[NOT YET SCHEDULED FOR ORAL ARGUMENT]

No. 17-5196

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

NICOPURE LABS, LLC, et al.,

Plaintiffs-Appellants,

v.

FOOD & DRUG ADMINISTRATION, et al.,

Defendants-Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

BRIEF FOR APPELLEES

BRETT A. SHUMATE
Deputy Assistant Attorney General

JESSIE K. LIU
United States Attorney

MARK B. STERN
ALISA B. KLEIN
LINDSEY POWELL
TYCE R. WALTERS
(202) 616-5372
Attorneys, Appellate Staff
Civil Division, Room 7246
U.S. Department of Justice
950 Pennsylvania Ave., NW
Washington, DC 20530

CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to Circuit Rule 28(a)(1), the undersigned counsel certifies as follows:

A. Parties and Amici. Plaintiffs-appellants are Nicopure Labs, LLC, the Right to be Smoke-Free Coalition, the American E-Liquid Manufacturing Standards Association, the American Vaping Association, the Electronic Vaping Coalition of America, the Georgia Smoke Free Association, the Kentucky Vaping Retailers Association, Inc., the Louisiana Vaping Association, Maryland Vape Professionals, LLC, the New Jersey Vapor Retailers Coalition, the Ohio Vapor Trade Association, and the Tennessee Smoke Free Association.

Defendants-appellees are the U.S. Food and Drug Administration (FDA), Alex M. Azar II, Secretary of the U.S. Department of Health and Human Services, and Scott Gottlieb, MD, FDA Commissioner. Secretary Azar has been automatically substituted pursuant to Federal Rule of Appellate Procedure 43(c)(2).

The following entities and individuals participated as amici in support of plaintiffs in district court or on appeal:

- Consumer Advocates for Smoke-Free Alternatives Association
- NJOY, LLC
- National Center for Public Policy Research
- Smoke-Free Alternatives Trade Association
- State of Iowa
- TechFreedom

- Vape A Vet Project
- Washington Legal Foundation
- Philip Alcabes, Prof. of Public Health, College of Nursing & Public Health, Adelphi Univ.
- Edward Anselm, MD, Assistant Prof. of Medicine Icahn School of Medicine at Mount Sinai, Senior Fellow, R Street Institute
- Scott Ballin, Advisor to the Morven Dialogues on Tobacco, Nicotine, and Alternative Products Harm Reduction at the Univ. of Virginia, former Vice President for Public Policy and Leg. Counsel at the Am. Heart Assoc.
- Clive Bates, Director Counterfactual, Former Director, ASH (UK)
- Ernest Drucker, PhD, Research Scientist & Prof. of Public Health, College of Global Public Health, New York Univ.
- Konstantinos Farsalinos, MD, Research Scientist, Onassis Cardiac Surgery Center, Univ. of Patras, Greece
- William Godshall, MPH, Founder & Exec. Director, Smokefree Penn.
- Jacques LeHouezec, Consultant in Public Health, Président SOVAPE
- Bernd Mayer, PhD, Prof. & Chair, Dep't Pharmacology, University of Graz
- Jeff Nesbit, Exec. Director, Climate Nexus, Former Assoc. FDA Comm'r;
- Joel L. Nitzkin, MD, MPH, DPA, CEO of JLN MD Assocs., Senior Fellow for Tobacco Policy, R Street Institute
- Riccardo Polosa, MD, PhD, Prof. of Internal Medicine, Univ. of Catania
- Gilbert L. Ross, MD, Board-certified in Internal Medicine & Rheumatology
- Sally L. Satel, MD, Resident Scholar, American Enterprise Institute
- Michael B. Siegel, MD, Prof. of Community Health Sciences, Boston Univ. School of Public Health.
- Andrzej Sobczak, PhD, Prof., Head of Dep't Chemical Hazards & Genetic Toxicology, Inst. Occupational Medicine & Environmental Health
- David Sweanor, Adjunct Prof., Faculty of Law, Univ. of Ottawa Centre for Health Law, Policy & Ethics
- Michael B. Siegel, MD, Prof., Community Health Sciences, Dep't of Community Health Sciences, Boston Univ. School of Public Health

The following entities participated as amici in support of defendants in district court:

- American Academy of Pediatrics
- American Cancer Society Cancer Action Network
- American Heart Association
- American Lung Association
- American Thoracic Society
- Campaign for Tobacco-Free Kids
- Tobacco Control Legal Consortium
- Truth Initiative

B. Ruling Under Review. Plaintiffs seek review of the district court's July 21, 2017, Memorandum Opinion and Order (Judge Amy Berman Jackson) in Nos. 16-878 and 16-1210, which were consolidated for review. The opinion granted summary judgment for the government and is reported at 266 F. Supp. 3d 360.

C. Related Cases. The case on review has not previously been before this Court, and there are no related cases in any federal court of appeals. Nine other actions challenging FDA's deeming rule remain pending in district court. *Cigar Ass'n of Am. v. FDA*, No. 16-1460 (D.D.C.); *Cyclops Vapor 2, LLC v. FDA*, No. 16-556 (M.D. Ala.) (stayed); *En Fuego Tobacco Shop LLC v. FDA*, No. 18-28 (E.D. Tex.); *Faircloth v. FDA*, No. 16-5267 (S.D.W. Va.); *Hoban v. FDA*, No. 18-269 (D. Minn.); *Lost Art Liquids, LLC v. FDA*, No. 16-3468 (C.D. Cal.); *Moose Jooce v. FDA*, No. 18-203 (D.D.C.); *Rave Salon, Inc. v. Gottlieb*, No. 18-237 (N.D. Tex.); *Sanchez Icaza v. FDA*, No. 16-21967 (S.D. Fla.) (stayed and administratively closed).

Another case challenging certain compliance dates for the deeming rule is also pending in district court. *American Acad. of Pediatrics v. FDA*, No. 18-883 (D. Md.).

s/ Lindsey Powell
LINDSEY POWELL

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GLOSSARY

FDA	Food and Drug Administration
FDCA	Federal Food, Drug, and Cosmetic Act
JA	Joint Appendix
TCA	Family Smoking Prevention and Tobacco Control Act

INTRODUCTION

Electronic nicotine delivery systems, collectively referred to as "e-cigarettes," constitute the fastest growing segment of the tobacco market, and their use has surged among middle and high school students. Although e-cigarettes are often marketed as being less dangerous than conventional cigarettes, there is significant variation among e-cigarette products, and much about their potential risks remains unknown. It is possible that some e-cigarette products may offer certain benefits as part of a comprehensive approach to the regulation of tobacco products, but the available data indicate that many of these products present real risks. E-cigarettes typically contain nicotine, a highly addictive substance, and they often deliver a number of other harmful chemicals, including formaldehyde—sometimes at higher levels than conventional cigarettes. E-cigarette use may also lead individuals to begin using other tobacco products, or to increase such use.

In a final rule issued in May 2016, FDA exercised its authority to deem e-cigarettes to be tobacco products subject to the requirements set forth in Chapter IX of the Federal Food, Drug, and Cosmetic Act (FDCA), as amended by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act or TCA). The district court upheld the deeming rule over plaintiffs' numerous challenges, including their assertion that FDA lacked authority to deem e-cigarettes subject to Chapter IX. Plaintiffs present three issues on appeal. Plaintiffs urge that e-cigarettes should be exempt from the statutory framework for premarket review of new tobacco products;

that requiring premarket review of modified-risk tobacco products violates the First Amendment; and that prohibiting the distribution of free e-cigarette samples likewise violates the First Amendment. As the district court concluded, plaintiffs' contentions are without foundation.

Chapter IX of the FDCA requires premarket review of new tobacco products, defined as those that were not commercially marketed in the United States as of February 15, 2007, or were modified after that date. 21 U.S.C. § 387j(a)(1)-(2). As relevant to this appeal, applications to market a new tobacco product must include information regarding the product's ingredients, manufacture, and health risks. *Id.* § 387j(b)(1). FDA must deny an application if a product does not conform to manufacturing requirements or product standards, if its labeling is false or misleading, or if the applicant has failed to show that marketing the product "would be appropriate for the protection of the public health." *Id.* § 387j(c)(2). Plaintiffs argue that it is unreasonable for FDA to apply these provisions to e-cigarettes without altering them in some fashion. But these requirements were established by Congress, not FDA, and the agency properly declined to adopt plaintiffs' proposed alternatives to the extent they are at odds with the statute.

Chapter IX also requires premarket review of "modified risk tobacco product[s]," defined as those "sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products."

21 U.S.C. § 387k(b)(1). Under this provision, manufacturers of such products must file an application with FDA and demonstrate, among other requirements, that any claims "relating to the effect of the product on tobacco-related diseases and health-related conditions" are supported by scientific data and that the product will or is expected to benefit the health of the population as a whole. *Id.* § 387k(d), (g). This provision resembles the well-established requirement of premarket review of new drugs, *id.* § 355(a), and, like that requirement, raises no First Amendment concerns. *See Whitaker v. Thompson*, 353 F.3d 947, 953 (D.C. Cir. 2004).

Even if premarket review of modified-risk tobacco products were viewed as a regulation of commercial speech, it would readily satisfy review under *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557, 566 (1980), because it is narrowly tailored to serve the government's substantial interest in ensuring that statements about such products are complete, accurate, and relate to the product's overall risk. Plaintiffs' arguments to the contrary rest on unsupported characterizations of the requirement, which neither plaintiffs nor their amici have tested by filing an application to market a modified-risk tobacco product.

Plaintiffs' First Amendment challenge to the prohibition against distributing free e-cigarette samples is similarly insubstantial. The prohibition is an economic regulation, not a restriction of speech. And even if it were regarded as restricting commercial speech, it would properly be upheld as narrowly tailored to the

government's substantial interest in reducing youth access to tobacco products. For all of these reasons, the judgment of the district court should be affirmed.

STATEMENT OF JURISDICTION

Plaintiffs invoked the district court's jurisdiction pursuant to 28 U.S.C. §§ 1331, 2201 and 2202. JA __. On July 21, 2017, the district court granted the government's motion for summary judgment. JA __. On August 31, 2017, plaintiffs filed a timely notice of appeal. JA __; Fed. R. App. P. 4(a)(1)(B). This Court has jurisdiction pursuant to 28 U.S.C. § 1291.

STATEMENT OF THE ISSUES

1. Whether FDA correctly applied the statutory requirements for premarket review of new tobacco products to e-cigarettes, where those requirements are established by Congress and not subject to modification.

2. Whether the requirement that modified-risk tobacco products be subject to premarket review is consistent with the First Amendment.

3. Whether the prohibition on the distribution of free e-cigarette samples is consistent with the First Amendment.

PERTINENT STATUTES

Pertinent statutes are reproduced in the addendum to this brief.

STATEMENT

A. The Tobacco Control Act

1. The Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009) (codified at 21 U.S.C. § 387 *et seq.*), establishes a comprehensive scheme for the regulation of tobacco products, which Congress broadly defined to include "any product made or derived from tobacco that is intended for human consumption." 21 U.S.C § 321(rr)(1). Recognizing the health risks inherent in these products, the history of unsubstantiated and misleading claims by the tobacco industry, and the special hazards presented to children, *see* TCA § 2(1)-(6), (15), (38)-(42), (47)-(49), Congress legislated a series of requirements governing the manufacture, labeling, and marketing of tobacco products, and gave FDA substantial authority with respect to their regulation. Most of these provisions were enacted as Chapter IX of the FDCA.

This appeal implicates three provisions enacted by the Tobacco Control Act. First, Chapter IX of the FDCA requires premarket FDA review before "new tobacco product[s]," defined as those that were not commercially marketed in the United States as of February 15, 2007, or were modified after that date, may be introduced into interstate commerce. 21 U.S.C. § 387j(a)(1)-(2).[1] As relevant to this appeal,

[1] Congress provided two other premarket-review pathways, one for products that are "substantially equivalent" to a valid predicate, and another for products that

applications to market a new tobacco product must include reports concerning the product's health risks; a statement of the product's ingredients, components, and principles of operation; specified manufacturing information; and samples of the product and its proposed labeling. *Id.* § 387j(b)(1). By statute, FDA shall deny an application if the product does not conform to manufacturing requirements or product standards, its labeling is false or misleading, or the applicant has failed to show that marketing of the product "would be appropriate for the protection of the public health." *Id.* § 387j(c)(2).

In determining whether the marketing of a product would be appropriate for the protection of the public health, FDA is to consider "the risks and benefits to the population as a whole, including users and nonusers of the tobacco product," and must take into account "(A) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and (B) the increased or decreased likelihood that those who do not use tobacco products will start using such products." 21 U.S.C. § 387j(c)(4).

Second, Chapter IX requires premarket FDA review of "modified risk tobacco product[s]," defined as those that are "sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco

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are exempt from the requirements of substantial equivalence. 21 U.S.C. §§ 387e(j), 387j(a)(2).

products." 21 U.S.C. § 387k(b)(1). The statute identifies circumstances in which products are considered to be "sold or distributed" for such use, based on representations made on the product's label, labeling, or advertising, or through actions by the manufacturer that are directed at consumers. *Id.* § 387k(b)(2)(A).

In enacting this requirement, Congress found that, "[u]nless tobacco products that purport to reduce the risks to the public of tobacco use actually reduce such risks, those products can cause substantial harm to the public health to the extent that the individuals, who would otherwise not consume tobacco products or would consume such products less, use tobacco products purporting to reduce risk." TCA § 2(37). Historically, "consumers have misinterpreted advertisements in which one product is claimed to be less harmful than a comparable product, even in the presence of disclosures and advisories intended to provide clarification." TCA § 2(41). Congress determined 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 s[ell] or distribute[] 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).

