

The Vaping Epidemic and its Implications in Tobacco Regulation

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Abstract

The vaping epidemic has gripped the youth of the nation and is negatively impacting both personal and public health. Millions of young adults, youth and even adult smokers have been subjected to the risks of vaping without being fully informed. Various E-cig companies' practices directly led to widespread use of their product among youth populations. Recently, more than 2,172 cases of vaping associated lung injury have been reported with 37 deaths and counting. Other than the fact that E-cigs containing both THC and nicotine were used by these patients, the cause is unknown.

This paper aims to address the medical, legal and ethical implications presented by the vaping epidemic. To this end, it explores the current state of vaping, as well as the history behind it. Followed by an evaluation of the medical and pharmacological effects vaping has on individuals. The ethics of vaping in relation to both society and the individual will be discussed in the context of the goals of tobacco regulation and public health. We will then address the legality of E-cig companies' policies in regard to product design, advertising, and effective regulation of E-cigs.

The risk of vaping is severe, and many are uninformed regarding the contents and risks of their E-cigs, partly due to the practices of E-cig companies. The company JUUL will be referred to often as a standard for the industry since it is the most popular and well-known E-cig brand among youth.

INTRODUCTION: THE VAPING EPIDEMIC

Vaping is the act of inhaling and exhaling vapor produced by an e-cigarette or similar device. Many of the particles contain varying amounts of toxic chemicals linked to cancer, respiratory, and heart disease. Vaping is a recent trend for nicotine delivery and is commonly advertised as a method for cigarette users to use as a cessation aid or to switch to a healthier option. Vaping technology has been in the making, as early as in the 20th century, when several inventors and researchers tried to develop a product for nicotine delivery in an alternate form. The first commercially successful E-cigarette released in China in 2003. (1) Modern vape companies have been substantially more successful with the invention of salt nicotine (salt-nic) aerosol formulas because they are considered smoother by consumers. The less harsh nicotine delivery is very attractive to those who are usually turned away by other e-juice and tobacco products' harshness. (2) JUUL Labs, Inc.^[1] was founded on May 22, 2015 then pitched their pod based salt-nic system to Pax labs which was founded in 2007 to develop e-cigarette (E-cig)

products. The Juul was released on June 1, 2015, and its popularity rapidly spread among teens and young adults, making it the figurehead of the vaping industry. Later the company separated from Pax Labs in July 2017. (3)

Recently, climbing rates of E-cig use have led to the beginnings of a public health crisis that is spiraling into an epidemic specifically among the youth of our nation. This has caused several public health concerns pertaining to vaping. The first is that public perception of E-cigs mainly views them as safer than cigarettes, elevating them above the social stigma of cigarettes and other traditional tobacco products, undoing decades of public health work. It is also concerning that E-cigs entertain such widespread use, especially among youth and young adults. It is also likely that E-cig use increases the overall use of combustible tobacco. Additionally, the long-term health consequences for society and the individuals at risk are largely unstudied. Despite this lack of empirical knowledge hospitals across the United States are beginning to admit cases of vaping related

lung injuries, including multiple deaths.

The Food and Drug Administration (FDA) describes electronic nicotine delivery systems (ENDS) as noncombustible tobacco products, which contains an aerosol that is inhaled to deliver nicotine. (4) Public perception sees ENDS as a healthy alternative to cigarettes despite how little is known about these products. This puts populations at high risk because there will be increased recklessness in use of the product if people believe there is lessened consequences to their actions. While JUUL Labs Inc. and other companies have claimed that they never advertised their products as such, public misunderstanding indicates that this information was disseminated in some way. Even if indirectly, the introduction of vaping has ultimately depleted the social stigma around tobacco or nicotine products and originate because of the assumptions consumers made about ENDS. This is reflected in the reports of the National Youth Tobacco Survey, which found that 39% of middle and high school aged students reported they used E-cigs because of “use by a friend or family member” or social introduction. This was followed by 31% of youth citing the different flavors of vapes as the reason for use, 17.1% of youth stated that they used E-cigs because they were less harmful than other tobacco products. Other reasons for use stated are ease of access, cheaper than other tobacco products, and celebrity use. (5) These reasons are varied but the primary three demonstrate that there is a widespread public misconception about vaping that has led to a greater social acceptance of E-cigs and in reality tobacco use.

