Catching Vapors: The Proposed FDA Rule That Seeks to Regulate E-Cigarettes

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INTRODUCTION

Electronic cigarettes have been hailed as a saving grace by a growing number of smokers because the devices are believed by many to be a healthier alternative to cigars and cigarettes. Despite the operatic call of smokers seeking solace, the Food and Drug Administration (FDA) is taking a much more calculated approach. Before recognizing electronic cigarettes as a “safer” alternative to cigarettes, the FDA wants to find conclusive evidence of their safety for human consumption. Further, the FDA recognizes that even if electronic cigarettes are found to be safer than conventional cigarettes, it does not conclusively mean that electronic cigarettes are “safe.” Given the lack of scientific evidence supporting the safety of e-cigarettes, the FDA looks to effectively regulate their sale and continue to investigate their health effects before the ballooning vapor industry gains more steam.

The FDA has regulated America’s consumption and sale of food, drugs, and cosmetics since 1906.1 The organization began large scale regulation in 1936 with the passage of the Federal Food, Drug, and Cosmetic Act (FDCA).2 The FDA’s regulatory power expanded to other tobacco products such as snus and smokeless tobacco in 2009.3 The regulation on cigarettes expanded to additional tobacco products in Sottera, Inc. v.

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1 About FDA, FDA, http://www.fda.gov/AboutFDA/WhatWeDo/History/ (last visited Nov. 14, 2014).
2 Michelle Meadows, Promoting Safe and Effective Drugs for Over 100 Years, FDA, http://www.fda.gov/AboutFDA/WhatWeDo/History/CentennialofFDA/CentennialEditionofFDAConsumer/ucm093787.htm (last visited Nov. 14, 2014).
FDA. This expansion in the breadth of the FDA’s regulatory freedoms has grown and evolved with the industries they regulate.

In order for regulation to stay effective and relevant, a continuous and corresponding evolution must follow, lockstep, the course of evolution of the particular industries which are being regulated. Tasked with the duty of creating effective tobacco regulation for the general benefit of the health of the American people, the FDA cannot get it wrong. Doing so could damage public faith in the agency, embarrass the federal government, and lead millions of Americans astray. Consumers should be able to feel confident that the products and devices they are purchasing are safe for consumption and use. For these reasons, the FDA is taking an active, cautious approach in regulating electronic cigarettes and laying a foundation for regulation until further scientific research can provide conclusive determinations about the risks associated with electronic cigarette use. The proposed regulations being brought forth by the FDA are a step in the right direction because they provide reasonable and necessary regulation without choking off the industry.

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4 See Sottera, Inc. v. FDA, 627 F.3d 891 (D.C. Cir. 2010).
5 Meadows, supra note 2.
7 Id.
8 Id.
I. WHAT IS AN ELECTRONIC CIGARETTE?

Electronic cigarettes, often referred to as “e-cigarettes” or “e-cigs,” are battery-operated devices that contain nicotine. The devices are often designed to look like regular tobacco cigarettes. They are usually made up of a steel or plastic tubing, an atomizer that serves as a heating element, and a cartridge. The cartridge is filled with “a liquid mixture of nicotine, water, propylene glycol, and glycerol that facilitates the heating and vaporization process.” The cartridges are available in varying nicotine concentrations and numerous flavors such as the traditional tobacco or menthol, and also in many candy and fruit flavors. For an electronic cigarette to function, “an atomizer heats a liquid containing nicotine, turning it into a vapor that can be inhaled” by the user. When exhaled by the user, the cloud of vapor closely resembles the smoke exhaled by a traditional smoker from a traditional cigarette.

II. HOW DOES THE FDA SEEK TO REGULATE THE E-CIGARETTE INDUSTRY?

The proposed FDA regulation seeks to require makers of e-cigarettes to: 1) “register with the FDA and report ingredients” used in the products, 2) market products

10 Id.
12 Id.
13 Id. at 438.
14 Dale, supra note 9.
15 Id.
only after FDA review, 3) make claims of a reduced health risk only if FDA confirms the reduced risk scientifically and establishes that marketing the product will provide a “benefit the public health” in its entirety, 4) “not distribute free samples,” 5) institute minimum age requirements and identification restrictions for the purpose of preventing sales to underage purchasers, 6) end the sale of e-cigarettes in vending machines, except in establishments that do not admit minors, and 7) have health warnings on packaging. 

