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Big E-Tobacco: Regulatory Action without Clear Benefits

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Abstract

The U.S. e-cigarette industry has experienced rapid growth within the past few years, with some analysts estimating total sales in the range of $3 to $4 billion dollars in 2015. This growth has largely been attributed to the absence of both state and federal regulations. The Food and Drug Administration is now preparing to finalize its long-awaited "deeming regulation" that will categorize these products as regulated tobacco products, causing uncertainty for various stakeholders in the industry. However, there is little scholarship analyzing the proposed FDA regulatory implications on public health, the economy, and innovation. The purpose of this note is to advocate how these products can help millions live healthier lifestyles, create more jobs, and incentivize entrepreneurs to create better, safer products. In doing so, this note takes the position that the current FDA regulations on the e-cigarette industry create more consequences than benefits to society, and that the regulations should be mindful of the policy implications on the economy, public health, and innovation.

Keywords : Electronic Cigarette, E-Cigarette, Vapor, FDA, E-Cig, Vape, Tobacco

I. Introduction

Here is a personal fact: more than half of my family members are cigarette smokers. All of them have attempted to quit, more or less unsuccessfully. Each of them has used at least one type of cessation product in their lifetime, such as nicotine patches or gum, only to resume smoking after no more than a week. I realized as a witness that overcoming one's nicotine addiction was in some ways a near impossibility. However, I also realized that my relatives were addicted to just that — nicotine — and not the tobacco found in cigarettes per se. Indeed, the problem as

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it appeared to me was that there existed no product by which they could receive nicotine in a safer and more effective manner. And so long as such products did not exist, my relatives would continue to consume cigarettes along with the harmful chemicals associated with them.

Understandably, I became hopeful when I first heard about electronic cigarettes several years ago. Electronic cigarettes, or "e-cigarettes," are battery-powered devices that allow users to inhale nicotine vapor without fire, smoke, ash or carbon monoxide.[1] They may look like traditional cigarettes, although designs can vary greatly depending on the manufacturer.[2] An e- cigarette will typically consist of a (1) nicotine cartridge or nicotine liquid ("e-liquid"), (2) an atomizer or heating element, and (3) the battery/electronics.[3] Cartridges contain liquid nicotine, water, propylene glycol, and glycerol while e-liquid may contain propylene glycol and vegetable glycerin.[4] The atomizer vaporizes the liquid through heat and the battery/electronics powers the atomizer. In summary, e-cigarettes provide the "smoking" experience of traditional cigarettes, without the 4,000 chemicals and 400 toxins found in them.[5]

E-cigarettes are a major game changer in the tobacco industry. In 2014, a Wells Fargo market analysis concluded that there were a total of 8,500 e-cigarette stores in the United States that generated a total of $900 million in revenue for that year.[6] By 2015, the industry grew to somewhere between $3 to $4 billion dollars.[7]

The lack of traditional tobacco odor and taste is one explanation for the increases in use. Although e-cigarettes have the same age limit as traditional tobacco products, a 2014 National Youth Tobacco Survey found that e-cigarette use amongst middle and high school students tripled from 2013 to 2014, with high school users increasing from 660,000 to 2 million, and middle school users from 120,000 to 450,000.[8] The concern over how e-cigarettes have

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[1] *See, e.g.*, Andrea R. Vansickel et al., *A Clinical Laboratory Model for Evaluating the Acute Effects of Electronic "Cigarettes": Nicotine Delivery Profile and Cardiovascular and Subjective Effects*, 19 Cancer, Epidemiology, Biomarkers & Prevention OF1, OF8 (2010).

[2] For example, one online store's selection of e-cigarette products are telling of the wide range of choices available to consumers, http://www.e-cigarettes-online.net/designer-style-e- cigs.html (last visited May 2, 2016).

[3] For a more detailed explanation of how e-cigarettes work mechanically please see Christopher J. Brown et al., *Electronic Cigarettes: Product Characterisation and Design Considerations*, 23 Tob Control ii4, ii5-ii7 (2014), http://tobaccocontrol.bmj.com/content/23/suppl_2/ii4.full.pdf+html

[4] *Id.*

[5] *Id.*

[6] Benjamin F. Mitchell, *Cloudy future for vape shop owners*, USA Today (June 30, 2015), http://www.usatoday.com/story/money/2015/06/29/vape-shops-uncertain-future/71207512/

[7] Sara Rimer, *Behind the Vapor*, Boston University Research, http://www.bu.edu/research/articles/behind-the-vapor/; *See also* Robin Abcarian, *E- cigarettes appear here to stay: So put that in your mod and vape it*, Los Angeles Times (Dec. 4, 2014), http://www.latimes.com/local/abcarian/la-me-abcarian-vaping-column-20141205-column.html

been marketed,[9] the startling increase of youth users, and the scientific uncertainty of the public health implications has prompted calls for strong regulatory action.[10]

However, the road to regulation up to this point has been rocky at best. Beginning in 2008, the FDA tried to regulate e-cigarettes as unapproved drug and device combination products because they were often marketed as tobacco cessation aids.[11] Under that standard, e-cigarette manufacturers would have to prove that their products were safe and effective as advertised, which could cost hundreds of millions of dollars in clinical trials to prove.[12]

