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How Stricter E-Cigarette Regulations Will Keep The Traditional Cigarette in Power

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ABSTRACT

First harvested for export in 1612, tobacco has remained a large, and controversial, part of the United States' identity. In 1966, 42.6% of the American population smoked cigarettes. Currently, cigarette usage rate is around 14%, its lowest rate ever. Even with this sharp decline, cigarettes remain the number one cause of preventable deaths in the United States resulting in approximately 480,000 deaths per year. Nicotine, the active ingredient in tobacco, is an addictive drug, and many treatments exist for those attempting to quit. Recent studies have shown, however, that electronic nicotine delivery systems, more commonly known as "vapes" or "e-cigarettes", are more effective than the other forms of commonly used cigarette cessation devices. E-cigarettes have been marked by their own controversy, however, as they have shown to be exceedingly popular among adolescents. Due to the high underage use, many states began implementing their own regulations or bans on e-cigarettes, with the federal government eventually stepping in to attempt to limit underage use. These attempts may have the consequential side-effects of leading those using e-cigarettes as a cessation device to return to using traditional cigarettes and adding a barrier to current cigarette smokers wanting to quit. To remedy this, I propose that the United States Food and Drug Administration ("FDA") provide e-cigarettes with a specialized Over-the-Counter monograph that would allow adults access to what has shown to be an incredible cigarette cessation tool, while also limiting accessibility to minors.

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I. INTRODUCTION

A. The FDA's Regulatory Authority of E-Cigarettes

In 1996, the Food and Drug Administration ("FDA") attempted to assert jurisdiction over the regulation of tobacco products by claiming that nicotine is covered under the "drug" definition in the Federal Food, Drugs, and Cosmetics Act ("FDCA").[1] If so, cigarettes and smokeless tobacco are drug-device combinations as they are devices delivering nicotine to the body.[2] The FDA then promulgated regulations regarding the promotion, labeling, and accessibility of tobacco products in an attempt to decrease nicotine usage.[3] In response to these regulations, tobacco manufacturers, retailers, and advertisers filed suit against the FDA, leading to the 2000 Supreme Court case *Food and Drug Administration v. Brown & Williamson Tobacco Corp.* ("*Brown*").[4] In *Brown*, the Court held that "the FDA's claim to jurisdiction contravenes the clear intent of Congress"[5] because Congress had already spoken directly on the issue of tobacco product regulation by enacting tobacco specific legislation that did not involve the FDA.[6] Examples of such Congressional action include the Federal Cigarette Labeling and Advertising Act ("FCLAA"), which regulates cigarettes and "little cigars",[7] and the Comprehensive Smokeless Tobacco Health Education Act of 1986 ("CSTHEA"), which regulates smokeless tobacco.[8] The Court reasoned that since one main purpose of the FDCA is to ensure that FDA regulated products are "'safe' and 'effective' for [their] intended use,"[9] the FDA would have to ban tobacco products, which are "the single leading cause of preventable death in the United States."[10] Further, the risk tobacco products posed to public health precludes a finding that tobacco products can be safe for their intended use.[11] Since the adverse health effects of tobacco products were already well known when Congress enacted the FCLAA and the CSTHEA,[12] and Congress still decided to regulate the products as oppose to banning them, the Court concluded that it would be directly adverse to congressional intent for the

1. Food, Drug, and Cosmetic Act, ch. 675, Ch. II, § 201(g)(1), Pub. L. No. 111-31., 123 Stat. 1807 (1938) (codified as amended at 21 U.S.C. § 321(g)(1) (2021)). ("The term 'drug' means (A) articles recognized in the official United States Pharmacopœia, official Homœopathic Pharmacopœia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C). . . .").

2. Food and Drug Admin. v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 127 (2000), *superseded by statute*, Family Smoking Prevention and Tobacco Control Act of 2009, Pub. L. No. 111-31, 123 Stat. 1776, *as recognized in* Big Time Vapes, Inc. v. FDA, 963 F. 3d 436 (5th Cir. 2020).

3. *See id.* at 128.

4. *Id.* at 129-30.

5. *Id.* at 132.

6. *See* 15 U.S.C. § 1331 (2018).

7. *See id.*

8. *Brown*, 529 U.S. at 156; 15 U.S.C. § 4401 (2018).

9. *Brown*, 529 U.S. at 133-34; *see also* 21 U.S.C. § 393(b)(2) (2018).

10. *Brown*, 529 U.S. at 134-135.

11. *See id.* at 135.

12. *See id.* at 138.

FDA to have jurisdiction over tobacco products as the agency would be required to ban them under the FDCA.[13]

The FDA's authority to regulate tobacco products comes from the enactment of the Family Smoking Prevention and Tobacco Control Act ("TCA") on June 22, 2009, which amended the FDCA to include tobacco products.[14] Before this, tobacco products were only covered by the FDA in instances where the manufacturers made health claims about their tobacco product.[15]

Although the TCA gave the FDA jurisdiction over tobacco products, the amendment did not necessarily mean that the FDA could outright ban tobacco products for lack of safety, as may be surmised by *Brown*. The TCA gave the FDA jurisdiction to regulate all tobacco products as tobacco products, not as drugs or medical devices.[16] As such, the FDA no longer has to rely on the argument that such products are a drug or device to gain jurisdictional authority.[17]

The TCA "excludes from the meaning of 'tobacco product' any 'article that is a drug under 21 U.S.C. § 321(g)(1), a device under 21 U.S.C. § 321(h), or a combination product described in 21 U.S.C. § 353(g)."[18] As discussed in *Brown*, if the tobacco product is deemed to be a drug, a device, or a combination product, then the tobacco product must be banned under the FDCA.[19] This exclusion provision would be satisfied when a manufacturer of a tobacco product markets the product in a way that is outside the existing marketing standards set by tobacco specific legislation,[20] such as a claim of the product being a weight-loss aid or as a cessation device from traditional cigarettes.[21]

The FDA defines an e-cigarette as "an electronic device that delivers e-liquid[22] in aerosol form into the mouth and lungs when inhaled."[23] Under this definition, there are two types of devices, open e-cigarettes, devices where the user can refill with their own e-liquid, and closed e-cigarettes, which are not intended to be refilled and include disposable e-cigarettes and replaceable cartridge based devices.[24] The

13. *See id.* at 137-39.

14. *Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems: Guidance for Industry*, FOOD AND DRUG ADMINISTRATION: CENTER FOR TOBACCO PRODUCTS 3 (June 2019), https://www.fda.gov/media/127853/download [hereinafter *Premarket Tobacco Product Applications*].

