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

| | | |
|---|---|---|
| NICOPURE LABS, LLC,<br><br>Plaintiff,<br><br>v.<br><br>FOOD AND DRUG ADMINISTRATION, *et al.*,<br><br>Defendants. | ) | Civil Action No. 16-0878 (ABJ) |
| RIGHT TO BE SMOKE-FREE COALITION, *et al.*,<br><br>Plaintiffs,<br><br>v.<br><br>FOOD AND DRUG ADMINISTRATION, *et al.*,<br><br>Defendants. | ) | Civil Action No. 16-1210 (ABJ) |

## MEMORANDUM OPINION

An electronic cigarette, or "e-cigarette," is an electronic nicotine delivery device, comprised of a liquid, an atomizer or heating element that heats the liquid to create a vapor, and a battery that powers the heating element. Most liquids on the market contain nicotine.

On May 10, 2016, the Food and Drug Administration exercised its discretion to deem e-cigarettes to be "tobacco products" subject to the set of federal laws that govern the promotion and

marketing of conventional cigarettes.[1] Plaintiff Nicopure Labs, LLC, which manufactures the devices and the liquids, then brought this action against the FDA, the Acting Commissioner of Food and Drugs, and the Secretary of Health and Human Services, challenging the rule that announced the decision.[2] Nicopure claims that the deeming decision exceeded the agency's statutory authority under the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, *et seq.* ("FDCA"), as amended by the Family Smoking Prevention & Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1777 (2009) ("Tobacco Control Act" or "TCA"). Nicopure also contends that the deeming decision was arbitrary and capricious and should be set aside under the Administrative Procedure Act ("APA"), 5 U.S.C. § 706, and that several provisions of the Tobacco Control Act that now govern the vaping industry violate the company's First Amendment rights. Compl., *Nicopure Labs, LLC v. FDA*, 16–878 (ABJ) [Dkt. # 1] ("Nicopure Compl.").

In a separate action, the Right to be Smoke Free Coalition, American Vaping Association, Electronic Vaping Coalition of America, Georgia Smoke Free Association, Kentucky Vaping Retailers Association, Inc., Louisiana Vaping Association, Maryland Vaping Professionals, LLC, Ohio Vapor Association, Tennessee Smoke Free Association, and the New Jersey Retailers Coalition (collectively, "RSF"), filed their own challenge to the Deeming Rule on similar grounds.

---

1 *See* "Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products," 81 Fed. Reg. 28,974 (May 10, 2016) ("Deeming Rule"). The Court will refer to these products either as "e-cigarettes," "electronic nicotine delivery systems," or "ENDS." The products are known colloquially as "vaping" devices.

2 Nicopure's complaint named the former Commissioner of Food and Drugs, Robert Califf, and the former Secretary of Health and Human Services, Sylvia Matthews Burwell. Pursuant to Federal Rule of Civil Procedure 25(d), their successors, Commissioner of Food and Drugs Scott Gottlieb and Secretary of Health and Human Services Thomas E. Price have been automatically substituted as defendants.

Compl., *RSF v. FDA*, 16–1210 (ABJ) [Dkt. # 1] ("RSF Compl."). The Court consolidated the two cases, Order (June 28, 2016) [Dkt. # 19], and both sides have filed motions for summary judgment. After considering the record, the points and authorities set forth in the briefs submitted by both sides and the amici, and the arguments presented at a hearing on the motions, the Court will uphold the Deeming Rule.[3]

The Court wishes to reassure the many worried vapers who followed these proceedings closely that this case is not about banning the manufacture or sale of the devices. That is not what the Deeming Rule does or what it was intended to accomplish. In the Deeming Rule, the FDA simply announced that electronic cigarettes, or electronic nicotine delivery systems ("ENDS") would be subject to the same set of rules and regulations that Congress had already put in place for conventional cigarettes.

---

3 On July 8, 2016, Nicopure filed its motion for summary judgment. Nicopure Labs, LLC's Mot. for Summ. J. [Dkt. # 20] ("Nicopure Mot."); Mem. of P. & A. in Supp. of Nicopure's Mot. [Dkt. # 20-1] ("Nicopure Mem."). RSF filed its motion for summary judgment on July 25, 2016, joining in Nicopure's arguments concerning the issues raised in both complaints, and focusing on the issues unique to its motion. Pl. Trade Assocs.' Mot. for Summ. J. [Dkt. # 21] ("RSF Mot."); Mem. of P. & A. in Supp. of RSF's Mot. [Dkt. # 21-1] ("RSF Mem."). The government filed an opposition to both motions, as well as a cross-motion for summary judgment, on August 17, 2016. Defs.' Cross-Mot. for Summ. J. [Dkt. # 43] ("Defs.' Cross-Mot."); Mem. in Opp. to Pls.' Mots. for Summ. J. & in Supp. of Defs.' Cross-Mot. [Dkt. # 43] ("Defs.' Cross-Mem."). Plaintiffs jointly opposed the cross-motion and replied in support of their motions on August 26, 2016, Pls.' Joint Mem. in Opp. to Defs.' Cross-Mot. & Reply in Supp. of Pls.' Mots. for Summ. J. [Dkt. # 46] ("Pls.' Reply"), and defendants filed their cross-reply on September 9, 2016. Reply in Supp. of Defs.' Cross-Mot. [Dkt. # 48] ("Defs.' Cross-Reply"). The Court also received *amicus curiae* submissions from a number of groups in support of plaintiffs: Brief of Amicus Curiae Smoke-Free Alternatives Trade Ass'n in Supp. of Pl.'s Mot. [Dkt. # 30]; Brief of Amicus Curiae the Nat'l Center for Public Policy Research, and TechFreedom in Supp. of Pls. [Dkt. # 37]; Brief Amicus Curiae of the Vape a Vet Project in Supp. of Pls. [Dkt. # 39]; Brief of Amici Curiae Clive Bates & Fifteen Others in Supp. of Pls.' Mot. [Dkt. # 41]. And it received an *amicus curiae* submission from the Campaign for Tobacco-Free Kids and a number of other public health organizations in support of defendants. Brief of Amici Curiae Public Health Orgs. in Supp. of Defs.' Cross-Mot. [Dkt. # 45]. The Court held a hearing on the cross-motions on October 11, 2016. Min. Entry (Oct. 11, 2016); Tr. of Mots. Hr'g [Dkt. # 50] ("Hr'g Tr.").

The Rule requires manufacturers to subject their products to review before marketing them, to tell the truth when making any claims about their health benefits, and to warn consumers about the dangers of nicotine when offering a means to deliver the substance to consumers. In short, the manufacturers of e-cigarettes are now required to tell the 30 million people who use the devices what is actually in the liquid being vaporized and inhaled.

This case does not pose the question – which is better left to the scientific community in any event – of whether e-cigarettes are more or less safe than traditional cigarettes. The Rule did not purport to take the choice to use e-cigarettes away from former smokers or other adult consumers; the issue is whether the FDA has the authority to require that the choice be an informed one.

In the 2009 Tobacco Control Act, Congress mandated that "tobacco products" would be regulated by the Secretary of HHS, and it stated that the provisions of the statute would apply not only to cigarettes, but to other tobacco products that the Secretary deemed to be subject to the law in the future. In the rule in question in this case, the FDA exercised its discretion under the Act to deem e-cigarettes to be tobacco products subject to regulation under the Federal Food, Drug, and Cosmetic Act and the Tobacco Control Act. The agency unquestionably had the power to do so; indeed, the plaintiffs who brought this lawsuit and submitted 235 pages of argument to the Court do not challenge that general proposition even though they maintain that the agency should have taken a different approach to the task.

In the first portion of the case, though, plaintiffs claim that the FDA exceeded the authority given to it by Congress because certain types of devices or liquids do not fall within the statutory definition of a tobacco product that may be deemed to be subject to the TCA. But that challenge is extremely narrow. The challenge to the FDA's authority is not about whether the FDA had the

legal authority to regulate the "cigalikes"[4] that comprise a large portion of the e-cigarette market – the plaintiffs in this case concede that the agency may regulate those products. And plaintiffs do not challenge whether the FDA had the legal authority to regulate "closed" vaping systems, which use e-liquid that comes in a disposable cartridge.

What plaintiffs do claim is that the agency exceeded its reach when it stated that the deeming rule also covers "open" vaping systems – those built with refillable cartridges that hold the liquid. Plaintiffs do not object to the regulation of all open system devices; they do not question the agency's power to regulate open vaping systems that are sold packaged together with liquid containing nicotine or tobacco flavor. What plaintiffs contend is that the agency could not lawfully undertake to regulate any open devices sold empty and on their own without any liquid, and that it had no authority to regulate e-liquids that do not contain nicotine. Nicopure Compl. ¶¶ 21, 34; RSF Compl. ¶¶ 43, 111–17. However, the FDA has plainly stated that the rule does not cover e-liquids that do not contain, or are not derived from, nicotine or tobacco, unless those liquids are reasonably intended to be used with nicotine-containing liquids.

The Court concludes that the agency acted within the scope of its statutory authority: it was legally permitted to regulate that category of liquids, and to consider a refillable electronic nicotine delivery system to be a "component" of a tobacco product and therefore subject to regulation.

Plaintiffs also ask the Court to find that it was arbitrary and capricious to subject electronic cigarette and liquid manufacturers to burdensome premarket review and labeling requirements,

4 The term "cigalikes" refers to e-cigarettes that are designed to look like a traditional cigarette, with a small built-in cartridge containing pre-filled liquid. RSF Compl. ¶ 22. The parties refer to these devices as "closed systems," because the consumer cannot refill the liquid cartridge. *See id.*; Nicopure Compl. ¶ 4.

and that the cost-benefit analysis underlying the deeming decision was deficient. They also object to a number of the marketing restrictions triggered by the deeming decision on constitutional grounds.

It bears repeating that the provisions the plaintiffs find most objectionable were not crafted by the FDA as part of the Deeming Rule. Instead, they are requirements of the Tobacco Control Act that was enacted by Congress. Congress gave the FDA broad authority to deem new products to be "tobacco products" subject to that existing statutory regime, and the Court finds that it was not arbitrary and capricious for the agency to decide to take that action with respect to e-cigarettes.

This opinion will lay out the reasons for the Court's conclusions, and it will also explain why the new rules being applied to e-cigarettes do not violate the First or the Fifth Amendments to the Constitution, and why there was no requirement that the agency undertake the sort of formal cost-benefit analysis that plaintiffs claim was omitted here.

When all is said and done, the Court will grant the agency's cross-motion for summary judgment, and it will deny plaintiffs' motions for summary judgment.[5]

5 On June 8, 2017, the parties filed a joint notice alerting the Court that "the FDA has announced that it is deferring enforcement of all future compliance deadlines under the Deeming Rule for three months," in order to give "new leadership personnel at the Department and Health and Human Services and the FDA an opportunity to more fully consider the issues raised by the deeming rule." Joint Notice [Dkt. # 54]. While the Right to be Smoke Free Coalition believes that the Court should withhold its decision on the pending cross-motions until the agency's review is complete, *id.* at 2, no party has moved to stay the action, and nothing in this opinion prohibits the FDA from continuing to work with industry representatives to establish a mutually acceptable schedule for the implementation of the Rule. This opinion will refer to the compliance deadlines that are set out in the Rule itself, notwithstanding the fact that some of those deadlines have been extended.

## TABLE OF CONTENTS

## BACKGROUND

### I. Statutory Background – the Relevant Provisions of the Tobacco Control Act

The Tobacco Control Act was enacted in 2009.[6] Congress introduced the legislation by setting out forty-nine findings related to the public health risks posed by the use of tobacco products, and products containing nicotine in particular:

- "A consensus exists within the scientific and medical communities that tobacco products are inherently dangerous and cause cancer, heart disease, and other serious adverse health effects," TCA § 2(2);
- "Nicotine is an addictive drug," *id.* § 2(3);
- "Tobacco is the foremost preventable cause of premature death in America," *id.* § 2(13);
- "It is in the public interest for Congress to adopt legislation to address the public health crisis created by actions of the tobacco industry," *id.* § 2(29);

6 The FDA has engaged in previous attempts to regulate the tobacco industry. In 1996, it promulgated a rule that concluded that nicotine was a "drug" subject to the provisions of the Federal Food, Drug, and Cosmetic Act. *See* 61 Fed. Reg. 44619 (1996). But the Supreme Court rejected the agency's interpretation in *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000). The Court concluded that, in determining that nicotine was a "drug," the FDA had exceeded its statutory authority, and the Court struck down the regulation. *Id.* at 125–26. In 2009, Congress responded to the Court's decision by passing the Tobacco Control Act.

- Because the only known safe alternative to smoking is cessation, interventions should target all smokers to help them quit completely," *id.* § (2)(34).

In its findings, Congress emphasized the harms that arise when children use tobacco products, and the associated dangers of tobacco-related marketing to minors:

- "The use of tobacco products by the Nation's children is a pediatric disease of considerable proportions that results in new generations of tobacco-dependent children and adults," TCA § 2(1);

- "Virtually all new users of tobacco products are under the minimum legal age to purchase such products," *id.* § 2(4);

- "Tobacco advertising and marketing contribute significantly to the use of nicotine-containing tobacco products by adolescents," *id.* § 2(5);

- "Because past efforts to restrict advertising and marketing of tobacco products have failed adequately to curb tobacco use by adolescents, comprehensive restrictions on the sale, promotion, and distribution of such products are needed," *id.* § 2(6);

- "Children, who tend to be more price sensitive than adults, are influenced by advertising and promotion practices that result in drastically reduced cigarette prices," *id.* § 2(24).

Congress also made specific findings concerning the impact of what the statute calls "modified risk statements" – manufacturers' statements that certain products might reduce the risks associated with nicotine or tobacco – including labels announcing that a tobacco product is "low tar" or "light":

- "Unless tobacco products that purport to reduce the risks to the public of tobacco use actually reduce such risks, those products can cause substantial harm to the public health," TCA § 2(37);

- "The only way to effectively protect the public health from the dangers of unsubstantiated modified risk tobacco products is to empower the Food and Drug Administration to require that products that tobacco manufacturers sold or distributed for risk reduction be reviewed in advance of marketing, and to require that the evidence relied on to support claims be fully verified," *id.* § 2(43).

Finally, the statute recognizes that the FDA:

> [I]s a regulatory agency with the scientific experience to identify harmful substances in products to which consumers are exposed, to design standards to limit exposure to those substances, to evaluate scientific studies supporting claims about the safety of products, and to evaluate the impact of labels, labeling, and advertising on consumer behavior in order to reduce the risk of harm and promote understanding of the impact of the product on health.

*Id.* § 2(44).

### A. The Deeming Provision and the Definition of "Tobacco Product"

In light of those findings, Congress mandated in section 901 of the TCA that "[t]obacco products . . . shall be regulated by the Secretary [of Health and Human Services]." TCA § 901, *codified at* 21 U.S.C. § 387a. This unequivocal assignment of responsibility goes on to provide:

> This chapter shall apply to all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco **and to any other tobacco products that the Secretary by regulation deems to be subject to this chapter**.

*Id.*, *codified at* 21 U.S.C. § 387a(b) (emphasis added).

Congress then amended the definitions section of the Federal Food, Drug, and Cosmetic Act to define the term "tobacco product." TCA § 101. For purposes of the TCA, a "tobacco product" is:

> any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product).

21 U.S.C. 321(rr)(1). Neither the TCA nor the FDCA further defines the terms "component," "part," or "accessory."

### B. Premarket Review

In the TCA, Congress also imposes a number of regulatory requirements on all tobacco products. First, the statute requires that all "new tobacco products" must receive FDA approval before they may be introduced or delivered into interstate commerce. TCA § 910; 21 U.S.C. § 387j(a). The statute defines the term "new tobacco product" as "any tobacco product (including

those products in test markets) that was not commercially marketed in the United States as of February 15, 2007." *Id.* The law provides two main "pathways" to FDA approval: the less onerous "substantial equivalence" pathway, and the more demanding "premarket review" pathway.[7]

**1. The Substantial Equivalence Pathway**

One way to get a new tobacco product approved is to show that it is "substantially equivalent" to an existing tobacco product. 21 U.S.C. § 387j. The existing or "predicate" product to be used for comparison purposes must have been "commercially marketed . . . in the United States as of February 15, 2007." 21 U.S.C. § 387j(a)(2)(A)(i)(I).

To invoke the substantial equivalence or SE pathway, the sponsor of a new tobacco product must file a report demonstrating that the product is substantially equivalent to a product that had already been commercially marketed as of the February 2007 grandfather date. 21 U.S.C. § 387j(b). A new tobacco product is substantially equivalent to the predicate tobacco product if it:

> (i) has the same characteristics of the predicate tobacco product; or
>
> (ii) has different characteristics and the information submitted [in the substantial equivalence report] contains information . . . that demonstrates that it is not appropriate to regulate the product . . . because the product does not raise different questions of public health.

7 There is a third pathway – the "substantial equivalence exception" pathway, *see* 21 U.S.C. § 387j(a)(3)(A)(i)–(iii) – but that pathway is not implicated by the challenges brought in this case.

21 U.S.C. § 387j(a)(3)(A).[8] If the FDA concludes that the new tobacco product is substantially equivalent to the predicate tobacco product under either provision, it must issue an order allowing the product to be commercially marketed. 21 U.S.C. § 387j(c).

**2. The Premarket Review Process**

If a manufacturer of a new product cannot invoke the substantial equivalence pathway – because there was no predicate product on the market as of February 15, 2007 – it must obtain approval from FDA before it can market the product. *See* 21 U.S.C. 387j(a)(2). The sponsor of the new tobacco product must submit a detailed application that includes: "full reports of all information, published or known to, or which should reasonably be known to, the applicant, concerning investigations which have been made to show the health risks of such tobacco product and whether such tobacco product presents less risk than other tobacco products," and "a full statement of the components, ingredients, additives, and properties, and of the principle or principles of operation, of such tobacco product." 21 U.S.C. § 387j(b)(1).[9]

The FDA must either approve or deny a premarket review application within 180 days. 21 U.S.C. § 387j(c)(1)(A). A denial may only be based on one of the four reasons set forth in the statute: (1) the applicant has failed to show that the marketing of the product is appropriate for public health; (2) the manufacturing, processing, or packing process does not conform to statutory

8 The term "characteristics" is defined by the TCA to mean "the materials, ingredients, design, composition, heating source, or other features of a tobacco product." 21 U.S.C. § 387j(a)(3)(B).

9 Plaintiffs refer to these applications by the acronym "PMTA," or "premarket tobacco application." *See* Nicopure Compl. ¶ 38; RSF Compl. ¶ 34. To avoid confusion, the Court will refer to this process as "premarket review," and it will not use the acronym.

requirements; (3) the label is false or misleading; or (4) the application does not conform with the standards set for tobacco products in 21 U.S.C. § 387g. 21 U.S.C. § 387j(c)(2).[10]

### C. Ban on Distribution of Free Samples

In the TCA, Congress also specifically instructed the agency to regulate the distribution of free samples of tobacco products. TCA § 102. The statute directed the Secretary of Health and Human Services to reissue a 1996 final rule no sooner than 180 days after June 22, 2009, and it required that the rule amend the Federal Register to provide that "no manufacturer, distributor, or retailer may distribute or cause to be distributed any free samples of cigarettes, smokeless tobacco, or other tobacco products (as that term is defined in section 201 of the [FDCA])." 21 U.S.C. § 387a–1. Congress directed the agency to permit the distribution of free samples of smokeless tobacco "in a qualified adult-only facility,"[11] but it also demanded that the agency develop clear rules governing certain public events: no free samples of smokeless tobacco may be distributed "at any football, basketball, baseball, soccer, or hockey event or any other sporting or entertainment event determined by the Secretary to be covered by this subparagraph." *Id.* § 387a–1(2)(G).

---

10 The section of the TCA that provides standards for tobacco products indicates that the Secretary of HHS "may adopt tobacco product standards" in addition to those set forth by statute "if the Secretary finds that a tobacco product standard is appropriate for the protection of public health," and the statute provides factors for the Secretary to consider in making that determination. 21 U.S.C. § 387g(a)(3).

11 The statute defines "qualified adult-only facility" as "a facility or restricted area that": (1) requires appropriate authorities to check patrons' photo ID and verify their dates of birth; (2) does not sell, serve, or distribute alcohol; (3) is not located immediately across from a space used for youth-oriented marketing; (4) is a temporary structure, operated for the purpose of distributing free samples of smokeless tobacco; (5) is enclosed by a barrier; and (6) does not display any advertising or brand names. 21 U.S.C. 387a–1(a)(2)(G).

