IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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

MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF NICOPURE LABS, LLC'S MOTION FOR SUMMARY JUDGMENT

Benjamin C. Block
(D.C. Bar No. 479705)
Kevin King
(D.C. Bar No. 1012403)
COVINGTON & BURLING LLP
One City Center
850 Tenth Street, NW
Washington, DC 20001-4956
(202) 662-5205 (Telephone)
(202) 778-5205 (Fax)
bblock@cov.com
kking@cov.com

Counsel for Plaintiff
Nicopure Labs, LLC

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INTRODUCTION

Nicopure Labs, LLC challenges under the Administrative Procedure Act FDA's unlawful, arbitrary, and capricious regulation of vaping devices and e-liquids in the "Deeming Rule" (or "the Rule"), 81 Fed. Reg. 28,973 (May 10, 2016).

The Rule exceeds FDA's statutory authority in regulating non-nicotine-containing products such as batteries, software, tanks, vaporizers, and non-tobacco, non-nicotine-containing e-liquids. Congress expressly defined "tobacco product" as a product made or derived from tobacco and intended for human consumption. The majority of Nicopure's products are neither.

The Deeming Rule also fails "hard look" APA scrutiny. The Rule is fundamentally inconsistent, purporting to regulate vaping products to protect the public health, while simultaneously conceding that FDA does not know enough about vaping to determine its effect on public health. The Rule also turns Congress's intent on its head by subjecting vaping products to an insurmountable premarket authorization pathway while allowing cigarettes and other conventional tobacco products to either be grandfathered or eligible for far less-burdensome pathways. Furthermore, the Rule's cost-benefit analysis violates the APA by failing to quantify the Rule's benefits and grossly understating its costs.

Finally, the Rule violates the First Amendment. Its ban of free samples of vaping devices or e-liquids flunks the *Sorrell* and *Central Hudson* tests. Its restrictions on making truthful, non-misleading statements about vaping products (such as that they do not contain tar, or ash, or that they are smokeless) are unconstitutional for the same reasons. This Court should set aside the Deeming Rule.

REGULATORY AND FACTUAL BACKGROUND

As this case involves FDA's unlawful regulation of vaping products, a brief background on the source of the challenged rule and the vaping industry follows.

A. The Tobacco Control Act

FDA has promulgated the regulations at issue pursuant to its authority under the Family Smoking Prevention and Tobacco Control Act ("the TCA" or "the Act"). Congress enacted the TCA to, *inter alia*, address the "cancer, heart disease, and other serious adverse health effects" associated with use of "tobacco products" and to address various issues related to smoking and the use of cigarettes. Pub. L. No. 111–31, 123 Stat. 1777, §§ 2(2), (13)–(14), (16), (23)–(25), (31)–(32), (34), (38)–(39), (45), (47)–(48) (2009). The Act authorizes FDA[1] to regulate the manufacture, marketing, and distribution of "tobacco product[s]," defined as "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).

The TCA's burdens are manifold. Among other things, the Act: (i) makes it unlawful to market misbranded or adulterated tobacco products; (ii) requires manufacturers of tobacco products to submit detailed product and advertising information to FDA; (iii) requires manufacturers to register manufacturing facilities

[1] Although the Act charges the Secretary of Health and Human Services with administering the relevant provisions of the Act, the Secretary has delegated that authority to FDA and its Commissioner, Dr. Robert Califf. 21 U.S.C. §§ 387a, 387a–1. All defendants are collectively referred to as "FDA" or "Defendants."

with FDA and open such facilities for biannual FDA inspections; (iv) authorizes FDA to impose restrictions on the sale and distribution of tobacco products, and to require warning labels for tobacco products; (v) authorizes FDA to regulate the methods used in manufacturing tobacco products; (vi) grants FDA authority to mandate new product safety standards regarding the composition and characteristics of tobacco products; (vii) directs tobacco product manufacturers to keep certain records; (viii) requires manufacturers to obtain advance FDA authorization before making certain advertising and labeling claims; and (ix) grants FDA authority to promulgate testing requirements. 21 U.S.C. §§ 387a–387k, 387o, 387t.

No TCA restriction exerts more control or imposes more costs than the condition of premarket authorization. The TCA prohibits distribution of "new tobacco products" without FDA's prior authorization, *id.* § 387j(a)(2), and provides three primary options to obtain it:

- The substantial equivalence ("SE") pathway, which requires the manufacturer to show that its product "is substantially equivalent to a tobacco product commercially marketed ... in the United States as of February 15, 2007," *id.* § 387j(a)(2)(A)(i), or to a product that itself was approved by FDA as an "SE" product;

- The SE exemption pathway, which requires a manufacturer to show that its product is only a "minor modification" of a tobacco product that was on the market as of February 15, 2007, or approved under another pathway, and that the modification only involves a change in additive levels, *id.* §§ 387e(j)(3), 387j(a)(2)(A)(ii); and

- The premarket tobacco application ("PMTA") pathway, under which the manufacturer must obtain FDA authorization based on a detailed application documenting the product's health risks, ingredients, manufacturing methods, and other characteristics, *id.* § 387j(b)(1).

For vaping products, the PMTA pathway is the primary—if not the only avenue.[2] (*See* AR023,989 ("[N]early all [vaping] products will be subject to premarket review."), AR023,995–4,003 (describing the PMTA process, detailing FDA's estimates of the costs, and concluding that 99–100% of vaping products will be subject to PMTA requirement).); *see also Am. Biosci. Inc. v. Thompson*, 269 F.3d 1077, 1079 (D.C. Cir. 2001) (describing FDA's "new drug application" process, upon which the PMTA pathway is based, as "expensive and time-consuming"). FDA has approved only *one* PMTA application since the TCA was enacted.[3] That applicant submitted, *inter alia*, four clinical pharmacology studies, data from two clinical trials, study data spanning several decades, and extensive reports of testing.[4]

B. Vaping Products

"Vaping"—the "act of inhaling and exhaling the vapor," often but not always containing nicotine, "produced by an electronic cigarette or similar device"[5] is a new industry. Vaping products were just being introduced when the TCA was enacted. (Stamler Decl. ¶ 4.) In contrast to the traditional tobacco industry, which is stable

[2] Vaping products are not eligible for the SE pathway because no viable predicates exist. And they do not meet the criteria for the SE exemption pathway because they are not "minor modifications" of grandfathered or approved products.

[3] *See* FDA News Release, *FDA Issues First Product Marketing Orders Through Premarket Tobacco Application Pathway* (Nov. 10, 2015), www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm472026.htm.

[4] FDA, Premarket Tobacco Application (PMTA) Technical Project Lead (TPL) Review: Swedish Match North America, Inc., at 18, 20, 25–26 (Mar. 11, 2015), *available at* www.fda.gov/downloads/TobaccoProducts/Labeling/TobaccoProductReviewEvaluation/UCM472123.pdf.

[5] Oxford Dictionaries, oxforddictionaries.com/us/definition/american_english/vape.

and consolidated among a handful of large companies, thousands of small, independent, businesses comprise the vaping industry. *See, e.g.*, 81 Fed. Reg. at 29.076 ("most [vaping] businesses are small").

Vaping products include both "e-liquids" and "vaporizers." (Stamler Decl. ¶ 3.) E-liquid generally consists of propylene glycol, vegetable glycerin, and flavoring. (*Id.* ¶ 6.) Although some forms of e-liquid contain nicotine derived from tobacco, other e-liquid contains no nicotine at all. (*See id.*) Vaporizers, in turn, provide an electronic heat source to convert e-liquid into vapor, which the user inhales through a mouthpiece. (*Id.* ¶ 7.) There are two main types—open and closed systems. (*Id.* ¶ 8.) In closed systems, the amount of liquid, flavor, and nicotine content (if any) is set by the manufacturer and cannot be altered by the consumer. (*Id.* ¶ 9.) In contrast, consumers fill and refill open ("tank") systems with e-liquid sold by others, including at retail outlets known as "vape shops." (*Id.* ¶ 10.)

Peer-reviewed studies have concluded that vaping is much safer than using cigarettes, because vaping does not generate the toxins associated with combusting and smoking tobacco.[6] Indeed, the Rule acknowledges that studies show that:

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[6] *See* David T. Levy et al., *A Framework for Evaluating the Public Health Impact of E-Cigarettes and Other Vaporized Nicotine Products*, Soc'y for Study of Addiction 6 (Apr. 2016), www.onlinelibrary.wiley.com/doi/10.1111/add.13394/abstract ("The evidence suggests a strong potential for [vaping product] use to improve population health by reducing or displacing cigarette use in countries where cigarette prevalence is high and smokers are interested in quitting."); Tobacco Advisory Group of The Royal College of Physicians, *Nicotine Without Smoke: Tobacco Harm Reduction* 189 (Apr. 2016), www.rcplondon.ac.uk/file/3563 ("Large-scale substitution of e-cigarettes … for tobacco smoking has the potential to prevent almost all the harm from smoking in society.").

