IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NICOPURE LABS, LLC, Plaintiff, v. FOOD AND DRUG ADMINISTRATION, et al., Defendants.	Civil Action No. 16-878 (ABJ)
RIGHT TO BE SMOKE–FREE COALITION, et al., Plaintiffs, v. FOOD AND DRUG ADMINISTRATION, et al., Defendants.	Civil Action No. 16-1210 (ABJ)

DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT

For the reasons stated in the accompanying memorandum of law, Defendants respectfully cross-move for summary judgment on all claims raised in Plaintiffs' complaints. *See* Fed. R. Civ. P. 56.

Dated: August 16, 2016

Respectfully submitted,

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MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTIONS FOR SUMMARY JUDGMENT AND IN SUPPORT OF DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

Electronic cigarettes are the fastest growing segment of the tobacco market, and their use has spiked dramatically in recent years. They are now used by more than 13 percent of high school students, eclipsing conventional cigarettes as the most popular tobacco product among youth. Although they are often marketed as helping smokers quit, there is scant evidence to back such claims, and some evidence that they in fact *inhibit* cessation. At the same time, there is ample evidence that e-cigarettes present significant risks to the public health. To begin, they are principally designed to deliver nicotine—one of the most addictive substances known to man—and can do so as effectively as conventional cigarettes. Nicotine is also toxic—it impairs brain development in youth, causes pre-term delivery and stillbirth, and can be fatal at high doses. Some e-cigarettes deliver other toxic and carcinogenic chemicals, like formaldehyde and nickel, at levels higher than conventional cigarettes. Others have exploded in users' faces, causing burns and lost teeth. And while the ingredients of the staggering 4,000 to 8,000 e-liquids on the market are largely unknown, many contain diacetyl, acetyl propionyl, or various aldehydes—toxic chemicals that are especially common in candy-flavored varieties that appeal to youth.

Plaintiffs acknowledge none of these risks. Their briefs give no inkling that nicotine is highly addictive, that e-liquids often contain toxic chemicals, or that e-cigarettes can explode. Instead, Plaintiffs contend that e-cigarettes should not be regulated *at all*, because they are generally "safer" than conventional cigarettes—one of the deadliest products ever brought to market. But that is rather like saying that cars should not be regulated because they are safer than motorcycles. And it is no answer to the many risks of e-cigarettes that are known now, and that could be mitigated through FDA oversight.

The Court need not sift through this evidence, however, because Congress entrusted the decision whether to supervise tobacco products, including e-cigarettes, to the expert judgment of the FDA. There can be no doubt that "the FDA has authority under the Tobacco [Control] Act to regulate e-cigarettes," as the D.C. Circuit held in *Sottera, Inc. v. FDA*, 627 F.3d 891, 897 (D.C. Cir. 2010), and Plaintiffs cannot escape that conclusion simply because their "open-system" e-cigarettes are refillable. It is equally clear that the FDA's exercise of the deeming authority is committed to agency discretion, given that Congress authorized it to subject "any" tobacco product (except certain raw tobacco leaf) to the Tobacco Control Act as it "deems" fit. 21 U.S.C. § 387a(b). In any event, the FDA rationally explained why it deemed e-cigarettes subject to the Tobacco Control Act, given their many known risks, as well as why it rejected the regulatory alternatives that Plaintiffs prefer. While Plaintiffs fault the FDA for adopting a "one-size-fits-all" approach, the Tobacco Control Act makes deeming a necessary precondition to *any* regulation of e-cigarettes—including the age restrictions that Plaintiffs profess to support, Stamler Decl. ¶ 41—and Plaintiffs offer no statutory support for their alternative, *à-la-carte* approach.

There is likewise no basis to review the FDA's cost-benefit analysis, as the Tobacco Control Act requires no such analysis, and the Executive Orders under which the agency acted expressly preclude judicial review of its conclusions. Regardless, the FDA reasonably found that the costs of the deeming rule—an estimated $2 per beneficiary per year—were justified by its benefits, including more accurate labels, effective health warnings, and improved product consistency. Similarly misplaced are Plaintiffs' criticisms of the FDA's regulatory flexibility analysis, as the agency fully complied with the purely procedural requirements of the Regulatory Flexibility Act.

Plaintiffs' two First Amendment challenges—to the ban on the distribution of free samples, and to the premarket review of "modified risk" products—also lack merit. The free sample ban regulates conduct, not speech, and thus does not even implicate free speech concerns. And the premarket review of "modified risk" tobacco products is modeled after the premarket review of therapeutic drugs under the Federal Food, Drug, and Cosmetic Act ("FDCA"), which the D.C. Circuit has already upheld against First Amendment challenge. Moreover, both provisions would easily pass muster even if scrutinized as commercial speech, as they are narrowly tailored to prevent the harms that Congress foresaw.

Absent the deeming rule, the FDA cannot require e-cigarettes and e-liquids to have accurate labels. It cannot require warnings about their addictive potential. It cannot require that toxic and carcinogenic chemicals be reduced or eliminated. It cannot require that these products be made in accordance with good manufacturing practices. It cannot verify that purportedly "modified risk" products do, in fact, reduce risk. And it can do nothing to prevent risky products from falling into the hands of youth. The Court should reject Plaintiffs' suggestion that e-cigarettes are somehow so unique among tobacco products that they should escape regulation of these known risks.

BACKGROUND

A. Statutory Background

Congress crafted the Tobacco Control Act ("TCA") based on evidence gathered over decades by all three branches of government regarding the health risks of tobacco products and the tobacco industry's marketing practices. That evidence established four key points.

First, "tobacco use, particularly among children and adolescents, poses perhaps the single most significant threat to public health in the United States." *FDA v. Brown & Williamson*

Tobacco Corp., 529 U.S. 120, 161 (2000). "Each year, 440,000 people die of diseases caused by smoking or other forms of tobacco use—that is about 20 percent of all deaths in our nation." Statement of Vice Admiral Richard H. Carmona, U.S. Surgeon General, *reprinted at* 155 Cong. Rec. S6000 (June 3, 2009).

Second, the magnitude of the public health harm caused by tobacco use is "inextricably linked" to nicotine addiction. 75 Fed. Reg. 69,524, 69,528 (Nov. 12, 2010). "The pharmacologic and behavioral processes that determine tobacco addiction are similar to those that determine addiction to drugs such as heroin and cocaine." *Id.* The power of nicotine addiction is perhaps best illustrated by the failure rate of individual cessation efforts. In 2004, for example, "although approximately 40.5 percent of adult smokers reported attempting to quit . . . , only between 3 and 5 percent were successful." *Id*. at 69,529. The tobacco industry has long appreciated the importance of nicotine addiction to their sales. In an internal 1972 memo, one company acknowledged that "a tobacco product is, in essence, a vehicle for the delivery of nicotine"—a "potent drug with a variety of physiologic effects"—and that the "industry is then based upon the design, manufacture, and sale of attractive forms of nicotine." 146 Cong. Rec. H1849 (Apr. 5, 2000) (statement of Rep. Ganske) (quoting an R.J. Reynolds memo).

Third, the tobacco industry has long depended on recruiting underage users who become addicted before age 18. Congress found that, despite laws prohibiting the sale of tobacco products to minors, the "overwhelming majority of Americans who use tobacco products begin using such products while they are minors and become addicted to the nicotine in those products before reaching the age of 18." Legislative Finding 31, Pub. L. No. 111-31, § 2, 123 Stat. 1776 (2009). Congress additionally found that "[a]dvertising, marketing, and promotion of tobacco products have been especially directed to attract young persons to use tobacco products, and

these efforts have resulted in increased use of such products by youth." Legislative Finding 15; *see also United States v. Philip Morris USA, Inc.*, 449 F. Supp. 2d 1, 572 (D.D.C. 2006) (the "central purpose of the tobacco companies' image advertising is motivating adolescents to smoke"), *aff'd in part*, 566 F.3d 1095 (D.C. Cir. 2009).

Fourth, the tobacco industry for decades misled consumers about the health risks and addictiveness of its products. Beginning in 1964, with the landmark report "Smoking and Health," the Surgeon General has issued periodic reports on the health consequences of tobacco use and nicotine addiction. In response, tobacco manufacturers undertook a multi-pronged campaign to deny these health hazards and undermine the credibility of the studies, even though they knew the reports were accurate. These efforts are "demonstrated by not only decades of press releases, reports, booklets, newsletters, television and radio appearances, and scientific symposia and publications, but also by evidence of their concerted[] efforts to attack and undermine the studies in mainstream scientific publications such as the Reports of the Surgeon General." *Philip Morris*, 449 F. Supp. 2d at 855.

At the same time, tobacco companies sought to develop "health reassurance" products that consumers would believe pose lower health risks, provide an alternative to quitting, or represent a step in decreasing the level of dependence. *Philip Morris*, 566 F.3d at 1107. The manufacturers knew, however, that these ostensibly "modified risk" products actually provided no health benefit. Indeed, tobacco manufacturers "marketed and promoted their low tar brands to smokers—who were concerned about the health hazards of smoking or considering quitting—as less harmful than full flavor cigarettes despite either lacking evidence to substantiate their claims or knowing them to be false." *Id*.

B. The Tobacco Control Act

Against this backdrop, Congress enacted the Tobacco Control Act as a comprehensive scheme for the regulation of tobacco products. Pub. L. No. 111-31, 123 Stat. 1776 (2009) (codified at 21 U.S.C. § 301 *et seq.*). The Act addresses the manufacture and marketing of tobacco products in three principal ways.

First, Congress enacted measures to ensure accurate information about the ingredients of tobacco products and their health risks. For example, manufacturers of tobacco products subject to the Act must disclose to the FDA the identity and quantity of all ingredients—including nicotine and any other additives—in each product. 21 U.S.C. § 387d(a)(1)–(2). The labels on their products must accurately describe their contents. *Id.* § 387c. Smokeless tobacco must bear a warning label—such as "WARNING: Smokeless tobacco is addictive," 15 U.S.C. § 4402(a)(1)—and other tobacco products may be required to bear similar warnings, 21 U.S.C. § 387f(d)(1)–(2). And to ensure that products marketed as presenting reduced health risks actually do so, Congress required premarket FDA review of tobacco products purportedly posing "modified risks," such as a lower risk of disease, or reduced exposure to a harmful substance. *Id.* § 387k.

Second, Congress took steps to control the contents and quality of tobacco products. Manufacturers must register with the FDA, *id.* § 387e(b), file a list of tobacco products they make, *id.* § 387e(i), and adhere to manufacturing practices the FDA may prescribe, *id.* § 387f(e). Given the appeal of flavored products to children, Congress banned the use of all characterizing flavors (except tobacco and menthol) in cigarettes, including "strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, [and] coffee." *Id.* § 387g(a)(1)(A). For all tobacco products, Congress authorized the FDA to adopt standards regulating the level of any ingredient, including nicotine. *Id.* § 387g(a)(3). And to avoid

allowing potentially harmful tobacco products to saturate the market before regulators can catch up, as happened with cigarettes, Congress provided for premarket FDA review of new tobacco products, such as those entering the U.S. market after February 15, 2007. *Id.* § 387j.

Third, Congress directed the FDA to reissue, with certain changes, provisions of a 1996 rule that restricted several marketing practices used by the tobacco industry to recruit children and adolescents. 21 U.S.C. § 387a–1(a) (directing reissuance of portions of 21 C.F.R. part 897, now codified at 21 C.F.R. part 1140). Among other things, for cigarettes and smokeless tobacco, that rule bans the sponsorship of concerts and athletic events in the name of a tobacco brand, and bars the distribution of merchandise bearing a tobacco brand name or logo. 21 C.F.R. § 1140.34(a), (c). And for all tobacco products subject to Chapter IX of the FDCA, the rule generally bans the distribution of free samples. Pub. L. No. 111-31, § 102(a)(2)(G); 21 C.F.R. § 1140.16(d).[1]

Together, these provisions effectuate several of the Act's principal goals: to make "consumers . . . better informed" about "the health and dependency effects or safety of tobacco products"; to permit the FDA to "regulate the levels of tar, nicotine, and other harmful components" of tobacco products; and to ensure "effective oversight of the tobacco industry's efforts to develop, introduce, and promote less harmful tobacco products." Pub. L. No. 111-31, § 3(4)–(6).

Congress made the Tobacco Control Act applicable to four categories of tobacco products—"all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco"—as

[1] An exception to the rule permits the distribution of free samples of smokeless tobacco in "qualified adult-only facilities," narrowly defined by Congress as temporary facilities, enclosed by an opaque barrier free of advertising, where alcohol is not served and a law enforcement officer denies admission to underage youth without valid identification. Pub. L. No. 111-31 § 102(a)(2)(G); 21 C.F.R. § 1140.16(d).

well as "to any other tobacco products that the Secretary by regulation *deems* to be subject to this chapter." FDCA § 387a(b) (emphasis added); *cf. Webster v. Doe*, 486 U.S. 592, 600 (1988) (use of the word "deem" indicates that statute's implementation is "committed to agency discretion"). The Act "broadly defines tobacco products as extending to '*any* product made *or derived from* tobacco,'" *Sottera*, 627 F.3d at 897 (quoting 21 U.S.C. § 321(rr)(1)) (emphasis in original), "including any component, part, or accessory of a tobacco product," 21 U.S.C. § 321(rr)(1). In 2010, the D.C. Circuit held that e-cigarettes meet this definition and, accordingly, "the FDA has authority under the Tobacco [Control] Act to regulate electronic cigarettes, enabling it to mitigate or perhaps extinguish any harm to public health." *Sottera*, 627 F.3d at 899.

C. Regulatory Background

In the deeming rule, the FDA exercised that authority. The record before the agency demonstrates that e-cigarette use has recently spiked, particularly among minors, and raises significant public health concerns.

E-cigarettes appeared in China in the early 2000s and were available in the United States by early 2007. 81 Fed. Reg. at 28,978; Hajek et al. (2014) at 1801 (AR 22,954). The earliest—and still most popular—devices are often called "cig-alikes," given their resemblance to conventional cigarettes. *Id*. These devices generally consist of three basic parts: a cartridge of liquid typically containing nicotine ("e-liquid"), an atomizer with a heating element, and a battery and other electronics. *Sottera*, 627 F.3d at 893. When a user sucks on the device, the atomizer vaporizes the e-liquid, which is inhaled as an aerosol. *Id*.

Later variations on this design have come to be known as "vaping" devices. These come in a wide variety of forms, but generally fall into two categories: closed and open systems. In closed systems, the e-liquid is contained in a disposable cartridge. In open systems, in place of

the cartridge is a small tank, which users can refill with e-liquid. Despite some design variations, cig-alikes and vaping devices share the same basic features: an e-liquid, an atomizer with a heating element, and a battery and other electronics. Together, they are often generically referred to as e-cigarettes or—reflecting their primary function—electronic nicotine delivery systems ("ENDS"). *See, e.g.*, Surgeon General's Report (2014) at 752 (AR 15,336); 81 Fed. Reg. 28,974, 28,976 (May 10, 2016) (ENDS "includ[e] e-cigarettes, e-hookah, e-cigars, vape pens, advanced refillable personal vaporizers, and electronic pipes").

E-cigarette use in the United States was negligible in the 2000s but has risen dramatically in recent years. 81 Fed. Reg. at 29,028–29. Among adults, from 2012 to 2014, current use more than doubled, from 1.4 to 3.7 percent. *See* Zhu et al. (2013) at 3 (AR 23,871); Schoenborn & Gindi (2015) at 2 (AR 15,666). This spike is even more pronounced among youth: from 2011 to 2014, current use by high school students rose 8-fold, from 1.5 to 13.4 percent. 81 Fed. Reg. at 28,984. By 2014, e-cigarettes had eclipsed conventional cigarettes as the most widely used tobacco product among youth, with more than 2.4 million current users in middle and high school alone. *Id*.

The e-cigarette market has ballooned in tandem, with domestic sales reaching an estimated $3.5 billion in 2015. AR 23,950. Roughly two-thirds of this market is in cig-alikes, which are primarily distributed by the "big three" tobacco companies and largely sold alongside conventional cigarettes in supermarkets, pharmacies, convenience stores, and "big box" retailers, as well as online.[2] The remaining third of the market is in vaping devices, which are largely sold

[2] Jonathan Adler et al., *Baptists, Bootleggers, and E-Cigarettes*, at 22, Yale J. Reg. (forthcoming), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2683583; *see generally* Grana et al. (2013) at 72 (AR 21,015) (discussing big-tobacco company e-cigarette divisions).

online and in 5,000 to 10,000 "vape shops" across the country. *Id.*; AR 23,980–81. All told, about 640 to 800 different e-cigarette devices (or 800 to 1,000 unique packaging configurations) are now sold in the United States, AR 23,987–89—most of them imported from China, Grana et al. (2014) at 1972 (AR 15,582).

In contrast to conventional cigarettes, which are permitted in only two characterizing flavors—tobacco and menthol—a staggering 4,000 to 8,000 different varieties of e-liquid (or 5,000 to 10,000 unique packaging configurations) are now sold in the United States. RIA 76–78. Many of these are fruit or candy flavored, magnifying "their appeal to youth and young adults." 81 Fed. Reg. at 29,011; *see, e.g.*, Grana & Ling (2014) at 400 (AR 23,128) (73 percent of brands offer fruit flavors; 71 percent offer candy flavors). As Plaintiff Nicopure's website explains:

> You wanted more than just tobacco and menthol flavors, and we heard you. So we evolved and unveiled our eVo line of e-liquids.
>
> If you're looking for a more adventurous e-liquid experience, eVo is for you. The Harvest Collection features a medley of sweet and refreshing fruit flavors, while the Café Collection offers tantalizing gourmet pastry and mixed drink blends.

See https://www.nicopure.com/eliquid-brands/evo. Among Nicopure's offerings "bound to send your taste buds into overdrive" are "Wild Watermelon," "Summer Peach," "Piña Colada," and "FruitApalooza." *See* https://www.halocigs.com/e-liquid/fruit-flavors. Likewise, the three top-selling flavors at e-liquids.com, a large online retailer, are "Unicorn Milk" (strawberries and cream), "TNT" (strawberry, apple, and peach), and "I Love Donuts" (blueberries and pastry). *See* http://eliquid.com/collections/best-sellers.

This explosion in virtually unregulated products raises significant public health concerns. Although the FDA recognized that completely switching to e-cigarettes may reduce the risk of tobacco-related disease for individuals currently smoking conventional cigarettes—one of the

deadliest products ever brought to market—it found that e-cigarettes still pose a number of significant health and safety risks. 81 Fed. Reg. at 29,047.

First, nicotine is "one of the most addictive substances used by humans," 81 Fed. Reg. at 28,988, and "a powerful pharmacologic agent that acts in the brain and throughout the body," Surgeon General's Report (1988) at 14 (AR 1183). "[N]icotine is psychoactive ('mood altering') and can provide pleasurable effects," and "causes physical dependence characterized by a withdrawal syndrome that usually accompanies nicotine abstinence." *Id*. E-cigarettes can deliver as much nicotine as conventional cigarettes—sometimes more. 81 Fed. Reg. at 29,031.

