ORAL ARGUMENT NOT YET SCHEDULED

No. 17-5196

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

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

Plaintiffs-Appellants,

v.

FOOD AND DRUG ADMINISTRATION, *et al.*,

Defendants-Appellees.

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

BRIEF OF THE STATE OF IOWA AS *AMICUS CURIAE* IN SUPPORT OF PLAINTIFFS-APPELLANTS AND URGING REVERSAL

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

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

A. Parties

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

Amici in this Court: Clive Bates and Additional Public Health/Tobacco Policy Authorities; NJOY, LLC.

B. Rulings Under Review

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

C. Related Cases

This case has not previously been before this Court or any other court, and the State of Iowa is not aware of any related cases that are currently pending.

D. Authority to File

The State of Iowa has authority to file this *amicus curiae* brief under D.C. Circuit Rule 29(a)(2).

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GLOSSARY

MRTP — Modified Risk Tobacco Products

MRTPR — The FDA's Modified Risk Tobacco Product Rule

ENDS — Electronic Nicotine Delivery Systems

INTEREST OF AMICUS CURIAE AND SUMMARY OF ARGUMENT

Amicus is the State of Iowa, compelled to defend its strong interest in reducing the number of Iowans who smoke combustible tobacco products. "Of the 28,000 deaths in Iowa each year, 4,400 (16%) are caused by cardiovascular disease, chronic lung disease and cancer related to smoking."[1] Beyond Iowa, "[c]igarette use remains the leading cause of avoidable death in the United States."[2] Every death from smoking cigarettes is preventable; every combustible cigarette purchased represents a missed opportunity.

The difference of risk between combustible cigarettes and non-combustibles, like e-cigarettes, is dramatic. It has long been held that nicotine addicts and combustion kills. This happens because the combustion produces and contains carbon monoxide and over a hundred other toxic chemicals. *See* FDA, *Chemicals in Cigarettes: From Plant to Product to Puff* (updated Dec. 19, 2017), https://www.fda.gov/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm535235.htm. Public Health England has concluded that e-cigarettes are at least 95% less harmful than combustibles. *See* Royal Coll. of Physicians, *Nicotine*

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[1] Iowa Dep't of Pub. Health, *Iowa Adult Cigarette Use* at 1 (2014), https://idph.iowa.gov/Portals/1/userfiles/115/surveillance%2C%20evaluation%20and%20statistics/AdultPrevFctSheet201213_CgtDemgrph_150915WebnoACE.pdf.

[2] *See* Jonathan H. Adler, *Regulatory Obstacles to Harm-Reduction: The Case of Smoking*, 11 NYU J. L. & Liberty 426, 426 (2017) (citing Dep't of Health & Human Servs., *The Health Consequences of Smoking — 50 Years of Progress: A Report of the Surgeon General* (2014)).

Without Smoke: Tobacco Harm Reduction, 83–84 (2016). Iowa has approximately 400,000 cigarette smokers—about 200,000 will die from smoking-related disease. *See* Iowa Dep't of Pub. Health, *Iowa Adult Cigarette Use* at 1. If all Iowa smokers switched to e-cigarettes, upwards of 100,000 lives could be saved.

Iowa advocates for a harm-reduction approach, which would "reduce tobacco-related health risks while assuming continued use of tobacco or nicotine-containing products." *See* Kathleen Stratton et al., Nat'l Acad. of Sci. Eng'g & Med., *Public Health Consequences of E-Cigarettes* 18-1 (2018). Researchers generally agree that "completely substituting e-cigarettes for combustible tobacco cigarettes reduces users' exposure to numerous toxicants and carcinogens present in combustible tobacco cigarettes" and reduces "adverse health outcomes" associated with smoking. *See id.* at 18-13, 18-24.

Generally, every time an alternative product is purchased in place of a combustible tobacco product, overall health outcomes improve.[3] The FDA already acknowledges that electronic nicotine delivery systems ("ENDS") can offer

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[3] A characteristic example of how popularity affects the public health outcome comes from the use of snus by men in Sweden. . . . The high prevalence of snus and low prevalence of tobacco cigarette use among tobacco users is at least partly responsible for the lowest death rates from cancer and cardiovascular disease that are observed in Sweden compared to any other European Union country.

Konstantinos Farsalinos, *E-Cigarettes: An Aid in Smoking Cessation, or a New Health Hazard?*, 12 Therapeutic Advances in Respiratory Disease 1, 4 (2017), http://journals.sagepub.com/doi/pdf/10.1177/1753465817744960.

"substantial reductions in the exposure to harmful constituents" and eliminate "most of the chemicals causing smoking-related disease from combusted tobacco use." *See* 81 Fed. Reg. 28,974 (May 10, 2016) ("Deeming Rule"), at 29,030–31; *accord* 82 Fed. Reg. 2193, 2199 (Jan. 9, 2017) (noting ENDS "lower disease risk"). And yet, the FDA's Modified Risk Tobacco Product Rule ("MRTPR") prevents ENDS manufacturers from repeating the FDA's own findings without pre-market review, which requires a massive investment and potentially indefinite delays. *See* 21 U.S.C. § 387k(b)(2)(A)(i)(I), (g)(1)–(2).

