

INTRODUCING NEW USERS TO AN OLD POISON: THE TOBACCO INDUSTRY'S EFFORTS TO THWART THE FDA'S REGULATION OF E-CIGARETTES

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I. INTRODUCTION

It is likely that everyone reading this will have heard of E-Cigarettes (and vaping) and has at least a vague impression of claims made that they are less dangerous than traditional cigarettes. It is possible that this impression comes from the fact that they are advertised heavily in a way that cigarettes are not—at sporting events, through free coupons in the mail, and on the radio. They are also available in a multitude of flavors. That would not be possible unless the Food and Drug Administration (FDA) had decided that E-Cigarettes posed less of a threat to children's health than other tobacco products, would it?

But in fact, the FDA has made no such determination—quite the opposite. Under the FDA's authority to protect children from tobacco,¹ which is the only authority it has to regulate cigarettes at all, the Agency has already proposed a “deeming rule” to put E-Cigarettes in the same category as other tobacco products.² That is, a product perfectly legal for adults to purchase and enjoy,

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1. *What Are the New Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents?*, FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm208083.htm> (last updated Mar. 18, 2015) [hereinafter *Regulations to Protect Children*].

2. *Deeming—Extending Authorities To Additional Tobacco Products*, FOOD & DRUG ADMIN., <http://www.fda.gov/TobaccoProducts/Labeling/ucm388395.htm> (last updated Feb. 26, 2015) [hereinafter *Deeming—Extending Authorities*]; see also *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; Regulations on the Sale and Distribution of Tobacco Products and Requires Warning Statements for Tobacco Products*, 79 Fed. Reg. 23,142 (Apr. 25, 2014) (to be codified at 21 C.F.R. pts. 1100, 1140, and 1143) [hereinafter *Proposed Deeming Regulations*].

but not allowed to be marketed in ways attractive to children—and it is children who are being targeted here. Kids have heard anti-smoking warnings all their lives, but are led to believe that E-Cigarettes are different. A recent poll out of Utah found that “nearly one-third of teens who used E-Cigarettes in the past thirty days have never tried a cigarette.”³

So far, finalizing the rules is on hold because Congress is concerned that this form of regulation is the first step towards “banning” them,⁴ even though that has yet to come anywhere close to happening with regular cigarettes. At the close of its call for comments last July, the FDA had received seventy thousand comments.⁵ I have not read all of the comments quite yet, but it is a safe bet that none of them suggest that it is safe for kids to become addicted to nicotine, or that E-Cigarettes are any less addictive—because they are not.⁶ The nicotine in E-Cigarettes is the same nicotine—poison—as in any other tobacco products.⁷ Rather, the claims are about the relative dangers⁸ of E-

3. David Patton, *8 Facts About E-Cigarettes and Their Impact on Public Health*, UTAH POLICY (Feb. 16, 2015), <http://utahpolicy.com/index.php/features/policy-buzz/4823-8-facts-about-E-Cigarettes-and-their-impact-on-public-health>.

4. Steven Nelson, *House Leaders Rush to Defend E-Cigarettes From Possible FDA Bans*, U.S. NEWS & WORLD REP. (Dec. 3, 2014), <http://www.usnews.com/news/articles/2014/12/03/house-leaders-rush-to-defend-E-Cigarettes-from-possible-fda-bans>.

5. See Tim Devaney, *E-Cig Rules Draw More Than 70,000 Comments*, THE HILL (Aug. 7, 2014), <http://thehill.com/regulation/214631-e-cig-rules-draw-more-than-70000-comments>. The comment period was initially set to end July 9, 2014, but after strong pushback from various stakeholders, it was extended to August 8, 2014. See, e.g., *CASAA’S Second Request for Extension of FDA’s Comment Deadline*, CASAA (July 9, 2014), <http://blog.casaa.org/2014/07/casaas-second-request-for-extension-of.html> (highlighting the Consumer Advocates for Smoke-free Alternatives Association’s (CASAA) second request for an extension of the comment deadline); see also *E-Cig Update: FDA Extends Public Comment on New Proposed E-Cigarette Rules*, TECH TIMES (June 23, 2014), <http://www.techtimes.com/articles/9040/20140623/fda-extends-public-comment-proposed-e-cigarette-rule-proposals.htm>.

6. *DrugFacts: Electronic Cigarettes (E-Cigarettes)*, NAT’L INST. ON DRUG ABUSE, <http://www.drugabuse.gov/publications/drugfacts/electronic-cigarettes-E-Cigarettes> (last updated Sept. 2014).

7. *DrugFacts: Cigarettes and Other Tobacco Products*, NAT’L INST. ON DRUG ABUSE, <http://www.drugabuse.gov/publications/drugfacts/cigarettes-other-tobacco-products> (last updated Dec. 2014); see also Elizabeth Fernandez, *E-Cigarettes: Gateway to Nicotine Addiction for U.S. Teens, Says UCSF Study*, UCSF (Mar. 6, 2014), <http://cancer.ucsf.edu/news/2014/03/06/E-Cigarettes-gateway-to-nicotine-addiction-for-us-teens-says-ucsf-study.5186>; S. D. Wells, *E-Cigarettes—The Real ‘Gateway Drug’ for Youth That Leads to Smoking for Life*, NAT. NEWS (Apr. 17, 2014), http://www.naturalnews.com/044754_E-Cigarettes_gateway_drug_nicotine_addiction.html#.