The introduction of vaping to youth, has not only led to vaping becoming a fad but also widespread use of more than one tobacco product. According to the Centers for Disease Control and Prevention (CDC) up to 1 in 4 high school students and 1 in 14 middle school students have or are currently vaping. By 2018 the CDC claimed that 4.9 million underage individuals used tobacco products, E-cigs being the most common. Additionally, by 2018 around 11.3% of high school students and 2.4% of middle school students used more than one tobacco product. (6) This is referred to as dual use and the most popular form among middle school and high school students is the combination of E-cigs and cigarettes. (7) By comparison adult vaping rates are not nearly as high compared to youth vaping rates, demonstrating that ENDS are more attractive to the youth of the nation than the adult smokers. A survey from 2013 and 2014 reports on adult E-cig use and found that 5% of the U.S. over 25 adult population uses E-cigs. (7) Another study

supported this data again in 2016 citing 10.8 million adult e-cig users, of which 5% were never smokers before E-cig use, and 2.8 million were aged 18-24. It is also important to note the study found that 51.2% of adult e-cig users were under the age of 34. (8) Patterns of e-cig use among general populations demonstrate that use is more prevalent among young adults and youth.

Given the rampant use of ENDS by adult and youth populations very little is known about the long-term health effects of e-juice aerosol inhalation. Still we are just beginning to see the damage caused by E-cigs. The CDC report that as of October 29, 2019 around 1,888 vaping related lung illness cases have been reported from 46 states and 1 U.S. territory. To date 37 patients have died from their vaping related injuries. (9) 79% of patients are under 35, and 54% of the patients are under the age of 24. However, what is most concerning about this turn of events is that health officials and experts are unsure of which product has caused these vaping injuries. Many patients have reported the use of marijuana in THC vaping cartridges as well as nicotine solutions. 514 of the patients were surveyed and 86% said they had used THC products, and 34% reported exclusive use of THC products. 64% reported using nicotine E-cigs and only 11% of patients reported exclusive use of nicotine vaping. It is unknown whether vaping nicotine, THC or a combination of both has led to the development of this disease. (10) The underlying pathology of this disease is unknown, but researchers have identified vitamin E acetate as one of the contributors to disease. One of the Pathologist who examined the tissue samples stated, “They look like the kind of change you would expect to see in an unfortunate worker in an industrial accident where a big barrel of toxic chemicals spills”. (9) This continued risk to addicted minors and young adults is of greatest concern to public health. All efforts must be taken to identify the cause of the ‘vaping related illness’ and to curb youth vaping of both THC and nicotine.

[1] For the purposes of this paper JUUL will refer to the company while Juul will refer to the e-cigarette product.

BACKGROUND: HIDDEN HISTORY OF THE VAPING INDUSTRY

As demonstrated, there is a pertinent problem facing public health officials and the FDA regarding the widespread use of ENDS. However, this situation is not spontaneous, and the origins of the vaping epidemic extend far back and action on the behalf of the FDA is long overdue. Despite recent efforts to distance themselves from big tobacco, JUUL Labs has

recently sold large shares to Marlboro and Altria, signifying that E-cigs are just a new product in the growing tobacco market. The story of vaping begins in the 90's when the Tobacco Company Phillip Morris (PM) began researching the possibility of aerosol nicotine according to their internal documents. (11)

