

SMOKING AND VAPING E-CIGARETTE CONJECTURES, REALITIES AND IMPLICATIONS

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Abstract - It has been said that e-cigarettes are the new “evil weed” because they are being used by more young people now and they contain nicotine which entices people to smoke and perhaps get “hooked” on much stronger nicotine tobacco products. This article explores the realities and intense debate arising from the introduction and rapid growth of the e-cigarette. The authors examine the laws that apply, or could apply to e-cigarettes. The implications of the emergence of e-cigarettes are discussed; and appropriate practical recommendations are offered to various stakeholders and groups affected by this product. The federal Food and Drug Administration in the United States in April of 2014 proposed certain basic rules regarding the regulation of this new product. These rules are not law yet. The authors strive to present in a fair and balanced manner several sides to this controversy in a rational and logical manner.

Key words: e-cigarettes, smoking, FDA, vaping, nicotine, advertising to children.

I. INTRODUCTION TO E-CIGARETTES

Today, there is emerging a major tobacco controversy dealing with the phenomenal growth of a new smoking product – electronic cigarettes or, as popularly known, e-cigarettes. This new product has produced a heated debate between anti-smoking advocates and the manufacturers of the product and consequently a concomitant legal, ethical, and practical quandary for the stakeholders and groups affected by e-cigarettes, especially for government regulators, the medical community, and employers. Naturally, employers are concerned about the impact of e-cigarettes on the wellness and health of their employees and for policy-making regarding the work environment [21]. Are e-cigarettes a good and beneficial product, due to their low nicotine content, because, like nicotine patches, they perhaps can function as a smoking reduction and maybe cessation device? The principal problem, and the crux to solving the quandary, is that there is not yet a great deal of scientific information as to the harms or benefits that the product can cause. Nevertheless, the authors seek to present in a fair and balanced manner all the current and relevant information as well as the diverse opinions regarding e-cigarettes.

So what is an e-cigarette? E-cigarettes are battery-powered tubes that transform nicotine-laced liquid into a steam-like vapor, which is then inhaled by the user, or, as commonly called, “vaping.” Vaping is not smoking, proponents of e-cigarettes contend; rather, *vaping* is merely inhaling e-cigarette vapor and then exhaling a wispy cloud that quickly fades. Inhaling traditional cigarettes can be a very unpleasant experience, manifested by coughing and nausea; but not so with vaping, as e-cigarettes can be readily inhaled on the first puff with no attendant immediate adverse effects.

In addition to nicotine, e-cigarettes contain compounds that, at this time, are generally perceived to be safe, such as glycerine, which is found in many foods, and propylene glycol, which is the main ingredient in theatrical fog [19] and which has not been found to be harmful to human beings [27].

Electronic cigarettes typically consist of a metal tube, containing an atomizer, a battery, and a cartridge filled with a liquid nicotine solution, and a battery powering a coil that heats the solution into a vapor. When a user sucks on an e-cigarette, a light-emitting diode causes the tip to glow (but often glowing blue instead of red), and next the atomizer turns the liquid nicotine into a vapor. The user then exhales the vapor like smoke. So, the effect is to mimic a traditional tobacco product. The U.S. Federal Drug Administration provides a definition of an e-cigarette, to wit:

Electronic cigarettes, also known as e-cigarettes, are battery-operated products designed to deliver nicotine, flavor and other chemicals. They turn chemicals, including addictive nicotine, into an aerosol that is inhaled by the user. Most e-cigarettes are manufactured to look like conventional cigarettes, cigars, or pipes. Some resemble everyday items such as pens and USB memory sticks [16].

The toxicity of an e-cigarette will depend on the variations of strength in the nicotine solutions among the various brands [24]. The e-cigarette product typically includes a start-up kit, which contains the e-cigarette device, a set of nicotine cartridges, and batteries, all of which costs between \$60 and \$120. The tobacco company, Lorillard, based Greensboro, North Carolina, maker of Kent and Newport cigarettes, and maker of one of the leading brands of e-cigarettes, Blu, makes a starter pack that comes with a charger (which also can be used as a storage chamber) and which looks just like a pack of cigarettes. In addition, the starter pack comes with two batteries and five nicotine cartridges which will last for about 150 puffs apiece. The cost is about \$80 (with shipping extra) which is approximately equal to the price of 8 to 6 packs of traditional cigarettes [19].

