

# **Tobacco Industry Abuse of the Substantial Equivalence Pathway: The Case of Changing Cigarette Filter Ventilation**

**MICAH L. BERMAN, SARAH REISINGER, DESMOND JENSON, RICHARD O’CONNOR, K. MICHAEL CUMMINGS, IRINA STEPANOV, WARREN K. BICKEL, PETER G. SHIELDS & DOROTHY HATSUKAMI\***

## **ABSTRACT**

A major goal of the 2009 Family Smoking Prevention and Tobacco Control Act (TCA) was to end the tobacco industry’s practice of secretly manipulating product characteristics to increase their attractiveness and addictiveness. Under the law, “grandfathered” cigarette products that were marketed prior to the TCA’s enactment do not require premarket review, but any new or modified product that is not “substantially equivalent” to a grandfathered product requires an extensive assessment by the U.S. Food and Drug Administration (FDA) of a premarket tobacco product application (PMTA) before it can be sold. This Article reports that cigarette companies appear to have used the substantial equivalence (SE) review process in previously unreported ways that avoid the otherwise-required PMTA review: they appear to have modified currently available cigarette brands by using an entirely different product as the predicate product for purposes of the SE review, and to have changed product features gradually in ways that may have significant public health effects. Thus, FDA has authorized products marketed with the same branding and same packaging to be modified substantially—and with limited, if any, notice to the public, researchers, or consumers—under the SE review pathway, contrary to the law’s intent. This Article details one case study of such an SE authorization, provides broader evidence of cigarette product modifications occurring in the marketplace, and calls on FDA to take corrective action.

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\* Micah L. Berman, JD, Associate Professor of Public Health and Law, The Ohio State University; Sarah Reisinger, PhD, Associate Director, The Ohio State University—James Comprehensive Cancer Center; Desmond Jenson, JD, Lead Staff Attorney for Federal Regulation, Commercial Tobacco Control, Public Health Law Center; Richard O’Connor, PhD, Professor, Roswell Park Cancer Center; K. Michael Cummings, PhD, Professor, Medical University of South Carolina; Irina Stepanov, PhD, Mayo Professor, University of Minnesota School of Public Health; Warren K. Bickel, PhD, Professor, Fralin Biomedical Research Institute, Virginia Tech Carilion School of Medicine; Peter G. Shields, MD, Deputy Director, The Ohio State University—James Comprehensive Cancer Center; and Dorothy Hatsukami, PhD, Forster Family Chair in Cancer Prevention, University of Minnesota Masonic Cancer Center. Research reported in this Article was supported by grant numbers K07CA197221 and P01CA217806 from the National Cancer Institute (NCI). The content is solely the responsibility of the authors and does not necessarily represent the official views of the NCI or the National Institutes of Health.

## INTRODUCTION

Before the 2009 Family Smoking Prevention and Tobacco Control Act (TCA), tobacco companies could, and often did, introduce new products or modify existing ones without informing anyone, including consumers or public health officials.<sup>1</sup> One of Congress' goals for the TCA was to end the tobacco industry's practice of undisclosed manipulation of product characteristics in ways that could impact product use and potentially alter addictiveness, appeal, and the physical/chemical profile and toxicity of the smoke.<sup>2</sup>

The TCA requires the U.S. Food and Drug Administration (FDA) to be the gatekeeper to the U.S. tobacco market, with an explicit mandate to protect the public's health.<sup>3</sup> Under Section 910 of the TCA, commercial cigarette products available as of

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<sup>1</sup> For example, industry documents disclosed as part of the 1998 Master Settlement Agreement—an agreement between the major cigarette companies and forty-six states—show that Winston King Size cigarettes were modified more than ninety times between 1954 and 1981. None of these product modifications were shared with the public. *See, e.g.*, D. L. Isbister, R.J. Reynolds Brands R&D; Section E: History of Product Changes (Oct. 13, 1983) (unpublished internal corporate report) (on file with UCSF Library Truth Initiative at <https://www.industrydocuments.ucsf.edu/tobacco/docs/#id=khvm0097>); CTRS. FOR DISEASE CONTROL & PREV., HOW TOBACCO SMOKE CAUSES DISEASE: THE BIOLOGY AND BEHAVIORAL HEALTH BASIS FOR SMOKING-ATTRIBUTABLE DISEASE—A REPORT OF THE SURGEON GENERAL 17 (2010) (“Other changes during the past 50 years have included efforts that potentially have made cigarettes more addicting through the use of flavors, chemical treatments to alter the smell and appearance of cigarette smoke, methods to mask noxious sensory effects, and control of the nicotine dose. These approaches included new types of filters, tobacco blends, and ingredients; cigarette ventilation; control of pH; and efforts to reduce various volatile organic compounds in tobacco and smoke.”) (internal citation omitted). For a brief overview of the Master Settlement Agreement, see Steven A. Schroeder, *Tobacco Control in the Wake of the Master Settlement Agreement*, 350 NEW ENG. J. MED. 293, 293–95 (2004). For the full text of the agreement, see *Master Settlement Agreement*, NAT'L ASS'N ATTORNEYS GEN. (1998) <https://www.naag.org/assets/redesign/files/msa-tobacco/MSA.pdf>.

<sup>2</sup> In describing the need for the TCA, the House Energy and Commerce Committee wrote, “[t]he current lack of government regulation has allowed the tobacco industry to design new products or modify existing ones in ways that increase their appeal to children and that contribute to the risk and incidence of disease.” H.R. REP. NO. 111-58, pt. 1, at 4 (2009). It emphasized that these product modifications “not only make the products more appealing to youth but often result in exposure to additional carcinogens and other toxic constituents.” *Id.* The TCA's drafters sought to put an end to such practices by requiring premarket review for any product changes that made cigarettes more addictive, toxic, or attractive. *See id.* at 4; *see also* Desmond Jenson, Joelle Lester & Micah L. Berman, *FDA's Misplaced Priorities: Premarket Review Under the Family Smoking Prevention and Tobacco Control Act*, 25 TOBACCO CONTROL 246, 246 (2016) (“One aim of the [TCA's premarket review] requirement is to address the tobacco industry's history of manipulating its products to maximise addictiveness and increase attractiveness to consumers, and to prevent more harmful products from ever entering the market.”); CAMPAIGN FOR TOBACCO-FREE KIDS, DESIGNED FOR ADDICTION: HOW THE TOBACCO INDUSTRY HAS MADE CIGARETTES MORE ADDICTIVE, MORE ATTRACTIVE TO KIDS AND EVEN MORE DEADLY (2014) (detailing the methods by which the cigarette companies engineered their products to make them more attractive and addictive, and calling on FDA to take corrective action); Daniel Carpenter, Gregory N. Connolly & Lauren Kass Lempert, *Substantial Equivalence Standards in Tobacco Governance: Statutory Clarity and Regulatory Precedent for the FSPTCA*, 42 J. HEALTH POLITICS POL'Y & L. 607, 608 (2017) (“The [TCA] gives FDA the power to clamp down on the tobacco industry's ability to freely and clandestinely modify or introduce new tobacco products. In the past these changes entailed slight alterations to the product that undermined efforts to reduce demand or change social norms.”).

