**ORAL ARGUMENT NOT YET SCHEDULED**

**No. 17-5196**

**IN THE UNITED STATES COURT OF APPEALS**
**FOR THE DISTRICT OF COLUMBIA CIRCUIT**

NICOPURE LABS, LLC, RIGHT TO BE SMOKE FREE COALITION,

*Plaintiffs-Appellants*,

*v.*

FOOD AND DRUG ADMINISTRATION, *et al.*,

*Defendants-Appellees*.

On Appeal From The United States District Court
For The District Of Columbia

# BRIEF OF NJOY, LLC AS *AMICUS CURIAE* IN SUPPORT OF PLAINTIFFS-APPELLANTS AND URGING REVERSAL

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## CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to D.C. Circuit Rule 28(a)(1), *amicus curiae* NJOY, LLC certifies as follows:

### A. Parties

Except for the following, all parties, intervenors, and *amici* appearing before the district court and in this Court are listed in the Brief for Appellants:

*Amici* in this Court: State of Iowa; Clive Bates and Additional Public Health/Tobacco Policy Authorities; Consumer Advocates for Smoke-free Alternatives Association.

### B. Rulings Under Review

The ruling under review is identified in the Brief for Appellants.

### C. Related Cases

This case has not previously been before this Court or any other court. NJOY, LLC is not aware of any related cases before this Court or any other court.

## RULE 26.1 DISCLOSURE STATEMENT

NJOY, LLC is a limited liability company organized under the laws of the State of Delaware. It is a wholly owned subsidiary of NJOY Holdings, Inc., a privately held company, and no publicly held company holds a 10% or greater ownership interest in NJOY, LLC or its parent.

NJOY develops, imports, and distributes electronic nicotine delivery products (electronic cigarettes and vaping products). NJOY seeks to end smoking-related death and disease by offering satisfying, non-combustion alternatives to adult smokers and vapers, thereby making the combustion cigarette obsolete.

/s/ Theodore B. Olson
Theodore B. Olson

## STATEMENT REGARDING CONSENT TO FILE AND SEPARATE BRIEFING

All parties and proposed intervenors to this appeal have consented to the filing of this brief. NJOY, LLC submitted notice of its intent to file this *amicus curiae* brief on January 22, 2018.*

Pursuant to D.C. Circuit Rule 29(d), NJOY certifies that a separate brief is necessary to enable NJOY to provide its unique perspective on one of the issues raised in this appeal: whether the application to e-cigarette manufacturers of the Family Smoking Prevention and Tobacco Control Act's Modified Risk Tobacco Product ("MRTP") provisions—which subject truthful speech by NJOY and other manufacturers to a governmental preclearance requirement and accompanying delays, uncertainty, and a likely veto—violates the First Amendment. The MRTP preclearance requirement imposes intolerable restrictions on the ability of NJOY to disseminate accurate, scientifically supported information about its lawful e-cigarettes. In particular, NJOY desires to inform adult consumers that its e-cigarettes pose fewer health risks than combustible cigarettes and that vapor from its e-cigarettes is free of many of the substances found in the smoke of combustible cigarettes. Under the MRTP preclearance requirement, however, NJOY is barred

* No counsel for a party authored this brief in whole or in part, and no person other than *amicus curiae* and its counsel contributed any money that was intended to fund preparing and submitting this brief. *See* Fed. R. App. P. 29(a)(4)(E).

from conveying that truthful information to consumers unless it first receives authorization from the Food and Drug Administration ("FDA").

As a manufacturer committed to helping consumers switch completely from combustible cigarettes to e-cigarettes, NJOY has valuable insights and perspectives—distinct from those of other *amici*—regarding the speech burdens imposed by the MRTP preclearance requirement and the adverse effect that the requirement could have on the public health. NJOY has long been at the forefront of these issues. In February 2017, NJOY acquired the assets of NJOY, Inc., which, operating as Sottera, Inc., prevailed in *Sottera, Inc., dba NJOY v. FDA*, 627 F.3d 891 (D.C. Cir. 2010), where this Court upheld an injunction barring the FDA's attempt to ban e-cigarettes as unapproved drug-delivery devices. NJOY also manufactures the Standardized Research E-Cigarette—using grants from the National Institute on Drug Abuse, a division of the National Institutes of Health—for use in government-funded studies regarding e-cigarette products. NJOY is thus uniquely positioned to assist the Court in evaluating the FDA's regulatory approach to e-cigarettes.

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## GLOSSARY

| | |
|---|---|
| **E-Cigarette** | Electronic Cigarette |
| **FDA** | Food and Drug Administration |
| **MRTP Preclearance Requirement** | Modified Risk Tobacco Product Preclearance Requirement, 21 U.S.C. § 387k |
| **NJOY** | NJOY, LLC |
| **Tobacco Control Act** | Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009) |

## STATUTES AND REGULATIONS

All applicable statutes and regulations are contained in the Brief for Plaintiffs-Appellants.

## INTEREST OF *AMICUS CURIAE*

NJOY, LLC has been a leading innovator in the development of electronic cigarettes (or e-cigarettes) since the birth of the industry in the mid-2000s. NJOY develops, imports, and distributes e-cigarettes and other electronic nicotine delivery products. It is committed to offering satisfying, non-combustion alternatives to adult smokers, thereby making the combustible cigarette obsolete and ending smoking-related death and disease.

