NOT YET SCHEDULED FOR ORAL ARGUMENT

United States Court of Appeals for the District of Columbia Circuit

No. 17-5196

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

Plaintiffs-Appellants,

AMERICAN E-LIQUID MANUFACTURING STANDARDS ASSOCIATION; AMERICAN VAPING ASSOCIATION; ELECTRONIC VAPING COALITION OF AMERICA; GEORGIA SMOKE FREE ASSOCIATION; KENTUCKY VAPING RETAILERS ASSOCIATION, INC., doing business as Kentucky Smoke Free Association; LOUISIANA VAPING ASSOCIATION; MARYLAND VAPE PROFESSIONALS, LLC; NEW JERSEY VAPOR RETAILERS COALITION; OHIO VAPOR TRADE ASSOCIATION; TENNESSEE SMOKE FREE ASSOCIATION,

Plaintiffs-Appellees,

(For Continuation of Caption See Inside Cover)

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

BRIEF OF *AMICI CURIAE* FIRST AMENDMENT SCHOLARS IN SUPPORT OF APPELLEE

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May 9, 2018

v.

FOOD & DRUG ADMINISTRATION; ALEX MICHAEL AZAR, II, Acting Secretary of Health and Human Services; SCOTT GOTTLIEB, M.D., Commissioner of Food and Drug Administration,

Defendants-Appellees.

WASHINGTON LEGAL FOUNDATION,

Amicus Curiae for Appellant,

PUBLIC HEALTH LAW CENTER,

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NJOY, LLC,

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Amici Curiae for Appellee.

CERTIFICATE AS TO PARTIES, RULINGS, RELATED CASES, AND TYPE VOLUME

Pursuant to D.C. Circuit Rule 28(a)(1), *amici curiae* Robert C. Post, Jack Balkin, and Amy Kapczynski certify as follows:

A. Parties

All parties known to *amici* are listed in the Brief for Appellee.

B. Rulings Under Review

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

C. Related Cases

This case has not previously been before this Court or any other court, and *amici* are not aware of any related cases before this Court or any other court.

STATEMENT REGARDING CONSENT TO FILE AND SEPARATE BRIEFING

All parties and proposed intervenors to this appeal have consented to the filing of this brief.

No counsel for a party authored this brief in whole or in part, and no person other than *amici curiae* and their counsel has made any monetary contribution intended to fund preparing and submitting this brief. Fed. R. App. P. 29(a)(4)(E). *Amici*'s institutional affiliations are provided only for purposes of identification.

Pursuant to D.C. Circuit Rule 29(d), *amici* certify that a separate brief is necessary to enable *amici* to provide their unique perspective on one of the issues raised in this appeal: whether the First Amendment permits Congress to prohibit e-cigarette manufacturers from selling modified-risk tobacco products without approval.

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases:

Statutes:

Other Authorities:

GLOSSARY

FDCA	**FOOD, DRUG AND COSMETIC ACT**
MRTP	**MODIFIED RISK TOBACCO PRODUCT**
TCA	**TOBACCO CONTROL ACT**

INTEREST OF *AMICI CURIAE*

Amici are three First Amendment scholars at Yale Law School: Robert C. Post, Sterling Professor of Law; Amy Kapczynski, Professor of Law and Co-Director, Global Health Justice Partnership; and Jack Balkin, Knight Professor of Constitutional Law and the First Amendment, and Director of the Information Society Project. They study and litigate the nature of constitutionally permissible controls over commercial speech, including the regulation of pharmaceutical- and tobacco-related commercial speech by the Food and Drug Administration (FDA).

BACKGROUND

A. The Challenged Tobacco Control Act Provisions

In 2000, the Supreme Court held that FDA lacked congressional authorization to regulate the tobacco industry.[1] *See Food & Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000). Congress responded by enacting the Family Smoking Prevention and Tobacco Control Act ("TCA"), which supplied the authority and tools FDA believed necessary to protect public health. The TCA was supported by 49 specific congressional findings,[2] many of

[1] The FDA first attempted to assert jurisdiction over tobacco products in 1996 using its existing premarket authority over drugs and devices. *Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents*, 61 Fed. Reg. 44,396, 44,397 (Aug. 28, 1996).

[2] *See* Family Smoking Prevention and Tobacco Control Act ("TCA"), Pub. L. No. 111-31, 123 Stat. 1776 (2009).

which detail the efforts of the tobacco industry to market tobacco products to children and adolescents.

Congress found that the tobacco industry had for decades sought to deceive and mislead the public by marketing "light," "mild" and "low-tar" cigarettes which offered no health benefit.[3] To prevent future deceptions, the TCA empowered FDA proactively to regulate nicotine-delivering devices, providing "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." TCA § 3(4).

To serve that purpose, Section 911 of the TCA, codified at 21 U.S.C. § 387k, authorizes FDA to regulate the sale of "Modified Risk Tobacco Products ("MRTPs").[4] It permits manufacturers to sell MRTPs if they demonstrate to the

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[3] *See generally Discount Tobacco City & Lottery Inc. v. United States*, 674 F.3d 509 (6th Cir. 2010).

