

PATERNALISM AS A JUSTIFICATION FOR FEDERALLY REGULATING ADVERTISING E-CIGARETTES TO CHILDREN

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ABSTRACT

How the federal government should regulate e-cigarette advertising targeted towards children generates unique jurisprudential questions regarding the potential for infringement on children's liberty and autonomy. While it would seem unethical to restrict e-cigarette advertisements to adults, children are in a different category because they lack the maturity and decision-making skills to discern advertising falsehoods from reality. This is especially problematic with e-cigarette advertisements because long-term public health outcomes for children are at stake. This Note assesses the historical and modern regulatory measures used by Congress, the FDA, and the judiciary to regulate how the tobacco industry may advertise to children. Then, using John Stuart Mill's harm principle and idea of utilitarianism and Gerald Dworkin's theory of paternalism, this Note postulates how the federal government might appropriately regulate advertising e-cigarette products to children. Finally, this Note proposes a two-step paternalistic policy for how Congress and the FDA can effectively regulate e-cigarette advertisements targeted to children and prevent further harm to America's youth.

INTRODUCTION

Regulating e-cigarette¹ advertising targeted towards children² generates unique jurisprudential questions surrounding government infringement on

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1. "E-cigarettes," also known as vaping devices, e-vaporizers, or electronic nicotine delivery systems, are battery-operated devices that are used to inhale an aerosol that typically contains nicotine, flavorings, and other chemicals. *Vaping Devices (Electronic Cigarettes)*, NATIONAL INSTITUTE ON DRUG ABUSE (January 2020), <https://www.drugabuse.gov/publications/drugfacts/vaping-devices-electronic-cigarettes> [<https://perma.cc/4LZA-5BMV>].

2. "Children," for the purposes of this Note, are defined as minors under the age of eighteen. "Teenagers" and "teens" are included in this definition.

children’s liberty and autonomy.³ Can we as a society claim to strive to protect our children when we allow a powerful industry to aggressively advertise to children,⁴ preying upon their naiveté? Children are therefore different than adults because they are inherently more vulnerable as emotionally and intellectually immature members of society.⁵

Tobacco companies are prohibited from certain forms of advertising for traditional tobacco products.⁶ A primary example is advertising tobacco use for children. Under a theory of legal paternalism,⁷ the advertising rules for

3. This Note subscribes to Gerald Dworkin’s jurisprudential distinction between liberty and autonomy. Liberty is essentially a person’s ability to do what she wants, and to retain options which are unrestricted by the actions of others. GERALD DWORKIN, *THE THEORY AND PRACTICE OF AUTONOMY* 14 (1988) [hereinafter *THEORY AND PRACTICE*]. Autonomy, on the other hand, is a “second-order capacity” of people to ascertain their “first-order preferences, desires, wishes” to try to alter these sets of preferences relevant to their higher-order values. *Id.*, at 20. Additionally, this Note defines “children” primarily as adolescents and teenagers ages 13-17, using the term “children” interchangeably with “teens” or “adolescents”. However, tobacco companies likely intend to target children below the thirteen to seventeen age range as well. See Jennifer C. Duke, et al., *Exposure to Electronic Cigarette Television Advertisements Among Youth and Young Adults*, 134 *PEDIATRICS* 1 (July 2014), <https://pediatrics.aappublications.org/content/pediatrics/134/1/e29.full.pdf> [<https://perma.cc/M9DH-UQE6>] (explaining the results of a study showing there was a dramatic increase in the reach and frequency of e-cigarette television ads targeted to youth aged 12 to 17).

4. According to the National Institute on Drug Abuse, [a]mong middle school students, 52.8 percent are exposed to retail ads, 35.8 percent to [I]nternet ads, 34.1 percent to TV and movie ads, and 25.0 percent to newspaper and magazine ads. Among high school students, 56.3 percent are exposed to retail ads, 42.9 percent to internet ads, 38.4 percent to TV and movie ads, and 34.6 percent to newspaper and magazine ads. NAT’L INST. ON DRUG ABUSE, NAT’L INSTS. OF HEALTH, U.S. DEP’T OF HEALTH AND HUM. SERVS., *TEENS AND E-CIGARETTES*, www.drugabuse.gov/related-topics/trends-statistics/infographics/teens-e-cigarettes [<https://perma.cc/5EMA-JS7E>].

5. See Stanford Children’s Health, *infra* note 15.

6. Today, different marketing restrictions that apply to cigarettes apply to e-cigarette advertising. *Action needed on e-cigarettes*, TRUTH INITIATIVE (July 2018), <https://truthinitiative.org/news/action-needed-e-cigarettes> [<https://perma.cc/PG99-HTUP>]. Briefly outlining historical regulation on advertising tobacco to children, the Public Health Cigarette Smoking Act of 1969 required a package warning label from the Surgeon General and prohibited cigarette advertising on television and radio, with authority to the Department of Justice. Public Health Cigarette Smoking Act, Pub. L. No. 91-222, 84 Stat. 87 (1970). The Synar Amendment to the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) Reorganization Act of 1992 further restricted youths’ access to tobacco by mandating that all states and territories legally prohibit selling tobacco to minors. Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act, Pub. L. No. 102-321, 106 Stat. 323 (1992). Eventually, the 1998 Master Settlement Agreement between major tobacco companies, forty-six U.S. states, the District of Columbia and five U.S. territories transformed tobacco control by prohibiting tobacco advertising that targets minors under the age of 18. *Master Settlement Agreement*, TRUTH INITIATIVE (last visited Feb. 23, 2020, 2:40 PM), <https://truthinitiative.org/who-we-are/our-history/master-settlement-agreement> [<https://perma.cc/VT2V-AKZ2>].

7. In this Note, I apply soft paternalism as opposed to hard paternalism to the issue of regulating advertising e-cigarettes to children. According to Thaddeus Pope, as published in the *Georgia State Law Review*, the distinction is important yet not often discerned. Pope delineates the difference between the

e-cigarettes should be no different. This is especially true when we have proof that the most prevalent e-cigarette advertising campaigns lead to more teens picking up vaping.⁸

This Note posits that it is unethical to allow the tobacco industry to advertise and explicitly market e-cigarettes to children, because children lack the ability to differentiate falsehoods in advertising from reality. This issue is particularly problematic in cigarette advertising, where negative health outcomes are at stake. In cigarette advertising, the fact that cigarettes contain nicotine is common knowledge for adults. E-cigarettes, however, when targeted at children, highlight the dangers with advertising because data reveals that most adolescents are unaware that e-cigarettes contain nicotine.⁹

Using John Stuart Mill's harm principle¹⁰ as a guide, a Millian theory of legal paternalism prohibits allowing the tobacco industry to market e-cigarettes to children. Mill's notion of utilitarianism also reveals how the government might ethically curtail advertising e-cigarettes to children. Utility, specifically, is fundamentally based upon the best interests of humankind as a collective.¹¹ It is conceptually related to Mill's harm principle because both concern how the government can identify where it is

two by asserting that "soft paternalism" is morally uncontroversial because it "restrict[s] a subject's self-regarding conduct where the conduct is *not* substantially voluntary,"[emphasis in original] and that "hard paternalism" is morally controversial as it involves "restricting a subject's self-regarding conduct where the conduct is substantially voluntary." Thaddeus Mason Pope, *Counting the Dragon's Teeth and Claws: The Definition of Hard Paternalism*, 20 GA. ST. U.L. REV. 659, 661 (2004) [hereinafter Pope Dragon]. Both soft and hard paternalism are "liberty-limiting principles," and Pope explains that the champion of any state action employing hard or soft paternalism will bear the burden of proving that action's moral justifiability. *Id.* at 663-64.

8. See Meghan E. Morean et al., *High School Students' Use of Electronic Cigarettes to Vaporize Cannabis*, 136.4 PEDIATRICS 611-616 (2015) (last visited Sept. 7, 2018). E-Cigarette use is on the rise, and "the 2014 National Youth Tobacco Survey indicated that past-month e-cigarette use tripled among [high school] students from 4.5% in 2013 to 13.4% in 2014, surpassing all other tobacco use, including traditional cigarettes (9.2%);" see also Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, Div. A, § 2, 123 Stat. 1776 (2009). "(23) Children are more influenced by tobacco marketing than adults: more than 80 percent of youth smoke three heavily marketed brands, while only 54 percent of adults, 26 and older, smoke these same brands."

9. Chris Crawford, *Rise of 'JUULing' Among Youth Sparks Sharp Response AAFP Home*, AM. ACAD. OF FAM. PHYSICIANS (last visited Aug. 6, 2018, 5:09 PM), www.aafp.org/news/health-of-the-public/20180806juul.html [<https://perma.cc/VD4V-T8PK>]. 63% of JUUL users between the ages of 15-24 did not know the device contains any nicotine at all. *Id.* The unfortunate implication is that users in this age range are unaware they are inhaling an addictive chemical. *Id.* JUUL brand e-cigarettes, specifically, are also engineered to mimic the experience of inhaling a conventional cigarette. JUUL e-cigarettes use a different type of nicotine, called nicotine salts, that seem to approximate the mouth feel of cigarettes better than other e-cigarette brands. *Id.*

10. JOHN STUART MILL, ON LIBERTY (David Bromwich et al. eds., 2003) [hereinafter ON LIBERTY].

11. See *id.*

permissible to “authorize the subjection of individual spontaneity to external control.”¹² Like Mill’s harm principle, utility states that only the correct reasons will justify government intrusion on the individual.¹³ Building on Mill, regulating the advertising of e-cigarettes to children passes Gerald Dworkin’s three-prong threshold guide on limits to legitimate paternalism.¹⁴ We treat children differently than adults because they are less mentally developed and lack reason. The rational part of their brains has not yet developed¹⁵ and will not until around age twenty-five.¹⁶

We should employ legal paternalism and strictly regulate e-cigarette advertising to children. If we as a society remain bystanders to the tobacco industry’s moral turpitude in preying upon children’s lack of mental development to increase their profits, we too are culpable. This Note argues that employing Gerald Dworkin’s theory of government paternalism to prohibit e-cigarette manufacturers from advertising their products to children is both appropriate and justified under Mill’s harm principle and his idea of utility.¹⁷ This Note begins in Parts I and II with a brief outline of the regulatory history of advertising within the tobacco industry, then summarizes modern policies and assesses the current landscape of the tobacco industry’s practice of marketing e-cigarettes to children. Part III delves into an analysis tethered to Mill’s harm principle from *On Liberty* and Mill’s notion of utilitarianism. Part IV explores Dworkin’s interpretations of paternalism. Finally, in Part V, this Note proposes a policy recommendation for how Congress and the FDA can work together to make the same prohibitions against advertising traditional cigarettes to children apply to e-cigarettes, and then legislate an outright ban on marketing e-cigarettes to children.