8. Not all of the opposition to E-Cigarettes is based on public health issues, but rather, some of it may well be coming from states seeing to preserve tax revenue. See George Will, *Seeing Past E-Cigarettes’ Smokescreen*, THE COLUMBIAN (April 26, 2015), <http://www.columbian.com/news/2015/apr/26/seeing-past-e-cigarettes-smokescreen/> (“E-Cigarettes raise public-health issues, but also illustrate the unhealthy process by which public policy often is made. They

Cigarettes as opposed to tobacco or “conventional” cigarettes⁹ for people who already smoke.¹⁰ But this essay is about people who do not already smoke and are not yet addicted. And those people are very young. Almost everyone who becomes addicted started well before their eighteenth birthday.¹¹ The “peak years” for starting to smoke are between sixth and seventh grade,¹² and the next biggest group to whom E-Cigarettes are being marketed heavily is young adults.¹³

The decision by the world’s second and third largest tobacco companies to join forces in marketing E-Cigarettes and opposing regulation magnifies the threat to the health and safety of these young adults and children.¹⁴ This is because these companies have the resources to exploit the gaps in the law that allow them to engage in aggressive, youth-oriented marketing efforts, long prohibited for conventional cigarettes.¹⁵ Thus, while much of the debate surrounding the safety of E-Cigarettes emphasizes the absence of the considerable toxins produced by burning tobacco through conventional

illustrate a familiar phenomenon, the cooperation between ‘bootleggers and Baptists’, meaning merchants and moralists—those motivate by profits and those motivated by social improvement”).

9. A “conventional” or “tobacco-based” cigarette is a product that delivers nicotine by burning tobacco and producing smoke for the user to inhale. Anna Trtchounian et al., *Conventional and Electronic Cigarettes (e-cigarettes) Have Different Smoking Characteristics*, 12 NICOTINE & TOBACCO RES. 905, 905 (2010).

10. See, e.g., Letter from Lorillard Inc. to Div. of Dockets Mgmt., Food & Drug Admin. (Aug. 7, 2014) available at <http://www.regulations.gov/#!documentDetail;D=FDA-2014-N-0189-75711>, [hereinafter Lorillard Public Comment] (emphasizing that “[e]lectronic cigarettes present an unprecedented opportunity to move consumers of traditional tobacco products to lower-risk alternatives” [emphasis added]).

11. *Youth and Tobacco Use*, CTRS. FOR DISEASE CONTROL & PREVENTION http://www.cdc.gov/tobacco/data_statistics/fact_sheets/youth_data/tobacco_use/ (last updated Feb. 14, 2014) [hereinafter *Youth and Tobacco Use*].

12. CAMPAIGN FOR TOBACCO FREE KIDS PATH TO TOBACCO ADDICTION STARTS AT VERY YOUNG AGES, 1 (Jan. 6, 2015) available at <http://www.tobaccofreekids.org/research/factsheets/pdf/0127.pdf> [hereinafter PATH TO TOBACCO].

13. See Press Release, Durbin, Wasman, Harkin, Rockefeller & Members Of Congress: Report Shows E-Cigarette Marketing Campaign Lighting Up Among Young Users, (Apr. 14, 2014), available at <http://www.durbin.senate.gov/newsroom/press-releases/durbin-waxman-harkin-rockefeller-and-members-of-congress-report-shows-E-Cigarette-marketing-campaigns-lighting-up-among-young-users>.

14. See Michael J. De La Merced & Chad Bray, *To Compete With Altria, Reynolds American Is Buying Lorillard*, N.Y. TIMES (July 15, 2014), <http://dealbook.nytimes.com/2014/07/15/reynolds-american-to-buy-lorillard-for-27-4-billion/>.

15. See Laurie Halverson & Kathy Sheran, *Big Tobacco Lurks Behind E-Cigarettes*, STAR TRIBUNE (Apr. 10, 2014), <http://www.startribune.com/opinion/commentaries/254821801.html>.

cigarettes,¹⁶ there is not yet enough scientific evidence to assess the risks of nicotine use by children and young adults.¹⁷ Moreover, this evidence is difficult to develop because it would not be ethical to deliberately addict anyone to nicotine, let alone children or young adults.