(i) vaping devices enable "substantial reductions in the exposure to harmful constituents typically associated with smoking" when "compared to cigarettes"; (ii) "most of the chemicals causing smoking related disease from combusted tobacco use are absent" in the vapor generated by vaping devices; (iii) "the chemicals that are present" in vapor generated by vaping devices "pose limited danger"; and (iv) vaping devices "are likely to be much less, if at all, harmful to users or bystanders" than cigarettes. 81 Fed. Reg. at 29,030–31. All told, FDA was told of dozens of studies showing that vaping is less harmful than cigarettes. (*See, e.g.*, AR127,406–9; AR131,585.)

C. The Deeming Rule & Its Effect on Nicopure

On May 10, 2016, FDA published the Deeming Rule in the Federal Register. The scope of the Rule's reach is staggering: it purports to regulate as "tobacco products" a myriad of vaping products not made or derived from tobacco nor intended for human consumption—including open systems, "programmable software," "batteries," "digital display/lights," and "glass or plastic vial[s]." 81 Fed. Reg. at 28,975.

Nicopure, a small business, manufactures almost exclusively products covered by the Deeming Rule. (Stamler Decl. ¶ 17.) Its product portfolio includes a number of open-system vaporizers and a large number of replacement parts, closed-system vaporizers, and e-liquids (some with nicotine, some without). (*Id.* ¶¶ 6–7, 11.) No Nicopure product contains tobacco; only some contain nicotine derived from tobacco. (*Id.* ¶ 17.) Nevertheless, under the Deeming Rule, Nicopure will be required to file and obtain FDA approval of PMTAs for virtually all of its current products, and for nearly every future product developed, to continue selling them. (*Id.*)

The Rule also imposes substantial speech restrictions on Nicopure. As of the Rule's effective date, manufacturers, distributors, and retailers are prohibited from distributing "free samples" of vaping products. 81 Fed. Reg. at 29,054. This ban will eliminate the most significant tool for persuading retailers to stock Nicopure products, for educating consumers, and for obtaining direct market feedback. (*See* Stamler Decl. ¶¶ 35–40.) The Rule will also restrict Nicopure's ability to make truthful, non-misleading statements to consumers. (*Id.* ¶ 43.) Nicopure informs consumers that vaping produces no smoke, ash, or tar. (*See id.* ¶¶ 43–46.) But beginning on the Rule's effective date, the vaping industry will be subject to the restrictions on speech concerning "modified risk tobacco products" (the "MRTPR"), 81 Fed. Reg. at 29,005 (citing TCA § 911 & 21 U.S.C. § 387k), which prohibit manufacturers from informing consumers that its products are "free of a substance" without prior FDA authorization and approval.

In sum, the Deeming Rule will subject the overwhelming majority of Nicopure's products—including hundreds of products that are neither made nor derived from tobacco nor intended for human consumption—to the Act's premarket approval, reporting, recordkeeping, inspection, labeling, manufacturing, testing, and other requirements. This will severely burden Nicopure and its operations—forcing Nicopure to slash its product portfolio, suffocating further innovation, and costing millions of dollars. (*See* Stamler Decl. ¶¶ 20–28, 31–33.) [7]

[7] Nicopure's standing to seek review of the Deeming Rule is "self-evident," *Sierra Club v. EPA*, 292 F.3d 895, 899–900 (D.C. Cir. 2002), and is supported by the Declaration of Jeff Stamler, attached hereto.

STANDARD OF REVIEW

Summary judgment is "the mechanism for deciding, as a matter of law, whether the agency action is supported by the administrative record and otherwise consistent with the APA standard of review." *Sierra Club v. Mainella*, 459 F. Supp. 2d 76, 90 (D.D.C. 2006). The APA requires courts to "hold unlawful and set aside agency action, findings, and conclusions found to be … arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

This Court reviews FDA's interpretation of the TCA under *Chevron, U.S.A., Inc. v. NRDC*, 467 U.S. 837 (1984). The Court first "examines the statute *de novo*," *Int'l Union, United Mine Workers of Am. v. Mine Safety & Health Admin.*, 626 F.3d 84, 90 (D.C. Cir. 2010), and "employ[s] traditional tools of statutory construction" to determine whether Congress spoke unambiguously to "the precise question at issue," *Chevron*, 467 U.S. at 843 & n.9. Only if the statute is ambiguous does the Court consider "whether the agency's answer is based on a permissible construction of the statute." *Id.* at 843.

The APA further "requires that agency decisionmaking be both reasonable and reasonably explained." *Ind. Boxcar Corp. v. R.R. Retirement Bd.*, 712 F.3d 590, 591 (D.C. Cir. 2013). A rule is arbitrary and capricious when the agency, *inter alia*, does not consider relevant factors, fails to consider an important part of the problem, or adopts an approach counter to the evidence. *See Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43–44 (1983).

ARGUMENT

I. Non-Nicotine-Containing Products Are Not "Tobacco Products."

The Supreme Court has "stated time and again that courts must presume that a legislature says in a statute what it means and means in a statute what it says there." *Conn. Nat'l Bank v. Germain*, 503 U.S. 249, 253–54 (1992). Congress defined the term "tobacco product" as "any product made or derived from tobacco that is intended for human consumption … ." 21 U.S.C. § 321(rr)(1). Nicopure's open-system vaping devices (and their constituent parts) are neither "made or derived from tobacco," nor intended for human consumption. And its non-nicotine-containing e-liquids are not "made or derived from tobacco." In nevertheless purporting to regulate those products under the TCA, FDA acts contrary to law.

A. The Deeming Rule's application to non-nicotine-containing vaping devices and e-liquids is contrary to the TCA's text.

FDA acknowledges that "its authority is not so broad as to allow FDA to issue a regulation that contradicts a clear statutory provision." 81 Fed. Reg. at 28,993. Yet, that is exactly what FDA has done in purporting to regulate open-system vaping devices and non-nicotine-containing e-liquids, which are not made nor derived from tobacco. Numerous commenters pointed out that many vaping products do not meet the statutory definition of "tobacco product." (*See, e.g.*, AR131,642.) FDA's response was *ipse dixit*: "[A vaping product] is a tobacco product as long as it meets the definition of 'tobacco product' under section 201(rr) of the FD&C Act." 81 Fed. Reg. at 28,998.

The statutory text is unambiguous: To qualify as a "tobacco product," the product must be made or derived from tobacco and intended for human consumption or be a "component, part or accessory of" such a product. The majority of Nicopure's products do not meet that plain-language definition. An open-system vaporizer like the Triton, Reactor, or Tracer contains neither tobacco nor anything derived from tobacco, nor is it intended for human consumption. These vaporizers (or their batteries, spare tanks, software, mouthpieces, etc.) are also not "components" or "parts" of a "tobacco product"—they are not components or parts of a product made or derived from tobacco and intended for human consumption.

A "component" is a "constituent part" or "ingredient." Merriam-Webster Dictionary, www.merriam-webster.com/dictionary/component; *see also* Oxford English Dictionary, www.oed.com/view/Entry/37759 ("constituent element or part"). A "part" is "one of the subdivisions … into which something is or is regarded as divided and which together constitute the whole." *See* Merriam-Webster Dictionary, www.merriam-webster.com/dictionary/part. The Tritons, Reactors, and Tracers are not constituent parts or ingredients of a tobacco product. Nor are the non-nicotine-containing e-liquids. Each is its own, separate consumer product that contains neither tobacco nor anything derived from tobacco.

Furthermore, "[t]he normal rule of statutory construction assumes that identical words used in different parts of the same act are intended to have the same meaning." *Sorenson v. Sec'y of Treasury*, 475 U.S. 851, 860 (1986) (internal quotation marks omitted). The TCA further confirms, in numerous places, that the terms

"component" or "part" were not intended to reach separate finished products not made or derived from tobacco:

- Section 900 (21 U.S.C. § 387(17)) defines a "smoke constituent" as "any chemical or chemical compound in mainstream or sidestream tobacco smoke that either transfers from any component of the cigarette to the smoke or that is formed by the combustion or heating of tobacco, additives, or *other component* of the tobacco product" (emphasis added).

- Section 904 (21 U.S.C. § 387d(a)) requires manufacturers to list "all ingredients … added by the manufacturer to the tobacco, paper, filter, *or other part* of each tobacco product" (emphasis added).

- Section 907 (21 U.S.C. § 387g(a)(1)(A)) prohibits "a cigarette *or any of its component parts* (including the tobacco, filter, or paper)" from containing flavors (emphasis added).

Thus, repeatedly and consistently throughout the TCA, Congress used "component" and "part" to refer to items inseparable from the product made or derived from tobacco, not to refer to separate products not so made or derived. *See Japan Whaling Ass'n v. Am. Cetacean Soc'y*, 478 U.S. 221, 238–39 (1986) ("Without strong evidence to the contrary, we doubt that Congress intended the same phrase to have significantly different meanings in two adjoining paragraphs of the same subsection.").

