2023

Speech Regulation and Tobacco Harm Reduction

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Abstract

Regulation of commercial speech is a major component of federal regulation of tobacco products. Since adoption of federal tobacco legislation, the Food and Drug Administration has asserted regulatory authority over ENDS and other vaping products as "tobacco products," subjecting them to the same regulatory regime as traditional tobacco products even though such projects appear to pose less of a threat to public health. Such regulation, and the restriction on truthful speech in particular, may be having negative consequences for public health. Barring producers from informing consumers about the relative risks of vaping products and their potential to reduce smoking eliminates a potentially powerful tool for consumer education. Such restrictions are constitutionally dubious under existing First Amendment jurisprudence and may undermine the protection of public health as well.

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Forthcoming in JOURNAL OF FREE SPEECH LAW

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The authors would like to thank Joe Gitchell, B. Jessie Hill, and participants in the Information as Medicine workshop for comments on various drafts, and Sophie Dettling for her research assistance. All errors or omissions are those of the authors.

INTRODUCTION

Regulation of commercial speech is a major component of federal regulation of tobacco products. Even before enactment of the Family Smoking Prevention and Tobacco Control Act ("Tobacco Control Act"),[1] Congress authorized cigarette warning labels and the regulation of cigarette advertisements.[2] In 2009, this legislation expanded the regulation of speech, imposed a permitting regime for comparative health claims of alternative tobacco products and subjected cigarette alternatives, such as electronic nicotine delivery systems (ENDS) and other vaping products, to the same regulatory regime as cigarettes.[3]

Federal regulation of tobacco company speech was adopted to counteract tobacco industry misinformation and manipulation of consumers.[4] Controlling the advertisement, promotion, and labeling of tobacco products was embraced as a central element to reduce smoking rates and youth initiation in particular.[5] While the regulation of tobacco advertising and labeling was considered an important public health measure, it was nonetheless subject to First Amendment scrutiny.[6]

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[1] Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009) (codified in scattered sections of 5, 15, and 21 U.S.C.).

[2] *See*, e.g., Federal Cigarette Labeling and Advertising Act, 15 U. S.C. §§ 1331-1340; Public Health Cigarette Smoking Act of 1969, 15 U.S.C. 1331; Comprehensive Smoking Education Act, Pub. L. No. 98-474, 98 Stat. 2200 (1984) (codified in 15 U.S.C. §§ 4401-4408). On the history of tobacco regulation, see generally Bruce Yandle, Joseph A. Rotondi, Andrew P. Morriss, & Andrew Dorchak, *Bootleggers, Baptists & Televangelists: Regulating Tobacco By Litigation,* 2008 U. ILL. L. REV. 1225, 1259(2008) (summarizing history of tobacco regulation).

[3] *See infra* Part II.

[4] *See* U.S. DEP'T OF HEALTH AND HUMAN SERVICES, E-CIGARETTE USE AMONG YOUTH AND YOUNG ADULTS: A REPORT OF THE SURGEON GENERAL at 8 (2016).]

[5] *Id.* at 9.T

[6] *See, e.g.,* Lorillard Tobacco Co. v. Reilly, 533 U.S. 525 (2001) (holding the First Amendment restricts regulation of outdoor advertisements for smokeless tobacco and cigars); Disc. Tobacco City & Lottery, Inc. v. United States, 674 F.3d 509 (6th Cir. 2012) (holding regulations requiring tobacco companies to include warning labels on tobacco packaging and advertising did not violate the First Amendment); R.J. Reynolds Tobacco Co. v. FDA, 696 F.3d 1205 (D.C. Cir. 2012) (vacating FDA's graphic warning requirement on cigarette packaging); Nat'l

Since adoption of federal tobacco legislation, the Food and Drug Administration (FDA) has asserted regulatory authority over ENDS and other vaping products as "tobacco products," subjecting them to the same regulatory regime as cigarettes and other traditional tobacco products.[7] This not only includes leveling requirements and restrictions on advertising, but also restrictions on providing consumers with truthful, and potentially life-saving information about the relative risks of competing products.[8]

Regulatory constraints on the provision of truthful information to consumers may be having deadly consequences.[9] ENDS and other vaping products pose far less danger to users than combustible tobacco products, such as cigarettes.[10] Yet recent polling shows that most consumers have a poor understanding of the relative risks of tobacco products, and that public misunderstanding is getting worse.[11] Barring producers from informing consumers about the relative risks of vaping products and their potential to reduce smoking eliminates a potentially powerful tool for consumer education. Measures to prevent fraudulent or misleading marketing

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Ass'n of Tobacco Outlets, Inc. v. Providence R.I., 731 F.3d 71 (1st Cir. 2013) (holding Providence, RI's restriction on discounting tobacco products with coupons and multipack discounts falls outside of the First Amendment); Philip Morris USA, Inc. v. City & County of San Francisco, 345 Fed. Appx. 276 (9th Cir. 2009) (holding a San Francisco ordinance limiting the sale locations of cigarettes did not violate the First Amendment); Rockwood v. City of Burlington, 21 F. Supp. 2d 411 (D. Vt. 1998) (First Amendment challenge to law restricting advertisement of tobacco products in convenience stores); Penn Advertising v. Mayor & City Council, 63 F.3d 1318 (4th Cir. Md. 1995) (First Amendment challenge to an ordinance prohibiting outdoor cigarette advertisement); Yandle et al., *supra* note_ , at 1250 (explaining the bootlegger's tactical advantage of accepting some restrictions on alcohol advertisement).

[7] *See* 81 F.R. § 28973 (May 10, 2016).

[8] *See infra* __.

[9] *See* Jacob James Rich & Jonathan H. Adler, *Uneducating Americans on Vaping,* REGULATION, Summer 2003.

[10] *See* Amy Fairchild, Cheryl Healton, James Curran, David Abrams, & Ronald Bayer, *Evidence, Alarm, and the debate Over E-Cigarettes*, 366 SCI. 1318, 1319 (2019) ("In the case of adult smokers, there is solid scientific evidence that vaping nicotine is much safer than smoking."); David J.K. Balfour, Neal L. Benowitz, Suzanne M. Colby, Dorothy K. Hatsukami, Harry A. Lando, Scott J. Leischow, Caryn Lerman, Robin J. Mermelstein, Raymond Niaura, Kenneth A. Perkins, Ovide F. Pomerlau, Nacy A. Rigotti, Gary E. Swan, Kenneth E. Warner, & Robert West, *Balancing Consideration of the Risks and Benefits of E-Cigarettes*, 111 AMER. J. PUB. HEALTH 1661, 1662 (2021) (noting scientific bodies that have concluded ENDS are "less harmful" than combustible cigarettes). *See also infra* notes __ and accompanying text.

[11] *See infra* notes __ and accompanying text.

claims may be necessary, but current restrictions go so far as to outlaw the promotion of information acknowledged by the regulators themselves. Current restraints on truthful health information that could help or encourage smokers to quit are not only constitutionally dubious, they may undermine the protection of public health as well.

Part I of this essay describes what is currently understood about the relative health risks of ENDS and other vaping products, particularly as compared to combustible cigarettes. While uncertainties remain about the long-term risks posed by ENDS, the weight of existing scientific and medical evidence suggests that such products pose less risks to consumers and bystanders than cigarettes. The FDA concurs in this assessment. There is also strong evidence that such products can help smokers reduce their cigarette consumption and are more effective aids to smoking cessation than available FDA-approved alternatives.

Part II of this essay describes the current regulatory regime governing tobacco products and how this regime has been applied to ENDS and other vaping products. Under the Tobacco Control Act and the FDA's decision to deem ENDS as tobacco products, such products require FDA approval before they may be sold, much like drugs and medical devices. Such products are also subject to specific regulation under statutory provisions governing "modified risk tobacco products" if any relative risks claims are made about such products, and, in some cases, even as drugs or devices under the Federal Food, Drug and Cosmetic Act (FDCA).

Part III of this essay explains how the FDA's regulatory regime hampers the ability of ENDS manufacturers to inform consumers about the relative risks of their products and the potential use of ENDS as smoking cessation aids. Under current law, ENDS producers must also obtain FDA approval before making any comparative risk claims, such as claiming that such products are less dangerous than cigarettes. Further, if ENDS manufacturers wish to inform

smokers that ENDS may assist in smoking cessation, they must seek FDA approval for their products as drugs or devices. Even though such claims are accepted as true by the FDA, such speech is prohibited without prior FDA approval. In practice, this means that ENDS producers face greater restrictions on speech about their products than do other regulated entities, such as makers of nutritional supplements. These regulatory constraints hamper public health efforts and are constitutionally dubious.

Part IV explains why this regulation of health claims may be having serious negative consequences for public health. A majority of consumers, including current cigarette smokers, are misinformed about the relative risks posed by various nicotine products. Such public misunderstanding appears to be getting worse. Part V explains why the current regulation of speech about the relative risks of ENDS and other vaping products is highly questionable under current commercial speech jurisprudence insofar as the FDA is prohibiting the communication of truthful information about such products. Greater recognition and protection of the speech rights of ENDS producers is not only called for under existing First Amendment jurisprudence, it would also likely benefit public health

I. ENDS AND VAPING PRODUCTS

Electronic cigarettes, also known as "electronic nicotine delivery systems" (ENDS) or vapes, have been marketed in the United States since 2006.[12] Such products typically consist of a

[12] *See* Peter Hajek, Jean-Francois Etter, Neal Benowitz, Thomas Eissenberg, & Hayden McRobbie, *Electronic Cigarettes: Review of Use, Content, Safety, Effects on Smokers and Potential for Harm and Benefit*, 109 ADDICTION 1801 (2014), http://onlinelibrary.wiley.com/doi/10.1111/add.12659/full; Barbara Demick, *A High Tech Approach to Getting a Nicotine Fix*, L.A. TIMES (Apr. 25, 2009), http://articles.latimes.com/2009/apr/25/world/fg-china-

battery-powered atomizer, electronic components, and a cartridge that holds a liquid solution.[13] ENDS come in a variety of forms, including both disposable and rechargeable models, as well as modular products—vapors, tanks, and mods (VTMs)—that consumers may mix and match and fill with the vaping fluid of their choice.[14] The CDC reports that disposable e-cigarettes account for just over half of unit sales from brick-and-mortar retailers, with pre-filled cartridges making up most of the rest.[15] Reliable data for online retailers, vape shops and tobacco retailers is unavailable.[16] This makes it difficult to determine the volume of sales for vaping fluids used with VTMs.

Despite the label, e-cigarettes are not really cigarettes at all: They do not contain tobacco and their use does not involve combustion or the inhalation of smoke.[17] Instead, e-cigarettes heat and vaporize a propylene-glycol or glycerol solution that typically contains nicotine and some sort of flavoring.[18] Users inhale the vapor as a cigarette user might inhale smoke. For this reason, e-cigarette use is referred to as "vaping," and ENDS are increasingly referred to as "vapes."