There is considerable urgency to understand the interests of the tobacco industry in opposing regulation because the FDA's proposed "deeming" rule is currently considering regulations that would begin rigorous study of the health effects of E-Cigarettes on youth and, while these are underway, apply the marketing restrictions that apply to all tobacco products.¹⁸ In response, the tobacco industry is mounting a substantial counter campaign based on a series of highly misleading arguments that use the lack of data about the harms of directly ingesting nicotine as a basis for avoiding regulation.¹⁹

This essay seeks to identify the particular threat of E-Cigarettes to create life-long addicts and how the influence of the tobacco companies in Congress continues to hamper regulatory efforts to protect the public from the number one cause of preventable death in the U.S.²⁰ From a legal and public health perspective, it explicates the contradictions, evasions, and distortions being used to characterize E-Cigarettes as a safe alternative to conventional smoking and as an attractive and exciting activity for young adults.

II. A BRIEF BACKGROUND: WHAT ARE E-CIGARETTES?

It is unlikely that anyone under the age of twenty-six needs to be told that the topic under discussion here is "vaping," the practice of inhaling a nicotine solution²¹ using an E-Cigarette, a battery-powered, cigarette-shaped device.²²

16. Konstantinos E. Farsalinos & Riccardo Polosa, *Safety Evaluation and Risk Assessment of Electronic Cigarettes as Tobacco Cigarette Substitutes: A Systematic Review*, 5 THERAPEUTIC ADVANCES IN DRUG SAFETY 67, 74 (2014).

17. See, e.g., Janet Ralof, *Health Risks of E-Cigarette Emerge: Vaping Pollutes Lungs With Toxic Chemicals and May Even Make Antibiotic-Resistant Bacteria Harder To Kill*, SCIENCE NEWS (June, 3, 2014), <https://sciencenews.org/article/health-risks-e-cigarettes-emerge?mode=magazine&context=1835> (interviewing Dr. Stanton Glantz, Director of the Center for Tobacco Control Research and Education at the University of California, San Francisco).

18. See Proposed Deeming Regulations, *supra* note 2, at 23144, 23148.

19. See, e.g., Rick Jost, *Blue Haze: E-Cigarette Debate Heats Up*, DES MOINES REGISTER (June 1, 2014), <http://www.desmoinesregister.com/story/opinion/columnists/iowa-view/2014/06/01/E-CigaretteE-Cigarette-debate-heats/9830719/>; Dimitris Agrafiotis, *Smoking Bans Should Not Include E-Cigarette*, NOOGA (June 2, 2014), <http://nooga.com/166726/smoking-bans-should-not-include-e-cigarettes/>; see also Ann Robinson, *This Bickering Over E-Cigarettes Could Choke the Message*, THE GUARDIAN (June 2, 2014), <http://www.theguardian.com/commentisfree/2014/jun/02/e-cigarettes-dangers-benefits-stop-smoking>.

20. *Diseases and Death*, CTFRS FOR DISEASE CONTROL & PREVENTION, http://www.cdc.gov/tobacco/data_statistics/fact_sheets/fast_facts/ (last updated April 24, 2014).

21. See *What Is E-liquid?*, HOW TO VAPE, <http://www.howtovape.com/page7/page7.html> (last visited Feb. 2, 2015).

Thanks to the highly effective marketing of the industry,²³ vaping is already a popular activity on college campuses all over the country.²⁴ Unlike smokers who are increasingly banished to remote, outdoor locations, if allowed on campus at all, vaping is a highly social activity that takes place at parties and at vaping parlors that have popped up near campuses all over the country.²⁵

But the most important thing to know about E-Cigarettes is that they are, like tobacco-based cigarettes, primarily nicotine delivery devices and that nicotine is a highly addictive and dangerous substance.²⁶ It is also, for most people, a very effective and highly pleasurable drug. As one scientist explains, “[s]moking at once relaxes and stimulates the body. Seconds after inhalation nicotine reaches the brain and binds to receptor molecules on nerve cells, triggering the cells to release a flood of dopamine and other neurotransmitters that washes over pleasure centers. A few more puffs increase heart rate, raising alertness.”²⁷ However, “[t]he effect does not last long, [] spurring smokers to

22. Lowell Dale, *What Are Electronic Cigarettes? Are They Safer Than Conventional Cigarettes?*, MAYO CLINIC (Nov. 25, 2014), <http://www.mayoclinic.org/healthy-living/quit-smoking/expert-answers/electronic-cigarettes/faq-20057776>; see also *Nightly News: What Is an E-Cigarette?* (NBC television broadcast July 22, 2009), available at <http://www.nbcnews.com/video/nightly-news/32088369> (demonstrating characteristics of an e-cigarette and how it works).

23. See, e.g., *Blu Electronic Cigarettes* Stephen Dorf “*Rise Above Ashes*”, YOUTUBE (Jan. 22, 2014), <http://www.youtube.com/watch?v=sju3IijfVY> (demonstrating an example of e-cigarette marketing); see also Ceilia Shatzman, *Everything You Need to Know About E-Cigarettes*, TEEN VOGUE <http://www.teenvogue.com/beauty/health-fitness/2014-02/E-Cigarettes> (last visited June 26, 2014) (“makers of the new kind can try to get you interested however they want. From sponsorships at Bonnaroo to celebrity endorsement deals to fun flavors like cherry, vanilla, and peach, E-Cigarettes want to be your new best friend”).