Among other issues, this appeal raises a First Amendment challenge to a government-imposed gag order that blocks NJOY from truthfully describing its products to consumers. The Food and Drug Administration ("FDA") recently deemed e-cigarettes to be "tobacco products" subject to various provisions of the Family Smoking Prevention and Tobacco Control Act ("Tobacco Control Act"), Pub. L. No. 111-31, 123 Stat. 1776 (2009). *See* 81 Fed. Reg. 28,974, 29,053 (May 10, 2016). One of the statutory provisions that now applies to e-cigarettes by virtue of the FDA's action is the Modified Risk Tobacco Product ("MRTP") preclearance requirement. 21 U.S.C. § 387k. That requirement prevents NJOY and other e-cigarette manufacturers from making certain truthful statements about their products—including that they pose fewer health risks than combustible cigarettes and that e-cigarette vapor is free (or contains reduced levels) of various substances—unless and until they apply for and receive permission from the FDA.

*See id.* § 387k(a)-(b). And nothing in the statute requires the FDA to make a prompt decision on a manufacturer's application to speak by a fixed deadline.

As a direct result of the MRTP preclearance requirement, NJOY is prohibited from conveying accurate, scientifically substantiated information about its e-cigarettes to adult consumers. NJOY is required to keep the public in the dark about the comparative health benefits of switching from combustible cigarettes to e-cigarettes—even though the FDA allows e-cigarettes to be sold to adult consumers and has recently embraced those very health benefits in announcing a fundamental shift in its nicotine policy. The FDA's speech-licensing regime is an unconstitutional restriction on the right of NJOY and other e-cigarette manufacturers to communicate with consumers about their lawful products. And, by silencing e-cigarette manufacturers, the FDA perpetuates misinformation about the comparative health risks of e-cigarettes and combustible cigarettes, jeopardizing the health of millions of smokers who may be laboring under the misimpression that e-cigarettes are just as dangerous as (or even more dangerous than) combustible cigarettes.

Accordingly, NJOY's First Amendment rights and the success of its goal of helping smokers switch completely from combustible cigarettes to e-cigarettes are directly at stake.

## BACKGROUND

### A. There Is Extensive Scientific Evidence That E-Cigarettes Present Fewer Health Risks Than Combustible Cigarettes.

An e-cigarette is an electronic system for delivering nicotine. While e-cigarettes contain nicotine, they do *not* deliver that nicotine by means of combustion. Traditional combustible cigarettes, in contrast, deliver nicotine along with thousands of other chemicals by burning tobacco that smokers inhale.

As the FDA has recognized, there is extensive scientific evidence that e-cigarettes present fewer health risks than combustible cigarettes because e-cigarettes do not burn tobacco. In his recent landmark speech, FDA Commissioner Scott Gottlieb acknowledged that the "nicotine in cigarettes is not directly responsible for the cancer, lung disease, and heart disease that kill hundreds of thousands of Americans each year." Scott Gottlieb, Commissioner, FDA, *Protecting American Families: Comprehensive Approach to Nicotine and Tobacco* (July 28, 2017), goo.gl/gGQign (remarks as prepared for delivery). "[I]t's the other chemical compounds in tobacco, and in the smoke created by setting tobacco on fire," he continued, "that directly and primarily cause the illness and death, not the nicotine." *Id*.

Commissioner Gottlieb further explained that "there's a continuum of risk for nicotine delivery." *Protecting American Families*, *supra*. As he emphasized, e-cigarettes have the potential "to deliver nicotine" without "bring[ing] with it the

deadly consequences of burning tobacco and inhaling the resulting smoke." *Id.* In fact, the FDA is already comfortable describing e-cigarettes as "modified risk tobacco products"—as long as e-cigarette manufacturers themselves are not the ones highlighting that "modified risk." *See* Scott Gottlieb *et al.*, *Advancing Medicinal Nicotine Replacement Therapies as New Drugs – A new step in FDA's comprehensive approach to tobacco and nicotine* (Nov. 29, 2017), goo.gl/Z1ixQc. And while the FDA requires e-cigarettes that contain nicotine to carry labels disclosing that "[n]icotine is an addictive chemical," 21 C.F.R. § 1143.3, it does *not* require labels warning that e-cigarettes cause lung cancer, heart disease, or other ailments associated with combustible cigarettes.

Based on this scientific evidence, the FDA recently announced a comprehensive policy shift in its approach to tobacco products. Rather than prioritizing efforts to end the use of all tobacco products, the FDA's new policy will focus on reducing nicotine levels in combustible cigarettes while, at the same time, giving greater flexibility to e-cigarette manufacturers and promoting "changes that will move addicted smokers down th[e] continuum of risk to these less harmful products." *Protecting American Families*, *supra*.

Other public-health officials and scientific organizations have reached similar conclusions about the potential public-health benefits of e-cigarettes. According to the American Cancer Society, "switching to the exclusive use of

e-cigarettes is preferable to continuing to smoke combustible products." ACS Position Statement on Electronic Cigarettes (Feb. 2018), goo.gl/T25u2m. British regulators likewise advise consumers that, although e-cigarettes "aren't completely risk free," they "carry a small fraction of the risk of cigarettes." National Health Service, E-cigarettes, https://www.nhs.uk/smokefree/help-and-advice/e-cigarettes. "E-cigarettes," they explain, "don't produce tar or carbon monoxide, two of the most harmful elements in tobacco smoke. The liquid and vapour contain some potentially harmful chemicals also found in cigarette smoke but at much lower levels." *Id.*; *see also*, *e.g.*, Public Health England, *E-cigarettes: an evidence update* 5 (Aug. 2015), goo.gl/mCZPDk ("best estimates show e-cigarettes are 95% less harmful to your health than normal cigarettes"). And the National Academy of Sciences has found that "[t]he evidence about harm reduction suggests that across a range of studies and outcomes, e-cigarettes pose less risk to an individual than combustible tobacco cigarettes." *Public Health Consequences of E-Cigarettes*, at S-8 (2018), goo.gl/XSxSp3; *see also id.* at S-7 ("There is conclusive evidence that completely substituting e-cigarettes for combustible tobacco cigarettes reduces users' exposure to numerous toxicants and carcinogens.").