Second, nicotine is also toxic at high doses, and can harm adolescents, pregnant women, and fetuses. 81 Fed. Reg. at 29,033. The Surgeon General has concluded that nicotine exposure during pregnancy "contribut[es] to multiple adverse outcomes, such as pre-term delivery and stillbirth," and "has lasting consequences for [fetal] brain development." Surgeon General's Report (2014) at 126 (AR 14,708). Likewise, nicotine exposure during adolescence "may have lasting adverse consequences for brain development." *Id.* Further, ingesting or directly touching e-liquids can cause nicotine poisoning, which is sometimes fatal. 81 Fed. Reg. at 29,032. Between 2010 and 2013, some 1,700 e-liquid exposures were reported to U.S. poison control centers—mostly accidents involving children under 5. *Id*. In 2014, a toddler in upstate New York died after ingesting liquid nicotine. *Id*. at 29,036.

Third, other chemicals in e-liquids are also cause for concern. Nicopure alleges that e-liquids "generally" consist of "propylene glycol, glycerol, and flavors." Compl. ¶ 3. But, like most manufacturers, Nicopure does not disclose its *actual* ingredients, so what consumers are really inhaling is largely unknown. What information is available about the ingredients used in e-liquids shows that many present health concerns. For example, a study of 159 e-liquids with

sweet flavors (such as "toffee, chocolate, and caramel") found that "almost three quarters of the samples (74 percent) contained diacetyl or acetyl propionyl, both of which pose known inhalation risks." 81 Fed. Reg. at 29,029. A second study, of 30 e-liquids, "found that many flavors, including cotton candy and bubble gum, contain aldehydes, a class of chemicals that can cause respiratory irritation [and] airway constriction," and noted that "two flavors, a dark chocolate and a wild cherry, would expose e-cigarette users to more than twice the recommended workplace safety limit for the aldehydes vanillin and benzaldehyde." *Id*. A third study found that several cinnamon-flavored e-liquids contained yet another aldehyde, "cinnamaldehyde, which [is] highly toxic to human cells in laboratory tests." *Id*.; *see also, e.g., id*. at 29,031 (diethylene glycol, a toxicant, found in one e-liquid cartridge); Hutzler et al. (2014) at 1295 (AR 22,703) (ethylene glycol, a toxic compound commonly used in antifreeze, found to be the "dominant compound" of 5 of 28 e-liquids, and present in 7 others).

Fourth, among e-liquids, there is "significant . . . variability between labeled content and concentration and actual content and concentration." 81 Fed. Reg. at 28,984. One study found that some e-liquids "claiming to be nicotine-free actually contained high levels of nicotine." *Id*. at 29,034. Another reported that the "actual nicotine level of 65 percent of the e-liquids deviated by more than 10 percent from the nicotine concentrations printed on the[ir] labels." *Id*.

Fifth, among e-cigarette devices, variations in design and performance affect the amount of chemicals that are actually inhaled by users. Nicotine delivery "varies widely depending on product characteristics, user puffing behavior[,] and nicotine solution concentration, leaving smokers unaware of the nicotine levels they are receiving." 81 Fed. Reg. at 29,032. Thus, even when e-liquids are accurately labeled, "there is little relationship between nicotine in cartridges and nicotine in aerosol," largely because the "mechanical features" of e-cigarettes, "such as the

size of the battery, the nature of the heating element[,] and the ventilation holes, . . . play a major role." Hajek et al. (2014) at 3 (AR 22,956). Indeed, devices that "heat[] e-liquids to higher temperatures . . . may result in nicotine delivery that is actually higher than that of a conventional cigarette." 81 Fed. Reg. at 29,031.

These design variations also affect the delivery of other toxic chemicals. The solvents used in e-liquids—generally propylene glycol and glycerol—are chosen to create aerosols that simulate the look and feel of conventional cigarette smoke, but when vaporized at certain voltages, these solvents can produce some of the same harmful byproducts as conventional cigarettes, sometimes at higher levels. Cheng (2014) at ii13 (AR 23,072). For example, researchers have reported that devices operated at higher voltages deliver more formaldehyde, a known carcinogen, than conventional cigarettes. 81 Fed. Reg. at 29,031. One study found that e-cigarettes delivered no detectable formaldehyde at 3.3 volts, but twice the formaldehyde of conventional cigarettes at 5 volts. *Id*. at 29,030. Another study found that "increasing the voltage from 3.2 to 4.8 volts increased formaldehyde, acetaldehyde, and acetone levels from 4-fold to over 200-fold." *Id*. Devices with voltages that meet or exceed these thresholds are readily available. Nicopure itself advertises its "Reactor" e-cigarette as an "adjustable wattage and voltage" device whose power reaches a full "10.0 volts." *See* https://www.halocigs.com/reactor/starter-kit. There is also evidence that toxic heavy metals and silicates can be transferred from e-cigarette parts into the inhaled aerosol. One study of devices with a "cartomizer" (i.e., a combined cartridge and atomizer) found that they produced lead and chromium concentrations "within the range of conventional cigarettes," and nickel concentrations "2–100 times higher . . . than in Marlboro brand cigarettes." Williams et al. (2013) at 5 (AR 6977). Likewise, the packaging of e-liquids may affect the chemicals ultimately inhaled. Vials of e-liquid can leach

toxic compounds, and "these leachates may be inhaled when the e-liquids are used as intended, posing additional health risks." *Id*. at 29,015.

Sixth, the batteries and other components used in e-cigarettes also pose health and safety risks. Media reports have chronicled serious injuries—including facial burns and lost teeth—attributed to exploding batteries. *See* 81 Fed. Reg. at 29,035. The U.S. Fire Administration found 25 media reports of e-cigarette explosions or fires between 2009 and 2014, and concluded that the shape of e-cigarettes makes them more likely to shoot off like "flaming rockets" when a battery fails.[3] The U.S. Department of Transportation recently banned e-cigarettes from checked luggage, after fires at Boston Logan and LAX showed that the devices "can overheat and cause fires when the heating element is accidentally activated or turned on." 80 Fed. Reg. at 66,817, 66,817–18 (Oct. 30, 2015). And manufacturers are currently facing dozens of lawsuits across the nation over such alleged defects.[4] Nicopure, meanwhile, advertises that its e-cigarettes pose "no risk of fire hazards." *See* https://www.halocigs.com/why-halo/what-is-an-electronic-cigarette.

Seventh, e-cigarettes, like conventional cigarettes, may also harm nonusers. Secondhand aerosol contains nicotine, which is absorbed through passive exposure, "with one study showing levels comparable to passive smokers" of conventional cigarettes. Grana et al. (2013) at 2 (AR 20,945); *see also* 81 Fed. Reg. at 29,031–32. Indeed, studies show that "secondhand e-cigarette aerosols have been found to contain at least 10 chemicals known to cause cancer, birth defects,

[3] U.S. Fire Administration, Electronic Cigarette Fires and Explosions (Oct. 2014), at 1, *available at* http://www.usfa.fema.gov/downloads/pdf/publications/electronic_cigarettes.pdf?utm_source=website&utm_medium=pubsapp&utm_content=Electronic Cigarette Fires and Explosions&utm_campaign=TDL.

[4] Sarah Randazzo, *E-cigarette Users Sue Over Exploding Devices*, Wall Street Journal, July 3, 2016, *available at* http://www.wsj.com/articles/e-cigarette-users-sue-over-exploding-devices-1467538202.

or other reproductive harm," 81 Fed. Reg. at 29,031, including "acetaldehyde, formaldehyde, nickel, lead, [and] toluene," Grana et al. (2013) at 52 (AR 20,995). Thus, several researchers have urged consideration of the potential health risks posed by passive exposure, *see, e.g.*, *id*.; King et al. (2014) at 3 (AR 23,619); Schober et al. (2014) at 636 (AR 23,140), and the literature firmly rejects the claims of some manufacturers that secondhand aerosol is merely "harmless water vapor," Grana et al. (2013) at 88 (AR 21,031); *cf., e.g.,* AR 145,702 (screenshot from website of "blu" e-cigarettes) ("So instead of exposing yourself, and all those around you, to the thousands of dangerous toxins and chemicals found within cigarette smoke, electronic cigarettes simply produce a water vapor.").

Eighth, e-cigarette advertising specifically targets youth, mimicking the strategies previously used by "Big Tobacco"—to devastating effect—and thus banned for conventional cigarettes. In addition to the use of flavors attractive to youth, e-cigarette companies "air advertisements during events and programming with high levels of youth viewership," like the Super Bowl, the Academy Awards, and on ESPN and Comedy Central. Durbin et al. (2014) at 16 (AR 18,686). These advertisements often use celebrity endorsements "to depict e-cigarette smoking as glamorous, rebellious, sexy, and masculine." *Id*. at 17 (AR 18,688). Claims of lifestyle benefit—a hallmark of traditional tobacco advertising—are also common. A study of 59 e-cigarette websites showed that 73 percent made claims that e-cigarettes are modern or glamorous, 44 percent pointed to increased social status, 32 percent suggested enhanced social activity, 31 percent alluded to romantic advantages, and 22 percent used celebrities. *See* Grana & Ling (2014) at 399 (AR 23,127). Additionally, in 2012 and 2013 alone, six surveyed e-cigarette companies "sponsored or provided free samples at 348 events, many of which appear

geared toward youth," including concerts, music festivals, parties, and sporting events. Durbin et al. (2014) at 10 (AR 18,681).

The FDA recognized that, because e-cigarettes are still relatively new to the marketplace, the current evidence is insufficient to answer two key questions about their overall population-level effects on public health. First, it is unclear whether e-cigarettes might help some smokers quit, as Plaintiffs postulate. Although there is "some indication that such products may have the potential to help some individual users to quit using combusted tobacco products or to reduce their use of such products," "other evidence is to the contrary," and "some systematic reviews of available evidence indicate that there is currently insufficient data to draw a conclusion about the efficacy of e-cigarettes as a cessation device." 81 Fed. Reg. at 29,037. Indeed, e-cigarettes may actually *inhibit* quitting conventional cigarettes, as "adult smokers who begin to use e-cigarettes seldom completely quit combustible products," Primack et al. (2015) at 1019 (AR 23,907)—a particularly troubling prospect given the substantial risks of even light or intermittent smoking. As the Surgeon General has reported, "the strongest determinant of risk for many diseases (e.g., lung cancer) caused by tobacco use is the *duration*"—not the *quantity*—"of smoking." Surgeon General's Report (2010) at 78 (AR 1891). Unlike the various nicotine-replacement therapies currently approved by the FDA—such as transdermal patches, chewing gum, and lozenges—e-cigarettes "are not an FDA-approved cessation product," 81 Fed. Reg. at 29,037–38, and the U.S. Preventive Services Task Force, an independent, volunteer panel of national experts in prevention and evidence-based medicine, has concluded "that available data on the use of [e-cigarettes] for smoking cessation are quite limited and suggest no benefit among smokers intending to quit." AR 23,694.

Second, the extent to which e-cigarettes are a "gateway" to the use of other tobacco products, including conventional cigarettes, is also uncertain. Many tobacco consumers use more than one type of product—for example, smokeless tobacco and cigarettes—and such "dual use" complicates the analysis. *See, e.g.*, CDC, 62 Morbidity & Mortality Weekly Report 728, 729 (2013) (AR 22,577) (in 2011–2012, "among high school current e-cigarette users, 80.5% reported current conventional smoking"). For instance, despite the recent rise in youth e-cigarette use, one study found that, "in aggregate, there was no change in overall current tobacco use among middle and high school students." 81 Fed. Reg. at 28,984–85. At the same time, there is evidence to suggest that "youth may initiate tobacco use with [e-cigarettes], become addicted [to nicotine], and then dual use or move on to traditional tobacco products." 81 Fed. Reg. at 29,040. For example, in a one-year study of initially nonsmoking youth and young adults, 68.8 percent of e-cigarette users progressed toward smoking (i.e., either tried conventional cigarettes or indicated that they might), compared to just 18.9 percent of nonusers. 81 Fed. Reg. at 29,040–41; Primack et al. (2015) at 1018 (AR 23,906). This data is consistent with progression patterns seen with other tobacco products. For example, "in one study of male smokeless tobacco users who were nonsmokers at baseline . . . almost 40 percent of the original smokeless tobacco users had either switched to cigarettes or become dual users." 79 Fed. Reg. 23,142, 23,159 (Apr. 25, 2014). In another study, "current smokeless tobacco users were 233 percent more likely to have initiated smoking at the 1-year follow-up than nonusers." *Id*.

While these competing hypotheses are the subject of further research, the FDA concluded that the known risks posed by e-cigarettes warrant regulation now. As the agency explained, even if e-cigarettes were ultimately proven to be a net benefit to public health, regulation of those products would benefit public health even further. 81 Fed. Reg. at 28,984.

D. The Deeming Rule

In the challenged rule, the FDA deemed e-cigarettes, cigars, pipe tobacco, and other tobacco products—including their components and parts, but not accessories—subject to the Tobacco Control Act. The FDA defined the statutory term "component or part" 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.
> Component or part excludes anything that is an accessory of a tobacco product.

81 Fed. Reg. at 29,102. The preamble to the rule explains that this definition includes e-cigarette devices—including cig-alikes, vaping devices, and other ENDS—as well as e-liquids containing nicotine, atomizers, batteries, electronics, software, and some packaging. *Id*. at 28,975, 29015–19. The preamble also explains that whether nicotine-free e-liquids meet this definition "will be evaluated on a case-by-case basis," *id*. at 29,032, and may depend, for example, on whether they are "intended or reasonably expected to be used with or for the consumption of a tobacco product (e.g., [mixed] with liquid nicotine)," *id*. at 29,017.

At the same time, the FDA determined *not* to exercise its statutory authority to deem "accessories" of the newly deemed products subject to the Tobacco Control Act. *Id*. at 28,974. It defined "accessories" to mean items used with, but not made or derived from, tobacco that are "not intended or reasonably expected to affect or alter" a tobacco product (or that are expected to have such an effect solely by controlling moisture, temperature, or initial combustion). *Id*. at 29,102. Such accessories include conventional matches and lighters, ashtrays, cigar cutters, pipe pouches, hookah tongs, lanyards, and carrying cases. *Id*. at 28,975, 29,015–16, 29,019.

Although the deeming rule subjects e-cigarettes and other newly deemed products to the Tobacco Control Act effective August 8, 2016, for many provisions the FDA announced lengthy

compliance periods. For example, manufacturers have until December 2016 to register with the FDA and submit a product list, *id*. at 29,006, and the agency does not intend to enforce the ingredient listing requirement until February 2017, *id*. And although after August 8, 2016, *new* products may not enter the market without FDA authorization, for products *already* on the market then, the FDA does not intend to enforce the premarket review requirements for two years, until August 2018, while manufacturers submit applications, and for up to a third year, until August 2019, while the FDA reviews those applications. *Id.* at 29,010–12.

In addition, for "covered tobacco products"—which includes newly deemed products but "excludes any component or part that is not made or derived from tobacco," *id*. at 29,103, like some nicotine-free e-liquids and ENDS devices, *id*. at 29,017, 29,058—the FDA exercised its authority to regulate distribution, marketing, and labeling in two ways, 21 U.S.C. § 387f(d)(1)–(2). First, to reduce youth access, the rule bans sales to those under age 18, requires identification checks of purchasers age 26 and under, and bars vending-machine sales except in adult-only facilities. 81 Fed. Reg. at 29,103 (to be codified at 21 C.F.R. § 1140.14(b)(1)–(3)). These provisions took effect on August 8, 2016. Second, to help consumers better understand the implications of using these products, the rule requires packages and advertisements of cigarette tobacco, roll-your-own tobacco, and covered tobacco products other than cigars to state: "WARNING: This product contains nicotine. Nicotine is an addictive chemical." *Id*. at 29,104–05 (to be codified at 21 C.F.R. § 1143.3(a)–(b)). This warning must generally occupy 30 percent of the two principal display panels on packages and 20 percent of advertisements beginning in May 2018. *Id*.

In its Regulatory Impact Analysis ("RIA"), the FDA estimated that the rule would cost between $66 and $77 million per year—about $2 per current user of tobacco products—

principally for the premarket authorization of new, newly deemed products. RIA 5, 116.[5] In general, the FDA predicted that the rule would accelerate consolidation in the e-cigarette industry, reducing the number of devices and e-liquids on the market, both because manufacturers of poor-selling products would likely forgo seeking premarket authorization to avoid its costs, RIA 94, 104–05,[6] and because vape shops that currently mix their own e-liquids would likely convert to a pure retail model, RIA 48. Overall, the FDA expects the makers of 360 to 450 e-cigarette devices, and 1,250 to 2,500 e-liquids, to submit premarket applications, and other products to leave the market by the end of the compliance period in August 2018. RIA 84. The FDA also estimated that paperwork and labeling requirements would impose relatively modest burdens: registration and product lists are estimated to take each manufacturer four hours in the first year, and one hour per year thereafter, RIA 98; ingredient lists are forecast to take three hours per product, RIA 101; and labeling changes are predicted to cost between $387 and $12,533, depending on the size and complexity of the product, RIA 109–10.

The FDA concluded that these costs were justified by the rule's benefits. The minimum age, identification, and vending machine restrictions are expected to "constrain youth access to tobacco products and curb rising uptake"—particularly in the four states that currently permit e-cigarette sales to minors. RIA 63, 67. Health warning statements, prohibitions on false and

[5] The RIA responds to comments regarding the FDA's preliminary analysis of the rule's economic impact, RIA 7–58, sets out the final regulatory impact analysis, including projected costs, benefits, break-even calculations, and an assessment of four regulatory alternatives, *id*. at 58–127, and discusses the effects of the rule on small entities, *id*. at 128–134 (AR 10,592–675).

[6] The FDA estimated that the cost of preparing premarket applications would vary widely, depending on the complexity of the product, ranging from $12,112 to $402,824 per e-liquid, and $28,566 to $2,622,224 per e-cigarette device, with a weighted average of $131,643 per e-liquid and $466,563 per e-cigarette device. RIA 87–92. The agency predicted that, over time, these costs would decline as efficiencies build, more research develops, and manufacturers bundle applications and bridge data from one product to another.

misleading labeling, and review of supposedly "modified risk" products will address market failures caused by information asymmetries, RIA 59–60, which "will help consumers understand and appreciate the risks of using tobacco products," RIA 67. Premarket review "will increase product consistency," resulting in fewer defective and mislabeled products reaching the market and increasing consumer confidence in the industry. RIA 65, 67. And monitoring product ingredients will enable the FDA to regulate the level of harmful chemicals inhaled by users, including nicotine and formaldehyde, to protect the public health. RIA 67.

Because of uncertainty about the size of these benefits—some of which will be fully realized only with future regulation—the FDA found that it could not accurately quantify them, and thus could not directly compare them to the costs. 81 Fed. Reg. at 28,981; RIA 67; *see* OMB, Circular A–4 at 2 (2003) (recognizing that "[i]t will not always be possible to express in monetary units all of the important benefits and costs"). Thus, consistent with OMB guidance, it applied a "break-even" analysis—a well-established economic tool that asks how much the average beneficiary would have to be willing to pay for a rule for its benefits to equal its costs. *See id*. ("Threshold or 'break-even' analysis answers the question, 'How small could the value of the non-quantified benefits be (or how large would the value of the non-quantified costs need to be) before the rule would yield zero net benefits?'"). The FDA concluded that a cost of $2 annually per current tobacco user would be worth the rule's benefits, including more accurate labels, effective health warnings, improved product consistency, and premarket review of supposedly "modified risk" products. RIA 10–11, 16, 45, 115–16. Indeed, in some respects this break-even measure may overstate the costs of the rule, as its benefits will extend to nonusers who may be deterred from initiating use or protected from secondhand exposure. RIA 116.

