ORAL ARGUMENT NOT YET SCHEDULED

No. 17-5196

United States Court of Appeals
for the District of Columbia Circuit

NICOPURE LABS, LLC, RIGHT TO BE SMOKE FREE COALITION, *et al.*,

Appellants,

v.

FOOD AND DRUG ADMINISTRATION, *et al.*,

Appellees.

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

BRIEF OF *AMICI CURIAE* PUBLIC HEALTH GROUPS IN SUPPORT OF APPELLEES

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CORPORATE AND FINANCIAL DISCLOSURE STATEMENT

Amici curiae American Academy of Pediatrics, American Cancer Society Cancer Action Network, American Heart Association, American Lung Association, American Thoracic Society, Campaign for Tobacco-Free Kids, and Truth Initiative are all non-profit organizations committed to advancing the public health. No party to this filing has a parent corporation, and no publicly held corporation owns 10% or more of the stock of any of the parties to this filing.

TABLE OF CONTENTS

CORPORATE AND FINANCIAL DISCLOSURE STATEMENT i

TABLE OF AUTHORITIES iv

GLOSSARY viii

CERTIFICATE OF PARTIES, RULINGS UNDER REVIEW, AND RELATED CASES ix

STATUTES AND REGULATIONS x

STATEMENT OF IDENTITY AND INTEREST OF *AMICI CURIAE* 1

ARGUMENT 3

I. Appellants and their *amici* exaggerate the scientific evidence of claimed health benefits of e-cigarettes relative to conventional cigarettes and ignore the real health risks e-cigarettes pose 5

II. FDA review of modified-risk claims for e-cigarettes is necessary to determine whether e-cigarettes, as actually used, benefit the health of individuals and the public and is consistent with the First Amendment 10

A. Appellants and their amici avoid the central public health question that the TCA framework for modified-risk claims is designed to answer: Do e-cigarettes as they are actually used reduce the risk of disease to individual users and the population as a whole? 10

B. The scientific evidence suggests that in many circumstances e-cigarette use is associated with lower rates of smoking cessation and higher rates of smoking initiation 13

C. Modified-risk claims about e-cigarettes' relative safety warrant FDA oversight as much as false claims about low-tar cigarettes 17

D. There is a particularly compelling interest in reviewing e-cigarette makers' claims of relative safety because e-cigarettes that contain nicotine are addictive products that are being used by young persons and widely marketed in ways that appeal to young persons 20

E. FDA review of modified risk claims is narrowly tailored to advance Congress's compelling interest in reducing tobacco use 26

CONCLUSION 29

TABLE OF AUTHORITIES

CASES

Bates v. State Bar of Ariz.,
433 U.S. 350 (1977) 25

**Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*,
447 U.S. 557 (1980) 9, 18, 21, 28

**Disc. Tobacco City & Lottery, Inc. v. United States*,
674 F.3d 509 (6th Cir. 2012) 19, 28

FCC v. Pacifica Found.,
438 U.S. 726 (1978) 25

Ginsberg v. New York,
390 U.S. 629 (1968) 25

New York v. Ferber,
458 U.S. 747 (1982) 25

United States v. Philip Morris USA, Inc.,
449 F. Supp. 2d 1 (D.D.C. 2006) 19

Zauderer v. Office of Disciplinary Counsel of Sup. Ct. of Ohio,
471 U.S. 626 (1985) 9

STATUTES

21 U.S.C. § 387k(g)(1)(A) 11

21 U.S.C. § 387k(g)(1)(B) 11

Family Smoking Prevention and Tobacco Control Act,
Pub. L. No. 111-31, 123 Stat. 1777 (2009) 2, 12, 27

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Quick Stats: Cigarette Smoking Status Among Current Adult E-Cigarette Users, by Age Group-National Health Interview Survey,
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E-Cigarette Use Among Youth and Young Adults: A Report of the Surgeon General 88 (2016).....14

Dep't of Health & Human Servs.,
The Health Consequences of Smoking-50 Years of Progress: A Report of the *Surgeon General* (2014) 1, 8

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Public Health England's evidence-based confusion,
The Lancet, vol. 386 (Aug. 29, 2015) 6

Kaitlyn Berry, et al.,
E-cigarette initiation and associated changes in smoking cessation and reduction: the Population Assessment of Tobacco Health Study, 2013-2015, Tobacco Control, vol. 2018:0:1-7 (Mar. 24, 2018) 15

Katherine Zernike,
'I Can't Stop': Schools Struggle With Vaping Explosion,
N.Y. Times, Apr. 2, 2018 23

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CDC, MMWR, vol. 64, no. 38, 1061-65 (Oct. 2, 2015) 24

Mark L. Rubinstein, et al.,
Adolescent Exposure to Toxic Volatile Organic Chemicals from E-Cigarettes, Pediatrics, vol. 141, issue 4 (Apr. 2018).....8

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GLOSSARY

FDA	Food and Drug Administration
NASEM	National Academies of Sciences, Engineering, and Medicine
PHE	Public Health England
TCA	Family Smoking Prevention and Tobacco Control Act

CERTIFICATE OF PARTIES, RULINGS UNDER REVIEW, AND RELATED CASES

The parties and *amici* in this case, the ruling under review, and any related cases are described in the brief of Appellees.

STATUTES AND REGULATIONS

All applicable statutes and regulations are set forth in the brief of Appellees.

