United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued September 11, 2018 Decided December 10, 2019

No. 17-5196

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

AMERICAN E-LIQUID MANUFACTURING STANDARDS ASSOCIATION, ET AL.,
APPELLEES

v.

FOOD & DRUG ADMINISTRATION, ET AL.,
APPELLEES

Appeal from the United States District Court
for the District of Columbia
(No. 1:16-cv-00878)

Miguel A. Estrada argued the cause for appellant Nicopure Labs, LLC. With him on the brief for *amicus curiae* NJOY LLC were *Theodore B. Olson*, *Amir C. Tayani*, and *Jacob T. Spencer* in support of plaintiffs-appellants.

Eric P. Gotting argued the cause and filed the briefs for appellants Nicopure Labs, LLC and Right to Be Smoke-Free Coalition. *Douglas J. Behr* entered an appearance.

Thomas J. Miller, Attorney General, and *Jacob Larson*, Assistant Attorney General, Office of the Attorney General for the State of Iowa, were on the brief for *amicus curiae* State of Iowa in support plaintiffs-appellants.

James W. Bryan was on the brief for *amicus curiae* Consumer Advocates for Smoke-Free Alternatives Association in support of plaintiffs-appellants.

Cory L. Andrews and *Richard A. Samp* were on the brief for *amicus curiae* Washington Legal Foundation in support of plaintiffs-appellants.

Christopher G. Browning, *Jr.* and *Bryan Michael Haynes* were on the brief for *amici curiae* Clive Bates and Additional Public Health/Tobacco Policy Authorities in support of plaintiffs-appellants.

Lindsey Powell, Attorney, U.S. Department of Justice, argued the cause for appellees. With her on the brief were *Brett A. Shumate*, Deputy Assistant Attorney General, *Jessie K. Liu*, U.S. Attorney, and *Mark B. Stern*, *Alisa B. Klein*, and *Tyce R. Walters*, Attorneys.

Scott L. Nelson, *Allison M. Zieve*, and *Julie M. Murray* were on the brief for *amicus curiae* Public Citizen, Inc. in support of defendants-appellees.

Charles Sims was on the brief for *amici curiae* First Amendment Scholars in support of defendants-appellees.

Mark Greenwold, *Carlos T. Angulo*, and *Andrew N. Goldfarb* were on the brief for *amici curiae* Public Health Groups in support of defendants-appellees.

Thomas Bennigson was on the brief for *amicus curiae* Public Health Law Center in support of defendants-appellees.

Before: ROGERS and PILLARD, *Circuit Judges*, and SENTELLE, *Senior Circuit Judge*.

Opinion for the Court filed by *Circuit Judge* PILLARD.

PILLARD, *Circuit Judge*: Nicotine is among the most addictive substances used by humans. An e-cigarette delivers nicotine by vaporizing a liquid that includes other chemicals and flavorings. The device heats the liquid until it generates an aerosol—or "vapor"—that can be inhaled. The chemicals in the liquid vary, but any e-cigarette that contains nicotine is subject to federal regulation. The Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009) (Tobacco Control Act, TCA, or Act), addresses the American public's continuing addiction to tobacco products containing nicotine by empowering the Food and Drug Administration (FDA) to regulate their sale and marketing. The legislation grew out of Congress' recognition that more limited efforts to regulate tobacco products had "failed adequately to curb tobacco use by adolescents." *Id*. § 2(6), 123 Stat. at 1777. Based on extensive evidence of tobacco's widespread use and nicotine's addictive character and harmful effects, Congress found that the "use of tobacco products by the Nation's children is a pediatric disease of considerable proportions that results in new generations of tobacco-dependent children and adults." *Id*. § 2(1), 123 Stat. at 1777.

In enacting the Tobacco Control Act, Congress decided an immediate ban on a product to which millions of Americans were addicted would foster a black market and harm existing tobacco users and the broader public. *See* H.R. Rep. No. 111-

58, pt. 1, at 38 (Mar. 27, 2009). Congress instead took the then-current tobacco product market as a baseline from which to ratchet down tobacco products' harms to public health. *See id.* The Act does not authorize the FDA to ban nicotine in tobacco products or completely prohibit tobacco product sales. 21 U.S.C. § 387g(d)(3). It calls for regulation that is "substantially related to accomplishing the public health goals" of the Act, TCA § 2(30), 123 Stat. at 1778, and that "ensure[s]" tobacco products will not be "sold or accessible to underage purchasers," *id.* § 3(7), 123 Stat. at 1782.

To those ends, the Act bans the distribution of free samples of tobacco products. It also requires FDA premarket review of all new tobacco products, including e-cigarettes. The Act contains three approval pathways depending on the type of tobacco product: those that are purely recreational, those marketed as safer than existing tobacco products ("modified risk" tobacco products), and those marketed as smoking cessation products. The Act grandfathers tobacco products already on the market and, relative to that baseline, requires manufacturers of any new tobacco product to show that their product's public health harms do not exceed its benefits. *See* 21 U.S.C. § 387j. Modified risk products must meet more stringent public-health standards. *See id.* § 387k. And smoking cessation products must meet the FDA's even more exacting standards for a drug or device. *See id.* § 387k(c). No e-cigarette has yet sought and received clearance from the FDA under any of the three pathways.

Nicopure, an e-cigarette manufacturer and distributor, and an e-cigarette industry group, Right To Be Smoke-Free Coalition (jointly, Appellants or the Industry) raise three challenges. First, they argue that the FDA violated the Tobacco Control Act and the Administrative Procedure Act (APA) by not providing an easier premarket authorization pathway for e-

cigarettes. Then they claim that two provisions of the Tobacco Control Act violate the First Amendment. They challenge the premarket review standards applicable to modified risk tobacco products, contending that the standards impermissibly burden what they say are truthful, nonmisleading statements about e-cigarettes. They also challenge the ban on distribution of free samples of tobacco products, including e-cigarettes, as suppression of constitutionally protected expressive conduct.

We are unpersuaded by these challenges. E-cigarettes are indisputably highly addictive and pose health risks, especially to youth, that are not well understood. It is entirely rational and nonarbitrary to apply to e-cigarettes the Act's baseline requirement that, before *any* new tobacco product may be marketed, its manufacturer show the FDA that selling it is consistent with the public health. What is more, the First Amendment does not bar the FDA from preventing the sale of e-cigarettes as safer than existing tobacco products until their manufacturers have shown that they actually are safer as claimed. That conclusion is amply supported by nicotine's addictiveness, the complex health risks tobacco products pose, and a history of the public being misled by claims that certain tobacco products are safer, despite disclaimers and disclosures. Finally, nothing about the Act's ban on distributing free e-cigarette samples runs afoul of the First Amendment. Free samples are not expressive conduct and, in any event, the government's interest in preventing their distribution is unrelated to the suppression of expression. We accordingly affirm the district court's judgment sustaining the Tobacco Control Act and its application to e-cigarettes.

I. Background

A. Tobacco Control Act

In 1996, the FDA concluded an extensive factual investigation and rulemaking process during which it found that most smokers begin smoking as adolescents, become addicted to nicotine, and struggle with that addiction throughout their lives. Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. 44,396, 44,398-99 (Aug. 28, 1996). At the time of the study, approximately three million American adolescents smoked, and 82% of adults who had ever smoked had their first cigarette before the age of 18. *Id.* at 44,398. The FDA determined that one-third of adolescents who become smokers "will die prematurely as a result." *Id.* at 44,399. Propelled by its findings about health risks, addiction, and the need for accurate information about and effective controls on the uses of tobacco products, the FDA concluded that nicotine was a "drug" that it should regulate under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.* (FDCA), to protect the public health, *see* 61 Fed. Reg. at 44,397.

In response to the Supreme Court's holding that the FDA lacked authority under the FDCA to regulate tobacco as a drug, *see FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000), Congress enacted the Tobacco Control Act to empower the agency to regulate tobacco products. Congress found that "nicotine is an addictive drug" and that "[v]irtually all new users of tobacco products are under the minimum legal age to purchase such products." TCA §§ 2(3), (4), 123 Stat. at 1777. Based on decades of research, Congress made extensive findings about the public health risks of tobacco use: "A consensus exists within the scientific and medical communities

that tobacco products are inherently dangerous and cause cancer, heart disease, and other serious adverse health effects." *Id*. § 2(2), 123 Stat. at 1777.