STANDARD OF REVIEW

Under the Administrative Procedure Act ("APA"), an agency's decision must be upheld unless arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. *See* 5 U.S.C. § 706(2)(A). Under this deferential standard, the agency's decision is presumed valid, and the Court considers only whether it "was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 416 (1971). An agency decision may be deemed arbitrary and capricious only in circumstances where the agency "has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicle Mfrs. Ass'n v. State Farm*, 463 U.S. 29, 43 (1983). The Court may not "substitute its judgment for that of the agency." *Id*.

This deference is heightened even further in cases like this one involving scientific or technical decisions. "We will give an extreme degree of deference to the agency when it is evaluating scientific data within its technical expertise," *West Virginia v. EPA*, 362 F.3d 861, 871 (D.C. Cir. 2004), for "we cannot decide . . . whether technical evidence beyond our ken supports the proposition it is asserted to support," *Simpson v. Young*, 854 F.2d 1429, 1434 (D.C. Cir. 1988). "When examining this kind of scientific determination . . . a reviewing court must generally be at its most deferential." *Baltimore Gas & Elec. Co. v. NRDC*, 462 U.S. 87, 103 (1983). Indeed, "[i]n the face of conflicting evidence at the frontiers of science, courts' deference to expert determinations should be at its greatest." *Cellular Phone Task Force v. FCC*, 205 F.2d 82, 90 (2d Cir. 2000).

ARGUMENT

I. E-CIGARETTES—AND THEIR COMPONENTS AND PARTS—ARE PROPERLY REGULATED UNDER THE TOBACCO CONTROL ACT

Nicopure does not dispute that its *closed*-system e-cigarettes are properly subject to regulation under the Tobacco Control Act, *see* Nicopure Br. 9, nor could it under controlling D.C. Circuit precedent. Its contention that Congress intended to exempt *open*-system e-cigarettes from this comprehensive regulatory scheme, simply because their e-liquid cartridges or tanks are refillable, should be rejected.

A. The D.C. Circuit Has Squarely Held that the Tobacco Control Act Authorizes the FDA to Regulate E-Cigarettes

In *Sottera*, the D.C. Circuit held that the Tobacco Control Act authorizes the FDA to regulate e-cigarettes, which it described as "battery-powered products that allow users to inhale nicotine." 627 F.3d at 893. It hinted at no carve-out for products with refillable cartridges or tanks. On the contrary, the court explained that Congress enacted the Tobacco Control Act as a "'distinct regulatory scheme to address the problem of tobacco and health,'" meant to plug a "regulatory gap" in the FDA's authority. *Id*. at 894, 896 (citation omitted). The Court should reject Plaintiffs' invitation to tear holes in that comprehensive scheme.

The e-cigarette manufacturers in *Sottera* objected to the FDA's attempt to regulate their products as "drugs" or "devices" under the FDCA, arguing that the products must instead be regulated under the Tobacco Control Act. The D.C. Circuit agreed. Framing the question presented as "whether the FDA can regulate electronic cigarettes under the FDCA's drug/device provisions or whether it can regulate them only under the Tobacco [Control] Act's provisions," the court found the latter the "better reading." *Id*. at 894–95. Thus, it concluded that "the FDA

has authority under the Tobacco [Control] Act to regulate electronic cigarettes, enabling it to mitigate or perhaps extinguish any harm to public health." *Id*. at 899.

There is no meaningful difference between the e-cigarettes at issue here and those in *Sottera*. The common purpose of these electronic nicotine delivery systems ("ENDS") is—as their name indicates—to "allow users to inhale nicotine vapor." *Sottera*, 627 F.3d at 893. And their design and function are essentially the same: As Nicopure explains, "they use a heat source to convert e-liquid into a vapor, which the user inhales through a mouthpiece." Compl. ¶ 2; *see Sottera*, 627 F.3d at 893 ("When the user inhales, the electronics detect the air flow and activate the atomizer; the liquid nicotine is vaporized, and the user inhales the vapor."). The only difference, Nicopure alleges, is that while closed-system e-cigarettes may have "proprietary replacement cartridges," open systems "can be refilled by the consumer without restriction by the manufacturer." Compl. ¶ 4. That open systems are refillable with any e-liquid, rather than just the manufacturer's preferred e-liquid, however, hardly distinguishes them from the e-cigarettes at issue in *Sottera*—or from Nicopure's closed-system devices, which it concedes are regulable under the Tobacco Control Act. *See id*. ¶ 6 (referencing its "closed-system" devices); Nicopure Br. 9 (limiting its challenge to "open-system" devices and "non-nicotine-containing e-liquids"). Indeed, e-cigarette manufacturers often package refillable e-cigarettes together with their own e-liquids. Nicopure, for example, includes e-liquids in "starter packs" with each of the open-system e-cigarettes mentioned in its complaint. Compl. ¶ 9.[7]

Having insisted in *Sottera* that e-cigarettes are regulable as tobacco products, manufacturers cannot now avoid that conclusion simply by making their products refillable.

[7] *See* https://www.halocigs.com/triton/starter-kit; https://www.halocigs.com/tracer/starter-kit; https://www.halocigs.com/reactor/starter-kit.

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. *Sottera* leaves no room for such a broad and senseless exemption from the Tobacco Control Act's comprehensive regulatory scheme.

B. E-Cigarettes Are Properly Considered Tobacco Products—or Components or Parts Thereof—Regardless of Whether Their Cartridges or Tanks Are Refillable

Even if the Court were writing on a blank slate, it should reject Plaintiffs' claim that refillable e-cigarettes are exempt from regulation under the Tobacco Control Act. The statute expansively defines "tobacco product" to include not only things "made or derived from tobacco," but also any "component, part, or accessory," whether or not made or derived from tobacco. 21 U.S.C. § 321(rr)(1). The FDA's interpretation of the statutory terms "component" or "part," which Congress left undefined, is reasonable and merits substantial deference.

1. The FDA's Interpretation of the Tobacco Control Act Is Entitled to *Chevron* Deference

In interpreting a statute that the FDA is entrusted to administer, the Court follows "the familiar two-step framework of *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842–43 (1984)." *Sherley v. Sebelius*, 644 F.3d 388, 393 (D.C. Cir. 2011). Under *Chevron* step one, if Congress has "'directly spoken to the precise question at issue,'" then the Court must "'give effect to [its] unambiguously expressed intent.'" *Id.* (quoting *Chevron*, 467 U.S. at 843). If instead the "'statute is silent or ambiguous with respect to the specific issue,'" then, under *Chevron* step two, the Court must "defer to the administering agency's interpretation as long as it reflects 'a permissible construction of the statute.'" *Id.* (quoting *Chevron*, 467 U.S. at 843).

Here, the Tobacco Control Act "broadly defines" the term "tobacco product," *Sottera*, 627 F.3d at 897, as extending to "any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product," 21 U.S.C. § 321(rr)(1). Congress did not further define the terms "component, part, or accessory," and thus "left a gap for the agency to fill." *Chevron*, 467 U.S. at 843. The agency's expert judgment about how to fill that gap merits substantial deference under *Chevron*.

At *Chevron* step two, an agency need not establish that its construction of the statute "was the only one it permissibly could have adopted," *Rust v. Sullivan*, 500 U.S. 173, 184 (1991); *Northpoint Tech. v. FCC*, 414 F.3d 61, 69 (D.C. Cir. 2005), or that it is "the best interpretation of the statute," *United States v. Haggar Apparel Co.*, 526 U.S. 380, 394 (1999), or that it is "the most natural reading," *Pauley v. Beth Energy Mines*, 501 U.S. 680, 702 (1991). Rather, the agency's view is deemed to be permissible so long as it is not "flatly contradicted" by the statute. *Dep't of Treasury v. Fed. Labor Relations Auth.*, 494 U.S. 922, 928 (1990). This deference is heightened in "'a complex and highly technical regulatory program'" like this one, where "the identification and classification of relevant 'criteria necessarily require significant expertise and entail the exercise of judgment grounded in policy concerns.'" *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994). For Plaintiffs to prevail, they must demonstrate that the statute "cannot bear the interpretation adopted by the [FDA]" and that their alternative reading is the "only possible interpretation" of the statute. *Sullivan v. Everhart*, 494 U.S. 83, 89 (1990).

2. The FDA's Definition of "Component or Part" Is a Permissible Interpretation of the Statute

Under the Tobacco Control Act, it is not only things "made or derived from tobacco" that are tobacco products. 21 U.S.C. § 321(rr)(1). Any "component, part, or accessory" is also a

tobacco product—whether or not it is made or derived from tobacco. *Id*. In the deeming rule, the FDA defined "component or part" 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.
> Component or part excludes anything that is an accessory of a tobacco product.

81 Fed. Reg. at 29,102 (to be codified at 21 C.F.R. § 1100.3). That interpretation is faithful to the statutory text, and is supported by the Tobacco Control Act's structure, legislative history, and purpose, none of which suggest a carve-out for e-cigarettes.

The statutory text should be liberally construed, consistent with the FDCA's primary purpose "to protect consumers from dangerous products." *United States v. Sullivan*, 332 U.S. 689, 696 (1948). As the Supreme Court has explained, "Congress fully intended that the [FDCA]'s coverage be as broad as its literal language indicates . . . . [R]emedial legislation such as the [FDCA] is to be given a liberal construction consistent with the Act's overriding purpose to protect the public health." *United States v. Article of Drug Bacto-Unidisk*, 394 U.S. 784, 798 (1969).[8] Contrary to Plaintiffs' intimation, that text in no way limits the deeming authority to "traditional" tobacco products. While Congress required the FDA to regulate only four categories of products under the Tobacco Control Act—cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco—by also giving the FDA deeming authority, it recognized that other categories of products meet the definition of "tobacco product" and could be regulated by the FDA consistent with its expert judgment.

[8] *See also United States v. Cassaro, Inc.*, 443 F.2d 153, 155 (1st Cir. 1971) ("[T]he Supreme Court has consistently accorded the [FDCA] a broad construction."); *De Freese v. United States*, 270 F.2d 730, 735 (5th Cir. 1959) (FDCA must be "liberally construed" to give effect to its "comprehensive scope").

E-cigarettes were available in the United States by early 2007, 81 Fed. Reg. at 28,978, and Congress was well aware that they existed when it enacted the TCA in 2009, *see, e.g.*, 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."); 155 Cong. Rec. H4367 (Apr. 1, 2009) (statement of Rep. Buyer) (expressing concern that, if the TCA "were to pass, . . . these new innovative types of nicotine delivery devices could not make their access to the market").[9] Yet Congress declined to circumscribe the deeming authority by excluding e-cigarettes. It could easily have imposed such a limit, as it did for unprocessed tobacco leaf. 21 U.S.C. § 387a(c)(2) (the "provisions of this chapter shall not apply to tobacco leaf that is not in the possession of a manufacturer"). Congress imposed similar product-specific limitations on other authorities granted to the FDA under the statute—for example, prohibiting the agency from entirely banning "cigars," "little cigars," and "pipe tobacco," should it deem them subject to the Act. *Id*. § 387g(d)(3)(A). Similarly, it authorized the agency to fund its activities under the TCA through user fees on manufacturers and importers of "cigars" and "pipe tobacco," should it deem them. *Id*. § 387s(b)(2)(B)(i), (iii). But Congress did nothing to limit the deeming authority to such products. Instead, it made the definition of tobacco product expansive, extending to "any" component, part, or accessory of "any" product merely "derived" from tobacco. These are words of expansion, not exclusion, and they embrace not only traditional products, but also

[9] *See also* 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-heated cigarette."); 155 Cong. Rec. H4366 (Apr. 1, 2009) (statement of Rep. Buyer) ("[W]e're not really sure where on the continuum of risk" the "tobacco-heated cigarette" lies "along with the electronic cigarette because there isn't sufficient science yet to back that up.").

"innovative" ones like e-cigarettes. 155 Cong. Rec. H4367 (Apr. 1, 2009) (statement of Rep. Buyer).

The FDA's interpretation of "component or part" to include things intended or reasonably expected to "affect a tobacco product's performance, composition, constituents, or characteristics," 81 Fed. Reg. at 29,102, also accords with Congress's understanding of these terms, as used elsewhere in the statute. For example, in banning the use of characterizing flavorings (except tobacco and menthol) in cigarettes, Congress understood the "component parts" of a cigarette to include its "tobacco, filter, [and] paper." 21 U.S.C. § 387g(a)(1)(A) (referring to "a cigarette or any of its component parts (including the tobacco, filter, or paper)"). A cigarette's filter and paper obviously affect not only its physical "composition," but also its "performance" and "constituents." 81 Fed. Reg. at 29,102. In particular, the filter changes the mixture of chemicals delivered to the user by screening out certain particles, affects inhalation depending on its density and porousness, and makes smoke taste less harsh and therefore more tolerable. Likewise, the paper affects the burn rate and thus the rate of chemical delivery. Indeed, cigarette companies have long manipulated these components or parts to affect the performance of their products. *See, e.g.*, *United States v. Philip Morris USA Inc.*, 801 F.3d 250, 259 (D.C. Cir. 2015) ("[c]igarette companies control the impact and delivery of nicotine in many ways, including designing filters and selecting cigarette paper to maximize the ingestion of nicotine").

The FDA's interpretation is also consistent with a recent statute recognizing the agency's authority to regulate e-cigarettes and e-liquids. In the Child Nicotine Poisoning Prevention Act of 2015, which was enacted as a response to the "rapid rise in the popularity of electronic cigarettes" and the "concomitant[] . . . rapid rise in dangerous exposures to liquid nicotine," S.

Rep. No. 114-12, at 2 (2016), Congress authorized the Consumer Product Safety Commission to require that "liquid nicotine container[s]" be child-resistant, Pub. L. No. 114-116, § 2(a), 130 Stat. 3 (2016). But, aware of the then-proposed deeming rule, Congress included a "savings clause" specifically reserving the FDA's "authority . . . to regulate . . . nicotine, liquid nicotine, liquid nicotine *containers*, electronic cigarettes, electronic nicotine *delivery systems* or other similar products that *contain* or *dispense* liquid nicotine, or *any other* nicotine-related products"—"including [its] (A) authority under the . . . Tobacco Control Act . . . and (B) authority for the [deeming] rulemaking." *Id.* § 2(b)(1) (emphasis added). Congress thus recently affirmed that the FDA's authority broadly extends to products that contain, dispense, or deliver nicotine.

Plaintiffs' arguments to the contrary are unpersuasive. They principally contend that the terms "component" and "part" must be read "to refer to items *inseparable* from the product made or derived from tobacco, not to refer to separate products not so made or derived." Nicopure Br. 11 (emphasis added). But that argument has no basis in the text of the statute, which places no such limitation on the terms "component, part, or accessory." Congress could easily have defined tobacco products to include only "inseparable" components or parts, but instead it said "any."

Moreover, by Plaintiffs' logic, even the filter and paper of a cigarette would not qualify as components or parts, because they are not actually "inseparable." Some smokers empty the tobacco from a manufactured cigarette and refill its shell with other ingredients.[10] Others

[10] *See, e.g.*, Weedist, How To Make a Cigarette Spliff (Feb. 20, 2013), *at* http://www.weedist.com/2013/02/how-to-make-a-cigarette-spliff; spliffy1329, How To Roll a Spliff Using a Regular Cigarette (Jan. 13, 2011), *at* https://www.youtube.com/watch?v=rJ2Oxbkoc4g.

remove the filters of manufactured cigarettes and smoke them filterless.[11] And filters can also be taken from manufactured cigarettes and repurposed in rolled cigarettes, with or without other ingredients.[12] Congress nevertheless considered the filter and paper of a cigarette to be components or parts, even if they are not made or derived from tobacco. *See* 21 U.S.C. § 387g(a)(1)(A) (referring to "a cigarette or any of its *component parts* (*including* the tobacco, filter, or paper)") (emphasis added). Indeed, it contemplated that cigarettes and other tobacco products would have still *other*, unspecified components and parts. *See id*. § 387d(a)(1) (requiring listing of substances added "to the tobacco, paper, filter, *or other part* of each tobacco product") (emphasis added). Moreover, the "nicotine cartridge" and "battery" of closed-system e-cigarettes—which Plaintiffs do not dispute are regulable under the Tobacco Control Act, *see* Nicopure Br. 9—are often removable and replaceable,[13] yet the D.C. Circuit has described both of them as "parts," *Sottera*, 627 F.3d at 893. But on Plaintiffs' theory, once a component is removed from a tobacco product—indeed, unless it is entirely "inseparable" from that product—it ceases to be a component. The statutory definition of "tobacco product" contains no such limitation, and the FDA reasonably declined to add one.

Plaintiffs also fault the FDA's interpretation for including not only components and parts that *actually* affect the performance, composition, constituents, or characteristics of tobacco products, but also those that are "intended or reasonably expected" to do so. Nicopure Br. 13–

[11] *See, e.g.*, smokyeyes3, How To Remove the Filter of Your Cigarettes (Oct. 14, 2015), at https://www.youtube.com/watch?v=yyQV451Wgm4.

[12] *See, e.g.*, wikiHow, How to Roll a Cigarette ("Remove the filter from a store-bought cigarette. . . . Lay this filter into your rolled cigarette."), *at* http://www.wikihow.com/Roll-a-Cigarette.

[13] *See, e.g.*, https://www.halocigs.com/g6 (offering replacement batteries and "cartomizers" (i.e., combined e-liquid cartridges and atomizers) for Nicopure's closed-system "G6" e-cigarette).

14. This, they claim, is at odds with a statement in a 2013 FDA report to Congress, which Plaintiffs characterize as asserting that tobacco products cannot be defined by their "intended use." *Id*. But such a report cannot be considered the agency's authoritative interpretation of the statute, in contrast to the notice-and-comment rulemaking at issue here. Regardless, there is no conflict between the two, as Plaintiffs misread both the report and the statutory scheme.

The purpose of the 2013 report was to "examin[e] the best way to regulate, promote, and encourage the development of 'innovative products and treatments'" for tobacco dependence, including e-cigarettes. Report at 2 (citation omitted). It thus began by describing the two potential "pathways to market" for such products—the FDA's drug/device authority, and its tobacco product authority—and the "impact of *Sottera*" on those authorities. *Id*. at 2–3. While *Sottera* held that e-cigarettes may be regulated under the Tobacco Control Act, *see supra* at 23–25, it also noted that they may be regulated under the FDA's drug/device authority where "marketed for therapeutic purposes," 627 F.3d at 899—or, in the more precise words of the FDCA, where "'intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease,'" Report at 4 (quoting 21 U.S.C. § 321(g)(1)).