In 1994 PM came close to developing aerosol nicotine devices like the modern versions but delayed their production. Later the company would introduce their own E-cig called the MarkTen in 2013, following suit after other popular brands. After reviewing the documents experts stated, "rather than a disruptive technology, PM developed e-cigarette technology to complement, not compete with, conventional cigarettes and evade tobacco control regulations." (11) PM found a need for such a product because of competition from smoking cessation aids. Products like nicotine patches and gum not only offered smokers a chance to quit but an alternative to nicotine consumption. Since smoking cessation devices were effective at preventing habitual smokers from using cigarettes the company began researching their own alternative to smoking. (12) It was in PM's best interest to develop a product that was "complimentary" to cigarette use, rather than decrease cigarette use like other smoking cessation aids. However, during the 90's Congress and the FDA were pursuing regulation of the tobacco industry. This led to the development of the discreet "Project Ideal Smoke" which aimed "to design products that would be accepted (or even endorsed) by the medical community as less harmful than traditional cigarettes." (11) The tobacco industry would capitalize on the perceived healthier nature of E-cigs to avoid strict tobacco regulations. This also allowed them to avoid a classification that could be considered therapeutic like nicotine gum or patches. Toxicology reports for the aerosol and nicotine content of these experiments are unavailable. This absence of information is alarming since many ENDS still await product application reviews and approval from the FDA.

Currently, the e-cigarette market is dominated by 5 major competitors. PM being one among other big tobacco companies like Altria, JPI, and Imperial Brands. The analysis of the documents warned that "researchers and policymakers should recognize that PM developed e-cigarette technology to evade tobacco control regulations." (12) With the example of Phillip Morris, it is possible that E-cigs were developed under the guise of a smoking cessation device that is a healthier alternative to combustible tobacco,

in order to lure in low risk smokers.

Despite numerous warning signs only as recent as 2016 has the FDA successfully asserted jurisdiction over e-cigarettes and other ENDS. "As a result, e-cigarette companies are permitted to advertise on television and in mass media as well as through newer channels such as the Internet." (13) In the absence of effective regulations, amplitude of public health problems has arisen. The fact that E-cigs were not a public health priority has led to lack of funding for research into the products resulting in a modest understanding of the long-term health effects. E-cig users have no true understanding of the risks when they first began to use tobacco. It is also important to investigate the smoking cessation and initiation habits revolving around users of E-cigs. Additionally, the laze-faire attitude on E-cig advertising allowed the companies free reign with the youth of the nation. Finally, many tobacco laws were broken by these companies, it is therefore imperative that the consequences of these laws be enforced. As well as further legislation to ensure that the harm caused by this epidemic is actively rooted out and that such an event will not be able to happen again.

PHARMACOLOGICAL IMPLICATIONS

According to the website for JUUL electronic cigarette pods, the components for their formulation include glycerol, propylene glycol, nicotine, benzoic acid, and natural oils, extracts, and flavor. Among these ingredients, nicotine is infamous of being a highly addictive substance. Each pod consists of approximately 40 mg per pod based on a concentration of 59mg/ml, which is the approximate equivalent nicotine yield of a pack of cigarettes. (14)

When inhaled, nicotine is rapidly absorbed through mucous membranes and the respiratory tract. It is widely distributed in body tissues and can reach the brain within 7 seconds of absorption and peak in plasma concentration within 15 minutes. Mostly metabolized by the liver, nicotine is oxidized into its metabolites: cotinine and nicotine-1-oxide. The initial half-life is 2 to 3 minutes and the terminal half-life is 30 to 120 minutes. Eventually, nicotine will be excreted by the kidneys. (15)

Nicotine is a stimulant of the autonomic ganglia yielding both cholinergic and adrenergic effects that include tachycardia, bradycardia, stimulation of the receptors in the carotid and aortic bodies, release of epinephrine from the adrenal medulla, and stimulation of the chemoreceptor-trigger zone. Due to this, side effects of nicotine can include

palpitations, bronchospasm, mouth and throat irritation, mild headache, irritability, confusion, dizziness, anxiety, depression, restlessness, cravings, and insomnia. To a lesser extent, nicotine can also lead to pruritus, rash, acne vulgaris, nausea, and flatulence. Those who are most likely to be negatively affected by nicotine are those who suffer from hypertension, cardiovascular disease, and respiratory afflictions such as asthma or COPD. (16)

