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

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

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to Circuit Rule 28(a)(1), Appellants, through their undersigned counsel, submit this Certificate as to Parties, Rulings and Related Cases.

I. Parties, Amici, and Intervenors

A. Plaintiffs Before District Court

Nicopure Labs, LLC
Right To Be Smoke-Free Coalition
American E-Liquid Mfg. Standards Ass'n
American Vaping Association
Electronic Vaping Coalition of America
Georgia Smoke Free Association
Kentucky Smoke Free Association
Louisiana Vaping Association
Maryland Vape Professionals, LLC
New Jersey Vapor Retailers Association
Ohio Vapor Trade Association
Tennessee Smoke Free Association

B. Appellants

Nicopure Labs, LLC
Right To Be Smoke-Free Coalition, *including members*
- American E-Liquid Mfg. Standards Ass'n
- American Vaping Association
- Georgia Smoke Free Association
- Kentucky Smoke Free Association
- Louisiana Vaping Association
- Maryland Vape Professionals, LLC
- New Jersey Vapor Retailers Association
- Ohio Vapor Trade Association
- Tennessee Smoke Free Association
- Shenzhen E-Vapor Industry Association

C. Defendants Before District Court

U.S. Food and Drug Administration
Dr. Thomas E. Price, Secretary, Health and Human Services
Dr. Scott Gottlieb, FDA Commissioner

D. Appellees

U.S. Food and Drug Administration
Alex Azar, Secretary, Health and Human Services
Dr. Scott Gottlieb, FDA Commissioner

E. Amici In District Court Proceedings

TechFreedom
National Center for Public Policy Research
Smoke-Free Alternatives Trade Association
Vape A Vet Project
Clive Bates, Director, Counterfactual
Philip Alcabes, Professor of Public Health, College of Nursing and Public Health, Adelphi University, Garden City, New York
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Ernest Drucker PhD, Research Scientist and Professor of Public Health, College of Global Public Health, New York University
Konstantinos Farsalinos MD, Research Scientist, Onassis Cardiac Surgery Center, Athens, University of Patras, Greece
William T. Godshall, MPH, Founder and Executive Director, Smokefree Pennsylvania
Jacques Le Houezec, Consultant in Public Health, Président SOVAPE, Paris, France
Bernd Mayer, PhD, Professor & Chair, Dept. Pharmacology, University of Graz, Austria
Jeff Nesbit, Executive Director, Climate Nexus, New York; former Associate Commissioner, Food and Drug Administration
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Andrzej Sobczak PhD, Professor, Head of Department, Chemical Hazards and Genetic Toxicology, Inst. Occupational Medicine and Environmental Health, Sosnowiec, Poland
David Sweanor, JD, Centre for Health Law, Policy and Ethics, University of Ottawa
American Academy of Pediatrics
American Cancer Society Cancer Action Network
American Heart Association
American Lung Association
Truth Initiative
Tobacco Control Legal Consortium
American Thoracic Society

F. Amici Before D.C. Circuit

None. To date, the following entities have filed notices of intention to participate as amicus curiae in the appeal: (i) Washington Legal Foundation; and (ii) NJOY, LLC.

G. Intervenors

There are no intervenors in this case (whether in the District Court or D.C. Circuit). A motion to intervene filed by the American Academy of Pediatrics, American Cancer Society Cancer Action Network, American Lung Association, American Heart Association, Truth Initiative, and Campaign for Tobacco-Free Kids was filed on September 8, 2017 and is pending before this Court.

II. Decision Under Review

U.S. District Court for the District of Columbia, *Nicopure Labs v. FDA*, Nos. 16-0878, 16-1210 (consolidated) (ABJ), Order and Memorandum denying Petitioners' Motions for Summary Judgment and Granting Respondents' Cross Motion for Summary Judgment, 266 F. Supp. 3d 360 (July 21, 2017).

III. Related Cases

None.

RULE 26.1 DISCLOSURE STATEMENT

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure and Local Rule 26.1, Appellants Nicopure Labs, Inc. and the Right To Be Smoke-Free Coalition respectfully submit this Corporate Disclosure Statement as follows:

1. Nicopure Labs, LLC ("Nicopure") was founded in 2009 and is headquartered in Florida. The company manufactures and distributes vapor products, including electronic devices and e-liquids. Nicopure has no parent corporation, and no publicly-held company has a 10% or greater ownership interest in the company.

2. Right To Be Smoke-Free Coalition ("RSF" or "Coalition") is a non-profit trade association incorporated under the laws of the District of Columbia. RSF's purpose is to advocate for reasonable and responsible laws and regulations for vapor products. The Coalition's members include trade associations representing the vapor industry, as well as individual vapor product manufacturers, distributors, and retailers. Trade association members include the American E-Liquid Manufacturing Standards Association, American Vapor Coalition, Georgia Smoke Free Association, Kentucky Vaping Retailers Association, Inc., Louisiana Vaping Association, Maryland Vape Professionals, LLC, New Jersey Vapor Retailers Coalition, Ohio Vapor Trade Association, Tennessee Smoke Free Association, and the Shenzhen E-Vapor Industry Association. RSF has no parent

corporation, and no publicly-held company has 10% or greater ownership in the Coalition.

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GLOSSARY

APA	Administrative Procedure Act
ENDS	Electronic Nicotine Delivery System
FDA	Food and Drug Administration
FDCA	Food, Drug and Cosmetic Act
FTC	Federal Trade Commission
HPHC	Harmful or Potentially Harmful Constituent
MRTP	Modified Risk Tobacco Product
NAS	National Academies of Sciences
PHE	Public Health England
PMTA	Pre-Market Tobacco Application
RCP	Royal College of Physicians
QAOF	Qualified Adult-Only Facility
SKU	Stock Keeping Unit
TCA	Tobacco Control Act

INTRODUCTION

This appeal involves the public's on-going efforts to reduce the serious health impacts associated with combustible cigarettes by developing and promoting products that still deliver nicotine but, at the same time, substantially reduce harmful effects. Over the last decade, a new technological product – an Electronic Nicotine Delivery System ("ENDS"), which is commonly known as an "electronic cigarette" or "vapor product" – has emerged that offers significant promise. The National Academies of Sciences ("NAS"), Public Health England ("PHE"), and the Royal College of Physicians ("RCP") have repeatedly concluded that vapor products present significantly less health risk than cigarettes.[1] The U.S. Food and Drug Administration ("FDA") agrees. FDA has time and again acknowledged that using vapor products likely presents far less risk to individuals than smoking traditional cigarettes, and that consumers switching from combusted tobacco products to vapor products may significantly reduce harm.

In 2009, Congress addressed the devastating consequences of cigarette use in the Family Smoking Prevention and Tobacco Control Act ("TCA" or the "Statute"). The Statute imposes stringent requirements on cigarettes, such as pre-

[1] FDA022841-953; NAS, PUBLIC HEALTH CONSEQUENCES OF E-CIGARETTES, at 7, *available at* https://tinyurl.com/ycxlymgf; RCP, NICOTINE WITHOUT SMOKE: TOBACCO HARM REDUCTION (2016), at 189, *available at* https://tinyurl.com/ybg9p3k3.

market approval for new products, marketing and advertising limitations, and youth restrictions. One of the TCA's stated goals, however, is to ensure adult smokers continue to have access to innovative, less harmful tobacco products. In 2016, FDA "deemed" vapor products to be regulated "tobacco products" covered by the TCA ("Deeming Rule"). As such, vapor products are well-positioned to drive the TCA's harm reduction objectives. Indeed, substantial evidence indicates adult consumers, and particularly long-time smokers, look to vapor products in attempts to move away from deadly cigarettes. As FDA recently announced in a new comprehensive plan to regulate tobacco, there must be an "appropriate balance between regulation and encouraging development of innovative tobacco products that may be less dangerous than cigarettes."[2]

Regrettably, the TCA and Deeming Rule as applied by FDA have the opposite effect. The Statute prevents vapor companies from conveying truthful, non-misleading information that smokers use to make informed decisions about vaping. The Deeming Rule also prohibits free vapor product samples to adults, even though the TCA allows them for smokeless tobacco, and FDA recognized sampling plays a critical role when smokers make individualized choices as to the vapor product – and particularly flavored e-liquids – that will most effectively help

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

them make the switch. Finally, FDA refused to tailor a stricter pre-market approval process aimed at cigarettes so the vast majority of vapor product manufacturers and their products are not, as FDA has predicted, driven out of the marketplace.

The vapor industry is committed to safety and recognizes the need for reasonable, proportional regulation. Accordingly, Appellants do not challenge many provisions in the TCA and Deeming Rule, including those that guard against youth access, prevent misbranded products, or require submission of health and safety information to FDA. The government, however, imposes requirements that place unlawful and unconstitutional obligations on vapor companies.

JURISDICTIONAL STATEMENT

The District Court had jurisdiction under 28 U.S.C. §1331. This Court has jurisdiction under 28 U.S.C. §1291. Appellants appealed the District Court's July 21, 2017, Order and Memorandum Opinion on August 29, 2017.

STATEMENT OF ISSUES

1. Did the government violate the First Amendment by effectively banning vapor companies from informing adult consumers through truthful, non-misleading statements that: (i) a vapor product contains reduced levels, or is free, of a substance; (ii) a vapor product has certain manifest characteristics (*e.g.*, "no tobacco"); (iii) vapor products likely present less health risk to individual smokers

than traditional cigarettes (as FDA has publicly stated); or (iv) a particular vapor product presents less health risk than another tobacco product?

2. Did the government violate the First Amendment by banning free vapor product samples, including samples distributed to age-verified adults or at adult-only establishments, but at the same time allowing free samples of smokeless (*i.e.*, chewing) tobacco products?

3. Did FDA violate the TCA and Administrative Procedure Act ("APA") when it failed to tailor stringent pre-market approval provisions for cigarettes to less risky vapor products so the vast majority of manufacturers are not forced out of the market (as FDA has predicted), and adult consumers, as envisioned by the TCA, continue to have access to innovative, less harmful tobacco products?

