

Georgetown University Law Center
Scholarship @ GEORGETOWN LAW

2015

Effectively Regulating E-Cigarettes and Their Advertising—and the First Amendment

Eric N. Lindblom
Georgetown University Law Center, O'Neill Institute for National & Global Health Law, enl27@law.georgetown.edu

This paper can be downloaded free of charge from:
http://scholarship.law.georgetown.edu/ois_papers/95
http://ssrn.com/abstract=2579775

70 Food & Drug L.J. 57-94 (2015)

This open-access article is brought to you by the Georgetown Law Library. Posted with permission of the author.
Follow this and additional works at: http://scholarship.law.georgetown.edu/ois_papers

 Part of the Constitutional Law Commons, First Amendment Commons, Food and Drug Law Commons, and the Marketing Law Commons

Effectively Regulating E-Cigarettes and Their Advertising—and the First Amendment

ERIC N. LINDBLOM*

I. THE CURRENT DEBATE OVER E-CIGARETTES AND THE ABSENCE OF CONSTRUCTIVE REGULATION

There is a vigorous discussion in the public health community over how to regulate e-cigarettes and their marketing.[1] Based on the fact that e-cigarette use directly mimics smoking but is less harmful to users and nonusers, some public health experts favor a soft approach. They do not want regulation to interfere with the potential of e-cigarettes to help smokers quit or to help smokers switch to a harm-reducing way to consume nicotine, and want to err on the side of being more permissive.[2] Other public health experts favor a harder approach. They point to the fact that e-cigarette use is addictive and, at a minimum, still produces significant harms and risks compared to no tobacco or nicotine use at all. They also raise concerns that e-cigarette marketing can prompt some smokers to switch to e-cigarettes or to dual use instead of quitting all tobacco or nicotine use; increase relapse into nicotine addiction among former smokers; and increase youth and adult initiation into nicotine addiction, which could serve as a gateway into addicted smoking. They want a more strict approach, at least until more is known about e-cigarette harms and their impact on initiation, cessation and other use trends.[3]

Some countries have already explicitly banned e-cigarettes altogether.[4] Other countries allow the legal sale of e-cigarettes only if they first go through a formal

* Former Director of the Office of Policy at FDA's Center for Tobacco Products, currently on detail from the agency as a Senior Scholar at Georgetown University Law Center's O'Neill Institute for National and Global Health Law. The viewpoints expressed in this article are Mr. Lindblom's alone.

[1] For the purpose of this paper and its proposals, the term "e-cigarettes" includes any product or device marketed or used to inhale nicotine into the lungs other than through combustion and smoking. *See* Lauren K. Lempert et al., *The Importance of Product Definitions in U.S. E-cigarette Laws and Regulations*, 24 TOBACCO CONTROL (forthcoming 2015), *available at* http://tobaccocontrol.bmj.com/content/early/2014/12/14/tobaccocontrol-2014-051913 (advance copy published online ahead of print). For the purpose of this paper and its proposals, the term "e-cigarettes" includes any product or device marketed or used to inhale nicotine into the lungs other than through combustion and smoking.

[2] *See, e.g.*, Peter Hajek et al., *Electronic Cigarettes: Review of Use, Content, Safety, Effects on Smokers and Potential for Harm and Benefit*, 109 ADDICTION 1801, 1802 (2014); David B. Abrams, *Promise and Peril of E-cigarettes: Can Disruptive Technology Make Cigarettes Obsolete?*, 311 JAMA 135, 136 (2014); *see also* Robert West & Jamie Brown, Editorials, *Electronic Cigarettes: Fact and Faction*, 64 BRIT. J. GEN. PRAC. 442, 442 (2014).

[3] *See, e.g.*, Editorial, *E-cigarettes—Aid to Smoking Cessation or Smokescreen?*, 384 LANCET 829, 829 (2014); Dean E. Schraufnagel et al., *Electronic Cigarettes: A Position Statement of International Respiratory Societies*, 190 AM. J. OF RESPIRATORY & CRITICAL CARE MED. 611, 611–16 (2014); World Health Org., Framework Convention on Tobacco Control, Moscow, Russia, Oct. 13–18, 2014, *Electronic Nicotine Delivery Systems*, FCTC/COP/6/10 *passim* (July 21, 2014); Rachel Grana et al., *E-cigarettes: A Scientific Review*, 129 CIRCULATION 1972, 1972 (2014); Simon Chapman, Essay, *E-cigarettes: The Best and Worst Case Scenarios for Public Health*, 349 BMJ 5512 (2014).

[4] Argentina and Singapore are examples. *See, e.g.*, Inst. for Global Tobacco Control, Johns Hopkins Univ., U.S. STATE AND COUNTRY LAWS REGULATING E-CIGARETTES: A POLICY SCAN 7 (Oct. 1, 2014) [hereinafter

approval process and qualify as drugs or medical products that will safely and effectively promote a legitimate therapeutic purpose.[5] While that process may appear prudent, drug approvals typically require considerable supporting evidence and take a substantial amount of time and trouble to obtain. No e-cigarettes have yet qualified as drugs, and few have even submitted applications worldwide. Accordingly, countries that allow e-cigarettes on the market *only* as approved drugs or medical devices hinder and delay the potential for e-cigarettes to secure substantial public health gains, if not block it completely.

In other countries, including the United States, e-cigarettes are readily available and largely unregulated.[6] They are typically subject to only a patchwork of restrictions and requirements under pre-existing drug and consumer product laws and regulations.[7] On the plus side, this softer regulation permits smokers to obtain and use e-cigarettes as cessation aids or as a harm-reducing alternative way to consume nicotine. But the absence of regulation has also permitted the marketing of unnecessarily harmful and risky e-cigarettes. Moreover, the largely unconstrained advertising of e-cigarettes in the United States and elsewhere directly reaches youth and both non-smoking and smoking adults in ways that directly increase public health risks and harms.

A thoughtful, middle-ground approach to regulating e-cigarettes and their advertising could do much more to minimize e-cigarette health harms and risks while still allowing e-cigarettes to help smokers quit or serve as a viable harm-reducing alternative to smoking (without first going through a long and difficult drug-approval process). To date, however, no country has yet developed, much less implemented, a comprehensive regulatory scheme designed to do that in an effective way.[8]

POLICY SCAN].

[5] Australia and Canada are examples. *See, e.g.*, Hua-Hie Yong et al., *Trends in E-cigarette Awareness, Trial, and Use Under the Different Regulatory Environments of Australia and the UK*, 17 NICOTINE & TOBACCO RES. (forthcoming 2015), *available at* http://ntr.oxfordjournals.org/content/early/2014/11/28/ntr.ntu231 (advance copy published online ahead of print); *Notice: To All Persons Interested in Importing, Advertising or Selling Electronic Smoking Products in Canada*, HEALTH CAN. (Mar. 27, 2009), http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/prodpharma/applic-demande/pol/notice_avis_e-cig-eng.pdf.

[6] As discussed more fully below, the United States offers a formal approval pathway for e-cigarettes to be marketed as drugs but leaves non-drug e-cigarettes almost totally unregulated. Because no e-cigarettes have even applied to become drugs in the United States, by prohibiting the sale of non-drug e-cigarettes FDA could establish an at least temporary de facto complete ban in the United States. The Tobacco Control Act prohibits FDA from banning all cigarettes, all smokeless tobacco products, all little cigars, all other cigars, all pipe tobacco, or all roll-your-own tobacco products; but it does not prohibit FDA from banning all or some e-cigarettes (once the agency begins regulating non-drug e-cigarettes as tobacco products). Tobacco Control Act § 907(d)(3), 21 U.S.C. § 387g(c)(3) (2012). In addition, Congress, individual states, or local jurisdictions could also take action to ban all or some e-cigarettes.

[7] *See, e.g.*, POLICY SCAN, *supra* note 4. Some other countries, such as Togo and Costa Rica, specifically apply their existing tobacco control laws to e-cigarettes. This approach, which can include advertising bans, puts these countries somewhere between those with legal or de facto bans and those, such as the United States, that have not yet developed major new e-cigarette laws or rules. But treating e-cigarettes just like tobacco products fails to account for their differences, which can both impede their use as cessation aids or harm-reduction products and allow their marketing and sale to increase initiation and relapse into nicotine addiction and produce other preventable public health harms.

[8] Two middle-ground approaches to regulating e-cigarettes that might provide the foundation for a comprehensive regulatory scheme to minimize harms and maximize benefits are in the United Kingdom, which has established special restrictions on e-cigarette advertising, and in the new European Union Directive on tobacco products, which includes a range of provisions relating to e-cigarettes. *See, e.g.*, *New U.K. Advertising Rules for E-cigarettes*, COMMITTEES ADVERTISING PRAC. (Oct. 9, 2014), http://cap.org.uk/News-reports/Media-Centre/2014/New-ecig-ad-rules.aspx#.VMfh1C4TfwB; Directive 2014/40/EU, of the European Parliament and the Council of 3 April 2014 on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States Concerning the Manufacture, Presentation and Sale of Tobacco and Related Products

In the United States, the Food and Drug Administration (FDA) has taken an important first step in that direction by issuing a proposed rule to establish its active authority to regulate all non-drug e-cigarettes as tobacco products.[9] But the rule-making process has not included any significant new requirements or restrictions designed specifically for e-cigarettes or their advertising. For the most part, the rule making simply places e-cigarettes under the same requirements and restrictions that the statute applies to all "tobacco products."[10] That includes some constructive provisions, such as the Act's ban on false or misleading tobacco product labeling or advertising and its requirement that no tobacco products be marketed or promoted with any reduced-risk or reduced-exposure claims without first obtaining a permissive order from FDA.[11] But the rule making will not create the kind of regulatory framework necessary to minimize e-cigarette risks and harms or maximize their public health potential.

One possible reason for the absence of any significant new regulation directed at e-cigarette advertising in the deeming rule could be a concern that the regulation would be challenged or struck down as unconstitutional. Since 1976, the First Amendment's protections against government restrictions on speech have been applied to commercial speech (i.e., advertising and other communications to sell a product or service), making the regulation of tobacco product marketing more complicated.[12] As discussed below, however, FDA could largely avoid First Amendment constraints through exercising its enforcement discretion and administering the procedures, established by the Tobacco Control Act, that require new tobacco products to obtain new product or substantial equivalence orders from FDA before they may be marketed legally in the United States.

II. WE ALREADY KNOW ENOUGH ABOUT E-CIGARETTES TO REGULATE THEM MORE EFFECTIVELY

Another common refrain is that developing an effective regulatory structure for e-cigarettes requires more information and research.[13] Indeed, the debate in the public health community between those favoring softer versus harder approaches to regulating e-cigarettes has focused primarily on the lack of clear information about the actual effects of e-cigarette use and marketing on harms and use trends and, perhaps even more, on how to interpret the data and research that are available.[14] In particular, there

and Repealing Directive 2001/37/EC, 2014 O.J. (L127) (EU), *available at* http://ec.europa.eu/health/tobacco/products/index_en.htm.

[9] Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, 79 Fed. Reg. 23,142 (proposed Apr. 25, 2014) [hereinafter Deeming Rule] (to be codified at 21 C.F.R. pts. 1100, 1140, 1143). As discussed below, FDA already has authority to regulate certain e-cigarettes (those that make therapeutic claims) as drugs.

[10] *See id*.

[11] Family Smoking Prevention and Tobacco Control Act §§ 903, 911, 21 U.S.C. §§ 387c, 387k (2012).

[12] *See, e.g.*, Lorillard Tobacco Co. v. Reilly, 533 U.S. 525 (2001).

[13] *See, e.g.*, Kevin M. Walton et al., *NIH Electronic Cigarette Workshop: Developing a Research Agenda*, 17 NICOTINE & TOBACCO RES. 259, 260 (2015); Natalie McGill, *Research on E-cigarettes Examining Health Effects: Regulations Due*, 43 NATION'S HEALTH 10 (2013) (quoting FDA spokesperson Jennifer Haliski, who stated: "Further research is needed to assess the potential public health benefits and risks of electronic cigarettes and other novel tobacco products."); Daniella Saitta et al., *Achieving Appropriate Regulations for Electronic Cigarettes*, 5 THERAPEUTIC ADVANCES IN CHRONIC DISEASE 50, 50 (2014); Aruni Bhatnagar et al., *Electronic Cigarettes: A Policy Statement from the American Heart Association*, 130 CIRCULATION 1418, 1423 (2014).

[14] *See, e.g.*, Grana et al., *supra* note 3; Ann McNeill et al., *A Critique of a World Health Organization-Commissioned Report and Associated Paper on Electronic Cigarette*s, 109 ADDICTION 1972, 1982 (2014); Stanton Glantz, *Response to McNeill et al Criticism of the Report we Prepared for WHO and Subsequent*

has been considerable discussion about exactly how harmful e-cigarette use is compared to cigarette smoking, both to users and non-users, and about the extent to which: (a) smokers are using e-cigarettes to quit all cigarette or nicotine use or at least to switch completely to using only e-cigarettes; (b) youths who would not otherwise experiment with smoking or tobacco use are experimenting with e-cigarette use or becoming e-cigarette users; (c) cigarette smokers are engaging in dual use with e-cigarettes; and (d) former smokers are relapsing into addicted e-cigarette use. There are also questions about the degree to which experimentation and use of e-cigarettes serves as a gateway into addicted smoking and the extent to which former smoker relapse into e-cigarette use is a stepping stone back into regular smoking. Other questions concern whether smoker dual use with e-cigarettes or switching entirely to regular e-cigarette use might actually be interim steps toward quitting all smoking or all tobacco and nicotine use.[15]

While clearer, more complete answers to these questions would be interesting and informative, they are not necessary for determining the most effective way to structure the regulation of e-cigarettes and their marketing. Nor do these kinds of questions need to be answered before effective new e-cigarette regulations are drafted and implemented. All we need know to move forward constructively is the following:

1. Regardless of exactly how harmful the different types of currently available e-cigarettes are, it is already clear that e-cigarette use is, overall, at least somewhat less harmful to users and non-users than smoking.[16] That means public health gains are secured each time a smoker who would not otherwise quit all smoking switches entirely to using e-cigarettes instead.[17] Moreover, available data shows that switches from smoking to exclusive e-cigarette use

Review Paper in Circulation *on Ecigs*, CENTER FOR TOBACCO CONTROL RES. & EDUC. BLOG (Sept. 24, 2014, 02:19 PM), https://tobacco.ucsf.edu/response-mcneill-et-al-criticism-report-we-prepared-who-and-subsequent-review-paper-circulation-ecigs.

[15] *See e.g.*, Walton et al., *supra* note 13; Grana et al., *supra* note 3, at 1983.

[16] *See e.g.*, Charlotta Pisinger & Martin Dossing, *A Systematic Review of Health Effects of Electronic Cigarettes*, 69 PREVENTIVE MED. 248, 257 (2014); Konstantinos E. Farsalinos & Riccardo Polosa, *Safety Evaluation and Risk Assessment of Electronic Cigarettes as Tobacco Cigarette Substitutes: A Systematic Review*, 5 THERAPEUTIC ADVANCES DRUG SAFETY 67, 67 (2014); Hajek et al., *supra* note 2; Stephen Hecht et al., *Evaluation of Toxicant and Carcinogen Metabolites in the Urine of E-cigarette Users Versus Cigarette Smokers*, 17 NICOTINE & TOBACCO RES. (forthcoming 2015) (manuscript at 7) (on file with Food & Drug L.J.); Maciej Lukasz Goniewicz et al., *Levels of Selected Carcinogens and Toxicants in Vapour from Electronic Cigarettes*, 23 TOBACCO CONTROL 133, 133 (2014). In regard to secondhand exposure, as the previously cited studies show, e-cigarette aerosol vapor contains fewer toxins and generally lower levels of those it does contain compared to tobacco smoke. In addition, people near e-cigarette users face less secondhand exposure than persons near cigarette smokers because e-cigarettes do not produce any secondhand aerosol vapor directly from the e-cigarette, itself (i.e., no parallel to cigarette sidestream smoke) but only produce secondhand vapor from what the e-cigarette user inhales and then exhales (which is filtered through the user's lungs prior to release). *See, e.g.*, Jan Czogala, *Secondhand Exposure to Vapors from Electronic Cigarettes*, 16 NICOTINE & TOBACCO RES. 655, 655–60 (2014); *see also* Ingrid Torjesen, *E-cigarette Vapour Could Damage Health of Non-Smokers*, 349 BMJ 6882 (2014), *available at* http://www.bmj.com/content/349/bmj.g6882.