However, the issue of physiological and/or psychological dependence is a problem that can affect almost all patient populations. Because of nicotine's quick and thorough absorption to the brain tissues and its rapid euphoric effects, it is one of the most addictive substances known. Although some experts argue that e-cigarettes are less addictive than traditional cigarettes due to their slower absorption rates, a longitudinal cohort study done in 2015 has shown a connection to the use of e-cigarettes increasing the potential to the eventual use of traditional tobacco cigarettes. The population pool for the study consisted of 694 participants ranging in age from 16 to 26. At the beginning of the study, only 16 subjects (2.3%) were reported to have used e-cigarettes. Out of those e-cigarette users, almost 70% had moved on to using traditional cigarettes after a year. Meanwhile, only 20% of those who had not used e-cigarettes prior were now using traditional cigarettes. Although the participation number for prior exposed e-cigarette users is low, the trend can be seen. Also, the habitual acts of holding an e-cigarette and its mouthfeel, or the physical sensations produced in the mouth by smoking, are among the most frequent things complained about from those trying to quit cigarettes. The reverse may be true. The familiarity with common gestures from smoking an e-cigarette can make the jump to traditional cigarettes easier and less daunting. (17) This trend continues even among youth populations, as seen in two complimentary studies. The first study followed 9th grade students for a year and found that baseline E-cig users had a 7.9% chance of initiating tobacco use, as opposed to a 3.3% chance in E-cig never users. (18) The next study found that after following 11th grade students for a year that E-cig users had a 40.4% percent chance of initiating tobacco use, while those who had never used E-cigs at baseline had a 10.5% chance. (19) This shows that increased time of exposure, either social or through use of E-cigs, can lead to increased tobacco use among youth.

Although the other components of the JUUL proprietary blend seems to be benign due to their approval by the government as food additives, their safety may not translate

into its inhalant use. For example, glycerol and propylene glycol, which are used as substance carriers in JUUL's formulation, have shown to cause toxicological effects. In a 2015 study, researchers analyzed cell viability and oxidative stress on normal human bronchial epithelial (NHBE) cells 24 hours after exposure to 6 different aerosolized agents: glycerol alone, propylene glycol alone, e-cigarette liquids with 2.4% nicotine, e-cigarette liquid without nicotine, clean air as a positive control, and K3R4F research cigarettes as a negative control. In conclusion, they found that NHBE cells that were in the glycerol or propylene glycol alone groups both experienced significantly less cell viability and higher oxidative stress than the clear air control. Similarly, both NHBE cells in the e-cigarette liquid groups both showed less cell viability and increased oxidative stress. Although it can be argued that all groups show more cell viability and less oxidative stress than that of the negative control group of traditional cigarette smoke, it is safe to say that that e-cigarette smoke cannot be considered benign, even without the presence of nicotine. (20)

MEDICAL IMPLICATIONS

This section of the paper aims to investigate both the long-term and short-term physiological consequences of vaping. While studies and literature reviews have been completed due to the exponential increase in vaping prevalence, no firm conclusion had been drawn on the exact damages caused by vaping. Findings were frequently inconsistent in many aspects, with methodological issues and lack of long-term monitoring. Additionally, up to a third of these studies had a conflict of interest. However, recently, many case reports emerged presenting acute, severe respiratory distress after vaping. (21, 22, 23) In August 2019, the CDC reported that over 200 cases of severe respiratory distress cases have been identified with at least 2 deaths related to vaping. (24)

Toxic inhalation pneumonitis is often described as a heterogeneous group of chemically induced injuries to the upper respiratory tract and lung parenchyma, severity and manifestation of such damage depends on the toxic compound inhaled and quantity of inhalation. Vaping is known to contain a great quantity of these different types of toxic substances, such as nitrosamines and carbonyls, metals, volatile organic compounds, and propylene glycol (not found in conventional cigarettes), and so forth. Moreover, patients have been recurrently found using modified products or with add-on substances not intended by the manufacturer. It is suspected that tobacco combustion products, not nicotine, cause most of the adverse health effects of smoking;

although nicotine has been known to be a common drug of addition which proven to cause fetal lung/brain damage in animal experiments. (25) One article suggested that vaping in adolescence, due to the markedly different stage of brain development, can cause serious consequences later in life. It is also believed by others that vaping may affect receptor expression and inflammation in airways, making an individual more susceptible to infection and/or increase the risk of developing chronic obstructive pulmonary disease (COPD) or lung cancer.(26) More recently, according to the CDC, Vitamin E acetate, used as a thickening agent in THC-containing products, has also been identified as a concerning chemical in E-cigarette use associated lung injury (EVALI), being found in all bronchoalveolar lavage samples submitted to CDC. (24)