Ultimately, Dworkin’s and Mill’s liberal theory philosophies are deeply entwined. Mill’s principles of harm reduction and self-protection complement Dworkin’s theory of paternalism contemplating how one group

12. *See id.* at 81.

13. *Id.* As is later discussed in Part III of this Note, Mill provides that, “utility in the largest sense [is] grounded on the permanent interests of man as a progressive being.” *Id.*

14. Gerald Dworkin, *Paternalism*, 56 THE MONIST 64-84 (1972).

15. Stanford Children’s Health, *Understanding the Teen Brain*, LUCILE PACKARD FOUNDATION, www.stanfordchildrens.org/en/topic/default?id=understanding-the-teen-brain-1-3051

[<https://perma.cc/98GR-2FF7>] (last visited Jan. 3, 2019). It is not until one has reached adulthood that we begin thinking and making decisions using the rational parts of our brain. The Lucile Packard Children’s Hospital at Stanford University cites research that explains, “[a]dults think with the prefrontal cortex of the brain, the brain’s rational part... [but] [t]eens process information with the amygdala. This is the emotional part.” *Id.*

16. *Id.*

17. *See ON LIBERTY*, *supra* note 10, at 80-81.

can approach restricting the liberty, freedom, or autonomy of an individual and still be morally justified. This is a policy proposal that conforms to both Mill's harm principle and Dworkin's philosophy on paternalism.

I. LEGAL AND REGULATORY HISTORY

The tobacco industry has a long and complex regulatory history that has spurred today's challenges by e-cigarette companies against the current government-imposed status of e-cigarettes as tobacco products. Congress has enacted two controlling federal statutes, the Federal Food, Drug, and Cosmetic Act¹⁸ ("FD&C Act") and the Family Smoking Prevention and Tobacco Control Act of 2009¹⁹ (the "Tobacco Act"), which direct federal government regulation of tobacco and tobacco products today. Notably, the FDA never tried regulating recreational tobacco products prior to 1996,²⁰ when the FDA widened its scope of regulatory authority by asserting that nicotine is a drug which affects the function of the body under the definition of a "drug" as listed in 21 U.S.C. § 321(g)(1)(C),²¹ and cigarettes and smokeless tobacco therefore fall under the FDA's purview.²²

A. Tobacco Regulatory History

In 2000, the Supreme Court decided in *FDA v. Brown & Williamson Tobacco Corp.* that the FD&C Act does not authorize the FDA to regulate tobacco products.²³ A group of tobacco manufacturers, retailers, and advertisers had challenged specific FDA regulations which included access regulations prohibiting the sale of cigarettes or smokeless tobacco to persons younger than eighteen; prohibiting distribution of free samples; and prohibiting sales through self-service displays and vending machines except in adult-only locations.²⁴ Congress passed the Tobacco Act in 2009 to

18. Federal Food, Drug, and Cosmetic Act, Pub. L. No. 366-717, 52 Stat. 1040 (1938). Enacted in 1938, the original purpose of the FD&C was "[t]o prohibit the movement in interstate commerce of adulterated and misbranded food, drugs, devices, and cosmetics, and for other purposes."

19. Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009). The primary purpose of the Tobacco Act, enacted by the Obama Administration, was "[t]o protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products."

20. See *Sottera, Inc. v. FDA*, 627 F.3d 891, 894 (D.C. Cir. 2010).

21. 21 U.S.C. § 321 (LEXIS).

22. *Sottera*, 627 F.3d.

23. *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 160-61 (2000).

24. *Id.* at 128.

address the regulatory gap left open in *Brown & Williamson*.²⁵ The Tobacco Act provided a broader definition of tobacco products and includes all consumption products derived from tobacco.²⁶ One of Congress's primary purposes for the Tobacco Act was to strengthen regulation surrounding advertising tobacco products to children,²⁷ recognizing that they lack the same decision-making skills as adults.²⁸ Naturally, broadening the definition of "tobacco products" in the Tobacco Act has led to resistance from the tobacco industry on the stricter government regulation of their products.²⁹

B. E-Cigarette Regulatory History

E-cigarettes entered the United States in 2004 as an alternative product to combustible cigarettes.³⁰ Using a heated atomizer, e-cigarette users employ a "vaping" technique that consists of inhaling vaporized nicotine.³¹ Because conventional cigarettes are combustible cigarettes that burn the tobacco leaf,³² many believe that e-cigarettes are a healthier alternative. In

25. *Sottera*, 627 F.3d at 894.

26. *Id.* Specifically, the Tobacco Act defines tobacco products to mean "any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product..." and excludes items that qualify as drugs under the FD&C's drug provision. 21 U.S.C.S. § 321(rr)(1)-(2) (LEXIS).

27. The Tobacco Act also banned flavors in cigarettes except for menthol in order to curb youth appeal. *See* The Tobacco Act, *supra* note 19. However, flavors are still allowed in other tobacco products like e-cigarettes. *Id.*

28. The text of the Tobacco Act itself notes that "The use of tobacco products by the Nation's children is a pediatric disease of considerable proportions that results in new generations of tobacco-dependent children and adults," *supra* note 19, at § 2(1), and "[c]hildren, who tend to be more price sensitive than adults, are influenced by advertising and promotion practices that result in drastically reduced cigarette prices." *Id.* § 2(24).

29. In the second quarter of 2019, JUUL spent more than \$1 million on congressional lobbying alone, in anticipation of additional upcoming 2020 federal regulations. Sarah Owerhohle, *E-cig industry fractures over looming laws as Big Tobacco plays the long game*, POLITICO (Oct. 17, 2019), <https://www.politico.com/news/2019/10/17/e-cig-tobacco-fda-050357> [<https://perma.cc/S3YX-6K6J>].

30. Nick Dantonio, *Vape Away: Why a Minimalist Regulatory Structure is the Best Option for FDA E-Cigarette Regulation*, 48 U. RICH. L. REV. 1319, 1320 (2014). Much of the controversy surrounding e-cigarettes stems from the debate over whether they really are a more healthful alternative for consumers who would normally smoke traditional cigarettes. "Nicotine-infused e-cigarettes provide the user with a familiar-looking, smokeless product without combustible tobacco and the endless list of health effects associated with it. E-cigarettes allow users to 'vape' a nicotine fluid without inhaling the dozens of other chemical additives in combustible cigarettes that increase carcinogenicity." *Id.* at 1320-21.

31. *Id.* at 1321.

32. WORLD HEALTH ORG., *Countries Vindicate Cautious Stance on E-Cigarettes*, 92 BULL. OF THE WORLD HEALTH ORG. 856-57 (2014) ("*Cautious Stance*"), <http://dx.doi.org/10.2471/BLT.14.031214> [<https://perma.cc/TJ8Y-LEMM>].

reality, the difference in risk between conventional cigarette smoking and e-cigarette vaping is not fully understood and may in fact be overstated.³³ The World Health Organization has pointed out that while some studied brands of e-cigarettes have lower toxic emissions compared to combustible cigarettes, others contain the same amounts of carcinogenic ingredients that are found in conventional cigarettes³⁴ – including formaldehyde, a flammable chemical commonly used as a preservative in mortuaries.³⁵ Beyond concerns about the lack of clear data on toxicity levels in e-cigarettes as compared with combustible cigarettes, nicotine that is also present in e-cigarettes is known to be a highly addictive, neuro-degenerative substance that impairs brain development in children and fetuses that are exposed to nicotine.³⁶ Contrary to popular belief, some types of e-cigarettes deliver more nicotine than conventional cigarettes.³⁷

Hailing from a start-up in the Silicon Valley, the JUUL brand vaping device is one type of e-cigarette that produces more nicotine than combustible cigarettes.³⁸ While JUUL vaping devices were once considered a newcomer to the e-cigarette market, today, due to their immense popularity, they are ubiquitous with the term “e-cigarette” itself.³⁹ Aggressive tactics have been the hallmark of e-cigarette advertising

33. According to the World Health Organization, “There are about 500 e-cigarette brands out there, and only a few have been analyzed...[the] literature shows a great variety in the levels of the toxicants and nicotine they produce.” *Id.*

34. *Id.* at 857.

35. *Formaldehyde and Cancer Risk*, NAT’L CANCER INST., www.cancer.gov/about-cancer/causes-prevention/risk/substances/formaldehyde/formaldehyde-fact-sheet [<https://perma.cc/5SC7-VMCD>].

36. WORLD HEALTH ORG., *supra* note 30. The WHO offers a clear position on underage use of e-cigarettes: “WHO does not recommend the use of any form of nicotine for those who have never smoked or for children and pregnant women, and our report on e-cigarettes is consistent with this position.” *Id.* at 856. See also Angelica LaVito, *US health officials flag increasing popularity of flavored e-cigarettes as concern in new CDC study*, CNBC (Aug. 23, 2018, 12:22 PM), www.cnbc.com/2018/08/23/us-health-officials-flag-popularity-of-flavored-e-cigarettes-as-worry.html [<https://perma.cc/8PK4-ZLHX>]. Brian King, the deputy director for research translation in the CDC’s Office on Smoking and Health is quoted: “We know these [e-cigarette] products contain nicotine, which can harm the adolescent brain...while there could be benefits for adults wanting to quit smoking, ‘there’s no redeeming quality for kids.’” *Id.*

37. *Is Vaping Better Than Smoking?*, AMERICAN HEART ASSOCIATION (last reviewed Oct. 30, 2018), <https://www.heart.org/en/healthy-living/healthy-lifestyle/quit-smoking-tobacco/is-vaping-safer-than-smoking> [<https://perma.cc/XG8E-3ZYP>].