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cigarettes25. Although not developed for retail sale until the 21st century, early patents for smokeless delivery of nicotine were filed as early as 1965. *See* Jordan Paradise, *No Sisyphean Task: How the FDA Can Regulate Electronic Cigarettes*, 13 YALE J. HEALTH POL'Y L. & ETHICS 326, 352-53 (2013).

[13] See Riccardo Polosa, Brad Rodu, Pasquale Caponnetto, Marilena Maglia, & Cirino Raciti, *A Fresh Look at Tobacco Harm Reduction: The Case for the Electronic Cigarette*, 10 HARM REDUCTION J. 19, 22 (2013); Chitra Dinakar & George T. O'Connor, *The Health Effects of Electronic Cigarettes*, 375 NEW ENGL. J. MED.. 1372, 1372-73 (2016).

[14] The two types of e-cigarette devices are also characterized as "closed system" and "open system," respectively. *See* Nicopure Labs, LLC v. FDA, No. CV 16-0878 (ABJ), 2017 WL 3130312, at *11 (D.D.C. July 21, 2017).

[15] *See* Fatma Romeh M. Ali, Andrew B. Seidenberg, Elisha Crane, Elizabeth Seaman, Michael A. Tynan, Kristy Marynak, *E-cigarette Unit Sales by Product and Flavor Type, and Top-Selling Brands, United States, 2020–2022,* 72 MMWR MORB MORTAL WKLY REP. 672 (2023).

[16] *Ibid.*

[17] *See* Zachary Cahn & Michael Siegel, *Electronic Cigarettes as a Harm Reduction Strategy for Tobacco Control: A Step Forward or a Repeat of Past Mistakes?*, 32 J. PUB. HEALTH POL'Y 16, 17 (2011); Dinakar & O'Connor, *supra* note __, at 1372 (noting use of e-cigarettes "is fundamentally different from the combustion of tobacco, and consequently the composition of the aerosol from e-cigarettes and the smoke from tobacco is quite different.").

[18] *See* Polosa, et al., *supra* note __, at 22; Dinakar & O'Connor, *supra* note __, at 1374; Caroline Franck et al., *Ethical Considerations of E-cigarette Use for Tobacco Harm Reduction*, 17 RESPIRATORY RES. 53, 54-55 (2016). While most e-cigarette fluids contain nicotine, nicotine-free fluids are also available.

ENDS have proven to be a disruptive technology, threatening the market for traditional tobacco products, as well as other nicotine products.[19] Initially manufactured and distributed by small firms, ENDS are now made and sold by a range of firms, including the major tobacco companies which have both acquired ENDS producers and developed their own vaping products.[20] And, like other disruptive technologies, ENDS have become the subject of regulation, some of which is encouraged by incumbent firms seeking to suppress or constrain competition.[21]

ENDS are still a relatively new technology, and the rate of product evolution has been quite rapid.[22] As a consequence, the long-term health consequences of ENDS use remain unknown and unknowable.[23] Nonetheless, the majority of medical and scientific institutions that have considered the question have concluded that ENDS are significantly safer to consume than conventional cigarettes.[24] A 2018 National Academies of Sciences report, for instance, concluded there is "conclusive evidence that completely substituting e-cigarettes for combustible cigarettes reduces users' exposure to numerous toxicants and carcinogens present in combustible tobacco cigarettes."[25] It further found that "there is moderate evidence that second-hand exposure to nicotine and particulates is lower from e-cigarettes compared with combustible tobacco cigarettes."[26] The FDA has likewise acknowledged that "the inhalation of nicotine (i.e.,

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[19] *See* Jonathan H. Adler, Andrew P. Morriss, Roger E. Meiners, & Bruce Yandle, *Baptists, Bootleggers & Electronic Cigarettes*, 33 YALE J. ON REG. 313, 334 (2016).

[20] *See generally* Greta Hsu, *Evolution of Electronic Cigarette Brands From 2013-2014 to 2016-2017: Analysis of Brand Websites*, 20 J. MED. INTERNET RES. (2018), https://www.jmir.org/2018/3/e80/ .

[21] *See* Adler, et al.,, *supra* note __.

[22] *Id.* at 337.

[23] *See* Balfour, et al., *supra* note __, at 1662 (noting the lack of data on long term health effects).

[24] *Id.* at 1662 (noting the conclusions of the National Academies of Sciences, Engineering and Medicine and the British Royal College of Physicians).

[25] PUBLIC HEALTH CONSEQUENCES OF E-CIGARETTES at 11(David L. Eaton, Leslie Y. Kwan, Kathleen Stratton eds., 2018).

[26] *Ibid.*; s*ee also* Lion Shahab, Maciej L Goniewicz, Benjamin C Blount, Jamie Brown, Ann McNeill, K Udeni Alwis, June Feng, Lanqing Wang, & Robert West, *Nicotine, Carcinogen, and Toxin Exposure in Long-Term E-Cigarette and Nicotine Replacement Therapy Users,* 166(6) ANNALS OF INTERNAL MEDICINE 390-400 (2017).

nicotine without the products of combustion) is of less risk to the user than the inhalation of nicotine delivered by smoke from combusted tobacco products" since ENDS don't contain tar and other carcinogens found in combustible tobacco products.[27] Although the FDA warned that e-cigarettes pose similar addiction risks as combustible tobacco products, the agency justified its relative risk distinction because "the effects from nicotine exposure by inhalation are likely not responsible for the high prevalence of tobacco-related death and disease in this country."[28]

Even those medical institutions concerned about the possibility of encouraging youth or non-smokers to use vaping products have acknowledged the difference in risk. Johns Hopkins Medicine, for instance, explicitly states "Vaping is less harmful than smoking, but it's still not safe" in an article for the general public.[29] A similar type of article published by the Mayo Clinic echoed this sentiment, claiming "[e-cigarettes are] probably safer than cigarettes for sure, but they are not safe."[30]

Public health authorities in the United Kingdom have been less equivocal. After a comprehensive review of the available literature, Public Health England (the research arm of the United Kingdom's Department of Health and Social Care) concluded that e-cigarettes are significantly less harmful than other tobacco products, cigarettes in particular.[31] Specifically,

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[27] *See* 81 Fed. Reg. 28981 (May, 10, 2016).

[28] *Id.* (citing H.L. Waldrum, O.G. Nilsen, T. Nilsen, H. Rørvik, V. Syversen, A. K. Sanvik, O. A. Haugen, S. H. Torp, E. Brenna, *Long-Term Effects of Inhaled Nicotine*, 58 LIFE SCI. 1339 (1996); M. A. Russell, *Low-Tar Medium-Nicotine Cigarettes: A New Approach to Safer Smoking*, 1 BRIT. MED. J. 1430 (1976)).

[29] *See* Michael Joseph Blaha, *5 Vaping Facts You Need to Know*, John Hopkins Medicine (2023), https://www.hopkinsmedicine.org/health/wellness-and-prevention/5-truths-you-need-to-know-about-vaping.

[30] *See* Deb Balzer, *Vaping Unknowns: Mayo Clinic Expert Answers Questions About Vaping*, MAYO CLINIC NEWS NETWORK (August 29, 2019), https://newsnetwork.mayoclinic.org/discussion/vaping-unknowns-mayo-clinic-expert-answers-questions-about-vaping/.

[31] *See* A. MCNEILL, L.S. BROSE, R. CALDER, S.C. HITCHMAN, P. HAJEK, & H. MCROBBIE, PUB. HEALTH ENG., PHE PUB. GATEWAY NO. 2015260 E-CIGARETTES: AN EVIDENCE UPDATE 76 (2015), https://www.gov.uk /government /uploads/system/uploads/attachment_data/file/457102/Ecigarettes_an_evidence_update_A_report_commissioned_b

Public Health England, after conducting their own assessment of the available evidence, concurred with an international expert panel's estimate that e-cigarettes pose no more than five percent of the risk posed by tobacco cigarettes to users and others combined.[32]

These conclusions are based upon an abundance of research in the medical literature showing that vaping products have significantly safer short-term outcomes. For example, a 2017 study published in the *Annals of Internal Medicine* concluded that former smokers who completely switched to ENDS had significantly lower levels of carcinogens in their salivary and urinary samples compared to current smokers.[33] Subsequent research supported these results, finding that the levels of carcinogens found in the blood samples of former smokers who completely switched to e-cigarettes closely reflected those of never tobacco users within a year of cessation.[34] Indeed, a study published in *Tobacco Control* estimated that if every American smoker switched to e-cigarettes over a ten year period, approximately 6.6 million premature deaths from tobacco would be avoided.[35]

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y_Public_Health_England_FINAL.pdf ("An expert review of the latest evidence concludes that e-cigarettes are around 95% safer than smoked tobacco and they can help smokers to quit."); UNITED KINGDOM OFFICE FOR HEALTH IMPROVEMENT AND DISPARITIES, NICOTINE VAPING IN ENGLAND: 2022 EVIDENCE UPDATE (Sept. 29, 2022), https://www.gov.uk/government/publications/nicotine-vaping-in-england-2022-evidence-update.

[32] *See* David J. Nutt, Lawrence D. Phillips, David Balfour, H. Valerie Curran, Martin Dockrell, Jonathan Foulds, Karl Fagerstrom, Kgosi Letlape, Anders Milton, Riccardo Polosa, John Ramsey, & David Sweanor, *Estimating the Harms of Nicotine-Containing Products Using the MCDA Approach*, 20 EUR. ADDICTION RES. 218 (2014). The 2015 Public Health UK report concluded this was a "reasonable estimate." MCNEILL ET AL., *supra* note __.

[33] *See* Lion Shahab, Maciej L. Goniewicz, Benjamin C. Blount, Jamie Brown, Ann McNeill, K Udeni Alwis, June Feng, Lanqing Wang, & Robert West,*Nicotine, Carcinogen, and Toxin Exposure in Long-Term E-Cigarette and Nicotine Replacement Therapy Users*, 166 Annals of Internal Med. 390 (2017), https://www.acpjournals.org/doi/10.7326/M16-1107.