[4] Congress defined an MRTP as a product:

> (i) the label, labeling, or advertising of which represents explicitly or implicitly that—
>
> (I) the tobacco product presents a lower risk of tobacco-related disease or is less harmful than one or more other commercially marketed tobacco products;
>
> (II) the tobacco product or its smoke contains a reduced level of a substance or presents a reduced exposure to a substance; or

FDA that the product will "(A) significantly reduce harm and the risk of tobacco-related disease to individual tobacco users; and (B) 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."[5] It "does not ban truthful statements about health benefits or reduced risks; it simply requires that they be substantiated." *Nicopure Labs, LLC v. Food & Drug Admin.*, 266 F. Supp. 3d 360, 421 (D.D.C. 2017).

> (III) the tobacco product or its smoke does not contain or is free of a substance;
>
> (ii) the label, labeling, or advertising of which uses the descriptors "light", "mild", or "low" or similar descriptors; or
>
> (iii) the tobacco product manufacturer . . . has taken any action directed to consumers through the media or otherwise, other than by means of the tobacco product's label, labeling, or advertising ... that would be reasonably expected to result in consumers believing that the tobacco product or its smoke may present a lower risk of disease or is less harmful than one or more commercially marketed tobacco products, or presents a reduced exposure to, or does not contain or is free of, a substance or substances.

21 U.S.C. § 387k(b)(2)(A).

[5] There is an exception if the Secretary makes several findings, including that granting the application would promote the public health. 21 U.S.C. § 387k(g)(2)(A).

B. Appellants' First Amendment Objections to Section 387k

Appellants contend that § 387k violates manufacturers' First Amendment right to market e-cigarettes in a manner that history demonstrates will likely lead consumers to view them as less risky than comparable tobacco products, even though Appellants have not adequately demonstrated a comparative absence of risk. Appellants Br. at 20–22.

Appellants also contend that § 387k violates the First Amendment because it permits FDA "subjectively" to deny an MRTP application even when it agrees a vapor product presents less risk to individual users and satisfies the "population effects" standard of § 387k(g)(1)(B). This is supposedly so "because the provision requires applicants to prove that the product 'significantly' reduces harm to the individual, without quantifying 'significant.'" Appellants Br. at 22 (citing 21 U.S.C. § 387k(g)(1)(A).

ARGUMENT

I. THE CONSTITUTION DOES NOT FORBID GOVERNMENT FROM PROHIBITING THE SALE AND ADVERTISEMENT OF DANGEROUS PRODUCTS

The First Amendment does not bar Congress from prohibiting the sale of unapproved modified-risk tobacco products. If the sale of an unapproved modified-risk tobacco product is illegal, Congress may constitutionally prevent Appellants from advertising for the sale of that illegal MRTP.

Constitutional protection for commercial speech is determined by the *Central Hudson* test, which provides:

> In commercial speech cases, . . . a four-part analysis has developed. At the outset, [courts] must determine whether the expression is protected by the First Amendment. For commercial speech to come within that provision, it at least must concern lawful activity and not be misleading. Next, [courts] ask whether the asserted governmental interest is substantial. If both inquiries yield positive answers, [courts] must determine whether the regulation directly advances the governmental interest asserted, and whether it is not more extensive than is necessary to serve that interest.

Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of New York, 447 U.S. 557, 566 (1980). Step one of the *Central Hudson* test provides that advertisements (or product labels) do not "come within" the protections of the First Amendment if they do not "concern lawful activity" or are "misleading."

More than a decade ago, this Court used step one of the *Central Hudson* test to reject a First Amendment claim by a drug manufacturer who was not allowed to advertise his product as he wished. At issue in *Whitaker v. Thompson*, 353 F.3d 947 (D.C. Cir. 2004), was a challenge to the fundamental regulatory framework of the Federal, Food, Drug, and Cosmetic Act ("FDCA"). That Act defines "drugs" as "articles intended for use in the diagnoses, cure, mitigation, treatment or prevention of diseases," and prohibits manufacturers from selling new drugs without prior FDA approval. 21 U.S.C. § 321(g)(1). FDA approval requires a

showing of both safety and efficacy. *Id.* § 355.

There is no doubt of government's power to prohibit the sale of drugs. *Whitaker* held that Congress may define a "drug" in terms of the intent of those who sell a product. Whether FDA approval is required before the marketing of a substance thus "commonly turns on the nature of the claims made about the substance." *See id.* at 948–51.

The appellant in *Whitaker* sought to market saw palmetto with a label claiming it treated a disease. *Id.* at 948. When FDA denied the application because Whitaker hadn't obtained approval to market the substance as a "drug," Whitaker objected on the ground that FDA labeling restrictions violated his First Amendment rights. *Id.* at 952–53. This is essentially the same objection Appellants raise in this case.