[17] Unless it were an interim stage toward complete switching (or complete cessation), dual use with no reduction in smoking would not produce any health benefits and could increase overall harms. But it is possible that long-term dual use where the e-cigarette consumption sharply reduced the number of cigarettes smoked (e.g., by 50%) could secure some health benefits to the user, at least among heavy smokers. *See, e.g.*, Carole Hart et al., *Does Smoking Reduction in Midlife Reduce Mortality Risk? Results of 2 Long-term Prospective Cohort Studies of Men and Women in Scotland*, 178 AM. J. OF EPIDEMIOLOGY 770, 770 (2013) (also citing numerous studies). Such sharp smoking declines through using e-cigarettes would likely reduce secondhand smoke exposure, and possibly related harms, as well. But e-cigarette use that only modestly or temporarily reduced the number of cigarettes smoked (and did not move the user toward complete switching or cessation) would not likely secure any significant health benefits. *Id.*

are possible and already occurring, at least to some extent.[18] Related research indicates that using e-cigarettes, either exclusively or through dual use, can help smokers to quit smoking,[19] or even prompt some smokers not trying to quit to reduce their smoking or stop.[20] There is also some evidence that smokers who successfully use e-cigarettes to help them quit smoking are likely subsequently to stop using the e-cigarettes as well.[21]

2. Regardless of how harmful e-cigarettes currently are or are not, they could readily be made considerably less harmful and risky. For example, many e-cigarettes contain contaminants or other harmful or potentially harmful ingredients unnecessary for their operation, there have been reports of e-cigarettes exploding because of misuse or improper design or manufacture, and nicotine poisoning among children and others from e-cigarette liquids that could be sold in sealed or child-proof containers, has been increasing.[22] Addressing just these problems, to start, would reduce the potential harms from any e-cigarette use among youth or non-smokers or dual users and

---

[18] *See, e.g.*, Lois Beiner & Lee Hargrave, *A Longitudinal Study of Electronic Cigarette Use in a Population-Based Sample of Adult Smokers: Association with Smoking Cessation and Motivation to Quit*, 17 NICOTINE & TOBACCO RES. 127 (2015); Carla J. Berg et al., *Attitudes Toward E-cigarettes, Reasons for Initiating E-cigarette Use, and changes in Smoking Behavior after Initiation: A Pilot Longitudinal Study of Regular Cigarette Smokers*, 4 OPEN J. PREVENTIVE MED. 789–800 (2014); *see also* Lila J. Finney Rutten et al., *Use of E-Cigarettes Among Current Smokers: Associations Among Reasons for Use, Quit Intentions, and Current Tobacco Use*, NICOTINE & TOBACCO RES. (forthcoming 2015), *available at* http://ntr.oxfordjournals.org/content/early/2015/02/10/ntr.ntv003.abstract (advance copy published online ahead of print). The extent to which those switching from smoking to e-cigarette use would have quit smoking anyway, or sooner, or later, is not yet clear.

[19] *See, e.g.*, Maria Rosaria Gualano et al., *Electronic Cigarettes: Assessing the Efficacy and the Adverse Effects Through a Systematic Review of Published Studies*, 37 J. PUB. HEALTH (forthcoming 2015) (online PDF manuscript at 9), *available at* http://jpubhealth.oxfordjournals.org/content/early/2014/08/09/pubmed.fdu055.abstract (advance copy published online ahead of print); Hayden McRobbie et al., *Electronic Cigarettes for Smoking Cessation and Reduction*, COCHRANE LIBR. (Dec. 17, 2014), http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD010216.pub2/abstract.

[20] *See, e.g.*, Karolien Adriaens et al., *Effectiveness of the Electronic Cigarette: An Eight-Week Flemish Study with Six-Month Follow-up on Smoking Reduction, Craving and Experienced Benefits and Complaints*, 11 INT'L J. ENVTL. RES. & PUB. HEALTH 11220, 11243 (2014); *see also* Sara Kalkhoran et al., *Dual Use of Smokeless Tobacco or E-cigarettes with Cigarettes and Cessation*, 39 AM. J. HEALTH BEHAV. 276, 280–81 (2015).

[21] Jessica K. Pepper et al., *Reasons for Starting and Stopping Electronic Cigarette Use*, 11 INT'L J. ENVTL. RES. & PUB. HEALTH 10345, 10354–56 (2014) (three percent of former e-cigarette users surveyed stopped because they quit smoking or using nicotine); *see also* Jonathan Foulds et al., *Development of a Questionnaire to Assess Dependence on Electronic Cigarettes in a Large Sample of Ex-Smoking E-Cig Users*, 17 NICOTINE & TOBACCO RES. 186, 190 (2015) ("[T]he most parsimonious explanation of these results is that e-cig users are generally less nicotine dependent than they were as cigarette smokers."). *But see* Jean-Francois Etter, *Explaining the Effects of Electronic Cigarettes on Craving for Tobacco in Recent Quitters*, 148 DRUG & ALCOHOL DEPENDENCE 102, 106 (2015) (e-cigarettes that provide high levels of nicotine are the most satisfactory to smokers and best reduce craving for tobacco but also create stronger dependence).

[22] On e-cigarette contaminants, and other unsafe features, *see, e.g.*, David Barboza, China's E-cigarette Boom Lacks Oversight for Safety: Producing 90 Percent of World's Devices, With Hazards for Health Users, N.Y. TIMES, Dec. 14, 2014, at A1; Igor Burstyn, *Peering Through the Mist: Systematic Review of What the Chemistry of Contaminants in Electronic Cigarettes Tells us About Health Risks*, 14 BMC PUB. HEALTH 18 (2014). On unnecessary ingredients that likely cause harm, *see, e.g.*, Konstantinos Farsalinos et al., *Evaluation of Electronic Cigarette Liquids and Aerosol for the Presence of Selected Inhalation Toxins*, 17 NICOTINE & TOBACCO RES. 168, 173 (2015). On nicotine poisoning, *see, e.g.*, J.P. Vakkalanka et al., *Epidemiological Trends in Electronic Cigarette Exposures Reported to U.S. Poison Centers*, 52 CLINICAL TOXICOLOGY 542, 542 (2014). On explosions, *see, e.g.*, Dana Liebelson & Asawin Suebsaeng, *Should You Be Worried About Your E-cigarette Exploding?*, MOTHER JONES (Apr. 17, 2014, 5:00 AM), http://www.motherjones.com/environment/2014/04/e-cigarettes-explode-fda-timeline.

would increase the potential benefits from each smoker that switches to using e-cigarettes.

3. Even if made much less harmful, e-cigarettes will still be addictive and deliver nicotine and other ingredients in aerosol form directly into user's lungs and, to some degree, into the lungs of exposed non-users. Consequently, we already know that using e-cigarettes is and likely always will be more harmful to users and exposed nonusers than no tobacco or nicotine use or exposure at all.[23] That means public health risks and harms occur every time anyone uses e-cigarettes other than smokers who would not otherwise have quit all tobacco and nicotine use. Moreover, available data shows that this kind of harmful new initiation is not only possible but already occurring to some extent among youth (including those who have not tried smoking), adults who have never tried smoking, and former smokers who had previously quit all tobacco and nicotine use.[24] There is also some evidence that never-smokers who use e-cigarettes are more open to trying smoking than never-smokers who do not use e-cigarettes, but whether it is the e-cigarette use or some other pre-existing factors that makes them more open to smoking is not yet clear.[25] Regardless, available facts tell us that any e-cigarette use by youth, non-smokers or by smokers who would otherwise

[23] There is a large body of research on harms from consuming or inhaling nicotine. *See, e.g.*, U.S. DEP'T HEALTH & HUMAN SERVS., THE HEALTH CONSEQUENCES OF SMOKING—50 YEARS OF PROGRESS: A REPORT OF THE SURGEON GENERAL ch. 5 (2014) [hereinafter SURGEON GENERAL REPORT 2014]. On the harms and risks from e-cigarette use in particular, *see, e.g.*, Pisinger & Dossing, *supra* note 16, at 249; Goniewicz et al., *supra* note 16, at 133; and Hecht et al., *supra* note 16, at 6 (higher levels of certain carcinogens and toxins in urine of e-cigarette users compared to non-users of tobacco or nicotine); *see also* Melissa A. Suter et al., *Is There Evidence for Potential Harm of Electronic Cigarette Use in Pregnancy?*, BIRTH DEFECTS RES. PART A: CLINICAL & MOLECULAR TERATOLOGY (2014); Jessica L. Barrington-Trimis et al., *Flavorings in Electronic Cigarettes: An Unrecognized Respiratory Health Hazard?*, 312 JAMA 2493 (2014); AM. INDUS. HYGIENE ASS'N, INDOOR ENVT'L. QUALITY COMM. & RISK ASSESSMENT COMM., WHITE PAPER: ELECTRONIC CIGARETTES IN THE INDOOR ENVIRONMENT (Oct. 19, 2014), *available at* https://www.aiha.org/government-affairs/Documents/Electronc%20Cig%20Document_Final.pdf; Maciej L. Goniewicz & Lily Lee, *Electronic Cigarettes Are a Source of Thirdhand Exposure to Nicotine*, 17 NICOTINE & TOBACCO RES. 256, 258 (2015) ("Our work suggests that thirdhand exposure to nicotine is possible not just from tobacco cigarettes, but also e-cigarettes.").

[24] For example, recent Monitoring the Future data shows that more than twice as many tenth graders currently use e-cigarettes vs. currently smoke, with seven percent in that grade currently using e-cigarettes but never having smoked cigarettes (a percentage that is too large to consist of only tenth graders who would otherwise be smokers). L.D. Johnston et al., Press Release: *E-cigarettes Surpass Tobacco Cigarettes Among Teens*, UNIV. MICH. NEWS (Dec. 16, 2014, 12:01 AM), http://www.monitoringthefuture.org/pressreleases/14cigpr.pdf (related data tables at http://www.monitoringthefuture.org/data/14data.html#2014data-cigs); *see also* Suchitra Krishnan-Sarin et al., *E-cigarette Use among High School and Middle School Adolescents in Connecticut*, 17 NICOTINE & TOBACCO RES. (forthcoming 2015), *available at* http://ntr.oxfordjournals.org/content/early/2014/12/02/ntr.ntu243.full (advance copy published online ahead of print); Samir Soneji, *Multiple Tobacco Product Use Among U.S. Adolescents and Young Adults*, 24 TOBACCO CONTROL (forthcoming 2015), *available at* http://tobaccocontrol.bmj.com/content/early/2014/12/14/tobaccocontrol-2014-051913 (advance copy published online ahead of print). On e-cigarette use by non-smoker adults, *see, e.g.*, Erin L. Sutfin et al., *Electronic Cigarette Use by College Students*, 131 DRUG & ALCOHOL DEPENDENCE 214 (2013) (also finding that e-cigarette use by college smokers was not associated with intentions to quit); Robert C. McMillen et al., *Trends in Electronic Cigarette Use Among U.S. Adults: Use is Increasing in Both Smokers and Nonsmokers*, 17 NICOTINE & TOBACCO RES. (forthcoming 2015), *available at* http://ntr.oxfordjournals.org/content/early/2014/11/28/ntr.ntu213 (advance copy published online ahead of print); Robert C. McMillen et al., Recorded Presentation: *Susceptibility to Electronic Cigarette Use Among Current Nonsmokers*, AM. PUB. HEALTH ASS'N (Nov. 17, 2014), https://apha.confex.com/apha/142am/webprogram/Paper297773.html.

[25] *See, e.g.*, Rebecca Bunnell et al., *Intentions to Smoke Cigarettes Among Never-Smoking U.S. Middle and High School Electronic Cigarette Users, National Youth Tobacco Survey, 2011–2013*, 17 NICOTINE & TOBACCO RES. 228, 230 (2015); Blair N. Coleman et al., *Association Between Electronic Cigarette Use and Openness to Cigarette Smoking Among U.S. Young Adults*, 17 NICOTINE & TOBACCO RES. 212, 214 (2015). It is also likely that e-cigarette users who become addicted to nicotine and are used to inhaling it into their

have quit all tobacco and nicotine use produces at least some not insignificant public health harms and risks.

Unless new research somehow establishes that e-cigarette use is either already risk free (which is impossible) or is not and cannot be made significantly less harmful and risky to users and non-users than smoking (which is extremely unlikely if not impossible), what we already know about e-cigarettes tells us that to maximize public health gains, an effective regulatory scheme should seek to:

1. make e-cigarettes even less harmful to users and non-users;
2. increase their use as a cessation aid or as a substitute for smoking among smokers who would not otherwise quit all tobacco and nicotine use; and
3. minimize e-cigarette use among all other persons.[26]

III. A PROPOSED MODEL FOR REGULATING E-CIGARETTES BASED ON WHAT WE KNOW NOW

The less harmful e-cigarettes are made, the larger their potential upside (i.e., larger risk reductions from smokers switching to e-cigarette use) and the smaller their potential downside (e.g., reduced harms from other new e-cigarette use). How to make e-cigarettes as minimally harmful as is possible or practical is complicated because there are many different mechanisms and designs. Nevertheless, simple foundational steps to make e-cigarettes much less harmful or risky could be implemented immediately. New laws or regulations could, for example, require child-proof packaging for e-cigarette liquids to prevent accidental nicotine poisoning (as a recent New York State law has done); prohibit combustion in e-cigarettes (which can create or increase exposure to toxins or even cause the e-cigarettes to explode); require clear instructions for use (to prevent nicotine poisoning and product explosions from misuse); prohibit potentially harmful contaminants in the nicotine-containing liquids; and ban ingredients, other than nicotine or any other ingredients necessary to the operation of the e-cigarette, that might be harmful when converted from liquid to aerosol form and inhaled.[27] Another option might be to limit the voltage or temperatures that e-cigarettes can produce to turn their liquid into aerosol vapor, as there is evidence that high temperatures and voltages can expose users to higher, more harmful levels of formaldehyde than cigarettes, and viable lower voltages and temperatures produce no exposure.[28]

---

lungs would be more likely to try cigarettes and become regular smokers than people who are not addicted to nicotine.

[26] For both ethical and practical reasons, a possible fourth goal has been omitted: Increase youth and adult experimentation with e-cigarettes instead of with smoking in order to increase their initiation into e-cigarette use instead of into smoking. It is difficult to see how this goal could be directly promoted without marketing e-cigarettes to youth, or allowing such marketing, which would inevitably encourage e-cigarette experimentation and use not only among otherwise youth smokers but also among youth who would otherwise not smoke or use any tobacco or nicotine products. Moreover, it might be that some youth who would otherwise experiment and initiate into smoking would, under the regulatory framework proposed here, still initiate into e-cigarette use without additional encouragement to try e-cigarettes. But if the implementation of this regulatory framework were followed by reductions in youth e-cigarette use and corresponding increases in youth smoking, adjustments might be necessary.

[27] Even if contaminants or other unnecessary ingredients in e-cigarettes were not prevalent or, at existing levels, were determined not to present serious health risks, prohibiting more than insignificant trace levels would prevent higher levels, with related harms, from appearing in the future, and could also be a useful proxy toward ensuring good manufacturing practices and generally safer e-cigarettes.

[28] R. Paul Jensen et al., Letters, *Hidden Formaldehyde in E-cigarette Aerosols*, 372 NEW ENG. J. MED. 392, 392 (2015).

Achieving the two other regulatory goals for e-cigarettes is more complicated because it requires carefully regulating advertising. It is well established that product advertising in general, and tobacco product advertising in particular, prompts experimentation and increases or maintains use.[29] In fact, some of the e-cigarette advertising in the United States today closely resembles the irresponsible ways that cigarettes used to be advertised before new laws, lawsuits and settlements, and public pressure, reined in the cigarette companies.[30] That tells us that if e-cigarette advertising is not substantially regulated and restricted, it will increase initiation among youth and non-smoking adults.[31] Unrestricted e-cigarette advertising is also likely to include efforts to promote e-cigarettes as long-term complements to smoking through dual use (e.g., to be used when and where smokers may not smoke) or to reduce cessation among smokers. On the other hand, the power of advertising to influence consumer behavior tells us that, to maximize public health gains, e-cigarette advertising should still be allowed to reach those smokers who would not otherwise quit for the purpose of encouraging them to use e-cigarettes as either a quitting aid or a less harmful way to obtain nicotine.

Resolving these conflicts is difficult (even if we temporarily put aside the First Amendment issues). Ideally, e-cigarette advertising would be regulated so that it reached only: (1) those smokers who would not otherwise stop (to encourage only constructive, harm-reducing e-cigarette use by those smokers); (2) those former smokers who have switched to e-cigarettes (to keep them from relapsing into smoking); and, perhaps, (3) current, addicted e-cigarette users who have never smoked (to prevent them from moving to smoking as a more effective or desirable way to feed their e-cigarette-based nicotine addiction).[32] While that cannot be done precisely, it could be closely approximated by allowing e-cigarette advertising, for the most part, only through direct communications (such as email, text messages or regular mail) to pre-verified current adult smokers (including dual users), to pre-verified adult former smokers who are now using only e-cigarettes, and, possibly, to other pre-verified adults who daily or regularly use e-cigarettes.[33]

[29] In *Lorillard Tobacco Co. v. Reilly*, for example, the United States Supreme Court stated that "we have acknowledged the theory that product advertising stimulates demand for products, while suppressed advertising may have the opposite effect," and noted that the Massachusetts Attorney General had cited "numerous studies to support this theory in the case of tobacco products." 533 U.S. 525, 560–61 (2001). Since then, the research and other evidence showing that tobacco product advertising increases prevalence and use and restricting that advertising reduces it has grown considerably. *See, e.g.*, Lisa Henricksen, *Comprehensive Tobacco Marketing Restrictions: Promotion, Packaging, Price and Place*, 21 TOBACCO CONTROL 147, 149 (2012); *see also* Tobacco Control Act Pub. L. No. 111-31, § 2(15)–(23), 123 Stat. 1777 (2009) [hereinafter Tobacco Act Findings (15)–(23)] (Congressional findings). For example, finding (15) states, "Advertising, marketing, and promotion of tobacco products have been especially directed to attract young persons to use tobacco products, and these efforts have resulted in increased use of such products by youth," and Finding (22) states, "Tobacco advertising expands the size of the tobacco market by increasing consumption of tobacco products." *Id*.