38. LaVito, *supra* note 36. The JUUL vaping device comprises 70% of all e-cigarette sales; JUUL sales rose 728% between August 2017 and August 2018. *Id.*

39. Introduced in 2015 by San Francisco PAX Labs Inc., JUUL was valued at \$15 billion in June 2018. Crawford, *supra* note 9. JUUL now accounts for about 70% of convenience store e-cigarette business. *Id.*

campaigns aimed at teens.⁴⁰ Unlike traditional cigarette companies, E-cigarette companies frequently employ less conventional advertising venues, like advertising on clothing.⁴¹ Beyond advertising ploys like branded teen clothing and merchandise, e-cigarette companies like JUUL manufacture products with fruity or kid-friendly flavors like crème brûlée and mango specifically to target teens.⁴² E-cigarette manufacturers historically attempted to avoid FDA regulation by redefining e-cigarettes as non-tobacco products.⁴³ In *Sottera v. FDA*, an e-cigarette company, NJOY, challenged the FDA's regulatory authority under the FD&C Act in 2010 by filing suit.⁴⁴ The U.S. Court of Appeals for the D.C. Circuit held that e-cigarettes can only be subject to FDA regulation under the Tobacco Act, and that the FDA had exceeded its regulatory authority by attempting to expand its regulation via the FD&C Act.⁴⁵ The Tobacco Act, meanwhile, instated a "deeming" power that granted the FDA authority to regulate other products "made or derived from tobacco" and "intended for human consumption."⁴⁶

40. Youth exposure to e-cigarette ads is widespread and rampant, according to the CDC: "More than 10 million high school students and nearly 8 million middle school students were exposed to e-cigarette ads in 2014." *E-cigarette Ads and Youth*, CENTERS FOR DISEASE CONTROL AND PREVENTION (last updated March 23, 2017), <https://www.cdc.gov/vitalsigns/ecigarette-ads/index.html> [<https://perma.cc/C6W7-7SSY>]. Besides the overwhelming number of advertisements in circulation, these advertisements also employ tactics that make them qualitatively aggressive, as "many of the themes used in advertising for cigarettes are also now used to advertise e-cigarettes – including sex, independence, and rebellion." *Id.* Finally, data indicates there is a correlation between the number of e-cigarette ads generated and use by teens: "During the time e-cigarette ads have increased, there are also increases in e-cigarette use among US youth. From 2011-2014, e-cigarette use in the past 30 days increased from less than 1% to almost 4% among middle school students and from less than 2% to 13% among high school students." *Id.*

41. One study found that wearing clothing with tobacco products or logos is a characteristic that might make teens more at risk for smoking. Lisa Rapaport, *E-Cigarettes may lure teens who otherwise might not smoke*, REUTERS, (Jan. 23, 2017), <https://www.reuters.com/article/us-health-teens-e-cigarettes/e-cigarettes-may-lure-teens-who-otherwise-might-not-smoke-idUSKBN158009> [<https://perma.cc/BU5F-3RB8>].

42. Research shows that flavors attract teens to tobacco products; JUUL produces crème brûlée and mango flavored products. See LaVito, *supra* note 36.

43. See *Sottera, Inc. v. FDA*, 627 F.3d 891, 892 (D.C. Cir. 2010) (finding that "[c]ongress has authorized the Food and Drug Administration ('FDA') to regulate e-cigarettes under...the Family Smoking Prevention and Tobacco Control Act of 2009 (the 'Tobacco Act')")

44. Jonathan H. Adler, et al., *Baptists, Bootleggers & Electronic Cigarettes*, 33 YALE J. ON REG. 313, 333 (2016); see *Sottera*, 637 F.3d.

45. *Sottera*, 637 F.3d.

46. Adler et al., *supra* note 44, at 332. "Products 'deemed' to be 'tobacco products' under the Act become subject to many of its requirements, including the prohibition on adulterated or misbranded products, mandatory manufacturer registration and content disclosure requirements, restrictions on modified risk claims, and mandatory premarket review of products marketed after February 15, 2007." *Id.*

Since the Tobacco Act, however, courts have firmly upheld that e-cigarettes are bona fide tobacco products in the eyes of the law.⁴⁷ In July 2017, a manufacturer of e-cigarettes unsuccessfully challenged a United States District Court for the District of Columbia decision from May 2016 to “deem” e-cigarettes “tobacco products.”⁴⁸ The court in *Nicopure Labs v. FDA* held that the decision to deem e-cigarettes as tobacco products subject to laws governing conventional cigarettes “was not arbitrary and capricious”⁴⁹ and upheld the FDA’s new “Deeming Rule” regulations on tobacco products.⁵⁰ The D.C. District Court held that the FDA “was legally permitted to regulate that category of liquids, and to consider a refillable electronic nicotine delivery system to be a ‘component’ of a tobacco product and therefore subject to regulation.”⁵¹ Among other complaints, Nicopure Labs alleged that the Tobacco Act unfairly used a “one size fits all” approach by treating e-cigarettes the same way it treats cigarettes, and that this violates the Constitution’s due process and equal protection clauses.⁵² Nicopure Labs also alleged that the ban on free samples and the Act’s modified risk provision requiring “manufacturers of tobacco products to secure FDA’s approval before making truthful, non-misleading claims about their products,” violated the First Amendment and the Administrative Procedure Act.⁵³

The court relied on the two-step *Chevron* analysis. First, it determined that Congress did not clearly and unambiguously speak to the specific question. Then, because Congress did not unambiguously speak to the question, the court had to determine “whether the agency’s answer is based on a permissible construction of the statute.”⁵⁴ The court decided the FDA’s regulation met both steps of the *Chevron* analysis,⁵⁵ and the court held that the FDA may legally regulate even an “e-liquid” that does not contain nicotine as a “component” of a tobacco product if it is “reasonably expected” that the e-liquid would be used with or for the purpose of

47. *Brown & Williamson*, 529 U.S. 120 at 128.

48. *Nicopure Labs, LLC v. FDA*, 266 F. Supp. 3d 360, 366 (D.D.C. 2017).

49. *Id.* at 368.

50. *Id.* at 366.

51. *Id.* at 368. The court noted that it was the fact that e-cigarettes contain nicotine, a drug, which allows the FDA to regulate products containing nicotine. The court also specified that “the FDA has plainly stated that the rule does not cover e-liquids that do not contain, or are not derived from, nicotine or tobacco, unless those liquids are reasonably intended to be used with nicotine-containing liquids. *Id.*”

52. *Id.* at 379.

53. *Id.*

54. *Nicopure Labs*, 266 F. Supp. 3d at 379-80.

55. *Id.* at 391.

consuming a tobacco product.⁵⁶ By broadening the regulatory power of the FDA over e-cigarettes and related smoking accessories, the *Nicopure Labs* decision became the most recent step by the judiciary in endorsing a paternalistic government policy towards regulating e-cigarettes and advertising these products.⁵⁷ Congressional and judicial intent is now clear: e-cigarettes and e-cigarette products are tobacco products, and should be regulated as such.

C. Current Regulatory Measures

In late 2017, the Federal Trade Commission (“FTC”) and FDA launched an investigation into marketing tactics by e-cigarette companies designing e-cigarette products to resemble food and treats that are familiar to children.⁵⁸ In May 2018, the FTC and FDA announced that they had jointly issued thirteen warning letters to e-cigarettes companies that manufacture their products to resemble food products,⁵⁹ and by September 2018, the FDA and FTC announced they had issued a total of seventeen letters to companies that had misleadingly advertised nicotine-containing e-liquids as kid-friendly food products like cookies, candies, or juice boxes.⁶⁰ As of January 2020, the estimated percentage of high schoolers in the U.S. who use e-cigarettes has risen to 27.5%, a concerning increase from 20.8%

56. *Id.* at 390. The court’s determination is important because it allowed for the FDA to regulate even electronic cigarette products that contain no nicotine at all. This demonstrates the court’s openness to potentially wider future regulatory discretion for the FDA on regulating tobacco products marketed to kids.

57. The court also explained the scientific and public health impetus behind its decision in *Nicopure Labs*:

Moreover, the record before the [FDA] included a substantial volume of comments submitted by public health organizations such as the American Academy of Family Physicians, the American Academy of Pediatrics, the Cancer Action Network, the American Heart Association, the American Lung Association, and the American Psychological Association — all of which urged the agency to “strengthen[]” and make “comprehensive” the proposed Deeming Rule, in order to “prevent the manufacturers of tobacco products from designing and marketing their products in ways that undercut the full potential of the Tobacco Control Act to achieve its lifesaving objectives.”

Id. at 397.

58. FED. TRADE COMM’N., FTC, FDA TAKE ACTION AGAINST COMPANIES MARKETING E-LIQUIDS THAT RESEMBLE CHILDREN’S JUICE BOXES, CANDIES, AND COOKIES, (Jan. 20, 2020, 10:00 AM), <https://www.ftc.gov/news-events/press-releases/2018/05/ftc-fda-take-action-against-companies-marketing-e-liquids> [<https://perma.cc/F3N4-5E7U>].

59. *Id.*

60. CTR. FOR TOBACCO PRODUCTS, U.S. FOOD & DRUG ADMIN., E-LIQUIDS MISLEADINGLY LABELED OR ADVERTISED AS FOOD PRODUCTS (Nov. 29, 2018), <https://www.fda.gov/tobaccoproducts/newsevents/ucm605729.htm> [<https://perma.cc/9ZF6-XM3P>].

in 2018.⁶¹ Today, e-cigarettes are the most popular tobacco product used by middle school⁶² and high school students in the United States,⁶³ and data on their negative health effects continues to surface.

After receiving a whopping 525,302 public comments and expediting its review,⁶⁴ the FDA announced a new set of proposals in a November 2018 press release to tighten restrictions on flavored cigarettes and e-cigarettes.⁶⁵ FDA Commissioner Scott Gottlieb cited enticing e-cigarette flavors as the “core of the epidemic.”⁶⁶ Gottlieb explained that the flavors in e-liquids mimicking childhood foods like apple juice boxes and lollipops are what entice children to begin taking up a recreational habit that exposes them to a similar or identical amount of addictive nicotine as traditional cigarettes.⁶⁷ In other words, the kid-friendly flavors in e-cigarettes – and the advertising tactics used to promote them – are what lure children to pick up the e-cigarette habit initially. Gottlieb revealed that the most recent statistics on child and adolescent use of e-cigarettes was enough to

shock his conscience. [F]rom 2017 to 2018, there was a 78 percent increase in current e-cigarette use among high school students and a 48 percent increase among middle school students. The total number of middle and high school students currently using e-cigarettes rose

61. See Kirkham, *infra* note 77.

62. The 2014 Surgeon General’s Report citing troubling data from the 2011 and 2012 National Youth Tobacco Survey showed that the rates of middle schoolers using e-cigarettes began skyrocketing years ago. U.S. DEPT. OF HEALTH AND HUMAN SERVICES. U.S. DEP’T OF HEALTH AND HUM. SERVS., CTRS. FOR DISEASE CONTROL AND PREVENTION, NAT’L CTR. FOR CHRONIC DISEASE PREVENTION AND HEALTH PROMOTION, *The Health Consequences of Smoking: 50 Years of Progress. A Report of the Surgeon General*. OFFICE ON SMOKING AND HEALTH, (Printed with corrections Jan. 2014). Between 2011-2012, electronic cigarette use among U.S. middle school students doubled. *Id.* at 742-43.

63. Kristy Marynak, Andrea Gentzke, Teresa W. Wang, Linda Neff, Brian A. King, *Exposure to Electronic Cigarette Advertising Among Middle and High School Students*, CTRS. FOR DISEASE CONTROL AND PREVENTION, MORBIDITY AND MORTALITY WEEKLY REPORT (*MMWR*) (Mar. 16, 2018), doi: <http://dx.doi.org/10.15585/mmwr.mm6710a3> [<https://perma.cc/5SYR-Q6RH>].

64. See LaVito, *supra* note 36.

65. Maggie Fox, *FDA Restricts all Flavored E-Cigarettes; Moves to Ban Menthol*, NBC NEWS (Nov. 15, 2018 9:12 AM), <https://www.nbcnews.com/health/health-news/fda-restricts-all-flavored-e-cigarettes-moves-ban-menthol-n936471> [<https://perma.cc/K37A-QE5K>].