FDA erroneously concluded that the D.C. Circuit's decision in *Sottera Inc. v. FDA*, 627 F.3d 891 (D.C. Cir. 2010), establishes the agency's jurisdiction over products that do not contain tobacco or anything derived from tobacco. 81 Fed. Reg. at 29,043. *Sottera* did not and could not have done so, for two reasons. *First*, the issue presented in *Sottera* was whether FDA had authority to regulate e-cigarettes under the device provisions of the FDCA. *See* 627 F.3d at 892. The court had no occasion to rule on the meaning of the TCA, such that any discussion of the Act's meaning is

dicta. *Second*, the product at issue in *Sottera* itself contained nicotine derived from tobacco and was intended for human consumption.[8] There is no basis to conclude, contrary to the language that Congress used, that *Sottera* held that FDA may also regulate products containing neither tobacco nor anything derived from tobacco.

FDA may also argue that the words "component" or "part" are ambiguous. But at *Chevron* Step One, "'the issue is not so much whether the [statutory language] is, in some abstract sense, ambiguous, but rather whether, read in context and using the traditional tools of statutory construction, the term … encompasses [the government's interpretation].'" *Cal. Indep. Sys. Operator Corp. v. FERC*, 372 F.3d 395, 400 (D.C. Cir. 2004).[9] Put differently, "[i]t does not matter whether the word 'yellow' is ambiguous when the agency has interpreted it to mean 'purple.'" *United States v. Home Concrete & Supply, LLC*, 132 S. Ct. 1836, 1846 n.1 (2012) (Scalia, J., concurring). FDA therefore cannot say—as the Deeming Rule does—that a product that is neither made nor derived from tobacco nor intended for human consumption is nevertheless a "component" or "part" of a tobacco product.

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[8] *See* Verified Intervenor Complaint ¶ 15, *Smoking Everywhere, Inc. v. FDA*, No. 1:09-cv-00771 (D.D.C. May 8, 2009) (Dkt. 12–1).

[9] *See, e.g.*, *Sw. Airlines Co. v. Transp. Sec. Admin.*, 554 F.3d 1065, 1069–70 (D.C. Cir. 2009) (rejecting agency's interpretation of "screening passengers" even though "to screen" may have multiple meanings because the term is clear in context); *HolRail, LLC v. STB*, 515 F.3d 1313, 1317 (D.C. Cir. 2008) (holding that "the term 'cross' may have multiple meanings in some circumstances" but that "the statute, read in context, clearly resolves the case").

B. The Deeming Rule's application to non-nicotine-containing vaping products is contrary to the TCA's structure.

"[T]o defeat application of a statute's plain meaning, [an agency] must 'show either that, as a matter of historical fact, Congress did not mean what it appears to have said, or that, as a matter of logic and statutory structure, it almost surely could not have meant it.'" *Performance Coal Co. v. Fed. Mine Safety & Health Review Comm'n*, 642 F.3d 234, 238 (D.C. Cir. 2011) (quoting *Engine Mfrs. Ass'n v. EPA*, 88 F.3d 1075, 1089 (D.C. Cir. 1996)). FDA cannot do so.

The Rule tries to evade the plain meaning definition of "tobacco product" by "defining 'component or part' to mean any software or assembly of materials *intended or reasonably expected*: (1) To alter of affect the *tobacco product*'s performance, composition, constituents, or characteristics; or (2) to be used with or for the human consumption of *a tobacco product*." 81 Fed. Reg. at 29,015 (emphases added). FDA proceeds to grant itself license to "consider the totality of the circumstances" to ascertain the "intended or reasonably expected" use. *Id.*

That approach might have been appropriate if, in the TCA, Congress had adopted the definition framework of the drug or device provisions of the FDCA. But as FDA itself has previously recognized and told Congress: "Drugs and devices are defined by their intended use, *while tobacco products are not*."[10] In sharp contrast to the TCA and its definition of "tobacco product," in the drug and device provisions of

[10] 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*, at 4 (Nov. 11, 2013) (emphasis added, capitalization omitted) [hereinafter, "FDA, Report to Congress"].

the FDCA, Congress expressly defined the regulated products—"drugs" and "devices"—by their "intended" use. 21 U.S.C. § 321(g)(1) (drugs); *id.* § 321(h) (devices). FDA cannot, via interpretation, amend the TCA to adopt an "intended use" approach for "tobacco products" that Congress itself did not adopt. *See, e.g.*, *Russello v. United States*, 464 U.S. 16, 23 (1983) ("Where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." (brackets omitted)); *see also Utility Air Regulatory Grp. v. EPA*, 134 S. Ct. 2427, 2446 (2014) ("[A]n agency may not rewrite clear statutory terms to suit its own sense of how the statute should operate."). Rather, as FDA has conceded, in "contrast" to its device and drug authority, "FDA's authority to regulate tobacco products … depends first on the product's physical makeup."[11]

Furthermore, subjecting non-nicotine-containing vaping products to the Act leads to absurd results. By regulatory fiat, Nicopure must now inform FDA of the "ingredients" of its programmable software, displays, batteries, etc. 81 Fed. Reg. at 29,033, 29,046 (citing TCA §§ 904 & 915). But no one consumes software, displays, batteries, or other parts of an open vaping system, and there is no reason to think that Congress intended to subject these products to FDA regulation.

Accordingly, in purporting to regulate products that do not meet the statutory definition of a "tobacco product," FDA has exceeded its statutory authority.

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[11] *See* FDA, Report to Congress, *supra* n.10, at 5.

II. The Deeming Rule's Regulation of Vaping Devices and E-Liquids Cannot Withstand "Hard Look" APA Review.

"One of the basic procedural requirements of administrative rulemaking is that an agency must give adequate reasons for its decisions." *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. ----, 2016 WL 3369424, at *7 (U.S. June 20, 2016). In determining whether a rule complies with that requirement, courts must conduct "thorough, probing, in-depth review" of the agency's reasoning and a "searching and careful" inquiry regarding the rule's factual underpinnings. *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 415–16 (1971). Agency action is arbitrary and capricious—and must be "h[e]ld unlawful and set aside," 5 U.S.C. § 706(2)—when the agency fails to articulate "a rational connection between the facts found and the choice made," fails to base its decision "on a consideration of the relevant factors," "fail[s] to consider an important aspect of the problem," or "offer[s] an explanation for its decision that runs counter to the [record] evidence." *State Farm*, 463 U.S. at 43. The Deeming Rule fails this scrutiny in multiple respects.

A. The Deeming Rule is internally inconsistent.

Most fundamentally, the Rule is at war with itself regarding the rationale for regulating vaping products. FDA says that sweeping regulation of vaping products is necessary to protect the public health, while simultaneously conceding that it does not know enough about vaping to determine its effect on public health.

The Rule repeatedly makes these self-contradictory statements—sometimes within just a few sentences of one another. FDA acknowledges that promoting public health is the Rule's *raison d'être*. *See* 81 Fed. Reg. at 29,042 ("FDA is deeming

these products to address public health concerns."); *id.* at 28,983 ("regulation of the newly deemed products will be beneficial to public health"); *id.* at 29,014 (Rule designed "to protect the public health").)[12] But at the same time, FDA concedes that it does "not currently have sufficient data … to determine what effects e-cigarettes have on the public health." *Id.* at 29,984; *see id.* at 29,028–29 ("[W]e do not have sufficient data to determine what effects e-cigarettes have on public health at the population level. … [W]e do not currently have sufficient data about e-cigarettes … to fully determine what effects they have on the public health."). (*See also* AR023,930 ("[T]he welfare effects of including [vaping products] in this final rule are uncertain."); AR023,970 ("The health impact of e-cigarettes, for users and the public, cannot be determined with currently available data."); AR023,973 ("Reliable evidence on the impacts of warning labels, premarket review, and marketing restrictions on users of … [vaping products] does not, to our knowledge, exist.").)

The Deeming Rule cannot satisfy the APA's requirement of "reasoned decisionmaking" in light of this foundational conflict. *State Farm*, 463 U.S. at 52. The D.C. Circuit has held time and again that internal inconsistencies render agency action arbitrary and capricious. *See, e.g.*, *Bus. Roundtable v. SEC*, 647 F.3d 1144,

[12] Despite basing the Deeming Rule on a purported public health interest, FDA also says that there is no need "to establish that deeming will benefit public health," because "FDA is not required to meet a particular public health standard to deem tobacco products." 81 Fed. Reg. at 28,983. Irrespective of whether the TCA requires FDA to show that deeming a class of products to be "tobacco products" will advance public health, the APA undoubtedly requires FDA to "articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *State Farm*, 463 U.S. at 43 (internal quotation marks omitted).

1153 (D.C. Cir. 2011) (vacating rule that was "internally inconsistent and therefore arbitrary"); *Gen. Chem. Corp. v. United States*, 817 F.2d 844, 857 (D.C. Cir. 1987) ("Because the ICC's analysis … is internally inconsistent and inadequately explained, we find its ultimate conclusion … to be arbitrary and capricious."). This principle applies with special force here, as the contradiction in FDA's reasoning goes to the agency's very reason for promulgating the Rule.