Propylene glycol in vaping, a common e-liquid vehicle component, has been known to cause respiratory and ocular irritation in adults without asthma after short controlled occupational exposure, or the anticipated level of exposure for a period of time.(26) Inhalation exposure of "diacetyl", a flavoring chemical, was associated with "popcorn lung" disease. Diacetyl causes extensive scarring in small airways and was also known to be associated with bronchiolitis obliterans and other severe respiratory diseases including nonreversible lung obstruction. (27) There were some case reports that described patients experiencing respiratory failure from lipoid pneumonia secondary to vegetable glycerin found in e-cigarette. (28) Another case report suggested e-cig/vaping has been correlated with subacute bronchial toxicity (29). One study showed vaping does not decrease short-term pulmonary function (FEV1/FVC ratio), while others (31) showed using e-cigarette increased impedance, peripheral airway flow resistance and oxidative stress in healthy adult when compared with a control group. (31) Furthermore, aerosol produced is composed of 50 nm size particles that could induce "particular adverse effects". (32)

It should be noted that per the CDC (24), there is no specific marker or test for diagnosis of EVALI, thus rendering it diagnosed by exclusion of other possibilities. In addition, pulmonary findings on physical exam have often been unremarkable. Inflammatory markers may be elevated, (21) and urine toxicology screen may identify THC use. CXR Pulmonary infiltrates and CT opacities may correlate with EVALI. (23) Thus, it is important to keep a broad differential when evaluating patients with respiratory or constitutional symptoms with recent vaping to consider

possibilities of EVALI possibly with concomitant infections. Medical treatment so far has been focusing on inhaled corticosteroids (except for fungal pneumonia), which showed improvements in 82% of patients, with considerations of possible influenza antivirals and antibiotics if guideline suggests. Patients should be reassessed in 24-48 hours if not admitted to the hospital.

ETHICAL ANALYSIS

E-cigarette companies are targeting our youth and putting their lives at risk. In 2017, 3.62 million middle school and high school students were using e-cigarettes in some form according to the FDA.(6) Between 2017 and 2018 there was a 78% increase in vaping in high school students, resulting in a leap from 11.7% to 20.8%.(33) Unfortunately, to date, little is known about the long-term effects of e-juice aerosol inhalation. As of October 2019, over 1,479 people have been diagnosed with lung injuries due to vaping and 37 individuals have died from unknown causes in three dozen states. (34) States and public health agencies have issued warnings against e-cigarettes, and the CDC issued an extensive warning against vaping: "E-cigarette products should not be used by youth, young adults, pregnant women, as well as adults who do not currently use tobacco products. If you use e-cigarette products, monitor yourself for symptoms (e.g., cough, shortness of breath, chest pain) and promptly seek medical attention if you have concerns about your health." (35) In October 2019, the FDA issued the following warnings: 1) Do not use vaping products—particularly those containing THC—obtained off the street or from other illicit or social sources. 2) Do not modify or add any substances, such as THC or other oils, to vaping products, including those purchased through retail establishments. 3) No vaping product has been approved by the FDA for therapeutic uses or authorized for marketing by the FDA. The agency recommends contacting your health care provider for more information about the use of THC to treat medical conditions. 4) No youth or pregnant women should be using any vaping product, regardless of the substance. Adults who do not currently use tobacco products should not start using these products. If you are an adult who uses e-cigarettes instead of cigarette smoking, do not return to smoking cigarettes. 5) If you choose to use these products, monitor yourself for symptoms (e.g., cough, shortness of breath, chest pain) and promptly seek medical attention if you have concerns about your health. If you are concerned about your health after using a vaping product, contact your health care provider, or you can also call your local poison control center at 1-800-222-1222. Health care providers also

can contact their local poison control center. 36) Vaping is a national emergency and it seems clear that the tobacco industry is behind the marketing of e-cigarettes and ultimately the addiction of young people. The tobacco industry is in the business of selling nicotine, which is an addictive drug, and marketing it to young people is a brilliant financial strategy on their part. The issue today is that it has now become a matter of life and death.