<sup>3</sup> Carpenter et al., *supra* note 2, at 625 (explaining that under the TCA, FDA decisions about whether to authorize a new tobacco product—through either the PMTA or SE processes discussed *infra*—must be based on “whether the marketing of a new tobacco product would be appropriate for the protection of the public health”). As discussed in this paragraph, there are some “grandfathered” products that are exempted from any form of FDA premarket review, so long as they are not modified, though they are still subject to

February 15, 2007, are allowed to stay on the market (these are referred to as “grandfathered” or “pre-existing” products).<sup>4</sup> Before selling a new product or modifying currently available ones, though, tobacco companies must obtain FDA authorization.<sup>5</sup> Although the TCA requires FDA to conduct a rigorous review before authorizing the sale of a new or modified tobacco product, new or modified products that have the “same characteristics” as a lawfully marketed predicate product or that have different characteristics but “do[] not raise different questions of public health” may be authorized through the SE process.<sup>6</sup> SE authorization is less demanding than new product authorization because it only requires tobacco companies to show that any proposed product changes are minimal enough that they “do[] not raise different questions of public health.”<sup>7</sup> The standard for SE review is lower because it was intended to be a narrow exception that would essentially “maintain[] the tobacco industry’s pre-[TCA] status quo.”<sup>8</sup> By contrast, product modifications, even for grandfathered products, that are significant enough to “raise different questions of public health,” are supposed to go through the more rigorous PMTA premarket review pathway—the same as would be required for a completely new tobacco product.<sup>9</sup>

Though FDA’s gatekeeping role was intended to protect the public from unseen and potentially dangerous product changes, some tobacco companies appear to have developed strategies that have enabled them to avoid the PMTA review requirements.<sup>10</sup> This Article discusses two troubling industry practices that have not been reported on previously, that is, the use of the SE process to modify a product’s characteristics in ways that directly contradict the TCA’s intent. It appears the tobacco companies have submitted SE applications in which the “predicate product,” the grandfathered product to which the modified product is compared, is a different product with its own consumer base and distinct product characteristics from the product being modified. It likewise appears that FDA’s current policy allows for filter

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other FDA regulations, such as product standards that regulate the “construction, components, ingredients, additives, constituents, and properties” of a class of tobacco products. 21 U.S.C. § 387g(4) (2022).

<sup>4</sup> 21 U.S.C. § 387j (2022). FDA recently issued a notice that it will start using the term “pre-existing tobacco product” instead of “grandfathered tobacco product.” *CTP Updates “Grandfathered Tobacco Product” Term to “Pre-Existing Tobacco Product,”* U.S. FOOD & DRUG ADMIN. (Aug. 24, 2022), <https://www.fda.gov/tobacco-products/ctp-newsroom/ctp-updates-grandfathered-tobacco-product-term-pre-existing-tobacco-product>. Since this Article was written before that announcement, it uses the term “grandfathered” product.

<sup>5</sup> *Id.* Though not relevant to the discussion here, one exception to this general rule is that new products introduced between February 15, 2007 and March 22, 2011 were permitted to stay on the market during the time that they had Substantial Equivalence applications under review by FDA. See Jenson et al., *supra* note 2, at 247.

<sup>6</sup> 21 U.S.C. § 387e(j) (2022).

<sup>7</sup> 21 U.S.C. § 387j(a)(3) (2022).

<sup>8</sup> Matt Shechtman, *Smoking Out Big Tobacco: Can the Family Smoking Prevention and Tobacco Control Act Equip the FDA to Regulate Tobacco Without Infringing on the First Amendment?*, 60 EMORY L.J. 705, 730 (2011).

<sup>9</sup> *Id.*

<sup>10</sup> Jenson et al., *supra* note 2. The tobacco industry evaded the more thorough Premarket Tobacco Product Application (PMTA) process through its heavy reliance on the SE process instead. To date, there have been thousands of SE applications for cigarettes, but only two applicants have received PMTA marketing orders for products defined as cigarettes—22<sup>nd</sup> Century Group for a very low nicotine cigarette, and Philip Morris Products for a non-combusted “heat-not-burn” product.

ventilation changes of 11% or less through the SE pathway, which in our view contradicts the TCA's requirements for accessing the SE pathway. Such ventilation changes may have important public health ramifications on their own, and certainly could if multiple changes are "chained" together over time.<sup>11</sup> Based on this evidence, we urge FDA to immediately reconsider how it allows companies to select predicate products for use in SE applications and its policies for reviewing SE applications.

Part I of this Article explains the role of cigarette filter ventilation and why changes in filter ventilation can impact smoking behavior and health effects. Part II presents evidence that filter ventilation levels for numerous popular cigarette brands changed substantially over a period of less than two years, even though no SE authorization letters could be located for many of these changes. Part III recounts the case study of Marlboro Black Label, in which FDA issued an SE authorization for a product that used a different sub-brand as the predicate, which we see as a problematic use of the SE pathway. Part IV examines FDA's policy of allowing cigarette companies to make filter ventilation changes under an 11% threshold through the SE process, though this policy contradicts the TCA's plain language and is poorly justified scientifically. Part V then discusses the policy implications of these actions by the tobacco companies and FDA, and we conclude by calling on FDA or Congress to reconsider the current approach to SE authorizations.

## I. CIGARETTE FILTER VENTILATION

Cigarette filter ventilation refers to the use of various design features that dilute a cigarette's smoke with air, primarily the insertion of small holes into the cigarette filter paper. Because filter ventilation results in lower machine-tested yields of tar and nicotine, it was the main technology behind the tobacco companies' implicit marketing claims that "light" and "low tar" cigarettes were less harmful than "regular" cigarettes—claims that have conclusively been proven false.<sup>12</sup> Though the "light" and "low tar" descriptors have now been prohibited in the United States, most brands retain some level of filter ventilation, because by diluting the smoke it "increases cigarette appeal by making the smoke appear milder, smoother and easier to inhale."<sup>13</sup>

A recent expert report issued by the World Health Organization referred to filter ventilation as an "inherently deceptive technology," noting that "[v]entilation contributes to the harm of cigarette smoking, yet many smokers are unaware of ventilation and its function, even in their own brands."<sup>14</sup> Emerging evidence strongly suggests that ventilation increases the toxicity and harmfulness of cigarettes,<sup>15</sup> but

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<sup>11</sup> See discussion *infra* Part IV.

<sup>12</sup> See Min-Ae Song, Neal L. Benowitz, Micah Berman, Theodore M. Brasky, K. Michael Cummings, Dorothy K. Hatsukami, Catalin Marian, Richard O'Connor, Vaughan W. Rees, Casper Woroszylo & Peter G. Shields, *Cigarette Filter Ventilation and its Relationship to Increasing Rates of Lung Adenocarcinoma*, 109 J. NATL. CANCER INST. 12, June 2017, at 1.

<sup>13</sup> WORLD HEALTH ORG., REPORT OF THE MEETING TO REVIEW THE LATEST SCIENTIFIC EVIDENCE ON THE IMPACT OF CIGARETTE VENTILATION ON CIGARETTE USE 7 (2019), <https://www.who.int/publications/i/item/9789240041684>.

<sup>14</sup> *Id.* at 4.