STATUTES AND REGULATIONS

Pub. L. No. 111-31, 123 Stat. 1776 (2009), 21 U.S.C. §387 *et seq.* (ADD001); 81 Fed. Reg. 28,974 (May 10, 2016) (ADD079).

STATEMENT OF CASE

I. Factual Background

A. Vapor Products

Vapor products are a recent invention. Notably, they are not cigarettes, as they do not contain tobacco and there is no combustion or smoke. FDA150351.

Rather, the aerosol produced by an electronic device is created when a battery activates a heating coil that vaporizes a flavored e-liquid solution. FDA155130.

E-liquids are made using vegetable glycerin and/or propylene glycol, flavorings, and nicotine. FDA155131. Nicotine is used in most, but not all, e-liquids. FDA148942. Vapor products allow consumers to mimic smoking (called "vaping") by inhaling the aerosol through a mouthpiece, but without exposure to combustible smoke or thousands of chemicals found in tar. FDA155130-131.

The Deeming Rule applies to manufacturers, including brick-and-mortar vape shops that mix custom e-liquids. 81 Fed. Reg. at 29,044.

B. Vapor Products and Continuum of Risk

A large and growing body of scientific evidence demonstrates vapor products are far less risky than tobacco-containing cigarettes because e-liquids do not contain tobacco nor are they combusted or burned in the device. It is well-established that tobacco-combusting products are more harmful because smokers inhale pyrolyzed tobacco constituents, many of which are known human carcinogens and toxicants. FDA155128-130. Research suggests, however, non-combustible vapor products are safer and are expected to substantially reduce tobacco-related disease and death. FDA155128-143.

An increasing number of public health experts agree that vaping could be a valuable tool in tobacco harm reduction efforts. In 2014, over fifty tobacco,

nicotine, and public health specialists from around the world signed a letter to the World Health Organization emphasizing the importance of tobacco harm reduction through non-combustible vapor products. FDA147235-241. According to the signatories, available scientific evidence indicates that vapor products "could be among the most significant health innovations of the 21st Century – perhaps saving hundreds of millions of lives." *Id.*

Recently, PHE (a department of the British Government), calculated the level of harm caused by different nicotine delivery systems and took into account a wide range of risks (*e.g.*, addiction, lung damage), ultimately finding that vapor products are 95% less harmful than cigarettes. FDA022841-953. Beyond the potential health effects for individual consumers, there is also mounting scientific evidence that, on the *population* level, vapor products are not decreasing smoking cessation or increasing smoking initiation rates. This is because vapor products are primarily used by adult smokers to avoid significant health hazards associated with cigarettes. For example, PHE found that almost all of the 2.6 million adult vapers in England are current or ex-smokers, most of whom are using the devices to help them move away from cigarettes.[3] FDA183506-508; *see* 81 Fed. Reg. at 28,985 (noting smokers are more likely to try vapor products than others).

[3] Just last week, PHE issued another report confirming its earlier findings that switching completely from smoking to vaping results in substantial health benefits.

In fact, FDA concedes vapor products are likely less risky than cigarettes. 81 Fed. Reg. at 29,030 ("FDA recognizes that completely switching from combusted cigarettes to [vapor products] may reduce the risk of tobacco-related disease for individuals currently using combusted tobacco products, given the products' comparative placements on the continuum of nicotine-delivering products."); *id.* at 29,035 ("FDA agrees that use of [vapor products] is likely less hazardous for an individual user than continued smoking of traditional cigarettes."); *id.* at 28,981 (FDA "believes that the inhalation of nicotine (*i.e.*, nicotine without the products of combustion) is less of a risk to the user than the inhalation of nicotine delivered by smoke from combusted tobacco products"); *id.* at 29,032, 29,039.

II. Tobacco Control Act

The TCA contains three provisions that govern vapor products by virtue of the Deeming Rule and are also relevant to this appeal.

A. Modified Risk Claims

Under the TCA and Deeming Rule, a vapor product manufacturer must submit an extensive application and secure FDA's approval before it can make a modified risk tobacco product ("MRTP") claim. 21 U.S.C. §387k. A MRTP claim includes labeling or advertising, or other actions directed at consumers (*e.g.*,

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PHE, *Independent Expert E-Cigarettes Evidence Review* (Feb. 6, 2018), *available at* https://tinyurl.com/yb9aebkc.

statements in the media), representing explicitly or implicitly that: (i) the product presents a lower risk of disease or is less harmful than another tobacco product; or (ii) the product or smoke contains a reduced level of, or is free from, a substance, or that exposure to a substance is reduced or eliminated. 21 U.S.C. §387k(b)(2). Terms used in the past by traditional cigarette companies to mislead consumers, such as "light," "low," or "mild," are also covered. *Id.*

FDA may issue a MRTP order only after the manufacturer makes numerous showings based on scientific data. Specifically, the applicant must demonstrate that the product will:

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

21 U.S.C. §387k(g)(1) (emphasis added). As to the "population effects" prong, FDA must consider:

> (i) relative health risks of the subject tobacco product;
> (ii) likelihood that those who do not use tobacco products will start using the subject product (*i.e.*, initiation); and
> (iii) likelihood that users who would otherwise stop using tobacco products will start using the subject product (*i.e.*, cessation).

21 U.S.C. §387k(g)(4). As discussed below, the burden of proof is so high that FDA has not approved a single MRTP claim and it is unlikely that it ever will.

B. Free Samples

The TCA and the Deeming Rule ban free samples of vapor products to adult consumers, including in settings that prohibit youth access. 21 U.S.C. §387a-1(d)(1); 81 Fed. Reg. at 29,054; 21 C.F.R. §1140.16(d). For instance, the ban applies to adult vapers testing free samples of e-liquids and devices inside adult-only venues or vape shops where the product is fully consumed and/or never leaves the premises. 81 Fed. Reg. at 29,054. This is true even though the TCA allows free samples of smokeless (*i.e.*, chewing) tobacco in "qualified adult-only facilities" ("QAOF"). 21 U.S.C. 387a-1(d)(2). A QAOF is a temporary structure designed to distribute limited amounts of smokeless tobacco to adults that, *inter alia*, has a licensed security guard providing access to only those individuals who have attained a minimum age. 21 U.S.C. 387a-1(d)(2)(C).

C. Pre-Market Review

Manufacturers must submit a Pre-Market Tobacco Application ("PMTA") and obtain FDA authorization to keep their products on the market.[4] The PMTA

[4] Products commercialized by February 15, 2007 are "grandfathered" under the TCA and do not require pre-market authorization. 21 U.S.C. §387j(a)(1)(A). Thus, cigarettes marketed before that date are grandfathered. However, aside from an unidentified, rudimentary "e-cigar" claimed by FDA, no vapor products will be grandfathered. 81 Fed. Reg. at 28,978. As a result, new vapor products are ineligible for a less burdensome pre-market approval process, called the Substantial Equivalence pathway, because that requires a new product to be "substantially equivalent" to a grandfathered product. 21 U.S.C. §387j.

requires substantial amounts of information for each tobacco product, including prohibitively expensive clinical data showing that the product is "appropriate for the protection of public health." This "population effects" standard is similar to the one seen under the MRTP process, and requires FDA to account for the product's impact on smoking cessation and initiation rates. 21 U.S.C. §387j(c).

FDA established an August 8, 2018, PMTA filing deadline for vapor products on the market as of August 8, 2016. 81 Fed. Reg. at 28,978. As part of the new Comprehensive Plan, FDA extended the cutoff to August 8, 2022, and will allow such products to remain on the market pending PMTA review. However, any new vapor product, or change to an existing product, introduced after August 8, 2016, must first obtain a PMTA order, thus freezing the market for deemed products as of that date. *Id.* at 29,011 n.13. As discussed below, the PMTA standard has proven so difficult to satisfy that only one authorization – for a minor change in a long marketed smokeless tobacco product – has ever been granted.[5]

III. District Court Decision

A. Modified Risk Claims

The District Court denied Appellants claim that the MRTP standard violates the First Amendment and fails intermediate scrutiny under *Cent. Hudson Gas &*

[5] As a practical matter, this means the most lethal tobacco product – cigarettes – will remain grandfathered and exempt from PMTA review while ultimately minimizing competition from less risky, non-grandfathered products.

Elec. Corp. v. Pub. Serv. Comm'n of N.Y., 447 U.S. 557 (1980). Appellants argued the MRTP process prohibits vapor companies from making truthful, non-misleading statements (*e.g.*, "no tar") about their products to adult consumers who want to switch away from harmful cigarettes. They also maintained FDA had no evidence that claims made by the vapor industry potentially mislead consumers.

In summary fashion, the court cited *Discount Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509 (6th Cir. 2012), a case involving the regulation of traditional cigarettes and that industry's long history of misleading marketing campaigns, finding prior FDA approval is required because one cannot "unring the bell of misinformation after it has been rung." The District Court rejected Appellants' point that disclaimers could be used to avoid potentially misleading claims. The court noted Congress believed disclaimers, again in the context of cigarettes, would not be effective. The court did not address in detail the various types of objectively verifiable claims that would be made by vapor companies.

B. Free Samples

The District Court rejected Appellants' claim that the MRTP provision restricts expressive conduct and fails intermediate scrutiny under *Central Hudson.* Appellants argued the distribution of free samples is an "expressive act" protected by the First Amendment that conveys important information to smokers who want to switch to vapor products, including key consumer information about different e-

liquid flavors and device performance characteristics. Appellants also noted FDA had no data showing minors had actually obtained free samples of vapor products, and maintained FDA did not narrowly tailor the restriction by allowing distribution in adult-only facilities, prohibiting free samples from leaving such venues, and/or banning free samples at events frequented by minors.

However, the court held sampling is not an expressive act, and FDA could rely on older data regarding cigarette sampling and a survey showing vapor products had been distributed at public events where minors might have access. The court concluded, again based on *Discount Tobacco*, that restricting sampling to adult-only facilities was not required under the First Amendment. The court did not specifically address Appellants' other suggested alternatives.