A. Concerns Regarding Small Businesses

Discussion of the electronic cigarette industry may trigger thoughts of “big tobacco.” Much like a scene from AMC’s “Mad Men,” many might imagine a pack of tobacco industry fat cats in business suits, seated comfortably in a smoky board room in corporate America, planning the growth and expansion of a new and evolving market.17 The electronic cigarette industry is quite the opposite.18 Traditional cigarette companies have been largely uninvolved in the industry.19 While the bloated tobacco industry is worth about $90 billion in sales, the electronic cigarette industry is worth a much less gassy $1.7 billion—only a fraction of the size of big tobacco.20 On top of being a smaller

17 See Mad Men: Smoke Gets In Your Eyes (AMC television broadcast July 19, 2007).
19 Id.
overall market, there are approximately 200 companies that make up the fledgling industry in the United States, and most of them are small.21

Given the pocket-sized nature of the industry, small business advocates have been outspoken in their opposition to industry regulation.22 Small stores that sell vaporizers, often referred to as “vape shops”, are “popping up all over the country.”23 “There’s no vape shop anymore if this law goes through,” explained Greg Conley, president of the American Vaping Association.24 Anti-regulation advocates fear that new regulation may “choke off” these small businesses that make up the heart of the young industry, by forcing the companies to spend a large amount of money and time in order to get FDA approval before selling their products.25 These advocates believe new regulation may amount to a pocket full of money for a pocket full of vapors. This makes these small businesses vulnerable to infiltration by a big tobacco industry that “can spare the cash” to pay for the research, labor, and application necessary to grow their market share, and “squash”, or perhaps snuff out “the growing industry”.26

While it is true that new regulations will require a larger number of the small business owners in the industry, the new regulations are not so stringent as to effectively push them out. Instead, these regulations will have the effect of holding vape shops to a higher standard of performance, and demand that their product has met industry standards

21 Id.
23 Id.
24 Id.
25 Id.
26 Id.
before being used by consumers. While small businesses are essential to the American economy, the nation cannot be willing to sacrifice the safety of their products for the profits they may yield.

III. SOTTERA AND THE FDA’S AUTHORITY TO REGULATE

FDA currently has the authority to regulate tobacco products including cigarettes, cigarette tobacco, smokeless tobacco, and tobacco for self-rolling. The agency’s regulatory authority currently extends only to e-cigarettes “marketed for therapeutic purposes.” These products are regulated as devices. This authority does not extend to all other e-cigarettes, leaving a gap in the regulation of the e-cigarette market. To eliminate this gap, the FDA seeks to expand its authority to “electronic cigarettes, cigars, pipe tobacco, certain dissolvables that are not ‘smokeless tobacco,’ gels, and waterpipe tobacco.” While the “marketed for therapeutic purposes” rule does not grant the FDA the authority to regulate the aforementioned products, the authority to move forward on such regulation is based upon the United States Court of Appeals for the District of Columbia’s ruling in Sottera, Inc. v. Food and Drug Administration. In Sottera, the court held that the Tobacco Control Act gives the FDA the authority to regulate electronic cigarettes customarily marketed as tobacco products in addition to those

28 Id.
29 See id.
30 See id.
32 Sottera, Inc. v. FDA, 627 F.3d 891 (D.C. Cir. 2010).
marketed for therapeutic purposes. This ruling fills the gap and opens the remainder of the electronic cigarette industry to FDA regulation “under the provisions of the Tobacco Control Act.”

A. Sottera v. FDA

*Sottera* was a dispute between Sottera, Inc., doing business as NJOY, and the Food and Drug Administration. The dispute came about in April, 2009, when NJOY’s competitor, Smoking Everywhere Inc., brought an action seeking the court to grant a preliminary injunction that would bar the FDA from regulating electronic cigarettes “under the drug/device provisions of the FDCA” (Food, Drug, and Cosmetic Act.) In the same month, the FDA barred the entry of a shipment of NJOY products into the United States. The FDA blocked the shipment because “the e-cigarettes appeared to be adulterated, misbranded, or unapproved drug-device combinations under the FDCA.” NJOY then filed a complaint of their own against the FDA and joined Smoking Everywhere as a co-plaintiff seeking an injunction against the FDA. The primary issue in the case was whether the FDA had the authority to regulate the electronic cigarettes being sold by NJOY and Smoking Everywhere. The court explained that while the Supreme Court ruled that the FDA had no regulatory authority over tobacco products in *FDA v. Brown & Williamson* in 2000, the Family Smoking Prevention and Tobacco

33 *Id.* at 899.
34 *Id.* at 904.
35 *Id.* at 892.
36 *Id.* at 893.
37 *Id.*
38 *Id.*
39 *Id.*
40 Sottera, Inc. v. FDA, 627 F.3d 891, 892 (D.C. Cir. 2010).
Control Act was passed by Congress in 2009, giving the FDA regulatory authority over
“tobacco products.” The Tobacco Control Act defines “tobacco product” “as to include
all consumption products derived from tobacco except…drugs, devices, or drug-device
combinations under the FDCA.” The court recognized that the Tobacco Control Act
alone did “not affect, expand, or limit the FDA’s” regulatory authority over drugs and
devices. From this, the question of the case arises: “whether the FDA can regulate
electronic cigarettes under the FDCA's drug/device provisions or whether it can regulate
them only under the Tobacco Act's provisions.”

