ORAL ARGUMENT REQUESTED

CASE NO. 17-5196

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

Nicopure Labs, LLC and
Right To Be Smoke-Free Coalition,

Appellants,

v.

Food and Drug Administration, et al.,

Appellees.

On Appeal from the United States District Court for the District of Columbia
Case No. 1:16-cv-00878-ABJ
Hon. Amy Berman Jackson, U.S. District Judge

REPLY BRIEF OF APPELLANTS NICOPURE LABS, LLC AND RIGHT TO BE SMOKE-FREE COALITION

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GLOSSARY

ACS	American Cancer Society
APA	Administrative Procedure Act
FDA	Food and Drug Administration
FDCA	Food, Drug and Cosmetic Act
HPHC	Harmful and Potentially Harmful Constituent
LLM	Low, Light, and Mild
MRTP	Modified Risk Tobacco Product
NAS	National Academies of Sciences
PMTA	Pre-Market Tobacco Application
QAOF	Qualified-Adult-Only Facilities
TCA	Tobacco Control Act

INTRODUCTION

The Food and Drug Administration's ("FDA") appellee brief downplays the substantial public health benefits of vapor products for adult smokers, FDA Br. at 10-18, even though FDA stated numerous times during the rulemaking that vapor products are less harmful than traditional cigarettes, Nicopure Br. at 7. Moreover, one of FDA's supporting *amici* – the American Cancer Society ("ACS") – recently determined "[b]ased on currently available evidence, using current generation e-cigarettes is less harmful than smoking cigarettes," and concluded "switching to the exclusive use of e-cigarettes is preferable to continuing to smoke combustible products."[1] In announcing its Comprehensive Plan for regulating tobacco and nicotine, FDA recognized it must "strik[e] an appropriate balance between regulation and encouraging development of innovative tobacco products that may be less dangerous than cigarettes."[2] FDA Commissioner Dr. Scott Gottlieb and Mitch Zeller, Director of FDA's Center for Tobacco Products, also wrote in the *New England Journal of Medicine* that vapor products, when combined with

[1] ACS, *Position Statement on Electronic Cigarettes* (Feb. 15, 2018), https://tinyurl.com/ybadn9cl.

[2] FDA News Release, *FDA Announces Comprehensive Regulatory Plan to Shift Trajectory of Tobacco-Related Disease, Death* (July 28, 2017), https://tinyurl.com/y7bybf6c.

measures to reduce nicotine levels in cigarettes, "represent[] a promising foundation for a comprehensive approach to tobacco harm reduction."[3]

All of this is consistent with a recent National Academies of Sciences ("NAS") report commissioned by FDA that confirms vaping is less risky than smoking. The report, which is based on a review of over 800 articles, found: (i) conclusive evidence that completely substituting vaping with smoking reduces exposure to numerous toxicants and carcinogens; (ii) current evidence shows vapor products are less harmful than cigarettes; (iii) substituting vaping for smoking significantly reduces levels of biomarkers of exposure to toxicants; and (iv) vaping exclusively might be useful as a cessation aid in smokers.[4]

FDA's positions in this litigation, however, are at complete odds with these findings and the government's stated goals. The Modified Risk Tobacco Product ("MRTP") provision and free sample ban prevent vapor companies from making truthful statements and conveying information that would help adult consumers make informed decisions regarding vaping. This would include disclosures regarding specific exposure issues (*e.g.*, diacetyl) that consumers are discussing today and companies, armed with truthful information, should be able to make.

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[3] Scott Gottlieb, *et al.*, *Perspective: A Nicotine-Focused Framework for Public Health*, New Eng. J. Med. (Sept. 21, 2017), https://tinyurl.com/yatrpq68.

[4] NAS, PUBLIC HEALTH CONSEQUENCES OF E-CIGARETTES, at S-9, 18-2, 18-13, 18-23, https://tinyurl.com/ycxlymgf.

The Pre-Market Tobacco Application ("PMTA") will also force the vast majority of vapor companies and less harmful vapor products out of the market absent some tailoring of certain requirements. While the vapor industry is committed to preventing youth access,[5] the regulation of vapor products is not a one-sided affair. Under the First Amendment and Administrative Procedure Act ("APA"), Congress and FDA were required to adequately consider the interests of adult consumers and particularly those who are looking to move away from more dangerous cigarettes. Both failed in this regard.[6]

SUMMARY OF ARGUMENT

Congress and FDA had the burden to justify the MRTP and free sample speech restrictions and the overly stringent application of the PMTA. Of particular significance, Congress and/or FDA:

MRTP

- Failed to produce any evidence that the types of statements challenged in this case could potentially mislead the smoking/vaping public;
- Ignored multiple instances where third parties, including FDA itself and at least one *amici,* can and do make precisely the same or similar

[5] For example, JUUL Labs has dedicated $30 million over the next three years to fight underage access. Press Release, *JUUL Labs Announces Comprehensive Strategy To Combat Underage Use* (Apr. 25, 2018), https://tinyurl.com/y7p2aoeh.

