

# Should FDA Try to Move Smokers to E-Cigarettes and Other Less-Harmful Tobacco Products and, If So, How?

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## ABSTRACT

The emergence of e-cigarettes has produced major changes in the tobacco industry and to adult and youth tobacco use patterns. But there are sharp disagreements about the extent to which e-cigarettes might be helping or hurting efforts to reduce public health harms from smoking and other tobacco-nicotine use. There are also active disputes among tobacco control researchers and other experts about exactly how much less harmful e-cigarettes might be compared to smoking and about how e-cigarettes and their marketing might be affecting youth and adult initiation, cessation, switching, and relapse. Without trying to resolve these disputes, this article offers recommendations for specific U.S. Food and Drug Administration (FDA) actions that would produce large public health gains by shifting smokers to using less harmful e-cigarettes without creating any significant risk of delaying total cessation, increasing youth initiation, or prompting any other health-harming e-cigarette use. Based on a *Food and Drug Law Journal* Symposium panel that offered diverse tobacco control and tobacco industry viewpoints, this article offers recommendations designed to make sense not just for the public health but for FDA, the industry, and the White House—regardless of who is right or wrong in the ongoing debates about e-cigarette harmfulness and current impacts.

## BACKGROUND

The emergence and evolution of e-cigarettes as commercial products in the United States and throughout the world has generated considerable interest and excitement in the tobacco industry, among tobacco-nicotine users, and in the public health and

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tobacco control communities.<sup>1</sup> Many see e-cigarettes as being a possibly transformative tobacco-nicotine product because they are less harmful to users and exposed nonusers than smoking but enable smokers to satisfy their addiction by inhaling nicotine directly into their lungs, just like smoking. That makes using e-cigarettes a much more direct substitute for smoking than other noncombustible tobacco products (e.g., smokeless tobacco) or nicotine-delivery products (e.g., nicotine gum or patches).

From a tobacco industry perspective, e-cigarettes are already a transformative product category because they now constitute a small but significant, growing share of the U.S. tobacco-nicotine market (with estimated sales in 2017 equal to three percent of cigarette sales),<sup>2</sup> shifting the mix of products that the major tobacco companies offer and sell, and bringing many new e-cigarette-only manufacturers and retailers into the tobacco-nicotine industry.<sup>3</sup> Goldman Sachs tobacco industry analysts refer to e-cigarettes as “next generation products” (NGPs);<sup>4</sup> and industry analysts at Cowen & Company say that “[we] see the greatest potential for disruptive change in the last 60+ years in global tobacco, as regulators, manufacturers and consumers look to be increasingly aligned around reduced-risk proposition.”<sup>5</sup>

E-cigarettes could transform the industry more rapidly and substantively, with more assured public health benefits, if the tobacco industry or government acted even more aggressively to shift smokers to using e-cigarettes. Some in the industry might even welcome such large shifts, as it could reduce the amount of death and destruction caused by the industry’s products and marketing, and leave the industry with a more sustainable, profitable, and defensible long-term future.<sup>6</sup> Indeed, the website for Philip Morris International (PMI), one of the two largest multinational tobacco companies in the world, states that it is “Designing a Smoke-Free Future,”<sup>7</sup>

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<sup>1</sup> For the purposes of this paper e-cigarettes are defined as any tobacco-nicotine product through which consumers can inhale nicotine directly into their lungs without any combustion, whether called e-cigarettes, vaporizers, hookah pens, vaporized nicotine products (VNPs), electronic nicotine delivery systems (ENDSs) or something else. For example, although Philip Morris International (PMI)’s IQOS “heat-not-burn” tobacco product is not currently available in the U.S.A., it is considered an e-cigarette in this paper. “Tobacco industry” is meant to include all businesses with a significant stake in the sale and use of products for non-medical purposes that contain tobacco or nicotine, including the recent new entrants to the tobacco industry that manufacture, market, or sell only e-cigarettes.

<sup>2</sup> JUDY E. HONG ET AL., GOLDMAN SACHS, AMERICAS TOBACCO: FUTURE OF TOBACCO: ALL EYES ON US IQOS COMMERCIALIZATION PLAN AT MO’S INVESTOR DAY 2 (Oct. 30, 2017); see also Kristy L. Marynak et al., *National and State Trends in Sales of Cigarettes and E-Cigarettes, U.S., 2011–2015*, 53 AM. J. PREVENTIVE MED. 96, 99 (2017).

<sup>3</sup> See D. Levy et al., *An Economic Analysis of the U.S. Market for Vaporized Nicotine Products* (Georgetown University, Working Paper, 2018).

<sup>4</sup> JUDY E. HONG ET AL., *supra* note 3.

<sup>5</sup> V. AZER & A. GREY, TOBACCO: BRITISH AMERICAN TOBACCO: COMPANY UPDATE: BATS AND THE 1 BILLION CONSUMER OPPORTUNITY, COWEN EQUITY RESEARCH (Oct. 31, 2017). See, also, David O’Reilly, *Guest Post: BAT Executive on Disruption of Tobacco Industry*, COUNTERFACTUAL BLOG (Sept. 26, 2017), <http://www.clivebates.com/guest-post-bat-executive-on-disruption-of-the-tobacco-industry>.

<sup>6</sup> See generally, e.g., J. Robert Branton & David Sweanor, *Big Tobacco, E-cigarettes, and a Road to the Smoking Endgame*, 29 INT’L J. DRUG POL’Y 14 (2016); John P. A. Ioannidis et al., *Endgame: Engaging the Tobacco Industry in its Own Elimination*, 43 EUR. J. CLINICAL INVESTIGATION 1366 (2013).

<sup>7</sup> PHILLIP MORRIS INT’L, *Our Manifesto, Designing a Smoke-Free Future*, <https://www.pmi.com/who-we-are/designing-a-smoke-free-future> [<https://perma.cc/A9LQ-6WU7>]. This transformation, however, is not expected to happen rapidly. PMI CEO André Calantzopoulos has stated that PMI’s target is to obtain at least 30 percent of their sales (and about 38 to 42 percent of their net sales

and PMI has pledged to provide \$80 million per year for 12 years to establish the new Foundation for a Smoke-Free World, created “to accelerate global efforts to reduce health impacts and deaths from smoking, with the goal of ultimately eliminating smoking worldwide.”<sup>8</sup> In addition, the websites for Altria (parent company of the largest U.S. cigarette company, Philip Morris USA) and for Reynolds American (parent company of RJ Reynolds Tobacco Co., the second largest) all have major webpages about harm reduction and switching smokers to e-cigarettes or less harmful tobacco products (which other subsidiaries of the parent companies sell).<sup>9</sup>

From a public health perspective, e-cigarettes are already seen as transformative not only because of their market share and impact on the tobacco industry but because more high school youth use e-cigarettes than any other tobacco-nicotine product,<sup>10</sup> and e-cigarettes are now being used more frequently as cessation aids by smokers than nicotine patches or gum.<sup>11</sup> In addition, significant public health gains

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revenues) from reduced-risk, nonsmoked products by 2025 (and no estimates were provided regarding what portion of those sales of nonsmoked products would go to customers who would have otherwise quit all smoking and nicotine use, or to customers who would otherwise never have used any tobacco-nicotine product at all). André Calantzopoulos, Chief Exe. Officer, Philip Morris Int’l, Inc., Consumer Analyst Group of New York (CAGNY) Conference (Feb. 21, 2018).

<sup>8</sup> *About Us*, FOUND. FOR SMOKE-FREE WORLD, [www.smoke-free-world.org/about-us](http://www.smoke-free-world.org/about-us) [https://perma.cc/Y75Z-UAJ4]; see generally Derek Yach, *Foundation for a Smoke-Free World*, 390 LANCET 1807 (2017) (defending the foundation); Mike Daube et al., *Towards a Smoke-Free World? Philip Morris International’s New Foundation is Not Credible*, 390 LANCET 172 (2017) (commenting on Yach). But see, e.g., Matthew L. Meyers, *If Philip Morris Is Serious About a ‘Smoke-Free World,’ It Should Stop Marketing Cigarettes, Fighting Efforts to Reduce Smoking*, CAMPAIGN FOR TOBACCO-FREE KIDS (Sept. 13, 2017) [http://www.tobaccofreekids.org/press\\_releases/post/2017\\_09\\_13\\_pmi](http://www.tobaccofreekids.org/press_releases/post/2017_09_13_pmi) [https://perma.cc/ED7K-JLSX]; *American Cancer Society Statement on Philip Morris International Support of New Effort*, AM. CANCER SOC’Y, <http://pressroom.cancer.org/releases?item=720> [https://perma.cc/M5UQ-PV6E]; Ruth E. Malone et al., *A ‘Frank Statement’ for the 21st Century?*, BMJ BLOGS (Sept. 19, 2017) <http://blogs.bmj.com/tc/2017/09/19/a-frank-statement-for-the-21st-century> [https://perma.cc/F7VA-S87V]; *WHO Statement on Philip Morris Funded Foundation for a Smoke-Free World*, WORLD HEALTH ORG., (Sept. 28, 2017) <http://www.who.int/mediacentre/news/statements/2017/philip-morris-foundation/en/> [https://perma.cc/L78W-TF4V]; Clive Bates, *Letter to the Foundation for a Smoke Free World About Money, Governance, Conflicts and Philip Morris International*, COUNTERFACTUAL BLOG (Nov. 17, 2017) <https://www.clivebates.com/letter-to-the-foundation-for-a-smoke-free-world-about-money-governance-conflicts-and-philip-morris-international/> [https://perma.cc/XTC2-SRKV] (discussing letter from David Abrams et al. to Dr. Yach).

<sup>9</sup> See, e.g., *Tobacco Harm Reduction*, ALTRIA, <http://www.altria.com/Responsibility/Tobacco-Harm-Reduction/Pages/default.aspx> [https://perma.cc/SL9L-46N2]; *Tobacco Harm Reduction*, REYNOLDS AM., <http://sustainability.reynoldsamerican.com/tobacco-harm-reduction> [https://perma.cc/GWN8-P5UX]. But see, e.g., Press Release, Campaign for Tobacco-Free Kids, Philip Morris Hasn’t Changed—Company Aggressively Promotes Cigarettes Even as It Claims Focus on Less Harmful Products (Mar. 5, 2018), [www.tobaccofreekids.org/press-releases/philip-morris-hasnt-changed-company-aggressively-promotes-cigarettes-even-as-it-claims-focus-on-less-harmful-products](http://www.tobaccofreekids.org/press-releases/philip-morris-hasnt-changed-company-aggressively-promotes-cigarettes-even-as-it-claims-focus-on-less-harmful-products) [https://perma.cc/949G-9WRV].

<sup>10</sup> See generally Ahmed Jamal et al., *Tobacco Use Among Middle and High School Students—United States, 2011–2016*, 66 MORBIDITY & MORTALITY WKLY REP. 597 (2017). See also, Karl Fagerstrom et al., *E-Cigarettes: A Disruptive Technology That Revolutionizes Our Field?*, 17 NICOTINE & TOBACCO RES. 125 (Feb. 2015). [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4892710]

<sup>11</sup> Ralph S. Caraballo et al., *Quit Methods Used by US Adult Cigarette Smokers, 2014–2016*, 14 PREVENTING CHRONIC DISEASE 1, 2 (Apr. 2017) (finding that that three quarters of smokers trying to quit used multiple methods, and overall, quitting cold turkey was tried by 65.3 percent; gradually reducing 62 percent; substituting e-cigarettes for some cigs 35.3 percent; patch/gum 25.4 percent; replacing cigarettes completely with e-cigarettes 24.7 percent; cessation medications 12.2 percent.) But see, Terry F. Pechacek

can be secured when smokers who would not otherwise quit switch to using less harmful e-cigarettes, or when youth who would otherwise initiate into smoking use e-cigarettes, instead.

Moreover, the availability of e-cigarettes could weaken or eliminate many practical, ethical, and political obstacles to much stronger anti-smoking laws and regulations. For example, one of the major arguments against banning cigarettes or minimizing their nicotine levels has been that doing so would leave smokers with no legal and attractive way to satisfy or feed their addictions and could prompt the emergence of a large illicit market or swamp available cessation-assistance resources.<sup>12</sup> But because e-cigarettes now provide addicted smokers with a more viable and attractive legal alternative to cigarettes, those concerns are sharply diminished, if they do not disappear entirely.<sup>13</sup> More importantly, perhaps, the major tobacco companies might reduce their opposition to anti-smoking public health laws and regulations now that they can to some extent avoid lost sales from anti-smoking laws and regulations by shifting their smoking customers to e-cigarettes, which they also sell.<sup>14</sup>

In contrast, the goal from a pure public health perspective is to reduce tobacco use harms as sharply and quickly as possible and, ultimately, minimize all harmful tobacco use. That makes some members of the tobacco control and public health communities wary of any tobacco control strategy focused on shifting smokers to less-harmful-but-still-harmful tobacco-nicotine products—especially if it allows the tobacco industry to market e-cigarettes aggressively, expand overall tobacco use, and remain highly profitable and powerful). But others see enormous potential for new public health gains from promoting e-cigarettes as alternatives to smoking. As a result, serious divisions and disputes have arisen between those most encouraged by the emergence of e-cigarettes (sometimes called e-cigarette harm reduction enthusiasts) and those most wary of undesired consequences (sometimes referred to as e-cigarette skeptics).<sup>15</sup>

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et al., *The Potential That Electronic Nicotine Delivery Systems Can be a Disruptive Technology: Results From a National Survey*, 18 NICOTINE & TOBACCO RES. 1989, 1994–95 (Oct. 2016).

<sup>12</sup> See, e.g., H.R. REP. NO. 111-58, pt. 1, at 38 (2009).

<sup>13</sup> See, e.g., Neal L. Benowitz et al., *Reduced nicotine content cigarettes, e-cigarettes and the cigarette end game*, 6 ADDICTION (2017); Lawrence O. Gostin, Letter, *Regulating E-Cigarettes to Help Them Realize Their Potential as an Anti-Smoking Tool*, 351 BMJ h3767 (2015); Oscar Cabrera & Lawrence O. Gostin, *Indonesia has it Backward: It's Not e-cigarettes that are the Problem but Smoking*, O'NEILL INST. FOR NAT'L & GLOBAL HEALTH L. BLOG (May 29, 2015) <http://www.oneillinstituteblog.org/indonesia-has-it-backward-its-not-e-cigarettes-thats-the-problem-but-smoking> [https://perma.cc/2A4S-ZH3B].

<sup>14</sup> See, e.g., *A Common-Sense Approach*, PHILIP MORRIS INT'L, <https://www.pmi.com/our-business/about-us/our-views/regulation> [https://perma.cc/JJ9S-NBSQ] (last visited Feb. 5, 2018).

<sup>15</sup> See generally, e.g., Kenneth E. Warner, *How to Think—Not Feel—About Tobacco Harm Reduction*, NICOTINE & TOBACCO RES. (published online April 30, 2018) <https://academic.oup.com/ntr/advance-article/doi/10.1093/ntr/nty084/4990310>[using enthusiasts and sceptics labels]; Jonathan Gornal, *Why E-Cigarettes are Dividing the Public Health Community*, 350 BMJ h3317 (2015); Clive Bates, *53 Public Health Specialists Write to WHO About Alternatives to Smoking—Here's the Letter*, COUNTERFACTUAL BLOG (May 29, 2014) <https://www.clivebates.com/53-public-health-specialists-write-to-who-about-alternatives-to-smoking-heres-the-letter/> [https://perma.cc/UN95-L8BH]; Stanton A. Glantz, *Some Comments on the May 26 Letter from Public Health Specialists to WHO Director General Margaret Chan*, CTR. FOR TOBACCO CONTROL RES. & EDUC. BLOG (June 9, 2014) <https://tobacco.ucsf.edu/some-comments-may-26-letter-public-health-specialists-who-director-general-margaret-chan> [https://perma.cc/6T4D-RUXR]; Stanton A. Glantz, *129 Public Health and Medical Authorities from 31 Countries Write*

Put somewhat simply, the enthusiasts believe that efforts to shift smokers to e-cigarettes is likely to secure much larger gains than the status quo or other possible tobacco control options and is more politically viable, especially if it relies largely on industry action and market competition. To help make that happen, some support regulating and taxing e-cigarettes less strictly than cigarettes and other smoked tobacco products, along with more active government efforts to ensure that consumers understand that using e-cigarettes is much less harmful than smoking.<sup>16</sup>

In contrast, the e-cigarette skeptics worry that the big tobacco companies will use e-cigarettes and their marketing to renormalize both nicotine and tobacco use, reduce or delay total cessation, increase dual use with e-cigarettes to reduce or delay smoking cessation, increase relapse into regular nicotine and possibly tobacco use among former smokers, and increase initiation into regular nicotine and possibly tobacco use among youth and others who would not otherwise use any tobacco-nicotine product. They are also concerned that the tobacco industry will use the potential public health gains from switching smokers to e-cigarettes, and the industry's stated support for such a transition, to block or delay effective new government tobacco control measures.<sup>17</sup>

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*WHO DG Chan Urging Evidence-Based Approach to Ecigs*, CTR. FOR TOBACCO CONTROL RES. & EDUC. BLOG (June 16, 2014) <https://tobacco.ucsf.edu/129-public-health-and-medical-authorities-31-countries-write-who-dg-chan-urging-evidence-based-appro> [<https://perma.cc/CJK9-9XSY>]; *Glantz Letter to WHO – The Importance of Dispassionate Presentation and Interpretation of Evidence*, NICOTINE SCI. & POL'Y (June 29, 2014) <https://nicotinepolicy.net/n-s-p/2003-glantz-letter-to-who-the-importance-of-dispassionate-presentation-and-interpretation-of-evidence> [<https://perma.cc/7FT3-MQUQ>] (including letter to WHO commenting on letter to WHO from 129 public health and medical authorities from the 53 public health specialists who first wrote to WHO).

<sup>16</sup> See generally, e.g., Warner, *supra* note 16; Joel L. Nitzkin, *The Case in Favor of E-Cigarettes for Tobacco Harm Reduction*, 11 INT'L J. ENVTL. RES. & PUB. HEALTH 6459 (2014); Lynn T. Kozlowski & David B. Abrams, *Obsolete Tobacco Control Themes can be Hazardous to Public Health: Need for Updating Views on Absolute Product Risks and Harm Reduction*, 16 BMC PUB. HEALTH 432 (2016); Konstantinos E. Farsalinos & Jacques Le Houezec, *Regulation in the Face of Uncertainty: The Evidence on Electronic Nicotine Delivery Systems (E-Cigarettes)*, 8 RISK MGMT. & HEALTHCARE POL'Y 157 (2015); Lynn T. Kozlowski & David Sweanor, *Withholding Differential Risk Information on Legal Consumer Nicotine/Tobacco Products: The Public Health Ethics of Health Information Quarantines*, 32 INT'L J. DRUG POL'Y 17 (2016).; J. Robert Branston & David Sweanor, *Big Tobacco, E-Cigarettes, and a Road to the Smoking Endgame*, 29 INT'L J. DRUG POL'Y 14 (2016).

<sup>17</sup> See, e.g., Matthew L. Myers & Robin Koval, *Commentary: Philip Morris Says It Wants to Quit Cigarettes. But It's Just Blowing Smoke*, FORTUNE (Jan. 5, 2018) <http://fortune.com/2018/01/05/philip-morris-international-quit-smoking-cigarettes-tobacco/> [<https://perma.cc/EP4G-9CZS>]; Matthew L. Myers, President, Campaign for Tobacco-Free Kids, Presentation at Food and Drug Law Institute Symposium FDA & Health Behavior Regulation: Should FDA Try to Move Smokers to E-Cigarettes or Other Less-Harmful Tobacco-Nicotine Products and, if so, How? (Oct. 20, 2017) <https://www.fdpi.org/wp-content/uploads/2017/10/Symposium-Myers.pdf> [<https://perma.cc/XSD6-K5C9>]; see generally Michael Craig Watson & Mark Forshaw, *Why We Shouldn't Normalise the Use of E-Cigarettes*, 351 BMJ (2015); Mohammed Al-hamdani, *A Short Note on E-Cigarette Issues: Harm Reduction, Re-Normalization, and Big Tobacco*, 35 J. PUB. HEALTH POL'Y 132 (2014); Kenneth E. Warner, *supra* note 16; see generally also Gunnar Sæbø & Janne Scheffels, *Assessing Notions of Denormalization and Renormalization of Smoking in Light of E-Cigarette Regulation*, 49 INT'L J. DRUG POL'Y 58 (2017); Amy Fairchild & Ronald Bayer, *The Shadow of Big Tobacco Over E-Cigarettes and Harm Reduction*, STAT (May 8, 2017) <https://www.statnews.com/2017/05/08/ecigarettes-harm-reduction-big-tobacco/> [<https://perma.cc/J93T-732U>]; *The Top 8 Things the Industry Does to Encourage Youth to Use E-Cigarettes*, AM. LUNG ASS'N, <http://www.lung.org/our-initiatives/tobacco/reports-resources/sotc/by-the-numbers/8-things-industry-ecigs.html> [<https://perma.cc/7DA3-UEJ4>] (last visited Mar. 15, 2017).