The D.C. Circuit Court ruled that the FDA has the authority to regulate electronic
cigarettes. The court relied on the reasoning that, because the Tobacco Control Act
gave the FDA the power to regulate “customarily marketed tobacco products”, and
electronic cigarettes are products that are used by consumers to inhale vapor derived from
tobacco plants, the Tobacco Control Act expanded the regulatory authority of the FDA
over electronic cigarettes. In summation, the FDA can regulate “customarily marketed
tobacco products”, including e-cigarettes, through the Tobacco Control Act and “tobacco
products marketed for therapeutic purposes” through the drug/device provisions of the
FDCA.

41 Id. at 894.
42 Id.
43 Id.
44 Id.
45 Id. at 898.
46 Id. at 898-99.
47 Id.
IV. WHY REGULATION IS NECESSARY

Regulating any thriving industry in the United States is no easy task. American people have a healthy and vigorous skepticism of governmental authority and its role in their daily lives. This skepticism becomes amplified when the discussion of regulating a drug arises. Such a discussion might invoke thoughts of the government’s failed attempt at prohibition in the early 1900s, or the oppressive tea and sugar taxes levied by the British on the American colonies.48

Tobacco is as highly coveted in the United States as tea, beer, or sugar, especially when considering that the early foundation of the country was built on the roots of tobacco. The plant was so omnipresent in colonial American daily life that it was used as a legal tender in colonial Virginia.49 This relationship has continued into recent years. As late as 1965, 42.4% of Americans were smokers.50 While the percentage of American smokers has declined from 20.9% in 2005, to 17.8% in 2013, the tobacco industry has continued to thrive.51 Yet, 42.1 million Americans are smokers.52 This number becomes a staggering fact when considering that smoking cigarettes is the “leading cause of preventable disease and death in the United States.”53 The nicotine contained in

52 Id.
53 Id.
cigarettes is highly addictive and the chemicals that often accompany nicotine are harmful to human health.\textsuperscript{54} Although the Surgeon General incorrectly classified nicotine as “habituation [sic] and not addictive” in 1964, a 1988 Surgeon General’s report correctly “classified nicotine as an addictive drug.”\textsuperscript{55} For as long as cigarettes have been sold commercially, it has been a common practice of manufacturers to use harmful chemical additives.\textsuperscript{56} Even when tobacco companies knew of the dangers of the chemical additives, they continued to use them.\textsuperscript{57}

The FDA cannot revisit the same circumstances for electronic cigarettes and their users and err by not taking a proactive approach to regulation before the industry grows larger. The active, out front, regulatory approach being used by the FDA, is an effective attempt to not ‘fumble the ball’ and find themselves scrambling to correct their mistakes. The proposed regulation being brought forth is a reasonable foundation for the industry to build upon, and is being brought early enough for the growing industry to adapt, and not be stymied in the future by the restrictions of implementing large scale regulation. The proposed rules are stringent and potent enough to protect the consumer, hold the industry accountable, and limit the availability of electronic cigarette products to youths; while also being relaxed enough to not shackle the still unstable legs of the young industry.

\textsuperscript{55} Id.
\textsuperscript{56} Id. at 328.
\textsuperscript{57} Id.
V. PROPOSED PROVISIONS

A. Manufacturers Must Register with the FDA and Report Ingredients Used

The first provision requires manufacturers to register with the FDA and report the ingredients used in their product. This creates an important foundation for regulation by giving the FDA the opportunity to know which manufacturers are selling particular varieties and hold manufacturers accountable for the use of harmful materials and mechanisms. With a large share of the industry being run by “mom and pop vendors,” the manufacturing of the cartridge blends may vary from “eight to twenty milligrams of nicotine.” However, “some mom and pop shops will mix blends with up to 36 milligrams of nicotine, which is a lot, even for serious smokers.”58 With such a free-wheeling nature of practice in respect to nicotine concentrations, vape [sic] shops may also be taking the liberty of using harmful additives.59