A panel of this Court, including then-Judge Roberts, unanimously rejected Whitaker's First Amendment claim. *Id.* It explained that "the First Amendment allows the evidentiary use of speech to establish the elements of a crime or to prove motive or intent." *Id.* at 953. Accordingly, "[a]ssuming that the government may condition the sale of drugs on passage through the elaborate testing that the [FDCA] requires," it was "constitutionally permissible for the FDA to use speech, in the form of labeling, to infer intent for purposes of determining that Whitaker's proposed sale of saw palmetto extract would constitute the forbidden sale of an

unapproved drug." *Id.* If Congress may prohibit the sale of a product that is marketed with a prohibited intent, *Central Hudson* holds that Congress may constitutionally prohibit advertising for that illegal product.

Precisely this analysis applies to § 387k. Congress has authority to prohibit the sale of unapproved MRTPs. U.S. Const. art. I, § 8, cl. 3. The classification of a product as an MRTP turns on the intent with which it is sold, *i.e.* whether the product is sold as fit "for use to reduce harm or risk of tobacco-related diseases." 21 U.S.C. § 387k(a), (b)(1).

A product that is marketed as reducing the risk of disease is directly connected to the health of the public. It induces customer reliance and thus sharply increases potential health risks. *Whitaker* teaches that no constitutional concerns are raised when speech used to market products also establishes evidence of intent to sell an unapproved product to treat or prevent a disease, thus subjecting the product to the strict control of FDA regulations.

Central Hudson plainly holds that advertising for the sale of illegal MRTPs or illegal drugs does not "come within" the protection of the First Amendment. Here, as in *Whitaker*, the FDA may prevent advertising for tobacco products that have not been approved for sale to the public.

II. THE FIRST AMENDMENT DOES NOT BAR PRECLEARANCE REGIMES THAT SCREEN OUT MISLEADING COMMERCIAL CLAIMS BEFORE THEY ARE MADE

A. Misleading Commercial Speech May be Prohibited

The marketing of unapproved MRTPs may also be properly regulated because it is "misleading." Congress is "free to prevent the dissemination of commercial speech that is false, deceptive, or misleading," *Zauderer v. Off. of Disciplinary Couns. of Sup. Ct. of Ohio*, 471 U.S. 626, 638 (1985), including "communication[s] more likely to deceive the public than to inform it," *Cent. Hudson Gas & Elec. Corp.*, 447 U.S. at 563–64.

There is an important difference between commercial speech that is false and commercial speech that is "misleading." Commercial speech is "misleading" *if reasonable consumers would interpret it* to contain a message that is not true. *See Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pension Fund*, 135 S. Ct. 1318, 1327 (2015). As Judge Bork explained, "[i]n considering charges of false and deceptive advertising, the public's impression is the only true measure of deceptiveness." *F.T.C. v. Brown & Williamson Tobacco Corp.*, 778 F.2d 35, 39–40 (D.C. Cir. 1985).

The *Central Hudson* test focuses on the perception of consumers because constitutional protections for commercial speech are designed to ensure the "free flow" of commercial information to consumers *Va. State Bd. of Pharmacy v. Va.*

Citizens Consumer Council, Inc., 425 U.S. 748, 763 (1976); *see* Robert Post, *Compelled Commercial Speech*, 117 W. Va. L. Rev. 867 (2015). "The First Amendment's concern for commercial speech is based on the informational function of advertising," and hence "[t]here can be no constitutional objection to the suppression of commercial messages that do not accurately inform the public about lawful activity." *Cent. Hudson Gas & Elec. Corp.*, 447 U.S. at 563; *see also Va. State Bd. of Pharmacy*, 425 U.S. at 772.

B. Commercial Speech Can Imply Misleading Innuendo Even Though Literally True

"Obviously, much commercial speech is not provably false, or even wholly false, but only deceptive or misleading." *Va. State Bd. of Pharmacy*, 425 U.S. at 771. The Constitution poses no obstacle to [the government]'s dealing effectively with this problem," *id.*, including by barring speech which is "inherently likely to deceive" or speech through which there is a "history of deception and abuse worked upon the consuming public," *In re R. M. J.*, 455 U.S. 191, 202 (1982).

When evaluating the permissibility of government regulations of commercial speech, therefore, courts do not examine discrete statements to determine their truth or falsity in isolation. Instead they examine the total effect of a commercial message.

Specifically, to determine whether an advertisement is misleading, courts look to whether "consumers acting reasonably under the circumstances would

interpret [an] advertisement to contain" a false message. *POM Wonderful, LLC v. F.T.C.*, 777 F.3d 478, 499–500 (D.C. Cir. 2015). What matters is the "innuendo" or "overall net impression" which a "significant minority of reasonable consumers" take away from the message. *Id.* at 490.

Both the Supreme Court and this Court have made clear that bans on commercial speech that inherently mislead consumers are permissible, even if particular assertions within that speech, considered in isolation, may literally be true. In *Peel v. Attorney Registration & Disciplinary Commission of Illinois*, 496 U.S. 91 (1990), for example, the Supreme Court explained that "[a] lawyer's truthful statement that 'XYZ Board' has 'certified' him as a 'specialist in admiralty law' would not necessarily be entitled to First Amendment protection," unless the attorney could show that the certification was not a "sham" by "demonstrate[ing] that such certification is available to all lawyers who meet objective and consistently applied standards relevant to practice in a particular area of the law." *Id.* at 109. Even if the fact of board certification were true, communication of that fact would nevertheless mislead consumers if the innuendo of the certification were false; that is, if the certification carried no implication of advanced knowledge.