[34] *See* Maciej L.Goniewicz, Danielle M. Smith, Kathryn C. Edwards, Benjamin C. Blout, Kathleen L. Caldwell, Jun Feng, Lanqing Wang, Carol Christensen, Bridget Ambrose, Nicolette Borek, Dana van Bemmel, Karen Konkel, Gladys Erives, Cassandra A. Stanton, Elizabeth Lambert, Heather L. Kimmel, Dorothy Hatsukami, Stephen S. Hecht, Raymond S. Niaura, Mark Travers, Charles Lawrence, & Andrew J. Hyland,*Comparison of Nicotine and Toxicant Exposure in Users of Electronic Cigarettes and Combustible Cigarettes*, 1(8) JAMA NETWORK OPEN (December 14, 2018), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2718096

[35] *See* David T. Levy, Ron Borland, Eric N. Lindblom, Maciej L. Goniewicz, Rafael Meza, Theodore R. Holford, Zhe Yuan, Yuing Luo, Richard J. O'Connor, Raymond Niaura, & David B. Abrams, *Potential Deaths*

Among all of the public health considerations for e-cigarettes, the implications for pregnant mothers and their children might be the most visible. It is well established that smoking during pregnancy leads to adverse outcomes such as low birth weights,[36] complications that lead to miscarriages and premature births,[37] and obesity during childhood.[38] Some of these effects may be related to nicotine exposure in utero or other factors, but most of the research connects these adverse outcomes to mothers inhaling carbon monoxide in the smoke from combustible tobacco products, like conventional cigarettes.[39]

Research on ENDS use during pregnancy has shown the difference in risks. A study reviewing the outcomes of 129 live births at Coombe Women and Infants University Hospital in Ireland among women who exclusively used e-cigarettes, for example, found that their babies' measurements were similar to nonsmokers and larger than cigarette smokers, with no cases of serious maternal or infant morbidity.[40] These results have been continuously replicated, including a study in *The Lancet*'s eClinicalMedicine that found "Birth outcomes, namely birthweight, gestation and head circumference, did not differ for e-cigarette exposed infants compared with infants who were not prenatally exposed to nicotine. Cigarette exposed infants had a significantly lower birthweight … and reduced head circumference … in comparison to

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Averted in USA by Replacing Cigarettes with E-cigarettes, 27 TOBACCO CONTROL 18-25 (2018), https://tobaccocontrol.bmj.com/content/27/1/18

[36] *See* M. S. Kramer, *Determinants of Low Birth Weight: methodological Assessment and Meta-Analysis*, 65 BULL WORLD HEALTH ORGAN. (1987), https://pubmed.ncbi.nlm.nih.gov/3322602/

[37] *See* AnneCastles, E. Kathleen Adams, Cathy L. Melvin, Christopher Kelsch, & Matthew L. Boulton, *Effects of Smoking During Pregnancy: Five Meta-Analyses*, 16 AM. J. OF PREVENTATIVE MED. 208 (1999), https://www.sciencedirect.com/science/article/pii/S0749379798000890

[38] *See* E. Oken, E.B. Levitan, & M.W. Gillman, *Maternal Smoking During Pregnancy and Child Overweight: Systematic Review and Meta-Analysis*, 32 INT'L J. OF OBESITY 201 (2008), https://www.nature.com/articles/0803760

[39] *See* Anna Merklinger-Gruchala, Grazyna Jasienska, & Maria Kapiszewska, *Parity Conditions the Risk for Low Birth Weight After Maternal Exposure to Air Pollution*, 63 BIODEMOGRAPHY SOC'Y BIOLOGY 71 (2017), https://pubmed.ncbi.nlm.nih.gov/28287305/

[40] *See* Brendan P. McDonnell, Evan Bergin, & Carmen Regan, *Electronic Cigarette Use in Pregnancy is not Associated with Low Birth Weight or Preterm Delivery*, 220 AMERICAN J. OBSTETRICS & GYNECOLOGY S137 (2019), https://www.ajog.org/article/S0002-9378(18)31229-8/fulltext

non-exposed infants."[41] Some adverse outcomes for infants, such as decreased motor maturity, have been correlated with e-cigarette use during pregnancy.[42] But almost all studies on the topic conclude that ENDS use during pregnancy is substantially preferable to smoking.[43]

Since only about half of women who smoke quit smoking during pregnancy,[44] such research has led Public Health England to encourage the use of e-cigarettes by female smokers during pregnancy who are otherwise unable to quit.[45] This approach began in 2019 and has been followed by a 10 percent drop in the percentage of women who are known smokers at the time of birth.[46] ENDS were a common nicotine replacement tool among mothers during this period and were occasionally provided by government maternity services free-of-charge.[47]

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[41] *See* Suzanne Froggatt, Nadja Reissland, & Judith Covey, *The Effects of Prenatal Cigarette and E-Cigarette Exposure on Infant Neurobehaviour: A Comparison to a Control Group*, 28 ECLINICAL MEDICINE (2020), https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370(20)30346-1/fulltext

[42] *Id.* CDC DIVISION OF REPRODUCTIVE HEALTH, E-CIGARETTES AND PREGNANCY (Feb. 25, 2019), https://www.cdc.gov/reproductivehealth/maternalinfanthealth/substance-abuse/e-cigarettes-pregnancy.htm

[43] There is also some research suggesting that indoor vaping restrictions may increase infant mortality, likely due to an increase in smoking. *See* Michael Cooper & Michael F. Pesko, *The Effect of E-Cigarette Indoor Vaping Restrictions on Infant Mortality*, SOUTH. ECON. J. (2022), HTTPS://ONLINELIBRARY.WILEY.COM/DOI/FULL/10.1002/SOEJ.12564.

[44] *See* American College of Obstetricians and Gynecologists, Committee on Obstetric Practice, Tobacco and Nicotine Cessation during Pregnancy, Committee Opinion No. 807 (May 2020) https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2020/05/tobacco-and-nicotine-cessation-during-pregnancy ("approximately 54% of women who smoke before pregnancy quit smoking directly before or during pregnancy").

[45] *See* Ann McNeill, Leonie S. Brose, Robert Calder, Linda Bauld, and Debbie Robson, Public Health England, *Vaping in England: An Evidence Update Including Mental Health and Pregnancy* (2020), https://www.gov.uk/government/publications/vaping-in-england-evidence-update-march-2020/vaping-in-england-2020-evidence-update-summary#vaping-during-and-after-pregnancy

[46] *See* Walt Treloar, NHS, *Statistics on Women's Smoking Status at Time of Delivery: England* (2023), https://digital.nhs.uk/data-and-information/publications/statistical/statistics-on-women-s-smoking-status-at-time-of-delivery-england

[47] *See* Ross Thomson, Sue Cooper, John Waldron, Efe Mamuzo, Lisa McDaid, Joanne Emery, Lucy Phillips, Felix Naughton, & Tim Coleman, *Smoking Cessation Support for Pregnant Women Provided by English Stop Smoking Services and National Health Service Trusts: A Survey*, 19 INT. J. OF ENV'T RESEARCH AND PUB. HEALTH 1634 (2022), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8835166/; compare to K. Bowker, S. Lewis, L. Phillips, S. Orton, M. Ussher, F. Naughton, L. Bauld, T. Coleman, L. Sinclair, H. McRobbie, A. Khan, & S. Cooper, *Pregnant Women's Use of E-cigarettes in the UK: A Cross-Sectional Survey*, 128 BJOG 984(2021),,https://obgyn.onlinelibrary.wiley.com/doi/full/10.1111/1471-0528.16553. Due to the COVID-19 pandemic, it has been difficult to estimate the public health benefits of these interventions, but the UK's current tobacco control plan intends to reduce the prevalence of smoking during pregnancy from 9.1% to 6.0% with the help

In addition to being safer than conventional cigarettes, ENDS also appear to be a more effective tool for smoking reduction and cessation than available alternatives, including FDA-approved nicotine replacement therapies. *The New England Journal of Medicine* (*NEJM*) published a randomized controlled trial (RCT) comparing the effectiveness of e-cigarettes to nicotine-replacement products (like nicotine gum and patches) approved by the UK's Medicines and Healthcare products Regulatory Agency for smoking cessation, finding that e-cigarettes were approximately twice as effective.[48] A subsequent literature review of RCTs and randomized cross-over trials by the Cochrane Library supported the *NEJM*'s results, concluding that e-cigarettes were approximately 70% more effective in supporting smokers to quit than traditional nicotine-replacement products.[49] This review was recently updated with new studies and confirmed the previous results.[50]

II. REGULATING CIGARETTES AND DEEMED TOBACCO PRODUCTS

of e-cigarettes, which highlights their utility not just among mothers, but the general population. DEP'T OF HEALTH AND SOCIAL CARE, TOBACCO CONTROL PLAN: DELIVERY PLAN 2017 TO 2022 (June 7, 2018), https://www.gov.uk/government/publications/tobacco-control-plan-delivery-plan-2017-to-2022; DEP'T OF HEALTH AND SOCIAL CARE, SMOKE-FREE GENERATION: TOBACCO CONTROL PLAN FOR ENGLAND (July 18, 2017), https://www.gov.uk/government/publications/towards-a-smoke-free-generation-tobacco-control-plan-for-england.

[48] Peter Hajek, Anna Phillips-Waller, Dunja Przulj, Francesca Pesola, Katie Myers Smith, Natalie Bisal, Jinshuo Li, Steve Parr, Peter Sasieni, Lynne Dawkins, Louise Ross, Maciej Goniewicz, Qi Wu, & Hayden J. McRobbie, *A Randomized Trial of E-Cigarettes versus Nicotine-Replacement Therapy*, 380 N ENGL. J. MED. 629 (2019), https://www.nejm.org/doi/full/10.1056/NEJMoa1808779.

[49] Jamie Hartmann-Boyce, Hayden McRobbie, Nicola Lindson, Chris Bullen, Rachna Begh, Annika Theodoulou, Caitlin Notley, Nancy A. Rigotti, Tari Turner, Ailsa R. Butler, Thomas R. Fanshawe, & Peter Hajek, *Electronic Cigarettes for Smoking Cessation*, 10 COCHRANE DATABASE OF SYSTEMATIC REVIEWS (2020), https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD010216.pub4/full.

[50] Jamie Hartmann-Boyce, Nicola Lindson, Alisa R. Butler, Hayden McRobbie, Chris Bullen, Rachna Begh, Annika Theodoulou, Caitlin Notley, Nancy A. Rigotti, Tari Turner, Thomas R. Fanshawe, & Peter Hajek, *Electronic Cigarettes for Smoking Cessation*, 11 COCHRANE DATABASE OF SYSTEMATIC REVIEWS (2022), https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD010216.pub7/full.

Today tobacco products are heavily regulated in the United States, but this is a relatively recent development. For most of the Twentieth Century, the tobacco industry was largely unregulated.[51] Comprehensive regulation of tobacco products did not begin until the passage of federal legislation in 2009.

For over forty years, the federal government regulated tobacco advertising and promotion, with little regulation of the tobacco products themselves. After publication of the Surgeon General's 1964 report on the harms of cigarette smoking,[52] the Federal Trade Commission (FTC) sought to require dramatic warning labels on cigarette packages.[53] Congress responded by mandating milder warnings, preempting state-level efforts to require more explicit warnings.[54] A few years later—also in response to more aggressive agency initiatives—Congress prohibited cigarette and cigar advertising on television.[55]

In 1996, the FDA sought to regulate cigarettes and other tobacco products under the FDCA.[56] According to the FDA, nicotine constituted a "drug" and cigarettes and smokeless

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[51] *See generally* Peter D. Jacobson, Jeffery Wasserman, & John R. Anderson, *Historical Overview of Tobacco Legislation and Regulation*, 53 J. SOC. ISSUES 75 (1997). For a useful history of tobacco regulation and litigation, see also Yandle, et al., *supra* note __; RICHARD KLUGER, ASHES TO ASHES: AMERICA'S HUNDRED YEAR CIGARETTE WAR, THE PUBLIC HEALTH, AND THE UNABASHED TRIUMPH OF PHILIP MORRIS (1997). Until the 1990s, it was generally recognized that the FDA lacked authority over tobacco products under the Food, Drug & Cosmetic Act. *See* FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 143-55 (2000).

