IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NICOPURE LABS, LLC, *et al.*	)	
Plaintiffs,	)	
v.	)	Civ. No. 1:16-cv-0878-ABJ
FOOD AND DRUG ADMINISTRATION, *et al*.	)	
Defendants.	)	

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

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INTRODUCTION

FDA argues that this Court has no business scrutinizing the Deeming Rule, a regulation that governs thousands of products, affects billions of dollars in commerce, and spans over 130 pages in the Federal Register. On issue after issue, FDA insists that this Court must blindly defer to the agency's conclusions, going so far as to argue that its rulemaking is, in effect, subject to no judicial review whatsoever. But this is not the law. Rather, this Court should review the Deeming Rule for adherence to the Tobacco Control Act ("TCA"), the Administrative Procedure Act ("APA"), and the First Amendment. When it does so, this Court should vacate the Rule for several reasons.

To begin, the Deeming Rule exceeds FDA's statutory authority by purporting to regulate software, batteries, and a broad range of other products that are not "made or derived from tobacco" and thus fall outside the statutory definition of a "tobacco product." FDA insists that it may nevertheless regulate these products because, in the agency's view, they are "intended or reasonably expected" to be used with other products that are made or derived from tobacco. But that is not the statute Congress enacted, and the TCA's text, context, and history unambiguously show that FDA may "deem" a product only if that product—not a hypothetical combination of goods assembled by a consumer at some later juncture—contains or is derived from tobacco. This straightforward reading leaves FDA with ample authority over the vast majority of vaping devices and e-liquids, and there is no valid reason to depart from it here.

FDA attempts to shield a particularly unwarranted portion of the Rule—FDA's purported deeming of e-liquids that do not contain nicotine and are not derived from tobacco—by raising standing and ripeness objections. Nicopure has standing to challenge this aspect of the Rule because it sells e-liquids that do not contain nicotine. Whether or not the TCA provides FDA with authority to regulate those products is a pure question of law, the answer to which is "no."

The Deeming Rule also fails "hard look" review under the Administrative Procedure Act. Although FDA argues that the Rule is immune from such review based on the TCA's use of the word "deem," that language is insufficient to overcome the strong presumption of reviewability. Indeed, the Supreme Court and the D.C. Circuit have both held that agency action taken under similarly worded statutes is subject to judicial scrutiny, and there is no evidence that Congress intended to grant FDA an unreviewable power to subject products to agency regulation.

On the merits of APA review, the Deeming Rule falls short in several respects. *First*, it is internally inconsistent on a foundational matter—the Rule's justification. Although FDA states that the Rule is designed to promote public health, FDA repeatedly admits that it does "not currently have sufficient data … to determine what effects e-cigarettes have on the public health." 81 Fed. Reg. 28,974, 29,984 (May 10, 2016). In fact, far from promoting public health, the record shows that the Rule will lead to increased cigarette use—thus directly undermining Congress's goals of "promot[ing] cessation" and "reduc[ing] disease risk and the social costs associated with tobacco-related diseases." TCA § 3(9).

Second, the Rule imposes a nearly insurmountable premarket authorization requirement on vaping products without considering important alternatives—including a more flexible model employed by the European Union—or explaining why those alternatives would not be equally effective in achieving FDA's goals.

Third, FDA failed to reconcile the Rule with the TCA's overall structure, which shows that Congress intended FDA to achieve a balance between promoting health and ensuring the continued availability of tobacco products to adult consumers. TCA § 3(7). FDA wholly ignores the latter while conceding that the net effect of the Rule will be a mass exit of vaping manufacturers and vaping products from the marketplace.

Fourth, FDA erred in assessing the Rule's costs and benefits. Although FDA again asserts that its reasoning is exempt from judicial review, the agency is not correct. The TCA directs the agency "to impose *appropriate* regulatory controls on the tobacco industry," TCA § 3(8) (emphasis added), and the Supreme Court has held that such language requires an agency to consider whether a rule's benefits justify its costs. FDA insists that it was impossible to quantify the Rule's benefits and unnecessary to compute all of the Rule's costs, but precedent contradicts those arguments as well.

The Rule's flawed cost-benefit analysis independently contravenes the Regulatory Flexibility Act, which obligated FDA to consider meaningful alternatives to the proposed course of action that would have a less detrimental impact on small businesses. FDA instead failed to consider any such alternatives, in effect conducting no regulatory flexibility analysis at all.

Finally, the Rule violates the First Amendment by banning sampling of vaping products, and by prohibiting vaping manufacturers from making truthful, nonmisleading statements about the contents (or lack thereof) of their products without prior FDA authorization. These aspects of the Rule are content-based restrictions on speech that fail the heightened scrutiny required by the Supreme Court's decision in *Sorrell*. These aspects also fail the traditional *Central Hudson* test, because FDA has not met and cannot meet its burden of demonstrating that the restrictions are not more extensive than necessary to serve the proffered interest.

Accordingly, this Court should vacate the Deeming Rule's regulation of vaping products.

None of this is to say that FDA lacks the authority under the TCA to *appropriately* regulate vaping products made or derived from tobacco. Contrary to the straw man with which FDA begins its brief, Plaintiffs do not argue that vaping products "should not be regulated *at all*." Nor do Plaintiffs contend that FDA cannot consider potential youth access to vaping products. Plain-

tiffs share FDA's concerns here, although the fact that almost every state already prohibits sales to minors should also be factored in to that analysis (as should the fact that studies demonstrate that youth use of tobacco products is at an all-time low). Rather, Plaintiffs' point is that, as the TCA, APA, and First Amendment require, regulation of vaping products must be lawful.

There are significant differences between vaping and traditional tobacco products such as cigarettes, including the "substantial reductions to harmful constituents typically associated with smoking," offered by the former. 81 Fed. Reg. at 29,030–31. FDA's adoption of a Rule that threatens the very existence of the entire vaping industry, based on conduct that FDA attributes to a different industry—the pre-TCA tobacco industry—taken in the name of the public health when the agency acknowledges that it does not know the public health effects of vaping products, is not lawful.

ARGUMENT

I. FDA Lacks Authority to Regulate Products Not Made or Derived from Tobacco.

A. Products neither made nor derived from tobacco are not "tobacco products."

Federal agencies are creatures of statute and may exercise only those powers delegated to them by statute. *See, e.g.*, *La. Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 374 (1986) ("[A]n agency literally has no power to act ... unless and until Congress confers power upon it."); *FTC v. Dean Foods Co.*, 384 U.S. 597, 605 (1966); *W. Minnesota Mun. Power Agency v. FERC*, 806 F.3d 588, 593 (D.C. Cir. 2015). Under the express language of the TCA, FDA cannot regulate products that are not "made or derived from tobacco." 21 U.S.C. § 321(rr)(1).

FDA knows this. The agency told Congress that its "authority to regulate tobacco products … depends first on the product's physical makeup." FDA, Report to Congress, *Innovative Products and Treatments To Achieve Abstinence from Tobacco Use, Reductions in Consumption of Tobacco, and Reductions in the Harm Associated with Continued Tobacco Use* 5 (Nov. 11,

2013). This was correct, because, in defining the term "tobacco product" under the TCA, Congress told FDA that its authority to deem was limited to "any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product)." 21 U.S.C. § 321(rr)(1). In the Deeming Rule, however, FDA purported to grant itself the authority to regulate products that are *not* made or derived from tobacco, including batteries, software, glass vials, or non-nicotine-containing e-liquids. This exceeds FDA's statutory authority. *See* Nicopure Mem. (ECF 20-1) 9–14.

FDA says (at 23) that Congress did not intend to "exempt *open*-system e-cigarettes from this comprehensive regulatory scheme, simply because their e-liquid cartridges or tanks are refillable." But the issue is not whether a product is refillable. Under the TCA, the question is whether the product is made or derived from tobacco. An open-system vaping device, at least when sold without a nicotine-containing e-liquid, is neither made nor derived from tobacco. Nor are any of the product's components or parts. This is not a "broad and senseless exemption from the [TCA]'s comprehensive regulatory scheme." FDA Br. (ECF 42-2) at 25. Rather, this is adherence to the language that Congress used in granting FDA considerable, but not unlimited, authority over a particular class of products—those made or derived from tobacco. *See Conn. Nat'l Bank v. Germain*, 503 U.S. 249, 253–54 (1992) ("[A] legislature says in a statute what it means and means in a statute what it says there.").

FDA's attempt to exert control over these non-tobacco-containing products by classifying them as "components" or "parts" *of* a tobacco product is not filling a statutory gap, it is attempting to exercise authority that Congress has not granted. *See Util. Air Regulatory Grp. v. EPA*, 134 S. Ct. 2427, 2446 (2014) ("reaffirm[ing] the core administrative-law principle that an agency

may not rewrite clear statutory terms to suit its own sense of how the statute should operate"). As demonstrated in Nicopure's opening brief (at 10–12), the TCA repeatedly uses the words "components" or "parts" to refer to items that are physically part of a product containing tobacco (or material derived from tobacco) when introduced into commerce. *E.g.*, 21 U.S.C. § 387g(a)(1)(A) (referring to "a cigarette or any of its component parts (including the tobacco, filter, or paper)"); *id.* § 387d(a)(1) (requiring manufacturers of tobacco products to list "all ingredients … added by the manufacturer to the tobacco, paper, filter, or other part of each tobacco product").

In misstating Plaintiffs' position (at 31) as "once a component is removed from a tobacco product … it ceases to be a component," FDA gets it exactly backward: A product that does not contain or is not derived from tobacco when introduced into commerce is not a "tobacco product" under Congress's definition.[2] The critical error in FDA's interpretation is that it focuses not on the product sought to be regulated, but on a hypothetical product that a consumer *might* assemble at some point in the future. Congress did not authorize FDA to "deem" as "tobacco products" goods that are "intended or reasonably … expected" to be combined with tobacco or material derived from tobacco.[3] Rather, Congress limited FDA to products "made or derived from tobacco" and components or parts *of those products*. Honoring this clear statutory distinc-

[2] FDA's contrary interpretation is due no deference under *Chevron* because Congress has unambiguously stated that, to be a "tobacco product," a product must be "made or derived from tobacco." At *Chevron* step one, "the reviewing court must first exhaust the 'traditional tools of statutory construction' to determine whether Congress has spoken to the precise question at issue." *Bell Atl. Tel. Companies v. FCC*, 131 F.3d 1044, 1047 (D.C. Cir. 1997) (quotation marks omitted). Here, the traditional tools of construction clearly show that FDA lacks authority over finished products that are not made or derived from tobacco.