Unsurprisingly, e-cigarette manufacturers challenged this authority in federal court. In 2010, the United States Court of Appeals for the District of Columbia ("D.C. Circuit") held in Sotterra, Inc. v. FDA that as long as the plaintiff's e-cigarette products were not marketed for therapeutic use, then the FDA could only regulate e-cigarette products as tobacco products pursuant to the Family Smoking Prevention and Tobacco Control Act ("TCA").[13] The TCA gave the FDA authority to regulate tobacco products such as cigarettes, roll-your-own, and smokeless tobacco, but left out other tobacco products such as cigars, hookah tobacco, and, relevant here, electronic cigarettes.[14] Since the TCA gives the FDA authority to "deem" products as tobacco products if they meet the statutory definition of tobacco,[15] the FDA now intends to use this as the source of authority to

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[8] Press Release, Centers for Disease Control and Prevention, *E-cigarette use triples among middle and high school students in just one year* (April 16, 2015), http://www.cdc.gov/media/releases/2015/p0416-e-cigarette-use.html

[9] The FDA to date has sent a total of 8 warning letters to e-cigarette manufacturers (5 in 2010, 3 in 2015), which ordered these manufacturers to stop advertising its products as though approved by the FDA, whether express or implied. *See, e.g.*, Letter from Michael M. Levy, Jr., Director, Division of New Drugs and Labeling Compliance, to Sihui (Sam) Han, Owner, Cixi E- Cig Technology Inc, Ltd. (Sep. 8, 2010), http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm225187.htm.

[10] *See, e.g.*, Letter from Douglas E. Henley et al., Executive Vice President and Chief Executive Officer, American Academy of Family Physicians, to President Barack Obama, the White House (Apr. 28, 2015), http://www.ada.org/~/media/ADA/Advocacy/Files/ltr_150428_president_tobacco_deeming_nosi g.pdf?la=en ("In the absence of regulation, we have seen irresponsible marketing of unregulated products such as cigars and electronic cigarettes, often using tactics and sweet flavors that clearly appeal to youth. It's not wonder use of e-cigarettes by youth has skyrocketed.").

[11] Under the Food, Drug, and Cosmetic Act ("FDCA"), the FDA has to authority to regulate, among other items, "drugs" and "devices." *See* 21 U.S.C. §§ 321(g)-(h) (2009). However, the Supreme Court held in FDA v. Brown & Williamson Tobacco Corp., that asserting jurisdiction over tobacco products as drugs would go against Congressional intent, since the main purpose of the FDCA was to "ensure that any product regulated by the FDA is 'safe' and 'effective' for its intended use." 529 U.S. 120, 133 (2000). Under that analysis, the FDA would have to ban tobacco altogether from the marketplace since tobacco has been proven to be clearly dangerous. Thus, tobacco products cannot be considered drug or devices under the FDCA. *Id.* at 143. Since at least some parts of e-cigarettes — such as liquid nicotine — are from tobacco, whether such products can be properly categorized under the FDCA was unclear.

[12] *See, e.g.*, Erica Westly, *The Price of Winning FDA Approval*, Fast Company (Dec. 1, 2009), http://www.fastcompany.com/1460583/price-winning-fda-approval (stating that average out-of-pocket cost of developing a new drug, from inception to approval was $494 million dollars).

[13] Sottera, Inc. v. FDA, 627 F. 3d 891, 898 (D.C. Cir. 2010).

[14] *Id.*

regulate the e-cigarette industry.

After some delay, the FDA published its proposed regulation in 2014.[16] It hopes to finalize the regulations sometime later this year.[17] Since the proposed regulation would "deem"e-cigarette products as tobacco products, many of the current tobacco regulations would apply to e-cigarette products.[18]

> Some of these regulations include:
> - Registering with the FDA and reporting all product and ingredient listings
> - Only marketing new tobacco products after FDA review
> - Only making direct and implied claims of reduced risk if the FDA confirms that scientific evidence supports the claim and that marketing the product will benefit public health as a whole
> - No distributing of free samples
> - Including health warnings

There is currently little scholarship that addresses the proposed FDA regulations on the current e-cigarette industry. But with an industry that has brought in billions in revenue and is expected to surpass cigarette sales by 2047,[19] analyzing the proposed regulations on the industry is ever important. Here, I approach the analysis under three perspectives: public health, the economy, and innovation. I argue that the proposed regulations can be beneficial for public health, but come with dire consequences for the other two.

This note proceeds in four parts. Part I examines the public health arguments for and against e-cigarette products. It looks to current scientific research, and what harm these products pose to the population. It then argues that the proposed FDA regulations would benefit public health because of stronger oversight on how e-cigarette products are manufactured and advertised.

Part II investigates the industry's impact on the overall economy. It takes strong

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15 *See* 21 U.S.C. § 321(rr)(1) (2009) ("The term 'tobacco product' means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product").

16 Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 79 Fed. Reg. 80 (proposed Apr. 25, 2014), http://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM394914.pdf.

17 Sheila Kaplan, *E-cigarettes. Generic drugs. A guide to the FDA in 2016*, STAT News (Jan. 4, 2016), https://www.statnews.com/2016/01/04/fda-2016-agency-agenda/.

18 *See* 79 Fed. Reg. 80.

19 Kyle Stock, *The Real Reason Big Tobacco Loves E-Cigs*, Bloomberg Businessweek (Aug. 26, 2013), http://www.bloomberg.com/news/articles/2013-08-26/the-real-reason-big-tobacco-loves-e-cigs.

objection to a particular part of the regulation that would virtually destroy 99% of the existing e-cigarette businesses. It then explains how by keeping these businesses open, the government could raise large revenue through sales and excise taxes for further research, or to fund other social programs.