The agency did as Congress required. On March 19, 2010, the FDA promulgated a rule entitled "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents," 75 Fed. Reg. 13,225-03 (Mar. 19, 2010). The rule, which is now codified at 21 C.F.R. part 1140, contains the required language. *See* 21 C.F.R. § 1140.16.

**D. Ban on Modified Risk Statements**

As part of the regulatory regime imposed on tobacco products in the TCA, Congress also addressed manufacturers' attempts to market certain products as being less harmful to health than other tobacco products. By amending section 911 of the FDCA, the TCA prohibits the introduction of "any modified risk tobacco product" into interstate commerce unless that product has been pre-cleared by the FDA. TCA § 101; 21 U.S.C. § 387k(a). A "modified risk tobacco product" is defined first as "any tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products." 21 U.S.C. § 387k(b)(1). Second, the definition applies to a product:

> (i) the label, labeling, or advertising of which represents explicitly or implicitly that –
>
> (I) the tobacco product presents a lower risk of tobacco-related disease or is less harmful than one or more other commercially marketed tobacco products;
>
> (II) the tobacco product or its smoke contains a reduced level of a substance or presents a reduced exposure to a substance; or
>
> (III) the tobacco product or its smoke does not contain or is free of a substance;
>
> (ii) the label, labeling, or advertising of which uses the descriptors "light", "mild", or "low" or similar descriptors; or
>
> (iii) the tobacco product manufacturer . . . has taken any action directed to consumers through the media or otherwise, other than by means of the tobacco product' s label, labeling, or advertising . . . that would be reasonably expected to result in consumers believing that the tobacco product or its smoke may present a lower risk of disease or is less harmful than one or more commercially marketed tobacco

> products, or presents a reduced exposure to, or does not contain or is free of, a substance or substances.

21 U.S.C. § 387k(b)(2)(A).

A manufacturer that intends to market a tobacco product with modified risk representations must file an application with the Secretary of HHS demonstrating that any claims "relating to the effect of the product on tobacco-related diseases and health-related conditions" are supported by the scientific literature. 21 U.S.C. § 387k(d). An application may be granted "only if the Secretary determines that the applicant has demonstrated that" the product will:

> (A) significantly reduce harm and the risk of tobacco-related disease to individual tobacco users; and
>
> (B) benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products."

21 U.S.C. § 387k(g)(1).

There is an exception to that provision, "if the Secretary makes the finding required" by subsection (g)(1), and makes several additional findings listed in subsection (g)(2), which requires proof that an order granting the application would promote the public health, is limited to a claim that a product "does not contain or is free of a substance or contains a reduced level of a substance, or presents a reduced exposure to a substance in tobacco smoke," "scientific evidence is not available and . . . cannot be made available without conducting long-term epidemiological studies," and the available data "demonstrates that a measurable and substantial reduction in morbidity or mortality among individual tobacco users is reasonably likely in subsequent studies." 21 U.S.C. 387k(g)(2)(A).[12]

---

12 The TCA contains other provisions that are important to the protection of public health, such as requiring that tobacco products bear a warning about the addictive nature of the products, *see* 21 U.S.C. § 387f(d)(1)–(2), and banning all flavored cigarettes, but those provisions are not relevant to the issues in this lawsuit.

## II. Regulatory Background

On May 10, 2016, the FDA exercised the authority Congress conferred upon it in 21 U.S.C. § 387a(b) to deem e-cigarettes (and other products not relevant to this opinion) to be "tobacco products" subject to the TCA. Deeming Rule, 81 Fed. Reg. at 28,976 ("Products that meet the statutory definition of 'tobacco products' include . . . ENDS (including e-cigarettes, e-hookah, e-cigars, vape pens, advanced refillable personal vaporizers, and electronic pipes"). The statute defines a "tobacco product" to include "any component, part, or accessory of a tobacco product," 21 U.S.C. § 321(rr), but the agency made clear that it was regulating only components and parts of the newly-deemed tobacco products, not their accessories. *See* Deeming Rule, 81 Fed. Reg. at 28,975. According to the FDA, the purpose of the Rule was twofold:

> (1) To deem all products that meet the definition of "tobacco product" under the law, except accessories of a newly deemed tobacco product, and subject them to the tobacco control authorities in chapter IX of the [FDCA] and FDA's implementing regulations; and (2) to establish specific restrictions that are appropriate for the protection of public health for the newly deemed tobacco products.

*Id.* The agency announced that the Rule would become effective ninety days after publication, and that the "newly deemed products will become subject to the same [FDCA] provisions and relevant regulatory requirements to which cigarettes . . . are subject." *Id.* at 28,976.

So, as of August 8, 2016, the manufacturers of ENDS products have been subject to the following two statutory provisions that govern cigarettes and other tobacco products:

- The prohibition of the sale or distribution of products bearing "modified risk" descriptors (such as "light," "low," or "mild") and claims, without FDA approval; and
- The prohibition on the distribution of free samples.

*Id.*

The TCA would have also authorized the agency to impose the premarket review requirement on manufacturers immediately, thereby halting sales until premarket applications were approved. *See* 21 U.S.C. § 387b (finding that a tobacco product is adulterated if it is required to have a premarket review order but does not have one); 21 U.S.C. § 331(a) (making it unlawful to introduce an adulterated tobacco product into interstate commerce). But as part of the Deeming Rule, the agency opted to implement the statutory requirement more gradually. The FDA announced that all new tobacco products will be required to submit applications for premarket authorization of their products through one of the pathways under a "staggered initial compliance period[] . . . followed by continued compliance periods for FDA review:"

> [M]anufacturers of all newly deemed, new tobacco products will have a 12-, 18- or 24-month initial compliance period in which to prepare applications for marketing authorization, as well as a 12-month continued compliance period after those dates in which to obtain authorization from FDA (resulting in total compliance periods of 24, 30, or 36 months). After the close of the continued compliance period, products will be subject to enforcement unless they are grandfathered or are the subject of a marketing authorization order.

Deeming Rule, 81 Fed. Reg. at 28,977–78.[13]

As part of the Deeming Rule, the FDA defined the terms that Congress failed to define in the TCA. The decision applies to "components" and "parts" of the newly deemed tobacco products, and the agency defined "component or part" as "any software or assembly of materials intended or reasonably expected: (1) [t]o alter or affect the tobacco product's performance, composition, constituents, or characteristics; or (2) to be used with or for the human consumption of a tobacco product." Deeming Rule, 81 Fed. Reg. at 28,975.[14] The agency provided a "nonexhaustive list of examples of components and parts used with electronic nicotine delivery systems (ENDS) (including e-cigarettes):"

> E-liquids; atomizers; batteries (with or without variable voltage); cartomizers (atomizer plus replaceable fluid-filled cartridge); digital

---

13 According to the Deeming Rule, the compliance periods depend on the pathway selected:

- A manufacturer that elects to submit a substantial equivalence report must do so by February 8, 2018 – eighteen months after the Rule became effective.
- A manufacturer submitting a premarket review application must do so by August 8, 2018 – twenty-four months after the Rule became effective.
- Under either approach, FDA will continue the compliance period for at least twelve months while the applications are considered, and, on a case-by-case basis, FDA will defer enforcement further – to give the agency the time it needs to review and determine whether to grant the requests.

Deeming Rule, 81 Fed. Reg. at 28,977–78. As the Court explained above, those compliance deadlines have since been extended by three months. *See* Joint Notice at 2.

14 While the Deeming Rule recognizes that the TCA uses the term "component" and "part" as distinct terms, the agency decided "for purposes of this final rule," to use "the terms 'component' and 'part' interchangeably and without emphasizing the distinction between the terms." Deeming Rule, 81 Fed. Reg. at 28,975. But the agency also noted that it may "clarify the distinctions between 'component' and 'part' in the future." *Id.*

> display/lights to adjust settings; clearomisers, tank systems, flavors, vials that contain e-liquid, and programmable software.

*Id.*[15]

The agency added that its definition of "component or part . . . excludes anything that is an accessory of a tobacco product," and it defined the term "accessory" to mean:

> any product that is intended or reasonably expected to be used with or for the human consumption of a tobacco product; does not contain tobacco and is not made or derived from tobacco; and meets either of the following: (1) [i]s not intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of a tobacco product or (2) is intended or reasonably expected to affect or maintain the performance, composition, constituents, or characteristics of a tobacco product but (i) solely controls moisture and/or temperature of a stored product or (ii) solely provides an external heat source to initiate but not maintain combustion of a tobacco product.

*Id.* The agency explained that it was declining to regulate accessories of the newly-deemed tobacco products because "accessories, unlike components or parts, are expected to have little direct impact on the public health." *Id.*

## III. Factual & Procedural Background

An e-cigarette, or electronic nicotine delivery device, is a battery powered device that heats an "e-liquid." An individual uses an e-cigarette by inhaling a vapor through the mouthpiece of a device that heats an "e-liquid," producing a vapor which the user inhales through a mouthpiece. Decl. of Jeffrey Stamler [Dkt. # 20-2] ("Stamler Decl.") ¶ 3. There are two main types of e-cigarettes on the market today: closed systems and open systems. *Id.* ¶ 8. In a closed system,

---

15 Plaintiffs complain that the FDA has defined "component or part" broadly enough to encompass even batteries and software when they argue that the agency exceeded its authority. *See, e.g.*, Nicopure Mem. at 1, 10. But in the Deeming Rule, the agency specifically explained that it intended "to limit enforcement of the premarket authorization provisions to finished tobacco products," "sealed in final packaging intended for consumer use." Deeming Rule, 81 Fed. Reg. at 28,995. Therefore, as became clear during the hearing, plaintiffs' claim is focused on the application of the Deeming Rule to open system devices and nicotine-free liquids, and any challenge to the application of the rule to batteries or other parts alone would be premature.

"the amount of liquid, flavor, and nicotine content (if any) is set by the manufacturer and cannot be altered by the consumer." *Id.* ¶ 9. Closed-system products are available in both a single-use, disposable form – also known as a "cigalike" – and a "rechargeable" form, into which a user can insert a "proprietary replacement cartridge" that contains the e-liquid. *Id.*; RSF Compl. ¶ 22. In an open system, the device has a chamber or cartridge that can be refilled, and "the consumer separately purchases e-liquid of his or her choosing." Stamler Decl. ¶ 10. Consumers can purchase e-liquid directly from a manufacturer, or they can go to a retail establishment called a "vape shop." *Id.*[16]

Nicopure is a limited liability company based in Florida. Nicopure Compl. ¶ 9. It "distributes battery-powered vaping devices under the Triton, Reactor, Tracer, and G6 brand names." *Id.* Triton, Reactor, and Tracer are all open-system devices, and G6 is a closed-system device. *Id.* "Nicopure also manufactures and distributes nicotine-and-non-nicotine 'e-liquid' under the Halo and eVo brand names." *Id.*

On May 10, 2016, Nicopure filed suit to challenge the legality of the Deeming Rule in four respects. In Count I, Nicopure alleges that the FDA exceeded its statutory authority in violation of sections 706(2)(A) and (C) of the APA when it enacted the Deeming Rule, because the Rule's "definition of 'tobacco product' and attendant proposed reach of its provisions is unambiguously foreclosed by, and is an unreasonable construction of, the text of the [TCA]." Nicopure Compl. ¶ 34. At the hearing, Nicopure focused in particular on the Rule's application to open system devices and nicotine-free e-liquids. Hr'g Tr. at 13:14–14:15. But it also objects to the application of the rule to "hundreds of products that are neither made nor derived from tobacco nor intended

16 There is evidence in the record that pen-like open-system devices are also frequently used for the purpose of smoking marijuana. *See* AR 15,582, 20,956–57.

for human consumption," such as "programmable software, batteries, digital display/lights, and glass or plastic vials." Nicopure Compl. ¶¶ 21, 26 (internal quotation marks and alterations omitted). Notably, Nicopure does not argue that the FDA did not have the legal authority to deem e-cigarettes to be tobacco products.

Nicopure's Count II alleges that it was arbitrary and capricious for the FDA to enact a rule that requires e-cigarette manufacturers to undergo premarket review. Nicopure Compl. ¶¶ 36–45. The company maintains that the Deeming Rule "fails to come to grips with the extraordinary burden this approval regime will have, both on manufacturers and on FDA itself," *id.* ¶ 41, and that the Rule "arbitrarily discounts the safety benefits offered by vaping devices and e-liquids." *Id.* ¶ 42. In Count III, Nicopure alleges that the FDA violated the APA in promulgating the Rule because its cost-benefit analysis was deficient. It alleges that the FDA "overstates the Rule's benefits, fails to quantify the Rule's benefits, understates the Rule's tremendous costs, and erroneously concludes that the Rule's benefits outweigh its costs." *Id.* ¶ 48. Finally, Count IV brings two challenges under the First Amendment: that the restriction on modified-risk statements prohibits manufacturers from making truthful and nonmisleading statements about their products, and that the ban on the distribution of free samples violates Nicopure's right to free speech. *Id.* ¶¶ 54–55. Nicopure requests that the Court vacate the Deeming Rule and declare it unlawful. *Id.*, Relief Requested.[17]

The Right to be Smoke Free plaintiffs filed their eight-count complaint about a month later, on June 20, 2016. RSF Compl. The plaintiffs are "national and state-wide trade associations representing the entire ENDS industry (i.e., manufacturers, distributors, and retailors)." *Id.* at 1.

17 The complaint also requested a preliminary injunction, but Nicopure never filed the necessary motion, *see* Local Civil Rule 65.1, and it later abandoned its request for preliminary relief. *See* Min. Entry (June 8, 2016).

In Count I, RSF asserts that the Deeming Rule is arbitrary and capricious because it did not establish a new "Grandfather Date for ENDS products," and because the agency failed to "apply its enforcement authority so that some ENDS manufacturers, including e-liquid companies, would have the opportunity to forego the [premarket review] pathway and avail themselves of the option to submit SE Reports." *Id.* ¶ 75. Count II alleges that the agency's "application of the [premarket] process to ENDS products violates the APA, and, thus, should be set aside as unlawful and enjoined." *Id.* ¶ 82. In Count III, RSF objects to the fact that the FDA, in implementing the TCA, treated e-cigarettes in the same manner that it treats cigarettes, and it posits that this "one size fits all" approach violates the due process and equal protection clauses of the Constitution. *Id.* ¶¶ 88–89. Count IV alleges that the ban on free samples violates the First Amendment and the APA. *Id.* ¶¶ 90–100. In Count V, RSF alleges that the TCA's modified risk provision requires "manufacturers of tobacco products to secure FDA's approval before making truthful, non-misleading claims about their products," in violation of the First Amendment and the APA. *Id.* ¶¶ 101–10. Count VI challenges the definition of "tobacco product" under the APA. *Id.* ¶¶ 111–17. Count VII alleges that the FDA violated the Regulatory Flexibility Act, 5 U.S.C. § 601, *et seq.*, by failing to conduct an appropriate cost-benefit analysis. *Id.* ¶¶ 117–27. And Count VIII alleges that the failure to conduct an appropriate cost-benefit analysis violates the APA. *Id.* ¶¶ 128–33. RSF requests a declaration that the Deeming Rule violates the APA, the Regulatory Flexibility Act, and the First Amendment, and that that the Tobacco Control Act itself violates the First Amendment, the Due Process Clause, and the Equal Protection Clause. *Id.*, Request for Relief.[18]

18 RSF also requested "[a] preliminary and permanent injunction," but they, too, failed to comply with Local Rule 65.1.

In light of the substantial overlap between the two sets of allegations, the Court consolidated the cases. *See* Order (June 28, 2016) [Dkt. # 19].

**STANDARD OF REVIEW**

Summary judgment is appropriate when the pleadings and evidence show that "there is no genuine dispute as to any material fact and [that] the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). However, in cases involving review of agency action under the Administrative Procedure Act, Rule 56 does not apply due to the limited role of a court in reviewing the administrative record. *Select Specialty Hosp.-Akron, LLC v. Sebelius*, 820 F. Supp. 2d 13, 21 (D.D.C. 2011). Under the APA, the agency's role is to resolve factual issues and arrive at a decision that is supported by the administrative record, and the court's role is to "determine whether or not as a matter of law the evidence in the administrative record permitted the agency to make the decision it did." *Occidental Eng'g Co. v. INS*, 753 F.2d 766, 769–70 (9th Cir. 1985), citing *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 415 (1971); *see also Richards v. INS*, 554 F.2d 1173, 1177 & n.28 (D.C. Cir. 1977).

In reviewing an agency's interpretation of a statute, courts use the two-step analysis outlined in *Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842–43 (1984). Step one involves determining whether Congress has spoken directly to the precise question at issue. If it has, "the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress," and that is the end of the matter. *Id.*; *Nat'l Treasury Emps. Union v. Fed. Labor Relations Auth.*, 392 F.3d 498, 500 (D.C. Cir. 2004). If the statute is silent or ambiguous on the question, *Chevron* instructs the Court to go on to a second step and determine "whether the agency's answer is based on a permissible construction of the statute." *Chevron*, 467 U.S. at 843. An agency's interpretation will warrant deference if it is reasonable. *Pauley v. BethEnergy Mines, Inc.*, 501 U.S. 680, 702 (1991).

## ANALYSIS

### I. FDA did not exceed its statutory authority when it deemed both open system vaping devices and nicotine-free liquids to be "tobacco products."

In Count I of Nicopure's complaint, and in Count VI of the RSF complaint, plaintiffs challenge FDA's statutory authority to regulate two specific vaping products: open-system vaping devices that do not contain any e-liquid, and e-liquids that do not contain nicotine or that are not made or derived from tobacco. *See* Nicopure Compl. ¶¶ 33–34; RSF Compl. ¶¶ 111–17; Nicopure Mem. at 9–14.

Congress mandated in the TCA that "tobacco products . . . shall be regulated by the Secretary," and it made clear that its mandate applied not only to "all cigarettes, cigarette tobacco, roll your own tobacco, and smokeless tobacco," but also to "any other tobacco products that the Secretary by regulation deems to be subject" to its provisions. 21 U.S.C. § 387a. Congress defined "tobacco product" to include:

> any product made or derived from tobacco that is intended for human consumption, *including any component, part, or accessory of a tobacco product* (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product).

21 U.S.C. § 321(rr)(1) (emphasis added).

Nicopure argues that its "open-system vaping devices (and their constituent parts)" are not "tobacco products" because they are "neither 'made or derived from tobacco,' nor intended for human consumption[,]" and that Nicopure's "non-nicotine containing e-liquids are not 'made or derived from tobacco.'" Nicopure Mem. at 9.[19] The FDA takes the position that all of these items

19 Throughout its pleadings in this case, Nicopure repeatedly quotes just a portion of the statutory definition of "tobacco product" in this manner and omits the portion that includes any "component, part, or accessory" of a tobacco product. *See e.g.*, Nicopure Mem. at 1 ("Congress expressly defined 'tobacco product' as a product made or derived from tobacco and intended for human consumption. The majority of Nicopure's products are neither."). This leaves a misleading impression and the deliberate excision undercuts the persuasive force of plaintiff's arguments.

are "components" and "parts" of tobacco products and that therefore, they are covered by the statutory definition. The Court finds that the FDA was well within its statutory authority to regulate the narrow set of products at issue in this case.

### A. The D.C. Circuit has not yet decided the issue.

At the outset, defendants argue that judgment should be entered in their favor because the D.C. Circuit already ruled on the legality of the regulation of e-cigarettes in *Sottera, Inc. v. FDA*, 627 F.3d 891 (D.C. Cir. 2010). While it is true that the Court of Appeals addressed the issue of the regulation of some electronic cigarettes in that opinion, it did not decide the precise issues presented in this lawsuit.