Because more limited approaches had failed to curb tobacco use, including by adolescents, Congress insisted on "comprehensive restrictions on the sale, promotion, and distribution" of tobacco products. *Id*. § 2(6), 123 Stat. at 1777. Congress defined a "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 (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product)." 21 U.S.C. § 321(rr)(1); *see also Sottera Inc. v. FDA*, 627 F.3d 891, 897 (D.C. Cir. 2010). The Tobacco Control Act expressly empowers the FDA to deem new tobacco products that enter the market to be "tobacco products" subject to the Act's requirements. 21 U.S.C. § 387a(b).

In addition to a default premarket authorization pathway, Congress created a more rigorous pathway for modified risk tobacco products. The Act defines "modified risk tobacco products" as those a manufacturer intends to market "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). The Act established this pathway based on findings that modified risk tobacco products may encourage new users to take up tobacco products, rather than simply reduce risk to those who already use them. TCA § 2(37), 123 Stat. at 1780. Citing a Federal Trade Commission study, Congress noted that advertisements that claim one tobacco product is less harmful than another mislead consumers, even when the putatively less risky products contain "disclosures and advisories intended to provide clarification." *Id.* §§ 2(41), (42), 123 Stat. at 1780. Congress found that disclaimers and

other "[l]ess restrictive and less comprehensive approaches have not and will not be effective" in communicating risks associated with tobacco products sold as safer. *Id*. § 2(31), 123 Stat. at 1779. Congress therefore concluded that "the 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." *Id.* § 2(43), 123 Stat. at 1780.

B. Deeming Rule

In April 2014, the FDA issued its proposed rule to deem e-cigarettes and several other new items "tobacco products" under the Act.[1] *See* Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act: Proposed Rule, 79 Fed. Reg. 23,142 (Apr. 25, 2014). After accepting and reviewing comments, the FDA in May 2016 issued a final rule, effective August 2016, deeming the new items tobacco products. *See* Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act: Final Rule, 81 Fed. Reg. 28,974 (May 10, 2016) (Deeming Rule). The FDA concluded that treating e-cigarettes

[1] We use the term "e-cigarettes" to refer to the full range of products that the Industry calls "vapor products" and the FDA calls Electronic Nicotine Delivery Systems, or ENDS. They go by many other names as well, including e-cigs, cigalikes, e-hookahs, mods, vape pens, vapes, and tank systems. In physical form, these devices include "cigalikes," designed to look like traditional cigarettes, and electronic devices that look like other everyday objects, such as flash drives.

(as well as the other new items) as tobacco products—therefore subject to the Act's ban on distribution of free samples of tobacco products and its preclearance pathways for new, modified risk, and smoking-cessation products—would enable it to protect consumers from "initiat[ing] tobacco product use or continu[ing to] us[e] tobacco when they would otherwise quit." *Id.* at 28,976.

The FDA's Deeming Rule cited to a robust body of scientific evidence about the uses and risks of e-cigarettes and explained in detail how the evidence informed the agency's decision to subject them to the Act's requirements. We summarize some of the FDA's relevant findings here.

1. Nicotine is highly addictive and harmful, especially to youth. "Nicotine is one of the most addictive substances used by humans." *Id.* at 28,988 (internal quotation marks and citation omitted). "[N]icotine is the primary pharmacologic agent of tobacco that can be absorbed into the bloodstream and cause addiction." *Id.* at 29,047. "[A]ddiction to nicotine is the fundamental reason that individuals persist in using tobacco products, and this persistent use contributes to many diseases." *Id.* (internal quotation marks and citation omitted). Even without the combustion of tobacco solids that is responsible for so many of the carcinogens associated with conventional cigarettes, most e-cigarettes contain nicotine at levels that can be hard to determine, and in some instances deliver more nicotine than conventional cigarettes. *Id*. at 29,030-32.

Nicotine has acute toxicity at high doses, *id.* at 28,981, and nicotine poisoning is on the rise, *id.* at 29,035. The Deeming Rule noted the first death of a toddler from accidental poisoning from e-liquid. *Id.* at 29,036. Nicotine acts on both the brain and the body and can have "detrimental effects on the cardiovascular system and potentially disrupt the central

nervous system," *id.* at 29,033; *see also id.* at 29,047—effects to which adolescents are "particularly vulnerable," *id.* at 29,029. Evidence of nicotine's effect on animals suggests that exposure to nicotine before maturity can also disrupt brain development, decrease attention performance, and increase impulsivity, with effects lasting long into adulthood. *See id.* at 28,981, 29,047.

Because of "their developmental stage, and the fact that brain maturation continues into the mid-twenties, adolescents and young adults are more uniquely susceptible to biological, social, and environmental influences to use and become addicted to tobacco products." *Id.* at 29,047. Young people generally "underestimate the tenacity of nicotine addiction and overestimate their" ability to stop using it. *Id.* at 28,981 (internal quotation marks and citation omitted). Most people addicted to nicotine develop physical dependence before adulthood, and the addiction becomes lifelong. *Id.* People who become addicted to nicotine as adolescents may be at increased risk of developing substance abuse disorders and various mental health problems as an adult. *See id.* at 29,047.

2. E-cigarette liquids and vapor contain chemicals in addition to nicotine that pose known risks. The aerosol emitted from e-cigarettes is not simply water vapor; rather, e-cigarette aerosols have been found to contain at least carbonyls, tobacco specific nitrosamines, heavy metals, and volatile organic compounds. *Id.* at 29,029. E-liquids may contain formaldehyde, diacetyl, acetyl propionyl and various aldehydes. *Id.* at 29,029-31. Aldehydes, "a class of chemicals that can cause respiratory irritation" and "airway constriction," appear in many flavored e-cigarettes, including cotton candy and bubble gum. *Id.* at 29,029. One study found that the flavors "dark chocolate" and "wild cherry" exposed e-cigarette users to more than twice the recommended workplace safety

limit for two different aldehydes. *Id.* Like secondary smoke inhalation from conventional cigarettes, exhaled aerosol from e-cigarettes may include nicotine and other toxicants that can pose risks for non-users. *See id.* at 29,031-32.

3. Young customers are especially important for the tobacco industry, given that eighty percent of adult smokers start before age 18. *See* 79 Fed. Reg. at 23,153. A person who reaches age twenty-six without starting to use cigarettes is unlikely ever to smoke, Deeming Rule at 29,047, whereas youth users are likely to become permanently addicted, *id.* In developing e-cigarettes, the tobacco industry introduced many sweet flavors particularly appealing to children, including "gummy bear" and "bubblegum." *See* 79 Fed. Reg. at 23,157.

E-cigarette use is rampant and climbing sharply among middle and high school students. For example, e-cigarette use among high school students rose "nearly 800 percent from 1.5 percent in 2011 to 13.4 percent in 2014." Deeming Rule at 28,984; *see also id.* at 29,028-29.[2] Middle schoolers and high schoolers use e-cigarettes more than any other tobacco product. *Id.* at 28,984. People addicted to nicotine from using e-cigarettes may gravitate to conventional cigarettes; in particular, studies show that youth who use e-cigarettes are more likely to smoke conventional cigarettes. *See id.* at 28,985, 29,040-41.

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[2] Youth e-cigarette use has risen even more since then. The FDA and Centers for Disease Control and Prevention's 2019 survey found that over 5 million young people are currently using e-cigarettes, with almost 1 million using them daily. Overall, 27.5% of high schoolers and 10.5% of middle schoolers used e-cigarettes. *See* Karen A. Cullen, et al., *e-Cigarette Use Among Youth in the United States, 2019*, Journal of the American Medical Association, at E3, E6 (Nov. 5, 2019).

4. E-cigarettes have not been shown to reduce the incidence of conventional smoking. There is "insufficient data to draw a conclusion about the efficacy of e-cigarettes as a cessation device," *id.* at 29,041; *see also* 79 Fed. Reg. at 23,152; *id.* at 23,147, and the Industry is not seeking approval of e-cigarettes as smoking cessation products, nor is it instructing users in cessation, *see* Deeming Rule at 29,037-38. But e-cigarette manufacturers nonetheless have actively marketed their products as if they were a safer, healthier substitute for conventional cigarettes. *See id.* at 29,039-40. People addicted to nicotine thus may be misled into turning to e-cigarettes over evidence-based nicotine reduction therapies. *See id.* at 29,039. And people who would avoid combustible cigarettes as unhealthy may be led to believe that e-cigarettes are safer. *See id.* The effect of e-cigarettes is not just to lead some people away from combustible cigarettes. They also provide a trendy on-ramp to tobacco use for people who otherwise might never have used it. *See id.* at 29,036-37. Accordingly, while e-cigarettes have been touted as less risky than combustible cigarettes, those claims remain unproved. Meanwhile, e-cigarettes clearly have the potential to increase tobacco use and net health costs for the public as a whole. *Id.* at 29,038.

