

REGULATORY RESPONSE TO E-CIGARETTES

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I. INTRODUCTION

Public health organizations have been fighting the “war on cigarettes” for years, trying to put an end to the tobacco industry that is credited with causing an estimated 100 million deaths over the last century.¹ In the United States alone tobacco use continues to be the leading cause of preventable disease and death, with cigarette smoking causing about one in every five deaths each year, totaling over 480,000 deaths annually.² Recently, a new product has entered the market that some fear will undo the progress made against nicotine addiction and smoking. Electronic cigarettes, also called e-cigarettes, vapes, vape pens, or ENDS (electronic nicotine delivery systems), first entered commercial markets in the mid-2000s.³ Since that time, countries and regulatory agencies have grappled with how best to define and regulate the product. E-cigarette regulation is a difficult area because of the competing public health concerns and implications surrounding the product’s use. Proponents of e-cigarettes argue that the devices serve an important harm-reduction function. For chronic smokers, switching from traditional cigarettes to e-cigarettes can arguably reduce the amount of toxins consumed and serve as a gateway to cessation.⁴ Additionally, e-cigarettes can greatly reduce the societal harm associated with second-hand smoke inhalation because the devices discharge a less-harmful vapor. However, others argue that e-cigarettes pose a significant public health risk because they facilitate nicotine addiction, “re-normalize and re-glamorize smoking to vulnerable youth and developing world populations,”⁵ and are both accessible and appealing to a young population.⁶ Countries attempting to regulate these new products must sort e-cigarettes into one of the following categories: medical device, drug, tobacco product, or regular consumer product.

¹ *Countries Vindicate Cautious Stance on E-Cigarettes*, 92 BULL. OF THE WORLD HEALTH ORG. 856, 857 (2014), <http://www.who.int/bulletin/volumes/92/12/14-031214/en/>.

² *Tobacco Related Mortality*, CDC, https://www.cdc.gov/tobacco/data_statistics/fact_sheets/health_effects/tobacco_related_mortality/index.htm.

³ Marie-Claude Tremblay et al., *Regulation Profiles of E-cigarettes in the United States: A Critical Review with Qualitative Synthesis*, 13 BMC MED. 1, 1–6 (2015) (evaluating current federal and state e-cigarette regulations in the United States).

⁴ See Muhammad Aziz Rahman et al., *Electronic Cigarettes: Patterns of Use, Health Effects, Use in Smoking Cessation and Regulatory Issues*, 12 TOBACCO INDUCED DISEASES 1, 1–18 (2014) (evaluating the regulation and major public health concerns of e-cigarettes). “One study showed [e-cigarettes] to be as effective as nicotine patches in helping smokers to quit and superior to nicotine patches in reducing the number of cigarettes individuals smoked.” *Id.* at 2.

⁵ *Id.*

⁶ Tremblay et al., *supra* note 3, at 1.

Furthermore they must choose a regulatory scheme that best mitigates the risk to their population while maximizing potential harm-reduction benefits.

Part II of this Note will discuss the background of e-cigarettes, including the product design, market history, growing social use among teenagers, and health effects. Then this Note will compare the current regulatory schemes, including the framework for regulation promulgated by the World Health Organization. Part III will discuss benefits and shortcomings of regulation against a scheme of little or no regulation. Part IV will offer concluding remarks.

II. BACKGROUND

A. *Product Design: How e-Cigarettes Work*

E-cigarettes are “battery-powered devices that vaporize a flavored propylene glycol or glycerin solution, with or without nicotine, to simulate cigarette smoking.”⁷ The vapor is inhaled as one would inhale cigarette smoke. Users will experience a nicotine high similar to that of cigarette or hookah tobacco.⁸ Nicotine has been described by users as a cure all. “When you are sleepy it wakes you; when you are anxious, it relaxes you; when you are hungry, it takes your hunger away.”⁹

Originally, the products were designed to resemble traditional cigarettes. Now, users can choose from a broad range of designs. Some are slim, resembling a pen or cigar; others are bulkier and closer to the size of a pocket flask.

Once users have obtained the e-cigarette, they can then buy the liquid that will be vaporized. Although the designs vary, the user will generally put a few drops of liquid into the device which will then turn to vapor via heat by a coil. The liquid generally contains approximately 12% of nicotine, but higher concentrations are available. Liquid with no nicotine is usually geared toward users who are under eighteen and unable to buy the nicotine product. The pleasant flavors of the liquid, akin to the flavored tobacco in a hookah pipe, are what make the product appealing. Users can choose from a wide array of flavors, such as cinnamon roll, lemonade, fruit roll-up, gusher, coffee, coconut,

⁷ *Id.*

⁸ See *Nicotine Addiction and Your Health*, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, <http://betobaccofree.hhs.gov/health-effects/nicotine-health/> (“When you use tobacco products, nicotine is quickly absorbed into your bloodstream. Within 10 seconds of entering your body, the nicotine reaches your brain. It causes the brain to release adrenaline, creating a buzz of pleasure and energy.”).

⁹ Eliza Gray, *Electronic Cigarettes: The Future of Smoking*, TIME (Sept. 30, 2013), <http://content.time.com/time/subscriber/article/0,33009,3152409-3,oo.html>.

ice cream, and apple juice. An e-liquid cartridge, ranging in price from \$5 at the gas station to \$30 for an upscale brand at a specialty store, can last anywhere from a month to a day depending on how often users vape. Because the nicotine is contained in the liquid, regulation may be more heavily focused on the liquid than on the e-cigarette device itself. However, product design regulations governing how hot the coil can heat to will also be necessary.

B. Evolution of the e-Cigarette Market

Chinese pharmacist Hon Lik patented the first e-cigarette in 2003. A smoker himself, Lik lost his father to lung cancer and was searching for a safer way to get a nicotine fix.¹⁰ E-cigarettes became available in both U.S. and European markets approximately four years later.¹¹ Since e-cigarettes' introduction to the market demand has exploded. While China is still the biggest producer of e-cigarettes and e-liquids, in 2013, the industry was worth \$1.8 billion in the U.S. alone.¹² In 2014, that number increased to \$2.5 billion, and in 2015, to \$3.5 billion.¹³ The "e-cigarette global industry is projected to reach \$10 billion by 2017."¹⁴

Large transnational tobacco companies not wanting to lose their grip on the \$800 billion tobacco industry began investing in e-cigarette technology almost immediately. The current e-cigarette market is mostly split between e-cigarettes made by Big Tobacco,¹⁵ valued at \$1.5 billion, and vaporizers that use refillable liquid nicotine from small manufacturers, valued at \$2 billion.¹⁶ While the e-cigarette market was initially "dominated by companies with no links to the tobacco industry, it is increasingly owned by the tobacco industry." "All main transnational tobacco companies sell ENDS," and one company is even "launching legal proceedings over patents against its rivals as they become increasingly aggressive in the battle for the fast-growing e-cigarette market."¹⁷ The tobacco industry is "trying to regain the respectability it lost long ago by appearing to offer a solution with one

¹⁰ *Id.*

¹¹ Rahman et al., *supra* note 4.