<sup>15</sup> See Song et al., *supra* note 12 (conducting a causation analysis and concluding that the evidence strongly suggests that increases in filter ventilation have contributed to the rise in lung adenocarcinomas among smokers). This is in part because filter ventilation, by increasing air flow into the cigarette, reduces the burn time per cigarette, lowers the temperature at which a cigarette burns, and results in more incomplete

even if no more dangerous than other cigarettes, higher levels of ventilation produce a “lighter” smoke that misleads consumers into believing their cigarettes are less harmful than other brands when this is untrue.<sup>16</sup> This false perception of reduced harm, combined with the increased palatability of cigarettes with higher levels of ventilation, may facilitate smoking initiation and inhibit cessation, particularly by women and health-conscious smokers.<sup>17</sup> Evidence also suggests that ventilation increases addictiveness by permitting users to achieve their desired dose of nicotine more easily.<sup>18</sup>

## II. EVIDENCE OF CIGARETTE FILTER VENTILATION CHANGES OBSERVED<sup>19</sup>

To support the development of evidence that could inform regulatory action relating to cigarette filter ventilation, the National Cancer Institute funded a series of projects by the Consortium on Models Evaluating Tobacco (COMET), led by researchers at the University of Minnesota and The Ohio State University.<sup>20</sup> An unexpected finding by study staff that ventilation levels in the commercially available cigarettes being used in these studies were changing—potentially compromising the validity of the research conclusions—provided the impetus for this Article.

In October 2018, at the outset of the research project, study staff analyzed the filter ventilation level of eight sub-brands of the Marlboro cigarette brand that had been selected for use in the COMET studies.<sup>21</sup> Samples of these cigarettes were purchased at different locations (in Minnesota, Ohio, and New York), Universal Product Codes (UPCs) were recorded, and filter ventilation and other characteristics were assessed.

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combustion. These effects, in turn, lead to bigger puffs, deeper inhalation, larger particles in the smoke (which carry more toxicants and mutagens), deeper delivery into the lung, and consumption of more cigarettes per day. *Id.* at 4–5.

<sup>16</sup> Dana M. Carroll, Irina Stepanov, Richard O’Connor, Xianghua Luo, K. Michael Cummings, Vaughan W. Rees, Warren K. Bickel, Micah L. Berman, David L. Ashley, Maansi Bansal-Travers, Peter G. Shields & Dorothy K. Hatsukami, *Impact of Cigarette Filter Ventilation on U.S. Smokers’ Perceptions and Biomarkers of Exposure and Potential Harm*, 30 *CANCER EPIDEMIOLOGY BIOMARKERS & PREVENTION* 1, Jan. 2021, at 38; Lynn T. Kozlowski & Richard J. O’Connor, *Cigarette Filter Ventilation Is a Defective Design Because of Misleading Taste, Bigger Puffs, and Blocked Vents*, 11(Suppl. 1) *TOBACCO CONTROL* i40, Mar. 2002, at i47; NAT’L CANCER INST., *MONOGRAPH 13: RISKS ASSOCIATED WITH SMOKING CIGARETTES WITH LOW MACHINE-MEASURED YIELDS OF TAR AND NICOTINE 1* (2001).

<sup>17</sup> WORLD HEALTH ORG., *supra* note 13, at 25–26.

<sup>18</sup> Lynn T. Kozlowski, Marvin E. Goldberg, Berwood A. Yost, Erica L. White, Christine T. Sweeney & Janine L. Pillitteri, *Smokers’ Misperceptions of Light and Ultra-Light Cigarettes May Keep Them Smoking*, 15 *AM. J. PREVENTIVE MED.* 1, July 1998, at 9; Saul Shiffman, Janine L. Pillitteri, Steven L. Burton, Jeffrey M. Rohaya & Joe G. Gitchell, *Smokers’ Beliefs about “Light” and “Ultra Light” Cigarettes*, 10(Suppl. 1) *TOBACCO CONTROL* i17 (2001); Hilary A. Tindle, Nancy A. Rigotti, Roger B. Davis, Elizabeth M. Barbeau, Ichiro Kawachi & Saul Shiffman, *Cessation Among Smokers of “Light” Cigarettes: Results from the 2000 National Health Interview Survey*, 96 *AM. J. PUB. HEALTH* 1498 (2006).

<sup>19</sup> This section briefly summarizes methods and findings that will be presented more thoroughly by the authors in a peer-reviewed publication that is currently under development.

<sup>20</sup> *Consortium on Methods Evaluating Tobacco (COMET): Filter Ventilation and Product Standards*, NAT’L INSTS. OF HEALTH REPORTER, <https://reporter.nih.gov/project-details/9778766> (last visited Mar. 1, 2023).

<sup>21</sup> For purposes of the study design, the goal was to find cigarettes with varying levels of filter ventilation that otherwise had similar chemical and cigarette design characteristics.

Filter ventilation was measured for five to ten cigarettes randomly selected from twelve to eighteen packs of each sub-brand using the Sodim SMI-PDV apparatus.<sup>22</sup>

Beginning in January 2020, cigarettes marketed under the same sub-brand names were purchased at retail outlets again and were reassessed using the same methods. Four of eight study cigarette varieties (all Marlboro Black varieties) had increased in percent ventilation by an absolute number of 9% or more, with one variety registering a differential of 14% from the earlier round of testing (Table 1). Noting these discrepancies, the study staff visually compared Marlboro Black Kings manufactured in September 2018 and May 2020. The filter paper of the products manufactured in September 2018 had no visible ventilation holes; however, one row of ventilation holes was observed on the product manufactured in May 2020 (Figure 1). In addition, an examination of public online comment boards (PissedConsumer.com and Reddit.com) found that consumers had identified significant changes in the taste of Marlboro Black cigarettes in January and February 2019, with some suggesting that perhaps Philip Morris<sup>23</sup> had placed the wrong cigarettes in Marlboro Black packs. For example, one commenter posted on January 2019 that “I just bought two packs of Marlboro Black 100s . . . and it tastes like a light cigarette not a Marlboro Black 100.”<sup>24</sup> Dozens of people responded that they had noticed similar changes, with some mentioning the new filter ventilation holes.<sup>25</sup>

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<sup>22</sup> *Pressure Drop Testing Machine: Sodim SMI-PDV*, DIRECTINDUSTRY (last visited Mar. 1, 2023), <https://www.directindustry.com/prod/hauni/product-116079-2187113.html>.

<sup>23</sup> All references in this paper to “Philip Morris” refer to Philip Morris USA, Inc., which markets Marlboro cigarette brands (among others) in the United States. Philip Morris USA is a subsidiary of Altria Group, Inc. Philip Morris International, which markets Marlboro products outside of the United States, is a distinct company.