5. There has been very little rigorous or sustained scientific research on the effects of e-cigarettes. Although some of their immediate effects have been established, it is too soon to know their long-term impact. *Id.* at 28,984; *see also id.* at 29,028 (discussing gaps in existing data). Long-term, population-level research is underway, but has yet to be completed. *Id.* at 29,029. Some reports suggest that e-cigarettes may be safer than regular cigarettes. For instance, the Industry stresses a study by Public Health England that concluded e-cigarettes are only five percent as harmful to an individual user as conventional cigarettes. *See* Appellants' Br.

6; J.A. 245-357. Because the Public Health England study relied on data that did not consider the population effects of e-cigarettes—among several other problems—the FDA, unlike the Industry, did not find that study "sufficiently conclusive on the relative risks of using different tobacco products." Deeming Rule at 29,029-30.

C. Statutory Scheme

There is no amount of tobacco use that is health-protective for any individual. Congress in the Act nevertheless decided to take existing tobacco use in the United States as a baseline against which to evaluate "risks and benefits to the population as a whole," 21 U.S.C. § 387j(c)(4), when assessing the effect on public health. The FDCA, as amended by the Tobacco Control Act, uses a range of measures to reduce death and disease from tobacco use while weaning the public from widespread nicotine dependence.

Premarket Authorization. In general, all new tobacco products must be cleared by the FDA before they can be marketed and sold in the United States. *See id.* § 387j.[3] The

[3] An alternative route for premarket authorization of a new tobacco product, not directly relevant here, is to show that the new product is "substantially equivalent" to a product that was already on the market as of February 15, 2007. *See* 21 U.S.C. § 387e(j). The Industry contends that there were no e-cigarettes on the market as of February 15, 2007, so the only relevant approval pathways are those for new tobacco products *not* substantially equivalent to a preexisting product. For its part, the FDA identifies an e-cigarette "that may have been on the market on February 15, 2007." Deeming Rule at 28,978. In view of the Industry's position, we accept its conclusion that the substantial-equivalence pathway is unavailable to it. By the same token, an even more streamlined process is also inapplicable here. Under that process, a product that the FDA concludes has been

Act defines a tobacco product as "new" if it was not commercially marketed in the United States as of February 15, 2007. *Id.* § 387j(a)(1). The Act thus effectively grandfathers permission to market tobacco products then already on sale without premarket review of their public health implications or their suitability for the purposes for which they are sold.[4] For new products, the Act requires the FDA to assess their health effects on the population as a whole (a "population-effects" standard) in view of both the "likelihood that existing users of tobacco products will stop using such products," and the "likelihood that those who do not use tobacco products will start[.]" *Id.* § 387j(c)(4).

Every application for premarket authorization to market a new tobacco product must contain all extant reports of investigations of its health risks, a list of ingredients, and information to show it meets relevant tobacco product

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modified in only a minor respect from a product that was already permissibly marketed under the Act does not require even a substantial-equivalence report and may sidestep the application process altogether. 21 U.S.C. §§ 387j(a)(2)(A)(ii), 387e(j)(3).

[4] The proposed Deeming Rule included a two-year period (until November 2018) for manufacturers of any newly-deemed tobacco product to prepare and file their premarket authorization applications. 79 Fed. Reg. at 23,174. In August 2017, the FDA extended those deadlines by four years. *See* Ctr. for Tobacco Products, Food & Drug Admin., U.S. Dep't of Health & Human Servs., *Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule: Guidance for Industry* (Aug. 2017). As a result, the deadline for new-product premarket authorization applications for e-cigarettes that were on the market on August 8, 2016, became August 8, 2022. On July 12, 2019, a federal district court ordered a new deadline of May 12, 2020. *See Am. Acad. of Pediatrics v. FDA*, 399 F. Supp. 3d 479, 487 (D. Md. 2019), *appeal filed* No. 19-2130 (4th Cir. Oct. 30, 2019).

production standards. *See id.* § 387j(b)(1). As relevant here, the FDA "shall deny" the application if, based on the application and "any other information" in the agency's possession, 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;
> . . .
>
> (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 . . . , and there is a lack of adequate information to justify the deviation from such standard.

Id. § 387j(c)(2). In brief, a new product must be "appropriate" for the public health, not make false or misleading claims, and conform to existing tobacco product standards.

Modified Risk Products. The Act separately regulates tobacco products sold as safer than other tobacco products. *See* 21 U.S.C. § 387k. "No person may introduce or deliver for introduction into interstate commerce any modified risk tobacco product" that has not been cleared as such by the FDA. *Id.* § 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 Act further

specifies the definition of "a modified risk tobacco product" as a product—

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

Id. § 387k(b)(2)(A). A statutory exemption to section 387k(b)(2)(A)(i)(III)'s definition of a modified risk tobacco product—regarding sale of products as "free of" an identified substance—was designed for chewing tobacco. The exemption states that use of the phrases "smokeless tobacco," "smoke-free," and similar defined terms in advertising or labeling a tobacco product will not alone require that it be reviewed as a modified risk product under section 387k(b)(2)(A)(i). *Id.* § 387k(b)(2)(C).

The marketing of a modified risk product must "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." *Id.* § 387k(h)(1). In granting premarket approval to a modified risk tobacco product, the Secretary must take into account the benefit to the health of individuals and to the population as a whole by reference to the following information:

> (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 [approved] for smoking cessation . . . ; and
>
> (E) comments, data, and information submitted by interested persons.

Id. § 387k(g)(4).

A product may be marketed as presenting a lower risk of disease or harm than other tobacco products on the market (*e.g.*, "safer than combustible cigarettes") only if "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.

Id. § 387k(g)(1). An applicant for approval to sell a modified risk tobacco product is therefore held to a more robust public health standard than a manufacturer of an ordinary new tobacco product. In particular, the applicant must show that the product "significantly" reduces harm and the risk of harm from

tobacco-related disease to individual users below the risk from tobacco products they might otherwise use. *Id.* § 387k(g)(1)(A). And rather than meet the ordinary tobacco product standard that it merely be "appropriate for the protection of the public health," *id.* § 387j(c)(2)(A), the manufacturer of a modified risk tobacco product must show it will be a net public health "benefit," *id.* § 387k(g)(1)(B).

The Act also establishes a "Special Rule for Certain Products" with a less demanding and more targeted standard for the subset of modified risk products that purport to contain a reduced level or none of an identified substance (*e.g.*, "no diacetyl"). *See id.* § 387k(b)(2)(A)(i)(II) & (III). Modified risk products subject to the Special Rule need not show a prospect of "significantly" reduced harm or risk to the individual user and must be only "expected" to benefit the health of the population as a whole. *Id.* § 387k(g)(2)(B). A product under the Special Rule must show only that—

> (i) [an authorizing] order would be appropriate to promote the public health;
>
> . . .
>
> (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 [general standard for modified risk products]; 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.

Id. § 387k(g)(2)(A). The substance identified as reduced or absent must actually be harmful, the reduction must be substantial and accurate as labeled, the product must not expose the consumer to increased levels of other harmful substances, and consumer perception testing must show that consumers will not misinterpret a specific claim as an assurance of relative overall safety. *Id.* § 387k(g)(2)(B). An applicant under this Special Rule must also "conduct postmarket surveillance and studies" and submit the results to the Secretary annually to allow her 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 on which the order was based[.]" *Id.* § 387k(g)(2)(C)(ii).

Smoking Cessation Products. Products that the FDA recognizes as "smoking cessation products," marketed to help people quit smoking by treating tobacco dependence, are not considered ordinary or modified risk products, *id.* § 387k(c), but are subject to approval as medical drugs or devices under the FDCA, *see id.* § 355.