15. *See Federal Regulation of Tobacco: A Summary*, TOBACCO CONTROL LEGAL CONSORTIUM 2 (July 2009), https://www.publichealthlawcenter.org/sites/default/files/resources/tclc-fda-summary.pdf.

16. *See generally* 21 U.S.C. §393(b)(2) (providing guidelines when tobacco products could be regulated).

17. *See generally id.* (eliminating the drug or device requirement for regulation).

18. Smoking Everywhere, Inc. v. U.S. Food and Drug Admin., 680 F. Supp. 2d 62, 67 (D.D.C. 2010), *aff'd sub nom*. Sottera, Inc. v. Food & Drug Admin., 627 F.3d 891 (D.C. Cir. 2010).

19. Food and Drug Admin. v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 142 (2000), *superseded by statute*, Family Smoking Prevention and Tobacco Control Act of 2009, Pub. L. No. 111-31, 123 Stat. 1776, *as recognized in* Big Time Vapes, Inc. v. FDA, 963 F. 3d 436 (5th Cir. 2020).

20. *See e.g*. Federal Cigarette Labelling and Advertising Act (FCLAA)., Pub. L. No. 89-92, 79 Stat. 282 (1965) (codified as amended at 15 U.S.C. § 1331 (2018)); Comprehensive Smokeless Tobacco Health Education Act (CSTHEA), Pub. L. No. 99-252, 100 Stat. 30 (1986) (codified as amended at 15 U.S.C. § 4401 (2018)).

21. *See Smoking Everywhere*, 680 F. Supp. 2d at 67-68.

22. *Premarket Tobacco Product Applications*, *supra* note 14, at 6 (Definition of e-liquid: "*e-liquids* include liquid nicotine, nicotine- containing liquids (i.e., liquid nicotine combined with colorings, flavorings, and/or other ingredients), and liquids that do not contain nicotine or other material made or derived from tobacco, but that are intended or reasonably expected to be used with or for the human consumption of a tobacco product.")

23. *Id.*

24. *Id.*

FDA classifies both e-cigarettes and e-liquids as covered under the general term Electronic Nicotine Delivery System ("ENDS").[25]

As ENDS were not explicitly included in the TCA, it was unclear whether they were considered tobacco products and were to be regulated the same as traditional tobacco products, or as drug-device combination.[26] In the 2012 case *Smoking Everywhere v. U.S. Food and Drug Administration* (*Smoking Everywhere*), American e-cigarette distributers Smoking Everywhere and NJOY sued the FDA as a result of their 2008 refusal to allow importation of e-cigarettes.[27] The FDA contended that the imported e-cigarettes were "intended to affect the structure or function of the body, and to prevent, mitigate, or treat the withdrawal symptoms of nicotine addiction,"[28] making the e-cigarettes an unapproved drug-device combination under the FDCA.[29] The FDA argued that e-cigarettes were outside the scope of *Brown & Williamson* as neither the FLCAA nor the CSTHEA applied to e-cigarettes, and were not covered by the TCA.[30] The court responded that "this argument is bootstrapping run amuck"[31] and that Congress intended the TCA to cover non-traditional tobacco products because in the act they both single out traditional tobacco products and use the broader term "tobacco product."[32]

As a result of this clarification, on May 10, 2016 the FDA issued a final rule clarifying that their authority extends to any product that "meet(s) the statutory definition of 'tobacco product' in section 201(rr) of the FD&C Act," which includes ENDS products.[33] Any new tobacco product, as defined under FDCA § 910,[34] must undergo premarket review through either the manufacturer showing that the product is exempt from premarket review, the product is substantially equivalent to a non-new tobacco product, or filing a premarket tobacco application (PMTA).[35] In August of 2017, the FDA issued guidance announcing that it will not enforce the premarket review provision for ENDS products until 2022.[36] This guidance was vacated in the 2019 case *American Academy of Pediatrics v. FDA* amidst the backdrop of an alarming adolescent usage rate of ENDS products and a new lung disease affecting e-cigarette users.[37] The court ordered manufacturers to submit their

25. *Id.*
26. *See id.* at 63-67.
27. *Id.*
28. *Id.* at 67-68.
29. *Id.* at 68.
30. *Id.* at 71.
31. *Id.* at 70.
32. *Id.* at 71.
33. *Id.* at 3.
34. "Any tobacco product that was not commercially marketed in the United States as of February 15, 2007; or any modification of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007," Food, Drug, and Cosmetic Act, ch. 675, Ch. IX, § 910, Pub. L. No. 111-31., 123 Stat. 1807 (1938) (codified as amended at 21 U.S.C. § 387(j) (2019)).
35. *See* 21 U.S.C. § 387(j)(2) (2019).
36. Am. Acad. of Pediatrics v. Food and Drug Administration, 379 F. Supp. 3d 461, 468 (D. Md. 2019).
37. *Id.*; *see also* Teresa W. Wang et al., *E-Cigarette Use Among Middle and High School Students – United States, 2020*, 69 MORBIDITY & MORTALITY WEEKLY REPORT 1310, 1310 (Sep. 18, 2020) (stating that "[i]n 2020, approximately one in five high school students and one in 20 middle school students currently used e-cigarettes. By comparison, in 2019, 27.5% of high school students (4.11 million) and 10.5% of middle school students (1.24 million) reported current e-cigarette use."); *E-cigarette or Vaping Product Use-Associated Lung Injury (EVALI)*, YALE MEDICINE, https://www.yalemedicine.org/conditions/evali/ (last visited April 1, 2021) [hereinafter *E-cigarette or Vaping Product Use-Associated Lung Injury (EVALI)*]; *FDA Issues Proposed Rule for Premarket Tobacco Product Applications as Part of*

PMTAs by May 12, 2020.[38] This May 12th deadline was then extended to September 9, 2020 to provide manufactures relief from varying complications in filling out their PMTAs stemming from the coronavirus pandemic.[39]

B. The Current E-Cigarette Market

E-cigarettes were invented by Chinese pharmacist, Hon Lik, in 2003, and introduced to the American market in 2007.[40] In the 13-years that these devices have been on the U.S. market, e-cigarettes have grown into a 4.2 billion USD industry as of 2018, with an expected compound annual growth rate of 24.1% from 2019 to 2025, and a 12.41 billion USD valuation worldwide as of 2019.[41] In recent years, there has been a staggering increase in adolescent use of e-cigarettes, with a 2020 study revealing that "19.6% of high school students (3.02 million) and 4.7% of middle school students (550,000) reported current e-cigarette use."[42]

Although experts generally agree that ENDS products are less harmful than traditional cigarettes, the long-term effects of the products are still unclear.[43] In August of 2019, the Centers for Disease Control ("CDC") identified a lung disease, later named EVALI, that was linked to the use of e-cigarettes.[44] By February 18, 2020, there were a total of 2,807 hospitalizations or deaths in the United States resulting from EVALI, and the American Medical Association urged the public to avoid the use of e-cigarettes entirely.[45] Amidst this outbreak and the high rate of

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Commitment to Continuing Strong Oversight of E-cigarettes and Other Tobacco Products , FOOD AND DRUG ADMINISTRATION, (Sep. 20, 2019) https://www.fda.gov/news-events/press-announcements/fda-issues-proposed-rule-premarket-tobacco-product-applications-part-commitment-continuing-strong.