The Deeming Rule also suffers from a second basic logical flaw. FDA suggests that the Rule is justified because it will provide FDA with the ability "to obtain critical information regarding the health risks of newly deemed tobacco products." 81 Fed. Reg. at 28,975. That rationale is wholly circular and question begging: FDA cannot rationally justify a rule intended to address health risks by pointing to the need for information to determine whether those risks exist in the first place.

B. The Rule will undermine the TCA's public-health goals.

The Deeming Rule will also undermine the TCA's core goal of reducing the deaths and disease resulting from use of tobacco products. The Rule acknowledges that vaping products are safer than traditional tobacco products, yet at the same time imposes a regulation that will crush the vaping industry and preserve the pre-TCA cigarette-dominant status quo.

A substantial body of literature shows that vaping products offer important health advantages. For example, a 2015 study by Public Health England (AR022,842, AR022,845, AR022,916)—the governmental body charged to "protect and improve" England's "health and wellbeing"—concluded that vaping products are "likely to be much less, if at all, harmful to users or bystanders" when "com-

pared with cigarettes." 81 Fed. Reg. at 29,029–31. This study also determined, consistent with "a review by an international team of experts," that: (i) vaping products are "around 95 percent safer than smoking combusted cigarettes"; (ii) vaping products provide "substantial reductions in the exposure to harmful constituents typically associated with smoking"; and (iii) "most of the chemicals causing smoking-related disease from combusted tobacco use are absent" in the vapor produced by vaporizers, while "the chemicals that are present pose limited danger." *See id.*; *see also id.* at 29,029 ("[S]tudies have found that lower levels of toxicants are observed in e-cigarette aerosols than in combusted tobacco smoke.").

Other studies have reached the same basic conclusion. A peer-reviewed paper in *Cancer Prevention Research* found that cigarette users who switched to vaping products reported "reductions in exposure to carbon monoxide and the toxicant acrolein." *Id.* at 29,040. (*See also* AR129,153–60 (showing that e-vapor toxicant levels are "significantly lower" than in cigarette smoke, and are well below ambient workplace threshold limit values).) Similarly, several studies conclude that vaping poses "relatively little risk," produces vapor that "is less injurious than the smoke from cigarettes," and eliminates exposure to "the combustion products that are responsible for nearly all of smoking's damaging effects." (AR130,482–3; AR139,744.) In sum, dozens of studies and articles show that vaping products pose a substantially reduced health risk vis-à-vis cigarettes. (*See, e.g.*, AR127,406–9; AR131,576; AR150,351; AR151,105–6.)[13]

[13] *See also supra* n.6 (additional peer-reviewed studies).

The record also indicates that most vaping product users are current cigarette smokers or recent former smokers. *See* 81 Fed. Reg. at 29,028, 29,036. And the record contains significant evidence that vaping products help these cigarette smokers quit. *Id.* at 29,030. (*See also* AR130,486–9; AR139,746.)

Nevertheless, FDA insists that it is too early to tell whether vaping products present a public-health benefit. *See, e.g.*, 81 Fed. Reg. at 28,984, 29,028–32. Even were that correct—and the body of evidence outlined above strongly suggests otherwise—it is undisputed by FDA itself that vaping products are *far* less risky than cigarettes. Indeed, the Rule acknowledges that inhalation of e-vapor "is of less risk to a user than the inhalation of … smoke from combusted tobacco products," and that use of vaping products "is likely less hazardous for an individual user than continued smoking of traditional cigarettes." *Id.* at 29,033, 29,035.

The Deeming Rule arbitrarily and capriciously ignores this evidence entirely. Instead, it subjects vaping products—which FDA admits are "not responsible for the high prevalence of tobacco-related death and disease in this country," *id.* at 29,033—to the same set of rules that Congress designed to apply to the traditional tobacco products. Specifically, the Rule requires vaping products to comply with nearly all of the labeling, disclosure, sales, misbranding, and other provisions of the TCA that apply to cigarettes. *See* 81 Fed. Reg. at 29,000 ("The statute automatically subjects deemed products to the statutory requirements for 'tobacco products' in chapter IX of the [FDCA].").

In reality, the Rule imposes a *more* stringent set of rules on vaping products in the respect that matters most: premarket authorization. Unlike many cigarettes that were on the market as of February 15, 2007, and are thus exempt from pre-market-review requirements, or which can utilize the less burdensome SE pathway, vaping products may be sold only after navigating the lengthy and burdensome PMTA process. *See* 21 U.S.C. § 387j(a)(1)–(2). (*See also* AR023,989 ("[N]early all [vaping] products will be subject to premarket review.").) As FDA recognizes, the Rule will cause "substantial amounts of product … exit" and "firm exit" in the vaping industry, while allowing cigarettes and other traditional tobacco products to remain on the market. (AR023,933; *see also* AR023,931.)

The net effect of this all-or-nothing approach is to drive consumers back to cigarettes. (*See* AR150,357–8 (Rule will "likely … lead to an increase in the sale or consumption of even more harmful products—namely traditional cigarettes").) That outcome is directly at odds with two of Congress's core goals in passing the Act: "promot[ing] cessation" and "reduc[ing] disease risk and the social costs associated with tobacco-related diseases." TCA § 3(9). It is also incompatible with the Surgeon General's 2014 Report that "promotion of noncombustible products is much more likely to provide public health benefits only in an environment where the appeal, accessibility, promotion, and use of cigarettes and other combusted tobacco products are being rapidly reduced." 81 Fed. Reg. at 28,984. A regulation so at odds with Congress's stated purposes cannot withstand APA review. *See, e.g.*, *Envtl. Def. Fund v. EPA*, 852 F.2d 1316, 1329 (D.C. Cir. 1988).

C. FDA failed to consider reasonable alternatives.

Finally, the Deeming Rule is arbitrary and capricious because it fails to consider numerous alternatives that would avoid a "significant degree of product exit" (AR023,991.) while still achieving Congress's public-health objectives.

1. The Rule fails to meaningfully consider the burden of the PMTA requirement on the vaping industry.

FDA concedes that, under the Rule, a PMTA is effectively the sole approval pathway available for all but a handful of vaping products. (*See, e.g.*, AR023,989, AR023,995 (indicating that 99% of vaporizers and 100% of e-liquids are likely subject to the PMTA requirement).) As described above, the PMTA pathway is extremely burdensome. *See* 21 U.S.C. § 387j(b)(1); 81 Fed. Reg. at 28,991.

To obtain FDA approval, a PMTA must also show "that permitting th[e] produc[t] to be marketed would be appropriate for the protection of the public health." 81 Fed. Reg. at 28,991. This is a tremendous burden on its own: the Rule indicates that FDA will require data regarding an e-liquid's "likely impact when used in the [full] range of delivery systems available." *Id.* at 28,992.[14] And PMTAs for open-system vaping devices (or their components and parts) will need to demonstrate how the product (such as a replaceable heating coil) will perform "when used together with the range of other components and liquids available" on the market. *Id.* This would necessitate a staggering amount of testing given FDA's estimates

[14] FDA predicts that the need to cross-test every e-liquid with every available vaporizer, and every component with every other available component and e-liquid, will make it "difficult" to obtain premarket approval for parts, components, and open-system vaporizers. 81 Fed. Reg. at 29,017, 28,998. (*See also* AR024,007.) In actuality, the extent of testing required will make it *impossible* to obtain approval.

that "there are 5,000 to 10,000 e-liquid product-package combinations" and "800 to 1,000 delivery systems product-package combinations" on the market. (AR023,939.)

The Deeming Rule estimates that a single PMTA will, on average, take 1,500 hours to prepare, and cost $131,643 for e-liquid products and over $465,000 for vaporizer products. 81 Fed. Reg. at 29,078. (*See also* AR023,998–4,003.) Nicopure, with over 2,400 products, would have to invest 3.6 million hours (equal to 150,000 days or 411 years) to prepare PMTAs for all of its existing products. (*See* Stamler Decl. ¶¶ 13, 27.)[15] Even if Nicopure eliminated 80% of its products in response to the Deeming Rule, submitting PMTAs for the remaining 20% would take approximately 720,000 hours (equal to 30,000 days or 82.2 years) to complete. (*Id.* ¶ 27.) A dedicated team of 10 employees would take nearly a decade to complete that task if all 10 team members worked 24 hours a day, 7 days a week, 365 days a year—yet FDA has allotted only 2 years for compliance. 81 Fed. Reg. at 29,011. (*See also* AR149,701–2.)

FDA concedes that the cost and burden associated with the PMTA process will cause a substantial majority of vaping products "to exit" the market rather "than submit a premarket application." (AR023,989–90; *see also* AR023,933 (anticipating "substantial amounts of product consolidation and exit, as well as firm

[15] The Rule states that every vaping product must obtain its own PMTA, even when there are only slight differences between products. 81 Fed. Reg. at 28,995 ("any change in an ingredient level," "additio[n] or removal of ingredients," or similar change "yields a new tobacco product"). FDA has also asserted that every part and component must have its own PMTA—even when not sold separately. *Id.* (response to Comment 26).

exit").) But when the actual costs are taken into account, it becomes clear that the PMTA requirement will eviscerate the vaping industry. (AR043,316–7; AR 139,755; AR144,042–3; AR149,702.) This is particularly so because nearly all vaping companies are small businesses that lack the financial resources and staffing to carry out the testing and paperwork obligations required. 81 Fed. Reg. at 29,014, 29,076.