Congress therefore provided that, before placing a product on the market, manufacturers of modified-risk tobacco products must file an application with FDA and demonstrate, among other requirements, that any claims "relating to the effect of

the product on tobacco-related diseases and health-related conditions" are supported by scientific data, and that the product will or is expected to benefit the health of the population as a whole. 21 U.S.C. § 387k(d), (g). FDA generally may grant an application only if it finds that the product will "significantly reduce harm and the risk of tobacco-related disease to individual tobacco users" and will "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." *Id.* § 387k(g)(1). For applications that cannot satisfy section 387k(g)(1) and are limited to a claim that the product does not contain a particular substance, or contains a reduced level of that substance, FDA may grant the application if, among other requirements, the available scientific data demonstrate that the product "is expected to" benefit the health of the population as a whole and "is reasonably likely" to provide "a measurable and substantial reduction in morbidity or mortality among individual tobacco users." *Id.* § 387k(g)(2)(A)(iv), (B)(iv).

Third, the Tobacco Control Act directed FDA to reissue, with certain changes, provisions of a 1996 rule that restricted marketing practices that increased tobacco product use by children and adolescents. 21 U.S.C. § 387a-1(a). As relevant to this appeal, that rule generally prohibits the distribution of free samples of tobacco products. *See id.* § 387a-1(a)(2)(G); 21 C.F.R. § 1140.16(d)(1). Congress found that "[c]hildren, who tend to be more price sensitive than adults, are influenced by

advertising and promotion practices that result in drastically reduced" product prices, TCA § 2(24), and that "[b]ecause past efforts to restrict advertising and marketing of tobacco products have failed adequately to curb tobacco use by adolescents, comprehensive restrictions on the sale, promotion, and distribution of such products are needed," TCA § 2(6). Although Congress directed FDA to provide a narrow exception to the prohibition on free samples to allow the distribution of specified quantities of free smokeless tobacco samples in qualified adult-only facilities, *see* 21 U.S.C. § 387a-1(a)(2)(G); 21 C.F.R. § 1140.16(d)(2), the prohibition expressly applies to all other tobacco products, as defined by statute, *see* 21 U.S.C. § 387a-1(a)(2)(G).

2. Congress made these requirements immediately applicable to certain categories of tobacco products, including conventional cigarettes and smokeless tobacco, and it authorized FDA to bring within the scope of these requirements "any other tobacco products that the Secretary by regulation deems to be subject to this chapter." 21 U.S.C. § 387a(b). The provisions at issue apply automatically to all "tobacco product[s]" that FDA deems to be subject to Chapter IX of the FDCA. Congress broadly defined the term tobacco product as "any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product." *Id.* § 321(rr)(1).

In *Sottera, Inc. v. FDA*, 627 F.3d 891, 897 (D.C. Cir. 2010), this Court held that e-cigarettes, as customarily marketed, are properly subject to regulation under FDA's

authority under Chapter IX of the FDCA, rather than under FDA's preexisting authority to regulate drugs and devices. The opinion emphasized that the agency's authority under Chapter IX would enable it "to mitigate or perhaps extinguish any harm to public health" associated with e-cigarettes. *Id.* at 898. Plaintiffs in this case no longer challenge FDA's authority to deem e-cigarettes subject to Chapter IX.

B. E-cigarettes and FDA's 2016 Rule

1. In a final rule issued in May 2016, FDA exercised its authority under 21 U.S.C. § 387a(b) to deem all products that meet the definition of "tobacco product," excluding accessories of such products, to be subject to Chapter IX of the FDCA. 81 Fed. Reg. 28,974, 28,975 (May 10, 2016). E-cigarettes and their components and parts are among the tobacco products newly regulated as a result of this rule. *Id.*[2]

Although there is significant variation among the hundreds of e-cigarette devices now on the market, AR 23,987, such products generally consist of three basic parts: a cartridge containing "e-liquid," which typically contains nicotine and is frequently flavored; an atomizer with a heating element; and a battery and other electronics. *See Sottera*, 627 F.3d at 893; *see also* 81 Fed. Reg. at 28,975 (discussing e-

[2] FDA defined "component or part" to mean "any software or assembly of materials intended or reasonably expected: (1) To alter or affect the tobacco product's performance, composition, constituents or characteristics; or (2) to be used with or for the human consumption of a tobacco product. The term excludes anything that is an accessory of a tobacco product." 81 Fed. Reg. at 28,975; *see* 21 C.F.R. §§ 1100.3, 1143.1.

cigarette components and parts). Typically, when a user breathes in through a mouthpiece, the atomizer vaporizes the e-liquid, which is then inhaled as an aerosol. *See Sottera*, 627 F.3d at 893. E-liquids are available in thousands of varieties, AR 23,987, including many fruit and candy flavors that particularly appeal to youth, AR 18,675; 81 Fed. Reg. at 29,011, 29,014.

Some e-cigarettes, called "cigalikes," are made to resemble conventional cigarettes, while others are not. 81 Fed. Reg. at 29,038. A growing number of new e-cigarette products are made to look like everyday objects, like computer flash drives, and can more easily avoid detection in schools and other places where e-cigarettes are not allowed. Kate Zernike, *'I Can't Stop': Schools Struggle With Vaping Explosion*, N.Y. Times (Apr. 2, 2018).[3] For example, a new device called "JUUL," which is extremely popular among students, "fits easily in a pocket and looks nondescript when plugged into a laptop's USB drive to recharge or sitting on a desk." Anne Marie Chaker, *Schools & Parents Fight a 'Juul' E-Cigarette Epidemic*, Wall Street Journal (Apr. 4, 2018);[4] *see* FDA, *Statement from FDA Commissioner Scott Gottlieb, M.D., on new enforcement actions and a youth tobacco prevention plan to stop youth use of, and access to, JUUL and other e-cigarettes* (Apr. 2018) (announcing measures to combat youth use of products such as JUUL

[3] Available at https://www.nytimes.com/2018/04/02/health/vaping-ecigarettes-addiction-teen.html.

[4] Available at https://www.wsj.com/articles/schools-parents-fight-a-juul-e-cigarette-epidemic-1522677246.

that "have become wildly popular with kids" and are "more difficult for parents and teachers to recognize or detect," and noting a high rate of illegal sales to youth).[5] Even though such products do not physically resemble conventional cigarettes, some "closely mimic[] the feeling of inhaling cigarettes," and they "deliver[] a powerful dose of nicotine, derived from tobacco." Chaker, *supra*.

FDA's deeming rule made e-cigarettes subject to the requirements of Chapter IX of the FDCA without any further agency action. 81 Fed. Reg. at 28,975. The rule became effective on August 8, 2016—ninety days after its publication date. With respect to the premarket review provisions for new tobacco products, however, FDA provided a lengthy compliance period for products that were already on the market on the rule's effective date. *Id.* at 29,011. For noncombustible products, including most e-cigarettes, that were on the market as of August 8, 2016, the agency subsequently extended the compliance period until August 8, 2022. *See* FDA, *Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule: Guidance for Industry* 3 (4th ed. rev. Nov. 2017).[6]

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[5] Available at https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm605432.htm.

[6] Available at https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM557716.pdf. Public health groups have filed suit in the U.S. District Court for the District of Maryland challenging FDA's extension of these compliance dates. *American Acad. of Pediatrics v. FDA*, No. 18-883 (D. Md.).

2. In its rulemaking, FDA noted that the full measure of potential risks and benefits presented by e-cigarettes is not yet known. 81 Fed. Reg. at 28,984. But "[w]hether [e-cigarettes] generally may eventually be shown to have a net benefit on or harm to public health at the population level—and there have not yet been long-term studies conducted to support either claim at this time—*regulation* of [e-cigarettes] will still benefit public health." *Id.* "This final deeming rule affords FDA additional tools to reduce the number of illnesses and premature deaths associated with tobacco product use," in part by giving the agency "critical information regarding the health risks of newly deemed tobacco products." *Id.* at 28,975.

While it is possible that certain e-cigarette products may prove beneficial in some respects for some individuals, the available data suggest that many of these products present substantial risks, and regulation is necessary both to address those harms and to resolve uncertainty about the products' effects. E-cigarettes typically contain and deliver nicotine—"one of the most addictive substances used by humans," 81 Fed. Reg. at 28,988, and a powerful pharmacologic agent that acts in the brain and throughout the body, *id.* at 28,981, 28,986. Nicotine use during adolescence is associated with "long-term effects including decreased attention performance and increased impulsivity," and "can disrupt brain development and have long-term consequences on executive cognitive function." 79 Fed. Reg. 23,142, 23,154 (Apr. 25, 2014).

In the absence of labeling and manufacturing standards, it can be difficult for consumers to ascertain how much nicotine e-cigarettes will deliver. FDA found "significant . . . variability between labeled content and concentration and actual content and concentration," noting that some e-liquids "claiming to be nicotine-free actually contained high levels of nicotine." 81 Fed. Reg. at 28,984. One study found that more than half of the e-liquids examined contained nicotine concentrations that deviated by more than ten percent from the stated amount. *Id.* at 29,034. Variations in device design and performance also affect the amount of nicotine and other chemicals that are actually inhaled by users, all of which leaves users unaware of the nicotine levels they are receiving. *Id.* at 29,029-32. In some instances, e-cigarettes can deliver more nicotine than conventional cigarettes. *Id.* at 29,031.

Many e-liquids also contain other chemicals that pose known risks, including formaldehyde, diacetyl and acetyl propionyl, and various aldehydes. 81 Fed. Reg. at 29,029-31; *see* Joseph G. Allen, *The Formaldehyde in Your E-Cigs*, N.Y. Times (Apr. 4, 2018) (noting that "[s]tudy after study . . . has confirmed that e-cigs can deliver formaldehyde to the user," and they have "found diacetyl in over 75 percent of e-cigs tested").[7] There is also evidence that toxic heavy metals, including lead and silicates,

[7] Available at https://www.nytimes.com/2018/04/04/opinion/formaldehyde-diacetyl-e-cigs.html. Because the deeming rule was the product of notice-and-comment rulemaking, this action arises under the Administrative Procedure Act, and the Court's review of the rule is confined to the administrative record. *Florida Power & Light Co. v. Lorion*, 470 U.S. 729, 743-44 (1985); *see R.J. Reynolds Tobacco Co. v. FDA*,

can be transferred from e-cigarette parts into the inhaled aerosol. AR 6,977, 15,585; 81 Fed. Reg. at 29,015. In addition, studies show that secondhand e-cigarette vapor may contain substances—including formaldehyde, benzene, and acrolein—that pose a risk to non-users through passive exposure. *See* 81 Fed. Reg. at 29,031-32; *Competitive Enter. Inst. v. U.S. Dep't of Transp.,* 863 F.3d 911, 919 (D.C. Cir. 2017) (upholding regulation banning e-cigarette use on airplanes based in part on studies showing that "e-cigarette vapor in confined aircrafts could harm non-users").

Plaintiffs and their amici cite a 2016 report by Public Health England that asserts that e-cigarettes are 95% safer than conventional cigarettes. Br. 6. But this document reflects a survey, not a research study, and FDA explained at length why this document and a prior paper on which it relied are entitled to little weight. 81 Fed. Reg. at 29,030. In particular, the authors of the prior paper acknowledged the "lack of hard evidence" for their analysis, and they did not follow standard scientific practices. *Id.* Moreover, "population effects appear to be largely outside the scope of this analysis since the manuscript did not address the likelihood that the characteristics of the products would make them more or less likely to appeal to new users, be used in conjunction with other tobacco products[,] or discourage quitting." *Id.* Regardless,

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696 F.3d 1205, 1217-18 (D.C. Cir. 2012). Thus, plaintiffs' reliance on extra-record evidence in challenging the rule should be disregarded. *See Hill Dermaceuticals, Inc. v. FDA*, 709 F.3d 44, 47 (D.C. Cir. 2013). The government principally cites such materials for background and in response to plaintiffs' arguments.

the evidence on e-cigarettes continues to develop, and other studies suggest that cigarette smokers who also use e-cigarettes are less likely to quit smoking than cigarette smokers who do not also use e-cigarettes. *See id.* at 29,028, 29,037.

E-cigarettes are the fastest growing segment of the tobacco market, AR 124, and domestic sales of e-cigarettes are estimated to reach $5.5 billion in 2018, *see* Wells Fargo Sec., *Nielsen: Tobacco 'All Channel' Data 1/27, Marlboro Volume & Share Pressures Continue* 7 (Feb. 6, 2018).[8] The use of these products has surged among middle and high school students in particular, including those with no history of smoking, 81 Fed. Reg. at 28,984-85, 29,028-29, and e-cigarettes are now the tobacco product most commonly used by young people, AR 15,633, 15,635; 83 Fed. Reg. 12,294, 12,296 (Mar. 21, 2018). "After two decades of declining teen cigarette use," teen use of e-cigarettes "is exploding," and schools are struggling to manage the surging use of JUUL and other easily concealed e-cigarette devices. Chaker, *supra*; *see* Zernike, *supra*.

Compounding these concerns, the data also indicate that e-cigarettes may act as a gateway to other tobacco products. "There is *substantial evidence* that e-cigarette use increases [the] risk of ever using combustible tobacco cigarettes among youth and young adults." National Academies of Sciences, Engineering & Medicine, *Public*

[8] Available at https://1lbxcx1bcuig1rfxaq3rd6w9-wpengine.netdna-ssl.com/wp-content/uploads/2018/02/Nielsen-Tobacco-All-Channel-Report-Period-Ending-1.27.18.pdf.