Ethically, parents, medical associations, federal agencies, etc. must stand up and advocate for the most vulnerable members of our society. Solutions must be advanced that will protect the lives of our youth and improve their quality of life and survival. This is imperative for the youth, their families and society as a whole. It will be argued that—according to the ethical principles of respect for persons, beneficence/nonmaleficence, and justice—action must be taken immediately to address the concerns surrounding e-cigarettes and nicotine addiction for the best interest of all. Such action will not only save lives of the most vulnerable members of our society but will protect all citizens in the United States.

Respect for Persons

This principle incorporates two ethical convictions: first, that persons should be treated as autonomous agents; and second, that persons with diminished autonomy are entitled to protection. The principle of respect for persons thus divides into two separate moral requirements: the requirement to acknowledge autonomy and the requirement to protect those with diminished autonomy. (37) Respect for human persons refers to the right of a person to exercise self-determination and to be treated with dignity and respect. All people deserve autonomy and to be treated with dignity and respect. Failure to provide any person with adequate education and adequate health care, which includes the failure to protect children from nicotine addiction, violates this basic right of respect for persons. Proper education about e-cigarettes and the illnesses they may cause, government policies that protect vulnerable children, and using social media as a valuable tool to counter-act misinformation, will respect the rights of all people.

Second, as an autonomous agent an individual has the right of informed consent. Since children are minors, unless emancipated, parents have the right to know all information about products like e-cigarettes that target children, deceive them and even entice them with false information about the product and its addictive nature. The elements of informed

consent include professional disclosure, patient comprehension of the information, patient voluntariness and competence to consent. This means that all people have the right to know the risks concerning e-cigarettes. The Surgeon General of the United States argues that around 60% of teens believe e-cigarettes cause little to no harm. (38) There is a public perception that e-cigarettes are a healthy alternative to cigarettes. The problem is that research into the long-term effects of e-cigarettes is at an early stage and more research must be done to adequately explain the truth about possible risks and benefits of e-cigarettes. This is why the FDA is trying to restrict marketing assertions by JUUL and other companies about their products. Physiological and psychological dependence on nicotine is a proven fact that can affect all individuals. Nicotine's quick and thorough absorption into brain tissue and its rapid euphoric effects, make it one of the most addictive substances known. Specifically, it is becoming clear that the nicotine in these vaping devices has a major effect on the brain development of the youth. Numerous studies have shown, as stated above, that increased time of exposure, either social or through use of e-cigarettes, can lead to increased tobacco use among the youth. Until more research is done and we have accurate data regarding risks and benefits, we will never meet the criteria for true informed consent.

Children are minors but in the field of pediatrics physicians and bioethicists believe that children have the right of assent in regard to medical treatments and procedures. This applies to vaping, because minors must be given the facts surrounding e-cigarettes and their potential addictive nature, in a language they can comprehend. Assent is when an individual who lacks decisional capacity, or decisional authority, agrees to go along with a proposed medical intervention for him or herself. It should include the following four elements: First, helping the child achieve a developmentally appropriate awareness of the nature of his or her condition. Second, telling the child what he or she can expect with tests and treatments. Third, making a clinical assessment of the child's understanding of the situation and the factors influencing how he or she is responding (i.e., voluntariness). Fourth, soliciting an expression of the child's willingness to accept the proposed treatment or procedure. Regarding this final point, we note that no one should solicit a patient's views without intending to weigh them seriously. In situations in which the patient will have to receive medical care despite his or her objection, the patient should be told that fact and should not be deceived. (39) The problem is that many pediatricians lack knowledgeable and