Similarly, this Court in *POM Wonderful* upheld an FTC order prohibiting POM from advertising its pomegranate-based products as treating, preventing, or

reducing the risk of various ailments without preclearance and strong substantiation. 777 F.3d 478. POM sponsored research on the effects of pomegranate juice on cardiovascular health, prostate cancer, and erectile dysfunction, and marketed its products as "backed by . . . medical research at the world's leading universities" revealing "promising results for erectile, prostate and cardiovascular health." *Id.* at 484–88, 492. POM advertised specific positive results from some of its studies. *Id.* at 492.

Each of POM's statements, considered in isolation, was true. But because POM made no mention of the negative results of its studies, or the inherent scientific limitations that circumscribed the studies' findings, the overall innuendo communicated by its advertisements was misleading. *Id.* The FTC therefore prohibited POM's advertisements, at least in the absence of further substantiation that would validate the claims implicit in its innuendo.

This Court upheld the FTC order. It specifically rejected POM's First Amendment challenge, holding it constitutionally permissible to prohibit POM from engaging in advertising that "at least a significant minority of reasonable consumers" would interpret as "claim[ing] that drinking eight ounces of POM juice or ingesting one POMx Pill a day can treat, prevent, or reduce the risk of erectile dysfunction, prostate cancer, and heart disease." *Id.* at 499–503.

C. The First Amendment Does Not Prohibit Congress From Requiring Commercial Speakers To Demonstrate That Claims Are Not False and Misleading Before They Are Made

Central Hudson not only permits government to identify and prohibit false and misleading commercial speech, it explicitly permits this regulation to occur in appropriate circumstances through preclearance regimes. Commercial speech, unlike other forms of speech, is "such a sturdy brand of expression" that restrictions on commercial speech regulation are unlikely to chill it. *Cent. Hudson Gas & Elec. Corp.*, 447 U.S. at 570 n.13; *Va. State Bd. of Pharmacy*, 425 U.S. at 771 n.24. As a result, traditional prior restraint doctrine does not apply to commercial speech. *Cent. Hudson Gas & Elec. Corp.*, 447 U.S. at 570 n.13; *Va. State Bd. of Pharmacy*, 425 U.S. at 771 n.24. Indeed, the Supreme Court has explicitly identified prior restraint regimes as less intrusive restrictions than bans on commercial speech altogether, *Cent. Hudson Gas & Elec. Corp.*, 447 U.S. at 570 n.13, and it has repeatedly made clear that government may require commercial speakers to bear the burden of demonstrating that any claims within their commercial speech are true and not misleading.

In *Shapero v. Kentucky Bar Association*, 486 U.S. 466 (1988), the Court explicitly condoned the use of a preclearance regime under which the speaker bore the burden of demonstrating truthfulness. It struck down a categorical ban of targeted, direct-mail advertising by lawyers as an unconstitutional restriction of

commercial speech. Nevertheless, the Court recognized that "targeted, direct-mail solicitation presents lawyers with opportunities for . . . abuses," including misleading recipients to overestimate lawyers' familiarity with their cases or the direness of their legal problems. *Id.* at 476. To address such abuses, the Court explained, states may "supervise mailings" by requiring lawyers to file any targeted solicitations with a state agency, which may "require the lawyer[s] to prove the truth of the fact[s] stated." *Id.* at 478.

Similarly, in *Peel*, the Court explained that states may prohibit attorneys from advertising truthful specialty certifications if the certifications are misleading and amount to a "sham," and may "require an attorney who advertises 'XYZ certification' to demonstrate that such certification is available to all lawyers who meet objective and consistently applied standards relevant to practice in a particular area of the law." 496 U.S. at 109.

Preclearance regimes are particularly appropriate in contexts where "the public lacks sophistication," *In re R. M. J.*, 455 U.S. at 203; where it is "difficult[] for the average consumer to evaluate . . . claims through personal experience," *cf. Removatron Int'l Corp. v. F.T.C.*, 884 F.2d 1489, 1499 (1st Cir. 1989); or where "[p]ervasive government regulation," combined with "consumer expectations about such regulation, create a climate in which questionable claims . . . have all

the more power to mislead," *cf. Am. Home Prod. Corp. v. F.T.C.*, 695 F.2d 681, 697 (3d Cir. 1982).

So, too, preclearance regimes are appropriate where consumers lack meaningful autonomy. *See, e.g.*, Sylvia A. Law, *Addiction, Autonomy, and Advertising*, 77 Iowa L. Rev. 909, 945–54 (1992) (explaining that commercial speech that promotes products that produce harmful dependency in a significant proportion of users presents a special problem calling for special treatment). Consumers fighting addiction require special government protection.