STATEMENT OF IDENTITY AND INTEREST OF *AMICI CURIAE*[1]

Amici are public health organizations: the American Academy of Pediatrics; the American Cancer Society Cancer Action Network; the American Heart Association; the American Lung Association; the American Thoracic Society; the Campaign for Tobacco-Free Kids; and Truth Initiative (collectively, "Public Health *Amici*"). These non-profit organizations have worked for decades to protect the public from the devastating harms caused by tobacco products, the leading cause of preventable death in America, claiming over 480,000 lives every year.[2]

Public Health *Amici* have serious concerns about the public health effects of electronic cigarettes ("e-cigarettes"),[3] driven by: (1) sharply increasing e-cigarette use, especially among young people; (2) the emergence of thousands of varieties of flavored e-cigarettes, many appealing strongly to young people; (3) the conceded

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[1] No party's counsel authored this brief in whole or in part. No party or party's counsel made a monetary contribution intended to fund the preparation or submission of this brief, and no person other than *amici curiae* made such a monetary contribution. All parties have consented to the filing of this brief.

[2] *See* Dep't of Health & Human Servs., *The Health Consequences of Smoking-50 Years of Progress: A Report of* the *Surgeon General* 659 (2014) ("2014 Surgeon General's Report").

[3] As used herein, "e-cigarettes" includes all electronic nicotine delivery devices, and their parts and components, deemed by FDA to fall within the definition of "tobacco product." *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; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products (Final Rule), 81 Fed. Reg. 28974, 29028 (May 10, 2016) (the "Deeming Rule").

addictiveness of nicotine-containing e-cigarettes and the adverse effects of nicotine on the still-developing adolescent brain; (4) the presence in many e-cigarettes of hazardous or potentially hazardous constituents and ingredients; (5) substantial evidence that e-cigarette use increases the risk of combustible tobacco use by youth and young adults; and (6) evidence that e-cigarettes often lead to "dual use" with combustible cigarettes rather than contributing to abstinence from combustible cigarettes.

Public Health *Amici* support the Appellee Food and Drug Administration's ("FDA") Deeming Rule extending regulatory authority over tobacco products under the Family Smoking Prevention and Tobacco Control Act ("TCA")[4] to previously unregulated tobacco products, including e-cigarettes. Public Health *Amici* participated as *amici* in the district court and similarly oppose Appellants' efforts in this Court to dismantle or weaken this regulatory framework applicable to e-cigarettes. That framework is critical to FDA's efforts to advance the TCA's goal of protecting the public health.

[4] Pub. L. No. 111-31, 123 Stat. 1777 (2009).

ARGUMENT

Appellants' central argument is that the First Amendment prohibits FDA from regulating certain "modified-risk" claims about e-cigarettes.[5] This brief focuses on one set of modified-risk claims that Appellants and their *amici* assert is constitutionally immunized from government review: claims that e-cigarettes are "safer than" conventional cigarettes.

Appellants and their *amici* argue that because, in their view, it is "fundamentally true" that e-cigarettes are "dramatically less harmful than combustible cigarettes" (Brief of the State of Iowa as *Amicus Curiae* 23-24 ("Iowa *Amicus*")), the First Amendment prohibits FDA from implementing the TCA's carefully-tailored framework for premarket review of modified-risk claims. In essence, Appellants and their *amici* assert that the government should simply let any e-cigarette maker tout to consumers, with no government review or objective evaluation of supporting scientific evidence, the alleged safety of its products compared to conventional cigarettes.

The modified-risk provisions of the TCA, however, are exceptionally important because claims regarding the relative safety of e-cigarettes—whether false, misleading, or even partially or literally true but incomplete—could have

[5] Public Health *Amici* endorse the positions taken by Appellees on issues not specifically discussed in this brief.

severe public health consequences. That is particularly so in light of the skyrocketing use of e-cigarettes among adolescents, who often encounter e-cigarettes as their first experience with addictive nicotine products. This least mature and most vulnerable segment of the population are those most likely to be misled or confused by claims encouraging use of e-cigarettes where such claims do not fully address the public health issues associated with using these products.

Government review is also important to adult smokers. Although switching completely to some e-cigarette products might benefit individual smokers who would not otherwise quit smoking, many e-cigarettes may actually make it *less* likely that a smoker will quit, leading instead to "dual use" of cigarettes and e-cigarettes. The TCA reflects Congress's determination that the consequences of public health claims by tobacco product manufacturers are too important to be left exclusively in the hands of companies trying to persuade consumers to use their products. The TCA does not prohibit modified-risk claims, and its purpose is not to deny information to the public; rather, it provides a carefully tailored procedure to ensure such claims are accurate, backed by reliable science, *and* informative enough to permit adult consumers to make their own reasoned decisions.

No e-cigarette manufacturer has presented *any* modified-risk claim to FDA for review, so FDA has had no occasion to approve, disapprove, or modify any such claim. Thus, Appellants' First Amendment claim is an abstraction, and their

(and their *amici*'s) argument that the TCA's premarket review framework for modified-risk claims is a "prophylactic ban" on such claims (App. Br. 18) for e-cigarettes lacks any factual basis.

I. Appellants and their *amici* exaggerate the scientific evidence of claimed health benefits of e-cigarettes relative to conventional cigarettes and ignore the real health risks e-cigarettes pose.

General statements that e-cigarettes are "safer than" conventional cigarettes fail to provide sufficient information to consumers, especially young people, about the health risks of using e-cigarettes. Appellants and their *amici* greatly exaggerate what is known about the safety of e-cigarettes relative to cigarettes and oversimplify the relative health effect of using e-cigarettes by relying heavily on conclusions widely criticized in the public health community as arbitrary, unscientific, and misleading. Most significantly, they rely upon a statement by Public Health England ("PHE"), England's public health agency, that cites one group's unscientific assertion that e-cigarettes are 95% safer than traditional cigarettes. *E.g.*, App. Br. 6, Iowa *Amicus* 11-12; *Amicus* Brief of Clive Bates, *et al.* 5, 8 ("Bates *Amicus*").