2. FDA failed to consider reasonable alternatives.

An agency's failure to consider reasonable alternatives in a rulemaking violates the APA. *See Am. Gas Ass'n v. FERC*, 593 F.3d 14, 19 (D.C. Cir. 2010) (agency must consider all "reasonable alternatives" raised in comments); *Chamber of Commerce v. SEC*, 412 F.3d 133, 145 (D.C. Cir. 2005) (agency must consider "alternative[s]" and explain its rejection of those alternatives).

Three less burdensome options stand out among many that FDA should have evaluated. *First*, FDA could have collected sufficient data to reach a conclusion—one way or the other—regarding the health effects of vaping products *before* choosing whether and how to regulate them. *See* 81 Fed. Reg. at 28,983 (Comment 4), 29,042 (Comment 166). FDA took this data-driven approach with respect to flavored tobacco products, *id.* at 29,014, and should have followed suit regarding vaping products. Indeed, the Rule emphasizes that "FDA is funding more than 70 studies related to [vaping] products (AR024,062–3), including a "long-term, population-level" study regarding the health effects of vaping, 81 Fed. Reg. at 29,029. FDA has not adequately explained why it chose to deem vaping products before completing its research efforts.

Second, the Deeming Rule provides no meaningful response to several commenters' suggestion that FDA follow the European Union's approach to regulation of vaping products. (AR149,708–12.) Under this approach, FDA would subject vaping products to disclosure, advertising, good manufacturing practices, misbranding, and other requirements, but would *not* require vaping products to obtain premarket authorization. (AR130,503–4; AR150,356–9.) Such a regime would provide FDA with authority to collect substantial information from vaping manufacturers, ensure that vaping products are not labeled or advertised in misleading ways, allow FDA to prohibit the sale of vaping products to minors, and accomplish all of the other objectives set forth in the Rule. FDA has not explained why it needs the PMTA process *in addition to* these other regulatory powers to attain the TCA's goals.[16] This omission is particularly glaring as FDA has fashioned modified approval frameworks in the past for dietary supplements and over-the-counter drugs. (AR130,503.)

Third, FDA should have at a minimum considered crafting a streamlined PMTA process for products, such as vaporizers, that fall on the safer side of the risk continuum. (AR130,480–1; AR130,506–9; AR131,575.) Nothing in the TCA requires FDA to impose precisely the same regulatory framework on every tobacco product, regardless of their relative risks. Because vaping products "are different than con-

[16] FDA does argue that *all* of the TCA's restrictions, including the PMTA requirement, apply "automatically" to *all* newly deemed tobacco products, and that FDA lacks authority to modify the statutory grandfather date. 81 Fed. Reg. at 28,993, 29,000. Irrespective of whether those assertions are accurate, they are nonresponsive to the argument that FDA had discretion in fashioning the contours of the Deeming Rule, and that FDA should have exercised that discretion by pursuing the TCA's goals in a less burdensome fashion. (AR130,503–4, AR130,511.)

ventional tobacco products" that FDA characterizes as "less hazardous for an individual user than continued smoking of traditional cigarettes," 81 Fed. Reg. at 28,997, 29,035, FDA should treat them differently. The TCA gives effect to differences between types of products (e.g., by banning the distribution of free samples of cigarettes, but not of certain smokeless tobacco products, 21 U.S.C. § 387a–1(a)(2)), and there is no reason why the same principle should not apply to vaping products.

For example, a streamlined PMTA process could dispense with several costly study requirements and ensure that vaping products will be approved so long as they meet minimum performance standards. (AR130,506–17; AR131,596–98.) This approach would "drive consumers to the least harmful forms of nicotine products" (AR131,576.) and comport with the Surgeon General's admonition that vaping is "much more likely to provide public health benefits only in an environment where the appeal, accessibility, promotion, and use of cigarettes and other combusted tobacco products are being rapidly reduced." 81 Fed. Reg. at 28,984.

FDA has express statutory authority to consider and implement these alternatives. Specifically, FDA may "promulgate regulations for the efficient enforcement of" Chapter IX of the FDCA, which includes the TCA. 21 U.S.C. § 371(a). It is thus no answer for FDA to say that deeming under the TCA is an all-or-nothing affair; FDA could have chosen instead to issue tailored regulations under Section 371(a), as many commenters suggested. (*See, e.g.*, AR150,356–60.)

FDA was not "limited to a choice between" adopting the most stringent rule available and adopting no rule "at all"; the law instead required the agency to eval-

uate "lesser restriction[s]" brought to its attention. *New York v. Reilly*, 969 F.2d 1147, 1153 (D.C. Cir. 1992). The Small Business Administration faulted FDA's proposed rule on precisely these grounds, informing FDA that its proposed rule was "deficient" because it failed fully to "consider significant alternatives which accomplish the stated FDA objectives and which minimize the significant economic impact of the proposal on small entities, " and that its brief discussion of a handful of alternate approaches was insufficient because "[a]ll of the alternatives … considered" by FDA "would only [have] ma[de] marginal changes to the overall compliance costs to small entities."[17] (AR082,216–7.) FDA's final rule was equally deficient.

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

FDA issued the Rule based on a belief that "the benefits of the final rule justify the costs." (AR023,917.) That conclusion is arbitrary and capricious because FDA "opportunistically framed the costs and benefits of the rule; failed adequately to quantify certain costs or explain why those costs could not be quantified; neglected to support its predictive judgments; contradicted itself; and failed to respond to substantial problems raised by commenters." *Bus. Roundtable*, 647 F.3d at 1148–49. As the SBA put it: "FDA failed to discuss the quantitative or qualitative costs" of the Rule "on many potentially affected small entities" and omitted "essential information needed to properly inform the agency's decision making." (AR082,219.)

[17] The Deeming Rule addresses four alternatives, one of which dealt with cigars. 81 Fed. Reg. at 29,075. None of the other options addressed the PMTA requirement, which accounts for the largest share of the Rule's overall costs. (AR024,009.)

Congress directed FDA to only "impose *appropriate* regulatory controls on the tobacco industry." TCA § 3(8) (emphasis added). That is a Congressional directive for the agency to engage in a cost-benefit analysis in any rulemaking. *See Michigan v. EPA,* 135 S.Ct. 2699, 2706–07 (2015) (holding term "appropriate" to encompass cost/benefit factors). In addition, agencies must prepare "a qualitative and quantitative assessment of the anticipated costs and benefits of [a rule], including the costs and benefits to … the private sector" whenever a rule will impose over $100 million in inflation-adjusted costs. 2 U.S.C. § 1532(a)(2).

The APA's requirement of "reasoned decisionmaking" likewise requires agencies to "look at the costs as well as the benefits" of the rules they promulgate. *State Farm*, 463 U.S. at 52, 54. FDA correctly determined that a cost-benefit analysis of the Deeming Rule is required in light of these mandates, particularly because the Rule will cost the private sector nearly $1 billion, with a "significant" effect on small businesses. 81 Fed. Reg. at 29,074. (*See also* AR023,915–17.) But conducting a cost-benefit analysis is not the same as conducting a *reasoned* cost-benefit analysis, and here FDA's assessment violates the APA in several ways.

First, the Deeming Rule's cost-benefit analysis fails because FDA failed to quantify the Rule's benefits. Rather than compute even an approximation of the benefits that the Rule will provide, FDA says that "[t]he direct benefits of" the Rule "are difficult to quantify, and we cannot predict the size of these benefits at this time." 81 Fed. Reg. at 28,981, 29,075. (*See also* AR023,917 ("[I]t is not possible to compare benefits and costs directly.").) The difficulty of the task is no excuse. "[A]n

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) (citing *Chamber of Commerce*, 412 F.3d at 143). Even when faced with data that "vary enormously," "the agency's job is to exercise its expertise to make tough choices about which of the competing estimates is most plausible, and to hazard a guess as to which is correct, even if the lack of [directly relevant data] means that the estimate will be imprecise." *Pub. Citizen v. FMCSA*, 374 F.3d 1209, 1221 (D.C. Cir. 2004); *see also Bus. Roundtable*, 647 F.3d at 1150. It is not "sufficient for an agency to merely recite the terms 'substantial uncertainty' as a justification for its actions." *State Farm*, 463 U.S. at 52. An agency cannot realistically determine that a rule's benefits justify its costs if it does not have at least a general grasp of the rule's benefits.