An applicant seeking FDA approval of a new drug or device must submit "full reports of investigations" showing that the drug is safe and effective in use. *Id.* § 355(b)(1). The FDA and the applicant may meet to discuss the design and size of clinical trials that will form the basis for the effectiveness claim. *Id.* § 355(b)(5)(B). The Secretary may deny an application if it does "not include adequate tests by all methods reasonably applicable," if there is "a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof,"

or if the proposed labeling is "false or misleading in any particular." *Id.* § 355(d). "[S]ubstantial evidence" under this standard means "evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved[.]" *Id.* The FDA has approved as smoking cessation products some nicotine replacement therapies, such as patches, chewing gums, and nasal sprays. *See* Deeming Rule at 28,976, 29,037. New products proposed for smoking cessation may be treated as "breakthrough therapies" and fast-tracked through the approval process. *Id.* § 387r(a)(1).

Free Sample Ban. Finally, the Act bans the distribution of free samples of tobacco products. *Id.* § 387a-1(d)(1); *see also* 21 C.F.R. § 1140.16(d)(1). The only exception is for smokeless tobacco (*i.e.*, chewing tobacco), which may be distributed for free in "qualified, adult-only" facilities. *Id.* § 387a-1(d)(2).

D. Proceedings in the District Court

In May 2016, the Industry challenged the FDA's Deeming Rule and selected provisions of the Tobacco Control Act as contrary to the APA and the First Amendment. On the parties' cross-motions for summary judgment, the court sustained the Act and the Deeming Rule in full. *See Nicopure Labs, LLC v. FDA*, 266 F. Supp. 3d 360 (D.D.C. 2017). The district court's thorough opinion spans more than 60 pages in the official reporter.

At the outset, the district court stressed that it "wishes to reassure the many worried vapers who followed these proceedings closely that this case is not about banning the

manufacture or sale of the devices." *Id.* at 367. As the district court explained,

> [a ban] is not what the Deeming Rule does or what it was intended to accomplish. In the Deeming Rule, the FDA simply announced that electronic cigarettes, or electronic nicotine delivery systems ("ENDS") would be subject to the same set of rules and regulations that Congress had already put in place for conventional cigarettes.
>
> The Rule requires manufacturers to subject their products to review before marketing them, to tell the truth when making any claims about their health benefits, and to warn consumers about the dangers of nicotine when offering a means to deliver the substance to consumers. In short, the manufacturers of e-cigarettes are now required to tell the 30 million people who use the devices what is actually in the liquid being vaporized and inhaled.
>
> This case does not pose the question—which is better left to the scientific community in any event—of whether e-cigarettes are more or less safe than traditional cigarettes. The Rule did not purport to take the choice to use e-cigarettes away from former smokers or other adult consumers; the issue is whether the FDA has the authority to require that the choice be an informed one.

Id. The Industry has not pursued on appeal its broadside challenge to the FDA's decision to deem e-cigarettes "tobacco products" under the Act, including its challenges to relevant deadlines for e-cigarette compliance. Only the following three of the district court's holdings are at issue here.

First, the district court held that the FDA's decision to subject e-cigarettes to premarket authorization was non-arbitrary and supported by substantial evidence of nicotine's harmful and addictive character, adolescents' unique vulnerability to this harm and addiction, and the significant variability in labeled and actual content of several chemicals found in e-cigarettes. *Id.* at 393-95. It held that the FDA rationally rejected alternatives urged by the Industry in favor of "premarket review [that] is a creature of statute." *Id.* at 397.

Second, the district court held that the modified risk pathway did not violate the First Amendment. *Id.* at 419-21. Although the court thought the pathway imposed a restriction on speech, it held that it survived the scrutiny applicable to commercial speech under *Central Hudson Gas and Electric Corporation v. Public Service Commission*, 447 U.S. 557 (1980). Applying *Central Hudson*, the court recognized the substantial governmental interest in protecting the public health and preventing unsubstantiated and misleading claims about relative health benefits, especially where youth are concerned. *Nicopure Labs*, 266 F. Supp. 3d at 419-20. The modified risk pathway "directly and materially" advances those governmental interests in a reasonably fitting manner, the court held, because it "does not ban truthful statements about health benefits or reduced risks; it simply requires that they be substantiated." *Id.* at 421.

Third, the district court held that the ban on free samples of e-cigarettes was not constitutionally protected speech under the First Amendment, but a permissible conduct regulation. *Id.* at 412-15. It further held that, even if *Central Hudson* were applicable to the free sample ban, it meets that standard because it directly and materially advances the substantial governmental interest in preventing children and adolescents

from gaining access to tobacco products. *Id.* at 416-17. The court sustained the FDA's determination, based on its past experience with tobacco product giveaways, that no alternative to a ban on free samples would effectively prevent youth access, and that the ban is no broader than necessary because it permits "other, less risky marketing options" for e-cigarettes, including "discounting sample kits sold in stores to curious adults." *Id.* at 418.

We review the district court's grant of summary judgment *de novo*. *See Stand up for California! v. Dep't of Interior*, 879 F.3d 1177, 1181 (D.C. Cir. 2018); *Am. Freedom Defense Initiative v. WMATA*, 901 F.3d 356, 363 (D.C. Cir. 2018).

II. Discussion

A. Application of the New-Product Premarket Authorization Pathway to E-Cigarettes Does Not Violate the APA

The Industry contends that the FDA arbitrarily subjects e-cigarettes to the Tobacco Control Act's premarket authorization for new tobacco products because it has declined to "tailor" that process to e-cigarettes, instead imposing a "one-size-fits-all" regime that the Industry views as inappropriately "onerous." Appellants Br. 48. Under the ordinary premarket authorization pathway, the FDA must deny permission to market any product that, in light of its effects on the population as a whole, is not shown to be "appropriate for the protection of public health." 21 U.S.C. § 387j(c)(2)(A). The Industry objects that requiring premarket authorization—and, in particular, long-term clinical and epidemiological studies to satisfy the population-effects standard—imposes "enormous time and financial burdens" that it contends could drive much of the e-cigarette industry out of business. Appellants Br. 50-

54. E-cigarettes are "less risky" to the individual user than traditional tobacco products, the Industry asserts, and thus should be subject to less stringent authorization than the Act's ordinary premarket pathway. *Id*. at 4.

The Industry's claim that the FDA acted arbitrarily is miscast. The FDA has made no blanket rule excusing e-cigarettes from the premarket authorization requirement, nor could it. The premarket approval requirement is in the Act. It was Congress, not the FDA, that imposed it on new tobacco products, including e-cigarettes. There is no exemption in the Act for certain new tobacco products speculated to be less risky than other new tobacco products. Only tobacco products consistent with the population-effects standard fulfill the Act's requirement that each new tobacco product's risks not outweigh its benefits to the public health. Once the FDA deemed e-cigarettes to be "tobacco products"—a decision Appellants no longer challenge—e-cigarettes became subject to premarket authorization and the requirement to meet the population-effects standard. The "FDA is not authorized to deviate from this statutory standard." Deeming Rule at 28,999. The Industry's wholesale objection is to Congress' design, not to any arbitrariness on the FDA's part in carrying it out.

In requesting an easier path, the Industry impermissibly assumes the very public health conclusion that premarket authorization requires be substantiated before a product may be sold: that e-cigarettes are no more risky to the population as a whole than preexisting tobacco products, balancing the prospect that they may lead existing users to less harmful products or usage patterns against the risks that existing tobacco users will postpone reductions or intensify their usage and that non-users will start. The Industry has failed to show that the population-effects standard as applied to e-cigarettes is mismatched to the risks for which it is designed to screen, let

alone that the standard would completely prohibit e-cigarettes. Indeed, as of their complaint in this case, Appellants had not yet submitted to the process nor sought to work with the FDA to explore the most efficient appropriate course to make the requisite determinations regarding any actual e-cigarette.

Notably, although the FDA "may not modify the statutory pre-market review procedures, the agency has stated that it will be flexible in reviewing applications to the extent permitted by statute." Appellee Br. 26. The Act specifies that "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," including "clinical investigations." 21 U.S.C. § 387j(c)(5)(A). But it further provides that, if there is "valid scientific evidence" other than such investigations that is "sufficient to evaluate the tobacco product," the Secretary may authorize the FDA to make a determination on the basis of that evidence. *Id.* § 387j(c)(5)(B). The FDA has expressed willingness to accept scientific literature reviews instead of commissioned studies in support of e-cigarette applications in appropriate circumstances. Deeming Rule at 28,998. In short, the premarket authorization pathway is a creature of Congress not subject to challenge under the APA and, in any event, simply is not the blunt, arbitrary instrument that the Industry portrays.