### B. The Tobacco Control Act Imposes Sweeping Restrictions On Manufacturers' Speech About E-Cigarettes.

Despite substantial scientific evidence that e-cigarettes present fewer health risks than combustible cigarettes, the FDA has barred e-cigarette manufacturers

from conveying this potentially life-saving information to consumers without receiving pre-authorization from the agency.

When the FDA deemed e-cigarettes to be "tobacco products" for purposes of the Tobacco Control Act, it subjected e-cigarette manufacturers to the speech restrictions imposed by the Act's MRTP preclearance requirement, 21 U.S.C. § 387k. *See* 81 Fed. Reg. 28,974, 29,053 (May 10, 2016). That requirement prohibits—on pain of civil and criminal penalties—"the introduction of any 'modified risk tobacco product' into interstate commerce unless that product has been pre-cleared by the FDA." *Nicopure Labs, LLC v. FDA*, 266 F. Supp. 3d 360, 374; *see also* 21 U.S.C. § 387k(a). The Tobacco Control Act defines "modified risk tobacco product" based on the types of public statements that manufacturers make about the product. The definition includes any tobacco product "the label, labeling, or advertising of which represents explicitly or implicitly that" it "presents a lower risk of tobacco-related disease or is less harmful than one or more other commercially marketed tobacco products"; "contains a reduced level of a substance or presents a reduced exposure to a substance"; or "does not contain or is free of a substance." *Id.* § 387k(b)(2)(A)(i); *see also id.* § 387k(b)(2)(A)(iii) (extending same restrictions to any other "action directed to consumers" by "tobacco product manufacturer[s]").

Before engaging in speech that would render their products "modified risk tobacco products" under this statutory definition, e-cigarette manufacturers must submit their speech to the FDA for approval. *See* 21 U.S.C. § 387k(a). That submission must include detailed product information, sample labeling, research findings, consumer-use data, and *any* "*other information [that the FDA] may require*." *Id.* § 387k(d) (emphasis added). The FDA may not grant a manufacturer permission to speak without first presenting the application for public comment, *id.* § 387k(e), referring it to the Tobacco Products Scientific Advisory Committee for a recommendation, *id.* § 387k(f), and making detailed findings about the merits of the manufacturer's proposed speech, *id.* § 387k(g).

Generally, the FDA may authorize a manufacturer to speak only if it concludes that the product will "significantly reduce harm and the risk of tobacco-related disease to individual tobacco users" *and* "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). Alternatively, the FDA may grant the manufacturer time-limited authorization to speak, subject to ongoing "surveillance," if it makes *nine* detailed findings. *Id.* § 387k(g)(2). The standards for both alternatives are highly subjective. *E.g.*, *id.* § 387k(g)(2)(A)(i). And the FDA is not required to act on an application by any fixed deadline. *See id.* § 387k(*l*)(1)(F).

In addition, all licenses to speak are subject to numerous conditions. *See*, *e.g.*, 21 U.S.C. § 387k(h)(2) (regulating comparative claims), *id.* § 387k(h)(3) (authorizing the FDA to require additional label disclosures), *id.* § 387k(*i*) (requiring the manufacturer to conduct postmarket surveillance and studies). In light of these onerous requirements, few manufacturers have requested authorization to market a modified risk tobacco product, and not one has been granted leave to speak by the FDA. *See* FDA, Modified Risk Tobacco Products, goo.gl/qgyjfq.

### C. The MRTP Preclearance Requirement Prohibits NJOY From Telling Consumers The Truth About Its Products.

As a direct result of the MRTP preclearance requirement, NJOY cannot communicate truthful, scientifically substantiated information about its lawful products to adult consumers without FDA pre-authorization. For example, NJOY is barred from:

- informing consumers that e-cigarettes are far less risky than combustible cigarettes, including communicating the very conclusions that the FDA itself has reached about the "continuum of risk" posed by tobacco products;
- providing basic product information, including that e-cigarettes do not produce many of the substances found in the smoke of combustible

cigarettes and produce other substances in much lower levels than combustible cigarettes;

- stating that its e-cigarettes are "smokeless" or "smoke-free"; or
- advising consumers that its products are less risky than other types of e-cigarettes because, unlike some manufacturers, it adheres to exacting manufacturing standards that ensure that its products contain the precise amounts of nicotine and other ingredients specified by their designs.

## SUMMARY OF ARGUMENT

Applying the Tobacco Control Act's MRTP preclearance requirement to e-cigarette manufacturers is unconstitutional under any potentially applicable standard of First Amendment scrutiny because the FDA lacks any constitutionally sufficient justification for preventing NJOY and other manufacturers from disseminating truthful, scientifically supported information about the basic product characteristics of e-cigarettes and their reduced health risks compared to combustible cigarettes.

The MRTP preclearance requirement is an unconstitutional prior restraint because it prevents e-cigarette manufacturers from communicating accurate information about their products—unless and until the FDA grants their application to speak—without establishing adequate procedural protections or narrow and objective decision-making criteria. *See Se. Promotions Ltd. v. Conrad*,

420 U.S. 546, 559 (1975). In addition, the MRTP preclearance requirement restricts disfavored speech by disfavored speakers and is therefore subject to "heightened judicial scrutiny" that its content- and speaker-based restrictions cannot conceivably survive. *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 565 (2011).