Underlying this division between e-cigarette harm reduction enthusiasts and skeptics are conflicting research findings and related disputes about what available research and other evidence tells us regarding such directly related matters as:

- (a) How much less harmful is using e-cigarettes compared to smoking?<sup>18</sup>
- (b) Do e-cigarettes promote or dampen smoking cessation?<sup>19</sup>
- (c) To what extent is e-cigarette use reducing youth smoking or serving as a gateway to smoking for otherwise nonsmokers?<sup>20</sup> and

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<sup>18</sup> For a recent careful analysis of available research, see NAT'L ACADS. SCIS. ENGINEERING & MED., PUBLIC HEALTH CONSEQUENCES OF E-CIGARETTES 1–8 (Kathleen Stratton et al. eds. 2018) (concluding: “To the extent that laboratory tests of e-cigarette ingredients, in vitro toxicological tests, and short-term human studies suggest that e-cigarettes are likely less harmful than combustible tobacco cigarettes, due to lack of long-term epidemiological studies and large clinical trials, the implications for long-term effects on morbidity and mortality are not yet clear and the absolute safety of the products cannot be unambiguously assessed at this time.”). For examples of the ongoing dispute over exactly how less harmful e-cigarettes are, see Boris Reidel et al., *E-Cigarette Use Causes a Unique Innate Immune Response in the Lung Involving Increased Neutrophilic Activation and Altered Mucin Secretion*, 197 AM. J. RESPIRATORY & CRITICAL CARE MED. 492 (2018) (“These data challenge the concept that e-cigarettes are a healthier alternative to cigarettes.”); Ann McNeill et al., *E-Cigarettes: An Evidence Update* at 80 (2015) <https://www.gov.uk/government/publications/e-cigarettes-an-evidence-update> [<https://perma.cc/9FCK-6XHK>] (concluding that e-cigarettes are around 95 percent safer than smoked tobacco); Editorial, *E-Cigarettes: Public Health England’s Evidence-Based Confusion*, 386 LANCET 829 (2015); Ann McNeill et al., *E-Cigarettes: Need for Clear Communication on Relative Risks*, 386 LANCET 1237, 1237 (2015); David J. Nutt et al., *E-cigarettes are Less Harmful Than Smoking*, 387 LANCET 1160 (2016); Martin McKee & Simon Capewell, *Electronic Cigarettes: We Need Evidence, Not Opinions*, 386 LANCET 1239 (2015).

<sup>19</sup> For a recent careful analysis of available research, see NAT'L ACADS. SCIS. ENGINEERING & MED., PUBLIC HEALTH CONSEQUENCES OF E-CIGARETTES 17-17 (Kathleen Stratton et al. eds. 2018) (concluding: “Overall, there is limited evidence that e-cigarettes may be effective aids to promote smoking cessation.”); see also, e.g., Kaitlyn M. Berry et al., *E-cigarette initiation and associated changes in smoking cessation and reduction: the Population Assessment of Tobacco and Health Study, 2013–2015*, TOBACCO CONTROL (published online March 24, 2018) (daily e-cigarette initiators more likely to quit smoking or reduce use compared with non-users, but less frequent e-cigarette use not associated with cigarette cessation/reduction), <http://tobaccocontrol.bmj.com/content/early/2018/03/24/tobaccocontrol-2017-054108>; Daniel P. Giovenco & Cristine D. Delnevo, *Prevalence of Population Smoking Cessation by Electronic Cigarette Use Status in a National Sample of Recent Smokers*, 76 ADDICTIVE BEHAVIORS 129, 133 (2018) (“Overall, the relationship between e-cigarette use and quitting smoking is mixed, but the findings suggest that for some, frequent e-cigarette use may play a role in cessation.”); J. Hartmann-Boyce et al., *Electronic Cigarettes for Smoking Cessation*, 9 COCHRANE DATABASE SYSTEMATIC REVIEWS at 23 (2016) (providing that there is evidence that e-cigarettes help smokers to stop smoking in the long term but certainty about the effect is low); Sara Kalkhoran & Stanton Glantz, *E-Cigarettes and Smoking Cessation in Real-World and Clinical Settings: A Systematic Review and Meta-Analysis*, 4 LANCET RESPIRATORY MED. 116, 126 (2016) (“[T]he overall conclusion from the available studies is that e-cigarette use is associated with reduced smoke cessation in the real world.”); with critiques by Peter Hajek et al., *E-Cigarettes and Smoking Cessation*, 4 LANCET e23 (2016) and Menfil Andres Orelliana-Barríos et al., *E-Cigarettes and Smoking Cessation*, 4 LANCET e24 (2016), and a reply by Sara Kalkhoran & Stanton A. Glantz, *E-cigarettes and Smoking Cessation—Authors’ Reply*, 4 LANCET e26 (2016). See also Science Media Center, *Expert reaction to meta-analysis looking at e-cigarette use and smoking cessation* (Jan. 14, 2016). [<http://www.sciencemediacentre.org/expert-reaction-to-meta-analysis-looking-at-e-cigarette-use-and-smoking-cessation>]; Stanton A. Glantz, *Specific Responses to the “Expert” Criticism*, CTR. FOR TOBACCO CONTROL RES. & EDUC. BLOG (Jan. 1, 2016) <https://tobacco.ucsf.edu/our-new-meta-analysis-entire-relevant-literature-shows-e-cigarettes-used-are-associated-less-not-more-quit#comment-17171> [<https://perma.cc/QXJ3-BM9N>].

<sup>20</sup> For a recent careful analysis of available research, see NAT'L ACADS. SCIS. ENGINEERING & MED., PUBLIC HEALTH CONSEQUENCES OF E-CIGARETTES S-7 (Kathleen Stratton et al. eds. 2018) (concluding: “There is substantial evidence that e-cigarette use increases risk of ever using combustible tobacco cigarettes among youth and young adults.”). For subsequent research also finding gateway effects, see generally, e.g., Benjamin W. Chafee et al., *Electronic Cigarette Use and Progression From*

(d) Do flavors in e-cigarettes do more to attract smokers or to attract nonsmoking youth?<sup>21</sup>

Research relating to these questions is incomplete or otherwise inconclusive, and related arguments over the answers are common, complete with attacks on research that favors one side of the debate by those on the other.<sup>22</sup>

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*Experimentation to Established Smoking*, PEDIATRICS (Mar. 5, 2018); Shannon Lea Watkins et al., *Association of Noncigarette Tobacco Product Use With Future Cigarette Smoking Among Youth in the Population Assessment of Tobacco and Health (PATH) Study, 2013–2015*, 172 JAMA PEDIATRICS 181 (2018); Brian A. Primack et al., *Initiation of Traditional Cigarette Smoking after Electronic Cigarette Use Among Tobacco-Naïve US Young Adults*, 17 AM. J. MED. (forthcoming 2018); Krysten W. Bold et al., *Trajectories of E-Cigarette and Conventional Cigarette Use Among Youth*, 141 PEDIATRICS (2018). *But see* Lynn T. Kozlowski, *Vaping as a ‘Gateway’ to Smoking is Still More Hype Than Hazard*, *The Conversation* (Sept. 24, 2015), <https://theconversation.com/vaping-as-a-gateway-to-smoking-is-still-more-hype-than-hazard-47399>. For research finding no gateway effects, *see, e.g.*, Jean-Francois Etter, *Gateway Effects and Electronic Cigarettes*, ADDICTION (Aug. 7, 2017). *But see*, Simon Chapman & David Bareham, *Gateway Effects and Electronic Cigarettes: A Response to J-F Etter*, U. SYDNEY ESCHOLARSHIP REPOSITORY (Nov. 17, 2017); Stanton A. Glantz, *Addiction Continues to be the go-to Journal for E-Cigarette Promotion, This Time Attacking the Ecig Gateway Effect*, CTR. FOR TOBACCO CONTROL RES. & EDUC. BLOG (Nov. 11, 2017) <https://tobacco.ucsf.edu/addiction-continues-be-go-to-journal-e-cigarette-promotion-time-attacking-ecig-gateway-effect> [<https://perma.cc/V955-VLUT>]; Simon Chapman et al., *The Gateway Effect of E-cigarettes: Reflections on Main Criticisms*, NICOTINE & TOBACCO RES. (Apr. 6, 2018), <https://academic.oup.com/ntr/advance-article/doi/10.1093/ntr/nty067/4962533>.

<sup>21</sup> *See, e.g.*, Sumane Zare et al., *A Systematic Review of Consumer Preference For E-cigarette Attributes: Flavor, Nicotine Strength, and Type*, 13 PLOS ONE 1 (2018); Meghan E. Morean et al., *Preferring More E-Cigarette Flavors is Associated with E-Cigarette Use Frequency Among Adolescents but Not Adults*, 13 PLOS ONE (2018); James Tsai et al., *Reasons for Electronic Cigarette Use Among Middle and High School Students—National Youth Tobacco Survey, United States, 2016*, 67 MORBIDITY & MORTALITY WKLY REP. 196 (Feb. 16, 2018); *see generally* Saul Shiffman et al., *The Impact of Flavor Descriptors on Nonsmoking Teens’ and Adult Smokers’ Interest in Electronic Cigarettes*, 17 NICOTINE & TOBACCO RES. 1255 (2015), with the following comments and replies: Stanton A. Glantz, *Shiffman et al Paper in Nicotine & Tobacco Research is Not a Reliable Estimate of Effects of Ecig Flavors*, CTR. FOR TOBACCO CONTROL RES. & EDUC. BLOG (Feb. 18, 2015) <https://tobacco.ucsf.edu/shiffman-et-al-paper-nicotine-tobacco-research-not-reliable-estimate-effects-ecig-flavors> [<https://perma.cc/WW67-NGBA>]; Robert K. Jackler, *Comment, Nic & Tob Res Declines to Publish Another Critique of Shiffman*, CTR. FOR TOBACCO CONTROL RES. & EDUC. BLOG (Nov. 5, 2015) <https://tobacco.ucsf.edu/comment/15686#comment-15686> [<https://perma.cc/9B2K-7T49>]; and a reply: Saul Shiffman et al., *Comment, Shiffman et al Respond*, CTR. FOR TOBACCO CONTROL RES. & EDUC. BLOG (Mar. 9, 2015) <https://tobacco.ucsf.edu/comment/10351#comment-10351>. [<https://perma.cc/2JDU-TLW4>]; *see also* NAT’L ACADS. SCIS. ENGINEERING & MED., PUBLIC HEALTH CONSEQUENCES OF E-CIGARETTES (Kathleen Stratton et al. eds. 2018) (reviewing research relating to e-cigarettes and flavorings, but providing no specific findings or conclusions relating to their role in initiation or switching from smoking).

<sup>22</sup> *See supra* notes 19–22. From the enthusiasts side, *see also*, Clive Bates, *The Bullshit Asymmetry Principle Applied*, COUNTERFACTUAL BLOG (Sept. 28, 2014) <https://www.clivebates.com/the-bullshit-asymmetry-principle-applied/> [<https://perma.cc/8KR5-8HNW>]; Bethea A. Kleykamp, *Objectivity and Evidence in the 2016 Surgeon General’s Report on E-Cigarettes*, NICOTINE & TOBACCO RES. 1-2 (July 12, 2017); Riccardo Polosa et al., *A Critique of the US Surgeon General’s Conclusions Regarding E-Cigarette Use Among Youth and Young Adults in the United States of America*, 14 HARM REDUCTION J. (Sept. 6, 2017) <https://harmreductionjournal.biomedcentral.com/articles/10.1186/s12954-017-0187-5> [<https://perma.cc/YN2K-ZZRM>]. *But see*, *Comment, When Assessing Criticisms Keep in Mind How SGRs are Prepared*, CTR. FOR TOBACCO CONTROL RES. & EDUC. BLOG (Jan. 8, 2018) <https://tobacco.ucsf.edu/comment/17291#comment-17291>; Brian A. King et al., *Surgeon General’s Reports on Tobacco: A Continued Legacy of Unbiased and Rigorous Synthesis of the Scientific Evidence*, NICOTINE & TOBACCO RES. (Dec. 28, 2017) <https://www.ncbi.nlm.nih.gov/pubmed/29300946> [<https://perma.cc/MF25-3Q5B>]. From the sceptics side, *see, e.g.*, Stanton A. Glantz, *Five Myths About E-Cigarettes and Some of the Evidence that They Are, Well, Myths*, CTR. FOR TOBACCO CONTROL RES. & EDUC. BLOG (Nov. 20, 2017)

This article is not going to try to answer any of these questions or resolve any of the related disputes.<sup>23</sup> Instead, it will base its analysis on the following core facts that have been carefully drafted both to reflect available research and to be acceptable both to e-cigarette harm reduction enthusiasts and skeptics, and to anyone else who is at all familiar with the available literature.

- Exclusive e-cigarette use is less harmful/risky to users than smoking—but exclusive use of e-cigarettes is more harmful/risky to users than not using any e-cigarettes or any other tobacco or nicotine product at all.<sup>24</sup>
- Switching to dual use from smoking is not less harmful to users than just smoking and could be somewhat more harmful<sup>25</sup>—unless the dual use reduces smoking levels substantially, to very low levels.<sup>26</sup>

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<https://tobacco.ucsf.edu/five-myths-about-e-cigs-and-some-evidence-they-are-well-myths> [https://perma.cc/5QDD-CQP4]; John B. Correa et al., *Documenting the Emergence of Electronic Nicotine Delivery Systems as a Disruptive Technology in Nicotine and Tobacco Science*, 65 ADDICTIVE BEHAVIORS 179, 179 (2017) (systematic review of publications on e-cigarettes in peer-reviewed journals from 2006 to 2014 that “reinforces the idea that e-cigarettes are a disruptive technology exerting substantial influence on nicotine and tobacco science” and “suggests that opinions on e-cigarettes may be outpacing our scientific understanding.”); see generally Jeffrey Drope et al., *Key Issues Surrounding the Health Impacts of Electronic Nicotine Delivery Systems (ENDS) and Other Sources of Nicotine*, 67 CA 449 (2017).

<sup>23</sup> See, e.g., Allison M. Glasser et al., *Overview of Electronic Nicotine Delivery Systems: A Systematic Review*, 52 AM. J. PREVENTIVE MED. e33, e33–34 (2017) (“Studies indicate that ENDS are increasing in use, particularly among current smokers, pose substantially less harm to smokers than cigarettes, are being used to reduce/quit smoking, and are widely available. More longitudinal studies and controlled trials are needed to evaluate the impact of ENDS on population-level tobacco use and determine the health effects of longer-term vaping.”).

<sup>24</sup> See *supra* note 19; Talal Alzahrani et al., *Association Between Electronic Cigarette Use and Myocardial Infarction: Results from 2014 and 2016 National Health Interview Surveys*, Poster POS5-34, Annual Meeting, Society for Research on Nicotine and Tobacco, Baltimore, MD (Feb. 21, 2018), [https://c.ymcdn.com/sites/www.srnt.org/resource/resmgr/conferences/2018\\_Annual\\_Meeting/65388\\_SRNT\\_2018\\_Rapids\\_Abstr.pdf#page=12](https://c.ymcdn.com/sites/www.srnt.org/resource/resmgr/conferences/2018_Annual_Meeting/65388_SRNT_2018_Rapids_Abstr.pdf#page=12).

<sup>25</sup> See, e.g., Tingting Yao et al., *Relationship Between Spending on Electronic Cigarettes, 30-Day Use, and Disease Symptoms Among Current Adult Cigarette Smokers in the U.S.*, 12 PLOS ONE 1, 12 (2017); Boris Reidel et al., *E-Cigarette Use Causes a Unique Innate Immune Response in the Lung Involving Increased Neutrophilic Activation and Altered Mucin Secretion*, AM J. RESPIRATORY & CRITICAL CARE MED., 1, 1–24 (2017). Although dual use can be a step toward smoking cessation, some smokers dual use with e-cigarettes because they can use e-cigarettes where they cannot smoke, which could increase their overall consumption and reduce the inconvenience of smoking, thereby reducing motivations to quit. See, e.g., Lindsay Robertson et al., *Dual Use of Electronic Nicotine Delivery Systems (ENDS) and Smoked Tobacco: A Qualitative Analysis*, TOBACCO CONTROL 1, 1, 5 (2018).

<sup>26</sup> See, e.g., Allan Hackshaw et al., *Low Cigarette Consumption and Risk of Coronary Heart Disease and Stroke: Meta-Analysis of 141 Cohort Studies in 55 Study Reports*, 360 BRITISH MED. J., 1, 2 (2018); Rachna Begh et al., *Does Reduced Smoking if You Can’t Stop Make Any Difference?* 13 BIOMED CENT. MED., 1, 1–5 (2015); 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. EPIDEMIOLOGY, 1, 1–10 (2013); Peter Lee, *The Effect of Reducing the Number of Cigarettes Smoked on Risk of Lung Cancer, COPD, Cardiovascular Disease and FEV1—A Review*, 67 REG. TOXICOLOGY & PHARMACOLOGY, 372, 372–81 (2013); see also, Bill Poland et al., *Population Modeling of Modified Risk Tobacco Products Accounting for Smoking Reduction and Gradual Transitions of Relative Risk*, 19 NICOTINE & TOBACCO RES. 1277, 1278 (2017). On smoking reductions leading to smoking cessation, see generally, e.g., Elias M. Klemperer et al., *Reduction in Cigarettes Per Day Prospectively Predicts Making a Quit Attempt: A Fine-Grained Secondary Analysis of a Natural History Study*, NICOTINE & TOBACCO RES. (Mar. 22, 2018), <https://academic.oup.com/ntr/advance-article/doi/10.1093/ntr/nty056/4951442> [https://perma.cc/DS3X-H4WJ].



- Exposure to e-cigarette use is less harmful/risky to nonusers than exposure to smoking. However, exposure to e-cigarette use is more harmful/risky to nonusers (including newborns) than not being exposed to any smoking or e-cigarette use at all.<sup>27</sup>
- The harmfulness of e-cigarettes in the future will depend on product innovation and development, which will depend in large part on what new types of e-cigarettes FDA allows on the market through issuing new product orders, which currently available e-cigarettes FDA allows to stay on the market after they submit new product applications before the August 2022 deadline,<sup>28</sup> and other regulatory actions FDA takes relating to e-cigarettes.
- The extent to which e-cigarettes have beneficial or negative effects on cessation, switching, dual use, initiation, and relapse will also depend on product innovation and development and related FDA regulatory actions, as well as on industry marketing strategies for both e-cigarettes and smoked tobacco products, on government public education efforts, and on how FDA and state and local governments regulate e-cigarettes, cigarettes, and other smoked tobacco products and their marketing, distribution, and sale (which will have a powerful influence on industry strategies and practices).

Based on those core facts, FDA efforts to move smokers to using e-cigarettes could produce health gains by securing the following harm reduction gains:

A. Less harm to smokers if they switch completely to using e-cigarettes, instead—with additional harm reduction when the total switch just to e-cigarette use is a step toward total cessation.

B. Less harm to smokers if they switch to dual use that sharply reduces their smoking and takes it to very low levels—with additional harm reduction when the switch to dual use is a step toward more rapid smoking cessation.

C. Less harm from smokers who have temporarily quit relapsing into using e-cigarettes instead of back into smoking.

D. Less harm to exposed nonusers to the extent their exposure to smoking is replaced by exposure to e-cigarette use or otherwise reduced significantly.