However, in the Deeming Rule FDA examined and rejected the "95% safer" claim. FDA noted that the panelists conducting the underlying harm analysis "were selected without any formal criterion," that there was a "lack of hard evidence" supporting most of the harm analysis, and that the methodology for arriving at the

relative harm assessments underlying the "95% safer" conclusion was "unclear." 81 Fed. Reg. at 29029-30 (internal quotations omitted). Several peer-reviewed publications have sharply criticized the scientific reliability of the "95% safer" claim. *E.g.*, Editorial, *E-cigarettes: Public Health England's evidence-based confusion*, The Lancet, vol. 386, at 829 (Aug. 29, 2015) ("the opinions of a small group of individuals with no prespecified expertise in tobacco control were based on an almost total absence of evidence of harm. It is on this extraordinarily flimsy foundation that PHE based the major conclusion and message of its report."); Martin McKee & Simon Capewell, *Evidence about electronic cigarettes: a foundation built on rock or sand?*, British Med. J., vol. h4863, at 351 (Sept. 15, 2015).[6]

In February 2018, the National Academies of Sciences, Engineering, and Medicine ("NASEM") published a report, the *Public Health Consequences of E-Cigarettes*, which comprehensively reviewed the existing scientific literature. NASEM demonstrates that a great deal of scientific uncertainty still exists regarding the relative safety of e-cigarettes. For example, NASEM concluded that

[6] One of many fundamental flaws in the study underlying the PHE "95% safer" conclusion is that it rested on measures of *aggregate global* harm. Thus, as the study itself acknowledged, the panel's conclusion regarding relative harm reflected the fact that, worldwide, cigarettes' use is "*massively greater* … as compared with other products." David J. Nutt, et al., *Estimating the Harms of Nicotine-Containing Products Using the MDCA Approach*, Euro. Addiction Res., vol. 2014:20, at 223 (Apr. 3, 2014) (emphasis added).

even if e-cigarettes prove to be far less harmful than combustible tobacco cigarettes, "the absolute risks of the products cannot be unambiguously determined at this time. Long-term health effects, of particular concern for youth who become dependent on them, are not yet clear." NASEM at S-1.

Unlike Appellants and their *amici*, NASEM recognized the complexity of the issue:

> The net public health effect, harm or benefit, of e-cigarettes depends on three factors: their effect on youth initiation of combustible products, their effect on adult cessation of combustible products, and their intrinsic toxicity. If e-cigarette use by adult smokers leads to long-term abstinence from combustible tobacco cigarettes, the benefit to public health could be considerable. Without that health benefit for adult smokers, e-cigarette use could cause considerable harm to public health in the short- and long-term due both to the inherent harms of exposure to e-cigarette toxicants and to the harms related to subsequent combustible tobacco use by those who begin using e-cigarettes in their youth.

Id. The inconclusiveness of the scientific evidence and the complexity of determining the health impact of using these products makes FDA review of health claims critical.

Appellants and their *amici* fail to acknowledge the health risks that e-cigarettes pose, much less grapple with how to account for such risks in communications about modified risk. Numerous outside studies and FDA itself have concluded that e-cigarettes are not safe and present significant health risks:

- A recent study concluded that teen e-cigarette users' saliva and urine samples contained significantly higher amounts of five cancer-causing agents than samples from non-e-cigarette users.[7]

- Another recent study found that daily e-cigarette use approximately doubles the risk of cardiovascular disease compared to non-use.[8]

- NASEM concluded that "e-cigarettes are not without physiological activity in humans, but the implications for long-term effects on morbidity and mortality are not yet clear."[9]

- The vast majority of e-cigarettes, like traditional cigarettes, contain highly addictive nicotine, *often at the same levels as combustible cigarettes*. 81 Fed. Reg. at 29029, 29031. "[A]dolescents appear to be particularly vulnerable to the adverse effects of nicotine on the central nervous system," and nicotine may have lasting adverse effects on adolescent brain development. *Id*. at 29029, 29047.[10]

- Among experienced adult e-cigarette users, there is substantial evidence that nicotine intake from e-cigarettes can be comparable to cigarettes.[11]

- Many e-cigarette aerosols deliver harmful and/or potentially harmful constituents to users' lungs. 81 Fed. Reg. at 29029 (noting that many e-cigarettes "contain chemicals that could be dangerous to consumers when inhaled"); *id.* at 29030-32 (noting that e-cigarette use involves

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[7] Mark L. Rubinstein, et al., *Adolescent Exposure to Toxic Volatile Organic Chemicals from E-Cigarettes*, Pediatrics, vol. 141, issue 4 (Apr. 2018).

[8] Talal Alzahrani, et al., *Association between Electronic Cigarette Use and Myocardial Infarction: Results from the 2014 and 2016 National Health Interview Surveys*, Soc'y for Research on Nicotine and Tobacco, Poster POS5-34 (2018).

[9] NASEM S-6.

[10] *See also* 2014 Surgeon General's Report 121-22 (noting lasting damage to adolescent brain development from nicotine exposure).