Lorillard, in 2012, purchased Blu for \$135 million in cash; and the company has now increased its distribution to 125,000 stores [19]. The Blu brand is the market leader. However, another major tobacco company Altria, is planning to buy e-cigarette company Green Smoke for \$110 million [19]. Since e-cigarettes can come in the form of rechargeable kits, they require a larger financial investment than a pack of regular cigarettes, but typically are less expensive in the long-run. And then there are disposable e-cigarettes, which are frequently priced similarly to regular cigarettes. The e-cigarette typically has a warning label that it contains nicotine (which is addictive, but not a cancer-causing product) [15].

This nicotine, of course, is the same nicotine found in cigarettes and nicotine patches. However, e-cigarettes typically do not contain the tars, arsenic, and other chemicals which are common in conventional tobacco products and which have been linked to cancer [7]. Yet, these substances may have negative side effects, such as nausea, vomiting, and eye and skin irritation, according to a recent report from the Center for Disease Control and Prevention [18], but the reports of these adverse consequences are very small for e-cigarettes compared to the health problems reported for traditional cigarettes [18].

Currently, there are three large U.S. companies, Altria (which is the largest U.S. tobacco company), Reynolds, and Lorillard, and many smaller ones (such as Njoy, Vapor, and Victory Electronic Cigarettes) that sell e-cigarettes. The market leaders in the sale of regular cigarettes are the “big three” of Lorillard, Altria, and Reynolds. Altria now has an e-cigarette called Mark Ten and Reynolds has one called Vuse. Most e-cigarettes, the *Wall Street Journal* noted, are made in China [15]. Actually, according to *Bloomberg Businessweek* [19], though there is some question as to who invented the e-cigarette, the first commercial invention of the product was done by a Chinese pharmacist, Hon Lik, and, most interesting, was introduced to the Chinese and then Asian markets in 2004 as a smoking cessation device. Many versions of e-cigarettes are very similar to regular cigarettes in appearance, including having a sleek shape and glowing tip. Yet, no tobacco is burned or released, which distinguishes e-cigarettes from the traditional tobacco products. Thus, smoke as well as the dangerous carcinogens, carbon monoxide, and tar are not produced, as they are with traditional cigarettes. However, many e-cigarettes have vaping fluids that contain nicotine, which is the addictive agent in cigarettes. There was a 2009 study [31], done by the Federal Drug Administration, that analyzed 19 varieties of e-cigarettes found that one-half had the same carcinogens found in real cigarettes. Nicotine, according to the Surgeon General, is highly addictive and has immediate adverse biochemical effects on the brain and body, especially for young people and pregnant women [31]. Nicotine is a vasoconstrictor that narrows blood vessels and thus increases one’s blood pressure. However, according to McArdle [19], there is no evidence to date that inhaling nicotine vapor by means of e-cigarettes causes cancer. Moreover, a study concluded that a “preponderance of the available evidence” indicated that e-cigarettes are “much safer” than traditional cigarettes as well as comparable in toxicity to other nicotine replacement products, such as patches [19] (p. 58).

As can be seen in Figure 1, it is estimated that e-cigarettes will be a substitute for about 1.5 billion cigarettes, up from around 600 million one year earlier [25] (para. 3). Consequently, e-cigarettes have become a “big business.” In 2013, they have grown into a \$2 billion industry [28, 12, 13, and 14]. E-cigarettes represent globally more than one-half a trillion dollars of business each year [19]. Moreover, *Bloomberg Businessweek* [2] indicates that in 2014 e-cigarette sales are projected to reach \$1.5 billion to \$3 billion. According to Euromonitor International, the global market for e-cigarettes is expected to exceed \$5 billion in 2014 [7]. To

illustrate the rise in e-cigarette use, in 2008, only 50,000 of the devices were sold; but in 2012, 5 million were sold [28]. To further illustrate, the *Miami Herald* [31] reported on a Wells Fargo Securities Study that predicted that retail and online sales of e-cigarettes would grow by 240% from 2013 to 2014. In Colorado, where Reynolds introduced its Vuse e-cigarette in July of 2013, in a few months the product achieved a 55% market share [19].