There is no valid reason why FDA could not form at least a rough estimate of the Rule's benefits. FDA has quantified the benefits of health-focused rules before. In 2003, for example, FDA proposed a rule on the quality requirements for medical gloves to reduce the risk that HIV and other diseases would be transmitted during medical procedures. *See* 68 Fed. Reg. 15,404, 15,408 (Mar. 31, 2003). In doing so, FDA was able to quantify the reduction in anxiety that the rule would accomplish, using a "quality-adjusted life span" method—similar to the one discussed in the Rule (AR023,926)—to determine that the Rule would generate approximately $1.4 million in annual anxiety-reduction benefits. 68 Fed. Reg. at 15,413.[18] If FDA can

[18] *See also* 62 Fed. Reg. 55,852, 55,963–67 (Oct. 28, 1997) (FDA mammography-standards rule concluding that reducing the prevalence of false-positive tests would generate "$12.7 million" in benefits).

quantify the benefits of reducing anxiety, it can surely quantify the benefits of regulating consumer products such as vaporizers and e-liquids.

The Rule seeks to sidestep this error by employing a "break-even analysis," but that impressionistic inquiry is insufficient because (as FDA admits) it "is neither a benefit-cost analysis nor a measure of welfare gain." (AR023,922.) FDA's break-even analysis is also arbitrary because it relies on amorphous and unquantified benefits, such as "better align[ing] actual consumption and production decisions with socially optimal patterns." (AR024,026.) While not categorically barred from considering such benefits, agencies should rely on them only when a rule's effects are "impossible to quantify" despite the agency's "best attempt[s]." *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201, 1219 (5th Cir. 1991). Even in those cases, unquantified benefits may be used only to "tip the balance in close cases"; "[t]hey cannot … be used to effect a wholesale shift" in the analysis or as "a trump card allowing the [agency] to justify any cost calculus, no matter how high." *Id.*

Second, FDA substantially understates the Rule's costs. As outlined in Part II.C, *supra*, the Rule's estimates regarding the PMTA burden are divorced from reality. In addition, FDA arbitrarily elected *not* to quantify a wide range of costs, including: (i) costs to consumers of vaping products "due to loss of product variety or higher prices"; (ii) "recordkeeping costs for exporters of deemed tobacco products"; (iii) "compliance costs for components and parts other than complete … [vaping] delivery systems"; (iv) "the cost of testing and reporting for" harmful and potentially harmful constituents; and (v) "market adjustment (friction) costs" such as lost reve-

nues, job losses, and companies in the vaping industry going out of business. 81 Fed. Reg. at 29,075. (*See also* AR024,013–15, AR024,021–24.[19])

These costs are massive. The compliance burden for components and parts is illustrative. FDA estimates that PMTAs will be submitted for 1,250–2,500 e-liquids and 360–450 vaporizer systems (AR023,959), and each of these products consists of numerous components and parts. A vaporizer system typically includes a mouthpiece, battery, heating coil, storage tank, wiring, programmable software, and digital display; while e-liquid products involve the e-liquid itself, the vial or container in which the e-liquid is stored, a lid or stopper, etc. 81 Fed. Reg. at 29,016. (*See also* AR129,122–3.) *All* of those individual components will need to go through the PMTA process, which FDA says on average will cost over $465,000 and take 1,500 hours per application. If each of the 1,610–2,950 vaping products for which PMTAs are expected involve, on average, 4 components or parts (a conservative es-

[19] Compounding this arbitrary and capricious decision, FDA did not consider or respond to numerous comments and presentations made during meetings, at which FDA staff was present, with OMB's Office of Information and Regulatory Affairs, as none of these materials were produced in the Administrative Record, even though the Rule acknowledges that "FDA consulted with other Federal Agencies during the Federal Agency review process, required by Executive Order 12866." 81 Fed. Reg. at 28,983. *See* OMB, OIRA, RIN-0910-AG38 (listing 59 meetings involving OMB, FDA, and other parties, most with linked documents submitted at these meetings), www.reginfo.gov/public/do/eom12866SearchResults?view=yes &pagenum=0. The Rule states that "FDA has not received any data indicating that regulation 'will destroy almost all of the e-cigarette products on the market.'" 81 Fed. Reg. at 29,077. But Consumer Advocates for Smoke-free Alternatives Association provided comments and data at an OMB/OIRA meeting attended by Scott Chesemore of FDA demonstrating that "the net effect of the proposed regulations will be to permanently ban on the order of 99.99% of the roughly 100,000 e-cigarette products on the market today" and that the Rule "would immediately eliminate an entire sector of small and medium businesses from the country." CASAA Report to OMB/OIRA (Dec. 15, 2015), www.reginfo.gov/public/do/viewEO12866Meeting?viewRule=true&rin=0910AG38&meetingId=1456&acronym=0910HHS/FDA.

timate), then the aggregate cost of compliance will be $2.9–5.5 billion and 9.6–17.7 million hours (1,102–2,020 years). FDA cannot pretend that these costs do not exist.

The "unquantified" social costs will be significant as well. FDA admits that the Deeming Rule may backfire by causing users of vaping products to switch to more risky conventional tobacco products. (AR023,960, AR023,977; *see also* AR023,931 ("A reduction in the supply of electronic cigarettes could under some conditions yield negative health benefits").) FDA's purported cost-benefit analysis mentions this possibility, but then fails to consider it when determining whether the Rule's benefits justify its costs. (AR023,915–17.) FDA violated the APA by failing to bring its expertise to bear and "make tough choices" about the probable cost of these burdens. *Pub. Citizen*, 374 F.3d at 1221; *see also State Farm*, 463, U.S. at 52 ("uncertainty" does not excuse agency from the need to "exercise its judgment").

Third, FDA loads the dice by excluding the unquantified costs from its break-even analysis. FDA divides the Rule's total *quantified* costs by FDA's estimate of the number of tobacco product users, and then subjectively concludes that the Rule is justified because society is willing to pay the resulting amount to obtain the Rule's *unquantified* benefits. (AR023,915–17.) But FDA did *not* factor the unquantified costs into this analysis *at all*—for instance by recognizing that its willingness-to-pay number significantly underrepresented the Rule's *actual* costs, including the cost of product and firm exit from the market, billions of dollars in component compliance costs, testing for harmful constituents, and the health costs associated with consumers using cigarettes rather than vaping products.

Agencies may not treat costs and benefits inconsistently in this fashion. In *Ctr. for Biological Diversity v. NHTSA*, 538 F.3d 1172, 1198 (9th Cir. 2008), the court invalidated a rule in part because the agency had "put a thumb on the scale by undervaluing the benefits and overvaluing the costs of more stringent standards." The agency's cost-benefit analysis was "arbitrary and capricious because" the agency refused to quantify one set of uncertain benefits—the value of reducing carbon emissions—but "monetized other uncertain benefits, such as the reduction of … crash, noise, and congestion costs." *Id.* at 1202. The Deeming Rule suffers from all the same methodological defects. *See Bus. Roundtable*, 647 F.3d at 1151–52 (vacating SEC rule because its cost-benefit analysis "discounted the costs of" the Rule "but not the benefits" and "duck[ed] serious evaluation of [certain] costs").

Fourth, and finally, the Rule fails to determine whether the cost of regulating *vaping products* is justified by the benefits associated with such regulation. True, the Rule concludes that its overall benefits justify its overall costs (AR023,915–17), but this omnibus assessment is insufficient because the Rule addresses a broad range of products and issues, many of which have no bearing on the vaping industry. *E.g.*, 81 Fed. Reg. at 29,020–27 (cigars). The cost of regulating vaping products makes up the overwhelming majority of the Rule's total cost (AR024,009), and given the evidence that vaping products are substantially less harmful than cigarettes, it is far from clear that the marginal benefits of regulation justify the towering costs.

IV. The Deeming Rule Violates The First Amendment.

The Rule violates not only the APA, but the Constitution, as FDA has failed to meet its burden to justify restrictions on commercial speech. The Rule bans manufacturers, distributors, and retailers from distributing "free samples" of vaping products ("the sampling ban"). 81 Fed. Reg. at 29,054 (citing 21 C.F.R. § 1140.16(d)). And it prohibits these companies from making truthful, non-misleading statements about their products without FDA's prior approval. *Id.* at 29,053 (citing TCA § 911). In doing so, the Rule violates Nicopure's First Amendment rights.

The First Amendment protects commercial speech from "unwarranted governmental regulation." *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557, 561 (1980). Whether a restriction on commercial speech is valid under *Central Hudson* turns on four interrelated questions:

(1) whether the speech concerns lawful 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). FDA bears the burden of justifying restrictions on commercial speech.[20] *Edenfield v. Fane*, 507 U.S. 761, 770 (1993).

[20] In the Rule, FDA implies (incorrectly) that the public (through its comments) bore the burden of "provid[ing] evidence demonstrating that the distribution of free samples of [vaping products] would be consistent with protecting public health." 81 Fed. Reg. at 28,987.

Furthermore, "[t]he First Amendment requires heightened scrutiny whenever the government creates a regulation of speech because of disagreement with the message it conveys." *Sorrell v. IMS Health*, 564 U.S. 552, 566 (2011). While the D.C. Circuit has not yet addressed the issue, other courts have interpreted *Sorrell* to impose a two-step inquiry. *First,* a court determines whether the government has imposed content- and speaker-based restrictions. If so, heightened scrutiny applies. If not, then intermediate scrutiny applies. In either case, the court analyzes the *Central Hudson* factors, applying the appropriate level of scrutiny.[21]

Heightened scrutiny should apply here because the Rule imposes content- and speaker-based restrictions: it applies to manufacturers and distributors of vaping products, and bars them from making a specific, content-based class of statements about those products. But, as demonstrated below, the Rule fails the *Central Hudson* analysis, even without heightened scrutiny.