Thus, when the report summarized—in a subsection heading—that "drugs and devices are defined by their intended use, while tobacco products are not," it was using "intended use" as shorthand for the list of intended therapeutic uses in the FDCA's drug/device authority: "diagnosis, cure, mitigation, treatment, or prevention of disease." 21 U.S.C. § 321(g)(1). "Tobacco products are not" defined by those "intended uses," which are absent from the definition of that term in the Tobacco Control Act. Report at 4. Indeed, "the definition of 'tobacco product' *excludes* any item" marketed as having a therapeutic use. *Id*. at 5. Thus, in "the wake of *Sottera*, a product's intended use (e.g., as embodied in its marketing claims)

determines whether it will be regulated as a drug or device, rather than a tobacco product," as the report accurately explained. Report at 6.

Contrary to Plaintiffs' suggestion, the report did not say that "intent" was irrelevant to the definition of a tobacco product—much less to the definition of a component or part. Indeed, the statute itself refers to "intent," as a "'tobacco product' means any product made or derived from tobacco that is *intended* for human consumption," including any component, part, or accessory. 21 U.S.C. § 321(rr)(1). Thus, Plaintiffs' argument that the "intended use" of a tobacco product is irrelevant to its definition flatly contradicts the statute, and the FDA has not suggested otherwise.

C. E-Liquids Marketed as "Nicotine-Free" May Qualify as Tobacco Products—or Components or Parts Thereof—Although the Court Need Not Reach the Question

E-liquids that are marketed as "nicotine-free" may also qualify as tobacco products—or components or parts thereof—under certain circumstances. But the Court need not reach this issue, because Plaintiffs make no showing that the nicotine-free e-liquids they manufacture are even subject to the deeming rule.

1. Plaintiffs Lack Standing to Challenge the Deeming Rule's Hypothetical Application to Nicotine-Free E-Liquids

Because Plaintiffs make no showing that the nicotine-free e-liquids they manufacture are "components" or "parts" even subject to the deeming rule—by alleging, for example, that those e-liquids are intended to be mixed with liquid nicotine—they fail to establish that they are harmed by the rule, and thus lack standing to challenge it. *See Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992) (standing requires an "injury in fact" that is "actual or imminent, not conjectural or hypothetical").

In the deeming rule, the FDA did not purport to make *all* nicotine-free e-liquids subject to the Tobacco Control Act. Rather, the only nicotine-free e-liquids that the rule brings under the

FDA's regulatory authority are those that are made or derived from tobacco (such as tobacco-flavored varieties) or that otherwise meet the definition of a "component" or "part." 81 Fed. Reg. at 29,102. Thus, nicotine-free e-liquids not made or derived from tobacco are subject to the deeming rule *only* where they meet the definition of a "component or part"—for example, if they are "intended or reasonably expected to be used with or for the human consumption of a tobacco product (e.g., [mixed] with liquid nicotine)," *id*. at 29,017. The FDA explained that such "products will be evaluated on a case-by-case basis," *id*. at 29,032, that takes into account "the totality of the circumstances," including how the product is distributed and sold, *id*. at 29,015.

Here, Plaintiffs' spare allegation that some of the e-liquids they manufacture are nicotine-free, Nicopure Compl. ¶ 7, is insufficient to confer standing. Plaintiffs make no effort to explain how their nicotine-free e-liquids are manufactured, marketed, distributed, or sold. They do not allege that they package their nicotine-free e-liquids with products containing nicotine. They do not allege that they sell their nicotine-free e-liquids to customers who intend to mix them with products containing nicotine. *Cf. BBK Tobacco & Foods, LLP v. FDA*, 672 F. Supp. 2d 969, 971 (D. Ariz. 2009) (importer alleged that it intended its flavored rolling papers to be used with "roll-your-own" tobacco). Indeed, they do not even muster the conclusory allegation that their nicotine-free e-liquids meet the regulatory definition of a "component" or "part"—an assertion that could not be credited in any event without supporting facts. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

Absent such allegations, Plaintiffs fail to establish that the deeming rule even applies to the nicotine-free e-liquids they manufacture—much less that there is any likelihood the FDA would take enforcement action against them. At most, they allege a "hypothetical" harm, rather

than the "certainly impending" one required to confer standing and "reduce the possibility of deciding a case in which no injury would have occurred at all." *Lujan*, 504 U.S. at 560, 564 n.2.

2. Plaintiffs' Challenge to the Deeming Rule's Hypothetical Application to Nicotine-Free E-liquids Is Unripe

For similar reasons, Plaintiffs' challenge to the deeming rule's hypothetical application to their nicotine-free e-liquids is unripe. "The ripeness doctrine is drawn both from Article III limitations on judicial power and from prudential reasons for refusing to exercise jurisdiction." *Nat'l Park Hospitality Ass'n v. Dep't of the Interior*, 538 U.S. 803, 808 (2003) (quotation omitted). It "prevent[s] the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements." *Id*. The ripeness inquiry "evaluate[s] both the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration." *Abbott Labs. v. Gardner*, 387 U.S. 136, 149 (1967). Here, Plaintiffs satisfy neither prong of the inquiry, because they provide no reason to believe that the FDA will take enforcement action against their nicotine-free e-liquids when the premarket review compliance period ends in 2018—or indeed ever.

A "regulation is not ordinarily considered the type of agency action 'ripe' for judicial review under the [APA] until the scope of the controversy has been reduced to more manageable proportions, and its factual components fleshed out, by some concrete action applying the regulation to the claimant's situation in a fashion that harms or threatens to harm him." *Nat'l Park Hospitality*, 538 U.S. at 807; *see also Renne v. Geary*, 501 U.S. 312, 321–22 (challenge unripe where courts "possess no factual record of an actual or imminent application of [the provision] sufficient to present the . . . issues in 'clean-cut and concrete form'"). That is especially true where, as here, "the agency retains considerable discretion to apply the new rule on a *case-by-case* basis, particularly where there is a complex statutory scheme or there are other

difficult legal issues that are implicated by the agency action." *Sprint Corp. v. FCC*, 331 F.3d 952, 956 (D.C. Cir. 2003) (emphasis added). "In such circumstances, judicial review is likely to stand on a much surer footing in the context of a specific application of the regulation than could be the case in the framework of a generalized challenge." *Id.*

These principles apply in full force here. As noted, Plaintiffs make no showing that their nicotine-free e-liquids are "components" or "parts" subject to the deeming rule, let alone that the FDA is likely to take enforcement action against them. Any such decision would take place only after a "case-by-case" review, 81 Fed. Reg. at 29,032, that takes into account "the totality of the circumstances," *id*. at 29,015—including "direct and circumstantial objective evidence, which encompasses a variety of factors such as circumstances surrounding the distribution of the product or the context in which it is sold, and sales data," *id*. (citations omitted). If the FDA were ultimately to find reason to believe that Plaintiffs' nicotine-free e-liquids were being improperly marketed, it would typically first send a warning letter, giving them an opportunity to present contrary evidence.[14] If the FDA then determined that the e-liquids were noncompliant, it would typically give Plaintiffs a reasonable time to come into compliance before initiating an enforcement action. *Id*. And any enforcement action, such as for an injunction, 21 U.S.C. § 332, or a seizure of goods, *id*. § 334, would be reviewable in federal district court. But where, as here, "the FDA has not taken any specific action with respect to [Plaintiffs] or any of [their] products," then "the issues presented are not ripe for judicial review." *BBK Tobacco*, 672 F.

[14] *See* FDA Regulatory Procedures Manual, *available at* http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm176870.htm ("When it is consistent with the public protection responsibilities of the agency and depending on the nature of the violation, it is the [FDA's] practice to give individuals and firms an opportunity to take voluntary and prompt corrective action before it initiates an enforcement action.").

Supp. 2d at 976–77 (rejecting as unripe plaintiff's claim that flavored rolling papers could not be considered "component parts" of a cigarette).

Thus, given the uncertainty that any of Plaintiffs' nicotine-free e-liquids are even covered by the deeming rule, much less the likely targets of an enforcement action, as well as the fact-intensive nature of the "case-by-case" inquiry involved, "further factual development would 'significantly advance [the Court's] ability to deal with the legal issues presented,'" *Nat'l Park Hospitality*, 538 U.S. at 812, and the Court should defer their resolution until they "arise in some more concrete and final form," *State Farm Mut. Auto. Ins. Co. v. Dole*, 802 F.2d 474, 479 (D.C. Cir. 1986). In short, if the Court does not decide these questions now, it may never need to.

3. E-Liquids Marketed as "Nicotine-Free" May Qualify as Tobacco Products—or Components or Parts thereof—Under Some Circumstances

In any event, e-liquids marketed as "nicotine-free" may properly be considered tobacco products—or components or parts thereof—under certain circumstances. As the record demonstrates, some e-liquids "claiming to be nicotine-free actually contain[] high levels of nicotine." 81 Fed. Reg. at 29,034. Others are tobacco flavored, and are thus "made or derived from tobacco" regardless of their nicotine content. *Id*. at 29,102. And nicotine-free e-liquids are sometimes mixed with liquid nicotine before inhalation, *id.* at 29,017, affecting not only the "composition" of the substance ultimately vaporized, but also its "constituents" and "characteristics," *id*. at 29,102. For example, e-liquids generally use a base of propylene glycol and glycerol, chemicals that when vaporized at higher voltages deliver more formaldehyde, a known carcinogen, than conventional cigarettes. *See supra* at 13. E-liquids with sweet flavors often contain diacetyl, acetyl propionyl, and various aldehydes, which pose other health risks. *See supra* at 11–12. And that is to say nothing of the other unknown and undisclosed additives

in the 4,000 to 8,000 varieties of e-liquid currently on the market. *See supra* at 10–11. Given these effects on the chemicals ultimately inhaled by consumers, the FDA's definition of "component or part," which encompasses nicotine-free e-liquids that are "intended or reasonably expected to be . . . [mixed] with liquid nicotine," 81 Fed. Reg. at 29,017, was permissible and merits deference.

II. THE FDA RATIONALLY EXPLAINED WHY IT DEEMED E-CIGARETTES SUBJECT TO THE TOBACCO CONTROL ACT, AND ITS DECISION IS AMPLY SUPPORTED BY THE RECORD

Just as there can be no reasonable dispute that the Tobacco Control Act authorizes the FDA to regulate e-cigarettes and their components and parts, there is no doubt that the FDA appropriately exercised that authority in deeming such products subject to the Tobacco Control Act. As an initial matter, the FDA's exercise of its deeming authority is committed to agency discretion and not subject to review. But it would in any event readily withstand scrutiny under the APA.

The FDA's deeming rule marked the culmination of a comprehensive 5-year review of the scientific literature on e-cigarettes and other newly deemed products, including more than 275 scientific studies and other reports and 135,000 public comments. As that vast record makes clear, e-cigarettes present significant risks to the public health, ranging from the inhalation of toxic chemicals to the danger of explosion and bodily harm. In the deeming rule, the FDA carefully explained that, while questions remain about the overall effect of e-cigarettes on the public health, subjecting them to oversight under the Tobacco Control Act will help mitigate the many risks that are known *now*, and it rationally described why the regulatory alternatives preferred by e-cigarette manufacturers were either unavailable or inadequate. Particularly given the FDA's in-depth "evaluat[ion of] scientific data within its technical expertise," *West Virginia*, 362 F.3d at 871, its expert conclusion warrants substantial deference.

A. The FDA's Deeming Authority Is Committed to Agency Discretion

In the deeming provision, Congress authorized the FDA to subject "any" tobacco product (except certain raw tobacco leaf) to the Tobacco Control Act as it "deems" fit, without articulating any standards to cabin the agency's discretion. 21 U.S.C. § 387a(b), (c). Because the statute provides no standards for the Court to enforce, its implementation is committed to agency discretion, and APA review is precluded.

The APA grants a cause of action to "[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. It withdraws that cause of action "to the extent that . . . agency action is committed to agency discretion by law." *Id*. § 701(a)(2). "Agency action is committed to agency discretion by law when 'the statute is drawn so that a court would have no meaningful standard against which to judge the agency's exercise of discretion.'" *Steenholdt v. FAA*, 314 F.3d 633, 638 (D.C. Cir. 2003) (quoting *Heckler v. Chaney*, 470 U.S. 821, 830 (1985)). Here, the deeming provision says only: "This chapter shall apply . . . to any other tobacco products that the Secretary by regulation deems to be subject to this chapter." 21 U.S.C. § 387a(b). 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.

The Supreme Court recognized the discretion inherent in this formulation in *Webster v. Doe*, 486 U.S. 592, 600 (1988), where the statute authorized the CIA to terminate employees "whenever the Director 'shall *deem* such termination necessary or advisable in the interests of the United States.'" *Id*. (quoting 50 U.S.C. § 403(c)) (emphasis in original). Stressing that the statute did not limit termination to "when the dismissal *is* necessary or advisable to those

interests," the Court held on the basis of Congress's use of the word "deem" that the statutory "standard fairly exudes deference to the Director" and "foreclose[s] the application of any meaningful judicial standard of review." *Id*. (emphasis in original); *see also Claybrook v. Slater*, 111 F.3d 904, 909 (D.C. Cir. 1997) (noting that *Webster* gave "weight to [the] fact that [a] statute authorizes termination when [the] agency head 'shall deem [it] necessary or advisable' rather than when it 'is' necessary or advisable" (alteration in original)). Thus, the statute's implementation was committed to agency discretion, and APA review was precluded. *Webster*, 486 U.S. at 600–01. So too here.

B. The FDA Rationally Explained Why It Rejected the Regulatory Alternatives that Plaintiffs Prefer

Even if the Court were to find judicially manageable standards by which it could review the FDA's decision, the agency rationally explained why it deemed e-cigarettes subject to the Tobacco Control Act and why it rejected the regulatory alternatives that Plaintiffs prefer. The APA requires no more.

The Supreme Court has clearly defined the respective roles of agencies and courts on APA review. It is the agency's job "not only to appraise the facts and draw inferences from them but also to bring to bear upon the problem an expert judgment." *United States v. Detroit & Cleveland Nav. Co.*, 326 U.S. 236, 241 (1945). The Court's function, by contrast, is to confirm that the agency has "articulate[d] a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *State Farm*, 463 U.S. at 43. Under this deferential standard, the Court may not "substitute its judgment for that of the agency," even if it might have made a different policy choice. *Id*.

Plaintiffs argue that the deeming rule failed these minimum standards of rationality in four respects. They are wrong at each turn.

First, Plaintiffs contend that the deeming rule is "at war with itself" because the FDA supposedly "acknowledges that promoting public health is the Rule's *raison d'être*" yet "concedes that it does 'not currently have sufficient data . . . to determine what effects e-cigarettes have on the public health.'" Nicopure Br. 15–16. That is a transparent mischaracterization of the FDA's reasoning. To be sure, the FDA recognized that questions remain about the overall effect of e-cigarettes on the public health. *See supra* at 16–17. For example, if e-cigarettes were ultimately shown to help smokers quit—an unproven hypothesis at odds with much of the current evidence—then they might arguably be a net benefit to the public health. *See* 81 Fed. Reg. at 29,037. But whether e-cigarettes *themselves* benefit the public health, and whether the *regulation* of e-cigarettes would benefit the public health, are entirely separate questions. As the FDA explained, whether e-cigarettes "generally may eventually be shown to have a net benefit on or harm to public health at the population level—and there have not yet been long-term studies conducted to support either claim at this time—*regulation* of [them] will still benefit public health." *Id*. at 28,984. In other words, even if e-cigarettes were ultimately proven to be a net benefit to public health, regulation of those products would *further* benefit public health, because it would improve their quality and mitigate the risks that are known now. There is nothing at all "internally inconsistent," Nicopure Br. 15, about that claim.

Plaintiffs' passing suggestion that the FDA circularly "justif[ied] a rule intended to address health risks by pointing to the need for information to determine whether those risks exist in the first place" fails for similar reasons. *Id*. at 17. True, the FDA noted that the deeming rule will enable it to obtain additional "critical information regarding the health risks of newly deemed tobacco products," 81 Fed. Reg. at 28,975, such as lists of the ingredients in the 4,000 to 8,000 e-liquids currently on the market, many of which are currently undisclosed and unknown,

and would otherwise be unobtainable. But as the record amply demonstrates, more than enough is already known about the health risks of e-cigarettes and e-liquids—from the inhalation of toxic chemicals to the risk of explosion and bodily harm—to warrant regulatory oversight.

Federal agencies regulate all manner of consumer goods that, on balance, are a net benefit to society—including, for example, therapeutic drugs under the FDCA. Plaintiffs' suggestion that e-cigarettes should not be regulated because they are generally safer than conventional cigarettes is rather like saying that cars should not be regulated because they are safer than motorcycles.

Second, Plaintiffs hypothesize that the deeming rule will actually "undermine" public health by reducing the availability of e-cigarette products, driving users back to smoking, and increasing "the deaths and disease resulting from the use of tobacco products." Nicopure Br. 17. This is nothing more than conjecture, and the record casts doubt on several links in the speculative chain of inferences that Plaintiffs offer. For example, while the FDA recognized that the deeming rule would likely accelerate existing patterns of consolidation in the e-cigarette industry, it predicted that 266 to 322 e-cigarette devices and 900 to 1,800 e-liquids would remain available after the first round of premarket review, RIA 80. Plaintiffs point to no evidence that consumers would abandon e-cigarettes because of some reduction in product diversity.

Moreover, Plaintiffs mischaracterize the only support they cite for the proposition that the deeming rule will drive e-cigarette users back to smoking, Nicopure Br. 20 (citing AR 150,357–58)—a public comment from a trade association that disagreed with the FDA's cost-benefit analysis and therefore commissioned an "independent" study. While that study indeed predicted "an increase in the sale and consumption of . . . traditional cigarettes," AR 150,440, it forecast that usage rates would rise only "marginally," from 18.100 to 18.104 percent of the population,

or four *thousandths* of one percent, AR 150,418—far smaller than the one percent change assumed without explanation by some amici, *see* Bates Amicus Br. 9. Further, the study concluded that any harms from this rise would be *more than offset* by the deeming rule's benefits—such as longer lives and lower medical costs—for those who quit tobacco altogether. AR 150,420–21.