The MRTPR places a roadblock in public health advocates' path and frustrates harm-reduction objectives by requiring pre-market review of truthful, non-misleading claims that compare the health risks of using combustible tobacco products to the reduced health risks of using ENDS ("modified risk claims"). Fortunately, "[t]he First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good," and that directive "applies equally to [government] attempts to deprive consumers of accurate information about their chosen products." *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 503 (1996) (opinion of Stevens, J.).

Iowa supports rules that require pre-market review of any claim that a *combustible* tobacco product offers a comparatively lower risk than other tobacco/nicotine products—those claims are inherently misleading, and have

historically been used to mislead. But generalized modified risk claims for ENDS are different because they are *true*—and the MRTPR undermines momentum towards critical harm reduction by effectively silencing them.

I. THE MRTPR VIOLATES THE FIRST AMENDMENT BY PROHIBITING TRUTHFUL MODIFIED RISK CLAIMS THAT WOULD HELP PERSUADE CONSUMERS TO SWITCH FROM COMBUSTIBLE TOBACCO TO ENDS.

"The First Amendment's concern for commercial speech is based on the informational function of advertising." *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of N.Y.*, 447 U.S. 557, 563 (1980). Measures that burden commercial speech are reviewed under intermediate scrutiny. *See id.* at 566. Here, the MRTPR cannot withstand *Central Hudson* intermediate scrutiny because no substantial government interest is served by suppressing generalized, truthful modified risk claims that echo the FDA's conclusion that using ENDS is less harmful than using combustible tobacco products.

A. The MRTPR requires preclearance for truthful and non-misleading modified risk claims, and thus reaches speech protected by the First Amendment.

The MRTPR requires FDA pre-clearance for all ENDS marketing with any modified risk claims, whether truthful or misleading. *See* 21 U.S.C. § 387k(b)(2)(A). Thus, it reaches speech protected by the First Amendment.

The district court's *Central Hudson* analysis ended with the finding that "this provision does not ban truthful statements about health benefits or reduced risks [of modified risk tobacco products]; it simply requires that they be substantiated." *See* Opinion (7/21/17) at 93. But the FDA has not approved any MRTP applications, even when exhaustively substantiated. *See* Mem of P. & A. in

Supp. of Nicopure's Mot. [Dkt. # 20-1] ("Nicopure Mem."), at 39 & nn.24–25. As implemented thus far, the MRTPR would "effectively produce a total ban" on all modified risk claims. *See Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 583 n.3 (2001) (Thomas, J., concurring in part); *see also* News Release, *FDA Takes Action on Applications Seeking to Market Modified Risk Products* (Dec 14, 2016), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm533219.htm (requiring amendment to application for modified risk claim that snus present "substantially lower risks to health than cigarettes," despite clear success of snus in reducing rates of smoking-related disease/death when widely adopted in Sweden). And the MRTPR burdens ENDS manufacturers who make truthful modified risk claims with compliance costs, which can be exorbitant. *See* Opinion (7/21/17) at 65–67 (discussing regulatory impact analysis findings). Even if the FDA approved truthful modified risk claims more expeditiously, "its purpose to suppress speech and its unjustified burdens on expression" subjects it to First Amendment scrutiny. *See Sorrell*, 564 U.S. at 566.

B. The MRTPR requires preclearance for truthful and non-misleading modified risk claims, and thus reaches speech protected by the First Amendment.

The FDA asserts a "substantial government interest in preventing inaccurate and harmful health claims about tobacco products of the sort that the industry has made for many decades." *See* Deeming Rule, 81 Fed Reg. at 28,987; *cf. Discount*

Tobacco City & Lottery, Inc. v. United States, 674 F.3d 509, 534 (6th Cir. 2012) (focusing on "the risk that the tobacco industry will make fraudulent claims regarding the relative health benefits of the products that it markets."). Iowa agrees that combustible tobacco products were marketed with misleading comparative risk claims, and the FDA should continue to assert a substantial interest in silencing untrue/misleading modified risk claims that downplay the serious risks of combustible tobacco products. *See, e.g.*, Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111–31, § (2)(38) ("FSPTCA") ("[M]istaken beliefs about the health consequences of smoking 'low tar' and 'light' cigarettes can reduce the motivation to quit smoking entirely and thereby lead to disease and death.").

But the MRTPR prevents ENDS manufacturers from countering those misconceptions with true information—and many smokers are still under the impression that ENDS present the same health risks as combustible tobacco products. *See* Timothy R. Huerta et al., *Trends in E-Cigarette Awareness and Perceived Harmfulness in the U.S.*, 52(3) Am. J., Prev. Med. 339, 339 (2017) ("Perception that e-cigarettes were less harmful than regular cigarettes declined from 50.7% in 2012 to 43.1% in 2014.").[4] None of the legislative findings in the

[4] *See also* Alexander Persoskie et al., *Criterion Validity of Measures of Perceived Relative Harm of E-Cigarettes and Smokeless Tobacco Compared to Cigarettes*, 67 Addictive Behaviors 100, 100–05 (2017) (analyzing data showing that "[o]n direct measures, 26% of adults rated e-cigarettes as less harmful than cigarettes," and using behavioral data to confirm that "[d]irect measures appear to