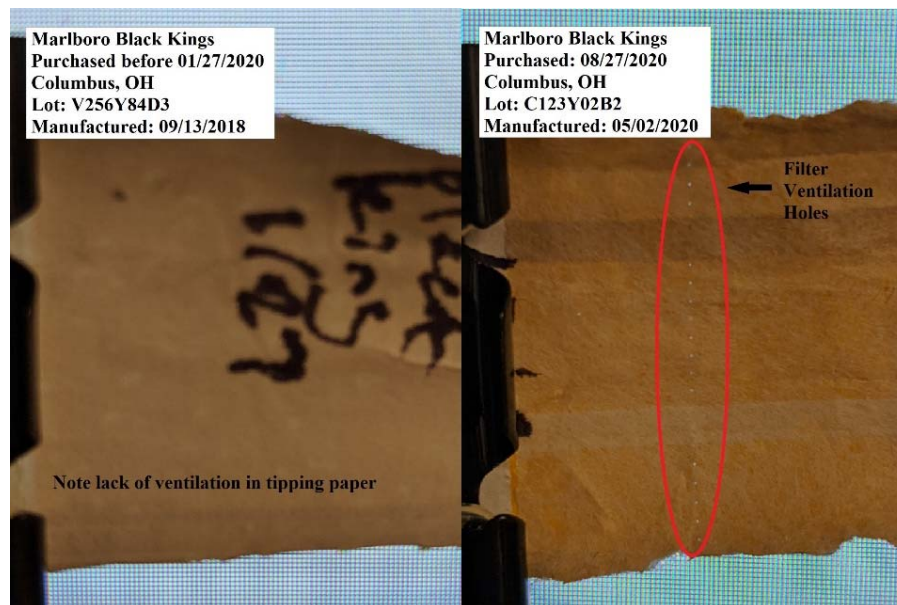
<sup>24</sup> *Did You Change the Design of Marlboro Black 100's*, PISSEDCONSUMER (Jan. 26, 2019), <https://marlboro.pissedconsumer.com/did-you-change-the-design-of-marlboro-black-100-s-201901261457491.html>.

<sup>25</sup> *Id.*

*Table 1. Changes in Filter Ventilation (%) for a Subset of Marlboro Cigarettes (Study Cigarettes)<sup>26</sup>*

Product/Brand	2018 Filter Ventilation Average (%)	2020 Filter Ventilation Average (%)	Difference
Black King Box	4.6	14.4	9.8
Black 100s Box	1.4	12.3	10.9
Menthol Black King Box	3.0	17.0	14.0
Menthol Black 100s Box	2.2	13.7	11.5
Special Blend Gold King Box	30.6	22.8	-7.8
Special Blend Gold 100s Box	36.8	29.5	-7.3
Menthol Gold King Box	37.6	34.0	-3.6
Menthol Gold 100s Box	34.3	30.3	-4.0

*Figure 1: Observed Changes in Marlboro Black Kings*



To ascertain the scope of changes in filter ventilation, study staff retested forty-five cigarette brands and sub-brands with the greatest market share in the United States

<sup>26</sup> Data on file with authors.

(using the same methods noted above, though with fewer packs tested).<sup>27</sup> The filter ventilation of these products had also been measured at the study's outset because they were the usual brands smoked by some study participants.<sup>28</sup> Overall, more than one-third of the forty-five products measured (n=17) increased or decreased in filter ventilation by at least 5% (n=6 and n=11, respectively) (Table 2). The majority of the brands that changed in ventilation percentage were Philip Morris USA Inc. products; however, R.J. Reynolds Tobacco Co. and ITG Brands also had brands that showed meaningful changes in ventilation.

*Table 2. Changes in Filter Ventilation (%) for a Subset of Commercially Available Cigarettes<sup>29</sup>*

Products	Manufacturer	Brand Market Share (%)	Increased $\geq 5\%$ (n)	Decreased $\geq 5\%$ (n)
<b>Marlboro</b> (n=23, including 8 study products)	Philip Morris USA Inc.	40	4	8
<b>Newport</b> (n=3)	R.J. Reynolds Tobacco Co.	14	0	0
<b>Camel</b> (filter only) (n=4)	R.J. Reynolds Tobacco Co.	8	1	0
<b>Pall Mall Box</b> (n=4)	R.J. Reynolds Tobacco Co.	7	0	1
<b>Natural American Spirit</b> (n=3)	Santa Fe Natural Tobacco Co.	2	0	0
<b>Winston</b> (n=6)	ITG Brands	2	1	1
<b>Kool</b> (n=2)	ITG Brands	2	0	1
<b>TOTAL</b> (n=47)			<b>6</b>	<b>11</b>

### III. USING A DIFFERENT PREDICATE PRODUCT

For the reasons outlined in Part I, meaningful changes in the filter ventilation of a cigarette product “raise different questions of public health” such that authorization

<sup>27</sup> *Tobacco Brand Preferences*, CTRS. FOR DISEASE CONTROL & PREVENTION (last updated May 14, 2021), [www.cdc.gov/tobacco/data\\_statistics/fact\\_sheets/tobacco\\_industry/brand\\_preference/index.htm](http://www.cdc.gov/tobacco/data_statistics/fact_sheets/tobacco_industry/brand_preference/index.htm).

<sup>28</sup> Participants were considered eligible for the study if they smoked cigarettes within a certain range of filter ventilation.

<sup>29</sup> Market share is defined as the percentage of total sales in the United States. Market share data was derived from *Tobacco Brand Preferences*, CTRS. FOR DISEASE CONTROL & PREVENTION, *supra* note 27, and JOHN C. MAXWELL, *THE MAXWELL REPORT: YEAR END & FOURTH QUARTER 2017 CIGARETTE INDUSTRY* (2018). Difference or change in ventilation was calculated as absolute change using pre-study and 2020 data. Percentages were rounded to the nearest tenth.



through the SE pathway should be precluded, and FDA should instead conduct the more thorough review required under the PMTA pathway. Yet, as the evidence shown in Part II demonstrates, cigarette companies are continuing to modify the filter ventilation levels of popular cigarette brands (Marlboro in particular). The case study of Marlboro Black Label described in this Part provides one example of FDA issuing an SE authorization letter when a different sub-brand was used as the predicate, potentially allowing for significant changes to ventilation levels (or other product characteristics) and establishing a dangerous precedent that could adversely impact public health.

We examined FDA's database of SE authorization letters to determine whether Philip Morris had obtained a marketing order that would allow the significant changes in ventilation levels observed in Marlboro Black products.<sup>30</sup> We discovered that FDA had issued SE orders for several Marlboro Black products in January 2019. For example, FDA authorized modifications to "Marlboro Black Label Box" via a letter dated January 24, 2019.<sup>31</sup> Notably, the authorization letter notes that the predicate product was *not* the existing version of the Marlboro Black Label brand. Instead, the predicate product was listed as "Marlboro Blend No. 27 Box"—*an entirely different product*.<sup>32</sup> FDA compared the new version of Marlboro Black Label to the predicate Marlboro Blend No. 27 Box product and reported that "the new and corresponding predicate tobacco products have identical ventilation" and thus "do not cause the new tobacco products to raise different questions of public health." However, FDA did not evaluate whether the modified product's ventilation was different from the previous version of Marlboro Black Label because that product was not selected as the predicate product. Similarly, in an SE authorization letter, "Marlboro Menthol Black Special Blend 100's Box" were compared not to the product previously marketed under that brand name, but instead to "Marlboro Menthol 100's Box," to which they were found identical in all respects (including ventilation percentage) except for the tipping paper.<sup>33</sup> While FDA found that there were no ventilation changes, FDA did not

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<sup>30</sup> *Marketing Orders for SE*, U.S. FOOD & DRUG ADMIN. (last updated Feb. 14, 2023), <https://www.fda.gov/tobacco-products/substantial-equivalence/marketing-orders-se>.