[3] FDA's interpretive error is particularly evident in the agency's assertion that "'[t]he statutory text should be liberally construed" to allow FDA "to protect consumers from dangerous products.'" FDA Br. 27 (quoting *United States v. Sullivan*, 332 U.S. 689, 696 (1948)). That is not what the TCA says. And in any event, FDA's invocation of *Sullivan* is improper because FDA itself has conceded that it does "not currently have sufficient data … to determine what effects e-cigarettes have on the public health." 81 Fed. Reg. at 29,984.

tion will not prevent FDA from regulating e-liquids that are derived from tobacco or from effectuating the TCA's broader objectives.[4] To the extent that there is a legitimate safety need to guard against exploding batteries and the like, that task falls not to FDA, but to the Consumer Product Safety Commission. *See, e.g.*, 15 U.S.C. § 2056(a) (authorizing the Commission to "promulgate consumer product safety standards").

B. Nicopure has standing to bring its ripe challenge to FDA's authority over non-nicotine-containing e-liquids.

As to non-nicotine-containing e-liquids, even FDA apparently recognizes that it has gone too far in trying to call them "tobacco products." Yet, FDA seeks to avoid judicial review of this statutory overreach on standing and ripeness grounds. *See* FDA Br. 33–38. That gambit should fail. Nicopure has standing, because it manufactures and sells non-nicotine- and non-tobacco-containing e-liquids. (Stamler Decl. ¶¶ 6, 11, 14.) This challenge is ripe; the Rule makes clear that FDA believes it has statutory authority to regulate non-nicotine containing e-liquids, and puts manufacturers of those products to the Hobson's choice of either complying with the Rule's requirements "or risking a possible 'enforcement action.' But, of course, that is no real choice at all. The [Rule] thus poses an immediate and significant practical hardship." *Philip Morris USA, Inc. v. FDA*, No. 1:15-cv-01590-APM, at 24–25 (D.D.C. Aug. 16, 2016) (holding challenge to an FDA "Guidance" regarding tobacco product labeling changes was ripe, citing additional cases).[5]

[4] The only vaping products in commerce when Congress enacted the TCA were closed-system devices. *See* FDA Br. 8 (describing the "earliest" products as closed-system "cig-alikes" and indicating that open-system products arrived "later").

[5] FDA's assertion (at 33) that it has regulatory authority over products "marketed as" nicotine-free simply avoids the question raised by Plaintiffs—whether FDA may, as the Rule asserts (*see* 81 Fed. Reg. at 29,016–17, 29,032), regulate e-liquids that *in fact* do not contain nicotine and are not derived from tobacco. The answer to that purely legal question is "no" for the reasons given above and in Nicopure's memorandum. *See* Nicopure Mem. 13–14.

The Rule purports to grant FDA license to decide whether a non-tobacco, non-nicotine-containing product is a "tobacco product" under a "totality of the circumstances" test regarding what FDA thinks the product is "intended or reasonably expected" to do. 81 Fed. Reg. at 29,012, 29,015; *see* FDA Br. 32–33. But, in stark contrast to the drug and device provisions of the FDCA, as FDA itself acknowledges, Congress did *not* define tobacco products in the TCA by their intended use. *See* FDA, Report to Congress, *supra*, at 4. ("Drugs and devices are defined by their intended use, *while tobacco products are not*" (emphasis added, capitalization omitted)).

Congress defined "tobacco product" to mean a product "made or derived from tobacco"; FDA does not have license to extend that definition to products *not* made or derived from tobacco, regardless of the circumstances. Indeed, under FDA's Rule, the agency could "deem" ice cream subject to the TCA, on the theory that it is reasonably expected that some people mix ice cream with tobacco essence to make tobacco-flavored ice cream.[6] FDA could likewise "deem" tupperware, on the ground that people may be expected to store e-liquids in the containers. Even standard off-the-shelf AA batteries are at risk of being deemed "tobacco products" under FDA's boundless theory, given that consumers often use them to power vaping devices.[7] "It is implausible that Congress meant the Act to operate in this manner," *King v. Burwell*, 135 S. Ct. 2480, 2494 (2015), and the absurdity of the three applications just discussed "should have alerted [FDA] that it had taken a wrong interpretive turn," *Utility Air*, 135 S.Ct. at 2446.

[6] *See, e.g.*, Anneli Rufus, Tobacco: Now It's in Ice Cream, The Huffington Post (Nov. 1, 2013), http://www.huffingtonpost.com/anneli-rufus/tobacco-now-its-in-ice-cr_b_3853685.html; The Cooking Channel, Recipe for Tobacco Whipped Cream (accessed Aug. 25, 2016), http://www.cookingchanneltv.com/recipes/tobacco-whipped-cream.print.html.

[7] *See, e.g.*, VapeDeals.com, Fixed 4.5V Mini Mod (Jan.1, 2015), http://vape.deals/4500mah-mod-9-95/ ("Takes Any AA Batteries").

C. *Sottera* did not and could not address whether FDA had authority under the TCA to "deem" non-tobacco and non-nicotine-containing products.

Finally, FDA is wrong to contend (at 23–24) that *Sottera* forecloses this Court from reviewing the Rule for adherence to the TCA. To begin, *Sottera* pre-dates the Rule, so the D.C. Circuit cannot have held that FDA's extension of authority over non-tobacco, non-nicotine-containing products was appropriate.

Furthermore, the product at issue in *Sottera* was an e-cigarette that contained liquid nicotine in the mouthpiece. *See Sottera, Inc. v. FDA*, 627 F.3d 891, 893 (D.C. Cir. 2010) ("The liquid nicotine *in each e-cigarette* is derived from natural tobacco plants." (emphasis added)). The D.C. Circuit thus did not address whether a product that contained no tobacco or nicotine would still be a "tobacco product." The Court of Appeals could not have definitively resolved that question because it was not presented in *Sottera*; any statements on the issue were not necessary to the decision and thus constitute nonbinding dicta. *See, e.g.*, *Tyler v. Cain*, 533 U.S. 656, 663 n.4 (2001) (statement that is not "necessary to th[e] result" is nonbinding "dictum").

Accordingly, this Court should vacate the Deeming Rule's application to non-tobacco and non-nicotine-containing products.

II. The Deeming Rule's Regulation of Vaping Devices and E-Liquids Fails "Hard Look" APA Review.

A. The Deeming Rule is not exempt from judicial review, but rather is subject to "hard look" scrutiny under the APA.

FDA overreaches in asserting that the Court is "precluded" from reviewing the Deeming Rule under the APA. *See* FDA Br. 39–40. Courts apply a "'strong presumption' favoring judicial review of administrative action." *Mach Mining, LLC v. EEOC*, 135 S. Ct. 1645, 1651 (2015); *see also Barlow v. Collins*, 397 U.S. 159, 166 (1970) ("Preclusion of judicial review" is "not lightly

to be inferred"). FDA thus "bears a heavy burden in attempting to show that Congress prohibited all judicial review of" the Deeming Rule. *Mach Mining*, 135 S. Ct. at 1651.

FDA cannot carry that heavy burden. According to FDA, the TCA's statement that it "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), shows that every aspect of the Deeming Rule is "committed to agency discretion by law." 5 U.S.C. § 701(a)(2). FDA's attempt to avoid judicial scrutiny of its rulemaking fails for four principal reasons.

First, this case is not one of the "rare instances" in which "there is no law to apply." *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 410 (1971). Rather, as FDA itself concedes (at 39), the TCA applies only to "tobacco products," and defines that term in a specific fashion. *See* 21 U.S.C. §§ 321(rr)(1), 387a(b). The Act provides detailed procedural requirements and limitations on FDA's rulemaking powers. *See, e.g.*, 21 U.S.C. §§ 387a(c)(2), 387a(d), 387a(g), 387g(d)(3), 387*l*(e). The Act also enumerates ten statutory purposes, one of which makes clear that FDA may only "impose *appropriate* regulatory controls on the tobacco industry," *id.* § 3(8) (emphasis added)—thus signaling that FDA must consider the costs and benefits of its action, *see Michigan v. EPA*, 135 S. Ct. 2699, 2706–07 (2015).[8] Accordingly, this case does not fall into the narrow category of cases in which it is "impossib[le]" to "devis[e] an adequate standard of review." *ICC v. Locomotive Engineers*, 482 U.S. 270, 282 (1987).

Second, the Rule does not involve issues that "traditionally [have] been committed to agency discretion." *Heckler v. Chaney*, 470 U.S. 821, 832 (1985). FDA relies on *Webster v. Doe*, 486 U.S. 592 (1988), but, unlike the TCA, the statute at issue there concerned "national security,

[8] Other purposes strike a balance between addressing public health while ensuring continued adult access to tobacco products and the development and marketing of relatively safer tobacco products. TCA §§ 3(4), (7). *See* Right To Be Smoke Free ("RSF") Mem. (ECF. 21-1) 15–17.

an area of executive action in which courts have long been hesitant to intrude." *Lincoln v. Vigil*, 508 U.S. 182, 192 (1993) (quotation marks omitted).[9]

Third, "the mere fact that [the TCA] contains discretionary language does not make [FDA's] action unreviewable." *Beno v. Shalala*, 30 F.3d 1057, 1066 (9th Cir. 1994). Courts have repeatedly held that APA review applies even when statutes use "deeming" language. In *Barlow*, the Supreme Court held that implementation of a statute allowing the Secretary of Agriculture to promulgate regulations "as he may *deem* proper" was not committed to agency discretion. 397 U.S. at 165–66 (emphasis added). The D.C. Circuit likewise held that the courts may review implementation of a statute directing the Secretary of Health and Human Services to "provide ... for such other exceptions and adjustments ... as the Secretary *deems* appropriate." *Marshall City Health Care Auth. v. Shalala*, 988 F.2d 1221, 1223–25 (D.C. Cir. 1993).