[30] *See, e.g.*, Press Release: *Durbin, Waxman, Harkin, Rockefeller & Members Of Congress: Report Shows E-cigarette Marketing Campaigns Lighting Up Among Young Users*, U.S. SENATOR DICK DURBIN (Apr.14, 2014), http://www.durbin.senate.gov/public/index.cfm/pressreleases?ID=06acef25-48b0-4d9a-857a-74f7b4fcd4d5 [hereinafter *Press Release from Senators*]; *see also* Jennifer C. Duke et al., *Exposure to Electronic Cigarette Television Advertisements Among Youth and Young Adults*, 134 PEDIATRICS 29, 30 (2013).

[31] Specific to e-cigarette advertising, *see, e.g.*, Pallav Pokhrel et al., *Receptivity to E-cigarette Marketing, Harm Perceptions, and E-cigarette Use*, 39 AM. J. HEALTH BEHAV. 121, 129 (2015). *See generally, e.g.*, U.S. DEP'T HEALTH & HUMAN SERVS., PREVENTING TOBACCO USE AMONG YOUTH AND YOUNG ADULTS: A REPORT OF THE SURGEON GENERAL, ch. 5 (2012) [hereinafter SURGEON GENERAL REPORT 2012].

[32] On whether e-cigarette use by never smokers might lead to smoking, *see, e.g.*, Coleman et al., *supra* note 25; Bunnell et al., *supra* note 25, at 10.

[33] Such pre-verification would be relatively easy to require or do. Many tobacco product businesses already have extensive lists of known or likely smokers or e-cigarette users, and similar lists could be readily

A major benefit of this approach is that it does not try to regulate separately all the different possible forms of e-cigarette advertising – ranging from Internet and television and other broadcast ads to ads in magazines to billboards and displays and ads at retail outlets—which could be quite complicated to structure, implement and enforce. Instead, it would prohibit all the different forms of publicly visible e-cigarette advertising (with some minor exceptions described below) and allow e-cigarette advertising only in direct communications to verified adult smokers, where it can both do the least harm and do the most good.

The proposed restrictions would be directed primarily to prevent e-cigarette advertising from encouraging e-cigarette initiation among youth or among adults who would otherwise never use tobacco or nicotine. But prohibiting this publicly visible advertising, including product displays at retail, would also help to prevent former smokers who had quit all tobacco or nicotine use from relapsing into e-cigarette use (which might then lead to a relapse back to smoking). It would also work to reduce e-cigarette use among non-smoking smokeless tobacco users.[34]

For the same reasons, this approach would also prohibit the delivery of any e-cigarette advertising through direct communications to anyone other than adult smokers or former smokers currently using e-cigarettes. Given the public health goal of allowing e-cigarette advertising only to encourage and sustain complete switching to e-cigarettes from smoking, there would be no public health justification for allowing the delivery of e-cigarette advertising to anyone else, with the possible exception of regular current e-cigarette users who have never smoked but might be at risk of becoming smokers because of their nicotine addiction.

Allowing direct e-cigarette advertising to existing adult smokers would, however, still allow the e-cigarette advertising to reach those current smokers who would otherwise quit successfully in the near future, possibly encouraging them to switch, instead. But there is currently no way to predict accurately who among the many smokers trying or planning to quit at any particular time will be among the small minority that actually quits successfully in the near future. Consequently, there is no practical way to exclude them from receiving the direct e-cigarette advertising without also excluding many more smokers who could benefit from receiving the advertising and being prompted to switch. For example, the direct e-cigarette advertising could be restricted not just to adult smokers but only to those adult smokers who also confirm that they are not currently trying to quit or planning to quit in the near future. That would sharply reduce exposure to the e-cigarette advertising among smokers who would otherwise quit. But

compiled (e.g., by website or email surveys) or purchased from existing vendors. *See, e.g.*, *Smokers Email Masterfile List*, NEXTMARK, INC., http://lists.nextmark.com/market?page=order/online/datacard&id=130172 (last visited Jan. 8, 2015) [hereinafter *Smokers Email Masterfile*] (including e-cigarette user segment and also offering mail and phone lists). In addition, software to verify that people with a specific name and associated address or email address are adults are also commercially available. *See, e.g.*, *Aristotle Industries Integrity ID and Age Verification Products*, INTEGRITY, http://integrity.aristotle.com/products (last visited Jan. 8, 2015). With these and other resources, e-cigarette sellers could both direct e-cigarette advertising only to verified adult smokers or former smokers who currently use e-cigarettes and could expand their lists of qualified recipients of that advertising by emailing or otherwise contacting verified adults, perhaps targeting those known or likely to be smokers or e-cigarette users, to confirm whether they are adult smokers or former smokers now using e-cigarettes. As a safety net, the e-cigarette sellers could also be required to include in their advertising messages a way that recipients could inform the sellers if they are not adults or are not current smokers or former-smoker e-cigarette users or could otherwise opt out of receiving the advertising.

[34] It is not yet clear whether a switch from using only smokeless tobacco to using only e-cigarettes would produce any significant health gains or losses for the users. But a switch from using just smokeless (with no secondhand exposure) to just e-cigarettes would expose nearby non-users to at least some increased risk of harm. Starting to consumer nicotine through the lungs through e-cigarette use might also increase the likelihood that a non-smoking smokeless user will progress into smoking.

it would also stop the ads from directly reaching the far larger group of smokers who say they are trying or planning to quit but will not actually do so. Because they do not want to smoke, but would not otherwise quit, these smokers are probably the most likely to respond beneficially to receive e-cigarette advertising that encourages switching.[35]

At the same time, the risk that the e-cigarette advertising communications might induce some smokers who would otherwise quit entirely to use e-cigarettes could be reduced by requiring the communications to include factual disclosures that make the following points:

- Smoking harms both the user and exposed family, friends and colleagues.
- The most effective way to minimize health harms and risks and maximize health improvements is by quitting all smoking and all other tobacco use altogether.
- E-cigarette use, while less harmful than smoking, is still harmful and risky.
- Smokers who cannot quit all tobacco use can still significantly reduce the amount of harm their tobacco use causes to themselves and others by switching from smoking to using e-cigarettes—but they must switch completely and stop all smoking to secure those health gains.
- More information and assistance about smoking health harms and the benefits from quitting can be obtained from 1-800-QUIT-NOW and at www.smokefree.gov.

This supplementary messaging to discourage switching instead of total cessation would also increase the chances that the advertising communications would work to prompt complete switching among those smokers who would not otherwise quit and to discourage dual use for any purpose other than a step toward switching or to total cessation. It would also help to prevent relapse among former smokers who have switched entirely to e-cigarettes, and would discourage never-smoking regular e-cigarette users from trying or using smoking to feed their nicotine addiction. Including this messaging in the e-cigarette advertising delivered directly to smokers and nonsmoking regular e-cigarette users would also reduce the risks of increasing initiation among any other nonsmokers or any youth who might end up seeing the ads, as well.[36]

In the United States, possible First Amendment constraints on compelling commercial speech could be avoided if this required additional messaging were made entirely factual and accurate and purely informational, and were identified as coming from the government (not the e-cigarette manufacturers or sellers).[37]

---

[35] In any given year, close to seventy percent of all smokers say they are interested in quitting, but only about fifty percent actually try to do so, and only about six percent successfully quit for at least six months. Ann Malarcher et al., *Quitting Smoking Among Adults—United States, 2001–2010*, MORBIDITY & MORTALITY WKLY. REP. (Ctrs. for Disease Control & Prevention, Atlanta, Ga.), Nov. 11, 2011, at 1513–19. That means that any e-cigarette advertising that excluded all smokers who say they are trying to quit or plan to do so soon would fail to reach more than 10 non-quitting smokers to encourage them to switch instead of smoke for every one otherwise quitter it avoided exposing to the e-cigarette ads for fear of inducing them to switch instead of quit. That lopsided ratio suggests that allowing the direct e-cigarette advertising communications to all verified current adult smokers would produce larger net public health benefits than allowing the ads only to pre-verified smokers who say they are not trying or planning to quit.

[36] Such nonsmokers and youth might see the ads if they are misdirected or if they are exposed to the ads after they are received by the targeted pre-verified adult recipients. Those most likely to be exposed would probably be close friends or members of the same family or household as the intended adult smoker or regular e-cigarette user recipients. But, because of that association, it is also likely that these unintended, secondary recipients of the ads would be smokers or former smoker e-cigarette users, themselves, or at risk of becoming smokers—which means that their exposure to the ads might also help to prevent or reduce smoking.

[37] *See, e.g.*, Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626, 651 (1985); R.J. Reynolds Tobacco Co. v. FDA, 696 F.3d 1205 (D.C. Cir. 2012); Am. Meat Inst. v. U.S. Dep't of Agric, 760 F.3d 18 (D.C. Cir. 2014) (overruling the holding in Reynolds v. FDA that the less-stringent *Zauderer* test for meeting

To increase potential public health benefits—and avoid possible First Amendment concerns about restricting commercial speech that does not threaten to increase initiation or reduce cessation—the e-cigarette sellers could also be permitted to communicate directly with doctors and other medical professionals about the possible health benefits from recommending that patients who smoke switch entirely to using e-cigarettes if they cannot or will not otherwise stop smoking.[38]

First Amendment concerns could be reduced even further by also providing some exceptions to the ban on publicly viewable e-cigarette advertising to enable retailers to notify potential legal customers that they sell e-cigarettes and to enable legal consumers to find and buy e-cigarettes.[39] An effective way to do that, while still minimizing any advertising that would attract youth or expose other at-risk consumers, would be to prohibit e-cigarette product displays and advertising at sales outlets but allow retailers to have a limited number of outdoor and indoor text-only signs, restricted in size, that could state only that e-cigarettes were available for sale at that location. If desired by the retailer, the permitted signs could also list the specific brands and their prices or state that additional information was available upon request to current adult smokers and regular e-cigarette users. Similar text could also be allowed in other retailer-sponsored advertising for the store, such as newspaper flyers.[40]

To avoid First Amendment concerns about restrictions on the content of commercial speech, it would be helpful to minimize any restrictions on the content of either the materials provided upon request at sales outlet or in the e-cigarette ads delivered directly to pre-verified adult current smokers and regular e-cigarette users (so long as it was not false or misleading).[41] But if First Amendment constraints were not applicable, or could be accommodated, it would be constructive to prohibit the e-cigarette materials or ads from including any messaging that suggested that e-cigarettes be used instead of quitting all tobacco and nicotine use or to complement or supplement smoking, instead of as an alternative. The ads could be left free to say nothing about smoking or to make accurate statements about possible risk reductions from using e-cigarettes exclusively instead of smoking. But e-cigarette ads such as those stating "Why Quit? Switch to

---

First Amendment standards applies only to compelled speech directed at the State's interest in preventing deception of consumers).

[38] *See, e.g.*, Thompson v. W. States Med. Ctr., 535 U.S. 357, 376–77 (2002) (stating that one of the reasons an FDA ban on the advertising of pharmacist-compounded drugs was unconstitutional was that it would prevent pharmacists from telling doctors about the drugs and their potential benefits to the doctors' patients).

[39] *See, e.g.*, Lorillard Tobacco Co. v. Reilly, where the United States Supreme Court struck down state restrictions on tobacco product advertising because the restrictions were overbroad and failed to appropriately take account of the fact that "tobacco retailers and manufacturers have an interest in conveying truthful information about their products to adults, and adults have a corresponding interest in receiving truthful information about tobacco products," noting, among other factors, that the restrictions could leave some retailers with "no means of communicating to passersby on the street that it sells tobacco products." 533 U.S. 525, 565 (2001). See also the concurrence by Justice Kennedy, joined by Justice Scalia, noting that the restrictions would even "prohibit a store from accurately stating the prices at which cigarettes are sold." 533 U.S. at 578.

[40] In *Lorillard*, the Court was troubled by the state law allowing retailers to have only a single 576 square-inch outdoor sign that stated "Tobacco Products Sold Here" in black text on white background. 533 U.S. 525, 585 (2001). The permitted signage proposed here would be much more extensive.

[41] On potentially heightened judicial scrutiny for commercial speech restrictions that are content-based, *see e.g.*, Sorrell v. IMS Health Inc., 131 S. Ct. 2653 (2011).

Blue,"[42] or promoting long-term dual use-cigarettes as a tobacco or nicotine product that smokers could use when and where they cannot smoke would not be permitted.[43]

With those possible exceptions, however, retailers could be left largely free to provide, upon request, whatever additional information or materials relating to the e-cigarettes they desired (e.g., verbally, by providing brochures or colorful ads, or by allowing consumers to handle the products or their packaging). But the sellers would be allowed to make the materials available only upon request to verified adults who state that they are smokers or regular e-cigarette users, and would be required also to provide the previously outlined factual disclosures regarding smoking harms and the need to switch exclusively to e-cigarettes (or quit all use) to secure significant health benefits.[44] With the same possible exceptions, sellers could also be left largely free to advertise their e-cigarettes any way that they wanted in the e-cigarette advertising delivered only through direct communications to pre-verified adult smokers and regular e-cigarette users (as long as the factual disclosures were included).

All of this permitted e-cigarette advertising would still have to comply with other restrictions and requirements in existing federal, state and local consumer protection and other laws, which typically prohibit false or misleading advertising (which is not protected by the First Amendment). While those laws have not yet been regularly enforced against e-cigarettes, once e-cigarettes are subject to FDA's tobacco product authority, the agency could take steps to ensure that all e-cigarette advertising complies with the Tobacco Control Act's prohibition against false or misleading tobacco product advertising.[45]

In countries that currently ban all tobacco product advertising or sharply restrict it, allowing e-cigarette advertising directly to current smokers and to e-cigarette users who are former smokers would give e-cigarettes a powerful competitive advantage over cigarettes. But even in countries, such as the United States, where cigarette advertising is not prohibited or restricted as sharply, limiting e-cigarette advertising to direct

[42] A copy of the Blu e-cigarette ad with this phrase, which ran in 2011, can be viewed online. Rutgers Sch. of Pub. Health, TRINKETS & TRASH, http://www.trinketsandtrash.org/viewImage.php?file_name=213543.jpg (last visited Jan. 23, 2015). The Blu electronic cigarette company is a subsidiary of Lorillard, Inc. (www.lorillard.com), also owner of the third largest cigarette company in the United States, Lorillard Tobacco Company, maker of Newport cigarettes.

[43] For examples of ads about being able to use e-cigarettes where smoking is prohibited see Stanford School of Medicine's online collection of "Smoke Anywhere" e-cigarette ads. *Stanford Research into the Impact of Tobacco Advertising*, STANFORD SCHOOL MED., http://tobacco.stanford.edu/tobacco_main/index.php (follow "E-cigs" hyperlink at top of page; then follow "Electronic Cigarette Ad Gallery" hyperlink; then follow "Freedom" hyperlink; then follow "Social Appeal" hyperlink) (last visited Jan. 23, 2015).

[44] Similar to bricks-and-mortar retailers, internet sellers could have only text notifications that they sell e-cigarettes on their publicly accessible website pages. But, subject to the same possible exceptions, they could, for the most part, have any e-cigarette advertising they wished on website pages that (using readily available age and ID verification software) could be accessed only by pre-verified adults who also state that they are current smokers or regular e-cigarette users. But the internet retailers would also be required to display the factual disclosures, or provide ready access to them, on those webpages. E-cigarette advertising inside adult-only retail outlets that primarily sell tobacco products might also be similarly unrestricted, but that would increase exposure to the ads among adults who are not current smokers, former smokers who now use e-cigarettes or other regular e-cigarette users. For more on this general approach to restricting tobacco product advertising at retail, *see* Micah Berman et al., *Tobacco Product Display Restrictions*, CENTER FOR PUB. HEALTH L. & TOBACCO POL'Y (Oct. 2010), http://publichealthlawcenter.org/sites/default/files/resources/nycenter-syn-tobproductdisplaybans-2013.pdf (last updated Apr. 2012).

[45] 21 U.S.C. § 387c(a)(1) (2012). At that time, FDA could also make sure that any permitted e-cigarette advertising did not violate the Act's prohibition against reduced-risk or reduced-exposure claims without a prior permissive order from FDA. 21 U.S.C. § 387k (2012). But given the goal of prompting current smokers who would not otherwise quit to switch to e-cigarette use, it might make sense to avoid impeding any reduced-risk claims made only to smokers that were not false or misleading.

communications to current smokers and certain former smokers should be enough to help prompt constructive switching to e-cigarette use. By itself, such direct advertising can be quite powerful, especially when allowed to make certain accurate reduced-risk claims. In addition, the vast majority of current smokers already view smoking as harmful and already want to quit, making them a relatively easy target for such e-cigarette advertising. Moreover, the ability of this direct advertising to prompt constructive switching (and prevent relapse to smoking) would likely depend, ultimately, less on the strengths or limitations of the advertising and more on the ability of e-cigarettes to offer an alternative that smokers would find attractive or at least acceptable.[46]

It might appear odd to some that the approach proposed here would restrict e-cigarette advertising and other marketing more severely than existing restrictions in the United States on cigarette advertising. But it does so precisely to make e-cigarettes and their advertising more effective anti-smoking tools. But placing similar constraints on cigarette sales and advertising would certainly make sense from a public health perspective—and much of the First Amendment analysis provided in this paper, especially if expanded and improved by others, should help to support efforts to do that.