<sup>31</sup> *Technical Project Lead (TPL) Review: SE0014912, SE0014913, SE0014914 and SE0014915*, U.S. FOOD & DRUG ADMIN. (2019), <https://www.fda.gov/media/126585/download>.

<sup>32</sup> We suspect that this use of a different predicate may have been a strategy Philip Morris used to change ventilation levels without undergoing PMTA review. However, although we know that the ventilation level of some Marlboro Black sub-brands shifted substantially during this period, we were unable to locate a pre-2019 version of the Marlboro Black Label Box sub-brand to directly measure changes in ventilation levels. A separate hypothesis for why a different sub-brand was used as the predicate is that Marlboro Black Label Box may not have been legally on the market prior to 2019, and thus the currently marketed version could not have been used as the predicate. It appears that Philip Morris introduced the Marlboro Black Label Box sub-brand in 2017. Philip Morris USA, UPC and Price List (Sept. 21, 2017) (on file with UCSF Library Truth Initiative at <https://www.industrydocuments.ucsf.edu/tobacco/docs/#id=yafc0233>) (listing prices effective September 24, 2017, and including a price for Marlboro Black Label Box for the first time). Introduction of a new product in 2017 would have required an SE (or exemption from SE) marketing authorization letter from FDA prior to sale. Troublingly, we were unable to locate such a letter for Marlboro Black Label Box prior to the 2019 letter discussed here. (We caution that FDA's database of SE authorization is not searchable and may not be fully complete.) Thus, it is possible that the 2019 SE authorization letter for Marlboro Black Label Box may have served to authorize the sale of product that had been illegally marketed prior to that point. If so, that is another troubling practice that deserves further scrutiny.

<sup>33</sup> *Technical Project Lead (TPL) Review: SE0014889, SE0014905, and SE0014908* (2019), U.S. FOOD & DRUG ADMIN. (2019), <https://www.fda.gov/media/126577/download>.

evaluate whether or not ventilation was being modified *compared to the product previously marketed under that brand name*.

Thus, it may be that Philip Morris used the SE process to modify its Marlboro Black brands in significant ways without undergoing PMTA review. If this was the case, Philip Morris did so by using *different sub-brands of Marlboro*, instead of the previously marketed products with the same sub-brand name, as the predicate products. Philip Morris argued to FDA that its modified Marlboro Black Label product was effectively identical to Marlboro Blend No. 27. We believe, as discussed further in Part V, that FDA should not have permitted Marlboro Blend No. 27 to be used as the predicate product for the SE review of changes to Marlboro Black Label, since the intent of the Tobacco Control Act was to have any modifications to a product that “raise different questions of public health” reviewed through the more rigorous PMTA process.<sup>34</sup> Allowing the company submitting the SE application to effectively swap in a different product as the predicate undermines the TCA’s structure and gives license to companies to dramatically change the characteristics of products marketed under the same brand or sub-brand with almost no notice to the public and without consideration by FDA of the public health effects of such changes.

Unless they were tracking FDA SE orders incredibly closely, consumers of Marlboro Black Label were uninformed that their cigarette brand has been modified—and they would have had no way of knowing *how* their product had been modified. The reality is that no consumer (or researcher) would be aware that Marlboro Black Label had been effectively converted into an *entirely different product*. If the use of a different product as the predicate resulted in significant changes to ventilation levels, those changes may have altered smoking behaviors and risk perceptions, as discussed in Part I.

Notably, the example of Marlboro Black sub-brands being compared to different sub-brands with different design features does not appear to be an isolated event, as we were able to find several other examples of Philip Morris using different sub-brands as the predicate products on SE applications.

#### IV. FDA GUIDANCE PERMITTING VENTILATION MODIFICATIONS

Using a predicate product marketed under a different brand or sub-brand name, as explained in the previous Part, appears to be one strategy tobacco companies have used to enable the substantial changes in ventilation described in Part II. We could not, however, find SE authorization letters to account for all the changes in ventilation that we observed, despite a thorough review of SE (and SE exemption) authorization letters listed on FDA’s website. This suggests that some tobacco product manufacturers may have modified the filter ventilation levels of their products (and perhaps made other changes) without presenting those product changes to FDA for SE review (or any other form of review) and authorization.<sup>35</sup>

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<sup>34</sup> 21 U.S.C. § 387j (2022).

<sup>35</sup> One possibility through which companies might be (arguably) legally evading FDA review is presented by a federal district court’s 2016 decision in *Philip Morris USA Inc. v. FDA*, 202 F. Supp. 3d 31 (D.D.C. 2016) (2015 WL 9275043). In that decision, which FDA did not appeal, the court ruled that modifying the labeling of product—including the product’s name and branding—does not require SE review by FDA. In the litigation, FDA argued that if labeling changes were excluded from SE review, a company could market a “new tobacco product” that is a grandfathered product with entirely new labeling and

One possible explanation of this phenomenon (other than as indicating potential evasion of the TCA's requirements<sup>36</sup>) may derive from a memorandum issued by the FDA Center for Tobacco Products' (CTP's) Office of Science in 2019. That memorandum, titled "BCP [Behavioral and Clinical Pharmacology Branch] Reviews of SE Reports Involving Changes in the Ventilation of Combusted Filtered Cigarettes," is not a guidance document or regulation, but was written to assist FDA reviewers with the evaluation of SE applications.<sup>37</sup> (SE applications are also referred to as SE reports.) The memorandum briefly summarizes the evidence relating to changes in cigarette filter ventilation, accurately concluding that "the current literature on combusted cigarettes indicates that user behaviors change with the introduction of significant changes to ventilation."<sup>38</sup> It states:

One industry study found that a change in ventilation from 0 to 12% significantly reduced "impact" and irritation of the mouth, nose, and throat (Hiriji [sic] & Hook, 1980), and another industry study found that an 8% increase in ventilation (from 25% to 33% ventilation) resulted in participants rating the more ventilated cigarette as milder and preferred

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branding. In that situation, "FDA would have no means of knowing that the product is intended to be physically identical to a lawful predicate" and "[e]ven if the agency could do so, it would have no reliable means of knowing whether the manufacturer's belief that the characteristics are the same is correct." Defendants' Memorandum of Points and Authorities in Support of their Motion to Dismiss, or in the Alternative, for Summary Judgment, and in Opposition to Plaintiffs' Motion for Summary Judgment at 37, *Philip Morris*, 202 F. Supp. 3d. By the same logic, under the ruling, a tobacco company could conceivably take an existing brand and, without any notice to either FDA or the public, change the *product* marketed under that brand name and labeling to a grandfathered tobacco product previously marketed under a different brand name. (For example, Philip Morris could theoretically take its Marlboro Black Label Box sub-brand and, while keeping the same name on the label, replace the product with what it previously marketed as Marlboro Blend No. 27 Box. It could then characterize such an action as a "change in labeling" of Marlboro Blend No. 27 Box, thereby evading any requirement for FDA review.) In the *Philip Morris* decision, the judge concluded that such *sub rosa* labeling changes could quickly be addressed if this practice became a problem, because FDA could engage in rulemaking under Section 903(b) of the TCA to require preauthorization of "wholesale name and labeling changes." *Philip Morris*, 202 F. Supp. 3d at 54. To date, however, FDA has not engaged in such rulemaking.