[52] *See* DEP'T OF HEALTH, EDUC. AND WELFARE, PUB. NO. 1103, SMOKING AND HEALTH: REPORT OF THE ADVISORY COMMITTEE TO THE SURGEON GENERAL OF THE PUBLIC HEALTH SERVICE (1964).

[53] Unfair or Deceptive Advertising and Labeling of Cigarettes in Relation to the Health Hazards of Smoking, 29 Fed. Reg. 8325 (July 29, 1965) (to be codified at 16 C.F.R. pt. 408).

[54] *See* Federal Cigarette Labeling and Advertising Act, Pub. L. No. 89-92, § 5(a), 79 Stat. 283 (1965). The preemption is codified at 15 U.S.C. § 1334(a) (2017). For a discussion of these developments, see Yandle et al., *supra* note 9, at 1249-51; *see also* Cipollone v. Liggett Grp., Inc., 505 U.S. 504, 513-15 (1992).

[55] *See* Public Health Cigarette Smoking Act of 1969, Pub. L. No. 91-222, 84 Stat. 87 (1970) (codified as amended at 15 U.S.C. §§ 1331-38); *see also* 15 U.S.C. § 1335 (2017). As Jack Calfee discusses, major cigarette companies often stood to benefit from the anti-competitive effects of advertising restrictions. *See* John E. Calfee, *The Ghost of Cigarette Advertising Past,* 10 REG. 35 (1986); *see also* John E. Calfee, *Cigarette Advertising, Health Information and Regulation Before 1970* (Fed. Trade Comm'n, Working Paper No. 134, 1985).

[56] *See* Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. 44,418 (1996).

tobacco products should be considered "drug delivery devices" under the Act.[57] On this basis, the FDA asserted regulatory jurisdiction over tobacco products and sought to regulate tobacco advertising and promotion pursuant to its extant regulatory authorities. Although the FDA's rules focused on advertising and promotion directed at children, treating cigarettes and smokeless tobacco as drug-delivery devices created the opportunity for broader regulation of tobacco products, if not their eventual prohibition.[58]

This effort to regulate tobacco products under the FDCA would not last long. The major tobacco companies filed suit, and ultimately prevailed in the Supreme Court.[59] Despite the seemingly plain language of the Act, the Supreme Court concluded that Congress had not delegated the FDA authority to regulate tobacco.[60] In the view of the Court's majority, the history of federal legislation concerning tobacco made clear that Congress had no intention to subject cigarettes and other tobacco products to FDA regulation, let alone to create the potential for the FDA to prohibit tobacco products because cigarettes could not be deemed "safe and effective" when used as intended.[61]

While the major cigarette producers had opposed the FDA's effort to regulate tobacco products under the FDCA, they soon had a change of heart. Waves of litigation including coordinate suits filed by state attorneys general and the resulting Master Settlement Agreement changed the incentives faced by the cigarette companies.[62] Philip Morris, in particular, sought

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[57] *Id.* at 44,397, 44,402.

[58] *See* George J. Annas, *Cowboys, Camels, and the First Amendment: The FDA's Restrictions on Tobacco Advertising*, 335 NEW ENGLAND J. OF MED. 1779, 17780 (1996).

[59] *See FDA v. Brown & Williamson Tobacco Co.*, 529 U.S. 120 (2000).

[60] *Id.* at 126 ("Congress has clearly precluded the FDA from asserting jurisdiction to regulate tobacco products.").

[61] *Id.* ("Such authority is inconsistent with the intent that Congress has expressed in the FDCA's overall regulatory scheme and in the tobacco-specific legislation that it has enacted subsequent to the FDCA.").

[62] *See* Yandle et al., *supra* note __, at 1270-71.

federal legislation to expressly authorize FDA regulation of tobacco products.[63] The nation's largest cigarette producer stood to benefit from federal regulation that would both suppress competition within the industry and provide insulation from future tort litigation.[64]

In 2009 Congress enacted the Family Smoking Prevention and Tobacco Control Act ("Tobacco Control Act"),[65] which gave the FDA formal authority to regulate cigarettes and other tobacco products, including those "made or derived from" tobacco.[66] The Tobacco Control Act imposes regulatory restrictions on cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco.[67] It also provided the FDA with the authority to reach other tobacco products, including pipes and cigars and at least some smoking alternatives that compete with tobacco but that could not be regulated under other existing authorities.[68]

The Tobacco Control Act created a new division within the FDA, the Center for Tobacco Products, which is authorized to develop and impose tobacco regulations and is financed by fees imposed on tobacco companies.[69] The Tobacco Control Act requires tobacco companies to disclose their product contents[70] and authorizes the FDA to set tobacco product standards.[71] The

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[63] *See* P.A. McDaniel & R.E. Malone, *Understanding Philip Morris's Pursuit of US Government Regulation of Tobacco*, 14 TOBACCO CONTROL 193 (2005), http://tobaccocontrol.bmj.com/content/14/3/193.full.

[64] *See* Samuel Lowenberg, *Smoke Screen: Why Is Philip Morris Supporting FDA Regulation of Cigarettes?*, SLATE (July 25, 2002), http://www.slate.com/articles/business/moneybox/2002/07/smoke_screen.html; *See also* Duff Wilson, *Philip Morris's Support Casts Shadow Over a Bill to Limit Tobacco*, N.Y. TIMES (Mar. 1, 2009), http://www.nytimes.com/2009/04/01/business/01tobacco.html (calling the resulting law it "the tobacco regulation that Philip Morris can live with.")..

[65] *See* Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009) (codified in scattered sections of 5, 15, and 21 U.S.C.).

[66] For an overview of the Tobacco Control Act, see C. STEPHEN REDHEAD & VANESSA K. BURROWS, CONG. RESEARCH SERV., R40475, FDA TOBACCO REGULATION: THE FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT OF 2009 (2009).

[67] *See* 21 U.S.C. § 387a(b) (2012).

[68] *See, e.g.*, Sottera, Inc. v. FDA, 627 F.3d 891, 898 (D.C. Cir. 2010) (holding that the FDA may not regulate e-cigarettes under the FDCA absent therapeutic claims by manufacturers).

[69] *See* 21 U.S.C. § 387a(e).

[70] *See* 21 U.S.C. §§ 387d, 387i.

[71] *See* 21 U.S.C. § 387g.

Act further provides for more explicit warning labels on tobacco products,[72] imposes stringent limits on tobacco product advertising and promotion,[73] and limits the use of flavoring in cigarettes.[74] It also adopts additional controls to prevent tobacco sales to minors.[75]

Significant for product development and innovation, the Act requires manufacturers to obtain premarket approval for new tobacco products. Those products marketed prior to February 15, 2007 and their substantial equivalents are grandfathered and exempt from the premarket approval requirement.[76] The FDA, for its part, enforces this rule strictly, and has concluded that even relatively modest changes in product design or packaging will be sufficient to identify a product as a new tobacco product, and not substantially equivalent to a product already on the market.[77] The Act further authorizes the FDA to "deem" other "tobacco products" to be subject to the Act's regulatory requirements.[78]

In May 2016, the FDA finalized regulations "deeming" e-cigarettes and other vaping products to be "tobacco products" subject to regulation under the Tobacco Control Act.[79] In reaching this decision, the FDA determined that e-cigarettes "should be regulated due to their

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[72] *See* 15 U.S.C. § 1333.
[73] *See* 21 U.S.C. §§ 387f, 387k(g).
[74] *See* 21 U.S.C. § 387g (a)(1).
[75] *See* 21 U.S.C. §§ 387f(d)(3).
[76] *See* 21 U.S.C. § 387j.
[77] *See* FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: DEMONSTRATING THE SUBSTANTIAL EQUIVALENCE OF A NEW TOBACCO PRODUCT: RESPONSES TO FREQUENTLY ASKED QUESTIONS (3d ed. Dec. 2016), *available at* http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM436468.pdf.
[78] Specifically, 21 U.S.C. §387a(b) provides,

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

The Act defines a "tobacco product" as

> any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product). 21 U.S.C. § 321(rr)(1).

[79] Final Deeming Rule, *supra* note __.

potential for public harm."[80] According to the agency, regulating e-cigarettes and similar products "is necessary to learn more about that potential."[81] This rule applies to all such products, including their components and parts,[82] as well as to new products that may be used to deliver nicotine or tobacco in the future.[83]

In deeming e-cigarettes to be subject to federal regulation, the FDA declared that e-cigarettes "meet the statutory definition of 'tobacco products'" because the nicotine in e-cigarettes is "made or derived from tobacco."[84] It further extended regulatory authority to e-cigarette "parts and components," including the various parts of open-system devices whether sold in combination or separately, but not e-cigarette accessories or nicotine-free liquids provided such liquids were not intended to be combined with nicotine-containing liquids.[85] In July 2017, a federal district court rejected a legal challenge to the broad scope of the FDA's rule,[86] and this decision was upheld on appeal.[87]

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[80] *Id*. at 28,983.

[81] *Id*. at 28,984.

[82] According to the FDA, regulated components and parts include: "E-liquids; atomizers; batteries (with or without variable voltage); cartomizers (atomizer plus replaceable fluid-filled cartridge); digital display/lights to adjust settings; clearomisers, tank systems, flavors, vials that contain e-liquids, [and] programmable software." *Id*. at 29,074.

[83] According to the FDA, "FDA envisions that there could be tobacco products developed in the future that provide nicotine delivery through means (e.g., via dermal absorption or intranasal spray) similar to currently marketed medicinal nicotine products, but which are not drugs or devices. These products would be "tobacco products" and subject to FDA's chapter IX authorities in accordance with this final deeming rule." *Id*. at 28,976.

[84] *Id*. at 28,976 ; *see also* 21 U.S.C. § 387a (defining tobacco products); 21 U.S.C. § 321rr(1) (including products "containing nicotine from any source, that is intended for human consumption" in the definition of tobacco products)

[85] Final Deeming Rule, *supra* note 39, at 28,995, 28,974, 29,032.

[86] *See* Nicopure Laps LLC v. FDA, 266 F. Supp. 3d 360, 421 (D.D.C. July 21, 2017).

[87] Nicopure Laps LLC v. FDA, 944 F.3d 267 (D.C. Cir. 2019); see also Cigar Ass'n of Am. v. United States FDA, 964 F.3d 56 (D.C. Cir. 2020) (holding the Deeming Rule did not give adequate notice of health warning requirements on cigar packaging.).

In separate litigation, the U.S. Court of Appeals for the D.C. Circuit rejected a challenge to Department of Transportation decision to prohibit e-cigarette use on commercial airlines under the pre-existing authority to prohibit smoking. *See* Competitive Enter. Inst. v. Dept. of Trans., 863 F.3d 911 (D.C. Cir. 2017).