38. *Am. Acad. of Pediatrics*, 379 F. Supp. 3d at 468.

39. *See Coronavirus (COVID-19) Update: Court Grants FDA's Request for Extension of Premarket Review Submission Deadline for Certain Tobacco Products Because of Impacts from COVID-19*, FOOD AND DRUG ADMINISTRATION (April 23, 2020), https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-court-grants-fdas-request-extension-premarket-review-submission-deadline.

40. Rachel Grana et al., *Background Paper on E-cigarettes (Electronic Nicotine Delivery Systems)*, CENTER FOR TOBACCO CONTROL RESEARCH AND EDUCATION 6 (Dec. 2013), https://escholarship.org/uc/item/13p2b72n#page=6.

41. GRAND VIEW RESEARCH, *U.S. E-cigarette And Vape Market Size, Share & Trends Analysis Report By Component, By Distribution Channel, By Product (Rechargeable, Disposable, Modular), And Segment Forecasts, 2019 – 2025*, (June 2019) https://www.grandviewresearch.com/industry-analysis/e-cigarette-vaping-market; GRAND VIEW RESEARCH, *E-cigarette And Vape Market Size, Share & Trends Analysis Report By Product (Disposable, Rechargeable), By Component (Vape Mod, E-liquid), By Distribution Channel, And Segment Forecasts, 2020 – 2027*, (Feb. 2020) https://www.grandviewresearch.com/industry-analysis/e-cigarette-vaping-market.

42. Wang et al., *supra* note 37, at 1310.

43. *See generally* David T. Levy et al., *Potential Deaths Averted in USA by Replacing Cigarettes With E-cigarettes*, TOBACCO CONTROL 2018:27:18, 18 (2018) (concluding "[t]he tobacco control community has been divided regarding the role of e-cigarettes in tobacco control. Our projections show that a strategy of replacing cigarette smoking with vaping would yield substantial life year gains, even under pessimistic assumptions regarding cessation, initiation and relative harm"); KATHLEEN STRATTON ET AL., NAT'L ACADEMIES OF SCI., ENG'G, & MED., PUBLIC HEALTH CONSEQUENCES OF E-CIGARETTES, 15-16 (2018).

44. *E-cigarette or Vaping Product Use-Associated Lung Injury (EVALI), supra* note 37.

45. *See Outbreak of Lung Injury Associated with E-cigarette Use, or Vaping*, CENTERS FOR DISEASE CONTROL (Feb. 25, 2020), https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html#cdc-recommends [hereinafter *Outbreak of Lung Injury Associated with E-cigarette Use*]; Patrice A. Harris, M.D., M.A., *AMA Urges Public to Avoid E-cigarette Use Amid Lung Illness Outbreak*,

adolescent use of ENDS, nine states and more than 250 cities enacted or planned e-cigarette bans or restrictions.[46] The federal government also took action, with President Trump announcing a ban on the sale of flavored e-liquids except for tobacco and menthol for cartridge based devices and raising the minimum age to buy tobacco products from 18 to 21.[47] Further research into EVALI, however, later revealed that the disease was not caused by traditional e-cigarettes, but by Vitamin E acetate found in e-cigarettes containing THC.[48]

The actions taken by federal and state governments to decrease adolescent usage of e-cigarettes seem to have been effective. The usage rates of 19.6% and 4.7% of high schoolers and middle schoolers in 2020, respectively, decreased from the 2019 usage rates of 27.5% of high schoolers and 10.5% of middle schoolers.[49] These actions are not without consequence, as stricter regulations and outright bans on these products may lead to an increase in traditional cigarette smokers and a decrease in cigarette cessation rates.[50] Rather than imposing stricter limitations or banning these products, I propose providing an easier new drug pathway to market for ENDS products along with providing the current tobacco product pathways. This would allow ENDS to be marketed as cessation devices, with the flavored ENDS being the most common among adults attempting to quit traditional cigarettes,[51] while still reducing adolescent access to the devices.

AMERICAN MEDICAL ASSOCIATION (Sep. 9, 2019), https://www.ama-assn.org/press-center/ama-statements/ama-urges-public-avoid-e-cigarette-use-amid-lung-illness-outbreak.

46. *See* Terry Turner, *Juul Ban*, DRUGWATCH, https://www.drugwatch.com/e-cigarettes/juul-ban/ (last modified March 16, 2021).

47. Dan Vergano, *Trump Just Announced A Nationwide Ban Of Flavored Vape Cartridges Except Tobacco And Menthol*, BUZZFEED NEWS (Jan. 2, 2020 1:43 PM), https://www.buzzfeednews.com/article/danvergano/trump-juul-flavor-ban.

48. *See Outbreak of Lung Injury Associated with E-cigarette Use, supra* note 45; Colin Poitras, *Rates of E-cigarette and Marijuana Use Not Associated With Larger Outbreaks of Vaping-Related Lung Injuries, YSPH Study Finds*, YALE SCHOOL OF PUBLIC HEALTH (Aug. 25, 2020), https://publichealth.yale.edu/news-article/26879/.

49. Wang et al., *supra* note 37, at 1310.

50. *See generally* Peter Hajek et al., *A Randomized Trial of E-Cigarettes Versus Nicotine-Replacement Therapy*, 380 N. ENGL. J. MED. 629, 629 (Jan. 30, 2019) (concluding "[e]-cigarettes were more effective for smoking cessation than nicotine-replacement therapy, when both products were accompanied by behavioral support"); Leonie S. Brose et al., *Associations Between Vaping and Relapse to Smoking: Preliminary Findings From a Longitudinal Survey in the UK*, 16:76 HARM REDUCTION J. (Dec. 30, 2019), https://harmreductionjournal.biomedcentral.com/articles/10.1186/s12954-019-0344-0 (concluding "[r]elapse to smoking is likely to be more common among ex-smokers vaping infrequently or using less advanced devices); Guy Bentley, *Cigarette Sales Increase as Vaping Bans Push People Back to Smoking*, REASON FOUNDATION (Aug. 24, 2020), https://reason.org/commentary/cigarette-sales-increase-as-vaping-bans-push-people-back-to-smoking/ (discussing potential results of the San Francisco ban on flavored tobacco products potentially leading to loss in revenue and increase in traditional cigarette sales.)