[6] FDA incorrectly states Appellants' suit arises solely under the APA and is thus limited to the administrative record. FDA Br. at 14-15 n.7. Appellants also challenge the Tobacco Control Act ("TCA") under the U.S. Constitution and therefore may rely on materials outside the administrative record.

statements, thus undermining the effectiveness of the MRTP provision;

- Failed to apply a rigorous form of intermediate scrutiny to the MRTP's content- and speaker-based restrictions; and

- Did not adequately consider a number of less intrusive alternatives (*e.g.*, disclaimers, FDA and FTC enforcement) to the MRTP's speech restrictions on vapor companies.

Free Samples

- Ignored their own statements showing an intent under the TCA and Deeming Rule to regulate communications through free samples;

- Improperly analogized free samples to pricing restrictions and product sales;

- Failed to show minors are gaining access to free samples of vapor products through adult-only channels;

- Did not adequately consider less burdensome alternatives to banning free samples that distinguish between adult- and youth-oriented venues; and

- Ignored the fact that vapor companies have no other ample alternatives to adequately convey important information to consumers.

PMTA

- Failed to tailor the PMTA process to the vapor industry, which in FDA's own words manufacture products that are less risky, so companies may rely on evidence other than long-term clinical or epidemiological studies to satisfy the "population effects" standard.

ARGUMENT

I. FDA Fails To Demonstrate The MRTP Provision Comports With The First Amendment When It Prohibits Truthful Statements Regarding Vapor Products

FDA argues the MRTP provision passes constitutional muster by deferring to congressional findings in the TCA, even though those dealt with the deadliest tobacco products, and insisting that only the vapor industry bears the burden of showing the challenged statements are not misleading. In doing so, FDA ignores numerous obligations imposed on the government by Supreme Court precedent before it can regulate the speech at issue here.[7]

First, FDA puts the cart-before-the-horse by insisting it is Appellants' duty – not the government's – to demonstrate in the first instance that entirely truthful statements are not potentially misleading. FDA Br. at 37-38. While FDA argues it has a strong interest in preventing misleading claims, merely because "asserted

[7] This Court should also reject, as did the District Court below, FDA's argument that the MRTP requirement is not subject to First Amendment protection because it resembles pre-market review for new drugs under the Food, Drug and Cosmetic Act ("FDCA"). FDA Br. at 27-30. The FDCA defines "drug" to include articles "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease." 21 U.S.C. §321(g)(1)(B). FDA maintains that under *Whitaker v. Thompson*, 353 F.3d 947 (D.C. Cir. 2004), it was not a First Amendment violation for FDA to rely on a drug's label to infer intent. But the MRTP does not turn on manufacturer intent. Instead, merely indicating the absence/amount of a substance or describing a product's characteristics is sufficient to require MRTP approval. Intent is irrelevant. 21 U.S.C. §387k(b)(2). *Discount Tobacco City & Lottery, Inc. v. U.S.*, 674 F.3d 509, 534 (6th Cir. 2012) (rejecting *Whitaker* argument).

interests are substantial in the abstract does not mean, however, that [a] blanket prohibition on solicitation serves them." *Edenfield v. Fane*, 507 U.S. 761, 770 (1993). Before restricting any speech, Congress and FDA had to show through studies, anecdotal evidence, or other support that the challenged statements – *e.g.*, simply listing the absence/amount of a substance – could mislead consumers to a significant degree. *Id.* at 770-71; Nicopure Br. at 25. It is not enough that Congress or FDA could reasonably conclude such statements might be misleading. *Edenfield*, 507 U.S. at 771 (government must show "harms it recites are real," and the restriction "will in fact alleviate them to a material degree."); *Greater New Orleans Broad. Ass'n v. United States*, 527 U.S. 173, 182 (1999) (rejecting reasonable basis approach seen in *Posadas de Puerto Rico Assocs. v. Tourism Co.*, 478 U.S. 328, 341-42 (1986)).