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

The Deeming Rule's prohibition of sampling of vaping products does not pass muster under *Central Hudson*, let alone under heightened scrutiny.

1. Samples are protected speech.

The Supreme Court has recognized that any form of solicitation "may have considerable value" by "allow[ing] direct and spontaneous communication between

[21] *See 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); *United States v. Caronia*, 703 F.3d 149, 163–64 (2d Cir. 2012); *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).

buyer and seller" and "more personal interchange." *Edenfield*, 507 U.S. at 766. Sampling allows buyers to "meet and evaluate" sellers and "explore in detail the way in which a particular product or service compares to its alternatives in the market." *See id.* These benefits are even more significant for "nonstandard products," *id.*, like those in the vaping industry. And the courts unanimously recognize that free samples are protected speech. *See, e.g.*, *Discount Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509, 538 (6th Cir. 2012) (holding that sampling is protected speech because it is a "promotional method[] that convey[s] the twin messages of reinforcing brand loyalty and encouraging switching from competitors' brands"); *Bailey v. Morales*, 190 F.3d 320, 321, 325 (5th Cir. 1999) (restrictions on "promotional gifts and items" offered by chiropractors violated the First Amendment); *Rockwood v. City of Burlington, Vt.*, 21 F. Supp. 2d 411, 415, 421–22 (D. Vt. 1998) (distribution of free samples was protected speech).[22]

2. The purported governmental interest is not furthered by the regulation of the protected speech.

The second and third parts of the *Central Hudson* framework are interrelated, with the second step asking "whether the asserted governmental interest served by the speech restriction is substantial" and third step asking "whether the speech

[22] In the Rule, FDA proffered its "*belie[f]* that distribution of free samples" lacks a "significant expressive element" and is "conduct not speech." 81 Fed. Reg. at 28,986 (emphasis added). But FDA's "belief" is not the law. The Rule also asserts that "a free sample ban is akin to a price restriction (*i.e.*, tobacco products cannot be free)" or a restriction on distribution—"form[s] of regulation that would not involve any restriction on speech." *Id.* Notably, the Sixth Circuit reversed the lower court's materially similar "sampling is not speech" rationale. *See Discount Tobacco*, 674 F.3d at 539.

restriction directly and materially advances the asserted governmental interest." *Greater New Orleans*, 527 U.S. at 185, 188. While Nicopure agrees that FDA has asserted a substantial interest (to "eliminate a pathway for youth to access tobacco products," 81 Fed. Reg. at 28,996), FDA has *not* demonstrated that the sampling ban will directly and materially advance this interest. Instead, FDA relies on conjecture and unproven belief. (FDA cites one reference to support the proposition that "free samples of cigarettes 'encourage experimentation by minors with a risk free and cost-free way to satisfy their curiosity.'" *Id.* at 29,054. But that study, more than two decades old, concerned only youth smoking of cigarettes.[23])

Without any analysis, FDA proclaims that it "*believes* that the same rationale [in that article] applies to [vaping] products." *Id.* (emphasis added). But FDA cannot satisfy its burden through "mere speculation or conjecture." *Edenfield*, 507 U.S. at 770; *see also Cent. Hudson*, 447 U.S. at 569 (rejecting the link between the interest and restriction as "tenuous").

FDA also cites *Discount Tobacco*'s inapposite conclusion that a sampling ban *on cigarettes* was supported by sufficient evidence that free samples of *cigarettes* were an "easily accessible source" for youth. 674 F.3d at 541. But this Court is not bound by the Sixth Circuit's assessment of a sampling ban on cigarettes, particularly when that decision both conflicts with prior case law and relies on evidence that is (at best) distantly relevant to current youth, products, markets, and norms vis-à-

[23] *See* Institute of Medicine of the National Academies, *Growing up Tobacco Free: Preventing Nicotine Addiction in Children and Youths* (1994), *available at* www.nap.edu/catalog/4757.html.

vis vaping products. *See Rockwood*, 21 F. Supp. 2d at 415, 423 (finding that a ban on the distribution of free samples was not "narrowly tailored to reduce underage smoking" because there were "alternative means of achieving" the aims of the restrictions); *Discount Tobacco*, 674 F.3d at 540–41 (citing various articles from 1994 and the 2000s about minors' use of traditional tobacco products).

In short, FDA failed to prove "the effectiveness" of the sampling ban "in fact" would reduce minors' access to vaping products to a material degree. *Nat'l Ass'n of Mfrs. v. SEC*, 800 F.3d 518, 524–25, 527 (D.C. Cir. 2015). FDA cannot rely on a "rote invocation" that a product may end up in the hands of minors, *Alexander v. Cahill*, 598 F.3d 79, 91 (2d Cir. 2010), but must instead "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), abrogated on other grounds by *Am. Meat Inst. v. U.S. Dep't of Agric.*, 760 F.3d 18, 22–23 (D.C. Cir. 2014) (en banc).

3. The total ban on sampling is more extensive than necessary.

Even if FDA had proven that the sampling ban will materially further a substantial interest, the ban is still "more extensive than is necessary to serve that interest." *Greater New Orleans*, 527 U.S. at 183–84. Restrictions on speech must be "narrowly drawn." *Cent. Hudson*, 447 U.S. at 567. "On the whole," the restriction should indicate that FDA "carefully calculated the costs and benefits associated with the burden on speech imposed by its prohibition." *Greater New Orleans*, 527 U.S. at 188 (quoting *City of Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 417 (1993)). Rather than conduct this careful calculation, FDA opted for the most extensive ban possible as a matter of first preference.

Comments to the proposed rule noted the overbreadth and harms of the ban. Consumers told FDA that free samples are "necessary to convince cigarette users to switch to" vaping because "their products are new." 81 Fed. Reg. at 29,054. Rather than address these concerns, FDA "clarif[ies]" that customers can "touch, hold, and smell" a product if they do not inhale or use it—a clarification that is of no use for vaping products. *Id.* Commenters also proposed various less restrictive alternatives, including those used with smokeless tobacco—namely, the limiting of free samples to adults at qualified-adult only facilities, but also prohibiting samples from leaving store premises and prohibiting the distribution of free samples at public events. *Id.* at 28,985–86, 29,054. With no explanation, FDA rejected these comments with the unsupported *ipse dixit* "belie[f]," that "it could [not] achieve the same results by allowing samples of newly deemed products in qualified adult-only facilities ["QAOF"], as FDA does with smokeless tobacco." *Id.* at 28,986.

The Rule thus demonstrates that, rather than engage in the careful consideration and analysis that *Central Hudson* requires, FDA acted on "the first strategy the Government thought to try." *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 373 (2002). "If the First Amendment means anything, it means that regulating speech must be a last-not first-resort." *Id.* But FDA has instead adopted a "blanket ban," especially "disfavored in the law" when less intrusive means are available. *See, e.g.*, *FF Cosmetics FL Inc. v. City of Miami Beach, Fla.*, 129 F. Supp. 3d 1316, 1326 (S.D. Fla. 2015); *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 500 (1996) (stating that "special care" should be taken in reviewing blanket bans).

B. The regulation of truthful, non-misleading statements about vaping devices and e-liquids violates the First Amendment.

The Deeming Rule further violates the First Amendment by subjecting Nicopure's truthful, nonmisleading statements about the contents of its product to FDA pre-review and approval under the MRTPR provisions of the TCA. While the pre-review process, in theory, only restricts modified risk claims, in practice it "effectively produce[s] a total ban." *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 583 n.3 (2001). FDA has *never* approved a modified risk tobacco product application.[24] Only one application—which included over 135,000 pages encompassing 50 years of data—has ever even been *considered* for review by FDA.[25]

1. Nicopure has standing to challenge to this aspect of the Deeming Rule.

Nicopure has standing to challenge the Rule's subjection of its products to the MRTPR provisions because Nicopure faces a credible and immediate threat of enforcement. Such a threat "can simultaneously ripen a preenforcement challenge and give the threatened party standing." *Navegar, Inc. v. United States*, 103 F.3d 994, 998 (D.C. Cir. 1997). Here, standing and ripeness boil down to whether there exists a "concrete and particularized" and "actual or imminent" threat of injury to Nicopure. *Susan B. Anthony List v. Driehaus*, 134 S. Ct. 2334, 2341 (2014). This

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[24] *See* FDA Advertising & Promotion Guidance for Modified Risk Tobacco Products, www.fda.gov/TobaccoProducts/Labeling/MarketingandAdvertising/ucm304465.htm.