51. Shannon Gravely, et al., *The Association of E-cigarette Flavors With Satisfaction, Enjoyment, and Trying to Quit or Stay Abstinent From Smoking Among Regular Adult Vapers From Canada and the United States: Findings From the 2018 ITC Four Country Smoking and Vaping Survey*, 22:10 NICOTINE AND TOBACCO RESEARCH 1831, 1834 (May 25, 2020).

II. EXPLORING THE PATHWAYS TO MARKET

A. Premarket Tobacco Product Applications and Substantial Equivalence

New tobacco products can enter the market in one of three ways: (1) by showing that the product is substantially equivalent to a previously approved tobacco product, (2) by showing that the product is exempt from showing substantial equivalence, or (3) completion and acceptance of a premarket tobacco application ("PMTA").[52]

PMTA's are required for any "new tobacco product"[53] that a company introduces or delivers for introduction into interstate commerce.[54] For a PMTA to be accepted, a manufacturer must show that allowing their new tobacco product on the market would be "appropriate for the protection of the public health."[55] In determining whether the product is appropriate, the FDA takes into account "(A) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and (B) the increased or decreased likelihood that those who do not use tobacco products will start using such products."[56] The manufacturing process of the product must also conform to good manufacturing practices under FDCA § 906 (e).[57] A manufacturer's labeling cannot be false or misleading, and must conform to the tobacco product standards found in FDCA § 907 or provide adequate information behind any change from the standards.[58]

Virtually all ENDS are expected to reach the market through PMTA's, due to the difficulty in identifying predicate ENDS products necessary for the substantial equivalence pathways.[59] To show substantial equivalence, ENDS manufacturers would need to identify a predicate tobacco product that was "commercially marketed (other than for test marketing) in the United States as of February 15, 2007."[60]

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52. Food, Drug, and Cosmetic Act, ch. 675, Ch. IX, § 910, Pub. L. No. 111-31., 123 Stat. 1807 (1938) (codified as amended at 21 U.S.C. § 387(j) (2019)).

53. A new tobacco product is defined as "(A) any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007; or (B) any modification (including a change in design, any component, delivery, or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007." Food, Drug, and Cosmetic Act, ch. 675, Ch. IX, § 910(a)(1)(A)-(B), Pub. L. No. 111-31., 123 Stat. 1807 (1938) (codified as amended at 21 U.S.C. § 387(j)(a)(1)(A)-(B) (2019)).

54. Food, Drug, and Cosmetic Act, ch. 675, Ch. IX, § 910, Pub. L. No. 111-31., 123 Stat. 1807 (1938) (codified as amended at 21 U.S.C. § 387(j) (2019)).

55. Food, Drug, and Cosmetic Act, ch. 675, Ch. IX, § 910(c)(2)(A), Pub. L. No. 111-31., 123 Stat. 1807 (1938) (codified as amended at 21 U.S.C. § 387(j)(c)(2)(A) (2019)).

56. Food, Drug, and Cosmetic Act, ch. 675, Ch. IX, § 910(c)(4)(A)-(B), Pub. L. No. 111-31., 123 Stat. 1807 (1938) (codified as amended at 21 U.S.C. § 387(j)(c)(4)(A)-(B) (2019)).

57. Food, Drug, and Cosmetic Act, ch. 675, Ch. IX, § 910(c)(2)(B), Pub. L. No. 111-31., 123 Stat. 1807 (1938) (codified as amended at 21 U.S.C. § 387(j)(c)(2)(B) (2019)).

58. Food, Drug, and Cosmetic Act, ch. 675, Ch. IX, § 910(c)(2)(C)-(D), Pub. L. No. 111-31., 123 Stat. 1807 (1938) (codified as amended at 21 U.S.C. § 387(j) (c)(2)(C)-(D) (2019)).

59. *See generally* Food, Drug, and Cosmetic Act, ch. 675, Ch. IX, § 910(a)(1)(A)-(B), Pub. L. No. 111-31., 123 Stat. 1807 (1938) (codified as amended at 21 U.S.C. § 387(j) (a)(1)(A)-(B) (2019) (indicating a predicate product existed before 2007); Grana et al., supra note 40 (indicating that E-cigarettes did not make it to American Markets until 2007).

60. Food, Drug, and Cosmetic Act, ch. 675, Ch. IX, § 910(a)(2)(A)(i)(I), Pub. L. No. 111-31., 123 Stat. 1807 (1938) (codified as amended at 21 U.S.C. § 387(j)(a)(2)(A)(i)(I) (2019)).

Since modern e-cigarettes that could potentially be used as a predicate product to make a showing of substantial equivalence were not introduced into the American market until 2007, this is a virtually impossible showing to make.[61] ENDS manufacturers likely could not argue that they are exempt from making a showing of substantial equivalence as the exemptions still require the locating of a predicate tobacco product that was commercially marketed as of February 15, 2007.[62] This only leaves ENDS manufacturers with the PMTA process pathway to the market if they want to distribute their product as a tobacco product.

As the September 9, 2020 deadline for ENDS manufactures to submit their PMTA's drew closer, the cost of PMTA's came under heavy criticism from the ENDS industry.[63] The FDA contended that completion of a PMTA would cost a manufacturer around $117,00 to $466,000, but this was considered a low estimate by those in the industry, with Amanda Wheeler, vape store owner and vice president of Rocky Mountain Smoke-Free Alliance,[64] estimating far more for these application.[65] And Joe Teller, category management director for Swedish Match, who completed eight PMTA's for their General Snus line of smokeless tobacco stating that "[the cost] was more than what we thought for . . . PMTA."[66] The high cost on the companies stem from the FDA considering every different flavor variant and nicotine strength, and combination thereof, as a different tobacco product, and thus needing a separate PMTA.[67]

B. New Drug Applications

If the manufacturer does not want to distribute their product as a tobacco product, there is also the option of distributing the tobacco product as a drug by going through the drug pathway to market.[68] For ENDS manufacturers, this is currently not a viable option.[69] Despite the shown benefits of ENDS products as tools for cigarette cessation, ENDS that claim health benefits would be considered an unapproved drug-device combination, and would have to undergo the requisite

61. *See generally* Grana et al., supra note 40 (indicating that E-cigarettes did not make it to American Markets until 2007).

62. *See generally* Food, Drug, and Cosmetic Act, ch. 675, Ch. IX, § 905(j)(3)(A), Pub. L. No. 111-31., 123 Stat. 1807 (1938) (codified as amended at 21 U.S.C. § 387(e)(j)(3)(A)(2019) (giving the requirements to be exempt from such applications).