FDA cites nothing in the TCA or administrative record showing any consideration was given to these types of statements for vapor products. Rather, Congress and FDA relied on "low," "light," and "mild" ("LLM") claims made by cigarette companies and assumed other statements relating to entirely different products that actually move smokers away from cigarettes would have the same effect. Nicopure Br. at 20. But LLM claims are nothing like the objectively true statements the vapor industry would like to make (*e.g.*, "no ash," "no diacetyl," or "no peanut allergens"). FDA maintains that statements made by the vapor

industry, albeit technically true, might be misleading depending on context. FDA Br. at 37-38 ("Congress reasonably determined" the restrictions were necessary). But this resembles the deferential approach in *Posadas* that has been abandoned. Indeed, one *amici's* attempt to bolster FDA only illustrates the dangers of assuming, without more, that a truthful statement can also be misleading. *Amici* hypothesize that "[i]f consumers are faced with a choice between 'no ash' e-liquids and regular e-liquids, there can be *no doubt* that a *significant number* will reasonably interpret 'no ash' to imply "healthier." First Amend. Scholars Br. at 20 (emphasis added). Given that no e-liquid contains ash – which is Appellants' point – it would be pure speculation to assume, without some evidence, how consumers would react to a "no ash" claim. It may be most consumers simply want to avoid ash and would not ascribe some larger significance to the claim and conclude the e-liquid is safer overall than other tobacco products.

In fact, FDA's shortcomings highlight a fundamental challenge with how Congress set up the TCA's deeming provision. Congress initially regulated cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco under the TCA, all products with long-existing, well-understood markets and risk profiles. 21 U.S.C. §387a(b). But FDA is also allowed to deem "any other tobacco product," including products that are novel and substantially different. This includes not only vapor products, which were in their infancy when the TCA

was adopted, but also tobacco products that have yet to be invented. In fact, in the Deeming Rule, FDA deemed all tobacco products going forward, whether they exist today or not. 81 Fed. Reg. 28,974 (May 10, 2016). But under this approach, FDA cannot simply assume unique and less risky products, like e-liquids and devices, are similar to those known by Congress when it passed the TCA. The judgment calls made by Congress in 2009, based on a long history of fraud committed by cigarette companies, do not necessarily apply years or decades later to non-cigarette manufacturers. Rather, in terms of the First Amendment, FDA must develop some record evidence that accounts for different characteristics and adjust accordingly. Unfortunately, that did not happen in the instant case.[8]

FDA's failure to initially justify these restrictions also moots any arguments that Appellants have inappropriately brought a facial challenge or asked the Court to apply the "overbreadth doctrine" to commercial speech. FDA Br. at 37; First Amend. Scholars Br. at 21 n.7; Public Citizen Br. at 33-34. There is no need for Appellants to test particular statements through the MRTP process for this Court to find the government failed, before ever applying the MRTP, to show these speech restrictions will directly and materially advance its interests. In any event, this is

[8] As such, FDA cannot rely on *Discount Tobacco* and its findings regarding the MRTP provision in the context of traditional cigarettes. FDA Br. at 43. That case did not involve the types of statements challenged in this case by vapor manufacturers and retailers.

not a facial challenge, but rather an "as applied" challenge limited to vapor products and specific types of objectively truthful statements.

Second, FDA ignores Supreme Court precedent holding that a restriction on speech does not directly and materially advance the government's interest when other parties not subject to the restriction will make the same types of statements to the public, thus working against the government's interests. Nicopure Br. at 26. As discussed above, FDA concludes that consumers might read too much into truthful statements indicating the absence/amount of a substance or describing a product's characteristics. But that risk, at least under FDA's thinking, would already exist because FDA and others will be making the same or similar representations to consumers. Under the TCA, FDA is obligated to publish quantities of "harmful and potentially harmful substances" ("HPHCs") by brand and sub-brand (and by omission indicating a substance's absence) in a way that consumers find understandable and not misleading. 21 U.S.C. §387d(e). Manufacturers of smokeless tobacco can market their products as "not consumed by smoking," "does not produce smoke," or "not smoke." 21 U.S.C. §387k(b)(2)(C). And FDA has stated repeatedly in public that vaping likely presents less overall risk to individuals than smoking cigarettes.

FDA responds that, with respect to its own statements, those are somehow less misleading because they are made in a noncommercial or scientific setting.

FDA Br. at 41. This is nonsensical. It goes without saying that consumers will look to FDA for information and guidance in their purchasing decisions. In fact, the stated purpose of the HPHC listing is to "place [the list] on public display" for the "lay person." 21 U.S.C. §387d(d)(1). It is naïve to assume consumers will not be privy to FDA's statements which are issued through press releases, published on the internet, and tagged on social media. Moreover, there is even a greater likelihood, at least under FDA's rationale, that consumers could imply too much as to relative risk based on FDA's statements because those are being made by an authoritative governmental body. Yet FDA never explains how its statements, or those of the smokeless tobacco industry, are any less likely to mislead than those made by vapor companies.[9]

Finally, the MRTP requirements significantly undermine the government's interests in another way. The MRTP provision guards against misleading statements that might compel consumers to use a relatively harmful product. TCA §2(37). In its opposition, FDA maintains vapor products contain harmful