In addition, other restrictions or requirements on e-cigarettes might be added to the regulatory approach proposed here, such as prohibiting their use in all smoke-free locations or banning e-cigarette flavors that could attract youth—if doing that would discourage e-cigarette use among youth and non-smokers and not disproportionately reduce constructive e-cigarette use as an alternative to smoking.[47] Another option to prevent youth initiation might be establishing or raising taxes on e-cigarettes, or taking other action to increase their minimum prices, so long as that would not

---

[46] Thanks to market competition, e-cigarette manufacturers would continue existing efforts to make e-cigarettes deliver nicotine to users in ways that are as attractive to smokers as possible. *See, e.g.*, William V. Lechner et al., *The Comparative Efficacy of 1st vs.2nd Generation Electronic Cigarettes in Reducing Symptoms of Nicotine Withdrawal*, ADDICTION (forthcoming 2015), *available at* http://onlinelibrary.wiley.com/doi/10.1111/add.12870/abstract (advance copy published online ahead of print). Indeed, the regulatory scheme here would likely accelerate those efforts because it would severely limit the companies' ability to market e-cigarettes to anyone other than smokers and former smokers. Constructive switching to e-cigarettes by smokers could be further enhanced by new government efforts to make cigarettes less attractive to smokers, which could range from plain packaging requirements and counter-marketing campaigns to banning menthol in cigarettes (but not e-cigarettes) or minimizing nicotine levels in cigarettes.

[47] Given that smokers in the United States already cannot smoke in smoke-free areas and rarely consume flavors other than tobacco and menthol, applying those additional restrictions to e-cigarettes and their use should not impede smoker switching to e-cigarette use as a less-harmful source of nicotine, much less as a cessation aid. But it is at least possible that allowing e-cigarette use in smoke-free areas or allowing flavored e-cigarettes might do more to encourage smokers to use e-cigarettes than increase e-cigarette or smoking initiation among youth—and, consequently, might produce a net public health gain (if preventing brand new youth harms is not given more weight than reducing harms among existing adult smokers). Moreover, the proposed e-cigarette advertising restrictions—by limiting youth exposure to e-cigarette advertising—might make prohibiting e-cigarettes from having flavors that attract youth less important for preventing youth experimentation. For a recent study finding that flavors are a major reason for youth e-cigarette experimentation, see Grace Kong et al., *Reasons for Electronic Cigarette Experimentation and Discontinuation Among Adolescents and Young Adults*, 17 NICOTINE & TOBACCO RES.(forthcoming 2015), *available at* http://ntr.oxfordjournals.org/content/early/2014/12/23/ntr.ntu257 (advance copy published online ahead of print). For a contrary finding see, for example, Saul Shiffman, *The Impact of Flavor Descriptors on Nonsmoking Teens' and Adult Smokers' Interest in Electronic Cigarettes*, 17 NICOTINE & TOBACCO RES. (forthcoming 2015), *available at* http://ntr.oxfordjournals.org/content/early/2015/01/24/ntr.ntu333 (advance copy published online ahead of print). *But see* Stanton Glantz, *Shiffman et al paper in Nicotine & Tobacco Research is not a reliable estimate of effects of ecig flavors*, CENTER FOR TOBACCO CONTROL RES. & EDUC. BLOG (FEB. 18, 2015, 8:33 PM), http://tobacco.ucsf.edu/shiffman-et-al-paper-nicotine-tobacco-research-not-reliable-estimate-effects-ecig-flavors; Jessica L. Barrington-Trimis et al., *Flavorings in Electronic Cigarettes: An Unrecognized Respiratory Health Hazard?*, 312 JAMA 2493 (2014), *available at* http://jama.jamanetwork.com/article.aspx?articleid=1935097.

disproportionately dampen smoker switching to e-cigarettes. One constructive approach, for example, might be to include even larger increases in the tax rates for cigarettes and other smoked tobacco products in any measure that establishes or increases e-cigarette taxes.

IV. HOW MIGHT FDA IMPLEMENT THIS PROPOSED REGULATORY FRAMEWORK?

Under existing laws, only FDA has the ability to regulate e-cigarettes and their advertising nationwide in as comprehensive a fashion as proposed here.[48] To do that, however, FDA must actively use its existing authority to regulate certain e-cigarettes as drugs or devices and activate and effectively use its separate authority to regulate other e-cigarettes as tobacco products.

Pursuant to a D.C. Circuit Court ruling in 2010, e-cigarettes that are marketed and sold for "therapeutic" purposes (i.e., with explicit or implicit "therapeutic" claims, such as claims that they will help smokers quit) are subject only to FDA's jurisdiction over drugs and devices, administered by FDA's Center for Drug Evaluation and Research (CDER).[49] Any such therapeutic e-cigarettes cannot be legally marketed or sold in the United States without first obtaining an order from FDA that approves the e-cigarette as a safe and effective drug or device. Although they deliver nicotine, a drug, e-cigarettes that do not make therapeutic claims may be regulated only under FDA's authority over tobacco products.[50]

Although e-cigarettes are being advertised in the United States with therapeutic claims (e.g., stating that they can help smokers quit),[51] FDA has not, since the 2010 court ruling, pursued any enforcement actions against any manufacturers or importers for illegally marketing e-cigarettes with therapeutic claims without the required prior

---

[48] Other existing federal laws and authorities relating to e-cigarettes are neither comprehensive nor being effectively enforced. For example, existing federal law prohibits product advertising that is false or misleading to consumers, 15 U.S.C. §§ 52, 55 (2012), but the United States Federal Trade Commission (FTC), which is in charge of enforcing those laws at the federal level, has not taken action against any e-cigarette companies. The FTC website, for example, does not appear to include any references to e-cigarettes. *See* FED. TRADE COMMISSION, www.ftc.gov (last visited Dec. 5, 2014).

[49] Sottera, Inc. v. FDA, 627 F.3d 891, 898–99 (D.C. Cir. 2010).

[50] It is not clear whether FDA could, under any of its existing authorities, regulate e-cigarettes that do not deliver nicotine (or some other drug), or regulate e-cigarette mechanisms sold without nicotine (or some other drug) that could be used to inhale nicotine but were not explicitly marketed for that purpose (i.e., were labeled and advertised for inhaling aerosols or vapors that did not contain any nicotine or other drug). If the agency could not reach all such products as drug-delivery devices or tobacco product accessories or through some other means, sellers could actively market these non-nicotine e-cigarettes and devices, perhaps including marketing directly to youth, as a way of encouraging and enabling nicotine-based e-cigarette use. In addition, the marketing of non-nicotine e-cigarettes and e-cigarette devices can also provide cover for the marketing of illicit nicotine-delivery e-cigarettes. In Australia, for example, where no nicotine-delivery e-cigarettes may be legally sold, non-nicotine e-cigarettes remain largely unregulated, and there is significant non-nicotine and nicotine e-cigarette use. *See, e.g.*, Yong et al., *supra* note 5.

FDA's proposed deeming rule does not assert jurisdiction over "accessories" to the newly deemed tobacco products, but any product "intended or expected to be used by consumers in the consumption of a tobacco product" is not considered an "accessory" but a "tobacco product" and would be subject to the deeming rule as proposed. *See* Deeming Rule, *supra* note 9, at 23,143.

[51] See, for example, "SmokeEnds" e-cigarettes, advertised online with text such as "Our company was inspired by a dear friend who smoked three packs of cigarettes a day; he eventually quit, using a similar product to ours today. . . I want to help others quit smoking." SMOKEENDS, www.smokeends.com (last visited Jan. 25, 2015).

order from FDA.[52] Nor has there been any public announcement about any e-cigarette company having submitted a drug approval application to FDA to obtain such an order for any e-cigarettes.[53]

On its June 2009 effective date, the Family Smoking Prevention and Tobacco Control Act ("Tobacco Control Act") provided FDA with extensive authority to regulate "tobacco products" and their manufacture, distribution, marketing and sale to protect the public health.[54] While it applied those tobacco product authorities only to cigarettes, roll-your-own cigarette tobacco, and smokeless tobacco products, it also gave FDA authority to "deem" any or all other products meeting the statutory definition of "tobacco product" to be subject to the Act and to FDA's active tobacco product regulation.[55] On April 14, 2014, through its Center for Tobacco Products, FDA issued a proposed rule that would deem all such tobacco products— including all e-cigarettes marketed without therapeutic claims (non-drug e-cigarettes)—to be subject to the Act's tobacco product requirements and to FDA's tobacco product regulation.[56] The public comment period closed on August 8, 2014, and FDA is expected to issue the final rule after it has considered all the comments, drafted responses, and made any changes to the proposed rule.

E-cigarettes placed under FDA's active tobacco product jurisdiction through the final deeming rule would automatically become subject to the Tobacco Control Act's prohibition against tobacco product free samples, its requirement that tobacco product ads or labeling not be false or misleading, and its modified risk provisions, which require any manufacturer or importer that wants to market a "modified risk tobacco product" (a tobacco product marketed with a reduced-risk or reduced-exposure claim) to first obtain a permissive order from FDA, which could include restrictions on how the claim could be advertised or otherwise communicated.[57] But the proposed rule did not include any new restrictions specifically relating to e-cigarette advertising.[58] While the agency could add some new advertising restrictions into the final rule, there are legal and practical impediments—and FDA typically does not make its final rules

---

[52] The FDA website page that provides access to all FDA Warning Letters sent to manufacturers and importers for suspected violations lists only five warning letters relating to e-cigarettes, all dated September 8, 2010. *Inspections, Compliance, Enforcement, and Criminal Investigations: Warning Letters*, FOOD & DRUG ADMIN., http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm (last updated Feb. 15, 2015).

[53] While it is possible that such an application has been submitted, but it being held confidential by FDA, in many cases, such applications are disclosed by the manufacturer or the industry press.

[54] Tobacco Control Act § 901(b), 21 U.S.C. § 387a(b)(2012).

[55] Id.

[56] Deeming Rule, *supra* note 9. The proposed rule included an option for consideration that would exclude "premium cigars" from being deemed.

[57] Tobacco Control Act § 911, 21 U.S.C. § 387k (2012). Tobacco Control Act § 911(h)(4) provides that an order permitting the marketing of a modified risk tobacco product order may require "that the product comply with requirements relating to the advertising and promotion of the tobacco product." 21 U.S.C. § 387k(h)(5) (2012).

[58] Many comments submitted on the proposed rule urged FDA to include additional advertising restrictions in the final version of the rule. For example, a collection of twenty-four major public health groups, including the American Cancer Society and the Campaign for Tobacco-Free Kids, proposed that the final version of the rule prohibit self-service displays, brand-name sponsorships, and brand names from non-tobacco products for all e-cigarettes and other newly deemed products put under FDA's tobacco product jurisdiction, and that the final rule also require advance notice to the agency of any new advertising via the Internet or other electronic communications to consumers. *See, e.g.*, Comment from American Academy of Family Physicians et al., regarding FDA Proposed Rule: Deeming Tobacco Products to be Subject to the Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act, (submitted Aug. 8, 2014), *available at* http://www.regulations.gov/#!documentDetail;D=FDA-2014-N-0189-79772.

stronger than its proposed rules in terms of either protecting the public health or placing requirements on the regulated industry.[59]

However, the regulatory framework established by the Tobacco Control Act makes it possible for FDA to regulate e-cigarettes and their advertising in the ways proposed here without including any new advertising restrictions or other provisions in the final deeming rule or any other future rulemaking.

A. *FDA's Enforcement Discretion.*

By the explicit terms of the Tobacco Control Act, on the effective date of the final FDA deeming rule any currently marketed brand of non-drug e-cigarettes that was not commercially marketed in the United States on February 15, 2007 may no longer be legally be sold in the United States until its manufacturer or importer submits an application to FDA and obtains either a new product order or an order finding that the specific brand of e-cigarettes is substantially equivalent to a brand of e-cigarettes that was on the market on February 15, 2007.[60] As it does not appear that any non-drug e-cigarettes currently on the market were commercially marketed on February 15, 2007 (and none of the e-cigarettes that are not tobacco products have the required FDA approvals), all e-cigarettes on the U.S. market will be illegal or prohibited products as of the effective date of the final deeming rule.

Because of this situation, the proposed deeming rule stated that FDA intended, after the rule's effective date, to exercise its enforcement discretion to allow existing e-cigarette brands to stay on the market, despite being illegal, if the manufacturers or importers submitted a new tobacco product or substantial equivalence application within twenty-four months, and would continue to exercise that enforcement discretion until FDA processed the application and issued a related order.[61] FDA also stated, however, that it would "consider revising its compliance policy should the Agency find that doing

---

[59] Thomas J. Hwang et al., *Quantifying the Food and Drug Administration's Rulemaking Delays Highlights the Need for Transparency*, 33 HEALTH AFFAIRS, 309, 309–15 (2014). FDA could make the final rule stronger by including new advertising restrictions for e-cigarettes if the agency determined that the restrictions were "appropriate for the protection of the public health" and consistent with the First Amendment's commercial speech protections; and were "logical outgrowths" from the proposed rule. Tobacco Control Act § 906(d), 21 U.S.C. § 387f(d) (2012); *see, e.g.*, Long Island Care at Home, Ltd. v. Coke, 551 U.S. 158 (2007).

[60] 21 U.S.C. § 387j (2012). It appears that FDA cannot change or re-interpret this date, and that it could be altered only through Congress passing a new law. There also does not appear to be any legislative history that explains the intention of Congress in regard to the statute's February 15, 2007 date and its effect on e-cigarettes once deemed to be under FDA's tobacco product authority. But e-cigarettes were being marketed and sold in the United States when Congress debated and passed the Tobacco Control Act into law in the spring of 2009. For example, FDA had already exercised its authority over drugs and devices to take enforcement actions against e-cigarettes in 2008. *See, e.g.*, Smoking Everywhere v. FDA, 680 F. Supp. 2d 62 (D.D.C. 2010) *aff'd sub nom*. Sottera, Inc. v. FDA, 627 F.3d 891 (D.C. Cir. 2010). Accordingly, it appears that Congress knew that the tobacco product market was changing, and included e-cigarettes, but, nevertheless, implemented the law to provide FDA with authority to regulate the marketplace so that any tobacco product (whether under the agency's original tobacco product jurisdiction or later deemed to be so) that was significantly different, from a public health perspective, or just raised "different questions of public health," compared to the tobacco products on the market on February 15, 2007 could not legally be sold in the United States unless FDA determined that allowing them on the market would be "appropriate for the protection of the public health" or could be made so by allowing the marketing only with certain advertising and marketing restrictions. *See* Tobacco Control Act § 910, 21 U.S.C. § 387j(a)(3), (c)(2) (2012). *But see* Letter from John A. Boehner et al., to the Honorable Sylvia M. Burwell, Secretary, U.S. Dep't Health & Human Servs. (Nov. 23, 2014), *available at* https://www.scribd.com/document_downloads/249057727?extension=pdf&from=embed&source=embed (House leadership urging FDA not to apply the February 15, 2007 grandfather date to e-cigarettes and other newly deemed tobacco products).

[61] Deeming Rule, *supra* note 9.

so is warranted, such as to better protect the public health."[62] It also specifically asked for comments concerning whether it should use its enforcement discretion to provide a twenty-four-month or longer grace period for all or some of the newly deemed tobacco products that become illegal tobacco products as of the effective date of the final deeming rule. FDA also asked whether, in providing such a grace period through enforcement discretion, it should take into account different factors, such as whether the product's marketing "is limited to existing adult users of the product" or "is unlikely to be seen or received by youth," or whether the product has different characteristics relating to combustibility, toxicity, flavors or nicotine.[63]

Given these statements in the proposed rule, the door is wide open for FDA to use its enforcement discretion to begin establishing the regulatory scheme for e-cigarettes that has been proposed here. To begin, FDA could announce that it will exercise its enforcement discretion, after the effective date of the final deeming rule, to allow all newly illegal non-drug e-cigarettes to remain on the market if the manufacturers or importers take the following actions:

- Submit a complete new product or substantial equivalence application (e.g., within twenty-four months of the deeming effective date, as suggested in the proposed rule).
- Ensure that the e-cigarettes comply with basic harm-reducing requirements, such as child-proof packaging, no combustion, no contaminants or unnecessary toxins (e.g., within twelve months).
- Stop taking any action to support or allow the advertising of the e-cigarettes to consumers except through direct communications to pre-verified adults who confirm that they are current smokers or former smokers who are now regular e-cigarette users—other than the listing of the e-cigarette brand name and price at retail outlets or in retailer ads (e.g., within 180 days).[64]
- Comply with the various requirements and restrictions in the Tobacco Control Act and related rules that apply to all newly deemed tobacco products (e.g., registration and reporting, no free samples, no false or misleading labeling or advertising).[65]
- Submit to FDA's Center for Tobacco Products (e.g., within 90 days) a signed document agreeing to take the above actions before the related deadlines.

To keep things simple and more manageable in this enforcement discretion context, FDA could omit using any additional enforcement discretion factors relating to any of the other restrictions or requirements of the proposed regulatory scheme for e-cigarettes. But the agency could still try to constrain the most egregious claims for e-cigarettes allowed to remain on the market by notifying the e-cigarette companies that it intends to exercise its enforcement discretion immediately to begin enforcement actions to remove from the market any e-cigarettes found to be making any therapeutic claims without the required prior drug or device approval orders from FDA or found to have any false or misleading labeling or advertising.[66] Given the goal of encouraging smokers to switch

---

[62] *Id.* at 23,175.