63. *See* Michael McGrady, *As the PMTA Deadline Looms, the Vaping Industry Faces Potential Disaster*, INSIDE SOURCES (Sep. 3, 2020) https://www.insidesources.com/as-the-pmta-deadline-looms-the-vaping-industry-faces-potential-disaster/.

64. Rocky Mountain Smoke-Free Alliance is a not-for-profit trade organization that represents small business owners and manufactures of ENDS in Colorado. *See Advocating for Vapor Businesses is OUR business!*, ROCKY MOUNTAIN SMOKE-FREE ALLIANCE, https://www.rmsfa.org/ (last visited April 2, 2021); *Meet Our Board*, ROCKY MOUNTAIN SMOKE-FREE ALLIANCE, https://www.rmsfa.org/meet-our-board (last visited April 2, 2021).

65. McGrady, *supra* note 63.

66. Melissa Vonder Haar, *6 Insights From CSP's Tobacco Update Webinar*, CSP DAILY NEWS (May 25, 2016), https://www.cspdailynews.com/tobacco/6-insights-csps-tobacco-update-webinar#page=4.

67. U.S. FOOD & DRUG ADMIN., *Commonly Asked Questions: About the Center for Tobacco Products*, (July 10, 2020), https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp/commonly-asked-questions-about-center-tobacco-products.

68. *See infra* notes 70-74 and accompanying text.

69. *See infra* notes 75-76 and accompanying text.

premarket review before they are allowed to reach the market.[70] Whether a drug-device combination product goes through the drug regulatory pathway or the device regulatory pathway depends on which part of the combination, the drug or device, contributes the most to the product's intended therapeutic effect.[71] For ENDS products that claim smoking cessation benefits, the drug product (the e-liquid) provides the claimed therapeutic effect, while the device portion is used to deliver the drug product.[72] FDCA § 505(a) states that "no person shall introduce or deliver for introduction into interstate commerce any new drug"[73] without an approved New Drug Application ("NDA"), with a new drug being defined as a drug that is "not generally recognized. . . as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof."[74] Thus, an ENDS product that claims to be useful in smoking cessation would be a new drug subject to an NDA due to the products not being generally recognized as safe and effective for use as a smoking cessation tool.

NDA's are even more costly than PMTA's, with an estimated cost of $2.8 billion, as they have much stricter criteria for acceptance.[75] For an NDA to be approved, the application needs to contain separate sections for clinical data on the drugs pharmacodynamics, efficacy, and safety; data from human pharmacokinetic studies; nonclinical studies; a full description of the manufacturing controls used; and the patent information of the product.[76] The time and cost necessary for an NDA is only feasible for large tobacco corporations and preclude most manufacturers from using this route.

C. Over-The Counter Monographs

A potential third option for ENDS products to reach the market is through the use of an over-the-counter monograph ("OTC" monograph), which is what allows products such as nicotine gum and transdermal nicotine patches to be sold without a prescription.[77] OTC monographs list the claims, labeling, dosages, and active ingredients of a product, and if the product matches everything on the list, allows it to be sold over-the-counter without a prescription.[78] Drugs that are given OTC

70. *See generally Smoking Everywhere Inc. v. U.S. Food and Drug Admin., 680 F.Supp.2d, 62, 63-71 (2018)*; Hajek, *supra* note 50; *Premarket Tobacco Product Applications*, *supra* note 14, at 9; U.S. FOOD & DRUG ADMIN., *Smoking Cessation and Related Indications: Developing Nicotine Replacement Therapy Drug Products*, 3–4, (Feb. 2019), https://www.fda.gov/media/121308/download [hereinafter *Smoking Cessation and Related Indications*].

71. 21 USC 353(g)(1)(C) (2018).

72. *Smoking Cessation and Related Indications*, *supra* note 70, at 4.

73. Food, Drug, and Cosmetic Act, ch. 675, Ch. V, § 505(a), Pub. L. No. 111-31., 123 Stat. 1807 (1938) (codified as amended at 21 U.S.C. § 355(a) (2018).

74. Food, Drug, and Cosmetic Act, ch. 675, Ch. II, § 201(9), Pub. L. No. 111-31., 123 Stat. 1807 (1938) (codified as amended at 21 U.S.C. § 3521(p) (2018).

75. *See generally*, Joseph A. DiMasi et al*., Innovation in the Pharmaceutical Industry: New estimates of R&D costs*, 47 J. OF HEALTH ECON. 20, 28 (May, 2016) (discussing the costs of development and clinical trial of drugs).

76. Food, Drug, and Cosmetic Act, ch. 675, Ch. V, § 505(b), Pub. L. No. 111-31., 123 Stat. 1807 (1938) (codified as amended at 21 U.S.C. § 355(b) (2021).

77. *See* U.S. FOOD & DRUG ADMIN*., Over-the-Counter (OTC) Drug Monograph Process,* (Sept. 3, 2020), https://www.fda.gov/drugs/over-counter-otc-drug-monograph-process [hereinafter *Drug Monograph Process*].

78. *See id.*

monographs are generally regarded as safe and effective, meaning that they are not considered a "new drug" under FDCA 201(p), and do not require an NDA.[79] As of the CARES Act, signed into law on March 27, 2020, the OTC monograph process is no longer subject to notice-and-comment rulemaking, and instead has adopted an administrative order process by which an order to add, remove, or change a monograph can be either initiated directly by the FDA or requested by a company.[80] The monograph is then reviewed by the FDA, and if accepted, codified in the Code of Federal Regulations.[81] Once finalized, a company can market a drug that has an OTC monograph without going through the premarket approval process.[82]

Usually, drugs that are given an OTC monograph were first prescription-only (Rx), and the manufacturer requested approval for OTC marketing.[83] An Rx-to-OTC switch requires the FDA to "look at the safety and effectiveness of the product, the benefit-to-risk ratio, and whether the labeling can be written in such a way that consumers can use the products safely without the intervention of a healthcare provider."[84] Individual drugs may also be granted OTC status, but not given an OTC monograph, as is the case with the current FDA approved OTC nicotine replacement therapies ("NRT").[85] Each of the OTC NRT's (nicotine gum, transdermal nicotine patches, and nicotine lozenges), became OTC through an Rx-to-OTC switch, meaning they originally went through the NDA pathway.[86]

III. AN OVER-THE-COUNTER MONOGRAPH FOR ENDS

A. Benefits of an OTC Monograph

An OTC monograph pathway for ENDS products would benefit manufacturers, consumers, and public health more than the PMTA pathway or the NDA pathway. Research has also shown that ENDS are more effective cigarette cessation tools than NRTs.[87] A 2019 study published in the New England Journal of Medicine compared the cigarette cessation rates of various NRTs to ENDS and concluded that ENDS were more effective cigarette cessation tools than NRTs.[88] The study found that "the 1-year abstinence rate was 18.0% in the e-cigarette group, as compared with 9.9% in the nicotine-replacement group."[89] Researchers also generally