The plaintiffs in *Sottera* manufactured what are referred to in this case as closed-system e-cigarettes: the Court described the products at issue as "battery-powered products that allow users to inhale nicotine vapor without fire, smoke, ash, or carbon monoxide" that were "[d]esigned to look like a traditional cigarette." *Id.* at 893. After the agency blocked the importation of plaintiffs' products because they "appeared to be adulterated, misbranded, or unapproved drug-device combinations under the FDCA," plaintiffs sought a preliminary injunction, seeking a ruling that their products could only be regulated under the TCA, and not under the FDCA. *Id.*

The D.C. Circuit held that while the "FDA cannot regulate customarily marketed tobacco products under the FDCA's drug/device provisions . . . it can regulate tobacco products marketed for therapeutic purposes under those provisions, and . . . it can regulate customarily marketed tobacco products under the [TCA]." *Id.* at 898. Thus, at the urging of the e-cigarette industry, the Court recognized that "the FDA has authority under the [TCA] to regulate electronic cigarettes, enabling it to mitigate or perhaps extinguish any harm to the public health." *Id.*

While the decision is an important part of the legal backdrop of this case, the *Sottera* Court's rejection of the drug/device provisions of the FDCA as a basis to regulate e-cigarettes does not answer the questions posed here: whether a particular category of ENDS products can be regulated as "components or parts" of tobacco products. Defendants note that the only difference between the products at issue in *Sottera* and the products sold by plaintiffs is the fact that plaintiffs manufacture open-system vaping devices. Defs.' Cross-Mem. at 24. And the agency suggests that the Court should not be swayed by what it sees as a change in position by the industry:

> Having insisted in *Sottera* that e-cigarettes are regulable as tobacco products, manufacturers cannot now avoid that conclusion simply by making their products refillable. Indeed, while the question presented in *Sottera* was whether e-cigarettes should be regulated as drugs/devices or instead as tobacco products, the choice Plaintiffs offer here is markedly different: whether refillable e-cigarettes should be regulated as tobacco products, or, as Plaintiffs urge, not at all.

*Id.* at 24–25. But plaintiffs have conceded that most ENDS products may be lawfully regulated under the TCA, and notwithstanding *Sottera*, the Court must go on to utilize the *Chevron* analysis to determine, as a matter of first impression, whether the agency has interpreted the statute properly.

**B. The FDA has the statutory authority to regulate open-system vaping devices.**

The threshold determination – whether the agency's reading of "component or part" to include empty open vaping devices, or nicotine-free liquids sold separately, is consistent with the TCA – turns on "whether Congress has directly spoken to the precise question at issue." *Chevron*, 467 U.S. at 842.

The D.C. Circuit has explained:

> Under the first step of *Chevron*, the reviewing court "must first exhaust the traditional tools of statutory construction to determine whether Congress has spoken to the precise question at issue." The traditional tools include examination of the statute's text, legislative history, and structure, as well as its purpose.

*Bell Atl. Tel. Cos. v. FCC*, 131 F.3d 1044, 1047 (D.C. Cir. 1997), quoting *Nat. Res. Def. Council v. Browner*, 57 F.3d 1122, 1125 (D.C. Cir. 1995). The court is required to utilize these methods to determine whether Congress has "unambiguously foreclosed the agency's statutory interpretation." *Catawba Cty. v. EPA*, 571 F.3d 20, 35 (D.C. Cir. 2009).

> Congress may have done so in one of two ways: either by prescribing a precise course of conduct other than the one chosen by the agency, or by granting the agency a range of interpretive discretion that the agency has clearly exceeded . . . And if the agency has either violated Congress's precise instructions or exceeded the statute's clear boundaries then, as *Chevron* puts it, "that is the end of the matter" – the agency's interpretation is unlawful.

*Vill. of Barrington v. Surface Transp. Bd.*, 636 F.3d 650, 659–60 (D.C. Cir. 2011).

Starting with the text, it is true that Congress did not specifically define the words "component" or "part" in the TCA. But "the absence of a statutory definition does not render a word ambiguous." *Nat. Res. Def. Council v. EPA*, 489 F.3d 1364, 1373 (D.C. Cir. 2007). In the absence of an express statutory definition, courts are simply bound to give the terms used in the statute their ordinary meaning. *Petit v. U.S. Dep't of Educ.*, 675 F.3d 769, 781 (D.C. Cir. 2012). The burden is on the plaintiffs challenging the agency interpretation to "do more than offer a reasonable, or even the best, interpretation" of the statute; plaintiffs must instead show "that the statute *unambiguously* forecloses the agency's interpretation." *Id.*, quoting *Vill. of Barrington*, 636 F.3d at 661. In other words, if a court determines "that statutory ambiguity has left the agency with a range of possibilities and that the agency's interpretation falls *within* that range, then the agency will have survived *Chevron* step one." *Vill. of Barrington*, 636 F.3d at 660.

The Court must therefore begin with the plain language of the TCA. *Lindeen v. SEC*, 825 F.3d 646, 653 (D.C. Cir. 2016), quoting *Cmty. for Creative Non-Violence v. Reid*, 490 U.S. 730,

739 (1989). The statutory definition of a "tobacco product" authorizes the FDA to extend the provisions of the TCA to cover:

> any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product).

21 U.S.C. § 321(rr)(1).

In exercising its deeming authority to regulate e-cigarettes under the TCA, the FDA defined the terms "component or part" together to mean: "any software or assembly of materials intended or reasonably expected: (1) to alter or affect the tobacco product's performance, composition, constituents, or characteristics; or (2) to be used with or for the human consumption of a tobacco product." Deeming Rule, 81 Fed. Reg. at 28,975. According to the FDA, applying this definition means that the term "tobacco product" covers not only all-in-one electronic nicotine delivery systems, but also empty open system devices and liquids sold separately, including nicotine-free liquids intended to be mixed with nicotine-based liquids. Defs.' Cross-Mem. at 25–40. Since the agency justifies these two applications of the statute on different grounds, and it has raised threshold jurisdictional issues with respect to the challenge to the regulation of e-liquids, this opinion will address the agency's authority to regulate the two challenged products separately.

**1. The FDA's characterization of an empty vaping device as a "component" of a tobacco product survives step one of the *Chevron* analysis.**

The FDA's approach to empty vaping devices is not inconsistent with the ordinary meaning of the terms "component" and "part" that are used in the statute, and therefore, it is not foreclosed by the TCA. To shed light on the ordinary meaning of an undefined statutory term, the Court turns to the dictionary. *See, e.g.*, *Taniguchi v. Kan Pac. Saipan, Ltd.*, 132 S. Ct. 1997, 2002 (2012).

The word "component" is defined in the Merriam Webster dictionary as "a constituent part," Component, Merriam-Webster Dictionary, http://www.merriam-webster.com/dictionary/component, and the dictionary offers the example of stereo components. *Id.* Similarly, the Oxford English Dictionary defines "component" to mean "[a] constituent element or part." Oxford English Dictionary, 2d ed. (1989). The word "part" is defined by Merriam-Webster as "an essential portion or integral element," Part, Merriam-Webster Dictionary, http://www.merriam-webster.com/dictionary/part, and by the Oxford English Dictionary as "[a] piece or section of something which together with another or others makes up the whole (whether actually separate from the rest or not)," and as "[a]n essential element; an integral portion of a larger whole." Oxford English Dictionary, 3d ed. (2005).[20]

The agency's interpretation is entirely consistent with the plain meaning of the statute: the device – which contains the heating element and the battery – and the liquid are the "components" of an electronic nicotine delivery system just as an amplifier and a speaker are "components" of a stereo system. And while a sophisticated audiophile might have some choices to make about what to include in a sound system today, the device plus the liquid are undeniably the two essential components of an open vaping system: a consumer cannot use a vaping device for its primary

20 The frequent appearance of the word "part" in the definition of "component" suggests that is was entirely appropriate for the FDA to consider them in tandem.

purpose without adding the liquid, and there is nothing to do with the liquid without the device. (Indeed, it might be fair to say that the device *is* the electronic nicotine delivery system.)[21]

Putting aside the dictionary, a better analogy might be that just as an empty fountain pen is obviously a "component" of an ink pen (or "writing system"), even when the ink is sold separately, and it is no less of a pen than a cartridge pen that comes packaged together with several disposable cartridges, so too the empty open device is a "component" of an electronic nicotine delivery system, particularly since plaintiffs agree that the device would constitute a tobacco product if it were simply packaged together with a few e-liquid cartridges. Hr'g Tr. at 14:22–15:5. There is no logic to plaintiffs' contention that the packaging should be dispositive, and the Court finds that the physical separation of the liquid from the device at the point of sale is of no significance. Both are "components."

---

21 To supplement the textual analysis, the FDA seeks to draw support from the legislative history of a related statute. It points out that when Congress authorized the Consumer Product Safety Commission to require that liquid nicotine containers be child resistant in the Child Nicotine Poisoning Prevention Act of 2015, Pub. L. No. 114-116, § 2(a), 130 Stat. 3 (2016), it expressly recognized FDA's authority to regulate e-cigarettes and their components, citing the FDCA, the TCA, and the then-pending Notice of Proposed Rulemaking concerning vaping products:

> Nothing in this Act shall be construed to limit or otherwise affect the authority of the Secretary of Health and Human Services to regulate, issue guidance, or take action regarding the manufacture, marketing, sale, distribution, importation, or packaging, including child-resistant packaging, of nicotine, liquid nicotine, liquid nicotine containers, electronic cigarettes, electronic nicotine delivery systems or other similar products that contain or dispense liquid nicotine, or any nicotine-related products . . .

*See* Defs.' Cross-Mem. at 29–30, citing Child Nicotine Poisoning Prevention Act of 2015, Pub. L. No. 114-116, § 2(b)(1), 130 Stat. 3 (2016). This provision in separate legislation does not provide powerful evidence of what Congress had in mind when it enacted the TCA, but its acknowledgement of the agency's power to regulate not just liquid nicotine and electronic cigarettes, but also nicotine delivery systems and "other similar products that contain *or dispense*" nicotine suggests that the FDA's reading of the statute is not inconsistent with Congressional intent.

Plaintiffs attempt to avoid this plain reading of the text of the statutory definition by pointing to the structure of the TCA. They argue that because Congress used the term "component" in other parts of the statute to "refer to items inseparable from the product made or derived from tobacco," and "not to refer to separate products not so made or derived," the vaping devices at issue here cannot be considered to be "components" or "parts." Nicopure Mem. at 11, citing *Japan Whaling Ass'n v. Am. Cetacean Soc'y*, 478 U.S. 221, 238–39 (1986) ("Without strong evidence to the contrary," the Supreme Court "doubt[s] that Congress intended the same phrase to have significantly different meanings in two adjoining paragraphs of the same subsection"). In other words, according to plaintiffs, any "component" or "part" referred to in the TCA must be inseparable from the whole notwithstanding the ordinary definitions of the terms. But a review of the statute does not bear this out.

Plaintiffs first point to 21 U.S.C. § 387(17), a provision that defines the term "smoke constituent" to include "any chemical or chemical compound in mainstream or sidestream tobacco smoke that either transfers from any component of the cigarette to the smoke or that is formed by the combustion or heating of tobacco, additives, or other component of the tobacco product." Nicopure Mem. at 11. They also cite 21 U.S.C. § 387d(a), which requires manufacturers to list "all ingredients . . . added by the manufacturer to the tobacco, paper, filter, or other part of each tobacco product." *Id.* And finally, plaintiffs rely on 21 U.S.C. § 387g(a)(1)(A), which prohibits "a cigarette or any of its component parts (including the tobacco, filter, or paper)" from containing flavors. Taking those portions of the statute together, plaintiffs argue that the context of the TCA as a whole supports their argument that the terms "component or part" must mean a part physically connected to the whole.

But "[t]o prevail on its *Chevron* Step One argument, [plaintiffs have] to do better than concoct an interpretation purportedly based on the statute's context. [Plaintiffs] 'must show that the statute unambiguously forecloses the [agency's] interpretation.'" *Pharm. Research & Mfrs. of Am. v. FTC*, 790 F.3d 198, 207 (D.C. Cir. 2015), quoting *Vill. of Barrington*, 636 F.3d at 661. Plaintiffs "context" argument fails to meet that standard. The three provisions cited do not prove plaintiffs' point because none specifically defines the terms "component" or "part," and each either uses the terms in passing, or simply lists examples of what components of a particular type of tobacco product might be. The fact that the components of a conventional cigarette may be physically connected to that item does not mean that the components of an entirely different sort of product must be.

Finally, the D.C. Circuit has directed reviewing courts to "exhaust the traditional tools of statutory construction," including examining a statute's purpose, when they embark on the "search for the plain meaning of the statute." *Bell Atl. Tel. Cos.*, 131 F.3d at 1047. Here, Congress specified that the purpose of the TCA was to give the agency flexibility in regulating tobacco products, and particularly those products that may be attractive to minors. The list of statutory purposes set out in the legislation includes: "to ensure that the Food and Drug Administration has the authority to address issues of particular concern to public health officials, especially the use of tobacco by young people and dependence on tobacco;" "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;" and "to impose appropriate regulatory controls on the tobacco industry." TCA §§ 3(2), (4), (8). These unequivocal statements of the intent behind the legislation support the Court's finding that the agency's commonsense interpretation is not inconsistent with the statutory definition of a tobacco product. Thus, the Court

finds that the FDA's conclusion that it has the authority to regulate open vaping systems, even if they are empty and packaged alone, is not precluded by the statute and survives analysis under the first step of the *Chevron* test.

**2. The FDA's interpretation is reasonable under *Chevron* step two.**

In the court's view, the ordinary terms "component" and "part" are not ambiguous, and the FDA's exercise of its deeming authority to cover the products at issue falls squarely within the limits of the statute. But to the extent the statute is ambiguous, for all of the same reasons, the agency's interpretation "is based on a permissible construction of the statute," *Chevron*, 467 U.S. at 843, and therefore, it "merits judicial deference." *Bell Atl. Tel. Cos.*, 131 F.3d at 1047.

The Court should "defer to the agency's permissible interpretation," so long as "the agency has offered a reasoned explanation for why it chose that interpretation." *Vill. of Barrington*, 636 F.3d at 660. At *Chevron* step two, a court "may not disturb an agency rule unless it is 'arbitrary or capricious in substance, or manifestly contrary to the statute.'" *Mayo Found. for Med. Educ. & Research v. United States*, 562 U.S. 44, 53 (2011), quoting *Household Credit Servs., Inc. v. Pfennig*, 541 U.S. 232, 242 (2004).

There is no linguistic or statutory basis for plaintiffs' contention that a component or part may only be regulated if it is "physically part of a product containing tobacco (or material derived from tobacco) when introduced into commerce." Pls.' Reply at 6; Nicopure Mem. at 10–12. Plaintiffs do not dispute that a vaping device can be regulated as a tobacco product when it comes all in one piece, or even in two pieces in one box. *See* Hr'g Tr. at 14:22–15:2 ("[Plaintiffs' counsel]: If it's sold in a kit with a nicotine-containing liquid, then that kit or that product that's being sold . . . would meet the definition of tobacco product because the product[] . . . includes the e-liquids that's got the nicotine derived from tobacco."). But the definition of "tobacco product"

is not limited to products made or derived from tobacco since it specifically includes "components" and "parts" of tobacco products. 21 U.S.C. § 321(rr)(1).

Plaintiffs object to the characterization of an empty ENDS device as a component on the basis that those devices are "separate consumer product[s] that contain[] neither tobacco nor anything derived from tobacco." *See* Nicopure Mem. at 10. But an empty open vaping system is not a generic consumer item with multiple potential functions, like a box or a bowl. The purpose of those items might not be evident until the consumer chooses to use them in a certain way. But an open-system vaping device is a unique item with a single function, and it is fundamental to the vaping process: you can't vape without it. Therefore, the FDA's interpretation of the term "component" to encompass an empty open system vaping device is based on a permissible construction of the TCA. *Chevron*, 467 U.S. at 843.

The Court reaches the same conclusion with respect to plaintiffs' challenge to the agency's treatment of e-liquids, but it must first address the jurisdictional questions raised by the defense.

### C. Plaintiffs have standing to challenge the application of the Rule to non-nicotine-based e-liquids, and their challenge is ripe, but the agency's interpretation passes muster under *Chevron*.

Plaintiffs challenge that portion of the Rule that purports to cover e-liquids that do not contain nicotine. In light of the definition of a tobacco product in section 321(rr)(1) of the TCA, the agency acknowledged in the Deeming Rule that it did not have the power to regulate e-liquids that are not made or derived from tobacco, or e-liquids that are not components or parts of a tobacco product. *See, e.g.*, Deeming Rule, 81 Fed. Reg. at 29,017. However, it stated its intention to regulate the entire line of e-liquid cartridges, "including cartridges that include varying degrees of nicotine or those that do not contain nicotine, if they meet the definition of component or part." *Id.* The FDA then advanced the position that an e-liquid without nicotine can be a "component" of a tobacco product under the TCA, and therefore subject to FDA regulation, "if it is intended or

reasonably expected to be used with or for the human consumption of a tobacco product (e.g., with liquid nicotine)." *Id.*[22] The Rule goes on to provide:

> FDA is not bound by the manufacturer or distributor's subjective claims of intent. Rather, FDA can consider the totality of the circumstances, including direct and circumstantial objective evidence, which encompasses a variety of factors such as the circumstances surrounding the distribution of the product or the context in which it is sold . . . and sales data.

*Id.* at 29,015.

Plaintiffs maintain that this aspect of the Rule contravenes the TCA, *see* Nicopure Mem. at 13–14, and before addressing the merits, defendants briefly argue that the Court lacks jurisdiction to hear this claim. They argue that plaintiffs lack standing because they have not alleged sufficient facts to demonstrate that their liquids are subject to the Rule. Defs.' Cross-Mem. at 33–35. Defendants also maintain that the claim is not ripe; they point out that plaintiffs do not yet know if the FDA will initiate enforcement proceedings against their non-nicotine-based e-liquids, and that, in light of the agency's stated intention to review nicotine-free e-liquids on a "case-by-case" basis, any challenge to that aspect of the regulation should wait until the agency initiates an enforcement proceeding. *Id.* at 35–37. Therefore, the Court must determine whether it has jurisdiction before it may go on to assess whether the agency's interpretation of the statute is reasonable.

---

22 As the agency explained at the hearing:

> So the rule doesn't purport to cover all nicotine-free e-liquids, it only purports to cover them under certain circumstances, and those are when the nicotine-free e-liquid is made or derived from tobacco. One example is a tobacco-flavored e-liquid, regardless of its nicotine content. Another example is if the nicotine-free e-liquid meets the definition of component or part. And so one example of that that the FDA gave is nicotine-free e-liquids that are intended to be mixed with liquid nicotine.

Hr'g Tr. at 30:15–31:7.

### 1. Plaintiffs have standing to challenge the application of the rulemaking to nicotine-free products because they manufacture those products.

Article III of the Constitution restricts the power of the federal courts to hear only "Cases" and "Controversies." U.S. Const. art. III, § 2, cl. 1. A federal court is "forbidden . . . from acting beyond its authority," *NetworkIP, LLC v. FCC*, 548 F.3d 116, 120 (D.C. Cir. 2008), and a court has "an affirmative obligation" to ensure that it has standing before reaching the merits of a dispute. *James Madison, Ltd. v. Ludwig*, 82 F.3d 1085, 1092 (D.C. Cir. 1996), quoting *Herbert v. Nat'l Acad. of Scis.*, 974 F.2d 192, 196 (D.C. Cir. 1992).

"The doctrine of standing gives meaning to these constitutional limits by 'identify[ing] those disputes which are appropriately resolved through the judicial process.'" *Susan B. Anthony List v. Driehaus*, 134 S. Ct. 2334, 2341 (2014) (alterations in original), quoting *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992); *see also Clapper v. Amnesty Int'l USA*, 133 S. Ct. 1138, 1146 (2013) ("'One element of the case-or-controversy requirement' is that plaintiffs 'must establish that they have standing to sue.'"), quoting *Raines v. Byrd*, 521 U.S. 811, 818 (1997). This "doctrine limits the category of litigants empowered to maintain a lawsuit in federal court to seek redress for a legal wrong." *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016).

"[T]he irreducible constitutional minimum of standing contains three elements." *Lujan*, 504 U.S. at 560. First, the plaintiff must have suffered an "injury in fact," or, in other words, "an invasion of a legally protected interest which is (a) concrete and particularized, and (b) actual or imminent." *Id.* "Second, there must be a causal connection between the injury and the conduct complained of," or, said another way, the injury alleged must be "traceable to the challenged action of the defendant." *Id.* Third, it must be likely that "the injury will be redressed by a favorable decision." *Id.* at 561.

Defendants argue that plaintiffs have not alleged sufficient facts to show that the regulation of nicotine-free liquids described in the Rule applies to their products, and that therefore, plaintiffs have failed to allege they will suffer any actual or imminent harm. They complain that "plaintiffs make no effort to explain how their nicotine-free e-liquids are manufactured, marketed, distributed, or sold," Defs.' Cross-Mem. at 34, and that plaintiffs "make no showing that the nicotine-free e-liquids they manufacture are . . . even subject to the deeming rule – by alleging, for example, that those e-liquids are intended to be mixed with liquid nicotine." *Id.* at 33.