The preclearance requirement fares no better under the traditional standard for examining restrictions on commercial speech because it prevents NJOY from telling consumers the truth about its products without directly advancing any substantial governmental interest in a narrowly tailored manner. *See Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557, 566 (1980). Indeed, there are numerous less-speech-restrictive alternatives available to the FDA to promote public health and prevent consumer deception, including well-funded public-education campaigns and powerful antifraud enforcement tools.

The consequences of the FDA's broad censorship authority could be fatal for Americans who are prevented from receiving accurate information about the reduced health risks that accompany switching from combustible cigarettes to e-cigarettes. The First Amendment protects NJOY's right to communicate this potentially life-saving information to consumers without first obtaining permission to speak from the FDA. As with any other lawful product, "the speaker and the audience, not the Government, should be left to assess the value" of truthful

information about e-cigarettes. *Greater New Orleans Broad. Ass'n v. United States*, 527 U.S. 173, 195 (1999).

## ARGUMENT

### APPLYING THE TOBACCO CONTROL ACT'S PRECLEARANCE REQUIREMENT TO E-CIGARETTE MANUFACTURERS VIOLATES THE FIRST AMENDMENT.

The First Amendment provides robust protection to truthful commercial speech about lawful products. *See Sorrell v. IMS Health Inc.*, 564 U.S. 552, 565-66, 571-72 (2011). That protection applies with full force to speech regarding e-cigarettes because "so long as the sale and use of tobacco is lawful for adults, the tobacco industry has a protected interest in communicating information about its products and adult customers have an interest in receiving that information." *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 571 (2001); *see also R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1211-17 (D.C. Cir. 2012), *overruled in part on other grounds by Am. Meat Inst. v. U.S. Dep't of Agric.*, 760 F.3d 18, 22 (D.C. Cir. 2014) (en banc).

Applying the Tobacco Control Act's MRTP preclearance requirement to e-cigarette manufacturers is incompatible with the First Amendment because the preclearance requirement imposes a prior restraint without adequate procedural and substantive safeguards; restricts disfavored speech by disfavored speakers; and burdens commercial speech without being narrowly tailored to advance any substantial governmental interest.

### A. The MRTP Preclearance Requirement Imposes An Unconstitutional Prior Restraint.

A prior restraint that conditions the right to speak on advance approval by the government is "the most serious and the least tolerable infringement on First Amendment rights," *Neb. Press Ass'n v. Stuart*, 427 U.S. 539, 559 (1976), because "a free society prefers to punish the few who abuse rights of speech *after* they break the law [rather] than to throttle them and all others beforehand," *Se. Promotions Ltd. v. Conrad*, 420 U.S. 546, 559 (1975). As a result, "[a]ny system of prior restraint . . . bear[s] a heavy presumption against its constitutional validity" and can survive constitutional scrutiny only if extensive procedural and substantive protections are in place. *Id.* at 558.

The Supreme Court has established three primary procedural safeguards that are "designed to obviate the dangers of a censorship system." *Freedman v. Maryland*, 380 U.S. 51, 58 (1965). First, "the burden of instituting judicial proceedings, and of proving that the material is unprotected, must rest on the censor." *Se. Promotions*, 420 U.S. at 560. Second, "any restraint prior to judicial review can be imposed only for a specified brief period and only for the purpose of preserving the status quo" pending a final judicial determination. *Id.* Third, "a prompt final judicial determination must be assured." *Id.* In addition to these three procedural requirements, any law that subjects "the exercise of First Amendment freedoms to [a] prior restraint . . . must contain narrow, objective, and definite

standards to guide the licensing authority." *Forsyth Cty. v. Nationalist Movement*, 505 U.S. 123, 131 (1992).

The MRTP preclearance requirement fits squarely within the definition of a prior restraint. It prevents manufacturers from selling "modified risk tobacco products" unless and until the FDA issues an order permitting the products to be "commercially marketed." 21 U.S.C. § 387k(a), (g). And it defines "modified risk tobacco products" as those products that are accompanied by certain types of speech—for example, speech "represent[ing] . . . that the tobacco product presents a lower risk of tobacco-related disease or is less harmful than one or more other commercially marketed tobacco products." *Id.* § 387k(b)(2)(A)(i). The MRTP preclearance requirement thus imposes strict limits on what manufacturers may say about their products without receiving the government's permission to speak.

Despite imposing a prior restraint on speech, the MRTP preclearance requirement lacks the procedural safeguards mandated by the First Amendment. First, the Tobacco Control Act places the burden on manufacturers to prove that their products meet its preclearance standards—rather than imposing the burden on the FDA to prove that a product does not satisfy those standards, as the First Amendment requires. *See Se. Promotions*, 420 U.S. at 560; *see also* 21 U.S.C. § 387k(g) (allowing commercial marketing "only if [the FDA] determines that *the*

*applicant has demonstrated* that [its] product" meets the statutory standards) (emphasis added).

Second, the Tobacco Control Act contains no requirement that the FDA make a preclearance determination within a "specified brief period." *Se. Promotions*, 420 U.S. at 560. To the contrary, it grants the FDA broad discretion to "establish a reasonable timetable" for review. 21 U.S.C. § 387k(*l*)(1)(F). In turn, the FDA has announced an entirely aspirational goal of reviewing and acting upon each application "within 360 days of receipt," FDA, Q&A: Modified Risk Tobacco Products, goo.gl/YfZYsC—a far cry from "the shortest fixed period" that would allow government review, which is what the First Amendment requires, *Freedman*, 380 U.S. at 59; *see also Teitel Film Corp. v. Cusak*, 390 U.S. 139, 141-42 (1968) (per curiam) (invalidating a 57-day period for reviewing proposed speech).