66. U.S. FOOD & DRUG ADMIN., STATEMENT FROM FDA COMMISSIONER SCOTT GOTTLIEB, M.D., ON PROPOSED NEW STEPS TO PROTECT YOUTH BY PREVENTING ACCESS TO FLAVORED TOBACCO PRODUCTS AND BANNING MENTHOL IN CIGARETTES (Nov. 15, 2018) (on file with the U.S. Food & Drug Administration).

67. *Id.*

to 3.6 million...[with] 1.5 million more students using these products than the previous year.⁶⁸

The data was compelling enough to prompt government action. Knowing that children become addicted to nicotine through e-cigarettes, the FDA outlined a two-fold proposal. First, Gottlieb directed the FDA's Center for Tobacco Products to protect children by having "all flavored electronic cigarette products (other than tobacco, mint, and menthol flavors or non-flavored products) sold in age-restricted, in-person locations and, if sold online, under heightened practices for age verification."⁶⁹ Second, the FDA announced that it would advance a Notice of Proposed Rulemaking to ban menthol in conventional cigarettes and tobacco products.⁷⁰ Various health and social groups have openly supported the proposals, yet many have also expressed their desire for greater change from the FDA.⁷¹

The desired change seemed to be on the horizon on January 2, 2020, when President Trump announced a ban on some e-cigarette flavors, including fruit and mint.⁷² The partial flavor ban, which went into effect on February 6, 2020, was criticized by public health advocates – including Gary Reedy, chief executive of the American Cancer Society – as being a toothless effort that does not go far enough to stop the tobacco industry from preying upon children, because teenagers will simply switch from their preferred flavor of mint to menthol, which will still be a legal flavor.⁷³ Beginning in February 2020, the FDA started enforcing the partial ban against e-cigarette manufacturers who sell banned flavors, and all e-cigarette manufacturers must apply to the FDA for permission to continue selling any banned flavors by May 2020.⁷⁴

68. *Id.* Commissioner Gottlieb's targeted approach towards flavored e-liquids should come as no surprise. Citing the same data, Gottlieb pointed to the fact that over two-thirds of high school current e-cigarette users are using flavored e-cigarettes, a significant increase since 2017. *Id.*

69. *Id.*

70. *Id.*

71. Fox, *supra* note 65. The Campaign for Tobacco-Free Kids said in response that the FDA has moved too slowly in the last six years to curb teen vaping, and the American Academy of Pediatrics also called on the FDA to take more action. *Id.* The NAACP also welcomed the menthol ban, explaining that African American smokers are historically targeted by the tobacco industry as menthol smokers. "For decades, data have shown that the tobacco industry has successfully and intentionally marketed mentholated cigarettes to African Americans and particularly African American women as 'replacement smokers' (and) that menthol smokers have a harder time quitting smoking." *Id.*

72. Chris Kirkham, *Trump administration restricts some e-cigarette flavors*, REUTERS (Jan. 2, 2020), <https://www.reuters.com/article/us-usa-vaping/trump-administration-restricts-some-e-cigarette-flavors-idUSKBN1Z11B7> [https://perma.cc/BS47-2BJJ].

73. *Id.*

74. *Id.*

Despite these regulatory measures to restrict minors' access to at least some forms of e-cigarettes that are popular among teens, this group remains heavily targeted by e-cigarette companies. Because of a lack of federal advertising restrictions, tobacco companies are still allowed to promote e-cigarette products through television and radio, thereby circumventing a 1971 ban on cigarette advertising to children through these outlets that was originally designed to reduce tobacco cigarette marketing to kids.⁷⁵ Other popular marketing avenues used by e-cigarette manufacturers include retail stores, the internet, and recreational venues and events.⁷⁶ The pervasiveness of aggressive advertising campaigns targeted at youths is staggering. A CDC study that used data from the 2014, 2015, and 2016 National Youth Tobacco Surveys to determine the numbers of middle and high school students who were exposed to e-cigarette advertising from retail stores (convenience stores, supermarkets, or gas stations), the internet, TV/movies, and newspapers and magazines found that youth exposure to e-cigarette advertisements from at least one source increased each year between 2014 and 2016.⁷⁷ While 68.9% of middle and high school students had seen an advertisement in 2014, by 2016 the percentage rose to 78.2%, or 20.5 million students.⁷⁸ This meant that nearly four out of five middle or high school students had seen at least one e-cigarette advertisement.⁷⁹

II. MILL'S HARM PRINCIPLE

A traditional component of the government's role is to reduce the harm experienced by its citizens.⁸⁰ However, the government must balance its interest in harm reduction with the fundamental interests in individual autonomy and liberty that are cornerstones of American constitutional and

75. *4 Marketing Tactics E-Cigarette Companies Use to Target Youth*, THE TRUTH INITIATIVE, (Aug. 9, 2018), <https://www.truthinitiative.org/research-resources/tobacco-industry-marketing/4-marketing-tactics-e-cigarette-companies-use-target> [<https://perma.cc/KYF9-PWGT>].

76. *Id.* A creative way in which one e-cigarette company targeted young adults through an event occurred when blu Cigs sponsored the Sasquatch! Music Festival in Washington in 2013. *Id.* The sponsored festival "...featured a vapor lounge with surprise guest appearances from top performers, device charging stations, an interactive social media photo booth and samples of blue Cigs." *Id.* The 2018 Sundance Film Festival – one of the most famous festivals in the country – was sponsored by JUUL e-cigarette company. *Id.*

77. Stacy Simon, Senior Editor, News, *Report: More and More Teens Seeing E-Cigarette Ads*, AMERICAN CANCER SOCIETY, (March 19, 2018), <https://www.cancer.org/latest-news/report-more-and-more-teens-seeing-e-cigarette-ads.html> [<https://perma.cc/U65N-PT3V>].

78. *Id.*

79. *Id.*

80. See Thaddeus Mason Pope, *Balancing Public Health Against Individual Liberty: The Ethics of Smoking Regulations*, 61 U. PITT. L. REV. 419, 428 (2000) [hereinafter Pope Public].

social values.⁸¹ In his essay *On Liberty*, British philosopher and classic liberal theory thinker John Stuart Mill⁸² asserts his harm principle: the “sole end for which mankind are warranted, individually or collectively, in interfering with the liberty of action of any of their number”⁸³ is “self-protection,”⁸⁴ or preventing harm to others.⁸⁵ In other words, the government, through collective action, may interfere with the liberty of action of any of their constituents only if the interference is done solely for self-protection.⁸⁶ Under this principle, the government may not, for example, implement laws creating victimless crimes. Mill’s harm principle values protecting individual liberty to the greatest possible extent, which requires governmental restraint and thereby limits infringements on basic human autonomy.⁸⁷ At the same time, however, the harm principle allows

81. Liberty, specifically, is a key conception that shaped the American natural-rights tradition, expressed in the opening of the Declaration of Independence. Carl Eric Scott, *The Five Conceptions of American Liberty*, NATIONAL AFFAIRS (Summer 2014), <https://www.nationalaffairs.com/publications/detail/the-five-conceptions-of-american-liberty> [https://perma.cc/FB3X-DW8T].

82. John Stuart Mill is regarded as one of the leading liberal theory philosophers.

The thought of John Stuart Mill is an archetypal example of liberalism, not because of its coherence, rigor, and internal consistency but, rather, because his thought is expansive, rich, and often contradictory. The tensions and ambiguities in Mill's thought are the tensions and ambiguities of the modern era concerning the most fundamental political, social, and spiritual questions: the nature of the human self.

John Lawrence Hill, *Mill, Freud, and Skinner: The Concept of the Self and the Moral Psychology of Liberty*, 26 SETON HALL L. REV. 92, 116 (1995).

83. ON LIBERTY, *supra* note 10, at 80.

84. *Id.* Mill explains that “the individual is sovereign” over his own self.

85. *Id.*

86. John Stuart Mill viewed legal liberties as permissions by the government to “engage in self-regarding acts.” Joseph William Singer, *The Legal Rights Debate in Analytical Jurisprudence from Bentham to Hohfeld*, 1982 WIS. L. REV. 975, 984 (1982). Mill and fellow classical analytical jurists Jeremy Bentham and John Austin invented a meta-theory of analytical jurisprudence founded on the distinction between self-regarding and other-regarding acts. *Id.* Their meta-theory of self-regarding acts served as a legitimating principle for the rules in force, and these classical descriptions also “minimized the extent to which the legal system allowed people to interfere with the permitted acts of others.” *Id.* at 985.

87. See John Lawrence Hill, *The Constitutional Status of Morals Legislation*, 98 KY. L.J. 1, 3-4 (2009-2010).

This principle has had a powerful symbolic influence on American constitutional ideals, presaging, in particular, the modern right to privacy. The most important consequence of the harm principle is that it rejects, as inconsistent with the principles of a free society, laws which prohibit private or “self-regarding” acts on grounds that the majority believes the activity to be morally objectionable. The term “morals legislation” has been used to designate laws prohibiting activities such as consensual homosexual relations, abortion, adultery, fornication, prostitution, bestiality, bigamy, adult incest, sadomasochism, gambling, the use of illegal drugs, euthanasia, and assisted suicide, to name a few. To the extent that the right to privacy is understood in Millian terms, it would immunize from constitutional attack all such laws, at least to the extent that they do not directly harm third parties.

for a condition under which the government may legitimately restrict an individual's autonomy.⁸⁸

Because liberty is sacred, Mill asserts that this principle must “govern absolutely the dealings of society with the individual in the way of compulsion and control, whether the means used be physical force in the form of legal penalties or the moral coercion of public opinion.”⁸⁹ Thus, Mill's harm principle permits government regulation where the regulation is meant to reduce harm to others through self-protection – the only legitimate end – even if it necessarily interferes with the liberty and autonomy of the individual.⁹⁰ Although Mill is sometimes criticized for wavering between libertarianism and authoritarianism,⁹¹ his expression of the harm principle in *On Liberty* suggests that Mill would approach the problem of regulating e-cigarette advertising to children from a more nuanced middle-ground position.⁹² Rather than allowing for the government implementing universal change, the harm principle carves out spheres in which the government may rightfully limit the autonomy of its citizens for harm reduction.

According to Mill, “[t]here is a limit to the legitimate interference of collective opinion with individual independence: and to find that limit, and maintain it against encroachment, is as indispensable to a good condition of human affairs, as protection against political despotism.”⁹³ Some argue that the harm principle could theoretically justify nearly any government regulation,⁹⁴ so long as the regulation is intended to prevent harm to others.⁹⁵ This view is short-sighted, because Mill's harm principle was

88. *Id.* “This liberty-limiting principle is recognized as the most morally legitimate because preventing or reducing harm to others is a traditional exercise of the state's police power, a classic and core function of government.” Pope Public, *supra* note 80, at 428.