C. Pre-Market Review

The District Court denied Appellants' claims that FDA violated the APA when, despite concluding the PMTA could force the vast majority of vapor manufacturers out of the market, FDA failed to tailor it so that, consistent with the TCA, adult consumers have adequate access to less risky vapor products. The court concluded the provision gives FDA discretion, but does not impose a statutory duty, to tailor the PMTA.

SUMMARY OF ARGUMENT

1. The MRTP provision violates the First Amendment because it effectively bans truthful, non-misleading statements by vapor companies that convey information needed by adult consumers to make informed purchasing decisions and switch away from cigarettes to less risky vapor products. The First Amendment protects the rights of consumers in the marketplace to obtain product-related information so they can make educated decisions. Vapor companies wish to tell adult consumers, for example, that their products do not contain certain substances ("no diacetyl" or "no allergens"), that they are unlike more dangerous cigarettes because they have "no tar" or produce "no combusted smoke," and they pose less health risk than cigarettes (as FDA has publicly stated numerous times).

But vapor companies cannot make these claims without prior FDA approval and, in all likelihood, will never be able to because FDA has never approved a claim under the stringent and cost prohibitive MRTP standard. As such, the MRTP process at least fails *Central Hudson's* intermediate scrutiny. *First*, it does not directly and materially advance the government's interest in protecting public health because others, including FDA and smokeless tobacco manufacturers, can make the same or similar statements. *Second*, Congress and FDA failed to consider less intrusive, non-speech alternatives for the vapor industry – *e.g.*, disclaimers, aggressive enforcement of misbranding prohibitions, post-marketing

surveillance, or recordkeeping requirements to confirm product claims – that Congress and FDA have otherwise found effective when dealing with other tobacco industries (*i.e.*, cigars and smokeless tobacco) or similar statements.

2. The free sample ban violates the First Amendment because it prohibits adult consumers from trying different vapor products and obtaining valuable information about a novel product category that will help them transition away from cigarettes. Sampling is an "expressive" act that is protected speech. As FDA conceded, sampling conveys information that allows consumers to make individualized choices and change their purchasing behavior. This is important where, as FDA also acknowledged, smokers may have a better chance of switching to vapor products if they can continually sample a variety of e-liquid flavors. Indeed, consumer surveys indicate that smokers rely heavily on flavor variability and the opportunity to try different e-liquids and devices when considering vaping as a substitute for deadly smoking.

Neither Congress nor FDA, however, demonstrated that the free sample ban survives, at a minimum, intermediate scrutiny. *First*, the ban does not directly and materially advance the government's interest in protecting against youth access. No evidence was presented showing that minors are obtaining free samples of vapor products, particularly from adult-only facilities or vape shops. FDA relied, instead, on outdated research regarding a different product – cigarettes – and a

report speculating minors might gain access at some public events (*e.g.*, concerts). Moreover, Congress and FDA allowed the smokeless tobacco industry to distribute free samples in special adult-access only venues, but without justifying why such exemption could not apply to other less harmful products. *Second*, FDA whole-heartedly endorsed minimum age restrictions and enforcement to prevent underage sales of vapor products, including from vending machines at adult-only venues. But FDA never explained why this narrowly-tailored approach would not work for free samples. Further, FDA never considered other less intrusive alternatives, such as allowing age-verified free samples at vape shops, but banning them at public events frequented by minors.

3. The TCA has an overarching goal of ensuring that adult smokers continue to have access to innovative, less risky tobacco products; but FDA failed to tailor the PMTA process to vapor products. FDA agreed that forcing vapor products to complete a one-size-fits-all PMTA process would eliminate over 95% of vapor product manufacturers, along with product variety those companies supply. Indeed, FDA has only approved one PMTA (which was not for a vapor product) since the TCA was adopted, and commenters submitted compelling evidence showing the PMTA will be time and cost prohibitive. FDA was obligated, therefore, to consider a less burdensome PMTA process for vapor products while still protecting public health. For instance, FDA could allow vapor

companies to rely on publicly-available research to show that a product presents less risk than cigarettes instead of requiring long-term, clinical or epidemiological studies for each e-liquid or device.

STANDARD OF REVIEW

This Court reviews the District Court's denial of summary judgment *de novo*. *Seed Co. v. Westerman*, 832 F.3d 325, 335 (D.C. Cir. 2016).

ARGUMENT

The MRTP provision and prohibition on free samples violate the First Amendment because they ban truthful, non-misleading information that consumers need to make fully informed choices regarding vapor products, particularly when attempting to switch away from deadly cigarettes.

I. The First Amendment Protects Consumers' Rights To Information

The First Amendment favors the free flow of information so that those in the commercial marketplace can make "intelligent and well-informed" decisions. *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council*, 425 U.S. 748, 763-65 (1976); *Cent. Hudson*, 447 U.S. at 563 ("The First Amendment's concern for commercial speech is based on the informational function of advertising."). This holds especially true when information implicates a consumer's health and safety. *Id.* at 763-64; *U.S. v. Caronia*, 703 F.3d 149, 166 (2d Cir. 2012). The First Amendment eschews a "paternalistic" approach that keeps consumers in the dark.

Rather, it assumes truthful "information is not in itself harmful, that people will perceive their own best interests if only they are well enough informed, and that the best means to that end is to open the channels of communication rather than close them." *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 375 (2002) (citation omitted). "More, not less" is the driving imperative.

The First Amendment, therefore, guards against "unwarranted governmental regulation" of commercial speech. *Cent. Hudson*, 447 U.S. at 561. Such restrictions are subjected to, at a minimum, intermediate scrutiny and are judged under the four-prong *Central Hudson* test. Courts ask whether:

(i) the speech concerns a lawful activity and is not misleading;
(ii) the asserted governmental interest is "substantial";
(iii) the restriction directly and materially advances the governmental interest; and
(iv) the restriction is no more extensive than is necessary to serve that interest.

Lorillard Tobacco Co. v. Reilly, 533 U.S. 525, 554-55 (2001). The government bears the burden of justifying any restrictions. *Edenfield v. Fane*, 507 U.S. 761, 770 (1993).

II. The Ban On MRTP Claims Violates The First Amendment

Consumers routinely seek information that would be helpful when attempting to move away from cigarettes and learn more about the features of particular vapor products. Unfortunately, the TCA and Deeming Rule keep such information completely away from adult consumers.

A. The MRTP Provision Is Effectively A Ban

While the MRTP provision means that manufacturers can, in theory, make such claims, in reality the standard has proven impossible to meet and, in essence, imposes a prophylactic ban on MRTP claims. To date, no MRTP application has been granted. FDA has received thirty-six submissions.[6] FDA refused to accept or file twenty-two; applicants withdrew another five; and eight submissions (filed for a Swedish Match smokeless tobacco product) were denied.[7] Only one more application is pending for the iQOS "heat-not-burn" system made by a large cigarette manufacturer.[8]

The Swedish Match and iQOS submissions illustrate the enormous undertaking that is required. The Swedish Match applications were about 200,000 pages. The iQOS submission is two-three million pages.[9] Both applications contained extensive human studies and testing, including two randomized clinical studies for Swedish Match and eight for iQOS.[10] FDA denied the Swedish Match

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[6] FDA, *FDA-TRACK: Agency-Wide Program Performance*, https://tinyurl.com/y7ypbkup.

[7] FDA, *Modified Risk Tobacco Products Overview*, https://tinyurl.com/ycfepzw3.

[8] FDA Docket No. 2017-D-3001, *Modified Risk Tobacco Product Application for iQOS System*, https://tinyurl.com/ybefklgm.

[9] David Marcus, Seeking Redemption, Big Tobacco Says New Products Eliminate 90 Percent Of Smoking Toxins, The Federalist, https://tinyurl.com/y9lmrcq2.

[10] FDA, *Swedish Match North Premarket Tobacco Product Application (PMTA) Technical Project Lead (TPL) Review, available at* https://tinyurl.com/y7tjxunb;

applications, despite finding that marketing the product would be appropriate for the protection of public health.[11] Moreover, though FDA's iQOS review is ongoing, FDA's Tobacco Product Scientific Advisory Committee recently voted against approval, despite significant reductions in harmful constituents compared to cigarettes, because the studies conducted purportedly did not show such reductions are likely to translate into measurable population-level reductions in morbidity or mortality.[12]

FDA also recently predicted manufacturers will rarely seek MRTP authorization. In a public notice regarding information to be submitted with each MRTP application, FDA anticipates that only three submissions will be filed per year. 83 Fed. Reg. 3158, 3161 (Jan. 23, 2018). This covers an infinitesimal fraction of the millions of newly deemed products that have been registered with FDA since the Deeming Rule was adopted.[13] 21 U.S.C. 387e(i) (requiring product registration). Further, FDA estimates that each applicant will invest 10,360 hours (or 431 days) for each submission. 83 Fed. Reg. at 3161. This corresponds with

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FDA, Briefing Document for Jan. 24-25, 2018 iQOS Tobacco Product Scientific Advisory Committee meeting, *available at* https://tinyurl.com/ybkyd8u4.

[11] *Supra* note 10.

[12] *US Panel Rejects Philip Morris Claim iQOS Tobacco Device Cuts Disease Risk*, the Guardian, *available at* https://www.theguardian.com/us-news/2018/jan/25/us-panel-rejects-philip-morris-claim-iqos-tobacco-device-cuts-disease-risk.

[13] FDA, *Search Tobacco Product Listings*, https://tinyurl.com/y9ysa2zj.

commenters who warned the MRTP process would be time and cost prohibitive, particularly for small vapor companies.[14] FDA114482; FDA075491.

B. The MRTP Provision Bans Truthful, Non-Misleading Claims

Congress articulated in the TCA a compelling interest in protecting the public from unsubstantiated claims that one tobacco product is safer than another. Pub. L. No. 111-31, §§2(37)-(43), 123 Stat. 1776, 1780 (2009). It was based primarily on concerns that tobacco companies had aggressively marketed "light," "low tar," and "mild" cigarettes to the public as safer than regular cigarettes knowing that such claims were false. *Id.* at §§2(38)-(39). FDA relied on the same rationale when deeming vapor products, thereby subjecting them to the MRTP process. 81 Fed. Reg. at 28,987, 29,039. Appellants are not challenging the ban on these or similar descriptors. 21 U.S.C. §387k(b)(2)(A)(ii).