Third, there is no guarantee that a "prompt final judicial determination" will be available to manufacturers seeking to market a modified risk tobacco product, *Se. Promotions*, 420 U.S. at 560, because judicial review will generally not be possible until the FDA has acted upon an application—which itself could take almost a year even if the FDA meets its entirely discretionary target—and nothing in the Tobacco Control Act requires courts to expedite manufacturers' legal challenges.

In addition to these procedural shortcomings, the Tobacco Control Act lacks any "narrow, objective, and definite standards," *Forsyth Cty.*, 505 U.S. at 131, to guide the FDA's review of preclearance applications. One of the primary "evils" condemned by the First Amendment is "a scheme" of speech regulation "that places unbridled discretion in the hands of a government official," *FW/PBS, Inc. v. City of Dallas*, 493 U.S. 215, 225-26 (1990), and that conditions the freedom of speech on "the appraisal of facts, the exercise of judgment, and the formation of an opinion" by an administrator, *Forsyth Cty.*, 505 U.S. at 131. In direct contravention of those principles, the Tobacco Control Act establishes a highly subjective, multifactor obstacle course for FDA preclearance of manufacturers' speech, *see* 21 U.S.C. § 387k(g), which turns on factors such as whether, in the FDA's view, the product will "benefit the health of the population as a whole" or "would be appropriate to promote the public health." *Id.* §§ 387k(g)(1)(B), 387k(g)(2)(A)(i). Applying those infinitely elastic standards, the FDA has *never* approved an MRTP preclearance application. *See* FDA, Modified Risk Tobacco Products, goo.gl/qgyjfq. The First Amendment does not permit the government to condition the speech of e-cigarette manufacturers on that sort of unbounded regulatory review, especially where it is not constrained by any meaningful procedural safeguards.

These First Amendment principles apply with full force to commercial speech. Because prior restraints are "particularly abhorrent to the First Amendment," there is "no reason why the requirement of procedural safeguards should be relaxed whether speech is commercial or not." *N.Y. Magazine v. Metro. Transp. Auth.*, 136 F.3d 123, 131 (2d Cir. 1998). Although this Court has not yet addressed the application of prior-restraint analysis to commercial speech, *see Pearson v. Shalala*, 164 F.3d 650, 660 (D.C. Cir. 1999), it should follow the majority view and hold that prior restraints of commercial speech cannot stand in the absence of extensive procedural and substantive protections. *Compare N.Y. Magazine*, 136 F.3d at 131 (applying prior-restraint principles in the commercial-speech context); *Desert Outdoor Advert., Inc. v. City of Moreno Valley*, 103 F.3d 814, 818 (9th Cir. 1996) (same); *In re Search of Kitty's E.*, 905 F.2d 1367, 1371 (10th Cir. 1990) (same), *with Disc. Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509, 532-33 (6th Cir. 2012).

Those courts that have refused to apply prior-restraint principles to commercial speech have relied on the observation that "commercial speech is . . . a sturdy brand of expression." *Disc. Tobacco*, 674 F.3d at 532 (citation omitted). But there can be no question that the Tobacco Control Act's onerous preclearance requirements will deter NJOY and other e-cigarette manufacturers from disseminating certain truthful information about their products. NJOY currently

desires to make a number of accurate representations about its products—including that its e-cigarettes present fewer health risks than combustible cigarettes and do not produce smoke—but has decided to remain silent as a direct result of the MRTP preclearance requirement. Nor has NJOY undertaken the time-consuming, expensive, and potentially futile task of attempting to satisfy the Tobacco Control Act's stringent preclearance standards. That is precisely the type of chilling effect on constitutionally protected speech that the prior-restraint doctrine seeks to prevent. And even if the prior-restraint doctrine did not apply with the same force to commercial speech, it would still condemn the Tobacco Control Act's burden-shifting, absence of short, concrete deadlines, and vague preclearance criteria.

Because the MRTP preclearance requirement lacks *any* of the constitutionally mandated procedural or substantive safeguards, it is an unconstitutional prior restraint on the speech of e-cigarette manufacturers.

### B. The MRTP Preclearance Requirement Cannot Survive The Heightened Scrutiny That Applies To Content- And Speaker-Based Regulation Of Protected Speech.

"The First Amendment requires heightened scrutiny whenever the government creates 'a regulation of speech because of disagreement with the message it conveys.'" *Sorrell*, 564 U.S. at 566 (quoting *Ward v. Rock Against Racism*, 491 U.S. 781, 791 (1989)). The MRTP preclearance requirement is subject to heightened First Amendment scrutiny because, "on its face," it "burdens

disfavored speech by disfavored speakers." *Id.* at 564; *see also Reed v. Town of Gilbert*, 135 S. Ct. 2218, 2226 (2015) ("Content-based laws . . . are presumptively unconstitutional.").

The MRTP preclearance requirement restricts a specific class of persons—"manufacturer[s]" of "tobacco products"—from communicating certain truthful information to their consumers—any information that would bring their products within the statutory definition of "modified risk tobacco product." 21 U.S.C. § 387k(b)(2)(A) (application is triggered by product's "label, labeling, or advertising" or "other action[s] directed to consumers" taken by "tobacco product manufacturers"). It does not restrict speech about topics other than the comparative health risks of tobacco products or the substances contained in or emitted by those products. *Id.* And it does not restrict speech by non-manufacturers—such as public-health organizations and advocacy groups—or by manufacturers of potentially competing nicotine-replacement products; all of those groups are free to communicate truthful (or untruthful) information about e-cigarettes without seeking FDA pre-authorization. *Id.* In short, the MRTP preclearance requirement "is designed to impose a specific, content-based burden on protected expression" by a limited class of speakers. *Sorrell*, 564 U.S. at 565. "It follows that heightened judicial scrutiny is warranted." *Id.*