¹² *Id.*

¹³ Tripp Mickle, *FDA Cloud Hangs Over Vape Shops*, WALL ST. J. (July 7, 2015), <https://www.wsj.com/articles/SB10130211234592774869404581088451777513530>.

¹⁴ Tremblay et al., *supra* note 3, at 1.

¹⁵ For more on Big Tobacco, see, Mark Schapiro, *Big Tobacco*, NATION (Apr. 18, 2002), <https://www.thenation.com/article/big-tobacco/>.

¹⁶ *FDA Cloud Hangs Over Vape Shops*, *supra* note 13.

¹⁷ *Electronic Nicotine Delivery Systems*, WHO FRAMEWORK CONVENTION ON TOBACCO CONTROL 1, 8 (July 8, 2014), http://apps.who.int/gb/fctc/PDF/cop6/FCTC_COP6_10-en.pdf.

hand, while continuing to create mass destruction with the other.”¹⁸ Now, “e-cigarettes are sold at Walmart, vaped by Katherine Heigl and Leonardo DiCaprio and advertised during the Super Bowl and the Oscars and on the hoods of NASCAR race cars.”¹⁹

Prior to August of 2016, e-cigarettes fell blissfully outside of the FDA’s tobacco regulatory powers. In a climate of little to no regulation in the United States, “more than 8,500 vape shops have sprung up in strip malls and stand alone stores across the country.”²⁰ Much of the industry’s “early success comes thanks to [its] near complete freedom from regulation, which has allowed dozens of small players to flourish.”²¹ Vape shops are not set up like typical retail stores; instead, they resemble bars or cafés. Users can enter with their vape pens and chat with the staff, sample new flavors, and socialize at the bar.

As the market has evolved, e-cigarettes have become part of a youthful cultural movement often referred to as “vape culture.”²² Vaping is seen as a social activity rather than a therapeutic one; in fact, “several studies demonstrated the recreational element of e-cigarette use. In one study that included two surveys of more than 3,500 e-cigarette users, only one showed a marginally significant correlation between use and a quit attempt in the last three months.”²³ Another study found that among university students, there was “no established association between e-cigarette use and intention to quit smoking.”²⁴ According to the Centers for Disease Control and Prevention (CDC), e-cigarette use in the United States by “tweens and teens tripled in 2014 to 13.4% from 4.5% in 2013.”²⁵ Besides the flavors, another large appeal for young consumers is the amount of vapor e-cigarettes produce. E-cigarettes “produce much more vapor, especially when adjusted to operate at high temperatures, than conventional cigarettes, which helps

¹⁸ *Countries Vindicate Cautious Stance on E-Cigarettes*, *supra* note 1, at 857.

¹⁹ Gray, *supra* note 9.

²⁰ *FDA Cloud Hangs Over Vape Shops*, *supra* note 13 (discussing the potential chilling effects and monetary losses resulting from FDA regulations).

²¹ Gray, *supra* note 9.

²² In 2014, Oxford Dictionaries announced ‘vape’ as its international Word of the Year 2014. Research “conducted by Oxford Dictionaries editors reveals that the use of the word *vape* in 2014 has more than doubled” compared with use in 2013. See *VAPE is Named Oxford Dictionaries Word of the Year in 2014*, OXFORD DICTIONARIES, <http://blog.oxforddictionaries.com/press-releases/vape-named-oxford-dictionaries-word-year-2014/>.

²³ Rahman et al., *supra* note 4, at 6.

²⁴ *Id.*

²⁵ Jilian Mincer, *As Youth Vaping Rises, Teens Cite the Allure of Tricks*, REUTERS (May 1, 2015), <http://www.reuters.com/article/us-ecigarettes-teens-tricks-insight-idUSKBN0NM49020150501>.

facilitate . . . vapor tricks.”²⁶ Vapers hold what are called cloud competitions where they compete to perform the best tricks and create the biggest and densest vapor clouds.²⁷ Thousands of YouTube and Instagram videos are posted daily “demonstrating expert vaping and how to perform tricks.”²⁸

E-cigarette liquid, sometimes called “e-liquid,” “juice,” “vape juice,” or “e-juice” by users, comes in many different flavors labeled and marketed for aesthetic appeal. A recent study indicated that e-liquids are “marketed in 7764 unique flavours.”²⁹ Ripe Vapes, a handcrafted line of e-cigarette liquids, features flavors such as Pear Almond (“envoking the polished pastries of Europe”) and Coconut Thai (“smooth coconut, rich and slightly sweet followed by after notes of fresh thai basil and bright lemongrass”).³⁰ Most lines are marketed toward a younger, hipper demographic with labels featuring UFOs, edgy graphics, and bearded hipsters. Even the names and flavors of the liquids are edgy and stylish with flavors modeled on well-liked sweets. For example, “Gush” draws its inspiration from the highly popular gummy candy Gushers. “Rolly” is based on the equally popular Fruit Roll-Up children’s snack, and “I LOVE Donuts” tastes like the delicious and sugary pastry.³¹

Because e-cigarettes have not been on the market for long, there is limited data on use by younger demographics such as teens and adolescents. However, the flavors and labeling certainly suggest the industry is targeting a younger market. In 2011 and 2012, the National Youth Tobacco Survey “reported a doubling in e-cigarette lifetime use (ever used) from 2011 to 2012 for both [American] middle school (1.4% to 2.7%) and high school (4.7% to 10.0%) students.”³² The survey also reported “current use (in the past 30 days) of e-cigarettes also doubled from 0.6% in 2011 to 1.1% in 2012 among middle school students and 1.5% in 2011 to 2.8% in 2012 among high school students.”³³ In 2014, the CDC issued a finding that “current e-cigarette use among middle and high school students tripled from 2013 to 2014.”³⁴ That means that current e-cigarette use, defined as using an e-

²⁶ *Id.*

²⁷ *Id.*

²⁸ *Id.*

²⁹ *Electronic Nicotine Delivery Systems*, *supra* note 17, at 9.

³⁰ RIPE VAPES: HANDCRAFTED JOOSE, <http://ripevapes.com>.

³¹ ELIQUID.COM, <https://www.eliqoid.com/products/alien-piss-by-bomb-sauce-e-liquid>.

³² Rebecca J. Williams & Rebecca Knight, *Insights in Public Health—Electronic Cigarettes: Marketing to Hawai‘i’s Adolescents*, 74 HAW. J. MED. & PUB. HEALTH 66, 66 (2015) (evaluating the emerging phenomenon of e-cigarette use and the potential public health threat the trend poses to Hawaii’s youth).