However, the MRTP provision reaches far beyond these cigarette marketing schemes. *First*, Appellants cannot simply indicate the presence or absence of potentially harmful ingredients, 21 U.S.C. §387k(b)(2)(i), even though FDA expressed concerns in the Deeming Rule about various chemicals, such as diacetyl and acetyl propionyl, that have been detected in some e-liquids and may pose inhalation risks. 81 Fed. Reg. at 29,029. Although exposure to these substances

[14] Even if the MRTP is not, in essence, a complete ban, the provision still constitutes an unconstitutional prior restraint. *N.Y. Magazine v. Metro. Transp. Auth.*, 136 F.3d 123, 131 (2d Cir. 1998).

would be of vital interest to consumers, vapor companies are prohibited from indicating a product is free of those chemicals or only contains a certain level without securing a MRTP order. 21 U.S.C. §§ 387k(b)(2)(A)(i)(III). This holds true even for statements indicating the absence of harmful allergens, which consumers routinely ask manufacturers about. ADD227 (Stamler Decl.). Given the insurmountable barrier posed by the MRTP process, this means consumers must buy e-liquids without knowing if they are assuming a health risk.

Second, the TCA restricts truthful statements about relevant vapor product characteristics. 21 U.S.C. §387k(b)(2)(i). E-liquids do not contain tobacco, are not burned or combusted, and do not create tar or ash. FDA155128-9; FDA150351. In fact, FDA has often distinguished between vapor products and "combustible" tobacco cigarettes. 81 Fed. Reg. at 28,987 (referring to vapor products as "noncombustible"), 28,984, 29,037; Comprehensive Plan, *supra* note 2. Moreover, the terms "tar" and "ash" are commonly defined as a "viscous liquid" or "solid residue" resulting from the "burning" or "combustion" of organic material, such as tobacco, a phenomenon that does not occur when vaping as e-liquids do not contain tobacco leaf.[15] Accordingly, in addition to phrases like "no tobacco," "no ash," or "no tar," it would be entirely truthful to state on a label or

[15] *Tar Definition*, Merriam-Webster.com (2017), https://tinyurl.com/ya5wuoqo; *Ash Definition*, *id.*, https://tinyurl.com/ybvkhjky.

advertisement "no burning," "no combustion," or "no combusted smoke." These claims would be highly relevant to smokers looking for alternatives.

Third, manufacturers cannot say to consumers what FDA has already said itself numerous times – vaping likely presents less overall risk to individuals than smoking cigarettes. *Supra* at 7. A retailer cannot make the same statement on its website or to a consumer at its vape shop.

Fourth, FDA can subjectively deny a MRTP claim even when it agrees a vapor product presents less risk to individual users and satisfies the "population effects" standard. This is because the provision requires applicants to prove the product "significantly" reduces harm to the individual – without quantifying "significant." 21 U.S.C. §387k(g)(1)(A). As such, the MRTP process does more than guard against misleading claims; rather, it restricts speech in pursuit of a policy objective – *i.e.*, only allowing products to be marketed that make a substantial public health impact – regardless of whether the underlying claim is actually true or not. This applies to all MRTP claims, whether the claim indicates the absence of a certain chemical or explicitly compares a vapor product to the health risks of a particular cigarette brand.

C. The MRTP Provision Is Subject To "Heightened" Scrutiny Under *Sorrell*

Congress and FDA do more than just ban certain statements. The speech prohibition is directed at particular messages and speakers and, thus, is subject to a

"heightened" level of scrutiny under the Supreme Court's decision in *Sorrell v. IMS Health Inc.*, 564 U.S. 552 (2011). When the government prohibits, or even burdens, speech in this manner, "heightened scrutiny" applies, and this is no less true for commercial speech. *Id.* at 565-66; *Caronia*, 703 F.3d at 164-65. While *Sorrell* did not explicitly hold "strict scrutiny" governs in these circumstances, the decision left no doubt that a court must view speech restrictions as presumptively invalid and the government has a heavy burden of proving otherwise. *Id.* at 571; *Dana's R.R. Supply v. Attorney Gen.*, 807 F.3d 1235, 1246 (11th Cir. 2015).

In particular, *Sorrell* requires a "content-neutrality" inquiry in which a court must first consider "whether the government regulation restricting speech [is] content- and speaker-based." *Caronia*, 703 F.3d at 163-64 (citing *Sorrell*, 564 U.S. at 562-65). A content-based restriction "target[s] speech based on its communicative content." *Reed v. Town of Gilbert*, 135 S. Ct. 2218, 2226 (2015). In other words, it regulates based on the "topic discussed or the idea or message expressed." *Id.* at 2227. Likewise, a speaker-based restriction distinguishes among speakers or favors certain speakers over others. *Sorrell*, 564 U.S. at 564.

On its face, the MRTP provision is content-based. Vapor companies are effectively prohibited, for example, from explicitly or even impliedly representing on a label or in advertising that a product presents fewer risks or is free of a certain substance. 21 U.S.C. §387k(b)(2). Similar constraints are placed on claims in the

media or otherwise that are "directed to consumers" about a product. *Id.* These restrictions turn on the *message* conveyed and are not content neutral.

Moreover, the provision disfavors vapor companies as speakers, but allows others to direct the same information into the marketplace. For instance, FDA stated repeatedly that vapor products likely present a lower risk profile than traditional tobacco products and is free to make those representations to consumers. *Supra* at 7. Further, smokeless tobacco manufacturers can and do advertise claims like "no smoke" or "smoke-free" without a MRTP order. 21 U.S.C. §387k(b)(2)(C). But an e-liquid manufacturer cannot make similar or identical statements on its website, and will likely never be able to given the substantial hurdles posed by the MRTP process.

Thus, the MRTP provision is subject to *Sorrell's* "heightened scrutiny" or, at a minimum, a rigorous form of *Central Hudson* analysis. As discussed below, the provision clearly fails under either approach.

D. The MRTP Provision Does Not Directly And Materially Advance The Government's Interests

While *Sorrell* did not explicitly articulate what constitutes "heightened scrutiny" when applied to commercial speech, this standard is consistent with the recent trend in Supreme Court and circuit court decisions to apply *Central Hudson*, and in particular the third and fourth prongs, in an increasingly rigorous manner. *Am. Meat Inst. v. U.S. Dep't of Agric.*, 760 F.3d 18, 43 (D.C. Cir. 2014) (Brown,

dissenting) ("The clear trajectory of the Supreme Court's jurisprudence is toward greater protection for commercial speech, not less"). Gone are the days where courts followed a more deferential approach seen in *Posadas de Puerto Rico Assoc. v. Tourism Co.*, 478 U.S. 328, 342 (1986), in which they did little to second guess the government's rationale for restricting speech. *See 44 Liquormart v. R.I.*, 517 U.S. 484, 505 (1996) (plurality opinion); *Greater New Orleans Broad. Ass'n v. United States*, 527 U.S. 173, 184 (1999).

As to the third prong – whether the speech restriction directly and materially advances a governmental interest – courts review the legislative or administrative record and, significantly, require the government to produce supporting data or other evidence. *Rubin v. Coors*, 514 U.S. 476, 489 (1994) (noting failure to present "any credible evidence" and rejecting "anecdotal evidence and educated guesses"); *Edenfield*, 507 U.S. at 771; *Ocheesee Creamery LLC v. Putnam*, 851 F.3d 1228, 1236 (11th Cir. 2017). The government's "burden is not satisfied by mere speculation or conjecture; rather, a governmental body . . . must demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree." *Greater New Orleans*, 527 U.S. at 188 (citation omitted). "[I]neffective or remote support for the government's purpose" is not sufficient. *Id.* (citation omitted).

Moreover, the third prong has proven a formidable hurdle where there are exceptions to the speech restriction, particularly when the information may be conveyed by some speakers but not others. *Sorrell*, 564 U.S. at 572-73 (prohibiting pharmacies from disclosing physician prescribing data to drug companies to protect physician privacy but allowing distribution of information to other entities); *Greater New Orleans*, 527 U.S. at 189-90 (finding irrational government prohibition of private casino advertising to reduce social ills of gambling but at the same time allowing advertising by tribal casinos); *Rubin*, 514 U.S. at 488-90 (invalidating restriction on beer labels reporting alcohol content to prevent "strength wars" among brewers where more potent beverages did not face the same restrictions); *Utah Licensed Beverage Ass'n v. Leavitt*, 256 F.3d 1061, 1073-74 (10th Cir. 2001) (striking advertising ban applying to some alcoholic beverages, but not others, where government interest was temperance). Such inconsistent treatment is particularly worrisome where the government does not explain or otherwise present evidence justifying the disparate treatment. *Greater New Orleans*, 527 U.S. at 193; *Leavitt*, 256 F.3d at 1073.

Here, the MRTP provision fails the third prong because FDA will be making claims to consumers – just as vapor companies would like to do – regarding the existence or absence of potentially harmful substances in specific products. Under the TCA, each manufacturer must submit to FDA a list and quantity of all "harmful

or potentially harmful constituents" ("HPHCs"), as designated by FDA, in each of its brands and sub-brands. 21 U.S.C. §387d(a)(3).[16] Significantly, FDA must then publish the data by brand and sub-brand 21 U.S.C. §387d(e). In other words, FDA will be informing the public what amount of HPHCs may be in a particular vapor product and, by omission, what HPHC-designated chemicals are not. Yet the MRTP process effectively prevents manufacturers from doing the same, even though that information may otherwise be in the public realm. While FDA is required to publish its disclosures in a "format that is understandable and not misleading to a lay person," 21 U.S.C. §387d(d)(1), such statements are not required to satisfy the MRTP standard.