Fourth, FDA does not cite a single case in which a court held that the content of a legislative rule is "committed to agency discretion." *Cf. Edison Elec. Inst. v. EPA*, 996 F.2d 326, 333 (D.C. Cir. 1993) (regulation interpreting a statute "is not the type of discretionary judgment concerning the allocation of enforcement resources that *Heckler* shields from judicial review"). The cases FDA relies upon involve personnel decisions (*Webster*), informal adjudications (*Steenholdt*), or no agency action at all (*Heckler*). FDA provides no reason why Congress would have intended to allow the agency to issue a rule that spans 132 pages in the Federal Register and af-

[9] *See also, e.g.*, *Franklin v. Mass.*, 505 U.S. 788, 817 (1992) (Stevens, J., concurring) ("[T]he Court has limited the exception to cases involving national security … or those seeking review of refusal to pursue enforcement actions."); *Hyatt v. U.S. Patent & Trademark Office*, 797 F.3d 1374, 1381 (Fed. Cir. 2015) (declining to apply exception, despite "close" textual similarity to statute in *Webster*, because statute did not "implicate the nation's security"); *Dickinson v. Sec'y of Defense*, 68 F.3d 1396, 1403 (D.C. Cir. 1995) (declining to follow *Webster* when statute did not involve "interests of national security"); *Saratoga Dev. Corp. v. United States*, 777 F. Supp. 29, 35–37 (D.D.C. 1991) (distinguishing *Webster* because it "was decided against the unique backdrop of national security concerns").

fects billions of dollars in commerce with no judicial oversight whatsoever. Were FDA's argument correct, FDA could regulate anything—bicycles, sandwiches, internet service, etc.—under the TCA "with no review and no recourse." *Hyatt*, 797 F.3d at 1382. A court "need not doubt the [FDA's] trustworthiness, or its fidelity to law, to shy away from that result"; rather, it "need only know—and know that Congress knows—that legal lapses and violations occur, and especially so when they have no consequence." *Mach Mining*, 135 S. Ct. at 1652–53. FDA's request that this Court abdicate its role simply goes "too far." *Id.* at 1652.

Accordingly, this Court must review the Deeming Rule for compliance with the APA. But continuing its theme that this Court should not deign to review the Rule, FDA presents the APA as a feckless statute—one that heaps deference upon deference and limits the Court to only a superficial analysis of the Deeming Rule's particulars. *See* FDA Br. 22, 40. In reality, however, the APA requires a "thorough, probing, in-depth review" of the agency's reasoning and a "searching and careful" assessment of a rule's factual underpinnings. *Citizens to Preserve Overton Park*, 401 U.S. at 415–16. "[T]he agency must provide a rational connection between the facts found and the choice made so as to afford the reviewing court the opportunity to evaluate the agency's decision-making process." *Republic Airline Inc. v. Dep't of Transp.*, 669 F.3d 296, 299 (D.C. Cir. 2012) (quotation marks omitted). Thus, the Deeming Rule passes APA muster only if it is the product of "reasoned decisionmaking" and "rests on a consideration of the relevant factors." *Michigan*, 135 S. Ct. at 2706 (quotation marks omitted); *see also Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2125 (2016) ("One of the basic procedural requirements of administrative rulemaking is that an agency must give adequate reasons for its decisions.").

B. The Deeming Rule fails APA review because it is internally inconsistent and contrary to the public health.

FDA seeks to justify the Deeming Rule on the ground that it will protect public health, *see* 81 Fed. Reg. at 29,042, despite repeatedly acknowledging that FDA does "not currently have sufficient data … to determine what effects e-cigarettes have on the public health." (AR029,984.) "Such self-contradictory, wandering logic does not constitute an adequate explanation of agency action." *Del. Dep't of Nat. Res. & Envtl. Control v. EPA*, 785 F.3d 1, 16 (D.C. Cir. 2015) (quotation marks omitted).

FDA protests this characterization of the Rule, but tellingly does not deny making the concession quoted above (or the many others quoted in the Plaintiffs' opening memoranda). *See, e.g.*, Nicopure Mem. 15–16. Instead, FDA seeks to sidestep its admissions by arguing that, regardless of vaping's health effects, "*regulation* of [vaping products] will still benefit public health." FDA Br. 41 (quoting 81 Fed. Reg. at 28,984). But the Rule itself contradicts that argument, too, explaining that "the welfare effects of including [vaping products] in the final rule are uncertain" and that regulating vaping products "could under some conditions yield negative health benefits." (AR 023930–31.)[10] Accordingly, the Deeming Rule is self-contradictory even under FDA's preferred interpretation, and thus fails the APA's requirement of reasoned decisionmaking. *See Bus. Roundtable v. SEC*, 647 F.3d 1144, 1153 (D.C. Cir. 2011) (vacating rule that was "internally inconsistent and therefore arbitrary").

FDA cannot escape this inherent and fundamental inconsistency by arguing for deference. The Rule presents (repeatedly), FDA's judgment that FDA does not know "what effects e-

[10] FDA also argues that "enough is already known about the health risks of e-cigarettes and e-liquids … to warrant regulatory oversight." FDA Br. 42. This assertion cannot be squared with FDA's repeated statements in the Rule that it does *not* know enough about vaping products to determine their effect on public health. *See* Nicopure Mem. 15–16 (collecting examples).

cigarettes have on the public health." 81 Fed. Reg. at 29,984; *see also id.* at 29,028–29. Having admitted that its scientific conclusion is that FDA does not know the public health effects of vaping, FDA cannot simultaneously argue for deference to its scientific expertise that regulation would benefit the public health.[11]

Equally unreasonable is FDA's circular assertion that the Deeming Rule is necessary "to obtain critical information regarding the health risks of newly deemed tobacco products." 81 Fed. Reg. at 28,975; *see* Nicopure Mem. 17. FDA defends this statement by arguing that ingredient listings and other data would be "unobtainable" in the Rule's absence, FDA Br. 41–42, but that is incorrect. FDA has broad authority—independent of the TCA—to "promulgate regulations for the efficient enforcement of" Title IX of the FDCA, 21 U.S.C. § 371(a). There is no valid reason why FDA could not have used that authority to obtain the data necessary to assess the health and safety effects of vaping products; FDA's failure to consider this approach further demonstrates the arbitrary and capricious nature of the Deeming Rule. *See* Section II.C, *infra.*

In fact, the Deeming Rule undermines the TCA's public-health goals. An iron law of economics teaches that reducing the supply of a product increases the product's price and depresses consumer demand. The Rule makes clear that it will cause "significant product exit and reduced entry" for vaping devices and e-liquids—the eradication of over 95 percent of the market. (AR023,931.) That outcome will directly undermine the TCA's goals of "promot[ing] cessation" and "reduc[ing] disease risk and the social costs associated with tobacco-related diseases," TCA § 3(9), by driving many consumers to switch from vaping products to cigarettes.

[11] The same holds true for FDA's parade of horribles regarding youth usage of tobacco products. FDA concedes that "there [has been] no change in overall current tobacco use" among youth in recent years. 81 Fed. Reg. at 28,984–85. Thus, even if youth use of vaping devices is increasing, overall health risks must be decreasing given the data showing that vaping is considerably safer than using other types of tobacco products. *See, e.g.*, 81 Fed. Reg. at 29,030, 29,033.

Study after study has concluded that vaping products present far fewer health and safety risks than cigarettes. (*See, e.g.*, AR022,846 (concluding that vaping is "around 95% safer than smoking combusted cigarettes")); Nicopure Mem. 18–19 (collecting other examples). FDA itself has recognized that vaping is "not responsible for the high prevalence of tobacco-related death and disease in this country" and that e-vapor "is of less risk to a user than the inhalation of … smoke from combusted tobacco products." 81 Fed. Reg. at 29,033. And the Surgeon General has observed that vaping can "provide public health benefits," but "only in an environment where the … use of cigarettes and other combusted tobacco products [is] being rapidly reduced." 81 Fed. Reg. at 28,984.

Studies have likewise concluded that the Deeming Rule will lead to increased cigarette use. A 2015 *Journal of Health Economics* report found that "e-cigarette access reduces teen smoking" (AR019,027), and that laws restricting access to vaping products result in a "large" increase in cigarette use. (AR019,032.) A second study found that the Deeming Rule's restrictions will cause over 10,000 vaping product users to "switch to cigarettes," resulting in a loss "of 37,180 life-years." (AR150,421.[12])

Notwithstanding this evidence before it, FDA argues in its brief (42) that there "is no evidence that consumers would abandon e-cigarettes because of some reduction in product diversity." But that cannot be correct under a regime in which over 95 percent of the market will soon vanish, and FDA has already conceded the point by acknowledging that the Rule will result in "consumer costs for users of [vaping products] due to loss of product variety or higher prices." (AR023,917.) Although quibbling over irrelevant details (*see* FDA Br. 42–43), FDA does not

[12] Considering that up to 6.4 million smokers are estimated to quit smoking as a result of vaping products, the aggregate loss of life-years due to the Deeming Rule is likely far greater. (*See* AR075,493.)

dispute that the Rule will cause over 10,000 consumers to switch from vaping to smoking. (AR150,421.) Nor could it, given the admissions that the Rule may "yield negative health benefits" and "could shift demand to other tobacco products." (AR023,931; AR023,977–78.)

The Deeming Rule also frustrates the TCA's purposes by cutting off innovation in the vaping market. As of the Rule's August 8, 2016 effective date, new vaping products may be marketed only *after* FDA considers and approves a corresponding pre-market tobacco product application ("PMTA"). *See* 81 Fed. Reg. at 29,011 n.13. Given that FDA has approved only *one* PMTA since the TCA was enacted, that process will take years to complete. *See* Nicopure Mem. 4. The upshot is that manufacturers *cannot* improve the safety of their products without first pulling them off the market for an extended period, and are barred from offering new products that pose reduced health risks. The crushing burden of PMTA review, in turn, provides a powerful *disincentive* for innovation into even safer vaping products.

FDA never explains how these results can be squared with Congress's goals of "promot[ing] cessation" and "reduc[ing] disease risk and the social costs associated with tobacco-related diseases." TCA § 3(9). Given that failure, and the substantial record evidence that the Rule will directly undermine Congress's purposes, the Deeming Rule fails APA review. *See* 5 U.S.C. § 706(2)(A); *N.Y. State Dept. of Social Servs. v. Dublino*, 413 U.S. 405, 419–420 (1973) ("We cannot interpret federal statutes to negate their own stated purposes."); *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. Ruckelshaus*, 719 F.2d 1159, 1165 (D.C. Cir. 1983) ("A statute should ordinarily be read to effectuate its purposes rather than to frustrate them.").

C. FDA failed to consider reasonable alternatives.

"To be regarded as rational, an agency must … consider significant alternatives to the course it ultimately chooses." *Allied Local & Reg'l Mfrs. Caucus v. EPA*, 215 F.3d 61, 80 (D.C. Cir. 2000). An agency must "address" and give "adequate reasons" for rejecting "alternative

way[s] of achieving [its] objective," *Delaware*, 785 F.3d at 17–18 (quotation marks omitted); *see also id.* at 11 ("We will reverse when … the agency did not engage the arguments raised before it."); *Chamber of Commerce v. SEC*, 412 F.3d 133, 145 (D.C. Cir. 2005). The Deeming Rule fails this test—and is therefore arbitrary and capricious—in multiple respects.[13]

First, as noted above, FDA could have collected sufficient data to determine whether vaping products pose a public health risk (or whether regulating such products would generate a public health benefit) before choosing whether and how to regulate them. *See also* Nicopure Mem. 23–24. FDA's only response to this argument is an irrelevancy. *See* FDA Br. 45. Regardless of whether Section 901 of the TCA requires FDA to consider public health when deciding whether to "deem" a tobacco product, the APA requires agencies to engage in "reasoned decisionmaking." *Michigan*, 135 S. Ct. at 2706; *see* Nicopure Mem. 16 n.12. FDA justified the Deeming Rule on the ground that it will advance the public health, *see* 81 Fed. Reg. at 29,042, so it has *no choice* but to explain how the Rule does so. Performing the sort of data collection advocated by Plaintiffs, which FDA could do without "deeming" vaping products and subjecting them to the crushing burden of the PMTA process, *see* Nicopure Mem. 25, would have enabled FDA to resolve that issue. FDA has no answer for this straightforward argument.