³³ *Id.*

³⁴ *Press Release: E-Cigarette Use Triples Among Middle and High School Students in Just One Year*, CDC (Apr. 16, 2015, 1:00 PM), <http://www.cdc.gov/media/releases/2015/p0416-e-cigarette-use.html>. The CDC issued a press release discussing what it had learned in surveys

cigarette on at least one day in the past thirty days, among high school students has risen from “approximately 660,000 to 2 million students.”³⁵ The CDC also noted that “this is the first time since the survey started collecting data on e-cigarettes in 2011 that current e-cigarette use surpassed current use of every other tobacco product overall, including conventional cigarettes.”³⁶ To emphasize the risk of teen nicotine use, the CDC also pointed to a 2012 Surgeon General’s Report that “found that about 90 percent of all smokers first tried cigarettes as teens; and that about three of every four teen smokers continue into adulthood.”³⁷

C. Health Effects

Scientific studies on e-cigarettes are relatively limited given the newness of the product coupled with “the lengthy lag time for onset of many diseases of interest, such as cancer, conclusive evidence about the association of ENDS use with such diseases will not be available for years or even decades.” However, “the limited testing has revealed wide variations in the nature of the toxicity of contents and emissions.”³⁸

Nicotine is highly addictive, more so than “harder” drugs like heroin or cocaine.³⁹ Withdrawal symptoms of those attempting to quit a nicotine addiction are “psychologically damaging; they feel anxious, depressed, irritable, bored, and unable to focus.”⁴⁰ Those who have used both heroin and nicotine report it is harder to kick a nicotine habit.⁴¹ Nicotine plays a “role in neuro-degeneration and there is evidence of brain development problems in children and fetuses that have been exposed to nicotine.”⁴² Inhalation of nicotine itself is addictive, “can have adverse effects during

conducted on e-cigarette use among American middle and high school students. The CDC reported a huge increase in just one year’s time, and recommended that action be taken to reduce the potential harm due to this rise in use. Notably, the survey also found that there was a decided increase in hookah smoking (roughly double). However, the rise of both hookah and e-cigarette use offset declines in use of more traditional products such as cigarettes and cigars. The CDC urged the FDA to increase categories of tobacco regulation to include both hookah and e-cigarette products. *Id.*

³⁵ *Id.*

³⁶ *Id.*

³⁷ *Id.*

³⁸ *Electronic Nicotine Delivery Systems*, *supra* note 17, at 3–4.

³⁹ Eighty-five percent of smokers who attempt to quit will relapse within a week. *Is Nicotine Addictive?*, NAT’L INST. ON DRUG ABUSE (July 2012), <http://www.drugabuse.gov/publications/research-reports/tobacco/nicotine-addictive>.

⁴⁰ Gray, *supra* note 9.

⁴¹ *Id.*

⁴² *Countries Vindicate Cautious Stance on E-Cigarettes*, *supra* note 1, at 856.

pregnancy and may contribute to cardiovascular disease.”⁴³ Additionally, nicotine “may function as a ‘tumor promoter,’” and “seems involved in fundamental aspects of the biology of malignant diseases, as well as of neurodegeneration.”⁴⁴ This evidence is at least sufficient enough, according to the World Health Organization (WHO), “to caution children and adolescents, pregnant women, and women of reproductive age about ENDS use because of the potential for fetal and adolescent nicotine exposure to have long-term consequences for brain development.”⁴⁵ Even those e-liquids that do not contain nicotine may have serious long-term health consequences. Evidence based on the assessment of chemical compounds in the liquids used in, and aerosol produced by, ENDS indicate the presence of cytotoxicity and carcinogenic compounds. These compounds were found to differ greatly across products, which may present as a logical regulatory target.

In addition to the health risks posed by inhalation, nicotine can also be harmful if ingested or if it comes into contact with the skin.⁴⁶ This threat can pose a particular risk to children who may accidentally ingest e-liquid if packaging is not childproofed. According to available reports from the United States and the United Kingdom, “the number of reported incidents involving nicotine poisoning has risen substantially as the use of ENDS has increased. The actual number of cases is probably much higher than those reported.”⁴⁷

The WHO Study Group on Tobacco Product Regulation concluded:

The existing evidence shows that ENDS aerosol is not merely “water vapour” as is often claimed in the marketing for these products. ENDS use poses serious threats to adolescents and fetuses. In addition, it increases exposure of non-smokers and bystanders to nicotine and a number of toxicants. Nevertheless, the reduced exposure to toxicants of well-regulated ENDS used by established adult smokers as a complete substitution for cigarettes is likely to be less toxic for the smoker than conventional cigarettes or other combusted tobacco products. The amount of risk reduction, however, is presently unknown.⁴⁸

⁴³ *Electronic Nicotine Delivery Systems*, *supra* note 17, at 3.

⁴⁴ *Id.*

⁴⁵ *Id.* at 4.

⁴⁶ *Id.*

⁴⁷ *Id.*

⁴⁸ *Id.* at 5.

D. Marketing

Unsurprisingly, marketing of e-cigarettes has grossly outstripped and preceded any regulatory oversight. According to a study done by Kantar Media, “in the first quarter of 2013, e-cigarette spending on advertising rose to \$15.7 million in the U.S., up from \$2 million in the same period” in 2012.⁴⁹ Advertising data from the study “shows placements . . . on mainstream media, on cable stations--e-cigarettes, unlike regular cigarettes, can advertise on TV [in the US]--as well as in magazines (including Time).”⁵⁰ Some of the innovative marketing techniques, such as endorsements by millennial YouTube vapers, may require creative regulation to combat. According to the WHO:

ENDS are being marketed to consumers in many media and forms, including television commercial, sports and cultural sponsorship, celebrity endorsement, social networking, online advertising, point-of-sale displays, pricing strategies, and product innovation. Some marketing clearly emulates the very successful tobacco advertising asserting an independent identity and a lifestyle choice, aligning oneself with celebrities, fashionable and youthful places and activities. Some ENDS are marketed not only as socially acceptable but as socially superior. Unsubstantiated or overstated claims of safety and cessation are frequent marketing themes aimed at smokers. Some ENDS marketing also promotes long-term use as a permanent alternative to tobacco, and a temporary one in public places where smoking is banned. ENDS marketing activities have the potential to glamorize smoking and attracting children and nonsmokers even if those are unintentional results.⁵¹

On the issue of sweetened flavorings of e-liquids, the WHO report on e-cigarettes noted, “expert opinion indicates that candy-like flavours could entice youths to experiment with ENDS and could also facilitate the development of tobacco dependence by enhancing the sensory rewards of ENDS use.”⁵² Historically, “the tobacco industry’s internal documents suggest that flavouring agents have played an important role in the industry’s

⁴⁹ Gray, *supra* note 9.