Third, Plaintiffs suggest that the deeming rule "fails to meaningfully consider the burden of the PMTA [i.e., premarket tobacco application] requirement" on e-cigarette and e-liquid manufacturers, and that its "actual costs" will "eviscerate the vaping industry." Nicopure Br. 21, 23. This is a naked repackaging of their cost-benefit analysis claim, and it should be rejected for the reasons explained below. *See infra* Part III at 50–59. In any event, the argument is both factually and legally mistaken. As a factual matter, while the FDA acknowledged that the cost of premarket applications would likely accelerate existing patterns of consolidation in the e-cigarette industry, RIA 78, it estimated that at least 266 e-cigarette devices and 900 e-liquids would remain available after the first round of marketing authorizations, with more to be authorized in subsequent years. RIA 80. Plaintiffs do not dispute the accuracy of those predictions, and courts are "particularly loath to second-guess" an agency's "'predictive judgments about the likely economic effects of a rule.'" *Newspaper Ass'n of Am. v. Postal Reg. Comm'n*, 734 F.3d 1208, 1216 (D.C. Cir. 2013) (citation omitted); *see also Rural Cellular Ass'n v. FCC*, 588 F.3d 1095, 1105 (D.C. Cir. 2009) ("The 'arbitrary and capricious' standard is particularly deferential in matters implicating predictive judgments."). Moreover, there is reason to doubt Nicopure's hyperbolic calculations about the effects of the rule on its own business, which are based on the faulty assumption that it will submit premarket applications for every item in its internal stockroom—including batteries, heating coils, and replacement parts—even

though the FDA plans to enforce the premarket application requirement only with respect to "finished tobacco products," 81 Fed. Reg. at 28,995, such as "e-cigarettes, or e-liquids sold separately to consumers," *id*. at 29,019.[15]

As a legal matter, even where a statute sets forth specific factors for an agency to consider, if Congress "did not assign the specific weight the [agency] should accord each of these factors, [the agency] is free to exercise [its] discretion in this area." *New York v. Reilly*, 969 F.2d 1147, 1150 (D.C. Cir. 1992); *Brady v. FERC*, 416 F.3d 1, 6 (D.C. Cir. 2005); *see also Sec'y of Agriculture v. Cent. Roig Refining Co.*, 338 U.S. 604, 611–12 (1950) (where statutorily mandated "consideration[s]" are not "mechanical or self-defining standards," they indicate Congress's recognition that they involve "wide areas of judgment and therefore of discretion"). Here, there can be no dispute that the FDA did, in fact, consider the burden of the premarket application requirement on e-cigarette manufacturers. RIA 80–97, 104. But in the deeming provision, Congress did not instruct the agency to give that consideration any particular weight—or, indeed, any weight at all. That it did not receive *conclusive* weight in the final calculus, as Plaintiffs demand, is therefore no reason to disturb the FDA's conclusions. *See, e.g.*, *Reilly*, 969 F.2d at 1150.

Fourth, Plaintiffs submit that the FDA rejected four alternative regulatory options without adequate explanation. They are mistaken. On arbitrary and capricious review, an agency is not held to account for every conceivable policy alternative; it need only "explain [the] rejection of an alternative that was [1] 'within the ambit of the existing Standard' and [2] shown . . . to be

[15] The term "finished tobacco product" "refers to a tobacco product, including all components and parts, sealed in final packaging intended for consumer use," 81 Fed. Reg. at 28,995—"e.g., filters, filter tubes, e-cigarettes, or e-liquids sold separately to consumers or as part of kits," *id*. at 29,019. An "e-liquid that is sold or distributed for further manufacturing into a finished ENDS product is not itself a finished tobacco product." *Id*. at 28,995.

effective." *Clinton Mem'l Hosp. v. Shalala*, 10 F.3d 854, 859 (D.C. Cir. 1993) (quoting *State Farm*, 463 U.S. at 48–51). Each of Plaintiffs' preferred regulatory approaches is either at odds with the deeming provision or would undermine its effectiveness.

To begin, Plaintiffs argue that the FDA should refrain from regulating e-cigarettes *at all*, pending further study. Nicopure Br. 23. Specifically, they contend that, before exercising the deeming authority, the FDA was required to "collect[] sufficient data" about e-cigarettes and "reach a conclusion . . . regarding the[ir] health effects." *Id*. But, as the FDA explained, this argument conflates the statutory standards in sections 901 and 906, which are entirely "separate authorities." 81 Fed. Reg. at 28,983. Under section 901, the FDA may subject "any" tobacco product to the Tobacco Control Act as it "deems" fit. *Id*. (citing 21 U.S.C. § 387a(b)). Then, under section 906, the FDA may restrict the "sale and distribution" of a deemed product "if the Secretary determines that such regulation would be appropriate for the protection of the *public health*." 21 U.S.C. § 387f(d)(1) (emphasis added). Because the deeming authority in section 901 contains no such "public health" standard—or, indeed, any standard at all—the "FDA is not required to meet a particular public health standard to deem tobacco products," as it correctly explained. 81 Fed. Reg. at 28,983. Furthermore, Plaintiffs' attempt to place the burden on the *FDA* to prove that e-cigarettes are a net harm, rather than on the manufacturer to show otherwise, is also inconsistent with section 910 of the statute, which puts the burden on the *manufacturer*, in its premarket application, to make a "showing that permitting [its] tobacco product to be marketed would be appropriate for the protection of the public health." 21 U.S.C. § 387j(c)(2)(A). In any event, Plaintiffs' suggestion that FDA oversight of e-cigarettes should be delayed indefinitely, Nicopure Br. 23, is hardly an "effective" regulatory alternative to the

deeming rule, *Clinton Mem'l*, 10 F.3d at 859, given the significant risks of e-cigarettes that are already known.

Plaintiffs next suggest that the FDA should have "follow[ed] the European Union's approach" to regulating e-cigarettes, which they claim would subject these products to "disclosure, advertising, good manufacturing practices, misbranding, and other requirements, but would *not* require [them] to obtain premarket authorization." Nicopure Br. 24. But that is not the statute that Congress wrote. Section 901 provides: "This *chapter*"—i.e., Chapter IX of the FDCA—"*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." 21 U.S.C. § 387a(b) (emphasis added). Section 910 falls within Chapter IX, and provides that premarket review "is *required*" for new tobacco products. 21 U.S.C. § 387j(a) (emphasis added). Thus, under the plain text of the statute, "FDA is authorized to deem products subject to 'chapter IX,' not to particular provisions of chapter IX," and "there are no exemptions from particular requirements for any product category," as the agency correctly explained. 81 Fed. Reg. at 29,004. Indeed, without first deeming e-cigarettes subject to the Tobacco Control Act, the FDA cannot exercise any of the regulatory powers that Plaintiffs concede are proper under the EU's approach. *See id.* at 28,983 (only "[o]nce products are [deemed] subject to chapter IX" can FDA "use other authorities in chapter IX . . . to take regulatory action with respect to such products"). Thus, under the Tobacco Control Act, deeming e-cigarettes is a necessary first step to any "effective" oversight. *Clinton Mem'l*, 10 F.3d at 859. Plaintiffs offer no alternative reading of the statutory framework, and their analogy to the allegedly "modified approval frameworks" for dietary supplements and over-the-counter drugs is misplaced, as they

are regulated under different statutory schemes that, unlike the Tobacco Control Act, do not generally require premarket review.

Plaintiffs' next suggestion—that the FDA "should have . . . considered crafting a streamlined PMTA process" for allegedly "safer" tobacco products like e-cigarettes—fails for similar reasons. Nicopure Br. 24–25. Plaintiffs offer no details about what this "streamlined" process would look like, aside from suggesting that it "could" avoid "costly study requirements" and include "minimum performance standards," *id*. at 25. But the baseline requirements for premarket applications are set by section 910 of the statute, which provides that those applications "shall" contain "full reports" of the "health risks" of the product, a "full statement" describing its ingredients and operation, a "full description" of the manufacturing methods used, and samples of the product and its labeling. 21 U.S.C. § 387j(b)(1). Although the statute permits the FDA to require still "other information" in premarket applications, *id*. § 387j(b)(1)(G), it does not authorize the agency to relax the statute's baseline requirements. And while the statute provides that the FDA "shall" deny premarket applications for products that vary without justification from "product standards" issued under section 907, *id*. §§ 387g(a)(3), 387j(c)(2)(D), the agency has no authority to adopt such standards for e-cigarettes unless it first deems them under section 901, as already explained, *see* 81 Fed. Reg. at 28,983. Then, and only then, can the FDA apply the principles of harm reduction and relative risk on a case-by-case basis when reviewing individual product applications for marketing.

Further, Plaintiffs' analogy to the exemption of smokeless tobacco from the Tobacco Control Act's general ban on free samples is inapt. Nicopure Br. 25. That exemption was crafted by Congress, not the agency, 21 U.S.C. § 387a–1(a)(2)(G), and Congress declined to create comparable exceptions to the premarket review process for "innovative" products like e-

cigarettes, despite concerns that under the Act they "could not make their access to the market," 155 Cong. Rec. H4367 (Apr. 1, 2009) (statement of Rep. Buyer). Indeed, while Congress did not subject older, grandfathered products to premarket review, it did require newer products to demonstrate that they are "appropriate for the protection of the public health" (or substantially equivalent to a grandfathered product or exempt from the substantial equivalence requirement) before being sold. 21 U.S.C. § 387j(a). Pub. L. No. 111-31. Thus, the statutory premarket review process *is* the process for the allegedly "safer" products that Plaintiffs claim to offer. *See* Nicopure Br. 25.

Finally, Plaintiffs argue that the FDA had the "statutory duty" to change the grandfather date—February 15, 2007—and that its failure to do so was arbitrary because, they claim, so many manufacturers will forgo premarket review that a "virtual ban on many (if not all) vaping product categories" will result. *See* Right To Be Smoke-Free Coalition ("RSF") Mot. 1; RSF Br. 2, 14. But, as the FDA explained, the agency "lacks authority to change the grandfather date, which is set by statute." 81 Fed. Reg. at 28,993. Plaintiffs' argument to the contrary is based solely on faulty inferences drawn from the "overall statutory design," RSF Br. 12, 18, not on the statute's plain text, which they concede favors the FDA's interpretation.

As explained above, the statute provides that a deemed product "shall" be subject to Chapter IX of the FDCA, and thus premarket review "is required" for "new" products. *See supra* at 46 (quoting 21 U.S.C. §§ 387a(b), 387j(a)). The statute further defines "new tobacco product" to mean "any" tobacco product "not commercially marketed in the United States as of February 15, 2007," 21 U.S.C. § 387j(a)(1)(A), or "any modification" of a tobacco product "commercially marketed in the United States after February 15, 2007," *id.* § 387j(a)(1)(B). Thus, by the statute's plain text, premarket review is required for any deemed product not on the

market as of February 15, 2007. The statute itself admits of no other reading, and Plaintiffs offer none.

The statutory context supports this reading. To begin, Congress authorized the FDA to modify certain statutory deadlines, but *not* the grandfather date, underscoring that the agency has no such authority. *See* Pub. L. No. 111-31, § 6(a), (d) (FDA may "extend or reduce" certain deadlines "within which *the Secretary* . . . is required to carry out and complete specified activities," but this authority "shall not apply to the obligations of any *other person* or to any other provision of this division" and, regardless, shall not exceed "90 days"). Moreover, the notion that enforcing the statutory grandfather date is at odds with Congress's supposed intent that "vaping products[] cannot be regulated to the extent that they are effectively banned from sale," RSF Br. 15, is counter to the facts and refuted by the statutory text. Plaintiffs strain to infer such a ban from the statute's prohibition on reducing nicotine yields to zero, *id*. (citing 21 U.S.C. § 387g(d)(3)(B)), but ignore the more relevant (and immediately preceding) provision that bars the FDA from entirely banning only certain categories of tobacco products—"all cigarettes," "all cigars," "all pipe tobacco," and "all roll-your-own-tobacco"—but not others, 21 U.S.C. § 387g(d)(3)(A). On this score, as with Plaintiffs' other proposed regulatory alternatives, the agency's interpretation of the statute is, at a minimum, a permissible one that merits deference. *See Chevron*, 467 U.S. at 844.

Regardless, the deeming rule comes nowhere close to banning e-cigarettes, either actually or "virtually." RSF Br. 2. Plaintiffs' claim that "between 95 and 97 percent of vaping product manufacturers will cease to exist as of . . . August 2018," RSF Br. 22, is a particularly gross distortion. They apparently arrive at this figure by collapsing the estimated 168 to 204 "manufacturers" of e-cigarettes and e-liquids with the thousands of vape shops that currently

meet that definition because they mix different e-liquids together. But the FDA "expect[ed] most vape shops to convert to a pure retail model," RIA 48, not to close entirely, and Plaintiffs offer no evidence to undermine that prediction.

At bottom, while the regulatory alternatives that Plaintiffs prefer may be less burdensome for manufacturers, they are hardly effective substitutes for deeming, which is a necessary precondition to any regulation of e-cigarettes under the Tobacco Control Act. The FDA rationally explained why it rejected them, and the APA requires no more.

III. THERE IS NO BASIS TO SECOND-GUESS THE FDA'S DETERMINATION THAT THE BENEFITS OF THE DEEMING RULE JUSTIFY ITS COSTS

There is likewise no basis to second-guess the FDA's cost-benefit analysis, as the Tobacco Control Act requires no such analysis, and the Executive Orders under which the agency acted expressly preclude judicial review of the agency's conclusions. Regardless, the FDA reasonably found that the costs of the deeming rule—an estimated $2 per beneficiary per year—were justified by its many benefits, including more accurate labels, effective health warnings, and improved product consistency.

A. APA Review of an Agency's Cost-Benefit Analysis under Executive Orders 12866 and 13563 Is Precluded

Contrary to Plaintiffs' suggestion, the FDA assessed the costs and benefits of the deeming rule not because any provision of the Tobacco Control Act required it to, but instead because "Executive Orders 12866 and 13563" did. 81 Fed. Reg. at 29,074; RIA 4; *cf.* Nicopure Br. 27. Alleged violations of these "Executive Orders cannot give rise to a cause of action" under the APA. *Fla. Bankers Ass'n v. U.S. Dep't of Treas.*, 19 F. Supp. 3d 111, 118 n.1 (D.D.C. 2014), *vacated on other grounds*, 799 F.3d 1065 (D.C. Cir. 2015).

"An Executive Order devoted solely to the internal management of the executive branch—and one which does not create any private rights—is not subject to judicial review." *Meyer v. Bush*, 981 F.2d 1288, 1297 (D.C. Cir. 1993). Executive Orders 12866 and 13563 are precisely such orders. While Executive Order 12866 directs federal agencies to "assess both the costs and the benefits of the intended regulation," EO 12866, § 1(b)(6) (Sept. 30, 1993), in a section titled "Judicial Review," it states:

> This Executive order is intended only to improve the internal management of the Federal Government and does not create any right or benefit, substantive or procedural, enforceable at law or equity by a party against the United States, its agencies or instrumentalities, its officers or employees, or any other person.

Id. § 10. Executive Order 13563, which "supplement[s] and reaffirms" Executive Order 12866, EO 13563, § 1(b) (Jan. 18, 2011), contains nearly identical language:

> This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

Id. § 7(d). Such language expressly precludes judicial review. In *Air Transportation Association of America v. FAA*, 169 F.3d 1 (D.C. Cir. 1999), the D.C. Circuit considered a similar Executive Order that required federal agencies to conduct a "'systematic analysis of expected benefits and costs'" for infrastructure investments, but was expressly "'intended only to improve the internal management of the executive branch and does not create any right . . . enforceable against the United States.'" *Id*. at 8 (quoting EO 12893). Based on this language, the court dismissed the plaintiff's challenges to the agency's cost-benefit analysis as "not subject to judicial review." *Id*. The court also flatly rejected the plaintiff's argument that "it does not seek to assert rights under the order but is merely referencing it to provide evidence of the arbitrary and capricious nature of the [agency's] decision," calling it "nothing more than an indirect—and impermissible—attempt to enforce private rights under the order." *Id*. at 9.

In the wake of *Air Transportation Association*, courts in this district have uniformly rejected attempts to obtain APA review of cost-benefit analyses conducted pursuant to Executive Orders 12866 and 13563. *See, e.g.*, *Fla. Bankers Ass'n*, 19 F. Supp. 3d at 118 n.1 (EOs 12866 and 13563); *Alliance for Natural Health v. Sebelius*, 775 F. Supp. 2d 114, 135 (D.D.C. 2011) (EO 12866); *see also Trawler Diane Marie, Inc. v. Brown*, 918 F. Supp. 921, 932 (E.D.N.C. 1995), *aff'd*, 91 F.3d 134 (4th Cir. 1996) (table) (EO 12866); *cf. Defenders of Wildlife v. Jackson*, 791 F. Supp. 2d 96, 120 (D.D.C. 2011) (EO 13186) ("[P]laintiffs' attempt to enforce this order is made hopeless by the language of the order itself, which explicitly rules out the possibility of judicial review."). This Court should not chart a different course.

B. The Tobacco Control Act Does Not Require the FDA to Conduct a Cost-Benefit Analysis when Exercising Its Deeming Authority

Because the Tobacco Control Act does not require the FDA to conduct a cost-benefit analysis when exercising its deeming authority, there is no basis for APA review of that analysis. Whether an agency's cost-benefit analysis is reviewable under the APA depends on the text of the authorizing statute. *Michigan v. EPA*, 135 S. Ct. 2699 (2015). In general, "[w]hen Congress has intended that an agency engage in cost-benefit analysis, it has clearly indicated such intent on the face of the statute." *Am. Textile Mfrs. Inst., Inc. v. Donovan*, 452 U.S. 490, 510 (1981); *see also City of Portland v. EPA*, 507 F.3d 706, 712 (D.C. Cir. 2007) (when "Congress wanted EPA to undertake cost-benefit analysis, it said so expressly"); *Inv. Co. Inst. v. CFTC*, 720 F.3d 370, 377–78 (D.C. Cir. 2013). Indeed, even where Congress wants an agency to engage in less formal economic analysis—or merely to consider the costs of regulation on a regulated party—it has generally made its intent clear in the statutory text. *See, e.g.*, *Nat'l Ass'n of Home Builders v. EPA*, 682 F.3d 1032, 1039 (D.C. Cir. 2012) ("[W]hen Congress . . . authorize[d] regulations

addressing lead-paint hazards, it instructed EPA to 'tak[e] into account reliability, effectiveness, and safety'—but did not mention cost.") (citation omitted).

By contrast, in the deeming provision, Congress not only declined to call for a cost-benefit analysis, but was silent as to costs altogether. 21 U.S.C. § 387a(b). Yet Congress clearly knew how to require the consideration of costs and benefits, and it did so explicitly elsewhere in the Tobacco Control Act.[16] Congress has been similarly explicit in other provisions of the FDCA.[17] Its silence on this score in the deeming provision is powerful evidence that it did not intend the FDA's deeming authority to turn on the potential costs of regulation on tobacco-product manufacturers. The Court should not read into the statute a requirement "to consider costs that has elsewhere, and so often, been expressly granted" by Congress. *Whitman v. Am. Trucking Ass'n, Inc.*, 531 U.S. 457, 467 (2001).

Plaintiffs' reliance on *Business Roundtable v. SEC*, 647 F.3d 1144 (D.C. Cir. 2011), is therefore misplaced. There, the statute expressly required the SEC "to consider the effect of a new rule upon 'efficiency, competition, and capital formation,'" *id*. at 1148 (quoting 15 U.S.C. §§ 78c(f), 78w(a)(2), 80a–2(c))—a "unique" provision that imposes a "'statutory obligation'" on the SEC "'to determine as best it can the economic implications of the rule,'" *id*. (citation omitted). The text of the deeming provision says nothing comparable.

[16] *See, e.g.*, 21 U.S.C. § 387i(a)(3) (directing FDA to consider "the cost of complying with [reporting] requirements and the need for the protection of the public health" to prevent "unduly burdensome" requirements).