Second, FDA should have considered the European Union's regulatory approach. *See* Nicopure Mem. 24. Under that approach, vaping products are subject to disclosure, advertising, good manufacturing practices, misbranding, and other requirements—but are *not* required to ob-

[13] FDA cites (at 44–45) *Clinton Memorial Hospital v. Shalala*, 10 F.3d 854, 859 (D.C. Cir. 1993), for the proposition that an agency "need only 'explain [the] rejection of an alternative that was [1] 'within the ambit of the existing Standard' and [2] shown … to be effective." But *Clinton* does not adopt such a rule, as is clear when the quoted language is read in context. The cases cited above, on the other hand, are the law of the Circuit regarding an agency's duty to consider and respond to alternatives.

tain costly premarket authorization. (AR130,503–4; AR150,356–9.) These tools would enable FDA to achieve the objectives laid out in the Deeming Rule, including improving product consistency, educating consumers, preventing false and misleading labeling, and so forth.

Rather than explaining why the European Union model would not lead to the public-health benefits FDA seeks to achieve, FDA responds by insisting that it has no discretion to adopt such a tailored approach. FDA Br. 46. That response is puzzling given FDA's repeated insistence that it has unfettered, unreviewable discretion in implementing the TCA. *See, e.g.*, FDA Br. 44 (asserting that FDA "is free to exercise [its] discretion in this area"); 81 Fed. Reg. at 28,977–78 (discussing FDA's exercise of its "enforcement discretion" under the TCA). It is also arbitrary, as FDA has exercised that discretion in several ways, for example by adopting a compliance schedule for several of the Deeming Rule's requirements, and by applying additional regulations to "covered tobacco products"—a category mentioned nowhere in the TCA and apparently created by FDA out of whole cloth. *See* 81 Fed. Reg. at 28,976–77. This discretion extends even to the PMTA requirement, which FDA now asserts is mandatory (FDA Br. 46),[14] as FDA is not requiring vaping manufacturers to file PMTAs until two years after the Rule's effective date. *See* 81 Fed. Reg. at 28,977–78.[15]

The end result is yet another fundamental internal inconsistency: FDA asserts broad discretion in one breath, but insists with the next that it is powerless to exercise discretion or to consider more flexible approaches. That contradictory approach will not wash under the APA.

[14] FDA errs in focusing narrowly on isolated phrases within Sections 901 and 910 of the TCA. *See* FDA Br. 46. A court's duty "is to construe statutes, not isolated provisions." *King*, 135 S. Ct. at 2489 (quotation marks omitted). Read in context and as a whole, as *King* requires, the TCA plainly allows for the sort of tailoring advocated by Plaintiffs here. *See* Nicopure Mem. 24–26.

[15] Although, as discussed in the RSF Plaintiffs' opening brief and below, this amount of time is wholly inadequate to complete the long-term clinical studies that will be required by FDA for PMTAs. *See* RSF Mem. 24–29.

FDA has a duty not to be arbitrary regarding its regulatory flexibility, and must explain why further informational gathering, or the European Union regulatory model, or other models presented in the comments would not work. *See* Nicopure Mem. 24 & n.16. "Because [FDA] too cavalierly sidestepped its responsibility to address reasonable alternatives, its action was not rational and must, therefore, be set aside." *Delaware*, 785 F.3d at 17–18; *see also Encino*, 136 S. Ct. at 2124 ("One of the basic procedural requirements of administrative rulemaking is that an agency must give adequate reasons for its decisions.").

Third, the handful of alternatives that FDA did bother to consider involved secondary or tertiary aspects of the Rule that would not have provided relief to the small businesses hit hardest. *See* Nicopure Mem. 26 & n.17.[16] The Small Business Administration faulted FDA on these grounds, but FDA did not respond. That omission is particularly striking considering that "approximately 90 percent" of the entities affected by the Deeming Rule—the entities that FDA says will "exit" the market rather than try to comply with the crushing burdens of the Rule—are small businesses. (*See* AR024,044); *see also* 81 Fed. Reg. at 29,014, 29,076.[17]

[16] FDA's response regarding the streamlined PMTA process proposed by Nicopure and discussed by commenters fails for the same reason. *See* Nicopure Mem. 24–25.

[17] Apparently concerned by its own analysis showing that at least 95 percent of all vaping product manufacturers will be forced out of business when the two year PMTA compliance period expires, RSF Mem. 21–22, FDA downplays its own numbers by arguing that most of those businesses are vape shops that only "mix different e-liquids together" and will simply "convert to a pure retail model," so that they should not be counted as businesses ceasing manufacturing activities prior to August 2018. FDA Br. 50. But that is not the position that FDA took in the Rule. *See SEC v. Chenery Corp.*, 318 U.S. 80, 87 (1943). In the preamble, the draft PMTA guidance for vaping products, and the final regulatory flexibility analysis, FDA stated in no uncertain terms that vape shops qualify as "manufacturers" subject to all of the TCA's requirements. *See, e.g.*, 81 Fed. Reg. at 28,979, 29,044; (*see also* AR028,362; AR184,756; AR184,776; AR184,819–20; AR184,868; AR184,881). FDA also included vape shops when it assessed the regulatory costs imposed on manufacturers under various TCA provisions. (*See, e.g.*, AR184,47–51.) And the agency acknowledged that *all* vape shops will likely stop manufacturing activities once the two year PMTA compliance period ends. (*See, e.g.*, AR184,820.)

D. FDA failed to reconcile the Deeming Rule with the TCA's structure.

In rejecting the various alternatives suggested by Plaintiffs and other commenters, FDA also fails to reconcile the significant impacts of the Deeming Rule on the vaping industry with the overall structure of the TCA. Contrary to FDA's characterization of the statute, the TCA is not a one-sided affair aimed at eradicating tobacco use. Rather, Congress required the agency in addressing public health concerns to also ensure reasonable access to the marketplace for relatively safer tobacco products. As noted by the RSF Plaintiffs, this regulatory scheme arises out of the plain language of the TCA and the Supreme Court's decision in *Brown & Williamson*. In its opening brief, however, FDA all but brushes aside these issues and, instead, tries (unsuccessfully) to distance itself from various statements that it made during the rulemaking clearly indicating that the Deeming Rule will not achieve the balance struck by Congress in the TCA.

As noted, the Rule acknowledges that it will cause at least 95 percent exit from the vaping market. And FDA fails to explain what will happen to the remaining manufacturers that it believes will stay in business. In its opening brief, FDA says, without explanation, that it "predicted" several hundred devices and potentially over one-thousand e-liquids will remain on the market after the initial PMTA compliance period, and then argues that this prediction deserves the Court's deference. FDA Br. 42–43. But an agency's "predictive judgment[]" is still subject to the APA and must be "reasonable." *Bellsouth Telecomm., Inc. v. FCC*, 469 F.3d 1052, 1060 (D.C. Cir. 2006). Moreover, "the deference owed agencies' predictive judgments gives them no license to ignore the past when the past relates directly to the question at issue." *Id.* Here, FDA has not offered any data or rationale justifying these assumptions. *See* RSF Mem. 22. Rather, these appear to be pure conjecture. And this Court should be wary of giving them any deference in light of past experience. Since the TCA was adopted in 2009, only one PMTA, which was supported by substantial long-term clinical and epidemiological data, has been approved by

FDA. *Id.* at 23. Moreover, it is implausible in the extreme for FDA to argue that it will be able to process *two thousand* PMTAs over the course of the next two years, as the Deeming Rule assumes. *See* RSF Mem. 23 n.15.

FDA contends that any discussion regarding the substantial degree of market exit is irrelevant as the TCA only explicitly prohibits a ban on traditional tobacco products (*i.e.*, cigarettes, smokeless tobacco, cigars, little cigars, pipe tobacco, and roll-your-own tobacco). FDA Br. 49 (citing 21 U.S.C. § 387g(d)(3)(A)). The agency argues that the TCA's prohibition on requiring the reduction of nicotine yields of a tobacco product to zero does not alter this conclusion. *Id.* (citing 21 U.S.C. § 387g(d)(3)(B)). However, this Court rejected such analysis in *Smoking Everywhere, Inc. v. FDA*, 680 F. Supp. 2d 62, 70–71 n.9 (D.D.C. 2010). In that case, this Court recognized that regulating vaping products under the FDCA's drug-device provisions would mean that "it is certainly possible, if not likely, that FDA would have to ban those products." *Id.* This Court then stated that Congress, in the TCA, "did not intend tobacco products delivering nicotine for recreational use to be classified as a drug-device combination and thus subject to a potential ban on nicotine yields." *Id.* In other words, it is unlawful to entirely ban nicotine-containing vaping products. Any rule that risks such a ban violates the APA. *See* 5 U.S.C. § 706.

Moreover, even if the Deeming Rule does not result in a *de facto* ban, Congress clearly did not envision a scenario in which the vast majority of vaping products would be forced from the marketplace even before their respective manufacturers have had a meaningful chance to apply for pre-market authorization. Left unaddressed by FDA in its opening brief is any acknowledgment that the agency must "continue to permit the sale of tobacco products to adults" and that, along these lines, the statute provides "flexible enforcement authority" regarding the development, introduction, and promotion of "less harmful tobacco products." TCA §§ 3(4),

3(7). While FDA argues that vaping products may present some health risks, it does not deny that, overall, they are safer than cigarettes. RSF Mem. 7–8. As such, the agency cannot arbitrarily limit access to the marketplace. Yet, FDA never explains how manufacturers will be able to submit compliant PMTAs before August 2018 given the lack of any long-term clinical studies necessary for pre-market approval, a point that FDA does not dispute. *Id.* at 24–27; *see also* 81 Fed. Reg. at 29,004 (acknowledging that "the lack of available independent laboratories to complete the testing" will cause compliance problems for "many small businesses").