⁵⁰ *Id.*

⁵¹ *Electronic Nicotine Delivery Systems, supra* note 17, at 9.

⁵² *Id.*

targeting of children and youth, and there is a concern that they could play the same role in the uptake of ENDS in these age groups.”⁵³ Minors traditionally receive greater protection through regulation because they are seen as a vulnerable demographic that may be more easily swayed through advertising.⁵⁴ Other industries such as alcohol and tobacco have seen their marketing subject to stringent regulation in relation to minors.⁵⁵ However, in the age of social media and the internet, regulation here could be a bit tricky as e-cigarette vendors often exclusively sell and market online, with heavy emphasis on social media advertising and endorsement.⁵⁶

E. Existing Regulation

1. World Health Organization Regulatory Framework

The World Health Organization Framework Convention on Tobacco Control (WHO FCTC) became effective in February 2005.⁵⁷ The WHO FCTC is the first global public health treaty.⁵⁸ The WHO FCTC:

was developed by countries in response to the globalization of the tobacco epidemic. It aims to tackle some of the causes of that epidemic, including complex factors with cross-border effects, such as trade liberalization and direct foreign investment, tobacco advertising, promotion and sponsorship beyond national borders, and illicit trade in tobacco products.⁵⁹

Parties to the WHO FCTC have implemented recommended measures such as increased pricing and tax measures on tobacco products as well as non-price measures such as restricting smoking in public places like public transportation systems and workplaces and regulating “the contents and emissions of tobacco products and the methods by which they are tested and

⁵³ *Id.*

⁵⁴ See generally Roscoe B. Starek, III, *The ABCs at the FTC: Marketing and Advertising to Children*, FED. TRADE COMMISSION (July 25, 1997), <https://www.ftc.gov/public-statements/1997/07/abcs-ftc-marketing-and-advertising-children>.

⁵⁵ *Id.*

⁵⁶ Tim K. Mackey, Angela Miner & Raphael E. Cuomo, *Exploring the e-cigarette e-commerce marketplace: Identifying Internet e-cigarette marketing characteristics and regulatory gaps*, 156 DRUG AND ALCOHOL DEPENDENCE 97, 99 (2015).

⁵⁷ *The WHO Convention on Tobacco Control: An Overview*, WHO FRAMEWORK ON TOBACCO CONTROL 1, 1 (Jan. 2005), http://www.who.int/fctc/about/WHO_FCTC_summary_January2015.pdf?ua=1.

⁵⁸ *Id.*

⁵⁹ *Id.*

measured.”⁶⁰ The FCTC “commits Parties not only to preventing and reducing tobacco consumption and exposure to tobacco smoke but also preventing and reducing nicotine addiction independently from its source. Therefore, while medicinal use of nicotine is a public health option under the treaty, recreational use is not.”⁶¹ The WHO FCTC specifically addressed the issue of electronic cigarettes in a conference held in Moscow in 2014.⁶² The WHO FCTC examined “emerging evidence on the health impacts of electronic nicotine delivery systems (ENDS) use . . . [identified] options for their prevention and control,” and presented its findings at this conference.⁶³ The Conference of Parties (COP), a governing body of the international treaty comprising of 179 countries, “decided that tax rates should be monitored, increased, and adjusted annually, taking inflation and income growth into account, as tobacco taxation is a known means of reducing smoking.”⁶⁴ Armando Peruga, a doctor of medicine and public health who works in the area of tobacco control for the World Health Organization, spoke on behalf of the WHO in respect to e-cigarette regulation.⁶⁵

The WHO FCTC outlined certain specific regulatory options that they deemed prudent in the e-cigarette industry. The first is regulating health claims that manufacturers and third parties can make on behalf of electronic cigarettes.⁶⁶ Specifically, the FCTC advised that manufacturers of electronic cigarettes should be prohibited “from making health claims for ENDS, including that ENDS are smoking cessation aids, until manufacturers provide convincing supporting scientific evidence and obtain regulatory approval.”⁶⁷ As with cigarettes, the FCTC also recommended regulation of the use of electronic cigarettes in public places to reduce harms associated with second hand smoke inhalation, particularly in indoor areas.⁶⁸

Another recommended regulatory option is the regulation of advertising, promotion and sponsorship while paying particular care to protect non-smokers and children. The FCTC recommended, at a minimum, that regulation should require advertisements of e-cigarettes clearly state that the product contains nicotine or may be used with nicotine solutions; that they should not target or appeal to non-smokers; that they should not implicitly or

⁶⁰ *Id.* at 2–3.

⁶¹ *Electronic Nicotine Delivery Systems*, *supra* note 17, at 10.

⁶² *Id.* at 1.

⁶³ *Id.*

⁶⁴ *Public Health Round-up*, 92 BULL. OF THE WORLD HEALTH ORG. 776, 777 (Nov. 2014), <http://www.who.int/bulletin/volumes/92/11/14-011114.pdf>.

⁶⁵ *Countries Vindicate Cautious Stance on E-Cigarettes*, *supra* note 1, at 857.

⁶⁶ *Id.*

⁶⁷ *Electronic Nicotine Delivery Systems*, *supra* note 17, at 11.

⁶⁸ *Id.*

explicitly target minors; that they should encourage smoking cessation; that they contain nothing that could be expected to promote the use of tobacco products; that they use no terms that may confuse or associate the product with tobacco; that they include factual health information that does not distort risk factors; and that they not contain health or medicinal claims unless the product is specifically licensed for those purposes. Additionally, the FCTC concluded that in solutions that contain nicotine, the regulations should require a clear statement of the addictive nature of nicotine and that the electronic cigarette is a nicotine delivery device as well as prohibit all suggestions that electronic cigarettes have positive qualities as a consequence of the addictive nature of the product.⁶⁹ The FCTC recommends protection from vested commercial interest providing that “[t]ransparency should be required from ENDS and tobacco companies advocating for and against legislation and regulation, both directly and through third parties.”⁷⁰

Further, the FCTC recommends that regulations should mandate health warnings, prohibit sales to minors and that governments should strengthen their existing tobacco surveillance and monitoring systems.⁷¹ Perhaps most practically, the FCTC advocates for regulation of product design and information.⁷² Specifically, electronic cigarettes should be regulated to minimize the “content and emission of toxicants” as much as possible; ban candy-like flavors that would appeal to minors; impede product alteration to use of other drugs such as cannabis oil; standardize nicotine delivery levels; mandate nicotine quality levels; and require registration of manufacturers and importers with regulatory agencies.⁷³

2. Existing Regulation

The regulation of e-cigarettes is first determined by the status the country gives to the products. There are three possible regulatory categories e-cigarettes fall into—medical or pharmaceutical device, tobacco product, or consumer product. Some countries, such as Singapore, have ratified or otherwise formally approved the WHO FCTC and are working within the guidelines set down by the WHO.⁷⁴ Within the European Union generally, regulation has “progressed independently with a hybrid approach; in February 2014, the European Parliament voted to regulate e-cigarettes as

⁶⁹ *Id.* at 12.

