

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

RIGHT TO BE SMOKE-FREE COALITION,)
et al.)
)
 Plaintiffs,)
v.)
)
FOOD AND DRUG ADMINISTRATION,)
et al.)
)
 Defendants.)
_____)

Civ. No. 1:16-cv-0878-ABJ

**MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF
PLAINTIFF TRADE ASSOCIATIONS’ MOTION FOR
SUMMARY JUDGMENT**

Eric P. Gotting (Bar No. 456406)
Azim Chowdhury (Bar No. 986331)
KELLER AND HECKMAN LLP
1001 G Street, N.W., Suite 500 West
Washington, D.C. 20001
Telephone (202) 434-4100
Facsimile (202) 434-4646
gotting@khlaw.com
chowdhury@khlaw.com

*Counsel for Plaintiffs
Right To Be Smoke-Free Coalition, et al.*

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Pub. L. No. 111-31, § 3(1), 123 Stat. 1776, 1781 (2009)..... 8

Pub. L. No. 111-31, § 3(4), 123 Stat. 1776, 1782 (2009)..... 16, 39

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Pub. L. No. 111-31, § 3(8), 123 Stat. 1776, 1782 (2009)..... 39

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S. Rep. No. 96-878, 1980 U.S.C.C.A.N. 2788 (1980)..... 32

Family Smoking Prevention and Tobacco Control Act, S. 2461, 108th Cong. (2004) 19

Family Smoking Prevention and Tobacco Control Act, H.R. 1108, 110th Cong. (2007)..... 19

HeLP America Act, H.R. 5951, 109th Cong. (2006)..... 19

National Tobacco Policy and Youth Smoking Reduction Act, S. 1415, 105th Cong. (1998)..... 19

Youth Smoking Prevention and Public Health Protection Act, S. 2626, 107th Cong. (2002) 19

SBA, *The RFA in a Nutshell: A Condensed Guide to the RFA* (Oct. 2010)..... 31

Zeller, *Reflections on the ‘Endgame’ for Tobacco Control*, *Tob. Control* 22:i40-i41 (2013)..... 17

ADDITIONAL SOURCES

FDA and NIH Study: *Population Assessment of Tobacco and Health*,
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FDA, *Tobacco Product Marketing Orders*,
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Premarket Tobacco Application (PMTA) Technical Project Lead (TPL) Review (2015),
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FDA, SE Reports,
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FDA, Snus PMTA Review,
www.fda.gov/TobaccoProducts/Labeling/TobaccoProductReviewEvaluation/ucm472108.htm
 24

FDA, PATH Study Overview, <https://pathstudyinfo.nih.gov/UI/StudyOverviewMobile.aspx>
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Plaintiff trade associations, pursuant to Fed. R. Civ. P. 56, submit this memorandum in support of their motion for summary judgment. The United States Food and Drug Administration (“FDA” or the “agency”) recently promulgated a final rule that comprehensively regulates vaping products, including e-liquids and vaping devices, for the first time at the federal level. The rule was adopted pursuant to the Food, Drug and Cosmetic Act (“FDCA”), as amended by the Family Smoking Prevention and Tobacco Control Act (“TCA”). *See* 81 Fed. Reg. 28,973 (May 10, 2016) (the “Deeming Rule”). The Plaintiffs, consisting of national and state-wide trade associations representing the entire vaping industry (*i.e.*, manufacturers, distributors, and retailers), bring this challenge to have portions of the Deeming Rule or TCA declared unlawful and vacated on administrative and/or constitutional grounds.¹

SUMMARY OF ARGUMENT

Plaintiffs are fully committed to the safety of vaping products, from manufacturing through distribution and sale, and recognize the need for reasonable regulation at the federal level. As such, Plaintiffs are not challenging many of the Deeming Rule’s provisions, including those aimed at guarding against youth access, preventing adulterated products, or providing FDA with extensive health and safety information regarding their products. The Deeming Rule in several places, however, sets forth requirements that reach beyond any reasonable level of regulatory oversight and imposes unlawful obligations on vaping product manufacturers.

¹ Pursuant to this Court’s Order dated June 28, 2016 (Dkt. No. 19), this supporting memorandum focuses on claims unique to Plaintiffs’ Complaint (Dkt. No. 1, Case No. 1:16-cv-01210; Counts One, Three, and Seven), filed on June 20, 2016, and does not specifically address causes of action that overlap with claims brought by Plaintiff Nicopure in its separate Complaint (Dkt. No. 1), filed on May 10, 2016. Accordingly, and per agreement among the parties, Plaintiffs adopt and incorporate by reference in support of their remaining claims the arguments set forth by Plaintiff Nicopure in its supporting memorandum (Dkt. No. 20), filed on July 8, 2016.

While the TCA provides FDA with broad regulatory authority over tobacco products, such authority is not unfettered. Indeed, the agency's authority is circumscribed by the statute's underlying purposes which strike a careful balance between various policy issues. Specifically, the statute provides that adults must have continued access to tobacco products (*i.e.*, FDA cannot ban or virtually eliminate such products from the marketplace), while at the same time it prohibits access to such products by underage consumers. Along similar lines, the TCA requires FDA to regulate in a flexible manner so that relatively safer products can be developed and commercialized while more dangerous ones are kept off the market. Any effort by FDA to deem additional tobacco products under the TCA must reflect these compromises.

During the rulemaking, FDA repeatedly acknowledged that using vaping products likely presents far less risk than smoking cigarettes and that individuals switching from combusted tobacco products to vaping products may significantly reduce their harm. The agency also recognized that the availability of vaping products could potentially lead to increased smoking cessation rates in this country and ultimately reduce tobacco-related disease and death. These conclusions are consistent with scientific research, both in the United States and abroad, finding that vaping products are substantially less risky than combustible tobacco products.

Nevertheless, FDA chose to regulate vaping products in a manner that is even *more* stringent than its regulation of cigarettes. Resulting in what will be a virtual ban on many (if not all) vaping product categories is FDA's decision to force vaping product manufacturers into a Pre-Market Tobacco Application ("PMTA") process that was actually designed to prevent the introduction of relatively more harmful tobacco products on the market. For each vaping product, a manufacturer will have to file a PMTA before August 2018 that will require, *inter alia*, long-term clinical studies which, as FDA concedes, do not yet exist. These longitudinal

studies must focus on population-level effects, such as the impact of each e-liquid or vaping device on overall smoking initiation or cessation rates. Vaping product manufacturers will not have sufficient time over the next two years to conduct such long-term clinical studies or have the financial resources to meet other PMTA informational requirements that, according to the agency, will likely reach into the millions of dollars for each product application.

As a consequence, the agency effectively writes out of the statute another form of pre-market authorization, called the Substantial Equivalence (“SE”) pathway, that Congress intended for FDA to use in a more flexible exercise of enforcement authority so that relatively less risky products, like vaping products, remain on the market and are available to adult consumers. The SE pathway, while also imposing substantial informational requirements on manufacturers, does not necessarily require long-term clinical studies and, as such, is not as burdensome in terms of time and financial resources as PMTAs. Thus, instead of tailoring the pre-market process based on the type of tobacco product involved, the agency unlawfully adopted a “one-size-fits-all” pre-market regime that ignores vaping products’ overall lower risk profile.

As discussed below, the Deeming Rule’s short-comings are several fold. First, FDA has applied a statutory February 15, 2007 grandfather date to vaping products that was intended for traditional tobacco products, like cigarettes. FDA was required under the statute to set a new grandfather date which would have allowed vaping products to take advantage of the more flexible SE pathway. Second, FDA did not consider, as required under the Regulatory Flexibility Act (“RFA”), 5 U.S.C. §§ 601, *et seq.*, any significant alternatives that, in the absence of a new grandfather date, would have allowed vaping product manufacturers sufficient time to develop the extensive information, including long-term clinical studies, necessary to successfully navigate the more stringent PMTA process. As it stands now, such data cannot be generated by

the PMTA deadline of August 2018. Third, even if FDA is correct in that it must apply the February 15, 2007 grandfather date to vaping products, this means that the TCA itself violates substantive due process and is unconstitutional. Under this scenario, there would be no rational relationship between the TCA's underlying purposes and the means chosen by Congress to accomplish such goals. Indeed, as FDA conceded during the rulemaking, virtually all manufacturers will exit the vaping market, thus depriving adults of a relatively safer tobacco product and a chance to reduce or, better yet, quit their smoking habits.

FACTUAL BACKGROUND

The following provides a brief summary of the vaping industry and types of products relevant to Plaintiffs' claims.

A. Vaping Products

Vaping products (often referred to by the general public as "electronic cigarettes" or "e-cigarettes") are a relatively new invention.² It is important to note that these are not traditional tobacco products, such as cigarettes, as they do not contain tobacco and there is no combustion or smoke. AR150,351. Rather, the aerosol (vapor) produced by a vaping device is created when a battery activates a heating coil that vaporizes a flavored e-liquid solution. AR155,130.

There are several categories of vaping products. Some devices are designed to look like a traditional cigarette – often called "cigalikes" – with a small, built-in cartridge containing pre-filled e-liquid. AR155,131. In industry parlance, these are referred to as "closed systems." AR045,114. Closed systems are also called "first generation" devices, as they were the first type of vaping product to appear on the commercial market. AR114,240; AR155,131.

² FDA refers to these products as Electronic Nicotine Delivery Systems (or "ENDS"). However, to be consistent with phrasing employed by Nicopure in its supporting memorandum, Plaintiffs use the terms "vaping products," "vaping devices," and "e-liquids."