FDA had a statutory obligation to achieve a balance between protecting the public health and ensuring that vaping product manufacturers have a reasonable opportunity to commercialize their products. The agency had various tools at its disposal to meet these objectives, whether by establishing a modified grandfather date, using its enforcement discretion to give at least some manufacturers access to the SE pathway, or (as discussed below) extending the two-year PMTA compliance period so that manufacturers would have enough time to conduct and complete the necessary long-term clinical studies. FDA's failure to consider any of these options constitutes arbitrary and capricious rulemaking.[18]

[18] FDA maintains that it cannot address the grandfather date because Section 6 of the TCA prohibits extending certain deadlines under the statute. FDA Br. 49 (citing TCA § 6(a), (d)). The agency misreads that provision. Section 6 only applies to "obligations" under the statute that must be "carr[ied] out and complete[d]" within a "specified deadline." The grandfather date is neither an obligation nor a deadline. The agency also misses the point regarding RSF Plaintiffs' substantive due process claim. *See* FDA Br. 65–70. Contrary to FDA's statements, the government's stated interests do not relate solely to public health. The government also expressed an interest in preserving some parts of the tobacco product market. Indeed, that is the very purpose of the grandfather clause. The problem with strictly enforcing the February 15, 2007 grandfather date against deemed products, however, is that it leads to absurd results—*i.e.*, the vaping industry will all but disappear, an outcome in direct conflict with the compromise set forth in the TCA itself. And it is this type of irrational approach—where the means chosen by Congress do not achieve the ends—that implicates the Due Process Clause. *See* RSF Mem. 38–40.

III. The Deeming Rule Is Invalid Because It Is Premised on an Arbitrary and Capricious Cost-Benefit Analysis.

FDA adopted the Deeming Rule based on a belief that the Rule's benefits justify its staggering costs. *See* 81 Fed. Reg. at 28,981 ("FDA has concluded that the benefits of the final rule justify the costs."). The Deeming Rule is arbitrary and capricious because that belief is both substantively unreasonable and inadequately explained, and because FDA violated the Regulatory Flexibility Act in issuing the Rule.

A. FDA's arguments regarding Executive Orders are irrelevant.

FDA leads off by attacking a straw man. Although FDA goes on at length regarding the law governing judicial review of an agency's compliance with Executive Orders 12866 and 13563, *see* FDA Br. 50–52, that body of law is irrelevant because none of Plaintiffs' arguments rests on those Executive Orders (or any others, for that matter). FDA seeks to paper over this fact by including a "*cf.*" citation to a page of Nicopure's opening memorandum, *see* FDA Br. 50, but the arguments that appear on that page are based on the TCA and the APA, *see* Nicopure Mem. 27 ("FDA's assessment violates *the APA* in several ways" (emphasis added)).

B. FDA must consider costs and benefits when regulating under the TCA.

Contrary to FDA's argument, the agency had a clear statutory duty to consider the Deeming Rule's costs and benefits. One of the TCA's core purposes is "to impose *appropriate* regulatory controls on the tobacco industry." TCA § 3(8) (emphasis added). As the Supreme Court made clear in *Michigan*, "'appropriate' is the classic broad and all-encompassing term that naturally and traditionally includes consideration of all the relevant factors"—including whether a rule's costs are justified by its benefits. 135 S. Ct. at 2707 (quotation marks omitted). Indeed, "[a]gencies have long treated cost as a centrally relevant factor when deciding whether to regulate," because "[c]onsideration of cost reflects the understanding that reasonable regulation

ordinarily requires paying attention to the advantages and the disadvantages of agency decisions." *Id.*; *see also Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 54 (1983) ("[t]he agency was correct to look at the costs as well as the benefits" of its rule).

FDA's attempts to evade this straightforward analysis are unconvincing. FDA first argues (53–54) that it need not consider the Rule's costs or benefits because the specific provision it invokes—21 U.S.C. § 387a(b)—does not use the word "appropriate" or mention costs. The relevant question, however, is whether *the TCA* requires a cost-benefit analysis. *See King*, 135 S. Ct. at 2489 ("Our duty, after all is to construe statutes, not isolated provisions." (quotation marks omitted)).[19] The Act plainly calls for costs to be taken into account by directing FDA to "impose *appropriate* regulatory controls on the tobacco industry." TCA § 3(8) (emphasis added).

FDA also contends that it need not consider the Deeming Rule's costs and benefits because Congress imposed such a requirement in other portions of the TCA (and FDCA), but not in Section 901. *See* FDA Br. 53 & n.16. The Supreme Court's decision in *Michigan* forecloses this argument. Just as it did not matter in *Michigan* that other portions of the Clean Air Act expressly mentioned cost, *see* 135 S. Ct. at 2709, it is immaterial here that other sections of the TCA (and FDCA) do so. "It is unreasonable to infer that, by expressly making cost relevant to other decisions, the Act implicitly makes cost irrelevant to the appropriateness of regulating" vaping products. *Id.*

[19] FDA also invokes the interpretive canon that the specific controls over the general, *see* FDA Br. 54, but that canon applies only when two provisions conflict with one another. *See Nat'l Cable & Telecomms. Ass'n, Inc. v. Gulf Power Co.*, 534 U.S. 327, 335 (2002) ("specific statutory language should control more general language *when there is a conflict between the two*" (emphasis added)). Here, there is no conflict: FDA may exercise its deeming authority, but must consider costs and benefits when doing so.

C. FDA's cost-benefit analysis is unreasonable and inadequately explained.

Regardless of whether FDA was obligated to consider the Rule's costs and benefits, the reality is that FDA did so, and that the agency based its decision to regulate vaping products on that analysis. *See* 81 Fed. Reg. at 28,981. Having conducted and relied upon that analysis, FDA cannot evade APA review of its reasoning. *See State Farm*, 463 U.S. at 43; *Republic Airline*, 669 F.3d at 299. Three aspects of FDA's cost-benefit analysis violate the APA's requirement of reasoned decisionmaking.

First, FDA failed to quantify the Deeming Rule's benefits. *See* Nicopure Mem. 27–28. FDA insists that it was not required to do so because the Rule's benefits are "too difficult to quantify or monetize." FDA Br. 56 (citing OMB, Circular A-4: Regulatory Analysis 27 (Sept. 17, 2003)).[20] But as the D.C. Circuit has admonished several times, "an agency may not shirk a statutory responsibility simply because it may be difficult." *NetCoalition v. SEC*, 615 F.3d 525, 539 (D.C. Cir. 2010); *see also Pub. Citizen v. FMCSA*, 374 F.3d 1209, 1221 (D.C. Cir. 2004). Nor may an agency "merely recite the terms 'substantial uncertainty' as a justification for its actions." *State Farm*, 463 U.S. at 52. Simply put, an agency cannot discern whether a regulation's costs are justified unless it has at least a ballpark understanding of the regulation's benefits. FDA has prepared such estimates in the past, and it should have done so here as well. *See* Nicopure Mem. at 28–29.

Citing only a law review article (by a former OIRA Administrator) and an OMB Circular, FDA insists that it may avoid quantifying the Rule's benefits by performing a "break-even" analysis instead. *See* FDA Br. 58. Precedent is to the contrary; an impressionistic "break even"

[20] The Executive Branch may not define away the requirements of judicial review under the APA by issuing an OMB Circular. *Cf. Marbury v. Madison*, 5 U.S. 137, 177 (1803) ("It is emphatically the province and duty of the judicial department to say what the law is.").

analysis is permissible only when benefits are "impossible to quantify," and only then to "tip the balance in close cases." *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201, 1219 (5th Cir. 1991). FDA has not shown that either of those conditions is satisfied here. Indeed, the fact that a private economist computed the Rule's putative costs and benefits shows that it would *not* have been impossible for FDA to quantify the Rule's benefits. (*See* AR150,420.)

Second, FDA substantially understates the Rule's costs—and in particular the costs associated with the PMTA requirement. *See* Nicopure Mem. 29–31. To begin, FDA stacks the deck by omitting the massive "unquantified" costs associated with product and market exit. *See* Nicopure Mem. 29–30. As to the costs that FDA did attempt to quantify, FDA complains that Nicopure's estimates are exaggerated, but that is incorrect. The true cost of the PMTA requirement is likely $3–5 million per product, nearly ten times FDA's estimate. (Stamler Decl. ¶ 22; *see also* AR023,948.) FDA disagrees with those totals. Tellingly, however, FDA does not dispute that, using its own calculations, completing PMTAs for all 1,610–2,950 vaping products that FDA expects to remain on the market will require between 1,102 and 2,020 *years* of private-sector work. *See* Nicopure Mem. 30–31. Even after distributing that work among all regulated firms, FDA has not shown that it will be possible for manufacturers to comply with the PMTA requirement in the allotted two-year window.

FDA brushes this concern off by asserting that it currently "plans" to enforce the PMTA requirement "only for finished tobacco products," rather than for all tobacco products, components, and parts. FDA Br. 57. But FDA's "plans" can change and are in any event irrelevant to the costs imposed by the *Rule*, which applies with full force to tobacco products, components, and parts—including (according to FDA) every heating coil, glass vial, software program, battery, and digital display included in a retail vaping product. *See, e.g.*, 81 Fed. Reg. at 28,975.

Moreover, the class of products currently subject to enforcement—"finished tobacco products"—is broad and includes not only complete vaping devices but also components such as "filters or filter tubes sold separately to consumers or as part of kits." 81 Fed. Reg. at 28,995.

Third, the Deeming Rule is arbitrary and capricious because it does not assess the costs or benefits associated with regulating vaping products. *See* Nicopure Mem. 32. The Rule includes a general discussion of its *overall* costs and *overall* benefits, but that is insufficient in view of the Rule's expansive scope. FDA argues (at 60) that an agency need not perform a separate analysis for every affected product. That may be true in the abstract, but it is insufficient here. Vaping products account for the overwhelming majority of the Rule's costs, and represent one of two major product categories affected by the Rule (cigars being the other). (*See, e.g.*, AR024,009–12, AR024,042.) Thus, the APA's requirement of reasoned decisionmaking dictates that FDA should at a minimum have explained why the benefits of regulating vaping products justify the associated costs. *See Encino*, 136 S. Ct. at 2125.

D. FDA violated the Regulatory Flexibility Act.

Contrary to FDA's claims, the agency also fails to comply with the procedural requirements of the Regulatory Flexibility Act. FDA concedes that it must address "all of the legally mandated subject areas" listed in the Regulatory Flexibility Act. FDA Br. 61. This includes considering "significant" alternatives, such as extended compliance periods, that would markedly lessen burdens on small entities. 5 U.S.C. §§ 603(c), 604(2), (6). As Congress instructed, agencies must give "explicit consideration to a range of alternatives that would '*substantially*' reduce the economic impact of the rule on … small businesses." S. Rep. No. 96-878, at 10 (1980), *reprinted in* 1980 U.S.C.C.A.N. 2788, 2797 (emphasis added); *see also Nat'l Ass'n of Psychiatric Health Sys. v. Shalala*, 120 F. Supp. 2d 33, 43 (D.D.C. 2000) (agencies must make "reasonable,

good-faith effort[s] to canvass *major* options and weigh their probable effects" (emphasis added)).