79. *See id.*
80. *Id.*
81. For the general provisions and administrative procedures regarding recognition of over-the-counter drug, *see* 21 C.F.R. § 330.1¬ (2020) – § 330.15 (2020).
82. *Drug Monograph Process*, *supra* note 77.
83. CONSUMER HEALTHCARE PRODUCTS ASS'N, https://www.chpa.org/about-consumer-healthcare/faqs/FAQs-rx-otc-switch (last visited Mar. 6, 2021).
84. *Id.*
85. Azim Chowdhury & Samuel Jockel, *Spotlight on Tobacco | Future Developments in the Regulation of Electronic Nicotine Delivery Systems: Potential Over-the-Counter Pathway*, FOOD & DRUG L. INST., https://www.fdli.org/2018/10/spotlight-on-tobacco-future-developments-in-the-regulation-of-electronic-nicotine-delivery-systems-potential-over-the-counter-pathway/ (last visited Mar. 6, 2021); *Nicotine replacement therapy*, U.S. NAT'L LIBR. OF MED., https://medlineplus.gov/ency/article/007438.htm (last visited Mar. 6, 2021).
86. *See* Chowdhury & Jockel, *supra* note 85.
87. Hajek, *supra* note 50, at 629.
88. *Id*.
89. *Id.*

regard ENDS as safer than traditional cigarettes.[90] A 2017 study on the potential deaths averted in the United States by switching from traditional cigarettes to ENDS, under both pessimistic and optimistic models, found that "replacement of cigarette by e-cigarette use over a 10-year period yields 6.6 million fewer premature deaths with 86.7 million fewer life years lost in the Optimistic Scenario. Under the Pessimistic Scenario, 1.6 million premature deaths are averted with 20.8 million fewer life years lost."[91]

The benefits that an OTC monograph provides can be sorted into three categories: price, effectiveness as a cessation tool, and safety.

i. Price

One benefit of a monograph would be the potential to provide for a lower barrier to entry for manufacturers entering into the ENDS market because each individual product would no longer require premarket approval.[92] Not needing premarket approval means that the monograph would be both a cheaper and more reliable pathway to market, as the manufacturer would not have to make the various costly showings required by PMTAs or NDAs.[93] Instead, ENDS manufacturers would only need to match the contents of the monograph to reach the market.[94] This lower entry barrier would likely lead to more competition in the market, as fewer companies would be forced out of the industry under a monograph than the current PMTA pathway.[95] Easier access to the industry and more competition means that ENDS would likely be cheaper for consumers. As ENDS become cheaper, they will also become more attractive options to consumers wanting to quit smoking traditional cigarettes.

ii. Effectiveness as a Cessation Tool

An OTC monograph could allow for a wide assortment of flavors, or flavoring ingredients to be combined at the manufacturer's discretion, which were often the manufacturer's best-selling products.[96] More variety in nontobacco flavored ENDS may improve their effectiveness as a cessation device.[97] A 2020 study in *Nicotine & Tobacco Research* found that "[a] majority of regular vapers in Canada and the US use nontobacco flavors. Fruit and candy flavors lead to more satisfaction and enjoyment among users. While it does not appear that certain flavors are associated with a greater propensity to attempt to quit smoking among concurrent users,

90. Stratton, *supra* note 43, at 12 ("[t]he evidence about harm reduction suggests that across a range of studies and outcomes, e-cigarettes pose less risk to an individual than combustible tobacco cigarettes.")

91. Levy, *supra* note 43, at 18.

92. *See Drug Monograph Process*, *supra* note 77.

93. *See supra* notes 63-74 and accompanying text.

94. *See Drug Monograph Process*, *supra* note 77.

95. *See* McGrady*, supra* note 63.

96. *See* Victoria Forster, *Study: Juul Stopped Selling Their Fruit-Flavored Vaping Pods, With No Effect On Overall Sales*, FORBES (Apr. 17, 2020, 7:44 AM) https://www.forbes.com/sites/victoriaforster/2020/04/17/study-juul-ceasing-sales-of-fruit-flavored-e-cigarettes-had-no-effect-on-overall-sales/?sh=4f346d4c4cc5 (in October 2018, fruit flavors made up one-third of all sales of Juul flavors).

97. Gravely, *supra* note 51, at 1831-32.

nontobacco flavors are popular among former smokers who are exclusively vaping." [98] Flavored ENDS products are also the most popular among adolescents, and the limitations placed on flavored ENDS were enacted primarily to decrease adolescent usage.[99] An OTC monograph, combined with other sale restrictions, could combat this by placing limitations on where ENDS products could be sold, limiting the accessibility of the products to minors.[100]

iii. Safety

Perhaps the largest benefit of an OTC monograph pathway over the PMTA pathway for ENDS is that it would allow greater regulatory oversight over the health and safety of the products.[101] Scott Gottlieb, the previous FDA Commissioner, stated in an interview with CNBC that:

[An] over-the-counter regulatory pathway . . . would give us many more tools to look at both safety and benefit, and study whether or not an e-cigarette actually does promote smoking cessation and also give us many more tools to actually study the toxicology associated with it and see what effects it might have on the lung.[102]

Although the availability of an OTC monograph for ENDS provides many clear benefits, there are three immediately apparent issues with the pathway. The issue of adolescent usage of ENDS, whether using ENDS to quit traditional nicotine products leads to long-term nicotine abstinence, and the barriers that are inherent to the creation of an OTC monograph for a drug.