E. Less harm from youth who would otherwise become regular smokers becoming regular e-cigarette users, instead.

On the other hand, FDA efforts to move smokers to using e-cigarettes could produce health harms in the following ways:

a. More harm to smokers if they switch completely to using e-cigarettes when they would have otherwise quit all tobacco-nicotine use or done so more quickly.

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<sup>27</sup> See Esteve Fernández, *Particulate Matter from Electronic Cigarettes and Conventional Cigarettes: a Systematic Review and Observational Study*, 2 CURRENT ENVTL. HEALTH REP. 423, 427 (2015); Anne Y. Oh et al., *Do Electronic Cigarettes Impart a Lower Potential Disease Burden Than Conventional Tobacco Cigarettes? Review on E-cigarette Vapor Versus Tobacco Smoke*, 124 LARYNGOSCOPE 2702, 2703–2705 (2014).

<sup>28</sup> FOOD & DRUG ADMIN., GUIDANCE: EXTENSION OF CERTAIN TOBACCO PRODUCT COMPLIANCE DEADLINES RELATED TO THE FINAL DEEMING RULE (REVISED) (2017). *But see* Press Release, Campaign for Tobacco-Free Kids, Health Groups File Suit to Expedite FDA Review of E-Cigarettes, Cigars (Mar. 27, 2018).

b. More harm to smokers if they switch to dual use without sharply reducing their smoking when they would have otherwise quit all smoking or done so more quickly.

c. More harm if former smokers who would not otherwise relapse into any tobacco-nicotine use relapse into using e-cigarettes—with more harm when that e-cigarette use is a step toward relapse into smoking.

d. More harm to exposed nonusers if, because of e-cigarette-caused prevention of or delays to total smoking cessation or dual use, they are exposed to more smoking than they would otherwise have been exposed to, or are exposed to similar amounts of smoking plus new exposure to e-cigarette aerosols.

e. More harm to the extent that youth or adults who would not otherwise use any tobacco-nicotine product start regular/addicted e-cigarette use—with additional harms when the e-cigarette use is a step toward regular/addicted smoking.

The potential for FDA actions to shift smokers to e-cigarettes to produce these different health gains and harms is shown by some recent modeling studies. For example, a recent journal article projected that if virtually all cigarette smoking were replaced with e-cigarette use over the next 10 years that could, under its conservative assumptions (e.g., e-cigarettes 40 percent as harmful as cigarettes, higher residual smoking, more initiation), prevent 1.6 million premature deaths, and could, under its optimistic assumptions (e.g., e-cigarettes only five percent as harmful, low residual smoking, low initiation by otherwise nonsmokers), prevent 6.6 million premature deaths.<sup>29</sup>

An earlier modeling study, however, found both positive and negative net health impacts, depending on a wide range of different assumptions about switching, dual use, cessation, and initiation trends, as well as about relative harmfulness (and without assuming that smoking would be largely eliminated).<sup>30</sup> The study's most optimistic scenarios (e.g., considerable total switching, low or no cessation delays or initiation by otherwise nonsmokers) produced net health benefits even when e-cigarettes were assumed to be 50 percent as harmful as cigarettes, and its most pessimistic scenarios (e.g., considerable dual use with cessation delays, little total switching, increased initiation) produced net health harms even when e-cigarettes were assumed to be only one percent as harmful as cigarettes—with other, in-between scenarios having net positive or negative impacts depending on the what relative-harm assumptions were used.<sup>31</sup>

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<sup>29</sup> David T. Levy et al., *Potential Deaths Averted in USA by Replacing Cigarettes with E-Cigarettes*, TOBACCO CONTROL, 1, 3, 5 (2017) (noting that additional death and harm reductions, which the study mentions but did not model, would likely be secured by the shifts to e-cigarette use from smoking replacing third-party exposure to secondhand smoke with somewhat less exposure to less-toxic secondhand e-cigarette aerosol); see also, David T. Levy et al., *The Application of a Decision-Theoretic Model to Estimate the Public Health Impact of Vaporized Nicotine Product Initiation in the United States*, 19 NICOTINE & TOBACCO RES. 149, 154 (2016).

<sup>30</sup> Sara Kalkhoran & Stanton A. Glantz, *Modeling the Health Effects of Expanding E-Cigarette Sales in the United States and United Kingdom: A Monte Carlo Analysis*, 175 JAMA INTERNAL MED., 1671, 1676 (2015) (this study also did not model or estimate any health impacts from changes to third-party exposure to secondhand smoker or secondhand e-cigarette aerosol).

<sup>31</sup> For other e-cigarette impact modeling and related analyses, see Kenneth E. Warner & David Mendez, *E-cigarettes: Comparing the Possible Risks of Increasing Smoking Initiation with the Potential Benefits of Increasing Smoking Cessation*, NICOTINE & TOBACCO RES. (Mar. 28, 2018). <https://academic.oup.com/ntr/advance-article/doi/10.1093/ntr/nty062/4956222>; Samir S. Soneji et al., *Quantifying Population-level Health Benefits and Harms of E-cigarette Use in the United States*, 13 PLOS

These models and projections provide two important insights for answering the core question of this article.

First, these models assumed that e-cigarette use could be as much as 40 percent or 50 percent as harmful as smoking or as little as five percent as harmful. But, as these models show, even if e-cigarettes turn out to be only five percent as harmful, that can still create significant ongoing, partially offsetting harms in the context of smoker shifts to e-cigarettes and youth initiation into e-cigarette use instead of to smoking. Accordingly, even under the assumption that e-cigarette use were only about five percent as harmful as smoking, any FDA action to move smokers to e-cigarettes would, to secure maximum public health gains, want to try to minimize the risk of increasing any e-cigarette use that did not completely substitute for smoking or did not accelerate smoking or total cessation—at least to the extent those risks could be minimized without reducing overall net public health gains.

Second, the models reflect the core reality that the *net* public health benefits or harms caused by e-cigarettes will depend not just on the relative harmfulness of e-cigarette use compared to smoking but on the extent that both the health-helping behavior changes outlined above (A. to E.) and the health-hurting behavior changes (a. to e.) occur. And that will, in turn, depend primarily on such factors as the attractiveness and availability of e-cigarettes compared to cigarettes and other smoked tobacco products, which will depend largely on the amount and character of commercial marketing and product development of both e-cigarettes and smoked tobacco products, which will, in turn, be largely a function of what the companies are allowed to do by FDA and applicable laws. In other words, the impact e-cigarettes have on public health will largely depend on what actions FDA decides to take or not take regarding e-cigarettes and smoked tobacco products—which brings us to the key question of this article.

### **SHOULD FDA TRY TO MOVE SMOKERS TO E-CIGARETTES OR OTHER LESS HARMFUL TOBACCO-NICOTINE PRODUCTS?**

FDA is generally allowed to take action relating to nonmedical tobacco-nicotine products if the action they choose to take is “appropriate for the protection of the public health” or will “benefit the health of the population as a whole.”<sup>32</sup> But FDA is

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ONE 1 (2018); Bill Poland & Florian Teischinger, *Population Modeling of Modified Risk Tobacco Products Accounting for Smoking Reduction and Gradual Transitions of Relative Risk*, 19 NICOTINE & TOBACCO RES. 1277 (2017); Peter N. Lee et al., *Estimating the Effect of Differing Assumptions on the Population Health Impact of Introducing a Reduced Risk Tobacco Product in the USA*, 88 REG. TOXICOLOGY & PHARMACOLOGY 192 (2017); Andrew Hill & Oscar M. Camacho, *A System Dynamics Modeling Approach to Assess the Impact of Launching a New Nicotine Product on Population Health Outcomes*, 86 REG. TOXICOLOGY & PHARMACOLOGY 265 (2017); Eric D. Vugrin et al., *Modeling the Potential Effects of New Tobacco Products and Policies: A Dynamic Population Model for Multiple Product Use and Harm*, 10 PLOS ONE (2015). See, also, Stanton A. Glantz, *When assessing models that estimate the effects of e-cigarettes, the devil is in the details*, CTR. FOR TOBACCO CONTROL RES. & EDUC. BLOG (April 26, 2018) <https://tobacco.ucsf.edu/when-assessing-models-estimate-effects-e-cigarettes-devil-details>.

<sup>32</sup> Family Smoking Prevention and Tobacco Control Act (TCA), H.R. 1256, 111th Cong. §§ 906(d); 907(a), (c); 910(c), (d); 911(g) (2009) [21 U.S.C. §§ 387f(d); 387g(a), (c); 387j(c), (d); 387k(g) (2012)]. The TCA also specifically forbids FDA from taking certain actions under its tobacco control authorities, including requiring that tobacco products be sold only by prescription, prohibiting face-to-face sales of tobacco products in any specific category of retail outlets (e.g., no sales in pharmacies), establishing a minimum age of sale of tobacco products older than 18 years of age, banning all cigarettes (or certain

not required by law to initiate any new tobacco control regulations, public education campaigns, or even certain enforcement actions, no matter how “appropriate for the protection of the public health” taking those actions might be. Nor is FDA required, when it takes action, to take those actions that are the most appropriate for the protection of the public health or even to design those actions so that they are the most appropriate for the protection of the public health (unless not doing so would be “arbitrary and capricious” or “abuse its discretion”).<sup>33</sup>

While FDA could decide whether or not to take action to move smokers to e-cigarettes, or how to do so, based solely on health concerns, there are also a range of possible nonhealth reasons that could influence or govern FDA’s decisions, such as legal or political concerns wanting to avoid certain costs to the industry or burdens on FDA or other government entities, or what the White House allows or tells them to do. But, regardless of any nonhealth reasons FDA might consider, before actually taking any action to shift smokers to e-cigarettes FDA must, generally, be able to determine that taking the action is “appropriate for the protection of the public health” (and not be “arbitrary or capricious” or “abuse its discretion” in making that determination).<sup>34</sup> So it is under those standards that this article will explore its core question.

There appear to be two different legally viable “appropriate for the protection of the public health” approaches or strategies—or different ends of a spectrum—that FDA might adopt (or might be reasonably urged to adopt):

A *Pure Public Health Approach* would be the most aggressive “appropriate for the protection of the public health” strategy, whereby FDA would take those actions (within its authorities and constitutional constraints) that would be most likely to prevent and reduce tobacco use harms as quickly and sharply as possible. Implementing such an approach would require quickly implementing strong anti-smoking measures because smoking is by far the most common and harmful form of tobacco use. The major proponents of such an approach are the public health and tobacco control communities, including both e-cigarette harm-reduction enthusiasts and sceptics. The dispute between sceptics and enthusiasts (and variants thereof) is not about whether public health gains should be maximized as quickly as possible, but about how best to do so.

An *Adult Choice and Youth Protection Approach* is at the other end of the spectrum of possible “appropriate for the protection of the public health” strategies, whereby FDA would quickly take those actions that would prevent and reduce youth tobacco use and harms but only when doing so still allows adults to make informed decisions about what legal tobacco products they will or will not choose to use—and with no efforts to make any tobacco products less addictive, attractive, or available to adults, and no efforts to restrict tobacco industry marketing to adults (except to prevent inaccurate or misleading marketing to adults and, where possible, to prevent marketing that reaches and influences youth without interfering with providing product information to adults). The main public proponents of this approach to tobacco control have been the big tobacco companies and other members of the pre-

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other entire types of tobacco products), or requiring the reduction of nicotine yields of a tobacco product to zero. See TCA §§ 906(d)(1), (3); 907(d)(3) [21 U.S.C. §§ 387f(d)(1), (3); 387g(d)(3)].

<sup>33</sup> TCA, *supra* note 33, § 912(b) [21 U.S.C. § 387l(b)], incorporating by reference 5 U.S.C. § 706(2)(A).

<sup>34</sup> *Id.*

e-cigarette tobacco industry, and some organizations and individuals that put a high priority on individual autonomy and personal choice.<sup>35</sup> But some of the e-cigarette-only companies that have entered the tobacco industry, as well as some cigarette-selling companies that also sell e-cigarettes, appear to have moved beyond a pure adult-choice position and are now open to at least some explicit efforts by government to nudge or even actively move smokers away from smoking so long as comparable, less harmful products, such as e-cigarettes, are available to smokers as viable, direct alternatives.<sup>36</sup>

FDA action following either approach, or some midpoint strategy, would likely move some smokers to e-cigarettes as a byproduct, if nothing else. For example, any new FDA rules or other actions implemented to minimize youth tobacco harms under the Pure Public Health Approach or the Adult Choice/Youth Protection Approach, or to minimize overall tobacco use harms under the Pure Public Health Approach by preventing or reducing smoking, would almost certainly promote or prompt some switching to e-cigarettes (or other nonsmoked tobacco products), although not necessarily as the primary desired outcome.

Moreover, inherent in either approach is its requirement or expectation that FDA should also consider taking specific actions expressly for the purpose of moving some smokers or potential smokers to using e-cigarettes, instead, whenever that might be necessary or the best way to secure the approach's specific goals. In particular, under either approach, FDA would take action expressly to move youth smokers or experimenters to using e-cigarettes, instead, only if that were the most effective available way to prevent and reduce overall tobacco-nicotine use harms among youth—with the Adult Choice/Youth Protection Approach also ensuring that

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<sup>35</sup> See, e.g., Jessica Flanigan, *Double Standards and Arguments for Tobacco Regulation*, 42 J. MED. ETHICS 305, 310 (2016); Yvette Van der Eijk, *Ethics of Tobacco Harm Reduction from a Liberal Perspective*, 42 J. MED. ETHICS 273, 274 (2015); J. E. Katz, *Individual Rights Advocacy in Tobacco Control Policies: An Assessment and Recommendation*, 14 TOBACCO CONTROL ii31, ii33, ii36 (2005); B. J. Fox, *Framing Tobacco Control Efforts Within an Ethical Context*, 2 TOBACCO CONTROL SUPPL ii38, ii40 (2005). But see, e.g., Eric N. Lindblom, *Are There Any Ethical Barriers to Effective Antismoking Measures?*, 107 AM. J. PUB. HEALTH 1364, 1364, (2017). On smoker rights groups, see, e.g., Elizabeth A. Smith & Ruth E. Malone, *We Will Speak as the Smoker: The Tobacco Industry's Smokers' Rights Groups*, 17 EUR. J. PUB. HEALTH 306, 309–10 (2007); FORCES INT'L, <http://www.forces.org> [<https://perma.cc/6FFZ-PMNT>]; HAW. SMOKERS ALLIANCE, <http://hawaiiismokersalliance.net> [<https://perma.cc/U27N-NC48>].

<sup>36</sup> See, e.g., Jennifer Maloney, *Altria, Anticipating FDA Rule, Is Developing Reduced-Nicotine Cigarettes*, DOW JONES INST'L NEWS (Nov. 2, 2017); Toni Clarke, *Philip Morris International CEO Cheers U.S. FDA Tobacco Proposal*, REUTERS (Aug. 22, 2017), <https://www.reuters.com/article/us-pmi-ceo-interview/philip-morris-international-ceo-cheers-u-s-fda-tobacco-proposal-idUSKCN1B20A0> [<https://perma.cc/729U-MGPW>]. *Vaping Advocacy*, NJOY (Feb. 5, 2017) <http://njoy.com/vaping-advocacy> [<https://perma.cc/E9UL-Q8EF>]. Some in the tobacco industry likely desire an approach that would make it easier for the industry to maximize profits without regard to public health consequences—such as a pure adult-choice approach without regard for impacts on youth or something even more permissive. But such an approach could neither be “appropriate for the protection of the public health” nor otherwise comply with the Tobacco Control Act or be consistent with its goals. Besides the fact that any such approach would likely sharply increase existing tobacco use harms among both adults and youth, the Tobacco Control Act specifically prohibits any advertising, promotion, and labeling that is false or misleading. TCA, *supra* note 33, § 903(a)(1), (7) [21 U.S.C. § 387c(a)(1), (7)]. And any industry action to increase tobacco-nicotine use among youth would contradict the youth-protection goals of the Act, TCA § 3(2) [21 U.S.C. § 387 (note), Purpose (2)], and would encourage violations of the federal prohibition against tobacco product sales to those under 18 (as well as violate virtually any defensible ethical standards for corporate or business conduct).

adult consumer choice would not be excessively hampered. Under the Pure Public Health Approach, actions expressly to move adult smokers to using e-cigarettes would be taken only if they were the most effective, politically viable way available to prevent and reduce overall tobacco-nicotine use harms among adults and secure overall reductions in tobacco use harms. But under the Adult Choice/Youth Protection Approach, no action to reduce tobacco harms would be taken that would force smokers to stop smoking or to move to e-cigarettes (unless it could be justified from a youth-protection perspective). Instead, FDA actions would consist only of working to ensure that smokers were able to make fully informed decisions about continuing to smoke or trying to switch or quit; were not manipulated by tobacco industry labeling, advertising, or other action to keep smoking instead of trying to quit or switch; and had access to information and assistance to help them switch or quit if they chose to try to do so. But those actions, while respecting adult choice, could still promote considerable amounts of switching to e-cigarettes.

### **WHAT COULD FDA DO TO MOVE SMOKERS TO E-CIGARETTES?**

E-cigarettes are already subject to a number of requirements and restrictions under federal law and FDA regulations. Most notably, manufacturers of e-cigarettes sold in the U.S. market must register and make various reports to FDA; e-cigarettes may not be sold to persons under the age of 18; free samples are prohibited; liquid nicotine must be in child-proof packaging; packages must have nicotine-addiction warning label by August 2018; e-cigarettes currently on the U.S. market (as of August 8th, 2016) must submit an application to obtain an FDA new product or substantial equivalence order by August 2022 to stay on market; any brand-new e-cigarettes (or existing e-cigarettes that are significantly changed) must obtain a new product order before entering the U.S. market; and manufacturers may not make reduced-risk claims about their e-cigarettes without first obtaining a permissive Modified Risk Tobacco Product (MRTP) order from FDA.<sup>37</sup>

Building on that base, FDA has numerous possible tools, well beyond just issuing new regulations, that it could legally employ pursuant to its Tobacco Control Act (TCA) authorities for moving smokers to using e-cigarettes, if it reasonably determined that doing so would be “appropriate for the protection of the public health.” For example, FDA could:

- Include relative-risk information or encouragement for smokers to switch in FDA public statements, website pages, reports, documents, press releases, and other communications to the public or to smokers.

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<sup>37</sup> See, e.g., Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products (Deeming Rule), 81 Fed. Reg. (2016) [21 C.F.R. §§ 1100, 1140, 1143]; FOOD & DRUG ADMIN., GUIDANCE: EXTENSION OF CERTAIN TOBACCO PRODUCT COMPLIANCE DEADLINES RELATED TO THE FINAL DEEMING RULE (REVISED) (2017); Child Nicotine Poisoning Prevention Act of 2015, S. 142, 114th Cong. (2016), 15 U.S.C. § 1472a. *But see* Press Release, Campaign for Tobacco-Free Kids, Health Groups File Suit to Expedite FDA Review of E-Cigarettes, Cigars (Mar. 27, 2018). Some states and localities have established minimum age laws for purchasing tobacco products, including e-cigarettes, that are higher than the federal minimum age of eighteen. FDA has no authority to raise the federal minimum age, which can only be increased by Congress.

- Engage in public education campaigns to provide relative-risk information to smokers and otherwise encourage smokers to switch to e-cigarettes.<sup>38</sup>
- Engage in public education campaigns to instruct smokers on how e-cigarettes can be used most effectively as a smoking-cessation or total-cessation tool.
- Engage in public education campaigns that not only discourage smoking and experimentation with smoking among youth but also include specific content and special targeting directed at moving youth who would otherwise experiment with smoking to experiment with e-cigarettes, instead.
- Issue new rules to inform smokers about relative risks or the potential benefits from complete switching through requiring warning labels or inserts/onserts for cigarettes and other smoked tobacco products and/or for e-cigarettes.<sup>39</sup>
- Issue new rules to make cigarettes and other smoked tobacco products less addictive, attractive, or available.<sup>40</sup>
- Issue new rules to make e-cigarettes more attractive and available to smokers.<sup>41</sup>
- Not issue any new rules that place new restrictions or requirements on e-cigarettes or their advertising or other marketing which are as or more strict, costly, or burdensome as the parallel restrictions or requirements placed on cigarettes or other smoked products.
- Provide expedited new product order pathways to make it more quick and easy for new types or brands of e-cigarettes that would likely increase smoker moves to e-cigarettes to get the permissive FDA orders they need to be allowed on the U.S. market.<sup>42</sup>

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<sup>38</sup> For examples of the kinds of public education campaigns FDA's Center for Tobacco Products has initiated, targeting specific subpopulations, see FOOD & DRUG ADMIN., *Tobacco Products, Public Education Campaigns*, [www.fda.gov/tobaccoproducts/publichealtheducation/publiceducationcampaigns](http://www.fda.gov/tobaccoproducts/publichealtheducation/publiceducationcampaigns), [https://perma.cc/5D3M-QULC].