24. See Shatzman, *supra* note 23; see also *Academic Minute: E-Cigs and Real Cigs*, INSIDE HIGHER EDUCATION (May 20, 2014), <https://www.insidehighered.com/audio/2014/05/20/e-cigs-and-real-cigs> (discussing a study correlating adolescent cigarette and e-cigarette use).

25. Shatzman, *supra* note 23; see also *Vaping On Campus-What You Need to Know!*, E CIG LOUNGE (Sept. 17, 2014), <http://eciglounge.themagicmist.com/e-cigarettes/vaping-at-university/>; but see *Emerging Issues in Campus Tobacco Policies*, TOBACCO-FREE CAMPUS INITIATIVE (June 28, 2014, 12:32 PM), <http://tobaccofreecampus.org/content/emerging-issues-campus-tobacco-policies>.

26. See *Harms of Smoking and Health Benefits of Quitting*, NAT’L CANCER INST., <http://www.cancer.gov/cancertopics/factsheet/Tobacco/cessation> (last updated Jan. 12, 2011); WORLD HEALTH ORG., *GENDER, WOMEN AND THE TOBACCO EPIDEMIC 137* (2010), available at http://www.who.int/tobacco/publications/gender/en_tfi_gender_women_addiction_nicotine.pdf (where Chapter 7 discusses nicotine addiction); see also Justin Stafford, *Opinion: Emphasis Needs to Be Placed on Treatment for Nicotine Addiction*, THE DAILY REVEILLE (Mar. 19, 2014), http://www.lsureveille.com/opinion/opinion-emphasis-needs-to-be-placed-on-treatment-for-nicotine/article_8de9ed9e-ae9f-11e3-b2e2-0017a43b2370.html; Angela Hilton, *Editorials: Stopping Smoking: the Importance of Nicotine Addiction*, 55 THORAX BMJ 256, 256 (Apr. 2000).

27. Alisa Opar, *Do Electronic Cigarettes Really Help Smokers Quit?*, SCL AM. (May 7, 2013), <http://www.scientificamerican.com/article/do-electronic-cigarettes-help-smokers-quit/> (“The effect does not last long, however, spurring smokers to light up again. Over time, the

light up again. Over time the number of nicotinic receptors increases—and the need to smoke again to reduce withdrawal symptoms such as irritability.²⁸

Almost all smokers want to quit, yet have a very difficult time quitting despite the availability of nicotine in gum or patches.²⁹ Preliminary evidence suggests that E-Cigarettes have a role to play in helping people who want to quit.³⁰ Scientists believe this is because the addiction is not to nicotine alone, but rather to the act of smoking.³¹

III. DISCUSSION

A. *Why Do E-Cigarettes Pose a Particular Threat to Young Adults?*

Because nicotine makes tobacco so addictive, it has always been in the interest of tobacco companies to get customers started as soon as possible. Marketing to youth took on a special importance, however, as smoking became less and less attractive to adults.³² The marketing of E-Cigarettes to young adults of college-age represents a significant and troubling potential to increase the number of life-long smokers. According to the Centers for Disease Control and Prevention (CDC), “[n]early 9 out of 10 smokers first tried cigarettes by age 18, and 99% first tried cigarettes by age 26.”³³ For this reason, efforts at

number of nicotinic receptors increases—and the need to smoke again to reduce withdrawal symptoms such as irritability”).

28. *Id.*

29. *See id.*

30. *See ‘Cool’ Factor Separates E-cigarettes from Nicotine Inhalers, Study Finds*, SCI. DAILY (June 3, 2014), <http://www.sciencedaily.com/releases/2014/06/140603135805.htm>; *see also* Jamie Brown et al., *Real-World Effectiveness of E-cigarettes When Used to Aid Smoking Cessation: A Cross-Sectional Population Study*, 109 *ADDICTION* 1531, 1532 (2014).

31. *See How to Quit Smoking: A Guide to Kicking the Habit for Good*, HELPGUIDE.ORG (Feb. 2015) <http://www.helpguide.org/articles/addiction/how-to-quit-smoking.htm> (“smoking tobacco is both a physical addiction and a psychological habit . . . the act of smoking is ingrained as a daily ritual . . . [and] may be an automatic response for you to smoke a cigarette with your morning coffee, while taking a break from work or school, or during your commute home at the end of a long day”); *see also* Brown, *supra* note 30, at 1537.

32. Beginning in 1964 with the Surgeon General’s report linking smoking to cancer, adult tobacco use has steadily declined, leading the tobacco industry to try and fill in the gaps by marketing to young people. “*Light*” *Tobacco Products Pose Heavy Health Risks*, FOOD & DRUG ADMIN <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm227360.htm> (Mar. 30, 2015) [hereinafter “*Light*” *Tobacco Products*].