[9] Similarly, Congress never explained why the exempted statements made by the smokeless tobacco industry would not be potentially misleading. There is no difference between a claim of "smokeless" and a vapor company's claim of "no burning," "no combustion," or "no combusted smoke." Nicopure Br. at 21-22. All are undoubtedly true. FDA also does not question the truthfulness of statements like "no ash" and "no tar." FDA's only objection is to "no tobacco" because e-liquids contain nicotine derived from tobacco. FDA Br. at 36 n.16. But as FDA knows, e-liquids contain highly purified nicotine, a distinct chemical, that has been completely separated from the tobacco leaf. FDA155121. Nicotine is not tobacco.

substances, thus justifying these speech restrictions. FDA Br. at 33-34. But it is the MRTP regulation that also prevents the vapor industry from telling consumers a certain product does not contain (or contains a reduced amount of) those types of substances. Nicopure Br. at 20-21. The MRTP provision thus prevents manufacturers from conveying important information regarding potential risks (as identified by FDA) and consumers from making informed choices to avoid these substances, confirming the MRTP's counterproductive nature.

Third, FDA misses the salient point regarding *Sorrell v. IMS Health Inc.*, 564 U.S. 552 (2011), when arguing the case does not suggest a more exacting level of scrutiny when speech restrictions are content-based. FDA Br. at 39-40 n.17. That decision confirms prior Supreme Court precedent holding when a restriction is content- or speaker-based courts must, at a minimum, apply a particularly rigorous form of intermediate scrutiny under *Central Hudson*. Nicopure 22-34. For example, in *Greater New Orleans*, the Court struck down a restriction on advertising by private casinos but not tribal casinos. 527 U.S. at 176. The Court required the government to justify its line-drawing among different speakers. *Id.* at 193. The Court stated:

> [T]he Government presents no sound reason why such lines bear any meaningful relationship to the particular interest asserted . . . Even under the degree of scrutiny that we have applied in commercial speech cases, decisions that select among speakers conveying virtually identical messages are in serious tension with the principles undergirding the First Amendment.

Id. at 193-94.

Likewise, *Sorrell* struck down a Vermont law banning the use of physician prescribing data by drug companies to protect physician privacy, and in particular to guard against the pressure of knowing that their decisions are being monitored, but allowing the same information to be used by others. 564 U.S. at 575-76. The Court noted the "State does not explain why detailers' use of prescriber-identifying information is more likely to prompt these objections than many other uses permitted by" the law. *Id.* at 576. As discussed above, FDA repeatedly failed to justify their regulation of truthful statements made by vapor companies when others can make the same or similar statements unabated.

Fourth, FDA's argument that the MRTP does not constitute an effective ban on truthful statements is belied by the evidence. FDA Br. at 36. Left unmentioned in FDA's response is its recent prediction that only three MRTPs will be submitted annually, thus leaving countless vapor manufacturers, as a practical matter, unable to inform consumers through truthful claims. Nicopure Br. at 19. Also ignored is the fact that no MRTP has ever been approved. *Id.* at 18. And it is of no moment the MRTP provision provides for an alternative pathway if claims are limited to the absence/amount of a substance. 21 U.S.C. §387k(g); FDA Br. at 35. That pathway, which is discretionary, is exceedingly narrow, *e.g.*, 21 U.S.C. §387k(g)(2)(A), and still requires manufacturers, regardless of the truthfulness of a

claim, to prove the product is not only expected to benefit the health of the population as a whole, but that such claim will not be perceived by consumers to be a reduced-risk claim, 21 U.S.C. §387k(g)(2)(B)(iii)-(iv), §387k(g)(4).

Fifth, FDA provides no indication it considered, as required by Supreme Court precedent, the costs and benefits of less intrusive alternatives to the challenged speech restrictions in the context of vapor products. Nicopure Br. at 30-31. FDA continues to rely on Congress's determination with respect to more dangerous cigarettes and smokeless tobacco that disclaimers would not be effective. FDA Br. at 42-43. But the vapor marketplace is much different. The truthful statements that vapor companies would like to make will help consumers make informed decisions whether to switch away from cigarettes and to (as FDA concedes) a less harmful product. That fact alone makes for a much different cost/benefit analysis under *Central Hudson's* narrow tailoring prong, as the First Amendment promotes the free flow of truthful information to consumers. *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council*, 425 U.S. 748, 763-65 (1976). FDA conducted such an analysis in other analogous contexts. For example, FDA allows disclaimers by cigar manufacturers to correct unsubstantiated perceptions regarding relative risk. Nicopure Br. at 32-33. But it did not do so here.

II. FDA Fails To Show The Free Sample Ban Complies With The First Amendment

A. FDA Improperly Analogizes Free Samples To Price Restrictions And Product Sales

FDA asserts the free sample ban only regulates conduct, not speech, and is not subject to First Amendment protection. FDA Br. at 44. It argues no expressive conduct is involved when a consumer tries a product. *Id.* at 44-45. Rather, FDA claims free samples are more akin to price regulations which are not subject to First Amendment challenge and, in particular, are no different than selling a product. *Id.* FDA's response fails on numerous grounds.