"Commercial speech is no exception" to this rigorous scrutiny, especially "where," as here, the "information can save lives." *Sorrell*, 564 U.S. at 566. It was unnecessary in *Sorrell* for the Supreme Court to define the precise contours of the "stricter form of judicial scrutiny" applicable to content- and speaker-based restrictions on commercial speech because the law at issue in that case could not survive scrutiny even under *Central Hudson*. *Id.* at 571. It does not follow, however, that a content- and speaker-based restriction on commercial speech is constitutional merely because it satisfies *Central Hudson*. *See id.* at 572 (the government "must show *at least* that the statute directly advances a substantial governmental interest and that the measure is drawn to achieve that interest") (emphasis added). The district court therefore erred in applying *Central Hudson* without regard for *Sorrell*. *See* 266 F. Supp. 3d 360, 412.

In fact, the district court completely ignored *Sorrell*'s express requirements. For example, in upholding the MRTP preclearance requirement, the court reasoned that the provision supposedly "does not ban truthful statements about health benefits or reduced risks; it simply requires that they be substantiated." 266 F. Supp. 3d at 421. That description of the preclearance requirement has no footing in reality; in practice, the requirement's severe burdens amount to a *de facto* ban on manufacturers' speech on topics that would render a product a

"modified risk tobacco product" within the meaning of the Tobacco Control Act. *See supra* at 7-8.

But even if the district court's description were accurate, that reasoning directly contravenes *Sorrell*'s instruction that "[l]awmakers may no more silence unwanted speech by burdening its utterance than by censoring its content." 564 U.S. at 566; *see also United States v. Playboy Entm't Grp., Inc.*, 529 U.S. 803, 812 (2000) (the "Government's content-based burdens must satisfy the same rigorous scrutiny as its content-based bans"). Thus, whether a burden or a ban, the MRTP preclearance requirement must be subjected to exacting judicial scrutiny—which the district court failed to undertake and, as made clear below, the requirement could not possibly survive.

### C. The MRTP Preclearance Requirement Cannot Survive Constitutional Scrutiny Under *Central Hudson*.

It is beyond dispute that e-cigarette "manufacturers have an interest in conveying truthful information about their products to adults, and adults have a corresponding interest in receiving truthful information about [these] products." *Lorillard*, 533 U.S. at 564. And, as the district court itself acknowledged, the MRTP preclearance requirement "is a clear restriction on truthful and non-misleading speech" by e-cigarette manufacturers. 266 F. Supp. 3d at 419. Thus, to sustain the requirement's speech restrictions under *Central Hudson*, the FDA must establish that the requirement: (1) furthers a substantial governmental interest,

(2) directly and materially advances that interest, and (3) does so in a way that is "not more extensive than is necessary to serve that interest." *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557, 566 (1980). Under this standard, the FDA "bears the burden of justifying its attempt to restrict commercial speech . . . and its burden is not light." *R.J. Reynolds*, 696 F.3d at 1218.

The district court and the FDA in its briefing below identified two governmental interests that supposedly justify the MRTP preclearance requirement: (1) "protecting public health" and (2) "preventing false and misleading tobacco industry claims about the relative health benefits of its products." Defs.' Mem. in Supp. of Cross-Mot. for Summ. J. ("Defs.' Mem.") 80, ECF No. 43; *see also* 266 F. Supp. 3d at 419-20. Neither interest can withstand scrutiny.

### 1. The FDA Has Not Shown That The MRTP Preclearance Requirement Will Directly Advance Public Health Or That Less Restrictive Means Would Fail.

"[T]o sustain a restriction on commercial speech," the government "must demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree." *Edenfield v. Fane*, 507 U.S. 761, 770-71 (1993). The FDA has not remotely carried its heavy burden of showing that application of the MRTP preclearance requirement to e-cigarettes will directly and materially benefit public health. *See R.J. Reynolds*, 696 F.3d at 1219-21

(invalidating proposed graphic warnings for combustible cigarettes because the "FDA ha[d] not provided a shred of evidence . . . showing that the graphic warnings will 'directly advance' its interest in reducing the number of Americans who smoke").

When the FDA decided to apply the MRTP preclearance requirement to e-cigarettes, it acknowledged that it did "not have sufficient data to determine what effects e-cigarettes have on public health at the population level." 81 Fed. Reg. 28,974, 29,028 (May 20, 2016); *see also* Defs.' Mem. 16-17 ("the current evidence is insufficient to answer two key questions about th[e] overall population-level effects [of e-cigarettes] on public health": "whether e-cigarettes might help some smokers quit" and "the extent to which e-cigarettes are a 'gateway' to the use of other tobacco products"). And the FDA conceded that "completely switching from combusted cigarettes to [e-cigarettes] may *reduce* the risk of tobacco-related disease." 81 Fed. Reg. at 29,030 (emphasis added). More recently, the FDA announced a fundamental policy shift premised on the public-health *benefits* of persuading smokers of combustible cigarettes to switch to e-cigarettes. *See supra* at 3-4.

Thus, the most the FDA could offer in support of a public-health rationale would be a supposed concern that truthfully informing consumers that e-cigarettes pose fewer health risks than combustible cigarettes and expose users to reduced

levels of specific substances *might* cause non-smokers to use e-cigarettes, which *might* cause them long-term health problems or *might* lead some people (who would not otherwise do so) to try combustible cigarettes, which *might* offset the population-wide health benefits of consumers' switching from combustible cigarettes to e-cigarettes. *See*, *e.g.*, 81 Fed. Reg. at 29,038 ("Even products that are less toxic than combusted tobacco products on an individual user basis *may* increase public health harms if, for example, they encourage nonusers to start using tobacco products.") (emphasis added).