⁷⁰ *Id.*

⁷¹ *Id.* at 13.

⁷² *Id.*

⁷³ *Id.*

⁷⁴ *See generally id.* at 1 n.2.

tobacco products . . . [except] those claiming therapeutic benefit as medicinal devices.”⁷⁵ This regulation “will include a restriction on purchase age to a minimum of 18, close limitations on advertising and marketing including health warnings on packaging and the imposition of manufacturing standards.”⁷⁶

Spanish health officials have elected to classify e-cigarettes as a “regular consumer product” but, “specific regulation is applicable to nicotine containing e-cigarettes.”⁷⁷ Likewise, France has enacted regulations that limit levels of nicotine in e-liquid and require safe packaging but otherwise classify e-cigarettes as a “regular consumer product.”⁷⁸ In contrast, the United Kingdom regulates e-cigarette products containing nicotine as medical devices.⁷⁹ U.K. public health officials reason that “even a small dose of nicotine has pharmacological effects and that there is too much scientific uncertainty to establish a minimum threshold, that all nicotine-containing e-cigarettes, regardless of the level of nicotine, should be considered pharmaceuticals.”⁸⁰ Similarly in Belgium, “nicotine-containing e-cigarettes, as well as other e-cigarettes accompanied by a medical claim, are considered pharmaceuticals in need of a marketing authorization.”⁸¹

Vaping has quickly become trendy in Malaysia with one vaping association reporting at least 500,000 Malaysians are vaping, while another reports that the number is closer to a million.⁸² The Malaysian E-Vaporizers and Tobacco Alternatives Association reports that “Malaysia’s vaping market is only second to that of the United States and was worth and estimated RM2.8 billion (US\$639 million)” as of 2014.⁸³ E-liquids in Malaysia are even offered in regional flavors such as mango lassi, honeydew, lychee, and bandung.⁸⁴ In October of 2015, the Malaysian Cabinet considered following Singapore’s lead of implementing an outright ban on e-

⁷⁵ Rahman et al., *supra* note 4, at 6.

⁷⁶ *Id.*

⁷⁷ Egenie Syx, *The Case of the Electronic Cigarette in the EU*, 21 EUR. J. HEALTH L. 161, 170–71 (2014) (analyzing electronic cigarette regulations within the framework of the European Union).

⁷⁸ *Id.* at 172–73.

⁷⁹ *Id.* at 172.

⁸⁰ *Id.*

⁸¹ *Id.* at 174.

⁸² Sumisha Naidu, *Malaysia to Regulate Sale of E-cigarette Liquids*, CHANNEL NEWSASIA (Nov. 9, 2015), <http://www.channelnewsasia.com/news/asiapacific/malaysia-to-regulate-sale/2248560.html>.

⁸³ *Id.*

⁸⁴ Jeলেখ Abu Baker, *E-cigarettes – a Potent Mix of Danger for the Young*, STRAITS TIMES (Nov. 19, 2015), <http://www.straitstimes.com/opinion/e-cigarettes-a-potent-mix-of-danger-for-the-young>.

cigarettes as the Minister of Health “has been concerned about the long-term health risks [of e-cigarettes] and fears that people who never smoked before were taking up vaping for fun.”⁸⁵ The Cabinet decided against a ban, but Malaysia’s Director General of Health announced that e-liquid that contains nicotine will be regulated under the Poisons Act; therefore “the sale of e-liquids containing nicotine can only be supplied by licensed pharmacists and registered medical practitioners.”⁸⁶ After the announcement, Malaysia’s Health Ministry began carrying out raids, reportedly raiding “more than 300 stores selling electronic cigarettes nationwide, raising howls of complaints from the store owners at the surprise move to seize their goods.”⁸⁷ The Director-General of Health said that “a study by the National Poison Centre at the Science University of Malaysia found that 40mg of nicotine contained in 10ml of vape liquids could instantly kill an adult person,” and therefore the product need to be subject to strict regulation.⁸⁸

Singapore has banned the sale of e-cigarettes entirely under the Tobacco (Control of Advertisements and Sale) Act.⁸⁹ Singapore’s Ministry of Health shares:

the WHO and UK’s concerns over the lack of efficacy and safety of e-cigarettes, and their effects on long term health. Until there is strong, conclusive evidence supporting the safety and efficacy of e-cigarettes, [the] Ministry will continue to adopt a prudent approach and prohibit the import, distribution, and sale of e-cigarettes in Singapore.⁹⁰

Dr. Lam Pin Min, speaking on behalf of Singapore’s Ministry of Health, stated that while “electronic cigarettes (e-cigarette) have been marketed as safer, healthier alternatives to tobacco smoking, and as smoking cessation devices . . . their effectiveness in helping smokers quit tobacco use has yet to be demonstrated . . .”⁹¹ The Ministry notes:

⁸⁵ Naidu, *supra* note 82.

⁸⁶ *Id.*

⁸⁷ Petaling Jaya, *300 E-cigarette Stores Raided in Malaysia*, STRAITS TIMES (Nov. 7, 2015, 5:00 AM), <http://www.straitstimes.com/asia/se-asia/300-e-cigarette-stores-raided-in-malaysia>.

⁸⁸ *Id.*

⁸⁹ Press Release, *Singapore’s Response to World Health Organisation’s (WHO) Report*, SINGAPORE MINISTRY OF HEALTH (Aug. 27, 2014), https://www.moh.gov.sg/content/moh_web/home/pressRoom/pressRoomItemRelease/2014/singapore_s-response-to-world-health-organisations--who--report.html.

⁹⁰ *Electronic Cigarettes Question No. 700*, SINGAPORE MINISTRY OF HEALTH (Nov. 11, 2013), https://www.moh.gov.sg/content/moh_web/home/pressRoom/Parliamentary_QA/2013/electronic-cigarettes.html.