Preclearance regimes are also appropriate whenever the truth of claims can be determined *only* through rigorous scientific investigation. Preclearance regimes in such contexts create incentives for product merchandizers to produce the information necessary to substantiate the innuendo contained in product advertising. The government interest in the production of such information is an important justification for our present regime of pre-clearance review for the marketing of new drugs. Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 Mich. Telecomm. & Tech. L. Rev. 345, 370 (2007); *see also* Jeanie Kim & Amy Kapczynski, *Promotion of Drugs for Off-Label Uses: The US Food and Drug Administration at a Crossroads*, 177 JAMA Intern Med. 157 (2017).

Preclearance is especially important when misleading consumers is likely to result in "serious[]" consequences like "health hazards." *Cf. Removatron Int'l*

Corp., 884 F.2d at 1499; *Am. Home Prod. Corp.*, 695 F.2d at 706 (same); *see generally* Section III *infra*. Such hazards are particularly prominent in the context of addictive products, like tobacco, which can cause irreversible damage to consumers.

In the context of MRTPs, as in the context of drugs generally, such significant health hazards are all too obvious and demonstrated by extensive historical experience.

D. The MRTP Provision Crafted by Congress Permissibly Requires Preclearance of Reduced-Risk Health Claims Before They Reach The Public

Even if the Court concludes that the MRTP directly regulates commercial speech, the MRTP preclearance regime withstands constitutional scrutiny in light of the principles articulated above.

Constitutional analysis of the MRTP regime must be taken in historical context. Tobacco companies knew by the 1970s that cigarette smoking caused disease, that nicotine was addictive, and that secondhand smoke was hazardous to health. *United States v. Philip Morris USA Inc.*, 566 F.3d 1095, 1119 (D.C. Cir. 2009). They also knew that "light" cigarettes did "not present lower health risks than regular cigarettes." *Id.*

Yet for decades tobacco companies continued to market and promote "low tar" and "light" cigarette brands to "smokers—who were concerned about the

health hazards of smoking or considering quitting—as less harmful than full flavor cigarettes despite either lacking evidence to substantiate their claims or knowing them to be false." *Id.* at 1107. They "engaged in massive, sustained, and highly sophisticated marketing and promotional campaigns to portray their light brands as less harmful than regular cigarettes, and thus an acceptable alternative to quitting," knowing full well that "marketing which emphasized reductions in tar and nicotine was false and misleading." *United States v. Philip Morris USA, Inc.*, 449 F. Supp. 2d 1, 860–61 (D.D.C. 2006).

The misleading marketing of "lower-risk" cigarettes was wildly successful. By 2006, "approximately 50% of all smokers of lower tar cigarettes chose such products because they perceive[d] them to be a 'healthier' cigarette and a potential step toward quitting." *Id.* Even then, tobacco manufacturers continued to use "so-called brand descriptors such as 'light,' 'medium,' and 'mild' to market their brand extensions as low in tar with full knowledge that a substantial number of smokers interpret[ed] th[o]se descriptors as indicating a less harmful cigarette." *Id.* at 861.

This misleading marketing of a harmful and addictive product imposed serious health risks on the country's population, many of whom persisted in smoking because they had been convinced by misleading marketing that they were mitigating their health risks. A bipartisan coalition of Congress responded by

enacting the TCA in 2009. 111 Cong. Rec. 9,699, 14,731 (2009) (recording a 298–112 vote in the House, and a 79–17 vote in the Senate).

The findings that support the TCA establish the addictive nature of nicotine; the grave public health risks posed by the use of tobacco products and products containing nicotine; the harms that arise when children use tobacco products; and the associated dangers of tobacco-related marketing to minors. TCA § 2(1)-(6), (13), (24), (29), (34).

Congress further found that there was a long history of misleading marketing in the context of tobacco products, including specifically:

- the marketing of tobacco products in ways that consumers perceive as lower-risk causes serious health consequences, including death, if those claims are not true, TCA § 2(36)-(37);
- consumers have historically been, and are substantially likely to be, misled by incomplete, inaccurate and unsubstantiated claims about ostensibly "lower-risk" tobacco products, TCA § 2(38)-(41);
- consumers have historically misinterpreted marketing terms such as "low tar" and "light" as indicating that a tobacco product poses a reduced risk, TCA § 2(38);
- consumers have historically misinterpreted claims that one tobacco product is safer than a comparable product, even in the presence of disclaimers and advisories, TCA § 2(41); and
- "[p]ermitting manufacturers to make unsubstantiated statements concerning modified risk tobacco products, whether express or implied, even if accompanied by disclaimers would be detrimental to the public health," TCA § 2(42).

Because tobacco companies have strong incentives to discover new and creative ways to market dangerous tobacco products, as well as to exploit the public's lack of knowledge, Congress concluded that

> [t]he only way to effectively protect the public health from the dangers of unsubstantiated modified risk tobacco products is to empower the Food and Drug Administration to require that products that tobacco manufacturers sold or distributed for risk reduction be reviewed in advance of marketing, and to require that the evidence relied on to support claims be fully verified.

TCA § 2(43).

In sum, the creation of the MRTP regime was a direct response to the long and deadly history of tobacco companies using isolated terms that were literally true (but in context deeply misleading) to lead consumers – including children – incorrectly to believe that certain newer tobacco products were safer than older ones. Even Appellants concede that Congress "articulated . . . a compelling interest in protecting the public from unsubstantiated claims that one tobacco product is safer than another." Appellants Br. at 20.