Part III looks to the innovation of e-cigarette products since their inception and how the products have become more sophisticated over time. It shows how the FDA regulations reduce risk of manufacturing defects but ultimately stifle innovation and improvement as a whole due to the expenses associated with tobacco applications.

Part IV concludes with brief suggestions on how to balance the interests of various stakeholders as the industry is expected to continuously grow or be destroyed later this year.

II. Current Studies Indicate that E-Cigarette Products are Less Harmful than Traditional Tobacco Products

Within the e-cigarette industry the public health problem is two-fold: product advertising and potential health risks to consumers. As a statement by the FDA in 2014 articulated, "e-cigarettes have not been fully studied so consumers currently don't know the potential risks of e-cigarettes when used as intended, how much nicotine or other potentially harmful chemicals are being inhaled during use, or whether there are any benefits associated with using these products."[20] There is truth to this statement. Much, if not most, of the e-cigarette market operates on an "honor system," meaning that consumers who purchase e-cigarette products take their advertised information at face value. Ultimately, this means that the average consumer is unable to independently verify if the products they purchase contain what they purport to contain and at what level they claim. In addition, there are no long-term case studies that have been conducted that show the effects of using these products, thus the current medical studies are unable to answer the possible health consequences of long-term use.

Early research indicates that e-cigarette products are physically harmful, which of course is an obvious conclusion given that one is still ingesting nicotine.[21] For example, one study that tested over 51 different flavors of e-liquid found 39 of the 51 flavors positive for diacetyl, which is associated with a disease widely known as "popcorn lung."[22] But the

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[20] Food and Drug Administration, Electronic Cigarettes (e-Cigarettes), http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm172906.htm (last visited Feb. 5, 2016).

[21] Nicotine alone poses its own health risks: chronic exposure to nicotine is associated with a variety of cardiovascular ailments, including hearth disease, and high doses of nicotine can cause potentially fatal nicotine poisoning. *See* Centers for Disease Control and Prevention, NICOTINE: Systemic Agent, http://www.cdc.gov/niosh/ershdb/emergencyresponsecard_29750028.html (last visited Feb. 27, 2016).

[22] *See* Joseph G. Allen et al., *Flavoring Chemicals in E-Cigarettes: Diacetyl, 2,3- Pentanedione, and Acetoin in a Sample of*

presence of diacetyl in e- cigarette products is at least 750 times lower than that of a tobacco cigarette.[23] Additional studies have found the presence of formaldehydes, which are an industrial biocide and other tobacco- specific impurities and nitrosamines.[24]

Despite these findings, most agree based upon current research that e-cigarettes are less harmful than traditional tobacco products.[25] For example, a recent study published in February 2016 found that smokers who reduced or quit smoking by switching to e-cigarettes may lower their systolic blood pressure in the long term; this reduction is apparent in smokers with elevated blood pressure.[26] Moreover, it has been found that a lesser amount of volatile organic compounds were retained in the respiratory system after e-cigarette smoking as opposed to tobacco.[27] The proper question therefore, is not whether e-cigarettes products are harmful, but rather how harmful are they compared to traditional tobacco products. Since the idea is that e-cigarettes seem to be less harmful than tobacco products based on research conducted so far, ultimately consumers are choosing the lesser

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51 Products, Including Fruit-, Candy-, and Cocktail- Flavored E-Cigarettes, Environmental Health Perspectives (Dec. 8, 2015), http://ehp.niehs.nih.gov/wp-content/uploads/advpub/2015/12/ehp.1510185.acco.pdf

[23] *See* Kazutoshi Fujioka et al., *Determination of Toxic Carbonyl Compounds in Cigarette Smoke*, Environmental Toxicology (July 28, 2015),
http://onlinelibrary.wiley.com/doi/10.1002/tox.20153/epdf (finding average inhaled daily diacetyl dose in smoking to be roughly 6718 micrograms).

[24] *See* Letter from R. Paul Jensen et al., Portland State University, to Editor, New England Journal of Medicine (Jan. 22, 2015),
http://www.nejm.org/doi/pdf/10.1056/NEJMc1413069; *See also* Food and Drug Administration, Summary of Results: Laboratory Analysis of Electronic Cigarettes by FDA,
http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm173146.htm (last visited Feb. 28, 2016); *See also* Kaleigh Rogers, *Vaping Emits Less Formaldehyde than Previously Thought*, VICE, Feb. 25, 2016) (finding that the presence of diacetyl and formaldehyde was less than 1 mg in e-cigarettes while traditional tobacco emitted the same substances over 1.5 mg).

[25] For example, the American Association of Public Health Physicians supports the use of e-cigarettes by adults because they are safer than regular cigarettes. News Medical Life Sciences & Medicine, *AAPHP: E-cigarettes are not wildly dangerous alternatives as they have been* portrayed (Nov. 17, 2009),
http://www.news-medical.net/news/20091117/AAPHP-E-cigarettes-are-not-wildly-dangerous-alternatives-as-they-have-been-portrayed.aspx. *See also* Harrell et al., *Electronic nicotine delivery systems ("e-cigarettes"): Review of safety and smoking cessation efficacy*,
http://www.ncbi.nlm.nih.gov/pubmed/24898072 (finding that compared to tobacco cigarettes, available evidence suggests that e-cigarettes are often substantially lower in toxic content, cytotoxicity, associated adverse effects, and secondhand toxicity exposure).