<sup>39</sup> See, e.g., Eric N. Lindblom et al., *FDA-Required Tobacco Product Inserts & Onserts – and the First Amendment*, 72 FOOD & DRUG L.J. 1, 2, 4, 6, 9 (2017); Burcu Mucan & Crawford Moodie, *Young Adult Smokers' Perceptions of Plain Packs, Numbered Packs and Pack Inserts in Turkey: A Focus Group Study*, TOBACCO CONTROL 1, 1, 2, 5 (2017).

<sup>40</sup> See generally CAMPAIGN FOR TOBACCO-FREE KIDS, DESIGNED FOR ADDICTION: HOW THE TOBACCO INDUSTRY HAS MADE CIGARETTES MORE ADDICTIVE, MORE ATTRACTIVE TO KIDS AND EVEN MORE DEADLY (2014), [https://www.tobaccofreekids.org/assets/content/what\\_we\\_do/industry\\_watch/product\\_manipulation/2014\\_06\\_19\\_DesignedforAddiction\\_web.pdf](https://www.tobaccofreekids.org/assets/content/what_we_do/industry_watch/product_manipulation/2014_06_19_DesignedforAddiction_web.pdf) [https://perma.cc/4EK9-YSTR].

<sup>41</sup> See, e.g., Terry F. Pechacek et al., *The Potential That Electronic Nicotine Delivery Systems Can Be a Disruptive Technology: Results From a National Survey*, 18 NICOTINE & TOBACCO RES. 1989, 1994–1995 (Oct. 2016) (concluding that e-cigarettes must become more attractive to smokers, or cigarettes made less attractive, for e-cigarettes to realize their potential as a disruptive technology that replaces conventional cigarettes). But see Theodore L. Wagener et al., *Have Combustible Cigarettes Met Their Match? The Nicotine Delivery Profiles and Harmful Constituent Exposures of Second-Generation and Third-Generation Electronic Cigarette Users*, 26 TOBACCO CONTROL, e26, e26, e27 (2017) (discussing the industry developing e-cigarettes that deliver nicotine even more like cigarettes, making them more attractive as substitutes).

<sup>42</sup> TCA, *supra* note 33, § 910 [21 U.S.C. § 387j].

- Provide an expedited pathway to enable e-cigarette manufacturers to get FDA Modified Risk Tobacco Product orders more quickly and easily so that they can advertise their e-cigarettes to smokers with reduced-risk claims.<sup>43</sup>
- Exercise its enforcement discretion to make cigarettes and other smoked tobacco products less attractive and available to smokers and to make e-cigarettes more attractive and available.<sup>44</sup> That could be done, for example, by FDA putting a top priority on enforcing existing TCA provisions and related rules against cigarettes and other smoked tobacco products and/or postponing or forgoing enforcement of the TCA and related rules against e-cigarettes and their manufacturers and sellers.<sup>45</sup>
- Support increases in federal, state, and local government tax rates and minimum prices for cigarettes and smoked tobacco products and encourage other government tax and price policies that will help to make e-cigarettes more economically attractive to smokers.<sup>46</sup>

### WHAT SHOULD FDA DO TO MOVE SMOKERS TO E-CIGARETTES?

As noted above, in most cases, FDA could not take any of these actions to move smokers to using e-cigarettes unless it first determined that doing so is “appropriate for the protection of the public health.” Moreover, within that context, FDA might reasonably follow either the Pure Public Health Approach or the Adult Choice/Youth Protection Approach, or something in between, to decide which actions to take (although the former approach would be the best for protecting and improving the public health). Moreover, when FDA decides what action to take or how to structure a chosen action but does not have sufficient real-world experience or related research

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<sup>43</sup> TCA, *supra* note 33, § 911 [21 U.S.C. § 387k]. See, e.g., Eric N. Lindblom, *Effectively Regulating E-Cigarettes and Their Advertising—and the First Amendment*, 70 FOOD & DRUG L. J. 57, 58, 68, 93 (2015).

<sup>44</sup> On enforcement discretion in general, see, e.g., *Heckler v. Chaney*, 470 U.S. 821, 831 (1985) (declining to review FDA’s decision not to take enforcement action, stating that it has “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”); see also Clifford Rechtschaffen, *Promoting Pragmatic Risk Regulation: Is Enforcement Discretion the Answer?*, 52 UNIV. KAN. L. REV. 1327, 1334, 1336 (2004). On enforcement discretion by FDA in the context of e-cigarettes, see Lindblom, *supra* note 44, at 72–74. FDA exercised its enforcement discretion to a considerable extent in its tobacco control deeming rule and its subsequent guidance extending the deadlines for e-cigarettes to meet various statutory deadlines that FDA had set in the deeming rule through its enforcement discretion. *Supra*, note 38.

<sup>45</sup> A current example is FDA choosing not to enforce against any e-cigarettes that are currently on the U.S. market illegally because they do not have a permissive FDA new product or substantial equivalence order if they were legally on the U.S. market at the time the FDA deeming rule went into effect (Aug. 8, 2016), and allowing all such e-cigarettes to stay on the U.S. market without being enforced against so long as they submit an application for a permissive order before August 8, 2022. FOOD & DRUG ADMIN., GUIDANCE: EXTENSION OF CERTAIN TOBACCO PRODUCT COMPLIANCE DEADLINES RELATED TO THE FINAL DEEMING RULE (REVISED) (2017).

<sup>46</sup> FDA cannot set any tax rates, itself, but could support cigarette and other tobacco tax or price increases through public statements of various kinds. In addition, FDA could support higher prices for cigarettes and other smoked tobacco products by prohibiting certain forms of discounting and price discounts, such as coupons or buy-two-get-one-free deals.



to project related public health impacts accurately, it might also follow some versions of the medical maxim to “do no harm” (e.g., do not do anything to make matters worse) or the precautionary principle, which basically says that when an activity (e.g., an FDA tobacco control intervention) raises threats of harm to human health, precautionary measures should be taken even if there is no scientific certainty that the harms will occur.<sup>47</sup>

Accordingly, this article will look at those major options FDA could take—within its statutory authorities and applicable constitutional constraints and based on currently available research and other evidence—to move smokers to e-cigarettes that would best promote the goals of either the Pure Public Health Approach or the Adult Choice/Youth Protection Approach, respectively. It will also consider how those actions might be structured and implemented to work most effectively to promote the different goals of those two approaches, while also avoiding, to the extent possible, the risk of creating any offsetting or significant brand-new harms to innocents (i.e., those who would not have been harmed but for the FDA action).

For the Pure Public Health Approach, that means selecting and designing the options to produce the largest net reductions in tobacco use harms through prompting total quitting; prompting switching to e-cigarettes (or other less-harmful tobacco and/or nicotine products) among those smokers who will not quit all use; and, to the extent possible, reducing any related risks of promoting any of the health-harming behavior changes, at least so long as that can be done without significantly reducing overall net reductions in tobacco-nicotine harms.<sup>48</sup> For the Adult Choice/Youth Protection Approach, it means selecting and designing the options to work as effectively as possible to prevent and reduce youth tobacco use harms without preventing adults from obtaining product information from manufacturers and choosing to use whatever currently available tobacco products they want.

Fortunately, there are powerful options available to FDA that would secure substantial public health gains from moving many smokers to e-cigarettes (or to quit all tobacco-nicotine use) without creating any risk of prompting any significant amount of the harm-increasing behavior changes. But some of these measures could be seen as interfering with an approach that gave special deference to protecting adult choice. However, other strong options that are fully consistent with adult choice are also available. Although some of the available options could create some significant risks of increasing health-harming e-cigarette use, there are ways to structure many of those options to reduce those risks without significantly reducing

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<sup>47</sup> On “do not harm,” see, e.g., Daniel Sokol, *First, Do No Harm Revisited*, 347 *BMJ* F6426 (2013). On “do not harm” in the regulatory context, see generally Edward Warren & Gary E. Marchant, *More Good Than Harm: A First Principle for Environmental Agencies and Reviewing Courts*, 20 *ECOLOGY L.Q.* 379, 379–440 (1993). On the precautionary principle, see, e.g., Ashley M. Bush et al., *Employing the Precautionary Principle to Evaluate the Use of E-Cigarettes*, 4 *FRONTIERS IN PUB. HEALTH* 1, 1, 3, 4 (2016); Marco Martuzzi, *The Precautionary Principle: In Action for Public Health*, 64 *OCCUPATIONAL & ENVTL. MED.* 569, 569 (2007); Bernard D. Goldstein, *Problems in Applying the Precautionary Principle to Public Health*, 64 *OCCUPATIONAL & ENVTL. MED.* 571, 571 (2007); David Kriebel, *The Reactionary Principle: Inaction for Public Health*, 64 *OCCUPATIONAL & ENVTL. MED.* 573, 573 (2007); and L. Rushton, *The Precautionary Principle in the Context of Multiple Risks*, 64 *OCCUPATIONAL & ENVTL. MED.* 574, 574 (2007); see generally; Daniela Saitta et al., *A Risk Assessment Matrix for Public Health Principles: The Case for E-Cigarettes*, 14 *INT’L J. ENVTL. RES. & PUB. HEALTH* 1, 2, 15, 16 (2017).

<sup>48</sup> Saitta, *supra* note 48, at 8–10, 13, 16.

their power to promote the various health-improving behavior changes and without significantly shrinking their positive net impacts on the public health.

The following possibilities for FDA action are among those most frequently discussed or recommended by either the tobacco control and public health communities or the tobacco industry, including independent e-cigarette manufacturers, that appear best able to secure the largest public health gains or the largest shifts from smoking to e-cigarette use, work consistently with the specific goals of either the Pure Public Health Approach or the Adult Choice/Youth Protection Approach, or both, and avoid any significant First Amendment concerns by not seriously impeding the ability of tobacco or e-cigarette companies to communicate with their legal customers.<sup>49</sup>

### *Best Options for Switching Smokers to E-Cigarettes Under the Pure Public Health Approach*

The following two FDA actions would prompt large numbers of smokers to quit all tobacco-nicotine use or replace all or much of their smoking with e-cigarette use, and prompt large numbers of youth either to not initiate into any regular tobacco-nicotine use or to initiate into e-cigarette use instead of smoking—with no significant risk of increasing any of the health-harming behavior changes.

#### *Minimizing Nicotine Levels in Cigarettes and Similarly Smoked Tobacco Products.*

By setting and enforcing maximum nicotine levels for cigarettes (and similarly smoked tobacco products, including tobacco that could be used for roll-your-own) at the trivial minimum levels already achievable using readily available technologies and procedures, FDA could ensure that cigarettes would no longer be able to initiate nicotine addiction among new experimenters or users or to sustain or feed smokers' existing nicotine addictions (no matter how much or how intensely they smoked).<sup>50</sup> For example, published studies have found that lower-nicotine cigarettes with the currently lowest nicotine levels and yields (e.g., 0.4 mg nicotine per gram or 0.6 mg per cigarette, or with test-measured smoking yields of 0.05 mg of nicotine per

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<sup>49</sup> See, e.g., *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 564, 565, 571 (2001).

<sup>50</sup> FDA has clear authority to reduce nicotine levels in all cigarettes and/or other tobacco products so long as they do not require the cigarettes or other tobacco products to have a nicotine yield of zero. TCA, *supra* note 33, § 907(a)(3), (d)(3)(B) [21 U.S.C. § 387g(a)(3), (d)(3)(B)]. For more on the nuts and bolts of establishing a law or rule to minimize nicotine levels, and the supporting research, see Eric N. Lindblom, *Filling in the Blanks on Reducing Tobacco Product Addictiveness in the FCTC Partial Guidelines for Articles 9 & 10* (O'Neill Institute for National & Global Health Law, Working Paper No. 1, 2014), at 2, 3, 5, [http://www.law.georgetown.edu/oneillinstitute/resources/documents/O'Neill\\_Institute\\_Working\\_Paper\\_Article\\_9\\_and\\_10\\_Guidelines\\_V2.pdf](http://www.law.georgetown.edu/oneillinstitute/resources/documents/O'Neill_Institute_Working_Paper_Article_9_and_10_Guidelines_V2.pdf) [<https://perma.cc/YB47-EFA9>]. For subsequent related research, see, e.g., Tracy T. Smith et al., *Impact of Smoking Reduced Nicotine Content Cigarettes on Sensitivity to Cigarette Price: Further Results From a Multi-Site Clinical Trial*, 112 *ADDICTION* 349, 350, 355 (2017); Dorothy Hatsukami et al., *Reduced Nicotine Content Cigarettes and Use of Alternative Nicotine Products: Exploratory Trial*, 112 *ADDICTION* 156, 157–62 (2017); Eric Donny et al., *Randomized Trial of Reduced-Nicotine Standards for Cigarettes*, 373 *NEW ENGLAND J. MED.* 1340, 1340–41 (2015); Natalie Walker et al., *Abrupt Nicotine Reduction as an Endgame Policy: A Randomised Trial*, 24 *TOBACCO CONTROL* e251, e251, e256 (2015); see also, Tracy T. Smith et al., *Whether to push or pull? Nicotine reduction and non-combusted alternatives - Two strategies for reducing smoking and improving public health*, *PREVENTIVE MEDICINE* (Mar. 29, 2018). <https://www.sciencedirect.com/science/article/pii/S0091743518301105>.

cigarette) do not prompt smoker compensation, as do low-nicotine cigarettes with higher levels, and produce more promising results in regard to promoting smoking cessation.<sup>51</sup> Capping nicotine levels at such low levels would prevent new initiation into nicotine addiction by youth (and adults) experimenting with smoking and would prompt many adult and youth smokers either to quit completely or to secure the nicotine they crave from e-cigarettes (or possibly other nicotine-delivery products).<sup>52</sup>

At the same time, minimizing nicotine in smoked tobacco products to levels that could not create or sustain nicotine addiction would not create any risk of increasing or encouraging any of the harm-increasing uses of e-cigarettes, such as dampening smoking cessation or increasing new initiation into e-cigarette use by otherwise nonusers, and it would eliminate the risk of nicotine-addicted e-cigarette use leading to nicotine-addicted smoking.

In July 2017, FDA Commissioner Scott Gottlieb announced that FDA is actively considering reducing nicotine levels in cigarettes as part of a broader relative-risk approach to FDA's tobacco control activities, and he authored a related article in the *New England Journal of Medicine* with FDA Center for Tobacco-Products Director Mitch Zeller.<sup>53</sup> On March 16, 2018, FDA issued a related Advanced Notice of Proposed Rulemaking.<sup>54</sup> However, FDA has issued ANPRMs relating to other substantive tobacco control regulatory actions before and never taken any further public action.<sup>55</sup>

Arguments against minimizing nicotine levels in cigarettes often parallel earlier arguments made against banning them, including claims that doing so would prompt the emergence of a large, new illicit market in full-nicotine cigarettes or overwhelm existing cessation-assistance resources by addicted smokers desperate to get the

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<sup>51</sup> See, e.g., Sarah S. Dermody et al., *Greater Reductions in Nicotine Exposure While Smoking Very Low Nicotine Content Cigarettes Predict Smoking Cessation*, 24 TOBACCO CONTROL 536, 537–38 (2015); Dorothy K. Hatsukami et al., *Reduced Nicotine Content Cigarettes: Effects on Toxicant Exposure, Dependence and Cessation*, 105 ADDICTION 343, 343, 344, 348, 352 (2010); David Hammond & Richard J. O'Conner, *Reduced Nicotine Cigarettes: Smoking Behavior and Biomarkers of Exposure Among Smokers Not Intending to Quit*, 23 CANCER EPIDEMIOLOGY, BIOMARKERS & PREVENTION 2032, 2033 (2014); see also Kenneth A. Perkins et al., *Threshold Dose for Behavioral Discrimination of Cigarette Nicotine Content in Menthol vs. Non-menthol Smokers*, 234 PSYCHOPHARMACOLOGY 1255, 1255, 1261, 1262, 1263 (2017). It is worth noting that the very-low-nicotine cigarettes produced these beneficial results regarding cessation in existing environments where full-nicotine cigarettes remained readily available, and other smokers, possibly including friends or family members of the study participants, were still smoking those full-nicotine cigarettes, making relapse to smoking full-nicotine cigarettes much easier and more likely than it would be if a new nicotine-limit for all cigarettes were implemented.

<sup>52</sup> See generally Benjamin J. Apelberg et al., *Potential Public Health Effects of Reducing Nicotine Levels in Cigarettes in the United States*, 2018 NEW ENGLAND J. MED.

<sup>53</sup> Press Release, Food & Drug Admin., FDA Announces Comprehensive Regulatory Plan to Shift Trajectory of Tobacco-Related Disease, Death: Agency to Pursue Lowering Nicotine in Cigarettes to Non-addictive Levels and Create More Predictability in Tobacco Regulation (July 28, 2017) <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm568923.htm> [<https://perma.cc/HC29-QUVA>]; Scott Gottlieb & Mitchell Zeller, *A Nicotine-Focused Framework for Public Health*, 377 NEW ENGLAND J. MED. 1111, 1112, 1113 (2017); see Clarke, *supra* note 37.

<sup>54</sup> Tobacco Product Standard for Nicotine Level of Combusted Cigarettes, 83 Fed. Reg. 11,818 (proposed Mar. 16, 2018).

<sup>55</sup> See generally FOOD & DRUG ADMIN., *Tobacco Products: Rules and Regulations*, <http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm283974.htm> [<https://perma.cc/K6AG-W6NS>].

nicotine they craved.<sup>56</sup> While these arguments already had serious problems previously,<sup>57</sup> the ready availability of legal e-cigarettes (which allow users to inhale nicotine into the lungs just like cigarettes) provide an attractive alternative for smokers compared to illicit, less conveniently available full-nicotine cigarettes, and offer an appealing source of relief for any smokers unable to obtain conventional cessation assistance.<sup>58</sup>

If a nicotine-minimization rule applied only to cigarettes, many cigarette smokers would switch to other full-nicotine smokable tobacco products, instead of quitting all use or moving to e-cigarettes, and secure no harm reductions. To avoid such substitution, any such FDA rule would need to apply to any other smoked tobacco products, including tobacco useable for roll-your-own, that could be smoked like a cigarette (probably all smoked tobacco products except, perhaps, for large, premium cigars or bona fide pipe tobacco that cannot be actively inhaled when smoked). To make the rule work most effectively, a nicotine-minimization requirement would also need to go into effect immediately, rather than be phased in through a step-by-step reduction in nicotine levels. Otherwise, many smokers could still get the nicotine they craved by smoking more cigarettes or smoking more intensely until the phase-in brought the nicotine down to un-actionable levels. Even with an immediate reduction to minimal levels, it is possible that some smokers might try to continue smoking while also using e-cigarettes or other nicotine sources to obtain the nicotine they could no longer get from smoking; but the increased costs and inconvenience of such an overlapping-use response make it unlikely to have any staying power.

Although minimizing nicotine levels in cigarettes and similarly smoked tobacco products would take full-nicotine versions off the legal market in the United States, thereby reducing adult choice, it would still leave adults with directly parallel legal choices in the form of e-cigarettes that could provide all the nicotine adult smokers

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<sup>56</sup> See, e.g., H.R. REP. NO. 111-58, pt. 1, at 38 (2009), <https://www.congress.gov/congressional-report/111th-congress/house-report/58/1> [<https://perma.cc/5EQ4-TLMA>] (“The Committee notes that prohibition of a product that is used regularly by a large number of heavily addicted adult users would pose different questions of public health . . . For example, the health care system might not be capable of handling the sudden increased demand for cessation assistance in the case of a more broadly used product, leaving millions of smokers without medical support. In addition, the sudden removal of a legal source for such a product without the type of consideration and review that FDA will be able to conduct might unnecessarily increase the illegal black market risk, which could also pose a health hazard to users.”).