The Centers for Disease Control and Prevention “analyzed data on calls to U.S. Poison Centers” which reported electronic cigarette exposure from September 2010 to February 2014.60 The study found that the proportion of monthly exposure calls in relation to electronic cigarettes increased dramatically “from 0.3% in September 2010 to 41.7% in February 2014.”61 The study also found that reports of electronic cigarette exposure were “more frequent in the summer months” and 51.1% of poisonous electronic

59 See id.
60 Kevin Chatham-Stevens, et al., Notes from the Field: Calls to Poison Centers for Exposures to Electronic Cigarettes — United States, September 2010–February 2014, MORBIDITY AND MORTALITY WEEKLY REPORT (Apr. 4, 2014).
61 Id.
cigarette exposures were among young children.\textsuperscript{62} Such a study is an illustration of the critical nature of “developing strategies to monitor and prevent future poisonings.”\textsuperscript{63} As the CDC explains, “[h]ealth-care providers; the public health community; e-cigarette manufacturers, distributors, sellers, marketers; and the public should be aware that e-cigarettes have the potential to cause acute adverse health effects and represent an emerging public health concern.”\textsuperscript{64} This provision of the proposed law provides an essential means for the FDA to oversee the ingredients being used in the marketplace and prevent the use of harmful chemicals that pose a risk to human health and well-being.

\textbf{B. Manufacturers May Only Market Products After FDA Review}

This provision of the proposed rule would require that before a “new tobacco product” can enter the marketplace, it will first have to be reviewed and approved by the FDA.\textsuperscript{65} “‘New tobacco product’ is defined as ‘any tobacco product…that was not commercially marketed in the United States as of February 15, 2007; or any modification […] of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007.’”\textsuperscript{66} Because most electronic cigarette varieties fall under the classification of “new tobacco products,” their entry into the marketplace must earn approval by three means: (1) applying for pre-market review and receiving approval by the FDA, (2) becoming grandfathered by obtaining an order certifying that the product or one of “substantial equivalence” was marketed commercially before February 15,

\textsuperscript{62} Id.
\textsuperscript{63} Id.
\textsuperscript{64} Id.
\textsuperscript{66} Id.
2007, or (3) by the manufacturer filing “a request under §1107.1 (21 CFR § 1107.1) and obtain[ing] an exemption from the requirements related to substantial equivalence.”67 After this rule becomes final, manufacturers will have 24 months to submit an application with the FDA and obtain product approval.68

The effect of this provision is to act as a gatekeeper for new products entering the marketplace. Without this provision of the rule, the rule would have no teeth. It would be counterintuitive for the FDA to make a rule for the protection of consumers and the preservation of the public health but not require the affected industries to follow and abide by the rule’s provisions before putting the product into the marketplace.

Failure to include such a provision would allow companies to sell untested, unapproved products without FDA oversight and then attempt to reign in nonconforming products after they have already entered the stream of commerce and met the mouths and lungs of an innumerable number of American consumers. This would be akin to a consumer hiring a contractor to build a new house without blueprints or guidance from local fire or building codes, then renovating the house after it was completed in order to fix any mistakes. It would make much more sense to lay out a floor plan and relevant building codes ahead of time, and then build the new house in according to the new rules. That is the function of this provision. Requiring new products to be approved by the

67 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. 23142, 23174 (April 25, 2014) (to be codified at 21 C.F.R. pts. 1100, 1140, and 1143) [hereinafter Regulations].
68 Id.
FDA before being brought into the marketplace helps to ensure that all new products will meet FDA health and marketing requirements before being sold.

C. Modified Risk Tobacco Products: Manufacturers may only make claims of a reduced health risk if the FDA confirms the reduced risk scientifically and that marketing the product will provide a “benefit the public health” in its entirety.

This provision would force manufacturers to meet “rigorous criteria” before they can be authorized as a “modified risk product” and legally make claims that their products have a reduced risk to consumer health.69 A “modified risk tobacco product” is a product that is “sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products.”70 Earning the title of a “modified risk tobacco product” can be achieved only if an applicant manufacturer demonstrates that the product in its normal use by consumers, will “significantly reduce harm and the risk of tobacco related disease to individual tobacco users” and provide a “benefit to the health of the population as a whole,” inclusive of both users and non-users of tobacco products.71

Considering the significant detail in the application process, the high burden of proof for applicants seeking the “modified risk tobacco product” title, and the fact that the FDA itself describes its intention to make the application criteria “rigorous,” it can be inferred that the administration is seeking to significantly limit the number of products