A similarly irrational approach is applied to statements that describe important characteristics of a tobacco product, allowing smokeless tobacco manufacturers to make such claims but not the vapor industry. There is no record evidence that factual and truthful phrases like "no burning," "no ash," or "no combusted smoke" would be misinterpreted by vapers. *Cent. Hudson*, 447 U.S. at 563 (citations omitted) (Government must show claim is "more likely to deceive the public than to inform it."). The TCA, however, expressly allows smokeless tobacco manufacturers to make similar claims about their products without prior

[16] HPHCs in Tobacco Products and Tobacco Smoke: Established List, 77 Fed. Reg. 20,034 (Apr. 3, 2012).

FDA approval. Specifically, phrases like "not consumed by smoking," "does not produce smoke," or "not smoke" are not MRTP claims. 21 U.S.C. §387k(b)(2)(C). Neither Congress nor FDA showed, however, that those statements are any more truthful or non-misleading than comparable phrases the vapor industry would like to make. Instead, the government is picking and choosing among similar speakers and messages, allowing some but effectively banning others, without any reasonable basis. Such arbitrary distinctions are not permitted under the First Amendment. *Greater New Orleans*, 527 U.S. at 193.

Finally, the same constitutional shortcomings are seen with FDA's statements regarding the relative risk of vapor products. The government presented no evidence that adult consumers will be potentially misled if a vapor manufacturer represents on its website that vaping likely presents less health risk to the individual than smoking. Indeed, FDA does not believe such statements risk misleading consumers, as it has made such public declarations numerous times.

Ironically, where the MRTP provision is intended to avoid confusion or misinformed decisions, it has the opposite effect. From this perspective, it is easy to see how a government's "paternalistic approach" entails its own substantial risks – keeping consumers uninformed – which is why the Supreme Court has routinely deemed it unconstitutional. "It is precisely this kind of choice, between the danger of suppressing information, and the dangers of its misuse if it is freely available,

that the First Amendment makes for us." *Va. State Bd.*, 425 U.S. at 770; *see Edenfield*, 507 U.S. at 767 ("The general rule is that the speaker and the audience, not the government, assess the value of the information presented.").

E. The MRTP Provision Is Not Narrowly Tailored To Serve The Government's Interests

Sorrell's "heightened scrutiny" is also consistent with recent applications of *Central Hudson's* fourth prong – where the restriction cannot be more extensive than necessary to serve the government's interest – as courts have made it increasingly difficult to overcome this final inquiry. Despite the Supreme Court holding in *Bd. of Trs. v. Fox*, 492 U.S. 469, 480 (1989), that the First Amendment does not require the "least restrictive means," speech restrictions have more recently been struck down simply where non-speech related alternatives exist and the government has failed to explain why they do not adequately address its stated interest. *Cent. Hudson*, 447 U.S. at 570-71 (government must show why less restrictive means are ineffective). The Supreme Court has made "clear that if the Government could achieve its interests in a manner that does not restrict speech, or that restricts less speech, the Government *must do so*." *Thompson*, 535 U.S. at 371 (emphasis added) (citations omitted); *see Sorrell*, 564 U.S. at 575 (noting the "State offers no explanation why remedies other than content-based rules would be inadequate"); *Greater New Orleans*, 527 U.S. at 180.

Specifically, the government must evaluate the costs and benefits of the restriction when compared to non-speech regulation. *Id.* at 188 ("On the whole . . . the challenged regulation should indicate that its proponent 'carefully calculated' the costs and benefits associated with the burden on speech imposed by its prohibition.") (citation omitted). The Supreme Court's decision in *Lorillard*, which involved a prohibition on outdoor tobacco advertising within 1,000 feet of a school or playground, highlights how difficult it is to satisfy this burden. In invalidating the regulation, the Court stressed where a restriction sweeps broadly and applies uniformly in different circumstances, there is a risk the government has not carefully calculated the speech interests involved. 533 U.S. at 561.

In particular, the government should have further tailored the restriction so as to target those advertising practices that appeal to youth, but not at the same time substantially prevent or even effectively ban the free flow of truthful information to adult consumers. *Id.* at 561-63 (noting restrictions would significantly limit outdoor advertising in heavily populated areas and criticizing government's failure to consider less intrusive alternatives, such as only banning larger signs). The Court concluded, even where Congress acts to prevent underage tobacco use, the government must recognize that adults have a "corresponding interest in receiving truthful information about tobacco products." *Id.* at 564-65.

The MRTP provision fails *Central Hudson's* fourth prong because it is far broader than necessary to address the government's interest. As noted above, both Congress and FDA justify the MRTP process on deliberately false claims made by traditional tobacco companies using subjective phrases, such as "low," "mild," and "light." *Supra* at 20. But the provision also captures disclosures that are clearly distinct as they are objective facts and easily verifiable – *e.g.*, "no diacetyl" or "no burning." Moreover, it bans truthful representations that FDA has publicly stated on numerous occasions – *e.g.*, vapor products are "likely less hazardous for an individual user" than cigarettes. *Supra* at 7. The government was thus required to account for the substantial costs imposed by restricting adult access to information, and better tailor the restrictions to guard against any potentially misleading claims. It did not do so.

FDA never addressed, for example, the use of disclaimers, one of the most straightforward methods of reducing the risk of allegedly misleading statements. This holds true even though the Supreme Court and circuit courts have frequently invalidated speech restrictions where the government failed to consider disclaimers. *Cent. Hudson*, 447 U.S. at 571; *Thompson*, 535 U.S. at 376; *Ocheesee Creamery*, 851 F.3d at 1240 (disclaimer clarifying meaning of "skim milk" claim); *Int'l Dairy Foods Ass'n v. Boggs*, 622 F.3d 628, 639 (6th Cir. 2010) (disclaimer clarifying scope of "rbST free" hormone claim). In the TCA, after discussing the

misuse of "low," "mild," and "light" claims, Congress noted, albeit in conclusory fashion and without citation, the Federal Trade Commission ("FTC") found consumers had in the past misinterpreted advertisements even in the presence of disclaimers. Pub. L. No. 111-31, §§2(38)-(42), 123 Stat. 1776, 1780. But there is no indication Congress specifically considered the very different types of vapor-related claims discussed above.

Interestingly, in the Deeming Rule, FDA explicitly approved the use of a disclaimer by cigar manufacturers – "Warning: Cigars Are Not a Safe Alternative to Cigarettes" – to correct the "unsubstantiated perception, especially among young people, that cigars are less hazardous than cigarettes." 81 Fed. Reg. at 29,070; 79 Fed. Reg. 23,142, 23,169 (Apr. 25, 2014). FDA said this "warning requirement will help consumers understand and appreciate the risks of cigars." *Id.* In fact, FTC originally approved this disclaimer in a 2000 consent order with major tobacco companies, 79 Fed. Reg. at 23,168-69, and it is identical to a disclaimer required for smokeless tobacco. Pub. L. No. 111-31, §204, 123 Stat. 1846. But FDA did not present evidence as to why vapor manufacturers cannot use similar disclaimers when making truthful statements (*e.g.*, "No Combusted Smoke; Vaping is Not a Safe Alternative to Discontinuing Nicotine Containing Products").

The government also failed to consider relying on its authority to enforce against misleading disclosures pursuant to the TCA's misbranding and adulteration

provisions, 21 U.S.C. §§387b, 387c, even though FDA recognized this enforcement authority "will help reduce consumer confusion and misperception" where labels or advertising are false or misleading. 81 Fed. Reg. at 29,051. For example, in response to concerns that some e-liquid labels have incorrectly reported nicotine levels, FDA directed that "the manufacturer will be subject to enforcement action for misbranding." *Id.* at 29,069. But FDA did not discuss why diligent enforcement of these provisions would be insufficient to deter companies from making other potentially misleading claims.

The government also did not consider requiring manufacturers to maintain records substantiating a claim (*e.g.*, lab tests showing an e-liquid does not contain diacetyl or allergens). Those records could be turned over to FDA at the time the claim is made or be available for inspection upon request. Indeed, this is precisely the protocol FDA requires under the Deeming Rule when a manufacturer asserts to FDA that a tobacco product does not contain nicotine and is therefore not required to include a nicotine addictiveness warning on a label. *Id.* at 29,060. Manufacturers are allowed to "self-certify" that certain products are nicotine-free provided they keep all supporting information and make it available for FDA review. *Id.* Moreover, with regard to HPHCs, FDA has a built-in process to verify claims that a product does not contain a certain HPHC or only contains a reported

amount. Yet FDA did not explain why these approaches can be used in some instances to confirm MRTP-like claims but not others.

In the end, there was a complete lack of analysis by the government to gauge the efficacy of less-intrusive alternatives, whether standing alone or in combination with each other. *Thompson*, 535 U.S. at 373 (State must consider combinations of alternatives). Nowhere did FDA ask if several options working together – enforcement actions, recordkeeping requirements, disclaimers, post-market surveillance, and even the deterrent effect of FTC fraud actions (15 U.S.C. §45) or state consumer protection and product liability lawsuits – could maintain the free-flow of important health and safety information to adult vapers.[17] When the government asserts an interest in protecting consumers from potentially misleading speech, "the preferred remedy is more disclosure, rather than less." *Bates v. State Bar of Ariz.*, 433 U.S. 350, 375 (1977).[18]

[17] Notwithstanding the TCA and Deeming Rule, the FTC may act against vapor companies for unfair or deceptive acts or practices regarding marketing and sale of vapor products. It may initiate enforcement actions to ensure statements are truthful, not misleading, and adequately substantiated.

[18] FDA argued the Sixth Circuit in *Discount Tobacco* held the MRTP provision satisfies *Central Hudson's* third and fourth prongs. 81 Fed. Reg. at 28,987. But the First Amendment cost/benefit analysis in that case, which involved traditional cigarettes, is much different than one involving vapor products that present a lower risk profile. *Discount Tobacco* did not involve the suppression of critical information that consumers use when deciding whether to move away from cigarettes. The government must account for such distinctions, particularly when

III. The Free Sample Ban Violates The First Amendment

The free sample ban raises significant First Amendment concerns as adult smokers will lose the most effective and efficient means of obtaining product-specific information when trying to switch away from deadly cigarettes.