89. ON LIBERTY, *supra* note 10, at 80. It is appropriate that regulating advertising e-cigarettes to children should thus be governed by this principle according to Mill, since it concerns a control over a liberty – the freedom to choose to smoke e-cigarettes – and the potential for “physical force in the form of legal penalties,” policing the manner in which the tobacco industry may advertise such products to children. *Id.*

90. *Id.*

91. Oskar Kurer, *John Stuart Mill on Government Intervention*, 10 HISTORY OF POLITICAL THOUGHT 3, 457–480 (1989), www.jstor.org/stable/44797145 [<https://perma.cc/D334-326W>].

92. See ON LIBERTY, *supra* note 10.

93. ON LIBERTY, *supra* note 10, at 76.

94. Pope Public, *supra* note 80, at 433. Pope points out that while some philosophers could find the harm principle might justify any policy, this is not a belief that Pope shares.

95. Mill is notoriously ambiguous on his belief in absolute liberty. See Kurer, *supra* note 91, at 458. According to Kurer, “He was in turn both a libertarian and a paternalist.” *Id.*

never intended to be a *carte blanche* for the government to enforce any regulation on a whim arbitrarily and capriciously.⁹⁶

The *Nicopure Labs* decision is a salient example of a recent government policy reflecting the ultimate goal of the Millian harm principle.⁹⁷ By interpreting the FDA's regulatory authority over tobacco products as broadly as possible within Congress's statutory language, the court affirmed a government policy that limited children's liberty in deciding for themselves if they would like to use e-cigarette tobacco products, but did this for the means of protecting children from harm by others more powerful than them: the tobacco industry. In this way, the *Nicopure Labs* decision is a classic expression of the harm principle's intent to protect those who cannot protect themselves.⁹⁸

To frame the *Nicopure Labs* decision in another way under Mill's liberal theory philosophy espoused in *On Liberty*, the *Nicopure Labs* decision also promotes Mill's theory of utility.⁹⁹ To this, Mill writes:

It is proper to state that I forego any advantage which could be derived to my argument from the idea of abstract right, as a thing independent of utility. I regard utility as the ultimate appeal on all ethical questions; but it must be utility in the largest sense, grounded on the permanent interests of man as a progressive being. Those interests, I contend, authorize the subjection of individual spontaneity to external control, only in respect to those actions of each, which concern the interest of other people.¹⁰⁰

Mill expands the concept of utility by offering the theory that there are negative acts that people can do to harm the interests of others, as well as positive acts that one may carry out for the benefit of other individuals which a person "may rightfully be compelled to perform."¹⁰¹ The Millian threshold for legitimate regulation that effectuates utility is high,¹⁰² as Mill

96. While advocating that the government should employ the harm principle, Mill muses that it does not always achieve a balance between over and underregulating: "[T]he interference of government is, with about equal frequency, improperly invoked and improperly condemned." *ON LIBERTY*, *supra* note 10, at 80.

97. See *Nicopure Labs, LLC v. FDA*, 266 F. Supp. 3d 360, 366 (D.D.C. 2017).

98. *ON LIBERTY*, *supra* note 10.

99. *ON LIBERTY*, *supra* note 10, at 81.

100. *Id.*

101. *Id.*

102. Kurer contends that Mill's set of secondary principles, his "theories of justice and of the improvement of man, together with their implications," provide us with a workable theory of government intervention. Kurer, *supra* note 91, at 461. "If, on balance, intervention results in 'progress,' then it is justified. If, on balance, negative effects preponderate, intervention should not proceed." *Id.*

contends it should be. Utility, the “ultimate appeal on all ethical questions,” must be so grounded in the furtherance of mankind that it can authorize the limitation of “individual spontaneity” by external, or governmental, control.¹⁰³ Nothing less than objectively legitimate ends, namely those that benefit other individuals, will justify government restriction on an individual’s right to liberty.¹⁰⁴

Legitimate ends become even more relevant when Mill explores the question of where the “appropriate region of human liberty”¹⁰⁵ exists. He answers that

there is a sphere of action in which society, as distinguished from the individual, has, if any, only an indirect interest; comprehending all that portion of a person’s life and conduct which affects only himself, or if it also affects others, only with their free, voluntary, and undeceived consent and participation.¹⁰⁶

Here Mill’s “sphere of action” delineates the limit of legitimate government regulation: when a person’s conduct affects others *without* their “free, voluntary, and undeceived consent.”¹⁰⁷ This question of where the appropriate region of liberty lies becomes complicated when considering the interests of children – individuals who have not yet reached the age of consent.

Moreover, when considering whether the *Nicopure Labs* decision falls within Mill’s delineated “sphere of action,”¹⁰⁸ it is not going too far to say that the court likely viewed the FDA expanding its authority to regulate marketing tobacco products to children as a “positive act”¹⁰⁹ of utility that the FDA could carry out to the benefit of children. The FDA’s actual intent, to deem and therefore regulate e-cigarette products as tobacco products, fits with Mill’s definition of “the disposition of mankind,” that it is “whether as rulers or as fellow-citizens, to impose their own opinions and inclinations

103. “It is self-evident that the government has to enforce justice, to protect those rights which society is called to uphold.” *Id.* at 468.

104. Under his notion of a free society, Mill asserts that “The only freedom which deserves the name, is that of pursuing our own good in our own way, so long as we do not attempt to deprive others of theirs, or impede their efforts to obtain it.” *ON LIBERTY*, *supra* note 10, at 83. Mill wants to protect individual autonomy, which he characterizes as the individual’s right to pursue “their own good in their own way.”

105. *Id.* at 82.

106. *Id.* at 82.

107. *Id.* at 82.

108. *ON LIBERTY*, *supra* note 10, at 82.

109. *Id.* at 81.

as a rule of conduct on others.”¹¹⁰ While safeguarding children from future addiction to nicotine and its neurodegenerative effects is unquestionably in the interest of children, Mill warns that government intervention must be observed vigilantly, because it is simply in humankind’s nature, which he refers to as “the disposition of mankind,” to abuse any allocation of power over another.¹¹¹ The question then turns to that of consent and assessing whether the positive act is affecting the intended beneficiaries only with their voluntary consent and participation so as not to fall outside of the permissible sphere of action and curtail the liberty of the individual.¹¹²

The FDA instated broad regulatory authority due to a harm principle-guided motive to protect others – the children being marketed to – who have not given their “free, voluntary, and undeceived consent and participation.”¹¹³ While restricting regulation of e-cigarette advertising targeting adults would not be legitimate under the Millian theory of liberty, consent is a different question for children because data shows that children are more vulnerable to these aggressive advertisements.¹¹⁴ It is irresponsible to allow the tobacco industry to specifically target young consumers when a direct causal effect has been established between targeted e-cigarette advertising and children beginning smoking habits that harm their physical welfare.¹¹⁵ A March 2018 study in the *Journal of the American Medical Association*, found young adults who are exposed to advertisements for these non-cigarette tobacco products are significantly more likely to try

110. *Id.* at 84. Oskar Kurer summarizes Mill’s justification for government intervention: “If by government intervention an overall increase in ‘progress’ can be achieved (associated in Mill’s mind with increased happiness), then government intervention is called for.” Kurer, *supra* note 91, at 480.

111. Mill cautions that humans must exercise restraint against their own instincts to power-grab when given the opportunity: “...the power [to impose their own opinions and inclinations] is not declining, but growing, unless a strong barrier of moral conviction can be raised against the mischief, we must expect, in the present circumstances of the world, to see it increase.” ON LIBERTY, *supra* note 10, at 84.

112. ON LIBERTY, *supra* note 10, at 82. Qualifying the concept of “undeceived consent and participation,” Mill elaborates: “When I say only himself, I mean directly, and in the first instance: for whatever affects himself, may affect others through himself, and the objection which may be grounded on this contingency, will receive consideration in the sequel. This, then, is the appropriate region of human liberty.” *Id.*

113. *Id.* at 82.

114. See Kaplan, *infra* note 162; see also Wilcox, *infra* note 161.

115. See Wendy E. Parmet, *Paternalism, Self-Governance, and Public Health: The Case of E-Cigarettes*, 70 U. MIAMI L. REV. 879, 881-82 (2016)

E-cigarettes are the most popular form of electronic nicotine delivery systems (“ENDS”). They deliver nicotine through the inhalation of a heated vapor rather than combustion. Supporters argue that they offer a safer alternative to smoking and the opportunity for a new regulatory strategy, one based on harm reduction. Critics, in contrast, point to potential health risks. They also worry that e-cigarettes will renormalize smoking and reverse declines in smoking rates.

them.¹¹⁶ The National Institute on Drug Abuse estimates that seven out of ten teenagers are exposed to e-cigarette advertising.¹¹⁷ Both children and adults who smoke e-cigarettes are likely to be dual-users, smoking conventional nicotine cigarettes as well.¹¹⁸

Because children do not have the fully-developed ability to form and give consent to being targeted by malevolent tobacco product marketing techniques,¹¹⁹ the FDA regulation in question in *Nicopure Labs* was a legitimate act that served utility within the limits of the “sphere of action.”¹²⁰ Both Mill’s harm principle and the concept of utility for self-protection are illustrated by the court’s decision to uphold FDA regulatory power over tobacco products in *Nicopure Labs*. The decision was of the sort which resides in Mill’s sphere of action and justifies limiting the liberty of children.¹²¹

III. DWORKIN’S CONCEPT OF LEGITIMATE PATERNALISM ALSO JUSTIFIES GOVERNMENT PATERNALISM IN PROTECTING CHILDREN FROM E-CIGARETTE ADVERTISING

Philosopher Gerald Dworkin muses that a paternalistic act can be defined as relative to the “outcomes [which] it produces.”¹²² In his essay

116. This is according to a study of nearly 11,000 people ages 12 to 24. 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 444–451 (2018) (concluding “[r]eceptivity to tobacco advertising was significantly associated with progression toward use in adolescents. Receptivity was highest for e-cigarette advertising and was associated with trying a cigarette.”), doi:10.1001/jamapediatrics.2017.5756. The conclusion of the study: “Receptivity to tobacco advertising was significantly associated with progression toward use in adolescents. Receptivity was highest for e-cigarette advertising and was associated with trying a cigarette.” *Id.*

117. NAT’L INST. ON DRUG ABUSE, NAT’L INST. OF HEALTH, U.S. DEP’T OF HEALTH AND HUM. SERVS., *supra* note 4.

118. Lisa Rapaport, *Teens who try e-cigarettes more likely to start smoking*, REUTERS HEALTH (Jan. 27, 2016), <https://www.reuters.com/article/us-health-teens-ecigarettes-smoking-idUSKCN0V52FW> [<https://perma.cc/WE6M-NSQ3>].