71 Id. at 3.
earning the title.\textsuperscript{72} This is likely due to the fact that electronic cigarettes have earned a reputation for being healthier than conventional cigarettes, but no empirical evidence exists to adequately substantiate such a claim.\textsuperscript{73} Despite this lack of evidence, new data being introduced suggests that electronic cigarettes “either do not contain nor have lower levels of several tobacco-derived harmful and potentially harmful constituents compared with cigarettes and smokeless tobacco.”\textsuperscript{74}

Given the evidence in defense of the benefits of electronic cigarettes, this provision acts to allow for and promote the development and sale of approved modified risk products without opening the floodgates of the industry to make unsubstantiated health claims about the benefits of their products. It acts much less like a barrier or wall, and more like a filter. This prevents the propagation of the idea that electronic cigarettes are safer than conventional cigarettes and the potential deception of the American consumer before the claims can be legitimized.

\textit{D. Manufacturers May Not Distribute Free Samples}

In November 2010, a Minnesota resident, Erwin Lingitz, was arrested for violating “societal norms and common customer understanding regarding free-sample practices.”\textsuperscript{75} When searched, police found “about a dozen soy sauce packets and 1.46

\begin{thebibliography}{9}
\bibitem{72} Modified Risk Tobacco Products, supra note 69.
\bibitem{74} Aruni Bhatnagar et al., \textit{Electronic Cigarettes- A Policy Statement From the American Heart Association}, CIRCULATION - JOURNAL OF THE AMERICAN HEART ASSOCIATION, http://circ.ahajournals.org/content/early/2014/08/22/CIR.0000000000000107.full.pdf.
\end{thebibliography}
pounds of summer sausage and beef stick samples." While the actions taken by Lingitz were anomalous and comical, the impulse to take advantage of something free is relatively universal. In some cases, the use of free samples has increased product sales by 2000 percent. This number serves as an example of how free samples can drive consumers to purchase goods they would not have otherwise chosen to buy.

This provision would ban the distribution of free samples of electronic cigarettes and electronic cigarette products, namely cartridges. As illustrated above, the free distribution of sample products has the possibility to drive up electronic cigarette use and attract new users, possibly youths, to nicotine and electronic cigarettes. While this might be good for commerce and the wealth of the industry, the overriding health concerns and risks of addiction outweigh the commercial benefits. This provision functions as an important pillar in the ongoing fight to prevent nicotine addiction.

The distribution of free electronic cigarette cartridges has also been used as a scam technique, and in 2011 the Better Business Bureau issued a warning telling consumers to be cautious of free trials for electronic cigarettes. The Bureau received hundreds of complaints from consumers “who thought they were getting a free trial, but often ended up losing hundreds of dollars in recurring credit or debit card charges.” These deceptions sometimes come in the form of email advertisements that promise a

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76 Id.  
77 Id.  
78 Id.  
79 Id.  
81 Id.
free trial, but fail to mention that the consumer, must cancel within 15 days in order “to avoid being billed the full price of the kit of $109.95 and future monthly shipments.”  

E. Minimum Age Requirements and Identification Restrictions

While a federal minimum age requirement exists for conventional cigarettes, no such federal requirement currently exists for electronic cigarettes and “just more than half of states impose age restrictions.”  

Given this gap in regulation, one of the primary public concerns regarding electronic cigarettes surrounds the threat they pose to America’s youth.  

Electronic cigarettes have the possibility of benefitting entrenched adult smokers to completely end, or substantially reduce, their nicotine dependence, and prevent relapse.  

However, the devices also pose the risk of exposing impressionable “young people to the world of nicotine,” and acting as a gateway drug that could lead youths to nicotine dependence and the use of other tobacco products.  

For these reasons, it is imperative that regulation exists to shield young people from the influence of nicotine and keep electronic cigarettes out of the hands of America’s youth.  

The institution of federal minimum age requirements and the requirement to provide identification to validate age is an essential first step in the protection of youth from nicotine and its dangers.

82 Id.
84 Id.
85 Id.
86 Id.
“Minimum age and identification requirements” currently exist for “cigarettes and smokeless tobacco.”\textsuperscript{87} These requirements prohibit the sale of tobacco products to purchasers under the age of eighteen.\textsuperscript{88} What the proposed rule would do is extend the minimum age requirement of eighteen years to electronic cigarettes and all other covered tobacco products.\textsuperscript{89} The ultimate purpose of the regulation is to reduce “the number of people who suffer from tobacco-related illnesses and death and the number of people who are exposed to secondhand smoke.”\textsuperscript{90} The FDA has determined that such restrictions are necessary and appropriate for “the protection of the public health with respect to the risks and benefits to the population as a whole,” including “the increased likelihood that existing users will quit using tobacco products and the decreased likelihood that new users will initiate tobacco use.”\textsuperscript{91}