<sup>36</sup> Outright evasion of the TCA's requirement would not be unprecedented. *See, e.g.*, Jenson et al., *supra* note 2, at 250–51 (describing FDA inaction in response to the new cigarette products launched without FDA authorization); Nicholas Florko & Elissa Welle, *The FDA Stands By as the Vaping Industry Flouts its Orders*, STAT NEWS (Aug. 24, 2022), <https://www.statnews.com/2022/08/24/the-fda-stands-by-as-the-vaping-industry-flouts-its-orders/> ("[A] STAT investigation found that vape companies are regularly flouting the FDA's orders. They're making, stocking, and selling . . . illicit goods. And the agency is just letting it happen.").

<sup>37</sup> *See* Memorandum from Megan Schroeder, Acting Branch Chief of Behavioral and Clinical Pharmacology in the Office of Science, CTP, to Division of Product Science 1 (July 8, 2019) (on file with FDA at <https://www.fda.gov/media/132023/download>) [hereinafter BCP Reviews of SE Reports Memorandum]. This memo replaced a prior BCP memo which had stated that a *relative* change "of 20% or more from the predicate product to the new product would result in a BCP deficiency." *Id.* at 1. As people who follow FDA tobacco regulation closely, none of the co-authors were aware of either of these memos until recently. That is likely because they were not publicly disclosed until FDA (at an unknown date) "put these documents on [its website] in response to . . . frequent Freedom of Information Act requests." *Reviewer Guides and Scientific Policy Memoranda About FDA Review of Tobacco Product Applications*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/reviewer-guides-and-scientific-policy-memoranda-about-fda-review-tobacco-product-applications> (last updated Oct. 25, 2019).

<sup>38</sup> BCP Reviews of SE Reports Memorandum, *supra* note 37, at 2.

(Philip Morris, 1989). This milder taste can result in a reduction of perceived health risk (Kozlowski & O'Connor, 2002).<sup>39</sup>

Based on this brief (one-paragraph) discussion, the memorandum then concludes that “an absolute change of 12% in ventilation from a predicate product to a new product may cause the new product to raise different questions of health” and will therefore “likely result in a BCP deficiency.”<sup>40</sup> (A BCP deficiency would mean that the applicant would need to provide additional information to FDA to explain why its SE application should not be rejected on this basis.<sup>41</sup>) The flip side of this conclusion appears to be that FDA will presume that changes in ventilation levels from the predicate to the modified product that are *less than 12%* do not “raise different questions of public health” and will not preclude an SE authorization.

This approach, however, does not follow from the evidence presented. The memorandum bases this approach on one industry-funded study conducted more than forty years ago concluding that a 12% change in a cigarette’s ventilation level had significant effects on consumer perceptions. However, it does not follow from that finding that changes of less than 12% do not have similar effects (or other effects relevant to public health). Indeed, the memorandum’s very next sentence referenced another industry study finding that an 8% increase in ventilation has similar effects that could impact consumer behavior.<sup>42</sup> Thus, FDA’s conclusion that ventilation changes of less than 12% do not preclude an SE authorization seems poorly justified.

In 2021 (after the ventilation changes described in Part II were observed), FDA then issued a formal, legally binding regulation “establish[ing] the general procedures FDA intends to follow when evaluating SE reports.”<sup>43</sup> In the preamble to the final rule,<sup>44</sup> FDA listed eighteen examples of changes that are likely (assuming no other problematic product modifications) to satisfy the standard for SE authorization, including “an absolute increase or decrease in ventilation of 11 percent or less between the new and predicate tobacco product.”<sup>45</sup> The regulation included no further

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<sup>39</sup> *Id.*

<sup>40</sup> *Id.*

<sup>41</sup> This extra step of giving the applicant the opportunity to cure the deficiency is arguably not required, but it is reflective of FDA’s pattern of taking “an overly generous approach to clearly deficient [SE] applications.” Jenson et al., *supra* note 2, at 250.

<sup>42</sup> BCP Reviews of SE Reports Memorandum, *supra* note 37 at 2.

<sup>43</sup> Content and Format of Substantial Equivalence Reports; Food and Drug Administration Actions on Substantial Equivalence Reports, 86 Fed. Reg. 55,224 (Oct. 5, 2021) (codified at 21 C.F.R. pts 16, 1107) [hereinafter Substantial Equivalence Rule].

<sup>44</sup> The preamble is technically not part of the regulation itself, but it is a required element of rulemaking that provides a statement by FDA of the regulation’s basis and purpose.

<sup>45</sup> Substantial Equivalence Rule, 86 Fed. Reg. at 55,236. Oddly, the preamble explains that these are examples of changes that are “likely to be appropriate to proceed as same characteristics” under SE review. Section 910 of the TCA states that SE authorization is appropriate if the new or modified product “has the same characteristics as the predicate tobacco product” or if it “has different characteristics that . . . [do] not raise different questions of public health.” 21 U.S.C. § 387j(a)(3)(A)(iii) (2022). One could argue that a minor change is filter ventilation that may not raise “different questions of public health”—and people could reasonably disagree about how minor the change must be to satisfy that requirement—but cigarettes with different levels of filter ventilation do not have the “same characteristics.” FDA’s reliance of the “same characteristics” prong to authorize these product changes may be based on the *Philip Morris* decision, in which the court held that “the ‘same characteristics’ prong may encompass similar, but not necessarily

discussion or explanation of this point, other than a citation to the same 1980 industry study referenced in the BCP memorandum.<sup>46</sup> Thus, the statement is presumably based on the BCP memorandum, though the minor difference between “12% or less” and “11% or less” is not explained.<sup>47</sup>

The 2019 BCP memorandum (the approach of which was later formalized, with a minor change, in the 2021 regulation) provides a possible explanation as to why we observed numerous products changing their ventilation levels by 5% or more without associated SE authorization letters. The 2019 memo suggested that changes in ventilation level of 12% or less are permissible, and we found several examples of changes in product ventilation that were just under that 12% threshold (see Table 1).<sup>48</sup> Importantly, we do not read the 2019 BCP memorandum or the subsequent 2021 regulation to suggest that submission of SE applications is not required when product modifications are under the thresholds indicated by FDA. To the contrary, both the TCA and the 2021 regulation state that an SE application and marketing authorization is required for “[a]ny modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product.”<sup>49</sup> Nonetheless, it is possible that tobacco companies, aware of the 2019 memorandum, concluded that so long as they kept their changes to filter ventilation under the 12% (later 11%) threshold, FDA would not use its limited enforcement resources to penalize the companies for failing to submit SE applications.<sup>50</sup>

## V. DISCUSSION AND POLICY IMPLICATIONS

Whether by using cigarette products marketed under different brands or sub-brands as predicates, or by taking advantage of FDA’s unsupported conclusion that ventilation changes below a 12% or 11% threshold do not “raise different questions of public

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identical, products,” *Philip Morris*, 202 F. Supp. 3d at 54, but we believe it distorts the plain meaning of the statute.

<sup>46</sup> Substantial Equivalence Rule, 86 Fed. Reg. at 55,273 n.7.

<sup>47</sup> The BCP memorandum concluded that changes in ventilation of less than 12% do not raise “different questions of public health” that would preclude SE authorization. The 2021 rule, however, states that products that change their ventilation percentage by less than 11% have the “same characteristics,” which is a separate basis for authorizing SE applications. The shift to relying on a different prong of Section 910 of the TCA is also unexplained.