A. Samples Are Protected Speech

Providing free samples and allowing adults to test products constitutes expressive conduct protected under the First Amendment. Whether conduct is "sufficiently imbued with elements of communication" depends on whether there is "an intent to convey a particularized message" and "the likelihood [is] great that the message [will] be understood by those who view it." *Tex. v. Johnson*, 491 U.S. 397, 404 (1989) (citations and internal quotations omitted). Here, the vapor industry provides free samples because the product category is novel, and adults often search for detailed information about specific product experience and performance that might help them switch away from cigarettes. This is the quintessential example of what the First Amendment protects in the commercial context – promoting the free-flow of information so consumers can make "intelligent and well-informed" decisions. *Va. State Bd.*, 425 U.S. at 763-65.

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the restrictions are content- and speaker-based, so there is some degree of proportionality between means and ends. *Sorrell*, 564 U.S. at 572.

First, this exchange of information is readily apparent to both buyer and seller when free samples are placed in front of a consumer, whether at an adult-only venue or vape shop, who can then test the e-liquids and/or devices with the help of a representative. Vapor products are relatively new to the marketplace and many consumers have little to no experience with these emerging products. FDA141041; FDA146594; FDA154903. Free samples allow adults to experiment and determine which products best fit their individualized needs or if they provide the same satisfaction as their current product. *Id.*; ADD224 ("Only sampling allows buyers to explore, in detail, the way a product compares to alternatives and to learn about their own preferences.").

Sampling is particularly important as adults turn to vaping when attempting to move away from cigarettes. *Id.*; FDA150271; FDA161119; FDA158208. As FDA acknowledged, "Free samples encourage current and non-tobacco product consumers to try different and new tobacco products, enabling them to learn about their own preferences and possibly change their purchasing behavior as a result." FDA184853; *see* 81 Fed. Reg. at 29,054 ("Comments on e-cigarettes argued that, because their products are new, free samples are necessary to convince cigarette users to switch to them.").

FDA recognized the critical importance of experimenting with product variety, stating the "availability of alternatives to traditional tobacco flavors in

some products (*e.g.*, ENDS) may potentially help some adult users who are attempting to transition away from combusted products." 81 Fed. Reg. at 28,977. Indeed, in one consumer survey, "[a]pproximately 65.5% of former smokers . . . consider[ed] e-liquid flavors important in helping them transition completely to vaping and away from smoking." FDA155149; *see* FDA130191; FDA150361-2; FDA079516; FDA031418; FDA154903-04.

Information conveyed through free samples, including free puffs at point of sale, is integral to this process. As one vapor retailer put it, sampling "not only helps customers find the flavors that work best for them, but allows curious smokers a chance to get a feel for personal vaporizers. Many of our customers were very skeptical the first time they walked into our stores, believing that nothing would be able to take the place of combustible cigarettes. However, after having a chance to sample the device and some flavors, they have much more confidence." FDA155148.

In another survey, vapers trying to cut down on cigarettes reported they were more likely to switch using tobacco flavored e-liquids, but they eventually move to other non-tobacco flavors. FDA155148. Flavor variability was particularly important. Survey participants used three different types of flavors on a regular basis, with former smokers switching more frequently than current smokers. They also used different flavors on a daily basis or during the day. Not surprisingly, new

vapers gravitated to tobacco flavors, while fruit flavors were more popular with experienced vapers. Participants ranked flavors as "very important" when moving away from cigarettes. *Id.*; *see* FDA150361-2; FDA130191-2.

Indeed, this form of personalized exchange is precisely the type of communication that is protected under the First Amendment. The Supreme Court made clear in *Edenfield* that "personal solicitation is commercial expression to which the protections of the First Amendment apply." 507 U.S. at 765. In so holding, the Court focused on the "considerable value" of educating consumers through in-person interactions. *Id.* at 766.

> [S]olicitation allows direct and spontaneous communication between buyer and seller. A seller has a strong financial incentive to educate the market . . . solicitation produces more personal interchange between buyer and seller . . . Personal interchange enables a potential buyer to meet and evaluate the person offering the product or service . . . For the buyer, it provides an opportunity to explore in detail the way in which a particular product or service compares to its alternatives in the market. In particular, with respect to nonstandard products . . . these benefits are significant.

Id.

Second, where the free samples are not used or consumed in a commercial establishment, such conduct is still protected by the First Amendment. Information regarding the product's quality and characteristics will still be conveyed through the free samples and, as FDA observed, consumers will likely understand and use that information when making decisions in the marketplace. FDA184853 (FDA

stating that free samples encourage product switching by imparting information to consumers that can impact purchasing behavior).

Indeed, the First Amendment is implicated where free samples are intended to promote product switching by consumers. In *Discount Tobacco*, the Sixth Circuit recognized that distributing free cigarette samples is a promotional method that encourages switching from competitors' brands, and held 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 538-39; *see Rockwood v. City of Burlington*, 21 F. Supp. 2d 411, 423 (D. Vt. 1998); *Bailey v. Morales*, 190 F.3d 320, 325 (5th Cir. 1999). Significantly, commenters noted free samples have been critical in convincing consumers to shift away from cigarettes and start vaping. FDA031418; FDA141043-4; FDA146594; ADD224. In fact, FDA conceded "the lack of free samples may discourage consumers from purchasing different products." FDA184853.

Third, the government's "regulation is related to the suppression of free expression." *Johnson*, 491 U.S. at 403. The ban on free samples is not limited to non-expressive conduct, such as mere distribution; it is also aimed at the communitive aspect of sampling. Congress was concerned that tobacco advertising would "attract" youths, that minors would be "influenced" by such marketing, and that advertising would "entice" them into tobacco use. Pub. L. No.

111-31, §§2(5), (15), (20), (23), (32), 123 Stat. 1777-79. FDA was likewise focused in the Deeming Rule on more than mere access and further highlighted the messaging associated with advertising. 81 Fed. Reg. at 29,986-87 (noting a free sample "increases social pressure" on youths to try vapor products and that the ban will "help to reduce initiation").

B. The Free Sample Ban Does Not Directly And Materially Advance The Government's Interests

As sampling has a significant communicative element, the ban is subject to, at a minimum, *Central Hudson's* third prong which, as with the MRTP provision, must be rigorously applied consistent with *Sorrell's* "heightened" level of scrutiny. The blanket prohibition is content-based because it restricts the ability of adult consumers to obtain certain information regarding vapor products, including flavors and device performance. *Reed*, 135 S. Ct. at 2226. The ban also discriminates based on the identity of the speaker. *Sorrell*, 564 U.S. at 564. As discussed above, smokeless tobacco companies can hand out free samples of their product, but vapor retailers cannot do the same. The prohibition therefore "burdens disfavored speech by disfavored speakers." *Id.*

Under this approach, the government must offer adequate evidentiary support. *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1218-20 (D.C. Cir. 2012) (invalidating graphic tobacco warnings where FDA's evidence only showed that they "might" result in reduced consumption, but did not demonstrate that they

would "directly" cause a material decrease in smoking rates or "actually" lead smokers to quit). In the instant case, FDA failed to show that the ban "directly and materially" advances the government's interest in preventing access to vapor products and subsequent "youth initiation" of cigarette use. 81 Fed. Reg. at 28,986-87. FDA primarily relied on two sources of information: (i) an almost quarter-century old report noting minors had obtained free samples of cigarettes in the past, focusing on venues that are frequented by youths (*e.g.*, concerts)[19]; and (ii) a 2014 survey showing free samples of vapor products had been distributed at events like motorsport races that appear to be youth-oriented.[20] *Id.* at 28,986.

This evidence, however, does not show an all-encompassing free sample ban will "in fact" prevent youth access and the initiation of cigarette use to a "material degree." *Greater New Orleans*, 527 U.S. at 188. *First*, neither report examined sampling in adult-only venues (*e.g.*, trade shows) or vape shops. FDA did not cite any evidence demonstrating underage individuals are obtaining free samples in any amounts at these establishments, particularly where samples are used or consumed by adults on the premises and never taken off-site. Where the government

[19] Inst. of Med. of the Nat'l Acad., Growing Up Tobacco Free: Preventing Nicotine Addiction in Children and Youths, at 216 (1994), *available at* https://tinyurl.com/yd23qkym.

[20] Richard J. Durbin et al., Gateway to Addiction? A Survey of Popular Electronic Cigarette Manufacturers and Targeted Marketing to Youth (2014), *available at* https://tinyurl.com/ya64bwg8.

prevents truthful information about flavors and device performance from being conveyed, it must put forth sufficient evidence that the restriction actually addresses the issue to a significant degree. *See 44 Liquormart*, 517 U.S. at 506 (plurality opinion) (restriction must "significantly reduce" underage use).

Second, regardless of venue, the ban is inconsistent with the TCA's exemption for smokeless tobacco samples distributed from a QAOF. 21 U.S.C. § 387a-1(d); 21 U.S.C. §1140.16(d). There is no evidence justifying this distinction or explaining why free samples of smokeless tobacco pose less risk to minors than vapor products. Moreover, FDA has not presented any data showing that minors are gaining access to free samples of vapor products in substantially greater numbers when compared to smokeless tobacco. While the government guards against youth access for one product, it irrationally risks access to another. All of this raises serious First Amendment concerns, as the government has distinguished speakers based on content, allowing the smokeless tobacco industry, but not others, to market free samples. *Greater New Orleans*, 527 U.S. at 194 ("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.").

In any event, the only report cited by FDA that considers vapor products contains no data indicating that minors are, in fact, accessing free samples at public

events and that those samples could lead substantial numbers of youth to start smoking. Whether such level of access "might" occur is not grounds for restricting the free flow of information in the marketplace. *R.J. Reynolds*, 696 F.3d at 1219.