B. The First Amendment Does Not Bar "Modified Risk Tobacco Product" Premarket Review of E-Cigarettes Designed For Use To Reduce Harm Or The Risk of Disease

As we have explained, all tobacco products entering the market after February 2007 must obtain FDA authorization pursuant to one of three statutory paths, depending on whether

the product is (a) a new tobacco product, (b) a new modified risk tobacco product, or (c) a new smoking cessation product. The least demanding of those three paths is the standard for a new tobacco product that is not sold or distributed either for use to reduce the harm or risk of disease from tobacco consumption, nor to help the customer quit, but as an ordinary tobacco product for recreational use by adults. Again, the Act requires the manufacturer of such a product to establish that, viewed in the context of products currently on the market, its new product will not be a step backward for the public health. The most demanding of the three paths, in contrast, is for new tobacco products intended to be used for smoking cessation. Manufacturers of any smoking cessation product must gain FDA approval by showing its efficacy as a "drug or device" for curbing addiction. The Industry does not challenge either of those paths on First Amendment grounds.

The Industry's First Amendment challenge is focused on the modified risk product pathway, which applies to products not cleared for smoking cessation but that the manufacturer nonetheless seeks to market "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). Whether a product falls in the modified risk category turns on how the manufacturer describes the product's characteristics and intended use. The Industry contends that FDA's use of a manufacturer's claims about its product's characteristics—such as a claim that the product is "safer than cigarettes" or produces "no tar"—to assign the product to the appropriate review pathway burdens speech in violation of the First Amendment.

We are unpersuaded for two reasons. First, our precedent explicitly approves the use of a product's marketing and labeling to discern to which regulatory regime a product is

subject, and to treat it as unlawful insofar as it is marketed under a different guise. As we held in *Whitaker v. Thompson*, 353 F.3d 947 (D.C. Cir. 2004), the FDA's reliance on a seller's claims about a product as evidence of that product's intended use, in order that the FDA may correctly classify the product and restrict it if misclassified, does not burden the seller's speech. Second, even if we were to scrutinize the FDA's reliance on new tobacco product descriptors as a burden on the Industry's commercial speech, the modified risk product pathway clears First Amendment scrutiny because it is reasonably tailored to advance the substantial governmental interest in protecting the public health and preventing youth addiction.

1. Speech as Evidence of Product Type. In *Whitaker*, we approved the FDA's use of claims made by a "saw palmetto extract" manufacturer to determine whether the product was subject to the demanding premarket approval applicable to drugs, or could be marketed under the less demanding standards for dietary supplements. 353 F.3d at 223-24. Once the manufacturer made a "drug claim" regarding treatment of a disease or its symptoms, it was required to clear the FDA's drug approval pathway, and its sale accompanied by a drug claim without approval as a drug became unlawful. *Id.* at 953; *see also Village of Hoffman Estates v. Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 502 (1982) (finding exempt from First Amendment scrutiny a village ordinance that required a license for sale of certain smoking devices when they were marketed with intent to be used with marijuana or other illegal drugs, even though no license was needed to market the same items for other uses). The modified risk product pathway similarly regulates only products "sold or distributed for use to reduce harm[.]" 21 U.S.C. § 387k(b)(1). Just as the government may consider speech that markets a copper bracelet as an arthritis cure or a beach ball as a lifesaving

flotation device in order to subject the item to appropriate regulation, so, too, the FDA may rely on e-cigarette labeling and other marketing claims in order to subject e-cigarettes to appropriate regulation. *See Whitaker*, 353 F.3d at 953; *cf. Brown & Williamson*, 529 U.S. at 170 (Breyer, J., dissenting) ("[E]ven in the absence of express claims, the FDA has regulated products that affect the body if the manufacturer wants, and knows, that consumers so use the product." (citations omitted)).

The Industry seeks to market e-cigarettes as safer than competitor tobacco products without subjecting them to the requirements of the corresponding premarket review pathway. It stresses repeatedly the usefulness of manufacturers' proposed modified risk characterizations to adult consumers of tobacco products who might be interested in switching from traditional cigarettes. It claims that "long-time smokers . . . look to vapor products in attempts to move away from deadly cigarettes," Appellants Br. 2, "vapor products are primarily used by adult smokers to avoid significant health hazards associated with cigarettes," *id*. at 6, and that "[c]onsumers routinely seek information that would be helpful when attempting to move away from cigarettes and learn more about the features of particular vapor products," *id*. at 17. Yet the Industry seeks to sidestep public-health protections by avoiding the modified risk product pathway. It does so even as it fails to address the most risky potential uses: intensified use rather than diminution by existing tobacco users, and uptake of e-cigarettes by people, including youth, who otherwise avoid tobacco products altogether but who are persuaded to try a modified risk tobacco product as a putatively healthier alternative.

The Industry would distinguish *Whitaker* by contending that the FDA's modified risk product pathway does not use

proffered claims that e-cigarettes are safer than combustible cigarettes to establish the manufacturer's intent in marketing the product, but to regulate the message itself. Reply 5 n.7. But the same could be said of the FDA regulation in *Whitaker* where, unaccompanied by the speech that characterized it, the extract could be lawfully sold. Deliberately selling an e-cigarette as less risky without going through the requisite regulatory review for reduced-risk tobacco products renders the sale-as-labeled unlawful, just as selling saw palmetto extract as a drug without FDA premarket approval was unlawful. It is well established that "commercial speech related to illegal activity" is not subject to constitutional protection. *Central Hudson*, 447 U.S. at 564. "[S]peech proposing an illegal transaction [is speech] which a government may regulate or ban entirely." *Hoffman Estates*, 455 U.S. at 496.

Under *Whitaker*, therefore, the FDA does not run afoul of the First Amendment when it relies on manufacturer statements defining modified risk products.

2. Permissible Conditions on Commercial Speech. Even if we view the modified risk pathway as burdening speech, it passes constitutional muster. The modified risk product pathway—like the other pathways—applies only to products containing nicotine, which, as all concede, is an inherently addictive, dangerous class of products. It authorizes the FDA to treat marketing of a tobacco product with implicit or explicit assurances that it is safer than other tobacco products as making a claim that is misleading until the manufacturer shows otherwise. The Act does not ban manufacturers from making accurate claims that their products have less risky attributes, but requires them to substantiate such claims with evidence of their overall public health effects in advance of marketing, and to show that the proposed product as marketed will not mislead

consumers as to its safety. If a manufacturer shows its product is in fact safer, and shows that consumer perception accurately grasps the nature and limits of any safety claim, the product will be marketable. Because the Act withholds from market only those tobacco product claims that, upon review, are found to be misleading, it bars only commercial speech that by definition is unprotected by the First Amendment.

Under *Central Hudson*, a statute regulating commercial speech that is "neither misleading nor related to unlawful activity" must clear a three-part test: (1) it must be supported by a "substantial" governmental interest; (2) it must "directly advance [that] state interest"; and (3) the speech restriction must be no "more extensive than is necessary to serve that interest." 447 U.S. at 564-66. Placing an obligation on a manufacturer to demonstrate that an e-cigarette is in fact safer before it may market it as such easily satisfies this test.

First, the government has a substantial interest in ensuring that any modified risk statements are accurate and non-misleading in order to protect consumers from buying a highly addictive product with a false sense of the risks it presents. To that end, the modified risk pathway is designed to identify marketing that would spread specious or unsubstantiated information and to intervene before those products go on sale. Congress found that the "dangers of products sold or distributed as modified risk tobacco products that do not in fact reduce risk are so high that 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), 123 Stat. at 1780. That interest is especially powerful given that younger customers are consistently the principal market for new tobacco products. The Supreme Court has acknowledged that "tobacco use, particularly among children and adolescents,

poses perhaps the single most significant threat to public health in the United States." *Brown & Williamson*, 529 U.S. at 161; *see also Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 528 (2001) ("The governmental interest in preventing underage tobacco use is substantial, and even compelling[.]"). The Industry itself concedes, as it must, that Congress "articulated . . . a compelling interest in protecting the public from unsubstantiated claims that one tobacco product is safer than another." Appellants Br. at 20. Given the addictive nature of nicotine and the unexamined health effects of e-cigarettes, that substantial interest amply supports protecting the public health from the dangers of e-cigarette use encouraged by unsubstantiated, misleading claims of relative safety.