Plaintiff Nicopure has supplied the Court with a declaration stating that it manufactures approximately 160 different kinds of nicotine-free e-liquid, *see* Stamler Decl. ¶ 14, and therefore, the Court finds that it has standing to challenge the agency's decision to regulate these products as part of the Rule. It is of little moment that plaintiffs have not specified whether their nicotine-free liquids are or are not intended to be mixed with liquid nicotine, since the agency has already specifically stated that it is not bound to take manufacturers at their word. Thus, under the terms of the Rule, plaintiffs could be subject to enforcement proceedings if they do not submit their nicotine-free e-liquids to the premarket review process. *See* 21 U.S.C. 387j(a)(2).

**2. Plaintiffs' challenge to the regulation of nicotine-free products is ripe.**

The Court also finds that plaintiffs' challenge to this aspect of the rule is ripe, notwithstanding the agency's assurances that, should plaintiffs violate the law, the agency would assess whether enforcement was appropriate "after a 'case-by-case' review," Defs.' Cross-Mem. at 36, quoting Deeming Rule, 81 Fed. Reg. at 29,032, which would "take into account 'the totality of the circumstances.'" *Id.*, quoting 81 Fed. Reg. at 29,015.

"The ripeness doctrine generally deals with when a federal court can or should decide a case. Part of the doctrine is subsumed into the Article III requirement of standing, which requires a petitioner to allege *inter alia* an injury in fact that is 'imminent' or 'certainly impending.'" *Am.*

*Petrol. Inst. v. EPA*, 683 F.3d 382, 386 (D.C. Cir. 2012). And "[e]ven if a case is 'constitutionally ripe,' . . . there may also be 'prudential reasons for refusing to exercise jurisdiction.'" *Id.*, quoting *Nat'l Park Hosp. Ass'n v. Dep't of Interior*, 538 U.S. 803, 808 (2003). As the D.C. Circuit has explained:

> The fundamental purpose of the ripeness doctrine is "to prevent the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies, and also to protect the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties."

*Sprint Corp. v. FCC*, 331 F.3d 952, 957 (D.C. Cir. 2003), quoting *Nat'l Park Hosp.*, 538 U.S. at 807–08. While the constitutional aspect of ripeness may involve the same impending injury-in-fact requirement that is necessary for standing, the prudential aspect of ripeness requires more: a court must "balance[] 'the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration.'" *Nat'l Treasury Emps. Union v. United States*, 101 F.3d 1423, 1427–28 (D.C. Cir. 1996), quoting *Abbott Labs. v. Gardner*, 387 U.S. 136, 149 (1967), and citing *Duke Power Co. v. Carolina Envtl. Study Grp., Inc.*, 438 U.S. 59, 81–82 (1978). The fitness of an issue for judicial decision depends on whether there are "contingent future events that may not occur as anticipated, or indeed may not occur at all." *Thomas v. Union Carbide Agric. Prods. Co.*, 473 U.S. 568, 580–81 (1985) (citations omitted).

In *Abbott Laboratories*, the Supreme Court considered two factors in evaluating whether a pre-enforcement challenge was ripe for adjudication: First, it considered whether "the issue tendered is a purely legal one," and second, it asked whether the issue presented was a "final agency action" under the APA. 387 U.S. at 149–50. "[P]urely legal claim[s]" are "presumptively reviewable." *Nat'l Ass'n of Home Builders v. U.S. Army Corps of Eng'rs* (*"NAHB"*), 417 F.3d 1272, 1282 (D.C. Cir. 2005), quoting *Nat'l Mining Ass'n v. Fowler*, 324 F.3d 752, 757 (D.C. Cir.

2003). And the D.C. Circuit has rejected the notion that a future exercise of agency discretion makes a purely legal claim unripe. *Id.*

Defendants argue that plaintiffs do not know whether the FDA will ever initiate enforcement proceedings against their non-nicotine-based e-liquids, and that in light of the agency's stated intention that it will review nicotine-free e-liquids on a "case-by-case" basis, any challenge to that aspect of the regulation should wait until the agency decides to initiate an enforcement proceeding. Defs.' Cross-Mem. at 35–37.

But that line of reasoning has been rejected by binding D.C. Circuit precedent. In *NAHB*, the plaintiffs challenged the issuance of certain permits by the Army Corps of Engineers under the Clean Water Act. *Id.* at 1274. The Army Corps was authorized by statute to issue permits either on a class-wide basis, or on a case-by-case basis. *Id.* The agency's regulations required that a "case-by-case" or "individual" permit be issued only after the agency completed a comprehensive procedure, which included "site-specific documentation and analysis, public interest review, public notice and comment, and, if necessary, a public hearing." *Id.* at 1275. Plaintiffs challenged the agency's issuance of particular class-wide permits, and argued that the agency had exceeded its statutory authority, and that it had acted in violation of the APA, when it issued certain regulations surrounding those permits. *Id.* at 1277. The district court dismissed the case, concluding that a plaintiff's challenge was not a final agency action "until [his] individual permit is rejected." *Id.* at 1278.

But the Court of Appeals reversed the judgment of the district court, noting that the question was better framed as a ripeness inquiry, and that the challenge was ripe for adjudication. *See id.* at 1281. Plaintiffs, the Court of Appeals explained, were challenging the Army Corps's "statutory authority . . . and that the Corps failed to offer a reasoned basis for their [decision]," and

it held that those "purely legal" issues were ripe for adjudication. *Id.* at 1281–82. As to the Army Corps's argument that its decision was not "fit for review because their applicability to a given activity remains within the Corps'[s] discretion," the Court of Appeals replied, "[w]e have already debunked this theory," and it noted that just because "the Corps retains some measure of discretion with respect to the [challenged decisions] does not make the [plaintiffs'] purely legal challenge unripe." *Id.* at 1282.

Plaintiffs here are in a similar posture to the plaintiffs in *NAHB*. The agency has indicated that its enforcement activities against manufacturers who produce non-nicotine based e-liquids will be undertaken on a case-by-case basis. Deeming Rule, 81 Fed. Reg. at 29,032. And while defendants ask the Court to wait until the agency decides to enforce the statute on a manufacturer of non-nicotine-based e-liquid, the Court can determine whether the statute authorizes the regulation of those products in the first instance. The question in this case is not about whether the regulation will apply to a particular nicotine-free e-liquid; the challenge is whether nicotine-free e-liquids can be regulated *at all*. There may very well be future litigation about whether the agency's case-by-case review was lawful – but that is not the challenge being brought in this case.

So the Court can determine under *Chevron* whether the nicotine-free e-liquids at issue are subject to regulation.

**3. The agency's interpretation of the definition of "tobacco product" to include certain non-nicotine-containing e-liquids meets the *Chevron* test.**

Nicopure challenges whether the agency can lawfully regulate nicotine-free e-liquids. *See* Nicopure Mem. at 9–14. Nicopure's CEO has averred that 83% of the company's products do contain nicotine, Stamler Decl. ¶ 14, so the challenge relates to a relatively small percentage of the liquids that Nicopure sells. The agency explains that the Deeming Rule only purports to regulate nicotine-free e-liquids in three circumstances: (1) when e-liquids claiming to be nicotine-free

actually contain high levels of nicotine, Defs.' Cross-Mem. at 37, quoting Deeming Rule, 81 Fed. Reg. at 29,034; (2) when the e-liquid is tobacco flavored – because that flavor is "made or derived from tobacco," *id.*, quoting Deeming Rule, 81 Fed. Reg. at 29,102; and (3) when the e-liquid is reasonably expected to be mixed with liquid nicotine – because those liquids would be "components or parts" of a tobacco product. *Id.*, citing Deeming Rule, 81 Fed. Reg. at 29,017. This approach comports with the statute.

There is no dispute in this case that e-liquids that are marketed as nicotine-free but that actually contain nicotine, and e-liquids that are tobacco-flavored, are clearly and unambiguously covered by the TCA's definition of "tobacco product," *Chevron*, 467 U.S. at 842, because both are "made or derived from tobacco." 21 U.S.C. § 321(rr)(1).[23] What Nicopure challenges is the FDA's authority to regulate those liquids that do not contain nicotine.[24]

---

23 *See* Hr'g Tr. at 10:1–6 (conceding that plaintiffs are not challenging the agency's authority to regulate closed cartridge systems where the liquid in the system is nicotine that is made or derived from tobacco); *id.* at 32:1–4 (not objecting to defendants' argument that the agency can regulate tobacco-flavored e-liquids).

24 While it may be true that some percentage of the Nicopure's products are not tobacco based and do not initially contain nicotine, *see* Stamler Decl. ¶ 6 ("Although some of Nicopure's e-liquid products contain nicotine, others do not."), any consumer who chooses to purchase a flavored liquid online – including fruit or dessert flavored items with youthful appeal such as "grape vape" or "cookie karma" – is immediately offered a choice to purchase the liquid at seven different levels of nicotine content, ranging from 0 milligrams per milliliter to 24 milligrams per milliliter. *See, e.g.*, https://www.halocigs.com/e-liquid/premium-flavors/. So even e-liquids that do not "contain" nicotine and sold with nicotine in them. Stamler avers that "of Nicopure's approximately 950 e-liquid SKU's, 83% contain nicotine. The remaining e-liquid SKU's do not contain nicotine and are not made or derived from tobacco." Stamler Decl. ¶ 14. But he does not specify what portion of its sales ultimately involve that relatively small percentage of nicotine-free liquids, and of those, which are sold to retail outlets where the nicotine can also be added, according to the users' individual specifications. Indeed, the declaration makes clear that Nicopure's open-system devices are popular "because of their flexibility and options." *Id.* ¶ 12.

The agency takes the position that it may lawfully regulate an e-liquid that does not contain nicotine as a "component" of a tobacco product where the e-liquid "is intended or reasonably expected to be used with or for the human consumption of a tobacco product (e.g., with liquid nicotine)." Deeming Rule, 81 Fed. Reg. at 29,017. The Court must give the term "component" its ordinary meaning, *Petit*, 675 F.3d at 781, and the burden is on the plaintiffs to show "that the statute *unambiguously* forecloses the agency's interpretation." *Id.*, quoting *Vill. of Barrington*, 636 F.3d at 661 (emphasis in original).

Plaintiffs advance the theory that because "Congress defined 'tobacco product' to mean a product 'made or derived from tobacco[,] FDA does not have license to extend that definition to products *not* made or derived from tobacco, regardless of the circumstances." Pls.' Reply at 8. But plaintiffs are ignoring the applicable half of the statutory definition. The agency is not relying on a showing that nicotine-free e-liquids are "made or derived from tobacco" to justify its authority to regulate them; it contends that a nicotine-free e-liquid is a "component" of a tobacco product which is comprised of several components. Deeming Rule, 81 Fed. Reg. at 29,017.

This interpretation is not inconsistent with the TCA. The statutory definition of a regulable "tobacco product" specifically includes any component of a tobacco product, 21 U.S.C. § 321(rr), and if an ENDS device with nicotine or a tobacco derivative in it is, as plaintiffs acknowledge, a tobacco product, then a nicotine-free liquid that gets added to the mix – to provide flavor or make the inhalation experience less harsh – becomes a "component" of the tobacco product when it is added.

So because plaintiffs have not met their burden to show "that the statute *unambiguously* forecloses the agency's interpretation," *Vill. of Barrington*, 636 F.3d at 661, the agency's

interpretation can be upheld at *Chevron* step one.[25] And plaintiffs have not proffered any reasons for why it would be an unreasonable interpretation at step two.

## II. The FDA's decision to deem e-cigarettes to be tobacco products comports with the APA.

In Count II of Nicopure's complaint, and in Count II of RSF's complaint, plaintiffs allege that the decision to subject companies to premarket review is arbitrary and capricious in violation of the Administrative Procedure Act. Nicopure Compl. ¶¶ 35–45; RSF Compl. ¶¶ 76–82. And in Count III of Nicopure's complaint and Count VIII of RSF's complaint, plaintiffs allege that the agency's cost-benefit analysis was unlawful because the agency failed to consider alternatives and failed to adequately quantify the costs and the benefits of the Deeming Rule. Nicopure Compl. ¶¶ 46–51; RSF Compl. ¶¶ 128–33.

Plaintiffs find fault in many aspects of the regulatory regime. But the requirements that plaintiffs claim are unreasonable flow automatically from the statute. Thus, the only issue to be resolved is whether the final agency action – the decision to deem ENDS products to be subject to the TCA – was arbitrary and capricious. The remainder of plaintiffs' concerns are better directed to Congress.

It is important to note at the outset that the decision to deem e-cigarettes to be tobacco products will not ban e-cigarettes from the market. It will unquestionably subject the products to heightened regulation, but the deeming decision does not – and could not – completely ban those products from the market. The question before the Court, therefore, is whether it was reasonable

---

25 Plaintiffs observe that under the terms of the statute, the agency may only regulate nicotine that is made or derived from tobacco, and that therefore, it cannot regulate products containing synthetic nicotine. Hr'g Tr. at 10:7–13; 11:10–17. But neither plaintiff seems to manufacture products that contain synthetic nicotine – nicotine that is made or derived in a laboratory or from other non-tobacco sources. *See id*. at 35:3–15. So the Court does not need to reach the issue of whether the agency may lawfully regulate e-liquids that contain synthetic nicotine.

for the agency to conclude that vaping should no longer be completely unregulated, given the marked increase in use, the absence of any regulation of the products and manufacturers in the market, and the potential for public harm given the known dangers of nicotine.

### A. Legal Standard

Under the Administrative Procedure Act, 5 U.S.C. § 701 *et seq.*, the agency's role is to resolve factual issues and arrive at a decision that is supported by the administrative record, and the court's role is to "determine whether or not as a matter of law the evidence in the administrative record permitted the agency to make the decision it did." *Occidental Eng'g Co.*, 753 F.2d at 769–70, citing *Overton Park*, 401 U.S. at 415; *see also Richards*, 554 F.2d at 1177 & n.28. A court must "hold unlawful and set aside agency action, findings, and conclusions" that are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," 5 U.S.C. § 706(2)(A), in excess of statutory authority, *id.* § 706(2)(C), or "without observance of procedure required by law," *id.* § 706(2)(D). However, the scope of review is narrow. *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). The agency's decision is presumed to be valid, *see Overton Park*, 401 U.S. at 415, and the court must not "substitute its judgment for that of the agency." *State Farm*, 463 U.S. at 43. A court must be satisfied, though, that the agency has examined the relevant data and articulated a satisfactory explanation for its action, "including a 'rational connection between the facts found and the choice made.'" *Alpharma, Inc. v. Leavitt*, 460 F.3d 1, 6 (D.C. Cir. 2006), quoting *State Farm*, 463 U.S. at 43.

### B. The APA dispute is justiciable.

While the APA allows for judicial review of agency decisions for "[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within

the meaning of a relevant statute," 5 U.S.C. § 702, agency action is unreviewable "to the extent that . . . agency action is committed to agency discretion by law." *Id.* § 701(a)(2). Judicial review is foreclosed where the relevant statute is "drawn so that a court would have no meaningful standard against which to judge the agency's exercise of discretion." *Heckler v. Chaney*, 470 U.S. 821, 830 (1985); *see also Sierra Club v. Jackson*, 648 F.3d 848, 855 (D.C. Cir. 2011); *Steenholdt v. FAA*, 314 F.3d 633, 638 (D.C. Cir. 2003). The Supreme Court has cautioned that this exception to the APA should be construed narrowly. *See Webster v. Doe*, 486 U.S. 592, 599 (1988) ("[S]ubsection (a)(2) applies 'in those rare instances where statutes are drawn in such broad terms that in a given case there is no law to apply.'"), quoting *Overton Park*, 401 U.S. at 410; *Barlow v. Collins*, 397 U.S. 159, 166 (1970) ("Preclusion of judicial review . . . is not lightly to be inferred."). The Court has recently cautioned that there is a "strong presumption" in favor of judicial review of administrative action, *Mach Mining, LLC v. EEOC*, 135 S. Ct. 1645, 1651 (2015), quoting *Bowen v. Mich. Acad. of Family Physicians*, 476 U.S. 667, 670 (1986), which can be rebutted where a "statute's language or structure demonstrates that Congress wanted an agency to police its own conduct." *Id.*

The agency argues that its decision to deem is so committed to agency discretion that it is unreviewable. Defs.' Cross-Mem. at 39–40. It points to the deeming provision of the TCA, *id.* at 39, which gives the Secretary of HHS the authority to apply the TCA's provisions "to any other tobacco products that the Secretary by regulation deems to be subject to [the TCA]," 21 U.S.C.§ 387a(b), and it argues that "Congress's choice of the deferential word 'deems' and the absence of any standard – beyond the requirement that the product meet the definition of a 'tobacco product' – demonstrate that Congress committed the exercise of this authority to the agency's broad discretion." Defs.' Cross-Mem. at 39.

The government relies primarily on *Webster v. Doe*, 486 U.S. 592 (1998) for the proposition that the Secretary's decision to "deem" is committed to agency discretion. *See* Defs.' Cross-Mem. at 7–8. In *Webster*, the Supreme Court reviewed a provision of the National Security Act of 1947, which provided that the Director of the CIA "may, in his discretion, terminate the employment of any officer or employee of the Agency whenever he shall deem such termination necessary or advisable in the interests of the United States." *Webster*, 486 U.S. at 594, quoting 50 U.S.C. § 403(c). The Court observed that Congress gave the CIA responsibility "to protect all sources of intelligence information from disclosure," and thus vested "extraordinary deference [in] the Director." *Id.* at 601. The Court concluded that because "[s]hort of permitting cross-examination of the Director concerning his views of the Nation's security and whether the discharged employee was inimical to those interests," there was "no basis on which a reviewing court could properly assess an Agency termination decision." *Id.* at 600.

The D.C. Circuit disagreed with government's reading of *Webster* in *Marshall County Health Care Authority v. Shalala*, 988 F.3d 1221 (D.C. Cir. 1993). In *Marshall County*, the government cited *Webster* for the proposition that it was the word "deem" in the National Security Act in *Webster* that made the Director's decision unreviewable. *See id.* at 1224. The Court of Appeals rejected that argument; it explained that that lack of justiciability in *Webster* stemmed not from the word "deem," but rather from the phrase "advisable in the interests of the United States." *Id.* And it noted that in *Webster*, "[t]he statute, after all, dealt with national security – an area in which the judiciary almost invariably defers to the executive branch." *Id.*

In this case, when the Secretary exercised the authority to "deem" e-cigarettes to be tobacco products, the agency was interpreting the statutory definition of "tobacco product." So while it is

true that the statute did not provide standards for when and how the agency was to exercise its discretion to deem, the Court concludes that the decision is reviewable.

However, the language of the deeming provision – with its use of the words "may" and "deem," is the kind of language that, even if judicial review is permitted, "fairly exudes deference." *Webster*, 486 U.S. at 600. And the Court of Appeals has reaffirmed that APA review in cases like this one should be undertaken with deference. *See Nuclear Energy Inst., Inc. v. EPA*, 373 F.3d 1251, 1289 (D.C. Cir. 2004) (advising that when a court reviews an agency's evaluation of "scientific data within its technical expertise," its review should be "extremely deferential"), quoting *Huls Am. Inc. v. Browner*, 83 F.3d 445, 452 (D.C. Cir. 1996). Courts review scientific judgments of the agency "not as the chemist, biologist, or statistician that [courts] are qualified neither by training nor experience to be, but as a reviewing court exercising [its] narrowly defined duty of holding agencies to certain minimal standards of rationality." *Ctr. for Biological Diversity v. EPA*, 749 F.3d 1079, 1087–88 (D.C. Cir. 2014) (quoting "[d]ecades of decisions" of the Court of Appeals on scientific deference), quoting *Ethyl Corp. v. EPA*, 541 F.2d 1, 36 (D.C. Cir. 1976). The Court's APA review must therefore be undertaken with that deference in mind.

### C. The FDA's decision to deem e-cigarettes to be tobacco products is reasonable and supported by the record.

The decision to deem e-cigarettes to be tobacco products is not arbitrary and capricious for a number of reasons. First and foremost, nicotine is indisputably harmful. Deeming Rule, 81 Fed. Reg. at 28,988 (describing nicotine as "one of the most addictive substances used by humans"). There is evidence in the record that e-cigarettes "may deliver as much nicotine as other tobacco products," *id.* at 29,029, 29,031, and even when they deliver less amounts of nicotine, "lower levels of nicotine . . . still have the potential to addict users." *Id.* at 29,031.