[26] *See* Konstantinos Farsalinos et al., *Effect of continuous smoking reduction and abstinence on blood pressure and heart rate in smokers switching to electronic cigarettes* (Jan. 9, 2016), http://link.springer.com/article/10.1007/s11739-015-1361-y.

[27] *See* Esther Marco et al., *A rapid method for the chromatographic analysis of volatile organic compounds in exhaled breath of tobacco cigarette and electronic cigarette smokers* (July 29, 2015),
http://www.ncbi.nlm.nih.gov/pubmed/26243705 (finding that tobacco cigarette smoke involved a much larger burden of organic compounds into smokers, including benzene, toluene, naphthalene and other pollutants of general concern).

of two evils when deciding to opt for e-cigarettes.

E-cigarette advertising poses further questions about public health concerns. Prospective consumers may erroneously conclude that e-cigarette products are actually healthy[28] and that their use comes without any consequences. This impression can be formed through both omissions and misrepresentations of information. On one hand, e-cigarette products have no regulatory obligation to provide warning labels on its products, which may cause consumers to mistakenly believe that there are no health consequences to using the product. On the other hand, some e-cigarette businesses have presented "Certificate of FDA Registration" on their websites, which has misled consumers into believing that the FDA approves its products.[29] Such practices have led to at least one class action lawsuit filed in federal court.[30]

E-cigarette advertising is particularly troubling due to its effects on youths and young adults. For example, youth may be attracted to e-cigarettes through the variety of e-liquid flavors available, including fruit, candy, and savory flavors. According to the Center for Disease Control and Prevention ("CDC"), nearly 9 out of 10 smokers tried their first cigarettes by age 18 and 99% of them by the age of 26.[31] Once they start, smoking can continue be a perpetual habit for youths. For this reason, efforts at smoking prevention have focused on youths of high school age and younger. If e-cigarette products attract new smokers in the young adult group,[32] they can substantially expand the pool of life-long nicotine addicts.

The proposed FDA regulations have strong benefits and would help resolve some of the advertising and public health concerns. From the outset regulations would authorize the FDA to take action against products that are determined to be adulterated and misbranded, reducing the potential public health dangers of such products.[33] Through regulation the FDA would be correcting any possible misconception that, because e-cigarettes are not regulated, they must be safe. Thus, the proposed regulations help both consumers and e-cigarette manufacturers in equal measure — the former through confidence in government oversight and the latter through restricted tort liability.

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[28] *See infra* fn. 30

[29] Letter from Ann Simoneau, Director, Office of Compliance and Enforcement, Food and Drug Administration, to Claire Riddington-Smith, Director, Vaperz Ltd. (Apr. 2, 2015) http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm441314.htm ("these statements … on your website … mislead consumers into believing, that the above-listed tobacco products are approved by the FDA").

[30] *See In re NJOY, Inc. Consumer Class Action Litigation*, 120 F. Supp. 3d 1050, 1050 (Aug. 14, 2015) (District court holding that proposed class was ascertainable where plaintiffs filed action against manufacturer of e-cigarettes for false advertisements and misleading omissions regarding safety of smoking e-cigarettes compared to traditional cigarettes).

[31] *See* Centers for Disease Control and Prevention, Youth and Tobacco Use, http://www.cdc.gov/tobacco/data_statistics/fact_sheets/youth_data/tobacco_use/ (last visited Mar. 2, 2016).

[32] *See supra* note 8.

[33] 21 U.S.C. § 387b-c (2009).

The proposed regulations also would benefit public health by ensuring that new e-cigarette products on the market are not substantially harmful to consumers. Because e-cigarette manufacturers would be required to accurately disclose the ingredients of their products, consumers will no longer have to rely upon an honor system to trust that products actually contain what they purport to contain.[34] In other words, FDA regulation would ensure that the consumer has access to accurate information on what they are purchasing, rather than relying on a vendor who may have a financial bias in the matter. Thus, the proposed regulations bring stronger quality control to the consumer market.[35]

From a public health perspective, regulations on products are beneficial because they ensure that vendors and manufacturers are held accountable when conducting business with consumers. Indeed, all stakeholders desire regulations insofar as there are public health concerns. Government regulation helps manufacturers create products within a reliable framework, builds confidence in consumers when purchasing those products, and aids regulatory agencies in determining compliance. It is unsurprising, therefore, that there are no substantial objections to the proposed regulations on public health grounds.

III. As Introduced, the Proposed Regulations Destroy Existing E-Cigarette Businesses

The e-cigarette industry is booming. There are roughly 2.75 million Americans that use some form of e-cigarette product.[36] CDC studies show that e-cigarette use quadrupled in a single year from 2009 to 2010.[37] Some financial analysts speculate that e-cigarette sales

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[34] *See* Food and Drug Administration, Preliminary Regulatory Impact Analysis, *Deeming Tobacco Products to be Subject to the Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations Restricting the Sale and Distribution of Tobacco Products and Required Warnings Statements for Tobacco Product Packages and Advertisements* (Apr. 2014),
http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/UCM394933.pdf ("a proposed deemed tobacco product in package form would need to add to its label: the name and place of business of the tobacco product manufacturer, packer, or distributor; an accurate statement of the quantity of the product's contents in terms of weight, package, measure, or numerical count").