[17] *See, e.g.*, 21 U.S.C. § 350i(a)(1)(B) (requiring FDA to consider "risks, costs, and benefits" of guarding against intentional adulteration of food); 21 U.S.C. § 360eee–1(g)(4)(A)(iii)(III) (requiring FDA to consider the "public health benefits . . . in comparison to the cost of compliance" with new regulations for the pharmaceutical supply chain).

The Supreme Court's recent decision in *Michigan v. EPA* is consistent with this principle. There, the statute directed the EPA to regulate power plant emissions "if [it] finds such regulation is appropriate and necessary." 42 U.S.C. § 7412(n)(1)(A). The Court held that, "read naturally in [that] context," the phrase "'appropriate and necessary' requires at least some attention to cost." *Michigan*, 135 S. Ct. at 2707. It emphasized, however, that "[t]here are undoubtedly settings in which the phrase 'appropriate and necessary' does not encompass cost." *Id*. The key, it explained, is to read the statutory terms "fairly and in context." *Id*. at 2709.

Here, Plaintiffs ask the Court to pluck a single word out of the statute and ignore the rest. Seizing on the word "appropriate" in the eighth of the statute's ten general purposes, they argue that by seeking "to impose appropriate regulatory controls on the tobacco industry," Pub. L. No. 111-31, § 3(8), Congress imposed a "directive for the agency to engage in a cost-benefit analysis in *any* rulemaking," Nicopure Br. 27 (emphasis added). That is mistaken. "Caution is always advisable in relying on a general declaration of purpose to alter the apparent meaning of a specific provision." *National Wildlife Fed'n v. Gorsuch*, 693 F.2d 156, 178 (D.C. Cir. 1982). Here, Congress's general goals should not be read to override the specific text of the deeming provision, which contains no words of limitation. *See Gozlon-Peretz v. United States*, 498 U.S. 395, 407 (1991) ("A specific provision controls over one of more general application.").

As noted earlier, the deeming provision says only that the Tobacco Control Act "shall apply . . . to any other tobacco products that the Secretary by regulation *deems* to be subject to" its provisions, 21 U.S.C. § 387a(b)—inherently deferential language that commits deeming decisions to agency discretion, *see supra* Part II.A at 39–40; *Webster*, 486 U.S. at 600 (statute's use of "deem" indicates that its implementation was "committed to agency discretion by law"). This stands in contrast to other provisions of the statute where Congress explicitly directed the

FDA to regulate only where "appropriate." For example, the FDA may regulate the ingredients of a tobacco product only after "making a finding" that regulation "is *appropriate* for the protection of the public health," considering the "risks and benefits to the population as a whole." 21 U.S.C. § 387g(a)(3)(A), (B)(i) (emphasis added). Indeed, even if Congress had added the word "appropriate" to the deeming provision itself—perhaps by authorizing the FDA to subject other products to the Act where it "deems appropriate"—it would not have overridden the deference "fairly exude[d]" to the agency by the use of the word "deem." *Cf. Webster*, 486 U.S. at 600 (agency authorized to act "whenever it 'shall *deem* such termination necessary' . . . not simply when the dismissal *is* necessary").

In enacting the Tobacco Control Act, Congress was no doubt aware that additional regulation might impose costs on the manufacturers of tobacco products. But nothing in the Act suggests that those were the harms that Congress was concerned about when authorizing the FDA to deem additional products subject to the Act. Because the text of the Tobacco Control Act does not require the FDA to conduct a cost-benefit analysis when exercising its deeming authority, there is no basis for APA review of that analysis. Plaintiffs' arguments to the contrary are "nothing more than an indirect—and impermissible—attempt to enforce private rights under the [Executive] order[s]" that required that analysis in the first place. *Air Transp. Ass'n*, 169 F.3d at 9.

C. The FDA in Any Event Properly Concluded that the Benefits of the Deeming Rule Justify Its Costs

Even if the agency's cost-benefit analysis were subject to review, it would readily withstand scrutiny. The principle "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 polices." *Consumer Elecs. Ass'n v. FCC*, 347 F.3d 291, 303 (D.C. Cir. 2003)

(quoting *State Farm*, 463 U.S. at 43). Accordingly, courts "review [an agency's] cost-benefit analysis deferentially." *Am. Trucking Associations, Inc. v. Fed. Motor Carrier Safety Admin.*, 724 F.3d 243, 253 (D.C. Cir. 2013). When reviewing a challenge to an agency's cost-benefit analysis, a court must limit its role 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 v. Peck*, 751 F.2d 1336, 1342 (D.C. Cir. 1985).

Plaintiffs fail to meet the high burden required to cast doubt on the FDA's analysis. Plaintiffs first complain that the agency did not quantify all benefits and costs. Nicopure Br. 27–31. But "some important benefits and costs . . . may be inherently too difficult to quantify or monetize given current data and methods," OMB, Circular A–4: Regulatory Analysis 27 (Sept. 17, 2003), and "the law does not require agencies to measure the immeasurable," *Inv. Co. Inst.*, 720 F.3d at 379. "As predicting costs and benefits without reliable data is a primarily predictive exercise, the [agency] need[s] only to acknowledge [the] factual uncertainties and identify the considerations it found persuasive in reaching its conclusions as to the costs and benefits." *Sec. Indus. & Fin. Markets Ass'n v. CFTC*, 67 F. Supp. 3d 373, 432 (D.D.C. 2014); *see also* EO 12866, § 1(a) (agencies should describe "qualitative measures of costs and benefits that are difficult to quantify").

Here, because the rule is an enabling regulation and future FDA actions related to newly deemed products are currently unknown, and because more information is still needed to fully identify the long-term health effects of some of these products, *see* RSF Br. 29, the FDA explained that the direct benefits of the deeming rule "are difficult to quantify" and cannot be

predicted "at this time." 81 Fed. Reg. at 28,981.[18] Nevertheless, the agency provided an extensive, qualitative discussion of the rule's benefits, as well as the benefits of several regulatory alternatives. RIA 62–68, 122–127. In the absence of a Congressional mandate requiring a "rigorous, quantitative economic analysis," the FDA's qualitative analysis is more than sufficient. *See Inv. Co. Inst.*, 720 F.3d at 379 (citation omitted).

Similarly, the agency provided summaries of quantifiable costs, RIA 113–15, as well as a thorough, qualitative discussion of other costs, *id.* at 68–114; *see also* 81 Fed. Reg. at 29,075 (quantifying certain costs over 20 years). Plaintiffs' suggestion to the contrary is unfounded, as are their wildly exaggerated cost calculations. For instance, the FDA estimated that the average cost of a premarket application for an e-liquid would be less than a third of that for an e-cigarette. RIA 86–92. Yet Plaintiffs apply the much higher e-cigarette estimates to not only 360–450 e-cigarettes but also 1,250–2,500 e-liquids, inflating their initial cost estimates by a factor of five. *See* Nicopure Br. 30. In addition, although the FDA plans to enforce the premarket application requirement only for finished tobacco products, *see supra* at 44 & n.15 Plaintiffs mistakenly assert that "[a]ll . . . individual components" must apply for premarket authorization, and they therefore multiply the total number of products by four as a "conservative estimate" to account for components and parts, Nicopure Br. 30–31.[19] Plaintiffs' calculations are simply not credible.

[18] While a broad range of assumptions could be used as part of a quantitative analysis, the results of such an analysis would be largely unhelpful because it would primarily be based on the assumptions rather than data. In addition, quantifying only a few categories often leads to the incorrect assumption that other categories have zero benefit.

[19] Plaintiffs also mistakenly assert that the "FDA arbitrarily elected *not* to quantify a wide range of costs." Nicopure Br. 29. But the FDA either quantified and considered such costs, or reasonably explained why they were unquantifiable. *E.g.*, 81 Fed. Reg. at 29,090 (exporter

There is similarly no merit to Plaintiffs' complaint about the agency's decision to use a "break-even" analysis. Plaintiffs suggest that a break-even analysis is an extraordinary tool reserved for the rarest of rulemakings. *See* Nicopure Br. 29. That is incorrect. In fact, where agencies "lack information that would make quantification possible[,] [w]ithin the federal government, the standard practice is breakeven analysis." Cass R. Sunstein, *The Limits of Quantification*, 102 Calif. L. Rev. 1369, 1385 (2014). OMB has similarly recognized the utility of a break-even analysis, explaining to agencies that "[i]f the non-quantified benefits and costs are likely to be important, you should carry out a threshold [i.e., break-even] analysis to evaluate their significance." OMB, Circular A-4 at 2. Here, the FDA appropriately used a break-even approach in light of the unquantified benefits associated with the rule. 81 Fed. Reg. at 29,075. Unlike in *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201, 1219 (5th Cir. 1991), where the agency failed to compute costs and benefits past a certain year, and also double-counted certain costs, here there is simply no basis to conclude that the FDA chose a break-even approach "'to effect a wholesale shift' in the analysis," Nicopure Br. 29 (quoting *Corrosion Proof Fittings*, 947 F.2d at 1219).

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recordkeeping costs); RIA 101–02 (costs regarding harmful and potentially harmful constituents); RIA 44, 103 (loss of product variety); RIA 104, 152 (market adjustment costs); *see also* RIA 143–44 (loss of product variety, recordkeeping costs, compliance costs for certain components and parts, market adjustment costs, etc.). Plaintiffs' allegation that the agency failed to respond to comments made during meetings between industry and OMB, Nicopure Br. 30 n.19, also lacks merit. The FDA reasonably determined that such third-party submissions, made after the close of the comment period, were not part of the record. *See, e.g.*, *Montrose Chem. Corp. of California v. U.S. EPA*, 172 F.3d 920 (D.C. Cir. 1999) (table) ("[G]enerally an agency is not under an obligation to consider comments submitted after the close of the comment period."). In any event, the OMB submission from Consumer Advocates for Smoke-free Alternatives Association ("CASAA") that Nicopure cites is similar to the comments that CASAA submitted to the FDA regarding the degree of market exit, *see* AR 139,054, an issue that the FDA addressed, *e.g.*, RIA 79.

The Court should likewise reject Plaintiffs' claim that the FDA "loads the dice by excluding the unquantified costs from its break-even analysis." *Id*. 31. Plaintiffs misunderstand the fundamentals of a break-even analysis. Because a break-even analysis provides a direct estimate of the monetary value that potential beneficiaries would have to be willing to pay for the rule's provisions, it can incorporate only quantifiable costs. Accordingly, the FDA did not include any unquantified benefits or unquantified costs in the break-even analysis. RIA 115–16. Having adequately described the costs, benefits, and uncertainties, the FDA reasonably concluded that the benefits would justify the costs. *Id*. at 9; *see Inv. Co. Inst. v. U.S. CFTC*, 891 F. Supp. 2d 162, 189 (D.D.C. 2012) ("Where an agency has acknowledged public comments regarding costs of the new rule and concluded that such costs are justified by gains in other areas, the agency has sufficiently taken into consideration these facts."), *aff'd*, 720 F.3d 370 (D.C. Cir. 2013).

Further, Plaintiffs' reliance on *Center for Biological Diversity v. NHTSA*, 538 F.3d 1172, 1198 (9th Cir. 2008), is misplaced. Nicopure Br. 32. There, the Ninth Circuit faulted the agency for not monetizing the benefit of carbon emissions reduction. *Ctr. for Biological Diversity*, 538 F.3d at 1198–1203. But the agency had "fail[ed] to include in its analysis the benefit . . . in either quantitative or qualitative form," *id*. at 1198, whereas here Plaintiffs do not contest that the FDA described unquantified benefits and costs qualitatively, *see* Nicopure Br. 26–32. Similarly, in *Business Roundtable*, the agency "fail[ed] to view a cost at the margin," 647 F.3d at 1144, but here it is undisputed that the FDA described all costs, whether quantitatively or qualitatively, *see* Nicopure Br. 26–32.

Finally, Plaintiffs' theory that the FDA should have separately "determine[d] whether the cost of regulating *vaping products* is justified by the benefits" lacks merit. Nicopure Br. 32

(emphasis in original). In its regulatory impact analysis, the FDA separately broke out all major costs for the e-cigarette industry, including premarket applications and labeling changes. Plaintiffs offer no authority, and Defendants are aware of none, suggesting that every product or industry affected by a rulemaking is entitled to a separate cost-benefit analysis. By contrast, courts have upheld rulemakings based on analyses that broadly address projected benefits and costs. *E.g.*, *Inv. Co. Inst.*, 891 F. Supp. 2d at 189.

The FDA has not "merely recite[d] the terms 'substantial uncertainty' as a justification for its actions," Nicopure Br. 28 (quoting *State Farm*, 463 U.S. at 52); rather, it "explain[ed] the evidence which is available" and "offer[ed] a rational connection between the facts found and the choice made," *State Farm*, 463 U.S. at 52. Its cost-benefit analysis therefore survives any applicable APA scrutiny.

IV. THE FDA FULLY COMPLIED WITH THE REGULATORY FLEXIBILITY ACT

Plaintiffs' contention that the FDA violated the Regulatory Flexibility Act by failing to consider an extension of the two-year premarket tobacco application ("PMTA") compliance period is similarly meritless. *See* RSF Br. 29–38. The FDA received comments on all sides of this issue, and it explained why it declined to adopt the approach that Plaintiffs prefer. That explanation was more than adequate to satisfy the purely procedural requirements of the Regulatory Flexibility Act.[20]

The Regulatory Flexibility Act requires agencies to "assess the impact of their regulations on small businesses." *U.S. Cellular Corp. v. FCC*, 254 F.3d 78, 88 (D.C. Cir. 2001). For certain

[20] Plaintiffs also reference in a footnote other alternatives that the RIA "should have addressed," but do not claim that the FDA's approach to these alternatives constituted a violation of the Regulatory Flexibility Act. *See* RSF Br. 36 n.23. These alternatives are addressed in Section II.B, above.

rules, agencies must prepare a final regulatory flexibility analysis that includes, among other things, descriptions of specific aspects of the rule, the compliance requirements, and the steps the agency has taken to minimize the impact on small entities consistent with the stated objectives of applicable statutes. 5 U.S.C. § 604(a); *see, e.g.*, *Nat'l Tel. Coop. Ass'n v. FCC*, 563 F.3d 536, 540 (D.C. Cir. 2009). The analysis must also include "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." 5 U.S.C. § 604(a)(6).

Section 604 "do[es] not alter in any manner standards otherwise applicable by law to agency action." 5 U.S.C. § 606. "Purely procedural, . . . section 604 requires nothing more than that the agency file a [final Regulatory Flexibility Act analysis] demonstrating a reasonable, good-faith effort to carry out [RFA's] mandate." *U.S. Cellular Corp.*, 254 F.3d at 88 (citation omitted). Accordingly, if an agency prepares an analysis that "addressed all of the legally mandated subject areas, it complies with the Act." *Nat'l Tel. Coop. Ass'n*, 563 F.3d at 540; *see also Nat'l Ass'n of Mortgage Brokers v. Bd. of Governors of Fed. Reserve Sys.*, 773 F. Supp. 2d 151, 178 (D.D.C. 2011).

For purposes of section 604, an agency is not required to discuss every potential alternative in detail; rather, it need only "respond to relevant comments and consider reasonable alternatives." *Grand Canyon Air Tour Coal. v. FAA*, 154 F.3d 455, 471 (D.C. Cir. 1998) (citing *State Farm*, 463 U.S. at 51); *see also N.C. Fisheries Ass'n, Inc. v. Gutierrez*, 518 F. Supp. 2d 62, 96 (D.D.C. 2007) (agency complied with section 604 even though it "could have conducted further study, considered additional alternatives, or provided an even more detailed explanation"). An agency complies with section 604 where it "set[s] forth in detail the reasons

for adopting the new regime as a whole and the reasons for preferring it to a series of alternatives." *Little Bay Lobster Co. v. Evans*, 352 F.3d 462, 471 (1st Cir. 2003). "And, where the agency has addressed a range of comments and considered a set of alternatives to the proposal adopted, the burden is upon the critic to show why a brief response on one set of comments or the failure to analyze one element as a separate alternative condemns the effort." *Id*; *see also Zero Zone, Inc. v. United States Dep't of Energy*, No. 14-2147, 2016 WL 4177217, at *21–23 (7th Cir. Aug. 8, 2016).

The FDA performed a complete analysis and thus met the Regulatory Flexibility Act's requirements. That analysis is contained in the Federal Register preamble and laid out in great detail in sections 3 and 4 of the RIA. *See generally* Small Entity Effects, RIA §§ 3–4; *see also id.* App. 4 at 147 (listing small business topics in preamble and final analysis). The agency formally identified and assessed four alternatives to the final rule: exempting premium cigars entirely from the regulation; extending the compliance period for labeling changes to 36 months; reducing the compliance period for labeling changes to 12 months; and not extending the premarket review compliance policy to new, flavored tobacco products. *Id.* § 3.G. In addition, the rule specifically considered and addressed comments concerning the premarket review compliance period, including whether to adopt the compliance policy described in the preamble to the proposed rule. *See* 81 Fed. Reg. at 29,001 ("[W]e believe the compliance period is appropriate, and it takes into account the time for firms to generate and submit the information for a PMTA. The requirements and costs of a PMTA may vary based on the type and complexity of the product."); *id.* at 29,010 ("Taking the diverse comments on these issues . . . into account, FDA has decided to implement the compliance policy with staggered initial compliance periods based on the expected complexity of the applications . . . ."); *id.* (stating that

agency "may consider, on a case-by-case basis, whether to defer enforcement of the premarket authorization requirements for a reasonable time period"); *id.* at 29,011 (discussing consideration of "different compliance periods for different product categories").[21]

Further, and contrary to Plaintiffs' assertions, the FDA extensively responded to comments regarding compliance periods for premarket review requirements. *Id.* at 29,012–15. As the FDA discussed, some comments recommended that the FDA (1) extend the compliance period to five years; (2) refrain from applying the compliance timeframe to manufacturers of newly deemed products; (3) prioritize review of products currently on the market; and (4) base the compliance period on the date the agency issues category-specific guidance. *Id.* With respect to the impact on small businesses in particular, the FDA noted that "[s]everal comments expressed concern that even the proposed 24-month compliance period was not sufficient to submit complete applications for all their products," and that "[s]everal comments also expressed concern that the 24-month proposed compliance period would benefit larger companies with more resources to complete product applications at the expense of small and mid-size companies." *Id.* at 29,014. Of course, other comments urged that the FDA take an entirely different approach, namely one that imposed *greater* restrictions on deemed products. *E.g.*, *id.* at 29,012 (noting some comments "argued that establishing similar timeframes for the newly deemed products only benefits industry and is detrimental to public health"); *id.* at 29,013 ("[M]any other comments stated that the contemplated 2-year compliance period was too long"); *id.* at 29,013–14 ("Some comments also suggested that manufactures that sell flavored tobacco

[21] While Plaintiffs focus on the contents of the RIA, RSF Br. 32–33, the Court may also consider the final rule in determining compliance with section 604. *E.g.*, *N.C. Fisheries Ass'n*, 518 F. Supp. 2d at 96; *Ranchers Cattlemen Action Legal Fund United Stockgrowers of Am. v. USDA*, 415 F.3d 1078, 1102 (9th Cir. 2005), *as amended* (Aug. 17, 2005).

products or that market tobacco products to children should not be afforded any compliance period to satisfy the premarket review requirements.").