Health Consequences of E-Cigarettes 16-30 (2018) (*Public Health Consequences*);[9] *see* AR 15,663, 23,909. School officials "fear that the devices are creating a new generation of nicotine addicts." Zernike, *supra*. A recent study estimated that through e-cigarette use in 2014 alone, 168,000 adolescents and young adults would transition to smoking conventional cigarettes in 2015, and eventually become daily cigarette smokers, resulting in more than 1.5 million years of life lost. Samir S. Soneji et al., *Quantifying population-level health benefits & harms of e-cigarette use in the United States*, PLOS ONE 13(3):e0193328, at 1 (Mar. 14, 2018).[10]

Evidence indicates that e-cigarette marketing specifically targets youth, mimicking the strategies historically used by the tobacco industry to devastating effect. AR 18,674-93. Indeed, many of the same companies that dominate the cigarette industry are leading actors in the e-cigarette market. *See* Business Wire, *Technavio Announces Top Six Vendors in the Global E-Cigarette Market from 2016 to 2020* (June 15, 2016).[11] E-cigarette companies have advertised their products "during events and programs with youth viewership," AR 18,686, and in magazines with substantial youth readership, AR 265-70. And they have sponsored or provided free samples at events geared toward youth, including concerts, music festivals, parties, and sporting events.

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[9] Available at http://nationalacademies.org/hmd/Reports/2018/public-health-consequences-of-e-cigarettes.aspx.

[10] Available at https://doi.org/10.1371/journal.pone.0193328.

[11] Available at https://www.businesswire.com/news/home/20160615005016/en/Technavio-Announces-Top-Vendors-Global-E-Cigarette-Market.

81 Fed. Reg. at 28,986; AR 18,681-82. The proliferation of sweet-flavored e-cigarette varieties tends to further increase the products' attractiveness to young people. *See* 83 Fed. Reg. at 12,296-97; 81 Fed. Reg. at 29,014; 79 Fed. Reg. at 23,146-47; *see also* FDA, *FDA, FTC take action against companies misleading kids with e-liquids that resemble children's juice boxes, candies and cookies* (May 1, 2018) (reporting that the federal government recently issued warnings to manufacturers that have been marketing e-liquids to resemble kid-friendly products such as juice boxes, candy, and whipped cream, and noting that one product "not only resembles a Unicorn Pop lollipop but is shipped with one").[12]

C. Procedural Background

Plaintiffs, an e-cigarette manufacturer and industry associations, filed this suit in May 2016, alleging as relevant to this appeal that FDA unreasonably applied the statutory requirements of premarket review for new tobacco products to e-cigarettes without modifying those requirements. Plaintiffs further alleged that the requirement of premarket review for modified-risk tobacco products and the prohibition on the distribution of free e-cigarette samples violate the First Amendment.[13]

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[12] Available at https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm605507.htm.

[13] Plaintiffs also raised numerous other challenges on which the agency prevailed at the district court, but none is at issue on appeal.

The district court granted summary judgment for FDA. With respect to plaintiffs' claim that FDA should have taken a different approach to premarket review of new e-cigarettes, the court explained that "premarket review is a creature of statute," Op. 54, and that FDA correctly concluded that "all tobacco products going through the [premarket] pathway must meet all the requirements for a premarket authorization in [21 U.S.C. § 387j] before FDA can issue such an authorization," Op. 55 (quoting 81 Fed. Reg. at 28,998) (first alteration in original). The court observed that plaintiffs' proposed alternatives to premarket review do not satisfy the statutory requirements and "would have been contrary to the TCA." *Id.*

The district court also rejected plaintiffs' contention that the requirement of premarket review for modified-risk e-cigarette products violates the First Amendment. The court concluded that regulation of modified-risk tobacco products is subject to review under *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557, 566 (1980), and that the premarket-review requirement readily satisfies that standard. Op. 76-78, 90-93 & n.37. The court explained that the government has a substantial interest in protecting the public health by preventing the marketing of tobacco products that make misleading or unsubstantiated modified-risk claims, which may lead individuals to begin using, or continue to use, tobacco products based on mistaken perceptions of risk. Op. 91. And the court found premarket review appropriately tailored to further those interests, dismissing plaintiffs'

contention that disclaimers would be a less restrictive and equally effective option. Op. 92-93. The court noted that Congress expressly considered and rejected that approach. *Id.*

The district court likewise rejected plaintiffs' First Amendment challenge to the prohibition on the distribution of free e-cigarette samples. The court concluded that this prohibition is not a restriction on speech because it is "focused on conduct—a means of distribution of e-cigarettes that presents a particular risk of providing the product to underage users." Op. 81. The prohibition is properly viewed as a form of price regulation that does not implicate the First Amendment. Op. 82-83 (collecting cases). The court further held that, even if the prohibition were properly viewed as a speech restriction, it would readily withstand review under *Central Hudson* because the government has a substantial interest in eliminating youth access to tobacco products, and the prohibition is narrowly tailored to further that interest. Op. 84-89.

SUMMARY OF ARGUMENT

I. The Tobacco Control Act "automatically subjects deemed products to the statutory requirements for 'tobacco products' in chapter IX of the [FDCA]," including the requirement of premarket review for new tobacco products. 81 Fed. Reg. at 29,000. Accordingly, once FDA deemed e-cigarettes that are tobacco products to be subject to the authorities set forth in Chapter IX—a decision plaintiffs do not challenge on appeal—the requirements of premarket review for new tobacco

products applied to e-cigarettes as a matter of course. By statute, applications seeking a marketing authorization order under 21 U.S.C. § 387j(c) "shall" contain reports of the health risks of the product, a statement describing the product's ingredients and operation, a description of the manufacturing methods used, and samples of the product and its labeling. *Id.* § 387j(b)(1). Plaintiffs disregard the plain text of the statute in urging that it was arbitrary and capricious for FDA not to alter the requirements established by Congress. As the district court correctly concluded, the statute forecloses plaintiffs' argument that e-cigarettes should be subject to separate standards. Op. 55.

II. Plaintiffs' constitutional challenges likewise lack merit. Premarket review of modified-risk tobacco products resembles the longstanding FDCA provisions for premarket review of new drugs. Under both provisions, the government looks to how a product will be used in order to determine whether it is the type of product subject to premarket review. And in both contexts, a manufacturer's claims about a product may be considered as evidence of its intended use. This Court has previously held that such evidentiary use of speech is consistent with the First Amendment. *Whitaker v. Thompson*, 353 F.3d 947, 953 (D.C. Cir. 2004).

Even if the premarket-review requirement were regarded as a regulation of commercial speech, the requirement is narrowly tailored to further a substantial interest, as required by *Central Hudson Gas & Electric Corp. v. Public Service Commission*,

447 U.S. 557, 566 (1980). Plaintiffs do not dispute that the government's public health interests are compelling. They assert that less restrictive measures such as disclaimers would adequately further those interests. Congress considered such alternatives, however, and reached a contrary conclusion. *See* Op. 92-93. In enacting this requirement, Congress made extensive findings concerning the dangers inherent in unsubstantiated or misleading health claims about tobacco products, and it concluded that premarket review is the only means of preventing these harms. TCA § 2(36)-(43); *see Discount Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509, 537 (6th Cir. 2012), *cert. denied sub nom. American Snuff Co. v. United States*, 133 S. Ct. 1996 (2013). Plaintiffs provide no basis to reject Congress's judgment.

III. The prohibition on the distribution of free samples of tobacco products does not implicate the First Amendment because it regulates economic activity rather than expression. As the district court correctly explained, the prohibition is a price regulation that is "focused on conduct—a means of distribution of e-cigarettes that presents a particular risk of providing the product to underage users." Op. 81. But even if the prohibition were viewed as a speech restriction, it would withstand review under *Central Hudson* because it is narrowly tailored to further the government's compelling interest in preventing youth access to tobacco products. *See Discount Tobacco*, 674 F.3d at 541.

STANDARD OF REVIEW

This Court reviews a district court's grant of summary judgment de novo. *Chenari v. George Washington Univ.*, 847 F.3d 740, 744 (D.C. Cir. 2017).

ARGUMENT

I. Congress Established Procedures for Premarket Review of New Tobacco Products and Did Not Authorize, Much Less Require, FDA To Modify Those Requirements as Plaintiffs Suggest.

Chapter IX of the FDCA forecloses plaintiffs' contention that FDA was obligated to modify, for e-cigarettes, the statutory procedures governing premarket review of new tobacco products. Op. 55. Congress stated that "[t]his chapter shall apply to all" enumerated products "and to any other tobacco products that the Secretary by regulation deems to be subject to this chapter." TCA § 901; *see* 21 U.S.C. § 387a. As FDA explained, section 387j, which establishes the procedures for premarket review of new tobacco products, "is one of the statutory provisions that apply automatically to all tobacco products, including newly deemed products." 81 Fed. Reg. at 29,000. Pursuant to that provision, a tobacco product that was not commercially marketed in the United States as of February 15, 2007, or was modified after that date, is subject to premarket FDA review. 21 U.S.C. § 387j(a)(1)-(2).

By statute, an application for premarket authorization under 21 U.S.C. § 387j(b) must contain particular information, including reports concerning the product's health risks; a statement of the product's ingredients, components, and principles of operation; specified manufacturing information; and samples of the product and its

proposed labeling. *Id.* § 387j(b)(1)(A)-(G). FDA may not grant such an application unless the agency determines that permitting the product to be marketed "would be appropriate for the protection of the public health," *id.* § 387j(c)(2)(A), taking into account "the risks and benefits to the population as a whole," including "the increased or decreased likelihood that existing users of tobacco products will stop using such products" and that "those who do not use tobacco products will start using such products." *Id.* § 387j(c)(4).

The district court correctly recognized that, "[o]nce the Secretary of HHS made the decision to deem [e-cigarettes] as tobacco products, the requirement of premarket review is established by statute." Op. 52. Chapter IX of the FDCA provides that "all tobacco products going through the [premarket] pathway must meet all the requirements for a premarket authorization in [§ 387j] before FDA can issue such an authorization." Op. 55 (quoting 81 Fed. Reg. at 28,998) (first alteration in original). In rejecting plaintiffs' contention that FDA should have altered these requirements as they apply to e-cigarettes, the district court correctly concluded that doing so "would have been contrary to the TCA." *Id.*

Plaintiffs assert that FDA was required to "structure the [premarket review] requirements to reflect continuum of risk so adults have continued access to tobacco products." Br. 48. But Congress itself weighed the risks and benefits of allowing new tobacco products to enter the market prior to FDA review, and, as relevant here, it

chose to balance those considerations by directing FDA to determine, in advance of a product's introduction into the marketplace, whether the marketing of the product would be appropriate for the protection of public health. 21 U.S.C. § 387j(c).

In urging that Congress intended FDA to consider regulatory alternatives to premarket review, plaintiffs invoke separate portions of the Tobacco Control Act. Citing the Act's statement of purpose, plaintiffs assert that Congress intended that "FDA should only 'impose *appropriate* regulatory controls on the tobacco industry.'" Br. 49 (quoting TCA § 3(8)). But while Congress conditioned certain exercises of FDA's authority under Chapter IX on a finding that "regulation would be appropriate for the protection of the public health," 21 U.S.C. § 387f(d)(1); *see id.* § 387g(a)(3) (similar), Congress uniformly required premarket review of new tobacco products without predicating it on such a finding.

Similarly, citing the Act's statement of purpose, plaintiffs point to FDA's "new and flexible *enforcement* authority[.]" Br. 49 (quoting TCA § 3(4)) (emphasis altered); *see* Br. 50 (citing 21 U.S.C. §371(a) (granting FDA authority to adopt regulations "for the efficient *enforcement*" of the FDCA) (emphasis added)). But flexibility in FDA's enforcement authority does not alter the statutory requirements for premarket review. In any event, such general statements of purpose do not undermine the clear command of sections 387a and 387j. *See* Op. 61 (plaintiffs "have not pointed to any . . . case law that would imply statutory prerequisites from a general, introductory

statement of purpose"); *see Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 384 (1992); *National Wildlife Fed'n v. Gorsuch*, 693 F.2d 156, 178 (D.C. Cir. 1982).

Although FDA may not modify the statutory premarket-review procedures, the agency has stated that it will be flexible in reviewing applications to the extent permitted by statute, which may accommodate some of plaintiffs' concerns. 81 Fed. Reg. at 28,998. For example, the final rule states that "some applicants may not need to engage in resource-intensive clinical investigations and provide long-term data to prepare and submit" an application. *Id.* at 29,078. And FDA has stated in draft guidance that scientific-literature reviews may be acceptable in some circumstances, and has discussed alternatives to randomized, controlled trials. *See* FDA, *Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems: Draft Guidance for Industry*, at 44-45 (May 2016).[14] Thus, to the extent plaintiffs are urging that FDA should have considered allowing manufacturers to rely on a scientific-literature review, rather than requiring controlled studies in all cases, Br. 55, the agency has indicated its willingness to do so to the extent appropriate and permitted by statute.

Finally, plaintiffs contend that compliance with these requirements will be cost-prohibitive and cause most manufacturers to exit the industry. Br. 50-54. Having chosen not to challenge FDA's cost-benefit analysis directly, plaintiffs fail to explain

[14] Available at https://www.fda.gov/downloads/tobaccoproducts/labeling/rulesregulationsguidance/ucm499352.pdf.

how that analysis bears on the question presented. As explained above, Congress made these premarket-review requirements applicable to all new tobacco products that FDA deems subject to the authorities in Chapter IX. It did not direct FDA to apply these requirements selectively after weighing costs and benefits in the way plaintiffs urge. In any event, as the district court observed in considering a separate challenge not renewed on appeal, FDA made a "careful assessment of the costs and benefits" of the rule. Op. 70. The agency acknowledged that premarket review will impose real costs and cause some market consolidation, but it predicted that between 266 and 332 vaping devices, and between 900 and 1,800 e-liquids, will remain on the market at the end of the compliance period. AR 23,991. FDA reasonably concluded that the costs associated with the rule were justified by its substantial benefits. 81 Fed. Reg. at 28,980-81; AR 23,973, 24,027.