More recently, devices have been developed and commercialized that differ in size and shape, being somewhat larger than cigalikes, which also contain an e-liquid tank that can be refilled by consumers with an e-liquid of their choice. AR155,131. These are called “open systems.” AR127,072. The devices and e-liquids are typically purchased separately. AR031,440. Open systems are often referred to as “second” or “third” generation products, as they provide more advanced features (*e.g.*, more powerful batteries) and represent the fastest growing segment of the vaping industry. AR160,838; AR155,131.

E-liquids, whether used in closed or open systems, are manufactured using three or four primary ingredients – vegetable glycerin and/or propylene glycol, flavorings, and liquid nicotine. AR155,131. Nicotine is used in most, but not all, e-liquids. AR148,942. The nicotine, in turn, may be derived from tobacco or non-tobacco sources (*e.g.*, eggplant), or produced synthetically in a lab. AR043,508; AR150,353-354.

Each vaping product category (*i.e.*, closed systems, open system devices, and open system e-liquids) allows consumers to mimic the act of smoking (called “vaping”) by inhaling through a mouthpiece the aerosol from the vaporized e-liquid, but without exposure to harmful smoke or tar. AR155,130-131.

B. Vaping Products and Continuum of Risk

A large and growing body of scientific evidence demonstrates that vaping products are far less risky than traditional tobacco-containing products, particularly cigarettes. This is due to the fact that the e-liquid used in vaping devices does not contain tobacco *per se* nor is it intended to be combusted or burned in the vaping device. It is well established that tobacco-combusting products are the most harmful and dangerous type of tobacco product because they result in the inhalation of pyrolyzed tobacco constituents, many of which are known human carcinogens and

toxicants. AR155,128-130. Research suggests, however, that because vaping products (and in particular, e-liquids) do not contain tobacco, the use of non-combustible vaping products is far safer than combustible tobacco and is expected to result in a vast reduction in tobacco-related disease and death over the coming years, especially for those consumers who are already addicted to cigarettes – provided, however, that these innovative products are allowed to remain on the market to compete with cigarettes, *see* AR155,128-143, an outcome that, as we will see below, Congress explicitly envisioned under the TCA.³

An increasing number of scientific and public health experts from the United States and around the world agree that vaping is significantly less harmful than smoking cigarettes and a valuable tool for tobacco harm reduction efforts. In 2014, over 50 tobacco, nicotine, and public health specialists from around the world signed a letter to the World Health Organization (“WHO”) emphasizing the importance of tobacco harm reduction through the use of “low risk non-combustible tobacco products (which includes e-cigarettes).” AR147,235-241. According to the signatories, the available scientific evidence – much of which is summarized in the

³ For example, in 2014 a team of researchers from the Center for the Study of Tobacco Products at Virginia Commonwealth University reviewed the available scientific literature on the pharmacodynamics, pharmacokinetics and health impacts of vaping products among smokers and non-smokers. AR114,838-847. The researchers determined that while the aerosol produced from vaping devices may contain some of the toxicants present in tobacco smoke, the levels are significantly lower and that compared with combustible tobacco cigarettes, vaping products are likely to be much less, if at all, harmful to users or bystanders. The study authors concluded that if vaping products were allowed to compete with cigarettes in the open market smoking-related morbidity and mortality would likely decrease. Similarly, researchers from the Center for Prevention and Treatment of Tobacco Smoking and the University of Catania, conducted a systematic review of existing laboratory and clinical research on the potential risks from vaping compared with the well-established effects of cigarette smoking. AR119,698-714. The researchers concluded that currently available evidence indicates that vaping is by far a less harmful alternative to smoking, and significant health benefits are expected in smokers who switch from tobacco to vaping products.

Administrative Record – indicates that vaping products “could be among the most significant health innovations of the 21st Century – perhaps saving hundreds of millions of lives.”

Recently, Public Health England (“PHE”), a department of the British Government, calculated the level of harm caused by different nicotine delivery systems, from cigarettes to cigars, pipes, nicotine patches and e-cigarettes, and took into account a wide range of risks (*e.g.*, addiction, lung damage) and ultimately found that vaping products are 95% less harmful than traditional cigarettes. AR022,841-953.

Beyond the potential health effects on individual consumers, there is also mounting scientific evidence that, on the *population* level, the availability of vaping products is not decreasing smoking cessation or increasing smoking initiation rates. This is because vaping products are primarily used by adult smokers as a smoke-free alternative to reduce or quit smoking and to avoid the significant health hazards associated with cigarettes. For example, PHE found that almost all of the 2.6 million adult vapers in England are current or ex-smokers, most of whom are using the devices to help them quit smoking or to prevent them going back to cigarettes. The report indicates that very few adults and young people who have never smoked are becoming regular vapers (less than 1% in each group). AR183,506-508.

In fact, FDA conceded during the rulemaking that vaping products likely present a lower risk profile than traditional tobacco products. *See, e.g.*, 81 Fed. Reg. at 29,030 (“FDA recognizes that completely switching from combusted cigarettes to [vaping products] may reduce the risk of tobacco-related disease for individuals currently using combusted tobacco products, given the products’ comparative placements on the continuum of nicotine-delivering products”); *id.* at 29,032 (FDA “agrees that the exhaled aerosol from [vaping product] users is potentially less hazardous than secondhand smoke from combusted cigarettes”); *id.* at 29,035 (“FDA agrees

that use of [vaping products] is likely less hazardous for an individual user than continued smoking of traditional cigarettes”); *id.* at 29,039 (FDA conceding that “[vaping products] may potentially provide cessation benefits”); *id.* at 28,971 (FDA “believes that the inhalation of nicotine (*i.e.*, nicotine without the products of combustion) is less of a risk to the user than the inhalation of nicotine delivered by smoke from combusted tobacco products”).

REGULATORY BACKGROUND

The following summarizes key provisions from the TCA and the Deeming Rule that are relevant to the claims addressed in this supporting memorandum.

A. The Tobacco Control Act

The TCA was adopted by Congress on June 22, 2009 and provides FDA with authority to regulate the “manufacture, marketing, and distribution of tobacco products.” Pub. L. No. 111-31, § 3(1), 123 Stat. 1776, 1781 (2009). FDA was initially charged under the TCA with regulating traditional tobacco products – *i.e.*, “all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco.” However, the agency was also given authority to regulate in the future “any other tobacco products that [FDA] by regulation deems to be subject to this chapter.” 21 U.S.C. § 387a(b). Under the Deeming Rule, FDA subjects all other tobacco products, including closed systems, open system devices and e-liquids, to the TCA’s requirements. 81 Fed. Reg. at 28,974-75.⁴

For purposes of Plaintiffs’ claims, the relevant provisions are those that require pre-market authorization from FDA for any “new tobacco product” – *i.e.*, a tobacco product that was first marketed or modified after the grandfather date. The TCA establishes a grandfather date of

⁴ For purposes of the TCA, the term “tobacco product” is defined to mean, in part, “any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product.” 21 U.S.C. § 321(rr).

February 15, 2007. 21 U.S.C. § 387j. As such, any product that was commercialized before the grandfather date may remain on the market without seeking pre-market approval. *Id.* However, manufacturers of “new tobacco products” must use one of three “pathways” to secure FDA authorization before introducing the product into interstate commerce.

1. **Pre-Market Tobacco Application (“PMTA”) Pathway** – This is the most extensive pre-market review process. It requires manufacturers to submit, *inter alia*, substantial amounts of information for each new tobacco product showing that marketing the product is “appropriate for the protection of public health.” This “population effects” standard requires FDA to take into account the product’s impact on the population as a whole, including the likelihood that people will stop using tobacco products (*i.e.*, cessation), as well as start using them (*i.e.*, initiation). 21 U.S.C. § 387j(c).
2. **Substantial Equivalence (“SE”) Pathway** – This is a more abbreviated form of pre-market review when compared to the PMTA. Under this pathway, a manufacturer must show that the new tobacco product is “substantially equivalent” to a tobacco product that was commercially marketed in the United States as of the grandfather date (*i.e.*, “predicate product”). 21 U.S.C. § 387e(j). The term “substantially equivalent” means that the tobacco product either has the same “characteristics” (*e.g.*, materials, ingredients, design, composition, heating source, or other features) as the predicate product or has different characteristics but does not raise different questions of public health. 21 U.S.C. § 387j(a).
3. **SE Exemption Pathway** – FDA may exempt from SE requirements certain minor changes to existing tobacco products (*e.g.*, additive levels). 21 U.S.C. § 387e(j).

With regard to the PMTA “population effects” standard, a PMTA submission must contain extensive data regarding the new tobacco product, including all information from investigations on the health risks of such product and data regarding whether the product presents less risk than other tobacco products. 21 U.S.C. § 387j(b). In particular, these investigations “may include . . . clinical” (*i.e.*, human) studies and other “valid scientific evidence” that FDA considers “sufficient to evaluate” the product. 21 U.S.C. § 387j(c).

B. The Deeming Rule

The Deeming Rule subjects all products that meet the definition of “tobacco product” (except “accessories” of deemed products) to virtually all of the TCA’s provisions that were initially applied to cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. These include the pre-market review provisions. 81 Fed. Reg. at 28,976. The Deeming Rule applies to any manufacturers of vaping products, including brick-and-mortar vape shops that mix or prepare e-liquids or modify vaping devices. 81 Fed. Reg. at 29,044.⁵

With regard to the pre-market provisions, FDA did not require all “new tobacco products” (*i.e.*, deemed products introduced into the market after the grandfather date) to immediately file PMTAs or SE Reports. Rather, the agency established pre-market compliance periods where manufacturers of such products will have staggered time-periods to file applications under one of the three marketing pathways noted above. Significantly, for PMTAs, manufacturers will only have two (2) years from the Deeming Rule’s effective date to submit an application. As for SE Reports and SE Exemption requests, manufacturers will have eighteen (18) months and twelve (12) months, respectively, from the effective date to make a filing.