[25] *See ibid*. Commentators have expressed skepticism that the application will be approved. *See* Sabrina Tavernise, *Swedish Company Asks F.D.A. to Remove Warnings From Smokeless Tobacco Product*, N.Y. Times (Apr. 8, 2015), www.nytimes.com/2015/04/09/health/swedish-company-asks-fda-to-remove-warnings-from-smokeless-tobacco-product.html.

requirement is met when a plaintiff alleges "(i) an intention to engage in a course of conduct arguably affected with a constitutional interest, (ii) but proscribed by a statute, and (iii) there exists a credible threat of prosecution thereunder." *Babbitt v. United Farm Workers Nat'l Union*, 442 U.S. 289, 298 (1979) (numbering added).

Nicopure meets these elements. *First*, Nicopure is engaged in a course of conduct affected with a constitutional interest. Nicopure states on the website for its Halo-branded e-liquid that "no smoke is released," "there is no [t]ar," and "[n]o ash" is made from vaping. (Stamler Decl. ¶ 45.) Nicopure wishes to continue making these statements, which are speech protected by the First Amendment. *See Lorillard*, 533 U.S. at 571.

Second, the Rule threatens Nicopure's intended future conduct with prohibition. Under the MRTPR, "[n]o person may introduce or deliver … any modified risk tobacco product" without first obtaining an order from FDA. 21 U.S.C. § 387k(a). This includes a label or advertising which represents that a product "does not contain or is free of a substance." *Id.* § 387k(b)(2)(A)(i); *see also* 81 Fed. Reg. at 29,062 (Rule applies to "Internet web pages"). The statements that "no smoke is released," "there is no [t]ar," and "[n]o ash" is made from vaping are subject to the MRTPR.

Finally, the threat of future enforcement is substantial. FDA enforcement under the MRTPR is a common occurrence. Since December 2010, FDA has issued 244 enforcement letters that allege violations of the MRTPR.[26] Indeed, there is a

[26] *See* FDA Warning Letters (search for "modified risk tobacco product"), www.fda.gov/ICECI/EnforcementActions/WarningLetters.

history of past enforcement against others who have made the type of statements that Nicopure wishes to continue making, including products described as having a "small amount of tar"[27] or "reduc[ing] the amount of smoke."[28] The circumstances here are thus analogous to those in *Susan B. Anthony*, in which the Supreme Court held that Article III standing requirements were met by plaintiffs who raised a preenforcement challenge to a law prohibiting "false statements" during a political campaign. *Susan B. Anthony*, 134 S. Ct. 2334.

2. FDA's professed interests are not directly and materially advanced by its regulation of truthful, non-misleading speech about vaping products.

"Truthful advertising related to lawful activities is entitled to the protections of the First Amendment." *In re R.M.J.*, 455 U.S. 191, 203 (1982). In nevertheless subjecting that speech to regulation, FDA advances two interests: (i) "public health benefits" and (ii) preventing the "use of unsubstantiated modified risk claims, which may mislead consumers." 81 Fed. Reg. at 28,976, 29,039. Because FDA fails to show how the MRTPR directly and materially advance either interest, the Court should set aside FDA's decision.

First, FDA does not meet its burden to show the Rule "directly advance[]" FDA's stated interest in protecting public health. *Cent. Hudson*, 447 U.S. at 566. As FDA concedes, vaping products "are different than conventional tobacco products." 81 Fed. Reg. at 28,997, offer "substantial reductions in the exposure to harmful con-

[27] FDA Warning Letter to Alexander Carter, www.fda.gov/iceci/enforcementactions/warningletters/2015/ucm445430.htm (May 1, 2015).

[28] FDA Warning Letter to www.cigoutlet.net, www.fda.gov/iceci/enforcementactions/warningletters/2015/ucm463528.htm (Sept. 15, 2015).

stituents," and eliminate "most of the chemicals causing smoking-related disease from combusted tobacco use." *Id.* at 29,030–31.

FDA would have to show that the MRTPR, by restricting truthful and non-misleading speech about the contents or characteristics of using vaping products, somehow benefits the public health on a population-wide basis. As shown in Part II.A, *supra*, FDA admits that it cannot. *Id*. at 29,028 ("[The FDA] do[es] not have sufficient data to determine what effects e-cigarettes have on public health at the population level."). Instead, the Rule reports powerful contrary evidence: "[T]here is emerging data that some individual smokers may potentially use [vaping] to transition away from combustible tobacco products." *Id.* at 29,037. Consumers who vape had a "higher quit rate [20%] than those who used [nicotine replacement therapies] like patches or gum [10%] or those that did not use a cessation aid [15%]." *Id.*

Second, FDA contends that the MRTPR "will prevent the use of unsubstantiated modified risk claims, which may mislead consumers[.]" *Id.* at 29,053. But "rote invocation of the words 'potentially misleading,'" cannot "supplant the [government's] burden to 'demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree.'" *Ibanez v. Fla. Dep't of Bus. & Prof'l Regulation*, 512 U.S. 136, 146 (1994) (quoting *Edenfield*, 507 U.S. at 771). Otherwise, any restriction of speech could be justified on such grounds.

FDA offers no evidence that consumers have been, or will be, misled by the vaping industry. Nor is it disputed that Nicopure's statements regarding the lack of smoke, ash, or tar from its products are truthful. As discussed, FDA concedes that

vaping products are "less hazardous for an individual user than continued smoking of traditional cigarettes."). 81 Fed. Reg. at 29,035. FDA's concern about "the possibility of deception in hypothetical cases is not sufficient to rebut the constitutional presumption favoring disclosure over concealment." *Peel v. Attorney Registration & Disciplinary Comm'n of Ill.*, 496 U.S. 91, 111 (1990); *cf. Brown v. Entm't Merchs. Ass'n*, 564 U.S. 786, 803 n.9 (2011) ("[T]he government does not have a compelling interest in each marginal percentage point by which its goals are advanced.").

FDA also suggests that the Rule is justified based on a history of "inaccurate and harmful health claims" made by "the [tobacco] industry." 81 Fed. Reg. at 28,987. But FDA cites no history of deception with respect to vaping. The vaping industry includes different companies and different products. As FDA recognizes: (1) there is substantial evidence that vaping products are actually less harmful than traditional cigarettes; and (2) vaping products "are different than conventional tobacco products." *Id.* at 28,997. In light of these material differences, different regulation of truthful, non-misleading speech is warranted.

3. The MRTPR is more extensive than necessary to serve the professed interests regarding vaping products.

Even if the professed interests are advanced by applying the MRTPR to vaping products, FDA fails to show the restrictions are not "more extensive than is necessary" to serve the government's interests. *Cent. Hudson*, 447 U.S. at 566.

When the government asserts an interest in protecting consumers from potentially misleading commercial speech, "the preferred remedy is more disclosure, rather than less." *Bates v. State Bar of Ariz.*, 433 U.S. 350, 375 (1977). In particular,

the Supreme Court has "repeatedly point[ed] to disclaimers as constitutionally preferable to outright suppression." *Pearson v. Shalala*, 164 F.3d 650, 657 (D.C. Cir. 1999) (collecting cases). Instead of restricting Nicopure from disseminating truthful information to consumers, FDA could have simply required disclaimers, such as that the statements: (i) are not approved by FDA; (ii) do not establish that the product is safer than any other tobacco product; or (iii) do not change the fact that quitting nicotine products altogether is healthier than using vaping products.

FDA's blanket approach further fails to recognize that Nicopure has a constitutionally protected interest in "conveying truthful information about [its] products to adults, and adults have a corresponding interest in receiving truthful information about [Nicopure's] products." *Lorillard*, 533 U.S. at 564. A consumer choosing between purchasing Nicopure's e-liquid, or a competitor's e-liquid that contains diacetyl or acetyl propionyl, would not have the benefit of knowing which product is free of those substances. (Stamler Decl. ¶ 46.) Consumers routinely inquire about ingredients because of allergies and other concerns. But the Rule prohibits Nicopute from even making a truthful statement that, for instance, its products do not contain peanuts, a known allergen. Because the First Amendment "directs [courts] to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good," the Rule's application of the MRTPR to vaping products should be vacated. *44 Liquormart*, 517 U.S. at 503.

CONCLUSION

In the Deeming Rule, FDA has purported to regulate products outside the scope of its statutory authority. It has purported to subject Nicopure and the rest of the vaping industry to crushing regulation in the interest of the public health while conceding that there may not be any public health interest in the regulation. FDA compounded this improper approach by ignoring reasonable, more flexible alternatives to the "all-or-nothing" approach taken with respect to vaping products. The agency also abdicated its obligation to conduct a reasoned cost-benefit analysis. And it has violated Nicopure's First Amendment rights. This Court should set aside the Deeming Rule's regulation of vaping devices and e-liquids.

Respectfully submitted,

/s/

Benjamin C. Block
(D.C. Bar No. 479705)
Kevin King
(D.C. Bar No. 1012403)
COVINGTON & BURLING LLP
One City Center
850 Tenth Street, NW
Washington, DC 20001-4956
(202) 662-5205 (Telephone)
(202) 778-5205 (Fax)
bblock@cov.com
kking@cov.com

Counsel for Plaintiff
Nicopure Labs, LLC

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