FDA argues that it considered three alternatives in the final regulatory flexibility analysis. But as discussed below, two of the alternatives would actually have *increased* burdens on small entities, while the other one would result in only a small decrease in labeling costs. As such, the regulatory flexibility analysis fails to address in any manner the devastating impact that the Deeming Rule will have on the broader vaping industry—*i.e.*, that virtually all manufacturers, as indicated by the agency's own analysis, will be forced out of the market in two years. *See* RSF Mem. 21–22. The Regulatory Flexibility Act undoubtedly requires more.

Despite that Act's clear mandate, and despite the flaws in its initial analysis having been pointed out in detail by the Small Business Administration (AR082,216–17), FDA did not consider *any* significant alternatives in its final regulatory flexibility analysis, let alone options that would address whether the two-year PMTA compliance period for products already on the market is sufficient for manufacturers to conduct long-term clinical studies. *See* RSF Mem. 25–26. Instead, two of the alternatives considered in the final regulatory flexibility analysis were not alternatives at all, as they would have, by FDA's own admission, actually increased economic burdens on manufacturers. (AR184,873 at Tbl. 35 (reducing compliance period for labeling changes to 12 months); AR184,874–6 (not extending the two year compliance period to new flavored tobacco products.)) *See also* FDA Br. 62. The remaining alternative, extending the compliance period to 36 months for labeling requirements, would have only reduced overall costs to manufacturers, according to the agency, by one to three percent. (AR184,873 at Tbl. 35.) Needless to say, these so-called "alternatives" fall well short of anything that could be reasona-

bly characterized as "significant" or "major." This omission, standing alone, is grounds for this Court to find that FDA violated the Regulatory Flexibility Act.[21]

Perhaps recognizing this substantial shortcoming, FDA maintains that it nevertheless considered a longer compliance period in the preamble to the Deeming Rule. FDA Br. 62–64. However, as the RSF Plaintiffs pointed out in their opening brief, the agency simply acknowledged this option and stated, without providing any justification, that a two-year compliance period was sufficient for manufacturers to meet their PMTA obligations. RSF Mem. 35. But a mere acknowledgment of the manufacturers' concerns is not sufficient. An agency has not engaged in reasonable decisionmaking when it "fail[s] to respond *meaningfully* to objections raised by a party." *BNSF Ry. Co. v. Surface Transp. Bd.*, 741 F.3d 163, 168 (D.C. Cir. 2014) (citations omitted) (emphasis added). In its opening brief, FDA provides no citations to the preamble or the administrative record where it explains, at any level of detail, whether manufacturers will be able to conduct and complete long-term clinical studies required for PMTAs over the next two years. *See* FDA Br. 62–64. Given FDA's admissions that no long-term studies exist, RSF Mem. 25–26, and that there will be a mass exit of vaping product manufacturers when the compliance period expires, one would expect at least some evaluation of the time and resource requirements of such research and a discussion whether the two-year compliance period is adequate. Indeed, the TCA demands as much, as FDA must account for the continuum of risk and balance any regulation against a potential ban or virtual elimination of entire tobacco product categories. *See* RSF Mem. 13–27.

[21] The Regulatory Flexibility Act cases cited by FDA in its opening brief do not hold otherwise. In each of those decisions, the agency considered significant alternatives to the final rule and fairly addressed issues raised by plaintiffs. FDA Br. 60–64. FDA does not cite to any cases in which an agency completely failed, as the agency did here, to satisfy one of the statute's procedural elements.

FDA responds that it considered steps that would help manufacturers, pointing out that it has issued draft guidance on PMTAs, that manufacturers will be able to use master files containing research conducted by others, or that they may rely on "published literature and marketing information with appropriate bridging studies" when submitting their applications. FDA Br. 64. But this is no answer at all, as all of these options assume the existence of long-term clinical studies. In the draft PMTA guidance document and the preamble to the Deeming Rule, FDA repeatedly states that it is unlikely that a PMTA will be approved without long-term clinical studies when, as the agency concedes is the case now, there is no "established body" of evidence regarding the public or population impact of the product. (AR028,382; AR028,384; AR028,396.) *See also* 81 Fed. Reg. at 28,997, 29,001, 29,077, 29,079–80. Similarly, master files and the ability to rely on already published literature are of no help to manufacturers if no long-term research exists. Indeed, FDA cannot point to a single PMTA that has been filed and approved to date under the TCA without extensive long-term clinical data. RSF Mem. 23.

FDA concedes that it must make a "good faith effort to carry out [the Regulatory Flexibility Act's] mandate." FDA Br. 61. This necessarily entails, however, a "careful and meaningful study" of significant alternatives so that an agency has effectively addressed concerns raised by a proposed rule. *S. Offshore Fishing Ass'n v. Daley*, 995 F. Supp. 1411, 1436–37 (M.D. Fla. 1998); *see also Dist. Hosp. Partners, L.P. v. Burwell*, 786 F.3d 46, 59 (D.C. Cir. 2015) (agencies must "consider significant and viable and obvious alternatives") (citations omitted). Here, FDA failed to do so.

IV. The Deeming Rule Violates the First Amendment.

In addition to the errors outlined above, the Deeming Rule also violates the First Amendment in two respects.

First, the Rule imposes a categorical ban on free samples of vaping products at all times in all places and to all recipients. FDA adopted that prohibition despite failing to develop *any* record evidence that free samples of vaping products pose health or safety risks. FDA also failed to show why a narrower and more targeted restriction would not serve the agency's goals.

Second, the Rule prohibits speech such as advertisements or packaging indicating that a product is "smokeless" or contains no peanuts, until *after* FDA has issued an order allowing it, under the so-called "modified risk" provisions. The Rule restrains or proscribes such speech even when it is truthful and nonmisleading, and does so even though the record is barren of evidence showing that this speech threatens public health.

Both of these restrictions fail the heightened test for content-based speech restrictions adopted in *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 565 (2011), and both likewise fail the traditional *Central Hudson* test applied to commercial speech restrictions, *see Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557, 561 (1980). Accordingly, both aspects of the Deeming Rule must be set aside.

A. The Deeming Rule's regulation of vaping device and e-liquid samples violates the First Amendment.

1. The sampling ban regulates speech.

FDA seeks to avoid First Amendment scrutiny of the sampling ban by arguing that sampling is not speech. But FDA does not and cannot dispute that *all* courts addressing the issue have squarely held that sampling is protected speech under the First Amendment. *See* Nicopure Mem. 35 (citing *Discount Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509, 538 (6th Cir. 2012); *Bailey v. Morales*, 190 F.3d 320, 321, 325 (5th Cir. 1999); *Rockwood v. City of Burlington, Vt.*, 21 F. Supp. 2d 411, 415, 421–22 (D. Vt. 1998)). FDA responds only to the Sixth Circuit's decision in *Discount Tobacco*, faulting it for "not differentiat[ing] free samples from

pricing tools, like coupons," which have been held not to merit constitutional protection as speech. FDA Br. 72. But FDA's own cited cases explicitly distinguish sampling as an activity and limit their holdings to price restrictions. *See Nat'l Ass'n of Tobacco Outlets v. City of Providence, R.I.*, 731 F.3d 71, 78 n.7 (1st Cir. 2013) (declining to consider precedent dealing with "free samples and promotional gifts" rather than "price regulation"); *Nat'l Ass'n of Tobacco Outlets v. City of N.Y.*, 27 F. Supp. 3d 415, 426–27 (S.D.N.Y. 2014) (finding no preemption under a statute dealing with sampling of tobacco products, because the ordinance at issue "*only* addresses the sale of partially discounted cigarettes" (emphasis in original)). In contrast, as recognized in *Discount Tobacco*, a ban on sampling is a ban on expressive activity. 674 F.3d at 539.

But for FDA's extreme position here, it should be self-evident that sampling entails communicative elements worthy of the First Amendment's protection. *See, e.g.*, *Texas v. Johnson*, 491 U.S. 397, 404 (1989) (stating that whether "particular conduct possesses sufficient communicative elements to bring the First Amendment into play" turns on (1) whether there is an "intent to convey a particularized message" and (2) whether "the likelihood was great that the message would be understood" (quoting *Spence v. Washington*, 418 U.S. 405, 410–11 (1974))); *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 569 (2001) (assessing whether sales practices have an inherent "communicative component" to merit protection under the First Amendment).

Inherent in sampling is an intent to inform consumers about a product's characteristics and quality, in a way that is inimitable without an actual purchase. Indeed, by definition, a "sample" is "a small amount of something that gives [buyers] information" about a product[22]; "A relatively small quantity of material, or an individual object, *from which the quality* of the mass,

[22] Merriam–Webster Dictionary, www.merriam-webster.com/dictionary/sample.

group, species, etc. which it represents *may be inferred*."[23] Sampling's important role in providing information dates well before our Nation's founding.[24] As opposed to coupons and price tinkering, sampling is essential to educating consumers and obtaining immediate, spontaneous feedback from the market. (Stamler Decl. ¶¶ 35–40.) As FDA itself concedes, sampling is an effective means of communicating and encouraging consumers "to try different and new … products, enabling them to learn about their own preferences and possibly change their purchasing behavior as a result." (AR 24,014.) As a result, sampling falls easily within the type of "direct and spontaneous communication between buyer and seller" that allows "more personal interchange" that the First Amendment protects. *Edenfield*, 507 U.S. at 766. Rather than implicating "the regulation of prices, without more," *City of Providence, R.I.*, 731 F.3d at 78, the sampling ban affects a prototypical form of commercial speech.

2. The sampling ban fails scrutiny under Sorrell *and* Central Hudson.

The First Amendment protects commercial speech from "unwarranted governmental regulation." *Cent. Hudson*, 447 U.S. at 561. FDA bears the burden of showing that the sampling ban satisfies all four elements of the *Central Hudson* test: (1) whether the speech concerns lawful

[23] Oxford English Dictionary, www.oed.com/view/Entry/170414 (emphasis added).