II. The Requirement of Premarket Review of Modified-Risk Tobacco Products Is Consistent with the First Amendment.

A. The requirement of premarket review of modified-risk tobacco products resembles the requirement of FDA review of new drugs and does not implicate the First Amendment.

Section 387k(a) provides that "[n]o person may introduce or deliver for introduction into interstate commerce any modified risk tobacco product" that has not been subject to premarket FDA review. 21 U.S.C. § 387k(a). A modified-risk tobacco product is "any tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed

tobacco products." *Id.* § 387k(b)(1). The statute sets forth circumstances in which products are considered to be sold or distributed for such use. *Id.* § 387k(b)(2)(A).

The requirement of premarket review of modified-risk tobacco products resembles in critical respects the longstanding requirement of premarket review of new drugs, and, like that requirement, is not properly viewed as a restriction of speech. The FDCA requires premarket FDA review of "new drug[s]," 21 U.S.C. § 355(a), and it defines drugs to include articles "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease," *id.* § 321(g)(1). "Intended use" is an objective standard that "commonly turns on the nature of the claims made about the substance." *Whitaker v. Thompson*, 353 F.3d 947, 948 (D.C. Cir. 2004). As this Court explained, "[i]tems to be sold with 'drug claims,' including foods and dietary supplements, are subject to extensive testing," while "foods or dietary supplements that merely make 'health claims' pass muster far more easily." *Id.*; *see United States v. Article . . . Consisting of 216 individually Cartoned Bottles, More or Less, of an Article Labeled in Part: Sudden Change*, 409 F.2d 734, 739 (2d Cir. 1969) ("Regardless of the actual physical effects of a product, it will be deemed a drug . . . where the labeling and promotional claims show intended uses that bring it within the drug definition.") (footnote omitted).

This Court in *Whitaker* explained that, because "the First Amendment allows the evidentiary use of speech . . . to prove motive or intent," "it is constitutionally

permissible for the FDA to use speech, in the form of labeling, to infer intent for purposes of determining" whether a product is subject to premarket review. 353 F.3d at 953 (quotation marks omitted). The Court thus approved the requirement of premarket review of new drugs, in which "claims about a product by its manufacturer and vendors, including product labeling, serve as evidence of the sellers' intent that consumers will purchase and use the product for a particular purpose—and, therefore, as evidence of whether the product is or is not a drug." *Id.*; *see United States v. Lebeau*, 654 F. App'x 826, 830-31 (7th Cir. 2016) (per curiam) (reaching the same conclusion), *cert. denied*, 137 S. Ct. 1084 (2017).

A similar analysis applies in this case. The premarket-review requirement for tobacco products that purportedly reduce health risks works in much the same way as the new-drug approval provisions. Chapter IX of the FDCA requires premarket FDA review of a "modified risk tobacco product," 21 U.S.C. § 387k(a), and it defines such a product in terms of the use for which it is sold or distributed: A tobacco product is a modified-risk product if it is "'sold or distributed for use to reduce harm or the risk of tobacco-related disease,'" *id.* § 387k(b)(1).

Similar to the drug context, the use for which a tobacco product is sold or distributed may be determined from explicit or implicit representations on the product's label, labeling, or advertising, as well as other actions by the manufacturer that are directed at consumers. *Id.* § 387k(b)(2)(A). Thus, FDA considers statements

made by a manufacturer in determining whether a product "is sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products," and is thus, by statute, a modified-risk tobacco product subject to premarket review. *Id.* § 387k(b)(1). As this Court held in *Whitaker*, such evidentiary use of speech to determine the purpose for which a product is marketed does not raise First Amendment concerns. 353 F.3d at 953; *cf. Flytenow, Inc. v. FAA*, 808 F.3d 882, 894 (D.C. Cir. 2015) (upholding the Federal Aviation Administration's reliance on pilots' communications as evidence that they were holding themselves out as common carriers and thus subject to particular agency rules).

B. If viewed as a regulation of commercial speech, premarket review of modified-risk tobacco products would withstand First Amendment scrutiny.

1. If viewed as a regulation of commercial speech, the requirement of premarket review of modified-risk tobacco products would readily withstand First Amendment review. "The First Amendment's concern for commercial speech is based on the informational function of advertising." *Central Hudson*, 447 U.S. at 563. Consequently, there is no protection for "commercial messages that do not accurately inform the public about lawful activity" or relate to illegal activity. *Id.* at 563-64. If the communication is neither misleading nor related to unlawful activity, the government may impose restrictions that directly advance a substantial government

interest and are no more extensive than necessary to serve that interest. *Id.* at 566; *United States v. Philip Morris USA Inc.*, 855 F.3d 321, 327 (D.C. Cir. 2017).

This standard does not require the legislature to employ "the least restrictive means" of regulation or to achieve a perfect fit between means and ends. *Board of Trustees v. Fox*, 492 U.S. 469, 480 (1989). It is sufficient that the legislature achieve a "reasonable" fit by adopting regulations "in proportion to the interest served." *Id.*; *see Spirit Airlines, Inc. v. U.S. Dep't of Transp.*, 687 F.3d 403, 415 (D.C. Cir. 2012) (stating the inquiry as "whether the fit between the government's ends and the means chosen to accomplish those ends 'is not necessarily perfect, but reasonable'") (quotation marks omitted).

Here, "there is a compelling governmental interest in ensuring that statements about modified risk tobacco products are complete, accurate, and relate to the overall disease risk of the product." TCA § 2(40); *see Spirit Airlines*, 687 F.3d at 415 ("there is no question that [the government's] interest in ensuring the accuracy of commercial information in the marketplace is substantial" (quoting *Edenfield v. Fane*, 507 U.S. 761, 769 (1993) (alterations in original)). Historically, tobacco product manufacturers—including many of the same companies now prominent in the e-cigarette market, *see supra* p. 17—have made modified-risk claims, despite knowing them to be false or unsubstantiated, in order to persuade health-conscious consumers to use certain tobacco products on the understanding that they present a lower risk. *See Discount*

Tobacco City & Lottery, Inc. v. United States, 674 F.3d 509, 535 (6th Cir. 2012), *cert. denied sub. Nom. American Snuff Co. v. United States*, 133 S. Ct. 1996 (2013); *United States v. Philip Morris USA Inc.,* 566 F.3d 1095, 1107 (D.C. Cir. 2009) (per curiam). Such statements were highly effective, leading many "who would otherwise not consume tobacco products[,] or would consume such products less," to engage in use that "substantially increased [their] likelihood of suffering disability and premature death." TCA § 2(37). Congress concluded that, "[u]nless tobacco products that purport to reduce the risks to the public of tobacco use actually reduce such risks, those products can cause substantial harm to the public health . . . includ[ing] thousands of unnecessary deaths." *Id.*

The requirement of premarket review of modified-risk products is narrowly tailored to further the government's interest in preventing such harms. Indeed, Congress determined that "[t]he only way to effectively protect the public health from the dangers of unsubstantiated modified risk tobacco products is . . . to require that products that tobacco manufacturers s[ell] or distribute[] 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). FDA elaborated on the need for premarket review in bringing e-cigarettes within the scope of this requirement. The agency explained that consumers, and young adults in particular, "often mistakenly think non-cigarette tobacco products are safe alternatives to cigarettes," and the

marketing of modified-risk products can create or corroborate that impression. 79 Fed. Reg. at 23,146; *see also* AR 20,906 (finding that 79.1% of juvenile respondents who had used e-cigarettes within the past thirty days reported that risk perception influenced their choice); Zernike, *supra* (reporting that many "teenagers equate safer with safe").

Although further research is needed to fully understand the effects of e-cigarettes, the available evidence shows that e-cigarettes pose significant risks. *See* 81 Fed. Reg. at 29,029-31; HHS, *E-Cigarette Use Among Youth & Young Adults: A Report of the Surgeon General*, 124-25 (2016) (*Surgeon General Report*).[15] E-cigarettes typically contain nicotine, which is highly addictive. And they can deliver toxic and carcinogenic chemicals like formaldehyde at levels as high as or higher than conventional cigarettes. AR 15,585, 22,820; 81 Fed. Reg. at 29,029. Many e-cigarettes also contain or emit other dangerous substances. AR 15,585, 15,588; *Public Health Consequences* 5-1 (identifying tobacco-specific nitrosamines, aldehydes, metals, volatile organic compounds, phenolic compounds, polycyclic aromatic hydrocarbons, tobacco alkaloids, and drugs among the harmful substances found in e-cigarette liquids and aerosols). A recent study found "significantly greater toxicant exposure in adolescent e-cigarette users compared with their nonusing peers." Mark L. Rubenstein et al.,

[15] Available at https://e-cigarettes.surgeongeneral.gov/documents/2016_sgr_full_report_non-508.pdf.

Adolescent Exposure to Toxic Volatile Organic Chemicals from E-Cigarettes, Pediatrics 141(4):e20173557, at 5 (Apr. 2018).

Plaintiffs and their amici insist that e-cigarettes provide clear benefits for individuals addicted to conventional cigarettes. But while completely switching from conventional cigarettes to e-cigarettes may reduce the risk of tobacco-related disease, *see* 81 Fed. Reg. at 29,030, there is also evidence that cigarette smokers will not make that switch. *Id.* at 29,028, 29,037 (noting evidence that individuals who use e-cigarettes may be less likely to quit smoking than cigarette smokers who do not also use e-cigarettes). The science on these products is evolving, and significant questions remain about these claimed benefits. *See Public Health Consequences* 17-12, 17-17.

Moreover, even for products that may remove a degree of risk for individual users, it is still necessary to consider the products' risks for the population as a whole, including whether they are likely to lead non-smokers to begin using such products, or lead smokers who might otherwise quit to instead opt to use a modified-risk tobacco product. *See* 21 U.S.C. § 387k(g)(4)(C); TCA § 2(37); 81 Fed. Reg. at 29,053. The possibility that certain e-cigarette products could provide some benefits for some users in no way undermines the need for this requirement, just as the potential benefits of a new drug do not vitiate the need for premarket review. The requirement of premarket review of modified-risk tobacco products is narrowly tailored to ensure

that consumers are not injured by products marketed with unsubstantiated or misleading statements.

Indeed, Congress further tailored the modified-risk requirements by providing two different pathways for FDA review. For the first, the applicant must provide scientific evidence showing 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) (emphasis added). If scientific evidence is not available to support that showing, and if any representations that would cause the product to be modified-risk are limited to having a reduced level or being free of a substance, Congress has provided an alternative pathway under section 387k(g)(2). Under that pathway, the applicant's burden with respect to population-level effects is limited to showing that the product "*is expected to* 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." *Id.* § 387k(g)(2)(B)(iv) (emphasis added); *see id.* § 387k(g)(2)(A)(iv) (requiring applicants proceeding under that pathway to show that specified benefits for individual tobacco users are "reasonably likely in subsequent studies"). Congress thus tailored the modified-risk provisions by imposing different evidentiary requirements depending in part on the type of claim.

2. Plaintiffs incorrectly assert that the premarket-review requirement "bans truthful, non-misleading claims," Br. 20 (capitalization omitted), and that "[v]apor companies are effectively prohibited, for example, from explicitly or even impliedly representing on a label or in advertising that a product presents fewer risks or is free of a certain substance" (Br. 23). As the district court explained, "notwithstanding plaintiffs' rhetoric, this provision does not ban truthful statements about health benefits or reduced risks; it simply requires that they be substantiated." Op. 93. Neither Congress nor FDA has barred the types of claims that plaintiffs advance in their brief—*e.g.*, that their products do not contain diacetyl or acetyl propionyl, or contain "no ash." Br. 21-22. To the contrary, FDA has reiterated that the premarket-review requirement "does not prohibit [e-cigarette] manufacturers from making claims that the[ir products] are safer than conventional tobacco products," or from making other modified-risk claims, "if they can provide evidence to satisfy the requirements" established by Congress. 81 Fed. Reg. at 29,040.[16]

Plaintiffs insist that applications to market modified-risk products will invariably be denied, even though they simultaneously insist that the science supporting such claims is clear. Br. 6, 20; NJOY Br. 19-20. These assertions might be more credible if plaintiffs or their amici had filed even a single application to market a

[16] Plaintiffs assert that a "no tobacco" claim would be truthful, Br. 21, but a product containing nicotine derived from tobacco—as e-liquids typically do—cannot accurately be described as a "no tobacco" product.

modified-risk tobacco product. They have not. Nor has FDA issued a warning letter or taken enforcement action against any e-cigarette product based on the failure to have an authorized modified-risk tobacco product application. Plaintiffs simply ask the Court to accept their contention that the premarket-review provision is a ban on truthful advertising.

Plaintiffs also incorrectly suggest that every statement that a product is free of a substance would trigger the concerns the statute seeks to address. Br. 20-21. There may well be contexts in which plaintiffs could market a product with substance-free claims (e.g., peanut-free, lactose-free) without the submission of a premarket-review application. FDA would take a case-by-case approach to such products, considering the language of the claim, surrounding context, and any other relevant evidence such as consumer perception and understanding of a product's risks in the context of other tobacco products. *See* 81 Fed. Reg. at 28,987-88. Plaintiffs' assertions do not begin to carry their heavy burden in asserting a facial challenge and provide no basis for setting aside the statute. *See Washington State Grange v. Washington State Republican Party*, 552 U.S. 442, 449-50 (2008) (noting that facial challenges are particularly disfavored where they "rest on speculation" and risk a "premature interpretation of [a rule] on the basis of [a] factually barebones record[]").