<sup>48</sup> There is only one product listed in Table 1 (Black King Menthol) that changed in ventilation percentage by more than 12% during the study period. One study investigator (I. Stepanov) recorded a higher ventilation level for that product before the study period started, suggesting that the ventilation level may have changed multiple times.

<sup>49</sup> Substantial Equivalence Rule, 86 Fed. Reg. at 55,276 (emphasis added).

<sup>50</sup> This would not be an unreasonable assumption, given FDA’s inability to conduct SE reviews in a timely manner. See Micah Berman, “*Substantial Equivalence*”: Massive Backlog at the FDA Center for Tobacco Products, YALE J. ON REG. NOTICE & COMMENT BLOG (Sept. 15, 2015), <https://www.yalejreg.com/nc/substantial-equivalence-massive-backlog-at-the-fda-center-for-tobacco-products-by-micah-berman/>. This has led to the agency’s eventual decision to abandon its review of approximately 1,500 SE applications. *FDA Update on Provisional Substantial Equivalence (SE) Review Process*, U.S. FOOD & DRUG ADMIN. (Apr. 5, 2018), <https://www.fda.gov/tobacco-products/ctp-newsroom/fda-update-provisional-substantial-equivalence-se-review-process>. It is also possible that not all SE authorization letters have been posted, that the tobacco companies submitted SE applications that were never acted upon, or that there is some other explanation we have not identified.

health,” some major cigarette companies have been able to continue tweaking the design and formulation of their brands. This has occurred with virtually no transparency to consumers. This violates the spirit of the TCA, which was intended to put an end to such product manipulation and consumer deception, and FDA is, in effect, ratifying this conduct.

#### A. *Changing the Predicate Product*

As a matter of law, is it permissible to use a different brand or sub-brand as the predicate product (as opposed to currently marketed version of the product being modified) when submitting an SE application? Under Section 905(j) of the TCA, the predicate product must be “a tobacco product commercially marketed (other than for test marketing) in the United States as of February 15, 2007, or . . . a tobacco product that the [FDA] has previously determined [to be] substantially equivalent and that complies with the requirements of this Act.”<sup>51</sup> The plain language of the law suggests that perhaps *any* grandfathered product or product previously authorized under the SE pathway can serve as the predicate; when a specific brand is being modified, there is no explicit requirement that the currently marketed version of the same product serve as the predicate, even though this is likely what Congress envisioned.

On the other hand, as Carpenter et al. have argued, the TCA’s requirement that products authorized through the SE process must “not raise different questions of public health” was intended to reference the “public health standard” that appears throughout the TCA.<sup>52</sup> Under the public health standard, which otherwise applies to new or modified products, the manufacturer must show that allowing the product to be sold would be “appropriate for the protection of the public health,” taking into account not just changes to the physical characteristics of the product itself, but also how the new or modified product might influence population-level patterns of use, including initiation and cessation.<sup>53</sup> SE products are exempted from this type of review *only because* FDA is required to ensure that “different questions of public health” are not raised by the product. Authorizing SE products that use a different brand, with substantially different product characteristics, as the predicate is thus arguably inconsistent with this regulatory scheme because changes in ventilation (or other product characteristics) do, as suggested above, “raise different questions of public health.” The language of the statute is unclear about whether such “different questions of public health” must narrowly relate to a comparison with the claimed predicate product; FDA arguably has the authority to construe this phrase more broadly, which would be more consistent with its public health mandate under the TCA.<sup>54</sup> If FDA instead allows different products to be used as the predicate, there would be nothing

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<sup>51</sup> 21 U.S.C. § 387e(j)(a) (2022).

<sup>52</sup> Carpenter et al., *supra* note 2. Our point (and Carpenter et al.’s) is *not* that the “public health standard” governs the SE review process. Rather, it is that the SE pathway was intended to be a narrow exception to the PMTA review requirement and that any decisions involving “different questions of public health” were to be assessed through the PMTA process under the “public health standard.” The SE requirement should be interpreted and applied in line with that intent.

<sup>53</sup> 21 U.S.C. § 387j(c)(4) (2022). The same “public health standard” is repeated with slight variations throughout the TCA.

<sup>54</sup> In the 2021 rule, FDA appeared to reject this interpretation, stating that “[b]oth the same characteristics and different characteristics prongs are specific to the comparison between a new tobacco product and its predicate.” Substantial Equivalence Rule, 86 Fed. Reg. at 55,239.

stopping companies from changing brands from non-menthol to menthol under the SE pathway or using a more toxic predicate product despite the apparent harms to public health.

Whether or not these SE authorizations are legal, permitting the currently marketed version of a product to be substantially changed by using a different brand or sub-brand as the predicate is misleading to the public and could adversely impact public health. Under this approach, a modified product may be marketed with the same branding, the same packaging, and the same UPC code as a previously marketed product despite being a different cigarette. While consumers might expect companies to make slight “tweaks” (as they do with other consumer products), no consumer would reasonably expect that cigarettes carrying the same branding would be converted to a different cigarette overnight. Moreover, consumers are not typically informed of these changes; in the Marlboro Black case, confused and concerned consumers found each other on the internet to confirm that they were not alone, recognizing that their favored product had been altered.<sup>55</sup>

### *B. Ventilation Changes Under FDA’s Threshold*

FDA’s unsupported conclusion that products with ventilation changes of less than 12% or 11% are presumptively “substantially equivalent” under the TCA gives the tobacco companies wide berth to make meaningful modifications to their products with minimal oversight and limited public disclosure.<sup>56</sup> Such product changes are problematic whether authorized by FDA, as permitted by the 2019 memorandum and 2021 regulation, or implemented without FDA review, as appears to have been the case for some products.

One significant concern is that FDA’s thresholds create the opportunity for cigarette companies to make substantial changes to cigarette filter ventilation over the course of a few years. This is because once a product is granted SE authorization, it can be used as the predicate for a future SE application. In this way, product changes (right up to the threshold permitted by FDA) can be “chained” together, allowing for “the introduction of what amounts to a new tobacco product by means of successive and iterative modifications” that evades the TCA’s process for PMTA review.<sup>57</sup> This phenomenon of “chaining” is not merely hypothetical; it is a well-known problem for medical devices.<sup>58</sup> Moreover, cigarette company documents illustrate that chaining together small incremental modifications in a cigarette brand’s design has been a common marketing strategy,<sup>59</sup> something the TCA was intended to halt.

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<sup>55</sup> See *supra* note 24.

<sup>56</sup> It was the COMET investigators’ decision to re-measure filter ventilation levels in the middle of the study, and not just at the outset, that led to the discovery that ventilation levels in commonly used cigarettes were changing with no public notice. It is unclear the degree to which such changes have occurred over the lifespan of the Tobacco Control Act, which was supposed to put an end to such product manipulation.

<sup>57</sup> Carpenter et al., *supra* note 2, at 615.

<sup>58</sup> Omar Robles, *Mapping the Predicate Chain for Medical Device Approval*, LAW360 (Apr. 20, 2021), <https://www.law360.com/articles/1377073/mapping-the-predicate-chain-for-medical-device-approval>.