[35] Press Release, Centers for Disease Control and Prevention, *New CDC study finds dramatic increase e-cigarette-related calls to poison centers* (Apr. 3, 2014),
http://www.cdc.gov/media/releases/2014/p0403-e-cigarette-poison.html (The number of e- cigarette related calls to poison centers rose from one per month in September 2010 to 215 per month in February 2014). From a policy perspective, stronger quality control coupled with warning labels has the potential to greatly reduce the number of poison control incidents.

[36] Statistic Brain, Electronic Cigarette Statistics,
http://www.statisticbrain.com/electronic-cigarette-statistics/ (last visited Mar. 8, 2016).

[37] *See* John Tierney, *A Tool to Quit Smoking Has Some Unlikely Critics*, The New York Times (Nov. 7, 2011),
http://www.nytimes.com/2011/11/08/science/e-cigarettes-help-smokers-quit-but-they-have-some-unlikely-critics.html?_r=0.

will surpass traditional cigarettes by 2047,[38] and currently the industry is estimated to be worth in the $3 to $4 billion dollar range.[39]

However, the current proposed regulations would effectively destroy the entire industry by eliminating nearly all existing businesses. The controversy in the FDA proposed guideline is the "grandfather" date provision which requires all e-cigarette products marketed after February 15, 2007 to seek approval through either a "substantial equivalence" predicate, or the premarket tobacco application ("PMTA").[40] Through the "substantial equivalence" path, an e-cigarette manufacturer would have to show that their products have the "same characteristics" or raise the same public health issues as predicate products on which they rely.[41] However, since virtually no e-cigarette products existed on the U.S. marketplace prior to February 15, 2007, e-cigarette manufacturers would have to seek approval through the PMTA.[42]

A PMTA requires an e-cigarette manufacturer to provide sufficient evidence and analysis to allow the FDA to determine that approving its product on the market would be "appropriate for the protection of public health."[43] The statute requires that the FDA consider related health risks and benefits not only to users but to the population as a whole, including non-users, taking into account the likely effect of the product's marketing on whether existing tobacco product users will quit or current non-users will start using tobacco products.[44] For this reason, the PMTA process is extremely expensive, with some estimating that it will cost about $2 to $20 million dollars to complete the application.[45]

Unfortunately, this means that only large companies with sufficient capital would be able to actually afford to go through this process, which is nearly impossible for most existing e-cigarette businesses to afford.[46] What you would likely find under this scenario is the

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[38] *See supra* note 19.

[39] *See supra* note 7.

[40] 79 Fed. Reg. 80 (proposed Apr. 25, 2014).

[41] 21 U.S.C. § 387j(3)(A)(i) (2009).

[42] *See infra* Part III.

[43] 21 U.S.C. § 387j(c)(2)(A) (2009).

[44] Food and Drug Administration, *Commonly Asked Questions: About the Center for Tobacco Products*, http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/AbouttheCenterforTobaccoProducts/ucm378205.htm (last visited Feb. 28, 2016).

[45] *See* Bill Godshall, *What is the Grandfather Date of the Tobacco Control Act & How Will it Impact the Vapor Industry?*, Smoke-Free Alternatives Trade Association (Aug. 4, 2015) http://sfata.org/what-is-the-grandfather-date-of-the-tobacco-control-act-and-how-will-it-impact-the-vapor-industry/ ("a recent Wall Street Journal article cited the regulatory consulting company Sci-Lucent LLC estimating it would cost $2-$10 million to submit a PMTA, while my 2014 comment to the FDA estimated it would cost $3-$20 million to submit a PMTA that FDA would actually evaluate").

[46] *See* Press Release, Smoke-Free Alternatives Trade Association, *U.S. Vape Shops Average $26K in Monthly Sales, According to Industry Index* (Dec. 16, 2015), http://sfata.org/u-s-vape-shops-average-26k-in-monthly-sales-according-to-industry-index/ (showing that U.S. e-

three largest tobacco companies in this country taking over the e-cigarette industry. In the last couple of years, Altria Group (formerly Philip Morris), R.J. Reynolds, and Lorillard (commonly known as "Big Tobacco"), have attempted to move into this market space. All three companies have bought and acquired e-cigarette companies, created subsidiaries to manufacture these products, and have been highly successful at selling them by wielding their considerable market power.

Recognizing this issue, some in Congress introduced H.R. 2058 (sponsored by Congressman Tom Cole) on April 28, 2015, which would eliminate the February 15, 2007 "grandfather" date. More recently, Congressman Robert Aderholt introduced a "rider" to the 2016 Agricultural Spending Bill in the House Appropriations Committee which would change the grandfather date to the effective date of the final rule of the "deeming regulation."[47] The changing of the grandfather date alone would allow many small businesses to compete with the larger tobacco companies in that, these businesses would not necessarily be required to go through a long and expensive approval application. There has also been strong opposition against the February 15, 2007 date by influential leaders such as Grover Norquist.[48]

Some may wonder why February 15, 2007 was the date chosen for the grandfather provision. February 15, 2007 is the date the House and Senate bills that eventually became the The TCA was introduced in Congress after previous versions of the bill had failed to pass.[49] Although it was H.R. 1256 (introduced March 3, 2009) that was ultimately signed by the President, it was probably the February 15, 2007 date that was kept in the legislation, at least in part because that was the date that put the tobacco industry on notice that it would be subject to the FDA's authority and how it would be regulated.[50]

The actual date of the grandfather provision will have a tremendous economic effect on the e-cigarette industry. For example, even if a company were able to establish that an

cigarette stores average $26,000 in monthly sales. There would not be nearly enough revenue to cover the PMTA costs under these averages); *see also* Whip Villarreal, *Vaping shops say FDA regulation could put them out of business*, Los Angeles Times, Aug. 10, 2015, http://www.latimes.com/business/la-fi-vaping-shops-20150810-story.html (reporting on how many e-cigarette stores fear that their businesses can be eliminated through the proposed FDA regulations).