IV. The Free Sample Ban Is Not Narrowly Tailored To Serve The Government's Interests

The ban on free samples also fails *Central Hudson's* fourth prong because it is "not sufficiently tailored to its goal." *Rubin*, 514 U.S. at 490. By any measure, the prohibition sweeps broadly. Not only does the provision seek to protect minors, it also substantially restricts adults from acquiring critical information. This holds true even if free samples are distributed in adult-only facilities or after the TCA's minimum age requirement (under 18 years old) for sales is verified through proper identification. 81 Fed. Reg. at 29,057; 21 C.F.R. §1140.10, 1140.14. FDA must carefully consider the burdens imposed on adult consumers' right to receive information through free samples and further tailor any restrictions to better target the government interests involved. *Lorillard*, 533 U.S. at 561-63. Unfortunately, this obligation was ignored.

FDA maintained the free sample ban is a "minor restriction" and vapor companies "remain free to inform consumers about their products. . . . [and] communicate truthful and nonmisleading information to adult consumers." 81 Fed. Reg. at 28,987. FDA argued customers can still "touch, hold, and smell" vapor products without violating the free sample prohibition. *Id.* at 29,055. But

this response completely ignores the role sampling plays in the vapor community and the significant amount of information that will not be conveyed if consumers cannot test free samples.

As discussed above, smokers report that sampling is part of a continual process of moving away from cigarettes. *Supra* at 36-38. It is self-evident that a consumer will need to actually taste and experience the sensation of different flavors, and how various devices deliver those products; merely touching an e-liquid bottle or smelling a sample would be useless. FDA admitted that flavor variability may help some adults move to vaping, and ultimately realize a health benefit, but then prohibits the most effective and efficient method for those same consumers to obtain relevant information. 81 Fed. Reg. at 28,977, 29,011.

There are other non-speech, less intrusive alternatives, whether standing alone or in combination, that could adequately guard against youth access to free samples. The most obvious is to enforce already existing minimum age verification requirements. FDA148940; FDA158215; FDA158207. Indeed, FDA repeatedly concluded that applying the TCA's minimum age restrictions to the sale of tobacco products, coupled with aggressive enforcement, will effectively decrease youth access and initiation, and is appropriate for protecting the public health. 81 Fed. Reg. at 29,057-59; 79 Fed. Reg. at 23,160-62. In fact, in an apparent nod to the First Amendment, FDA stated this approach constitutes a

"reasonable restriction[] to curb youth tobacco product use that would not hamper adult access to these products." 79 Fed. Reg. at 23,161.

Along similar lines, FDA concluded that tobacco products could be sold through vending machines, consistent with protecting the public health, provided they are located in facilities that prohibit access to minors. 81 Fed. Reg. at 29,059; 79 Fed. Reg. at 23,162; *see* 21 C.F.R. §1140.16(c)(2)(ii). FDA also acknowledged this option strikes a reasonable balance between protecting minors and adult consumer interests. 79 Fed. Reg. at 23,162; 81 Fed. Reg. at 29,059.

FDA further recognized an additional non-speech alternative – FDA public education campaigns for both retailers and youth – could help reduce underage access and initiation, especially when combined with minimum age verifications and enforcement. 81 Fed. Reg. at 29,058; 79 Fed. Reg. at 23,161 (FDA stating that a "number of studies have observed at least some correlation between the enforcement of youth access restrictions and reduced tobacco product use among youth when enforcement is coupled with educational campaigns, and FDA has conducted and plans to continue to conduct various types of public education regarding tobacco products."); 79 Fed. Reg. at 23,160 ("FDA intends to work with

retailers to emphasize the importance of continued training for employees so that they will understand age restriction as well as how to enforce it.").[21]

Despite FDA's enthusiastic endorsement of minimum age restrictions, enforcement programs, and educational campaigns, FDA never explained why such non-speech alternatives would not work equally as well for free samples. FDA's only response was brief and conclusory. It simply rejected age verification as an option by citing to the Sixth Circuit's decision in *Discount Tobacco*, where that court held the free sample ban was narrowly tailored because cigarettes were easily accessible to minors, even with industry's voluntary programs to limit distribution to underage individuals. 81 Fed. Reg. at 28,986-87. But voluntary programs are not the same as the nationwide enforcement of minimum age restrictions. FDA never reconciled the Sixth Circuit's conclusion with FDA's more recent approval of age verification and enforcement programs for the sale of vapor products. Indeed, consideration of costs and benefits for vapor products is much different than for the cigarettes at issue in *Discount Tobacco*. Here, consumers are searching for truthful information regarding a novel and potentially

[21] On August 8, 2017, FDA announced it would pursue a new public health education effort designed to prevent youth from using vapor products. FDA News Release, FDA to Expand Public Education Campaign to Focus on Prevention of Youth E-Cigarette Use (Aug. 8, 2017), https://tinyurl.com/yahacaaz.

life-saving product category. There is much more at stake in the instant case where helpful information is lost to an overly-broad and unjustified speech restriction.

FDA was similarly dismissive of suggestions that free samples of vapor products only be allowed at QAOFs, as is permitted under the TCA for smokeless tobacco. FDA141043. FDA argued it would have to determine the "type of facility, means of access, type(s) of tobacco products distributed, and portion sizes for each type of tobacco product" that could leave the premises. 81 Fed. Reg. at 28,986. But both Congress and FDA have already addressed these issues in detail. *See* 21 U.S.C. 387a-1; 21 C.F.R. §1140.16(d). FDA and regulated entities know exactly how a QAOF must be set up and operated. FDA further claimed that it does not have sufficient information to set limits on the sample sizes that could be taken out of a QAOF. 81 Fed. Reg. at 28,987. This point is irrelevant, however, if vapers were required to consume or use the vapor product onsite and never take a sample off the premises. Moreover, if FDA believed that it needed more information on sample sizes, the First Amendment requires FDA to further explore that alternative (*e.g.*, by collecting the necessary information), rather than summarily rejecting that option out of hand. *Thompson*, 535 U.S. at 373 ("If the First Amendment means anything, it means that regulating speech must be a last – not first resort.").

Finally, there are other non-speech alternatives that FDA did not address at all, whether standing alone or in combination with others. For instance, FDA could prohibit free samples at only certain types of public events (*e.g.*, concerts) that are frequented by minors, or require that free samples, regardless of venue type, only be used or consumed onsite. Further, there is a complete absence on FDA's part to examine various combinations of less intrusive options that might prove equally successful in preventing youth access. *See id.* For example, FDA could require QAOFs at public events where youths are present, but only age verifications at adult-oriented facilities, like vape shops. In short, FDA could have further tailored the free speech restriction given how the vapor marketplace operates in different circumstances so as not to "unduly impinge" on the adult consumer's right to obtain beneficial information. *Lorillard*, 553 U.S. at 565.

V. FDA Failed To Tailor The PMTA To Less Risky Vapor Products

FDA failed to structure the PMTA requirements to reflect continuum of risk so adults have continued access to tobacco products and there is a viable market for less harmful products. In the TCA, Congress struck a balance between protecting minors and ensuring sufficient availability of products that will help adult consumers avoid cigarette-related death and disease. But FDA applied a one-size-fits-all approach requiring vapor products to navigate an onerous PMTA process applying to much risker, non-grandfathered cigarettes. And it did so while

concluding this will eliminate over 95% of vapor manufacturers, along with the product variety they supply. Thus, FDA violated the TCA and APA by not acting in accordance with the TCA's overall structure, and arbitrarily and capriciously ignoring its own findings. 5 U.S.C. §706(2); *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43 (1971) (agency action must be set aside when it "runs counter to the [record] evidence").

A. The TCA Requires FDA To Regulate Based On Risk

The PMTA must be viewed in light of the TCA's overall statutory structure and underlying purposes. *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 125 (2000) (FDA "may not exercise its authority [under the Food, Drug and Cosmetic Act ("FDCA")] 'in a manner that is inconsistent with the administrative structure that Congress enacted into law'") (citation omitted). Congress directed that FDA "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." Pub. L. No. 111-31, §3(7), 123 Stat. at 1782. Further, adults must have access to products that are safer than cigarettes. The statute "provide[s] new and *flexible* enforcement authority to ensure that there is effective oversight of the tobacco industry's efforts to develop, introduce, and promote less harmful tobacco products." *Id.* at §3(4) (emphasis added). As such, FDA should only "impose *appropriate* regulatory controls on the tobacco industry." *Id.* at §3(8) (emphasis

added); 21 U.S.C. §371(a) (granting FDA authority to adopt regulations "for the efficient enforcement" of the FDCA).

This approach is consistent with the unique regulatory regime Congress established for tobacco products over the past half century. As the Supreme Court discussed in *Brown & Williamson*, various statutes leading up to the TCA imposed certain controls on cigarettes, like advertising and warning restrictions, while ensuring that adult consumers had continued access. 529 U.S. at 138-39. Taken together, these statutes reflected a Congressional intent not only to provide information about the health risks of tobacco use, but also a desire that "tobacco products remain on the market." *Id.* at 139.

B. The Deeming Rule Will Virtually Eliminate The Vaping Industry

Subjecting vapor products to the same PMTA requirements as cigarettes, however, risks nearly eliminating the vapor industry when the PMTA filing deadline for currently marketed vapor products expires in August 2022. According to FDA, there are between 168-204 manufacturers of e-liquids and vaping devices, and an additional 3,500 to 7,000 vape shops that manufacture vapor products. FDA184820. FDA then assumed all of these vape shops would forego submitting PMTAs and either exit the market completely or switch to retail only. Thus, 95%-97% of manufacturers will cease to exist within the next half-decade. 81 Fed. Reg. at 29,076 (FDA conceding most manufacturers are "small").

Moreover, a large-scale exodus from the market may significantly impact flavor variability. As detailed above, vapers regularly seek out new and distinct flavors when moving away from cigarettes, which includes sampling at their local vape shops. *Supra* at 36. Based on one study, FDA found that there were at least 7,764 unique e-liquid flavors. FDA184826. FDA then estimated that between 50% and 87.5% of e-liquids would not go through the PMTA process and will exit the market. FDA184829. Given FDA concluded the PMTA will result in "consumer costs for users due to loss of product variety or higher prices," FDA184863, substantial losses in consumer choice could have serious consequences for the TCA's goal of reducing tobacco-related harm.