B. The Lingering Issue of Adolescent Use

The issue of potential adolescent use of flavored ENDS could be mitigated by restricting the distribution of the products in ways where it would be more difficult for the adolescents to reach them, rather than wholly taking the products off of the market or imposing the costly burden that is a PMTA. A major step towards this has already been accomplished with the nationwide T21 laws enacted on December 20, 2019, amending the FDCA by raising the minimum legal age for tobacco products from 18 years-old to 21 years-old.[103] Prior to the amendment, nineteen states raised the state-wide minimum legal age for tobacco products to 21, with Hawaii and California being the first to implement T21 laws on January 1, 2016, and June 9, 2016, respectively.[104] Although it is too early to know the substantive effects of the FDCA amendment, the results of the state-led T21 laws have been mixed. The

98. *Id.* at 1832.
99. Vergano, *supra* note 47.
100. *See infra* notes 105-113 and accompanying text.
101. *See* Angelica LaVito, *FDA may consider over-the-counter regulation for e-cigarettes*, CNBC (Mar. 28, 2018 10:16 AM), https://www.cnbc.com/2018/03/28/fda-may-consider-over-the-counter-regulation-for-e-cigarettes.html.
102. *Id.*
103. Food, Drug, and Cosmetic Act, ch. 675, Ch. IX, § 906(d), Pub. L. No. 111-31., 123 Stat. 1807 (1938) (codified as amended at 21 U.S.C. § 387f(d)(3)(A)(ii) (2019).
104. CTR. FOR DISEASE CONTROL, *Tobacco 21: Policy Evaluation for Comprehensive Tobacco Control Programs* 4-5, https://www.cdc.gov/tobacco/stateandcommunity/tobacco_control_programs/surveillance_evaluation/tobacco-21-policy-evaluation/pdfs/T21-policy-evaluation-guide-508.pdf (last visited April 2, 2021); Xueying Zhang, et al., *Evaluation of California's 'Tobacco 21' law*, TOBACCO CONTROL 2018:27:656, 656 (2018).

results of a study published January 13, 2020 revealed that "[f]ollowing the T21 in Hawaii, average monthly cigarette unit sales dropped significantly (−4.4%, $p<0.01$) coupled with a significant decrease in menthol market share (−0.8, $p<0.01$)," and concluded that "[a]s part of a comprehensive approach to prevent or delay tobacco use initiation, T21 laws may help to reduce sales of cigarette and large cigar products most preferred by US youth and young adults."[105] These results are not across the board, however, as a February 27, 2020 study on the effects of the T21 laws in California found "[n]egligible changes in cigarette and e-cigarette use. . . observed pre-T21 versus post-T21," and concluded that "[p]ost-T21, few participants were refused purchase of any tobacco product, despite the illegality of such sales. Better enforcement of T21 is needed to improve the efficacy of T21 legislation."[106] As the long-term effects of T21 laws are not yet certain, further limitations need to be implemented in the distribution of ENDS to reduce the availability of the products to minors before additional flavored ENDS, which are favored by both adolescents and adults attempting to quit traditional cigarettes, should reach the market.[107] If classified as an OTC product, there is already the groundwork for a model distribution method for ENDS as a cessation device rather than a tobacco product in the distribution limitations that the FDA placed on Nicorette (nicotine gum) during their switch from prescription drug to OTC.[108] The FDA restricted the sale of Nicorette to drugstores, mass merchandisers, and supermarkets, and prohibited its sale in convenience stores such as gas stations.[109] The FDA also required the company to not sell "trial size" or "sample" packs, package each piece of gum in child resistant packaging, offer incentives to retailers to place Nicorette with the other OTC drugs, and provide a smoking cessation program in the form of a toll-free phone number on the packaging.[110]

For ENDS products, the limitations of restricting the sale to drugstores, mass merchandisers, and supermarkets, and prohibiting their sale in conveniences stores, coupled with a limitation on the online sales of the products, would arguably have the greatest impact in keeping the products out of reach for adolescents. In 2019, three-fourths of adolescents who used Juul, the most commonly sold e-cigarette brand, obtained the product at a physical retail location, and approximately half of all e-cigarette sales in the United States were through vape shops[111] or the

105. Rebecca Glover-Kudon, et al., *Cigarette and cigar sales in Hawaii before and after implementation of a Tobacco 21 Law*, TOBACCO CONTROL 2021:30:98, 98 (2021).

106. Sara Schiff, et al., *E-cigarette and cigarette purchasing among young adults before and after implantation of California's tobacco 21 policy*, TOBACCO CONTROL 2021:30:206, 206 (2021).

107. Gravely, *supra* note 51, at 1831.

108. *See* letter from Debra L. Bowen, M.D., Acting Director, Division of Over-the Counter Drug Products, and Cynthia G. McCormick, M.D., Director, Division of Anesthetic, Critical Care, and Addiction Drug Products, to David Schifkovitz, Associate Director, Regulatory Affairs, SmithKline Beecham Consumer Healthcare (Dec. 23, 1998), https://www.accessdata.fda.gov/drugsatfda_docs/nda/98/18-612S025_Nicorette_Approv.pdf (OTC approval letter to Nicorette that places marketing limitations on the product).

109. *See id.*

110. *See id.*

111. A "Vape Shop" is a physical retail store that "sells products such as vape pens, tanks, mods, e-juices, e-hookahs, advanced systems, and their accompanying components along with e-liquid solutions or cartridges. These stores may or may not have a vaping lounge or vaping bar inside as well. Many vape shops operate on non-traditional retail hours, opening closer to noon and closing later at night." *See E-Cigarettes at the Point of Sale*, COUNTER TOBACCO, https://countertobacco.org/resources-tools/evidence-summaries/e-cigarettes-at-the-point-of-sale/ (last visited April 2, 2021) [hereinafter *E-Cigarettes at the Point of Sale*].

internet.[112] A 2018 study showed that, in California, tobacco and vape shops had the highest rate of sales of vape products to underage adolescent decoys than any other retailer type at 44.7%.[113] Internet retail poses a similar problem, where a significant number of middle and high schoolers obtained their e-cigarettes online,[114] and a 2015 study finding that "minors successfully received deliveries of e-cigarettes from 76.5% of purchase attempts, with no attempts by delivery companies to verify their ages at delivery."[115] Conversely, according to the same 2018 California study, pharmacies had the lowest failure to check identification for e-cigarettes rate at approximately 10%, and small markets and supermarkets had the lowest violation rate for underage e-cigarettes at approximately 12%.[116] As such, placing distribution limitations on ENDS similar to those that are already placed on Nicorette, which restricts the sales of the product to drug stores, mass merchandisers, and supermarkets, combined with the T-21 laws and the prohibition of online sales of ENDS, would likely have a large beneficial impact in keeping the products out of the hands of adolescents.

C. ENDS and Nicotine Abstinence

The overall goal of ENDS as cessation tools would be complete abstinence from nicotine, rather than trading one addiction for another. To be an effective tool for eventual nicotine abstinence, the addictiveness of ENDS would need to be comparable to other NRTs such as nicotine gum or transdermal nicotine patches, and less addictive than traditional tobacco products.[117] There does not seem to be a general consensus in the scientific community yet as to whether using ENDS as a cigarette cessation tool leads to a continuing dependence on nicotine.[118]

D. Barriers to ENDS as an Over-the-Counter Drug

Perhaps the largest obstacle for ENDS to be given an OTC monograph is that they would first have to be generally regarded as safe and effective ("GRASE") before they can be given a monograph, and it may not be enough that they are both generally regarded to be safer than traditional cigarettes and have shown to be a better cigarette cessation tool than current NRTs.[119] For a drug to be considered GRASE:

112. *See* Fatma Romeh, et al., *E-cigarette Unit Sales, by Product and Flavor Type — United States, 2014–2020*, 69 MORBIDITY & MORTALITY WEEKLY REPORT 1313, 1316 (Sep. 18, 2020).