First, FDA's position completely ignores the underlying purpose of commercial speech doctrine as articulated by the Supreme Court in *Va. State Bd.* It is the "dissemination of information" or "free flow of commercial information" through "advertising" that warrants First Amendment protection so consumers can make "intelligent and well informed" purchasing decisions. 425 U.S. at 763-65. In that case, the Court struck down a statute that banned advertising of prescription drug prices, in part, because it would deprive low income citizens of information that would help them find the most affordable drugs. *Id.* at 763-64.

The same dynamic is at play when vapor companies advertise through free samples. A substantial amount of information is furnished through free samples regarding e-liquid flavors and device performance that consumers both demand

and require so they can decide whether to switch away from more risky cigarettes or to continue vaping – what could literally be a life-saving decision. Nicopure Br. at 36-38. *Edenfield*, 507 U.S. at 766 (solicitation allows buyer to "explore in detail the way in which a particular product or service compares to its alternatives in the market").

This focus on "information" in the commercial context also illustrates why FDA's analogy to product sales and pricing restrictions quickly falls apart. When a consumer buys a product, he/she has already made a marketplace decision. That consumer has now acted on any information gathered through advertising (*i.e.*, speech). At that point, the First Amendment no longer has any role in facilitating the free flow of information and is inapplicable. That is not the case with advertising novel products like e-liquids and devices through free samples. *Philip Morris USA, Inc. v. City & Cty. of San Francisco*, 345 F. App'x 276, 277 (9th Cir. 2009) (distinguishing "advertising" and "selling" cigarettes for purposes of the First Amendment). Similarly, when the government merely regulates prices, it does not intend to prevent the exchange of commercial information; rather, the primary goal is to shape the behavior or conduct of a player in the marketplace. *Expressions Hair Design v. Schneiderman*, 137 S. Ct. 1144, 1150 (2017) (setting price to regulate how much sellers can collect); *44 Liquormart v. R.I.*, 517 U.S. 484, 530 (1996) (O'Connor, J. concur) (setting higher prices to discourage alcohol

consumption). But when the government regulates "how sellers may communicate prices" – as the TCA and Deeming Rule dictate how vapor companies may communicate product-related information – the First Amendment is implicated. *Expressions Hair Design*, 137 S. Ct. at 1151.

Second, FDA never acknowledges, let alone applies, the Supreme Court's test for determining whether "particular conduct possesses sufficient communicative elements to bring the First Amendment into play" – namely "[a]n intent to convey a particularized message" and whether the "message would be understood by those who viewed it." *Tex. v. Johnson*, 491 U.S. 397, 404 (1989) (citations and internal quotations omitted). Instead of grounding its characterization of free samples in this approach, FDA simply makes the bald assertion it is only regulating conduct. FDA Br. at 44. But this turns a blind eye to the extensive record evidence that manufacturers and retailers not only offer free samples with the specific intent to convey important information to potential and current vapers, but also that consumers themselves understand testing free samples will help them make critical choices in the marketplace affecting their health and well-being. Nicopure Br. at 36-38. Vapor products are still relatively new and the product experience is different than smoking. It is not surprising that a robust adult

sampling dynamic has evolved, particularly in vape shops and adult-only expos. But that is never addressed in FDA's brief.[10]

The Fifth Circuit's decision in *Bailey v. Morales*, 190 F.3d 320 (5th Cir. 1999) is illustrative. There, a Texas statute prohibited chiropractors, with certain exceptions, from giving out anything of value (*e.g.*, promotional gifts or items) to solicit employment. *Id.* at 321. Texas argued it was only regulating conduct, not speech. *Id.* at 325. However, the court rejected this subjective characterization and instead applied the intent-based test articulated in *Johnson*. *Id.* It held chiropractors are intentionally conveying a message – "hire me, try my service" – and that consumers understand "free samples" are "common marketing tools." *Id.* The same holds true here, but to an even greater extent. Vapor companies are not only using free samples as advertising in the traditional sense – "please buy my e-liquid" – they are also passing on product information consumers demand when contemplating a switch from more harmful cigarettes – *e.g.*, "this blueberry-flavored e-liquid tastes better than your menthol-flavored cigarette." *Discount Tobacco*, 674 F.3d at 538 (holding First Amendment applies to free samples as they are "promotional methods that convey the twin messages of reinforcing brand

[10] None of the cases cited by FDA remotely involve this unique and continuous exchange of information between seller and consumer through free samples. *See, e.g.*, *Arcara v. Cloud Books, Inc.*, 478 U.S. 697, 698, 705 (1986) ("general applicability" statute addressing lewd behavior).

loyalty and encouraging switching from competitors' brands"). The only effective way to convey that message is through sampling; merely saying it is not enough.