47 *See* U.S. House of Representatives, Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Bill, 2016, pp. 70-71, http://appropriations.house.gov/uploadedfiles/hrpt-114-hr-fy2016-agriculture.pdf

48 *See, e.g.*, Letter from Grover Norquist, President of Americans for Tax Reform, to Members of Congress (Nov. 24, 2015), https://www.atr.org/sites/default/files/assets/ATR%20Support%20for%20Predicate%20Date%20Change.pdf ("Since 2007, significant innovation in the electronic cigarette and vapor product has occurred, meaning nearly 99% of the life-saving vapor products on the market will cease to exist").

49 *See* S. 625, 110th Cong. § 1 (2007) (introduced by Senator Edward "Ted" Kennedy).

50 Family Smoking Prevention and Tobacco Control Act, H.R. 1256, 111th Cong. (1st Sess. 2009).

e-cigarette product had been marketed in the U.S. prior to February 15, 2007 pursuant to a substantial equivalence pathway, those products from early 2007 would likely be quite primitive and different from today's e-cigarette products, making substantial equivalence impossible.[51] Along with the costs of the PMTA application, current e-cigarette companies will be unable to successfully receive approval.

As the proposed FDA regulation would kill 99% of existing companies, some speculate that this would affect roughly 8,000 to 12,000 e-cigarette shops in the United States, and an estimated 1,000 manufacturers and wholesalers of e-cigarette products.[52] Others estimate that when "hybrid" shops that sell both e-cigarette products and tobacco products are included in the regulation, the number can inflate to 35,000 stores.[53]

From an economic perspective, the government has a financial incentive to keep these businesses alive as opposed to allowing the e-cigarette industry dominated by only a few larger companies. Although there a variety of ways that new businesses contribute to stimulating the economy, I focus here on only one aspect: taxes. One can predict market analysis by looking at the number of users, sellers, and products sold. Here, e-cigarette products have the potential to be taxed similarly to that of tobacco products and therefore provide a promising avenue of both state and federal revenue.[54]

In the tobacco market, cigarettes are usually taxed separately from other tobacco products like chewing tobacco, snuff, cigars, and little cigars.[55] Tobacco products can be taxed in a number of different ways, through imposition of excise taxes, sales taxes, and value-added taxes, or some combination thereof. In February 2009, the President signed into a law a bill that included a large increase in federal excise taxes on tobacco, which more than doubled the existing tax on cigarettes from 39 cents to $1.01 per pack.[56] It was designed to help pay the cost of the children's health insurance under the State Children's Health Insurance Program.[57] As a result of this change, tax revenue increased from $7.6

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[51] *See infra* Part III.

[52] Laurie Tarkan, *How new rules could kill the vaping boom*, Fortune (Sep. 29, 2015), http://fortune.com/2015/09/29/vaping-fda-rules/.

[53] Norm Bour, *How Many Vape Shops Are There in the U.S.A.?,* VAPE Magazine (Jan. 3, 2015), http://vapenewsmagazine.com/november-2014/how-many-vape-shops-are-there-in-the-u-s-a.

[54] Chuck Marr et al., *Higher Tobacco Taxes Can Improve Health and Raise Revenue*, Center on Budget and Policy Priorities (Mar. 19, 2014), http://www.cbpp.org/research/higher-tobacco-taxes-can-improve-health-and-raise-revenue.

[55] Campaign for Tobacco-Free Kids, *State Excise Tax Rates for Non-Cigarette Tobacco* Products, https://www.tobaccofreekids.org/research/factsheets/pdf/0169.pdf (last visited Mar. 15, 2016).

[56] Section 283 of the 1982 Tax Equity and Fiscal Responsibility Act, P.L. 97-248 (enacted Sept. 3, 1982); section 11202 of the Omnibus Budget Reconciliation Act of 1990, P.L. 101-508 (enacted Nov. 5, 1990); section 9302 of the Balanced Budget Act of 1997, P.L. 105-34 (enacted Aug. 5, 1997); section 701 of the Children's Health Insurance Program Reauthorization Act, P.L. 111-3 (enacted Feb. 4, 2009).

[57] *Id.*

billion in 2008 to $17.1 billion in 2010.[58] If e-cigarette products are taxed through similar excise taxes, both state and federal governments can expect additional funds that can be used as part of their annual budgets.[59] Some states have already begun taxing e-cigarette products in certain jurisdictions.[60]

Alternatively, if the proposed FDA regulations become finalized without revising the currently existing grandfather date, the economic consequences will be a deathblow to the e- cigarette industry. If we consider the earlier estimate that 99% of current e-cigarette companies will go out of business, it makes sense that 99% of the potential tax revenue will disappear along with them, which would leave the industry at a startling $30,000 to $40,000.00 initial value on tax revenue.[61]Although this assumes that consumers will not make the switch from their current products to what is left of the 1%, it will at least take some time for Big Tobacco companies to move into this space and grow the revenue of industry again to what it was originally before the FDA regulations.