Second, the modified risk product pathway directly advances this substantial interest. Regulating lawful but addictive and harmful products in a manner protective of the public health presents distinct challenges: Products that may help addicted consumers to transition to less harmful ones may promote the public health, whereas products that appeal to new users are virtually certain to harm it. These products call for rigorous and balanced assessment, especially when a single product may hold both kinds of potential. The modified risk product pathway codifies that balanced scientific review.

The modified risk product pathway regulates only those products marketed as *safer* than those already on the market. A manufacturer may not introduce *any* new tobacco product, even under the ordinary premarket authorization pathway, until the FDA considers its population-wide impact and is satisfied that, considering both individual and population effects, it is in fact "appropriate" for the protection of the public health. 21 U.S.C. §§ 387j(c)(2)(A), (4). Under the modified risk product pathway, a manufacturer seeking to sell its product as less risky must likewise take into account "both users of tobacco products

and persons who do not currently use tobacco products," *id*. at § 387k(g)(1)(B), but must meet a standard higher than is required of ordinary tobacco products. Such a product must be more than "appropriate" for the public health; a modified risk product requires a demonstration that it will "significantly" reduce harms and risks of tobacco-related disease to individual users, *id*. at § 387k(g)(1)(A), and will "benefit" the health of the population as a whole, *id*. at § 387k(g)(1)(B).

Requiring those showings directly advances the government's interest in accuracy and public health. Given that *no* tobacco product has *ever* been shown to be safe, Congress ensured that the FDA will not lightly authorize the sale of tobacco products as carrying reduced health risk. The modified risk standard requires a showing of significant harm reduction and clear net benefit in order to ensure that any claim that describes a tobacco product as safer is justified. To offset risks of intensified use of products perceived as safer, the manufacturer must show benefits to the individual and the public as a whole. A new product sold as less risky because it reduces harm to an individual who already smokes may misrepresent its public health benefits if it "raises the aggregate number of people (especially juveniles) who use tobacco because it leads them to believe that an unsafe product is *relatively* safe[.]" *Discount Tobacco City & Lottery Inc. v. United States*, 674 F.3d 509, 536 (6th Cir. 2012).

The Act's "Special Rule" for certain products in the modified risk category also directly advances the government's interest by preventing misleading marketing of products sold as free of or containing a reduced level of a substance. 21 U.S.C. § 387k(g)(2)(A)(ii). It sets out for those products a less stringent standard; they need not meet the "significant" reduction of harm standard, and also need only be "*expected* to benefit the health of the population as a whole." *Id*.

§ 387k(g)(2)(B)(iv). That standard applies where the manufacturer is able to establish that (1) the reduction claim is accurate and the overall reduction in exposure to the substance at issue is substantial, (2) the product does not expose consumers to higher levels of other harmful substances, and (3) consumer testing shows that consumers will not be misled by the claim. *Id.* § 387k(g)(2)(B)(i)-(iii). Each element of the inquiry is targeted towards ensuring that any specific-substance claim that consumers may understand as a relative safety claim is accurate and not misleading.

The modified risk product pathway therefore passes *Central Hudson*'s second requirement that it directly advance Congress' substantial interest in promoting the public health by preventing misleading information about a highly addictive product.

Finally, the modified risk product pathway meets *Central Hudson*'s third requirement that the regulation be "not more extensive than necessary" to serve the government's interest. *Central Hudson*, 447 U.S. at 566. This is the heart of the Industry's challenge. In making this "fit" determination, "the least restrictive means is not the standard; instead, the case law requires a reasonable fit between the legislature's ends and the means chosen to accomplish those ends[.]" *Lorillard Tobacco*, 533 U.S. at 556 (internal quotation marks and citations omitted).

The modified risk pathway is reasonably tailored to prevent the sale of highly addictive, risky products on terms that are likely to mislead consumers. Congress found that "the 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), 123 Stat. at 1780. As applied to the proposed marketing of e-cigarettes as less risky than other products—whether generally or by specifying that they contain less or none of a particular substance—the modified risk pathway appropriately requires that manufacturers substantiate their safety claims in advance. The modified risk product pathway's Special Rule accommodates the more concrete nature of claims that a tobacco product is free of or contains a reduced level of a particular substance by accepting a more focused and conditional showing.

The Industry primarily highlights its desire to promote products as involving reduced levels of harmful substances. The Special Rule for such products is tailored to allow the manufacturer to argue that scientific evidence establishing its appropriateness for the public health is unavailable and not easily attainable, 21 U.S.C. § 387k(g)(2)(A)(iii), and to instead submit a lesser showing followed by post-market monitoring of the product's impact on consumers, *id.* § 387k(g)(2)(C)(ii). The pathway thus reasonably tailors the requisite substantiation to the type of product. For products marketed as generally less harmful, scientific studies must show that a "substantial reduction in morbidity or mortality among individual tobacco users *occurs*" with their use, whereas for those marketed under the Special Rule only as less harmful because they contain a reduced level of a substance, the manufacturer must show only that reduced morbidity and mortality is "*reasonably likely*." *Id.* § 387k(*l*)(1)(A) (emphasis added). The FDA is entitled to impose these reasonable requirements on manufacturers of products containing nicotine—like makers of dangerous or potentially dangerous pharmaceuticals—to show at the threshold that their marketing claims are accurate and not misleading.

The Industry objects that its claims cannot constitutionally be subject to premarket approval because, in its view, they are accurate. But modified risk claims that might be technically accurate if viewed in isolation are in fact often misunderstood by consumers. In particular, consumers have been misled about the health consequences of claims that a tobacco product did not contain or contained reduced level of a harmful substance: "[M]any smokers mistakenly believe that 'low tar' and 'light' cigarettes cause fewer health problems than other cigarettes," which "can reduce their motivation to quit smoking entirely and thereby lead to disease and death." TCA § 2(38), 123 Stat. at 1780. By the same token, product labeling or advertising that touts an e-cigarette as free of a specified ingredient may mislead consumers to view the product as generally safer, even if other chemicals it contains, such as formaldehyde, are equally or more harmful than the disclaimed ingredient. The Industry's claims of accuracy are unsubstantiated, and it has yet to submit an application with appropriate consumer-perception evidence.

The First Amendment test of regulation of potentially misleading commercial speech allows for contextual determination of accuracy based on consumers' understanding. In evaluating regulation of commercial speech to prevent misleading claims, we look to whether "consumers acting reasonably under the circumstances" would understand a product claim to contain a false message. *POM Wonderful, LLC v. FTC.*, 777 F.3d 478, 499-500 (D.C. Cir. 2015). In appropriate circumstances, even "innuendo" or an "overall net impression" received by a "significant minority of reasonable consumers" can mean that a statement is misleading to consumers. *Id*. at 490. Because the rationale supporting First Amendment protection of commercial speech is "the informational function of advertising," "[t]he government may

ban forms of communication more likely to deceive the public than to inform it." *Central Hudson*, 447 U.S. at 563. And "misleading commercial speech is not only subject to restraint; '[it] may be prohibited entirely.'" *Ass'n of Private Sector Colleges & Univs. v. Duncan*, 681 F.3d 427, 457 (D.C. Cir. 2012) (quoting *In re R.M.J.*, 455 U.S. 191, 203 (1982)). That is because "elimination of false and deceptive [advertising] claims serves to promote the one facet of commercial price and product advertising that warrants First Amendment protection—its contribution to the flow of accurate and reliable information relevant to public and private decisionmaking." *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 781 (1976) (Stewart, J., concurring).

Moreover, when the speech in question addresses matters on which the "public lacks sophistication," then "misstatements that might be overlooked or deemed unimportant in other advertising may be found quite inappropriate[.]" *In re R.M.J.*, 455 U.S. at 200. The importance and complexity of assessing the effectiveness of one lawyer versus another, for example, supports the constitutionality of regulating attorney advertising to "correct omissions that have the effect of presenting an inaccurate picture[.]" *Id.* at 201. So too here. The modified risk pathway seeks to 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." 21 U.S.C. § 387k(h)(1). Tobacco products are by definition harmful and addictive, and choosing among them based on comparative safety is inherently risky and complex, making the public especially susceptible to being misled and harmed.