Third, FDA's claim that the ban on free samples is simply geared toward regulating conduct is belied by the TCA and FDA's own statements showing that the government's interest focuses on the communicative aspect of free samples – a fact never addressed by FDA in its opposition. As the Sixth Circuit held in *Discount Tobacco*, the TCA's "regulation of sampling and continuity programs is an attempt to regulate the 'communicative impact' of the activity, not the activity itself." 674 F.3d at 539; *Rockwood v. City of Burlington*, 21 F. Supp. 2d 411, 423 n.9 (D. Vt. 1998) ("Because it is precisely the content of the advertising-promotion of tobacco products [including a ban on free samples of cigarettes to limit youth consumption] – that triggers the City's concern, the City cannot logically maintain that its regulation is content-neutral.").

Indeed, Congress made clear in the TCA that it was targeting "*communication* by tobacco manufacturers and sellers" by "restrict[ing] those advertising and promotional practices which are most likely to be seen and heard by youth most likely to *entice* them into tobacco use." TCA §§2(32) (emphasis added); *see* TCA §§2(5), (15), (20), (23). Importantly, when Congress made this declaration, it was referring to advertising and marketplace communications via

free samples. 21 U.S.C. §387a-1; TCA §2(32); Nicopure Br. at 39-40.[11] Likewise, in the Deeming Rule, FDA stressed the messaging associated with free samples that risks "increas[ing] social pressure" on minors to try vapor products, and involves products that are "socially attractive" and subject to "social . . . influences." 81 Fed. Reg. at 28,986. As such, FDA cannot credibly argue that it is regulating conduct and not the advertising aspect of free samples.

B. FDA Does Not Justify The Free Sample Ban Under *Central Hudson's* Third And Fourth Prongs

FDA also maintains the free sample ban satisfies the last two prongs of the *Central Hudson* standard, making only three limited points: (i) free samples of tobacco products have been distributed in the past at youth-oriented events like concerts; (ii) voluntary efforts by cigarette companies to limit youth access have not been successful; and (iii) the use of "qualified-adult-only facilities" ("QAOFs"), which allows the distribution of free samples of smokeless tobacco, will not work for vapor products. FDA Br. at 48-49. All of this falls well short of adequately justifying a prophylactic ban on free samples.

[11] Specifically, Congress referenced back to regulations FDA had adopted in 1996 which also banned free samples of tobacco products. TCA §2(30); 61 Fed. Reg. 44615 (Aug. 28, 1996). The Supreme Court struck down these regulations in *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000). The TCA directed FDA to re-promulgate those regulations, with some modifications, including the free sample ban. 21 U.S.C. §387a-1(a)(2)(G).

First, FDA's response ignores Supreme Court precedent requiring some evidence showing the restriction will, in fact, directly and materially advance the government's interest in preventing youth access. *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 489 (1995); *Edenfield*, 507 U.S. at 770-71. Nowhere in FDA's brief or the administrative record is there any evidence – whether through studies, surveys, anecdotal reports, or otherwise – demonstrating that underage individuals are obtaining free samples of vapor products from venues or events only frequented by adults – *e.g.*, vape shops, trade shows, and adult-oriented concerts. FDA only mentions youth-oriented events. In fact, vast swaths of the vapor marketplace – primarily vape shops – are swept-up in the free sample ban when it is pure speculation and conjecture on FDA's part to conclude that minors have easy access to samples through such channels. This approach is not permitted under the First Amendment and should not be countenanced here. *Greater New Orleans*, 527 U.S. at 188 (government must show "harms it recites are real").[12]

Second, FDA never comes to terms with the list of non-speech related alternatives that would also restrict youth access to free samples. As the Supreme Court noted in *Cincinnati v. Discovery Network*, "[i]f there are numerous and obvious less-burdensome alternatives to the restriction on commercial speech, that

[12] This also makes FDA's heavy reliance on *Discount Tobacco's* conclusions regarding the distribution of "cigarette" samples to youth wholly inappropriate. FDA Br. at 47-39. That decision did not involve the vapor market.

is certainly a relevant consideration in determining whether the 'fit' between ends and means is reasonable." 507 U.S. 410, 418 n.13 (1993). Here, FDA could implement individually or in combination a host of alternatives, such as:

(i) prohibiting free samples at youth-oriented events;
(ii) limiting free samples to adult-only, age-verified facilities where the sample must be used or consumed on-site so as to prevent removal and any access by the general public;
(iii) aggressively enforcing minimum age requirements (21 C.F.R. §1140.16(c)(2)(ii)); and
(iv) conducting education campaigns aimed at minors.