<sup>59</sup> See, e.g., D. L. Isbister, *supra* note 1 (recording the numerous incremental changes made to Winston KS and Winston Lights KS products); Geoffrey Ferris Wayne & Gregory N. Connolly, *How Cigarette Design Can Affect Youth Initiation into Smoking: Camel Cigarettes 1983–93*, 11 TOBACCO

Even without such “chaining,” FDA’s conclusion that products with absolute differences in filter ventilation of 11% or less have the “same characteristics”<sup>60</sup> is deeply puzzling. As noted, FDA’s analysis relied on one industry study from 1980 that reached no such conclusion, and, as far as we are aware, FDA came to its policy decision without any consultation with the many researchers with expertise in cigarette filter ventilation.

### C. *Substantial Equivalence and Public Health*

The “substantial equivalence” language in the TCA was borrowed, with modifications, from the regulatory framework applicable to medical devices. SE review in that context has been controversial, with “the public, legislators, the Government Accountability Office, the Department of Health and Human Services Office of the Inspector General, and the courts, including the Supreme Court . . . all question[ing] the logic and value of the [substantial equivalence] process” after some high-profile failures to protect the public from dangerous medical devices.<sup>61</sup> Soon after the enactment of the TCA, FDA invited the Institute of Medicine (IOM; now the National Academies of Medicine) to review the SE process for medical devices. The IOM recommended that Congress eliminate the SE review process for medical devices and replace it with a process that “provides a reasonable assurance of safety and effectiveness throughout the device life cycle,” something the SE process is not designed to do.<sup>62</sup> The IOM committee took the position that authorizing new products based solely on “substantial equivalence” is incompatible with a review process that prioritizes “safety and effectiveness.”<sup>63</sup>

Similarly, the SE process in the tobacco context does not prioritize the protection of public health. It was designed, in a compromise with the tobacco industry, to be a minor exception to the general principle that FDA’s tobacco regulatory decisions are based on what is “appropriate for the protection of the public health” (the so-called “public health standard”). But FDA’s loose application and enforcement of the SE requirements, as described in this Article, allows product modifications to be introduced without undergoing the PMTA review process governed by the public health standard, subverting the TCA’s design and potentially threatening the public’s health.

In addition, the e-cigarette industry has repeatedly pointed to the unfairness inherent in the fact the SE review process can be used for cigarettes—the most harmful form of tobacco use—but is unavailable for less harmful products like e-cigarettes. This is because the SE pathway is only available for products that were commercially marketed as of February 15, 2007, which excludes nearly all e-cigarettes. E-cigarette manufacturers have unsuccessfully sued FDA and lobbied Congress in attempts to gain access to the SE pathway by moving the grandfathering date to a later point.<sup>64</sup> We

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CONTROL i32 (2002) (reviewing industry documents and detailing how R.J. Reynolds used gradual product changes to make its products more appealing to youth).

<sup>60</sup> See *supra* note 45.

<sup>61</sup> INST. OF MED., MEDICAL DEVICES AND THE PUBLIC’S HEALTH: THE FDA 501(K) CLEARANCE PROCESS AT 35 YEARS xi (2011).

<sup>62</sup> *Id.* at 196.

<sup>63</sup> *Id.* at 5.

<sup>64</sup> See, e.g., *Nicopure Labs, LLC v. FDA*, 266 F. Supp. 3d 360, 398 (D.D.C. 2017), *aff’d*, 944 F.3d 267 (D.C. Cir. 2019) (rejecting argument that FDA should have modified the grandfathering date because



do not support changing the grandfathering date, which would push FDA further away from a focus on public health, but the critique that it is unfair to apply one set of (looser) rules to more harmful combustible products, and another set of (more stringent) rules to e-cigarettes has some merit.

## CONCLUSION

In this paper, we describe how Philip Morris and other companies may have modified the filter ventilation levels of their cigarettes with (and perhaps without) authorization from FDA. Beyond the impact on research, these product modifications may allow tobacco companies to continue their decades-long history of modifying tobacco products to promote initiation, deter quitting, and maximize addictiveness—the exact conduct the TCA’s premarket review requirements were intended to stop.

We call on FDA to:

- Consider new guidance or rulemaking to require that when an SE application is submitted for a currently marketed brand (or sub-brand), the predicate product must be the currently marketed version of that same brand (or sub-brand).<sup>65</sup>
- Issue new regulations or guidance to end its policy of permitting changes of a cigarette product’s ventilation—including changes of 11% or less—through the SE process.
- Allow for outside participation in the SE review process to the extent permissible by law. As public health groups explained to FDA in 2013, “by treating the process of considering substantial equivalence applications as a closed process, FDA is depriving itself of the advice of those with real expertise on relevant scientific issues,” while tobacco companies are afforded extensive opportunities for dialogue and input.<sup>66</sup> At minimum, FDA could engage the Tobacco Products Scientific Advisory Committee to provide expert comments on SE applications.
- Make information about SE applications and decisions (including denials) transparent to the full extent permissible by law and more easily accessible and searchable. The current website reporting on SE decisions is not searchable, making it difficult to determine if a

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“it was Congress that set the grandfather date in the TCA, and [plaintiff] has not pointed the Court to any authority for the proposition that the agency can ignore a statutory command”); *The Grandfather Date—What Are the Alternatives*, KELLER & HECKMAN (Oct. 26, 2015), <https://www.khlaw.com/insights/grandfather-date-what-are-fdas-alternatives> (discussing efforts to get Congress to change the grandfathering date).

<sup>65</sup> In addition, FDA should require companies granted SE applications to provide post-marketing surveillance data to ensure that the approved products are not contributing additional harm to public health. Such data could include information on product sales, consumer profiles, and consumer product perceptions.

<sup>66</sup> *Comments in Response to Submissions of Other Parties on Demonstrating Substantial Equivalence for Tobacco Products*, Docket Nos. FDA–2010–D–0635, FDA-2011-D-0147 and FDA- 2010-N-0646, CAMPAIGN FOR TOBACCO FREE KIDS (Jan. 28, 2013), [https://www.tobaccofreekids.org/assets/content/what\\_we\\_do/federal\\_issues/fda/regulatory/2013-01-28%20FINAL%20SE%20Comments.pdf](https://www.tobaccofreekids.org/assets/content/what_we_do/federal_issues/fda/regulatory/2013-01-28%20FINAL%20SE%20Comments.pdf).

particular product has been the subject of an SE application or decision.

- Investigate whether the apparent changes in ventilation reported in this Article were FDA-authorized and take appropriate corrective action if not.
- Engage in rulemaking under Section 903(b) to require product name and labeling changes to undergo prior authorization.<sup>67</sup>
- Enhance monitoring for unauthorized product changes and new products introduced without FDA review, to ensure that the premarket review process is not evaded.

In addition to these changes, Congress may wish to review whether the SE provisions of the TCA need to be amended. At minimum, Congress should clarify that when an SE application has been submitted for a currently marketed brand or sub-brand, an entirely different product cannot be used as the predicate, and that FDA should not authorize significant changes in filter ventilation or other product characteristics through the SE process. In addition, Congress should assess whether the SE process should be eliminated to ensure a thorough FDA review of new and modified products centered on protecting public health.

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<sup>67</sup> See *supra* note 35.