119. See Kaplan, *infra* note 162.

120. *Id.* The “improvement of man” – the advancement of his intellectual and moral faculties – was one of Mill’s core concerns. Kurer, *supra* note 91, at 462. Government intervention done for the improvement of man falls within Mill’s sphere of action.

121. Dworkin characterizes Mill’s and Thomas Hobbes’s view of liberty as “the absence of interference with a person’s actions.” THEORY AND PRACTICE, *supra* note 3, at 105.

122. Gerald Dworkin, *Defining Paternalism*, in PATERNALISM THEORY AND PRACTICE 26 (Christian Coons et. al. eds., 2013) [hereinafter DEFINING PATERNALISM].

Defining Paternalism,¹²³ Dworkin suggests policies which “limit[] a person’s liberty for her own good, or for the reason that it benefits her or improves her situation in some way” would be paternalistic.¹²⁴ According to Dworkin, reasons, motivations, institutions, acts, and policies can all be paternalistic.¹²⁵ There are many circumstances under which we would interact with paternalism. Familiar examples of legal paternalism relevant to everyday life include protective laws like legislation requiring boaters to wear life jackets, or laws requiring the use of a helmet while riding a motorcycle.¹²⁶ Paternalism has traditionally applied to policies regulating the consumption of tobacco products.¹²⁷ Dworkin addresses a normative constraint on paternalism by asking if A’s act violates B’s autonomy, or if A’s act need not be a violation of B’s autonomy in order to be considered paternalism.¹²⁸ Like Mill, Dworkin concedes that there are certain circumstances which create scenarios that make government regulation permissible, and even beneficial for the greater societal good. Paternalism

123. Dworkin outlines eight definitions of paternalism, in which he suggests the variety of different dimensions upon which each possible definition could place value; Dworkin’s definition that is most applicable to the scope of this Note is Definition G. *Id.* at 28-31. Dworkin also lists outcomes vs. motives, actual vs. hypothetical motives, and motives vs. reasons as dimensions considered in different combinations throughout the eight definitions of paternalism. *Id.* at 26-27.

124. *Id.* at 30. Dworkin expands on the phrase “for her own good” within the definition by explaining that “to limit a person’s liberty ‘for her own good’ is to limit her liberty for a certain kind of reason: that this policy will promote her welfare or improve her situation in some way.” *Id.*

125. *Id.*

126. Kenneth Einar Himma, *Philosophy of Law*, INTERNET ENCYCLOPEDIA OF PHILOSOPHY, <https://www.iep.utm.edu/law-phil/#SSH2a.ii> [<https://perma.cc/7RF6-2MBT>]; DEFINING PATERNALISM, *supra* note 122, at 26; *see generally*, 72 A.L.R.5th 607. On the validity of traffic regulations requiring motorcyclists to wear helmets,

The appellant cited John Stuart Mill, *On Liberty* (1859), for the proposition that “the only purpose for which power can rightfully be exercised over any member of a civilized community, against his will, is to prevent harm to others. His own good, either physical or moral, is not a sufficient warrant.”

Id.

127. “Paternalism is at the normative center of increasingly pressing public health questions concerning the permissibility of restrictions on the consumption of tobacco products and sugary, fatty foods.” Pope Dragon, *supra* note 7, at 660-61.

128. DEFINING PATERNALISM, *supra* note 122, at 120. Dworkin offers the following hypothetical to illustrate this normative constraint:

Consider the case where a husband hides his sleeping pills because he fears that his wife may find them and use them to commit suicide. A definition of paternalism might classify the husband’s act as non-paternalistic on the grounds that what A does is not a violation of a sphere of autonomy of his wife. She has no right that he keep his sleeping pills in clear view. Or, one might consider the act as paternalistic even while conceding this point. In some sense he substitutes his judgment for hers in the belief that his judgment is better than hers.

Id.

charts the scope of the circumstances which justify such curtailment of individual liberty.

Dworkin offers an important caveat: a policy is paternalistic under this definition when the government is acting to limit a person's liberty *if and only if* (1) the "policy cannot be fully justified if this reason [for acting] is not counted in its favor," and (2) "the government adopts it only because someone in the relevant political process takes or has taken this reason as sufficient to justify it."¹²⁹ Therefore, if the government is enacting the policy for a purely self-serving reason or solely because an agent of the government has determined a self-serving reason fully justifies the policy, then Dworkin does not consider the policy paternalistic.

Dworkin deepens the construction of the policy definition of paternalism by noting that government intervention should not be assumed an insult to the person being restricted.¹³⁰ The government paternalistically intervening on the behavior of a citizen should not be viewed as a judgment that they are a bad person.¹³¹ Dworkin further explains:

People make lots of mistakes in their practical judgments about what is best for them. This is something that those being paternalized can acknowledge without assuming that there is something fundamentally inadequate about their decision-making capacities. If we overrule their judgment, we need only be referring to a common human condition, not some fundamental defect of the person.¹³²

Dworkin says that the paternalistic policy's advocate will argue that the regulated cannot have sole discretion over how they are regulated, since the intervention is claimed to be legitimate.¹³³ Dworkin holds his own definition of liberty, however.¹³⁴ He believes that "...we think of liberty (or freedom, which I use as a synonym) as the ability of a person to do what he wishes and to have significant options that are not closed or made less eligible by the actions of other agents or the workings of social institutions."¹³⁵ Autonomy, to Dworkin, is akin to liberty but not quite the

129. *Id.* at 31.

130. *Id.* at 38. However, Dworkin concedes that "Of course, a judgment is being made that the conduct is defective, and a judgment is also made that you would not recognize this on your own. . ."

Id.

131. *Id.* Dworkin asserts that there is no global judgment being made on the person being restricted, and even if it were, he questions if that would constitute an insult. *Id.*

132. *Id.* at 37.

133. *Id.* at 38.

134. Compare with Mill's definition of liberty, ON LIBERTY, *supra* note 10.

135. *Id.*

same. Borrowing from the Millian camp of justifiable limitations on individual autonomy, Dworkin believes “...that self-determination can be limited without limiting liberty.”¹³⁶

To constitute paternalism, a person’s autonomy must be violated,¹³⁷ and therefore giving sufficient treatment to discovering whose autonomy is being violated and for what purpose is integral to evaluating any paternalistic policy.¹³⁸ Dworkin asserts that “[a]utonomy is a richer notion than liberty, which is conceived either as mere absence of interference or as the presence of alternatives. It is tied up with the idea of being a subject, of being more than a passive spectator of one’s desires and feelings.”¹³⁹ Examining a paternalistic policy invites us to acknowledge that this inherent violation of autonomy raises questions about how we can justify paternalism.¹⁴⁰

Dworkin offers a guiding heuristic to help us assess the validity of paternalistic intervention, which is “to ask under what conditions does A’s attempts to substitute his or her judgment for B’s constitute treating B as less than a moral equal.”¹⁴¹ According to Dworkin, the value of autonomy is derived from its ability to allow people to define their very nature, give “meaning and coherence to their lives,” and “take responsibility for the kind of person that they are.”¹⁴² In the same breath, Dworkin explains that we can also think of situations in which a person would want to have their autonomy denied.¹⁴³ Because Dworkin carves out this exception, paternalism creates a scenario in which the government is right in exercising a moral function of the law¹⁴⁴ for a legitimate paternalistic end under

136. THEORY AND PRACTICE, *supra* note 3, at 105.

137. *Id.* at 123.

138. Dworkin lays out the imperative: “What we must ascertain in each case is whether the act in question constitutes an attempt to substitute one person’s judgment for another’s, to promote the latter’s benefit.” *Id.*

139. THEORY AND PRACTICE, *supra* note 3, at 107. Dworkin believes that “there must be a usurpation of decision making, either by preventing people from doing what they have decided or by interfering with the way in which they arrive at their decisions” for someone to be treated paternalistically. *Id.* at 123.

140. *Id.*

141. *Id.* at 124. Importantly, Dworkin acknowledges that the relationship between what is best for a person and that person’s wants “is not a simple one.” *Id.*

142. THEORY AND PRACTICE, *supra* note 3, at 20.

143. *Id.* at 124. In these situations, there is the “possibility of justifying some paternalistic intervention.” *Id.*

144. See Hill, *The Constitutional Status of Morals Legislation*, *supra* note 86, at 5. “It is well within the constitutional authority of the states to achieve many, though not quite all, of the types of state interests traditionally associated with the ‘moral function of law.’”

Dworkin's definition.¹⁴⁵ Moreover, while considerations of limiting an individual's liberty, freedom, and autonomy are always relevant while debating a new government infringement on any of these fundamental values, the debate is made especially complex when the individuals that would be deprived of any of these entities are children. If weighing the value of limiting a citizen's sense of autonomy were not difficult enough, evaluating that of a child's is still more challenging.

Related to the theory of autonomy, Dworkin also writes about proxy consent, which is particularly relevant to actions made on behalf of children:

The moral and practical issue that is raised by proxy consent is the issue of when one individual may make decisions about, speak for, and represent the interests of another. In the case of a fetus, or a young child, or a mentally retarded person, or an unconscious person, or a person in great mental distress, or a person who has been found "unfit" to perform certain obligations and duties, the individual whose interests are to be secured and rights protected is viewed as *not in a position to, not competent to, make certain important decisions*.¹⁴⁶

To this end, Dworkin explains that proxy consent is not actually a real type of consent.¹⁴⁷ Rather, it is an approach for a situation such as regulating the marketing of e-cigarettes to children, where the receiving individuals cannot give their consent.¹⁴⁸ Children are not simply worse at giving consent than adults, they are members of a class of persons who are not competent to give consent. Dworkin says that

[w]hat we must ascertain in each case [of proposed policy] is whether the act in question constitutes an attempt to substitute one person's judgment for another's, to promote the latter's benefit. It is because

145. See DEFINING PATERNALISM, *supra* note 122, at 30 (explaining that "[t]o limit a person's liberty 'for her own good' is to limit her liberty for a certain kind of reason: that this policy will promote her welfare or improve her situation in some way").

146. THEORY AND PRACTICE, *supra* note 3, at 85 (emphasis added). Dworkin notes here that in both the political and biomedical fields, there are special "conflicts between the interests of individuals and the interests of some larger group." *Id.* at 865-85. This seems especially applicable to the tension between the interests of e-cigarette and tobacco product manufacturers and the interests of the individual children who are being marketed to by these companies.

147. *Id.* at 89.

148. *Id.* at 89. Dworkin specifically references a comparison of adults to children, noting that "[u]nlike the stockholder who signs his proxy over to management, and hence explicitly consents to their authority, neither children nor the mentally retarded nor the comatose have expressly abandoned their rights to decide." *Id.*

of the violation of the autonomy of others that normative questions about the justification of paternalism arise.¹⁴⁹

Proxy consent and paternalism are two interrelated ideas that both raise questions of who is authorized to decide on another's behalf.¹⁵⁰ Of the two, only paternalism contemplates the theoretical justification of substituting of one person's judgment for another's.