Nicopure Br. at 44-48. In both its opposition and the administrative record, FDA's response is brief – it only argues that industry-based voluntary programs and "qualified adult-only facilities" ("QAOFs") used by the smokeless tobacco industry to distribute free samples will not work. FDA Br. at 48-49. Yet more is required. The government must not only explain why many other available alternatives would prove inadequate, *Sorrell*, 564 U.S. at 575, it also "must" implement any viable options that restrict less speech, *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 371 (2002). There has been a complete failure in this regard.

In fact, FDA's treatment of free samples is totally one-sided, without any sense of balance between the government's interest in preventing youth access with Congress's stated goal of allowing adults continued access to less harmful tobacco products. TCA §3(4), (7); *see Greater New Orleans*, 527 U.S. at 188 (government must carefully calculate the costs and benefits associated with the

burden on speech imposed by its prohibition). As the Supreme Court held in *Lorillard Tobacco Co. v. Reilly*, when striking down an advertising ban near schools and playgrounds as not narrowly tailored, the government must recognize adults also have a "corresponding interest in receiving truthful information about tobacco products." 533 U.S. 525, 564 (2001).[13]

Third, contrary to FDA's claims, there are no "ample" alternatives for vapor companies to adequately convey product-related information to adult consumers outside of testing free samples. FDA Br. at 46. For those looking to switch and stay away from traditional cigarettes, record evidence shows they must be able to understand how the product works, taste various flavors, and experience the sensation and performance levels of different devices. Nicopure Br. at 36-38. It is not enough for sellers to simply make representations through other channels, such as written materials or retailer demonstrations.

FDA argues companies could charge consumers each time they test a sample. FDA Br. at 46. But charging per puff or small sample size presents a risk that adult consumers – whether because they are price sensitive, reluctant to spend money on an unfamiliar or novel product, or otherwise – will sample less, thereby

[13] Because the government's interest targets advertising and communicative aspects of free samples, *U.S. v. O'Brien*, 391 U.S. 367 (1968) does not apply. But even if it did, the fee sample ban still fails as that test contains the same narrow tailoring requirement as *Central Hudson*.

limiting the amount of information conveyed through sampling. FDA141041. Vapers engage in a routine and ongoing sampling process of multiple products as they switch from cigarettes. Nicopure Br. at 37-38. The act of constantly paying for each sample tested presents an unnecessary hurdle. Less intrusive options would ensure the free flow of valuable product information.

Finally, FDA's response again never acknowledges the Supreme Court is particularly skeptical of bans in the commercial context that are content- or speaker-based, thus regulating some and not others. *Sorrell*, 564 U.S. at 572-73. Neither Congress nor FDA ever justified why the smokeless tobacco industry may distribute free samples in QAOFs, but not other product manufacturers or retailers. 21 U.S.C. §387a-1(a)(2)(G). Congress and FDA offered no explanation as to why the same security measures used by smokeless tobacco companies would be any more effective in keeping youth out than if used by other industries. They also never gathered information necessary to assess if QAOFs would, in fact, work for other product types (*e.g.*, preventing consumers from leaving the QAOF with a sample). *Greater New Orleans*, 527 U.S. at 193 (government must explain how line-drawing relates to stated interest).

III. FDA Fails To Demonstrate The PMTA Provision Does Not Require Tailoring For Vapor Products Regarding The Population Effects Standard

FDA maintains the TCA requires vapor products to satisfy all pre-market review requirements applying to more dangerous cigarette and smokeless products. FDA argues it is not obligated to tailor the PMTA process to less harmful vapor products and, in particular, what information or data are necessary to demonstrate that such products "would be appropriate for the protection of the public health." FDA Br. at 23-25. FDA also summarily concludes the PMTA's "population effects" requirement will not virtually ban vapor products and otherwise promises to consider, in its discretion, alternatives under the "population effects" standard on a case-by-case basis (*e.g.*, requiring scientific-literature review instead of product-specific clinical or epidemiological studies). FDA Br. at 26-27. FDA's response falls short for the following reasons.

First, contrary to FDA's intimations, Appellants do not seek a complete exemption from the PMTA or the "population effects" standard. FDA Br. at 1-2. Appellants are not challenging the PMTA requirements at 21 U.S.C. §387j(b)(1)(A)-(G) (*e.g.*, submitting information regarding health risks, ingredients, production processes, etc.), and are only arguing FDA either was required to, or arbitrarily and capriciously failed to, tailor how the vapor industry demonstrates compliance with the "population effects" provision. 5 U.S.C. §706.

Such tailoring is necessary because requiring randomized, controlled trials or long-term epidemiological studies for each e-liquid and device would, by FDA's own admission, virtually eliminate entire categories of vapor products. Not only did FDA find up to 97% of manufacturers and 87.5% of e-liquids will cease to exist before the PMTA filing deadline, FDA also failed in its response to cite any evidence that vapor companies will still submit thousands of compliant PMTAs before the cutoff. Only a few PMTAs have been accepted for review by FDA since the TCA was adopted, with only one ultimately being approved. FDA's numbers are entirely unsupported. Nicopure Br. at 50-54.