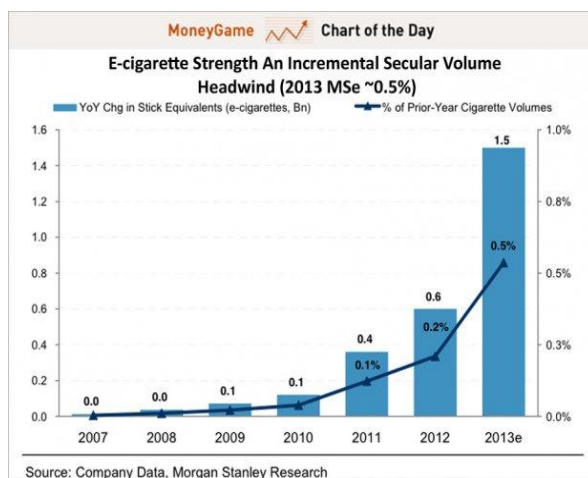


Figure 1 – E-cigarette Growth (Ro, 2013)

Bloomberg Businessweek [19], citing a projection by Bloomberg Industries, predicts that e-cigarette sales could exceed that of traditional cigarettes as early as 2023. The rapid rise in the popularity and use of e-cigarettes has presented a difficult ethical and legal issue for all levels of government – federal, state, and local [1, 5, and 6]. There have been a deluge of questions regarding e-cigarettes: Do they pose a potential risk because of the nicotine and other chemicals; will they lead young people into traditional smoking; yet is there some health benefit associated with new products? These questions will be addressed in this article.

II. LEGAL ANALYSIS

As emphasized, the development of this new product has created a series of legal questions for government regulators at all levels of government as they may not necessarily be a good alternative to traditional cigarettes [23]. Therefore, more research and analysis regarding the use and promotion of e-cigarettes are needed from scientific, ethical and legal perspectives. In this paper, we will imitate the discussion on the legal issues related to e-cigarettes.

On the federal level, there is not yet any federal regulation for e-cigarettes, though current law bans the sale of traditional cigarettes to minors. The Federal Drug Administration (FDA), specifically its Center for Tobacco Products, does have the authority to regulate e-cigarettes; and the FDA deemed e-cigarettes to be a tobacco product; and consequently in April of 2014 the FDA commenced the rulemaking process in this area. Formerly, the FDA had not labeled e-cigarettes a tobacco product which would give the agency the authority to regulate the product [9, 10]. The FDA is expected, at a minimum, to promulgate a rule prohibiting the sale of e-cigarettes to minors less than 18 years of age. However, until the FDA rules

become law, the sale of e-cigarettes, even to minors, is legal pursuant to federal law. Political pressure in part helped to convince the FDA to act in this area. For example, Representative Henry Waxman (D-Calif.) had declared that “with over a million youth now using e-cigarettes, FDA needs to act without further delay to stop the companies from marketing their addictive products to children” [9, 10] (p. 3D). And Senator Dick Durbin, along with 10 other Democratic lawmakers, had issued a report that condemned e-cigarette companies from launching what they deemed to be aggressive marketing campaigns targeting minors [9, 10].

Some legal history is revealing, to wit: in 1994, the Occupational Safety and Health Administration proposed a broad smoking ban that would have applied to more than a million workplaces. Yet the effort was eventually abandoned due to mounting criticism and threats, including death threats to government regulators; but also because employers had begun adopting their own smoking bans. So, by 2007, around 91% of U.S. employers, according to Weber and Esterl [28], were subject to smoking restriction policies. There is no federal ban on e-cigarettes yet, though the Federal Drug Administration (FDA) has contemplated a ban or some restrictions on selling the product, particularly to minors [16]. The agency has held up regulating in this area, saying it will need more research as to the health benefits and risks of e-cigarettes [31]. However, the FDA on its website does now explicitly warn consumers that e-cigarettes have not been fully studied and consequently consumers presently do not know the health risks, especially how much nicotine or other potentially harmful chemicals are actually inhaled during use, and also that consumers do not know if there are any benefits associated with the product [16]. The FDA encourages consumers to report any adverse effects from using e-cigarettes and accordingly provides a Safety Reporting Portal. CNN.com [29] also reported that a proposal to regulate e-cigarettes has been under review at the White House Office of Management and Budget since October of 2013.

The federal Department of Health and Human Services (HHS) apparently has deferred to the FDA, stating on the HHS website that there are “many unknowns” with e-cigarettes, including the health effects of long-term use; and thus because the product is not yet approved by the FDA for “therapeutic uses,” it cannot be recommended by HHS as a smoking cessation aid [11]. HHS, however, does emphasize that e-cigarettes contain nicotine, which is a “highly addictive substance”; and the agency also has a warning regarding minors: “These products may be attractive to kids. Using e-cigarettes may lead kids to try other tobacco products – including conventional cigarettes – which are known to cause disease and lead to premature death [11].