With the deeming rule, the FDA effectively extended the Act's regulatory framework to e-cigarettes. This includes requiring manufacturers to register and disclose product contents, prohibiting the sale of adulterated or misbranded products, and limiting advertising and promotional activities. Under the deeming rule, the FDA also prohibited sales to minors, mandated health warnings on product packaging, and severely limited vending machine sales. Perhaps most significantly, the FDA's deeming rule imposed a pre-market approval requirement on all e-cigarette products developed in the past ten years.[88] This rule is likely to produce significant consolidation within the e-cigarette industry, in no small part because the pre-market approval requirement operates a significant barrier to entry. As with prior tobacco regulation, this is likely to inure to the benefit of larger corporations, including tobacco companies that seek to operate within the ENDS market, while simultaneously reducing innovation and the harm reduction potential of e-cigarettes.[89]

While acknowledging the evidence that e-cigarettes are in all likelihood less harmful than tobacco cigarettes, the FDA claimed that the rule would benefit public health "by affording FDA critical information regarding the health risks of such products," preventing the marketing and sale of "new" products without prior FDA approval, and "preventing the use of unsubstantiated modified risk claims, which may mislead consumers and lead them to initiate tobacco product use or to continue using tobacco when they would otherwise quit."[90]

Thus far, the FDA has rejected the vast majority of PMTA submissions made by manufacturers of ENDS and other vaping products. Out of almost 26 million PMTA

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[88] *See* Final Deeming Rule, *supra* note 39, at 28,974. *See also* Tripp Mickle, *FDA Cloud Hangs Over Vape Shops*, WALL ST. J. (July 7, 2015), https://www.wsj.com/articles /SB10130211234592774869404581088451777513530.

[89] *See* Adler, et al., *supra* note __.

[90] Final Deeming Rule, *supra* note ___, at 28,976.

submissions submitted as of March 2023,[91] the FDA has only authorized forty-five products, approximately half of which are ENDS.[92] Only three companies (R.J. Reynolds Vapor Co., NJOY, and Logic Technology Development) have had their products approved.[93] Several companies have gone to court, challenging the FDA's denial of their product applications as arbitrary and capricious.[94] As of this writing, most of these challenges have failed, but some have prompted stern language from circuit court judges.[95] Others have prompted the FDA to reconsider its initial denials.[96]

Although the FDA originally estimated that the average initial cost of a PMTA would be approximately $131,643 for an e-liquid and $466,563 for an ENDS delivery system,[97] companies

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[91] *See* U.S. FOOD & DRUG ADMIN., FDA MAKES DETERMINATIONS ON MORE THAN 99% OF THE 26 MILLION TOBACCO PRODUCTS FOR WHICH APPLICATIONS WERE SUBMITTED (Mar. 15, 2023), https://www.fda.gov/tobacco-products/ctp-newsroom/fda-makes-determinations-more-99-26-million-tobacco-products-which-applications-were-submitted

[92] *See* U.S. FOOD & DRUG ADMIN., PREMARKET TOBACCO PRODUCT MARKETING GRANTED ORDERS (June 14, 2023), https://www.fda.gov/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-granted-orders#:~:text=To%20date%2C%20the%20FDA%20has,e%2Dcigarette%20products%20and%20devices. Note that the FDA tdefines individual products quite narrowly.

[93] Philip Morris has also obtained approval for several heated, but non-combusted, tobacco products called "HeatSticks" or iQOS. *Id*.

[94] *See* Nude Nicotine Inc. v. U.S. Food & Drug Admin., CV 21-71321, 2023 WL 4384447 (9th Cir. July 7, 2023) (rejecting challenge to FDA denial of premarket tobacco product application); Magellan Technology Inc. v. U.S. Food & Drug Admin., 70 F.4th 622 (2nd Cir. 2023) (same); Gripum LLC. v. United States FDA, 47 F.4th 553 (7th Cir. 2022) (same); Avail Vapor, LLC. v. United States FDA, 55 F.4th 409 (4th Cir. 2022) (same); Prohibition Juice Co. v. United States FDA, 45 F.4th 8 (D.C. Cir. 2022) (same); Breeze Smoke, LLC v. FDA, 18 F.4th 499, 506 (6th Cir. 2021) (same).

[95] *See* Wages & White Lion Invs. LLC. v. FDA, 16 F.4th 1130 (5th Cir. 2021) (granting temporary stay of FDA denial of premarket tobacco product application and accusing FDA of "surprise switcheroo"); Wages & White Lion Invs. LLC. v. FDA, 41 F.4th 427, 442 (5th Cir. 2022) (Jones, E., dissenting) (calling FDA regulation "a mockery of 'reasoned' administrative decision-making"), *vacated & reh'g granted* 58 F.4th 233; *see also* Breeze Smoke, 18 F. 4th at 507 ("The FDA likely should have more thoroughly considered Breeze Smoke's marketing plan.").

[96] *See FDA Rescinds Previously Disclosed Marketing Denial Order for Turning Point Brands' Vapor Products*, BUSINESSWIRE, Oct. 11, 2021, https://www.businesswire.com/news/home/20211011005139/en/FDA-Rescinds-Previously-Disclosed-Marketing-Denial-Order-for-Turning-Point-Brands%E2%80%99-Vapor-Products; Christina Jewett, *F.D.A. Lets Juul Appeal Ban and Stay on the Market During a Review*, N.Y. TIMES, JUL. 6, 2022 (reporting FDA granted administrative stay of marketing denial order due to "scientific issues" after U.S. Court of Appeals for the D.C. Circuit granted Juul's request for temporary administrative stay).

[97] *See* U.S. FOOD & DRUG ADMIN., DEEMING TOBACCO PRODUCTS TO BE SUBJECT TO THE FOOD, DRUG, AND COSMETIC ACT, AS AMENDED BY THE FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT; REGULATIONS

that have successfully acquired approval have reported their costs to range between $5 and $8 million per product.[98] Such barriers to entry nearly eliminate competition from smaller companies, and could have motivated much of the tobacco industry's support for legislation like the Tobacco Control Act.[99]

Of particular concern for speech regulation and public health, the Tobacco Control Act also regulates "modified risk tobacco products" (MRTPs). Specifically, the Act prohibits the marketing and sale of MRTPs without prior FDA approval.[100] The Act defines an MRTP as "any tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products."[101] It further creates an application process for MRTPs, somewhat similar to the approval process for new drugs and devices,.[102] As the FDA noted in the deeming rule, the prohibition on selling "modified risk" tobacco products "applies automatically to deemed products."[103]

As of March 16, 2023, 2022, the FDA has only approved fifteen MRTP applications.[104] Most approved products have been smokeless tobacco products, such as eight types of snus (an oral smokeless tobacco product which is usually placed between the lip and gum) produced by

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RESTRICTING THE SALE AND DISTRIBUTION OF TOBACCO PRODUCTS AND REQUIRED WARNING STATEMENTS FOR TOBACCO PRODUCT PACKAGES AND ADVERTISEMENTS, at 88 (May 2015).

[98] *See* FED. TRADE COMMISSION, CORRECTED POST-TRIAL PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW OF RESPONDENTS ALTRIA GROUP, INC. AND JUUL LABS, INC., at 24 (Sept. 26, 2021.

[99] *See* P. A. McDaniel & R.E. Malone, *Understanding Philip Morris's Pursuit of U.S. Government Regulation of Tobacco*, 14 TOBACCO CONTROL 193 (2005); Yandle, et al., *supra* note __. https://tobaccocontrol.bmj.com/content/14/3/193

[100] *See* 21 U.S.C. § 387k(a).

[101] *See* 21 U.S.C. § 387k(b)(1).

[102] *See* 21 U.S.C. § 387k(g).

[103] Final Deeming Rule, *supra* note 39, at 29,039.

[104] *See* U.S. FOOD & DRUG ADMIN., MODIFIED RISK TOBACCO PRODUCTS (March 16, 2023), https://www.fda.gov/tobacco-products/advertising-and-promotion/modified-risk-tobacco-products#summary.

Swedish Match and one type of Copenhagen snuff.[105] Others include heated-tobacco products made by Philip Morris, known as iQOS or "Heatsticks," and low-nicotine cigarettes that are equally as harmful as conventional combustible cigarettes, but may now be advertised as containing less nicotine than regular cigarettes.[106] As of this writing, no ENDS have been approved as MRTPs.

III. REGULATING HEALTH-RELATED INFORMATION ABOUT TOBACCO PRODUCTS

The FDA has acknowledged that ENDS pose less risks to users than do combustible tobacco products. "Vaping is not as dangerous as combustible tobacco," according to FDA Commissioner Robert Califf.[107] "We know that in general, e-cigarette have lower risks than a conventional cigarette," said Brian King, Director of the FDA's Center for Tobacco Products in 2023.[108] As his predecessor, Mitch Zeller, explained:

> E-cigarettes... compared to cigarettes have far fewer harmful compounds in the vapor... we still have more than 30 million addicted adult cigarette smokers. Almost all of whom are concerned about their health and have some interest in quitting. So, if a typical pack-a-day cigarette smoker could completely substitute all of his or her cigarettes with e-

[105] On the lower risk posed by snus, see Elizabeth Clarke, Keith Thompson, Sarah Weaver, Joseph Thompson & Grant O'Connell, 16 HARM REDUCTION J. 62 (2019); *see also* Brad Rodu & Carl V. Phillips, *Switching to Smokeless Tobacco as a Smoking Cessation Method: Evidence from the 2000 National Health Interview Survey*, 5 HARM REDUCTION J. 18 (2008).

[106] U.S. FOOD AND DRUG ADMIN., MODIFIED RISK GRANTED ORDERS (March 16, 2023), https://www.fda.gov/tobacco-products/advertising-and-promotion/modified-risk-granted-orders.

[107] 'A Conversation with the FDA's Robert Califf', March 6, 2023 (https://www.wsj.com/video/events/a-conversation-with-the-fda-robert-califf/FAD7049E-455A-4168-BFB2-041EB78A7D4F.html)

[108] 'The Future of Vaping in the US: A Conversation with FDA's Dr. Brian King', February 24 2023 (https://www.youtube.com/watch?v=zfQ8u59z8Ac); *see also* Nicholas Florko, *FDA's Top Tobacco Regulator Is Ready to Talk About the Benefits of E-cigs Versus Cigarettes*, StatNews, Feb. 24, 2023.

> cigarettes, there's no question that that person, that hypothetical pack-a-day smoker, would be reducing their risk compared to continuing to smoke a pack of cigarettes every day.[109]

More formally, in the *Federal Register*, the FDA has acknowledged that "the inhalation of nicotine (i.e. nicotine without the products of combustion) is of less risk to the user than the inhalation of nicotine delivered by smoke from combusted tobacco products."[110] Also according to the FDA, "several studies support the notion that the quantity of toxicants [in e-cig vapor] is significantly less than those in tobacco cigarettes and tobacco smoke and similar to those contained in recognized nicotine-replacement therapies."[111]

The FDA has also acknowledged that such products may help some smokers quit. As King noted, "there is a growing body of literature that has shown that people are using e-cigarettes to quit smoking completely."[112] The FDA has also made this observation in the *Federal Register* noting, "there is emerging data that some individual smokers may potentially use ENDS to transition away from combustible tobacco products."[113] Under existing law and FDA policy, however, ENDS manufacturers may not communicate any of the above information without first getting FDA approval to communicate such messages after submitting to a lengthy and costly authorization process.