⁹¹ *Id.*

e-cigarettes that claim to be smoking cessation products to help smokers quit tobacco use should demonstrate their safety and effectiveness with the same level of scientific rigor required for approved Nicotine-Replacement Therapies under the Medicines Act. As yet, there have been no applications to register ENDS as smoking cessation therapies.⁹²

A study conducted by the Health Sciences Authority in Singapore “found poor consistency between actual nicotine in e-cigarettes and the amount labelled.”⁹³ However, although Singapore has banned import and distribution of e-cigarettes, many report they can still be obtained illegally through local online channels.⁹⁴ Nevertheless, e-cigarettes have largely not caught on in Singapore like they have in other markets suggesting the ban has been successful overall. However, Singapore does not have a ban on traditional cigarettes which means, “[i]t’s a lot easier for teenagers to get traditional cigarettes” in Singapore than electronic cigarettes.⁹⁵

Likewise, in Australia, “the regulatory process has not been subject to the same debate, because the Therapeutic Goods Administration (TGA) essentially banned e-cigarettes” when they initially came on the market.⁹⁶ The TGA “prohibits importation, supply and sale of goods claiming therapeutic benefit that it has not approved, which applies to e-cigarettes marketed as smoking cessation aids.”⁹⁷ To address e-cigarette products not marketed as such, “it also bans the sale of goods not containing tobacco that are designed to resemble tobacco products, whether the resemblance is in the product itself or its packaging.”⁹⁸

Regulation of e-cigarettes will be handled in the United States by the Food and Drug Administration (FDA), which is statutorily authorized to regulate food and drug safety by Congress. Initially, the FDA attempted “to regulate e-cigarettes as drug-delivery devices,” which would have placed them under a relatively stringent regulatory regime.⁹⁹ However, “this was blocked by lawmakers because the products made no therapeutic claim, arguing they should instead be regulated as tobacco products because they contained tobacco-derived nicotine.”¹⁰⁰ Regulating e-cigarettes as a tobacco product

⁹² Press Release, *supra* note 89.

⁹³ *Electronic Cigarettes Question No. 700*, *supra* note 90.

⁹⁴ Baker, *supra* note 84.

⁹⁵ *Id.*

⁹⁶ Rahman et al., *supra* note 4, at 6.

⁹⁷ *Id.*

⁹⁸ *Id.*

⁹⁹ *Id.* at 5.

¹⁰⁰ *Id.*

rather than a drug-delivery device gives the FDA much less power in the regulatory structure. The FDA's Center for Tobacco Products (CTP), which regulates cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco, "held three public workshops to obtain information on electronic cigarettes and the public health" in addition to receiving public comments until July 2015.¹⁰¹ The FDA then issued a "proposed rule that would extend the agency's tobacco authority to cover additional products that meet the legal definition of a tobacco product, such as e-cigarettes."¹⁰² In May of 2016 the FDA finalized a rule, effective August 8, 2016, that includes e-cigarettes and their nicotine vapor solutions in their regulation of tobacco products. Whereas before e-cigarettes escaped the FDA's regulatory scheme, they can now regulate e-cigarettes using the same methods they have employed to regulate tobacco, such as restrictions on marketing and sales to minors. The new rule forbids the sale of e-cigarettes and vapor solutions to minors, forbids giving away vapor samples, and forbids the sale of e-cigarette products in vending machines. Allowing a grandfather period of two years, manufacturers will now be required to include ingredient labels on their vapor solutions and report any potentially harmful constituents in the products.

To understand the e-cigarette regulation climate in the United States, a brief understanding of U.S. tobacco regulation is necessary. The FDA did not receive authority to regulate tobacco until the passage of the Tobacco Control Act by Congress in 2009.¹⁰³ The FDA had long fought for the authority to regulate the industry of a consumable product with such a substantial impact on the health and welfare of U.S. citizens. Before 1996, the tobacco industry was regulated solely through state law and some limited congressional statutes. Most of these laws were prohibitions on the sale of tobacco products to minors.

Federal regulations were passed relating to advertising of cigarettes in the 1960s and 1970s. In 1965, Congress passed the Federal Cigarette Labeling and Advertising Act, which required cigarette cartridges to be labeled with a health warning.¹⁰⁴ In 1970, the Public Health Cigarette Smoking Act was passed, banning cigarette ads on the radio and television and requiring a

¹⁰¹ *Electronic Cigarettes (e-Cigarettes)*, U.S. FOOD AND DRUG ADMINISTRATION, <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm172906.htm> (describing the FDA's current status and stance on e-cigarettes and their regulation).

¹⁰² *Id.*

¹⁰³ *See generally Tobacco Control Act*, U.S. FOOD AND DRUG ADMIN., <https://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm246129.htm> (last updated Mar. 16, 2017).

¹⁰⁴ *Federal Cigarette Labeling and Advertising Act*, Pub. L. No. 89-92, 79 Stat. 282 (1965).

Surgeon General Warning label to be affixed to all cigarette cartridges.¹⁰⁵ In 1996, the FDA made an attempt to assert authority over tobacco products. However, the tobacco companies sued. The case went before the United States Supreme Court in *FDA v. Brown & Williamson Tobacco Corp.*,¹⁰⁶ Ultimately, the Supreme Court decided that the FDA had no statutory authority to regulate the tobacco industry.¹⁰⁷ In 2007, the issue went before the Fifth Circuit in *Brown v. Brown & Williamson Tobacco Corp.* The case was largely related to the legality of marketing “light” cigarettes.¹⁰⁸ The tobacco companies appealed the decision of the district court, which ruled in favor of the appellee’s claims under the Louisiana Unfair Trade Practices and Consumer Protection Act.¹⁰⁹ The companies argued that federal law should trump state law.¹¹⁰ The Fifth Circuit agreed and found in favor of the tobacco companies.¹¹¹ In response to these court rulings, in 2009, Congress passed the Family Smoking Prevention and Tobacco Control Act, which finally designated specific regulatory powers to the FDA.¹¹²

The Tobacco Control Act “makes clear that the FDA’s role is to regulate and protect the public health”¹¹³ The Act “puts in place specific restrictions on marketing tobacco products to children and gives FDA authority to take further action in the future to protect public health.”¹¹⁴ The provisions include bans on sales to minors, public access vending machine sales, sales of packages of fewer than twenty cigarettes, tobacco-brand sponsorships of sport and entertainment events or other social or cultural events, free giveaways of sample cigarettes and brand name non-tobacco promotional items.¹¹⁵ There are several restrictions under the Act, the FDA cannot: “[r]equire prescriptions to purchase tobacco products[, r]equire the

¹⁰⁵ *Public Health Cigarette Smoking Act of 1969*, Pub. L. No. 91-222, 84 Stat. 87 (1970). The Act, signed into law by President Richard Nixon in 1970, demonstrated the shift in attitude toward smoking and the recognition that smoking posed serious health concerns to the American public.

¹⁰⁶ *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000).

¹⁰⁷ *Id.* at 161.

¹⁰⁸ *Brown v. Brown & Williamson Tobacco Corp.*, 479 F.3d 383 (5th Cir. 2007).

¹⁰⁹ *Id.* at 386.

¹¹⁰ *Id.* at 386–88.

¹¹¹ *See id.* at 393–96.