[24] For example, farmers used them to prove the quality of their corn and other produce to buyers at distant markets, *see The Compleat Englifh Tradesman* 43–44 (1727), while publishers distributed free newspapers to reach a critical mass of subscribers, *see Documents Relating to the Colonial History of the State of New Jersey*, Vol. XI, at xxvii (1894). Since then, the importance of samples as "a direct source of information to the consumer" has continued, *see* Amir Heiman et al., "Learning and Forgetting: Modeling Optimal Product Sampling Over Time," 47 *Management Science* 532, 533 (Apr. 2001), especially when it comes to "introduc[ing] new and unusual products." Lawrence J. Marks & Michael A. Kamins, "The Use of Product Sampling and Advertising: Effects of Sequence of Exposure and Degree of Advertising Claim Exaggeration on Consumers' Belief Strength, Belief Confidence, and Attitudes," XXV *Journal of Marketing Research* 266, 266–67 (Aug. 1988). Sampling allows for "a direct experiential effect that reduces the risk of product uncertainty" and is "more conducive to product training and demonstration." Heiman, *supra*, at 533.

activity and is not misleading; (2) whether the governmental interest for the restriction is "substantial"; (3) whether the restriction directly and materially advances the interest; and (4) whether the restriction is "not more extensive than is necessary to serve that interest." *Greater New Orleans Broad. Ass'n v. United States*, 527 U.S. 173, 183–84, 188 (1999) (quoting *Cent. Hudson*, 447 U.S. at 566); *see Edenfield v. Fane*, 507 U.S. 761, 770 (1993).

In assessing restrictions on commercial speech, courts historically applied an "intermediate" standard of review. The Supreme Court recently clarified in *Sorrell*, however, that the "First Amendment requires heightened scrutiny whenever the government creates a regulation of speech because of disagreement with the message it conveys." 564 U.S. 552, 566 (2011) (quotations and citations omitted). Under *Sorrell*, a regulation of commercial speech that is content- and speaker-based is "presumptively invalid" and subject to "heightened judicial scrutiny." *Id*. at 562–67.[25]

Sorrell, as other courts have acknowledged, imposes a two-step inquiry. Nicopure Mem. 34 (citing *Retail Digital Network, LLC v. Appelsmith*, 810 F.3d 638, 648 (9th Cir. 2016); *1-800-411-Pain Referral Serv., LLC v. Otto*, 744 F.3d 1045, 1054–55 (8th Cir. 2014); *Caronia*, 703 F.3d at 163–64); *see also In re Tam*, 808 F.3d 1321, 1335 (Fed. Cir. 2015) (*en banc*); *King v. Governor of N.J.*, 767 F.3d 216, 236 (3d Cir. 2014)). A court first determines whether the government has imposed content- and speaker-based restrictions. If so, "heightened" scrutiny applies

[25] In another straw man, FDA faults Plaintiffs (at 73) for explaining how other Circuits have considered *Sorrell*, given that, as Plaintiffs pointed out, the D.C. Circuit has not yet addressed how it affects the *Central Hudson* analysis. *See* Nicopure Mem. 34 & n.21. In contrast to that authority, the only case cited by FDA for the proposition that *Sorrell* had no impact on the framework for commercial speech, *Fleminger, Inc. v. HHS*, 854 F. Supp. 2d 192, 197 (D. Conn. 2012), has been called into doubt given the Second Circuit's subsequent case law recognizing that *Sorrell* had some effect, even if the exact contours continue to be developed, *see United States v. Caronia*, 703 F.3d 149, 163–64 (2d Cir. 2012).

to the analysis. If not, a less searching "intermediate" scrutiny applies. In either case, the court then analyzes the restriction using the four-factor *Central Hudson* test, applying the appropriate level of scrutiny.

The Deeming Rule's sampling ban is subject to heightened scrutiny under *Sorrell* because it "burdens disfavored speech by disfavored speakers" and "seek[s] to keep people in the dark for what the government perceives to be their own good." *Sorrell*, 564 U.S. at 564, 577 (quoting *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 503 (1996)). FDA has banned a specific type of speech for a *specific* product category; FDA offers no explanation why the ban does *not* constitute a content-based restriction on that activity. *See id.* at 571. The sampling ban cannot survive heightened *Sorrell* scrutiny because FDA has not demonstrated the strong means-ends fit or precise tailoring required to uphold content- and speaker-based restrictions. *See, e.g.*, *Appelsmith*, 810 F.3d at 648–50 (describing contours of heightened *Sorrell* scrutiny).

But even assuming *arguendo* that only intermediate scrutiny applies, FDA still cannot satisfy the vigorous protection afforded under the modern commercial-speech framework of *Central Hudson*. To meet that test, FDA must prove, with sufficient data, that the sampling ban will "in fact" reduce minors' access to vaping products to a material degree, and that the ban is "reasonably tailored to serve that end." *Nat'l Ass'n of Mfrs. v. SEC*, 800 F.3d 518, 524–25, 527, 542 (D.C. Cir. 2015). At no point—either in the Deeming Rule or in its brief—does FDA show that an outright sampling ban will further its goal of preventing or reducing vaping among minors. Instead, FDA simply reiterates the findings of a study on the effect that banning *cigarette samples* will have in curtailing *smoking* among minors in the *middle of the 1990s*, and then tries to connect that to the present day by postulating that sampling has been offered at large events that "*appear* to be youth-oriented." 81 Fed. Reg. at 28,986 (emphasis added) (cited by FDA Br.

75–76). (*See also* AR18,579–80 (section of the 1994 article dealing with cigarette samples at large, public events); AR18,681–82, AR18,694–704 (noting events where samples have been offered—such as Mercedes-Benz Fashion Week, the Emmy Awards Gift Lounge, and the Republican National Convention—without any findings regarding whether samples actually came into the possession of minors).) None of this is evidence that free samples at these events were *actually* targeted toward minors, let alone evidence of a *single instance* in which a free sample of a vaping product ended up in the hands of minors.

Most critically, there is *no* indication in the Administrative Record that an outright ban of sampling—in any forum, and to any audience—will materially prevent minors from accessing vaping products. FDA has thus failed to meet its burden in "'carefully calculat[ing]' the costs and benefits associated with the burden on speech," *Greater New Orleans*, 527 U.S. at 188 (quoting *City of Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 417 (1993)), rather than reverting to a "blanket ban" (especially "disfavored in the law") as a matter of first preference. *FF Cosmetics FL Inc. v. City of Miami Beach, Fla.*, 129 F. Supp. 3d 1316, 1326 (S.D. Fla. 2015).

Instead, FDA has ignored less-restrictive alternatives, such as prohibiting free samples (of *any* quantity or type) at large, public events or from leaving qualified business premises. This repeats a flaw that runs throughout FDA's rulemaking—a refusal to consider flexible, less restrictive or burdensome alternatives. This failure is particularly problematic when FDA has already adopted such less restrictive measures with respect to smokeless tobacco. And it is no answer for FDA to say (at 76) that customers can "touch, hold, and smell their products without violating the free sample ban" because the Rule makes clear that a customer is not allowed to light (or inhale) a vaping product, meaning that a consumer cannot actually sample these products in any meaningful way. 81 Fed. Reg. at 29,026.

In summary, FDA's approach rests on "conjecture" that is inadequate to show a "direc[t] and materia[l] advance[ment]" of the governmental interests at stake. *Greater New Orleans*, 527 U.S. at 185, 188. Because FDA fails to meet its burden on the third and fourth interrelated factors of the *Central Hudson* framework, *Edenfield v. Fane*, 507 U.S. 761, 770 (1993), the sampling ban must be vacated with respect to vaping products.

B. The Deeming Rule's Restrictions on Truthful, Nonmisleading Speech Violate the First Amendment.

The Rule also violates the First Amendment by subjecting vaping products to the "modified risk tobacco product" speech restrictions of the TCA. These restrictions, set forth in 21 U.S.C. § 387k, prohibit manufacturers from informing consumers that their products are "free of a substance" without prior FDA approval. In other words, the Rule prohibits vaping manufacturers from informing consumers what is *not* in their products. That restriction directly restrains Nicopure's ability to make truthful and nonmisleading statements in contravention of both *Sorrell* and *Central Hudson*.

1. The modified risk restrictions do not escape First Amendment review.

Continuing its theme of hoping to avoid judicial scrutiny of its actions, FDA first overreaches in arguing that *Whitaker* controls whether the modified risk restrictions should withstand First Amendment analysis. FDA Br. 78–80 (discussing *Whitaker v. Thompson*, 353 F.3d 947 (D.C. Cir. 2004)).

First, FDA has already raised and lost this very argument in the context of tobacco products. In *Discount Tobacco*—the decision upon which FDA relies in the Final Rule to justify the constitutionality of the modified risk restrictions, 81 Fed. Reg. at 28,987—the Sixth Circuit addressed a First Amendment challenge to the restrictions raised by tobacco companies. 674 F.3d at 509. FDA argued in its response that the modified risk restrictions "paralle[l] preexisting

FDCA provisions applicable to drugs, and like the drug provisions, it presents no First Amendment problem." *Id*. (citation omitted). Plaintiffs replied that First Amendment analysis was warranted, as the modified risk restrictions "rende[r] a product's sale illegal based on promotional speech" and are no different from laws that "directly proscrib[e] promotional speech." *Id*. (citation omitted). The Sixth Circuit rejected FDA's argument and held that *Central Hudson* applied. *Id*. (noting that the Supreme Court in *Brown & Williamson* rejected a similar attempt to draw an analogy between tobacco regulation and FDA's regulation of drugs). This Court should similarly reject FDA's position.

Second, other judicial decisions concerning the FDCA further caution against broad application of *Whitaker*. In *Caronia*, the Second Circuit rejected the government's contention that the prohibition on off-label use under the FDCA played only an "evidentiary" role in misbranding claims and evaluated the provision as a speech restriction under *Central Hudson*. 703 F.3d at 149, 160–62 (finding "the proscribed conduct for which [defendant] was prosecuted was precisely his speech in aid of pharmaceutical marketing."). Likewise, in *Pearson v. Shalala*, the D.C. Circuit evaluated and rejected FDA's prohibition of health claims for dietary supplements under *Central Hudson*. 164 F.3d 650, 659 (D.C. Cir. 1999) ("It is undisputed that FDA's restrictions on appellants' health claims are evaluated under the commercial speech doctrine."); *see also Amarin Pharma, Inc. v. U.S. Food & Drug Admin.*, 119 F. Supp. 3d 196, 227–28 (S.D.N.Y. 2015); *Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51, 59 (D.D.C. 1998)[26] ("This court is hard pressed to believe that the agency is seriously contending that 'promotion' of an activity is conduct and not speech, or that 'promotion' is entitled to no First Amendment protection.").

[26] *Appeal dismissed, judgment vacated in part sub nom. Washington Legal Found. v. Henney*, 202 F.3d 331 (D.C. Cir. 2000).

Third, FDA fails to recognize clear and meaningful differences between the modified risk restrictions and the premarketing provisions of the FDCA. Under the FDCA, for example, drug manufacturers are "required to demonstrate, through clinical trials, the safety and efficacy of a new drug *for each intended use or indication*." *Caronia*, 703 F.3d at 153 (citing 21 U.S.C. § 355(d)) (emphasis added). The speech being restricted—the intended use of a drug—thus bears some reasonable relationship to the evidentiary proof required by FDA—the safety and efficacy of the drug for that intended use. *See* 21 U.S.C. § 355(d).

