco products has the potential to break through the harm reduction debate that has consumed and divided the tobacco control community.[167]

As Richard Daynard suggested in 2009, communities around the country could (and, generally, have the legal authority to) prohibit cigarette sales while allowing for the sale of potentially less harmful products, like e-cigarettes.[168] This is the legislative mechanism for forcing the industry to live up to its own rhetoric and for communities to express—as some already have—that they have had enough of the entirely preventable disease and death that cigarette use has caused.[169]

One community, or even one state, prohibiting the sale of cigarettes

166 Office on Smoking & Health, U.S. Dep't of Health & Human Servs., The Health Consequences Of Smoking—50 Years of Progress: A Report of the Surgeon General 7 (2014) [hereinafter 2014 Surgeon General's Report] https://www.ncbi.nlm.nih.gov/books/NBK179276/pdf/Bookshelf_NBK179276.pdf (concluding that "[t]he burden of death and disease from tobacco use in the United States is overwhelmingly caused by cigarettes and other combusted tobacco products[and that] rapid elimination of their use will dramatically reduce this burden"); Michael C. Fiore et al., *Smoke, the Chief Killer: Strategies for Targeting Combustible Tobacco Use*, 370 New Eng. J. Med. 297, 297–99 (2014).

167 Notably, fostering such division has been a deliberate goal of the tobacco industry. Patricia A. McDaniel et al., *Philip Morris's Project Sunrise: Weakening Tobacco Control by Working With It*, 15 Tobacco Control 215, 215 (2006) (reviewing internal Philip Morris documents and detailing the company's "explicit divide-and-conquer strategy against the tobacco control movement, proposing the establishment of relationships with PM-identified 'moderate' tobacco control individuals and organisations and the marginalisation of others").

168 *See* Daynard, *supra* note 7, at 2. Because of state-level preemption and limitations on home rule authority, the ability of local jurisdictions to prohibit cigarette sales at the local level must by analyzed on a state-by-state basis.

169 *See* Patricia A. McDaniel & Ruth E. Malone, *Tobacco Industry and Public Health Responses to State and Local Efforts to End Tobacco Sales From 1969-2020*, PLOS One, May 22, 2020, at 1 (reviewing more than 20 local efforts around the U.S. to end or severely restrict cigarettes sales). Full consideration of the merits of phasing out cigarette sales is beyond the scope of this article. For a thoughtful consideration of the potential benefits and challenges, see Smith & Malone, *supra* note 9, at 7. Importantly, phasing out cigarette sales could help to address the significant and persistent smoking-related disparities that exist along lines of "educational attainment, poverty status, age, health insurance status, race/ethnicity, and geography." Office on Smoking & Health, U.S. Dep't Of Health & Human Servs., Smoking Cessation: A Report of the Surgeon General 7 (2020). One challenge, though, is that these disparities might be further exacerbated if cigarettes sales are only phased out in high socioeconomic status communities such as Beverly Hills.

would not make them unavailable—only more difficult to access.[170] But if cigarettes were harder to come by, the "harm reduction" potential of e-cigarettes would be far more likely realized. As summarized in the 2014 Surgeon General's Report: "[t]he impact of . . . noncombustible [e-cigarettes] on population health is much more likely to be beneficial in an environment where the appeal, accessibility, promotion, and use of cigarettes and other combusted tobacco products are being rapidly reduced, especially among youth and young adults."[171] Accordingly, the 2014 Surgeon General concluded that "greater restrictions on sales, particularly at the local level, including bans on entire categories of tobacco products, could significantly alter the strategic environment for tobacco control."[172] Put more directly, in Richard Daynard's words, such measures could "save[] millions of lives."[173]

170 To avoid replaying the failed punitive approach of the War on Drugs, any such laws should prohibit the commercial sale of cigarettes, not their possession or use. Daynard, *supra* note 7, at 3 ("[T]he US 'War on Drugs' has earned a bad reputation by targeting users for draconian sanctions; the phase-out, by contrast, should be of the commercial sale of cigarettes, and should not punish private possession or consumption.").

171 2014 Surgeon General's Report, *supra* note 166, at 859.

172 *Id.*

173 Daynard, *supra* note 7, at 2.

Conclusion

Professor Daynard has pointed out numerous benefits that can result—and have resulted—from tobacco litigation, even in the absence of a final judgment for the plaintiffs. These include uncovering previously hidden evidence of industry misconduct (which has reshaped the public's image of the industry) and pressuring the industry into "the first stirrings of responsible behavior."[174] But, as noted at the outset, litigation poses dangers as well. Litigation losses can establish troubling legal precedents that influence future public heath cases, even outside the context of tobacco.[175] And perhaps the most unfortunate legacy of tobacco litigation has been the way other health-harming industries have learned from the tobacco industry to engage in the same "scorched earth" litigation tactics and to manufacture doubt even where none exists.[176]

The conclusion of this article is, therefore, a qualified one: new avenues for litigation should be thoroughly explored, but they should be approached strategically and with caution. The available evidence suggests that the major tobacco companies could have developed e-cigarette-like products decades ago, even potentially incorporating the nicotine salts that drove JUUL's recent success. But they chose not to. To protect their bottom lines, they suppressed products that could have demonstrated far less deadly ways of delivering nicotine. Whether this evidence could be used to establish the availability of a reasonable alternative design under products liability law is unclear, but—with the tobacco companies now positioning e-cigarettes as a safer alternative product for cigarette smokers—there may be a more viable case to make than ever before.

Regardless of the decisions made in terms of litigation strategy, it is time to demand that the industry live up to its rhetoric. It cannot credibly claim to be helping current smokers transition to less harmful products so long as it is still aggressively promoting its cigarette brands and fighting against smoking-related regulations. We need a movement to build support for "endgame" policies that will phase out the sale of cigarettes—the deadliest consumer product ever created. Aided by the ever-growing historical record of the industry's misdeeds, litigation may help spur along that process, but it will also require political organizing, community engagement, public

174 Daynard, *supra* note 6, at 1.

175 *See* Berman, *supra* note 3.

176 *See generally* David Michaels, Doubt Is Their Product: How Industry's Assault on Science Threatens Your Health (2008); Naomi Oreskes & Erik M. Conway, Merchants of Doubt: How a Handful of Scientists Obscured the Truth on Issues from Tobacco Smoke to Climate Change (2011).

education, and consensus building. Though it will undoubtedly be difficult, an incremental legislative approach starting at the local level provides the best route to achieving Professor Daynard's goal of doing what was once unthinkable—and, by so doing, save millions of lives.