FSPTCA assert a substantial interest in silencing truthful modified risk claims that dispel misconceptions and steer users *away* from combustible tobacco products. *See* FSPTCA, at § 2; *cf.* Deeming Rule, 81 Fed. Reg. at 28,998 ("[I]f ENDS promote transition from combustible tobacco use among current users, there could be a public health benefit."). Indeed, the government should be overjoyed at any modified risk claim that reduces combustible tobacco use, which is "the foremost preventable cause of premature death in America" and kills 480,000 each year. *See* FSPTCA, at §2(13); Dep't of Health & Human Servs., *The Health Consequences of Smoking*, *supra* at 676–79; *accord* Royal Coll. of Physicians, *Nicotine Without Smoke*, at 188–90 ("Allowing messages on [ENDS] harm relative to smoking in commercial and government media campaigns could help to reverse the growing misconception that e-cigarettes and tobacco cigarettes are similarly harmful.").

The government cannot claim a substantial interest in prohibiting modified risk claims that are neither untruthful nor misleading, and that reduce combustible tobacco use. *See 44 Liquormart*, 517 U.S. at 496–97 ("[A] State's paternalistic assumption that the public will use truthful, nonmisleading commercial

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provide valid information about individuals' harm beliefs"); *cf.* Ann McNeill et al., *E-Cigarettes: An Evidence Update* at 6, 11, 57–62 (Pub. Health England 2015) ("There has been an overall shift towards the inaccurate perception of [ENDS] being as harmful as cigarettes over the last year in contrast to the current expert estimate that using [ENDS] is around 95% safer than smoking."), https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/457102/Ecigarettes_an_evidence_update_A_report_commissioned_by_Public_Health_England_FINAL.pdf.

information unwisely cannot justify a decision to suppress it."). But the MRTPR effectively silences truthful/beneficial modified risk claims by burdening them with arbitrary roadblocks, which renders it unconstitutionally overbroad.

All MRTP applications must include supporting scientific research on the product's effects, observational data on "how consumers actually use" the product, and "such other information as the Secretary may require." 21 U.S.C. § 387k(d). No MRTP can be approved without establishing that the product, "as it is actually used by consumers," will "benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products." *See id.* § 387k(g)(1)(B) & (g)(2)(B)(iv). That determination involves considering "the increased or decreased likelihood that persons who do not use tobacco products will start using the [MRTP]." *See id.* § 387k(g)(4)(C). Proving any particular effect of a specific product on consumers' hypothetical behavior will require long-term market studies that the FDA can arbitrarily reject if it disagrees with necessarily speculative assumptions. Additionally, if the FDA construes the required showings about potential long-term health effects to require "long-term, population-level research" and "longitudinal studies," an entire generation of smokers will continue to use combustible tobacco products while the MRTPR forces ENDS manufacturers to hold their tongues. *See* Deeming Rule, 81 Fed. Reg. at 29,029; *accord id.* at 29,014 ("More research, especially longitudinal

research, is needed to understand how flavoring impacts tobacco use over time."). ENDS manufacturers estimate that "submitting an application to get a product approved would take more than 1,700 hours and cost more than $1 million." *See* Sabrina Tavernise, *F.D.A. Imposes Rules for E-Cigarettes in a Landmark Move*, N.Y. Times (May 5, 2016), http://nyti.ms/23rXQXX. And even then, all relevant provisions emphasize that FDA approval is *discretionary*, which raises the specter of impermissibly arbitrary refusals to approve MRTP marketing that complies with all relevant requirements. *See, e.g.*, *City of Lakewood v. Plain Dealer Pub. Co.*, 486 U.S. 750, 755–59 (1988). All of these provisions and features will burden truthful modified risk claims to the point of silencing them.

C. Requiring that ENDS products carry a generalized modified risk disclaimer—coupled with post-market review and enforcement by the FDA, state attorneys general, and private claimants—would advance the asserted interest without suppressing true speech.

Generally, "if the Government could achieve its interests in a manner that does not restrict speech, or that restricts less speech, the Government must do so." *Thompson v. Western States Medical Center*, 535 U.S. 357, 371–72 (2002)). Leading cases that resolve First Amendment challenges to restrictions on commercial speech have typically viewed "disclaimers as constitutionally preferable to outright suppression." *Pearson v. Shalala*, 164 F.3d 650, 657 (D.C. Cir. 1999). "[D]isclosure requirements trench much more narrowly on an advertiser's interests than do flat prohibitions on speech." *See Zauderer v. Office of*

Disciplinary Counsel of Supreme Court of Ohio, 471 U.S. 626, 651 (1985); *see also Peel v. Attorney Registration and Disciplinary Comm'n of Illinois*, 496 U.S. 91, 110 & n.17 (1990).