There is also a bill in the U.S. Congress, introduced in the Senate in February of 2014 by Senator Barbara Boxer (D-California) to regulate the sale of e-cigarettes. The bill is co-sponsored by Senator Dick Durbin (D-Illinois) and Senator Tom Harkin (D-Iowa). The bill is called the Protecting Children from Electronic Cigarette Advertising Act of 2014 [22]. The proposed law makes it illegal for companies to promote e-cigarette use for minors as well as to target the marketing and advertising of e-cigarettes to minors. The bill

also directs the Federal Trade Commission to determine what constitutes such prohibited promotion and “targeted” marketing and advertising. The bill defines an e-cigarette as follows: “a battery operated product designed to deliver nicotine, flavor, or other chemicals and that turns chemicals, such as nicotine, into an aerosol that is inhaled by the user.” Sanctions for aiming advertising at children would be civil fines up to \$16,000 [22].

Furthermore, in 2013, the *Wall Street Journal* [12] reported the attorneys general in 40 states have urged the Food and Drug Administration to regulate the manufacturing, sale, and advertising of e-cigarettes in order to keep them away from children. The attorneys general emphasized that certain advertisements for the product are geared to children, for example, by using cartoon characters. Ike monkeys, in the ads (as opposed to traditional cigarette makers who are banned from using cartoon characters).

While the FDA is still continuing to study e-cigarettes, and will get many reports and studies during the public “comment” part of the rulemaking proceeding, some states and several cities have taken the legislative lead in regulating the product. On the state and local government level, 24 states and the District of Columbia ban smoking in the American workplace, but only four states, New Jersey, Utah, Arkansas, and North Dakota, have added e-cigarettes to their smoking bans. Clozel and Siegel [8, 9 and 10] point out that more than 28 states, including New York, California, and Colorado, now ban e-cigarette sales to minors, as do the cities of Boston, Seattle, Indianapolis, and Miami [17]. Miami also prohibits the sale of e-cigarettes in vending machines (Green, 2014). Miami-Dade County has banned e-cigarettes from its buildings as well as the buildings owned by the Jackson Health System [17]. Also in Florida, three cities in Broward County, Sunrise, Weston, and Lighthouse Point have recently banned the sale of e-cigarettes to minors; and Weston has also banned their sale in vending machines [26]. Regarding Lighthouse Point, the rationale for the ban was written into the ordinance, to wit: “Flavored nicotine vaporizers can lead young people into a lifetime of addiction” [26] (p. 1). Chicago recently restricted e-cigarette use [19]. Also, in Florida, a bill has been introduced in the legislature to prohibit the sale of electronic cigarettes to minors [17]; the bill has been passed by a Senate committee and a similar version by the House; the bill is on a “fast track” for legislative approval [20]. New York City too recently banned the smoking of e-cigarettes in all public places [30]. The NYC ban was an amendment to the Smoke-Free Air Act, which prohibits smoking in public places, such as restaurants, bars, parks, beaches, places of employment, as well as any other areas where traditional smoking is prohibited. Retail stores in NYC, however, can still sell e-cigarettes [30]. The *Wall Street Journal* [28] reported that more than 100 cities ban e-cigarettes in areas where regular cigarettes are also banned. And in Idaho, Bannock County (population 80,000) banned e-cigarettes from all county buildings, including the courthouse, county jail, and fairground facilities. The reason for the county ban was that some courthouse employees complained about indoor vapors. However, Bannock County has not extended the ban to private workplaces and restaurants because local government leaders

do not have enough information yet as to the health consequences of vaping.

Any marketing and advertising of e-cigarettes must be truthful and not deceptive or misleading pursuant to regulations by the Federal Trade Commission as well as the Federal Drug Administration. A deceptive ad can be false, that is, an outright lie or misrepresentation, as well as misleading. A misleading ad is one that causes the reasonable consumer to reach an erroneous conclusion. Moreover, the “reasonableness” standard for an ad that is geared to a target audience, particularly a susceptible one such as young people, is determined by reference to that target group and not consumers as a whole. Furthermore, a misleading ad can also be a “half-truth” ad, wherein something significant about the product, especially if health or safety related, is omitted in the advertising or marketing of the product [6]. Therefore, any advertising of nicotine cartridges in e-cigarettes must state truthfully, accurately, and fully just what they are supposed to contain. And, of course, the advertising cannot be deceptive or misleading as to any health benefits to be derived from the product. \

Internationally, the *Wall Street Journal* [14] noted that Mexico, Brazil, and several Asian countries restrict e-cigarette sales; and that France and the European Union are considering limits to the sale of the product. Britain in 2014 indicated that it would ban the sale of e-cigarettes to minors under the age of 18 (as it has with conventional cigarettes) because of the possible adverse health effects as well as the need for further medical research (Reuters, 2014). However, McArdle [19] pointed out that in October of 2013 the European Parliament rejected a proposal to regulate e-cigarettes as medical devices. Yet in February of 2014 [3], it was pointed out that the European Parliament has promulgated several restrictions on e-cigarettes, to wit: a ban on advertisements, a requirement for childproof packaging, a requirement of pictorial safety warnings, and a limit on the nicotine content of the product.