Congress' knowledge of the history of tobacco marketing strongly supports its decision to require premarket approval to prevent misleading marketing of some tobacco products as less risky than others. The record is clear that tobacco manufacturers used unsubstantiated or false modified risk claims about tobacco products to entice consumers to use and become addicted to them. *See Discount Tobacco*, 674 F.3d at 534-45. Those statements proved especially consequential in the marketing of addictive, dangerous products. Many people "who would not otherwise consume tobacco products, or would consume such products less," were induced to use hazardous products marketed as safer and healthier, and millions struggled with a lifetime of addiction as a result. *Id.* § 2(37), 123 Stat. at 1780.

In the e-cigarette context, the FDA found that marketing of e-cigarettes as less risky had already led consumers (especially young adults) to "often mistakenly think non-cigarette tobacco products are safe alternatives to cigarettes." 79 Fed. Reg. at 23,146. Consumers have frequently and erroneously read narrow safety statements about an identified substance as materially complete claims that the product is safe overall. Accordingly, for claims that e-cigarettes contain a reduced level or are free of a dangerous substance, the modified risk pathway fittingly requires the "testing of actual consumer perception" to show that "consumers will not be misled into believing that the product . . . is or has been demonstrated to be less harmful" more broadly, or "to present less of a risk of disease" overall than other commercially marketed tobacco products. 21 U.S.C. § 387k(g)(2)(B).

In attempts to show that the regulation is more extensive than necessary, the Industry presents alternative approaches that it asserts the government was required to have taken

instead of the modified risk product pathway. None is convincing.

First, the Industry contends that Congress could have required disclaimers on modified risk products in order to clarify any misleading statements. But Congress considered and rejected that option, finding that disclaimers had been ineffective to prevent deceptive tobacco marketing in the past. TCA § 2(41), 123 Stat. at 1780. As Congress noted, tobacco 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, are misinterpreted by consumers." *Id.* The risk of misinterpretation regarding a highly addictive product supports the FDA's choice of preclearance over a disclaimer requirement.

Second, the Industry argues that post-market enforcement would address the FDA's concerns, and that the FDA did not adequately consider requiring manufacturers to maintain records substantiating their product characterizations that could subsequently be inspected by the FDA. Each of those suggestions seeks to place the onus on the government, rather than on manufacturers. Each would require the FDA to investigate the harms of an open-ended litany of substances that might appear in e-cigarettes, and to continually test products for their presence. Restricting the government's regulatory options in that way is inappropriate for products containing harmful and addictive substances about which the public is known to be easily misled and about which the manufacturer has superior information. The FDA has already noted inaccuracies in claims made by various e-cigarettes about their nicotine content, *see, e.g.*, Deeming Rule at 29,034, and significant variability between labeled and actual content of various chemicals, *id.* at 28,984. Once inaccurate or

misleading information influences people to start using a powerfully addictive substance, damage has been done.

This is not, therefore, a case in which the government has not "offered any reason why" alternative, less restrictive regulations would fall short in protecting the public interest. *Thompson v. Western States Med. Ctr.*, 535 U.S. 357, 373 (2002). Instead, taking into account a highly addictive product with known and unknown health risks, and a history of claims likely to mislead many people down a path of lifelong addiction, the modified risk product pathway is a fitting means to protect the accuracy of information and the public health.

The Industry's reliance on *Sorrell v. IMS Health Inc.*, 564 U.S. 552 (2011), is also misplaced. The Court in *Sorrell* held that barring pharmaceutical companies from accessing doctors' records of prescriber information unconstitutionally restricted "sophisticated and experienced consumers," namely prescribing physicians, from accessing "truthful, nonmisleading advertisements" that would have aided them in making more informed prescription decisions. *Id.* at 577-78 (internal quotation marks and citation omitted). In contrast, here, the consumers most likely to be targeted and misled by the two types of modified risk products are not sophisticated professional physicians, but ordinary laypeople, including adolescents. They are not choosing from a range of potentially beneficial health options in line with their professional obligations; they are considering whether to take up use of an indisputedly unhealthy, addictive tobacco product.

And, unlike the statute in *Sorrell*, the modified risk product pathway does not create a blanket ban on information going to one speaker while placing no restrictions on its dissemination to others. The Court in *Sorrell* faulted the regulation for keeping objective information—lists of prescribers—from

pharmaceutical marketers while private and academic researchers were free to buy and use the same information. *Id.* at 563. But here, there is no analogous information that others may use that the Industry may not. First, the modified risk product pathway does not impose an absolute bar, but allows e-cigarette manufacturers to make marketing claims that they have shown are accurate and nonmisleading. Products accompanied by descriptive claims are therefore not excluded from the marketplace of information, only evaluated first to prevent them from misleading consumers. Second, the Industry has identified no actor other than the FDA that it contends may—without premarket approval—make the claims it seeks to make in connection with a commercial transaction. *Sorrell*'s concerns about suppression of advertising messages in the marketplace of ideas are inapposite here, where the products are acknowledged to be risky and addictive, are subject to premarket approval, not a ban, and no comparable speech by others is permitted.

Finally, the Industry points out that the Act permits smokeless tobacco—also known as chewing tobacco—to be marketed as "smokeless" or "smoke free" without being cleared as a modified risk product, while the same terms cannot be used to describe e-cigarettes. 21 U.S.C. § 387k(b)(2)(C). It contends this is an "arbitrary distinction[]" not "permitted under the First Amendment." Appellants' Br. 28. The regulatory treatment of chewing tobacco calls into question the government's interest in regulating e-cigarettes, they claim, just as the exemption of tribal casinos from a broadcast-advertising ban on casino gambling in *Greater New Orleans Broadcasting Ass'n, Inc. v. United States*, 527 U.S. 173, 193 (1999), undermined the government's asserted interest in curbing gambling's social costs. *See also Rubin v. Coors Brewing Co.*, 514 U.S. 476, 488-89 (1995) (invalidating alcohol-content labeling restriction applicable to beer, but not

wine and spirits). But the exemption for smokeless tobacco products is not arbitrary.

Congress concluded that chewing tobacco could be identified as "smokeless" without pre-approval for two reasons. First, chewing tobacco has for decades been identified as "smokeless" to distinguish its intended use from smoking tobacco sold loose for roll-your-own cigarettes or pipes. *See* 21 U.S.C. § 387(18) ("[A]ny tobacco product that consists of cut, ground, powdered, or leaf tobacco and that is intended to be placed in the oral or nasal cavity."). This rationale is inapplicable to e-cigarettes. Second, unlike e-cigarettes, which involve heating of e-liquid and inhalation of the resulting vapor into the lungs, chewing tobacco is not inhaled. Deeming Rule at 28,987; *see Competitive Inst. v. U.S. Dep't of Transp.*, 863 F.3d 911, 919 (D.C. Cir. 2017) (sustaining a rule that prohibits e-cigarette use on airplanes, in part because "e-cigarette vapor in confined aircrafts could harm non-users"). To the extent that consumers may view "smokeless" as a claim about relative pulmonary risk, decades of experience supports the FDA's allowance of that claim for chewing tobacco whereas the FDA lacks any similar track record regarding e-cigarettes. This narrow and justified exception is not the kind of fatal inconsistency that might call into question the government's interest in promoting public health through preventing the commercial dissemination of misleading speech about new tobacco products.

In sum, even if the modified risk product pathway is treated as a speech restriction that implicates the First Amendment, it meets the *Central Hudson* standard, as well as any further scrutiny under *Sorrell*.

C. The Free Sample Ban Does Not Violate the First Amendment.

Finally, Appellants challenge the Act's ban on free samples of tobacco products as applied to e-cigarettes. 21 U.S.C. § 387a-1(a)(2)(G); 21 C.F.R. § 1140.16(d)(1). Distribution of free samples as a marketing technique seeks to entice people who otherwise would not try a product to use it and, based on their experience, to continue doing so. But products given out for free are often not consumed by their immediate recipients, who may have little or no interest in the giveaways so set them aside where curious children can find them. The purpose of the e-cigarette sample ban is to eliminate an easily accessible source for youth that are especially vulnerable to the risks of tobacco use and addiction. *See* Deeming Rule at 28,986.

The Industry argues that the free sample ban is a violation of e-cigarette manufacturers' First Amendment right to freedom of expression. But the ban targets conduct, not speech, and it is far from clear how that conduct is expressive. As the district court noted, the Industry has not identified the "entirely unstated" message it believes is silenced by the free sample ban. *Nicopure Labs*, 266 F. Supp. 3d at 413. The Industry says that free samples are "expressive" because they "convey[] important information to smokers who want to switch to vapor products, including key consumer information about different e-liquid flavors and device performance characteristics." Appellants' Br. 11-12**.** Free samples are, in the Industry's view, "the quintessential example of what the First Amendment protects in the commercial context" because they are "the most effective and efficient means of obtaining product-specific information when trying to switch away from deadly cigarettes." *Id*. at 35. The Industry thus appears to be urging us to afford constitutional protection to the

informational value of customers' experience trying out vaping, including the experience of sampling the available flavors and sensations.