<sup>57</sup> Neither of these problems could arise unless the nicotine-minimization rule prompted enormous numbers of smokers to abandon the legal minimal-nicotine cigarettes (which would be terrific for improving the public health). Moreover, black market full-nicotine cigarettes would not likely be available quickly enough or in sufficient amounts in enough conveniently accessible sales outlets throughout the country to serve as ready alternatives for smokers no longer able to get the nicotine they craved from legal cigarettes. Establishing and maintaining such a network of illicit supply, distribution, and sales would be enormously more complicated and difficult than the existing illicit market for tax-evading cigarettes (which readily obtains contraband cigarettes from nearby low-tax states or Tribal lands and relies largely on otherwise legal retailers for sales outlets). See, e.g., Lindblom, *supra* note 51, at 2, 10–11; Christopher Griffiths, *Illicit Trade in Tobacco Products after Implementation of an FDA Product Standard*, FOOD & DRUG ADMIN., (Mar. 15, 2018), <https://www.fda.gov/downloads/TobaccoProducts/NewsEvents/UCM601047.pdf> [<https://perma.cc/5EQ4-TLMA>]. Accordingly, moving to illicit full-nicotine cigarettes would not be a ready option for the vast majority of smokers when a nicotine-minimization rule went into effect. In addition, while it would be best to provide effective cessation assistance to any smokers who wanted it when a nicotine-minimizing rule went into effect, any who could not access formal cessation assistance because of excessive demand would simply have to quit on their own (as many smokers have done in the past) or switch to legally available tobacco-nicotine products to continue feeding their addiction.

<sup>58</sup> See, e.g., Lindblom, *supra* note 51, at 13-14; see also Griffiths, *supra* note 58.

want because of their addiction and deliver it in much the same way (through inhalation). Some still might see the minimizing nicotine proposal as inconsistent with the adult-choice side of the Adult Choice/Youth Protection Approach. But it could nevertheless be seen as consistent with the overall approach given the relatively minor adult-choice restrictions compared to the enormous new youth protections from preventing their becoming chemically addicted to cigarettes or other smoked tobacco products. Moreover, the FDA plan to reduce nicotine levels in cigarettes has been surprisingly well received by the major tobacco companies that sell cigarettes in their public statements, at least if it is part of a broader relative-risk regulatory approach.<sup>59</sup>

*Banning Menthol and Other Added Flavors in Cigarettes and  
Similarly Smoked Tobacco Products.*

Making cigarettes and other smoked tobacco products less attractive to many smokers and experimenting youth by banning menthol in cigarettes (the only characterizing flavor other than tobacco allowed for cigarettes),<sup>60</sup> while also banning all flavors other than tobacco in all tobacco products that can be smoked like cigarettes, might not be necessary if the nicotine levels in all cigarettes and similarly smoked tobacco products were already minimized. Done on its own, banning the flavors would not be as effective as nicotine minimization, because it would reach only about half of all cigarettes and similarly smoked tobacco products. Flavored brands now account for somewhat more than half of the cigar market; but there are fewer cigar smokers than cigarette smokers and only a bit more than one-fourth of all cigarettes consumed in the United States are menthol.<sup>61</sup> Unlike with a nicotine minimization rule, after menthol and other flavors were banned in combustible tobacco products smokers could still respond by moving to a full-nicotine cigarette or similarly smoked tobacco product (albeit one with no added menthol or other flavors).

Nevertheless, a menthol and flavor ban for cigarettes and other smoked tobacco products could, by itself, still produce large public health gains by prompting a substantial number of those currently smoking the flavored versions to quit all use or

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<sup>59</sup> See, e.g., Maloney, *supra* note 37; Clarke, *supra* note 37; Angelica Lavito, *The Tobacco Industry Says It's Ready to Reduce Harm*, CNBC (Sept. 13, 2017), <https://www.cnbc.com/2017/09/13/tobacco-industry-to-innovate-cigarettes-fda-regulator-still-skeptical.html> [<http://perma.cc/3CSZ-ZZ3B>] (reporting on Reynolds American CEO's response to FDA nicotine reduction proposal). Any industry concerns could be further reduced by ensuring that the rule provided adequate time for the cigarette companies to re-tool to produce the minimum nicotine cigarettes and allowed them to sell off their inventories of already manufactured full-nicotine cigarettes (with provisions to stop pre-effective date stockpiling)—e.g., by prohibiting the manufacture of non-nicotine-maximizing smoked products as of 180 days after the rule is in place and prohibiting their sale starting 60 days later. If nicotine levels were minimized, cigarette companies could not replace nicotine with some other addictive substance because any such changes would be prohibited absent a permissive new-changed product order from FDA, which would have to find that adding in the new addictive substance was appropriate for the protection of the public health.

<sup>60</sup> TCA, *supra* note 33, § 907(a)(1)(A) [21 U.S.C. § 387g(a)(1)(A)].

<sup>61</sup> See generally Cristine Delnevo et al., *Changes in the Mass-Merchandise Cigar Market Since the Tobacco Control Act*, 26 TOBACCO CONTROL 349 (2017); FED. TRADE COMM'N, FED. TRADE COMM'N CIGARETTE REPORT FOR 2015 9, 7B (2017), [https://www.ftc.gov/system/files/documents/reports/federal-trade-commission-cigarette-report-2015-federal-trade-commission-smokeless-tobacco-report/2015\\_cigarette\\_report.pdf](https://www.ftc.gov/system/files/documents/reports/federal-trade-commission-cigarette-report-2015-federal-trade-commission-smokeless-tobacco-report/2015_cigarette_report.pdf) [<https://perma.cc/6LLK-5VBN>].

shift to menthol or flavored e-cigarettes;<sup>62</sup> and by preventing some youth from initiating into any nicotine-tobacco use at all or to initiate into flavored e-cigarette use, instead.<sup>63</sup> Available research indicates, for example, that menthol in cigarettes is associated with greater addiction and less cessation success, and with increases in smoking initiation by youth and young adults.<sup>64</sup> In addition, more than half of youth first try a menthol cigarette.<sup>65</sup> Adding to its benefits, banning menthol and other flavors would not promote any of the health-harming behavior changes because it would do nothing to discourage smoking cessation and would not make e-cigarettes more attractive to anyone other than current smokers of flavored tobacco products.

Although eliminating menthol cigarettes and other flavored smoked tobacco products as legal commercial products could be seen as inconsistent from a pure adult-choice perspective, the choices available to adults would be less restricted than under a nicotine-minimization rule. Adult smokers could still choose to buy legal nonflavored cigarettes and other nonflavored smoked tobacco products if they wanted to continue inhaling nicotine through smoking, and they could legally buy menthol and other flavored e-cigarettes if they wanted to continue inhaling nicotine with those flavors. But the offsetting increased protections for youth would be less, as well, given that they could still readily get addicted to smoking through legally available products (even if the lack of flavors and menthol might reduce the numbers that experiment or the number who move on from experimenting to regular, addicted use). Accordingly, banning menthol and other flavors from cigarettes and similarly smoked tobacco products likely ranks as less attractive than minimizing nicotine levels under both the Pure Public Health Approach and the Adult Choice/Youth Protection Approach.

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<sup>62</sup> See generally Michael Chaiton et al., *Association of Ontario's Ban on Menthol Cigarettes With Smoking Behavior 1 Month After Implementation*, JAMA INT. MED. (Mar. 5, 2018); John Buckell et al., *Should Flavors be Banned in E-cigarettes? Evidence on Adult Smokers and Recent Quitters from a Discrete Choice Experiment*, (Nat'l Bureau of Econ. Res. Working Paper No. 23865 Sept. 2017), <http://www.nber.org/papers/w23865> [<https://perma.cc/D7WP-2ZXA>].

<sup>63</sup> See generally James Nonnemaker et al., *Initiation with menthol cigarettes and youth smoking uptake*, 108 ADDICTION 171 (Jan. 2013).

<sup>64</sup> See, e.g., FOOD & DRUG ADMIN., PRELIMINARY SCIENTIFIC EVALUATION OF THE POSSIBLE PUBLIC HEALTH EFFECTS OF MENTHOL VERSUS NONMENTHOL CIGARETTES (2013), <https://www.fda.gov/downloads/ucm361598.pdf> [<https://perma.cc/D23N-SNEH>]; FOOD & DRUG ADMIN., REFERENCE ADDENDUM: FDA'S PRELIMINARY SCIENTIFIC EVALUATION OF THE POSSIBLE PUBLIC HEALTH EFFECTS OF MENTHOL VERSUS NONMENTHOL CIGARETTES (2013), <https://www.fda.gov/downloads/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments/UCM362600.pdf> [<https://perma.cc/6CBA-R792>]; FOOD & DRUG ADMIN. TOBACCO PRODS. SCI. ADVISORY COMM., MENTHOL CIGARETTES AND THE PUBLIC HEALTH: REVIEW OF THE SCIENTIFIC EVIDENCE AND RECOMMENDATIONS—FINAL (2011), <https://wayback.archive-it.org/7993/20170405201731/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM269697.pdf> [<https://perma.cc/PDV2-V77M>]. For more recent research, see generally Matthew F. Thompson et al., *Menthol Enhances Nicotine-Induced Locomotor Sensitization and In Vivo Functional Connectivity in Adolescence*, J. PSYCHOPHARMACOLOGY (2017); RJ Wickham, *How Menthol Alters Tobacco-Smoking Behavior: A Biological Perspective*, 88 YALE J. BIOLOGY & MED. 279 (2015). See generally WORLD HEALTH ORG., ADVISORY NOTE: BANNING MENTHOL IN TOBACCO PRODUCTS (2016).

<sup>65</sup> See, e.g., Joanne D'Silva et al., *Differences in Subjective Experiences to First Use of Menthol and Non-Menthol Cigarettes in a National Sample of Young Adult Cigarette Smokers*, NICOTINE & TOBACCO RES. 1, 3 (Aug. 2017).

Then again, if the nicotine minimization rule were implemented, also eliminating menthol and other flavors from cigarettes and similarly smoked tobacco products would likely do little to increase overall public health gains. If cigarettes and other similarly smoked tobacco products did not have actionable levels of nicotine, youth and others who experimented with smoking them because of the flavors would not become nicotine addicted. Similarly, any nicotine-addicted youth or adult smokers who tried to continue smoking because of the menthol or other flavors in their smoked tobacco products with newly minimized nicotine levels would likely quickly abandon them when their addictive cravings were not satisfied. Those smokers who continued, despite the new minimal nicotine levels, would have their nicotine addiction weakened or eliminated over time, and would also likely quit, given that the vast majority of smokers wish they had never started and would like to stop.<sup>66</sup>

*Best Options for Switching Smokers to E-Cigarettes from a Pure Adult-Choice Perspective*

The following three proposals for FDA action would do nothing to force adults to change their behavior or limit their choices. They would encourage complete switching from smoking to e-cigarette use by providing adult smokers with more product choices, more information about the choices available to them, and, in particular, more information about the benefits from totally switching, and more encouragement to do so. If done carelessly, however, such efforts could also promote e-cigarette use among nonsmokers and non-users, or enable the tobacco companies to do so, which could increase initiation into e-cigarette use among youth and adults who would otherwise not use any tobacco or nicotine product, increase relapse into e-cigarette use by former smokers and former e-cigarette users who would not otherwise relapse into any tobacco-nicotine use, and promote the other previously described harm-increasing behavior changes. The following proposals have been carefully designed to minimize those risks to the extent possible without significantly reducing the proposals' ability to shift smokers to e-cigarettes constructively.

*PMTA Fast-Track to Make It Quicker and Easier for  
Manufacturers of Certain E-Cigarettes to Obtain the FDA New  
Product Orders They Need to Allow the E-Cigarettes onto the  
U.S. Market.*

Under the TCA, any new or significantly changed e-cigarette (or other tobacco product) cannot be sold legally in the U.S. market unless its manufacturer or importer first submits a Premarket Tobacco Application (PMTA) and obtains a permissive new product order from FDA finding that it would be "appropriate for the protection of the public health" to allow the product to be marketed and sold.<sup>67</sup> This requirement prevents new or changed products that would increase overall health

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<sup>66</sup> See, e.g., Stephen Babb et al., *Quitting Smoking Among Adults—United States, 2000–2015*, 52 MORBIDITY & MORTALITY WKLY REP. 1457, 1457 (Jan. 6, 2017).

<sup>67</sup> TCA, *supra* note 33, § 910, 910(c)(2)(A) [21 U.S.C. § 387j; 387j(c)(2)(A)]. There is also an entirely separate pathway for staying on the market or being allowed to enter the market that requires showing that the product is "substantially equivalent" to a tobacco product already legally on the market on February 15, 2007 (i.e., not a new or substantially changed product compared to the predicate). TCA §§ 905(j), 910(a)(2) [21 U.S.C. §§ 387e(j), 387j(a)(2)]. But this pathway might not be readily available to e-cigarettes because of a lack of February 15, 2007 predicate e-cigarettes.

harms or produce no net health benefits from getting on the U.S. market. But it can also operate as a disincentive to constructive product innovation and impede or delay the market entry of e-cigarettes that are either less harmful than those already on the market or could serve as more effective smoking substitutes. Indeed, the standard process for obtaining a new product order appears to be quite difficult, time consuming, expensive, and uncertain, especially for companies without extensive research and legal resources. To date, FDA has issued only eight new product orders to allow new tobacco products onto the U.S. market (and all to the same company for directly related products).<sup>68</sup> Not surprisingly, the potentially negative impact of the new product order process on e-cigarette innovation is a frequently expressed concern of both the industry and e-cigarette harm reduction enthusiasts.<sup>69</sup>

When deciding whether a new/changed tobacco-nicotine product may be allowed on the market, FDA must consider not only whether it is less harmful to users and exposed nonusers than similar products on the market but also whether allowing it on the market (complete with its advertising and other marketing) would likely create public health gains or losses through its impacts on nonusers and on initiation, cessation, switching, relapse, and other tobacco use trends and behaviors.<sup>70</sup> Determining those likely impacts—and the net results for public health—is typically quite complicated and difficult. But the TCA empowers FDA to simplify that analysis—and reduce the risks that the new product’s marketing will increase initiation or relapse or reduce cessation or promote other health-harming behavior changes—by placing labeling and advertising requirements and restrictions on any new/changed tobacco-nicotine it allows on the market.<sup>71</sup>

With these powers and other authorities, FDA could create a fast-track process for obtaining new product orders that would enable new or improved e-cigarettes (and other tobacco-nicotine products) to get on the market more quickly and easily if they

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<sup>68</sup> FOOD & DRUG ADMIN., *Marketing Orders for Tobacco Products*, <https://www.fda.gov/TobaccoProducts/Labeling/TobaccoProductReviewEvaluation/ucm339928.htm> [<https://perma.cc/NF64-PKT5>].

<sup>69</sup> See, e.g., Altria, *Comments on Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems; Draft Guidance for Industry*, Docket No. FDA-2015-D-2496 (July 11, 2016). On the other hand, there are concerns that FDA has not been enforcing the new product requirements strictly enough and is allowing new and substantially changed tobacco products to enter the market without the required new product orders. See, e.g., Desmond Jenson et al., *FDA’s Misplaced Priorities: Premarket Review Under the Family Smoking Prevention and Tobacco Control Act*, 25 TOBACCO CONTROL 246, 250–51 (2016). The time, trouble, and expense and other difficulties involved in new or substantially changed e-cigarettes getting an FDA new product order to enable them to enter the U.S. market is entirely separate from the problem faced by e-cigarettes already on the market, which must submit an application to obtain an FDA new product order or substantial equivalence order by August 2022 if they want to stay on the market. See, e.g., FOOD & DRUG ADMIN., GUIDANCE: EXTENSION OF CERTAIN TOBACCO PRODUCT COMPLIANCE DEADLINES RELATED TO THE FINAL DEEMING RULE (REVISED) (Nov. 2017) <https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM557716.pdf> [<https://perma.cc/3ZJ7-BCZ4>]. Competitive Enterprise Institute, *CEI Joins Coalition Opposing FDA Rule on E-cigarettes* (Jan. 17, 2017), [https://cei.org/sites/default/files/TF\\_Coalition\\_Letter\\_Vaping\\_1.17.17.pdf](https://cei.org/sites/default/files/TF_Coalition_Letter_Vaping_1.17.17.pdf) [<https://perma.cc/C8ZT-9T5L>]. But e-cigarettes already on the market, or related variations, could also take advantage of the fast-track process proposed here.

<sup>70</sup> TCA, *supra* note 33, § 910(c)(4) [21 U.S.C. § 387j(c)(4)].

<sup>71</sup> TCA, *supra* note 33, § 910(c)(1)(B) [21 U.S.C. § 387j(c)(1)(B)]. Although the burden is on the manufacturer submitting the application for a new product order to provide adequate research and other evidence to enable FDA to determine that issuing an order would be “appropriate for the protection of the public health,” FDA often considers additional research and evidence that other interested parties submit or that FDA finds or develops on its own.



were clearly likely to reduce overall health harms—e.g., by being less harmful than e-cigarettes already on the market or more effective as smoking substitutes—and would be designed and marketed in ways that reduced the risk of promoting any of the health-harming behavior changes, such as increasing overall youth initiation. Such a fast-track process might have the following elements.

To best protect the public health, eligibility for the fast-track process would be restricted to those e-cigarettes that were: (a) considerably less harmful to users and exposed nonusers than smoking (with any nonsmoked, noncombusted, non-exploding, tobacco-nicotine product presumed to qualify); (b) as uncontaminated as reasonably possible; and (c) free of any additives (including flavorings) unnecessary to its operation as a nicotine-delivery product that are harmful or potentially harmful constituents (HPHCs), or that create potentially harmful levels of HPHCs during the product's use, which are consumed or experienced by users or exposed nonusers.<sup>72</sup>

Another option to protect against the new fast-track products inadvertently attracting youth might be to require that the e-cigarettes also have no youth-attracting flavors other than menthol (which could be kept as a direct cigarette-flavor parallel).<sup>73</sup> However, there are already many different types of e-cigarettes with more than 7,700 different flavors already being marketed in the U.S.;<sup>74</sup> so it might not provide any significant protections for youth to prohibit fast-track products from having flavors—at least until August 2022 (the current deadline for when manufacturers of currently available e-cigarettes must submit applications to receive FDA new product orders to enable their e-cigarettes to stay on the market).<sup>75</sup> That suggests that the fast-track process could initially be available to e-cigarettes with any nontoxic flavors, but with the condition that the manufacturer must submit a subsequent new product application for any fast-track authorized e-cigarettes with added flavors receiving fast-track permissive orders would have to submit another new product application by August 2022 to continue being marketed with those flavors. But if research and experience establishes that specific nontoxic flavors encourage and sustain significant increases in switching from smoking, without significantly increasing initiation among otherwise non-using youth or adults, FDA could add them to a list of permitted flavors for e-cigarettes receiving permissive new product orders through either the fast-track or the regular process.

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<sup>72</sup> See, e.g., Rachel Z. Behar, *Comparing the Cytotoxicity of Electronic Cigarette Fluids, Aerosols and Solvents*, TOBACCO CONTROL (Apr. 10, 2018), <http://tobaccocontrol.bmj.com/content/early/2018/04/10/tobaccocontrol-2016-053472>. Diana Crow, *Some E-Cigarette Flavors May Be More Harmful Than Others*, ATLANTIC MONTHLY (Nov. 28, 2017) (referencing Allyson E. Kennedy et al., *E-Cigarette Aerosol Exposure Can Cause Craniofacial Defects in Xenopus Laevis Embryos and Mammalian Neural Crest Cells*, 12 PLOS ONE (Sept. 28, 2017)).

<sup>73</sup> See generally M.B. Harrell et al., *Flavored Tobacco Product Use Among Youth and Young Adults: What if Flavors Didn't Exist?*, 3 TOBACCO REGULATORY SCI. 168 (Apr. 2017), <https://www.ncbi.nlm.nih.gov/pubmed/28775996> [<https://perma.cc/P4BK-5MKU>]; H. Dai & J. Hao, *Flavored Electronic Cigarette Use and Smoking Among Youth*, 138 PEDIATRICS e20162513 (Dec. 2016); M.B. Harrell et al., *Flavored E-Cigarette Use: Characterizing Youth, Young Adult, and Adult Users*, 5 PREVENTATIVE MED. REPS. 33 (2016); see also *supra*, note 22.