The proposed regulations will have serious consequences on the economy. As stated before, the grandfather date would eliminate most existing e-cigarette businesses due to owners being unable to pay for the costly PMTA process. By a simple revision of the date, these businesses can be kept alive while the government can move to find solutions in adopting excise taxes on these products similar to that of traditional tobacco products. The promising tax revenues that could be brought through the e-cigarette industry can help state and federal governments to fund other social programs with a significant boost to their annual budgets.

IV. The Proposed Regulations Would Stifle Innovation

If the grandfather date is not revised, the proposed regulations will have the effect of stifling innovation in the e-cigarette industry because all new products will have to go through the PMTA process before market approval. Until now, e-cigarette products have become more sophisticated in design and functionality where businesses have competed for market share through continued innovation and quality of their products.[62]

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[58] *Id.*

[59] *See supra* note 54.

[60] *See, e.g.*, Minnesota Department of Revenue, *E-cigarettes are Taxable in Minnesota*, http://www.revenue.state.mn.us/businesses/tobacco/Documents/ecigarette_flyer.pdf (last visited Apr. 1, 2016).

[61] *See supra* note 7. This calculation is based of the Wells Fargo market analysis of the e- cigarette industry that was estimated to be $3 to $4 billion dollars.

[62] Richard Craver, *Vuse overwhelming e-cig competition*, Winston-Salem Journal (May 29, 2015), http://www.journalnow.com/business/business_news/local/vuse-overwhelming-e-cig-competition/article_01f18c48-7ba1-5520-af32-b007025c6f9f.html.

Although e-cigarette products have gained wide popularity only within the past few years, the first electronic cigarette can be traced back to 1963. Hebert A. Gilbert filed the first electronic cigarette patent in 1963 for a product by which there was flavored cartridges, heating elements, and smokeless flavored air.[63] According to Gilbert, the product never made it to production because the manufacturer that he pitched the idea to simply did not like it, most likely due to a nonexistent market.[64]

Things took a turn in 2003, when Hon Lik, a Chinese pharmacist, started to loathe his own tobacco addiction.[65] After losing his father to lung cancer, he envisioned an effective nicotine device that would help him and others like him to quit smoking cigarettes.[66] Lik's original product[67] consisted of a battery, plastic cartridge containing nicotine solution suspended in propylene glycol, and an ultrasonic atomizer.[68] That same year, Lik filed the first patent in 2003 in China for his device, and thus the e-cigarette was introduced to the U.S. markets through market sales sometime between 2006 and 2007.[69]

As e-cigarettes started to gain popularity in the 2000s, so did the subculture. While most consumers liked the existing e-cigarette products on the market, some consumers desired more out of their e-cigarette experience. Since the engineering of e-cigarettes are not awfully complicated (i.e., battery, heating element, and nicotine liquid),[70] many began to experiment and modify their own e-cigarette configurations. A modified flashlight was one of the first common e-cigarette experiments and the foundation for which many e-cigarette products on the market today base their engineering.[71] Flashlights were easy to work with since it

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63 U.S. Patent No. 3,200,819A (filed Apr. 17, 1963).

64 Interview with Herbert A. Gilbert, Original Patent Holder, U.S. Patent No. 3,200,819A (Oct. 2, 2013), at http://www.ecigarettedirect.co.uk/ashtray-blog/2013/10/interview-inventor-e-cigarette-herbert-a-gilbert.html ("Those I showed it to could have done it but they chose to wait for the patent to expire and then filed their own versions. I showed it to chemical companies, pharmaceutical companies and tobacco companies and they did what they did to try to protect their markets").

65 Martinne Geller, *E-cigs a 'consumer-driven' revolution born from a bad dream*, Reuters (Jun. 9, 2015), http://www.reuters.com/article/us-ecigarettes-inventor-idUSKBN0OP1YV20150609.

66 *Id.*

67 P.H., *E-cigarette patent wars: A case of the vapers*, The Economist (Mar. 17, 2014), http://www.economist.com/blogs/schumpeter/2014/03/e-cigarette-patent-wars.

68 An ultrasonic atomizer of liquids is the process by which disintegration of liquids into droplets results from the unstable surface waves generate at the free surface of a thin film that forms as the liquid spreads over the atomizing surface. The most common example would be an aerosol-type product, where liquid is transformed into a smoke, mist-like state. D. Sindayihebura et al., *Experimental Study of Thin Liquid Film Ultrasonic Atomization*, http://sites.uclouvain.be/term/recherche/ultrasonique/art0197.pdf.

69 Lik filed numerous patents in the U.S. as he sought to bring his inventions into the U.S. marketplace. *See, e.g.*, U.S. Patent No. D590990S1 (filed Jun. 13, 2008).

70 *See supra* note 3.

71 Michael Grothaus, *Trading addictions: the inside story of the e-cig modding scene*, Engadget (Oct. 1, 2014), http://www.engadget.com/2014/10/01/inside-story-e-cig-modding-uk/.

consisted of a hollow tube for batteries, a switch, and threading where a light bulb is placed.[72] Rather than a light bulb, one could easily install absorbent material to place nicotine liquid directly on that material so that the battery would heat the liquid to produce vapor.