113. *E-Cigarettes at the Point of Sale, supra* note 111.

114. *Where do Youth get their E-Cigarettes?,* TOBACCO FREE KIDS, https://www.tobaccofreekids.org/assets/factsheets/0403.pdf (last visited April 2, 2021).

115. Rebecca_S. Williams, et al., *Electronic Cigarette Sales to Minors via the Internet*, JAMA PREDIATR. 2015:169(3):e1563, 1563 (March 2, 2015), https://jamanetwork.com/journals/jamapediatrics/article-abstract/2174572.

116. *E-Cigarettes at the Point of Sale, supra* note 111.

117. *See generally* Chowdhury & Jockel, *supra* note 85 (explaining the NRT process).

118. *See generally e.g.* Chen, at al., *Use of Electronic Cigarettes to Aid Long-Term Smoking Cessation in the United States: Prospective Evidence From the PATH Cohort Study,* AM. J. OF EPIDEMIOLOGY 2020:189(12): 1529, 1529 (July 2020) (concluding that ENDS "may contribute to continuing nicotine dependence."); Guodong Liu, et al., *A Comparison of Nicotine Dependence among Exclusive E-cigarette and Cigarette Users in the PATH Study*, PREV. MED. November:104:86, 86 (2017) (that "everyday exclusive e-cig users report lower dependence than comparable cigarette users.").

119. *See* Chowdhury & Jockel, *supra* note 85; Hajek, *supra* note 50, at 629.

First, the particular drug product must have been subjected to adequate and well-controlled clinical investigations that establish the product as safe and effective.

Second, those investigations must have been published in the scientific literature available to qualified experts.

Third, experts must generally agree, based on those published studies, that the product is safe and effective for its intended uses. At a minimum, the general acceptance of a product as GRASE must be supported by the same quality and quantity of scientific and/or clinical data necessary to support the approval of a New Drug Application.[120]

Requiring the same amount and quality of data as an NDA is a high bar, and an issue with ENDS lies in the relative recentness with which they appeared on the market.[121] The other OTC smoking cessation products, nicotine gum, nicotine lozenges, and nicotine patches, have all been on the market much longer than ENDS, with nicotine lozenges, approved in 2002, being the most recent.[122] ENDS products have only been on the market since 2007, and there is still a great amount of uncertainty over the long-term effects of the products.[123] Also, as mentioned above, an NDA may be prohibitively expensive for more ENDS manufacturers.[124] As the vast majority of ENDS manufacturers would not be able to afford this process, either one of the top ENDS manufacturers (who are likely the least affected by the PMTA requirements) would need to make the request to the FDA and collect the data, or the FDA would need to initiate the process on their own accord through an administrative order.[125]

IV. CONCLUSION

An OTC monograph for ENDS would allow manufacturers to market the products to their full potential as cessation devices for a low cost, would make ENDS accessible for adults while also providing a barrier against underage use, and would allow for more regulatory oversight as to the safety of the products. Providing another safe tool to help the millions of American's overcome their addiction to traditional cigarettes, while preventing nonsmokers and adolescents from developing a nicotine addiction, should be among the top priorities of the United States. Although cigarette smoking rates in the United States have decreased from 20.9% in 2005, to 14.0% in 2019, it is still the leading cause of preventable deaths at 480,000 a year.[126] Nicotine is among the most addictive substances in the world, and in 2018 only 7.5% of the 34.2 million Americans that smoked cigarettes managed to quit successfully.[127]

120. U.S. FOOD & DRUG ADMIN., *GRASE*, https://www.accessdata.fda.gov/scripts/cder/training/otc/topic3/topic3/da_01_03_0040.htm (last visited April 2, 2021).
121. *See* Grana et al., supra note 40.
122. *See* Chowdhury & Jockel, *supra* note 85.
123. *See* Grana et al., supra note 40; Stratton, *supra* note 43, at 21.
124. *See supra* notes 63-67 and accompanying text.
125. *See generally Drug Monograph Process*, supra note 77.
126. CTR. FOR DISEASE CONTROL, *Current Cigarette Smoking Among Adults in the United States* (last updated Dec. 10, 2020), https://www.cdc.gov/tobacco/data_statistics/fact_sheets/adult_data/cig_smoking/index.htm.
127. *5 Most Addictive Drugs*, AMERICAN ADDICTION CENTERS, https://americanaddictioncenters.org/adult-addiction-treatment-programs/most-addictive (last updated Feb. 22, 2021); CTR. FOR

ENDS have the potential to be the most effective cigarette cessation tool on the market, and even under pessimistic models of long-term health effects, the complete replacement of traditional cigarettes with ENDS would save approximately 1.6 million lives over a 20-year period.[128] The current pathways to market for the products, however, do not allow ENDS to live up to this life-saving potential. The available tobacco pathway for ENDS, PMTA's, limit the manufacturers to not allow them to market the products as cessation devices. If the manufacturer wants to market their ENDS product as a cessation tool, they must complete an NDA, which is much too expensive, and would only allow for ENDS products to be sold with a prescription, severely limiting their accessibility. Perhaps the largest barrier to ENDS obtaining an OTC monograph is the lack of a scientific consensus on the long-term health effects of the products.[129] Paradoxically, an OTC monograph would give the FDA more oversight in the research of the products.[130] Regardless, the scientific consensus on ENDS products is that they are overall safer than traditional cigarettes, and any step towards safely decreasing the number of traditional tobacco users in the United States is a step that should be taken.[131]

DISEASE CONTROL, *Smoking & Tobacco Use: Smoking Cessation: Fast Facts,* https://www.cdc.gov/tobacco/data_statistics/fact_sheets/cessation/smoking-cessation-fast-facts/index.html (last updated May 21, 2020); CTR. FOR DISEASE CONTROL, *Smoking & Tobacco Use: Fast Facts,* https://www.cdc.gov/tobacco/data_statistics/fact_sheets/fast_facts/index.htm#cigarette-smoking (last updated May 21, 2020).

128. *See* Levy, *supra* note 43, at 18.

129. *See* Stratton, *supra* note 43, at 21.

130. *See* LaVito, *supra* note 101.

131. Stratton, *supra* note 43, at 12 ("[t]he evidence about harm reduction suggests that across a range of studies and outcomes, e-cigarettes pose less risk to an individual than combustible tobacco cigarettes.").