Plaintiffs' other arguments are premised on a misunderstanding of the purpose of premarket review and the different ways in which claims can be misleading.

Plaintiffs fail to acknowledge that even technically accurate statements have the power to mislead and, indeed, have historically been used to deceive consumers about the health risks of tobacco products. They suggest, for example, that a statement that a product does not contain diacetyl or acetyl propionyl is straightforwardly true. But such a product may contain other harmful substances, potentially in greater concentrations than those found in other tobacco products. In those circumstances, a statement implying that the product is safer than other products would be misleading.

Moreover, as noted above, even if a statement were true for an individual user, it might not reduce the risk for the population as a whole—for example if non-smokers begin using such products based on the belief they are safe or less risky than other tobacco products, or if smokers who might otherwise quit instead opt to use a modified-risk tobacco product. *Discount Tobacco*, 674 F.3d at 536 ("A claim that a product is less risky if it reduces harm to an individual, when that harm is externalized to others, is inherently misleading."). Based on its substantial experience with tobacco-related risk claims, Congress reasonably determined that premarket review is necessary to avoid the harms associated with unsubstantiated or misleading statements of this type. TCA § 2(40).

The requirement of premarket review for modified-risk tobacco products bears no resemblance to the state statute at issue in *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 563-64 (2011), relied on by plaintiffs, which imposed "restrictions on the sale,

disclosure, and use" of records that revealed the prescribing practices of individual doctors. The purpose of those restrictions was to prevent pharmaceutical companies from tailoring their drug promotions to particular doctors and thereby "communicating with physicians in an effective and informative manner." *Id.* at 564. In that context, the Supreme Court stated that "the 'fear that people would make bad decisions if given truthful information' cannot justify content-based burdens on speech," *id.* at 577 (quoting *Thompson v. Western States Med. Ctr.*, 535 U.S. 357, 374 (2002)), and it stressed that this principle applies with particular force when the audience "consists of sophisticated and experienced consumers," *id.* (quotation marks omitted). By contrast, premarket review of modified-risk tobacco products is meant to prevent the continued dissemination of false, misleading, or unsubstantiated information, not to protect people from the effects of truthful and nonmisleading information. The need for the requirement is particularly acute in the context of addictive products that present a variety of health risks, and in an industry with a history of making misleading risk claims, including through marketing targeted at youth.[17]

[17] Nothing in *Sorrell* suggests that a more exacting level of scrutiny might apply to commercial-speech restrictions on the grounds that they are content-based. *See Retail Digital Network, LLC v. Prieto*, 861 F.3d 839, 846 (9th Cir. 2017) (en banc) (*Sorrell* "did not mark a fundamental departure from *Central Hudson*'s four-factor test, and *Central Hudson* continues to apply" to regulations of commercial speech, regardless of whether they are content based); *Missouri Broad. Ass'n v. Lacy*, 846 F.3d 295, 300 n.5 (8th Cir. 2017) ("The upshot [of *Sorrell*] is that when a court determines commercial

Plaintiffs additionally argue that requirement of premarket review for modified-risk products is unconstitutional because it arbitrarily distinguishes among tobacco products. In particular, plaintiffs assert that the law impermissibly allows manufacturers of smokeless tobacco to identify their products as "smokeless" or "not consumed by smoking" without receiving authorization to market such products as modified risk, *see* 21 U.S.C. § 387k(b)(2)(C), yet does not let manufacturers of e-cigarette products make similar claims absent FDA review. Br. 27-28.

In enacting that provision, Congress simply concluded that products long known as "smokeless tobacco" may continue to be identified as "smokeless." Plaintiffs do not contend that e-cigarettes have historically been identified in this way. Moreover, identifying these products as "smokeless" could imply that they, like smokeless tobacco, yield no airborne emissions. But, by design, e-cigarette products generally heat e-liquid in order to emit a vapor or aerosol. *See* 81 Fed. Reg. at 28,987 (noting that smokeless tobacco products, in contrast to e-cigarettes, do not "require the use of heat, inhalation of the product into the lungs, or exhalation of constituents into the close environment"). And Congress defined "smoke constituent" to refer to any chemical "that is formed by the combustion *or heating* of tobacco, additives, or

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speech restrictions are content- or speaker-based, it should then assess their constitutionality under *Central Hudson*.") (quotation marks omitted; alteration in original); Op. 76 ("[T]he *Sorrell* opinion did not alter or replace the *Central Hudson* immediate scrutiny standard to be applied to commercial speech.").

other component of the tobacco product." 21 U.S.C. § 387(17) (emphasis added). Notably, studies have found toxic chemicals in e-cigarette vapor and aerosol. *See* 81 Fed. Reg. at 29,031-32; *Surgeon General Report* 119, 124-25; *Competitive Enter. Inst. v. U.S. Dep't of Transp.*, 863 F.3d 911, 914 (D.C. Cir. 2017) (citing 81 Fed. Reg. 11,415, 11,420 (Mar. 4, 2016)).

Plaintiffs also urge that premarket review of modified-risk products is unconstitutional because "FDA will be making claims to consumers—just as vapor companies would like to do—regarding the existence or absence of potentially harmful substances in specific products," and they assert that the rule thus discriminates based on the identity of the speaker. Br. 26. In this respect, plaintiffs cite the requirement that FDA make available information concerning the type and quantity of all harmful or potentially harmful constituents in each tobacco product, 21 U.S.C. § 387d(e), and that it do so in a "format that is understandable and not misleading to a lay person," *id.* § 387d(d)(1). Plaintiffs also observe that FDA has publicly stated that e-cigarettes as a group may present a lower risk profile than combustible tobacco products. Br. 24-26. FDA's noncommercial statements, including any comprehensive publication of constituent information and the statements the agency makes while participating in ongoing scientific discussions, are in no way analogous to marketing statements declaring or implying that a tobacco product presents a comparatively low risk. *See Discount Tobacco*, 674 F.3d at 532-33

("[A]dvertising which links a product to a current public debate is not thereby entitled to the constitutional protection afforded noncommercial speech.") (quoting *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 67-68 (1983)).

Plaintiffs additionally assert that premarket review is unconstitutional because the government could further its interests through other means—such as requiring warnings labels or disclaimers, or taking postmarket enforcement action against manufacturers that make misleading or unsubstantiated claims. As noted above, Congress considered and rejected the contention that disclaimers could adequately protect against consumer deception in this context, noting findings by the Federal Trade Commission (FTC) that such statements had been ineffective in the past. TCA § 2(41); *see* Op. 92; *accord FTC v. Brown & Williamson Tobacco Corp.*, 778 F.2d 35, 42-43 (D.C. Cir. 1985) (upholding FTC's determination that a disclaimer would not suffice to cure a misleading but technically accurate advertising claim). A public education campaign, *see* NJOY Br. 26, would fall short for the same reasons. There is "no reason to upend—or intrude upon—Congress's determination and express rejection of the idea that requiring disclaimers for modified risk tobacco products would be effective." *Discount Tobacco*, 674 F.3d at 537 (alterations and quotation marks omitted). That Congress has found warnings or disclaimers useful in other contexts, *see* Br. 32, does not undermine its conclusion that disclaimers would not be adequate to address

the risks associated with unverified modified-risk claims about highly addictive tobacco products.

With respect to the suggestion that postmarket enforcement actions could suffice to cure this problem, "the government has made a reasonable determination that, 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." *Discount Tobacco*, 674 F.3d at 537; *see* TCA § 2(36)-(37).[18] And plaintiffs' suggestion that FDA could simply require manufacturers to retain records substantiating a claim (*e.g.*, showing that an e-liquid does not contain diacetyl or acetyl propionyl) again elides the ways in which technically accurate statements have been used to mislead consumers about the health risks of tobacco products. *See supra* pp. 37-38.

[18] Plaintiffs forfeited any argument that the requirement of premarket review of modified-risk products constitutes a prior restraint by failing to raise the issue in district court and relegating the argument to a single sentence in a footnote (Br. 20 n.14) in their opening appellate brief. *See Keepseagle v. Perdue*, 856 F.3d 1039, 1053 (D.C. Cir. 2017) ("It is well settled that issues and legal theories not asserted at the District Court level ordinarily will not be heard on appeal."); *Hutchins v. District of Columbia*, 188 F.3d 531, 539 n.3 (D.C. Cir. 1999) (per curiam) ("We need not consider cursory arguments made only in a footnote."). Amici's discussion of the issue does not change that analysis, given that this Court ordinarily "w[ill] not entertain an *amicus'* argument if not presented by a party." *Michel v. Anderson*, 14 F.3d 623, 625 (D.C. Cir. 1994). The argument in any event lacks merit. It is doubtful that the prior-restraint doctrine applies to commercial speech. *See Discount Tobacco*, 674 F.3d at 532-33. And even if it did, it would require only that the rule be narrowly tailored to advance a substantial government interest, *see id.*; *Nutritional Health All. v. Shalala*, 144 F.3d 220, 228 (2d Cir. 1998)—a standard satisfied in this case, as discussed above.

III. The Prohibition on the Distribution of Free E-Cigarette Samples Is Also Consistent with the First Amendment.

A. The prohibition against free samples regulates product pricing, not speech, and therefore does not implicate the First Amendment.

Plaintiffs assert that the prohibition against distributing free samples of e-cigarettes violates their First Amendment rights. But, as the district court correctly held, the prohibition is "focused on conduct—a means of distribution of e-cigarettes that presents a particular risk of providing the product to underage users." Op. 81.

Prohibiting the distribution of free products is a form of price regulation that "simply regulate[s] the amount that a store c[an] collect" for the item. *Expressions Hair Design v. Schneiderman*, 137 S. Ct. 1144, 1150 (2017). It is well established that "price regulations and other forms of direct economic regulation do not implicate First Amendment concerns." *National Ass'n of Tobacco Outlets, Inc. v. City of Providence*, 731 F.3d 71, 77 (1st Cir. 2013). Although the Supreme Court has held that the communication of prices is protected commercial speech, it has made equally clear that pricing practices are not. *See Expressions Hair Design*, 137 S. Ct. at 1150-51; *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 507 (1996) (plurality op.); *see also Thompson*, 535 U.S. at 372 (referring to price regulations as "non-speech-related"). Accordingly, the government may establish minimum prices and similar economic regulations without implicating the First Amendment. *See Expressions Hair Design*, 137 S. Ct. at 1150; *44 Liquormart*, 517 U.S. at 507; *see also Philip Morris USA, Inc. v. City & Cty. of San*

Francisco, 345 F. App'x 276, 277 (9th Cir. 2009) (holding that selling cigarettes is not protected expressive activity).

The prohibition against distributing free e-cigarette samples is a quintessential price control, effectively providing that the price of e-cigarettes must be more than zero. Such a requirement is not meaningfully distinguishable, for First Amendment purposes, from other forms of economic regulation—for example, rules establishing a minimum price, *Expressions Hair Design*, 137 S. Ct. at 1150; *44 Liquormart*, 517 U.S. at 507, or prohibiting certain types of coupons and discounts, *National Ass'n of Tobacco Outlets*, 731 F.3d at 77.

Plaintiffs do not endeavor to distinguish these cases. Instead, they assert that relevant "[i]nformation [is] conveyed through free samples," noting that sampling is important in persuading consumers to switch products. Br. 37. But plaintiffs are unable to "clearly articulate what implicit statement is allegedly being made" by distributing samples free of charge. Op. 80. Ultimately, what a free sample does (like a paid sample) is permit a consumer to determine whether the consumer likes the product. Plaintiffs assert that "[f]ree samples allow adults to experiment and determine which products best fit their individualized needs or if they provide the same satisfaction as their current product." Br. 36. But it is not through the expression of ideas or information that free samples have this effect. Rather, it is by enabling consumers to try the product. Plaintiffs erroneously conflate the subjective

experience of the consumer in using the product with First Amendment-protected speech.

Contrary to plaintiffs' suggestion, the prohibition on distributing free samples does not prevent any sort of "personalized exchange" or "personal solicitation." Br. 38-39 (citing *Edenfield*, 507 U.S. at 765; *Bailey v. Morales*, 190 F.3d 320, 325 (5th Cir. 1999)). Manufacturers and retailers may still provide ample product information to potential consumers, and they may provide product samples at a cost that is more than zero. The fact that trying a tobacco product may help a consumer determine whether the product is to his taste does not give manufacturers a First Amendment right to provide product samples free of charge. Because the prohibition against distributing free samples regulates conduct that lacks a significant expressive element, it does not implicate the First Amendment. *See Arcara v. Cloud Books, Inc.*, 478 U.S. 697, 706-07 (1986).

Plaintiffs note that the Sixth Circuit in *Discount Tobacco* held that the prohibition against distributing free samples is a restriction on speech—although the court sustained the restriction under *Central Hudson*. In reaching that conclusion, the Sixth Circuit considered the prohibition in conjunction with prohibitions on the distribution of branded non-tobacco items and free promotional gifts, and it concluded that such conduct had expressive value. *Discount Tobacco*, 674 F.3d at 538-

59; *see also National Ass'n of Tobacco Outlets*, 731 F.3d at 78 n.7 (distinguishing in dicta the provision of free samples and promotional gifts from other price regulations).

When properly considered on its own terms, however, it is clear that the prohibition against distributing free product samples is not a restriction on speech. As the district court explained, the prohibition is "not part of a broader restriction on the marketing of e-cigarettes, and it is not aimed at whatever minimum 'communicative impact' the distribution of e-cigarette samples might have." Op. 81 (footnote omitted). To the extent the Sixth Circuit suggested otherwise, this Court should not adopt its conclusion for the reasons stated above.