The MRTP regime was intended "to provide 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." TCA § 3(4). Its unequivocal purpose is to "prohibit unproven health claims by tobacco product manufacturers." H.R. Rep. No. 111-58, pt. 1, at 3 (2009).

The history above and the findings by Congress more than justify the scope of the MRTP provision and its conclusion that consumers are likely to interpret the following as indicating that a tobacco product is "safer" than comparable alternatives:

- labels indicating reduced levels of a substance;
- labels indicating that a product does not contain or is free of a substance;
- labels or marketing with the descriptors "light", "mild", or "low" or similar descriptors;
- marketing that would reasonably be expected to result in consumers believing that a product or its smoke may present a lower risk of disease or is less harmful than commercially marketed tobacco products; and
- marketing that asserts a product presents a reduced exposure to, does not contain, or is free of, a tobacco substance or substances.

21 U.S.C. § 387k(b)(2). This list is not arbitrary. It reflects a history of precisely the kind of claims that in the past have been misinterpreted by consumers in ways that have posed significant threats to public health.

Congress's preclearance regime is particularly appropriate given (1) the addictive nature of tobacco products; (2) the history of mislabeling in the tobacco industry, including with respect to vaporizer manufacturers; (3) the history of tobacco manufacturers successfully using terms like "low tar" as proxies to signal to consumers that their products are a safer alternative to traditional tobacco

products; and (4) the use by tobacco products of adolescents, who are a primary target of tobacco advertising. *See Friedman v. Rogers*, 440 U.S. 1, 13 (1979) (misleading commercial speech includes proxy claims where there is a history of abuse); *cf. POM Wonderful*, 777 F.3d at 490–91 (determination of whether speech is misleading turns on context, consumer expertise, and risk, among other factors); *Removatron Int'l Corp.*, 884 F.2d at 1499 (preclearance particularly appropriate where there are serious health hazards).

Against this backdrop, Appellants' First Amendment challenges to the MRTP regime must be rejected. Labels marketing e-liquids as containing a reduced or no amount of a particular substance—*e.g.*, "reduced nicotine" or "no ash"—are plainly misleading for the very reasons "light," "mild," and "low-tar" brand descriptors are misleading. If consumers are faced with a choice between "no ash" e-liquids and regular e-liquids, there can be no doubt that a significant number will reasonably interpret "no ash" to imply "healthier."

It may be the case that "no ash" e-liquids are healthier that regular e-liquids. But the whole point is that no one knows with requisite scientific certainty. And in this context, we are literally playing with fire. We are now facing an entire young population that could easily become addicted to these new tobacco products, and, via this gateway, to conventional cigarettes. Given the enormity of the stakes, Congress is justified in regulating these products, and more specifically in

regarding such advertising as misleading unless companies can demonstrate that "no ash" or "reduced nicotine" e-liquids are in fact "healthier" than comparable e-liquids.

Similarly, to claim that "vaping[6] likely presents less overall risk to individuals than smoking cigarettes," Appellants Br. at 22, is no different than to claim that "smoking 'light' cigarettes likely presents less overall risk than smoking regular cigarettes." It may be true that vaping is less dangerous, but given the risks to public health, advertising meant to convey that message can legally be regarded as misleading unless proven to be true by relevant scientific evidence.[7]

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[6] "Vaping" is "to inhale vapor through the mouth from a usually battery-operated electronic device (such as an electronic cigarette) that heats up and vaporizes a liquid or solid." *"Vape"*, Merriam-Webster.com (last visited May 8, 2018).

[7] Appellants also contend that § 387k violates the First Amendment because it permits FDA to "subjectively" deny an MRTP application. Appellants may be contending that the statutory standard is too vague or uncertain to cabin the discretion of FDA officials. But this argument manifestly fails because "significant" is a well understood term of regulatory art in health law. *E.g.*, 21 U.S.C. § 360e-3 (providing expedited review for breakthrough devices that offer "significant" advantages). Alternatively, Appellants may be arguing that FDA officials might not apply or that they might ignore the statutory standard. But this argument is not ripe; there will be time enough to challenge FDA action if and when the agency breaks trust with its congressional mandate. Finally, appellants might be arguing that the statute is overboard. But "the First Amendment overbreadth doctrine does not apply to" commercial speech. *Shapero v. Kentucky Bar Ass'n*, 486 U.S. 466, 478 (1988); *accord Bd. of Trs. v. Fox*, 492 U.S. 469, 481 (1989); *Ohralik v. Ohio State Bar Ass'n*, 436 U.S. 447, 462 n.20 (1978); *Bates v. State Bar of Arizona*, 433 U.S. 350, 379–81 (1977). Unless and until Appellants

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Vaporizers are the new cigarettes. There is an "explosion" in their popularity.[8] Despite the substantial known and unknown health risks of vaping, many manufacturers exercise no more caution than cigarette companies in their marketing. On May 1, 2018, for example, the FDA issued 13 warning letters to manufacturers marketing vaporizers to children in packages that look like juice boxes and candy.[9]

History repeats itself. Our history with tobacco products has been long and disastrous. The First Amendment poses no obstacle to Congress learning from that history to proactively prohibit the very sort of abusive marketing that in the past ensnared thousands upon thousands of cigarette consumers.