Following each initial compliance period, manufacturers who have made timely submissions will then have an additional twelve (12) months to continue marketing their products; however, if at the end of this continued compliance period FDA has either denied an application or failed to issue a decision, such manufacturers will be subject to enforcement actions for failure to obtain pre-market authorization. 81 Fed. Reg. at 28,978.

It must be noted, however, that the compliance periods only apply to non-grandfathered deemed products that were on the market on the Deeming Rule’s effective date. Manufacturers

⁵ The Deeming Rule becomes effective 90 days from the date of publication. The rule was published on May 10, 2016, thus the effective date is August 8, 2016.

of “new” deemed tobacco products (including modifications to existing products) intended to be introduced into interstate commerce after the effective date must *first* obtain FDA marketing authorization through one of the three pre-market pathways (*i.e.*, PMTA, SE Report, or SE Exemption request), effectively freezing the market for deemed products on August 8, 2016. *See* 81 Fed. Reg. at 29,011 n.13.

STANDARD OF REVIEW

Summary judgment must be granted when the evidence establishes that “there is no genuine dispute as to any material fact and the movant is entitled to a judgment as a matter of law.” Fed. R. Civ. P. 56(a); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986).

Under the Administrative Procedure Act (“APA”), a court must hold unlawful and set aside agency action found to be “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law . . . [or] in excess of statutory jurisdiction, authority, or limitations, or short of statutory right.” 5 U.S.C. § 706. As to the arbitrary and capricious standard, the Court asks whether the agency has:

relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation of its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.

Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983). The agency must also “articulate a satisfactory explanation for its action, including a rational connection between the facts found and the choices made.” *Id.*

ARGUMENT

I. The TCA Required FDA to Establish an Alternative Grandfather Date for Vaping Products to Avoid Banning or Virtually Eliminating the Vaping Market

During the rulemaking, vaping product manufacturers asked FDA to establish an alternative grandfather date for vaping products or otherwise exercise its enforcement discretion by not applying the February 15, 2007 date. *See, e.g.*, AR155,176; AR161,098-99.

Manufacturers were concerned that enforcing the 2007 grandfather date would effectively ban or nearly eliminate entire vaping product categories. *Id.*; *see also* AR130,174 (“E-cigarettes would not be grandfathered for marketing, unlike traditional combustion products that were marketed before February 2007. They likely would not have a viable pathway for marketing approval”). The agency rejected those requests, however, arguing that it “lacks authority to change the grandfather date, which is set by statute.” 81 Fed. Reg. at 28,993.

As discussed below, FDA misread the grandfather date, interpreting it in isolation, and failed to consider it in light of the TCA’s overall statutory design. When properly construed, it is clear that Congress did not intend for the February 15, 2007 grandfather date to be strictly applied to all deemed tobacco products, particularly where it would ban or virtually eliminate entire categories of safer products from the marketplace. In fact, FDA’s own regulatory impact analysis demonstrates that vaping products will either be banned or nearly eliminated from commercialization under the Deeming Rule. Where FDA claimed otherwise, the agency failed to provide any supporting data or explanation. Accordingly, FDA violated the APA and acted contrary to law when it refused to set an alternative grandfather date for vaping products.

A. FDA Failed to Interpret the Grandfather Date Within the Context of the TCA’s Underlying Purposes and Goals

The Supreme Court has held on numerous occasions that a statutory provision which appears to take on one meaning when read in isolation will take on an entirely different meaning when considered in light of the overall regulatory regime. *Food and Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 125 (2000) (FDA “may not exercise its authority ‘in a manner that is inconsistent with the administrative structure that Congress enacted into law’”) (citation omitted); *see also Ass’n of Am. Physicians and Surgeons, Inc. v. U.S. Food and Drug Admin.*, 226 F. Supp. 2d 204, 221-22 (D.D.C. 2002) (*quoting Brown & Williamson*).

Indeed, a “fundamental canon of statutory construction [is] that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme.” *Utility Air Regulatory Group v. Env’tl. Protection Agency*, 134 S.Ct. 2427, 2441 (2014) (citation omitted); *see also Am. Physicians*, 226 F. Supp. 2d at 211 (the “court should not analyze the FDCA’s provisions in isolation, divorced from their broader context”) (citations omitted); *New York State Bar Ass’n v. Fed. Trade Comm’n*, 276 F. Supp. 2d 110, 119 (D.D.C. 2003) (the “meaning – or ambiguity – of certain words or phrases may only become evident when placed into context”) (citation omitted).

Further, courts may not adopt an interpretation that completely writes out of a statute a provision that was otherwise designed to help meet the statute’s underlying goals and objectives. *See, e.g., King v. Burwell*, 135 S.Ct. 2480, 2493 (2015) (rejecting petitioners’ reading of the Affordable Care Act that would eliminate key provisions aimed at the statute’s goal of controlling insurance premium costs). Likewise, an agency cannot interpret statutory provisions in a way that would change the overall regulatory scheme. *MCI Telecomm. Corp. v. AT&T Co.*, 512 U.S. 218, 229-32. (1994) (holding Federal Communications Commission could not make

rate filing optional for certain carriers where it would undermine the Communication Act's goal of preventing price discrimination and stabilizing rates).

As discussed below, when these principles are appropriately applied to the TCA and the grandfather date, it is readily apparent that FDA has the authority, and in fact the statutory duty, to establish an alternative grandfather date for vaping products.

B. The TCA is Intended to Promote the Development and Marketing of Relatively Safer Tobacco Products like E-Liquids and Vaping Devices

The grandfather date cannot be considered in a regulatory vacuum, but rather must be viewed in the full context of the TCA's overall statutory structure and the unique regulatory regime Congress has established for tobacco products over the past half century. As the Supreme Court discussed in *Brown & Williamson*, Congress struck a balance over the course of six different pieces of tobacco legislation, all adopted before the TCA, that subjected traditional tobacco products (*e.g.*, cigarettes and smokeless tobacco) to certain regulatory controls, like advertising and labeling restrictions, while at the same time ensuring that adult consumers had continued access to such products. 529 U.S. at 138-39. When taken together, these statutes reflected a Congressional intent not only to provide the public with adequate information about the health risks of tobacco use, but also a desire that "tobacco products remain on the market" given their significant role in the national economy. *Id.* at 139.

In *Brown & Williamson*, FDA had adopted a final rule that would have regulated tobacco products under the FDCA's stringent pre-market authorization process for medical devices, which would have required a finding that cigarettes and smokeless tobacco are "safe and effective" for their intended use before they could enter the commercial market. *Id.* at 136. Because these products are inherently unsafe and not intended for any therapeutic benefit, however, they would not be able to satisfy such a stringent health standard. Accordingly, the

Supreme Court vacated the rule, finding that cigarettes and smokeless tobacco would be effectively banned if regulated under the FDCA, a result that would directly contravene long-standing Congressional policy. *Id.* at 139.

In response, Congress adopted the TCA in 2009, amending the FDCA and giving FDA authority to regulate tobacco products. *Sottera, Inc. v. Food and Drug Admin.*, 627 F.3d 891, 894 (D.C. Cir. 2010). However, as this Court noted in *Smoking Everywhere, Inc., et al. v. U.S. Food and Drug Admin.*, 680 F. Supp. 2d 62, 70 n.9 (D.D.C. 2010), Congress explicitly preserved in the TCA the notion that tobacco products, including vaping products, cannot be regulated to the extent that they are effectively banned from sale. In that case, which involved the seizure by FDA of several shipments of imported closed system vaping devices, the agency argued that vaping products are not subject to the TCA and, instead, should be regulated under the FDCA as a drug-device combination. *Id.* at 67. But as this Court pointed out, one provision of the TCA “expressly forbids FDA from ‘requiring the reduction of nicotine yields of a tobacco product to zero’” *Id.* at 70 n.9 (*citing* 21 U.S.C. § 387g(d)(3)(B)). As such, “[i]t is apparent . . . that Congress did not intend tobacco products delivering nicotine for recreational use to be classified as a drug-device combination and thus subject to a potential ban on nicotine yields.” *Id.* In other words, like the traditional tobacco products in *Brown & Williamson*, this Court held that regulating vaping products under the FDCA’s drug and device pre-market provisions would force them out of the market, an outcome expressly prohibited by Congressional intent.

In fact, the plain language of the TCA makes clear that FDA must strike a balance when regulating vaping products so that it does not ban or nearly eliminate entire categories of such products. This is evident from two underlying purposes expressly set forth by Congress in the TCA. First, FDA must “continue to permit the sale of tobacco products to adults in conjunction

with measures to ensure that they are not sold or accessible to underage purchasers.” Pub. L. No. 111-31, § 3(7), 123 Stat. at 1782; *see, e.g.*, H.R. Rep. No. 111-58, Pt. 1, at 33 (2009) (FDA must “continue to permit the sale of tobacco products to adults”).

Second, Congress directed FDA to regulate in a manner that allows continued adult access to products that are safer than traditional tobacco products (*e.g.*, cigarettes). In particular, the TCA is designed “to provide new and *flexible* enforcement authority to ensure that there is effective oversight of the tobacco industry’s efforts to develop, introduce, and promote less harmful tobacco products.” Pub. L. No. 111-31, § 3(4), 123 Stat. at 1782 (emphasis added); *see also id.* at § 3(4) (requiring FDA to only “impose *appropriate* regulatory controls on the tobacco industry”) (emphasis added); 21 U.S.C. § 371(a) (granting FDA authority to adopt regulations “for the efficient enforcement” of the FDCA).