E-cigarette companies could ask themselves the same question posed by Dworkin on consent and representation: "What gives some persons the right to command others, to obligate others to obey such commands, and to enforce such commands by the use of coercion?"¹⁵¹ While the companies' aggressive advertising tactics targeted at children are arguably not *per se* "commands," they do use manipulative marketing tactics to induce children to buy their products. The average targeted child may feel they will gain social acceptance, status, harmless fun, or even scholarship money by buying these e-cigarette products.¹⁵² This apparent double standard between tobacco companies and the government can potentially be resolved by referring back to Mill's harm principle doctrine: interfering with the autonomy of the e-cigarette advertisers to disperse their advertisements by allowing the government to regulate them is justified.¹⁵³ The State's interference in e-cigarette advertising to children is justified by the only legitimate means – to prevent harm from being incurred by children, and for their self-protection.¹⁵⁴ While there is "intrinsic desirability of exercising the capacity for self-determination,"¹⁵⁵ children are rightly subjected to paternalistic policies that protect them from permanent bodily damage when they do not yet have the ability to rationally weigh the consequences of their actions, especially when their actions are being induced through manipulative advertising tactics.

Dworkin also offers an alternate, related possible justification for limiting autonomy: "Suppose that most people in a community would consent to a certain practice, but a minority would not [. . .] Knowing that we will be in the minority on some issues, and the majority on others, it is reasonable not to demand unanimity for certain issues."¹⁵⁶ Dworkin

149. *Id.* at 123.

150. THEORY AND PRACTICE, *supra* note 3, at 85.

151. *Id.* at 86.

152. See Binkley, *infra* note 173.

153. ON LIBERTY, *supra* note 10, at 80.

154. See Mill's idea of self-protection, *supra* note 83.

155. THEORY AND PRACTICE, *supra* note 3, at 112.

156. *Id.*

suggests that the policy makers consider several conditions to balance the interests between the majority and the minority whenever there is a split. “The relevant conditions are: (1) that the majority interest must be important (such as health); (2) that the imposition on the minority must be relatively minor...(3) that the administrative and economic costs of not imposing on the minority would be very high.”¹⁵⁷ Increasing regulation on marketing e-cigarettes to youth satisfies each of Dworkin’s proposed considerations: a government policy to restrict advertising e-cigarettes to children is (1) an important public health concern that (2) only imposes a loss of autonomy for children to take up a habit known to cause nicotine addiction, and (3) the economic costs of not implementing such a policy are the health expenditures necessary to treat widespread lung disease and nicotine addiction that will inevitably afflict the young generation.

The trickier question is whether government regulation of marketing for e-cigarette products to children constitutes “hard” or “soft” paternalism.¹⁵⁸ Exploring this distinction is necessary to analyze the type of paternalistic policy these regulations would constitute. Dworkin distinguishes between “hard” and “soft” paternalism to further explain government motivation in acting paternalistically over its citizens: “Soft paternalism is the view that (1) paternalism is sometimes justified, and (2) it is a necessary condition for such justification that the person for whom we are acting paternalistically is in some way not competent.”¹⁵⁹ Government regulation of advertising e-cigarettes to minors seems to be applicable under Dworkin’s definition of soft paternalism.¹⁶⁰

Under the first prong of Dworkin’s soft paternalism qualifications, and aligned with Mill’s harm principle, the government is morally justified in regulating e-cigarette advertising to children because it serves the one legitimate end of self-protection. The second requirement for soft paternalism is also met, because children are not themselves competent to discern the falsehoods present in the advertising of harmful substances.¹⁶¹

157. *Id.* at 128.

158. THEORY AND PRACTICE, *supra* note 3, at 124.

159. *Id.*

160. *Cf.* Pope Public, *supra* note 80, at 430. “If soft paternalism represents interventions that do not interfere with autonomy, then the only real paternalism is ‘hard’ or ‘strong’ paternalism, which constrains individuals’ decisions even when those decisions are informed and voluntary.” As discussed earlier, the difference in level of ethical controversy is what distinguishes the two forms of paternalism. *See* Pope Dragon, *supra* note 7.

161. *See* Stanford Children’s Health, *supra* note 15 (explaining that children tend to think with the emotional part of their brain before the rational part is fully developed). *See also* Brian L. Wilcox,

Dworkin believed that paternalism is justifiably applied to children because they do not possess some of the cognitive and emotional faculties required for completely rational decision-making.¹⁶²

Whatever future regulation the federal government will impose on regulating marketing e-cigarettes to children, it must lie at the nexus between Mill and Dworkin's liberal theories in order to best serve society's interest in helping avoid harm to children. Moreover, it must serve this goal without needlessly curbing the liberty and autonomy of children.

IV. POLICY RECOMMENDATION

Because e-cigarettes are legally¹⁶³ and functionally tobacco products, they should be subject to the same regulation as traditional tobacco products. Recognizing e-cigarettes as tobacco products is especially necessary when this type of tobacco product is specifically targeted to adolescents via advertising tactics designed to appeal to children. Because e-cigarettes and e-cigarette accessories carry the potential for addiction and myriad long-term health effects like combustible cigarettes, these products should be given the same treatment by the government as tobacco products.¹⁶⁴ E-cigarettes should therefore be similarly regulated so that they cannot be marketed to consumers under misleading advertising tactics. This principle should be most rigorously applied to advertising targeting the portion of society most vulnerable to being manipulated by aggressive advertising tactics: children.

The U.S. Food and Drug Administration has proposed a rule establishing regulatory authority over all non-drug e-cigarettes as tobacco products, but this proposed rule lacks updated requirements that are specifically tailored to advertising e-cigarettes.¹⁶⁵ Initial steps to increasing

et. al., *Report of the APA Task Force on Advertising and Children*, AMERICAN PSYCHOLOGICAL ASSOCIATION (Feb. 20, 2004), <https://www.apa.org/pi/families/resources/advertising-children.pdf> [<https://perma.cc/QQF3-SUSB>] (“Reviews of research demonstrate that the advertising of both tobacco and alcohol products creates more than brand awareness. The consensus of both short-term experimental research and longitudinal studies is that advertising and marketing contribute to youth smoking and alcohol consumption”).

162. Dr. Yehiel S. Kaplan, *The Right of a Minor in Israel to Participate in the Decision-Making Process Concerning His or Her Medical Treatment*, 25 *FORDHAM INT'L L.J.* 1085, 1098 (2002). Notably, Dworkin believes that children who do not lack these capacities should not be subject to paternalism. *Id.*

163. *Sottera, Inc. v. FDA*, 627 F.3d 891 (D.C. Cir. 2010).

164. See WORLD HEALTH ORGANIZATION, *supra* note 32.

165. Eric N. Lindblom, *Effectively Regulating E-Cigarettes and Their Advertising—and the First Amendment*, 70 *FOOD & DRUG L.J.* 55 (2015). Lindblom refers to “non-drug” e-cigarettes as those that do not have a therapeutic use and have not already been deemed “drugs” by the FDA. *Id.* at 57.

FDA regulation on advertising e-cigarettes to children has already begun, namely through the FDA and FTC working together to voice concern to e-cigarette companies about their advertising tactics through the seventeen letters issued jointly during 2018.¹⁶⁶ But government regulation must go further by adopting a more paternalistic policy, akin to Dworkin's definition of government-driven paternalism, in order to prevent further harm from being inflicted on children.

Through a liberal theory lens, the best solution is for the FDA to pursue a strictly paternalistic strategy in building regulatory policies surrounding e-cigarette marketing to youth. Adopting the paternalistic approach is a protectionist measure benefitting individual children. Since children lack adult competency to make rational product selection choices for themselves¹⁶⁷ e-cigarette companies should not specifically market to them at all. In addition, the FTC and FDA should take steps to further the efforts of the federal government's newly created Youth Tobacco Prevention Plan.¹⁶⁸ Of paramount importance, Congress must eliminate and ban e-cigarette marketing to children.

The federal government should adopt a two-step paternalistic approach¹⁶⁹ implemented through Congress and the FDA.¹⁷⁰ The first step is for Congress to enact legislation that will explicitly and unambiguously call for all marketing restrictions on advertising traditional cigarettes to youth to apply in the exact same way to advertising e-cigarettes to minors.

The second step is that the FDA must simultaneously generate new and specific marketing restrictions on e-cigarette advertisements targeted to youths. The FDA should author new regulations that ban e-cigarette

166. In response to the 17 letters sent by the FDA and FTC between May and September 2018, every misleadingly advertised product on the list was removed from the market. CTR. FOR TOBACCO PRODUCTS, *supra* note 60.

167. See Stanford Children's Health, *supra* note 15.

168. Part of the FDA's Comprehensive Plan for Tobacco and Nicotine Regulation, one of the three key focus areas of the Youth Tobacco Prevention Plan is "curbing marketing of tobacco products aimed at youth." CTR. FOR TOBACCO PRODUCTS, U.S. FOOD & DRUG ADMIN., FDA'S YOUTH TOBACCO PREVENTION PLAN, (Jan. 16, 2019), <https://www.fda.gov/TobaccoProducts/PublicHealthEducation/ProtectingKidsfromTobacco/ucm608433.htm> [<https://perma.cc/UFG4-CCYV>].

169. This Note advocates for a soft paternalism approach towards government intervention on the regulation of advertising e-cigarette products to children. See DEFINING PATERNALISM, *supra* note 122, at 30.

170. At the time of this Note's publishing, advertising e-cigarettes to children remains minimally regulated while tobacco companies are forbidden from specifically advertising traditional tobacco products to children. Given the considerable traction this issue has gained since 2017, (outlined in Section II, sub-section B of this Note,) it is possible a policy similar to the one outlined in this Note has already been proposed or is even on its way to being implemented by Congress or the FDA.

manufacturers from creating new electronic tobacco products designed to emulate branded food and beverage products. These include products typically associated with kids¹⁷¹ – like Peanut Butter Cup or Strawberry Cotton Candy – but should also include banning electronic tobacco products from being modeled after any branded food product, even ones that may not necessarily be associated only with children.¹⁷² With clear congressional intent, courts will also be able to readily uphold these regulations when they are inevitably challenged by e-cigarette companies in court as the tobacco industry begins losing a huge portion of their client base in the youngest age bracket due to advertising loss. Another paternalistic regulation that the FDA should impose is a ban on allowing e-cigarette companies to sponsor events where it is reasonably foreseeable that the majority of attendees are younger than twenty-five, including music festivals, film festivals, and major sporting events. More importantly, e-cigarette companies should not be allowed to sponsor academic scholarships for teens. Currently, e-cigarette brands have started offering college scholarships on university websites and have invited entries for essay contests on “the potential benefits of vaping.”¹⁷³ Through the college scholarship avenue, e-cigarette and vaporizers manufacturers have even managed to get their branding on esteemed universities’ websites, such as Harvard University.¹⁷⁴

The FDA should also impose a ban on allowing e-cigarette companies to create or distribute branded merchandise to youth. As part of the Millian harm principle to achieve self-protection, the FDA should use its power to legitimately prevent children from being exposed to branded clothing and merchandise that will only increase the number of harmful e-cigarette advertisements that they encounter regularly. The lack of regulation on e-

171. See Rachel Bluth, *'Peanut Butter Cup' Vape: Is This Dessert Or An E-Cigarette Flavor?*, KAISER HEALTH NEWS (Mar. 26, 2018) <https://khn.org/news/peanut-butter-cup-vape-is-this-dessert-or-an-e-cigarette-flavor/> [<https://perma.cc/Z7GQ-TJPG>] (providing examples of e-cigarette products designed to look like familiar branded food products: “[t]hese smoking products use chemical solutions with nicotine flavored with “juices” that have names like “Bubble Pop,” “Strawberry Cotton Candy” and “Peanut Butter Cup”).