[11] NASEM 4-43.

regular inhalation of toxicants).[12]

- FDA found that many flavors that make e-cigarettes more appealing to young persons contain constituents that are hazardous when inhaled, noting, among other data, a study showing that almost three-quarters of 159 tested e-liquid flavors contained diacetyl or acetyl propionyl, substances that pose known inhalation risks. *Id*. at 29029. FDA also cited data showing that cinnamon-flavored e-liquids contained cinnamaldehyde, a chemical highly toxic to human cells. *Id.*

In light of this evidence, general claims that e-cigarettes are "safer than" conventional cigarettes omit critical information about the serious risks associated with e-cigarettes and obscure those risks by representing e-cigarettes as a largely harm-free alternative to conventional smoking. Such incomplete and misleading statements are entitled to no First Amendment protection, even were they literally true. *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557, 566 (1980); *see also Zauderer v. Office of Disciplinary Counsel of Sup. Ct. of Ohio*, 471 U.S. 626, 652 (1985) (upholding regulation of truthful commercial speech where the possibility of consumer deception was "self-evident").

Appellants also ignore differences in the risk profile of different e-cigarettes as well as the variation in health effects depending on how the product is used. They seek the right to make claims about an entire class of products without FDA review of the scientific evidence regarding any specific product. Yet the

[12] *See also* NASEM S-3, Conclusion 5-1 (finding "conclusive evidence that in addition to nicotine, most e-cigarette products contain and emit numerous potentially toxic substances").

heterogeneity of e-cigarettes precludes accurate generalization about their health effects and requires product-by-product analysis.[13] Claims that are not product-specific mask the substantial differences among e-cigarettes. Given the diversity of e-cigarettes and their health effects, FDA has a powerful interest in ensuring that health claims are supported by sound scientific evidence applicable to specific products. The TCA's review requirement is carefully tailored to advance this substantial government interest.

II. FDA review of modified-risk claims for e-cigarettes is necessary to determine whether e-cigarettes, as actually used, benefit the health of individuals and the public and is consistent with the First Amendment.

A. Appellants and their *amici* avoid the central public health question that the TCA framework for modified-risk claims is designed to answer: Do e-cigarettes as they are actually used reduce the risk of disease to individual users and the population as a whole?

As NASEM found, there is no evidence that the use of e-cigarettes reduces disease risk to smokers unless e-cigarettes completely displace the use of cigarettes.[14] Appellants' First Amendment claim rests on the assumption that the

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[13] *See* NASEM 5-32, Conclusion 5-2 (citing "conclusive evidence that … the number, quantity, and characteristics of potentially toxic substances emitted from e-cigarettes is highly variable and depends on product characteristics … and how the device is operated."). *See also* 81 Fed. Reg. at 28984, 29031 (noting the "significant variability in the concentration of chemicals amongst [e-cigarette] products—including variability between labeled content and concentration and actual content and concentration.")

[14] NASEM Conclusions 18-2 and 18-3.

evidence is sufficient to conclude that all e-cigarettes used in any way actually function as a complete substitute for, and therefore reduce overall use of, conventional cigarettes. Based on this false assumption, Appellants and their *amici* insist that the government lacks a substantial interest in requiring manufacturers seeking to make modified-risk claims to provide FDA with sound scientific evidence underlying those claims and demonstrating how consumers will understand them. *E.g.*, Iowa *Amicus* 17-18 ("None of the legislative findings in the [TCA] assert a substantial interest in silencing truthful modified-risk claims that dispel misconceptions and steer users away from combustible tobacco products."); Bates *Amicus* 17, § III ("*Because Vaping Substitutes for Smoking*, It Offers Important Public Health Gains. . . .") (emphasis added).

But Appellants and their *amici* assume away a central public health question: *To what extent do e-cigarettes actually help smokers quit smoking or avoid smoking initiation completely and thereby benefit the public health*? The TCA requires this question to be answered for *every* tobacco product, e-cigarettes or otherwise, claiming to pose lower health risks than combustible cigarettes. *See* 21 U.S.C. § 387k(g)(1)(A)-(B) (requiring that applicant demonstrate that modified-risk product as actually used, 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"). Put another way, the TCA seeks to prevent claims that would harm public health and therefore requires manufacturers to give FDA the opportunity to review the scientific evidence supporting their claim and evaluate how consumers will understand the claim and how the claim will affect consumer behavior.

Requiring such evidence for modified-risk claims is a far cry from a "ban" (App. Br. 18) on such claims and furthers a substantial government and public health interest—to ensure that modified-risk claims are based on reliable science, are accurately stated, and do not entice consumers into using products that will not actually help them stop using cigarettes or other combusted tobacco products, or encourage non-users to initiate use. As Congress explained:

> [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. Those who use products sold or distributed as modified-risk products that do not in fact reduce risk, rather than quitting or reducing their use of tobacco products, have a substantially increased likelihood of suffering disability and premature death.

TCA § 2(37), 123 Stat. 1780.

Ensuring that products claimed to reduce risk actually have that effect is particularly important because tobacco products, including most e-cigarettes,

deliver nicotine in quantities that create and sustain addiction. Even for existing adult smokers, continued nicotine addiction may undermine ultimate complete cessation of tobacco use—clearly the best individual health result. Any benefit e-cigarettes might confer even for existing smokers is therefore confined to those who otherwise would not quit.

Moreover, there are real dangers that new users who start with "safer" tobacco products will also use other nicotine products to satisfy and sustain their addiction. It is indisputable that a nicotine addict is more likely to try a cigarette than someone who has not used the drug.

B. The scientific evidence suggests that in many circumstances e-cigarette use is associated with lower rates of smoking cessation and higher rates of smoking initiation.