Second, the agency explained that "adolescents appear to be particularly vulnerable to the adverse effects of nicotine on the central nervous system," and that nicotine may have lasting effects on adolescent brain development. *Id.* at 29,029, 29,033. And the agency detailed the "alarming" rise in e-cigarette use by middle and high school students. *Id.* at 29,028. In particular, the agency cited data showing that "the rate of e-cigarette use" among high school students "increased from 1.7 percent in 2011 to 7.7 percent in 2013, and 2.7 percent of high school students who had never tried a cigarette indicated that they were considering using e-cigarettes in the next year." *Id.* While the agency acknowledged that "long-term studies are not yet available to determine whether these youth and young adults are only experimenting with tobacco use, becoming established ENDS users or dual users, or transitioning to combusted products," it also noted the absence of evidence that would enable it "to conclude that youth and young adults are using ENDS as a means to quit smoking." *Id.* The FDA also explained that "[r]esearchers noted that some teens are more likely to use e-cigarettes prior to combustible tobacco products for several reasons including the availability of e-cigarettes in flavors attractive to youth." *Id.* at 28,985.

Moreover, the increase in adolescent users is not the entire story. Among adults, the use of e-cigarettes has more than doubled between 2012 and 2014 – from 1.4 percent to 3.7 percent. *See* AR 23,871, AR 15,666. And the agency found that:

> [E]vidence from the most recent studies on ENDS use among young adults and adults indicates that among adults who had never smoked cigarettes, prevalence of ever e-cigarette use was highest among young adults aged 18 to 24 and decreased with increasing age. However, current cigarette smokers and recent former smokers (i.e., those who quit smoking within the past year) were more likely to use e-cigarettes than long-term former smokers (i.e., those who quit smoking more than 1 year ago) and adults who had never smoked. Current cigarette smokers who had tried to quit in the past year were also more likely to use e-cigarettes than those who had not tried to quit. It is noted that it cannot be determined by the research findings: (1) Whether former cigarette smokers who now exclusively use e-cigarettes would not have ceased smoking cigarettes regardless of e-cigarette use; and

> (2) whether the e-cigarette use preceded quitting or the quitting occurred first and then was followed by later e-cigarette use.

Deeming Rule, 81 Fed. Reg. at 28,985.

Furthermore, given the proliferation of these products, "[a]t present, there is significant variability in the concentration of chemicals amongst products – including variability between labeled content and concentration . . . and actual content and concentration." Deeming Rule, 81 Fed. Reg. at 28,984. In other words, the manufacturers, if they remain unregulated, are free to mislabel their products without consequence. *See id.* at 29,034; *id.* at 29,029 ("Absent a regulatory standard, FDA acknowledges that it may not be possible to account for the wide variability of concentrations of constituents in [e-cigarette] flavors."). So the agency concluded that requiring premarket review of e-cigarettes, and regulating modified-risk claims, would benefit public health.

In light of all of those findings, and in light of the deference that the Court must give the agency on APA review, the Court finds that there is a rational relationship between the facts found and the choice made. *See Alpharma*, 430 F.3d at 6. The Court's conclusion is buttressed by these Congressional findings in the TCA, which apply with equal force to the regulation of e-cigarettes:

- "Nicotine is an addictive drug," TCA § 2(3);
- "Virtually all new users of tobacco products are under the minimum legal age to purchase such products," *id.* § 2(4);
- "Tobacco advertising and marketing contribute significantly to the use of nicotine-containing products by adolescents," *id.* § 2(5);
- "Because past efforts to restrict advertising and marketing of tobacco products have failed adequately to curb tobacco use by adolescents, comprehensive restrictions on the sale, promotion, and distribution of such products are needed," *id.* § 2(6);
- "It is in the public interest for Congress to enact legislation that provides the Food and Drug Administration with the authority to regulate tobacco products and the advertising and promotion of such products," *id.* § 2(12);
- "It is essential that the Food and Drug Administration review products sold or distributed for use to reduce risks or exposures associated with tobacco

products and that it be empowered to review any advertising and labeling for such products," *id.* § 2(36);

- "It is also essential that manufacturers, prior to marketing such products, be required to demonstrate that such products will meet a series of rigorous criteria, and will benefit the health of the population as a whole, taking into account both users of tobacco products and persons who do not currently use tobacco products." *Id*. [26]

**D. Plaintiffs' arguments that the Rule is arbitrary and capricious are not persuasive.**

Plaintiffs argue that the decision to deem e-cigarettes to be tobacco products is arbitrary and capricious because the Deeming Rule is "at war with itself regarding the rationale for regulating vaping products;" it will "undermine the TCA's core goal of reducing the deaths and disease resulting from use of tobacco products;" and it "fails to consider numerous alternatives that would avoid a 'significant degree of product exit' while still achieving Congress's public-

26 The legislative history reflects that Congress was well aware of the advent of e-cigarettes at the time that the TCA was passed. Defs.' Cross-Mem. at 28 & n.9, citing 155 Cong. Rec. H6626 (June 12, 2009) (statement of Rep. Buyer) ("[I]n the marketplace right now, there are many different types of products . . . [Y]ou have an electronic cigarette, whereby it's a nicotine delivery device."), and 155 Cong. Rec. H4367 (Apr. 1, 2009) (statement of Rep. Buyer) (expressing concern that "these new innovative types of nicotine delivery devices could not make their access to the market."); 155 Cong. Rec. S6010 (June 3, 2009) (statement of Sen. Burr) ("Then we have a new category called electronic cigarettes . . . It actually runs off a battery. It extracts the nicotine and delivers it into the system in a totally different way than the tobacco-headed cigarette."). Indeed, Senator Burr seemed to propose that all electronic cigarettes should be "grandfathered" in to the SE pathway. 155 Cong. Rec. S6335–36 (June 9, 2009) (statement of Sen. Burr) ("There are electronic cigarettes . . . and other products that have less risk. All those products in February 2007 were not in the marketplace. They are banned. They are eliminated. What are we asking the FDA to do? We are asking them to grandfather three categories of products and let all adults who choose to use a tobacco product choose from the most risky categories . . . Any claim – any claim – that [the proposed TCA] reduces the cost of health care is only because we have grandfathered in smokers who will die sooner, not that we have allowed them a pathway through this bill to ever experience not only products that are currently on the marketplace that reduce the risk from 100 percent to as little as 1 percent, but we have completely eliminated any additional innovation in product in the future . . . ."). The fact that Congress passed the TCA in its current form notwithstanding the concerns raised by Congressman Buyer and Senator Burr provides further support for the conclusion that the Secretary's decision to deem e-cigarettes to be tobacco products, and therefore subject to premarket review, is reasonable and fully consistent with the intent of the statute.

health objective." Nicopure Mem. at 15–26. And RSF seems to argue that the decision to subject e-cigarettes to the premarket review requirement is arbitrary and capricious because the agency "offers no evidence or explanation as to how such manufacturers will be able to conduct the necessary long-term clinical health studies, which FDA concedes do not exist, within the two year compliance period." RSF Compl. ¶ 79.

Once the Secretary of HHS made the decision to deem ENDS as tobacco products, the requirement of premarket review is established by statute. So the question is not whether it is arbitrary and capricious to make these plaintiffs comply with those requirements. The question is, instead, whether it was reasonable for the agency to determine that it was appropriate to subject ENDS products – the majority of which plaintiffs agree are covered by the statute – to the regulatory regime that Congress specifically determined *must* be imposed on *all* tobacco products.

Nicopure also argues that the Deeming Rule ignores evidence "that vaping products are *far* less risky than cigarettes." Nicopure Mem. at 19 (emphasis in original). It states that the agency has disregarded evidence that "inhalation of e-vapor 'is of less risk to a user than the inhalation of . . . smoke from combusted tobacco products,' and that use of vaping products 'is likely less hazardous for an individual user than continued smoking of traditional cigarettes.'" *Id.*, quoting Deeming Rule, 81 Fed. Reg. at 29,033, 29,035. For that reason, Nicopure argues that the Rule is "at war with itself." Nicopure Mem. at 15–16. But this argument is not persuasive. Just because there is evidence that e-cigarettes may be less risky than conventional cigarettes does not mean that e-cigarettes are not risky at all, and the agency detailed its concerns about the addictive nature and health risks of nicotine inhalation alone, particularly in adolescents. *See* Deeming Rule, 81 Fed. Reg. at 28,981 ("The Surgeon General has long recognized that the addictive nature of tobacco products is due to the presence of highly addictive nicotine that can be absorbed into the

bloodstream."); *id.* at 28,983–85 ("FDA noted in the [notice of proposed rulemaking] that many public health benefits will flow from deeming tobacco products (including e-cigarettes and other ENDS). Even if a category of products were to prove generally beneficial, individual products within that category may raise concerns. For example, some products may be particularly attractive to youth or deliver unexpected high levels of toxicants.").

Moreover, the record before the agency included a substantial volume of comments submitted by public health organizations such as the American Academy of Family Physicians, the American Academy of Pediatrics, the Cancer Action Network, the American Heart Association, the American Lung Association, and the American Psychological Association – all of which urged the agency to "strengthen[]" and make "comprehensive" the proposed Deeming Rule, in order to "prevent the manufacturers of tobacco products from designing and marketing their products in ways that undercut the full potential of the Tobacco Control Act to achieve its lifesaving objectives." Comments of 24 Public Health Organizations to the Proposed Deeming Rule (Dkt. No. FDA-214-N-0189) (Aug. 8, 2014) at 4; *see also* AR 145,543 (including the first page of those comments). Given the deference that the Court gives to scientific judgments, *Ctr. for Biological Diversity*, 749 F.3d at 1087–88, the Court finds that plaintiffs' objections do not overcome the agency's scientific judgment that regulation of ENDS products under the TCA is in the interest of public health.

### E. The agency appropriately rejected plaintiffs' suggested regulatory alternatives.

As the D.C. Circuit has explained, agencies "ha[ve] wide discretion to determine where to draw administrative lines," *ExxonMobil Gas Mktg. Co. v. FERC*, 297 F.3d 1071, 1085 (D.C. Cir. 2002), quoting *AT&T Corp. v. FCC*, 220 F.3d 607, 627 (D.C. Cir. 2000), and courts "are generally unwilling to review line-drawing performed by [the agency] unless a [challenger] can demonstrate

that the lines drawn . . . are patently unreasonable, having no relationship to the underlying regulatory problem." *Id.*, quoting *Cassell v. FCC*, 154 F.3d 478, 485 (D.C. Cir. 1998). But agencies must also consider "reasonable alternatives" as part of the requirement of "reasoned decisionmaking." *See Am. Gas Ass'n v. FERC*, 593 F.3d 14, 19 (D.C. Cir. 2010); *see also State Farm*, 463 U.S. at 43 (requiring agencies to "articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made.").

Nicopure argues that the agency failed to "meaningfully" consider alternatives to the premarket review requirement, including three options in particular. Nicopure Mem. at 21. First, Nicopure contends that the agency should have waited to deem until the agency had "sufficient data to reach a conclusion – one way or the other – regarding the health effects of vaping products *before* choosing whether and how to regulate them." *Id.* at 23 (emphasis in original). Second, Nicopure contends that the agency should have adopted the European Union's approach to regulating vaping products, which includes many of the same requirements, but does not require premarket review. *Id.* at 24. Third, Nicopure faults the agency for failing to consider "crafting a streamlined [premarket review] process for products, such as vaporizers, that fall on the safer side of the risk continuum." *Id.*

The law is clear that plaintiffs are not entitled to the regulatory alternative that they prefer. Rather, the Court must give appropriate deference to the expertise of the agency, and ensure that the agency considered the alternatives proffered by the plaintiffs and rejected them for reasons that are rational.

And it bears repeating that premarket review is a creature of statute and not a new regulatory requirement dreamed up and imposed on ENDS manufacturers by the FDA. The EU model would subject manufacturers to disclosure, advertising, good manufacturing practices,

misbranding, and other requirements, but it would not require manufacturers to obtain premarket review. *See* Nicopure Mem. at 24. Whatever one might think about the benefits of the EU approach as a policy matter, a rule that adopted that approach would have been contrary to the TCA, because the TCA requires that all tobacco products must undergo some kind of premarket review. 21 U.S.C. § 387j(a). Plaintiffs argue that the agency could exercise enforcement discretion – and that it exercised similar discretion in allowing for an extended compliance schedule. *See* Pls.' Reply at 18. There is certainly nothing in the statute or the Rule that would bar the parties from engaging in constructive negotiations to establish a more manageable timeline. But the fact that there may be reasons for the agency to be flexible when implementing the premarket review requirements does not mean it was unreasonable for the agency to decline to adopt the EU approach and eliminate premarket review altogether. *See* Deeming Rule, 81 Fed. Reg. at 28,998.

Similarly, plaintiffs' argument about a "streamlined" premarket review process, *see* Nicopure Mem. at 24, finds little support in the TCA, and the agency appropriately rejected that argument as well. *See* Deeming Rule, 81 Fed. Reg. at 28,998. As the agency concluded, "all tobacco products going through the [premarket] pathway must meet all the requirements for a premarket authorization in section 910 of the [FDCA] before FDA can issue such an authorization." *Id.*

Finally, the agency did consider the suggestion that it should defer the deeming regulation indefinitely, and it rejected it, finding that it did not have to "meet a particular public health standard to deem tobacco products." *See* Deeming Rule, 81 Fed. Reg. at 28,983. And it supported its decision by setting out the public health benefits of the rule in great detail. *Id.* at 28,983–85.

### F. The decision not to change the grandfather date for substantially equivalent products is not arbitrary and capricious.

In Count I of the Right to be Smoke-Free complaint, plaintiffs complain that under the Deeming Rule, no ENDS products will be able to utilize the substantial equivalence pathway for approval, and this will "effectively ban ENDS products from the marketplace." RSF Compl. ¶ 74. RSF alleges: "FDA had the authority and statutory duty to either establish a new Grandfather Date for ENDS products or apply its enforcement authority so that some ENDS manufacturers, including e-liquid companies, would have the opportunity to forego the [premarket review] pathway and avail themselves of the option to submit SE reports." *Id.* ¶ 75. But here again, RSF's complaint about the impact of the grandfather date provision is better directed to Congress than the FDA.

As the Court explained in the background section of this opinion, one way to get a new tobacco product approved under the TCA is to show that it is "substantially equivalent" to an existing tobacco product. 21 U.S.C. § 387j(a). This pathway is only available to existing or "predicate" products that had been "commercially marketed . . . in the United States as of February 15, 2007." 21 U.S.C. § 387j(a)(2)(A). So, to the extent that there were no "substantially equivalent" ENDS products on the market as of that date, the substantial equivalence pathway would not provide a pathway to seek approval of that product.

Thus, it was Congress that set the grandfather date in the TCA, and RSF has not pointed the Court to any authority for the proposition that the agency can ignore a statutory command. RSF argues that "[w]hen 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." RSF Mem. at 18. But "the starting point for interpreting a statute is the language of the statute itself." *CPSC v. GTE Sylvania, Inc.*, 447 U.S. 102, 108 (1980). The statute

unambiguously points to a specific date – February 15, 2007 – and it contains no exceptions for items deemed to be tobacco products in the future. 21 U.S.C. § 387j(a)(2)(A).[27] While the Court is sympathetic to RSF's policy argument that as new products come to market, the grandfather date will become obsolete, *see* RSF Mem. at 18–19, the path forward is to seek an amendment to the statute, which is already underway. Hr'g Tr. at 57:22–58:1 ("THE COURT: Isn't your problem with Congress and not the agency? And aren't you already working on that right now? [Counsel for RSF]: We are. There are two bills in front of Congress right now.").

The statute is clear, and FDA had no power to change it. So RSF's challenge to the grandfather date fails.

**G. FDA's imposition of compliance deadlines was not arbitrary and capricious.**

Under the terms of the Rule, a manufacturer who wishes to submit a premarket review application must do so by August 8, 2018 – twenty-four months after the Rule became effective. Deeming Rule, 81 Fed. Reg. at 28,978. After August 8, 2018, FDA will continue the compliance period for at least twelve more months, and, on a case-by-case basis, it will defer enforcement further to give the agency the time it needs to review and determine whether to grant the requests. *Id.*

RSF alleges in Count II that the agency's decision to establish a two-year compliance period to comply with the premarket review requirement was arbitrary and capricious because companies will not be able to complete the necessary applications in the required timeframe. RSF Compl. ¶¶ 77–82. The Court finds that the agency reasonably balanced the competing comments it received, from the view that FDA should "craft the [premarket review] process to acknowledge

27 This is true notwithstanding the legislative history that reveals that this very issue was raised at the time the statute was under consideration. *See* footnote 25, *supra*, quoting 155 Cong. Rec. S6335–36 (June 9, 2009) (statement of Sen. Burr).

the position of e-cigarettes on the continuum of nicotine-delivering products," to the position that the FDA should "impose strict regulations on the sale of e-cigarettes, including extensive premarket review, to ensure that future generations are not burdened by nicotine addiction." Deeming Rule, 81 Fed. Reg. at 29,000.

The FDA explained:

> Some comments expressed concern about the extended availability of newly deemed, new tobacco products without scientific review. Others provided additional data regarding youth and young adult use of flavored tobacco products. In addition, other comments discussed the potential public health benefits from the availability of certain flavored newly deemed products . . . . Taking the diverse comments on these issues, as well as the uncertainty regarding the positive or negative impact on public health from products like ENDS, into account, FDA has decided to implement the compliance policy with staggered initial compliance periods based on the expected complexity of the applications, followed by continued compliance periods for FDA review, such that our enforcement discretion will end twelve months after each initial compliance period. Under the policy described here for the staggered compliance periods, and while FDA is conducting its review of marketing applications during the continued compliance period, the Agency does not intend to take enforcement action against products remaining on the market for failure to have a premarket authorization order.

*Id.* at 29,010

While other approaches may have been reasonable as well, the Court is not persuaded that the agency's decisions about whether to impose a compliance period at all, and how long a period would be necessary, are irrational given the range of viewpoints that had been presented during the notice and comment period. *See Alpharma*, 460 F.3d at 6. Therefore, the Court concludes that the agency's imposition of a compliance period did not violate the APA.

RSF argues that if the Deeming Rule is not vacated, "FDA risks banning or nearly eliminating the e-liquid and device categories from the market when the two year [premarket review] compliance period expires." RSF Mem. at 21. RSF is particularly concerned because

premarket review applications usually require long-term clinical studies, and those studies do not currently exist. *See id.* at 25; *see also* Deeming Rule, 81 Fed. Reg. at 28,984, 29,028.

But the FDA specifically took that issue into consideration, and plaintiff's concerns are somewhat premature. The Deeming Rule recognizes that "in some cases, it may be possible for an applicant to obtain a [premarket review] 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." Deeming Rule, 81 Fed. Reg. at 28,997. And on the day that the agency promulgated the Deeming Rule, it also issued a draft guidance on premarket review applications. *See* Draft FDA Guidance for Industry, Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems (May 2016), AR 28,350. The guidance recognizes that a marketing authorization may issue "if there is an established body of evidence regarding the health impact (individual or population) of [a] product or a similar product that can be adequately bridged to [that] product, such as data from the published literature or government-sponsored databases." *Id.*, AR 28,395–96.

**III. The Deeming Rule is not invalid due to any deficiencies in the cost-benefit analysis.**

In Count III of the Nicopure complaint and in Count VIII of the Right to be Smoke-Free complaint, plaintiffs allege that the Deeming Rule violates the APA because the agency's cost-benefit analysis was insufficient. Nicopure Compl. ¶¶ 47–51; RSF Compl. ¶¶ 129–33. But the agency was not required to undertake a cost-benefit analysis when it implemented the statutory deeming provision. And even if "some" cost-benefit analysis was required, the agency did "some" analysis in this case, and there is no legal authority for the proposition that the Court has the authority to review it *de novo* as plaintiffs seem to be asking it to do. Because the balance struck by the agency was reasonable, the Court finds that the cost-benefit analysis was adequate.

### A. The agency was not required to do a cost-benefit analysis.

Plaintiffs point to the Supreme Court's recent decision in *Michigan v. EPA*, 135 S. Ct. 2699 (2015) as support for their contention that the FDA was required to complete a cost-benefit analysis before taking action under the deeming provision. *See* Nicopure Mem. at 26–27. But that decision, which involved a statutory obligation to undertake the analysis, does not apply in this case.