As for the few remaining manufacturers, FDA predicted there will be 1,250-2,500 PMTAs submitted for e-liquid products, and 360-450 PMTAs for devices, before the compliance period expires. FDA184834. These numbers are completely unrealistic. Nowhere in the administrative record did FDA provide supporting data or any underlying rationale for these assumptions. Moreover, if history is any indication, it is easy to see just how speculative FDA's predictions are. Since the TCA was adopted, a total of only five PMTAs have been filed. Four of those applications were rejected. The remaining PMTA was approved for

eight Swedish Match smokeless tobacco products.[22] Thus, it simply strains credulity for FDA to claim that the vaping industry will file hundreds, if not thousands, of PMTAs when not even the well-funded traditional tobacco industry could muster a fraction of those numbers over the last decade.

In reality, completing a PMTA will be cost prohibitive for all but the largest vapor companies, and even those manufacturers will only seek FDA approval for very few products. FDA184838 (FDA stating PMTA expected to reduce number of flavor variants and product lines). While FDA estimated a range of costs for e-liquid and device PMTAs, virtually all manufacturers will fall on FDA's high-end estimate of over $2 million per product submission. FDA184837, 40-41. This is because, to satisfy the "population effects" standard, FDA has indicated that long-term clinical and epidemiological studies will likely be required. 81 Fed. Reg. at 28,997. But as FDA conceded, no such studies currently exist. *Id.* at 28,984, 29,028-31, 29,041. As FDA estimated this research will be the most expensive aspect of an application, FDA184836-837, several million dollars for each PMTA will likely be the norm before the 2022 deadline.[23]

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[22] FDA, *Tobacco Product Marketing Orders, available at* https://tinyurl.com/ybohhopy.

[23] The Swedish Match product had been used for over 30 years and its PMTA was accompanied by "data spanning several decades," including clinical pharmacology studies, clinical trials regarding cessation effects, longitudinal and cross-sectional

Moreover, as manufacturers have multiple brands and vapor products, which can number in the thousands, PMTA costs will quickly sky rocket. FDA requires a PMTA for each "finished tobacco product" – *i.e.*, a product, including all components or parts, sealed in final packaging for the consumer. 81 Fed. Reg. at 28,995. This would not only include a complete vapor device (including heating coils and e-liquid), but also every single e-liquid formulation sold separately. *Id.* Further escalating costs, manufacturers may need to test each finished product in a range of circumstances to satisfy the PMTA standard. For example, an e-liquid or heating coil sold separately would need to be tested with many different devices. *Id.* at 28,994. FDA's cost estimates assume a separate PMTA will be required for each similarly branded product. FDA184838.

Vapor companies attested to the enormous time and financial burdens imposed by the PMTA process. Appellant Nicopure, for example, has approximately 2,400 individual stock keeping units ("SKUs") for e-liquids, devices, and parts. ADD217. Even if Nicopure eliminated 80% of its products, using FDA's estimated average of 1,500 hours to prepare an application, it would take 10 employees working 24/7 nearly a decade to complete the task. ADD222. Reducing its 950 e-liquid SKUs to 100 products would, after applying FDA's

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studies on consumer use patterns, and substantial epidemiological studies. *Supra* note 10, at 7, 20, 25-26, 29.

average PMTA cost of $131,643 per e-liquid product, FDA184838, total $13 million dollars. *See* ADD217, ADD219. And that unreasonably assumes little to no clinical or epidemiological research would be needed. The device PMTAs would be even more burdensome. Applying FDA's average PMTA cost of $466,563, FDA184842, just 25 devices or separately sold parts would exceed $11 million. ADD219; FDA130192-94 ($230 million for 700 products); FDA161084 ($25-$75 million for three devices and 20 e-liquids). Small manufacturers, including vape shops, simply cannot bear such oppressive compliance costs.[24]

C. FDA Must Consider Reasonable PMTA Alternatives

As the majority of vapor companies may disappear, along with product variability, FDA had the discretion, and statutory duty, to tailor the PMTA process so adults have continued access to a variety of less risky products. According to FDA, it "agrees that a continuum of nicotine-delivering products does exist as demonstrated by the lower levels of toxicants in ENDS in comparison to cigarettes, and may warrant different requirements for products at different ends of this continuum." 81 Fed. Reg. at 29,027. As such, commenters suggested ways to streamline the PMTA process and reduce the financial burden while, at the same

[24] The Small Business Administration also commented that FDA's proposed Deeming 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." FDA082216.

time, meeting the overall objectives of the PMTA standard. For instance, FDA could explicitly require vapor manufacturers, in lieu of costly product-specific clinical or epidemiological studies, to rely on a scientific literature review regarding harm reduction to show that vapor products are "appropriate for the public health." FDA129147. FDA could develop regulations specific to the vapor industry defining which studies would meet criteria under the public health standard without requiring long-term research. *Id.* Indeed, Congress gave FDA such discretion within the PMTA provision itself, only requiring clinical studies "when appropriate" and permitting use of other "valid scientific evidence." 21 U.S.C. §§387j(c)(5). Similar comments advocated for a flexible PMTA process. 81 Fed. Reg. at 28,997 (suggesting a user registry with demographic cessation and initiation data rather than product-specific long-term studies).

FDA, however, summarily dismissed these alternatives. FDA argued it cannot deviate from a one-size-fits-all PMTA provision. *Id.* at 28,997-98, 29,000. But the TCA mandates *appropriate* regulation. Congress explicitly gave FDA "flexible enforcement authority" to promote safer, innovative products, and intended for FDA to strike a balance between protecting the public health and ensuring reasonable adult access to such products. Indeed, the Supreme Court has held repeatedly that an agency cannot interpret a provision in isolation where it would otherwise threaten the statute's underlying goals and objectives. *King v.*

Burwell, 135 S. Ct. 2480, 2492 (2015) ("[W]ords of a statute must be read in their context and with a view to their place in the overall statutory scheme.").

VI. This Court Should Deny The Motion To Intervene

This Court should deny Movant-Intervenors' ("Movants") motion to intervene (Doc. #1692194). *First*, Movants speculate FDA might not fully defend their interests because FDA stayed proceedings in two similar cases and recently extended the PMTA filing deadline. Under Fed. R. Civ. P. 24(a)(2), intervention-as-of-right must be denied where "existing parties adequately represent [movant's] interest." FDA has not asked to stay this appeal and made clear it will adequately defend the Deeming Rule. In response to Movant's attempts to intervene in two other cases, FDA pledged "the government intends to continue defending [the Rule]." *Cigar Ass'n of Am. v. FDA*, No. 1:16-cv-1460 (D.D.C.), FDA Resp. Br. at 6 (Doc. 43); *Cyclops Vapor 2 v. FDA*, No. 2:16-cv-556 (M.D. Ala.), FDA Resp. Br. at 6 (Doc. 65). Moreover, while FDA did not take a position on the pending motion, it suggested Movants "may present their arguments as *amici*," thus clearly signaling it intends to fully defend. (Doc. #1695437). Indeed, FDA reaffirmed its commitment to the Deeming Rule in the Comprehensive Plan. *Supra* note 2. Mere speculation on Movants' part is insufficient and, without more, is also grounds for denying permissive intervention. *Alfa Int'l Seafood v. Ross*, 321 F.R.D. 5, 9 (D.D.C. 2017); *Cigar Ass'n*, 2017 WL 467535, at *9.

Second, the motion was untimely as it was filed over six months after Movants first concluded that FDA might not mount a defense, and almost two months after they filed similar motions in *Cyclops* and *Cigar Ass'n*. *Cyclops*, Mot. Intervene at 8-9, 18-19 (Doc. 33); *Cigar Ass'n*, Mot. Intervene at 7-8, 16 (Doc. 36). "[I]ntervention after judgment will usually be denied where a clear opportunity for pre-judgment intervention was not taken." *Associated Builders & Contrs., Inc. v. Herman*, 166 F.3d 1248, 1257 (D.C. Cir. 1999). Timeliness is judged based on time elapsed since the suit was filed, the movant's underlying justifications, and potential prejudice to the parties. *U.S. v. British Tobacco Australia Servs. Ltd.*, 437 F.3d 1235, 1238 (D.C. Cir. 2006). Here, Appellants will be potentially prejudiced as Movants apparently intend to convince FDA through intervention and settlement negotiations to roll-back the discretionary extension of the PMTA filing deadline, an issue that is not implicated on appeal.

Third, Movants do not have Article III standing as they have not demonstrated an injury in fact. *Crossroads Grassroots Policy Strategies v. FEC*, 788 F.3d 312, 316 (D.C. Cir. 2015). All but one of the Movants allege "organizational" standing, arguing changes to the Deeming Rule would force them to engage in more public education and counseling. But courts routinely deny standing on these grounds. *Food & Water Watch, Inc. v. Vilsack*, 808 F.3d 905, 919-20 (D.C. Cir. 2015); *Cigar Ass'n*, 2017 WL at *6 (citing cases). While

Movants also argue this suit could limit the amount of information that is available about vapor products, they substantially overstate this risk. Appellants are not challenging most TCA provisions that require the submission of information to FDA, like ingredient listings, HPHC test results, and health studies. Moreover, as discussed above, only a relatively few PMTA and MRTP applications will likely be filed. Finally, as to the remaining Movant, that group failed to demonstrate "representational" standing, as it did not submit a declaration of any member showing how the litigation will adversely impact their medical practices in a "personal and individual way." *Animal Legal Defense Fund, Inc. v. Glickman*, 154 F.3d 426, 433 (D.C. Cir. 1998).

CONCLUSION

This Court should: (i) declare that the MRTP provision and free sample ban violate the First Amendment; (ii) remand the PMTA provisions of the Deeming Rule so FDA can properly apply the TCA to the vapor industry; and (iii) deny Movants' request to intervene.

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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 12,997 words according to the count of Microsoft Word.

/s/ Eric P. Gotting
Eric P. Gotting

CERTIFICATE OF SERVICE

I hereby certify that on this 12th day of February, 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

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