B. The prohibition against distributing free e-cigarettes would in any event withstand First Amendment review.

Even if the prohibition against distributing free samples implicated the First Amendment, the provision would readily withstand review under *Central Hudson*. As plaintiffs concede, the government has a substantial interest in preventing youth access to tobacco products. *See* Op. 84-85. Like other tobacco products, e-cigarettes are "physiologically addictive, and socially attractive to youth," and the provision of free samples substantially increases the risk of youth access and addiction. 81 Fed. Reg. at 28,986 (quoting *Discount Tobacco*, 674 F.3d at 541). Preventing such access is particularly important in light of the "*substantial evidence* that e-cigarette use increases risk of ever using combustible tobacco cigarettes among youth and young adults." *Public Health Consequences* 16-30; *see* AR 15,663, 23,909.

Prohibiting the distribution of free e-cigarettes directly furthers the government's interest. Congress found that youth are especially price sensitive. TCA § 2(24). And free samples of tobacco products provide an "easily accessible source of these products to young people," notwithstanding measures to restrict distribution of such samples to underage persons. *Discount Tobacco*, 674 F.3d at 541. Free samples give youth a cost-free way to satisfy their curiosity about tobacco products, and when distributed at cultural or social events may increase social pressure on young people to use the products. 81 Fed. Reg. at 28,986. With respect to e-cigarettes in particular, FDA cited evidence of extensive handouts of free samples at youth-oriented events and an attendant risk of increased use. *See id.* "[T]he prohibition against free samples will eliminate a pathway for youth to access tobacco products." *Id.*; *Discount Tobacco*, 674 F.3d at 541 (concluding that the prohibition "embodies a narrow fit between the harm articulated and the restriction employed").

Plaintiffs argue that they should be allowed to distribute free samples of e-cigarettes in qualified adult-only facilities, as Congress provided for smokeless tobacco. *See* Br. 42. But Congress expressly limited the exception for samples of smokeless tobacco to that product. *See* 21 U.S.C. § 387a-1(a)(2)(G). And FDA further concluded that allowing the distribution of free e-cigarette samples in qualified adult-only facilities "could still allow for access to tobacco products in a manner that will have a negative public health impact." 81 Fed. Reg. at 28,987. The exception for

smokeless tobacco substantially restricts the circumstances in which samples may be provided, and limits the portion size of the permitted sample in a way that is not practical for e-cigarettes, which vary significantly in design, performance, portioning, and the potential to spur addiction in new users. *See* 21 U.S.C. § 387a-1(a)(2)(G); 81 Fed. Reg. at 28,986-87. FDA considered whether the narrow exception for smokeless tobacco could be extended by regulation to e-cigarettes and concluded that doing so would undermine the government's interests in preventing youth access to these products. *See* 81 Fed. Reg. at 28,987, 29,003.

The Sixth Circuit upheld the prohibition against the distribution of free samples of conventional cigarettes, *see Discount Tobacco*, 674 F.3d at 541, and the court's reasoning applies with equal force in this case. Previous attempts to limit free samples to adults have not been successful, *see id.*, and FDA has found that "young people, including elementary school children, can obtain free samples easily . . . despite industry-developed, voluntary codes that supposedly restrict distribution of free samples to underage persons," 61 Fed. Reg. 44,396, 44,460 (Aug. 28, 1996); *see* 81 Fed. Reg. at 28,986-87. The prohibition against the distribution of free samples is appropriately tailored to these risks, particularly given the growing appeal of e-cigarettes to youth.

CONCLUSION

For the foregoing reasons, the judgment of the district court should be affirmed.

Respectfully submitted,

BRETT A. SHUMATE
Deputy Assistant Attorney General

JESSIE K. LIU
United States Attorney

MARK B. STERN
ALISA B. KLEIN
s/ Lindsey Powell
LINDSEY POWELL
TYCE R. WALTERS
(202) 616-5372
Attorneys, Appellate Staff
Civil Division, Room 7246
U.S. Department of Justice
950 Pennsylvania Ave., NW
Washington, DC 20530
lindsey.e.powell@usdoj.gov

MAY 2018

CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing brief uses a proportionately spaced, 14-point font and contains 11,769 words according to the count of this office's word processing system, and thus complies with Rule 32(a)(7)(B)(i) of the Federal Rules of Appellate Procedure.

s/ Lindsey Powell
LINDSEY POWELL

CERTIFICATE OF SERVICE

I hereby certify that on May 2, 2018, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the D.C. Circuit by using the appellate CM/ECF system. All participants in the case are registered CM/ECF users and will be served by the appellate CM/ECF system.

s/ Lindsey Powell
LINDSEY POWELL

ADDENDUM

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21 U.S.C. § 387a – FDA authority over tobacco products

(a) In general

Tobacco products, including modified risk tobacco products for which an order has been issued in accordance with section 387k of this title, shall be regulated by the Secretary under this subchapter and shall not be subject to the provisions of subchapter V.

(b) Applicability

This subchapter shall apply to all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and to any other tobacco products that the Secretary by regulation deems to be subject to this subchapter.

(c) Scope

(1) In general

Nothing in this subchapter, or any policy issued or regulation promulgated thereunder, or in sections 101(a), 102, or 103 of title I, title II, or title III of the Family Smoking Prevention and Tobacco Control Act, shall be construed to affect, expand, or limit the Secretary's authority over (including the authority to determine whether products may be regulated), or the regulation of, products under this chapter that are not tobacco products under subchapter V or any other subchapter.

(2) Limitation of authority

(A) In general

The provisions of this subchapter shall not apply to tobacco leaf that is not in the possession of a manufacturer of tobacco products, or to the producers of tobacco leaf, including tobacco growers, tobacco warehouses, and tobacco grower cooperatives, nor shall any employee of the Food and Drug Administration have any authority to enter onto a farm owned by a producer of tobacco leaf without the written consent of such producer.

(B) Exception

Notwithstanding subparagraph (A), if a producer of tobacco leaf is also a tobacco product manufacturer or controlled by a tobacco product manufacturer, the producer

shall be subject to this subchapter in the producer's capacity as a manufacturer. The exception in this subparagraph shall not apply to a producer of tobacco leaf who grows tobacco under a contract with a tobacco product manufacturer and who is not otherwise engaged in the manufacturing process.

(C) Rule of construction

Nothing in this subchapter shall be construed to grant the Secretary authority to promulgate regulations on any matter that involves the production of tobacco leaf or a producer thereof, other than activities by a manufacturer affecting production.

(d) Rulemaking procedures

Each rulemaking under this subchapter shall be in accordance with chapter 5 of title 5. This subsection shall not be construed to affect the rulemaking provisions of section 102(a) of the Family Smoking Prevention and Tobacco Control Act [21 U.S.C. 387a–1(a)].

(e) Center for tobacco products

Not later than 90 days after June 22, 2009, the Secretary shall establish within the Food and Drug Administration the Center for Tobacco Products, which shall report to the Commissioner of Food and Drugs in the same manner as the other agency centers within the Food and Drug Administration. The Center shall be responsible for the implementation of this subchapter and related matters assigned by the Commissioner.

(f) Office to assist small tobacco product manufacturers

The Secretary shall establish within the Food and Drug Administration an identifiable office to provide technical and other nonfinancial assistance to small tobacco product manufacturers to assist them in complying with the requirements of this chapter.

(g) Consultation prior to rulemaking

Prior to promulgating rules under this subchapter, the Secretary shall endeavor to consult with other Federal agencies as appropriate.

21 U.S.C. § 387a-1 – Final Rule

(a) Cigarettes and smokeless tobacco

(1) In general

On the first day of publication of the Federal Register that is 180 days or more after June 22, 2009, the Secretary of Health and Human Services shall publish in the Federal Register a final rule regarding cigarettes and smokeless tobacco, which—

(A) is deemed to be issued under chapter 9 [1] of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 387 et seq.], as added by section 101 of this division; and

(B) shall be deemed to be in compliance with all applicable provisions of chapter 5 of title 5 and all other provisions of law relating to rulemaking procedures.

(2) Contents of rule

Except as provided in this subsection, the final rule published under paragraph (1),[2] shall be identical in its provisions to part 897 of the regulations promulgated by the Secretary of Health and Human Services in the August 28, 1996, issue of the Federal Register (61 Fed. Reg. 44615–44618). Such rule shall—

(A) provide for the designation of jurisdictional authority that is in accordance with this subsection in accordance with this division and the amendments made by this division;

(B) strike Subpart C—Labels and section 897.32(c);

(C) strike paragraphs (a), (b), and (i) of section 897.3 and insert definitions of the terms "cigarette", "cigarette tobacco", and "smokeless tobacco" as defined in section 900 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 387];

(D) insert "or roll-your-own paper" in section 897.34(a) after "other than cigarettes or smokeless tobacco";

(E) include such modifications to section 897.30(b), if any, that the Secretary determines are appropriate in light of governing First Amendment case law, including the decision of the Supreme Court of the United States in Lorillard Tobacco Co. v. Reilly (533 U.S. 525 (2001));

(F) become effective on the date that is 1 year after June 22, 2009; and

(G) amend paragraph (d) of section 897.16 to read as follows:

"(d)(1) Except as provided in subparagraph (2), no manufacturer, distributor, or retailer may distribute or cause to be distributed any free samples of cigarettes, smokeless tobacco, or other tobacco products (as such term is defined in section 201 of the Federal Food, Drug, and Cosmetic Act).

"(2)(A) Subparagraph (1) does not prohibit a manufacturer, distributor, or retailer from distributing or causing to be distributed free samples of smokeless tobacco in a qualified adult-only facility.

"(B) This subparagraph does not affect the authority of a State or local government to prohibit or otherwise restrict the distribution of free samples of smokeless tobacco.

"(C) For purposes of this paragraph, the term 'qualified adult-only facility' means a facility or restricted area that—

"(i) requires each person present to provide to a law enforcement officer (whether on or off duty) or to a security guard licensed by a governmental entity government-issued identification showing a photograph and at least the minimum age established by applicable law for the purchase of smokeless tobacco;

"(ii) does not sell, serve, or distribute alcohol;

"(iii) is not located adjacent to or immediately across from (in any direction) a space that is used primarily for youth-oriented marketing, promotional, or other activities;

"(iv) is a temporary structure constructed, designated, and operated as a distinct enclosed area for the purpose of distributing free samples of smokeless tobacco in accordance with this subparagraph;

"(v) is enclosed by a barrier that—

"(I) is constructed of, or covered with, an opaque material (except for entrances and exits);

"(II) extends from no more than 12 inches above the ground or floor (which area at the bottom of the barrier must be covered with material that restricts visibility but may allow airflow) to at least 8 feet above the ground or floor (or to the ceiling); and

"(III) prevents persons outside the qualified adult-only facility from seeing into the qualified adult-only facility, unless they make unreasonable efforts to do so; and

"(vi) does not display on its exterior—

"(I) any tobacco product advertising;

"(II) a brand name other than in conjunction with words for an area or enclosure to identify an adult-only facility; or

"(III) any combination of words that would imply to a reasonable observer that the manufacturer, distributor, or retailer has a sponsorship that would violate section 897.34(c).

"(D) Distribution of samples of smokeless tobacco under this subparagraph permitted to be taken out of the qualified adult-only facility shall be limited to 1 package per adult consumer containing no more than 0.53 ounces (15 grams) of smokeless tobacco. If such package of smokeless tobacco contains individual portions of smokeless tobacco, the individual portions of smokeless tobacco shall not exceed 8 individual portions and the collective weight of such individual portions shall not exceed 0.53 ounces (15 grams). Any manufacturer, distributor, or retailer who distributes or causes to be distributed free samples also shall take reasonable steps to ensure that the above amounts are limited to one such package per adult consumer per day.

"(3) Notwithstanding subparagraph (2), no manufacturer, distributor, or retailer may distribute or cause to be distributed any free samples of smokeless tobacco—

"(A) to a sports team or entertainment group; or

"(B) at any football, basketball, baseball, soccer, or hockey event or any other sporting or entertainment event determined by the Secretary to be covered by this subparagraph.

"(4) The Secretary shall implement a program to ensure compliance with this paragraph and submit a report to the Congress on such compliance not later than 18 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act.

"(5) Nothing in this paragraph shall be construed to authorize any person to distribute or cause to be distributed any sample of a tobacco product to any individual who has not attained the minimum age established by applicable law for the purchase of such product.".

(3) Amendments to rule

Prior to making amendments to the rule published under paragraph (1), the Secretary shall promulgate a proposed rule in accordance with chapter 5 of title 5.

(4) Rule of construction

Except as provided in paragraph (3), nothing in this section shall be construed to limit the authority of the Secretary to amend, in accordance with chapter 5 of title 5, the regulation promulgated pursuant to this section, including the provisions of such regulation relating to distribution of free samples.

(5) Enforcement of retail sale provisions

The Secretary of Health and Human Services shall ensure that the provisions of this division, the amendments made by this division, and the implementing regulations (including such provisions, amendments, and regulations relating to the retail sale of tobacco products) are enforced with respect to the United States and Indian tribes.

(6) Qualified adult-only facility

A qualified adult-only facility (as such term is defined in section 897.16(d) of the final rule published under paragraph (1)) that is also a retailer and that commits a violation as a retailer shall not be subject to the limitations in section 103 (q) [3] and shall be subject to penalties applicable to a qualified adult-only facility.

(7) Congressional review provisions

Section 801 of title 5 shall not apply to the final rule published under paragraph (1).

(b) Limitation on advisory opinions

As of June 22, 2009, the following documents issued by the Food and Drug Administration shall not constitute advisory opinions under section 10.85(d)(1) of title 21, Code of Federal Regulations, except as they apply to tobacco products, and shall

not be cited by the Secretary of Health and Human Services or the Food and Drug Administration as binding precedent:

(1) The preamble to the proposed rule in the document titled "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco Products to Protect Children and Adolescents" (60 Fed. Reg. 41314–41372 (August 11, 1995)).