As noted above, the Tobacco Control Act creates a special approval process for MRTPs that is distinct from the approval process for "new" tobacco products. What constitutes an

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[109] "Tobacco control and prevention efforts in the U.S.," January, 2022 (https://edition.pagesuite-professional.co.uk/html5/reader/production/default.aspx?pubname=&edid=eafd5770-a722-408e-839f-9ccb2c7fa1cb&pnum=18):

[110] 81 Fed. Reg. 28981

[111] 79 Fed. Reg. 23157

[112] Future of Vaping, *supra* note __.

[113] 81 Fed. Reg. 29037

MRTP? The statute defines an MRTP as "any tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products."[114] The statute goes on to define what qualifies as being sold or distributed" for such purposes quite capaciously to include any labeling or marketing which represents "explicitly or implicitly" that:

> (I) the tobacco product presents a lower risk of tobacco-related disease or is less harmful than one or more other commercially marketed tobacco products;
>
> (II) the tobacco product or its smoke contains a reduced level of a substance or presents a reduced exposure to a substance; or
>
> (III) the tobacco product or its smoke does not contain or is free of a substance.[115]

Thus, the Tobacco Control Act bars the seller of a vaping product from telling consumers that its products "produce no smoke, only vapor" or that it contains lower levels of specified contaminants or nicotine. Such factually true claims may not be made without first obtaining MRTP approval. As interpreted by the FDA, this also applies to claims such as "healthier alternative to smoking," even though the FDA does not dispute the truth of this claim. [116] As the

[114] 21 U.S.C. § 387k(b)(1).
[115] *See* 21 U.S.C. § 387k(b)(2)(A)(i).
[116] Clarification of When Products Made or Derived from Tobacco Are Regulated as Drugs, Devices, or Combination Products, 82 Fed. Reg. 2193, 2205 (Jan. 9, 2017).

agency explained in a follow-up rulemaking designed to clarify the scope of FDA regulation of newly deemed tobacco products,

> A manufacturer's making a modified risk claim for a specific tobacco product renders the product an MRTP, which can be marketed only after the manufacturer substantiates any modified risk claims in an MRTP application and after FDA determines that the product meets the statutory standard.[117]

The Tobacco Control Act, by its terms and as interpreted by the FDA, bars manufacturers from engaging in any marketing or labeling that provides factual information to consumers, including basic information about product contents, let alone potential health risks or comparative health claims.

As for the potential for smokers to use ENDS as a way to reduce or quit smoking, the FDA's position is that communicating such messages requires obtaining FDA approval as a medical drug, device, or combination product. Under a January 2017 regulation, any tobacco product "intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease, *including use in the cure or treatment of nicotine addiction (e.g., smoking cessation)*, relapse prevention, or relief of nicotine withdrawal symptoms," is "subject to regulation as a drug, device, or combination product."[118] According to the FDA, "if an ENDS product seeks to be marketed as a cessation product, the manufacturer must file an application with FDA's Center for Drug Evaluation

[117] 82 Fed. Reg. 2193, 2212 (Jan. 9, 2017).

[118] 21 C.F.R. § 1100.5. *See also* Clarification of When Products Made or Derived from Tobacco Are Regulated as Drugs, Devices, or Combination Products, 82 Fed. Reg. 2193, 2194 (Jan. 9, 2017) (emphasis added).

and Research (CDER) and no ENDS have been approved by FDA as effective cessation aids."[119]

As with modified risk claims, the FDA has adopted a fairly broad conception of what sorts of claims about the use of ENDS products would trigger the approval requirement or could trigger regulation of an e-cigarette as a medical product. According to the FDA, "claims such as 'treatment of tobacco dependence,' 'wean yourself off of nicotine,' 'for people who wish to quit smoking,' 'stop smoking aid,' 'prevent relapse,' or 'stay quit' generally will bring a product within" the parameters for regulation as a medical product.[120] Further, "if the instructions provided by the manufacturer convey that the product is to be used as a cessation device, then the product will generally be regulated as a medical product." As with the regulation of medical devices, the FDA also made clear that in determining the "intended use" of a product, the FDA will look at "'any . . . relevant source,' including but not limited to the product's labeling, promotional claims, and advertising."[121]

The FDA has closely guarded the right to make relative health claims. At the beginning of 2019, JUUL Labs Inc. launched its "make the switch" campaign, which targeted current cigarette smokers.[122] One ad noted that "the average smoker tries to quit over 30 times" and urged adult smokers to "make the switch."[123] Although JUUL never made a specific relative risk claim, the FDA considered the company's marketed statements such as

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[119] Final Deeming Rule, *supra* note __, at 29,036.

[120] 82 Fed. Reg. 2193, 2205 (Jan. 9, 2017). The FDA expressly notes that these are just illustrative examples and not an exclusive list. *Id.* at 2205 n.14.

[121] 82 Fed. Reg. 2193, 2212 (Jan. 9, 2017).

[122] Brian Jenssen, *JUUL Ad Campaign "Target Adult Smoker," But New Research Shows Youth-focused Past*, POLICYLAB BLOG (May 17, 2019), https://ldi.upenn.edu/our-work/research-updates/juul-ad-campaign-targets-adult-smokers-but-new-research-shows-youth-focused-past/.

[123] *See* JUUL Labs, *New JUUL Labs Adult Education Campaign*, NEWSROOM (Jan. 8, 2019), https://www.juullabs.com/new-juul-labs-adult-education-campaign/.

"[JUUL is] a smart, really well thought-out alternative to smoking" tantamount to communicating "less harmful than cigarettes."[124] Moreover, the FDA sent the company a Warning Letter claiming "JUUL has marketed JUUL products as modified risk tobacco products," without an appropriate FDA order."[125]

Under the FDA's interpretation of its own authority, a manufacturer could be sanctioned for merely quoting the FDA's own statements in an advertisement or on a webpage, even if followed by a prominent disclaimer indicating that the FDA had not sanctioned or approved the manufacturer's claim for its specific product. (The FDA acknowledges that such a prohibition may raise First Amendment concerns, but this has not changed the FDA's legal position.[126]) Any such efforts to encourage or facilitate smoking cessation are only allowed if first approved by the FDA—and subjecting simple, truthful marketing claims to FDA approval is not a way to get the message out. The FDA itself has also failed to educate current smokers on relative risks.[127] If there is going to be competitive discovery of ways to educate adults, and smokers in particular, about the relative risks of nicotine products, it must occur in a dynamic, competitive marketplace. Such discovery is not compatible with government-imposed prior restraints on what sorts of truthful claims manufacturers are allowed to make.

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[124] Letter from Mitchell Zeller to Kevin Burns (Sept. 9, 2019), https://www.fda.gov/media/130859/download

[125] *Ibid.*; Letter from Ann Simoneau to Kevin Burns (Sept. 9, 2019), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/juul-labs-inc-590950-09092019

[126] 82 Fed. Reg. at 2209. As of this writing, litigation challenging the MRTP provisions of the Tobacco Act have been unsuccessful. See Discount Tobacco City & Lottery Inc. v. United States, 674 F.3d 509 (6th Cir. 2012).

[127] *See e.g.*, U.S. FOOD AND DRUG ADMIN., THE REAL COST E-CIGARETTE PREVENTION CAMPAIGN (July 21, 2023), https://www.fda.gov/tobacco-products/real-cost-campaign/real-cost-e-cigarette-prevention-campaign (public education campaign highlighting risks of vaping and not providing comparative risk information); U.S. FOOD AND DRUG ADMIN., FDA LAUNCHES NEW CAMPAIGN: "THE REAL COST" YOUTH E-CIGARETTE PREVENTION CAMPAIGN (May 1, 2020), https://www.fda.gov/tobacco-products/youth-and-tobacco/fda-launches-new-campaign-real-cost-youth-e-cigarette-prevention-campaign (describing campaign to highlight "potential health risks" of vaping).

IV. THE PUBLIC HEALTH CONSEQUENCES OF REGULATING HEALTH-RELATED CLAIMS

The FDA may be aware that ENDS pose less risks to users than do combustible tobacco products, and that ENDS may be a more effective way to reduce or quit smoking, but many Americans are not. Indeed, since the FDA endeavored to regulate ENDS under the Tobacco Control Act, public ignorance of the relative risks of competing tobacco products has gotten worse, and those with a financial interest in educating the public, and smokers in particular, about the relative benefits of vaping over smoking have been prevented from communicating that message.[128]

Recent surveys show that a majority of Americans have inaccurate views about the relative risks of vaping products. According one study of changing perceptions of harm from ENDS versus combustible cigarette use, "From 2012 to 2017, the proportion of US adults who perceived e-cigarettes as less harmful than cigarettes decreased significantly" and that "during the same time period, the perception of e-cigarettes to be equally or more harmful than cigarettes increased significantly."[129] Interestingly enough, the study found the greatest change between 2012 and 2015. And it was in April 2014 that the FDA formally proposed regulating e-cigarettes as tobacco products.

Since then, public misperceptions have only gotten worse. In 2016, respondents rejected the proposition that "vaping is healthier than traditional cigarettes" by a margin of 47 percent to

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[128] *See* Rich & Adler, *supra* note __.

[129] Jidong Huang, Bo Feng, Scott R. Weaver, Terry F. Pechacek, Paul Slovic, & Michael P. Eriksen, *Changing Perceptions of Harm of e-Cigarette vs Cigarette Use Among Adults in 2 US National Surveys From 2012 to 2017*, 2 JAMA NETW. OPEN 7, 15 (2019)

32 percent in Reuters–Ipsos polling.[130] By 2019, the same proposition was rejected 63 percent to 23 percent. A similar shift was observed on the question of whether "vaping is a good way to help people quit smoking."[131] Respondents rejected that proposition 43 percent to 37 percent in 2016 and 58 percent to 29 percent in 2019.[132] According to one 2020 survey of adults, for example, approximately 35.6% believed that e-cigarettes were "as harmful" as conventional cigarettes, while 28.3% believed that e-cigarettes were "more harmful" than conventional cigarettes, marking the first year that both beliefs together were held by a majority of Americans.[133]

Public misunderstanding of the relative risks of vaping products is concerning because such knowledge affects the willingness of smokers to try and use ENDS to reduce and quit smoking. Current smokers who believe ENDS are less harmful that cigarettes are twice as likely to completely switch to vaping.[134] Similarly, dual e-cigarette and combustible cigarette users who perceive e-cigarettes as less harmful than cigarettes have triple the odds of becoming exclusive e-cigarette users.[135] Research also suggests these misperceptions about the relative

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[130] CHRIS KAHN & ALLY J. LEVINE, REUTERS/IPSOS, BETTER THAN CIGARETTES? (2019), https://www.reuters.com/graphics/HEALTH-VAPING-POLL/0100B2BZ1F4/index.html.