Appellants and their *amici* ignore significant evidence showing that their presumption of complete substitutability is wrong; in many circumstances e-cigarette use *does not* reduce combustible cigarette use or benefit the public health. This evidence suggests that in the real world e-cigarettes are most often not used *instead of* combustible cigarettes, but rather *in tandem* with combustible cigarettes, and that e-cigarettes users are more likely to go from being non-smokers to being smokers. These realities render vague, simplistic statements about the relative safety of e-cigarettes confusing or misleading—and in either case harmful to the public health. For example:

- The U.S. Surgeon General found that while more research is needed, e-cigarette use is "strongly associated" with the use of other tobacco products among youth and young adults, including conventional cigarettes.[15]

- NASEM found "substantial evidence that e-cigarette use increases risk of ever using combustible tobacco cigarettes among youth and young adults," and "moderate evidence that e-cigarette use increases the frequency of subsequent combustible tobacco cigarettes use" among youth and young adults.[16]

- A 2015 survey by the Centers for Disease Control and Prevention found that the majority of current e-cigarette users (58.8%) were also current cigarette smokers.[17]

- A recent study found that among youth who had experimented with cigarettes, those who had also used e-cigarettes were nearly twice as likely to become established smokers of traditional cigarettes.[18]

- Another study concluded that e-cigarettes cause net harm to public health on a population level. Estimating the number of persons who will stop cigarette smoking because of e-cigarette use and the number who initiated e-cigarette use and will transition to cigarette smoking, the authors found that "e-cigarette use in 2014 would lead to

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[15] Dep't of Health & Human Servs., *E-Cigarette Use Among Youth and Young Adults. A Report of the Surgeon General* 88 (2016).

[16] NASEM 16-30, 16-32.

[17] Dep't of Health & Human Servs., Ctrs. for Disease Control ("CDC"), *Quick Stats: Cigarette Smoking Status Among Current Adult E-Cigarette Users, by Age Group-National Health Interview Survey*, Morbidity and Mortality Weekly Report, vol. 65, no. 42, 1177 (2015).

[18] Shannon Lee Watkins, et al., *Association of Non-Cigarette Tobacco Product Use with Future Cigarette Smoking Among Youth in the Population Assessment of Tobacco and Health (PATH) Study, 2013-2015*, JAMA Pediatrics, vol. 172(2) (Jan. 2, 2018).

1,510,000 years of life lost"—even using the flawed 95% relative harm reduction number Appellants and their *amici* invoke.[19]

- FDA found "dual and polytobacco use pattern[s] appear[] to be common among adolescents and young adults." 81 Fed. Reg. at 29040.

Moreover, NASEM found that dual use of cigarettes and e-cigarettes "is not a proven method for combustible tobacco cigarette cessation." NASEM 18-24. FDA reached the same conclusion. *E.g.*, 81 Fed. Reg. at 29028 ("[T]here is not sufficient evidence to conclude that youth and young adults are using [e-cigarettes] as a means to quit smoking."); *id.* at 29037 (finding that systematic reviews found insufficient evidence to conclude that e-cigarettes aid smoking cessation).[20] Another recent study found that while daily use of some e-cigarettes increases the likelihood of cessation, others do not, even when used daily, and that overall, less frequent use of e-cigarettes decreases the likelihood of cessation.[21] These studies rebut Appellants' and their *amici*'s claim (*e.g.*, Bates *Amicus* 9-10) that e-cigarettes

[19] Samir S. Soneji, et al., *Quantifying population-level health benefits and harms of e-cigarette use in the United States*, PLOS ONE 13(3), at 1 (Mar. 14, 2018).

[20] *See* also Brian A. King, et al., *Awareness and Ever Use of Electronic Cigarettes Among U.S. Adults, 2010-2011*, Soc'y for Research on Nicotine & Tobacco 2013, vol. 15, no. 9, at 1623 (Sept. 2013) ("There is currently no conclusive scientific evidence that e-cigarettes promote long-term cessation, and e-cigarettes are not included as a recommended smoking cessation method by the U.S. Public Health Service.").

[21] Kaitlyn Berry, et al., *E-cigarette initiation and associated changes in smoking cessation and reduction: the Population Assessment of Tobacco Health Study, 2013-2015*, Tobacco Control, vol. 2018:0:1-7 (Mar. 24, 2018).

deserve credit for recently reduced rates of traditional cigarette smoking in the United States—reductions that began years before the advent of e-cigarettes.[22]

Appellants and their *amici* cherry-pick statements by FDA and NASEM to support their "safer than" claims for e-cigarettes (*e.g.*, Iowa *Amicus* 12-13 (citing FDA), 21 (citing NASEM); Bates *Amicus* 7 (citing NASEM); App. Br. 7 (citing FDA)). Indeed, FDA and NASEM have acknowledged that *when used as complete substitutes for combustible cigarettes*, e-cigarettes may benefit individual health by reducing users' exposure to tobacco smoke's carcinogens and toxicants. *E.g.*, 81 Fed. Reg. at 29030 (noting that "*completely switching from combusted cigarettes to [e-cigarettes]* may reduce the risk of tobacco-related disease for individuals currently using combusted tobacco products") (emphasis added); NASEM S-7 ("[T]here is conclusive evidence that *completely substituting e-cigarettes for combustible tobacco cigarettes* reduces users' exposure to numerous toxicants and carcinogens present in combustible tobacco cigarettes.") (emphasis added). But FDA and NASEM, unlike Appellants and their *amici*, also recognize that the scientific evidence demonstrates that e-cigarettes most often are *not* used as complete substitutes for conventional cigarettes and in many circumstances may, in fact, increase the risk of smoking initiation. Moreover, NASEM concluded that

[22] In fact, NASEM found that recent declines in youth cigarette smoking are consistent with trends that predate widespread use of e-cigarettes and do not represent a sharp break with that trend. NASEM 16-28.

there is "no available evidence whether … dual use changes morbidity or mortality compared with those who only smoke combustible tobacco cigarettes." NASEM 18-25, Conclusion 18-3. This evidence demonstrates a substantial governmental interest in ensuring that manufacturers seeking to make modified risk claims for e-cigarettes meet the statutory requirements.