This extraordinary argument, if accepted, would extend First Amendment protection to every commercial transaction on the ground that it "communicates" to the customer "information" about a product or service. Even if we could bridge the gap between the opportunity to use a product and the expression of an "idea," the Supreme Court has long rejected the "view that an apparently limitless variety of conduct can be labeled 'speech' whenever the person engaging in the conduct intends thereby to express an idea." *United States v. O'Brien*, 391 U.S. 367, 376 (1968); *see also Barnes v. Glen Theatre, Inc.*, 501 U.S. 560, 570 (1991). Indeed, "[i]t is possible to find some kernel of expression in almost every activity a person undertakes—for example, walking down the street or meeting one's friends at a shopping mall—but such a kernel is not sufficient to bring the activity within the protection of the First Amendment." *City of Dallas v. Stanglin*, 490 U.S. 19, 25 (1989). The services offered at a particular hotel may in part be intended to encourage a guest to return there the next time she travels, and eating a certain brand of fast food or breakfast cereal may inform a family about whether it is a type of food that suits them. But the seller's intention that those experiences leave consumers with helpful information that encourages future purchases does not convert all regulation that affects access to products or services into speech restrictions subject to First Amendment scrutiny.

Even if the e-cigarette free sample ban somehow imposed an incidental speech burden, the restriction itself applies to conduct and is imposed "for reasons unrelated to the communication of ideas," so would not implicate the First Amendment. *Lorillard Tobacco*, 533 U.S. at 569. The free

sample ban is not directed at the communication of information, but at the danger that children—to whom e-cigarettes cannot legally be sold—will obtain and use them. It is well documented that free samples of tobacco products "give young people a risk-free and cost-free way to satisfy their curiosity about tobacco products," and can be an introduction into lifelong addiction. Deeming Rule at 28,986 (internal quotation marks and citations omitted). Young people tend to be more price sensitive than adult consumers, so are particularly susceptible to becoming exposed through free samples. TCA § 2(24), 123 Stat. at 1778; *see also* Deeming Rule at 28,986. The ban does not seek to restrict the manufacturer's ability to communicate, but only to distribute its product free of charge. It leaves open many ways to help customers make product choices. It permits manufacturers to sell sample kits and retail facilities to "allow customers to touch, hold, and smell their products without violating the free sample ban." Deeming Rule at 29,055. The prohibition against distributing e-cigarettes for free is a conduct regulation that readily clears the rational-basis review applicable to ordinary market regulation.

The free sample ban's character as a conduct restriction is underscored by its bearing only on product price: Under section 1140.16(d)(1), manufacturers may not offer e-cigarettes at zero dollars. 21 C.F.R. § 1140.16(d)(1). The Supreme Court in *Expressions Hair Design v. Schneiderman*, 137 S. Ct. 1144 (2017), recently reaffirmed that ordinary price regulation does not implicate constitutionally protected speech. The surcharge ban at issue in *Expressions Hair Design* was "not like a typical price regulation," the Court observed, because—unlike the bar here against charging $0 for e-cigarettes—it did not actually restrict price; it prohibited sellers from quoting a credit card "surcharge" above the cash price, and directed that they instead offer a "discount" for paying

cash. *Id.* at 1150. That regulation, limited to the retailer's characterization of the incremental price difference, was designed to send a particular message about the charge. That is why, the Court held, it implicated speech in a way that an ordinary price restriction would not. *Id*. at 1150 (citing *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 507 (1996) (plurality opinion) (minimum prices or taxes would not restrict speech); *id.* at 524 (Thomas, J., concurring in part and concurring in the judgment); *id.* at 530 (O'Connor, J., concurring in the judgment)). The Court emphasized that a typical price restriction is constitutionally valid—even though it incidentally regulates the content of speech through requiring the seller to communicate only the lawful price. *Expressions Hair Design*, 137 S. Ct. at 1150-51. But such a law's "effect on speech would be only incidental to its primary effect on conduct, and 'it has never been deemed an abridgment of freedom of speech or press to make a course of conduct illegal merely because the conduct was in part initiated, evidenced, or carried out by means of language, either spoken, written, or printed.'" *Id.* at 1151 (quoting *Rumsfeld v. Forum for Acad. & Inst. Rights, Inc.*, 547 U.S. 47, 62 (2006)) (further citations omitted). The ban on free tobacco product samples is no different from a typical price restriction; it simply prevents purveyors from offering their e-cigarettes for free, and the Industry identifies no speech component like the price-related commentary in *Expressions Hair Design* that would implicate the First Amendment.

The constitutionality of the prohibition against free e-cigarettes samples is unaffected by the Act's allowance for distribution of free samples of chewing tobacco at "qualified, adult-only" facilities. *See* 21 U.S.C. § 387a-1(a)(2)(G); 21 C.F.R. § 1140.16(d)(2). To the Industry, that exception shows the ban "guards against youth access for one product" but "irrationally risks access to another." Appellants' Br. 42.

Because the sample ban does not regulate expression, the exception for chewing tobacco is permissible so long as it is not "so arbitrary as to fail the rational basis test." *Glickman v. Wileman Bros. & Elliott, Inc.*, 521 U.S. 457, 496 (1997). Anyone with even basic awareness of e-cigarettes and chewing tobacco, and their differential health consequences for and uptake by youth, will readily discern rational reasons to treat free samples of chewing tobacco differently from free samples of e-cigarettes. E-cigarettes are discreet and trendy in a way that chewing tobacco is not. Additionally, Congress' limited exemption for free samples of chewing tobacco in specified, controlled circumstances reflects Congress' knowledge of youth access and usage derived from years of experience. As the Industry concedes, no comparable information exists for e-cigarettes. Additionally, users of e-cigarettes inhale into their lungs myriad potentially hazardous substances not limited to those derived from tobacco. Congress' decision to exempt chewing tobacco but not e-cigarettes from the free sample ban readily survives rational basis review.

The Industry points to *Discount Tobacco* as support for its characterization of the free sample ban as "an attempt to regulate the 'communicative impact' of the activity, not the activity itself." 674 F.3d at 539. The Sixth Circuit addressed a regulation covering a range of clearly communicative promotional activities—including the distribution of tobacco-branded merchandise (t-shirts, baseball caps, bobblehead dolls) and event sponsorships—together with a prohibition on free product samples, and its First Amendment analysis grouped them together as "marketing bans." *Id*. We do not agree that banning the free distribution of a tobacco product itself is properly equated for First Amendment purposes with a ban on giving away logoed merchandise or sponsoring events in order to promote a brand. Even treating the sample ban as a "marketing ban," however, the *Discount Tobacco* court

concluded that any burden on the expressive element of free e-cigarette samples was easily justified by the FDA's "overwhelming evidence" of the danger that free samples fall into the hands of young people. *Id*. at 541. The court held that, although "an opportunity for an underage nonsmoker to actually try a tobacco product, at no cost, may serve as the best advertisement of all for a product that is physiologically addictive, and socially attractive to youth, . . . placing cigarettes and other tobacco products into the hands of minors clearly undermines the purposes and interests undergirding the Act." *Id.* The court thus concluded that "[b]anning such practices embodies a narrow fit between the harm articulated and the restriction employed." *Id*.

The same rationale provides added support for application of the free sample ban to e-cigarettes. The Industry urges us to distinguish *Discount Tobacco* on the ground that "consideration of costs and benefits for vapor products is much different than for the cigarettes at issue" in that case, because where e-cigarettes are concerned, "consumers are searching for truthful information regarding a novel and potentially life-saving product category." Appellants' Br. at 46-47. Given the relatively unknown and potentially grave risks of e-cigarettes to all users, and their extraordinary allure to middle and high school students, we cannot agree.

* * *

For the reasons discussed above, we hold that the Tobacco Control Act's premarket authorization pathway for new products does not violate the APA, and that both the preclearance pathway for modified risk products and the free sample ban are constitutional. Accordingly, we affirm the district court's judgment.

So ordered.