[131] *Ibid.*

[132] *Ibid.*

[133] Priti Bandi, Samuel Asare, Anuja Majmundar, Nigar Nargis, Ahmedin Jemal, & Stacey A. Fedewa, *Relative Harm Perceptions of E-Cigarettes Versus Cigarette, U.S. Adults, 2018-2020*, 63 AM. J. PREV. MED. 186 (2022), https://www.sciencedirect.com/science/article/pii/S0749379722001775

[134] *See* Sooyong Kim, Saul Shiffman, & Mark Sembower, *U.S. Adult Smokers' Perceived Relative Risk on ENDS and Its Effects on Their Transitions Between Cigarettes and ENDS*, 22 BMC PUBLIC. HEALTH 1771 (2022).

[135] *See* Alexander Persoskie, Erin Keely O'Brien, & Karl Poonai, *Perceived Relative Harm of Using E-cigarettes Predicts Future Product Switching Among U.S. Adult Cigarette and E-cigarette Dual Users*, 114 ADDICTION 2197 (2019).
https://pubmed.ncbi.nlm.nih.gov/31278802/

risks of tobacco products are also shared by many physicians, which could influence the advice that doctors give their patients who smoke.[136]

ENDS and combustible cigarettes are also economic substitutes, particularly among youth. Although smoking has generally dropped among all age groups over the past two decades,[137] observational studies show that increases in e-cigarette sales are followed by faster reductions in conventional cigarettes sales. According to one recent study, an e-cigarette tax in Minnesota that consequently reduced e-cigarette sales prevented approximately 32,400 smokers from quitting, which the authors further estimate would have prevented 1.8 million smokers from quitting nationwide if the tax would have been levied across the country.[138] Further city-level research published in *JAMA Pediatrics* showed that a comprehensive tobacco flavor ban (including vapor products) led to more youth smoking in San Francisco.[139] These sorts of studies show that efforts to constrain or discourage ENDS use can increase cigarette consumption, something that should be of significant concern for public health.

V. WHAT ABOUT THE FIRST AMENDMENT?

[136] *See* Michael B Steinberg, Michelle T Bover Manderski, Olivia A Wackowski, Binu Singh, Andrew A Strasser, & Cristine D Delnevo, *Nicotine Risk Misperception Among U.S. Physicians*, 36 J. GEN. INTERN. MED. 3888 (2020).

[137] SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMIN. (SAMHSA), 2020 NSDUH ANNUAL NATIONAL REPORT (Oct. 25, 2021), https://www.samhsa.gov/data/report/2020-nsduh-annual-national-report.

[138] Henry Saffer, Daniel Dench, Michael Grossman, & Dhaval Dave, *E-Cigarettes and Adult Smoking: Evidence from Minnesota*, 60 JOURNAL OF RISK AND UNCERTAINTY 207 (2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7491748/; Rahi Abouk, Charles Courtemanche, Dhaval Dave, Bo Feng, Abigail S. Friedman, Johanna Catherine Maclean, Michael F. Pesko, Joseph J. Sabia, & Samuel Safford, *Intended and Unintended Effects of E-Cigarette Taxes on Youth Tobacco Use*, 87 J. HEALTH ECON. 102720 (2023), https://pubmed.ncbi.nlm.nih.gov/36565585/; Michael F. Pesko & Janet M. Currie, *E-Cigarette Minimum Legal Sale Age Laws and Traditional Cigarette Use Among Rural Pregnant Teenagers*, 66 J. HEALTH ECON. 71 (2020).

[139] Abigail S. Friedman, *A Difference-in-Differences Analysis of Youth Smoking and a Ban on Sales of Flavored Tobacco Products in San Francisco, California*, 175 JAMA PEDIATRICS 863 (2021), https://jamanetwork.com/journals/jamapediatrics/fullarticle/2780248.

The federal government's current approach to truthful claims about the relative risks and risk-reduction benefits of ENDS is not only bad public health policy, it is also at odds with existing First Amendment jurisprudence. Advertising, labeling, and other speech about products receives First Amendment protection as commercial speech, even when the products at issue are regulated by the FDA.[140] This includes tobacco-related labeling and advertising,[141] and includes health-related claims about products and services.[142] While the protection that such claims get is less robust than that core protected speech, it is still significant.[143] Over the past several decades the Supreme Court has repeatedly reaffirmed that commercial speech receives meaningful constitutional protection.[144] While government measures to prevent fraud or luring unwitting

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[140] *See* Richard A. Samp *Courts Are Arriving at a Consensus on Food and Drug Administration Speech Regulation*, 58 FOOD & DRUG L.J. 313, 314 (2003) ("every major lawsuit challenging FDA speech restrictions has proceeded under the assumption that the speech in question is commercial in character"); *see also* Nathan Cortez, *Can Speech by FED-Regulated Firms Ever Be Noncommercial?*, 37 AM. J.L. & MED. 388 (2011)..

[141] *See* Lorillard Tobacco Co v. Reilly, 533 U.S. 525 (2001). Of note, in *Lorillard* the tobacco companies had sought even greater protection for their advertising. As considered by the Court, the question was less whether such advertising would be protected as it was how much protection it would receive, and some justices questioned whether existing commercial speech doctrine was sufficiently protective. *See Lorillard*, 533 U.S. at 571 (Kennedy, J., concurring in part and concurring in the judgment); *id.* at 572 (Thomas, J., concurring in part and concurring in the judgment).

[142] The Supreme Court initially defined commercial speech as that speech which "propose[s] a commercial transaction" Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc., 425 U.S. 748, 762 (1976). Subsequent opinions have expanded the definition to include information about products and services offered by manufacturer or seller for the purpose of encouraging the purchase of the good or service in question, even if such communication or advertising includes health-related information. *See* Bolger v. Youngs Drug Products Corp., 463 U.S. 60, 67 (1983). *See also* Thompson v. Western States Medical Center, 535 U.S. 357 (2002) (applying commercial speech doctrine to FDA regulation advertising about compounded drugs).

[143] *See* Sorrell v. IMS Health, Inc., 131 S.Ct. 2653, 2659 (2011) ("the government's legitimate interest in protecting consumers from commercial harms explains why commercial speech can be subject to greater governmental regulation than noncommercial speech."(internal quotation omitted)); Thompson v. W. States Med. Ctr., 535 U.S. 357, 374 (2002) (noting the *Central Hudson* test applied to commercial speech is "significantly stricter than the rational basis test").

[144] *See, e.g.*, Sorrell v. IMS Health Inc., 131 S.Ct. 2653, 2659 (2011); Milavetz, Gallop & Milavetz, P.A. v. United States, 559 U.S. 229, 249–50 (2010); Lorillard Tobacco Co. v. Reilly, 533 U.S. 525, 565–71 (2001); Greater New Orleans Broad. Ass'n v. United States, 527 U.S 173, 195–96 (1999); 44 Liquormart, Inc. v. Rhode Island, 517 U.S. 484, 516 (1996); Rubin v. Coors Brewing Co., 514 U.S. 476, 491 (1995). As some commentators have noted, in some recent cases, the Court has "seemed to suggest that commercial speech has parity with pure (noncommercial) speech," though it has not said as much. Barbara J. Evans, *The First Amendment Right to Speak about the Human Genome*, 16 U. PA. J. CONST. L. 549, 187 (2014). *See also* Rodney A. Smolla, *Afterword: Free the Fortune 500! The Debate over Corporate Speech and the First Amendment*, 54 CASE W. RES. L. REV. 1277, 1292

consumers are permissible, it is particularly difficult for the government to suppress or restrict the provision of truthful information to consumers.[145]

The formal test applied to the regulation of commercial speech was articulated in *Central Hudson Gas & Electric Corp. v. Public Service Commission*.[146] *Central Hudson* establishes a four-part test. First, in order to qualify for protection, the speech must concern lawful activity and not be fraudulent or inherently misleading.[147] Second, courts consider whether the government has asserted a "substantial" governmental interest, such as preventing consumer deception or protecting public health.[148] Third, if so, courts consider whether the regulation "directly advances" the government's asserted interest[149] and, fourth, whether it is "more extensive than is necessary to serve that interest."[150]

In *Lorillard Tobacco v. Reilly*, the Supreme Court applied the *Central Hudson* test to regulations limiting tobacco product advertising, and readily concluded that only the latter two prongs of the test were at issue because the products at issue were legal, but the government indisputably had a substantial interest in preventing youth smoking.[151] The Court explained that these prongs still required careful examination of the advertising restrictions at issue because "tobacco retailers and manufacturers have an interest in conveying truthful information about

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(2004) ("Examination of actual case decisions demonstrates that the trajectory of modern commercial speech law has been an accelerating rise of protection for advertising.").

[145] In Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc., Justice Blackmun explained that it was "a matter of public interest" that consumer decisions "in the aggregate, be intelligent and well informed," and that this makes "the free flow of commercial information . . . indispensable." 425 U.S. 748, 765 (1976).

[146] Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n, 447 U.S. 557 (1980).

[147] *Id.* at 564.

[148] *Id.* at 566.

[149] *Ibid.*

[150] *Ibid.*

[151] *See Lorillard*, 533 U.S. at 555 ("Only the last two steps of *Central Hudson*'s four-part analysis are at issue here.").

their products to adults, and adults have a corresponding interest in receiving truthful information about tobacco products."[152] The same is true in the case of ENDS and other vaping products.

FDA-approved ENDS are lawful products and factually truthful claims about such products are not inherently misleading. The federal government also has a substantial interest in protecting public health, which can justify regulation of ENDS for the purposes of preventing youth consumption, preventing nicotine addiction, and preventing consumers from being misled.[153] As with the tobacco advertising at issue in *Lorillard*, this does not mean that the FDA can lawfully suppress, let alone prohibit, the communication of such information by manufacturers. The "compelling" nature of the state's interest in preventing youth smoking in *Lorillard* did not absolve of it the need to observe First Amendment limits on state regulation.[154] Consumers also have a significant interest in information about the health consequences of the products they purchase and consume.

The third and fourth prongs of the *Central Hudson* test constrain the government's ability to adopt overbroad or poorly justified restrictions on commercial speech. Rote invocation of "public health" is insufficient to justify restrictions on truthful commercial speech. The government must be able to show that such restrictions advance the asserted interest "in a direct and material way."[155] This burden is "not satisfied by mere speculation or conjecture."[156]

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[152] *Lorillard*, 533 U.S. at 564.

[153] *See* Lawrence O. Gostin & Gail H. Javitt, *Health Promotion and the First Amendment: Government Control of the Informational Environment*, 79 THE MILBANK QUARTERLY 547, 568 (2001)(noting that protection of public health is a substantial governmental interest).

[154] *Lorillard*, 533 U.S. at 564; *see also* Reno v. American Civil Liberties Union, 521 U.S. 844, 875 (1997) ("the governmental interest in protecting children from harmful materials . . . does not justify an unnecessarily broad suppression of speech addressed to adults.").

[155] Rubin v. Coors Brewing Co., 514 U.S. 476, 487 (1995); *see also* ("a governmental body seeking to sustain a restriction on commercial speech must demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree").

[156] *Rubin*, 514 U.S. at 487.