33. *See Youth and Tobacco Use*, *supra* note 11. Once started, smoking continues to be an activity for young people. *See Health Effects of Smoking Among Young People*, WORLD HEALTH ORG., http://www.who.int/tobacco/research/youth/health_effects/en/ (last visited April 2, 2015). *See also Cigarettes Smoking in the United States*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/tobacco/campaign/tips/resources/data/cigarette-smoking-in-united-states.htm> (last updated Mar. 13, 2015) (noting 20.1% of adults aged 25–44 years smoke, but only 19.9% of adults aged 45–64 and 8.8% of adults 65 and older).

smoking prevention have focused on young people of high school-age and younger.³⁴ But if E-Cigarettes can attract new smokers in the eighteen to twenty-six age groups, they can substantially expand the pool of life-long nicotine addicts.

Because the demographics of smoking make youth such an important market tobacco companies, restricting their ability to do so has become the focus of government regulation.³⁵ What is so ironic about the current marketing campaigns for E-Cigarettes is that they are like some kind of “Mad Man” era throwback to exactly the kinds of highly effective, but now illegal techniques, such as adding flavoring,³⁶ seeking celebrity endorsements,³⁷ sponsoring music events,³⁸ and engaging in intense media advertising that now includes not just television, radio, movies, and print, but also relies heavily on social media.³⁹ Already, over the past three to five years, young adults have been subject to substantial amounts of E-Cigarette marketing.⁴⁰

Another concern expressed by those seeking to regulate E-Cigarettes is that conventional tobacco products can satisfy nicotine cravings just as easily

34. See generally PATH TO TOBACCO, *supra* note 12.

35. See *infra* Part III.B.

36. *Bubble Gum E-Liquid*, MY FREEDOM SMOKES, <https://www.myfreedomsmokes.com/old-timey-bubblegum-e-liquid.html> (last visited on Feb. 2, 2015) (also advertising the availability of drink, candy, dessert, and fruit flavors).

37. John Tozzi, *Nicotine Fix: Celebrities Pitching E-Cigarettes Make a Nightmare for Public Health Officials*, BLOOMBERG BUS. (June 30, 2014), <http://www.businessweek.com/articles/2014-06-30/lady-gagas-deal-to-promote-blu-ecigs-is-a-public-health-nightmare>.

38. *Blu eCigs Covers Your Butt at Bonnaroo Music & Arts Festival*, PR NEWSWIRE (June 10, 2013), <http://www.prnewswire.com/news-releases/blu-ecigs-covers-your-butt-at-bonnaroo-music—arts-festival-210813791.html>.

39. *7 Ways E-Cigarette Companies Are Copying Big Tobacco’s Playbook*, CAMPAIGN FOR TOBACCO-FREE KIDS (Oct. 2, 2013), http://www.tobaccofreekids.org/tobacco_unfiltered/post/2013_10_02_ecigarettes. See, e.g., *Teens’ Exposure to E-Cigarette Ads Skyrockets*, N.Y. DAILY NEWS (June 2, 2014), <http://www.nydailynews.com/life-style/health/teens-exposure-e-cig-ads-soars-article-1.1814112>; Kristen East, *E-Cigarette Market Boom Targets Youth*, WASH. TIMES (June 2, 2014), <http://www.washingtontimes.com/news/2014/jun/2/e-cigarette-market-boom-targets-youth/?page=all>; see also Jennifer C. Duke et al., *Exposure to Electronic Cigarette Television Advertisements Among Young and Young Adults*, 134 PEDIATRICS e29, e29 (2014).

40. Results from a recent analysis of National Youth Tobacco Surveys (NYTS), conducted by the CDC and FDA, suggest the aggressive E-Cigarette marketing is paying off and for the first time in NYTS, current E-Cigarette use surpassed current use of every other tobacco product, including cigarettes. Rene A. Arrazola et al., *Tobacco Use Among Middle and High School Students—United States, 2011-2014*, 64 MORBIDITY & MORTALITY WKLY. REP. 373, 380 (April 17, 2015). See also *Use of E-Cigarettes Triples Among U.S. Teens*, NPR (April 16, 2015), <http://www.npr.org/blogs/health/2015/04/16/400144741/use-of-e-cigarettes-triples-among-u-s-teens>; Beth Greenwood, *The Risks of Youth E-Cig Use*, DAILYRX (April 23, 2015), <http://www.dailyrx.com/electronic-cigarettes-may-pose-risks-children-and-adolescents>.

as E-Cigarettes.⁴¹ Although this is sometimes mocked as an out-of-touch “gateway” argument, in fact, this is a misunderstanding.⁴² Unlike the process in which those who first abuse prescription drugs are more prone to seek out illegal drugs,⁴³ here the individual who becomes addicted to nicotine can get it in an array of easily available, legal products including cigarettes, cigars, pipe tobacco, and chewing tobacco.⁴⁴

B. *Who Regulates E-Cigarettes*

One of the reasons why it can be difficult to follow the arguments of those opposed to regulation of E-Cigarettes is because they often conflate the regulations regarding where smoking is permitted with regulations covering how E-Cigarettes can be sold and marketed. Yet, these invoke very different sources of law. Calls to stop the “ban” on E-Cigarettes refer to the location restrictions imposed by state and city governments, as well as private schools, offices, and shopping centers. These are based on concerns about exposure to “second-hand” smoke and are matters of state, city, and local concern and thus, are not under the jurisdiction of the FDA.⁴⁵ Moreover, E-Cigarette advocates have been spectacularly unsuccessful in achieving exemptions from “no smoking” areas. As human resources law expert Jay Hux explains, “These