The opinion in *Michigan v. EPA* concerned the provision of the Clean Air Act related to electric utility steam generating units. 135 S. Ct. at 2705. In the Act, Congress directed the EPA to conduct a study of the public health hazards related to emissions from these power-plants, and it required the agency to regulate the emissions "if the Administrator finds such regulation is appropriate and necessary after considering the results of the study." 42 U.S.C. § 7412(n)(1)(A). Faced with this mandatory language, the EPA determined "that cost [made] no difference to the initial decision to regulate," *Michigan*, 135 S. Ct. at 2706, and it read the Clean Air Act to preclude the consideration of "*any* type of cost" as part of the decision of whether or not to regulate the emissions. *Id.* at 2707 (emphasis in original).

However, the Supreme Court ruled that it was implicit in the use of the specific words "appropriate and necessary" that some consideration of cost should be part of the analysis. *Id.* at 2707. Therefore, it concluded that "it was unreasonable for EPA to read § 7412(n)(1)(A) to mean that cost is irrelevant to the initial decision to regulate power plants." *Id.* at 2711.

Here the statutory provision at issue does not include the words that led the Supreme Court in *Michigan v. EPA* to call for some assessment of costs as part of the decision that had been delegated to the agency. The Tobacco Control Act mandates that tobacco products "shall" be regulated by the Secretary, and it requires that its provisions be applied not only to conventional cigarettes, but also to "any other tobacco products that the Secretary by regulation deems to be

subject to this chapter." 21 U.S.C. § 387a(b). The statute does not limit the Secretary's authority to deem to when he finds it "appropriate and necessary" to do so. Therefore, plaintiffs can point to no source for a requirement that costs be taken into account when the deeming power is exercised, and *Michigan v EPA* is distinguishable.[28]

Plaintiffs have scoured the rest of the statute, though, and they point to one of the ten stated purposes of the TCA: "to impose appropriate regulatory controls on the tobacco industry." Nicopure Mem. at 27, quoting TCA § 3(8). They argue that the use of the word "appropriate" in the background section of the statute requires the agency to evaluate costs when exercising its authority under the deeming provision. *Id.* But plaintiffs have not pointed to any legal precedent that would authorize a court to add limits to a statutory provision that contains no limits simply because the word "appropriate" can be found in another part of the legislation, much less any case law that would imply statutory prerequisites from a general, introductory statement of purpose. *Michigan v. EPA* certainly does not go that far.[29]

Even if the plaintiffs were correct in their assertion that one should look to the introductory sections of a statute to shed light on a clear statutory directive, a review of the entire set Congressional findings that accompany the TCA reinforces the conclusion that the legislature did

---

28 Indeed, the Supreme Court observed that even when the words "appropriate and necessary" do appear, "[t]here are undoubtedly settings in which the phrase . . . does not encompass cost," *Michigan*, 135 S. Ct. at 2711; there is nothing in the opinion that requires a cost-benefit analysis when they do not appear.

29 Plaintiffs assert that *Michigan v. EPA* "forecloses" the defendant's argument to this effect, Pls.' Reply at 24, but here they misread the decision again. In *Michigan*, the Supreme Court rejected the EPA's argument that since other parts of the Clean Air Act expressly mentioned cost, one could not imply a cost-benefit analysis to be necessary in section 7412(n)(1)(A) in the absence of an explicit requirement there. 135 S. Ct. at 2708–09. But the "appropriate and necessary" language that was read to impose the requirement to consider costs was found in the very provision of the Clean Air Act that was under review; the Court did not suggest that it could be imported from some other general introductory statements found elsewhere in the statute.

not intend to circumscribe the agency's authority. *See, e.g.*, TCA § 2(12) (finding that "it is in the public interest for Congress to enact legislation that provides the Food and Drug Administration with the authority to regulate tobacco products and the advertising and promotion of such products. The benefits to the American people from enacting such legislation would be significant in human and economic terms"); *id.* § 2(36) (finding that the FDA's authority to review modified-risk claims and to require premarket review of tobacco products "will benefit the health of the population as a whole"); *id.* § 2(44) (finding that the "Food and Drug Administration is a regulatory agency with the scientific expertise to identify harmful substances in products to which consumers are exposed," and that the agency "routinely makes decisions about whether and how products may be marketed in the United States"). Congress's statements of purpose further emphasize the breadth and legitimacy of the agency's authority, and they weigh against plaintiffs' attempt to read hurdles into the deeming provision that are not supported by the text of the provision itself. *See, e.g.*, TCA § 3(1) (explaining that the purpose of the TCA is "to provide authority to the [FDA] to regulate tobacco products under the [FDCA], by recognizing it as the primary Federal regulatory authority with respect to the manufacture, marketing, and distribution of tobacco products"); *id.* § 3(3) (explaining that another purpose of the TCA is "to authorize the [FDA] to set national standards controlling the manufacture of tobacco products and the identity, public disclosure, and amount of ingredients used in such products"). For all of these reasons, the Court finds that the decision in *Michigan v. EPA* did not impose any requirement that the FDA assess the costs of compliance before deeming e-cigarettes to be tobacco products.

### B. Even if *Michigan v. EPA* does apply, the agency complied with its requirements.

Moreover, the problem in *Michigan* was that the agency failed to conduct any cost-benefit analysis at all, and the Court concluded that the "appropriate and necessary" language gave rise to

a requirement to conduct *some* consideration of costs. *Michigan*, 135 S. Ct. at 2711 (holding that it was "unreasonable for EPA to read § 7412(n)(1)(A) to mean that cost is irrelevant to the initial decision to regulate power plants," and requiring the agency to "consider cost – including, most importantly, cost of compliance – before deciding whether regulation is appropriate and necessary"). The Court made it quite clear that it did not read the statute to require a formal cost-benefit analysis, and it underscored that it would not dictate what the assessment should consist of.

> We need not and do not hold that the law unambiguously required the Agency, when making this preliminary estimate, to conduct a formal cost-benefit analysis in which each advantage and disadvantage is assigned a monetary value. It will be up to the Agency to decide (as always, within the limits of reasonable interpretation) how to account for cost.

*Id.*

Here, the administrative record reflects that the agency expressly considered both the burdens the decision would impose on the vaping industry and the benefits to the public. *See* Deeming Rule, 81 Fed. Reg. at 28,980. Thus, even if the agency was bound by the decision in *Michigan v. EPA* to pay "some attention to cost," 135 S. Ct. at 2707, that was done in this case, and the decision cannot be overturned on that basis.

### C. The agency's consideration of costs and benefits satisfied the APA.

Plaintiffs contend that the Court should reject the outcome of the agency's assessment of costs and benefits under the APA. But the Supreme Court made it clear in that even when such an analysis is required, the Court cannot review it *de novo. See Michigan*, 135 S. Ct. at 2711 ("It will be up to the agency to decide (as always, within the limits of reasonable interpretation) how to account for cost.").

In situations where a cost-benefit analysis is required by the applicable statute, the Court must analyze the agency's decision making with deference. *See Consumer Elecs. Ass'n v. FCC*,

347 F.3d 291, 303 (D.C. Cir. 2003) (holding that the principle set forth in *State Farm* that "a court is not to substitute its judgment for that of the agency" is "especially true when the agency is called upon to weigh the costs and benefits of alternative policies"), quoting *Ctr. for Auto Safety v. Peck*, 751 F.2d 1336, 1342 (D.C. Cir. 1985); *see also Am. Trucking Ass'ns, Inc. v. Fed. Motor Carrier Safety Admin.*, 724 F.3d 243, 254 (D.C. Cir. 2013) ("It is not for us to undertake our own economic study and substitute the Court's views for those of the agency."). When a court reviews a challenge to an agency's cost-benefit analysis, its role is limited to determining "whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment," *Ctr. for Auto Safety*, 751 F.2d at 1342, quoting *State Farm*, 463 U.S. at 43, because "[s]uch cost-benefit analyses epitomize the types of decisions that are most appropriately entrusted to the expertise of an agency." *Id.*, quoting *Office of Commc'n of United Church of Christ v. FCC*, 707 F.2d 1413, 1440 (D.C. Cir. 1983). Thus, the plaintiffs must overcome a high threshold to show error. *Am. Trucking Ass'ns*, 724 F.3d at 254, quoting *NAHB*, 682 F.3d at 1040. With that deference in mind, the Court concludes that the balance the agency struck in this case was reasonable.

The FDA prepared a Regulatory Impact Analysis which weighed the costs and benefits of the Deeming Rule, *see* AR 23,912–24,067 ("RIA"). In the RIA, the agency described the benefits of the Deeming Rule as "potentially coming from":

- premarket review, which will result in fewer harmful or addictive products from reaching the market than would be the case in the absence of the rule;
- youth access restrictions and prohibitions on free samples, which can be expected to constrain youth access to tobacco products and curb rising uptake;
- health warning statements, which will help consumers understand and appreciate the risks of using tobacco products;

- prohibitions against false or misleading claims and unsubstantiated modified risk claims; and
- other changes, such as FDA monitoring of product developments and changes and required ingredient listings.

*Id.* at AR 23,978. While the agency conceded that it could not "quantify the benefits of the final rule due to lack of information and substantial uncertainties associated with estimating its effects," it concluded that the rule was justified in light of those "welfare gains." *Id.* It explained:

> Asserting our authority over these tobacco products will also enable FDA to take further regulatory action in the future as appropriate for the protection of public health. These further regulatory actions would be expected to yield benefits in turn. The rule will enable FDA to determine the number of regulated entities, establish effective compliance programs, and monitor the number and types of products that are being marketed to the public. It will also authorize the agency to take enforcement action against adulterated or misbranded products, reducing the potential public health dangers of such products. By asserting authority over all products that meet the statutory definition of tobacco product (except for accessories of the newly deemed tobacco products), FDA will also be correcting any possible misperception that, because certain tobacco products are not regulated, they must be safe.

*Id.* at 23,973. While the agency conceded in the RIA that "[r]eliable evidence on the impacts of . . . premarket review, and marketing restrictions on users of . . . ENDS does not, to our knowledge, exist," it concluded that the Deeming Rule was justified by "the welfare gains" of the rule, which "would be equal to the value that affected individuals attribute to mechanisms that better align consumption and production decisions with socially optimal patterns." *Id.*

And as to costs, the agency began its assessment in the RIA by attempting to quantify the number of affected entities. It found that "the baseline number of manufacturers and importers of ENDS products is uncertain," but it estimated that there were between 640 and 800 ENDS devices on the market, and between 19,900 to 79,800 e-liquid mixtures on the market. RIA, AR 23,980, 23,989 (Table 6). In light of an industry survey that found that "[t]oo many companies are making e-liquid in their kitchens/bathrooms," the FDA concluded that "few if any of [those companies]

will continue to manufacture after this final rule takes effect," and so it limited its analysis to "the formal manufacturers in the market." *Id.* at 23,980.

The agency identified three main potential costs: product consolidation, compliance, and market adjustment.

- **Product consolidation**. Because "nearly all ENDS products will be subject to premarket review," the agency predicted "considerable product consolidation and exit." RIA, AR 23,989–90. It assumed that "54 percent of delivery systems and somewhere between 50 and 87.5 percent of e-liquids [would] not submit a marketing application and will exit the market after the initial compliance period . . . ends." RIA, AR 23,990. The agency made the assumption that "90 percent of products seeking marketing authorization will obtain marketing authorization," which the agency explained was "comparable to the high end of observed medical product approval rates." *Id.* at 23,990 & n.38. So, after the compliance period ends, the agency anticipated that between 266 to 332 vaping devices, and between 900 to 1,800 e-liquids would remain on the market. *Id.* at 23,991 (Table 7). But the agency also noted that the cost of product exit would be mitigated by the increase in the "overall quality level of the products in the market compared to the quality level that would otherwise prevail" without the premarket review process. *Id.*

- **Compliance costs**. The agency conceded that "[e]stimating expected costs of submitting [premarket review applications] is made complicated not only by the flexibility firms have to decide on how best to provide the information in the [premarket review application], but also by the diversity of products in the ENDS category." RIA, AR 23,997. That difficulty notwithstanding, the agency estimated that an initial premarket review application – covering up to fifteen products per application – would cost between $181,686 and $2,014,120 per application. *Id.* at 23,998 (Table 11a). And for delivery devices, the agency estimated a total cost of $285,656 to $2,622,224 per application. *Id.* at 24,001–02 (Table 12a). Given the number of participants in the market, the agency predicted a total cost of complying with the premarket review requirements of between about $164 million and $329 million for e-liquids, and between $131 million and $164 million for delivery devices. *Id.* at 24,009 (Table 17).

- **Market adjustment**. In light of the agency's prediction of market consolidation, another cost that the agency recognized was the cost of "market adjustment," such as the "friction costs" of displaced workers looking for other jobs. RIA, AR 24,015. But because of the "considerable uncertainties associated with predicting effects of the rule on business decisions," the agency concluded that it lacked "a basis for estimating the costs of market adjustment here." *Id.*

Taking all of those costs together, the agency estimated in the RIA the quantified and unquantified costs of the Deeming Rule to the ENDS industry:

- **Quantified costs.** The agency estimated that that the present value of the quantified costs for ENDS products ranged from $507.6 million to $738.6 million. RIA, AR 24,025–26.

- **Unquantified costs**. The agency did not quantify other costs, such as "some consumer costs for users . . . due to loss of product variety or higher prices," "compliance costs for components and parts," "the cost of testing and reporting for harmful and potentially harmful constituents," "market adjustment (friction) costs," "exit of manufacturers," and "the switch to pure retailing among retailers such as vape shops who currently engage in manufacturing activities." *Id.* at AR 24,024.

The RIA measured the Deeming Rule's potential value "by dividing its total costs by the number of people expected to benefit from it." *Id.* at AR 24,026–27. It explained that the basis for this calculation is that it "measures what the rule's expected beneficiaries would need to be willing to pay on average for the rule in order for the benefits to equal the costs." *Id.* at AR 24,027.

The RIA's "primary estimate of the value of costs of this final rule, annualized over 20 years, is $66.4 million with a 3 percent discount rate and $77.1 million with a 7 percent discount rate." RIA, AR 24,027. And the agency cited data in the RIA showing approximately 34.9 million users of newly-deemed tobacco products. *Id.* So the RIA concluded that the "break-even annual willingness-to-pay for this rule . . . [is] approximately $2 per current user at both discount rates." *Id.* The agency noted, though, that the Deeming Rule also has an impact on non-users of tobacco products, both from a deterrence perspective, and from a reduction in second-hand exposure. *Id.* And the agency factored in the benefits to parents, to the extent that their children are deterred from use. *Id.* While FDA could not quantify the numbers of people in those categories, it noted that "the break-even annual willingness-to-pay would be even lower than the estimated $2 per user." *Id.*

FDA incorporated the RIA's analysis into the Deeming Rule. Deeming Rule, 81 Fed. Reg. at 28,980–81. The agency concluded in the Rule that "[t]he direct benefits of making each of the newly deemed tobacco products subject to the requirements of [the FDCA] are difficult to quantify," so it did not "predict the size of these benefits at this time." *Id.* And the agency summarized the quantified costs over a twenty year period in a table. *Id.* Based on that analysis, the agency concluded that "the benefits of the final rule justify the costs."

> Among other effects, new products will be subject to an evaluation to ensure they meet the appropriate public health standard for the pathway before they can be marketed, labeling cannot contain misleading statements, and FDA will be made aware of the ingredients in newly deemed tobacco products. If, 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 such products from appearing on the market and worsening the health effects of tobacco product use.

*Id.*

Plaintiffs argue that "conducting a cost-benefit analysis is not the same as conducting a *reasoned* cost-benefit analysis," and they identify four reasons why the agency's cost-benefit analysis should be found to violate the APA. Nicopure Mem. at 27–32.

First, plaintiffs argue that in failing to quantify the benefits of the rule, the agency "shirk[ed] a statutory responsibility simply because it [was] difficult." *Id.* at 27–28, quoting *NetCoalition v. SEC*, 615 F.3d 525, 539 (D.C. Cir. 2010). They posit that "[a]n agency cannot realistically determine that a rule's benefits justify its costs if it does not have at least a general grasp of the rule's benefits." *Id.* at 28. While it is true that the agency concluded that the "direct benefits [of the Deeming Rule] . . . are difficult to quantify" monetarily, it is disingenuous to argue that the agency did not articulate "at least a general grasp of the rule's benefits," because the RIA provided substantial detail on the benefits of the rule, and the reasons why quantification was not possible. *See* RIA, AR 23,973–78. And, as noted above, there was no statutory duty to quantify

the benefits at all, and even if such a duty can be implied from a statutory provision that lacks any requirement that the agency must find regulation to be "appropriate and necessary," *Michigan v. EPA* does not require that the benefits be quantified in any particular way when compared to the costs.

Second, plaintiffs contend that the FDA "substantially understate[d] the Rule's costs" because its estimates on the costs of premarket review are "divorced from reality," and because the agency failed to quantify a number of impacts, such as the "market adjustment (friction) costs" of lost revenues, job losses, and companies leaving the industry. Nicopure Mem. at 29–30, quoting Deeming Rule, 81 Fed. Reg. at 29,075. But the Court is not empowered to "undertake [its] own economic study and substitute the Court's view for those of the agency." *Am. Trucking Ass'ns*, 724 F.3d at 254. The agency acknowledged that the determination of the cost of premarket review was difficult to quantify, but it nonetheless developed estimates. RIA, AR 23,997–24,002. It also explained its assessment of why the market adjustment costs were not quantifiable: because of the "considerable uncertainties associated with predicting effects of the rule on business decisions." *Id.* at 24,015.

Third, plaintiffs argue that "FDA loads the dice" because it excludes the unquantified costs from its break-even analysis. Nicopure Mem. at 31. According to the agency, the break-even analysis must, by design, include only the quantifiable costs, AR 24,026–27 ("Without being able to quantify the rule's benefits, a measure with which a rule's potential value can be compared is obtained by dividing its total costs by the number of people expected to benefit from it."), and Nicopure does not offer anything beyond its sharp language to explain why this approach is unreasonable.

Finally, plaintiffs argue that the Deeming Rule "fails to determine whether the cost of regulating [ENDS] products is justified by the benefits associated with such regulation." Nicopure Mem. at 32. But there is no legal support for the proposition that every product or industry affected by a rulemaking is entitled to a separate cost-benefit analysis. And while the Deeming Rule did not directly weigh the costs of vaping against the benefits, it did separately address the costs to each of the regulated product categories, including the overall costs to the vaping industry. *See, e.g.*, RIA, AR 24,025–26. Plaintiffs admit that they lack legal authority for their argument, Pls.' Reply at 27, and they rely solely on the conclusory argument that the agency's decision lacked reason. *Id.*

While plaintiffs would surely have assessed the various costs and benefits in a different manner, the Court does not have the power to take up the agency's analysis *de novo*. *See Michigan*, 135 S. Ct. at 2711. Given the agency's careful assessment of the costs and benefits to the entire ENDS industry, the Court finds that the agency considered the relevant factors and did not make a "clear error of judgment" when it exercised its discretion to deem electronic cigarettes to be tobacco products under the TCA and therefore subject to the statutory premarket review requirements. *Ctr. for Auto Safety*, 751 F.2d at 1342.

## IV. The agency complied with the purely procedural requirements of the Regulatory Flexibility Act.

RSF alleges in Count VII that the agency violated the Regulatory Flexibility Act, as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. § 601, *et seq.*, by failing to consider significant alternatives to the Deeming Rule, and by failing to appropriately balance the costs and benefits of the Deeming Rule on small businesses. RSF Compl. ¶¶ 119–27.

"The Regulatory Flexibility Act requires that agencies issuing rules under the Administrative Procedure Act publish a final regulatory flexibility analysis." *Nat'l Tel. Coop. Ass'n v. FCC*, 563 F.3d 536, 540 (D.C. Cir. 2009), citing 5 U.S.C. § 604. As the Court of Appeals has explained:

> Such an analysis must meet certain statutory requirements. It must state the purpose of the relevant rule and the estimated number of small businesses that the rule will affect, if such an estimate is available. In addition, each analysis must summarize comments filed in response to the agency's initial regulatory flexibility analysis, along with the agency's assessment of those comments. Finally, each analysis must include "a description of the steps the agency has taken to minimize the significant economic impact" that its rule will have on small businesses, "including 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."

*Id.*, quoting 5 U.S.C. § 604(a)(6).