Today, there are "digital" e-cigarettes with variable voltage/wattage settings, e-cigarettes with complex circuitry, pen-shaped and cylindrical-shaped e-cigarettes for user comfort, and a variety of premade atomizers.[73] A comprehensive search by Shu-Hong Zhu et al. found that in January 2014, there were over 460 different brands of e-cigarettes and 7764 unique nicotine liquid flavors.[74] From a period of over 17 months, the study found that there was a net increase of 10.5 brands and 242 new flavors per month.[75] The results show that there is strong growth within the industry where consumers have a wide variety of options to purchase these devices.

However, the proposed regulations have the effect of stifling this growth because current e-cigarette manufacturers would be unable to pay for the PMTA process. As a result, consumers would have to rely on either Big Tobacco or companies with large capital for continuous innovation of these products. But because of the limited competition with such large market share between these companies, there is little incentive to pursue aggressive innovation, particularly where that market share is not threatened by smaller inventors unable to bring their products to market.[76] This is particularly important since innovation has brought better quality control directly to the consumer.[77] Thus, the idea that innovation would be left to only a few companies in the marketplace is unfortunate.

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[72] *Id.*

[73] Onvaping, Beginners Guide to Vaping, *Ch. 4 E Cig Battery Basics: Cig-a-Likes, Egos, and Mods,* http://onvaping.com/guide/beginners-guide-to-vaping/ch-4-e-cig-battery-basics-cig-a-likes-egos-and-mods/ (last visited April 1, 2016).

[74] Shu-Hong Zhu et al., *Four hundred and sixty brands of e-cigarettes and counting: implications for product regulation*, Moores Cancer Center (May 12, 2014), http://tobaccocontrol.bmj.com/content/23/suppl_3/iii3.full.pdf+html.

[75] *Id.*

[76] The economic effects of an oligopoly — a market in which only a few firms dominate market — have been historically proved and documented. Common effects of an oligopoly include restriction on output, price exceeding average costs, and lower efficiency. Oligopolies also have the greater potential for collusion (either express or implied) in violation antitrust laws. Richard A. Posner, *Oligopoly and the Antirust Laws: A Suggested Approach*, 21 Stan. L. Rev. 1562, 1564-1575 (1969).

[77] For example, there have been reports that some e-cigarette products have "exploded" or caught on fire without any user error. There is a strong incentive to bring higher quality products to the marketplace in order to gain larger market share. *See, e.g.*, Debra Goldschmidt, *Man says e-cigarette battery exploded in his pocket*, CNN (Feb. 25, 2016), http://www.cnn.com/2016/02/25/health/e-cigarette-explodes-in-mans-pocket/.

V. Balancing the Interest of Stakeholders

The e-cigarette industry has grown tremendously over the past few years. These products are promising from a public health policy perspective since they can help cigarette smokers as part of a larger harm reduction strategy. But in order for e-cigarettes to reach its full utilization, the proposed regulations must be changed to balance the interest of stakeholders.

While the proposed regulations do bring great benefits to public health, they also come with damning economic and innovative consequences to the industry. The regulations protect consumers by way of introducing safer products but destroy entrepreneurs and business owners in the process. In order to balance the interest of all parties the grandfather date must either be eliminated, or amended to a more recent date. In doing so, more businesses can be kept alive and the industry can continue to grow.

Beyond regulations, changing how these products are categorized can also balance interests of stakeholders. In Britain, e-cigarette products are considered medical cessation devices that can be prescribed by physicians,[78] therefore having the possibility of being covered under health insurance.[79] As a result, Britain's system creates an incentive for entrepreneurs to enter into the market because of the major profits that could be made and attract those on the fence that would not switch from traditional cigarettes because of the cost. Having a similar structure in the U.S. could mitigate some of the financial liabilities associated with the PMTA, while reaching a larger group of individuals that hope to quit traditional tobacco.[80]

As the FDA regulations inch closer to becoming finalized later this year, vested parties are seemingly worried that there will not be a careful balance between public health, the economic effects, and innovation. Many consumers fear that the wide selection of products will disappear, resulting in the loss of being able to choose which products are best suited for their needs. It will be the responsibility of FDA and Congress to ensure that these

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[78] Currently, physicians prescribe a variety of drugs to smokers attempting to quit tobacco such as varenicline, bupropion, and nortriptyline. These drugs are generally anti-depressants that help patients with nicotine withdrawal by interfering with nicotine receptors in the brain. American Cancer Society, *Guide to Quitting Smoking*, http://www.cancer.org/healthy/stayawayfromtobacco/guidetoquittingsmoking/guide-to-quitting-smoking-help-phys-rx-drugs (last visited Apr. 1, 2016).

[79] Kate Kelland, *UK regulators licence BAT e-cigarette as quit-smoking medicine*, UK Reuters (Jan. 4, 2016), http://uk.reuters.com/article/uk-health-bat-ecigarette-idUKKBN0UI1FV20160104.

[80] If e-cigarettes were created for therapeutic purposes, the manufacturer would have to go through the FDA regulatory process like any other drug or device. This process itself has its own costs associated with it, but the investment security rests on the possibility that a physician can prescribe the product as part of a harm reduction strategy. In that case, insurance coverage for consumers could help draw a larger market and therefore mitigate the costs of R&D. In contrast, a PMTA requires a prospective consumer to purchase e-cigarette products out of pocket that results in uncertain return-on-investment.

regulations make good policy in light of both current scientific research and economic implications.

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