When these underlying goals are read together, Congress clearly required FDA to tailor its regulations, including any deeming rules, to a product category’s specific risk profile and to use the TCA’s provisions to continually drive the development and commercialization of relatively safer tobacco products.⁶

Indeed, FDA acknowledged this regulatory approach during the rulemaking, at least in principle. The agency recognized that the PMTA’s stringent public health standard (*i.e.*, population effects standard) is primarily designed to prevent the introduction of tobacco products that are more dangerous than traditional products, like cigarettes. According to FDA, “[i]f, without the final rule, new products would pose substantially greater health risks than those already on the market, the premarket requirements made effective by this final rule would keep

⁶ *See also* 21 U.S.C. § 387r(b) (requiring FDA to submit a report to Congress examining how to “regulate, promote, and encourage the development of innovative products” to achieve reductions in tobacco use and related harms); Pub. L. No. 111-31, § 2(10), 123 Stat. at 1777 (TCA recognizing importance of tobacco industry to the “Nation’s economy”).

such products from appearing on the market and worsening the health effects of tobacco product use.” 81 Fed. Reg. at 29,075; *see also* 79 Fed. Reg. at 23,196 (same); AR010,598, -603 (same); 21 U.S.C. § 387j(b)(1)(A) (TCA requiring a PMTA to include information showing that the health risks of a given tobacco product “present[] less risk than other tobacco products”).⁷ As Mitch Zeller, Director of FDA’s Center for Tobacco Products, has noted, “[a]nyone who would ponder the endgame must acknowledge that the continuum of risk exists and pursue strategies that are designed to drive consumers from the most deadly and dangerous to the least harmful forms of nicotine delivery.” Zeller, *Reflections on the ‘Endgame’ for Tobacco Control*, Tobacco Control 22:i40-i41, at i40 (2013).⁸

In this respect, Congress did not intend for potentially safer tobacco products, like e-liquids and vaping devices, to be subject to a “one-size-fits-all” approach whereby the PMTA pathway is the only option for pre-market authorization. As shown below, forcing all vaping manufacturers down the PMTA route will virtually eliminate or even ban the commercialization of entire vaping product categories. Rather, Congress directed FDA to account for continuum of risk relative to more harmful traditional tobacco products (*e.g.*, cigarettes) so that safer product categories continue to enter and remain on the market. Accordingly, the TCA requires the agency to exercise regulatory “flexibility” as it applies to various statutory provisions, including the grandfather date, in a way that achieves that result.

⁷ *See also* AR155,177 (the “underlying purpose for establishing the Grandfather Date was to create a rigorous premarket process to ensure that new, more harmful tobacco leaf-containing products did not enter the market”).

⁸ *See also* 79 Fed. Reg. at 23,147 (FDA stating that “there are distinctions in the hazards presented by various nicotine-delivering products”); *id.* at 23,152 (“FDA realizes that while all tobacco products are potentially harmful and potentially addictive, different categories of tobacco products may have the potential for varying effects on public health”).

C. Applying the February 15, 2007 Grandfather Date to Vaping Products Will Eliminate the SE Pathway as a Viable Option for Pre-Market Authorization

When viewed in the TCA's overall statutory context, it is apparent that Congress did not intend for the February 15, 2007 grandfather date to be strictly applied to all categories of deemed products. One of the primary means through which the TCA provides FDA with regulatory flexibility, and thus allows relatively safer products to be commercialized, is the SE pathway. Under Section 910 of the statute, a non-grandfathered product may forego the more burdensome PMTA process by obtaining a FDA marketing authorization finding that the product is "substantially equivalent" to a grandfathered one. 21 U.S.C. §§ 905(j), 387j(a). While Congress did not intend for every product within a category to be eligible for SE authorization, it is also true that it did not anticipate that FDA would completely eliminate the SE pathway as an option. This is because without the SE pathway the TCA's pre-market review process becomes a "one-size-fits-all" regime, forcing all new product categories first introduced after the grandfather date to obtain PMTA authorization and, even worse, subjecting entire product categories to the risk of an effective ban. It goes without saying that this regulatory approach does nothing to achieve the balance struck by Congress under the statute.

Another way to look at the grandfather date is from the perspective of the deeming mechanism itself. Under the TCA, there is no time limit on how far into the future FDA may deem a tobacco product. 21 U.S.C. § 387a(b). This means that the agency can deem a product 10, 20, 50, or even 100 years or more after the TCA's date of enactment (*i.e.*, June 22, 2009). Any deeming, therefore, will likely include product categories that were not even invented, let alone developed for commercial markets, as of February 15, 2007. As more time passes between the grandfather date and the point of deeming, the chances of relying on the SE pathway for market authorization quickly drop to zero. In fact, even with respect to traditional tobacco

products, Congress recognized this problem and took steps to avoid it. As Congress debated various versions of the TCA over the span of a decade, it kept moving the grandfather date forward so that there was never more than 0-3 years between the grandfather date and the date that the particular legislation was introduced.⁹ Congress was guarding against the possibility that traditional tobacco product manufacturers would not be able to use the SE pathway for recently developed products. Likewise, Congress could not have intended for the February 15, 2007 date to apply to tobacco products that are deemed a decade or more later.¹⁰

But that is what FDA has done under the Deeming Rule, applying the grandfather date to “all other categories of products that meet the statutory definition of ‘tobacco product,’” now or in the future. 81 Fed. Reg. at 28,974. Under FDA’s reading, many deemed product categories, whether existing vaping products or some other innovative technology that has yet to be conceived, will not be able to establish substantial equivalency based on the long since passed date of February 15, 2007 or avail themselves of the SE pathway. Thus, FDA’s approach completely writes out of the TCA a key provision that would otherwise provide the agency with

⁹ When this legislation was first introduced in 1998, the grandfather date was set at August 11, 1995. *See* National Tobacco Policy and Youth Smoking Reduction Act, S. 1415, 105th Cong. (1998). When the legislation was reintroduced in 2002, Congress updated the grandfather date to June 1, 2002 and, subsequently, the grandfather date was never set more than two or three years prior to when later bills were introduced. *See* Youth Smoking Prevention and Public Health Protection Act, S. 2626, 107th Cong. (2002); *see also* Family Smoking Prevention and Tobacco Control Act, S. 2461, 108th Cong. (2004) and HeLP America Act, H.R. 5951, 109th Cong. (2006) (both using a grandfather date of June 1, 2003). Finally, the legislation that ultimately became the TCA was introduced on February 15, 2007, the grandfather date we see today. *See* Family Smoking Prevention and Tobacco Control Act, H.R. 1108, 110th Cong. (2007).

¹⁰ The February 15, 2007 date makes sense for traditional tobacco products, like cigarettes, which have been on the market for decades. It allows continued adult access to those products, while at the same time guarding against the commercialization of more dangerous products in the future. This “balance” would not be achieved, however, if that date is applied to vaping products. As a consequence, manufacturers asked FDA to establish a new grandfather date for vaping products that would mirror Congress’s pegging of the grandfather date for traditional tobacco products to the TCA’s date of introduction (*i.e.*, such as setting a grandfather date of April 25, 2014, the day that FDA introduced the proposed Deeming Rule). *See, e.g.*, AR155,178 n.152.

flexibility to tailor its regulation and enforcement authority to different tobacco product categories with a more favorable risk profile. Instead, those deemed product categories will be prohibited from the marketplace if manufacturers are unable to file a compliant PMTA by the end of the two year compliance period. It is hard to believe that Congress, which has for decades pursued a “balanced” approach that even allows cigarettes to remain on the market, adopted the TCA with such a draconian outcome in mind.

Yet this is precisely what will happen to both the e-liquid and device categories under the Deeming Rule. FDA has conceded that it will be extremely difficult for those in the vaping industry to rely on the SE pathway. *See, e.g.*, 81 Fed. Reg. at 28,992 (“However, manufacturers of . . . [vaping products] would have great difficulty showing that a product is substantially equivalent to a combusted cigarette or a smokeless tobacco product.”); *id.* at 28,977 (“[W]e understand that, for some newly deemed tobacco products, particularly novel products, there may not be appropriate predicate products that were on the market on February 15, 2007, to support a SE claim”); *see also* AR028,356 (FDA stating that “[g]iven the possible absence of valid predicates . . . for use in the substantial equivalence pathway, FDA expects to receive PMTA submissions from manufacturers of newly deemed [vaping products]”); AR023,989 (“[N]early all [vaping] products will be subject to premarket review”).