But the statute's "requirements are '[p]urely procedural.'" *Id.*, quoting *U.S. Cellular Corp. v. FCC*, 254 F.3d 78, 88 (D.C. Cir. 2001). While the statute sets out "precise, specific steps an agency must take," *Aeronautical Repair Station Ass'n, Inc. v. FAA*, 494 F.3d 161, 178 (D.C. Cir. 2007), it "imposes no substantive constraint on agency decisionmaking." *Nat'l Tel. Coop. Ass'n*, 563 F.3d at 540. The statute simply requires agencies to publish analyses that address specific topics, and if it does so, it has complied with the Regulatory Flexibility Act. *Id.*

Here, the agency completed a Regulatory Impact Analysis which contains a discussion of all of the required topics: The agency explained the purpose of the Deeming Rule. RIA, AR 23,969–73; *see* 5 U.S.C. § 604(a)(1). It responded to the comments to the initial regulatory flexibility analysis. AR 23,918–69; *see* 5 U.S.C. § 604(a)(2)–(3). It estimated the number of small businesses that the Deeming Rule would affect. AR 23,039–42; *see* 5 U.S.C. § 604(a)(4). It described the reporting, recordkeeping, and compliance costs. AR 23,991–24,026; *see* 5 U.S.C.

§ 604(a)(5). And it discussed significant proposed alternatives. AR 24,033–38; *see* 5 U.S.C. § 604(a)(6).

RSF argues that the agency violated the Regulatory Flexibility Act because it did not consider any alternatives to the burdens of the premarket review process, such as extending the two-year compliance period for premarket applications to be filed. RSF Mem. at 32–33. But the agency did specifically respond to concerns raised about the two-year compliance period. *See* Deeming Rule, 81 Fed. Reg. at 28,997–98 (explaining the agency's response to comments – on both sides of the issue – about the length of the compliance period). And even if an agency's explanation could be open to debate, the Regulatory Flexibility Act "requires nothing more than that the agency file a [final Regulatory Flexibility Analysis] demonstrating a 'reasonable, good-faith effort to carry out [the statute]'s mandate.'" *U.S. Cellular*, 254 F.3d at 88, quoting *Alenco Commc'ns, Inc. v. FCC*, 201 F.3d 608, 625 (5th Cir. 2000).

Because the agency complied with the procedural requirements of the Regulatory Flexibility Act, judgment will be entered in favor of defendants on Count VII of RSF's complaint.

## V. The Deeming Rule is not unconstitutional; RSF has abandoned its equal protection claim, and its due process argument fails.

Count III of the Right to be Smoke-Free complaint alleges that the TCA – not the Deeming Rule – violates the equal protection clause and RSF's right to substantive due process. RSF Compl. ¶¶ 83–89. Since RSF has abandoned the equal protection argument,[30] only the due process argument remains. The due process argument is premised on the allegation that Congress has

30 In its equal protection claim, RSF objected to the fact "FDA treats ENDS products the same as traditional tobacco products," even though "ENDS present a lower (and different) risk profile than cigarettes." RSF Compl. ¶ 88. RSF contended that its right to equal protection had thereby been violated because "Congress has treated differently situated products in a similar manner." *Id.* This turns the equal protection clause on its head, but RSF abandoned the claim by failing to mention it in their summary judgment papers. *See Aera Energy LLC v. Salazar*, 691 F. Supp. 2d 25, 34 n.6 (D.D.C. 2010).

acted irrationally by declining to tailor the premarket review process to ENDS products. *See id.* ¶¶ 85–87.

The Due Process Clause provides that "[n]o person shall be . . . deprived of life, liberty, or property, without due process of law." U.S. Const. amend. V. "The first inquiry in every due process challenge is whether the plaintiff has been deprived of a protected interest in 'property' or 'liberty.'" *Am. Mfrs. Mut. Ins. Co. v. Sullivan*, 526 U.S. 40, 59 (1999). Fundamental liberty interests are those that "are, objectively, deeply rooted in this Nation's history and tradition and implicit in the concept of ordered liberty, such that neither liberty nor justice would exist if they were sacrificed." *Washington v. Glucksberg*, 521 U.S. 702, 720–21 (1997). For a law to permissibly infringe on an individual's fundamental liberty interest, it must be narrowly tailored to serve a compelling government interest. *Id.* at 721. By contrast, when a law infringes on a nonfundamental liberty interest, it will be upheld unless there is "no 'rational relationship between [the law] and some legitimate governmental purpose.'" *Gordon v. Holder*, 721 F.3d 638, 656 (D.C. Cir. 2013), quoting *Am. Bus. Ass'n v. Rogoff*, 649 F.3d 734, 742 (D.C. Cir. 2011).

It bears noting that RSF has not pointed to any fundamental right or liberty interest affected by the TCA, *see* RSF Compl. ¶¶ 83–89; RSF Mem. at 38–40. But when one applies the rational basis test that RSF concedes is appropriate, RSF Mem. at 38–39, the TCA passes muster.

RSF asks the Court to find that the TCA is unconstitutional because it creates a premarket review system that plaintiff feels it will never be able to satisfy. RSF Mem. at 39–40. But rational basis review "is not a license for courts to judge the wisdom, fairness, or logic of legislative choices, *FCC v. Beach Commc'ns, Inc.*, 508 U.S. 307, 315 (1993), and courts must uphold legislation "[e]ven if the classification involved . . . is to some extent both underinclusive and overinclusive." *Vance v. Bradley*, 440 U.S. 93, 108 (1979). Here, a rational basis can be discerned

on the face of the TCA. *See Gordon*, 721 F.3d at 657 ("Although we are by no means restricted to the stated reasons for passing a law in our search for a 'rational basis,' we need look no further than the statute itself to discern three rational bases for the [law]."), quoting *Beach Commc'ns*, 508 U.S. at 315. Congress set forth a number of rational reasons for the premarket review requirement in the purposes section of the TCA: "to authorize the Food and Drug Administration to set national standards controlling the manufacture of tobacco products;" "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;" "to ensure that consumers are better informed," and "to impose appropriate regulatory controls on the tobacco industry." TCA §§ 3(3), (4), (6), (8).

Because the TCA has a rational basis, judgment will be entered for defendants on RSF's due process challenge.

## VI. The marketing restrictions in the Tobacco Control Act do not violate the First Amendment.

In the Tobacco Control Act, Congress directed the FDA to promulgate regulations restricting the distribution of free samples of tobacco products. TCA § 102. The statute also amended the Food, Drug, and Cosmetic Act to require manufacturers to apply for approval before they could market any tobacco product with a claim that it was "for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products." TCA § 101; 21 U.S.C. § 387k(b)(1). Nicopure and RSF allege that application of these statutory requirements to the vaping industry violates the First Amendment.

Count IV of both the Nicopure and RSF complaints alleges that the ban on the distribution of free samples of vaping devices or e-liquids is an unconstitutional restraint on the right to free speech. Nicopure Compl. ¶ 55; RSF Compl. ¶¶ 93–100. Plaintiffs also allege – in Count IV of

the Nicopure complaint and Count V of the RSF complaint – that the TCA's regulation of "modified-risk" statements violates their First Amendment Rights. Nicopure Compl. ¶ 54; RSF Compl. ¶¶ 102–10.

It is questionable whether the mere distribution of a product sample rises to the level of constitutionally protected expression at all. But even if the claimed communicative element inherent in this practice implicates the First Amendment, the Supreme Court has made it clear that "when 'speech' and 'nonspeech' elements are combined in the same course of conduct, a sufficiently important governmental interest in regulating the nonspeech element can justify incidental limitations on First Amendment freedoms." *United States v. O'Brien*, 391 U.S. 367, 376 (1968). Under the *O'Brien* test, "a government regulation is sufficiently justified if it is within the constitutional power of the Government; if it furthers an important or substantial governmental interest; if the governmental interest is unrelated to the suppression of free expression; and if the incidental restriction on alleged First Amendment freedoms is no greater than is essential to the furtherance of that interest." *Id.* at 377. To be upheld, though, a regulation must leave open ample alternative channels for communication. *Clark v. Cmty. for Creative Non-Violence*, 468 U.S. 288, 293 (1984); *see also Edwards v. District of Columbia*, 755 F.3d 996, 1002 (D.C. Cir. 2014).

Moreover, to the extent the TCA regulates speech directly, it is well established that "[t]he constitution . . . accords a lesser protection to commercial speech than to other constitutionally guaranteed expression." *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 562–63 (1980), citing *Ohralik v. Ohio State Bar Ass'n*, 436 U.S. 447, 456 (1978). In *Central Hudson*, the Supreme Court established a four-part test for determining whether the regulation of commercial speech violates the First Amendment; the court is required to ask: (1) is the expression protected by the First Amendment? (2) is the asserted government interest substantial? (3) does

the regulation directly advance the governmental interest? and (4) is the regulation more extensive than is necessary to serve that interest? *Id.* at 566. As the Ninth Circuit recently observed in *Retail Digital Network, LLC v. Prieto*, No. 13-56069, 2017 WL 2562047, at *6 (9th Cir. June 14, 2017), while the Supreme Court "has engaged in considerable debate about the contours of First Amendment protection for commercial speech, and whether *Central Hudson* provides a sufficient standard," it has continued to utilize the *Central Hudson* framework in the commercial context.

For the reasons set forth below, the Court concludes that the distribution of free samples is not protected speech, and that even if the act of handing out one's product involves some expression, the FDA's restriction of this activity passes the *O'Brien* and *Central Hudson* tests. *See S.F. Arts & Athletics, Inc. v. U.S. Olympic Comm.*, 483 U.S. 522, 535–537, 537 n.16 (1987) (evaluating a law under *O'Brien* and *Central Hudson* together because "their application . . . is substantially similar"). The Court also concludes that the TCA's regulation of modified risk statements in this commercial setting satisfies *Central Hudson*. Both aspects of the statute, now extended to electronic nicotine delivery systems by virtue of the Deeming Rule, directly advance a substantial government interest, and neither is more extensive than necessary.

### A. *Central Hudson* has not been supplanted by *Sorrell.*

Plaintiffs argue that in light of the Supreme Court's decision in *Sorrell v. IMS Health*, 564 U.S. 552 (2011), the regulations under review must be subjected to the heightened scrutiny that applies to content-based restrictions on speech. Nicopure Mem. at 34. But the *Sorrell* opinion did not alter or replace the *Central Hudson* immediate scrutiny standard to be applied to commercial speech, and indeed, the Court struck down the state statute involved by invoking the elements of the *Central Hudson* test.

In *Sorrell*, the Supreme Court examined a Vermont law which restricted the sale, disclosure, or use of prescriber-identifying information by pharmacies for marketing purposes, and the disclosure of the information to drug manufacturers in particular. 564 U.S. at 558–59. At the outset, the Court determined whether the law involved a restriction based on the content of the communication or the identity of the speaker, and it determined, in that context, that a regulation on the dissemination of information – that it could be provided to some but not others, and for some purposes but not others – was a pure content-based restriction on speech that was subject to heightened scrutiny under the First Amendment. *Id.* at 563–64.[31] But the Court did not go on to specifically address the state's argument that a lower standard should apply to a law that would burden only commercial speech because it found that the statute could not even pass muster under *Central Hudson*. "To sustain the targeted, content-based burden [that the Vermont law] imposes on protected expression, the State must show at least that the statute directly advances a substantial governmental interest and that the measure is drawn to achieve that interest." *Id.* at 572; *see also id.* at 571 ("[T]he outcome is the same whether a special commercial speech inquiry or a stricter form of judicial scrutiny is applied."). At no point, though, did the Court identify what a stricter test would involve.

The D.C. Circuit has not yet addressed the question of whether *Sorrell* calls for a new approach to regulations of commercial speech. But the other circuits that have considered the question have all continued to apply the *Central Hudson* framework to commercial speech cases. In *Retail Digital Network, LLC v. Prieto,* the Ninth Circuit reasoned that while "[i]n *Sorrell*, the

31 This means that if *Sorrell* has any bearing on this case, it would apply only to the content-based rules concerning modified-risk claims and not to the ban on the dissemination of free samples, which, if it involves speech at all, is a regulation that only incidentally burdens the communicative aspect of the conduct being regulated.

Court entertained the potential application of a 'stricter form of judicial scrutiny,'" it ultimately assessed the statute in question under the *Central Hudson* standard, and it relied on cases applying *Central Hudson* when it analyzed the critical third and fourth factors. 2017 WL 2562047, at *8. The Ninth Circuit also observed that the *Sorrell* opinion reiterated the "core principle[] . . . that commercial speech may be subject to greater regulation than non-commercial speech." *Id.* at *9; *see also id.* ("We are not alone in arriving at this conclusion. In commercial speech cases post-*Sorrell*, the Second, Fourth, Sixth, and Eighth Circuits similarly have, at bottom, continued to apply *Central Hudson*.").[32]

So to the extent the Court finds that the TCA restricts commercial speech, it will apply the *Central Hudson* test.

### B. The Tobacco Control Act's ban on the distribution of free samples is constitutional.

#### 1. The Tobacco Control Act's ban on the distribution of free samples regulates conduct, not speech.

The regulation of pure conduct does not ordinarily implicate First Amendment concerns. While the Supreme Court "has applied First Amendment scrutiny to a statute regulating conduct which has the incidental effect of burdening the expression of a particular political opinion," *Arcara v. Cloud Books, Inc.*, 478 U.S. 697, 702 (1986), citing *O'Brien*, 391 U.S. at 367, the Court has emphasized that this doctrine has boundaries.

---

32 Plaintiffs argue that other circuits have applied *Sorrell* to commercial speech, *see* Nicopure Mem. at 34 n.21, but none of the decisions cited hold that *Sorrell* has replaced *Central Hudson*. *See, e.g.*, *1-800-411-Pain Referral Serv., LLC v. Otto*, 744 F.3d 1045, 1055 (8th Cir. 2014) ("The upshot is that when a court determines commercial speech restrictions are content- or speaker-based, it should then assess their constitutionality under *Central Hudson*."); *United States v. Caronia*, 703 F.3d 149, 164 (2d Cir. 2012) ("The [*Sorrell*] Court did not decide the level of heightened scrutiny to be applied, that is, strict, intermediate, or some other form . . . .", and concluding that the government failed to justify a criminal prosecution "even under *Central Hudson*'s less rigorous intermediate test").

> We cannot accept the view that an apparently limitless variety of conduct can be labeled "speech" whenever the person engaging in the conduct intends thereby to express an idea.

*O'Brien*, 391 U.S. at 376. With that in mind, the Court has observed that an activity affected by a generally applicable governmental regulation must have "a significant expressive element" to warrant First Amendment protection. *Arcara*, 478 U.S. at 706–07.

In *Arcara*, the district attorney brought an action under a New York public nuisance statute to shut down an adult book store, alleging that the owners were aware that the solicitation of prostitution and sexual activity were occurring openly on the premises. *Id.* at 698–99. The owners of the store opposed the action on First Amendment grounds, arguing that the closure of the establishment would interfere with their First Amendment right to sell books. *Id.* at 700. The New York Court of Appeals held that it was necessary to analyze the regulation under the *O'Brien* test because the closure order would impose an incidental burden on the owners' bookselling activities. *Id.* at 705. But the Supreme Court disagreed and distinguished the circumstances before it from the symbolic draft card burning in *O'Brien*. It explained that the Court had subjected governmental restrictions to scrutiny in the past "only where it was conduct with a significant expressive element that drew the legal remedy in the first place, as in *O'Brien*, or where a statute based on a nonexpressive activity has the inevitable effect of singling out those engaged in expressive activity." *Id.* at 706–07. It found that the legislation resulting in the closure of the store was directed at conduct that had nothing to do with expression, and it was not moved by the fact that the implementation of the provision could have "some conceivable burden" on First Amendment activities. *Id.*

Since *Arcara*, the D.C. Circuit has explained that a District of Columbia law imposing a curfew on juveniles did not regulate expressive conduct at all, holding that while the curfew

restriction "regulates the activity of juveniles during nighttime hours[,] it does not, by its terms, regulate expressive conduct." *Hutchins v. District of Columbia*, 188 F.3d 531, 548 (D.C. Cir. 1999).

This case does not involve symbolic action undertaken to convey a political message, and even any commercial message is entirely unstated. Plaintiffs argue that "sampling is essential to educating consumers and obtaining immediate, spontaneous feedback from the market." Pls.' Reply at 33. But this does not suggest that distributing samples conveys any particular message. Indeed, plaintiffs describe the activity in terms of its desired effect rather than its meaning: "sampling is an effective means of communicating and encouraging consumers 'to try different and new . . . products, enabling them to learn about their own preferences and possibly change their purchasing behavior as a result.'" *Id.*, quoting AR 24,014. Plaintiffs add: "[i]nherent in sampling is an intent to inform consumers about a product's characteristics and quality." *Id.* at 32. But the fact that plaintiffs cannot even clearly articulate what implicit statement is allegedly being made, and they can say no more than "inherent in sampling *is an intent*," reveals that there is little likelihood that the message will be clearly understood by others.

Even if the Court were to view the distribution of free samples as inherently expressive – "try this!" – that limited message is not a "significant element" of the conduct being regulated. All sellers of products are animated by the intent that first time customers will become aware of a product's quality or value and the hope that those consumers will continue to purchase the product in the future. But courts have found that sale of products in general, and the sale of cigarettes in particular, is not protected speech. *See Phillip Morris USA, Inc. v. City & Cty. of San Fran.*, 345 F. App'x 276, 277 (9th Cir. 2009) ("Selling cigarettes isn't [protected expressive activity] because it doesn't involve conduct with a 'significant expressive element.' It doesn't even have 'an

expressive component."'), quoting *Arcara*, 478 U.S. at 701–02; *Talk of the Town v. Dep't of Fin. & Bus. Servs.*, 343 F.3d 1063, 1069 (9th Cir. 2003). If "buy this!" is not expression, then handing the merchandise out for free does not change the analysis.

The authorities plaintiffs cite do not require a different outcome. Plaintiffs rely on *Discount Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509 (6th Cir. 2012), but the relevant portion of that case involved a challenge to a multi-part marketing regulation that not only banned the distribution of free samples, but also banned the distribution of non-tobacco items such as tote bags bearing tobacco brand logos; prohibited "continuity programs" involving the provision of free gifts in consideration for a tobacco purchase; and forbid prohibited tobacco companies from sponsoring athletic, musical, and other events. *Id.* at 537–38. The plaintiffs in that case argued that they were engaged in communication "reinforcing brand loyalty" and "encouraging switching from competitors' brands." *Id.* at 538. While the Sixth Circuit concluded that the set of marketing restrictions as a whole was "an attempt to regulate directly the communicative impact of the conduct," *id.* at 539, quoting *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 567 (2001), which implicated the First Amendment, *id.*, it dealt with the set of rules as a whole and did not specifically find that the distribution of free samples alone had a significant expressive element.

Here, the sample ban is not part of a broader restriction on the marketing of e-cigarettes,[33] and it is not aimed at whatever minimal "communicative impact" the distribution of e-cigarette samples might have. Instead, it is focused on conduct – a means of distribution of e-cigarettes that presents a particular risk of providing the product to underage users.

---

33 While the Tobacco Control Act is at issue in this case too, the Deeming Rule does not impose the same restrictions as the TCA imposes. *See* Deeming Rule, 81 Fed. Reg. at 29,041 ("[A]t this time, only some of the restrictions in part 1140 . . . will apply to the newly deemed products . . . . additional provisions in part 1140 (including . . . sale and distribution of nontobacco items, and sponsorship of events) will not apply to the newly deemed products.").

The second case plaintiff cites, *Bailey v. Morales*, 190 F.3d 320 (5th Cir. 1999), is not binding in this Circuit, and it can be distinguished from the case at hand. *Bailey* concerned a criminal statute that banned doctors from giving anything of value to prospective patients. *Id.* at 325. The Fifth Circuit held that giving something of value conveyed the following message: "hire me, try my service," *id.*, and that the message was likely to be understood.

But this Court is not necessarily persuaded that this rises to the level of a constitutionally protected "significant expressive element." Also, *Bailey* involved the exchange of something of value for a prospective customer's business, which would typically result after a more explicit conversation. That alone reduces the communicative aspect of the conduct. *Rumsfeld v. Forum for Academic & Institutional Rights, Inc.*, 547 U.S. 47, 66 (2006) ("The expressive component of a law school's actions is not created by the conduct itself but by the speech that accompanies it. The fact that such explanatory speech is necessary is strong evidence that the conduct . . . is not so inherently expressive that it warrants protection under *O'Brien*.").