ENDS-specific disclaimers would be a constitutionally preferable alternative to the MRTPR and would fulfill the same objectives. Instead of prohibiting truthful, non-misleading modified risk claims, the FDA could require ENDS products to carry a mandatory disclaimer that succinctly explains the FDA's general findings regarding ENDS products, like this:

THIS PRODUCT IS LESS HARMFUL THAN CIGARETTES BUT NOT AS SAFE AS NOT SMOKING OR VAPING AT ALL

Those eighteen words (in addition to language about the addictive property of nicotine products) would summarize the scientific community's findings. *See* Kathleen Stratton et al., Nat'l Acad. of Sci. Eng'g & Med., *Public Health Consequences of E-Cigarettes* at 18-1 ("There 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."). Mandatory disclaimers are a "far less restrictive alternative" that would fully address the concerns identified in the FSPTCA, by the FDA, by *Discount Tobacco*, and by the district court. *See Thompson*, 535 U.S. at 376.

Such disclaimers would eliminate most commercial incentives to make untruthful or misleading modified risk claims. If the FDA-mandated disclaimer informs consumers that ENDS are comparatively less harmful than cigarettes, many rational ENDS manufacturers will determine that making additional modified risk claims could expose them to legal liability without adding anything meaningful to the FDA's original proclamation. Others would identify an incentive to "develop products about which truthful positive health claims can be made"—as long as they were free to make truthful modified risk claims that would "position their products as healthier or less dangerous than their competitors." *See* Adler, *Regulatory Obstacles*, at 464; *see also* J. Howard Beales III, *Health-Related Claims, the Market for Information, and the First Amendment*, 21 Health Matrix: J. Law-Med. 7, 8–10 (2011) (discussing incentives for product advertising that highlights "the absence of a negative characteristic" in comparison to competing products that possess those negative characteristics).

That disclaimer requirement could work in tandem with rigorous after-market review of suspicious modified risk claims. The deterrent value of potential FDA action can be supplemented by the potential for untruthful modified risk claims to create massive tort liability. *See, e.g.*, *Altria Group, Inc. v. Good*, 555 U.S. 70, 72–76, 87–91 (2008); 21 U.S.C. § 387p(b) (clarifying that FSPTCA did not affect "the liability of any person under the product liability law of any State").

Indeed, any ENDS product would be "misbranded" if its labeling or advertising are misleading, and the FDA could seek injunctions against sale of those products, along with massive monetary penalties and/or product seizures for violating applicable provisions of the FDCA. *See* 21 U.S.C. §§ 331(a), 332(a), 333(f)(9)(B), 334(a)(2), 387c(a)(1) & (a)(7)(A). The Iowa Attorney General's Office is prepared to take action against any untruthful health claims, and could join with other states in multistate actions against malfeasant companies. State Attorneys General have a rich and successful history of multistate litigation and enforcement, especially in tobacco-related areas.

Discount Tobacco rejected the possibility of "post-market review of deceptive claims" because such measures "have already been tried and found wanting" and the addictive quality of nicotine makes it "a virtual impossibility to unring the bell of misinformation after it has been rung." *See Discount Tobacco*, 674 F.3d at 537. It is true that post-market review was ineffective at stopping large cigarette manufacturers from misleading the public—the entire industry colluded to obfuscate the issue, suppress unfavorable research, and create sham entities to spread misinformation about cigarettes, unconnected to any specific brand. *See id.* But there are two important differences. First, the claims made about cigarettes were fundamentally and totally false. Here, the modified risk claims being made—that e-cigarettes are dramatically less harmful than combustible cigarettes—are

fundamentally true. This changes the constitutional analysis, and also removes any lingering incentive to make potentially misleading claims. Second, this burgeoning market for ENDS is different: it is crowded with smaller manufacturers who, unlike "Big Tobacco," cannot afford to flaunt the FDA with impunity (or create numerous future tort claimants) and cannot expect to capture a meaningfully large share of the market from any collusive scheme. *See* Shu-Hong Zhu et al., *Four Hundred and Sixty Brands of E-Cigarettes and Counting: Implications for Product Regulation*, 23 Tobacco Control iii3, iii5–6 (2014) (finding "a net increase of 10.5 brands and 242 new flavors per month" in ENDS markets, and observing newer sellers were "significantly less likely to make those claims that made e-cigarettes controversial in the first place"). Additionally, an ENDS-exclusive company has outstripped "Big Tobacco" and currently boasts the largest market share among all ENDS purveyors. *See* Richard Craver, *Juul Continues to Expand E-Cig Market Share Gap with Vuse; Newport Keeps Ticking Up*, Winston-Salem Journal (Jan. 10, 2018), http://www.journalnow.com/business/juul-continues-to-expand-e-cig-market-share-gap-with/article_a18fad85-7200-5bc1-a148-a4055bdf2e4b.html.

"[C]oncern about the possibility of deception in hypothetical cases is not sufficient to rebut the constitutional presumption favoring disclosure over concealment." *See Ibanez v. Florida Dep't of Business and Prof'l Regulation*, 512 U.S. 136, 146 (1994) (quoting *Peel*, 496 U.S. at 111). This is a different industry

with more vulnerable players who compete for consumers who are well aware (and routinely reminded) that smoking is never safe and nicotine is addictive, in a relatively hostile legal/regulatory environment where the chief regulatory agency proclaims its frustration with misleading modified risk claims. *See* Deeming Rule, 81 Fed. Reg. at 28,975. There is no basis for concluding that, without pre-market review of modified risk claims, ENDS manufacturers would stake their livelihoods on untruthful modified risk claims—especially when the inclusion of a generalized, truthful modified risk claim in an FDA-mandated disclaimer would minimize any incentive to gild the lily with false claims. *Accord Lorillard Tobacco Co.*, 533 U.S. at 565 ("[T]o the extent that cigar products and cigar advertising differ from that of other tobacco products, that difference should inform the inquiry into what speech restrictions are necessary.").