In fact, the agency concluded that no e-liquids will be grandfathered under the February 15, 2007 date or be able to take advantage of the SE pathway. AR184,834 at Table 9; AR184,847 at Table 16. Moreover, with respect to vaping devices, FDA estimated that only one percent of the device market will be grandfathered, with only 11 percent of the existing market able to use the SE pathway. *Id.* However, FDA provided no justification or supporting data for these device estimates. The agency simply claimed that it has “identified a non-flavored e-

cigarette (also marketed as an “e-cigar”) that *may* have been on the market on February 15, 2007. This product *may* possibly be able to serve as an appropriate predicate for purposes of the SE pathway.” 81 Fed. Reg. at 28,978, 28,991 (emphasis added). This is pure speculation on the agency’s part. FDA refused to identify the product that might (or might not) help the device industry establish substantial equivalency and failed to provide any evidence that the device was, in fact, commercialized as of February 15, 2007. *Id.* (stating the burden on identifying a predicate product is on the SE applicant). As such, it is clear from FDA’s own analysis that the SE pathway will not, as a practical matter, be a viable option for the vaping industry.¹¹

D. Requiring All Vaping Products to Submit PMTAs Will Effectively Ban or Virtually Eliminate Such Products from the Marketplace

Without the SE pathway, FDA risks banning or nearly eliminating the e-liquid and device categories from the market when the two year PMTA compliance period expires. Again, FDA’s own numbers bear this out. The agency estimated that there are between 168 and 204 manufacturers of e-liquids and vaping devices. In addition, FDA claimed that there are 3,500 to 7,000 vape shops that manufacturer vaping products, including the mixing of e-liquids. AR184,820 at Table 4. FDA then admitted that all of these vape shops will either exit the market completely or switch to retail only (thus falling outside the Deeming Rule’s authority) within the

¹¹ Even if there was a single vapor product on the market before the February 15, 2007 grandfather date, it would have been a crude device having no similarity to the sophisticated “second” and “third” generation devices and e-liquids that we see on the market today. *See, e.g.*, AR130,181 (“[E]-cigarette designs have undergone such significant change over the past few years that current products likely do not have the same characteristics as any product that existed as of February 15, 2007”); AR154,901 (the SE pathway “is likely impossible due to substantial technological improvements since 2007 and due to lack of available information regarding grandfathered predicates to which we would otherwise compare our products”); AR149,926 (the SE pathway “will be impossible to apply for due to the great technological changes that have occurred since vapor product technology was in its infancy in 2007”); AR155,176 (“Even if there was a viable predicate e-cigarette on the market on the statutory Grandfather Date, such product would most likely be a rudimentary, disposable cigalike device” that would bear no resemblance to more advanced open system products).

next two years. *Id.* As a result, according to FDA, between 95 and 97 percent of the vaping product manufacturers will cease to exist as of the PMTA filing deadline of August 2018.

As for the few remaining manufacturers, FDA predicted that there will be 1,250-2,500 PMTAs submitted for e-liquid products, and 360-450 PMTAs for devices, within the two year compliance period. AR184,834 at Table 9. But these numbers appear to have been plucked out of thin air. Nowhere in the administrative record did FDA provide supporting data or any underlying rationale for these assumptions.¹²

Moreover, these numbers do not tell us how many PMTAs would actually be authorized by FDA, thus allowing vaping products to enter and remain on the market. Indeed, equally troubling is the fact that FDA merely “assume[ed]” that “90 percent of products seeking marketing authorization will obtain” approval, but then immediately disclaims the accuracy of that number. AR184,829. The agency stated:

We incorporate this assumption as a placeholder to acknowledge that it would not be realistic to expect 100 percent of products seeking marketing authorization to obtain marketing authorization. This 90% placeholder is comparable to the high end of observed medical product approval rates. The marketing authorization rate for tobacco products, however, may differ, and this placeholder is not a forecast of actual marketing authorization rates or an estimate based on currently regulated tobacco products.

AR184,829 n.38; *see also* AR184,785. Accordingly, FDA has no idea how many PMTAs will actually be filed or, more importantly, the number, if any, that will ultimately be authorized.

¹² These numbers also stand in stark contrast to FDA’s earlier estimates made during the proposed rulemaking. In 2014, FDA predicted that only 20-80 PMTAs would be submitted for vaping products before the end of the compliance period. AR010,627 at Table 21. But FDA’s estimates only two years later are between 36 and 80 times higher. FDA argued that the increase is due to the “rapid[ly] growing [vaping products] market since the [proposed rule] was published.” 81 Fed. Reg. at 29,091. Yet the agency did not discuss any data or information – *e.g.*, how fast the industry actually grew during the interim period – that would justify the substantial jump in estimates. Nevertheless, FDA offered no evidence or rationale for any of the PMTA estimates, whether made as part the proposed rule in 2014 or the Deeming Rule itself.

And if history is any indication, it is easy to see just how speculative FDA's PMTA estimates really are. Since the TCA was adopted in 2009, a total of only five PMTAs have been filed with FDA. Four of those applications were rejected. The remaining PMTA was submitted for eight products called Swedish Match "snus" smokeless tobacco.¹³ Snus is a product that has been used for over 30 years and, as a result, its PMTAs were accompanied by "data spanning several decades," including four clinical pharmacology studies, two clinical trials regarding cessation effects, longitudinal and cross-sectional studies on consumer use patterns, and substantial epidemiological studies regarding health effects.¹⁴ As discussed below, however, such long-term studies do not exist for e-liquids and devices. Thus, it simply strains credulity for FDA to claim that a nascent vaping industry will file hundreds, if not thousands, of PMTAs within the next two years when not even the traditional tobacco industry, with its decades of research, could muster a fraction of those numbers over the past nine years.¹⁵

¹³ See FDA, Tobacco Product Marketing Orders, *available at* <http://www.fda.gov/TobaccoProducts/Labeling/TobaccoProductReviewEvaluation/ucm339928.htm#1>.

¹⁴ See Premarket Tobacco Application (PMTA) Technical Project Lead (TPL) Review (2015), at 7, 20, 25-26, 29, *available at* <http://www.fda.gov/downloads/TobaccoProducts/Labeling/TobaccoProductReviewEvaluation/UCM472123.pdf>.

¹⁵ Even assuming FDA is correct and that thousands of PMTAs will be filed by August 2018, another feature of FDA's compliance policy ensures that the vast majority will never be approved before those manufacturers have to pull out of the market. As noted above, a manufacturer who timely submits a PMTA will have an additional 12 months to sell its product. However, if FDA does not make a final decision on the application by its self-imposed one year deadline, the manufacturer will have to cease all sales of the product. 81 Fed. Reg. at 28,978. Given FDA's poor track record in timely approving or denying pre-market applications for tobacco products, it is highly unlikely that more than a few (if any) manufacturers will make it through unscathed. For example, FDA currently has a backlog of SE Reports totaling over 4,000, extending all the way back to the program's 2011 inception. See <http://www.accessdata.fda.gov/scripts/fdatrack/view/track.cfm?program=ctp&id=CTP-OS-total-product-submissions-received&fy=all>. But PMTAs will take much longer to review and process, and based on FDA's PMTA estimates, it would have to approve up to 245 applications per month to avoid arbitrarily banning products. FDA offered no evidence in the record, however,

E. Long-Term Clinical Studies Required for PMTAs Do Not Exist

Driving the vaping industry's exit from the marketplace will be the fact that FDA has not provided manufacturers with sufficient time to generate the data required to satisfy the PMTA's population effects standard. PMTAs will require, *inter alia*, long-term clinical (*i.e.*, human) studies on numerous issues. This research, whether carried out by the manufacturer itself or conducted and shared by others, will have to provide extensive information regarding each e-liquid or vaping device seeking authorization, including:

1. Likelihood of initiation and cessation by both users and non-users;
2. Consumer perceptions (*e.g.*, how consumers perceive product risk);
3. Product use patterns (*e.g.*, how frequently consumers use a product);
4. Labeling comprehension (*e.g.*, how consumers understand the label);
5. Human factors (*e.g.*, normal use and foreseeable misuse);
6. Abuse factors (*e.g.*, nicotine addiction and exposures);
7. Biomarkers of harm and exposure (*e.g.*, tracking nicotine in the body); and
8. Health outcomes (*e.g.*, health effects from exposure to flavorings).

AR028,387-91.

FDA has conceded that long-term clinical studies will likely be required in vaping product PMTAs. *See, e.g.*, 81 Fed. Reg. at 28,997 (“However, in cases where there have been few or no scientific studies of a product’s potential impact on the public health, new nonclinical and clinical studies may be required for [PMTAs]”); AR028,382 (“Due to the emerging nature of

indicating that it would ever be able to keep this pace. Indeed, it took 8 months for FDA to review and approve the snus PMTA. *See* <http://www.fda.gov/TobaccoProducts/Labeling/TobaccoProductReviewEvaluation/ucm472108.htm>. Moreover, FDA’s 12 month cutoff is strikingly different from the compliance policy Congress established in the TCA for “provisional” SE Reports submitted by manufacturers of the originally regulated tobacco products (*e.g.*, cigarettes, cigarette tobacco, smokeless tobacco, and roll-your-own tobacco). If those manufacturers were able to submit SE Reports for non-grandfathered products by a March 22, 2011 statutory deadline, they were able to continue marketing those products until FDA finished its review of those applications and would only need to cease such marketing if the agency ultimately made a not substantially equivalent (NSE) determination. 21 U.S.C. § 387j(a)(2)(B). That is not the case for timely filed vaping product PMTAs.

[vaping] products . . . FDA acknowledges that there may be limited nonclinical or clinical research conducted on specific [vaping] products. Thus, it is likely that applicants will conduct certain investigations themselves and submit their own research findings as part of their PMTA”); AR028,382 (FDA noting that “nonclinical studies alone are generally not sufficient to support a determination that marketing of the product is appropriate for the protection of public health (PMTAs would generally need clinical data).”).

But at the same time, FDA has admitted that long-term data and information regarding vaping products do not exist. *See, e.g.*, 81 Fed. Reg. at 28,984 (“there have not yet been long-term studies conducted”), *id.* at 29,028 (“long-term studies are not yet available”), 29,031 (“no adequate data on long-term health effects”), *id.* at 29,041 (“[I]ong-term studies are not available”); AR028,366 (“Given the relatively new entrance of [vaping products] on the U.S. market, FDA understands that limited data may exist from scientific studies and analyses); *id.* at AR028,382 (“Due to the emerging nature of [vaping] products . . . FDA acknowledges that there may be limited . . . clinical research”); 79 Fed. Reg. at 23,152, 23,157, 23,166 (FDA noting lack of sufficient data regarding [vaping] products).