The FDA acknowledged, however, that it lacked scientific evidence to substantiate those fears and that it was instead hypothesizing about unknowable future events. *See*, *e.g.*, 81 Fed. Reg. at 28,998 ("[I]t is *possible* that [e-cigarettes] may result in overall public health harm if individuals who would not have initiated tobacco use in the absence of [e-cigarettes] ultimately graduate to combusted products (though scientific data regarding this hypothesis is unclear).") (emphasis added). The government cannot satisfy its demanding First Amendment burden through this chain of "mere speculation [and] conjecture." *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 487 (1995). And, even if there were evidence to support the FDA's earlier prognostication, "the 'fear that people would make bad decisions if given truthful information' cannot justify content-based burdens on

speech." *Sorrell*, 564 U.S. at 577 (quoting *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 374 (2002)).

In reality, rather than supporting any public-health goal, the MRTP preclearance requirement actually undermines it. Published studies show that many smokers believe e-cigarettes are just as dangerous as—or even more dangerous than—combustible cigarettes. *See*, *e.g.*, Harvard School of Public Health & Stat, *Americans' Perspectives on E-Cigarettes* 8 (Oct. 2015), goo.gl/ep1lJr (38% of those surveyed believed e-cigarettes are as harmful as, or more harmful than, combustible cigarettes). The FDA itself has concluded that this view is flawed and has adopted a policy that is designed to encourage smokers to switch to e-cigarettes and other non-combustible products that are lower down the "continuum of risk" than combustible cigarettes. *See Protecting American Families*, *supra*.

Yet, by preventing e-cigarette manufacturers from informing consumers that their products are less risky than combustible cigarettes, the MRTP preclearance requirement perpetuates consumer confusion about the relative health risks of e-cigarettes and entrenches the market dominance of combustible products, thereby frustrating the FDA's public-health objectives. It also effectively compels e-cigarette manufacturers to signal agreement, through their government-imposed silence, with the existing misapprehensions that many consumers harbor about the

relative risks of e-cigarettes and combustible cigarettes. *Cf. Zauderer v. Office of Disciplinary Counsel of Supreme Court*, 471 U.S. 626, 651 (1985) (compelled commercial speech is constitutional only if, among other requirements, it is "purely factual").[1]

The MRTP preclearance requirement is also far broader than necessary to advance public health. "The government" fails to demonstrate "a reasonable fit between means and ends" where, as here, "it presents no evidence that less restrictive means would fail." *Nat'l Ass'n of Mfrs. v. SEC*, 748 F.3d 359, 372 (D.C. Cir. 2014), *adhered to on reh'g*, 800 F.3d 518 (D.C. Cir. 2015), *and overruled in part on other grounds by Am. Meat Inst.*, 760 F.3d 18.

Other provisions of the Tobacco Control Act give the FDA powerful regulatory tools that it can use to promote public health without silencing constitutionally protected speech. For example, the FDA can mandate additional warning labels on e-cigarette labeling and advertising, *see* 15 U.S.C. § 1333(d), require testing and disclosure of e-cigarette ingredients and additives, 21 U.S.C. § 387*o*(b), and promulgate appropriately tailored restrictions on e-cigarette

[1] The FDA has expressed "concerns regarding quality control" of e-cigarettes, 81 Fed. Reg. at 29,035, but the MRTP preclearance requirement prevents NJOY from informing consumers that its products are less risky than those of some other manufacturers because NJOY stringently adheres to superior manufacturing standards and because its products do not contain particular substances found in some other manufacturers' e-cigarettes.

advertising that poses demonstrable public-health risks, such as advertising that appeals to children. *See id.* § 387f(d)(1). The FDA can also inform consumers about any potential health risks of e-cigarettes by instituting a public-education campaign, which could be amply funded by a portion of the hundreds of millions of dollars in annual "user fees" that tobacco companies are required to pay the FDA. *See* 81 Fed. Reg. at 29,058 ("FDA will continue to invest in a number of public education campaigns"); *see also* 21 U.S.C. § 387s (annual user fees). In fact, the FDA is already funding a public-education campaign with respect to youth through its Real Cost campaign. *See* FDA, The Real Cost Campaign, goo.gl/Q15B8H.

These readily available and at-least-equally-as-effective regulatory alternatives are fatal to any public-health justification for the MRTP preclearance requirement. The First Amendment does not permit the government to advance public health by "restraining certain speech by certain speakers" where it has failed to prove that less restrictive means would be inadequate. *Sorrell*, 564 U.S. at 577.

**2. The MRTP Preclearance Requirement Is Not Proportional To The FDA's Goal Of Preventing Consumer Deception.**

The FDA's second asserted interest—preventing "false and misleading" speech by e-cigarette manufacturers—fares no better. Defs.' Mem. at 80. The MRTP preclearance requirement is vastly more restrictive than necessary to prevent deceptive advertising by e-cigarette manufacturers and therefore lacks the

requisite "proportional[ity] to the resulting burdens placed on speech." *Sorrell*, 564 U.S. at 572.

The preclearance requirement's undifferentiated approach—requiring FDA pre-authorization of certain "truthful and non-misleading speech" by e-cigarette manufacturers (266 F. Supp. 3d at 420) because other speech on those topics may be untrue—is incompatible with the First Amendment. If the MRTP preclearance requirement were upheld, nothing would prevent the government from subjecting advertisements that foods are "low sodium," that beverages have "less sugar," or that cars have "enhanced safety features" to the same effective ban. Rather than silence all speakers, the government must take a targeted approach that separates truth from falsehood and constitutionally protected commercial speech from unprotected consumer deception. *See Zauderer*, 471 U.S. at 646 (government may not suppress "truthful and nondeceptive advertising simply to spare itself the trouble of distinguishing such advertising from false or deceptive advertising").