The district court deferred to legislative findings that permitting ENDS manufacturers to make modified risk claims, "even if accompanied by disclaimers would be detrimental to the public health." *See* Opinion (7/21/17) at 92–93 (quoting FSPTCA § 2(41)–(42)). But simply reciting that assertion cannot be enough carry the government's burden to demonstrate that less restrictive alternatives would be inadequate to solve the problem. *See Ibanez*, 512 U.S. at 146 (quoting *Edenfield v. Fane*, 507 U.S. 761, 771 (1993)) ("If the protections afforded commercial speech are to retain their force, we cannot allow rote invocation of the

words 'potentially misleading' to supplant the [government's] burden to demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree."). Because requiring a generalized modified risk disclaimer for ENDS products would achieve the asserted government interest without the MRTPR's unnecessary burdens on truthful commercial speech, the MRTPR cannot survive *Central Hudson* intermediate scrutiny.

D. Silencing truthful claims to protect non-smokers is unconstitutional, misguided, and counterproductive.

For any modified risk claim—including advertisements that simply repeat the FDA's findings on the reduced health risks that ENDS present— ENDS manufacturers need to prove their products "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." *See* 21 U.S.C. § 381k(g)(1)(B) & (2)(B)(iv). The FDA asserts that "it is possible that such products may result in overall public health harm if individuals who would not have initiated tobacco use in the absence of ENDS ultimately graduate to combusted products." *See* Deeming Rule, 81 Fed. Reg. at 28,998. That analysis, as applied to truthful claims, is constitutionally impermissible. Additionally, it misunderstands ENDS-related behavioral research. And, most importantly for Iowa, it suggests that relatively minor health impacts on non-smokers can justify allowing preventable deaths among smokers. Whatever happens to the MRTPR, these provisions should not survive.

1. Silencing truthful modified risk claims because of concerns about how consumers might behave when correctly informed is unconstitutional.

A truthful modified risk claim may fail pre-market review if the FDA finds the product is not beneficial to populations of non-smokers. *See* 21 U.S.C. § 381k(g)(1)(B) & (2)(B)(iv). "But 'the fear that people would make bad decisions if given truthful information' cannot justify content-based burdens on speech." *Sorrell*, 564 U.S. at 577 (quoting *Thompson*, 535 U.S. at 374). As applied "against truthful, nonmisleading commercial speech," this rationale relies upon "the offensive assumption that the public will respond 'irrationally' to the truth." *See 44 Liquormart*, 535 U.S. at 503 (quoting *Linmark Associates, Inc. v. Willingboro*, 431 U.S. 85, 96 (1977)). ENDS manufacturers "have an interest in conveying truthful information about their products to adults, and adults have a corresponding interest in receiving truthful information about [ENDS]." *See Lorillard Tobacco Co.*, 533 U.S. at 564. "It is precisely this kind of choice, between the dangers of suppressing information, and the dangers of its misuse if it is freely available, that the First Amendment makes for us." *See Virginia Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 770 (1976); *accord 44 Liquormart*, 535 U.S. at 496–97, 503. This application of the MRTPR to truthful modified risk claims is flatly unconstitutional.

2. Modified risk claims about ENDS are beneficial to public health under any rational set of assumptions.

Under all realistic scenarios, widespread adoption of ENDS would reduce combustible cigarette use and would be beneficial to public health.[5] It is almost absurd to suggest that informing consumers that e-cigarettes are significantly less harmful than cigarettes will produce more combustible smokers than keeping the truth from them. The MRTPR requires ENDS manufacturers to construct counterfactual speculations and invest heavily in longitudinal research to prove an effect that is already readily observable.

E-cigarette use rates for adults are at an all-time high, and combustible use rates are at an all-time low. *See* Elyse Phillips et al., *Tobacco Product Use Among Adults — United States, 2015*, 66 Morbidity & Mortality Wkly. Rep. 1209, 1211–14 (2017). The same pattern emerges among juveniles. *See* Ahmed Jamal et al., *Tobacco Use Among Middle and High School Students — United States, 2011–2016*, 66 Morbidity & Mortality Wkly. Rep. 597, 599–601 (2017). An obvious causal relationship emerges from data showing that "prolonged use of e-cigarettes is associated with a higher smoking cessation rate, independent of the effect of baseline intention to quit smoking." *See* Yue-Lin Zhuang et al., *Long-Term E-*

[5] *See* Kathleen Stratton et al., Nat'l Acad. of Sci. Eng'g & Med., *Public Health Consequences of E-Cigarettes* at 19-3 (noting that initiation/cessation modeling forecasts assuming the "extreme upper limit" of harms from e-cigarette were included to "illustrate the level of such negative effects necessary to counterbalance the potential benefits of e-cigarettes at the population level").