(2) The document titled "Nicotine in Cigarettes and Smokeless Tobacco Products is a Drug and These Products Are Nicotine Delivery Devices Under the Federal Food, Drug, and Cosmetic Act" (60 Fed. Reg. 41453–41787 (August 11, 1995)).

(3) The preamble to the final rule in the document titled "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents" (61 Fed. Reg. 44396–44615 (August 28, 1996)).

(4) The document titled "Nicotine in Cigarettes and Smokeless Tobacco is a Drug and These Products are Nicotine Delivery Devices Under the Federal Food, Drug, and Cosmetic Act; Jurisdictional Determination" (61 Fed. Reg. 44619–45318 (August 28, 1996)).

21 U.S.C. § 387j – Application for review of certain tobacco products

(a) In general

(1) New tobacco product defined For purposes of this section the term "new tobacco product" means—

(A) any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007; or

(B) any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007.

(2) Premarket review required

(A) New products An order under subsection (c)(1)(A)(i) for a new tobacco product is required unless—

(i) the manufacturer has submitted a report under section 387e(j) of this title; and the Secretary has issued an order that the tobacco product—

(I) is substantially equivalent to a tobacco product commercially marketed (other than for test marketing) in the United States as of February 15, 2007; and

(II) is in compliance with the requirements of this chapter; or

(ii) the tobacco product is exempt from the requirements of section 387e(j) of this title pursuant to a regulation issued under section 387e(j)(3) of this title.

(B) Application to certain post-February 15, 2007, products Subparagraph (A) shall not apply to a tobacco product—

(i) that was first introduced or delivered for introduction into interstate commerce for commercial distribution in the United States after February 15, 2007, and prior to the date that is 21 months after June 22, 2009; and

(ii) for which a report was submitted under section 387e(j) of this title within such 21-month period,

except that subparagraph (A) shall apply to the tobacco product if the Secretary issues an order that the tobacco product is not substantially equivalent.

(3) Substantially equivalent defined

(A) In general In this section and section 387e(j) of this title, the term "substantially equivalent" or "substantial equivalence" means, with respect to the tobacco product being compared to the predicate tobacco product, that the Secretary by order has found that the tobacco product—

(i) has the same characteristics as the predicate tobacco product; or

(ii) has different characteristics and the information submitted contains information, including clinical data if deemed necessary by the Secretary, that demonstrates that it is not appropriate to regulate the product under this section because the product does not raise different questions of public health.

(B) Characteristics

In subparagraph (A), the term "characteristics" means the materials, ingredients, design, composition, heating source, or other features of a tobacco product.

(C) Limitation

A tobacco product may not be found to be substantially equivalent to a predicate tobacco product that has been removed from the market at the initiative of the Secretary or that has been determined by a judicial order to be misbranded or adulterated.

(4) Health information

(A) Summary

As part of a submission under section 387e(j) of this title respecting a tobacco product, the person required to file a premarket notification under such section shall provide an adequate summary of any health information related to the tobacco product or state that such information will be made available upon request by any person.

(B) Required information

Any summary under subparagraph (A) respecting a tobacco product shall contain detailed information regarding data concerning adverse health effects and shall be made available to the public by the Secretary within 30 days of the issuance of a determination that such tobacco product is substantially equivalent to another tobacco product.

(b) Application

(1) Contents An application under this section shall contain—

(A) full reports of all information, published or known to, or which should reasonably be known to, the applicant, concerning investigations which have been made to show the health risks of such tobacco product and whether such tobacco product presents less risk than other tobacco products;

(B) a full statement of the components, ingredients, additives, and properties, and of the principle or principles of operation, of such tobacco product;

(C) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such tobacco product;

(D) an identifying reference to any tobacco product standard under section 387g of this title which would be applicable to any aspect of such tobacco product, and either adequate information to show that such aspect of such tobacco product fully meets such tobacco product standard or adequate information to justify any deviation from such standard;

(E) such samples of such tobacco product and of components thereof as the Secretary may reasonably require;

(F) specimens of the labeling proposed to be used for such tobacco product; and

(G) such other information relevant to the subject matter of the application as the Secretary may require.

(2) Referral to Tobacco Products Scientific Advisory Committee Upon receipt of an application meeting the requirements set forth in paragraph (1), the Secretary—

(A) may, on the Secretary's own initiative; or

(B) may, upon the request of an applicant,

refer such application to the Tobacco Products Scientific Advisory Committee for reference and for submission (within such period as the Secretary may establish) of a report and recommendation respecting the application, together with all underlying data and the reasons or basis for the recommendation.

(c) Action on application

(1) Deadline

(A) In general As promptly as possible, but in no event later than 180 days after the receipt of an application under subsection (b), the Secretary, after considering the report and recommendation submitted under subsection (b)(2), shall—

(i) issue an order that the new product may be introduced or delivered for introduction into interstate commerce if the Secretary finds that none of the grounds specified in paragraph (2) of this subsection applies; or

(ii) issue an order that the new product may not be introduced or delivered for introduction into interstate commerce if the Secretary finds (and sets forth the basis for such finding as part of or accompanying such denial) that 1 or more grounds for denial specified in paragraph (2) of this subsection apply.

(B) Restrictions on sale and distribution

An order under subparagraph (A)(i) may require that the sale and distribution of the tobacco product be restricted but only to the extent that the sale and distribution of a tobacco product may be restricted under a regulation under section 387f(d) of this title.

(2) Denial of application The Secretary shall deny an application submitted under subsection (b) if, upon the basis of the information submitted to the Secretary as part of the application and any other information before the Secretary with respect to such tobacco product, the Secretary finds that—

(A) there is a lack of a showing that permitting such tobacco product to be marketed would be appropriate for the protection of the public health;

(B) the methods used in, or the facilities or controls used for, the manufacture, processing, or packing of such tobacco product do not conform to the requirements of section 387f(e) of this title;

(C) based on a fair evaluation of all material facts, the proposed labeling is false or misleading in any particular; or

(D) such tobacco product is not shown to conform in all respects to a tobacco product standard in effect under section 387g of this title, and there is a lack of adequate information to justify the deviation from such standard.

(3) Denial information

Any denial of an application shall, insofar as the Secretary determines to be practicable, be accompanied by a statement informing the applicant of the measures required to remove such application from deniable form (which measures may include further research by the applicant in accordance with 1 or more protocols prescribed by the Secretary).

(4) Basis for finding For purposes of this section, the finding as to whether the marketing of a tobacco product for which an application has been submitted is appropriate for the protection of the public health shall be determined with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product, and taking into account—

(A) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and

(B) the increased or decreased likelihood that those who do not use tobacco products will start using such products.

(5) Basis for action

(A) Investigations

For purposes of paragraph (2)(A), whether permitting a tobacco product to be marketed would be appropriate for the protection of the public health shall, when appropriate, be determined on the basis of well-controlled investigations, which may include 1 or more clinical investigations by experts qualified by training and experience to evaluate the tobacco product.

(B) Other evidence

If the Secretary determines that there exists valid scientific evidence (other than evidence derived from investigations described in subparagraph (A)) which is sufficient to evaluate the tobacco product, the Secretary may authorize that the determination for purposes of paragraph (2)(A) be made on the basis of such evidence.

(d) Withdrawal and temporary suspension

(1) In general The Secretary shall, upon obtaining, where appropriate, advice on scientific matters from the Tobacco Products Scientific Advisory Committee, and after due notice and opportunity for informal hearing for a tobacco product for which an order was issued under subsection (c)(1)(A)(i), issue an order withdrawing the order if the Secretary finds—

(A) that the continued marketing of such tobacco product no longer is appropriate for the protection of the public health;

(B) that the application contained or was accompanied by an untrue statement of a material fact;

(C) that the applicant—

(i) has failed to establish a system for maintaining records, or has repeatedly or deliberately failed to maintain records or to make reports, required by an applicable regulation under section 387i of this title;

(ii) has refused to permit access to, or copying or verification of, such records as required by section 374 of this title; or

(iii) has not complied with the requirements of section 387e of this title;

(D) on the basis of new information before the Secretary with respect to such tobacco product, evaluated together with the evidence before the Secretary when the application was reviewed, that the methods used in, or the facilities and controls used for, the manufacture, processing, packing, or installation of such tobacco product do not conform with the requirements of section 387f(e) of this title and were not brought into conformity with such requirements within a reasonable time after receipt of written notice from the Secretary of nonconformity;

(E) on the basis of new information before the Secretary, evaluated together with the evidence before the Secretary when the application was reviewed, that the labeling of such tobacco product, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary of such fact; or

(F) on the basis of new information before the Secretary, evaluated together with the evidence before the Secretary when such order was issued, that such tobacco product is not shown to conform in all respects to a tobacco product standard which is in effect under section 387g of this title, compliance with which was a condition to the issuance of an order relating to the application, and that there is a lack of adequate information to justify the deviation from such standard.

(2) Appeal

The holder of an application subject to an order issued under paragraph (1) withdrawing an order issued pursuant to subsection (c)(1)(A)(i) may, by petition filed on or before the 30th day after the date upon which such holder receives notice of such withdrawal, obtain review thereof in accordance with section 387l of this title.

(3) Temporary suspension

If, after providing an opportunity for an informal hearing, the Secretary determines there is reasonable probability that the continuation of distribution of a tobacco product under an order would cause serious, adverse health consequences or death, that is greater than ordinarily caused by tobacco products on the market, the Secretary shall by order temporarily suspend the authority of the manufacturer to market the product. If the Secretary issues such an order, the Secretary shall proceed expeditiously under paragraph (1) to withdraw such application.

(e) Service of order An order issued by the Secretary under this section shall be served—

(1) in person by any officer or employee of the department designated by the Secretary; or

(2) by mailing the order by registered mail or certified mail addressed to the applicant at the applicant's last known address in the records of the Secretary.

(f) Records

(1) Additional information

In the case of any tobacco product for which an order issued pursuant to subsection (c)(1)(A)(i) for an application filed under subsection (b) is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, as the Secretary may by regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination of, whether there is or may be grounds for withdrawing or temporarily suspending such order.

(2) Access to records

Each person required under this section to maintain records, and each person in charge of custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

(g) Investigational tobacco product exemption for investigational use

The Secretary may exempt tobacco products intended for investigational use from the provisions of this subchapter under such conditions as the Secretary may by regulation prescribe.

21 U.S.C. § 387k – Modified risk tobacco products

(a) In general

No person may introduce or deliver for introduction into interstate commerce any modified risk tobacco product unless an order issued pursuant to subsection (g) is effective with respect to such product.

(b) Definitions In this section:

(1) Modified risk tobacco product

The term "modified risk tobacco product" means any tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products.

(2) Sold or distributed

(A) In general With respect to a tobacco product, the term "sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products" means a tobacco 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

(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 of which 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, after June 22, 2009, respecting the product 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.

(B) Limitation

No tobacco product shall be considered to be "sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products", except as described in subparagraph (A).

(C) Smokeless tobacco product

No smokeless tobacco product shall be considered to be "sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products" solely because its label, labeling, or advertising uses the following phrases to describe such product and its use: "smokeless tobacco", "smokeless tobacco product", "not consumed by smoking", "does not produce smoke", "smokefree", "smoke-free", "without smoke", "no smoke", or "not smoke".

(3) Effective date

The provisions of paragraph (2)(A)(ii) shall take effect 12 months after June 22, 2009, for those products whose label, labeling, or advertising contains the terms described in such paragraph on June 22, 2009. The effective date shall be with respect to the date of manufacture, provided that, in any case, beginning 30 days after such effective date, a manufacturer shall not introduce into the domestic commerce of the United States any product, irrespective of the date of manufacture, that is not in conformance with paragraph (2)(A)(ii).

(c) Tobacco dependence products

A product that is intended to be used for the treatment of tobacco dependence, including smoking cessation, is not a modified risk tobacco product under this section if it has been approved as a drug or device by the Food and Drug Administration and is subject to the requirements of subchapter V.

(d) Filing Any person may file with the Secretary an application for a modified risk tobacco product. Such application shall include—

(1) a description of the proposed product and any proposed advertising and labeling;

(2) the conditions for using the product;

(3) the formulation of the product;

(4) sample product labels and labeling;

(5) all documents (including underlying scientific information) relating to research findings conducted, supported, or possessed by the tobacco product manufacturer relating to the effect of the product on tobacco-related diseases and health-related conditions, including information both favorable and unfavorable to the ability of the product to reduce risk or exposure and relating to human health;

(6) data and information on how consumers actually use the tobacco product; and

(7) such other information as the Secretary may require.

(e) Public availability

The Secretary shall make the application described in subsection (d) publicly available (except matters in the application which are trade secrets or otherwise confidential, commercial information) and shall request comments by interested persons on the information contained in the application and on the label, labeling, and advertising accompanying such application.

(f) Advisory Committee

(1) In general

The Secretary shall refer to the Tobacco Products Scientific Advisory Committee any application submitted under this section.

(2) Recommendations

Not later than 60 days after the date an application is referred to the Tobacco Products Scientific Advisory Committee under paragraph (1), the Advisory Committee shall report its recommendations on the application to the Secretary.

(g) Marketing

(1) Modified risk products Except as provided in paragraph (2), the Secretary shall, with respect to an application submitted under this section, issue an order that a

modified risk product may be commercially marketed only if the Secretary determines that the applicant has demonstrated that such product, as it is actually used by consumers, 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.