Protecting use is of particular concern because “the adolescent brain is more vulnerable to developing nicotine dependence than the adult brain,” which could lead to long term defects in cognitive function and a heightened likelihood of developing other substance abuse and mental health disorders into adulthood.\textsuperscript{92} A September 2013 report from the Centers for Disease Control and Prevention reported that electronic cigarette use among middle and high school students doubled during 2011-2012, revealing that “an

\textsuperscript{87} Regulations, supra note 67, at 23160.
\textsuperscript{89} Id.
\textsuperscript{90} Id.
\textsuperscript{91} Id. at 23146.
\textsuperscript{92} Id.
estimated 1.78 million students have used electronic cigarettes as of 2012.”

Also noted is the fact that 160,000 of the students who have tried electronic cigarettes have not tried conventional cigarettes, suggesting that their initial gateway to nicotine was through the mouthpiece of an electronic cigarette. The report went on to explain that “developing strategies to prevent marketing, sales, and use of e-cigarettes among youths is critical,” in preventing addiction and the susceptibility of young people to the pressures and environmental influences leading them to the use of tobacco products.

This boost in pre-teen and teen electronic cigarette use may be explained by the increased exposure of young people to beliefs concerning electronic cigarettes they have received through the media. The advertisements of electronic cigarette companies currently reach “a broad audience that includes 24 million youth.” The exposure of youths “to television e-cigarette advertisements, measured by target rating points, increased 256% from 2011 to 2013.” This spike was largely driven by “a large advertising campaign” that was presented “on national cable networks.” If this trend in electronic cigarette advertisement continues, “awareness and use of e-cigarettes are likely

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94 Id.

95 Id.


97 Id.

98 Id.

99 Id.
to increase among teens and young adults.”\textsuperscript{100} The limiting of advertisement campaigns that drive youth exposure has been previously implemented in the traditional cigarette industry.\textsuperscript{101} Given that these ads account for much of the driving force behind youth exposure, as shown above, after age requirements take effect, reign in electronic cigarette advertisements is likely to be the next frontier in the regulation of the electronic cigarette industry and preventing its exposure to impressionable young consumers.

\textbf{F. The Sale of E-Cigarettes in Vending Machines to be Banned, With Exceptions}

The FDA seeks to limit sales of electronic cigarettes to youth by prohibiting all “vending machine sales, unless in a facility that never admits youth.”\textsuperscript{102} This would permit vending machine sales in locations such as 18 and over bars and nightclubs, so long as in the course of their business they never allow youths to enter.\textsuperscript{103} This action is part of an ongoing effort by the FDA to “make the next generation tobacco-free.”\textsuperscript{104}

In 2013, the FDA took on trans fats by preliminarily labeling them as “not generally recognized as safe.”\textsuperscript{105} Trans fats are often used in processed foods and desserts, such as microwave popcorn.\textsuperscript{106} This measure was taken as a means of limiting

\begin{itemize}
\item \textsuperscript{100} Id.
\item \textsuperscript{102} \textit{FDA Proposes to Extend its Tobacco Authority to Additional Tobacco Products, Including E-Cigarettes}, FDA (Apr. 24, 2014), http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm394667.htm [hereinafter \textit{FDA}].
\item \textsuperscript{103} See id.
\item \textsuperscript{104} \textit{FDA, supra} note 102.
\item \textsuperscript{105} \textit{FDA takes step to further reduce trans fats in processed foods}, FDA (Nov. 7, 2013), http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm373939.htm.
\item \textsuperscript{106} Id.
\end{itemize}
trans fat consumption in order to protect Americans’ health.107 With the growth in popularity of electronic cigarettes, there is another potential health risk lurking in America’s vending machines: nicotine.108 This risk is particularly notable for young people because vending machines are possibly “the most accessible outlet” of nicotine products for youths.109 The fact that vending machines “tend to be heavily used by minors” is largely attributable to the fact that vending machines are “self-service and mostly under control of neither retailers nor adults.”110 Youth access laws, such as the vending machine limits being proposed by the FDA, are of great value “for public health policy.”111 The introduction of people to tobacco products and nicotine “overwhelmingly occurs during teenagehood” ergo, “limiting youth access has the potential to significantly reduce future prevalence of tobacco dependence and tobacco related diseases among adults.”112

Understanding these risks, the State of California has already made attempts to ban the sale of electronic cigarettes in vending machines.113 Although the bill failed in committee, it represented the sentiment that many Californians do not want young people having easy access to nicotine and “do not want e-cigarettes to be as easy to purchase as a

107 Id.
110 Id. at 4.
111 Id.
112 Id.
113 Rosenhall, supra note 108.
can of soda pop or a Snickers bar.” It is fortunate that this proposed rule would fill the regulatory void and provide much needed regulation, not only for California, but for the nation.