Cigarette Use and Smoking Cessation: A Longitudinal Study with U.S. Population, 25 Tobacco Control i90, i94 (2016), http://dx.doi.org/10.1136/tobaccocontrol-2016-053096. And a recent Truth Initiative poll showed that "80% of former smokers and 69% of current smokers cited reducing or quitting smoking as at least one reason for using e-cigarettes." *See* Truth Initiative, *Vaping and Confused: Adult Smoker and Former Smoker Perceptions and Use of E-Cigarettes* at 4, 8 (2017), https://truthinitiative.org/sites/default/files/VapingAndConfused.pdf.

By acting as a substitute for combustible tobacco products, ENDS present an obvious public health benefit. But the MRTPR requires ENDS manufacturers navigate a convoluted, expensive, and arbitrary process to convince the FDA of public health impacts that are readily ascertainable and unambiguously positive. Even when a real-life experimental group offered the world's greatest example of successful harm reduction—namely, Sweden's massive public health triumph from widespread adoption of snus, which decimated rates of both combustible use and smoking-related diseases—the FDA refused to authorize any generalized modified risk claims. *See* Farsalinos, *E-Cigarettes: An Aid in Smoking Cessation*, *supra* at 4; News Release, *FDA Takes Action*, *supra*. This illustrates how FDA concerns about "those who do not use tobacco products" obstruct efforts to reach smokers who are currently at serious risk of smoking-related disease and preventable death.

3. ENDS are not a gateway to combustible tobacco for consumers who understand the comparative risks.

Concerns that juveniles/non-smokers will use ENDS and then "graduate" to combustible tobacco products are overblown. The FDA's own data is reassuring:

> Data reported by the CDC's National Center for Health Statistics (NCHS), which provides the first estimates of e-cigarette use among U.S. adults from a nationally representative household interview study, indicate that current cigarette smokers and recent former smokers (i.e., those individuals who quit smoking within the past year) were more likely to use e-cigarettes than long-term former smokers (i.e., those individuals who quit smoking more than one year ago) and adults who had never smoked.

See 81 Fed. Reg. 28,974 (May 10, 2016) ("Deeming Rule"), at 29,028; *see also* Andy S.L. Tan et al., *Comparison of Beliefs About E-Cigarettes' Harms and Benefits Among Never Users and Ever Users of E-Cigarettes*, 158 Drug & Alcohol Dependence 67, 73 (2016) (noting that "e-cigarette users tended to be current and former smokers in this sample"). ENDS products are mostly helping to bridge the gap for cigarette smokers who want to quit but still need nicotine or derive comfort from imitating familiar smoking behaviors—not for non-smokers who want to start smoking cigarettes. *See, e.g.*, Royal Coll. of Physicians, *Nicotine Without Smoke: Tobacco Harm Reduction* at 95–102, 128–29, 185–86.

The key to keeping consumers moving in that direction on the FDA's "continuum of risk" is ensuring that consumers have accurate information about comparative health risks. But U.S. adults are increasingly misinformed—they

"increasingly believe that e-cigarettes could be as harmful as combustible cigarettes," perhaps because "the nature of the regulatory environment influences perceptions of e-cigarettes." *See* Ban A. Majeed et al., *Changing Perceptions of Harm of E-Cigarettes Among U.S. Adults, 2012–2015*, 52(3) Am. J. Prev. Med. 331, 332, 335–36 (2017). By preventing ENDS purveyors from responding to "the urgent need to convey accurate information to the public, especially adult smokers, about the available scientific evidence of the harm of e-cigarettes compared with combustible cigarettes," the MRTPR sabotages progress towards harm reduction and creates the danger that consumers will stop moving down the risk continuum or reverse direction. *See id.* at 336.

Discount Tobacco highlighted "the government's compelling interest in reducing juvenile tobacco use." *See Discount Tobacco*, 674 F.3d at 536. Concerns about juveniles using ENDS as a "gateway" to combustible tobacco (like most "gateway drug" claims) mistake correlation for true causation. *See, e.g.*, Lynn T. Kozlowski & Kenneth E. Warner, *Adolescents and E-Cigarettes: Objects of Concern May Appear Larger Than They Are*, 174 Drug & Alcohol Dependence 209, 210–11 ("[C]haracteristics of the person and the context generally determine patterns of substance use more than which substance is used first."). Juvenile ENDS use is heavily experimental, rarely amounting to regular use and readily distinguishable from regular combustible use. *See* Andrea C. Villanti et al.,

Frequency of Youth E-Cigarette and Tobacco Use Patterns in the United States: Measurement Precision is Critical to Inform Public Health, 19 Nicotine & Tobacco Research 1345, 1349 (2017), https://doi.org/10.1093/ntr/ntw388 (noting juvenile use of e-cigarettes showed "high prevalence of ever use and higher rates of infrequent experimentation compared with cigarettes, but low daily use"); Cathy L. Backinger, Presentation, *Youth Use of Electronic Cigarettes* at 9 (Mar. 8, 2017) (reporting on CDC survey data showing juvenile use of e-cigarettes: 0.5% daily or frequent use, 3.1% past 30 day use, and 10.7% ever use"), http://goo.gl/TfQcWy; *cf.* McNeill et al., *E-Cigarettes: An Evidence Update*, *supra* at 55 (citing English survey data showing that "98.5% of experimenting students did not continue use" of e-cigarettes beyond initial experimentation).