¹¹² *Family Smoking Prevention and Tobacco Control Act*, Pub. L. No. 111-31, 123 Stat. 1776 (2007).

¹¹³ FDA: U.S. FOOD AND DRUG ADMINISTRATION, *Tobacco Products—Tobacco Control Act*, <http://fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm246129.htm> (providing a breakdown of the various elements of the Family Smoking Prevention and Tobacco Control Act, the resulting newfound authority of the FDA, and limitations to that authority).

¹¹⁴ *Tobacco Control Act*, U.S. FOOD AND DRUG ADMIN., *supra* note 103.

¹¹⁵ *Id.*

reduction of nicotine yields to zero[, b]an face-to-face sales in a particular category of retail outlets[, or b]an certain classes of tobacco products.”¹¹⁶ The Act requires smokeless tobacco products (snuff, chewing tobacco, snus) and advertisements to furnish visible warning to buyers and consumers.¹¹⁷ Every smokeless tobacco package and advertisement must contain one of the following warnings: “‘WARNING’: This product can cause mouth cancer. This product can cause gum disease and tooth loss. This product is not a safe alternative to cigarettes, [or s]mokeless tobacco is addictive.”¹¹⁸ Additionally, the warnings must cover at least 30% of two sides of the packaging and at least 20% of an advertisement.¹¹⁹ The Act requires that any claims made of “modified risk” products be supported by scientific evidence; this affects cigarette products labeled “natural,” “light,” “low,” “mild,” etc.¹²⁰ Additionally, the Act requires detailed disclosure of all ingredients contained in tobacco products, requires registration and inspection of tobacco companies, allows for the FDA to implement standards on tobacco products to protect public health (regulating nicotine levels or levels of other chemicals), bans cigarettes with characterizing flavors (excluding menthol and tobacco), and funds FDA regulation through a tax on tobacco products (based on market share).¹²¹ Currently, the FDA Center for Tobacco Products also regulates electronic cigarettes much the same way as other tobacco products.¹²²

3. Regulation and Trade Agreements

How a country ultimately chooses to classify the product has implications not only nationally but may affect international trade agreements as well. For example, the Trans-Pacific Partnership (TPP) Agreement¹²³ has a

¹¹⁶ *Id.*

¹¹⁷ *Id.*; see generally Jonathan Foulds & Helena Furberg, *Is Low-Nicotine Marlboro Snus Really Snus?*, 5 HARM REDUCTION J. 9 (2008) (“Swedish snus is a medium/high nicotine delivery, low-nitrosamine moist smokeless tobacco product that has been estimated to be at least 90% less harmful than smoked tobacco.”).

¹¹⁸ *Tobacco Control Act*, U.S. FOOD AND DRUG ADMIN., *supra* note 103.

¹¹⁹ *Id.*

¹²⁰ *Id.*

¹²¹ *Id.*

¹²² *Electronic Cigarettes (e-Cigarettes)*, *supra* note 101.

¹²³ The Trans-Pacific Partnership is a proposed trade agreement among the Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, United States, and Vietnam that aims to “promote economic growth; support the creation and retention of jobs; enhance innovation, productivity and competitiveness; raise living standards; reduce poverty in our countries; and promote transparency, good governance, and enhanced labor and environmental protections” which will apparently be achieved through economic incentives such as the eliminating or reducing tariffs. See *Summary of the Trans-Pacific Partnership Agreement*, OFFICE OF THE U.S. TRADE REPRESENTATIVE,

proposed provision relating to the handling of tobacco regulation between countries participating in the agreement.¹²⁴ Michael Froman, United States Trade Representative stated in reference to the TPP Tobacco Proposal:

Developed following extensive consultations with Congress and with a wide range of American stakeholders—from health advocates to farmers, representing many views on whether and how to address tobacco-related health policy measures in a trade agreement—this proposal will, for the first time in a trade agreement, address specifically the public health issues surrounding tobacco—preserving the ability of the United States and other TPP countries to regulate tobacco and to apply appropriate public health measures, and bringing health and trade officials together if tobacco-related issues arise—while remaining consistent with our trade policy objectives of negotiating a comprehensive agreement that does not create a precedent for excluding agricultural products. We will continue to keep our Congressional partners and stakeholders informed and involved as we negotiate this challenging and important issue with TPP partners, whom will be taking into account the same range of concerns.¹²⁵

Bill Corr, Deputy Secretary of the Department of Health and Human Services, issued the following statement on the issue:

HSS believes the proposed tobacco language in the Trans-Pacific Partnership trade negotiation will make a difference for tobacco control and public health efforts. The U.S. Government seeks to include this language because tobacco is a unique product—it is highly addictive, always harmful to human health, and the single most preventable cause of death in the world. Recognizing these facts about tobacco through

office/press-releases/2015/october/summary-trans-pacific-partnership. While the United States has rejected the TPP, this section remains relevant to show the effects of international regulation on tobacco products.

¹²⁴ *New U.S. Proposal on Tobacco Regulation in the Trans-Pacific Partnership*, OFFICE OF THE U.S. TRADE REPRESENTATIVE, <https://ustr.gov/New-Proposal-Tobacco-Regulation-Trans-Pacific-Partnership>.

¹²⁵ *Id.*

the TPP will represent an important step forward for public health in the international trade community.¹²⁶

This effort to be attentive to public health regulations of other countries is a turning point in international trade agreements and U.S. commerce objectives. The U.S. Chamber of Commerce has been known to try to dissuade and discourage other countries from implementing any anti-tobacco legislation and regulation. Chief executive of the chamber, Thomas Donohue,

has transformed the chamber into a powerful lobbying force, an evolution most starkly epitomized by its aggressive advocacy for tobacco. While the organization represents a variety of industries, its strategy has been a boon for cigarette makers, which have relied heavily on the chamber to push their agenda at home and abroad.¹²⁷

In a reprehensible policy decision, the chamber has begun “pressuring governments around the world to turn back antismoking legislation” including “an attack on excise tax in the Philippines, cigarette advertising bans in Uruguay and restrictions on smoking in public places in Moldova.”¹²⁸

In September 2013, the Chamber sent a letter to the prime minister of Jamaica voicing concerns over tobacco regulations requiring graphic labeling, claiming these labels “‘are not effective’ and create ‘unnecessary obstacles to trade.’”¹²⁹ However, functionally under the TPP, it seems as though any public health regulation promulgated in relation to e-cigarettes will be respected.

III. ANALYSIS

Although public health organizations such as the WHO have strongly advocated for clamping down on e-cigarette consumption through regulation, there are civil liberty advocates and laissez faire capitalists who argue that the market is better left largely unregulated. While the e-cigarette market in

¹²⁶ *Id.*

¹²⁷ Danny Hakim, *Big Tobacco's Staunch Friend in Washington: U.S. Chamber of Commerce*, N.Y. TIMES (Oct. 9, 2015), <http://www.nytimes.com/2015/10/10/business/us-chamber-of-commerces-focus-on-advocacy-a-boon-to-tobacco.html>.