More importantly, FDA is not aware of long-term studies necessary for manufacturers to address the population effects standard in a PMTA. *See, e.g.*, 81 Fed. Reg. at 28,984 (“[T]here have not yet been long-term studies conducted” indicating whether vaping products “may eventually be shown to have a net benefit on or harm to public health at the population level”); *id.* at 29,028 (“[W]e do not have sufficient data to determine what effects e-cigarettes have on public health at the population level”); *id.* (“Long-term studies are not yet available to determine” the impact of [vaping] products on underage use); *id.* at 29,030 (“Given the relatively new entrance of [vaping products] on the market, consumers have not had the duration of use for

researchers to fully assess the morbidity and mortality effects for [vaping products] on either the individual or the population”); *id.* at 29,041 (“Long-term studies are not available to conclude that [vaping products] are a proven cessation product”); 79 Fed. Reg. at 23,144, 23,152, 23,157, 23,166 (*e.g.*, “We do not currently have sufficient data about e-cigarettes . . . to determine what effects they have on the public health”).¹⁶

Not surprisingly, manufacturers expressed concerns during the rulemaking that, due to the lack of existing data and other factors, complying with the PMTA process will not be possible within the short, two year compliance period established under the Deeming Rule. *See, e.g.*, AR130,177, -179-80; AR145,304; AR150,360; AR161,104. FDA’s only response was that someday there will be sufficient long-term clinical and other data to support PMTAs and that manufacturers will achieve cost and time efficiencies by sharing information through confidential Tobacco Product Master Files (“TPMFs”) and public dockets. 81 Fed. Reg. at 28,997 (“FDA expects that, in some cases, it may be possible for an applicant to obtain a PMTA marketing authorization order without conducting any new nonclinical or clinical studies where there is an established body of evidence regarding the public health impact of the product. However, in cases where there have been few or no scientific studies of a product’s potential impact on the public health, new nonclinical and clinical studies may be required for market authorization”); *see also* 81 Fed. Reg. at 29,077, 29,080, 29,092.

But this puts the proverbial cart before the horse. If vaping product manufacturers are all but forced out of the marketplace because there is no SE pathway, there will be no long-term clinical data or other data to share going forward. FDA’s argument that master files and public

¹⁶ Of course, the lack of such data also does absolutely nothing to help manufacturers of new tobacco products introduced into the market after the Deeming Rule’s August 8, 2016 effective date, as they would not be eligible to take advantage of the compliance period.

dockets will help reduce PMTA burdens only wins the day if a sufficient number of manufacturers are able to conduct such research on a broad range of e-liquids and devices before August 2018. FDA failed, however, to explain how manufacturers will be able to generate a critical mass of data and information over the next two years to satisfy the PMTA requirements. Rather, the agency simply asserted, without more, that the compliance period is sufficient. *See, e.g.*, 81 Fed. Reg. at 29,001 (FDA stating that “we believe the compliance period is appropriate, and it takes into account the time frame for firms to generate and submit information for a PMTA”); *id.* at 29,012 (FDA noting, without further explanation, that it “believes that [the 2-year compliance period] will give sufficient time for manufacturers of such products to prepare high quality applications”). The agency’s own admissions prove otherwise.

Ironically, the end result is that FDA will actually regulate what it concedes are relatively safer products in a more stringent manner than it does more dangerous products like cigarettes. While manufacturers of traditional tobacco products have long taken advantage of the February 15, 2007 grandfather date and the SE pathway, vaping products are confined to a “one-size-fits-all” PMTA scheme. This cannot be what Congress intended as it turns the underlying purposes of the TCA – *i.e.*, driving safer products to the adult market – completely on their head.

F. PMTAs for E-Liquids and Vaping Devices Will Be Cost Prohibitive Given that Long-Term Clinical Studies Must Still be Conducted

Even if a few manufacturers attempt to file PMTAs within the next two years, and try to develop at least some supporting clinical data, FDA’s own cost estimates for PMTAs further reveal how difficult it will be for even the largest manufacturers to conduct these studies and submit compliant applications. During the rulemaking, the agency presented a range of average application costs for both e-liquids and devices during the compliance period. An application is

assumed to cover multiple, similar products, such as a branded e-liquid line using similar ingredients. The estimated cost ranges are as follows:

1. E-liquids: \$181,686 (low); \$1,110,050 (medium); \$2,014,120 (high)
2. Devices: \$285,656 (low); \$440,725 (medium); \$2,622,224 (high)

AR184,837 at Table 11a; AR184,840 at Table 12a. FDA also noted that conducting human or clinical studies will be the most expensive aspect of an application. AR184,836. As a manufacturer's ability to rely on existing clinical research decreases, one moves from the low estimates to the medium and high cost numbers. AR184,838-39.

But FDA then assumed that 85-90 percent of all manufacturers submitting PMTAs will fall in the low to medium range. AR184,837 at Table 11b; AR184,841 at Table 12b. In light of FDA's conclusions regarding the lack of clinical data, however, this assumption appears to be completely off-base. Without any existing clinical studies to rely upon, it is likely that the vast majority of manufacturers will fall on the high end of the estimated range, spending nearly two million dollars for every branded e-liquid or device. And as manufacturers often have multiple brands or types of vaping products, it is easy to see how PMTA costs will quickly sky rocket, turning the entire process into a cost-prohibitive exercise. *See* 81 Fed. Reg. at 29,076 (FDA conceding that most tobacco product manufacturers, including vape shops, are "small"); *see also* AR130,192-94 (large vaping manufacturer, with \$100 million in revenues and 700 separate products, concluding that the PMTA process will be "prohibitively expensive" as it would cost over \$230 million to file the applications).¹⁷

¹⁷ Another manufacturer gave the following example (using cost assumptions that appear consistent with FDA's medium to high cost estimates): "If you assume the average company offers three distinct e-cigarette devices and 20 distinct e-liquids, the costs could be as much as \$25 million to \$75 million dollars to develop the requisite PMTA applications." AR161,084; *see also* AR155,184-85 ("Even the smallest e-liquid producers often have dozens of unique products . . . while the largest companies produce hundreds or even thousands of unique formulations");

G. Conclusion

FDA's decision to apply the February 15, 2007 date to vaping products is arbitrary and capricious and does not comply with the TCA. Congress structured the statute so that relatively safer tobacco products are not banned or substantially restricted from the marketplace. Congress adopted this approach so that adult smokers would have access to a variety of safer products. What this means for the regulation of deemed products, and in particular how the grandfather date is applied, is that FDA cannot regulate with a "one-size-fits-all" approach, where an entire category of tobacco products is limited only to the PMTA pathway. This holds particularly true where the commercialization of potentially safer tobacco products is effectively banned or all but eliminated. Where a product category generally has a lower risk profile, as FDA concedes vaping products do, FDA must exercise the regulatory flexibility provided by Congress, preserve the SE pathway as a viable option, and thereby establish a new grandfather date.

II. The Regulatory Flexibility Act Required FDA to Consider Extending the Two Year PMTA Compliance Period to Address the Lack of Long-Term Clinical Data

Vaping product manufacturers submitted comments during the rulemaking requesting FDA to consider various alternatives that would address the lack of any long-term clinical or other population-level studies. In particular, they asked that the agency extend the two year PMTA compliance period, which first appeared in the proposed rule, so that manufacturers would have adequate time to develop and conduct such research. *See, e.g.*, AR145,304, AR161,104, AR130,179-80. FDA summarily rejected those suggestions without explanation. *See, e.g.*, 81 Fed. Reg. at 29,001.

AR157,508 ("Realistically, each [PMTA] . . . would cost successful applicants between \$2-4 million, and perhaps up to \$20 million"); AR149,926 (PMTAs "will require costly public health studies (estimated to cost between \$1M and \$4M)" per product).

As discussed below, the RFA imposed an affirmative duty on FDA to consider a longer compliance period given that, in the absence of any supporting clinical research, entire vaping product categories will disappear or be nearly eliminated from the marketplace. At a minimum, to the extent that FDA even addressed these suggestions, it was required to offer a substantive explanation for rejecting that alternative. The agency failed on both counts.

A. The RFA Requires Agencies to Consider Significant Alternatives that Reduce the Adverse Economic Impacts on Small Businesses and to Offer a Reasoned Explanation in the Event an Alternative is Rejected

The RFA, as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. §§ 601, *et seq.*, requires agencies to consider the “negative” impacts of regulatory actions on small businesses prior to rulemaking and to “design mechanisms to minimize any adverse consequences.” *Nat’l Ass’n of Psychiatric Health Sys. v. Shalala*, 120 F. Supp. 2d 33, 42 (D.D.C. 2000); *Southern Offshore Fishing Ass’n v. Daley*, 995 F. Supp. 1411 (M.D. Fla. 1998). Echoing some of the same themes seen in the TCA, Congress warned in the original RFA that federal regulations should not discourage innovation or create unnecessary barriers to market entry for small entities. Pub. L. 96-354, §§ 2(a)(4)-(5), 94 Stat. 1164 (1980). In 1996, after finding that the RFA had “too often been ignored by government agencies, resulting in greater regulatory burdens on small entities,” Congress amended the statute to explicitly grant small businesses the right to seek judicial review to “make Federal regulators more accountable” and allow small businesses “a meaningful opportunity for redress of excessive enforcement activities.” Pub. L. 104-121, §§ 202(5), 203(7), 110 Stat. 857 (1996).¹⁸

¹⁸ Where an agency has failed to comply with the RFA, courts may order corrective action, including remanding the rule to the agency or deferring enforcement against small entities unless continued enforcement is in the public interest. 5 U.S.C. § 611(a)(4).