G. Health Warnings Required on Packaging

Many consumers, who may use cartridges of varying nicotine concentrations, recognize the potential benefits of using electronic cigarettes for the purpose of gradually reducing their use of conventional cigarettes and nicotine products. A 2014 study conducted internationally and published in the *Journal of the American Medical Association* found that “85% of smokers who used e-cigarettes reported using them to quit.” Despite the high number of smokers aiming to kick their habit with the use of electronic cigarettes, “e-cigarette users did not quit more frequently than non-users.” The fact that such a high percentage of users sought out the products for the purpose of quitting, sheds light on the perspectives of many consumers who are seeking out a means to eliminate their nicotine dependence. Electronic vaporizers become their glowing beacon of hope, and they opt to fight fire with vapor. In the haze, it becomes very easy for nicotine addicts to simply pick up another habit, that conveniently may have the added perks of indoor use—until that is also further regulated.

If the cessation of smoking conventional cigarettes were the only conceivable purpose of electronic cigarettes, regulation might be much easier, because the provisions

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114 Id.
116 Id.
117 Id.
regarding use by youths and youth availability would likely be much more limited. However, that purpose is not the only use of electronic cigarettes. Many also use electronic cigarettes as a substitute for conventional cigarettes, because they are not allowed to smoke indoors. This pattern may lead many to dual use—two products, two habits. The FDA wants to prevent double use of electronic and conventional cigarettes, and prevent consumers from trading one habit for another, or worse, having two at the same time. Making consumers aware of the health risks associated with electronic cigarette use can help prevent this phenomenon.

In 1946, Camel Cigarettes published a print advertisement boasting that “More Doctors Smoke Camels.” Although the advertisement did not make any warrantees about the safety, or the lack thereof, of their product, the implication is clear: “Wise, noble, and caring” doctors who know what the human body needs to be healthy, believe Camel cigarettes are safe for their own regular consumption. This type of puffing is exactly the type of deception that the FDA wants to extinguish with the implementation of health warnings on the packaging of electronic cigarettes. This provision of the proposed law seeks to provide the consumer with a warning that explains the actual health risks of the product they are purchasing. In addition to the warnings providing vital information, the warnings will greet the consumer at two critical junctures: the time

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119 Id.
120 See Regulations, supra note 67, at 23164.
121 Id.
of purchase and the time of consumption. These warnings are necessary and beneficial because they have the power to dispel misinformation and provide consumers with a fact-based understanding of the product and the potential consequences of its use.

The proposed warnings will appear with “white text on a black background” or in “black text on a white background.” The proposed design will utilize the “Helvetica” font for the text and “comprise 30 percent of the area on the front of the package and 40 percent on the back of the package.” The warning is to read: “WARNING: This product contains nicotine derived from tobacco. Nicotine is an addictive chemical.”

This warning invokes an important question: what are the risks associated with nicotine in electronic cigarettes? Electronic cigarettes have been highly publicized as a safer alternative to cigarettes because they have fewer harmful chemicals. For this reason, tobacco consumers widely consider electronic cigarettes to be a healthier alternative to traditional cigarettes. True safety has not been established. There is only the unsubstantiated perception of relative safety. The nicotine contained in electronic cigarette cartridges is highly addictive. Most electronic cigarette cartridges “contain 24 mg/mL, 18 mg/mL, 12 mg/mL, or 6 mg/mL nicotine and are qualified by the manufacturers as high, medium, or low nicotine strength,” These compare to conventional cigarettes that contain approximately “10 to 15 mg of nicotine” per

122 Id.
123 Id.
124 Id. at 23164-65.
125 Id. at 23165.
126 Id. at 23166.
127 Grana et al., supra note 115.
128 Id.
129 Hardin, supra note 11, at 434.
130 Bhatnagar et al., supra note 74, at 5.
Most of the primary health concerns in conventional cigarettes surround combustion products added to the tobacco. Fortunately, most of these products are not present in electronic cigarettes; however, that does not mean electronic cigarette users are in the clear with respect to health concerns. Nicotine has the ability to induce the release of catecholamines in the body. Catecholamines are “hormones made by the adrenal glands” and are released “when a person is under physical or emotional stress.” Because catecholamines are known to increase the heart rate, augment blood pressure, and effect of insulin, they raise concerns about the heart and the risk of diabetes associated with nicotine. Further, nicotine in vitro can inhibit apoptosis (cellular death). Such an effect raises substantial concerns about the role of nicotine in “promoting the development and spread of cancer.”