¹²⁸ *Id.*

¹²⁹ *Making Tobacco's Case*, N.Y. TIMES (June 30, 2015), <http://www.nytimes.com/interactive/2015/06/29/us-chamber-commerce-cigarette-lobbying.html>.

the United States was not regulated prior to 2016, it served as an example of a successful, unregulated market in which small businesses were able to flourish because they faced few barriers to trade. Public health specialists have come down on the side of e-cigarettes as a powerful harm reduction tool. Notably, after the WHO issued their report, “53 international health experts wrote a joint letter urging the WHO’s general director to ‘resist the urge’ to ‘control and suppress’ electronic cigarettes by classifying them as equivalent to cigarettes for purposes of regulation.”¹³⁰

The director of the CDC, Thomas Frieden, pointed out that while there is still much we do not know about e-cigarettes, “we do know quite a bit: foremost, that they don’t combust tobacco and so do not produce carcinogenic tars and disease-producing gases, including carbon monoxide . . . [t]his advantage makes vaping at least 95 percent safer than smoking tobacco, according to toxicologists.”¹³¹ Therefore, proponents argue these products should be at least as available as their more harmful counterparts, if not more so. Those who champion e-cigarettes call for a regulatory scheme which will only minimally tax e-cigarettes so that smokers will be incentivized to make the switch, but most still agree that e-cigarettes should be kept out of the hands of children and teenagers.¹³² Sally Satel, a psychiatrist specializing in addiction medicine, has argued in favor of less e-cigarette regulation, in particular the stance taken by the WHO. She argues that public health officials “[m]isrepresenting the facts about e-cigarettes and instilling doubt about their superiority to cigarettes . . .” only hinders progress, keeping “smokers inhaling deadly toxins, . . . [because], [a]fter all, why give up the combustible devil you know if vaping is just as bad?”¹³³

As far as the potential harm to younger generations, e-cigarette proponents argue that there is “no sign of a gateway effect” from e-cigarettes to traditional tobacco products.¹³⁴ In the United States, while there are “more kids vaping each year, teen cigarette consumption . . . continues to fall.”¹³⁵ However, while kids may not be switching from e-cigarettes to traditional combustible cigarettes, they are still being hooked on nicotine where they probably were not before. Thomas Friedan lamented, “‘[t]his is another generation being hooked by the tobacco industry’”¹³⁶

¹³⁰ Sally Satel, *What’s Driving the War on E-Cigarettes*, NAT’L REV. (MAY 18, 2015, 4:00 AM), <http://www.nationalreview.com/article/418483/why-cdc-so-vehemently-anti-vaping-sally-satel>.

¹³¹ *Id.*

¹³² *Id.*

¹³³ *Id.*

¹³⁴ *Id.*

¹³⁵ *Id.*

¹³⁶ *Id.*

Some public health experts argue that in developing countries where cigarette smoking is endemic, e-cigarettes should be heavily promoted rather than restricted. China is often cited as an example of a country where vaping should be encouraged. China reports that one million deaths are caused each year by tobacco products consumption and the death toll is projected to rise in the coming years.¹³⁷ In China, where smoking has become a pervasive element of social culture, if just “1 percent of China’s smoking population turned to e-cigarettes, it would mean a market of about 3.5 million e-cigarette users” and a massive reduction in harm for the country.¹³⁸ However, while vaping may be a positive force in a country such as China, where public health efforts to combat smoking have been virtually nonexistent (“[o]nly 25% of Chinese adults have a comprehensive understanding of the health risks of smoking . . .”¹³⁹), it still may pose a greater risk in countries such as the United States who have significantly reduced their rates of smoking in the last twenty years. In Singapore, more than 1,900 people are still killed annually due to tobacco related diseases.¹⁴⁰ Some would argue a better strategy for their country would be to allow e-cigarettes, at least in a therapeutic context, rather than ban them outright, to reduce some of this tobacco related harm. Malaysia too might benefit from the harm reduction side of e-cigarettes as their population still sees more deaths due to cigarettes than other middle-income countries.¹⁴¹

IV. CONCLUSION

Given the massive investment Big Tobacco has made in the e-cigarette industry and the growing social vaping movement, it seems likely most countries will regulate e-cigarettes as a tobacco product, which will give way to stricter regulations than with an ordinary consumer product but less strict than one would see with a medical device.

E-cigarette regulation should be tailored to the needs of the specific country. The WHO framework better suits countries who have already launched public health campaigns against tobacco. These countries that have

¹³⁷ *Tobacco in China*, WORLD HEALTH ORG. W. PAC. REGION, <http://www.wpro.who.int/china/mediacentre/factsheets/tobacco/en/>.

¹³⁸ Yanzhong Huang, *E-Cigarettes: China’s Next Growth Industry*, FORBES (May 27, 2017), <https://www.forbes.com/sites/yanzhonghuang/2014/05/27/e-cigarettes-chinas-next-growth-industry/#7932d12f0c53>.

¹³⁹ Sally Satel, *Keep Vaping China Don’t Listen to the World Health Organization on E-Cigarettes*, FORBES (Oct. 21, 2015), <http://www.forbes.com/sites/sallysatel/2015/10/21/keep-vaping-china-dont-listen-to-the-world-health-organization-on-e-cigarettes/>.

¹⁴⁰ *Singapore*, THE TOBACCO ATLAS, <http://www.tobaccoatlas.org/country-data/singapore/>.

¹⁴¹ *Malaysia*, THE TOBACCO ATLAS, <http://www.tobaccoatlas.org/country-data/malaysia/>.

already reduced smoking in their population should focus on regulation that will restrict access for younger markets. While e-cigarettes have a legitimate use as a smoking cessation device, if they continue to addict new generations of users who would have otherwise remained nicotine independent, the relative good of the product would not outweigh the potential societal harm. The most prudent regulatory scheme would be one which would allow the product to remain easily available to those who are using it for a legitimately therapeutic purpose. Regulation should be heavily focused on reducing consumption of the product by children and teenagers. In this respect, the WHO framework serves as a functional and well thought out model for regulation. Less developed countries, such as China, may have populations with much higher rates of smokers who are less educated about the health risks of smoking. In these, countries while e-cigarettes should of course be regulated for quality and product safety, their use should be incentivized through regulation.

The electronic cigarette market is rapidly growing and clearly poses at least some risks to public health. In order to mitigate these risks, it is important that governments put regulatory schemes into place that appropriately respond to the risks posed by tobacco products in their country. At a minimum, regulation of the products themselves that put in place standards and quality control measures, as well as consumer labeling and packaging regulations, should be put into effect.