<sup>74</sup> See, e.g., Shu-Hong Zhu et al., *Four Hundred and Sixty Brands of E-Cigarettes and Counting: Implications for Product Regulation*, 23 TOBACCO CONTROL iii3, iii5 (2014).

<sup>75</sup> TCA, *supra* note 33, § 910 [21 U.S.C. § 387j]; FOOD & DRUG ADMIN., GUIDANCE: EXTENSION OF CERTAIN TOBACCO PRODUCT COMPLIANCE DEADLINES RELATED TO THE FINAL DEEMING RULE (REVISED) 8 (2017) [<https://perma.cc/82YH-6RSN>].

To prevent youth-attracting flavors, after August 2022 the fast-track for seeking new product orders would not be available for e-cigarettes with any flavors not on the permitted list. Although some argue that offering many different e-cigarette flavors are necessary to attract and retain smokers,<sup>76</sup> existing research shows that smoker desires to quit smoking and reduce health harms and risks are more powerful factors for attracting smokers to e-cigarettes;<sup>77</sup> and the fast-track products would be directly responsive to those desires. In addition, manufacturers that wanted to use additional flavors (or prohibited HPHCs) in a new e-cigarette to increase the product's effectiveness at attracting and keeping switching smokers could still go through the regular, nonfast-track new product process to get the required permissive new product order from FDA—e.g., by providing persuasive evidence that including the flavors (or HPHCs) would increase constructive switching without producing any offsetting harms either from product use or from increasing initiation by otherwise nonusers of any tobacco-nicotine product. Flavors would also be less necessary to attract smokers to those e-cigarettes that were allowed to make reduced-risk claims to smokers through a parallel fast-track for receiving FDA modified risk tobacco product (MRTP) orders, as described below. Moreover, full-nicotine e-cigarettes would not need flavors to attract addicted smokers if a nicotine-minimization rule were in place for cigarettes and similarly smoked tobacco products.<sup>78</sup>

To qualify for a fast-track new product order as clearly “appropriate for the protection of the public health,” the eligible e-cigarettes would also be required to show that they were likely to be either: (a) significantly less harmful to users or exposed nonusers than any e-cigarette of the exact same type that is already on the market; (b) not significantly more harmful than any e-cigarette of the same type but more likely to be used successfully as a complete alternative to smoking; (c) a brand new type of e-cigarette that is not significantly more harmful to users than the least harmful e-cigarettes already on the U.S. market and is as likely or more likely to serve as a complete alternative to smoking; or (d) a brand new type of tobacco product that is somewhat more harmful to users than the least harmful e-cigarettes on the market (but still substantially less harmful than smoking) but very likely to serve much more effectively as a complete alternative to smoking.<sup>79</sup> FDA could make

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<sup>76</sup> See, e.g., Carrie Wade, *California Needs To Think Twice About Banning Flavored E-Cigarettes*, The Hill (June 1, 2017), <http://thehill.com/blogs/pundits-blog/state-local-politics/335976-california-needs-to-think-twice-about-banning>.

<sup>77</sup> See, e.g., S. Bauhoff et al., *Perceptions of E-Cigarettes: A Comparison of Adult Smokers and Non-Smokers in a Mechanical Turk Sample*, 43 AM. J. DRUG & ALCOHOL ABUSE 311 (May 2017). See generally CTR. FOR SUBSTANCE USE RESEARCH, *ELECTRONIC VAPING PRODUCTS: RECOMMENDATIONS FOR A REGULATORY FRAMEWORK THAT RECOGNIZES THE POTENTIAL FOR POSITIVE HEALTH IMPACTS* (2017).

<sup>78</sup> It also appears that menthol and other flavors would be less necessary to attract and retain smokers to e-cigarettes if the smokers' smoked tobacco products were no longer permitted to have those flavors. John Buckell et al., *Should Flavors be Banned in E-cigarettes? Evidence on Adult Smokers and Recent Quitters from a Discrete Choice Experiment*, (Nat'l Bureau of Econ. Res., Working Paper No. 23865, Sept. 2017), <http://www.nber.org/papers/w23865> [<https://perma.cc/WX85-ZDPC>].

<sup>79</sup> This proposal assumes that, for fast-track purposes, it would not be appropriate for the protection of the public health to allow new e-cigarettes on the market if they were no less harmful or no more effective at prompting constructive switching than e-cigarettes already on the market. But if they are just like e-cigarettes already on the market, such e-cigarettes should be able to get on the market through the substantial equivalence pathway; and the non-fast-track new product pathway would also be available to e-cigarettes that did not qualify for the fast-track path.

these determinations relatively quickly without placing large burdens on applicants to provide related research and other evidence by focusing on the number and amounts of HPHCs in the product and/or delivered by the product to users to estimate relative harmfulness. For evaluating relative effectiveness for prompting switching, FDA could accept relatively simple, short-term comparative studies of attractiveness to smokers. But in both cases, FDA would also need to rely on rigorous post-market surveillance so that remedial action could quickly be taken if the new e-cigarette turned out to have more harmful impacts than expected on user health, initiation, switching, cessation, or relapse.

To further protect against any health-harming use of any e-cigarettes receiving the fast-track new product orders, the fast-tracked permissive orders would require that the product packaging and advertising include prominent warning text (perhaps with a neon yellow background), clearly coming from FDA and not the manufacturer, stating something like the following: “This product is harmful and addictive. However, if used by smokers who cannot otherwise quit as either a complete substitute for smoking or to sharply reduce one’s smoking, this product can significantly reduce health harms and risks to the user and to others who are exposed to the product’s use. But any other use of this product will increase health harms and risks to users and exposed nonusers.”<sup>80</sup>

In addition, because there is no appropriate-for-the-protection-of-the-public-health use for e-cigarettes other than as a substitute for smoking (or other more-harmful tobacco-nicotine use), e-cigarettes receiving fast-track permissive orders would be allowed on the market only as less harmful alternatives to cigarettes and smoking intended for use only as substitutes for smoking by smokers and former smokers.<sup>81</sup> This restriction would emphasize that e-cigarettes are beneficial and authorized by FDA only for sale and use as cigarette or smoking replacements, which is exactly how some e-cigarette companies view their products.<sup>82</sup>

Approving the e-cigarettes only as smoking substitutes would also make it easier for FDA to implement useful related advertising and labeling restrictions within existing First Amendment constraints. Put somewhat simply, the First Amendment protects against overly broad government restrictions on the ability of commercial firms to communicate relevant product information to their intended legal customers.<sup>83</sup> Permitting the fast-track e-cigarettes on the market only as smoking substitutes would narrow the definition of their legal customers, for the purpose of

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<sup>80</sup> On the effectiveness of a yellow background for warnings, *see generally* Lauren K. Lempert & Stanton A. Glantz, *Implications of Tobacco Industry Research on Packaging Colors for Designing Health Warning Labels*, 18 NICOTINE & TOBACCO RES. 1910 (2016).

<sup>81</sup> E-cigarettes could also be used, appropriately for the protection of the public health, as cessation aids, but FDA cannot let e-cigarettes onto the market for cessation or other therapeutic purposes through the new product pathway managed by the FDA Center for Tobacco Products. That can only be done by FDA’s Center for Drug Evaluation and Research, through granting a formal approval in response to the manufacturer’s application for the e-cigarette to be approved as a medical drug or device. But if allowing fast-track e-cigarettes on the U.S. market only as smoking substitutes intended by FDA to be purchased and used only by smokers and former smokers makes them into cessation aids, then the fast-track process might also have to include FDA approval of the e-cigarette as a cessation drug or device.

<sup>82</sup> *See, e.g., Juul Marketing Code*, JUUL LABS <https://www.juulvapor.com/marketing-code> [<https://perma.cc/AVX4-A8N7>] (“Juul is not intended for former smokers or never smokers. Juul is a switching product.”).

<sup>83</sup> *See, e.g., Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 564, 565, 571 (2001).

First Amendment analysis, only to smokers and former smokers (eliminating any First Amendment right to advertise the products to others).<sup>84</sup>

Consistent with that customer base definition, the advertising of fast-track authorized e-cigarettes could be permitted only in adult-access-only tobacco-selling retail outlets and through direct communications (direct mail, email, social media) to preverified adults who self-identify as current smokers or as former smokers who have switched to using e-cigarettes.<sup>85</sup> This restriction would still enable the manufacturer to market the new e-cigarette to adult smokers and relevant former smokers, but would minimize exposure to such advertising among youth and among others who would not benefit from using e-cigarettes but could be induced to do so by the ads.<sup>86</sup> Although this restricted advertising would still reach adult smokers trying to quit all use or planning to do so soon, creating a risk that some might switch to e-cigarette use, instead of quitting all use. But this risk would be quite small. In any given year, close to 70 percent of all smokers say they are interested in quitting, but only about 50 percent actually try to do so, and only about six percent successfully quit for at least six months.<sup>87</sup> Accordingly, for every smoker who would otherwise quit reached by the e-cigarette ads, the ads would reach more than 10 smokers trying or intending to quit who would otherwise fail and could, therefore, benefit from receiving the ads promoting e-cigarettes.

To avoid any First Amendment problems, no content-based restrictions or requirements would be placed on the permitted ads and communications; but the TCA prohibits false or misleading labeling or ads,<sup>88</sup> which receive no First amendment protections.<sup>89</sup> In addition, the TCA does not allow any nonmedical

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<sup>84</sup> Lindblom, *supra* note 44, at 87–89.

<sup>85</sup> 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. *See, e.g.*, M. Jane Lewis et al., *Evaluating Receipt of and Inability to Discontinue Tobacco Industry Direct Mail*, TOBACCO CONTROL (Mar. 27, 2018). Similar lists could also be readily 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 Feb. 1, 2018). 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.*, *Verification*, ARISTOTLE INDUSTRIES INTEGRITY DIVISION <https://integrity.aristotle.com/verification> [<https://perma.cc/FZN7-ECZR>]. 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.

<sup>86</sup> *See, e.g.*, John P. Pierce et al., *Association Between Receptivity to Tobacco Advertising and Progression to Tobacco Use in Youth and Young Adults in the PATH Study*, JAMA PEDIATRICS (Mar. 26, 2018), [https://jamanetwork.com/journals/jamapediatrics/fullarticle/2676069?utm\\_campaign=articlePDF&utm\\_medium=articlePDFlink&utm\\_source=articlePDF&utm\\_content=jamapediatrics.2017.5756](https://jamanetwork.com/journals/jamapediatrics/fullarticle/2676069?utm_campaign=articlePDF&utm_medium=articlePDFlink&utm_source=articlePDF&utm_content=jamapediatrics.2017.5756) (never-user youth receptivity to e-cigarette advertising associated with future e-cigarette use and smoking); Lauren Collins, *E-Cigarette Marketing and Communication: How E-Cigarette Companies Market E-Cigarettes and the Public Engages with E-cigarette Information*, NICOTINE & TOBACCO RES. 2–3 (Jan. 5, 2018) (reviewing research finding a suggested association between exposure to e-cigarette marketing and lower harm perceptions of e-cigarettes, intention to use e-cigarettes, and e-cigarette trial).

<sup>87</sup> *See, e.g.*, Babb et al., *supra* note 67.

<sup>88</sup> TCA, *supra* note 33, § 903(a)(1), (7)(A) [21 U.S.C. § 387c(a)(1), (7)(A)].

<sup>89</sup> *See, e.g.*, *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 554 (2001).

tobacco-nicotine product to be advertised with any reduced-risk or relative-risk claims unless the manufacturer first obtains a permissive MRTP order from FDA.<sup>90</sup> As described below, however, e-cigarettes receiving a fast-track or regular new product order could also be allowed to access a special fast-track for obtaining MRTP orders.<sup>91</sup>

Manufacturers or importers of e-cigarettes that did not meet the new product fast-track criteria or that wanted to market their e-cigarettes free of the fast-track requirements and restrictions could still apply for new product orders under the regular nonfast-track process. As it would not be changing in any way what may or may not get through the regular new product application process (the status quo), the fast-track process would not be creating any new restrictions or requirements on e-cigarettes or their advertising or marketing. The fast-track would also be fully consistent with protecting adult choice because it would not be restricting market access in any way but would be enabling new and substantially changed e-cigarettes to get on the market more quickly and easily, expanding the range of choices available to adult smokers.

By encouraging the development of e-cigarettes that are less harmful and more likely to serve as constructive smoking substitutes, and allowing them on the market more quickly and easily, the new product fast-track also fits well within the Pure Public Health Approach, and would work to reduce harms to youth. Any risk that it would increase harms among youth who would otherwise not incur any tobacco-nicotine harms would be very small, given the lesser harms from fast-track e-cigarettes compared to others on the market and the fast track's provisions designed to prevent the new e-cigarettes' advertising from reaching any youth or subsequently

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<sup>90</sup> TCA, *supra* note 33, § 911 [21 U.S.C. § 387k]. In addition, no e-cigarette may be labeled or marketed with therapeutic claims (e.g., as a cessation-assistance drug) without first being approved as a drug or device by FDA. *See, e.g., Clarification of When Products Made or Derived from Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding "Intended Uses,"* 82 Fed. Reg. 2193, 2198–99 (Jan. 9, 2017) (to be codified at 21 C.F.R. pts. 201, 801, & 1100).

<sup>91</sup> It might sound odd to propose putting stronger restrictions on the advertising of the fast-track e-cigarettes than currently apply to e-cigarettes already on the market or to cigarettes. But it would, as shown below, facilitate allowing those fast-tracked e-cigarettes also to make reduced-risk claims through a parallel MRTP fast track. Moreover, FDA may allow new or substantially changed e-cigarettes to enter the market only if doing so is found "appropriate for the protection of the public health"; and it is not yet clear whether allowing new entry e-cigarettes to do broader advertising would be "appropriate." In addition, FDA could by rule restrict the intended market and advertising of all e-cigarettes in this same way, or might determine that it must do so (to be "appropriate") in any future new product orders it issues pursuant to the new product applications all e-cigarettes now on the market must submit by August 2022. *But see generally* Dhaval M. Dave et al., *Does E-cigarette Advertising Encourage Adult Smokers to Quit?* (Nat'l Bureau of Econ. Res., Working Paper No. 24277, Feb. 2018), <http://www.nber.org/papers/w24277> [<https://perma.cc/VKU4-EMZ6>]. Although FDA has no authority to require cigarettes already on the market to secure new product orders, it would certainly be "appropriate for the protection of the public health" for FDA to issue a rule to restrict the advertising of cigarettes and other smoked tobacco products in much the same way as proposed here for new product fast-track e-cigarettes (e.g., by restricting their sale to only already addicted smokers and then allowing their advertising only through direct communications to pre-verified adults who self-identify as current smokers). For another description of this type of cigarette and tobacco product advertising restrictions, with related First Amendment analysis, *see* Lindblom, *supra* note 44, at 87–89; *see generally*, Eric N. Lindblom, Presentation at the E-Cigarette Summit Washington, D.C.: *How to Regulate E-Cigarettes?: Are We Asking the Right Questions?*, O'Neill Institute (May 8, 2017), <http://www.law.georgetown.edu/oneillinstitute/faculty/documents/Lindblom-E-CigSummitPresentation5-8-17.ppt>.

prompting any who would not otherwise use any tobacco-nicotine product from trying or using the new product e-cigarettes.<sup>92</sup>

The new product fast track would be much less necessary to prompt smokers to switch to using e-cigarettes and secure related health gains if FDA quickly implemented a nicotine-minimization rule for cigarettes and similarly smoked tobacco products. But it would still be a constructive initiative because it would encourage innovation to make e-cigarettes even less harmful than they already are, enable less harmful e-cigarettes to get on the market more quickly, and would provide a less burdensome pathway for many e-cigarettes already on the market that must meet the August 2022 new product application deadline and need to secure a new product order.

*Fast-Track to Enable Manufacturers to Obtain MRTP Orders from  
FDA More Quickly and Easily, Allowing Them to Market  
E-Cigarettes with Reduced-Risk Claims.*

One of the big concerns from those favoring an e-cigarette harm-reduction strategy is that many smokers and others do not understand that exclusive e-cigarette use is significantly less harmful to users and exposed others than smoking, and that not enough is being done to get accurate relative risk information to smokers.<sup>93</sup> Indeed, recent research indicates that while the vast majority of U.S. adults are now aware of e-cigarettes, only about 30 to 40 percent think that e-cigarettes are less harmful than regular cigarettes (with some recent declines in that percentage), although current smokers, compared to nonsmokers, were considerably more likely to think e-cigarettes were less harmful.<sup>94</sup> In an earlier study, using 2010 data, 15 to 30 percent of smokers did not believe that e-cigarettes were less harmful than regular

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<sup>92</sup> Some might argue that the proposed fast-track advertising restrictions would reduce the ability of the advertising to reach youth smokers or youth highly likely to become smokers and help prompt them to use e-cigarettes, instead. But allowing the fast-track e-cigarettes to be advertised only directly to adult smokers would reduce the risk of the new products and their advertising increasing overall youth initiation and the other previously described health-harming behavior changes. Moreover, allowing broader advertising and trying to curtail it only if it were causing more harm than good could be like closing the barn door only after the cows had gone. Because of possibly stronger First Amendment constraints against taking away rights than not permitting them in the first place, and the greater political difficulty in stopping a currently permitted activity rather than preventing it from the start, it might even be more like trying to put toothpaste back in the tube. See generally Andreas T. Schmidt, *Withdrawing Versus Withholding Freedoms: Nudging and the Case of Tobacco Control*, 16 AM. J. BIOETHICS 3 (2016). Here, as with other aspects of the various proposed FDA actions, it is considered more prudent to start with more protective restrictions that could be subsequently relaxed or readjusted if such changes were warranted by new research or experience.

<sup>93</sup> See, e.g., Valerie Briggs Solomon, Presentation at the *Food & Drug Law Journal Symposium, FDA & Health Behavior Regulation: Should the FDA Try to Move Smokers to E-Cigarettes or Other Less-Harmful Tobacco-Nicotine Products and, if so, How?* (Oct. 20, 2017), <https://www.fdli.org/wp-content/uploads/2017/10/Symposium-Briggs.pdf> [<https://perma.cc/XV2H-MP5N>].

<sup>94</sup> Timothy R. Huerta et al., *Trends in E-Cigarette Awareness and Perceived Harmfulness in the U.S.*, 52 AM. J. PREVENTIVE MED. 339, 343 (2017); Ban A. Majeed et al., *Changing Perceptions of Harm of E-Cigarettes Among U.S. Adults, 2012–2015*, 52 AM. J. PREVENTIVE MED. 331, 333 (2017); see also Ying Xu et al., *E-Cigarette Awareness, Use, and Harm Perception Among Adults: A Meta-Analysis of Observational Studies*, 11 PLOS ONE at 1 (Nov. 2016). But see Sarah E. Johnson et al., *Unpacking Smokers' Beliefs About Addiction and Nicotine: A Qualitative Study*, 31 PSYCHOLOGY OF ADDICTIVE BEHAVIORS 744, 744 (2017) ("The current findings provide insight that smokers may not be as misinformed regarding the relative harms of nicotine and tobacco, as has been suggested by quantitative evidence.").

cigarettes.<sup>95</sup> Going the other way, two 2017 research studies indicate that roughly half of all adult smokers would be interested in trying a tobacco product presented with a claim that it was less harmful than other tobacco products.<sup>96</sup>

As noted previously, a major impediment to manufacturers delivering e-cigarette relative-risk information to smokers is the TCA's Modified Risk Tobacco Product (MRTP) provisions, which prohibit manufacturers from labeling or advertising their e-cigarettes (or other tobacco products) with modified-risk or relative-risk claims unless they first obtain a permissive order from FDA finding that allowing the relative-risk claim would be appropriate for the protection of the public health.<sup>97</sup> Applying for an MRTP order can be quite expensive, complicated, and time-consuming; very few applications have been made and accepted since the Act went into effect in 2009, and FDA has not yet issued any permissive MRTP orders.<sup>98</sup> A major complication for establishing whether a proposed relative-risk claim would be appropriate for the protection of the public health is the difficulty in predicting accurately the extent to which it would prompt constructive switching from more harmful tobacco products to the less harmful MRTP, to what extent it would reduce or delay cessation, increase youth initiation, or prompt any of the other health-harming behavior changes, and whether the net impact would be clearly positive for the public health.