Although judicial review of agency compliance with the RFA is generally conducted under the APA, *see* 5 U.S.C. § 611(a)(1), the statute imposes explicit obligations on agencies when considering adverse effects on small entities. Specifically, the RFA requires agencies to conduct an initial regulatory flexibility analysis (“IRFA”) that must, *inter alia*:

Contain a description of any *significant alternatives* to the proposed rule which accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the proposed rule on small entities. Consistent with the stated objectives of applicable statutes, the analysis shall discuss significant alternatives such as – (1) the establishment of differing compliance or reporting requirements or *timetables* that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance and reporting requirements under the rule; . . . and (4) an exemption from coverage of the rule, or any part thereof, for such small entities.

5 U.S.C. § 603(c) (emphasis added). As the Office of Advocacy, Small Business Administration (“SBA”), has noted, the “keystone of the IRFA is the description of any significant alternatives” which “establishes the process for the agency to evaluate proposals that achieve the regulatory goals efficiently and effectively without unduly burdening small entities, erecting barriers to competition, or stifling innovation.” *See* SBA, *The RFA in a Nutshell: A Condensed Guide to the Regulatory Flexibility Act*, at 11-12 (Oct. 2010).¹⁹

Building on those provisions, the RFA then requires the agency to prepare a final regulatory flexibility analysis (“FRFA”) that must contain, *inter alia*:

a statement of the significant issues raised by the public comments in response to the [IRFA], a statement of the assessment of the agency of such issues . . . [and] a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected.

¹⁹ The SBA’s Office of Advocacy was established pursuant to federal law to “represent the views of small entities before federal agencies and Congress.” AR082,215.

5 U.S.C. § 604(2), (6). In other words, consistent with the APA, an agency must adequately explain its decisions regarding potential alternatives and justify them based on facts contained in the administrative record. *State Farm*, 463 U.S. at 43.²⁰

While the RFA is procedural in nature and does not require an agency to adopt a particular alternative that reduces regulatory burdens, the statute calls on the agency to make a “reasonable, good-faith effort to canvass *major* options and weigh their probable effects.” *Shalala*, 120 F. Supp. 2d at 43 (citation omitted) (emphasis added); *see also North Carolina Fisheries Ass’n, Inc. v. Daley*, 27 F. Supp. 2d 650, 658 (E.D. Va. 1998) (same); *Southern Offshore Fishing*, 995 F. Supp. at 1436-37 (requiring “good faith effort. . . to inform the public about potential adverse effects of [the] proposals and about less harmful alternatives”; stating that an agency must “engage in a careful and meaningful study” of the issues). This includes consideration of a “range of alternatives” that would “substantially reduce” the economic impact on small businesses. S. Rep. No. 96-878, at 10 (1980), *reprinted in* 1980 U.S.C.C.A.N. 2788, 2797 (internal quotations omitted). Thus, modest alternatives will not suffice. Moreover, the RFA “require[s] agencies to *clearly explain the rationale* for their actions to assure . . . those affected by the rule that proposed alternatives were given serious consideration.” S. Rep. No. 96-878, *supra*, at 14, 1980 U.S.C.C.A.N. at 2801 (emphasis added).

B. FDA Did Not Consider Any Significant Alternatives that Address the Lack of Long-Term Clinical Data or Otherwise Explain this Failure

In the instant case, FDA failed to consider any alternatives in the FRFA that address the devastating economic impacts that the Deeming Rule will have on the vaping industry. FDA concedes that “most affected entities are small” and that the rule “will have a significant

²⁰ Courts are only authorized under the RFA to review agency compliance with the FRFA (*i.e.*, there is no judicial review of IRFAs). 5 U.S.C. § 611(a)(1).

economic impact on a substantial number of small entities.” AR184,806-07; 81 Fed. Reg. at 29,074. In fact, as discussed above, the agency’s own numbers reveal that, at a minimum, 95 to 97 percent of all manufacturers will disappear before the two year compliance period expires, representing the whole of the vape shop industry subject to the TCA. AR184,820 at Table 4. Thus, the RFA placed an affirmative duty on FDA to seriously consider “major” alternatives that would “substantially reduce” adverse effects on small entities and justify any decision not to pursue those options. The agency, unfortunately, completely ignored these obligations.

Specifically, the agency failed to consider the most obvious alternative that would limit the risk of an effective ban while, at the same time, requiring small entities to submit PMTAs – namely, extending the two year compliance period so that vaping product manufacturers would have sufficient time to conduct long-term clinical studies. The RFA explicitly mentions extending compliance “timetables” as an example of a “significant alternative” and FDA clearly believes it has the authority to do so. 5 U.S.C. § 603(c). Indeed, manufacturers noted during the comment period that a two year compliance period is inadequate and will not allow for such research to be completed before August 2018. *See, e.g.*, AR145,304 (requesting a minimum 48 month compliance period due to “FDA’s current knowledge deficit and the likelihood that new tests and equipment will need to be developed and validated for use by industry in the interim”); AR161,104 (suggesting more than 24 months after FDA completes a “final” PMTA guidance document (which FDA has yet to complete) to initiate and conduct “long-term” studies); AR140,979 (stating that clinical studies on consumer perception, use patterns and health impacts “will take significantly more than two years to develop and complete”).

As one manufacturer explained, “[c]redible long-term studies could not possibly be conducted in that [two year] arbitrary timeframe.” AR130,180. The commenter continued:

Developing such population-level data generally requires conducting long-term epidemiological studies. While this standard may be feasible for combustion tobacco products that have been marketed for decades and the subject of extensive studies, it would be impossible to meet for new categories of products, especially e-cigarettes. While some studies have been conducted on e-cigarettes, the product has existed for barely ten years and widely marketed for less than half that time. In short, they have not existed for a long enough period of time for such studies to have been conducted. . . . Without providing any explanation or rationale, or apparently considering the realistic time limitations on conducting such research, the FDA has simply selected a seemingly random window in which producers must complete these complex studies. But it is unclear that such studies could even be *commenced* in that timeframe, because current methodologies and procedures are likely inadequate to address the TCA's new mandates for population-level public health data. Even if such a study were started today, it could take many more years for the data to be collected and analyzed in accordance with sound methodological principles. . . . Put simply, the FDA proposes . . . [a] classic Catch-22: unless a product is available to the public, long-term population-level studies of its effects cannot be conducted.

AR130,179-80 (emphasis in original).²¹

In fact, FDA's own longitudinal study of tobacco – the Population Assessment of Tobacco and Health Study (“PATH”) – demonstrates the arbitrary nature of the two year compliance period. FDA has touted its PATH study as a future source of information regarding population effects of tobacco products, but curiously leaves out any mention of when the study will be finished. *See, e.g.*, 81 Fed. Reg. at 29,040. According to the agency, data collected from PATH will “inform FDA's actions related to tobacco products, thereby helping to achieve the goals of the [TCA].” *See* “FDA and NIH Study: Population Assessment of Tobacco and Health, available at <http://www.fda.gov/TobaccoProducts/NewsEvents/ucm337005.htm> (“News and Events”). In particular, PATH focuses on the same issues that must be addressed by manufacturers under the PMTA's population effects standard, including cessation and initiation

²¹ This commenter raises a particularly important point as to timing. If vaping products are all but forced out of the market within the next two years, there will be no consumer use on which to base long-term clinical or epidemiological studies going forward, whether for a manufacturer's particular product or generally for a product category. As a practical matter, FDA is shutting the door on population-level research, now and in the future.

patterns, behavioral and health impacts, and consumer attitudes. *Id.* PATH is also specifically designed to look at vaping products. *See, e.g.*, 81 Fed. Reg. at 29,029 (assessing “potential smoking cessation among e-cigarette users”); *id.* at 29,038 (providing “information about the overall population health impacts of [vaping products]”).

FDA failed to mention, however, that PATH was launched back in 2011 and requires “at least three years” of interviews with each study participant. *See* PATH, Study Overview, *available at* <https://pathstudyinfo.nih.gov/UI/StudyOverviewMobile.aspx>. So far, data have only been collected for the first wave of interviews. *See, supra*, News and Events. Thus, FDA’s ongoing population effects research has already taken five years, far longer than the compliance period granted to vaping product manufacturers under the Deeming Rule.

Given the lengthy time periods required to complete this type of research, it is no surprise that FDA was unable to provide any support or underlying rationale for limiting the compliance period to two years despite the agency’s own admissions that there are no long-term clinical studies available. To the extent that the agency even addressed the issue, it simply stated in conclusory fashion that “we believe that the compliance period is appropriate, and it takes into account the time for firms to generate and submit the information for a PMTA.” 81 Fed. Reg. at 29,001; *see also id.* at 29,012, -14 (same). There was no analysis, for example, of how long it will take to develop the protocols, assemble the study participants, or meet with FDA regarding any planned long-term clinical studies. *See, e.g.*, 81 Fed. Reg. at 29,091 (FDA encouraging PMTA applicants to meet with the agency before conducting such research).²² And all of this must occur prior to actually conducting the longitudinal studies.