C. Modified-risk claims about e-cigarettes' relative safety warrant FDA oversight as much as false claims about low-tar cigarettes.

Appellants and their *amici* suggest that the First Amendment allows government regulation only of "false" modified-risk claims such as those previously made by cigarette companies about the health benefits of "light" and "low tar" cigarettes. *See, e.g.*, Iowa *Amicus* 14 ("[G]eneralized modified risk claims for [e-cigarettes] are different [from 'low-tar' claims] because they are *true* …"). They are incorrect on several fronts.

First, Appellants misstate the issue. The TCA ensures that scientific evidence underlying health claims made to the public is objectively evaluated by FDA, so that the public need not depend exclusively on manufacturers' self-interested evaluation of the science. It also ensures that such claims fully reflect the risks as well as the benefits both as to the specific product and as to the likely manner in which it will be used. The TCA's purpose is not to deny information to

adult consumers, but rather to ensure that health claims provide information that is both true and adequate to permit adult consumers to make informed choices.

Second, *Central Hudson* establishes that even truthful, non-misleading commercial speech can be regulated if regulation serves a substantial government interest and is sufficiently tailored. 447 U.S. at 566. Government has a substantial interest in preventing the serious public health harms resulting from claims that are literally true but based on inaccurate presumptions about how a product will actually be used.

Contrary to Appellants' arguments, the public health disaster caused by "light" and "low tar" cigarette claims presents an informative precedent. As FDA noted in the Deeming Rule, "The mistaken belief that 'light' and 'low tar' cigarettes were safer than other cigarettes prompted many smokers to switch to such products instead of quitting altogether." 81 Fed. Reg. at 29039. Similarly, because e-cigarette users most often *do not* completely substitute those products for conventional cigarettes, but rather engage in dual use of those products or use e-cigarettes as a precursor to combustible tobacco products, statements about e-cigarettes' relative safety provide a false promise of improved health, while discouraging behavior (*i.e.*, cessation, non-initiation) that *would* have significant positive health effects. As the Sixth Circuit explained in upholding the TCA's modified-risk provisions against First Amendment challenge by tobacco

companies, modified risk claims can have a negative impact on public health "if the marketing of a product as 'modified-risk' raises the aggregate number of people (especially juveniles) who use tobacco. . . ." *Disc. Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509, 536 (6th Cir. 2012). The evidence indicates the same use patterns occur with e-cigarettes.

Moreover, the distinction Appellants and their *amici* seek to draw between "low-tar" claims and modified-risk claims for e-cigarettes has only become apparent with 20/20 hindsight. For decades, tobacco companies falsely insisted that *their* "low tar" marketing claims were truthful and not misleading because they were based on results from standardized tests using smoking machines. *E.g.*, *United States v. Philip Morris USA, Inc.*, 449 F. Supp. 2d 1, 375-77 (D.D.C. 2006). The truth about "low tar" cigarettes' adverse health impact emerged only with advances in public health scientists' understanding of cigarette design technology, disclosure of internal industry documents, epidemiological research, and a better understanding of how smokers actually smoked "low tar" cigarettes in the real world—*i.e.*, they took more, deeper puffs to sustain their nicotine addiction, causing them to inhale more smoke, thus canceling out machine-measured difference in tar yields. Dep't. of Health & Human Servs., Nat'l Cancer Inst., *Monograph 13: Risks Associated with Smoking Cigarettes with Low Machine-*

Measured Yields of Tar and Nicotine (2001).[23] Similarly here, when evaluating a modified-risk claim for a particular e-cigarette, the First Amendment does not require FDA to uncritically accept e-cigarette makers' arguments about the relative safety of different products or assumptions about how their products are used, especially in the face of contrary evidence of real-world use.

D. There is a particularly compelling interest in reviewing e-cigarette makers' claims of relative safety because e-cigarettes that contain nicotine are addictive products that are being used by young persons and widely marketed in ways that appeal to young persons.

Appellants and their *amici* insist that FDA review of their relative safety claims unconstitutionally and paternalistically denies consumers access to information that they should be able to use as they wish. *E.g.*, App. Br. 16 ("The First Amendment eschews a 'paternalistic' approach that keeps consumers in the dark."). However, the modified risk requirements are not intended to deny information to consumers, but rather to ensure that health claims are supported by reliable science and complete enough to prevent misunderstanding. Moreover, *Central Hudson* permits regulation of truthful commercial speech, so long as the regulation is tailored to serve a substantial government interest. Significantly, the

[23] NASEM similarly cautioned that "[e]xposure to nicotine and toxicants from the aerosolization of flavorings and humectants is dependent on user and device characteristics." NASEM S-1, S-4.

modified risk requirements are designed to protect those least prepared to exercise sound, informed judgment about the potential risks and benefits of modified-risk products (including e-cigarettes)—children and teenagers.