41. *Nicotine Addiction and Your Health*, U.S. DEP’T OF HEALTH & HUMAN SERVS, <http://betobaccofree.hhs.gov/health-effects/nicotine-health/> (last visited Apr. 1, 2015); see also David Heitz, *A New Warning About E-Cigarettes and Heart Attack Risk*, HEALTHLINE NEWS (Dec. 15, 2013), <http://www.healthline.com/health-news/heart-e-cigarettes-and-heart-attack-risk-121513>; see also David Heitz, *A New Warning About E-Cigarettes and Heart Attack Risk*, HEALTHLINE NEWS (Dec. 15, 2013), <http://www.healthline.com/health-news/heart-e-cigarettes-and-heart-attack-risk-121513>; *Health Risks of Waterpipes, Smokeless Tobacco, and E-Cigarettes*, AM. SOC’Y OF CLINICAL ONCOLOGY (Jan. 1, 2015), <http://www.cancer.net/navigating-cancer-care/prevention-and-healthy-living/tobacco-use/health-risks-E-Cigarettes-smokeless-tobacco-and-waterpipes>.

42. Eric R. Kandel & Denise B. Kandel, *A Molecular Basis for Nicotine as a Gateway Drug*, 370 NEW ENG. J. MED. 932, 942 (2014) (“whether e-cigarettes will prove to be a gateway to the use of combustible cigarettes and illicit drugs is uncertain, but it is clearly a possibility. Nicotine acts as a gateway drug on the brain, and this effect is likely to occur whether the exposure is from smoking tobacco, passive tobacco smoke, or e-cigarettes”).

43. *Abuse of Prescription Pain Medications Risks Heroine Use*, NAT’L INST. ON DRUG ABUSE, <http://www.drugabuse.gov/related-topics/trends-statistics/infographics/abuse-prescription-pain-medications-risks-heroin-use> (last updated Jan. 2014).

44. *Tobacco Products*, ALCOHOL & TOBACCO TAX & TRADE BUREAU, <http://www.ttb.gov/tobacco/tobacco-products.shtml> (last updated Sept. 4, 2012).

45. Many states and municipalities have laws that regulate where use of E-Cigarettes is prohibited. See AMS. FOR NONSMOKERS’ RIGHTS, U.S. STATE AND LOCAL LAWS REGULATING USE OF ELECTRONIC CIGARETTES (Jan. 2015), available at <http://www.no-smoke.org/pdf/ecigsaws.pdf> (outlining (1) state laws restricting E-Cigarette use in 100% smoke-free venues, (2) state laws regulating E-Cigarette use in other venues, and (3) local laws restricting E-Cigarette use).

devices contain nicotine as well as detectable levels of known carcinogens and toxic chemicals, and prohibiting their use in the workplace eliminates the risk of any complaints from nonsmoking co-workers, customers or others annoyed by the vapors.”⁴⁶

The tobacco industry has been very successful in limiting the scope of the FDA’s authority.⁴⁷ Although the considerable health risks and addictive properties of tobacco use have been known since at least the late 1960s, the FDA lacked authority to study, let alone regulate, tobacco until the passing of the Family Smoking Prevention and Tobacco Control Act of 2009 (FSPTCA).⁴⁸ Far from giving the FDA full oversight over tobacco, however, the FSPTCA severely limited its jurisdiction to protecting children.⁴⁹ The FDA is specifically prohibited from banning cigarettes as an unsafe product.⁵⁰ Nevertheless, the FDA acted quickly to limit marketing and advertising practices that made smoking attractive to children. This included steps like banning the flavoring of tobacco and prohibiting the individual sale of cigarettes.⁵¹ What the FDA seeks to do now is to regulate E-Cigarettes as it does other tobacco products.⁵²

The tobacco industry also had considerable success in forestalling FDA regulation of E-Cigarettes when they were being marketed primarily to adults interested in quitting smoking.⁵³ E-Cigarette companies are taking full

46. Joanne Deschenaux, *Should Employers Ban E-Cigarettes in the Workplace?*, SOC’Y FOR HUMAN RESOURCE MGMT. (Feb. 21, 2014), <http://www.shrm.org/legalissues/stateandlocalresources/pages/should-employers-ban-e-cigarettes.aspx>.

47. Sharon Milberger et al., *Tobacco Manufacturers’ Defense Against Plaintiffs’ Claims of Cancer Causation: Throwing Mud at the Wall and Hoping Some of It Will Stick*, 15 TOBACCO CONTROL iv17, iv17 (Dec. 2006) (examining thirty-four personal injury lawsuits against tobacco manufacturers and concluding that the defendants were ultimately saying “Yes, smoking causes lung cancer, but not in people who sue us”).