Moreover, juveniles who have used both ENDS and combustible tobacco (beyond isolated experimentation) mostly use ENDS as *substitutes* for cigarettes.

> On a population level, it appears that youth are more likely to use e-cigarettes instead of cigarettes rather than use cigarettes because of e-cigarettes. . . . This matches several other studies that use policy variation from e-cigarette MLSA [minimum legal sale age] laws to document a pattern of substitution. . . . [A]bout 2/3rds of youth smoke before they vape (versus 1/3rd reporting the opposite relationship), which suggests that e-cigarettes are more likely to be used as 'exit ramps' rather than gateways.

Michael F. Pesko & Casey Warman, *The Effect of Prices on Youth Cigarette and E-Cigarette Use: Economic Substitutes or Complements?* at 9, 14 (2017), http://dx.doi.org/10.2139/ssrn.3077468; *see* Abigail S. Friedman, *How Does*

Electronic Cigarette Access Affect Adolescent Smoking?, 44 J. Health Econ. 300, 307 (2015) ("[A]nalysis of state bans on e-cigarette sales to minors indicates that these restrictions on e-cigarette access increase adolescent smoking by 0.9 percentage points, with the impact only evident once the ban goes into effect, and only among those subject to the ban."). The availability of ENDS products is an obvious and logical explanation for the sudden, precipitous, and unprecedented drop in juvenile combustible tobacco use.

> Countering the rise in [juvenile] e-cigarette use through 2014 was a striking decrease in cigarette smoking. From 2013–15, NYTS reported a 27% decrease in 30-day smoking prevalence among high school students. MTF found a very similar decrease of 30% among high school seniors. Both are unprecedented declines. The decreases recorded by MTF for each of 2013–14 and 2014–15, each exceeding 16%, surpassed the largest annual percentage decline in the survey's 40-year history. . . . These decreases in [juvenile] cigarette smoking are not consistent with e-cigarette use spurring smoking.

Kozlowski & Warner, *Adolescents and E-Cigarettes*, *supra* at 211. This replacement effect occurs because juveniles, as the primary targets of most anti-smoking campaigns, are comparatively more likely to know that ENDS are less harmful than cigarettes. *See* Bridget K. Ambrose et al., *Flavored Tobacco Product Use Among U.S. Youth Aged 12–17 Years, 2013–2014*, 314 J. Am. Med. Ass'n. 1871, 1872 tbl.2 (2015) (noting that 79.1% of juvenile respondents who had used e-cigarettes reported choosing them "because they might be less harmful to me than cigarettes," and 59.5% chose e-cigarettes "because they help people to quit

smoking cigarettes"). This body of research illustrates that concerns about ENDS products functioning as a "gateway" to cigarettes are largely illusory, that such dangers only materialize in the *absence* of true information about comparative health risks, and that harm reduction approaches can succeed if consumers are armed with accurate information. The MRTPR, as applied to truthful modified risk claims about ENDS, is fundamentally misguided and serves no substantial interest in public health.

4. The FDA should permit attempts to encourage smokers to stop using combustible tobacco products and to save them from preventable disease and death, regardless of minor impacts on new ENDS users.

The FDA's stated concern with ENDS products is that *non-smokers* will perceive them as safe alternatives to combustible tobacco, start using them, and become addicted to nicotine. *See* Deeming Rule, 81 Fed. Reg. at 28,998 ("Since ENDS products contain nicotine, it is possible that such products may result in overall public health harm if individuals who would not have initiated tobacco use in the absence of ENDS ultimately graduate to combusted products . . . or if the users would never have initiated tobacco use absent the availability of ENDS."). Both the district court and *Discount Tobacco* focused on that possibility: "in the context of a deadly and highly addictive product, it would be a virtual impossibility to unring the bell of misinformation after it has been rung." *See* Opinion (7/21/17) at 91–92 (quoting *Discount Tobacco*, 674 F.3d at 537). But the FDA *already*

requires every nicotine product to carry a disclaimer to inform consumers that nicotine is highly addictive. *See* Deeming Rule, 81 Fed. Reg. at 29,017, 29,060, 29,073–74 (confirming that "an e-liquid with nicotine is a covered tobacco product" and must include its warning that "[n]icotine is an addictive chemical"). Modified risk claims only impact consumers who choose to use nicotine, despite (or because of) its addictive quality—and for that set of nicotine users, the FDA "recognizes that completely switching from combusted cigarettes to ENDS may reduce the risk of tobacco-related disease" in light of "the products' comparative placements on the continuum of nicotine-delivering products." *See id.* at 29,030. Having identified the grievous health risks to cigarette smokers and the availability of less harmful alternatives, there is no time to waste. *See* Lynn T. Kozlowski & David T. Sweanor, *Young or Adult Users of Multiple Tobacco/Nicotine Products Urgently Need to Be Informed of Meaningful Differences in Product Risks*, 76 Addictive Behaviors 376, 377 (2018) (arguing "[t]he priority for this group of multiple-tobacco/nicotine product users should be to try to reduce risks as much as possible," because "to worry about gateways is like worrying about shutting the barn door after the horse has escaped."). Certainly, all consumers should be warned that nicotine is an addictive substance, and the FDA's disclaimer requirements ensure they will be. *See* Deeming Rule, 81 Fed. Reg. at 29060, 29069, 29073–74. But the smokers who are already addicted to nicotine—including juveniles—

deserve accurate information about the serious health risks inherent to combustible tobacco and about available alternatives that minimize those health risks. Each use of combustible tobacco products exposes a smoker (and anyone nearby) to carcinogenic, cancerous inhalants that are unique to combustible tobacco—and not present in ENDS. *See* Kathleen Stratton et al., Nat'l Acad. of Sci. Eng'g & Med., *Public Health Consequences of E-Cigarettes* at 18-13.