²² We also point out that, if FDA is correct that thousands of PMTAs will be filed within the next two years for vaping products, it will be extremely difficult for most manufacturers to schedule

FDA did conclude that it will take 5,000 hours to prepare a PMTA “for early applications that involve . . . preparing analysis of public health impacts, or for which reliance on master files is not possible.” *Id.* at 29,091. But a total workload estimate says nothing about how many years it will take a manufacturer to prepare and conduct longitudinal studies, which will necessarily be spread out over time. There is no indication that FDA gave this issue any “meaningful” thought or “serious” consideration.²³

Instead, FDA evaluated only a few modest proposals in the FRFA regarding vaping products – *i.e.*, changing the compliance period for labeling requirements and actually eliminating the compliance period for flavored tobacco products (which would do nothing to alleviate regulatory burdens). None of these alternatives, however, address the most significant economic impact on small entities – *i.e.*, the fact that eliminating the SE pathway and requiring all small businesses, including vape shops, to submit PMTAs may result in a complete ban of vaping product categories. It was under these circumstances that the SBA criticized FDA’s list of regulatory alternatives in the IRFA, stating that they “only make marginal changes to the overall compliance costs to small entities” and that FDA should “further consider alternatives

an early meeting with FDA before initiating any long-term research, leaving little time to conduct the actual studies. *See, e.g.*, AR161,089.

²³ The same holds true for another significant alternative, identified by Plaintiff Nicopure in its supporting memorandum, that would account for the time needed to develop long-term clinical data before applying the PMTA requirements – *i.e.*, that FDA should have waited for such research to be conducted before it ever deemed vaping products in the first place. *See* Nicopure Mem. at 23 (Dkt. No. 20-1). Moreover, to the extent that Nicopure discusses other significant alternatives, such as streamlining the PMTA process or exempting vaping products from filing PMTAs, FDA also failed to identify those as significant alternatives in the FRFA. While FDA generally argues that it does not have authority under the TCA to adopt those types of regulatory alternatives, *see, e.g.*, 81 Fed. Reg. at 28,997, 28,999-00, Nicopure correctly points out that the TCA does not require the agency to “impose precisely the same regulatory framework on every tobacco product.” Nicopure Mem. at 24. Indeed, as already discussed, FDA was required to exercise its authority in a flexible manner, taking into account the continuum of risk of tobacco products. As such, the FRFA should have addressed those alternatives as well.

that may be able to more greatly decrease the regulatory burden on small business while still allowing the FDA to meet its regulatory goals.” AR082,217. FDA never considered extending the compliance period in the IRFA.²⁴

Finally, we note that the clinical study requirements are in addition to a whole host of other non-clinical data that must be generated within the two year compliance period for each PMTA, including: (i) toxicological and pharmacological data of all ingredients and aerosols; (ii) in-vitro and in-vivo toxicological studies (*e.g.*, genotoxicity, cytotoxicity); (iii) computational modeling of any toxicants; (iv) potential human exposure studies at various device use levels; (v) aerosolization properties of each ingredient (*e.g.*, particle sizes); and (vi) a thorough public health and medical literature review. AR028,384-87. Again, the RFA does not identify any alternatives that would help small businesses, like vape shops, manage this overall workload, provide any details regarding the likely time estimates for each of these tasks, or demonstrate that, when taken together, small entities (or even larger manufacturers) will be able to satisfy these regulatory obligations by August 2018. *See, e.g.*, AR161,090; AR140,979 (manufacturers questioning whether they will be able to overcome these burdens in the next two years).²⁵

²⁴ In the end, FDA only made a limited number of concessions for small businesses – what FDA calls “small-scale manufacturers” – by extending a few reporting deadlines, such as submitting health-related documents and ingredient lists to the agency. The term “small-scale manufacturer” is defined as having 150 or fewer full-time equivalent employees and \$5 million or less in annual revenues. 81 Fed. Reg. at 28,980. This threshold is ten times lower, however, than the RFA’s definition of small entity. The RFA looks to SBA’s definition under the Small Business Act, which for tobacco product manufacturers is any business with less than 1,500 employees. 5 U.S.C. § 601(3); 13 C.F.R. 121.201; AR184,878 n.86. As such, FDA does not even provide relief to businesses that would be considered “small” by SBA’s standards.

²⁵ Vaping product manufacturers must also prepare a comprehensive Environmental Assessment (“EA”) pursuant to the National Environmental Policy Act (“NEPA”). NEPA, and its implementing Council on Environmental Quality (“CEQ”) regulations, require federal agencies to assess the environmental impacts of any proposed federal action – in this case, the issuance of PMTA marketing authorization orders – to ascertain the environmental consequences of such actions on the quality of the human environment. 42 U.S.C. § 4332(2); 40 C.F.R. § 1506.6.

C. Conclusion

FDA disregarded its own conclusions regarding the impending exit of vaping products from the marketplace and failed to explain why a short, two year PMTA compliance period would otherwise provide enough time for manufacturers to overcome the lack of long-term clinical data or meet the PMTA's other stringent demands. Accordingly, the agency's approach was arbitrary and capricious and violated the specific requirements set forth in the RFA.

III. The TCA Violates the Substantive Due Process Clause if the Statute Does Not Permit FDA to Set a New Grandfather Date

Throughout the rulemaking, FDA took the position that it "lacks authority to change the grandfather date, which is set by statute" and that the agency otherwise has no discretion in the matter. *See, e.g.*, 81 Fed. Reg. at 28,993, 29,075; AR184,757, -801. As shown above, this position misreads the grandfather date and that Congress, in fact, did not intend for the February 15, 2007 date to be strictly applied to deemed products. Nevertheless, assuming that FDA correctly reads the TCA, this creates another problem for the agency, as it would mean Congress drafted a statute that fails to meet the legislation's stated goals and objectives and, as such, violates the Due Process Clause of the Fifth Amendment.

The Due Process Clause provides that no person shall be "deprived of life, liberty, or property, without due process of law." U.S. Const., amend. V. Where a federal statute regulates economic interests, as does the TCA, courts will presume the law to be valid if it is "rationally related to a legitimate [government] interest." *City of Cleburne v. Cleburne Living Ctr.*, 473

Based on this information, FDA decides whether to prepare an Environmental Impact Statement ("EIS") or issue a Finding of No Significant Impact ("FONSI"). 21 C.F.R. § 25.20; 40 C.F.R. § 1501.4. An EA must consider, *inter alia*, the introduction and fate of materials (*e.g.*, e-liquids) in the environment, as well as energy and other resource demands. As with the long-term clinical data, the vaping industry will be starting from scratch and must also develop this information within the PMTA's two year compliance period.

U.S. 432, 440 (1985). However, the rational basis test is not toothless. Even assuming a legitimate governmental interest exists, there must also be a “rational relationship between that purpose and the means chosen by the [legislature] to accomplish it.” *Casket Royale, Inc. v. Mississippi*, 124 F. Supp. 2d at 434, 437-48 (S.D. Miss. 2000) (citing *Washington v. Glucksberg*, 521 U.S. 702, 728 (1997)). “There must be some congruity between the means employed and the stated end or the [rational basis] test would be a nullity.” *Cornwell v. Hamilton*, 80 F. Supp. 2d 1101, 1106 (S.D. Cal. 1999); see also *St. Joseph Abby v. Castille*, 712 F.3d 215, 223 (5th Cir. 2013) (government’s “chosen means must rationally relate to the [government’s] interest”). One indicia of such irrationality is where the statute not only “fails to advance the [stated] interest . . . [but also] actually diminishes it.” *Casket Royale*, 124 F. Supp. 2d at 440; see also *Cornwell*, 80 F. Supp. 2d at 1112 (finding that a “licensing regimen may work against the [government’s] professed interest in health and safety”).

In the instant case, FDA’s reading of the TCA creates an inherent conflict between the statute’s underlying purposes and the resulting regulatory scheme. As discussed above, key to the TCA’s goals of driving the innovation and commercialization of relatively safer products, as well as ensuring continued adult access to such products, is the SE pathway. Pub. L. No. 111-31, §§ 3(4), (7), 123 Stat. at 1782. It is this option that gives FDA the needed “flexibility” which Congress talks about in the TCA and allows the agency to regulate products with a lower risk profile in an “appropriate” manner. *Id.* at §§ 3(7), (8). But these objectives can only be achieved by establishing a new grandfather date for deemed products. Otherwise, as is the case with vaping products, almost a decade will have passed since February 15, 2007, thus effectively writing the SE pathway out of the statute for entire tobacco product categories.

Assuming Congress intended to apply the February 15, 2007 grandfather date to all deemed products, as FDA maintains, there is no rational connection between the resulting loss of the SE option and the TCA's overall goals. Citing to the statute's public health objectives, FDA argues that forcing vaping products into the PMTA process will help the agency gather information regarding the potential health risks of each e-liquid and vaping device. *See, e.g.*, 81 Fed. Reg. at 29,001. But under this view, there would always be a substantial risk that entire categories of relatively safer products will all but disappear before manufacturers ever file a PMTA. Thus, even from an information-gathering perspective, the TCA ultimately fails; FDA will never acquire the information in the first place. As such, Congress will have adopted a statute that actively works against itself and the very goals it set out to achieve. If so, application of the February 15, 2007 grandfather date to deemed products violates the Due Process Clause and must be declared unconstitutional.

CONCLUSION

Based on the foregoing, this Court should either set aside and vacate the challenged portions of the Deeming Rule as applied to vaping products or otherwise declare TCA's February 15, 2007 grandfather date unconstitutional.

Respectfully submitted,

/s/ Eric P. Gotting
Eric P. Gotting (Bar No. 456406)
Azim Chowdhury (Bar No. 986331)
KELLER AND HECKMAN LLP
1001 G Street, N.W., Suite 500 West
Washington, D.C. 20001
Telephone (202) 434-4100
Facsimile (202) 434-4646
gotting@khlaw.com
chowdhury@khlaw.com

CERTIFICATE OF SERVICE

I hereby certify that on July 25, 2016, the foregoing document was electronically filed with the Clerk of the Court using CM/ECF. I also certify that the foregoing document is being served on all counsel of record via transmission of notices of electronic filing generated by CM/ECF.

*/s/ Eric P. Gotting*_____