48. 21 U.S.C. § 387 (2009); see generally Bryan M. Haynes, *Understanding the Tobacco Control Act and FDA Investigative Process*, in INSIDE THE MINDS: RECENT DEVELOPMENTS IN FOOD & DRUG LAW—LEADING LAWYERS ON DEALING WITH INCREASED ENFORCEMENT, KEEPING UP-TO-DATE WITH FDA REQUIREMENTS, AND DEVELOPING COMPLIANCE PRACTICES (2013); Michael Freiberg, *Options for State and Local Governments to Regulate Non-cigarette Tobacco Products*, 21 ANNALS HEALTH L. 407, 409 (2012).

49. Margaret Gilhooley, *Tobacco Unregulated: Why the FDA Failed, and What To Do Now*, 111 YALE L.J. 1179, 1190 (2002); *Regulations to Protect Children*, supra note 1.

50. See generally Rachael Rettner, *Should Cigarettes Be Illegal?*, LIVE SCIENCE (Jan. 24, 2013), <http://www.livescience.com/26580-cigarettes-illegal.html>.

51. *Youth & Tobacco*, FOOD & DRUG ADMIN., <http://www.fda.gov/TobaccoProducts/ProtectingKidsfromTobacco/> (last updated Feb. 27, 2015).

52. See *Deeming—Extending Authorities*, supra note 2.

53. Karen Kaplan, *Electronic Cigarettes Help Smokers Quit in ‘Real World,’ Study Finds*, L.A. TIMES (May 20, 2014), <http://www.latimes.com/science/sciencenow/la-sci-sn-electronic-cigarettes-to-quit-smoking-20140520-story.html> (explaining that the study looks at the

advantage of its current exclusion from the FSPTCA by engaging in activities such as offering coupons and advertising on radio and television.⁵⁴

In March of 2014, however, Congress looked at E-Cigarettes differently and categorized them as tobacco products, thus, putting them under the jurisdiction of the FDA.⁵⁵ Once E-Cigarettes came under its jurisdiction through the new regulation, the FDA immediately included them in draft rules intended to broaden the definition of a “tobacco product” to include other innovative delivery systems, such as mini cigars, that were being marketed to children, but were exempt from regulation.⁵⁶

This gave the FDA the ability to study the effects of E-Cigarettes on children and young adults, as well as to regulate the manufacturing and marketing of these devices. But just because the FDA now has this power does not mean that they will be able to use it.

C. *What Arguments Are the Tobacco Companies Using to Oppose Regulation?*

The purpose of this essay is to draw attention to how the actions by the tobacco industry to acquire an industry that threatened to put them out of business, brings with it a level of political power that endangers the FDA’s ability to use its new authority to effectively protect children from a lifetime of addiction.⁵⁷ The argument most frequently used in opposition to regulating E-Cigarettes is the positive role they can play in helping those already addicted to conventional tobacco products.⁵⁸ E-Cigarettes have turned out to have

effectiveness of e-cigs in smoking cessation, but pointing out that big Tobacco is funding the study).

54. *World Travel and E-cigs*, EVER SMOKE (June 18, 2014), <http://www.learn.eversmoke.com/e-cig-world-regulations.html>.

55. See Press Release, Food & Drug Admin., FDA Proposes to Extend its Tobacco Authority to Additional Tobacco Products, Including E-Cigarettes (Apr. 24, 2014), available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm394667.htm>; see also *Deeming—Extending Authorities*, *supra* note 2.

56. For example, in a list the FDA describes as “Tobacco in its many forms” it now seeks to apply a uniform set of restrictions on marketing and access to children. *Recognize Tobacco in its Many Forms*, FOOD & DRUG ADMIN., <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm392735.htm> (last updated Feb. 13, 2015).

57. See Halverson & Sheran, *supra* note 15; Kevin Roose, *E-Cigarettes Are Pulling an Uber on the Tobacco Industry*, NY MAG. (July 14, 2014), <http://nymag.com/daily/intelligencer/2014/07/E-CigaretteE-Cigarettes-are-pulling-an-uber.html> (suggesting that allowing e-cigarettes to be marketed differently than traditional cigarettes is the same “as if Uber were allowed to put up huge billboards proclaiming its greatness anywhere it wanted to, and yellow cab operators were legally prohibited from doing anything to promote their cars”). See also Matthew Bandyk, *Big Tobacco Stubs Out E-Cigarette Competitors*, DAILY CALLER (Apr. 6, 2013), <http://dailycaller.com/2013/04/06/big-tobacco-stubs-out-e-cigarette-competitors/>.