Finally, the *Bailey* regulation was designed to prohibit a *quid pro quo*, and that bargain ("If you give me this, I will give you that") was the mutually understood message the Fifth Circuit felt obligated to protect. But the distribution of free samples does not communicate a request for reciprocation, and there is no obvious common understanding of some meaning that has been conveyed.[34]

Plaintiff's theory is further undermined by the line of cases holding that "price regulations and other forms of direct economic regulation do not implicate First Amendment concerns." *Nat'l Ass'n of Tobacco Outlets, Inc. v. City of Providence*, 731 F.3d 71, 77 (1st Cir. 2013) (ban on

34 The third case plaintiff cites, *Rockwood v. City of Burlington*, 21 F. Supp. 2d 411, 420 (D. Vt. 1998), found that free samples were speech covered by the First Amendment, but offered no reasoning in support of that conclusion, and the Court does not find it to be persuasive.

tobacco-product coupons and multi-pack discounts are not speech or expressive conduct), citing *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 507 (1996). At bottom, what the FDA sought to regulate, at Congress's direction, was the fact that the products would be free. Price regulations have long been considered non-speech-related means of controlling product distribution. *See Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 372 (2002) (holding that prohibiting pharmacists from selling compound drugs at wholesale prices would be "non-speech-related"); *see also 44 Liquormart*, 517 U.S. at 507 (finding that a direct regulation requiring higher prices would not involve any restriction on speech).

The government argues that if prohibiting sales at wholesale prices and banning coupons are not restrictions on speech, then neither is a ban on free samples. Defs.' Cross-Reply at 18–19. While plaintiffs assert that free samples allow sellers to "inform consumers about a product's characteristics and quality," Pls.' Reply. at 32, and that they are an "effective means of communicating and encouraging consumers 'to try different and new . . . products,'" *id.* at 33, quoting AR 24,014, coupons and promises of lower prices do the same. Plaintiffs note that the price regulation cases "distinguish sampling as an activity and limit their holdings to price regulation." *Id.*, citing *Nat'l Ass'n of Tobacco Outlets*, 731 F.3d at 78 n.7 ("We need not here consider the persuasive value of [free sample cases because] they did not involve price regulation, but rather the provision of free samples and promotional gifts."). But the cases offer no persuasive reason for drawing the distinction.

For these reasons, the Court concludes that the distribution of free samples is not sufficiently expressive to constitute protected speech, and that the regulation promulgated by the FDA in accordance with the instructions set forth in the TCA is a regulation of conduct, with, at

most, an incidental burden on commercial speech. This means that if the First Amendment applies at all, *O'Brien* is the appropriate test.

The Supreme Court took this approach in *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525 (2001), when it applied *O'Brien* to a Massachusetts sales practices regulation because "Massachusetts seeks to regulate the placement of tobacco products for reasons unrelated to the communication of ideas." *Id.* at 569. The Court held:

> The means chosen by the State are narrowly tailored to prevent access to tobacco products by minors, are unrelated to expression, and leave open alternative avenues for vendors to convey information about products and for would-be customers to inspect products before purchase.

*Id.* at 570. For the same reasons, the restrictions on distributing free samples withstand First Amendment scrutiny.

But even if one were to conclude that the ban is a regulation of speech, the legislation also satisfies the *Central Hudson* factors.

**2. Even if sampling is considered to be expression, plaintiffs concede that the government has a substantial interest in eliminating youth access to tobacco products.**

The *Central Hudson* test asks whether the expression that is being regulated is protected by the First Amendment; whether the government has asserted a substantial interest in regulating that expression; whether the regulation directly advances that governmental interest; and whether the regulation is more extensive than necessary to serve that interest. 447 U.S. at 566. So if one were to conclude that the first prong of the test has been met, the next issue to be addressed would be whether the government has asserted a substantial interest to justify the restriction on speech. *Id*.

The FDA asserts that it has a substantial interest in preventing children and adolescents from gaining access to tobacco products. *See* Deeming Rule, 81 Fed. Reg. at 28,996. The Supreme

Court has recognized that the state has a substantial interest in preventing youth tobacco use. *Lorillard*, 533 U.S. at 555, 564. And plaintiffs concede that the FDA has asserted a substantial interest – to "eliminate a pathway for youth access to Tobacco products." Nicopure Mem. at 36, quoting Deeming Rule, 81 Fed. Reg. 28,973, 28,996. So this factor has been established.

**3. The FDA has sufficient evidence to show that the sampling ban directly and materially advances the interest in eliminating youth access to tobacco products.**

The third *Central Hudson* question is whether the regulation directly and materially advances the substantial governmental interest. *Cent. Hudson*, 447 U.S. at 566.

The government's burden "is not satisfied by mere speculation or conjecture; rather, a governmental body seeking to sustain a restriction on commercial speech must demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree." *Greater New Orleans Broad. Ass'n v. United States*, 527 U.S. 173, 188 (1999), quoting *Edenfield v. Fane*, 507 U.S. 761, 770–71 (1993). So, "the regulation may not be sustained if it provides only ineffective or remote support for the government's purpose." *Id.*, quoting *Cent. Hudson*, 447 U.S. at 564.

The Supreme Court does not, however, "require that 'empirical data come . . . accompanied by a surfeit of background information," and it has "permitted litigants to justify speech restrictions by reference to studies and anecdotes pertaining to different locales altogether, or . . . to justify restrictions based solely on history, consensus, and 'simple common sense.'" *Lorillard*, 533 U.S. at 555, quoting *Florida Bar v. Went For It, Inc.*, 515 U.S. 618, 628 (1995). An agency may rely on evidence generated by analogous situations "so long as whatever evidence the [agency] relies upon is reasonably believed to be relevant to the problem the [regulation] addresses." *Hutchins*, 188 F.3d at 569, quoting *City of Renton v. Playtime Theatres, Inc.*, 475 U.S. 41, 51–52 (1986).

On this issue, the Sixth Circuit's analysis in *Discount Tobacco* comes out strongly on the side of the defendant. When the court was asked to evaluate a sampling ban on cigarettes, it observed that the FDA had proven that free samples of cigarettes were an "easily accessible source of the[] products to young people," 674 F.3d at 541, quoting 61 Fed. Reg. 44,460, and "freely obtainable, even with the tobacco industry's 'voluntary codes that supposedly restrict distribution of free samples to underaged persons.'" *Id.*, quoting 61 Fed. Reg. at 45,244–45 & nn.1206–08. Consequently, the Sixth Circuit concluded that "[b]anning such practices embodie[d] a narrow fit between the harm articulated and the restriction employed," and that "the government's position regarding its ban on product sampling is perhaps its most easily supported." *Id.*

The FDA seeks to ban the distribution of free samples of e-cigarettes because they are "a pathway for youth to access tobacco products, which can help in reducing youth initiation." Deeming Rule, 81 Fed. Reg. at 28,986. It has produced substantial evidence that its free sample ban will directly reduce access to vaping products by minors. The Deeming Rule noted that "[f]ree samples give young people a risk-free and cost-free way to satisfy their curiosity about tobacco products, and, when distributed at cultural or social events, may increase social pressure on young people to accept and use the samples." *Id.*, quoting 60 Fed. Reg. 41314, 41326. The FDA also pointed to anecdotal evidence of "extensive sampling of some newly deemed products in venues that attract youth, including" venues with large audiences, music festivals, and motorsport events, *id.*, and cited a study by the Institute of Medicine of the National Academies, "Growing up Tobacco Free: Preventing Nicotine Addiction in Children and Youths," 1994, http://www.nap.edu/catalog/4757.html, and a study by Senator Richard Durbin. Durbin, R., et. al., "Gateway to Addiction? A Survey of Popular Electronic Cigarette Manufacturers and Targeted Marketing to Youth," April 14, 2014.

The Institute of Medicine study demonstrates that youth are more likely to experiment with cigarettes when exposed to them via free samples, and the Durbin study demonstrates that youth are very likely to be exposed to offers of free samples of e-cigarettes. Applying "simple common sense," *Lorillard*, 533 U.S. at 555, the Court finds that all of this evidence goes well beyond the level of "conjecture and unproven belief." *See* Nicopure Mem. at 36.

And Nicopure's insistence that the FDA must show that minors in fact received e-cigarettes as free samples at one of the events "calls for an absurd preciseness," that is not necessary under *Central Hudson*. *Hutchins*, 188 F.3d at 544 (rejecting the assertion that the District of Columbia prove that its curfew resulted in a drop in juvenile arrests when it had relied on evidence from other cities that curfews reduce arrests). Because the FDA has shown that free e-cigarette samples will encourage youth initiation into use of electronic tobacco products, it has met its burden.[35]

**4. The ban on free samples is not more extensive than necessary to serve FDA's substantial interest.**

Finally, *Central Hudson* requires that the regulation may not be more extensive than necessary to serve the government's interest. *Cent. Hudson*, 447 U.S. at 566. *Central Hudson* "requires something short of a least-restrictive-means standard," *Bd. of Trs. v. Fox*, 492 U.S. 469, 477 (1989), but the agency still bears the burden to demonstrate a "reasonable fit" between the means chosen and the government interest pursued. *Id.* at 480; *see also Am. Meat Inst. v. U.S.*

35 This finding satisfies *O'Brien* as well. "An incidental burden on speech is no greater than is essential, and therefore is permissible under *O'Brien*, so long as the neutral regulation promotes a substantial governmental interest that would be achieved less effectively absent the regulation." *Rumsfeld*, 547 U.S. at 67, quoting *United States v. Albertini*, 472 U.S. 675, 689 (1985). "The issue is not whether other means . . . might be adequate, *id.*, and a regulation is not "invalid simply because there is some imaginable alternative that might be less burdensome on speech." *Albertini*, 472 U.S. at 689. Ultimately, this inquiry in this factor is the same as the "not more extensive than necessary" requirement of *Central Hudson*. *See S.F. Arts & Athletics, Inc.*, 483 U.S. at 537 n.16 ("Both [*Central Hudson*] and the test . . . under *O'Brien* require a balance between the governmental interest and the magnitude of the speech restriction.").

*Dep't of Agric.*, 760 F.3d 18, 26–27 (D.C. Cir. 2014) (en banc). The existence of "numerous and obvious less-burdensome alternatives to the restriction on commercial speech" marshals against a finding of a narrow tailoring, but the presence of "ample alternative channels for receipt" of the relevant information weighs in its favor. *Went For It*, 515 U.S. at 632, 634. The Court does not "require exhaustive evidence documenting the necessity" of one option over another, and it may rely on an agency's "reasonable, common sense determination" that the option chosen is preferable. *Nat'l Cable & Telecomms. Ass'n v. FCC*, 555 F.3d 996, 1002 (D.C. Cir. 2009).

In *Trans Union Corp. v. FTC*, 267 F.3d 1138 (D.C. Cir. 2001), the D.C. Circuit upheld a statute that allowed consumers to "opt out" of allowing telecommunication companies to sell their credit information despite the existence of a "marginally less intrusive" option that would have allowed them to "opt in," because "a regulation is not . . . invalid simply because a court concludes that the government's interest could be adequately served by some less-speech-restrictive alternative." *Id.* at 1142, quoting *Turner Broad. Sys., Inc. v. FCC*, 520 U.S. 180, 217–18 (1997). And the Supreme Court has held that the ability to advertise through telephone directories, legal directories, newspapers, billboards, radio, television, and recorded messages accessible through telephone were "ample alternative channels for receipt of information" sufficient to justify a regulation on direct mail. *Went For It*, 515 U.S. at 634.

Plaintiffs assert that a ban on sampling is more extensive than necessary because "free samples are 'necessary to convince cigarette users to switch to' vaping because 'the[] products are new.'" Nicopure Mem. at 37–38, quoting Deeming Rule, 81 Fed. Reg. at 29,054. Nicopure asserts that less restrictive alternatives such as (1) "limiting of free samples to adults at qualified-adult only facilities," (2) "prohibiting samples from leaving store premises," and (3) "prohibiting the distribution of free samples at public events" would be sufficient. *Id.* at 38.

But the FDA permissibly rejected these alternatives. The agency asserts that it "does not believe that it could achieve the same results by allowing samples of newly deemed products in qualified adult-only facilities," Deeming Rule, 81 Fed. Reg. at 28,986, and it points to previous findings that free samples of cigarettes are easily accessible, even to elementary school children, notwithstanding claimed industry efforts to restrict their distribution to underage persons. Defs.' Cross-Mem. at 77, citing 61 Fed. Reg. 44,396, 44,460; *see also Discount Tobacco*, 674 F.3d at 541.

Also, as the Supreme Court found in *Went For It*, there are "ample alternative channels" for delivering information about e-cigarettes to an appropriate adult audience, such as by discounting sample kits sold in stores to curious adults. *See Went For It*, 515 U.S. at 634. Plaintiffs can also inform consumers via demonstrations, promotional literature, and other advertising.

So the Court concludes that a ban on free samples is not "substantially broader than necessary to achieve the government's interest" given the availability of other, less risky marketing options for the vaping industry. *Trans Union Corp.*, 267 F.3d at 1143.[36]

In sum, the TCA's placement of restrictions on the distribution of free samples of tobacco products does not burden constitutionally protected speech, and if it does, it withstands scrutiny under both the *Central Hudson* and *O'Brien* tests.

### C. The regulation of modified-risk tobacco products satisfies the *Central Hudson* test.

The TCA requires manufacturers to obtain agency pre-approval before it introduces into interstate commerce any tobacco product "which represents explicitly or implicitly" that it is "less

36 The requirement of "ample alternative channels for receipt of information" needed to justify an incidental burden on speech under *O'Brien* is coextensive with the "not more extensive than necessary" factor in *Central Hudson*. *Went For It*, 515 U.S. at 634.

harmful" than other tobacco products, that it "contains a reduced level of a substance or presents a reduced exposure to a substance," or that it "is free of a substance." 21 U.S.C. § 387k. Plaintiffs contend that the TCA violates the First Amendment as applied to them because it prohibits them from making truthful and non-misleading claims about some of their products without agency pre-approval. Nicopure Mem. at 39. And they argue that while the statute "in theory, only restricts modified risk claims, in practice, it 'effectively produce[s] a total ban,'" because the FDA has never approved a modified risk tobacco product application. *Id.*, quoting *Lorillard*, 533 U.S. at 583 n.3.

Under *Central Hudson*, the Court must first "determine whether the expression is protected by the First Amendment." 447 U.S. at 566. "For commercial speech to come within that provision, it at least must concern lawful activity and not be misleading." *Id.* The TCA forbids manufacturers from *saying* something – that their product is "free" of a substance, or that it is less harmful than other tobacco products. *See* 21 U.S.C. § 387k. That is a clear restriction on truthful and non-misleading speech, which is appropriately analyzed under *Central Hudson*.[37]

The next question under *Central Hudson* is whether "the asserted governmental interest is substantial." *Cent. Hudson*, 447 U.S. at 566. The Deeming Rule states that the provision will

37 The government maintains that the Court need not review the "modified risk" provision under *Central Hudson* at all because the provision is based on the premarket review for "new drugs" as set forth in the Federal Food, Drug, and Cosmetic Act. Defs.' Cross-Mem. at 78. The D.C. Circuit has held that requiring premarket review of drugs based on their "intended use" is not subject to First Amendment scrutiny because "the First Amendment allows 'the evidentiary use of speech to establish the elements of a crime or to prove motive or intent.'" *Whitaker v. Thompson*, 353 F.3d 947, 953 (D.C. Cir. 2004), quoting *Wisconsin v. Mitchell*, 508 U.S. 476, 489 (1993). So the government argues that because "[t]he premarket review of tobacco products that purportedly reduce health risks functions in the same way as the FDCA provision" upheld in *Whitaker*, modified risk claims are not subject to First Amendment protection. Def.'s Cross-Mem. at 79. But *Whitaker* is inapplicable and the analogy fails because the modified risk provision at issue here does not turn on the question of the manufacturer's "intended use."

advance four governmental interests – "improv[ing]" and "protecting" public health, "prevent[ing] the use of unsubstantiated modified risk claims, which may mislead consumers and lead them to initiate tobacco product use or continue using tobacco when they would otherwise quit," "allow[ing] for better-informed consumers," and "help[ing] to prevent the use of misleading marketing targeted to youth populations." Deeming Rule, 81 Fed. Reg. at 29,053; *see also* Defs.' Cross-Mem. at 80 (asserting that the FDA has a substantial interest in "protecting public health and preventing false and misleading tobacco industry claims about the relative health benefits of its products."), citing TCA §§ 2(36)–(37), (40).

With this, the FDA has articulated a substantial interest in regulating modified-risk claims. *See, e.g.*, *Discount Tobacco*, 674 F.3d at 535; TCA § 2(40) ("The dangers of products sold or distributed as modified risk tobacco products that do not in fact reduce risk are so high that there is a compelling governmental interest in ensuring that statements about modified risk tobacco products are complete, accurate, and relate to the overall disease risk of the product."); *see also Edenfield*, 507 U.S. at 769 (finding a substantial government interest "in ensuring the accuracy of commercial information in the marketplace").[38]

The third and fourth inquiries under *Central Hudson* are whether the regulation directly advances the governmental interest, and whether the regulation is no more extensive than necessary to serve that interest. *Cent. Hudson*, 447 U.S. at 566.

38 Plaintiffs insist that the "FDA's argument rests on the faulty premise that the tobacco and vapor industries warrant the same treatment with respect to the modified risk restrictions." Pls.' Reply at 41. But once again, that premise was built into the statute by Congress, TCA §§ 2(36), (37), (43), and the need to protect the public from unsubstantiated health claims applies with equal force no matter how the nicotine is being delivered.

In upholding the modified risk provisions against a First Amendment challenge, the Sixth Circuit found that premarket review of modified risk claims was not more extensive than necessary because "the government has made a reasonable determination that, in the context of a deadly and highly addictive product, it would be a virtual impossibility to unring the bell of misinformation after it has been rung." *Discount Tobacco*, 674 F.3d at 537. That reasoning applies with equal force to the regulation of e-cigarettes.[39]

Plaintiffs assert that the modified risk regulation does not directly advance the governmental interest because, to do so, the "FDA would have to show that the [modified risk provision], by restricting truthful and non-misleading speech about the contents or characteristics of using vaping products, somehow benefits the public health on a population-wide basis." Nicopure Mem. at 42. But as with many other aspects of their challenge, plaintiffs lack legal authority for the standard they would have the Court impose. Plaintiffs also argue that the regulation is more extensive than necessary because instead of infringing on plaintiffs' constitutionally-protected interest in truthful and non-misleading speech, the FDA could have "simply required disclaimers, such as that the statements: (i) are not approved by the FDA; (ii) do not establish that the product is safer than any other tobacco product; or (iii) do not change the fact that quitting nicotine products altogether is healthier than using vaping products." *Id.* at 44. But Congress expressly rejected plaintiffs' argument that disclaimers would be adequate to achieve the government's interests. *See* TCA § 2(41) ("[C]onsumers have misinterpreted advertisements in which one product is claimed to be less harmful than a comparable product, even in the presence

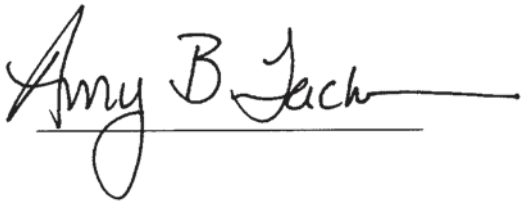
39 In response to comments about the constitutionality of the modified risk provision, the agency relied upon *Discount Tobacco*'s holding that the modified risk provision "is sufficiently tailored because it concerns only consumer-targeted speech about tobacco products' health effects or contents." Deeming Rule, 81 Fed. Reg. at 28,987, citing *Discount Tobacco*, 674 F.3d at 534–37.

of disclosures and advisories intended to provide clarification."); *id.* § 2(42) ("Permitting manufacturers to make unsubstantiated statements concerning modified risk tobacco products, whether express or implied, even if accompanied by disclaimers[,] would be detrimental to the public health.").

And in the end, notwithstanding plaintiffs' rhetoric, this provision does not ban truthful statements about health benefits or reduced risks; it simply requires that they be substantiated.[40] So the Court agrees with the Sixth Circuit that the modified risk provision directly and materially advances the government interests in preventing manufacturers from making false or misleading claims about their products, and it passes muster under the First Amendment.

**CONCLUSION**

For all of those reasons, the Court will deny plaintiffs' motions for summary judgment, and it will grant the agency's cross-motion for summary judgment. A separate order will issue.



AMY BERMAN JACKSON
United States District Judge

DATE: July 21, 2017

40 Furthermore, under 21 U.S.C. § 387k(g)(2)(A), the Secretary is specifically given discretion to approve a label if "any aspect of the label, labeling, and advertising for such product that would cause the tobacco product to be a modified risk tobacco product . . . is limited to an explicit or implicit representation that such tobacco product or its smoke does not contain or is free of a substance or contains a reduced level of a substance, or presents a reduced exposure to a substance in tobacco smoke."