[63] Deeming Rule, *supra* note 9, at 23,176–77.

[64] The ads could be allowed to be delivered to all regular e-cigarette users (not just those who are former smokers) but that could shift the focus away from the primary purpose for allowing e-cigarette sales (to prompt switching from smoking to only e-cigarette use) and allowing e-cigarette advertising to never-smoker regular e-cigarette users would not, at this point, likely work to prevent them from moving on to smoking because the ads would not yet be required to include the anti-smoking supplementary messaging.

[65] Deeming Rule, *supra* note 9, at 23,143.

[66] For example, the labels of many e-cigarettes sold in the United States currently include inaccurate listings of the products' nicotine content. *See, e.g.*, *Analysis of Nicotine Content of E-Liquid Samples*, SALT

to less-harmful e-cigarette use, however, FDA could also exercise its discretion not to take any enforcement action against any e-cigarettes, because they were being marketed with reduced-risk or reduced-exposure claims without a prior permissive order from agency (so long as they met all the enforcement discretion factors outlined above).

Because FDA would be exercising discretion only in respect to manufacturers or importers, it would not make sense to have that discretion depend in part on how retailers were choosing, independently, to advertise the e-cigarettes. But most brick-and-mortar retailer advertising of tobacco products is directly and substantially supported, if not entirely paid for, by tobacco product manufacturers (e.g., by providing posters or displays to retailers or paying them to display certain products or advertisements).[67] So the enforcement discretion criteria could reduce publicly visible advertising at retail outlets by requiring manufacturers and importers to agree not to take any action to support or allow the advertising of their e-cigarettes at retail outlets (other than the posting the names and prices of available brands), except to support advertising that would reach only certain pre-verified adults.

This enforcement discretion system would directly reflect and move toward the previously proposed regulatory scheme for e-cigarettes, and could be explained and supported accordingly. FDA could also independently justify these enforcement discretion criteria as temporary stopgap measures necessary to reduce the harms to the public health that would likely occur from FDA simply allowing all e-cigarettes made illegal by the statute to stay on the market provisionally until their manufacturers or importers had a reasonable time to submit substantial equivalence or new product applications and the agency then had a chance to consider the applications and issue related orders.

While this kind of agency action through enforcement discretion might seem overly ambitious to some readers, agency decisions regarding whether or not to take enforcement action, or the criteria it used to make those decisions, is rarely subject to judicial review. For example, in one of the major *Supreme Court rulings on enforcement discretion, the Court* refused to review FDA's decision not to take enforcement action, stating that it had "recognized on several occasions over many years that an agency's decision not to prosecute or enforce, whether through civil or criminal process, is a decision generally committed to an agency's complete discretion."[68] In another case following that ruling, the D.C. Circuit stated that "FDA enjoys complete discretion not to employ the enforcement provisions of the FDC Act, and those decisions are not subject to judicial review. As this court recently concluded, the provisions [of the FDC Act] authorize, but do not compel the FDA to undertake enforcement activity; they 'commit complete discretion to the [FDA] to decide how and when they should be exercised.'"[69]

Two major exceptions apply. Courts will review an agency's enforcement decisions: (1) if Congress has stated in the applicable law how it wants that discretion to be exercised (which is not the situation here with the Tobacco Control Act's provisions); or (2) when an agency, through a rule making or some other formal process, publicly establishes restrictive criteria that it will be using to make enforcement decisions, thereby

---

LAKE COUNTY HEALTH DEPARTMENT (Dec. 2014), http://ow.ly/i/8bZHm/original (finding actual nicotine content ranging from 88% to 840% more than stated amount).

[67] *See, e.g.*, E. C. Feighery et al., *How Tobacco Companies Ensure Prime Placement of Their Advertising and Products in Stores: Interviews with Retailers About Tobacco Company Incentive Programmes*, 12 TOBACCO CONTROL, 184, 184–88 (2003).

[68] *Heckler v. Chaney,* 470 U.S. 821, 831 (1985).

[69] Cmty. Nutrition Inst. v. Young, 818 F.2d 943, 950 (D.C. Cir. 1986) (quoting Schering Corp. v. Heckler, 779 F.2d 683, 686 (D.C. Cir. 1985)).

reducing the scope of its enforcement discretion.[70] In that latter situation, the courts can review the agency's exercise of its enforcement discretion against specific entities to make sure it follows that agency-established criteria.

Accordingly, FDA should be very careful that it does not impede its ability to implement the enforcement discretion strategy proposed here, or its ability to otherwise exercise its enforcement discretion, by establishing any restrictive criteria for exercising its enforcement discretion against those newly deemed tobacco products that are on the market illegally as of the effective date of the final deeming rule. For example, FDA could preserve its flexibility by announcing the enforcement discretion criteria proposed here as only internal guidelines or a policy statement, not as formal restrictions or as requirements established in a final rule that the agency would be obligated to follow unless or until it formally changed the statements in a subsequent rulemaking.[71]

The type of enforcement discretion suggested here follows along the line of FDA's action levels for contaminants in foods, where all foods with any amount of the contaminants are violating the applicable standard but the agency announces that it intends to enforce against only those with levels above an announced "action level." The Supreme Court has upheld the agency's implementation and use of such informal action levels through its enforcement discretion, without any related rulemaking or other notice and comment process.[72] The courts have also found that action levels implemented through enforcement discretion are not subject to judicial review (unless the agency begins treating them as substantive rules).[73]

Here, the fact that FDA would be exercising its enforcement discretion based not only on observable characteristics of the e-cigarettes and their marketing but also on whether the manufacturer or importer of the e-cigarettes submitted a formal pledge that it would take certain actions by certain deadlines is also permissible. For example, in a somewhat parallel situation, the D.C. Circuit found that the Environmental Protection Agency could exercise its enforcement discretion, without triggering judicial review, by deciding not to take enforcement action against violators that entered into an agreement with the agency requiring them to take various actions related to coming into compliance.[74]

Consistent with these cases, FDA could implement the proposed enforcement discretion process simply by announcing the criteria it plans to consider in deciding which e-cigarettes illegally on the market it will enforce against. But it would provide

[70] *See, e.g.*, Mass. Pub. Interest Research Grp., Inc. v. U.S. Nuclear Regulatory Comm'n, 852 F.2d 9, 16 (1st Cir. 1988) ("'Just as Congress can provide the basis for judicial review of nonenforcement decisions by spelling out statutory factors to be measured by the courts, so an agency can provide such factors by regulation. When an agency chooses to so fetter its discretion, the presumption against reviewability recognized in *Chaney* must give way.'" (quoting Ctr. for Auto Safety v. Dole, 846 F.2d 1532, 1535 (D.C. Cir. 1988))).

[71] *See, e.g.*, Farrell v. Dep't of Interior, 314 F.3d 584, 590–91 (2002) ("The general consensus is that an agency statement, not issued as a formal regulation, binds the agency only if the agency intended the statement to be binding." (citing Vitarelli v. Seaton, 359 U.S. 535, 539 (1959); Service v. Dulles, 354 U.S. 363, 373–74, 377–82 (1957))).

[72] Young v. Cmty. Nutrition Inst., 476 U.S. 974 (1986); *see also* Nat'l Mining Ass'n v. McCarthy, 758 F.3d 243, 252 (D.C. Cir. 2014) ("An agency action that merely explains how the agency will enforce a statute or regulation—in other words, how it will exercise its broad enforcement discretion or permitting discretion under some extant statute or rule—is a general statement of policy," and general statements of policy do not require notice and comment for implementation (and are not subject to pre-enforcement judicial review)).

[73] Cmty. Nutrition Inst. v. Young, 818 F.2d at 949.

[74] Ass'n of Irritated Residents v. EPA, 494 F.3d 1027 (D.C. Cir. 2007) While FDA lost a recent case relating to enforcement discretion, its holding does not apply to the analysis provided here, much less contradict it. Cook v. FDA, 733 F.3d 1, 7 (D.C. Cir. 2013) (FDA's attempted exercise of enforcement discretion to not sample or examine and to allow importation of apparently misbranded, unapproved drugs for lethal injections was found subject to judicial review and the failure to act was found not to be a matter of agency discretion because the relevant law "sets forth precisely" what FDA must do in the situation at issue).

better guidance to the industry regarding their subsequent applications for new product orders, and put the agency in a stronger position if there were any judicial review, if FDA also showed that, based on a careful consideration of relevant available evidence, it had determined that the enforcement discretion criteria met the core standard in the Tobacco Control Act for FDA tobacco product regulation by being "appropriate for the protection of the public health" (which could basically parallel the analysis provided earlier in this paper).[75] Such transparency, and asking for public input, could also help to protect against possible political or media attacks, while also providing FDA with additional information it could use to refine its enforcement discretion approach and inform its subsequent consideration of new product orders.

Whether FDA announced and explained the enforcement discretion criteria in the final deeming rule or through some other means, as soon as the agency had active jurisdiction over non-drug e-cigarettes it could begin proceedings to stop the marketing and sale of any such e-cigarettes that failed to meet the different criteria by the announced deadlines or that had obviously false or misleading claims in their advertising or labeling. If it had not already done so, FDA could also concurrently take action to stop the marketing and sale of any e-cigarettes that were not tobacco products but unapproved drugs or devices. Otherwise, manufacturers and importers could escape having to follow the proposed enforcement discretion criteria or comply with any FDA tobacco product requirements simply by making therapeutic claims for their e-cigarettes, which would convert them into unapproved (and unenforced against) drugs or medical devices.

With that loophole closed, FDA's exercise of its enforcement discretion as described would go a long way toward implementing the proposed regulatory approach for cigarettes, and that approach could be more fully implemented as a natural result of FDA's subsequent statutorily required review of the substantial equivalence and new product applications submitted for e-cigarettes by their manufacturers and importers.

B. *FDA's New Product Review Process*

As outlined above, after the final deeming rule puts e-cigarettes under FDA's active tobacco product jurisdiction it is likely that no e-cigarettes could become a legal tobacco product without first obtaining a new product or substantial equivalence order from FDA. It is improbable, however, that any e-cigarettes would be able to qualify for a substantial equivalence order, which requires a finding by FDA that the e-cigarettes are "substantially equivalent" to e-cigarettes that were commercially marketed in the United States on February 15, 2007. Even if an application were able to establish that an e-cigarette had actually been commercially marketed in the United States on that date, and could provide sufficient information about its characteristics, those e-cigarettes from early 2007 would likely be quite primitive and different from today's e-cigarettes, making any substantial equivalence finding impossible.[76]

---

[75] *See, e.g.*, Tobacco Control Act § 910(c), 21 U.S.C. § 387j(c) (2012).

[76] Tobacco Control Act §§ 910, 905(j), 21 U.S.C. §§ 387j, 387e(j) (2012). Even if a manufacturer or importer of a modern day e-cigarette could show that it was quite similar to an e-cigarette on the market on February 15, 2007, to obtain an SE order from FDA and become a legal e-cigarette, the manufacturer or importer would also have to show that the differences between its e-cigarette and the one on the market in 2007 do not "raise different questions of public health." 21 U.S.C. § 387j. Exactly what that phrase means has not yet been established, but it likely requires, at a minimum, that FDA not issue a substantial equivalence order to any e-cigarette that has any different characteristics compared to an e-cigarette found to be on the market on February 15, 2007 that might make it more harmful or risky to the public health than the 2007 version, such as having different kid-attracting flavors, being otherwise more attractive to youth or other potential users, or delivering different levels of nicotine or other ingredients or constituents.

To become legal tobacco products through the remaining new product order pathway, the applications would have to provide sufficient evidence and analysis to enable FDA to determine that allowing the e-cigarettes on the market would be "appropriate for the protection of the public health."[77] Relevant to this determination, the statute requires the agency to consider related health risks and benefits not only to users but to the population as a whole, including nonusers, taking into account the likely effect of the product's marketing on whether existing tobacco product users will quit or whether current nonusers will start using tobacco products.[78] In addition, the statute specifically authorizes FDA to include restrictions on the sale and distribution of the product, including its advertising, as a condition of issuing a permissive order (e.g., if the restrictions are necessary to make allowing the product on the market "appropriate for the protection of the public health").[79]

As previously discussed, there does not appear to be any public health justification for allowing e-cigarettes on the market as tobacco products unless they will be used by adequate number of smokers as a less-harmful way to consume nicotine, either indefinitely or prior to quitting all tobacco and nicotine use.[80] That means it would not be "appropriate for the protection of the public health" for FDA to issue a new product order that allowed any e-cigarettes to be marketed legally in the United States as a tobacco product unless doing so would promote that harm-reduction purpose. That suggests that FDA could not issue a new product order for any e-cigarettes that have not taken advantage of readily available measures, such as those described previously, to minimize the risk of harm to users and exposed nonusers. It also suggests that any order allowing an e-cigarette onto the U.S. market must include the kinds of previously described advertising restrictions and requirements to minimize the risks of increased initiation, reduced cessation, or harmful, long-term dual use, and increase the likelihood of constructive switching by smokers.

Following this analysis, FDA could further establish the regulatory scheme proposed here simply by considering each of the e-cigarette new product applications on a case-by-case basis and issuing a related order that either denies the application (making the e-cigarettes subject to being pulled from the market) or allows the e-cigarettes to stay on the market (subject to any advertising restrictions necessary to make that "appropriate for the protection of the public health"). No related rule or guidance would be required. However, to be more transparent, FDA could announce publicly or through communications to the industry that, based on its analysis of existing facts and evidence (paralleling the analysis provided here), the agency believes that it would be able to review e-cigarette new product applications more quickly and be more likely to issue orders allowing them on the market legally if the applicants:

- Proposed to market the e-cigarettes only as a harm-reduction product for smokers, and submitted related applications for both new product and a modified risk tobacco product orders.[81]

[77] Tobacco Control Act § 910(c), 21 U.S.C. § 387j(c) (2012).

[78] 21 U.S.C. § 387j(c)(4).

[79] 21 U.S.C. § 387j(c)(1)(B). On "sale and distribution" including advertising, the statute also explicitly gives FDA the authority to restrict and regulate advertising to the "full extent permitted by the first amendment to the constitution." *See* 21 U.S.C. § 387f(d)(1).

[80] A new product order application for e-cigarettes could not be supported by evidence showing that it would serve as an effective cessation aid because that would make it a drug, requiring a separate FDA new drug approval.

[81] If they did not make modified risk claims, the e-cigarette advertising directed to current adult smokers would not be as effective at prompting constructive switching solely to e-cigarette use (and would not be as appropriate for the protection of the public health), and such claims would make the e-cigarettes into modified

- Proposed to advertise the e-cigarettes with an accurate reduced-risk claim to encourage smokers to switch completely to using the e-cigarettes, instead (and FDA could provide model language).
- Proposed to advertise the e-cigarette to consumers only through direct communications to pre-verified adults who confirm that they are current smokers or regular e-cigarette users who are former smokers, without taking any action to promote or allow their advertising to consumers in any other way by retailers or other third parties—except for the posting of the e-cigarette brand name and price at retail outlets and in retail outlet advertising.[82]
- Proposed to include in those direct communications supplementary messaging regarding the greater health benefits from quitting all tobacco and nicotine use, the harmfulness of e-cigarette use, the e-cigarettes' viability as a harm-reduction product only if used exclusively instead of smoking; and the possible extra harms from dual use; and identifying sources of cessation assistance (and FDA could provide model text for applicants to adapt or use).
- Proposed that any communications concerning the e-cigarettes made to doctors or other health professionals would be for the sole purpose of educating them about the potential health benefits their smoker patients who would not otherwise quit could secure from switching completely to using e-cigarettes, with any such communications in written form including supplementary messaging similar to that sent in the communications to adult smokers.[83]
- Provided evidence establishing that the e-cigarettes complied with basic requirements to reduce their potential harmfulness (e.g., no combustion or risk of combustion, child-proof packaging, no contaminants or unnecessary toxins).

Concurrently, FDA could state that e-cigarette manufacturers and importers would remain free to submit applications to try to obtain substantial equivalence, new product or modified risk tobacco product orders, pursuant to the procedures and requirements set forth in the Tobacco Control Act, without meeting all or any of the other criteria identified by the agency as being likely to expedite review or increase the chances of a positive order.[84] All FDA would be saying is that it believes that it would likely be easier and faster for the agency to follow the statute's requirements and issue a permissive order pursuant to applications for e-cigarettes that met all the listed criteria, given the core facts that are already known about e-cigarette health harms and risks and the potential impact of their advertising on initiation, cessation, switching, dual use and relapse.

For example, FDA might point out that it would likely be impossible for the agency to find that it would be "appropriate for the protection of the public health" to allow any

risk tobacco products, requiring a modified risk tobacco product order. Even without any explicit or implied modified risk claims in the ads, themselves, it is possible that the required supplementary messaging, despite coming from the government, would make the e-cigarettes into modified risk tobacco products that require an MRTP order. Pursuant to the Tobacco Control Act, manufacturers and importers may submit a single application to obtain both a new product order and a modified risk tobacco product order at the same time. 21 U.S.C. § 387k(1)(4).

[82] As discussed above, FDA might also allow direct advertising to never-smoking regular e-cigarette users in order to discourage them from converting into smokers.