The MRTPR, the district court, and *Discount Tobacco* idealize "the nicotine abstinence demanded by the tobacco control community" while disregarding the monumental harms that will result when "millions of smokers will be dissuaded from switching to these much less hazardous alternatives." *See* Riccardo Polosa et al., *A Fresh Look at Tobacco Harm Reduction: The Case for the Electronic Cigarette*, 10:19 Harm Reduction J. at 8–9 (2013), https://doi.org/10.1186/1477-7517-10-19. Although well-intentioned, their "[a]ttempts to undermine this kind of harm reduction approach" by silencing truthful modified risk claims about ENDS "can play into the hands of the tobacco industry by fostering business as usual for deadly cigarettes." *See* Lynn T. Kozlowski, *Prospects for a Nicotine-Reduction Strategy in the Cigarette Endgame: Alternative Tobacco Harm Reduction Strategies*, 216 Int'l J. Drug Pol'y 543, 545 (2015). Major gains in public health and harm reduction are possible with a focus on changing behavior among people whose lives are at risk: cigarette smokers.

> This massive burden of death, disability and lost opportunity has been entirely avoidable, and much of it can still be prevented by measures that encourage as many smokers as possible, as soon as possible, to stop smoking. . . .
>
> [A]lmost all [approaches] would be complemented by promoting harm-reduction approaches that encourage smokers, who otherwise prove unwilling or unable to quit smoking, to switch to an alternative, low-hazard source of nicotine. . . .
>
> The evidence summarised in this report demonstrates that the emergence of e-cigarettes has generated a massive opportunity for a consumer- as well as a healthcare-led revolution in the way that nicotine is used in society.

See Royal Coll. of Physicians, *Nicotine Without Smoke*, at 182–83, 188.[6] Against that backdrop, no substantial government interest can be served by silencing truthful modified risk claims that would help save smokers' lives, pending a counterfactual analysis of non-smokers' hypothetical reactions.

[6] *See also* Shu-Hong Zhu et al., *E-Cigarette Use and Associated Changes in Population Smoking Cessation*, 358 BMJ at 5–6 (2017), https://doi.org/10.1136/bmj.j3262 (noting that "in 2014–15, e-cigarette users in the United States attempted to quit cigarette smoking and succeeded in quitting at higher rates than non-users," and that represents "the first time in almost a quarter of a century that the smoking cessation rate in the US has increased at the population level"); Riccardo Polosa, *Electronic Cigarette Use and Harm Reversal: Emerging Evidence in the Lung*, 13 BMC Med. at 1–3 (2015), https://doi.org/10.1186/s12916-015-0298-3 (discussing "emerging evidence that [ENDS] use can reverse harm from tobacco smoking"); *accord* Kathleen Stratton et al., Nat'l Acad. of Sci. Eng'g & Med., *Public Health Consequences of E-Cigarettes* at 18-24.

CONCLUSION

Requiring ENDS manufacturers to include disclaimers that provide generalized, truthful statements about modified risk, together with post-market review and enforcement, would address the purported public health interest in dispelling misconceptions about the health risks of ENDS in absolute terms, while allowing manufacturers to market ENDS products as comparatively healthier alternatives to combustible tobacco products, to encourage smokers to choose ENDS, and to help prevent them from dying preventable deaths. *See* Adler, *Regulatory Obstacles to Harm Reduction*, 11 NYU J. L. & Liberty at 427 ("In the case of tobacco harm reduction, entrepreneurs have the opportunity to do well by doing good."). The MRTPR chooses a more restrictive means to the same ends, which means it cannot survive intermediate scrutiny under *Central Hudson*.

About 400,000 Iowans smoke cigarettes. *See* Iowa Dep't of Pub. Health, *Iowa Adult Cigarette Use* at 1. They are addicted to nicotine, but they could avoid serious health risks associated with combustible tobacco if they used ENDS instead. The FDA accepts the overwhelming consensus among researchers: that ENDS are less harmful than combustible tobacco. Iowa wants smokers to hear that message from ENDS manufacturers at the point of sale (and everywhere else) until it changes their behavior—because when it does, it will have saved their lives.

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CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Appellate Procedure 32(g)(1), the undersigned certifies that this brief complies with the applicable typeface, type style, and type-volume limitations. This brief was prepared using a proportionally spaced type (Times New Roman, 14 point). Exclusive of the portions exempted by Federal Rule of Appellate Procedure 32(f) and D.C. Circuit Rule 32(e)(1), this brief contains **6,384** words. This certificate was prepared in reliance on the word-count function of the word-processing system used to prepare this brief.

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

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