The modified risk restrictions, on the other hand, are not tailored in scope. Take for example, a potential statement that Nicopure's products do not contain peanuts, a known allergen. By default, the modified risk restrictions require, before Nicopure may say that its products do not contain peanuts, that Nicopure prove that the product will (1) "significantly reduce harm and the risk of tobacco-related disease to individual tobacco users"; and (2) "benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products." 21 U.S.C. § 387k(g)(1).[27] The lack of proportionality between the required showing by applicants and the alleged modified risk statement ("no peanuts") is further magnified when taking into account the fact that FDA has *never* approved a modified risk tobacco product application. *See* Nicopure Mem. 39; *Lorillard*, 533 U.S. at 563 ("The uniformly broad sweep of the [restriction] demonstrates a lack of tailoring.").

[27] FDA points out (at 80) that under certain conditions, it may issue an order without long-term epidemiological studies. This provision, 21 U.S.C. § 387k(g)(2) entitled "Special Rule for Certain Products," however, nonetheless requires that applicants such as Nicopure prove that allowing its product on the market is "expected to benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products." *Id*. § 387k(g)(2)(B)(iv).

In sum, the modified risk restrictions provisions require a vaping manufacturer to do more—*much* more—than show that its proposed modified risk statement is truthful and nonmisleading. FDA hence cannot justify these restrictions on the ground that they are necessary to prevent false or misleading advertisements or to ensure that consumers are fully informed.

2. The modified risk restrictions are invalid under Sorrell *and* Central Hudson.

The Rule's modified risk restrictions for vaping products fail muster under *Sorrell* because they are "designed to impose a specific, content-based burden on protected expression." *Sorrell*, 564 U.S. at 565. The restrictions are content-based because they distinguish between "favored speech" and "disfavored speech," *i.e.*, modified risk statements as defined by FDA, "on the basis of the ideas or views expressed." *Turner Broad. Sys., Inc. v. FCC*, 512 U.S. 622, 643 (1994). The restrictions are speaker-based because they target one kind of speaker—those in the vaping industry, such as Nicopure—while allowing others to speak without restriction. Overall, this aspect of the Rule has the effect of silencing *only* the vaping industry from communicating with consumers in an effective and informative manner. *See Caronia*, 703 F.3d at 165. Accordingly, "heightened judicial scrutiny" applies. *Sorrell*, 564 U.S. at 565. The modified risk restrictions fail that heightened test because, as with the sampling ban, FDA has not shown that the restrictions employ the strong means-ends fit and precise tailoring required to justify a "presumptively invalid" content- and speaker- based speech restriction. *Id.* at 571; *see also Appelsmith*, 810 F.3d at 648–50.

The modified risk restrictions are also unlawful under even intermediate scrutiny. Specifically, FDA fails to show the modified risk restrictions are "not more extensive than necessary" to serve FDA's asserted interests, as required by the third and fourth prongs of *Central Hudson*. *Greater New Orleans*, 527 U.S. at 188 (under intermediate scrutiny the government "must demonstrate narrow tailoring of the challenged regulation to the asserted interest.").

To begin, FDA does not and cannot explain why a disclaimer—for example, "the absence of peanuts does not mean that this product is safer than other tobacco products"—would not address its professed concerns. *See* Nicopure Mem. 43–44. This failure is particularly glaring in that the Rule simultaneously requires mandatory warnings to appear on all deemed products. Instead, FDA offers (at 83) the non-sequitur that e-liquids are often flavored.

At bottom, FDA's arguments rest on the faulty premise that the tobacco and vaping industries warrant the same treatment with respect to the modified risk restrictions. FDA draws heavily on the tobacco industry's "long history" with "reduced risk" tobacco products. FDA Br. 81; *see also id*. at 83 (contending marketing for vaping products is "following the path of traditional tobacco product marketing"). The factual predicates supporting FDA's stance are likewise based almost entirely on the tobacco industry. For example, FDA contends that the government has a substantial interest in preventing "false and misleading *tobacco industry* claims" about its products. FDA Br. 80 (emphasis added). And that the modified risk restrictions are justified on the basis of the tobacco industry's "history of marketing 'low tar' cigarettes." *Id*. at 81 (also citing court decisions regarding cigarette products). Similarly, all but one of FDA's references to the TCA Legislative Findings appear to be characterizations of tobacco products and the tobacco industry.[28]

But FDA concedes, as it must, that the record here shows that vaping products are different from conventional tobacco products. 81 Fed. Reg. 28,997. There is powerful evidence that vaping products are safer on an individual basis than cigarettes, and may also be safer on a popu-

[28] *See* FDA Br. 80 (Legislative Findings 36, 37, and 40, each referring to risks associated with "tobacco products"), 80–81 (Legislative Finding 43, referring to products that "tobacco manufacturers sold or distributed for risk reduction"), 81 (Legislative Findings 38 and 39, referring to risks associated with "low tar" and "light" cigarettes). The one other reference concerns consumer misinterpretation of advertisements. *Id*. at 84 (Legislative Finding 41).

lation-wide basis. *See* Nicopure Mem. 15–17, 42. Likewise, the vaping and tobacco industries are different. Unlike the traditional tobacco industry, nearly all vaping companies, including Nicopure, are small businesses. 81 Fed. Reg. at 29,014, 29,076. (*See also* Stamler Decl. ¶ 4.) Indeed, as FDA concedes, the overwhelming majority of vaping products did not enter the U.S. market—and most vaping firms therefore did not exist—until after 2007. *See* 81 Fed. Reg. 29,002 ("For example, the ENDS product category, for which the market has changed dramatically since 2007, is likely to have a smaller proportion of grandfathered products than some other product categories."). (*See also* AR023,947 (100 percent of e-liquids and 99 percent of vaping devices not grandfathered because not on market as of February 2007).) As a result, FDA has no basis to paint vaping manufacturers with the same broad brush as it does cigarette manufacturers and other "legacy" tobacco businesses.

FDA's bare assertion (at 81) that the history of the tobacco industry regarding cigarettes "threatens to repeat itself" in the context of vaping products is insufficient to bridge this evidentiary gap. Rather, FDA must be held to its obligation to "find and present data supporting its claims *prior to* imposing a burden on commercial speech," *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1221 (D.C. Cir. 2012) (emphasis original);[29] *see also Edenfield*, 507 U.S. at 770–71 (the government cannot satisfy its burden by "mere speculation or conjecture."). Guilt by association and speculation are not substitutes for such evidence.

What little remains that directly relates to vaping products is insufficient to justify the broad-reaching restraints on speech imposed by the modified risk restrictions. While FDA contends (at 82) that there is some evidence that nicotine and other ingredients in some vaping

[29] *Overruled in part on other grounds by Am. Meat Inst. v. U.S. Dep't of Agric.*, 760 F.3d 18, 22 (D.C. Cir. 2014) (en banc).

products can cause adverse health effects, FDA does not dispute that vaping products offer important health advantages to traditional tobacco products. Nicopure Mem. 17–18. And as FDA admits, vaping is "not responsible for the high prevalence of tobacco-related death and disease in this country" and FDA "do[es] not have sufficient data to determine what effects e-cigarettes have on public health at the population level." 81 Fed. Reg. 29,028, 29,033. FDA also maintains that some unknown number of labels on vaping products were found to be inaccurate. FDA Br. 82. This modicum of evidence is insufficient to meet the government's burden to show that "the harms [FDA] recites are real and that [the modified risk restrictions] will in fact alleviate them to a material degree," and stands in stark contrast to the far-reaching effects of the modified risk restrictions and its strict evidentiary requirements. *Edenfield*, 507 U.S. at 770–71; *Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 417 (1993) (striking regulations because government did not "carefully calculat[e] the costs and benefits associated with the burden on speech imposed" by the regulations) (internal quotation marks omitted).

Finally, FDA's response that a speech prohibition is justified because "an addictive substance is at issue" (at 84) misses a key aspect of commercial-speech doctrine. Vaping products are legal, whether or not companies such as Nicopure are allowed to make certain truthful, non-misleading statements about their products. Nicopure thus has "a protected [First Amendment] interest in communicating information about its products" and legal purchasers have an equal "interest in receiving that information." *Lorillard*, 533 U.S. at 571. In the face of these interests, FDA cannot justify the modified-risk restrictions—which serve as a prior restraint on speech and "amoun[t] to precisely the kind of blunderbuss legislation that cannot satisfy the First Amendment's preference for resolving policy problems by regulating conduct rather than speech." *BellSouth Telecommunications, Inc. v. Farris*, 542 F.3d 499, 509 (6th Cir. 2008); *see also Eden-*

field, 507 U.S. at 770–71 (cautioning that without First Amendment protections for commercial speech, "[the government] could with ease restrict commercial speech in the service of other objectives that could not themselves justify a burden on commercial expression"). Less restrictive means such as disclaimers should have been considered and adopted. *See* Nicopure Mem. 44.

The Supreme Court's reasoning in *Lorillard* is particularly instructive. As explained in *Lorillard*, the government does not have limitless discretion to impose restrictions in pursuit of achieving a policy goal, however noble the cause. 533 U.S. at 571 ("Federal law, however, places limits on policy choices available to the [government]."). That principle is no less applicable to the vaping industry here than it was to the tobacco industry in *Lorillard*.

For all the above reasons, the Rule's application of the modified risk restrictions to vaping products should be vacated.

CONCLUSION

The Deeming Rule purports to regulate products outside the scope of FDA's statutory authority. Moreover, the Rule purports to subject Nicopure and the rest of the vaping industry to crushing regulation in the interest of the public health, while conceding that the Rule may produce no public health benefits at all. FDA compounded this improper approach by ignoring reasonable, more flexible alternatives to the "all-or-nothing" approach taken with respect to vaping products, and by failing to explain the choices made in the Rule. FDA also abdicated its obligation to conduct a reasoned cost-benefit analysis. And it has violated Plaintiffs' First Amendment rights. This Court should hold unlawful and set aside the Deeming Rule's regulation of vaping devices and e-liquids. *See* 5 U.S.C. § 706.

Respectfully submitted,

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August 26, 2016

CERTIFICATE OF SERVICE

I hereby certify that on August 26, 2016, I caused the foregoing document to be electronically filed with the Clerk of the Court using the Court's CM/ECF system. I further certify that the foregoing document is being served on all counsel of record via transmission of notices of electronic filing generated by CM/ECF.

/s/ Benjamin C. Block
Benjamin C. Block