[83] FDA might also state that applications proposing to communicate responsibly with doctors and other medical professionals regarding the possible benefits of recommending e-cigarette use to their smoker patients would not be restricted might also make it easier to find allowing the e-cigarettes on the market "appropriate for the protection of the public health" (because it would increase the likelihood that it would increase constructive switching from smoking)—or FDA could at least state that it did not think that prohibiting such communications would benefit the public health.

[84] 21 U.S.C. § 387j (for new product and substantial equivalence orders); 21 U.S.C. § 387e(j) (for substantial equivalence orders); 21 U.S.C. § 387k (for modified risk tobacco product orders).

e-cigarette on the market if it were more harmful to users or non-users than necessary, especially if its manufacturer had failed to take advantage of readily available ways to reduce their potential harmfulness, such as those outlined above. But the agency would also leave the door open to allow an applicant to show that its e-cigarettes were already as harmless as they could be without meeting some or all of those criteria.

Similarly, FDA could explain that it is difficult to imagine how allowing a manufacturer or importer to publicly advertise its e-cigarettes would not create unnecessary and much larger risks of increased youth or non-smoker initiation, as compared to allowing only more direct and less public advertising only to pre-verified adult smokers. But FDA would also leave the door open for an applicant to provide evidence that established that fewer or different advertising restrictions or other measures would work as well or better to reduce youth exposure or to prevent increased initiation. Less likely, an applicant could obtain a permissive order by providing sufficient evidence to establish that there would be no public health benefit from reducing exposure to e-cigarette advertising among youth or adult non-smokers, either because that advertising would not increase initiation into e-cigarette (or other tobacco product) use or because the e-cigarettes at issue posed no risk of causing any health harms to any users or non-users or of serving as a gateway to the use of more harmful tobacco products[85]

Developing and providing adequate, credible evidence to establish that any of these alternatives to meeting the proposed application criteria would make allowing the subject e-cigarettes on the market equally or more "appropriate for the public health" would likely be very difficult, and more costly and time consuming to the applicant. Having to evaluate that evidence would also make FDA's application review more complicated and time consuming than evaluating applications adopting the suggested application criteria. But these comparisons simply provide additional justification for FDA announcing that it believes it would be able to provide more rapid consideration and be more likely to be able to issue favorable orders for those applicants that chose to follow the presented criteria.[86]

At the same time, FDA could refine and improve those application criteria, and develop even stronger supporting evidence, through using the considerable new information that would become available during the enforcement discretion stage. If the enforcement discretion stage produced, as intended, a U.S. e-cigarette market dominated by manufacturers and importers complying with the enforcement discretion criteria, the related changes to youth and non-smoker e-cigarette initiation and smoker quit rates would inform FDA as to whether, and to what extent, it needed to require more comprehensive restrictions and requirements in the new product orders to better protect the public health. For example, if initiation among youth and nonsmokers dropped to trivial levels during the enforcement discretion stage, the agency might determine that there would be no likely public health benefit from using new product orders to impose

---

[85] FDA might also acknowledge a more complicated possibility: that an applicant might provide evidence adequate to establish that allowing more public e-cigarette advertising would work more effectively to promote complete switching to e-cigarettes among smokers, with the related public health gains being somewhat larger than any possible public health losses from the less restricted advertising increasing e-cigarette initiation among youth and non-smokers. But that raises some difficult ethical issues, beyond the reach of this paper, regarding whether FDA, in determining what is "appropriate for the protection of the public health," may (or must) value preventing new health harms from new initiation among youth or among adults who would not otherwise use any tobacco products equally or more highly than reducing harms among existing smokers.

[86] Because expressing this belief would not be a final agency decision or action, it could not be challenged in court. In any case, courts typically give considerable deference to agencies regarding good-faith, evidence-based determinations, especially in their areas of expertise. *See, e.g.*, Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837 (1984).

any restrictions or requirements that went beyond the criteria used in the enforcement discretion stage (e.g., by prohibiting certain flavored e-cigarettes or implementing additional advertising restrictions or requirements).

Conversely, if there were considerable e-cigarette use among youth and never-smoking adults after the enforcement discretion stage's full implementation, that would provide even more support for establishing related restrictions and requirements in the new product and modified tobacco product orders for e-cigarettes, such as requiring the factual disclosure messaging in the direct advertising to current smokers and e-cigarette users and prohibiting manufacturers from taking any action to support or permit retailer or other third party advertising other than through the kinds of advertising the orders permitted the manufacturers and importers to do themselves.[87]

C. *FDA's Drug and Device Regulation of E-cigarettes*

If FDA took all of these actions on the tobacco product side, all that might be needed on the drug side would be much more active enforcement against any e-cigarettes that qualified as unapproved drugs or devices, and were, therefore, free from having to comply with any requirements or restrictions placed on e-cigarette tobacco products. In some cases, it might be difficult to determine whether the e-cigarette claim was therapeutic (which would make it an illegal drug) or just a non-therapeutic reduced-harm or other health-related claim (which would not remove the e-cigarette from the tobacco product category). But the relevance of any such gray area would largely disappear if, during the enforcement discretion stage, FDA actively enforced against any e-cigarettes that were not meeting the enforcement discretion criteria—which would either be illegal tobacco products or illegal unapproved drugs. For example, if FDA moved to seize e-cigarettes for being illegally on the market as unapproved drugs because of an apparent therapeutic claim, and the manufacturer tried to block that enforcement by arguing that the e-cigarettes were actually tobacco products because the claim was not therapeutic, then the agency could simply seize the e-cigarettes as tobacco products that were illegally on the market without the required new product or substantial equivalence order (and likely without a required modified risk tobacco product order, as well). To speed things up, the initial warning letter sent to the manufacturer could state that the e-cigarette was illegally on the market because it was either an unapproved drug or a tobacco product without one or more required pre-market orders.

The more complex questions regarding how to regulate e-cigarettes that are approved drugs or devices will not arise until FDA issues an order approving some e-cigarettes as drugs or devices, and that is unlikely to occur anytime soon. Developing an application for such an order is complicated and time consuming, and the strict statutory requirements for qualifying as an approved drug that is "safe and effective" for its intended therapeutic use and the agency's related procedures and practices suggests that no e-cigarette is likely to enter the U.S. market as an approved drug or device for years to come.[88] If the only major additional benefit from qualifying an e-cigarette as

[87] If e-cigarette use among youth and never-smoking adults were at troubling levels after the order-issuing stage with these new requirements were well underway, and there were still highly visible retailer e-cigarette advertising, that would support also fully implementing all of the previously described retailer-directed requirements and restrictions. Implementing those additional restrictions directly on retailers (e.g., not allowing e-cigarette sales except to adults who confirmed they were smokers or e-cigarette using former smokers) would likely require a new rulemaking. But issuing the new rule would be much easier because of the evidence developed during the enforcement discretion and order-issuing stages showing that such new restrictions on retailer marketing were necessary to protect and promote the public health.

[88] 21 U.S.C. § 355(d) (2012). Arthur A.Ciociola et al., *How Drugs are Developed and Approved by the FDA: Current Process and Future Directions*, 109 AM. J. GASTROENTEROLOGY 620, 620–23 (2014); Leonard V.

an approved drug instead of as a legally marketable tobacco product were receiving legal authority to make cessation claims or other therapeutic claims (instead of only reduced-risk or harm-reduction claims), it is also possible that very few manufacturers and importers would ever try—especially if it became clear that they could qualify for legal marketing more quickly, easily and cheaply through the regulatory scheme for e-cigarette tobacco products proposed here.

The incentives to qualify as an approved drug would, however, be much stronger if e-cigarette drugs would be subject to far fewer advertising or other marketing restrictions than e-cigarette tobacco products (e.g., could be advertised on TV or sold as an over-the-counter drug with no age restrictions). Accordingly, to complement and support the tobacco-side regulation of e-cigarettes proposed here, FDA would, ideally, announce not only that it would work aggressively to pull any e-cigarettes off the market that appear to be unapproved drugs but also that it intends to subject any e-cigarettes that qualify as approved drugs to sales, advertising and other marketing restrictions that at least parallel those applied to e-cigarettes that are tobacco products.[89]

If FDA were confident that it could create such a parallel system of advertising and other marketing restrictions for e-cigarettes approved as drugs, it might make sense for the agency to issue a rule to create a related expedited pathway for e-cigarettes that meet certain pre-established criteria to obtain drug approvals for cessation-assistance purposes. Any subsequent e-cigarette cessation drug approvals, with parallel marketing restrictions, should help to increase quitting by smokers, not just by allowing cessation claims in the manufacturers' direct advertising to the smokers but also by providing doctors and other medical personnel with an FDA-approved e-cigarette cessation aid that they could recommend to their patients who smoke to help them quit smoking or all tobacco and nicotine use. To promote those kinds of recommendations by doctors and other medical professionals (and reduce possible First Amendment challenges), FDA could also allow manufacturers and importers that qualify their e-cigarettes as approved cessation aids to advertise those e-cigarettes directly to doctors and other medical personnel as suitable for prescribing or recommending to their smoking patients for cessation purposes.

V. WOULD THIS REGULATORY APPROACH TO E-CIGARETTE ADVERTISING BE CONSTITUTIONAL?

Congress has the authority to ban all e-cigarettes and FDA could effectively ban all e-cigarettes that are drugs (by finding that none could be "safe and effective" for any therapeutic purposes) and ban all e-cigarettes that are tobacco products (by finding that doing so would be "appropriate for the protection of the public health"). But the "power to prohibit or to regulate particular conduct does not necessarily include the power to prohibit or regulate speech about that conduct."[90] That means that FDA could still face considerable First Amendment challenges if it tried to impose the advertising restrictions in the regulatory scheme proposed here on e-cigarettes that were already being legally marketed and sold as tobacco products. But the actual situation with e-cigarettes is quite different because they will already be illegal products, through the terms of the Tobacco Control Act, as of the effective date of the final deeming rule. As

Sacks et al., *Scientific and Regulatory Reasons for Delay and Denial of FDA Approval of Initial Applications for New Drugs, 2000–2012*, 311 JAMA 378, 378–84 (2014).

[89] The main obstacle to FDA establishing such parallel advertising restrictions for approved e-cigarette drugs would be the First Amendment, which is considered in the next section of this paper.

[90] Greater New Orleans Broad. Ass'n, Inc. v. United States, 527 U.S. 173, 193 (1999).

proposed here, FDA would not be imposing advertising restrictions or requirements on legally marketed e-cigarettes. Instead, it would, first, simply be exercising enforcement discretion to focus its enforcement efforts on those illegal e-cigarettes that threaten to cause the most public health harm and then, second, allowing e-cigarettes onto the U.S. market as legal tobacco products pursuant to the procedures and requirements already established by the Tobacco Control Act, and only for the purpose of offering smokers a less harmful way to consume nicotine. Accordingly, the First Amendment challenges faced by the agency should be significantly reduced.

As the Supreme Court has stated, "so long as the sale and use of tobacco is lawful for adults, the tobacco industry has a protected interest in communicating information about its products and adult customers have an interest in receiving that information."[91] That conclusion directly supports its inverse, that the manufacturers, importers, and adult consumers of e-cigarettes made unlawful by the deeming rule no longer have any such protected interests. As the underlying first prong of the four-part *Central Hudson* test for whether government restrictions on commercial speech are constitutionally permissible states, there are no First Amendment protections for commercial speech "related to unlawful activity"[92]—and advertising to promote the sale of illegal e-cigarettes relates to unlawful activity. That means First Amendment constraints should not apply at all during the enforcement discretion stage, when the e-cigarettes would be illegal tobacco products, even if they were otherwise complying with the Tobacco Control Act or being sold in accordance with FDA's announced enforcement discretion criteria.

First Amendment protections also should not apply, later, to any advertising restrictions included in new product or modified risk tobacco product orders for e-cigarettes if they were voluntarily proposed by applicants and not required by FDA. Although those advertising restrictions would apply to legal tobacco products, they would be self-imposed by the applicant. Accordingly, the restriction, while in a government order, might not be seen as a restriction imposed by the government or through government action.[93] But even if including advertising restrictions in the orders, as proposed by the applicant, were found to be government action, potentially making the orders subject to First Amendment review, the applicant's voluntary proposal or consent to the restrictions should constitute a legally valid waiver of its related First Amendment rights because FDA neither required or compelled the applicant to include them in its application or consent to them being in any subsequent order.[94] Either way, First Amendment review should not apply.

---

[91] Lorillard Tobacco Co. v. Reilly, 533 U.S. 525, 571 (2001).

[92] Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y., 447 U.S. 557, 564 (1980).

[93] *See, e.g.*, Columbia Broad. Sys. v. Democratic Nat'l Comm., 412 U.S. 94, 114 (1973) (stating the First Amendment "is a restraint on government action, not that of private persons"). But there do not appear to be any federal court rulings on whether a government order including a speech constraint at the request of an applicant constitutes a constraint imposed by government action. In a different context, First Amendment challenges to speech-restrictive provisions in private agreements or contracts, courts have found that "judicial enforcement of terms that could not be enacted by the government has not ordinarily been considered state action." Ohno v. Yasuma, 723 F.3d 984, 998–99 (9th Cir. 2013) (citing Democratic Nat'l Comm. v. Republican Nat'l Comm., 673 F.3d 192, 204–05 (3d Cir. 2012)). But state action (violating the Equal Protection Clause) has been found when the courts enforce private agreements that discriminate against one of the parties. *Id.* But discrimination would not be an issue in FDA orders.

[94] *See, e.g.*, Henley v. Cuyahoga County Board, 141 F. App'x 437, 446 (6th Cir. 2005) ("[C]onstitutional rights, like rights and privileges of lesser importance, may be contractually waived where the facts and circumstances surrounding the waiver make it clear that the party foregoing its rights has done so of its own volition, with full understanding of the consequences of its waiver" (quoting Erie Telecomms., Inc. v. City of Erie, 853 F.2d 1084, 1096 (3d Cir. 1988))).

In addition, applicants would remain free to apply, instead, for an order with fewer or no advertising restrictions, and FDA would give any such applications full and fair consideration under the terms of the Tobacco Control Act. Consequently, this situation would not be an example of the government wrongfully making the granting of a government benefit contingent on the applicant giving up constitutional rights (the so-called "unconstitutional conditions" doctrine).[95]

It might be argued that FDA was offering a government benefit (expedited review) to applicants that give up their First Amendment rights (by proposing certain advertising restrictions described by the agency). But that should not trigger constitutional review so long as FDA was neither requiring applicants to give up any First Amendment rights to obtain a permissive order nor promising expedited treatment *and* a favorable order for those did. The agency would simply be telling the industry that, based on its analysis of available information regarding e-cigarettes and tobacco product marketing, it currently believes that it will likely be able to consider new product and modified risk tobacco product applications that propose such advertising restrictions more quickly and be more likely to approve them. In particular, FDA would be explaining that, absent such advertising restrictions, it would take considerable amounts of new evidence and analysis (beyond what it currently available publicly or to the agency) to establish that the marketing of any e-cigarettes would not threaten to increase initiation among youth and current non-smokers to such an extent as to make the product "inappropriate for the protection of the public health." In that context, if a manufacturer voluntarily decided to propose the suggested advertising restrictions in its application for a new product order (instead of taking advantage of the opportunity to provide evidence supporting fewer restrictions), there does not appear to be any basis for the applicant to challenge the inclusion of those advertising restrictions in any subsequent order as violating its First Amendment rights.

First Amendment review could apply, however, to any advertising restrictions that FDA included in a new product or modified risk tobacco product order that the applicant had not proposed or voluntarily adopted during the application process. But advertising constraints imposed in response to a manufacturer's application as a necessary requirement to enable FDA to find, as required by the Tobacco Control Act, that allowing the e-cigarettes onto the market as newly legal products would be "appropriate for the protection of the public health" should more easily survive First Amendment scrutiny than advertising restrictions that FDA might impose on its own initiative through a rule on all e-cigarettes after they were already on the market legally and already legally engaging in the commercial speech that would be restricted. It is, for example, possible that the different status of the products and their advertising at the time the restrictions are implemented might make it easier to impose them constitutionally through a new product order than a rule. But, as described below, the main reason that establishing the restrictions constitutionally might be easier through new product orders is because of practical consequences arising from the application and order procedures.

In this regard, the Sixth Circuit has already found that these kinds of procedures are constitutional and otherwise permissible, in its ruling upholding the Tobacco Control Act's modified risk tobacco product provisions—which require prior orders from

---

[95] *See*, *e.g.*, KT & G Corp. v. Oklahoma, 535 F.3d 1114, 1135 (10th Cir. 2008) ("The government 'may not deny a benefit to a person on the basis that infringes his constitutionally protected interests—especially, his interest in freedom of speech.'" (quoting Perry v. Sindermann, 408 U.S. 593, 597 (1972))). This is true even if the person has no entitlement to the benefit and even though the government can deny the benefit for a number of other reasons. *See id.; see also* United States v. Am. Library Ass'n, Inc., 539 U.S. 194, 210 (2003).