As FDA noted in the Deeming Rule, there has been an "alarming" rise in e-cigarette use by middle school and high school students in recent years. 81 Fed. Reg. at 29028. Between 2011 and 2014, the number of high school students reporting use of e-cigarettes during the previous 30 days increased nearly *800%*, from 1.5% to 13.4% (more than one in eight students). *Id.* at 28984, 29028. Between 2011 and 2013, the number of youths who had previously never smoked conventional cigarettes but who reported e-cigarette use increased from 79,000 to over 263,000. *Id.* at 29029. With "current use" defined as use at least once during the past 30 days, in 2016 more than 1.6 million high school students *and 500,000 middle school students* were using e-cigarettes.[24]

This extraordinarily disturbing increase in youth e-cigarette use is a consequence of the introduction of flavored e-cigarette products marketed to appeal to children—with flavors like cotton candy, gummy bear, and bubble gum. The TCA banned characterizing flavors in conventional cigarettes (except for

[24] Ahmed Jamal, et al., *Tobacco Use Among Middle and High School Students—United States, 2011-2016*, Dep't of Health & Human Servs., CDC, Morbidity & Mortality Weekly Rep., vol. 66, no. 23 (June 16, 2017); *see also* 81 Fed. Reg. at 28984 (over 2.4 million high school and middle school students reported current e-cigarettes use in 2014).

tobacco flavor and menthol) precisely because flavors appeal to kids. Flavored e-cigarettes similarly appeal to young people. The proposed Deeming Rule noted concerns that such flavors might appeal to youth. 79 Fed. Reg. 23142, 23157 (Apr. 25, 2014) (proposed Deeming Rule) (citing report that teenagers prefer e-cigarettes flavors like gummy bears "because it tastes really good"). One study showed that among 400 brands of e-cigarettes, 84% offered fruit flavors and 80% offered candy and dessert flavors.[25] According to FDA's 2013-2014 Population Assessment of Tobacco and Health survey, 85.3% of current youth e-cigarette users had used a flavored e-cigarette in the past month and 81.5% of current youth e-cigarette users said they used e-cigarettes "because they come in flavors I like."[26]

Indeed, in 2014, when it was marketing a leading brand of e-cigarettes, Lorillard Inc. stated on its "Real Parents Real Answers" website: "Kids may be particularly vulnerable to trying e-cigarettes due to an abundance of fun flavors such as cherry, vanilla, piña-colada and berry."[27] Given the obvious attraction of fruit-, candy-, and dessert-flavored products, 81 Fed. Reg. at 29014 (citing the

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[25] *See* Comments of the Campaign for Tobacco-Free Kids to Dkt. No. FDA-2014-N-1936, at 12 & n.26 (July 2, 2015) (citing Shu-Hong Zhu, et al., *Four Hundred and Sixty Brands of E-Cigarettes and Counting: Implications for Product Regulation*, Tobacco Control, vol. 23, suppl. 3, iii3-iii9 (2014)).

[26] B.K. Ambrose, et al., *Flavored Tobacco Use Among US Youth Aged 12-17 Years, 2013-2014*, JAMA (Oct. 26, 2015).

[27] *See* http://tinyurl.com/ecigstatement (last visited May 3, 2018).

Surgeon General's 2012 report), it is hardly surprising that use of these addictive products by kids has increased dramatically.

The risks posed by flavored e-cigarettes are exacerbated by extensive marketing of e-cigarettes in ways that appeal to kids. Such marketing frequently utilizes the same strategies that conventional cigarette makers used to attract young smokers, including use of cartoon characters, endorsements by entertainers popular with kids, sponsorships of athletic events and rock concerts, and characterization of e-cigarette users as cool or glamorous.[28]

The dramatic increases in e-cigarette use by young people, and the marketing of these products in ways that obviously attract young people, are of special concern because most e-cigarettes contain addictive levels of nicotine, often delivering as much nicotine as combustible cigarettes. 81 Fed. Reg. at 29029, 29031.[29] The best-selling e-cigarette, JUUL, which has captured a majority of the e-cigarette market and has overwhelming dominance among adolescents,[30] delivers

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[28] Comments of 24 Public Health Organizations to the Proposed Deeming Rule (Dkt. No. FDA-214-N-01898) (Aug. 8, 2014) at 21-26, 46-49.

[29] Even when e-cigarettes contain less nicotine than combustible products, "lower levels of nicotine … still have the potential to addict users…." 81 Fed. Reg. at 29031.

[30] *See, e.g.*, Katherine Zernike, *'I Can't Stop': Schools Struggle With Vaping Explosion*, N.Y. Times, Apr. 2, 2018, https://www.nytimes.com/2018/04/02/health/vaping-ecigarettes-addiction-teen.html; Anne Marie Chaker, *Schools and Parents Fight a JUUL E-Cigarette Epidemic*, Wall St. J., Apr. 4, 2018,

larger, more effective nicotine doses than its competitors and threatens to addict adolescents at record levels.[31] As FDA also concluded, "adolescents appear … particularly vulnerable to the adverse effects of nicotine on the central nervous system" and nicotine may have lasting adverse effects on adolescent brain development. 81 Fed. Reg. at 29029, 29033. Moreover, as discussed above, many flavors used in e-cigarettes to appeal to children contain constituents that are hazardous when inhaled. *Id*. at 29029.

Appellants and their *amici* argue that youth usage of e-cigarettes is largely experimental and does not represent a significant risk. *E.g.*, Bates *Amicus* 11. However, the National Youth Tobacco Survey estimated in 2014 that some 340,000 middle and high school age students were "frequent" users of e-cigarettes.[32] Moreover, Appellants' characterization of youth usage as "experimental" ignores that a large majority of youth who became addicted to

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https://www.wsj.com/articles/schools-parents-fight-a-juul-e-cigarette-epidemic-1522677246.

[31] JUUL's manufacturer claims that "JUUL is now the only alternative smoking product that delivers a nicotine experience truly akin to a cigarette, with two times the nicotine strength and three times the vapor quality of leading competitive products. *See* Press Release, Business Wire, PAX Labs, Inc. Introduces Revolutionary Technologies with Powerful E-Cigarette JUUL (Apr. 21, 2015), https://www.businesswire.com/news/home/20150421005219/en/PAX-Labs-Introduces-Revolutionary-Technologies-Powerful-E-Cigarette.