(2) Special rule for certain products

(A) In general The Secretary may issue an order that a tobacco product may be introduced or delivered for introduction into interstate commerce, pursuant to an application under this section, with respect to a tobacco product that may not be commercially marketed under paragraph (1) if the Secretary makes the findings required under this paragraph and determines that the applicant has demonstrated that—

(i) such order would be appropriate to promote the public health;

(ii) any aspect of the label, labeling, and advertising for such product that would cause the tobacco product to be a modified risk tobacco product under subsection (b) is limited to an explicit or implicit representation that such tobacco product or its smoke does not contain or is free of a substance or contains a reduced level of a substance, or presents a reduced exposure to a substance in tobacco smoke;

(iii) scientific evidence is not available and, using the best available scientific methods, cannot be made available without conducting long-term epidemiological studies for an application to meet the standards set forth in paragraph (1); and

(iv) the scientific evidence that is available without conducting long-term epidemiological studies demonstrates that a measurable and substantial reduction in morbidity or mortality among individual tobacco users is reasonably likely in subsequent studies.

(B) Additional findings required To issue an order under subparagraph (A) the Secretary must also find that the applicant has demonstrated that—

(i) the magnitude of the overall reductions in exposure to the substance or substances which are the subject of the application is substantial, such substance or substances are harmful, and the product as actually used exposes consumers to the specified reduced level of the substance or substances;

(ii) the product as actually used by consumers will not expose them to higher levels of other harmful substances compared to the similar types of tobacco products then on the market unless such increases are minimal and the reasonably likely overall impact of use of the product remains a substantial and measurable reduction in overall morbidity and mortality among individual tobacco users;

(iii) testing of actual consumer perception shows that, as the applicant proposes to label and market the product, consumers will not be misled into believing that the product—

(I) is or has been demonstrated to be less harmful; or

(II) presents or has been demonstrated to present less of a risk of disease than 1 or more other commercially marketed tobacco products; and

(iv) issuance of an order with respect to the application is expected to 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.

(C) Conditions of marketing

(i) In general

Applications subject to an order under this paragraph shall be limited to a term of not more than 5 years, but may be renewed upon a finding by the Secretary that the requirements of this paragraph continue to be satisfied based on the filing of a new application.

(ii) Agreements by applicant

An order under this paragraph shall be conditioned on the applicant's agreement to conduct postmarket surveillance and studies and to submit to the Secretary the results of such surveillance and studies to determine the impact of the order on consumer perception, behavior, and health and to enable the Secretary to review the accuracy of

the determinations upon which the order was based in accordance with a protocol approved by the Secretary.

(iii) Annual submission

The results of such postmarket surveillance and studies described in clause (ii) shall be submitted annually.

(3) Basis The determinations under paragraphs (1) and (2) shall be based on—

(A) the scientific evidence submitted by the applicant; and

(B) scientific evidence and other information that is made available to the Secretary.

(4) Benefit to health of individuals and of population as a whole In making the determinations under paragraphs (1) and (2), the Secretary shall take into account—

(A) the relative health risks to individuals of the tobacco product that is the subject of the application;

(B) the increased or decreased likelihood that existing users of tobacco products who would otherwise stop using such products will switch to the tobacco product that is the subject of the application;

(C) the increased or decreased likelihood that persons who do not use tobacco products will start using the tobacco product that is the subject of the application;

(D) the risks and benefits to persons from the use of the tobacco product that is the subject of the application as compared to the use of products for smoking cessation approved under subchapter V to treat nicotine dependence; and

(E) comments, data, and information submitted by interested persons.

(h) Additional conditions for marketing

(1) Modified risk products

The Secretary shall require for the marketing of a product under this section that any advertising or labeling concerning modified risk products enable the public to comprehend the information concerning modified risk and to understand the relative

significance of such information in the context of total health and in relation to all of the diseases and health-related conditions associated with the use of tobacco products.

(2) Comparative claims

(A) In general

The Secretary may require for the marketing of a product under this subsection that a claim comparing a tobacco product to 1 or more other commercially marketed tobacco products shall compare the tobacco product to a commercially marketed tobacco product that is representative of that type of tobacco product on the market (for example the average value of the top 3 brands of an established regular tobacco product).

(B) Quantitative comparisons

The Secretary may also require, for purposes of subparagraph (A), that the percent (or fraction) of change and identity of the reference tobacco product and a quantitative comparison of the amount of the substance claimed to be reduced shall be stated in immediate proximity to the most prominent claim.

(3) Label disclosure

(A) In general

The Secretary may require the disclosure on the label of other substances in the tobacco product, or substances that may be produced by the consumption of that tobacco product, that may affect a disease or health-related condition or may increase the risk of other diseases or health-related conditions associated with the use of tobacco products.

(B) Conditions of use

If the conditions of use of the tobacco product may affect the risk of the product to human health, the Secretary may require the labeling of conditions of use.

(4) Time

An order issued under subsection (g)(1) shall be effective for a specified period of time.

(5) Advertising

The Secretary may require, with respect to a product for which an applicant obtained an order under subsection (g)(1), that the product comply with requirements relating to advertising and promotion of the tobacco product.

(i) Postmarket surveillance and studies

(1) In general

The Secretary shall require, with respect to a product for which an applicant obtained an order under subsection (g)(1), that the applicant conduct postmarket surveillance and studies for such a tobacco product to determine the impact of the order issuance on consumer perception, behavior, and health, to enable the Secretary to review the accuracy of the determinations upon which the order was based, and to provide information that the Secretary determines is otherwise necessary regarding the use or health risks involving the tobacco product. The results of postmarket surveillance and studies shall be submitted to the Secretary on an annual basis.

(2) Surveillance protocol

Each applicant required to conduct a surveillance of a tobacco product under paragraph (1) shall, within 30 days after receiving notice that the applicant is required to conduct such surveillance, submit, for the approval of the Secretary, a protocol for the required surveillance. The Secretary, within 60 days of the receipt of such protocol, shall determine if the principal investigator proposed to be used in the surveillance has sufficient qualifications and experience to conduct such surveillance and if such protocol will result in collection of the data or other information designated by the Secretary as necessary to protect the public health.

(j) Withdrawal of authorization The Secretary, after an opportunity for an informal hearing, shall withdraw an order under subsection (g) if the Secretary determines that—

(1) the applicant, based on new information, can no longer make the demonstrations required under subsection (g), or the Secretary can no longer make the determinations required under subsection (g);

(2) the application failed to include material information or included any untrue statement of material fact;

(3) any explicit or implicit representation that the product reduces risk or exposure is no longer valid, including if—

(A) a tobacco product standard is established pursuant to section 387g of this title;

(B) an action is taken that affects the risks presented by other commercially marketed tobacco products that were compared to the product that is the subject of the application; or

(C) any postmarket surveillance or studies reveal that the order is no longer consistent with the protection of the public health;

(4) the applicant failed to conduct or submit the postmarket surveillance and studies required under subsection (g)(2)(C)(ii) or subsection (i); or

(5) the applicant failed to meet a condition imposed under subsection (h).

(k) Subchapter IV or V

A product for which the Secretary has issued an order pursuant to subsection (g) shall not be subject to subchapter IV or V.

(l) Implementing regulations or guidance

(1) Scientific evidence Not later than 2 years after June 22, 2009, the Secretary shall issue regulations or guidance (or any combination thereof) on the scientific evidence required for assessment and ongoing review of modified risk tobacco products. Such regulations or guidance shall—

(A) to the extent that adequate scientific evidence exists, establish minimum standards for scientific studies needed prior to issuing an order under subsection (g) to show that a substantial reduction in morbidity or mortality among individual tobacco users occurs for products described in subsection (g)(1) or is reasonably likely for products described in subsection (g)(2);

(B) include validated biomarkers, intermediate clinical endpoints, and other feasible outcome measures, as appropriate;

(C) establish minimum standards for postmarket studies, that shall include regular and long-term assessments of health outcomes and mortality, intermediate clinical

endpoints, consumer perception of harm reduction, and the impact on quitting behavior and new use of tobacco products, as appropriate;

(D) establish minimum standards for required postmarket surveillance, including ongoing assessments of consumer perception;

(E) require that data from the required studies and surveillance be made available to the Secretary prior to the decision on renewal of a modified risk tobacco product; and

(F) establish a reasonable timetable for the Secretary to review an application under this section.

(2) Consultation

The regulations or guidance issued under paragraph (1) shall be developed in consultation with the Institute of Medicine, and with the input of other appropriate scientific and medical experts, on the design and conduct of such studies and surveillance.

(3) Revision

The regulations or guidance under paragraph (1) shall be revised on a regular basis as new scientific information becomes available.

(4) New tobacco products

Not later than 2 years after June 22, 2009, the Secretary shall issue a regulation or guidance that permits the filing of a single application for any tobacco product that is a new tobacco product under section 387j of this title and which the applicant seeks to commercially market under this section.

(m) Distributors

Except as provided in this section, no distributor may take any action, after June 22, 2009, with respect to a tobacco product that would reasonably be 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 C.F.R. § 1140.16 – Conditions of manufacture, sale, and distribution

(a) Restriction on product names. A manufacturer shall not use a trade or brand name of a nontobacco product as the trade or brand name for a cigarette or smokeless tobacco product, except for a tobacco product whose trade or brand name was on both a tobacco product and a nontobacco product that were sold in the United States on January 1, 1995.

(b) Minimum cigarette package size. Except as otherwise provided under this section, no manufacturer, distributor, or retailer may sell or cause to be sold, or distribute or cause to be distributed, any cigarette package that contains fewer than 20 cigarettes.

(c) Vending machines, self-service displays, mail-order sales, and other "impersonal" modes of sale.

(1) Except as otherwise provided under this section, a retailer may sell cigarettes and smokeless tobacco only in a direct, face-to-face exchange between the retailer and the consumer. Examples of methods of sale that are not permitted include vending machines and self-service displays.

(2) Exceptions. The following methods of sale are permitted:

(i) Mail-order sales, excluding mail-order redemption of coupons and distribution of free samples through the mail; and

(ii) Vending machines (including vending machines that sell packaged, single cigarettes) and self-service displays that are located in facilities where the retailer ensures that no person younger than 18 years of age is present, or permitted to enter, at any time.

(d)(1) Except as provided in paragraph (d)(2) of this section, no manufacturer, distributor, or retailer may distribute or cause to be distributed any free samples of cigarettes, smokeless tobacco, or other tobacco products (as such term is defined in section 201 of the Federal Food, Drug, and Cosmetic Act).

(2)(i) Paragraph (d)(1) of this section does not prohibit a manufacturer, distributor, or retailer from distributing or causing to be distributed free samples of smokeless tobacco in a qualified adult-only facility.

(ii) Paragraph (d)(2) of this section does not affect the authority of a State or local government to prohibit or otherwise restrict the distribution of free samples of smokeless tobacco.

(iii) For purposes of paragraph (d) of this section, the term "qualified adult-only facility" means a facility or restricted area that:

(A) Requires each person present to provide to a law enforcement officer (whether on or off duty) or to a security guard licensed by a governmental entity government-issued identification showing a photograph and at least the minimum age established by applicable law for the purchase of smokeless tobacco;

(B) Does not sell, serve, or distribute alcohol;

(C) Is not located adjacent to or immediately across from (in any direction) a space that is used primarily for youth-oriented marketing, promotional, or other activities;

(D) Is a temporary structure constructed, designated, and operated as a distinct enclosed area for the purpose of distributing free samples of smokeless tobacco in accordance with this paragraph (d)(2) of this section;

(E) Is enclosed by a barrier that:

(1) Is constructed of, or covered with, an opaque material (except for entrances and exits);

(2) Extends from no more than 12 inches above the ground or floor (which area at the bottom of the barrier must be covered with material that restricts visibility but may allow airflow) to at least 8 feet above the ground or floor (or to the ceiling); and

(3) Prevents persons outside the qualified adult-only facility from seeing into the qualified adult-only facility, unless they make unreasonable efforts to do so; and

(F) Does not display on its exterior:

(1) Any tobacco product advertising;

(2) A brand name other than in conjunction with words for an area or enclosure to identify an adult-only facility; or

(3) Any combination of words that would imply to a reasonable observer that the manufacturer, distributor, or retailer has a sponsorship that would violate § 1140.34(c).

(iv) Distribution of samples of smokeless tobacco under paragraph (d)(2) of this section permitted to be taken out of the qualified adult-only facility shall be limited to one package per adult consumer containing no more than 0.53 ounces (15 grams) of smokeless tobacco. If such package of smokeless tobacco contains individual portions of smokeless tobacco, the individual portions of smokeless tobacco shall not exceed eight individual portions, and the collective weight of such individual portions shall not exceed 0.53 ounces (15 grams). Any manufacturer, distributor, or retailer who distributes or causes to be distributed free samples also shall take reasonable steps to ensure that the amounts in this paragraph (d)(2)(iv) are limited to one such package per adult consumer per day.

(3) Notwithstanding paragraph (d)(2) of this section, no manufacturer, distributor, or retailer may distribute or cause to be distributed any free samples of smokeless tobacco:

(i) To a sports team or entertainment group; or

(ii) At any football, basketball, baseball, soccer, or hockey event or any other sporting or entertainment event determined by the Secretary to be covered by paragraph (d)(3) of this section.

(4) The Secretary shall implement a program to ensure compliance with paragraph (d) of this section and submit a report to the Congress on such compliance not later than 18 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act.

(5) Nothing in paragraph (d) of this section shall be construed to authorize any person to distribute or cause to be distributed any sample of a tobacco product to any individual who has not attained the minimum age established by applicable law for the purchase of such product.

(e) Restrictions on labels, labeling, and advertising. No manufacturer, distributor, or retailer may sell or distribute, or cause to be sold or distributed, cigarettes or smokeless tobacco with labels, labeling, or advertising not in compliance with subpart D of this part, and other applicable requirements.