58. Lorillard Public Comment, *supra* note 10, at 61-67, Appendix 13.

characteristics that make them highly attractive to smokers in a way that other smoking cessation devices are not.⁵⁹ For reasons not yet fully understood, the process of inhaling heated nicotine liquid satisfies smokers' cravings as much as a tobacco-based cigarette.⁶⁰

The key weapon in the tobacco industry's fight against regulation was its successful efforts to refute evidence of the full extent of the product's dangers and addictive properties.⁶¹ One of the industry's most successful recent tactics in limiting the FDA's ability to interfere with its tobacco marketing was to claim protection under the First Amendment to the federal Constitution.⁶² It is using the identical tactic of cultivating young adults' inherent suspicion of efforts to thwart their independence by marketing E-Cigarettes as a fun and safe alternative to smoking. It is thus able to characterize efforts to apply the same kind of restrictions to E-Smoking that innovative science used to produce E-Cigarettes. It is exactly the same tactic that resulted in the industry's ban on advertising cigarettes with special filters as "safer."⁶³

The tobacco industry is also disputing the scientific evidence by claiming it is inconclusive as to the extent of E-Cigarette's dangers both to those who use them directly and to those exposed to vapor.⁶⁴ It has a track record of funding

59. See Edward F. Domino et al., *Denicotinized Versus Average Nicotine Tobacco Cigarette Smoking Differentially Releases Striatal Dopamine*, 15 NICOTINE & TOBACCO RES. 11 (Jan. 2013), available at <http://ntr.oxfordjournals.org/content/15/1/11.full.pdf+html>; Sibylla Chipaziw, *E-Cigarettes May Not Curb Nicotine Addiction as Believed*, GUARDIAN LIBERTY VOICE (May 30, 2014), <http://guardianlv.com/2014/05/E-Cigarettes-may-not-curb-nicotine-addiction-as-believed-2/> ("these vapor gadgets have great appeal compared to normal cigarettes . . . many flavors . . . sleek to the eye . . . discrete in smell . . . [and] there is also a chance to save money in the long run [] if one uses cartridges of good quality"); Amanda M. Barbeau et al., *Perceived Efficacy of E-Cigarettes Versus Nicotine Replacement Therapy Among Successful E-Cigarette Users: A Qualitative Approach*, 8 ADDICTION SCI. & CLINICAL PRAC. at 1, 5 (Mar. 5, 2013) (when asked how E-Cigarettes compare with traditional nicotine replacement therapies, one participant explained, "it's part the act . . . part the way it's delivered . . . the delivery [of other therapies] doesn't work, that's what I learned. Plain and simple").

60. However, this claim is subject to dispute. See Opar, *supra* note 27.

61. Lorillard Public Comment, *supra* note 10, at 14-18.

62. Eric N. Lindblom, *Effectively Regulating E-Cigarettes and Their Advertising—and the First Amendment* 70 FOOD & DRUG L. J. 57, 81-91 (2015). The First Amendment protects against government restrictions on speech, including commercial speech, such as advertising and other communications to sell a product or service. *Id.* at 59, 81-91.

63. As of a result of the FSPTCA, tobacco manufacturers are banned from using the terms "light," "mild," or "low" in product labeling and advertisements. "Light" Tobacco Products, *supra* note 32. The ban was based in part on studies demonstrating there had been no reduction in risk from such products and they may actually increase the risk of tobacco use. *Id.*

64. Lorillard Public Comment, *supra* note 10, at 14-18. However, other studies have found free radical toxins in E-Cigarette vapor and that exposure increased susceptibility to respiratory infections. Thomas E. Sussan et al., *Exposure to Electronic Cigarettes Impairs Pulmonary Anti-Bacterial and Anti-Viral Defenses in a Mouse Model*, 10 PLOS ONE, Feb. 4, 2015; see also Vaping May Not Be As Safe As Smokers Think, Research Suggests, THE GUARDIAN, (Feb. 4,

research that produces inconclusive, if not positive, results.⁶⁵ The effect is to shift considerable cost onto the FDA to fund its own research.

IV. CONCLUSION

There is nothing new in the struggle between public health advocates and those seeking to market addictive, tobacco-based products. What is new, however, is that until now, strong regulatory barriers had prevented the marketing of these products to children. The sharp drop in the number of smokers in the U.S. since those bans were put in place shows that while not perfect, they were effective. Therefore, the rise in U.S. children and adults who are taking up a newly designed nicotine delivery system, E-Cigarettes, in response to marketing campaigns targeted directly at them, must be of considerable concern. It is not helpful to let worn-out arguments about personal liberty impede the development of regulations intended to prevent children from becoming addicted to nicotine. What is helpful, is to distinguish between the issues of E-Cigarettes as a product helpful to those already addicted to nicotine from those relevant to protecting new users, children, and adults, from becoming addicted. Lack of scientific data about the ill effects of nicotine delivered through vapor as opposed to delivered through flames, is not the same thing as a full understanding of the risks of vaping to children and adults not already addicted. Until more is known about the risks of permanent addiction to E-Cigarettes, both in comparison to the addiction to burning tobacco and in comparison to not using tobacco at all, it is reckless to proceed as if these risks do not exist. It is therefore distressing to see children and young adults targeted with exactly the kind of youth-oriented marketing techniques, against which the FSPTCA is intended to provide protection.

2015), <http://www.theguardian.com/society/2015/feb/04/e-cigarettes-toxic-chemicals-research-finds-lung-damage>.

65. See, Kaplan, *supra* 53.