Second, FDA misreads Appellants' claim as relying primarily on the TCA's statements of purpose as imposing a tailoring duty on FDA. FDA Br. at 25-26. In fact, the PMTA provision itself expressly provides FDA with authority to forego requiring "well-controlled investigations," including "clinical investigations," to satisfy the "population effects" standard and, in their place, rely on other "valid scientific evidence . . . which is sufficient to evaluate the tobacco product." 21 U.S.C. §387j(c)(5)(B). It is through this provision that Congress gave FDA a tool to effectuate the TCA's goals of: (i) exercising "new and flexible enforcement authority to ensure that there is effective oversight of the tobacco industry's efforts to develop, introduce, and promote less harmful products"; and (ii) "continue to permit the sale of tobacco products to adults in conjunction with measures to

ensure that they are not sold or accessible to underage purchasers." TCA §§3(4), 3(7). *Comcast Corp. v. FCC*, 600 F.3d 642, 654 (D.C. Cir. 2010) ("statements of congressional policy can help delineate the contours of statutory authority").

While FDA maintains it will consider this option on a case-by-case basis, FDA Br. at 26, more is required where there is a risk, based on FDA's own findings, that entire categories of vapor products could be effectively banned before PMTAs are even submitted. FDA must allow vapor companies on an industry-wide basis to file PMTAs that rely on information and data alternatives to satisfy the "population effects" standard without having to conduct prohibitively expensive, long-term studies for each product before submitting an application. As demonstrated by the substantial market exit predicted by FDA prior to the PMTA cutoff date, and the lack of any evidence that FDA would approve more than a few PMTAs, it is unlikely that vapor companies will continue expending money and resources on their products without some commitment on FDA's part to tailor the filing requirements beforehand. At a minimum, it was arbitrary and capricious for FDA not to adopt this option or adequately consider it during the rulemaking. 81 Fed. Reg. at 28,997 (summarily dismissing option and casting doubt on whether FDA would even allow this approach on a case-by-case basis). *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43 (1971) (agency must "articulate a satisfactory explanation for its action").

Indeed, additional TCA provisions indicate Congress never intended for substantially less risky tobacco products to be effectively banned in such an arbitrary manner. For example, the PMTA requirements are geared, in part, to identify such products for commercialization. 21 U.S.C. §387j(b)(1)(A) (requiring a PMTA to include information showing that the health risks of a tobacco product "present[] less risk than other tobacco products"). But under FDA's approach, most manufacturers will never reach the point where they can make that showing. Congress also adopted provisions that allow FDA to regulate the safety of tobacco products so they may remain on the market. 21 U.S.C. §387f(e) (good manufacturing practices), §387g (tobacco product standards). However, these have no role if vapor manufacturers never initiate the PMTA process in the first place. Further, Congress instructed FDA to submit a report examining how to "regulate, promote, and encourage the development of innovative products" to achieve reductions in tobacco use and related harms. 21 U.S.C. §387r(b). Yet FDA seems intent on the opposite by sending a message that completing and submitting a PMTA is a futile endeavor.

Third, by reading the PMTA provision in isolation as requiring a one-size-fits-all approach, FDA applies the PMTA process "in a manner that is inconsistent with the administrative structure that Congress enacted into law." *Brown & Williamson*, 529 U.S. at 125 (citation and internal quotations omitted); *King v.*

Burwell, 135 S. Ct. 2480, 2492 (2015) (noting "fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme") (citation and internal quotations omitted). As discussed above, underlying the TCA is a clear intent to ensure that adults continue to have access to less harmful tobacco products, coupled with express provisions to achieve that goal. This is also consistent with Congress' long history of maintaining a marketplace for tobacco products and court decisions thwarting FDA's attempts to ban them outright, including vapor products. *Brown & Williamson*, 529 U.S. at 143; *Smoking Everywhere, Inc. v. FDA*, 680 F. Supp. 2d 62, 70-71 n.9 (D.D.C. 2010), *aff'd by Sottera, Inc. v. FDA*, 627 F.3d 891 (D.C. Cir. 2010). Accordingly, it makes no sense Congress established a pre-market requirement that, as a practical matter, will eliminate most vapor products before they even go through the PMTA process.

CONCLUSION

For the foregoing reasons, this Court should grant Appellants' requested relief under the First Amendment and APA.

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CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the requirements of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 6,499 words according to the count of Microsoft Word.

/s/ Eric P. Gotting
Eric P. Gotting

CERTIFICATE OF SERVICE

I hereby certify that on this 16th day of May, 2018, I electronically filed the foregoing document with the Court by using the CM/ECF system. All parties to the case have been served through the CM/ECF system.

/s/ Eric P. Gotting
Eric P. Gotting