As the old saying goes, “the law is always trying to catch up to technology,” and that maxim is perfectly illustrated with the new product of the e-cigarette. More research clearly is needed to ascertain the specific health benefits or harms of e-cigarettes. Nonetheless, the FDA has commenced the rulemaking process in attempt to promulgate rules to regulate e-cigarettes. Thus, there are two principal conclusions that can be drawn from the foregoing legal analysis: first, there are some laws that apply to e-cigarettes, many that could apply, and very soon may apply, to e-cigarettes, especially regarding their sale to minors; and second, to date, there is not a great deal of guidance from the legislatures, courts, and regulatory agencies on how all these legal principles will be applied to this new product. Yet, until there is more law, in many jurisdictions today the e-cigarette is a legal product, even when sold to minors.

III. IMPLICATIONS

E-cigarettes are certainly producing controversy, especially in the workplace. Many companies have policies, including strict rules, on the prohibition of smoking, and not only in the workplace but also off-premises too. The critical question is whether companies should decide to bring e-

cigarettes into the ban of smoking conventional tobacco products. The prudent company must be cognizant of the law, of course, as well as medical developments, but also must be aware of societal mores and trends pertaining to vaping. To illustrate the latter, even if permissible, allowing the employees to vape at work in front of customers, clients, and the general public may be considered “unprofessional”. Legally, though there is no federal law that protects smokers in the workplace or off-the-job” and prevents discrimination against them, the employer must be aware that any enforcement of smoking policies, including use of e-cigarettes, which is done in a discriminatory manner, may trigger a federal lawsuit pursuant to the Civil Rights Act if the discriminated group is a member of a protected category, such as minorities.

The health benefits of e-cigarettes are still being hotly debated. Some health experts say that because they provide nicotine without combustion, they are less risky to one’s health, and actually may, like nicotine patches, help people quit smoking. But the use of e-cigarettes by minors has doubled in recent years. Young people may think that “vaping” is harmless, but there may be adverse health ramifications for young people since nicotine is present. So, though e-cigarettes may be useful in smoking cessation, they may be dangerous to young people because they are attractive products which actually come in appealing “kid” flavors such as chocolate and cherry. Regulation, therefore, is needed to keep the product from children; and as such the Food and Drug Administration is now proposing a rule banning the sale of the product to minors. Even in the absence of regulation, manufacturers of e-cigarettes should be proactive and join the “campaign” to prevent minors from purchasing the product. Another socially responsible suggestion would be for e-cigarette manufacturers to place the liquid cartridges of the product in childproof containers to keep them away from very young children [18].

Some health experts condemn e-cigarettes as just another harmful toxin or pollutant [17]. Manufacturers and sellers of e-cigarettes should be direct and truthful with their literature and warning labels, particularly when informing consumers of the chemicals and other ingredients in the product. A socially responsible suggestion for manufacturers would be help smokers control and lessen their addiction to nicotine, for example, by gradually lowering the amount of nicotine in the product. This would reinforce the “image” of the product as a true smoking cessation device, which surely is in the ethically egoistic interest of the manufacturers.

IV. SUMMARY

The subject of e-cigarettes presents a quandary for all the stakeholder groups, including and especially the government and society as a whole. Are e-cigarettes helpful, or are they harmful? E-cigarettes may be a viable way for addicted smokers to quit traditional tobacco products; and thus they may be moral in that regard. Yet they may not be moral if e-cigarettes induce non-smokers, especially minors, to become consumers of the product. Presently, e-cigarettes seem to be a “step in the right direction” in the sense of being preferable for smokers than “real” cigarettes; but there is a “long way to go”

before definitive answers can be provided. Mainly, the product, legally, is now in the testing, analysis, discussion stage, though that discussion is going to be conducted in a very formal and legalistic manner during the FDA's rulemaking process. Yet is the e-cigarette a safe, effective substitute for traditional smoking or a smoking cessation tool? Or is it some type of Machiavellian device to get people, especially young people, "hooked" on the "evil weed" of tobacco. Clearly, more research and studies have to be done to ascertain the long-term health effects – good and/or bad – of e-cigarettes. The debate continues. That is the reality of e-cigarettes today!

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