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apply for MRTP status and are "subjectively" denied, they may not challenge the population effects standard.

[8] *See, e.g.*, Jia Tolentino, *The Promise of Vaping and the Rise of the Juul*, New Yorker, May 14, 2018, https://www.newyorker.com/magazine/2018/05/14/the-promise-of-vaping-and-the-rise-of-juul; Kate Zernike, *'I Can't Stop': Schools Struggle with Vaping Explosion*, N.Y. Times, Apr. 2, 2018, https://www.nytimes.com/2018/04/02/health/vaping-ecigarettes-addiction-teen.html.

[9] *See* Katie Thomas, *Vaping Products That Look Like Juice Boxes and Candy Are Target of Crackdown*, N.Y. Times, May 1, 2018, https://www.nytimes.com/2018/05/01/health/fda-crackdown-vaping-children.html.

III. STRIKING DOWN MRTP PRECLEARANCE WOULD CALL IN TO QUESTION LONGSTANDING HEALTH AND SAFETY PROTECTIONS ENACTED BY CONGRESS

Appellants and their *amici* urge the Court not only to reject application of *Whitaker* to the MRTP regime, but to sweep much further. They ask the Court to apply traditional prior restraint doctrine and heightened scrutiny in ways that would fundamentally undermine longstanding public health and consumer protection laws that hinge on pre-market approval processes. Appellants Br. at 17–34; NJOY Br. at 12–20. They argue that the First Amendment requires FDA to bear the burden of substantiation by proving that e-cigarettes are as dangerous as cigarettes, and that consumers will be misled by statements like "vaping presents less health risk to the individual than smoking." Appellants Br. at 28; NJOY Br. at 12–13, 21–22. They argue that FDA must rapidly review MRTP applications and issue determinations within weeks of receipt. NJOY Br. at 14. Most troublingly, they argue that the First Amendment *requires* Congress to rely on post-market enforcement actions, rather than pre-market approval regimes, as less restrictive alternatives. NJOY Br. at 27–28. Adopting any one of these arguments would fundamentally undermine Congress's ability to regulate dangerous products, including drugs, through premarket approval mechanisms.[10]

[10] *See* Christopher Robertson, *The Tip of the Iceberg: A First Amendment Right to Promote Drugs Off-Label*, 78 Ohio St. L.J. 1019, 1043 n.144 (2017)

The origins and evolution of pharmaceutical regulation demonstrate why *pre*-market review of commercial products and advertisements is critical to effectively regulating potentially dangerous products. Prior to 1906, there was no formal regulatory mechanism for the federal government to ban harmful products that were marketed for therapeutic or health purposes. As a result, the sale of "patent medicines" containing dangerous substances such as cocaine and heroin was widespread.[11] The patent medicine industry thrived on direct-to-consumer advertisements, including a range of unproven therapeutic claims for concoctions with no active ingredient or with harmful additives.[12]

With the Pure Food and Drug Act of 1906, Congress formalized the role of the FDA and granted the agency authority to penalize the marketing of misbranded or adulterated drugs, including fraudulent curative claims and false claims about a drug's chemical composition or purity. Ch. 3915, 34 Stat. 768 (1907). However,

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(noting that the FDA's premarket regulatory scheme could be challenged as a prior restraint on drug manufacturers' promotional speech).

[11] Wallace F. Janssen, *The Story of the Laws Behind the Labels*, FDA Consumer (FDA Magazine), June 1981, *available at* https://www.fda.gov/downloads/aboutfda/whatwedo/history/forgshistory/evolvingpowers/ucm593437.pdf.

[12] Daniel Carpenter, *Reputation and Power: Organizational Image and Pharmaceutical Regulation at the FDA* 77-78 (2010).

FDA could only act *after* a drug entered the market, and FDA bore the burden of establishing the falsity of a seller's claims. *Id.*[13]

In 1937, at least seventy-three people were fatally poisoned by diethylene glycol during the Elixir Sulfanilamide tragedy.[14] As the FDA scrambled to map the distribution of the drug and round up every bottle, legislators recognized that the FDA needed authority to prevent harm, not just respond to it.[15] While falling short of requiring premarket approval, the 1938 Federal Food, Drug, and Cosmetic Act ("FDCA") created a premarket notification system that prohibited companies from marketing a drug before at least notifying the FDA and giving it sixty days to evaluate the drug's safety. Ch. 675, 52 Stat. 1040.

Tragedy struck again in 1962, but this time the FDA was somewhat better equipped to shield Americans from harm. The sedative thalidomide, which had been advertised across Europe in the late 1950s and early 1960s as an anti-nausea medication for pregnant women, caused a horrific range of birth defects in

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[13] *See also* Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 Va. L. Rev. 1753, 1761 (1996) (describing the FDA's lack of premarket authority and its burden of proof with respect to fraudulent or false advertising as "two fundamental deficiencies" in the 1906 Act).

[14] Carpenter, *supra* n.12, at 85–87.