172. One example of this would be an electronic tobacco product designed to resemble a can of Reddi-Whip whipped cream, a food product that is not immediately associated with children but it still just as appealing as a branded food product specifically associated with kids, like candy.

173. See Collin Binkley, *Vaping essays: E-cigarette sellers offering scholarships*, ASSOCIATED PRESS NEWS (June 8, 2018), <https://apnews.com/a35ba8a0200c4a27943da3b9254b9fe5> [<https://perma.cc/7UQS-QG32>]. (offering a description of the types of academic scholarships currently offered by e-cigarette companies, “[t]he scholarships, ranging from \$250 to \$5,000, mostly involve essay contests that ask students to write about the dangers of tobacco or whether vaping could be a safer alternative. At least one company asks applicants to write about different types of e-cigarettes and which one they recommend”).

174. *Id.*

cigarette manufacturers producing branded clothing for children is another example of a banned form of advertising for traditional cigarettes that has not yet been enforced for e-cigarette tobacco products.¹⁷⁵

Some argue for an outright ban on e-cigarette products with kid-friendly flavors and marketed directly to children.¹⁷⁶ Indeed, some jurisdictions are already instituting bans. On June 5, 2018 San Francisco, California voted in a law prohibiting the sale of flavored tobacco products, including menthol cigarettes and flavored vaping liquids.¹⁷⁷ This law constituted the first outright ban in the United States. An international example is Israel; in August 2018, Israel's Health Ministry announced a future ban on the sale of any e-cigarette products containing more than 20 milligrams of nicotine for every milliliter of liquid,¹⁷⁸ effectively banning JUUL products in Israel.

While bans like these are no doubt effective steps towards the goal of keeping harmful e-cigarette products out of kids' hands, there are foreseeable problems with absolute bans on e-cigarettes. There is the potential for a black market by which children and adolescents will still be able to access flavored e-cigarette products from places where they are still legal. Considering we live in a globalized economy, it is highly possible that teens could find ways to import e-cigarettes, much like how teens are finding ways to order e-cigarettes online today from 18+ retailers.¹⁷⁹

Even if the risk for the creation of a black market was not a concern, there would still inevitably be immense opposition by the tobacco industry to banning e-cigarette products altogether and prohibiting their use even by consenting adults. Recent precedent from the Court of Appeals for the D.C. Circuit established that the FDA had exceeded its regulatory authority by using the FD&C Act merely to expand regulation of e-cigarettes.¹⁸⁰ It is

175. For a discussion on the intent of the Tobacco Act, *see supra* notes 23-24.

176. Michael R. Bloomberg & Matt Myers, *Ban Flavored E-Cigarettes to Protect Our Children*, THE NEW YORK TIMES (Sept. 10, 2019), <https://www.nytimes.com/2019/09/10/opinion/vape-deaths-children-bloomberg.html> [<https://perma.cc/Y87V-SK6T>].

177. Yang YT, Glantz S., *San Francisco Voters End the Sale of Flavored Tobacco Products Despite Strong Industry Opposition*, 169 ANN INTERN MED. 708-709. doi: 10.7326/M18-2317.

178. Ronny Linder-Ganz, *In blow to Juul, Israel to ban some e-cigarettes*, HAARETZ (2018), <https://www.haaretz.com/israel-news/.premium-in-blow-to-juul-israel-to-ban-some-e-cigarettes-1.6360627> [<https://perma.cc/8JFK-3YJK>].

179. "According to the 2018 NYTS (National Youth Tobacco Survey), 5.7% of middle and high school e-cigarette users under 18 report buying e-cigarettes from the Internet." Laura Bach, *Where Do Youth Get Their E-Cigarettes?*, CAMPAIGN FOR TOBACCO-FREE KIDS (Dec. 3, 2019), <https://www.tobaccofreekids.org/assets/factsheets/0403.pdf> [<https://perma.cc/5T4X-ELWX>]. Additionally, due to a lack of regulatory enforcement, minors have an easy time completing their online e-cigarette purchases: "studies have found that youth successfully purchased e-cigarettes over the Internet in 94 to 97 percent of their online purchase attempts." *Id.*

180. *See Sottera, Inc. v. FDA*, 627 F.3d 891 (D.C. Cir. 2010).

therefore unlikely that courts will be willing to uphold a federal law granting the government the authority to outlaw a product entirely.

Moreover, there is limited evidence supporting the use of e-cigarettes as part of a smoking cessation program for adults who smoke combustible cigarettes.¹⁸¹ In the same press release announcing the FDA's proposals for eliminating flavored e-liquids marketed to youths, Commissioner Gottlieb endorsed improving the technology for Electronic Nicotine Delivery Systems (ENDS) to provide an alternative nicotine delivery system for adults seeking to obtain satisfying levels of nicotine without the negative effects of smoking.¹⁸² A growing body of research shows that electronic cigarettes are a better "harm reduction" option for adults who would otherwise smoke cigarettes, because users can sometimes choose the dose of nicotine delivered through e-cigarettes, and the most hazardous substances in cigarettes are those other than nicotine that come under combustion in traditional cigarettes.¹⁸³ It bears repeating, however, that nicotine is the addictive substance in tobacco,¹⁸⁴ and its ability to create an unhealthy habit in unaware, young users warrants paternalistic government regulation. Under paternalism, what can and should be ethically removed from the marketplace is any product specifically marketed to children that is strongly supported by data to cause adverse health effects, not any similarly hazardous product that is marketed only to adults.¹⁸⁵

Each of the policies recommended in this Note is squarely paternalistic under Dworkin's Definition G, because "a policy is paternalistic...if it cannot be justified by non-paternalistic reasons alone, and the government adopts it only because someone in the relevant political process takes some paternalistic reason as sufficient to justify it."¹⁸⁶ It is otherwise difficult to justify regulating marketing harmful e-cigarette tobacco products to children for non-paternalistic reasons, because in fact such marketing stimulates the economy and benefits commerce.

181. NAT'L INSTS. OF HEALTH, *What We Know About Electronic Cigarettes*, SMOKEFREE.GOV, <https://www.smokefree.gov/quit-smoking/ecigs-menthol-dip/ecigs> [https://perma.cc/35KA-R3MU]. The government-funded National Cancer Institute's Smokefree.gov website cautions that e-cigarettes are not approved by the FDA as a quit smoking aid. *Id.* But see Fox, *supra* note 65, "Health and Human Services Secretary Alex Azar said it seems clear that e-cigarettes can be used by adult smokers as a safer alternative to burnt tobacco."

182. See U.S. FOOD & DRUG ADMIN, *supra* note 66.

183. See Adler, *supra* note 44, at 340-42.

184. *Id.* at 340.

185. DEFINING PATERNALISM, *supra* note 122, at 30.

186. DEFINING PATERNALISM, *supra* note 122, at 31. See also, Fox, *supra* note 65, for an example of multiple social justice groups urging quicker action by the FDA, the FDA being the actor in the relevant political process that can instate the desired paternalistic policy.

If the harmfulness factor and consent issues were eliminated, there would be little to which to object. What this points to, however, is the fact that children are the ones who are being targeted by e-cigarette manufacturers is what inherently makes these government policies paternalistic.¹⁸⁷ Just as the FDA's ban on tobacco for children was for their own benefit,¹⁸⁸ any ban on marketing e-cigarette product advertising to children will be similarly paternalistic.

The second factor of paternalism is also met. Government is the collective action of citizens. Thus, any government action to restrict advertising e-cigarettes to children occurs through someone in the relevant political process – the “*someone* in the relevant political process [who] takes some paternalistic reason as sufficient to justify [the regulation]” refers to both Congress and the courts.¹⁸⁹ The legislative and judicial branches of government, in the case of advertising e-cigarettes to children, are within the “relevant” political process.¹⁹⁰

CONCLUSION

Increasing the FDA's authority to regulate and restrict the tobacco industry's ability to advertise e-cigarette products to children is inherently a restriction on the individual autonomy of children. The goals of preventing deleterious health effects and protecting children from going down the path of nicotine addiction are what make these types of regulations fall within Mill's sphere of action and justify government infringement on autonomy under Mill's harm principle.¹⁹¹ Children are not able to make decisions for themselves in their best interests the same way that adults can. The state has a valid interest in implementing a paternalistic policy that will protect the health of children. Their overall well-being, which includes living a life free from nicotine addiction, is a part of that valid state interest.

Both Dworkin and Mill drive at the heart of the same idea of assessing objectively valid reasons for limiting liberty. If the limitation is purely soft paternalism¹⁹² and meant to protect those who are not able to protect themselves, then that is a valid paternalistic policy. A paternalistic

187. Specifically, these are government policies that fall under the category of soft paternalism. See Pope Public, *supra* note 80; see also THEORY AND PRACTICE, *supra* note 3, at 124.

188. See Pope Public, *supra* note 80. Pope explains that the FDA's action was paternalistic in nature: “In other words, the FDA aimed to control children's access to tobacco for their own good.” *Id.*

189. DEFINING PATERNALISM, *supra* note 122, at 31.

190. *Id.*

191. See ON LIBERTY, *supra* note 10.

192. THEORY AND PRACTICE, *supra* note 3, at 124.

government scheme targeting the advertising of e-cigarettes and e-cigarette products to children is the appropriate solution to improve children's health prospects. Such a scheme will result in a diminished chance of the next generation developing nicotine addiction and suffering the health effects of long-term tobacco use. If the government refrains from enacting a paternalistic policy, on the other hand, our society will see this looming public health concern come to fruition, to the detriment to mankind. The federal government, acting through Congress and the FDA, is justified under theories of utilitarianism and paternalism to resolve the problem. While paternalism is a restraint on personal autonomy and liberty, advertising e-cigarettes to children creates the unique conditions which call for soft paternalism¹⁹³ as the correct solution. Mill and Dworkin would agree that the government owes children protection when they cannot protect themselves.

193. See Pope Public, *supra* note 80; see also THEORY AND PRACTICE, *supra* note 3, at 124.