[32] Linda J. Neff, et al., *Frequency of Tobacco Use Among Middle and High School Students—United States*, 2014, Dep't of Health & Human Servs., CDC, MMWR, vol. 64, no. 38, 1061-65 (Oct. 2, 2015).

cigarettes began by "just experimenting," and thereby became addicted to nicotine and ignores evidence showing that kids who initiate tobacco use with e-cigarettes are more likely to become smokers.[33]

The Supreme Court has upheld legislation "aimed at protecting the physical and emotional well-being of youth" even when the laws have implicated constitutionally-protected speech. *See New York v. Ferber*, 458 U.S. 747, 757 (1982); *FCC v. Pacifica Found.*, 438 U.S. 726, 749-50 (1978) (upholding FCC regulation of constitutionally protected indecent speech because "the government's interest in the 'wellbeing of its youth' … justified the regulation of otherwise protected expression") (quoting *Ginsberg v. New York*, 390 U.S. 629, 640 (1968)). *See also Bates v. State Bar of Ariz.*, 433 U.S. 350, 383 & n.37 (1977) (noting that "different degrees of regulation may be appropriate in different areas" depending on the "sophistication of its audience" and upholding regulation of attorney advertising on the grounds that "the public lacks sophistication concerning legal services").

Likewise, the government has a strong interest in protecting children from messages that are *directed at them* (as well as adults), that encourage use of products that are unsafe, and that increase the likelihood they will start or continue smoking combusted cigarettes, but that make no mention of these potential adverse

[33] *See, e.g.*, *supra* pp. 14-15 and nn.18-21.

consequences. E-cigarette use by youth does increase the risk of subsequent cigarette use for many. Claims that "[e-cigarettes] are not a gateway to combustible tobacco for *consumers who understand the comparative risks*" (Iowa *Amicus* 30) (emphasis added) fall flat when e-cigarettes are widely used by those least likely to understand these risks. *See*, *e.g.*, Proposed Deeming Rule, 79 Fed. Reg. at 23159 (noting research finding that "young people may not have the ability to rationally consider the risks and benefits involved with smoking and its long-term effects" and "wrongly perceive that they are personally at less risk than others who smoke").

E. FDA review of modified risk claims is narrowly tailored to advance Congress's compelling interest in reducing tobacco use.

Appellants and their *amici* argue that including disclaimers in statements that e-cigarettes are safer than cigarettes—without requiring FDA review of such claims or the effect of the disclaimer itself—is a less restrictive way of advancing the government's interests and therefore an approach compelled by the First Amendment. However, no e-cigarette maker has proposed any disclaimers to FDA in the context of a specific modified-risk claim. This argument is premature and speculative.

The hypothetical disclaimers that Appellants and their *amici* propose—for example, Iowa's proposed disclaimer that e-cigarettes are "not as safe as not

smoking or not vaping at all" (Iowa *Amicus* 21) (emphasis omitted)—are inadequate. Someone, especially a young person, might begin to use e-cigarettes knowing that they are less safe than not smoking at all, but not understanding the increased likelihood of becoming a smoker as a result. The disclaimer suggested by Iowa, which describes risk profiles in a vacuum, would provide grossly inadequate information. This is especially true where, as here, the product is attractive to young people, who lack the fully formed judgment needed to evaluate complex, nuanced, or incomplete marketing messages.

Congress mandated FDA review to ensure that modified risk claims would be supported by scientific evidence, properly understood by consumers, and adequately informative. The TCA expressly views disclaimers as inadequate to ensure that modified-risk claims align with the TCA's overarching statutory purpose. Congress noted the "compelling governmental interest" in ensuring that modified-risk claims "relate to the *overall disease risk* of the product"—*i.e.*, that modified risk products contribute to reducing overall disease risks from tobacco products. TCA Section 2(40), 123 Stat. 1780 (emphasis added). Congress determined that requiring substantiation of these effects through premarket review was the "*only way*" to protect the public health from the risks of unsubstantiated claims that, even if accompanied by disclaimers, were "detrimental to the public health." *Id.* at Section 2(42)-(43) (emphasis added). The Sixth Circuit cited these

conclusions in finding that the "requirement that [tobacco companies] demonstrate harm reduction at both the individual and general level … survives *Central Hudson*'s fit and tailoring test"). *Disc. Tobacco*, 674 F.3d at 536. Where, as with e-cigarettes, the risks may vary depending on particular product characteristics and patterns of use, Congress's carefully tailored process is particularly important and should not be invalidated.

Finally, contrary to Appellants' contentions, Congress's conclusion that disclaimers were inadequate to mitigate misleading claims was not limited to claims about "light" and "low tar" cigarettes. Congress's rejection of disclaimers as insufficient to provide critical information about a tobacco product's overall disease risk applies to *all* modified-risk claims relating to *all* tobacco products, including e-cigarettes. There is no constitutional or other compelling reason to exempt e-cigarettes from the TCA's modified risk requirements.

CONCLUSION

For the foregoing reasons and those expressed in Appellees' brief, this Court should affirm the district court's decision.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the requirements of Federal Rule of Appellate Procedure 27(d)(2), because it contains 6,470 words, according to the count of Microsoft Word. I further certify that this brief complies with typeface requirements of Rule 27(d)(1)(E) because it has been prepared in 14-point Times New Roman Font.

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CERTIFICATE OF SERVICE

I hereby certify that on this 9th day of May, 2018, I electronically filed the foregoing Brief of *Amici Curiae* Public Health Organizations in Support of Appellees. All parties to the case have been served through the CM/ECF system.

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