The extent to which relative-risk claims might prompt some harm-increasing uses of e-cigarettes is suggested by recent research indicating that roughly 10 percent of former smokers and three to 10 percent of never smokers would be interested in trying a tobacco product presented with a claim that it was less harmful than other tobacco products, with interest higher among younger adults.<sup>99</sup> An earlier study similarly found that about six percent of former smokers were interested in trying a cigarette marketed with reduced-risk claims (but did not query never smokers).<sup>100</sup> Although these levels of interest are relatively small compared to the interest smokers report in trying tobacco products with reduced-risk claims, they suggest a still significant interest in potentially harm-increasing uses of e-cigarettes.<sup>101</sup>

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<sup>95</sup> Jennifer L. Pearson et al., *E-Cigarette Awareness, Use, and Harm Perceptions in US Adults*, 102 AM. J. PUB. HEALTH 1758, 1762 (2012).

<sup>96</sup> Erin Keely O'Brien et al., *U.S. Adult Interest in Less Harmful and Less Addictive Hypothetical Modified Risk Tobacco Products*, NICOTINE & TOBACCO RES. (2017) (When asked "[i]f a tobacco product made a claim that it was less harmful than other tobacco products, how likely would you be to use that product?," half of all smokers and ten percent of former and never smokers reported interest in trying.); Jennifer L. Pearson et al., *Adult Interest in Using a Hypothetical Modified Risk Tobacco Product: Findings from Wave 1 of the Population Assessment of Tobacco and Health Study (2013-14)*, 113 ADDICTION 133, 117-118 (2017) (asking a similar question with 54.4 percent of established adult smokers reporting interest in trying a tobacco product with reduced-risk claim vs. 16.7 percent of all adults, and 3.0 percent of never smoking adults).

<sup>97</sup> TCA, *supra* note 33, § 911 [21 U.S.C. § 387k].

<sup>98</sup> FOOD & DRUG ADMIN., *Modified Risk Tobacco Products*, <https://www.fda.gov/TobaccoProducts/Labeling/TobaccoProductReviewEvaluation/ucm304465.htm> [<http://perma.cc/6WDJ-6NXX>].

<sup>99</sup> See generally O'Brien, *supra* note 97; Pearson, *supra* note 97, at 117.

<sup>100</sup> Saul Shiffman et al., *Smoker and Ex-Smoker Reactions to Cigarettes Claiming Reduced Risk*, 13 TOBACCO CONTROL 78, 82 (2004).

<sup>101</sup> These findings would not be worrying if the former smokers and never smokers interested in trying the tobacco product with the reduced-harm claim were those with the highest risk, respectively, of relapsing into smoking or initiating into smoking, anyway. In that case, trying the reduced-risk product could be harm-reducing. But the study did not investigate whether the former smokers interested in trying

It is also possible that e-cigarette reduced-risk claims could reduce some smokers' interest in quitting smoking (e.g., by engaging in dual use, instead). For example, a recent analysis of three years of national health survey data found that among smokers "no relationship was observed between e-cigarette awareness and past-year quit attempts or quit intentions, but those that viewed e-cigarettes as less harmful were less likely to have a past-year quit attempt."<sup>102</sup> In addition, the previously mentioned reduced-risk-claim cigarette study found that almost a quarter of the smokers receiving the claim misunderstood it to mean that the reduced-risk cigarette was completely safe—suggesting that simple relative-risk messages can easily be misunderstood and, therefore, possibly misapplied in harmful ways.<sup>103</sup>

A carefully designed fast-track MRTP process for e-cigarettes could, however, directly reduce all of these concerns about possibly increasing harm-increasing e-cigarette use and minimize any risk that the permitted reduced-risk claims might produce public health losses instead of gains. In particular, limiting eligibility to the fast track only to the cleanest and least harmful e-cigarettes (i.e., those that could qualify for the previously discussed PMTA fast-track) would reduce the initial harms to any youth or otherwise nonusers of tobacco-nicotine products who might be prompted to try the e-cigarette because of its reduced-risk claim. Allowing the relative-risk claims to be made only directly to smokers would target the messaging directly to those who could benefit from receiving it, while sharply reducing the extent that the messaging would reach nonsmokers or former smokers and the related risk of prompting health-harming e-cigarette uses. And carefully structuring the reduced-risk claims could further reduce the likelihood that they would prompt health-harming e-cigarette use by any youth, former smokers, or otherwise nonusers of any tobacco-nicotine product who might still be exposed to the claims.

All that could be done, first, by making the fast-track MRTP process available only to those e-cigarettes that had qualified for a fast-track new product order, or could, and would thereby be subject to the same requirements and restrictions regarding labeling and advertising. In addition, once any e-cigarettes had received permissive MRTP orders, any subsequent e-cigarettes seeking a fast-track MRTP order would have to show FDA that they were likely to be either less or no more harmful than the existing MRTP e-cigarettes (using the same kind of harmfulness tests as described for the PMTA fast-track) and no less attractive or effective as smoking substitutes, or only somewhat more harmful than the existing MRTP e-cigarettes but much more attractive or effective as smoking substitutes.<sup>104</sup> Showing

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the reduced-harm-claim tobacco product were likely to relapse into smoking; but the interest the study found in never-smoker adult interest is clearly troubling given that pre-e-cigarettes relatively few never-smoker adults ever initiated into smoking or other tobacco-nicotine use.

<sup>102</sup>Huerta, *supra* note 95, at 339; see generally Jessica K. Pepper et al., *How Hearing About Harmful Chemicals Affects Smokers' Interest in Dual Use of Cigarettes and E-Cigarettes*, 96 PREVENTATIVE MED. 144 (2017); Shiffman, *supra* note 101, at 82.

<sup>103</sup>Shiffman, *supra* note 101, at 82.

<sup>104</sup>The fast-track (or regular) MRTP fast-track process could create even stronger incentives for constructive e-cigarette product innovation by providing that if an e-cigarette receives a permissive MRTP order and it is likely significantly less harmful than e-cigarettes of the same type already on the market with MRTP orders (and no less likely to serve as an effective e-cigarette substitute), or is likely to be much more effective at serving as a smoking alternatives (without being significantly more harmful), then FDA will rescind the MRTP orders for the more-harmful or less-effective e-cigarettes as of 180 days after the applicant's MRTP order is granted and it enters the market (unless post-marketing surveillance has indicated that the product actually does not meet the criteria relating to relative harmfulness and



that an e-cigarette would be as attractive and effective as an existing MRTP e-cigarette as a smoking substitute could be done by showing it has the same or very similar characteristics and labeling as the MRTP e-cigarettes. Another option would be standard consumer-preference research, which could also be used to show that the fast-track e-cigarette would likely be more attractive and effective as a smoker substitute than an existing MRTP e-cigarette.

Pursuant to the incorporated new product fast-track criteria, the relative-risk claims could only be delivered through advertising in adult-only tobacco product selling outlets and through direct communications to preverified adult smokers or former smokers who are using e-cigarettes. These restrictions would enable reduced-risk claims to be delivered directly to the target audience that could benefit from receiving the claims, while reducing the risk that the relative-risk claims could also reach and attract youth or current adult nonusers.

To further reduce the risk that the permitted reduced-risk claims and messaging might prompt health-harming behavior changes, the fast-track would require that the messaging consist only of accurate, nonmisleading statements about reduced harms and risks to self and others from switching from smoking to using the e-cigarettes—and would be required to include accurate, not-misleading statements meant to prevent less-beneficial behavior change regarding: (a) the harms and risks from dual use if it does not sharply reduce smoking (unless it is a prompt step toward such sharp reductions or complete quitting); (b) the harms and risks from exclusive e-cigarette use or any e-cigarette use that is not replacing smoking; and (c) how complete cessation of all tobacco-nicotine use is the best way to maximize reduced risks and protect one's health. To simplify the process, the relative-risk claims could be required to follow an FDA-developed research-based template designed to meet these criteria and affect smoker behavior as positively for health as effectively as possible (perhaps with the reduced-risk messaging identified as coming from FDA, instead of the manufacturer, to enhance its credibility). Any e-cigarettes receiving a fast-track MRTP order could also be required to provide this kind of relative-risk and related information in more detailed FDA-authored product inserts or onserts, as well.<sup>105</sup>

As with the fast-track new product orders, FDA would need to do thorough postmarketing surveillance so that it could quickly rescind or revise the MRTP order if the permitted relative-risk claims were producing unexpected health-harming impacts on users or consumer behaviors.

Manufacturers or importers of e-cigarettes that did not meet the MRTP fast-track criteria or did not want to comply with the fast track's requirements and restrictions could still apply for a permissive order to make relative-risk claims under the regular nonfast-track MRTP process.<sup>106</sup> So the MRTP fast-track would not be creating any new constraints on e-cigarettes, e-cigarette advertising, or e-cigarette manufacturers or importers.

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effectiveness). The 180-day period would not only provide time for post-market surveillance but would also ensure that the e-cigarettes with the earlier MRTP orders had a reasonable period on the market to compensate for the time, trouble, and expense they incurred to obtain those orders, and would also provide time for them to modify their products and secure new MRTP orders.

<sup>105</sup>See generally Lindblom, *supra* note 40; Mucan & Moodie, *supra* note 40.

<sup>106</sup>For a similar proposal for expedited review of e-cigarette new product and MRTP applications, see, e.g., Lindblom, *supra* note 44, at 77–78.

This MRTP fast-track would be much less necessary for shifting smokers to using e-cigarettes if FDA quickly implemented a nicotine minimization rule for cigarettes and similarly smoked tobacco products, as described above. But the MRTP fast-track would certainly be useful if any nicotine-delivering smoked-and-inhaled tobacco products remained on the market.

Because the MRTP fast-track would enable relevant product and product-use information to be provided to adult smokers more quickly and easily, it would not hinder or restrict adult choice in any way but would likely help to prompt additional smoker experimentation with e-cigarettes and subsequent sustained use of e-cigarettes as a smoking replacement. Any risks of increasing health harms to any youth would be quite small, given the fast track's efforts to: (a) minimize exposure among youth to the e-cigarettes advertising or reduced-risk claims; (b) provide information and warnings with the reduced-risk claims to try to prevent any exposed otherwise nonuser youth from trying the e-cigarette or becoming regular users; (c) prohibit youth-attracting flavors (with the possible exception of menthol); and (d) ensure the e-cigarettes are as free of contamination and toxins as possible. Moreover, the marketing of the e-cigarettes with reduced-risk claims would likely reduce harms among otherwise smoking youth by prompting some to switch from smoking to e-cigarette use or never start smoking, either because they received the reduced-risk information secondhand or through the modeling effects of having their parents or other adults in their lives switching from smoking to e-cigarette use in response to the MRTP claims.<sup>107</sup>

*FDA Public Education Campaign About Harm Reduction from  
Smokers Switching to E-Cigarettes.*

Members of both the tobacco industry as well as e-cigarette harm reduction enthusiasts have called for more efforts by FDA (and other government agencies) to inform smokers or the public about e-cigarette use being less harmful than smoking, or at least to eliminate misperceptions that they are similarly harmful.<sup>108</sup> Such an effort could supplement the educational efforts in the proposed MRTP fast track, or be done separately, given that relative-risk information clearly coming from the government or health professionals, instead of from the tobacco industry sellers of the products, would likely be perceived as more reliable by smokers and others.<sup>109</sup> As with the MRTP relative-risk claims, the primary goal would be to provide accurate and not misleading information about relative risk to smokers, and encourage them to switch to e-cigarette use if they cannot quit all use, without reaching nonsmokers who might be prompted to initiate health-harming e-cigarette

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<sup>107</sup>See, e.g., Kathrin Schuck et al., *Bidirectional Influences Between Parents and Children in Smoking Behavior: A Longitudinal Full-Family Model*, 15 NICOTINE & TOBACCO RES. 44, 47–48 (2013).

<sup>108</sup>See, e.g., Lynn T. Kozlowski & David Sweanor, *Withholding Differential Risk Information on Legal Consumer Nicotine/Tobacco Products: The Public Health Ethics of Health Information Quarantines*, 32 INT'L J. DRUG POL'Y 17, 18–19 (2016); Solomon, *supra* note 94.

<sup>109</sup>Solomon, *supra* note 94, at 12 (citing Health Information National Trends Survey); Kathleen R. Case et al., *Source Credibility and E-Cigarette Attitudes: Implications for Tobacco Communication*, 16 HEALTH COMM. 1, 5 (2017) (suggesting that non-industry, non-government sources of information might be most effective).

use. Such government educational efforts could also target medical personnel who are likely to provide patients who smoke with advice about quitting or switching.<sup>110</sup>

The most direct way to target smokers effectively, with minimal risk of reaching those who might use e-cigarettes in health-harming ways, would be for FDA to require special FDA-authored warning labels or onserts on cigarette packs and the packages of similarly smoked tobacco products, or package inserts. Moreover, providing this information directly linked to the packages of the smoked tobacco products would also be the most safe and effective way to reach youth smokers directly. A warning label that could be added into the currently required rotations of warning labels for cigarette packs might read something like: "Switching from smoking to using only e-cigarettes or other noncombusted tobacco or nicotine products can significantly reduce, but not eliminate, harms and risks to the user and exposed nonusers." To try to promote constructive switching while also reducing risks of health-harming e-cigarette use, the required onserts or inserts could provide basically the same reduced-risk and supplementary content described above for the MRTP claims permitted under the proposed MRTP fast track, including guidance on effective switching and total quitting strategies and information on how to obtain additional assistance.

Others have proposed much more public educational efforts, such as media campaigns, or at least having all government agency statements and websites relating to smoking or tobacco use be more active about explicitly stating that e-cigarettes are less harmful than smoking and that smokers should switch to reduce their harms and risks from tobacco-nicotine use.<sup>111</sup> But public TV, radio, and social media campaigns (as opposed to direct messaging only to verified smokers), even if carefully targeted, would likely reach well beyond the target audience of smokers who would benefit from switching or youth who would otherwise initiate into smoking, thereby possibly increasing health-harming e-cigarette use. Moreover, FDA-required warnings, inserts, and onserts for cigarettes and similarly smoked tobacco products and other direct messaging to smokers, along with FDA efforts to education medical personnel, could make any such public media educational efforts much less necessary, if needed at all, for reaching and influencing smokers to switch constructively to e-cigarettes or for reaching youth at risk of initiating into smoking. By prompting addicted smokers to move away from cigarettes and other smoked tobacco products, an FDA nicotine-minimization rule would also make such public educational efforts less necessary, if needed at all.

In the absence of a nicotine-minimizing rule or other very strong, new anti-smoking measures, mass media efforts to educate the families, friends, and peers of smokers and youth at high risk of becoming smokers about the health benefits of switching to e-cigarettes could also help to prompt additional or more rapid switching. But such mass media efforts would create the same risk of reaching nonsmoking youth and others and possibly increasing nonbeneficial e-cigarette use as other broad-based public education campaigns about e-cigarettes and relative risk. Moreover, many of the family members, friends, and peers of regular smokers and most-at-risk youth are also smokers and would already be receiving the e-cigarette-

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<sup>110</sup>See generally Julie M. Donohue et al., *Whom Do Older Adults Trust Most to Provide Information About Prescription Drugs?* 7 AM. J. GERIATRIC PHARMACOTHERAPY 105, 109–112 (Apr. 2009) (finding doctors and pharmacists most trusted sources of drug information, especially among older adults).

<sup>111</sup>See, e.g., Solomon, *supra* note 94.

switching information through the warning labels, inserts, or onserts or any of the other strategies that were adopted to deliver relative-risk and switching information directly and exclusively to smokers. In addition, nonsmoker family members and friends of smokers would likely see the pack warnings, inserts, or onserts or the other direct messaging to smokers done by the government or allowed by an MRTP fast track. It is also likely that FDA rules to require warning labels, inserts, or onserts, and FDA fast-track orders allowing manufacturer e-cigarette reduced-risk claims to be delivered to smokers would generate considerable media attention, which many friends, family members, and peers of smokers would see. So the added value from reaching smoker families, friends, and peers with mass media education campaigns about e-cigarettes seems relatively small, especially in light of the cost of developing and implementing effective government media campaigns compared to the cost of an FDA rule to deliver that information through required warning labels, inserts, or onserts or the cost of an FDA MRTP fast-track.

It would be cost effective, however, and create very little risk of increasing youth initiation into e-cigarette use, for FDA, CDC, and other government agencies that provide information about smoking or health to ensure that their public statements and website offerings do not mislead any significant number of people about the relative harmfulness of e-cigarettes versus smoking or about the benefits to smokers from switching from smoking to using e-cigarettes. But any such effort should also ensure that people are not misled to think that e-cigarette use is less addictive or harmful than it actually is, especially in comparison to not trying or using any tobacco-nicotine at all.

### *Other Related Options*

#### *FDA Product Standard to Make E-Cigarettes Cleaner, More Reliable, and Less Toxic.*

A new FDA product standard for e-cigarettes could help to move smokers to using e-cigarettes, instead, by increasing confidence in e-cigarettes and their reduced-risk reliability. For example, a new product standard could prohibit contamination beyond readily achievable levels, prohibit additives that are HPHCs (unless, like nicotine, they are necessary for the operation of the e-cigarette), include provisions to protect against e-cigarette explosions or burns, and include other measures to ensure reliable and safe operation and minimize harms and risks from consumption.<sup>112</sup>

To work well, however, any such rule would have to be careful to avoid reducing risks in current e-cigarettes that might impede the development of new technologies that would allow them to serve as even less harmful and more attractive and effective cigarette and smoking substitutes. For example, setting maximum internal temperatures or voltages for e-cigarettes during their use may reduce explosion risks

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<sup>112</sup>Although potentially devastating to users when they occur, fires or explosions caused by e-cigarettes have been relatively uncommon. Lawrence A. McKenna, Jr., *Electronic Cigarette Fires and Explosions in the United States 2009-2016*, U.S. FIRE ADMIN. (July 2017), [https://www.usfa.fema.gov/downloads/pdf/publications/electronic\\_cigarettes.pdf](https://www.usfa.fema.gov/downloads/pdf/publications/electronic_cigarettes.pdf). But see R.J. Reynolds Vapor Co., press release, *Urgent: Voluntary Product Recall of Vuse Vibe Power Units* (April 13, 2018), [http://s2.q4cdn.com/129460998/files/doc\\_news/2018/Vuse-Vibe-Recall-Press-Release-Final.pdf](http://s2.q4cdn.com/129460998/files/doc_news/2018/Vuse-Vibe-Recall-Press-Release-Final.pdf).

or the creation of various toxins, such as aldehyde;<sup>113</sup> but it could also block the development or sale of new, more safe and effective e-cigarette technologies that use higher temperatures without creating explosion risk, harmful toxins, or other new user harms or risks. A more flexible approach would be to require premarket testing to ensure against explosions and the like and to prohibit e-cigarette liquids from containing any additives or ingredients unnecessary for the operation of the e-cigarette that are harmful or potentially harmful constituents (HPHCs) or that create potentially harmful levels of HPHCs when consumed by users as a vapor or aerosol during the e-cigarettes operation. To be even more flexible, the standard might also include an exception to allow minimum amounts of any HPHC additives necessary to make the e-cigarette significantly more palatable and pleasing to smokers—but only if the amount added were under the levels that create any significant health risk or created only a very small additional health risk to users and no less harmful, less risky alternatives to the additive were available. Such an exception would not, for example, permit the use of any flavorings that are known HPHCs or create known HPHCs when vaporized whenever there were any less-HPHC or non-HPHC flavorings.<sup>114</sup>

The ability of such a product standard to move many smokers to e-cigarettes would be limited by the Tobacco Control Act provisions, which prohibit manufacturers from labeling or advertising any e-cigarette (or other nonmedical tobacco-nicotine product) as FDA-approved or deemed safe,<sup>115</sup> or, without first obtaining a permissive MRTP order, as less harmful or risky than another tobacco product. But that problem could be addressed by establishing the previously discussed fast-track MRTP process or by putting parallel provisions in the new e-cigarette product standard, thereby allowing manufacturers to communicate directly in a nonmisleading way only to smokers about the product standard's impact on their e-cigarette characteristics, harms, and risks.<sup>116</sup>

This kind of e-cigarette product standard should be consistent with both the Pure Public Health Approach and the Adult Choice/Youth Protection Approach. Although

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<sup>113</sup>See, e.g., Otmar Geiss et al., *Correlation of Volatile Carbonyl Yields Emitted by E-Cigarettes with the Temperature of the Heating Coil and the Perceived Sensorial Quality of the Generated Vapours*, 219 INT'L J. HYGIENE & ENVTL. HEALTH 268, 276 (2016).