In addition to the health risks associated with nicotine, propylene glycol, another important ingredient in electronic cigarette cartridges, has recently been under scrutiny. Fireball, a cinnamon flavored whiskey variety, was recently recalled in Europe for containing an excessive amount of propylene glycol which, in Europe, is more than “one gram per kilogram by volume.” Propylene glycol, an ingredient in antifreeze, is

131 Id.
132 Id.
133 Id.
134 Id.
136 Bhatnagar, et al., supra note 74, at 5.
137 Id.
138 Id.
139 Id.
currently approved by the FDA for consumption in America. The implementation of a protective policy in relation to propylene glycol in Europe may signal a future change in FDA policy and, perhaps, health warnings on electronic cigarettes that address the health risks associated with the inhalation of propylene glycol.

VI. CONCLUSION

The growing electronic cigarette industry presents regulatory challenges and opportunities to not revisit the mistakes of the past. Timely revisions of the proposed rule present the FDA with an opportunity to establish standards for electronic cigarette manufacturing, sale, and use. Proactive regulation and thorough oversight of new regulations is likely to afford manufacturers adequate time to adapt and make the required amendments to their products to ensure compliance.

This law has not yet taken effect, but it is essential that all of the enumerated provisions that have been proposed become a law. Each provision exists for the benefit of the consumer and the cumulative health of both nicotine users and non-nicotine users. A final date for the implementation of the proposed law has not yet been established. When the complete draft of the proposal finally becomes a law, tobacco manufacturers will have 24 months to submit their products for approval. The FDA is currently working to educate the public on the provisions of the proposed law, while keeping an open ear to the opinions of the public before the proposed regulation becomes law. These efforts by the FDA represent an effort to provide consumers and manufacturers with the time and

\[ Id. \]
information they need to make informed decisions about the products they use and sell. This provides a degree of ease to transitioning into the implementation of the new law.

In an effort to gauge the pulse of the public on the issue of electronic cigarettes, the FDA held an open comment period for all who are concerned or stand to be affected by the provisions of new regulation. The 75-day open comment period opened on April 25, 2014 and terminated on July 9, 2014.\textsuperscript{141} While the open comment period lasted, it attracted 37,928 comments from the American public.\textsuperscript{142} The FDA will also be conducting a “planned series of workshops” for the purpose of gathering information and promoting the discussion of electronic cigarettes and how they relate to public health.\textsuperscript{143}

The provisions of the proposed law have been primarily created for the purpose of limiting exposure of the nation’s youth to nicotine products, protecting adults who are currently using nicotine products, and overseeing the electronic cigarette industry, the ingredients it uses, and the manner in which those products are sold. The provisions that require manufacturers to register, report ingredients, market only after FDA review, and only make claims of reduced health risk if the FDA approves, serve the function of holding the electronic cigarette industry to a high standard. This limits the public’s exposure to harmful chemicals and carcinogens, and preventing the industry from making unfounded health claims that may run the risk of misleading the public into purchasing harmful products. The requirement of health warnings on packaging also benefit the public health by disclosing to consumers the risk of addiction and making other potential

\begin{footnotes}
\footnotetext[141]{See Regulations, supra note 67, at 23144.}
\footnotetext[142]{Id.}
\footnotetext[143]{A Public Workshop- Electronic Cigarettes and the Public Health, FDA (Nov. 13, 2014), http://www.fda.gov/TobaccoProducts/NewsEvents/ucm414814.htm.}
\end{footnotes}
risks known. Banning the distribution of free samples prevents the introduction of youths and consumers to nicotine that they may not have purchased, or otherwise become addicted to. This provision is one facet of the rule that acts to prevent the exposure and introduction of children to nicotine. The provisions that include minimum age and identification requirements for purchase, and ban the sale of electronic cigarettes in vending machines, also act for the purpose of protecting children and teens. The regulation serves to make this generation the last to suffer from nicotine addiction in drastically high numbers. This would not only benefit the nation’s youth, but also the national health as a whole.

While these proposed standards provide a foundation for the evolution of the industry, they are not exhaustive. More regulation will likely come as different methods, uses, and concerns come about. Given current concerns about youth, addiction, and ingredients, in the coming years, the FDA is likely to introduce more regulation concerning electronic cigarette flavors, limits on marketing, and bans on certain additives. The issue of electronic cigarettes has proven to be highly important to the nation’s well-being, and is likely to continue to be at the forefront of new regulatory issues.