The FDA responded to each of these comments, ultimately concluding that the two-year compliance period was appropriate, particularly given the steps the agency has taken "to provide helpful feedback to industry to encourage more complete, streamlined submissions and reviews." *Id.* at 29,010–15. Supplementing these responses, the FDA explained elsewhere in the rule that it may consider information such as published literature and marketing information with appropriate bridging studies, *id.* at 28,998, and that the use of master files will create additional efficiencies, *id.* at 28,999, which further address Plaintiffs' concern about their ability (or alleged inability) to meet the PMTA requirements, RSF Br. 33. The FDA's response to these comments was therefore more than sufficient. *City of Portland*, 507 F.3d at 714 ("The agency's response to public comments need only enable us to see what major issues of policy were ventilated . . . and why the agency reacted to them as it did."); *Am. Iron & Steel Inst. v. EPA*, 115 F.3d 979, 1005–06 (D.C. Cir. 1997) (response to comment sufficient where it "demonstrates that the agency at least considered whether it should adopt [an alternative] model"); *see also Nat'l Tel. Coop. Ass'n*, 563 F.3d at 542 (agency adequately addressed alternatives policy options where it explained that alternatives would deny benefits to and otherwise harm consumers); *Sierra Club v. EPA*, 353 F.3d 976, 986 (D.C. Cir. 2004) (agency reasonably articulated decision in providing that suggested alternative is "impracticable"). While Plaintiffs may not agree with the substance of the FDA's response to comments regarding the two-year compliance period, such an objection is not germane to the Court's review under the Regulatory Flexibility Act. *See U.S. Cellular Corp.*, 254 F.3d at 88.

Accordingly, the agency's discussion of alternatives in both the RIA and the rule itself amply satisfies the requirements of section 604.[22]

V. THE TOBACCO CONTROL ACT COMPORTS WITH SUBSTANTIVE DUE PROCESS

Plaintiffs' claim that the Tobacco Control Act violates substantive due process because, in setting a fixed grandfathering date, "Congress drafted a statute that fails to meet the legislation's stated goals and objectives," RSF Br. 38, also lacks merit. Plaintiffs identify no fundamental right or liberty interest affected by the Act, and their claim should fail for that reason alone. At most, the Act affects the ease with which they can bring new products to market—a purely economic interest, not a fundamental one. The Supreme Court has not invalidated economic or social welfare legislation on substantive due process grounds since the 1930s, and the Court should decline Plaintiffs' invitation to return to that long-discredited era.

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. Although this clause "provides heightened protection against government interference with certain fundamental rights and liberty interests," *Washington v. Glucksberg*, 521 U.S. 702, 722 (1997), the Supreme Court has cautioned that courts should be "reluctant to expand the concept of substantive due process because guideposts for responsible decisionmaking in this unchartered area are scarce and open-ended," *Collins v. City of Harker Heights*, 503 U.S. 115, 125 (1992).

[22] Even if Plaintiffs' claim under the Regulatory Flexibility Act were meritorious, Plaintiffs would not necessarily be entitled to relief. Instead, if the Court finds that "continued enforcement of the rule is in the public interest," 5 U.S.C. § 611(a)(4)(B), the rule should remain in effect. *See N.C. Fisheries Ass'n*, 518 F. Supp. 2d at 82 ("the conclusion that the amendment violates the . . . RFA would not obligate the Court to enjoin its enforcement"). Given the potential harm of newly deemed products described above, the public interest is so decidedly in favor of the rule, and any procedural error sufficiently harmless, that the Court should exercise its discretion not to vacate the rule.

The "first inquiry in every due process challenge is whether the plaintiff has been deprived of a protected interest in 'property' or 'liberty.'" *Ralls Corp. v. Comm. on Foreign Inv.*, 758 F.3d 296, 315 (D.C. Cir. 2014). A plaintiff must provide "a 'careful description' of the asserted fundamental liberty interest" when raising a substantive due process claim. *Chavez v. Martinez*, 538 U.S. 760, 775–76 (2003). Vague generalizations "will not suffice." *Id.* at 776.

Here, Plaintiffs do not allege that the Tobacco Control Act has affected a fundamental right. *See* Coalition Compl. ¶¶ 27–89. In fact, they make no attempt to articulate—in either their complaint or their summary judgment motion—any right or liberty interest implicated by the Act. *See* Coalition*id*.; RSF Br. 38–40. On this basis alone, Plaintiffs' substantive due process claim must fail. *See Glucksberg*, 521 U.S. at 721; *cf. George Washington Univ. v. Dist. of Columbia*, 318 F.3d 203, 206 (D.C. Cir. 2003) ("Although [the substantive due process] doctrine normally imposes only very slight burdens on the government to justify its actions, it imposes none at all in the absence of a liberty or property interest.").

Further, even if Plaintiffs could identify a right affected by the Tobacco Control Act, the statute would easily survive rational basis review—which Plaintiffs concede is the applicable standard. *See* RSF Br. 38–39. Legislative acts "adjusting the burdens and benefits of economic life come to the Court with a presumption of constitutionality, and . . . the burden is on one complaining of a due process violation to establish that the legislature has acted in an arbitrary and irrational way." *Usery v. Turner Elkhorn Mining Co.*, 428 U.S. 1, 15 (1976). Under this "highly deferential" standard, a court must uphold the law if it is "rationally related to a legitimate government interest." *Empresa Cubana Exportadora de Alimentos y Productos Varios v. U.S. Dep't of Treasury*, 638 F.3d 794, 800 (D.C. Cir. 2011).

Congress designed the Tobacco Control Act to provide "effective oversight of the tobacco industry's efforts to develop, introduce, and promote less harmful tobacco products," Pub. L. No. 111-31, § 3(4), and to "ensure that consumers are better informed" by "requir[ing] tobacco product manufacturers to disclose research which has not previously been made available, as well as research generated in the future, relating to the health and dependency effects or safety of tobacco products," *id.* § 3(6). These are undeniably legitimate aims. *E.g.*, *Turner Broad. Sys. v. FCC*, 520 U.S. 180, 189–90 (1997) (recognizing that consumer protection is legitimate governmental interest); *Hodel v. Virginia Surface Min. & Reclamation Ass'n, Inc.*, 452 U.S. 264, 300 (1981) (health and safety).

Further, the means chosen by Congress, including the establishment of a fixed grandfathering date, are rationally related to these goals. Congress carefully crafted a system whereby "new" tobacco products would be prevented from entering the market unless found (1) "appropriate for the protection of the public health" upon review of a premarket tobacco application, 21 U.S.C. § 387j(c)(2)(A); (2) "substantially equivalent" to a grandfathered product, *id.* § 387j(a)(2)(A); or (3) exempt from the "substantially equivalent" requirements, *id.* §§ 387e(j), 387j(a)(2)(A)(ii). The statutory scheme thus indisputably promotes the Act's goals of public health and consumer protection by authorizing the agency to evaluate the health risks and other characteristics of new, potentially harmful products before they enter the marketplace. *Cf. Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695, 712–13 (D.C. Cir. 2007) (the "Government has a rational basis for ensuring that there is a scientifically and medically acceptable level of knowledge about the risks and benefits of [a potentially toxic] drug" "prior to [its] distribution . . . outside of controlled studies").

The grandfathering date also promotes these purposes. That date—February 15, 2007—is when the legislation was introduced in Congress. *See* H.R. 1108, 110th Cong. (2007); 21 U.S.C. § 387j(a)(1)(A). Consistent with the statute's goals of consumer protection and public health (as well as common sense), Congress defined a "new tobacco product" to include one "not commercially marketed"—and thus about which the potential harms were unknown—as of the date that Congress took up this issue. 21 U.S.C. § 387j(a)(1)(A); *cf.* Pub. L. No. 111-31, § 3(6). The grandfathering date is therefore neither arbitrary nor illogical. *Cf. City of New Orleans v. Dukes*, 427 U.S. 297, 303–05 (1976) (per curiam) (upholding grandfathering provision that allowed only street vendors with at least eight years of experience to continue operating in the French Quarter; the provision survived rational basis scrutiny because "rather than proceeding by the immediate and absolute abolition of all pushcart food vendors, the city could rationally choose initially to eliminate vendors of more recent vintage").

Plaintiffs' remaining arguments are unpersuasive. First, Plaintiffs contend that the Tobacco Control Act's goals "can only be achieved" if the statute allows the FDA to establish a new grandfathering date for deemed products. RSF Br. 38–40. But Congress's selection of a fixed grandfathering date reflects a rational compromise among competing interests. *See* Pub. L. No. 111-31, at § 3(4)–(9). And while Plaintiffs indicate that Congress should have drafted the Act to allow the FDA to set a later date for the end of grandfathering for deemed products, they fail to explain how a potentially and presumptively much later date would be consistent with the statutory goals of public health or consumer protection. *See* RSF Br. 39–40.[23]

[23] Notably, Plaintiffs do not attempt to identify a specific grandfathering date that, in their opinion, would promote the statute's goals to comport with substantive due process. *See* RSF Br. 38–40. Nor do they propose how regularly the FDA should reset the date, nor explain

Second, Plaintiffs are incorrect to suggest that a fixed grandfathering date is inconsistent with Congress's stated purpose of "provid[ing] new and flexible enforcement authority" to the FDA. *See* RSF Br. 39 (referencing Pub. L. No. 111-31, § 3(4)). A fixed date facilitates the agency's use of that authority by providing a bright-line cut-off date to the agency. *Cf. Armour v. City of Indianapolis*, 132 S. Ct. 2073, 2081 (2012) (finding classification had rational basis based on "administrative considerations"). Third, Plaintiffs' argument finds no support in the fact that Congress debated tobacco-control legislation at great length. *See* RSF Br. 19 & n.10 ("As Congress debated various versions of the TCA over the span of a decade, it kept moving the grandfather date forward so that there was never more than 0–3 years between the grandfather date and the date that the particular legislation was introduced."). To the contrary, this extended consideration of the issues confirms that Congress set the fixed grandfathering date not arbitrarily, but with purpose. *See Bellaire Corp. v. Shalala*, 995 F. Supp. 125, 134 (D.C. Cir. 1997) (concluding that means chosen to achieve legislative goals were rational, and noting that legislation "was only enacted after years of debate").

Finally, while some manufacturers may be adversely impacted by a fixed grandfathering date, RSF Br. 39–40, the possibility of such an impact does not render the Tobacco Control Act irrational or arbitrary. *See Heller v. Doe ex rel. Doe*, 509 U.S. 312, 321 (1993) ("A classification does not fail rational-basis review because it is not made with mathematical nicety or because in practice it results in some inequality." (citation omitted)). This is particularly true given the uncertainty associated with new tobacco products. *Gonzales v. Carhart*, 550 U.S. 124, 163

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whether the statute would be irrational if the FDA were permitted to reset the date but chose not to do so. *See id.*

(2007) ("The Court has given state and federal legislatures wide discretion to pass legislation in areas where there is medical and scientific uncertainty.").

Because Congress's objectives were plainly legitimate and its chosen means were rational, under the deferential standard of review applied to substantive due process challenges to economic and social welfare legislation, the inquiry ends there. *See Turner Elkhorn*, 428 U.S. at 15. The Court should not accept Plaintiffs' invitation to "sit as a superlegislature to judge the wisdom or desirability of legislative policy determinations made in areas that neither affect fundamental rights nor proceed along suspect lines," *City of New Orleans*, 427 U.S. at 303, and should instead reject Plaintiffs' substantive due process claim.[24]

VI. THE DEEMING RULE IS CONSISTENT WITH THE FIRST AMENDMENT

Plaintiffs' two First Amendment challenges—to the ban on the distribution of free samples, and to the premarket review of "modified risk" products—also lack merit. The free sample ban regulates conduct, not speech, and thus does not even implicate the First Amendment. And the premarket review of "modified risk" tobacco products ("MRTP") is modeled after the premarket review of therapeutic drugs under the FDCA, which the D.C. Circuit has upheld against the same constitutional attacks that Plaintiffs bring here. Moreover, both provisions would easily pass muster even if scrutinized as commercial speech, as they are narrowly tailored to further legitimate interests.

[24] In Count Three of their complaint, the Coalition Plaintiffs also allege a violation of the equal protection component of the Fifth Amendment's Due Process Clause. Coalition Compl. ¶¶ 83–89. Plaintiffs have apparently abandoned that claim, as they fail to mention it in their summary judgment motion. *See Serv. Employees Int'l Union Nat'l Indus. Pension Fund v. Harborview Healthcare Ctr. Inc.*, No. 15-0627, 2016 WL 3248183, at *3 n.9 (D.D.C. June 10, 2016).

A. The Ban on Free Samples Comports with the First Amendment

In the Tobacco Control Act, Congress directed the FDA to issue a rule generally barring the distribution of free samples of tobacco products, including deemed products such as e-cigarettes. *See* 21 U.S.C. § 387a–1(a)(2)(G). Banning free samples "eliminate[s] a pathway for youth access to tobacco products, which can help in reducing youth initiation and therefore short-term and long-term morbidity and mortality resulting from these products." 81 Fed. Reg. at 28,986. This is a "critical" measure because products like e-cigarettes "are highly addictive and can lead to a lifetime of tobacco use, with attendant adverse health consequences," *id.*, and contain harmful chemicals that lead to independent adverse health effects, *id.* at 29,029.

The ban on free samples does not implicate, much less violate, the First Amendment. As the Supreme Court has explained, provisions that regulate conduct without a significant expressive element do not raise First Amendment concerns, *see Arcara v. Could Books, Inc.*, 478 U.S. 697, 706–07 (1986), and any minimal speech interest that Plaintiffs might assert is far outweighed by the need to curb underage tobacco use.

1. The Free Sample Ban Regulates Conduct, Not Speech

The ban on the distribution of free samples of e-cigarettes is a direct regulation of the distribution of a product, and there is no constitutional right to distribute free samples of harmful and addictive products. As the Supreme Court has made clear, "restrictions on protected expression are distinct from restrictions on economic activity, or, more generally, on nonexpressive conduct." *Sorrell v. IMS Health*, 564 U.S. 552, 567 (2011); *cf. Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 372 (2002) (explaining that the government may regulate demand and supply through price regulation, characterizing such measures as "non-speech-related" means); *see also 44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 507 (1996) (plurality)

(explaining that price regulation "would not involve any restriction on speech"); *Nat'l Ass'n of Tobacco Outlets v. City of New York*, 27 F. Supp. 3d 415, 419–21 (S.D.N.Y. 2014) (upholding city ordinance providing that no retailer may "sell, offer for sale, or otherwise provide cigarettes [or tobacco products] to a consumer for less than the listed price" as regulating price, not speech) (alteration in original). It is equally well established that "the First Amendment does not prevent restrictions directed at commerce or conduct from imposing incidental burdens on speech." *Sorrell*, 564 U.S. at 567. The prohibition on the distribution of free samples is a restriction on commerce and conduct, not a restriction on speech. *See, e.g.*, *Nat'l Ass'n of Tobacco Outlets v. City of Providence, R.I.*, 731 F.3d 71, 77–78 (1st Cir. 2013) (tobacco-product coupons and multi-pack discounts are neither speech nor expressive conduct). To the extent there is any incidental impact on speech, the government has a substantial interest in preventing the distribution of free products for public consumption, including by youth, with the potential to cause addiction and otherwise harm those consumers.

Plaintiffs cite three cases in which courts have analyzed free sample bans as speech restrictions under the First Amendment. *See* Nicopure Br. 35. In *Discount Tobacco City & Lottery v. United States*, 674 F.3d 509, 537 (6th Cir. 2012), for example, the Sixth Circuit upheld the Tobacco Control Act's sampling ban, reasoning that samples are a "promotional method[] that convey[s] the twin messages of reinforcing brand loyalty and encouraging switching from competitors' brands." 674 F.3d at 538. But measures taken to influence consumer conduct do not necessarily convey a message, and the Sixth Circuit's logic does not differentiate free samples from pricing tools, like coupons or other discounts, which, as just discussed, have been held not to implicate the First Amendment. Each of these practices can reinforce brand loyalty and each can encourage switching by reducing financial barriers, but these are outcomes, rather

than "messages" as the Sixth Circuit suggests. If regulations setting minimum prices do not implicate the First Amendment, *see 44 Liquormart*, 517 U.S. at 507, then neither does the provision banning free samples. *Discount Tobacco* and the other cases Plaintiffs cite cannot be squared with the principles set out by the Supreme Court, and the Court should not follow them.

2. If Viewed as a Regulation of Speech, the Free Sample Ban Would Withstand First Amendment Scrutiny

Even if the Court concludes that the ban on free samples implicates the First Amendment, it survives the test articulated in *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557 (1980), for review of restrictions on commercial speech. *See Discount Tobacco*, 674 F.3d at 541 (upholding TCA's ban on free samples under *Central Hudson*).

To begin, Plaintiffs are mistaken to suggest that the Supreme Court's decision in *Sorrell v. IMS Health*, 564 U.S. 552 (2011), fundamentally altered the *Central Hudson* analysis. Nicopure Br. 34. The D.C. Circuit has not so held, *see R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1226 n.4 (D.C. Cir. 2012) (Rogers, J., dissenting) ("Notwithstanding any intimations it may have made in cases such as *Sorrell* . . . , the Supreme Court has continued to apply the more deferential framework of *Central Hudson* to commercial speech restrictions."), *overruled on other grounds by Am. Meat Inst. v. U.S. Dep't of Agric.*, 760 F.3d 18 (D.C. Cir. 2014) (en banc), and other courts have held to the contrary, *see, e.g.*, *Wag More Dogs Ltd. v. Cozart*, 680 F.3d 359, 366 n.4 (4th Cir. 2012) ("Preceding Supreme Court decisions . . . are entirely consistent with *Sorrell*."); *Fleminger, Inc. v. HHS*, 854 F. Supp. 2d 192, 197 (D. Conn. 2012) ("*Sorrell* did not impact the traditional framework for evaluating commercial speech under the First Amendment.").

In any event, this case bears little resemblance to *Sorrell*, in which the government regulated speech based on "disagree[ment] with the message it conveys," *Sorrell*, 564 U.S. at 566, and "nowhere contend[ed] that . . . the provision challenged [t]here w[ould] prevent false or misleading speech," *id*. at 579. Neither the free sample ban nor the MRTP premarket review requirement involves a similar content-based restriction, and *Sorrell* therefore has no bearing on this case. *See also Mass. Ass'n of Private Career Schools v. Healey*, No. 14-13706, 2016 WL 308776, at *9 (D. Mass. Jan. 25, 2016) ("*Sorrell* is replete with language indicating that the Supreme Court would not categorically apply strict scrutiny to content-based commercial-speech regulations that are justified on consumer-protection grounds.").