FDA finding that tobacco products making reduced-harm or reduced-exposure claims will actually benefit users and the overall public health before they may be marketed legally (and also authorize the agency to impose restrictions on the advertising of those products as necessary to make permitting their marketing appropriate for the protection of the public health).[96]

That holding applied the so-called four-part *Central Hudson* test established by the Supreme Court. That test is regularly used to evaluate whether restrictions on commercial speech are constitutional, and it would apply to any First Amendment challenges to FDA new product orders.[97] To date, cases applying the *Central Hudson* test to restrictions on tobacco product advertising typically assume that the advertising qualifies for constitutional protections under the first-prong of the text, which requires that the commercial speech not be "more likely to deceive the public than inform it" and not be "related to illegal activity" in order to qualify for First Amendment protections.[98] But reasonable arguments can be made that the publicly viewable forms of e-cigarette advertising subject to the proposed restrictions do not actually qualify for First Amendment protections.

For example, if the proposed advertising restrictions were challenged, the government could offer evidence and analysis showing that the effected advertising is "more likely to deceive the public than inform it" because of the products' inherent addictiveness and harmfulness and the ads inability to disclose that in an understandable, not misleading way; or because simply seeing such publicly visible advertising makes some consumers believe, mistakenly, that the products are appropriate or even safe for use by any consumers (e.g., because the government is not restricting the advertisements).[99] Specifically in regard to e-cigarettes, for example, research has found that higher exposure to e-cigarette ads make young adults more likely to be ignorant or have incorrect views about e-cigarettes containing nicotine.[100] There is also evidence that the use of different colors and descriptors in the labeling and advertising of cigarettes makes significant numbers of consumers inaccurately believe that some brands or sub-brands are less harmful than others.[101] In addition, the government could also reference

[96] Tobacco Control Act § 911, 21 U.S.C. § 387k (2009); Disc. Tobacco City & Lottery, Inc. v. United States, 674 F.3d 509 (6th Cir. 2011).

[97] Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y. (*Central Hudson*), 447 U.S. 557, 566 (1980) ("In commercial speech cases, then, a four-part analysis has developed. At the outset, we must determine whether the expression is protected by the *First Amendment*. For commercial speech to come within that provision, it at least must concern lawful activity and not be misleading. Next, we ask whether the asserted governmental interest is substantial. If both inquiries yield positive answers, we must determine whether the regulation directly advances the governmental interest asserted, and whether it is not more extensive than is necessary to serve that interest." (emphasis added)); *see also* Lorillard Tobacco Co. v. Reilly, 533 U.S. 525 (2001) (the most recent case where the Supreme Court applied the *Central Hudson* test to restrictions on tobacco product advertising).

[98] *Central Hudson*, 447 U.S. at 563–64.

[99] *See, e.g.*, Andrew A. Strasser et al., *PREP Advertisement Features Affect Smokers' Beliefs Regarding Potential Harm*, 17 TOBACCO CONTROL i32 (2008). More evidence could be developed relatively quickly to provide additional support through surveys, focus groups, and more sophisticated studies of consumer reactions to different samples of the advertising and of their reported related beliefs.

[100] Ashley Sanders-Jackson et al., *Knowledge About E-cigarette Constituents and Regulation: Results From a National Survey of U.S. Young Adults*, 17 NICOTINE & TOBACCO RES. (forthcoming 2015), *available at* http://ntr.oxfordjournals.org/content/early/2015/01/24/ntr.ntu276 (advance copy published online ahead of print).

[101] *See, e.g.*, Israel T.Agaku et al., *Cigarette Design and Marketing Features are Associated with Increased Smoking Susceptibility and Perception of Reduced Harm Among Smokers in 27 E.U. Countries*, 24 TOBACCO CONTROL (forthcoming 2015), *available at* http://tobaccocontrol.bmj.com/content/early/2014/10/21/tobaccocontrol-2014-051922.abstract (advance copy published online ahead of print); Ron Borland & Steven

the long history of misleading and manipulative advertising by the tobacco industry, often in subtle or subliminal ways, and the evidence showing that e-cigarettes are using parallel advertising strategies.[102]

The government could also assert that the restricted advertising directly relates to illegal activity because it would be encouraging e-cigarette use among youth, and sales to youth would be federally prohibited and purchases and possession by youth are illegal in a growing number of states.[103] The restricted ads could also be seen as concerning illegal activity if FDA order allowing the e-cigarettes on the market permitted their sale only to current or former smokers and the ads encouraged their use by other adults, as well.

A counter-argument is that even if most, or all, of the e-cigarette ads at issue mislead consumers or concern unlawful activity, and future e-cigarette ads are likely to do the same, future e-cigarette ads could be structured and delivered in ways that do not mislead consumers or concern illegal activity, thereby qualifying for First Amendment protections. To accommodate this possibility, any rule or order establishing the proposed advertising restrictions could also include a mechanism that would exempt any specific ads that were not misleading and did not concern illegal activity. For example, FDA could establish a process whereby it would exempt specific ads from having to comply with the restrictions if the seller provided evidence showing that the ads would not mislead consumers or increase youth initiation and would not have any other impacts that would make allowing the e-cigarettes to stay on the market inappropriate for the protection of the public health.[104]

Even if the court did not agree with these arguments that the advertising subject to the restrictions did not qualify under the first prong of the *Central Hudson* test for First Amendment protections, making these argument would still establish a much more helpful foundation or context for the court's analysis of the remaining prongs of the test. As the 3rd Circuit recently stated, for example, "[t]he more misleading the advertisement, the more constitutional leeway is granted the [government] in restricting it."[105]

Savvas, *The Effects of Variant Descriptors on the Potential Effectiveness of Plain Packaging*, 23 TOBACCO CONTROL 58 (2014).

[102] *See, e.g.*, *Press Release from Senators*, *supra* note 30; Duke et al., *supra* note 30, at 5–6; *see also, e.g.*, Disc. Tobacco City & Lottery, Inc. v. United States (*Discount Tobacco*), 674 F.3d 509, 535 (6th Cir. 2011) ("Evidence in the congressional record demonstrating a pattern of [potentially deceptive] advertisements . . . [may be] adequate to establish . . . the likelihood of deception" (quoting Milavetz, Gallop & Milavetz, P.A. v. United States, 559 U.S. 229 (2010))). The case goes on to describe some of the evidence of the tobacco industry's history of deceptive advertising and concludes that "[t]here is no question that the harm caused by the tobacco industry's use of misleading advertising and marketing tactics regarding the relative risks of certain tobacco products is real and significant." *Discount Tobacco*, 674 F.2d at 535. While disclaimers might be seen as a remedy that the tobacco industry could use to stop their advertising from being misleading, there is evidence that disclaimers frequently further confuse or mislead consumers rather than prevent them from being misled in the first place. *See, e.g.*, Kesten C. Green & J. Scott Armstrong, *Evidence on the Effects of Mandatory Disclosures*, 31 J. PUB. POL'Y & MARKETING 293 (2012); *see also* Micah L. Berman, *Manipulative Marketing and the First Amendment*, GEO. L.J. (forthcoming), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2294107.

[103] *See, e.g.*, Kristy Marynak et al., *State Laws Prohibiting Sales to Minors and Indoor Use of Electronic Nicotine Delivery Systems—United States, November 2014*, MORBIDITY & MORTALITY WKLY. REP. (Ctrs. for Disease Control & Prevention, Atlanta, Ga.), Dec. 12, 2014, at 1145. *But see* Educ. Media Co. v. Swecker, 602 F.3d 583, 588 (4th Cir. 2010) (finding that ads for age-restricted products primarily intended for underage buyers concerns lawful activity, and is therefore protected by the First Amendment, because the ads are also intended for adult of-age buyers).

[104] Such a mechanism would also help to counter any claims that the restrictions were "more extensive than necessary," under the fourth-prong of the *Central Hudson* test, which is discussed below.

[105] Dwyer v. Cappell, 762 F.3d 275, 280 (3d Cir. 2014). The court also noted that "[a]dvertising that is inherently misleading or has proven to be misleading in practice "may be prohibited entirely." *Id.* (quoting *In re* R.M.J., 455 U.S. 191, 203 (1982)).

Under the second prong, the government must show that it is implementing the restrictions to promote a government interest that is substantial.[106] In the Sixth Circuit case applying the *Central Hudson* test to various provisions in the Tobacco Control Act, the primary asserted government interest was preventing or reducing youth tobacco use, which the Supreme Court has found to be substantial.[107] But the government's only asserted interest for the Act's modified risk tobacco product provisions was to prevent fraudulent claims and consumer deception.[108] To provide a stronger foundation for defending the proposed e-cigarette advertising restrictions in either new product or modified risk tobacco product orders, FDA could also assert the government's substantial interest in ensuring that any new tobacco products allowed to be marketed in the United States will be "appropriate for the protection of the public health," and also assert the government's more specific substantial interests in ensuring that the e-cigarette advertising: (a) will not increase public health harms; (b) will not increase youth initiation into e-cigarette or other tobacco product use; and (c) will help reduce the health harms caused by smoked tobacco products.[109]

Given what is known about the power of advertising, the proposed advertising restrictions, by reducing exposure to cigarette advertising among youth and nonsmokers, should also be found to promote these substantial government interests directly, thereby satisfying the third-prong of the *Central Hudson* test.[110] In fact, Supreme Court has already stated that "we have acknowledged the theory that product advertising stimulates demand for products, while suppressed advertising may have the opposite effect."[111]

The fourth and final prong of the *Central Hudson* text requires that the advertising restrictions also be "not more extensive than necessary" to advance the asserted

[106] Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y. (*Central Hudson*), 447 U.S. 557, 566 (1980).

[107] *Discount Tobacco*, 674 F.3d 509, 519 (6th Cir. 2011) ("[T]he State's interest in preventing underage tobacco use is substantial, and even compelling" (quoting Lorillard Tobacco Co. v. Reilly, 533 U.S. 525, 564 (2001))).

[108] *Discount Tobacco*, 674 F.3d at 534–35.

[109] There should not be any question that these are each legitimate substantial government interests for the purposes of First Amendment commercial speech analysis, especially in the context of new product orders. *See Discount Tobacco*, 674 F.3d at 548 (stating that the government can show a substantial interest in alleviating the effects of tobacco advertising on juvenile consumers). *See generally, e.g.*, *Central Hudson*, 447 U.S. 557 (1980); 44 Liquormart, Inc. v. Rhode Island, 517 U.S. 484, 504–05 (1996) (stating that government has a substantial interest in "reducing alcohol consumption" or "promoting temperance"); Rubin v. Coors Brewing Company, 514 U.S. 476, 477 (1995) ("The Government has a significant interest in protecting the health, safety, and welfare of its citizens by preventing brewers from competing on the basis of alcohol strength, which could lead to greater alcoholism and its attendant social costs."). In *R.J. Reynolds*, the D.C. Circuit stated: "Like the district court, we are skeptical that the government can assert a substantial interest in discouraging consumers from purchasing a lawful product, even one that has been conclusively linked to adverse health consequences." R.J. Reynolds Tobacco Co. v. FDA, 696 F.3d 1205, 1218 n.13 (D.C. Cir. 2012). But that statement was dicta and related only to government warning labels asserting that smokers should quit, not to non-assertive, non-content restrictions on tobacco product advertising to prevent it from discouraging cessation among those who would otherwise quit (or from producing other public health harms).

[110] *Central Hudson*, 447 U.S. at 566.

[111] Lorillard Tobacco Co. v. Reilly, 533 U.S. 525, 557 (2001) (also noting that the Massachusetts Attorney General had cited "numerous studies to support this theory in the case of tobacco products"); *see also Discount Tobacco*, 674 F.3d at 548 (endorsing government evidence that "preventing juveniles from viewing tobacco advertising materially impacts their decision to use tobacco"); United States v. Edge Broad. Co., 113 S. Ct. 2696, 2707 (1993) ("If there is an immediate connection between advertising and demand, and the federal regulation decreases advertising, it stands to reason that the policy of decreasing demand for gambling is correspondingly advanced."). The Supreme Court has also "permitted litigants to justify speech restrictions by reference to studies and anecdotes pertaining to different locales altogether, or even, . . . to justify restrictions based solely on history, consensus, and 'simple common sense.'" Lorillard Tobacco Co. v. Reilly, 533 U.S. at 555 (quoting Florida Bar v. Went For It, Inc., 515 U.S. 618, 628 (1995)).

substantial government's interests.[112] What, exactly "not more extensive than necessary" means appears to have changed over time; but in the most recent Supreme Court application of that test it stated that "if the Government could achieve its interests in a manner that does not restrict speech, or that restricts less speech, the Government must do so."[113]

However interpreted, it should not be difficult to meet this standard. Most fundamentally, any less-extensive restrictions would, by definition, work less well to reduce exposure to the advertising among youth and among those who would suffer health harms from using e-cigarettes. But that would work directly against the government's substantial interest in reducing illegal youth use and the negative public health impacts of e-cigarette advertising by minimizing such exposure to that advertising. Those less-extensive means would, therefore, not be acceptable or constitutionally required alternatives.[114]

Accordingly, no viable less-extensive restrictions appear to exist. Nevertheless, to satisfy the First Amendment it might still be necessary to establish that the proposed advertising restrictions would not "unduly impinge on the [sellers'] ability to propose a commercial transaction and the adult [consumers'] opportunity to obtain information about products" or on "tobacco retailers and manufacturers . . . interest in conveying truthful information about their products to adults, and [the] adults . . . corresponding interest in receiving truthful information about tobacco products."[115] In fact, this test might apply even more clearly and specifically here, where the public health goals of the restrictions would be thwarted if manufacturers and sellers were not able to propose that adult smokers and e-cigarette using former smokers buy and use e-cigarettes instead of smoking or if those consumers were not able to receive that information.

But the fact that only smokers and e-cigarette users who are former smokers could benefit from using e-cigarettes and, more importantly, the e-cigarettes are being allowed on the market legally only for those specific consumers' use, could also narrow the scope of the seller and consumer interests that merit First Amendment protection. Given the courts well established deference to agency determinations, especially in their areas of expertise, the courts should have to accept and follow any bona fide formal determination by FDA that the only way it could be "appropriate for the protection

---

[112] *Central Hudson*, 447 U.S. at 566.

[113] Thompson v. W. States Med. Ctr., 535 U.S. 357, 371 (2002). Previously, the Court has stated that the "no more extensive than necessary" test is more permissive than the strict scrutiny "least restrictive means" test used in other non-commercial speech contexts, stating that all the former requires is a "reasonable fit" between the ends and means chosen to accomplish those ends, "a means narrowly tailored to achieve the desired objective." Lorillard Tobacco Co. v. Reilly, 533 U.S. at 556.

[114] Under current case law, there does not appear to be any First Amendment justification for the courts to rule that FDA should impose less restrictive advertising constraints if that would cause increased public health harms or reduce the amount of secured public health benefits. For example, the Supreme Court has not imposed or suggested any test or procedure for balancing or evaluating the size of any secured public health gains against the severity of any related commercial speech constraints. *See, e.g.*, Sorrell v. IMS Health Inc., 131 S. Ct. 2653, 2674 (2011) ("[G]overnment laws and regulations may significantly restrict speech, as long as they also 'directly advance' a 'substantial' government interest that could not 'be *served as well* by a more limited restriction.'" (quoting *Central Hudson*, 447 U.S. at 564 (emphasis added))). Nor could the Tobacco Control Act be read to require FDA to impose only the minimum advertising restrictions necessary to enable the agency to determine that allowing the e-cigarettes on the market would produce at least some net public health gains. The Act gives FDA authority to impose restrictions that will maximize the potential public health benefits and minimize the possible health harms and risks from allowing the tobacco product on the market. Indeed, failing to require advertising restrictions to minimize the risk of new health harms and maximize the likelihood and size of new harm reductions could be seen as "inappropriate for the protection of the public health."

[115] Lorillard Tobacco Co. v. Reilly, 533 U.S. at 529, 565.

of the public health" to issue an order allowing e-cigarettes on the market is to make them legally available as a less harmful alternative to smoking only to existing smokers and to former smokers who are using e-cigarettes.[116] But such a finding (especially if used to prohibit sales of e-cigarettes to anyone other than these intended consumers) should mean that sellers do not have any First Amendment interest or right to convey e-cigarette information to anyone other than those adult smokers or adult e-cigarette users who are former smokers. Similarly, the only consumers who should have any interest or right to receive or obtain information about the e-cigarettes should be those same legal and order-intended consumers. That suggests that the final First Amendment question is whether the advertising restrictions unduly impinge on the sellers' ability to communicate relevant commercial information about e-cigarettes to those legal adult consumers for whose use the e-cigarettes were allowed on the market.

Because the proposed advertising restrictions are meant to allow the sellers to reach and influence these specific consumers (while minimizing exposure among others), they should satisfy this last First Amendment hurdle. In fact, through the order-issuing stage no direct restrictions or requirements are placed on retailers, and e-cigarette manufacturers and importers would be readily able to communicate with their legal customers, both directly and indirectly by: (a) delivering e-cigarette advertising, with no content restrictions, directly to any pre-verified adults who are among the categories of consumers who can secure public health benefits from using e-cigarettes; (b) having their e-cigarette brand names, with prices, listed at brick-and-mortar and Internet retail outlets that sell them or in any other advertising for such retail outlets;[117] and (c) delivering educational materials and other advertising to doctors or other medical professionals for the purpose of informing them about the possible health benefits to their smoker patients from switching to e-cigarettes.[118]

These advertising pathways leave sellers adequate direct and indirect means to communicate relevant product information to their legal consumers. But some might argue that smaller e-cigarette manufacturers typically do not have as extensive lists of smoker mailing or email address lists as larger manufacturers, making it more difficult for them to do the kind of direct advertising allowed in this proposed system. Thanks to the Internet and other technologies (such as commercially available age and ID verification software), however, email and mailing lists can be readily developed or purchased to allow for related direct emails or regular mailings – and likely cost considerably less than some of the prohibited public forms of advertising, such as TV or radio ads, billboards, magazine ads, or displays at retail outlets.[119] E-cigarette manufacturers and importers with more resources would be able to afford more of the permitted advertising than those with fewer resources. But that is the way our market system works and is no different than the current situation. Moreover, there is nothing in the First Amendment or the Tobacco Control Act that prohibits or restricts the ability of FDA to take action

---

[116] *See, e.g.*, Federal Power Commission v. Florida Power & Light, 404 U.S. 453, 463 (1972) ("[W]e recognize the relevant agency's technical expertise and experience, and defer to its analysis unless it is without substantial basis in fact.").