<sup>114</sup>See, e.g., Diana Crow, *Some E-Cigarette Flavors May Be More Harmful Than Others*, ATLANTIC MONTHLY (Nov. 28, 2017) (referencing Allyson E. Kennedy et al., *E-Cigarette Aerosol Exposure Can Cause Craniofacial Defects in Xenopus Laevis Embryos and Mammalian Neural Crest Cells*, 12 PLOS ONE (Sept. 28, 2017)); *E-liquid Database*, CENTER FOR TOBACCO REGULATORY SCI. & LUNG HEALTH, <http://eliquidinfo.org> [<https://perma.cc/AY27-PGTQ>] (offering test results for e-cigarette flavors, with wide range from low to high potential toxicity, and showing that a large number of flavors appear to have quite low toxicity risk); Pebbles Fagan et al., *Sugar and Aldehyde Content in Flavored Electronic Cigarette Liquids*, NICOTINE & TOBACCO RES. 1–8 (2017).

<sup>115</sup>TCA, *supra* note 33, § 103(b), amending 21 U.S.C. § 331 by adding new (tt).

<sup>116</sup>To the extent that it became well known to smokers that the FDA product standard had made all available e-cigarettes cleaner, more reliable, and less harmful and risky, it is likely that some youth, otherwise non-users of any tobacco-nicotine products, and former smokers would also learn all that, as well, possibly increasing the likelihood of their engaging in the health-harming behavior changes. But any such spillover effect from manufacturers' direct communications to smokers (and the temporary media attention the new product standard would receive when in process and when implemented) would likely be quite small, especially in comparison to the impact on smokers. Moreover, the manufacturers' messaging would have all the preventive content described in the MRTP fast-track proposal to further protect against non-constructive e-cigarette use by youth or others.

it would reduce the ability of adults to choose and legally purchase e-cigarettes that were contaminated, unreliable, or unreasonably toxic, those kinds of constraints are typically accepted by all but the most rabid proponents of personal autonomy and individual choice. Although minimizing nicotine levels or eliminating menthol and other flavors in all cigarettes and similarly smoked tobacco products would move far more smokers to e-cigarettes than this type of product standard, it would serve as a helpful complement to those more aggressive shifting measures by reducing the harms and risks to those smokers who switched to e-cigarettes.

*Make It Less Difficult, Costly, and Time Consuming for  
E-cigarettes (and Other Nicotine Replacement Therapies) to  
Obtain Necessary FDA Approvals to be Marketed as  
Therapeutic Products and Labeled and Advertised with  
Cessation-Assistance Claims.*

Often overlooked in discussions focusing on how FDA, through its Center for Tobacco Products, should regulate e-cigarettes or encourage shifting from smoking to e-cigarettes is the fact that no e-cigarette may be labeled or marketed with an explicit or implied therapeutic claim—such as stating that it can serve as a cessation aid—without first being approved by FDA through its Center for Drug Evaluation and Research (CDER) as a “safe and effective” medical drug or device.<sup>117</sup> So far, no e-cigarette has received such CDER approval.<sup>118</sup> FDA has approved nicotine patches, gum, and lozenges as nicotine replacement therapies (NRTs) that can help smokers quit.<sup>119</sup> But they have not been approved as long-term cessation therapies for smokers to use indefinitely instead of smoking. There have also been regular claims that the approval process for drugs or devices that could serve as cessation aids or minimally harmful smoking substitutes has been too restrictive—as well as expensive and time consuming—because the harms, risks, and benefits from potential cessation aids were evaluated against a situation of no harms and risks instead of against the harms and risks from continued smoking.<sup>120</sup>

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<sup>117</sup>See, e.g., Clarification of When Products Made or Derived from Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding “Intended Uses,” 82 Fed. Reg. 2193, 2198–99 (Jan. 9, 2017) (to be codified at 21 C.F.R. pts. 201, 801, and 1100).

<sup>118</sup>There have, however, been regular reports of e-cigarettes being illegally advertised and sold with cessation claims, especially online. See, e.g., Elizabeth G. Klein et al., *Online E-Cigarette Marketing Claims: A Systematic Content and Legal Analysis*, 2 TOBACCO REG. SCI. 252, 258 (2016); Rachel A. Grana & Pamela M. Ling, *Smoking Revolution? A Content Analysis of Electronic Cigarette Retail Websites*, 46 AM. J. PREVENTIVE MED. 395, 401 (2014). But very few e-cigarette companies have been enforced against by FDA for making unauthorized cessation claims in the past five years. See, e.g., FOOD & DRUG ADMIN., *Warning Letters* (Mar. 6, 2018), <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters> [<https://perma.cc/T5LU-HXXW>]; FOOD & DRUG ADMIN., *Import Alert 66-41* (Nov. 30, 2017) [https://www.accessdata.fda.gov/cms\\_ia/importalert\\_190.html](https://www.accessdata.fda.gov/cms_ia/importalert_190.html) [<https://perma.cc/WVN5-N9QL>] (listing only two companies with e-cigarettes or e-cigarette components that are considered unapproved drugs and should not be allowed to enter the United States, with those listings carried over from 2014).

<sup>119</sup>See, e.g., FOOD & DRUG ADMIN., *Want to Quit Smoking? FDA-Approved Products Can Help* (Dec. 11, 2017) <https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm198176.htm> [<https://perma.cc/6X9E-PPXZ>]. But see Eric C. Leas et al., *Effectiveness of Pharmaceutical Smoking Cessation Aids in a Nationally Representative Cohort of American Smokers*, 110 J. NAT'L CANCER INST. at 2 (Dec. 21, 2017).

<sup>120</sup>See, e.g., Letter from Christopher W. Hansen, President, Am. Cancer Soc'y Cancer Action Network et al., to Scott Gottlieb, Comm'r, FDA (Oct. 13, 2017); Comments of Campaign for Tobacco-Free Kids in Docket No. FDA-2016, Psychopharmacologic Drug Advisory Committee & Drug Safety and

By thoughtfully addressing these problems, FDA could make additional drugs and devices, including e-cigarettes, available as both cessation aids and as long-term less harmful smoking replacements (much as methadone is available to addicts as a harm-reducing heroin substitute).<sup>121</sup> In particular, FDA could:

- Evaluate proposed new NRTs, or new indications and labeling for already approved NRTs, based on a risk-benefit analysis that compares the proposals against smokers continuing to smoke (which will kill half of them and significantly harm the rest).
- Ensure that all approved labeling for existing NRTs do not discourage their longer-term use as smoking-cessation aids, so long as their use is replacing or substantially reducing smoking (e.g., by stating or implying that using NRTs for long periods of time instead of smoking or to sharply reduce one's smoking is not beneficial).<sup>122</sup>
- Encourage the development of NRTs that could deliver nicotine to users more like smoking (e.g., rapidly via the lungs), without any increase in harmfulness.
- Facilitate constructive innovation—e.g., by creating a fast-track for certain NRT applications and by relying more on postmarket surveillance and market withdrawals to protect against abusive, ineffective, or counterproductive use of approved NRTs.<sup>123</sup>
- Make obtaining FDA-CDER approvals to market e-cigarettes for cessation-assistance or other therapeutic purposes more valuable by more actively enforcing against e-cigarette manufacturers and sellers that illegally make such claims without obtaining the required prior FDA-CDER approvals.<sup>124</sup>

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Risk Management Advisory Committee Meeting of September 14, 2016 (Aug. 30, 2016); Letter from Janet Woodcock, Dir., Ctr. for Drug Evaluation & Research, to Nirav R. Shah et al. (Apr. 1, 2013); Written Comments of Campaign for Tobacco-Free Kids in Docket No. FDA-2012-N-1148 (Jan. 16, 2013).

<sup>121</sup>The United Kingdom's Medicines and Healthcare Products Regulatory Agency has authorized an e-cigarette, brand name Voke, as a cessation aid that may be prescribed by doctors. See, e.g., *E-cigarette Device Given NHS Prescription License*, NAT'L HEALTH EXECUTIVE (Apr. 1, 2016), <http://www.nationalhealthexecutive.com/Health-Care-News/e-cigarette-device-given-nhs-prescription-licence> [<https://perma.cc/5ZMJ-ERA9>].

<sup>122</sup>FDA took some constructive steps in 2013, when it issued its notice, *Modifications to Labeling of Nicotine Replacement Therapy Products for Over-the-Counter Human Use*, 78 Fed. Reg. 19,718, 19,719–20 (Apr. 2, 2013). Additional constructive changes to NRT labeling appear to be underway. See also FOOD & DRUG ADMIN., *Nicotine Replacement Therapy Labels May Change* (Apr. 1, 2013), <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm345087.htm> [<https://perma.cc/GPX8-N49L>]; FOOD & DRUG ADMIN., *Nicotine Steering Committee; Establishment of a Public Docket; Request for Comments*, 83 Fed. Reg. 7123–24 (Feb. 20, 2018). <https://www.gpo.gov/fdsys/pkg/FR-2018-02-20/pdf/2018-03341.pdf>.

<sup>123</sup>To further encourage ongoing product innovation, FDA and CDER might also consider establishing procedures so that whenever an applicant's proposed NRT was found significantly more safe and effective than the NRTs of the same type already on the market, FDA would allow the new NRT to make claims regarding its greater safety and efficacy, compared to its competitors' products, in its labeling and advertising—and possibly consider withdrawing its approvals for any much less safe or effective NRTs of the same type.

<sup>124</sup>As noted above, there have been regular reports of e-cigarettes being illegally advertised and sold with cessation claims, especially online. See *supra*, note 119; See also, Letter from Am. Cancer Soc'y–Cancer Action Network et al., to Janet Woodcock, Dir., Food & Drug Admin. Ctr. for Drug Evaluation & Research (Oct. 14, 2015).

- Coordinate the NRT medical drug and device approvals by FDA's Center for Drug Evaluation and Research (CDER) with the MRTP process for permitting tobacco product relative-risk claims by FDA's Center for Tobacco Products (CTP).<sup>125</sup>

These measures would likely result in more e-cigarettes more quickly obtaining the necessary approval from FDA to market their e-cigarettes as therapeutic cessation aids. That would likely increase the number of smokers who would try e-cigarettes to reduce their smoking—either because they would receive previously prohibited cessation-claim advertising or communications from the manufacturers, see the over-the-counter cessation-aid e-cigarettes at their pharmacy, or because their doctors would suggest or prescribe the FDA-approved cessation-aid e-cigarettes. In addition, more smokers might stick with the FDA-approved cessation-aid e-cigarettes as long-time replacements for smoking (instead of relapsing into smoking) because their labeling and advertising would promote (and not discourage) that kind of use, and the cost of the e-cigarette cessation aid would be covered by health insurance. Moreover, past history with FDA-approved NRTs allowed to be marketed over-the-counter with cessation claims suggests that the risk of any harmful, nontherapeutic use by youth or adults of e-cigarettes approved as cessation aids would likely be small.<sup>126</sup> To further reduce that risk, the e-cigarettes approved to be marketed as therapeutic NRTs with cessation-assistance claims could also be required to have the same kind of additional warnings and information in their labeling and advertising suggested previously for any e-cigarettes allowed to make reduced-risk MRTP claims to dampen further any counterproductive use.

Accordingly, this FDA-CDER measure should help to produce significant net public health gains with little risk of creating new harms to youth. It also does not in any way restrict adult choice. Although FDA has resisted these kinds of reforms in the past, Commissioner Gottlieb and the Directors of both CDER and the Center for Tobacco Products have recently announced a new initiative to consider exactly these types of reforms, as part of FDA's efforts to create a comprehensive relative-risk approach to regulating all medical and nonmedical tobacco-nicotine products.<sup>127</sup>

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<sup>125</sup>For more detail regarding these and other steps FDA and CDER might take regarding NRTs and therapeutic e-cigarettes, see, e.g., Letter from Christopher W. Hansen, *supra*, note 121; Comments of Campaign for Tobacco-Free Kids in Docket No. FDA-2016, Psychopharmacologic Drug Advisory Committee and Drug Safety & Risk Management Advisory Committee meeting of September 14, 2016 (Aug. 30, 2016); see also David Sweanor, *Regulatory Imbalance Between Medicinal and Non-Medicinal Nicotine*, 95 ADDICTION (Supplement 1) S25, S27 (Jan. 2000).

<sup>126</sup>See, e.g., Saul Shifman & Christine T. Sweeney, *Ten Years After the Rx-to-OTC Switch of Nicotine Replacement Therapy: What Have We Learned About the Benefits and Risks of Non-Prescription Availability?*, 86 HEALTH POLICY 17 (Apr. 2008); Lisa M. Klesges et al., *Use of Nicotine Replacement Therapy in Adolescent Smokers and Nonsmokers*, 157 ARCHIVES PEDIATRICS & ADOLESCENT MED. 517, 519 (2003) (finding one percent of never-smoking youth had ever tried NRT).

<sup>127</sup>Scott Gottlieb et al., *Advancing Medicinal Nicotine Replacement Therapies as New Drugs—A New Step in FDA's Comprehensive Approach to Tobacco and Nicotine*, FDA VOICE (Nov. 29, 2017) <https://blogs.fda.gov/fdavoices/index.php/2017/11/advancing-medicinal-nicotine-replacement-therapies-as-new-drugs-a-new-step-in-fdas-comprehensive-approach-to-tobacco-and-nicotine> [https://perma.cc/S72V-TDXX]; The Food and Drug Administration's Approach To Evaluating Nicotine Replacement Therapies; Public Hearing; Request for Comments, 82 Fed. Reg. 56,759, 56,760 (Nov. 29, 2017); Press Release, Matthew L. Meyers, President, Campaign for Tobacco-Free Kids, *FDA Takes Welcome Step to Support Development of Products that Can Help More Smokers Quit* (Nov. 29, 2017), [https://www.tobaccofreekids.org/press-releases/2017\\_11\\_29\\_fda](https://www.tobaccofreekids.org/press-releases/2017_11_29_fda) [https://perma.cc/P28X-YVZK]. But see Stanton A. Glantz, *Is FDA Going to End Up Helping Prolong the Tobacco Epidemic? It's Beginning to*



Although it might not be necessary as a means to accelerate constructive switching from smoking to e-cigarette use if the proposed rule to minimize nicotine levels were implemented, this FDA-CDER measure would be a good complement to any aggressive anti-smoking measures because it would make a broader range of FDA-approved, safe-and-effective cessation aids available. For example, if menthol were banned for cigarettes and other smoked tobacco products, some smokers who might otherwise simply switch to using nonflavored cigarettes might switch to the FDA-approved e-cigarette NRTs, instead (e.g., because the sellers could aggressively market them with cessation claims when the menthol ban was going into effect or their doctor recommended it). For the same reason, it could be helpful to complement any menthol and other flavor ban with the proposed fast-track to all certain e-cigarette sellers to make relative-risk claims.

## CONCLUSION

There are, of course, other tobacco control rules or other actions that FDA could take to try to secure public health gains by moving smokers to e-cigarettes, NRTs, or other less harmful tobacco-nicotine products. This article has tried to focus on those that would work most powerfully and effectively, with as little risk of any collateral damage as possible. It has also focused on those interventions that would be most consistent with any possible FDA approach that wanted to minimize or avoid interfering with adult consumer choices (no matter how distorted they might be by tobacco-nicotine addiction). At the same time, it rejects the idea that it could possibly be appropriate for the protection of the public health or consistent with the goals and intent of the Tobacco Control Act for FDA either to do nothing significant or to implement only those measures entirely consistent with protecting adult choice, regardless of any related increased harms to youth or others or failures to protect them.

Any ethical or thoughtful members of the tobacco-nicotine industry (or the medical nicotine industry) should support (or at least not oppose) the recommendations outlined in this article. Besides securing large public health gains, implementing all or some of the options recommended here would help to move more smokers to e-cigarettes more quickly, which the major tobacco companies and the companies that sell only e-cigarettes both say they want. Moreover, this article's recommendations are designed to do that only by placing new restrictions or requirements on cigarettes and smoking or by making smoking alternatives more attractive or more readily marketed as smoking alternatives—without placing any new restrictions or requirements on e-cigarettes or their marketing and use. There is, consequently, no downside for those companies that manufacture or import only e-cigarettes to support all the proposed options, including the most aggressive anti-smoking measures. It would not only be ethical to do so, but fully consistent with their profit-maximizing goals. The big tobacco companies should similarly support all of the recommendations, despite the impact on the companies' cigarette and smoked tobacco product sales and overall bottom line. Supporting these recommendations would much more quickly create a tobacco industry and tobacco

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*Look That Way*, CTR. FOR TOBACCO CONTROL RESEARCH & EDUC. (Nov. 30, 2017), <https://tobacco.ucsf.edu/fda-going-end-helping-prolong-tobacco-epidemic-its-beginning-look-way> [https://perma.cc/2DGC-4U44].

products marketplace that would no longer be responsible for killing hundreds of thousands of people in the United States every year and would create a much more sustainable and defensible long-term future for the industry and its products.

Because of the large public health gains they would secure compared to almost anything else FDA is likely to try to do or be allowed to do, members of the tobacco control and public health communities should also strongly support all of the article's recommended options—whether they are e-cigarette-switching harm reduction enthusiasts or skeptics. All of the options described here would work effectively to secure significant net public health gains and prevent unnecessary harmful side effects, regardless of how much less harmful e-cigarettes currently on the market actually are compared to cigarettes, and regardless of how e-cigarettes are currently impacting cessation, initiation, relapse, dual use, and other tobacco-nicotine use behaviors.

Moreover, support from the public health community for FDA to establish carefully designed fast tracks for obtaining new product and MRTP orders would not only allow for the kind of constructive product innovation and MRTP claims that will benefit the public health rather than threaten it but could also prevent much more draconian Congressional fixes or related FDA practices to address the industry's related complaints.

Along the same lines, the tobacco industry is less likely to aggressively oppose efforts by the tobacco control and public health communities to prohibit menthol and other flavors if the proposed ban applies only to cigarettes and similarly smoked tobacco products—and those flavors that do not increase toxicity are still allowed for e-cigarettes and other noncombustible tobacco-nicotine products.

FDA should implement some or all of these options for all of the reasons that the public health community and the tobacco industry should support them. Doing so would not only be appropriate for the protection but fully consistent with FDA's statutory authorities and applicable constitutional constraints. It is also hard to imagine anything else FDA could do, instead, that would be more appropriate or beneficial for the health of this country—even if FDA (or the White House) also wanted to promote and protect adult consumer choice or maintain a healthy and sustainable tobacco-nicotine industry.

Moreover, close to a million people still die prematurely from smoking every two years, with millions more suffering from smoking-caused disability, disease, and other harms—creating enormous costs and other burdens for our economy; our federal, state, and local governments; and our society.<sup>128</sup> More aggressive and effective action by FDA to reduce those harms and costs is long overdue. But despite the extensive additional powers and authorities given FDA by the Tobacco Control Act, its Center for Tobacco Products continues to face substantial political and bureaucratic obstacles to getting anything done. Perhaps this article's recommendations and analysis—building on panel presentations from different public health and industry viewpoints—can support the development of a clear and strong consensus in the tobacco control and public health communities about what FDA should do, secure related support (or reduced opposition) from the tobacco-

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<sup>128</sup>See, e.g., CAMPAIGN FOR TOBACCO-FREE KIDS, *Toll of Tobacco in the United States of America* (Jan. 19, 2018), <https://www.tobaccofreekids.org/assets/factsheets/0072.pdf> [<https://perma.cc/QX9E-R8QC>] (citing additional references).

nicotine industry or its various members, thereby helping reduce the political and bureaucratic timidity that has blocked FDA in the past.