One less restrictive alternative to the Tobacco Control Act's across-the-board preclearance requirement would be for the FDA to achieve its anti-deception objective by bringing enforcement actions against e-cigarette manufacturers that make misleading statements. *See* 81 Fed. Reg. at 29,051 (the FDA "will be able to take enforcement action against any tobacco product that does not meet basic [adulteration and misbranding] requirements"); *see also* 21 U.S.C. § 331

("misbranding" prohibition). E-cigarette manufacturers that make misleading representations about their products face an array of serious consequences, including no-tobacco-sale orders, 21 U.S.C. § 333(f), civil penalties, *id.* § 333(f)(9), administrative detention of tobacco products, *id.* § 334(g), import refusals, *id.* § 381(a), seizures, *id.* § 334(a)(2), injunctions, *id.* § 332, and criminal penalties, *id.* § 333(a). In addition, the FDA can address any possibility of consumer confusion about the relative health risks of e-cigarettes by requiring appropriate disclaimers on labeling and advertising or initiating a public-education campaign. *See supra* at 25-26.

The FDA made no attempt to demonstrate that there has been a history of consumer deception by e-cigarette manufacturers that would render these alternatives inadequate. *See Ibanez v. Fla. Dep't of Bus. & Prof'l Regulation*, 512 U.S. 136, 143 (1994) (the government "must demonstrate that the harms it recites are real" before silencing commercial speech). The FDA instead pointed to inaccurate claims made in the past by manufacturers of combustible cigarettes. *See* 81 Fed. Reg. at 29,039. And it relied on an opinion from the Sixth Circuit upholding the Tobacco Control Act's preclearance requirement as applied to combustible cigarettes because "in the context of a deadly and highly addictive product, it would be a virtual impossibility to unring the bell of misinformation after it has been rung." *Disc. Tobacco*, 674 F.3d at 537. The district court likewise

relied on the Sixth Circuit's analysis to uphold application of the preclearance requirement to e-cigarettes. *See* 266 F. Supp. 3d at 420 ("That reasoning applies with equal force to the regulation of e-cigarettes."). But the Sixth Circuit's reasoning that combustible cigarettes are a "deadly" product is manifestly inapposite here because neither the FDA nor the scientific community believes that e-cigarettes are "deadly"—in fact, they have indicated just the opposite. *See* 81 Fed. Reg. at 29,035 ("FDA agrees that use of [e-cigarettes] is likely less hazardous for an individual user than continued smoking of traditional cigarettes."); *see also Public Health Consequences of E-Cigarettes*, *supra*.

Moreover, even if some of the less-restrictive-alternatives available to the FDA have been found to be inadequate in the context of combustible cigarettes, the FDA has pointed to no comparable evidence indicating that those measures would fail when applied in the e-cigarette setting. *See Disc. Tobacco*, 674 F.3d at 535 (describing "a pattern of deception" by manufacturers of combustible cigarettes). There is no evidence that e-cigarette manufacturers have engaged in a pattern of coordinated deception akin to the conduct in which combustible-cigarette manufacturers were found to have engaged in the past. Nor is there any support for the proposition that speakers can lose their First Amendment freedoms based on the conduct of *different* speakers regarding *different* products. To the contrary, insofar as e-cigarette "advertising differ[s] from that of other tobacco products, that

difference should inform the inquiry into what speech restrictions are necessary." *Lorillard*, 533 U.S. at 565. Perversely, the FDA's actions will *protect* the market dominance of combustible cigarettes by limiting speech about their less-risky competitors.

Applying the MRTP preclearance requirement to e-cigarettes is far from "necessary." *Lorillard*, 533 U.S. at 565. Because the FDA has myriad less-restrictive alternatives, its imposition of that *de facto* ban on broad categories of truthful, scientifically supported speech by e-cigarette manufacturers is flatly inconsistent with the First Amendment.

## CONCLUSION

"'The First Amendment directs [courts] to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good.'" *Sorrell*, 564 U.S. at 577 (quoting *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 503 (1996) (opinion of Stevens, J.)). There is compelling evidence that the FDA's misguided paternalism regarding e-cigarettes is not merely constitutionally unjustified, but could also have grave public-health consequences. The emerging scientific consensus is that e-cigarettes are vastly less likely to cause cancer, heart disease, and other serious ailments than combustible cigarettes. The FDA's ban on truthful, non-misleading statements about the relative health risks of e-cigarettes and the substances contained in

e-cigarette vapor will inevitably keep millions of smokers from hearing facts that could persuade them to switch to e-cigarettes—a decision that could ultimately save their lives.

This Court should reverse the district court's judgment and hold that the FDA's application of the Tobacco Control Act's MRTP preclearance requirement to e-cigarettes is unconstitutional.

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## CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Appellate Procedure 32(g)(1), the undersigned certifies that this brief complies with the applicable typeface, type style, and type-volume limitations. This brief was prepared using a proportionally spaced type (Times New Roman, 14 point). Exclusive of the portions exempted by Federal Rule of Appellate Procedure 32(f) and D.C. Circuit Rule 32(e)(1), this brief contains 6,498 words. This certificate was prepared in reliance on the word-count function of the word-processing system used to prepare this brief.

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**CERTIFICATE OF SERVICE**

I certify that on this 20th day of February 2018, I caused a true and correct copy of the foregoing brief to be served via electronic mail upon all counsel of record by operation of the Court's ECF system.

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