[117] *See, e.g.*, WV Ass'n of Club Owners & Fraternal Servs., Inc. v. Musgrave, 553 F.3d 292 (4th Cir. 2009) (holding no violation of the First Amendment by law banning all external retail advertising of on-site video lotteries except for uniform signs outside of the premises indicating that the lottery products are available there). In reaching its finding, the Court stated that the restrictions struck a balance so that the advertising can inform consumers that the products are available but "does not prey on vulnerable populations." *Id.* at 307.

[118] Thompson v. W. States Med. Ctr., 535 U.S. 357, 376–77 (2002).

[119] *See, e.g.*, *Smokers Email Masterfile*, *supra* note 33.

"appropriate for the protection of the public health" that also makes it more difficult for all or some tobacco product firms to compete successfully in the marketplace.

Using a different tactic, however, manufacturers might argue that the proposed advertising restrictions are more restrictive than necessary because they could design advertising for their e-cigarettes using one or more of the prohibited public forms of advertising so that it would not increase youth or nonsmoker initiation or otherwise work to increase public health harms and would work more effectively to prompt more adult smokers to switch entirely to e-cigarettes. But if they had adequate evidence to show that they could do that, they could include it with the related advertising proposals in their applications for new product orders, and FDA would issue a corresponding permissive order. This readily available pathway to avoiding having to comply with all the advertising restrictions proposed here underscores why it would be extremely difficult for any court to find the proposed restrictions unconstitutional when established through final FDA new product orders. The agency would require the restrictions in a final order only if the applicant had failed to provide evidence that allowing its e-cigarettes on the market with less restrictive or less extensive advertising restrictions would still be at least as "appropriate for the protection of the public health." But if the applicant had failed to show that any such less extensive means existed during the application and order process, it is unlikely that the applicant could establish, during a later lawsuit claiming First Amendment violations, that FDA should have employed less restrictive or less extensive advertising restrictions when it issued the order.

It is not clear whether an applicant could at some point provide evidence in its new product application to justify some less-restrictive approach to advertising that could allow the e-cigarettes onto the market as "appropriate for the protection for the public health." But to make the courts more comfortable with any advertising restrictions imposed by FDA in new product orders, the agency could include provisions in the orders stating that applicants receiving an order with advertising restrictions could subsequently apply to have those restrictions modified or eliminated by submitting new evidence showing that they are no longer appropriate for the protection of the public health or are more extensive than necessary, either in general or in regard to specific advertising proposed by the applicants.[120]

FDA could further establish that the advertising restrictions were "no more extensive than necessary" by showing the impracticality of permitting manufacturers or other sellers of e-cigarettes to use the more public forms of advertising more freely. Because of the well-established and court-recognized power of advertising,[121] the only way the agency could possibly do that, without creating high risks of increasing initiation among youth and other public health harms would be either to: (a) establish strict time, place and manner and/or content restrictions on those publicly accessible ads; or (b) review

[120] Tobacco Control Act § 910(c)(1)(B), 21 U.S.C § 387j(c)(1)(B) (2012). This statute authorizes FDA to impose advertising restrictions in new product orders, so long as they are appropriate for the protection of the public health, which implicitly provides authority to modify or eliminate those restrictions whenever that is appropriate for the protection of the public health. *See also* Tobacco Control Act §§ 910(d), 911(i), 911(j), 21 U.S.C. §§ 387j(d), 387k(i), 387k(j) (2012) (providing FDA with authority to review and withdraw or suspend new product and modified risk tobacco product orders, respectively.) To eliminate any possible ambiguity, and provide extra protections against claims that including the advertising restrictions in new product orders is "more extensive than necessary," the agency could state in the orders that it would modify those restrictions to be less extensive whenever those receiving the orders submit evidence showing that the modifications would be appropriate for the protection of the public health, and the agency could also establish related procedures for the submission of that evidence and its review.

[121] *See, e.g.*, Lorillard Tobacco Co. v. Reilly, 533 U.S. 525, 560–61 (2001); Henricksen, *supra* note 29; Tobacco Act Findings (15)–(23), *supra* note 29; *Press Release from Senators*, *supra* note 30, at 9, 16; Duke et al., *supra* note 30; Pokhrel et al., *supra* note 31; SURGEON GENERAL REPORT 2012, *supra* note 31.

and test all such ads before they were used to ensure that they would not increase initiation among youth or produce any public health harms. However, because most other countries with active tobacco control strategies simply ban all tobacco product advertising, there is not much research on whether it is possible to regulate permitted tobacco product advertising to reduce undesirable public health impacts as effectively as through minimizing exposure, or on how that might be done. But history has shown that the tobacco industry is remarkably adept at adjusting to advertising regulations or bans to dampen or eliminate their beneficial impact;[122] and the continual development of increasingly sophisticated and subtle advertising strategies and new advertising technologies make it extremely difficult, if not impossible, for research or regulators to keep up. Consequently, it would likely be beyond FDA's expertise or capacity to design less-extensive restrictions on the time, place and manner or content of e-cigarette advertising restrictions that had any likelihood of working as effectively to promote its substantial public health interests as the proposed advertising restrictions directed at minimizing exposure among certain populations.

For many of the same reasons, as well as capacity issues, it would be even more difficult for FDA to review all e-cigarette ads before they were used to evaluate the likelihood that they would, alone or in coordination with other ads or marketing practices, produce negative public health outcomes that contradicted the agency's purposes for allowing the e-cigarettes on the market or otherwise made the marketing of the e-cigarettes inappropriate for the protection of the public health. It is unlikely that FDA has or could be provided with sufficient resources to review every new or different e-cigarette ad before it was released without creating enormous backlogs and delay. Doing so effectively would be even more complex and expensive, requiring extensive testing of each ad, both on its own and in conjunction with other ads and marketing, and with different focus groups of different types of youth and adult non-smokers and smokers.

In many cases, the only way FDA would know with any confidence whether a certain ad, on its own or in a series, would not increase initiation or other undesirable public health outcomes would be if the ad were put into public circulation and FDA carefully monitored and analyzed its impacts. Such real-world testing of e-cigarette advertising would, however, mean that any increased initiation or other public health harms caused by the advertising could be addressed by the agency only after the harms had already occurred. But allowing such likely health harms to occur before taking action to prevent them cannot be considered appropriate for the public health. More to the point, a regulatory approach that allows e-cigarette advertising to increase public health harms, and that will restrict that advertising more severely only after it causes serious public health harms, should not be considered a viable "less extensive" restriction on commercial speech than the proposed advertising restrictions, which would do more to prevent the public health harms from occurring in the first place. Measures that are

---

[122] *See, e.g.*, Constantine I. Vardavas et al., *Changes in Tobacco Industry Advertising Around High Schools in Greece Following an Outdoor Advertising Ban: A Follow-up Study*, 22 TOBACCO CONTROL 299, 299–301 (2013); Ross MacKenzie et al., *Thailand—Lighting up a Dark Market: British American Tobacco, Sports Sponsorship and the Circumvention of Legislation*, 61 J. OF EPIDEMIOLOGY & CMTY. HEALTH 28, 28–33 (2007); Mary Assunta & S. Chapman, *The World's Most Hostile Environment: How the Tobacco Industry Circumvented Singapore's Advertising Ban*, 13 TOBACCO CONTROL ii57, ii51–57 (2004); Stacy M. Carter, *Going Below the Line: Creating Transportable Brands for Australia's Dark Market*, 12 TOBACCO CONTROL iii87, iii87–94 (2003).

less effective at achieving the government's substantial interests, even if they restrict speech less, cannot be "less extensive alternatives" for First Amendment purposes.[123]

These points, added to the prior analysis, suggest that placing the proposed advertising restrictions in new product orders would satisfy all aspects of the *Central Hudson* test. But the required supplementary messaging in the e-cigarette advertising would still need to be structured to fit within the First Amendment constraints on compelled commercial speech.[124] That should not be difficult. First, as described above, the required messaging would be directed exclusively at advancing the government's substantial interests (rather than only "reasonably related" as the courts have required).[125] In addition, the messaging could also be designed to be purely informational, non-controversial, and identified as coming from the government (and not the sellers).[126] To be even more certain the supplementary messaging would pass constitutional scrutiny, any graphic images could be avoided or, if included could be purely informational and not designed to evoke an emotional response.[127] To make the required messaging even more defensible, their size and format could be structured to ensure that the messaging would be noticed by the consumers receiving the e-cigarette advertising but not be unduly expensive or burdensome for the sellers to include.

VI. WHY NOT ISSUE A NEW E-CIGARETTE RULE, INSTEAD?

The forgoing analysis suggests that the advertising restrictions imposed by FDA through new product orders should pass constitutional muster, so long as the agency also follows all the procedures required by law, and is not "arbitrary and capricious" in determining that the restrictions are necessary to enable the agency to issue an order allowing the e-cigarettes on the market as "appropriate for the protection of the public health."[128]

If FDA decided, however, to implement this regulatory scheme solely through issuing a rule, the agency would not enjoy the previously described protections against First Amendment challenges that would be secured through establishing e-cigarette advertising restrictions only through enforcement discretion (where the products are illegal and have weaker, if any, First Amendment protections) and through new product and modified risk tobacco product orders (when constitutional rights may be waived and the applicants have the burden of presenting evidence that allowing their products on the market with fewer advertising constraints is "appropriate for the protection of the public health"). Notice-and-comment rulemaking would also probably take five years

---

[123] *See* Thompson v. W. States Med. Ctr., 535 U.S. 357 (2002); *see also supra* note 113 and accompanying text.

[124] Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626 (1985); R.J. Reynolds Tobacco Co. v. FDA, 696 F.3d 1205 (D.C. Cir. 2012); Am. Meat Inst. v. U.S. Dep't of Agric, 760 F.3d 18 (D.C. Cir. 2014).

[125] *Zauderer*, 471 U.S. at 628, 651.

[126] For example, if including the 1-800-QUIT-NOW phone number or other cessation assistance information were thought to be "ideological and not informational," "not warnings but admonitions," or "unabashed attempts to . . . browbeat consumers into quitting," and, therefore, were thought to go beyond the scope of permissible compelled speech, those aspects of the supplementary messaging could be omitted or revised. *R.J. Reynolds*, 696 F.3d at 1211, 1216–17.

[127] *Id*.

[128] The "arbitrary and capricious" standard for such agency action is established in the Administrative Procedure Act, 5 U.S.C. § 706 (2012), and Section 912 of the Tobacco Control Act applies it to any judicial review of FDA tobacco product regulations or orders, Tobacco Control Act § 912(b), 21 U.S.C. § 387(l)(b) (2012).

or more, while the process outlined above could be initiated soon after the deeming rule effective date.

The disadvantages from using a rulemaking to establish the advertising restrictions would be most severe if FDA had, before issuing the final rule, already issued orders permitting e-cigarettes to be on the market as legal tobacco products without those restrictions. To issue such orders, FDA would have to find that it is "appropriate for the protection of the public health" to allow the e-cigarettes on the market without the advertising restrictions; and that would make it much more difficult to establish that the advertising restrictions in the new rule were "appropriate for the protection of the public health." The agency could try to show that it was, first, "appropriate for the protection of the public health" to allow the e-cigarettes on the market without the advertising restrictions, and, second, even more "appropriate for the protection of the public health" to subject them subsequently to additional advertising restrictions through the rule. But FDA would still be in a much weaker position because the agency could no longer argue that the advertising restrictions were necessary to make having the e-cigarettes on the market be" appropriate for the protection of the public health," which provides a much stronger foundation for defending the restrictions against First Amendment challenges.

Most of these rulemaking challenges could be avoided if FDA could initiate and complete the rulemaking to establish the proposed e-cigarette product-safety and advertising restrictions during its implementation of the enforcement discretion stage proposed here and, especially, prior to issuing any orders allowing any e-cigarettes on the market without any advertising restrictions. But that might be difficult, given the time it takes to issue a final rule and the requirement in the Tobacco Control Act that FDA issue new product orders within 180 days of receiving a complete application from the manufacturer. It is possible, however, that FDA could issue only negative orders prior to the effective date of the new rule, finding that it would not be appropriate for the protection of the public health to allow any e-cigarettes on the market until the rule was in effect. Making that same point, FDA could, alternatively, issue permissive orders that would not go into effect until after the final rule establishing the advertising restrictions was in place.

But even if done in these ways, issuing a rule to establish the proposed advertising restrictions would still be more difficult to defend against First Amendment attacks than advertising restrictions imposed through new product orders, and would still take considerably longer to implement. In either case, implementing the enforcement discretion stage, as described here, would sharply reduce e-cigarette-related health harms while the orders and/or rule were being developed and implemented.

VII. CONCLUSION

This paper has tried, first, to refocus the existing debate and discussion about e-cigarettes on figuring out what can be done now, without waiting for more research or data, to minimize e-cigarette harms while allowing them to realize their public health potential. Toward that end, it has presented the following core facts about e-cigarettes and their advertising that are already known, stated cautiously to seek general consensus: (1) e-cigarette use is addictive and is, to at least some not insignificant extent, more harmful and risky than no nicotine or tobacco use at all; (2) e-cigarette use is, to at least some significant extent, less harmful to users and nonusers than smoking, and could be made even less harmful; and (3) e-cigarette advertising, if not constrained, is likely to increase youth and non-smoker addiction and use and could increase non-beneficial dual use by smokers.

Those core facts support a regulatory scheme that allows e-cigarettes on the market only to serve as effective cessation aids or to offer smokers who would not otherwise quit with a less harmful way to consumer nicotine, while also preventing any offsetting harms through increased initiation, reduced cessation, or harmful dual use. Given existing practical and legal constraints, that cannot be done perfectly. But the approach proposed here provides a way to regulate e-cigarettes that would work to minimize the public health risks from e-cigarettes while still allowing them to pursue their public health potential. It offers a way to allow for meaningful public health gains without any serious downside risk of new health harms that could offset or overwhelm the those benefits. In other words, this paper suggests a way to begin regulating e-cigarettes immediately that would be appropriate for the protection and promotion of the public health, and might be the most effective approach available (especially if complemented with new efforts to make cigarettes and other similarly smoked products less attractive, less satisfying, or less readily available to smokers).

As an initial proposal for regulating e-cigarettes and their advertising, the basic framework suggested here could certainly benefit from additional scrutiny and analysis. As it stands, however, it hopes to provide some assistance to anyone, in any country, trying to determine how e-cigarettes might be regulated effectively to serve as a helpful weapon against smoking, the largest tobacco-related public health problem throughout the world.

More specific to the United States, this paper has then gone further to suggest how FDA might use its existing drug and tobacco product authorities to implement this type of approach to e-cigarettes to protect and promote the public health—taking full advantage of existing procedures and statutory deadlines in the Tobacco Control Act to facilitate compliance with the First Amendment and to produce related health gains quickly. Here, too, additional scrutiny and analysis is needed and welcome.

Whether implemented in the United States or elsewhere, modifications to the details of the proposed approach could make it more or less demanding on e-cigarette manufacturers, importers and sellers. That would marginally alter the size and timing of the related public health benefits in one direction or another. But the hope here is that any quibbling over those or other details will not obscure or delay the development of a new consensus among both e-cigarette "hawks" and "doves" about how to proceed now to regulate e-cigarettes most effectively for the public health.

If history is any guide, industry opposition to any significant new e-cigarette regulations will likely be severe. But the approach proposed here could provide e-cigarette companies with a reasonable transition period, require only the most common-sense product changes that some e-cigarette companies have already made or endorsed, and, despite the new advertising restrictions, still leave them able to compete effectively for their appropriate consumers, including an expedited pathway toward making modified risk claims to smokers.

Whether this approach might fit within FDA's current regulatory priorities for tobacco products and its related enforcement priorities and capacity is for the agency to decide. This approach focuses the regulation of e-cigarettes specifically on reducing smoking—which should be the top priority of any tobacco control efforts seeking to maximize public health gains. But there might be other, more effective strategies available to FDA to reduce smoking and its harms more quickly and sharply. Nevertheless, FDA will have to do something in regard to exercising enforcement discretion as soon as the final deeming rule makes all e-cigarettes illegal products, and the agency will at some point thereafter have to decide what orders to issue in response to e-cigarette applications

for new product and, possibly, modified risk tobacco product orders. With luck, this paper will generate further discussion and analysis to help inform the agency's actions and decisions in those areas.

It may also be worth noting that the analysis here regarding how FDA could exercise its enforcement discretion in regard to e-cigarettes made illegal by the final deeming rule, and how it could handle related new product applications, could be applied similarly to other newly deemed products that become illegal tobacco products.