Thus, the longstanding *Central Hudson* analysis continues to apply, and the free sample ban readily complies with its requirements. "The Constitution . . . accords a lesser protection to commercial speech than to other constitutionally guaranteed expression." *Central Hudson*, 447 U.S. at 562–63. "In commercial speech cases, then, a four-part analysis has developed." *Id.* at 566. First, the court determines whether the speech at issue is misleading or related to unlawful activity. If so, the speech is entitled to no protection. If not, the court "ask[s] whether the asserted governmental interest is substantial." *Id*. Finally, under the third and fourth steps, the court "must determine whether the regulation directly advances the governmental interest asserted, and whether it is not more extensive than is necessary to serve that interest." *Id.* Courts do not require the government to employ "the least restrictive means" of regulation or to achieve a perfect fit between means and ends. *Boards of Trustees v. Fox*, 492 U.S. 469, 480 (1989). It is sufficient that the legislature achieve a "reasonable" fit by adopting regulations "in proportion to the interest served." *Id*.

As Plaintiffs concede, the government has a substantial interest in preventing and reducing juvenile tobacco use. *See* Nicopure Br. 36. Research suggests that young people are "more influenced by smoking behavior" in their social circles, "more vulnerable to developing nicotine dependence," and more likely to experience permanent brain changes as a result of nicotine use. 81 Fed. Reg. at 29,047. E-cigarettes are now the most commonly used tobacco product among middle school and high school students, thus warranting the FDA's particular attention. *Id.* at 28,984. Studies show that high school students who have used e-cigarettes are more likely than nonusers to begin using combustible tobacco products over the next year, suggesting that e-cigarettes may serve as a gateway to traditional tobacco products. *See* Leventhal et al. (2015) at 706 (AR 15,663) (finding "new evidence that e-cigarette use is prospectively associated with increased risk of combustible tobacco use initiation during early adolescence"); Primack et al. (2015) at 1021 (AR 23,909) (finding that "the use of e-cigarettes at baseline was significantly associated with progression along the trajectory to cigarette smoking over 1 year . . . even among a population that was attitudinally nonsusceptible to smoking at baseline").

The sampling ban will directly advance the FDA's interest in curtailing juvenile use of tobacco products. Prohibiting free samples directly targets a practice that appeals particularly to youth. The Institute of Medicine explained in 1994 that "[s]amples encourage experimentation by providing minors with a risk-free and cost-free way to satisfy their curiosity." AR 18,579. The distribution of such samples in places frequented by minors further "increases the likelihood that minors will obtain the tobacco products." *Id.*

This reasoning is as true today as it was in 1994 and, contrary to Plaintiffs' suggestions, its applicability to e-cigarettes requires no "speculation" or "conjecture." Nicopure Br. 36. Free

samples of any product, including e-cigarettes, are, by their very design, a risk-free and cost-free way to try something new. Moreover, just as with traditional tobacco products, companies have been distributing e-cigarette samples at large events geared toward young people. *See* 81 Fed. Reg. at 28,986 (describing e-cigarette companies distributing free samples at events such as "music festivals and motorsport events"); Durbin et al. (2014) at 10 (AR 18,681) (reporting that six surveyed e-cigarette manufacturers "sponsored or provided free samples at 348 events, many of which appear geared toward youth"). Thus, "the prohibition against free samples will eliminate a pathway for youth access to tobacco products, which can help in reducing youth initiation and therefore short-term and long-term morbidity and mortality resulting from these products." 81 Fed. Reg. at 28,986.

The ban on free samples is also sufficiently tailored. The Sixth Circuit held that banning free samples of tobacco products "embodies a narrow fit between the harm articulated and the restriction employed." *Discount Tobacco*, 674 F.3d at 541. That remains true here. Prohibiting free samples is a narrow and limited restriction on the distribution of e-cigarettes that leaves open "ample alternative channels for receipt of information." *Florida Bar v. Went For It, Inc.*, 515 U.S 618, 634 (1995). The free sample ban does not interfere with Plaintiffs' ability to inform consumers about their products through demonstrations, promotional literature, and other truthful and nonmisleading advertising. *See* 81 Fed. Reg. at 29,026 (explaining that retailers can "allow customers to touch, hold, and smell their products without violating the free sample ban"). Indeed, if Plaintiffs are convinced that getting consumers to try the product is particularly important to their advertising, then the FDCA and its implementing regulations do not prohibit Plaintiffs from offering significant discounts on the kinds of "sampling kits" they now provide for free to entice first-time users, *see* Stamler Decl. ¶ 38, in order to reduce the financial barrier.

Plaintiffs argue that a narrower regulation could limit free samples to qualified adult-only facilities, as is the case with smokeless tobacco.[25] *See* Nicopure Br. 38. But the FDA has reason to believe that such a ban would not be "at least as effective" in achieving its regulatory purposes. *Reno v. Am. Civil Liberties Union*, 521 U.S. 844, 874 (1997). Previous attempts to limit free samples to adults have not been successful. As the FDA explained in its earlier rulemaking, on which the Sixth Circuit relied, "young people, including elementary school children, can obtain free samples easily . . . despite industry-developed voluntary codes that supposedly restrict distribution of free samples to underage persons." 61 Fed. Reg. 44,396, 44,460; *see also Discount Tobacco*, 674 F.3d at 541; 81 Fed. Reg. at 28,986. Moreover, the exception for smokeless tobacco sampling carefully restricts the portion size of the permitted sample. *See* 21 U.S.C. § 387a–1(a)(2)(G). Similar limitations are simply not feasible for e-cigarettes, which vary significantly within and among brands in design, performance, and the amount of chemicals they deliver. *See* 81 Fed. Reg. at 29,003. The Sixth Circuit upheld the total ban on free samples of tobacco products despite the existing exemption for smokeless tobacco. *See Discount Tobacco*, 674 F.3d at 541. Its reasoning applies with equal force here, particularly in light of the tremendous and continuing growth of e-cigarettes in the youth market.

C. Premarket Review of Modified Risk Tobacco Products Does Not Violate the First Amendment

In addition to requiring premarket FDA review of "new" tobacco products, 21 U.S.C. § 387j, the Tobacco Control Act also requires premarket review of "modified risk" tobacco products, *id*. § 387k. This provision authorizes the FDA to review scientific evidence that a tobacco product sold or distributed to consumers as a lower-risk product will, in fact, "reduce

[25] Congress itself crafted the exemption to the ban on free samples of tobacco products and limited that exemption to smokeless tobacco. *See* 21 U.S.C. § 387a–1(a)(2)(G).

harm or the risk of tobacco-related disease associated with commercially marketed tobacco products" and will or is expected to benefit the health of the population as a whole. *Id.* § 387k(g). The statutory MRTP premarket review requirements are patterned after the premarket review of new drugs under the FDCA, which has already been upheld under the First Amendment by binding circuit precedent. *See Whitaker v. Thompson*, 353 F.3d 947, 948 (D.C. Cir. 2004). The reasoning in that decision requires the same result here. Moreover, even if analyzed under *Central Hudson*, the MRTP premarket review requirement should be sustained. *See Discount Tobacco*, 674 F.3d at 534–37.

1. The MRTP Premarket Review Requirement Parallels the Preexisting Requirement for Drugs, Which the D.C. Circuit Upheld

The FDCA requires premarket FDA review of "new drugs," and defines "drugs" to include articles "intended for use in the diagnosis, care, mitigation, treatment, or prevention of disease." 21 U.S.C. § 321(g)(1). "Intended use" is an objective standard that turns on the nature of the claims made about the products. *Whitaker*, 353 F.3d at 948. "Regardless of the actual physical effects of a product, it will be deemed a drug . . . where the labeling and promotional claims show intended uses that bring it within the drug definition." *United States v. Article . . . Consisting of 216 Cartoned Bottles, More or Less, Sudden Change*, 409 F.2d 734, 739 (2d Cir. 1969) (citing cases); *see also Kordel v. United States*, 335 U.S. 345 (1948) (holding that "health food products" were drugs because they were claimed to ameliorate various ills). Under the statute, "claims about a product by its manufacturer and vendors, including product labeling, serve as evidence of the sellers' intent that consumers will purchase and use the product for a particular purpose—and, therefore, as evidence whether the product is or is not a drug." *Whitaker*, 353 F.3d at 953.

In *Whitaker*, the D.C. Circuit considered the FDCA scheme in a First Amendment challenge similar to Plaintiffs' challenge here. The plaintiff in *Whitaker* argued that the FDCA prohibited him from making a "true and non-misleading statement about its [product's] salutary effects" and thus "violate[d] the First Amendment's limits on restrictions of commercial speech." *Id.* at 952. Although the district court considered and upheld the FDCA premarket review under *Central Hudson*, the D.C. Circuit determined that such an analysis was unnecessary. *Id.* at 953. Instead, the court held that the statute's use of a manufacturer's statements about a product as evidence of its intent that the product be used as a drug presented no First Amendment problems because "the First Amendment allows 'the evidentiary use of speech to establish the elements of a crime or to prove motive or intent.'" *Id.* (quoting *Wisconsin v. Mitchell*, 508 U.S. 476, 489 (1993)).

The premarket review of tobacco products that purportedly reduce health risks functions in the same way as the FDCA provision the D.C. Circuit upheld in *Whitaker*. The Tobacco Control Act requires premarket review of a "modified risk tobacco product," which is defined as a product "sold or distributed for use to reduce harm or risk of tobacco-related disease." 21 U.S.C. § 387k(a), (b)(1); *cf. id.* § 321(g)(1) (defining drugs to include articles "intended for use in the diagnosis, care, mitigation, treatment, or prevention of disease"). Thus, under the Tobacco Control Act, as under the FDCA, the use for which a product is sold or distributed is determined from claims made on labeling and advertising, as well as other claims the manufacturer directs to consumers that would reasonably be expected to cause consumers to believe the product presents reduced risk. *Id.* § 387k(b)(2)(A).

Like the plaintiff in *Whitaker*, Plaintiffs here characterize the MRTP premarket review procedure as the regulation of "truthful, non-misleading" statements. Nicopure Br. 39. But the

purpose of MRTP premarket review is to evaluate the manufacturer's evidence that the product will achieve its claimed risk reduction for individual users and will, or is expected to, benefit the health of the population as a whole, 21 U.S.C. § 387k(g), and thus to serve as a check on false, misleading, and unsubstantiated claims in order "to effectively protect the public health," Legislative Finding 42. Plainly, Congress can require that tobacco companies—like pharmaceutical companies—make an evidentiary showing backing up their products.

Plaintiffs claim with apparent certainty that "vaping does not generate the toxins associated with combusting and smoking tobacco," and that the products are free of certain substances. Nicopure Br. 5; Stamler Decl. ¶¶ 5, 44. Indeed, Nicopure states that it has "invested a significant amount of time and more than $184,000 to test its products to ensure that diacetyl and acetyl propionyl are absent." Stamler Decl. ¶ 46. Such testing will likely aid Nicopure in seeking MRTP review, especially since, pursuant to § 387k(g)(2), the FDA may issue MRTP orders for certain products under certain conditions where there are no long-term epidemiological studies available.

2. In Any Event, the MRTP Premarket Review Requirement Readily Withstands Review Under *Central Hudson*

Because *Whitaker* makes clear that the First Amendment allows a manufacturer's claims about a product to be considered in determining what kind of product it is, and in particular, whether it is subject to premarket review, *Central Hudson* analysis is unnecessary. Nevertheless, the provision is also easily sustained under that framework.

The government has a substantial interest in protecting public health and preventing false and misleading tobacco industry claims about the relative health benefits of its products. Legislative Findings 36–37, 40; *Discount Tobacco*, 674 F.3d at 535. In enacting the Tobacco Control Act, Congress determined that premarket FDA review is the "*only way* to effectively

protect the public health from the dangers of unsubstantiated modified risk tobacco products." Legislative Finding 43 (emphasis added).

The need for review of modified risk tobacco products is illustrated by the tobacco industry's long history of selling and distributing purportedly "reduced risk" tobacco products that have not, in fact, reduced risk—a history that threatens to repeat itself in the context of e-cigarettes, which implicate many of the same actors and already have employed many of the same strategies. In enacting the Tobacco Control Act, Congress explicitly referenced the industry's history of marketing "low tar" cigarettes with misleading health claims. *See* Legislative Findings 38 & 39. For decades, tobacco companies "marketed and promoted their low tar brands to smokers—who were concerned about the health hazards of smoking or considering quitting—as less harmful than full flavor cigarettes despite either lacking evidence to substantiate their claims or knowing them to be false." *Philip Morris*, 566 F.3d at 1107. The companies also failed to disclose to the Federal Trade Commission their research "showing that [machine] test results do not reflect the amount of tar and nicotine that consumers of 'light' cigarettes actually inhale." *Altria Group, Inc. v. Goode*, 555 U.S. 70, 90 n.14 (2008). And "[w]e now know that low-tar cigarettes not only did not provide a public health benefit, but they also may have contributed to an actual increase in death and disease among smokers." Statement of Vice Admiral Richard H. Carmona, U.S. Surgeon General, *reprinted at* 155 Cong. Rec. S6000 (June 3, 2009). This history is particularly significant given that roughly two-thirds of the e-cigarette market is in cig-alikes, which are primarily distributed by the "big three" tobacco companies and largely sold alongside conventional cigarettes.

Contrary to Plaintiffs' assertion, *see* Nicopure Br. 41, the FDA has also shown that the MRTP premarket review requirement advances its interest in protecting the public health. The

FDA has sufficient information to conclude that e-cigarette use has negative health effects. As the Surgeon General has reported, "adolescents appear to be particularly vulnerable to the adverse effects of nicotine on the central nervous system," and adolescent use of e-cigarettes is rising. 81 Fed. Reg. at 29,029. Nicotine use during pregnancy could result in preterm delivery, stillbirth, and sudden infant death syndrome, and can alter development of the lungs and brain. Surgeon General's Report (2014) at 117–25 (AR 14,699–707). The FDA has also "identified concerns regarding the toxicants in e-liquid and the exhaled aerosol and the nicotine delivery from e-cigarettes." 81 Fed. Reg. at 29,029. These toxicants, including nicotine, carbonyl compounds, and volatile organic compounds, are known to have adverse health effects. Farsalinos et al. (2015) at 172–73 (AR 22,739–40). Moreover, studies have revealed inaccurate claims on e-cigarette labels. 81 Fed. Reg. at 29,034 (noting study that "found nicotine content labels to be highly inaccurate and determined that products claiming to be nicotine-free actually contained high levels of nicotine"); Grana et al. (2013) at 40 (AR 20,983) (reporting that various e-cigarette products do not contain nicotine in the amount labeled on the package and do not perform consistently as intended, even within the brand). The FDA clearly has an interest in ensuring that products sold or distributed as providing a reduced risk actually do so, particularly where the product being sold is both addictive and harmful. Further, as the Sixth Circuit held, if the sale or distribution of a modified-risk product "raises the aggregate number of people (especially juveniles) who use tobacco because it leads them to believe that an unsafe product is *relatively* safe, instead of merely affecting the apportionment of current users, then the government's compelling interest in reducing juvenile tobacco use is not met." *Discount Tobacco*, 674 F.3d at 536.

Plaintiffs would have the Court reject Congress's conclusions about the necessity of MRTP premarket review based on a supposed distinction between two branches of the tobacco industry: the manufacturers of traditional tobacco products, on the one hand, and manufacturers of e-cigarettes, on the other. But the interest in premarket review applies similarly in this context. Although there are certainly many smaller manufacturers and independent vape shops in the e-cigarette market, it is dominated by the major tobacco companies. *See* Adler at 22; Grana et al. (2013) at 72–73 (AR 21,015–16).

Moreover, studies show that e-cigarette marketing is following the path of traditional tobacco product marketing in targeting young adults and making unsubstantiated health claims. Grana et al. (2013) at 19 (AR 20,968). E-cigarette companies have emphasized flavors attractive to youth, utilized celebrity endorsements to advertise and glamorize vaping, and sponsored events targeted at young adults. *See* Grana & Ling (2014) at 399–401 (AR 23,127–29) (describing e-cigarette branded race car used at NASCAR, "increased television advertising for e-cigarettes featuring celebrities," and flavor offerings such as "Belgian waffle" and "Dr. Pepper"); Durbin et al. (2014) at 10–13 (AR 18,681–84) (noting that e-cigarette manufacturers sponsored "high profile music festivals, parties, and motorsports events," and listing flavors including "Strawberry Champagne, Pineapple Luau, Snappin' Apple, Rodeo Drive, and Bombshell"). A systematic analysis of retail website e-cigarette marketing found that while "health benefit was the most frequent claim" there "is little empirical evidence to substantiate it." *See* Grana & Ling (2014) at 400 (AR 23,128). Indeed, studies show that "users perceive [e-cigarettes] as healthier than cigarette smoking and useful for smoking cessation," even though available epidemiologic studies show "no association between use and quitting." *Id.* at 395 (AR 23,123).

Even if the tobacco industry had no history of false and misleading statements about the relative health risk of their products, Congress's determination that the government should ensure the accuracy and completeness of a manufacturer's modified-risk claims through premarket FDA review when an addictive substance is at issue clearly advances the government's substantial interest in protecting the public health. After-the-fact enforcement comes too late for the addicted consumer. *See Discount Tobacco*, 674 F.3d at 537 (upholding the MRTP premarket review requirement as "not more extensive than necessary to address the government's interests"). As the Sixth Circuit recognized, "it would be a virtual impossibility to unring the bell of misinformation after it has been rung." *Id.* And Congress specifically considered the kinds of disclosures Plaintiffs contend would be sufficient. Nicopure Br. 43–44. In rejecting their adequacy, Congress cited the Federal Trade Commission's findings that "consumers have misinterpreted advertisements in which one product is claimed to be less harmful than a comparable product, even in the presence of disclosures and advisories intended to provide clarification." Legislative Finding 41. Thus, Congress determined that "[p]ermitting 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." Legislative Finding 42. Although in *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999), the D.C. Circuit concluded that disclaimers would suffice to protect consumers from inaccurate health claims about certain dietary supplements, the court stressed that those supplements did not "in any fashion *threaten* consumers' health and safety," and distinguished drugs because "the potential harm presumably is much greater." *Id.* at 656 & n.6. Here, the potential for harm and addiction from the inhalation of nicotine and other dangerous chemicals and toxins is amply demonstrated in the record.

Thus, like the ban on the distribution of free samples, the MRTP premarket review requirement is fully consistent with the First Amendment.

CONCLUSION

For the foregoing reasons, the Court should deny Plaintiffs' motions for summary judgment, grant Defendants' cross-motion for summary judgment, and enter judgment in favor of Defendants on all claims.

Dated: August 16, 2016

Respectfully submitted,

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NICOPURE LABS, LLC, Plaintiff, v. FOOD AND DRUG ADMINISTRATION, et al., Defendants.	Civil Action No. 16-878 (ABJ)
RIGHT TO BE SMOKE-FREE COALITION, et al., Plaintiffs, v. FOOD AND DRUG ADMINISTRATION, et al., Defendants.	Civil Action No. 16-1210 (ABJ)

[PROPOSED] ORDER

Upon consideration of Defendants' cross-motion for summary judgment, it is hereby

ORDERED that the motion is **GRANTED**; and it is

FURTHER ORDERED that Plaintiffs' motions for summary judgment are **DENIED**; and it is

FURTHER ORDERED that judgment is entered in favor of Defendants, and against Plaintiffs, on all claims raised in the complaints.

SO ORDERED.

Dated: _____

_____
AMY BERMAN JACKSON
United States District Judge