[15] *Id.* at 91–93.

thousands of infants in Europe and Australia, ranging from loss of limbs to organ damage and even death.[16]

In 1960, before the devastating effects of thalidomide were known, the manufacturer attempted to introduce the drug to the U.S. market and submitted an application to notify the FDA.[17] During the short premarket notification period, Frances Kelsey, an FDA reviewer and physician, became aware of reports of birth abnormalities that began to surface in other countries and rejected the application.[18] Despite intense pressure from the manufacturer[19] and animal studies that suggested the drug's safety, she continued to withhold approval until the company could prove with more rigorous evidence that there was no link between the drug and birth defects.[20] By 1962, Kelsey's judgment was proven correct, and she was eventually recognized as a national hero.[21]

As the story of Kelsey's hard-fought resistance came to light, Congress moved to strengthen the 1938 premarket notification system and passed the 1962 Kefauver-Harris Amendments to the FDCA. The 1962 Amendments transformed

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[16] *Id.* at 119, 238–39.

[17] *Id*. at 240.

[18] *Id*.

[19] *Id.* at 240.

[20] *Id*. at 240, 243.

[21] *Id*. at 119.

the FDA's modest premarket safety notification system into the current premarket approval regime that imposes on companies the burden to demonstrate both safety *and* efficacy prior to selling a new drug. Pub. L. No. 87-781, 76 Stat. 780 (codified as amended in sections of 21 U.S.C.).

Through the exercise of its expanded premarket authority, the FDA has since standardized the drug development process and created the modern clinical trial system.[22] The FDA's premarket system now typically requires companies to design and conduct randomized, double-blind, placebo-controlled clinical studies at each phase of clinical research in order to generate reliable evidence about a drug's risks, benefits, and optimum dosage for specific uses.[23]

FDA's success in building out the modern drug approval process lies in its power to prevent companies from selling medicines for an intended use without high-quality data demonstrating the safety and efficacy of their drugs. Critically, FDA can prevent sales *even if* marketers only make literally true claims about drugs, such as claims that "some evidence"—*e.g.*, non-randomized, uncontrolled trial data—shows that the drug "works" for a particular condition.

The FDA's premarket demand for high-quality data has been a vital tool in preventing harmful or ineffective drugs from entering the market, and the

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[22] *Id.* at 269–80.

[23] *Id.*

modernization of the drug approval process is credited as a key factor in substantially increasing life expectancy in the twentieth century.[24]

Congress deliberately modeled the premarket review framework for MRTPs after the contemporary framework for the regulation of pharmaceuticals.[25] Congress required the FDA, within two years of the TCA's enactment in 2009, to establish guidance on scientific evidence required to assess MRTPs, including minimum standards for studies showing reduction in morbidity and the appropriate use of biomarkers and clinical endpoints to substantiate health-related claims. 21 U.S.C. § 387k(l)(1). It was perfectly rational to place this burden on the FDA, which by virtue of expertise developed through the drug approval process already possessed the necessary expertise to evaluate scientific research and set standards for tobacco products.[26]

Effectively, the radical constitutional arguments advanced by Appellants and their *amici* would take us back to the anarchic days of 1906. Appellants and their

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[24] Naitee Ting et al., *Phase II Clinical Development of New Drugs* 28 (2017).

[25] C. Stephen Redhead & Vanessa K. Burrows, Cong. Research Serv., *FDA Tobacco Regulation: The Family Smoking Prevention and Tobacco Control Act of 2009*, at summary page (2009).

[26] *The Need for FDA Regulation of Tobacco: Hearing Before the S. Comm. on Health, Education, Labor, and Pensions*, 110th Cong. 41 (2007) (statement of Jack E. Henningfield, Ph.D).

amici propose a regime where MRTPs, despite their complex chemical compositions, are not subject to the rigorous and uniform scientific standards that can only be applied and enforced through a premarket approval system. Worse than that, adopting Appellants' and their *amici*'s position would call into constitutional question the entire regulatory framework by which FDA currently maintains the safety and health of the American population.

If this Court were to strike down provisions of the TCA requiring prior restraints or the production of scientific evidence, it would rip the heart out of standard FDA provisions prohibiting the marketing of new drugs until they had first been shown to be safe and effective. Any such holding would leave the health of the American people at the mercy of an inevitable onslaught of misleading, profit-seeking advertising, an onslaught that history sadly demonstrates will produce serious health hazards as to which post-market enforcement remedies will prove far too little and too late.[27]

[27] If the Court does not apply *Whitaker* here and holds that the MRTP provision violates the First Amendment, it should make clear that *Whitaker* still stands and that this case does not disrupt the FDA's premarket authority over drugs or myriad other laws that rely on a preapproval system. *Cf. Pearson v. Shalala*, 164 F.3d 650, 656 n.6 (1999) (striking regulations for dietary supplements but noting that "[d]rugs, on the other hand, appear to be in an entirely different category—the potential harm presumably is much greater").

CONCLUSION

For the foregoing reasons, the judgment below rejecting Appellants' First Amendment challenge to the MRTP preclearance regime should be affirmed.

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