Rather, the government "must demonstrate that the harms it recites are real and that its restrictions will alleviate them to a material degree."[157] And while courts often defer to federal agency claims about scientific matters within their expertise, it is unclear such deference should be shown when governmental actions are subject to heightened constitutional scrutiny.[158]

The Supreme Court has "rejected the notion that the Government has an interest in preventing the dissemination of truthful commercial information in order to prevent members of the public from making bad decisions with the information."[159] If the government is concerned that consumers might be misled if information is incomplete, there are other steps that can be taken that impose less of a burden on speech, such as the requirement of disclaimers or additional disclosures. The consideration of such alternatives is required to satisfy the fourth prong of *Central Hudson*. As the U.S. Court of Appeals for the D.C. Circuit explained in the context of FDA regulation of nutritional supplements, "when government chooses a policy of suppression over disclosure—at least where there is no showing that disclosure would not suffice to cure misleadingness—government disregards a 'far less restrictive' means."[160] Similarly, insofar as the government is concerned about advertising directed at minors, this does not relieve the government of meeting its burden under *Central Hudson*.[161]

In *Pearson v. Shalala*, the D.C. Circuit found "dubious" the FDA's argument that "health claims 'lacking significant scientific agreement' are *inherently* misleading."[162] In that case, the FDA was concerned about health claims concerning nutritional supplements, about which there

[157] Edenfield v. Fane, 507 U.S. 761, 770-71 (1993).
[158] *See* Jonathan H. Adler, *Super Deference and Heightened Scrutiny*, 74 FLA. L. REV. 268 (2022) (explaining why deference to agency scientific determinations is incompatible with heightened scrutiny).
[159] Thompson v. Western States Med. Ctr., 535 U.S. 357, 374 (2002).
[160] Pearson v. Shalala, 164 F.3d 650, 658 (D.C. Cir. 1999).
[161] *See Lorillard Tobacco,* 533 U.S.
[162] *Pearson*, 164 F.3d at 655.

was not a wealth of medical research. Accepting the FDA's assertion that such claims were not based upon a scientific consensus, the court still rejected the FDA's "paternalistic assumption" that consumers would necessarily be misled by such information.[163] Instead of prohibiting such claims, the D.C. Circuit suggested, the FDA had to at least to consider how such information could be presented to consumers with appropriate qualifications or disclaimers.[164]

Unlike the nutritional supplements at issue in *Pearson*, the most relevant health-related claims about ENDS have already been embraced by the FDA. At least with regard to such claims, it would seem fantastical for the FDA to claim that such information could not be presented to consumers without misleading them. Like other tobacco products, ENDS must already be sold with FDA-prescribed warning labels.[165] This ensures that consumers are made aware of the FDA's concerns about the risks of such products, such as the risk of nicotine addiction. The FDA would well require additional warnings to accompany truthful health claims, including a disclaimer that such claims have not been evaluated or endorsed by the FDA or that they are made without the FDA's approval.[166] The current policy of imposing a prior restraint on truthful claims about the relative health benefits of ENDS and other vaping products is not only poor health policy, it is difficult to reconcile with existing commercial speech precedent.

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[163] *Pearson*, 164 F.3d at 655. In subsequent cases, the D.C. Circuit has affirmed the federal government's authority to prohibit health claims that are not substantiated by significant research. *See* Bellion Spirits, LLC v. U.S., 7 F.4th 1201 (D.C. Cir. 2021).

[164] *Pearson*, 164 F.3d at 659. *See also* Evans, *supra* note __, at 605 ("*Pearson I* suggests that when a claim has considerable evidence to support it but the evidence is mixed or unclear, the proper approach is to disclose the uncertainty rather than ban the speech altogether.").

[165] U.S. FOOD AND DRUG ADMIN., RETAILERS: CHART OF REQUIRED WARNING STATEMENTS ON TOBACCO PRODUCT PACKAGING AND ADVERTISING (Aug. 8, 2018), https://www.fda.gov/tobacco-products/retail-sales-tobacco-products/retailers-chart-required-warning-statements-tobacco-product-packaging-and-advertising.

[166] Of course, this might be an awkward disclaimer for the FDA to require if all a manufacturer were to do was quote the FDA's own statements.

CONCLUSION

If Americans, and smokers in particular, do not understand the relative risks of combustible and non-combustible products, how can this be addressed? The traditional answer is better public health campaigns: push government agencies to develop and promote more balanced and accurate public health messages. We are skeptical of such approaches and believe that respecting free speech principles with regard to truthful information about the relative risks of tobacco products could help protect public health.

Better messaging from governmental authorities may be helpful, but it can only do so much, particularly at a time of reduced trust in authorities.[167] In the wake of the COVID-19 pandemic, public health authorities have taken a massive credibility hit. A 2021 poll by the Robert Wood Johnson Foundation and the Harvard T.H. Chan School of Public Health found that barely half of Americans put significant trust in the Center for Disease Control and only 37 percent had much trust in the National Institutes of Health or the FDA.[168] America today is a low-trust environment, and governmental health authorities are not well-trusted by large swaths of the American population.[169]

The public health challenge is how to educate Americans, and smokers in particular, about the relative risks of ENDS compared to combustible cigarettes. More precisely, the challenge is to discover how to most effectively convey that information. And insofar as discovery is what is necessary, competitive marketplace dynamics are more promising than

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[167] *See* Adler & Rich, *supra* note __.

[168] ROBERT WOOD JOHNSON FOUNDATION AND HARVARD T.H. CHAN SCHOOL OF PUBLIC HEALTH, THE PUBLIC'S PERSPECTIVE ON THE UNITED STATES PUBLIC HEALTH SYSTEM 5 (May 2021), https://www.hsph.harvard.edu/wp-content/uploads/sites/94/2021/05/RWJF-Harvard-Report_FINAL-051321.pdf.

[169] *Ibid.*

governmental edicts issued from on high. As F.A. Hayek instructed, competition is "first and foremost a discovery procedure."[170]

If we want to discover how to teach consumers that ENDS are less dangerous than cigarettes and can help smokers quit, we want to harness self-interest and enable those who stand to benefit from the discovery of such knowledge to compete with each other. As Hayek explained, "Competition as a discovery procedure must rely on the self-interest of the producers, that is it must allow them to use their knowledge for their purposes, because nobody else possesses the information on which they must base their decision."[171] The problem, however, is that the existing regulatory regime makes it difficult—and in some cases illegal—for producers to attempt to educate their own consumers about the potential benefits and relative risks of their own products.

At present, ENDS manufacturers compete with each other, and against combustible tobacco products, across a range of product attributes, including price, convenience, taste, mouth feel, nicotine content, and aesthetics. By differentiating their products from others, they can hope to gain market share. The product attributes they cannot compete on, however, are health and safety. ENDS manufacturers are not allowed to make claims about the relative risks of their products as compared to other ENDS products, or even of combustible cigarettes, without first getting FDA approval. Nor do FDA regulations allow ENDS manufacturers to tell consumers that vaping might help them reduce or quit smoking unless they wish to go through a lengthy process that's equivalent to new drug approval.

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[170] F.A. Hayek, *Competition as a Discovery Procedure*, 5 QUARTERLY J. OF AUSTRIAN ECON. 9 (2002)
[171] F.A. *The Political Order of a Free People*, 3 LAW LEGISLATION AND LIBERTY 68 (1998).

FDA restrictions on the ability of producers to differentiate their products through health and safety claims foreclose a potentially promising way to educate consumers about the potential health benefits of switching from smoking to vaping. Research on product marketing has shown the consumer benefits of allowing product manufacturers to make truthful and non-misleading health-related claims.[172] Where competing producers can position their products as healthier or less dangerous than their competitors, they have an incentive to both educate consumers about the relative health benefits of their products as well as to develop products about which truthful positive health claims can be made.

In the 1980s, Kellogg's launched a marketing campaign for All-Bran® cereal, emphasizing the National Cancer Institute's conclusion that high-fiber diets could reduce risks of some cancers.[173] This initiative led to an increase in health claims about high-fiber foods, an increase in food product fiber content, and an increase in consumer fiber consumption.[174] Allowing firms to communicate the health benefits of their products both led to healthier products and healthier consumer choices.[175] Why wouldn't we want there to be a similar dynamic for nicotine products? If Volvo can pitch its cars by highlighting their relative

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[172] *See* FED. TRADE COMM'N, FTC TO FDA: ALLOWING MORE, TRUTHFUL HEALTH CLAIMS FOR FOOD AND DIETARY SUPPLEMENTS LIKELY TO BENEFIT BOTH CONSUMERS AND COMPETITION (Jan. 29, 2004), https://www.ftc.gov/news-events/news/press-releases/2004/01/ftc-fda-allowing-more-truthful-health-claims-food-dietary-supplements-likely-benefit-both-consumers . *See also*, J. Howard Beales, *Health Related Claims, the Market for Information, and the First Amendment*, 21 HEALTH MATRIX 7 (2011).

[173] *See* John E. Calfee & Janis K. Pappalardo, *Public Policy in Health Claims for Food*, 10 J. PUB. POLICY & MARKETING 33 (1991), https://journals.sagepub.com/doi/10.1177/074391569101000104; V.S. Freimuth, S.L. Hammond, & J. A. Stein, *Health Advertising; Prevention for Profit*, 78 AM. J. OF PUB. HEALTH 557 (1988), https://ajph.aphapublications.org/doi/abs/10.2105/AJPH.78.5.557; Rebecca Tushnet, *It Depends on the What the Meaning of "False" Is: Falsity and Misleadingness in Commercial Speech Doctrine*, 41 LOYOLA L.A. L. REV. 227, (2007)

[174] *See* John E. Calfee et al., *supra* note __, at 39.

[175] *Ibid.*; A.S. Levy & R.C. Stokes, *Effects of a Health Promotion Advertising Campaign on Sales of Ready-to-Eat Cereals*, 102 PUB. HEALTH REP. 398 (1987),https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1477858/.

crashworthiness (which necessarily requires highlighting the risk of car crashes),[176] why should an ENDS manufacturer not be allowed to explain why their product is less dangerous than combustible alternatives?

It is certainly true that all nicotine products pose risks, but the risks are not equivalent. Allowing manufacturers to educate consumers about relative risks both makes product safety a more salient product characteristic and helps increase consumer knowledge. Barring ENDS manufacturers from explaining the relative health benefits of their products makes as much sense as prohibiting car makers from advertising about auto safety. Allowing ENDS manufacturers the ability to make their products more desirable than cigarettes on health grounds will give them a substantial incentive to figure out how to communicate that message to consumers, and smokers in particular. While constraints on health-related information may be justified in some contexts, in the case of tobacco products, excessive (and arguably unconstitutional) constraints on speech are compromising public health.

[176] *See* VOLVO CAR CORP., VOLVO XC90 AWARDED TOP SAFETY RATING BY IIHS (Sept. 17, 2015), https://www.media.volvocars.com/us/en-us/media/pressreleases/167391/volvo-xc90-awarded-top-safety-rating-by-iihs?preview=true&t=61d31c57-620f-4bef-a640-041c08db2be6 (emphasizing crashworthiness of Volvo vehicles compared to automaker's vehicles.); 'For Life- When You Feel Safe You Can be Truly Free', Feb. 13, 2023 (https://youtu.be/UZtS5AO_1b0).