data about the effects of vaping to have conversations with their patients about the potential harms and risks. Pediatricians must become more knowledgeable about the effects of vaping in order to make sure their patients are fully informed about these products. The focus for these pediatricians must be on what is in the best interest of their patient. The child is their immediate patient. We know that vaping is widespread. A government-funded US survey released in December 2018 showed that 37% of 12th graders reported vaping over the past year. This is a 10% increase from 2017. (40) We know that children are being deceived by the marketing of these products. Advertisements state that vaping is safer than the use of cigarettes. We know that JUUL and other companies are targeting kids and putting them in serious danger. Pediatricians have the ethical responsibility to initiate conversations with their patients regarding vaping and the addictive nature of nicotine. Unless children have the correct facts regarding e-cigarettes, they will be unable to give informed assent to this issue. Assent is a basic guideline within the principle of respect for persons. For children to attain informed assent, parents and pediatricians must educate them about the medical implications of vaping. The failure of pediatricians and parents to be proactive in addressing the medical needs of this most vulnerable population in regard to vaping is causing needless suffering and possibly even more deaths. To deny all people, especially children the right to know the true effects of nicotine and vaping devices clearly violates the ethical principle of respect for persons and our responsibility to help others in society.

Beneficence/Nonmaleficence

The principle of beneficence involves the obligation to prevent, remove, or minimize harm and risk to others and to promote and enhance their good. Beneficence includes nonmaleficence, which prohibits the infliction of harm, injury, or death upon others. In medical ethics this principle has been closely associated with the maxim *primum non nocere* ("Above all, do no harm"). The amount of misinformation and deceptive marketing techniques is one factor that has led to the increase of vaping in the United States. This lack of public education has allowed some people to believe that the benefits of vaping outweigh the risks, which is clearly untrue. Vaping is causing deaths and addictions and innocent lives are at stake.

Medical professionals, researchers, government agencies have, as moral agents, an ethical responsibility to treat people in a way that will maximize benefits and minimize

harms. Failure to adequately communicate and educate people about vaping and e-cigarettes' short and long-term effects and other side-effects, is not in the best interest of individuals or the society as a whole. The central issue facing government regulators is whether the potential benefits of this new technology, that being that it could reduce smoking related deaths, will outweigh the risks, like those posed to the youth. From the JUUL website we know their cigarette pods contain glycerol, propylene glycol, nicotine, benzoic acid, and natural oils, extracts, and flavor. Among these ingredients, nicotine is infamous of being a highly addictive substance. Each pod consists of approximately 40 mg per pod based on a concentration of 59mg/ml, which is the approximate equivalent nicotine yield of a pack of cigarettes. (15) Studies have shown that nicotine is addictive, and its medical side-effects are numerous and dangerous. "To become inhalable, nicotine or THC must be mixed with solvents that dissolve and deliver the drugs. The solvents, or oils, heat up during aerosolization to become vapor. But some oil droplets may be left over as the liquid cools down and inhaling those drops may cause breathing problems and lung inflammation. The inhaling of oil into the lungs can result in death." (41) The problem is many of the vaping ingredients are not listed on the products, which violates the principle of beneficence and can potentially cause direct harm to the individual. Nicotine is proven to be addictive no matter how it is transported. In addition, adding ingredients like THC and other additives to the pods, has proven to be life-threatening.

By contrast, JUUL is conducting research to prove that its products are a net public health good. That is, they benefit as a viable option to combustible cigarettes. This research is vital because they must answer the safety concerns being raised by the FDA. "The company recently started a science website promoting its new research grants. But so far, JUUL has reported funding studies only by the Centre for Substance Use Research, base in Scotland, and collaborating with few independent laboratories. The Glasgow organization, which has done most of JUUL's outside research, is well known to tobacco control; advocates, who have long criticized its studies for playing down the danger of youth addiction to e-cigarettes." (42) JUUL's research seems biased and flawed. To understand the full dimensions of e-cigarettes and vaping devices we need transparency and honesty in the scientific research. This can only be accomplished if said research is done by independent, reputable centers. Failure to recognize this great need is a failure not only of the test of beneficence; it may also be a

failure of the test of nonmaleficence.

Justice

This principle recognizes that each person should be treated fairly and equitably and be given his or her due. The issue of e-cigarettes and vaping devices also focuses on distributive justice: the fair, equitable, and appropriate distribution of medical resources in society. At a time when reforming healthcare in this country has become a high priority, failure to initiate preventative measures that would save medical resources and possibly human lives in the long-run violates the principle of justice and specifically distributive justice.

Accurate information about the risks and benefits of vaping, collaboration among various medical associations, federal agencies and public advocacy groups is vital if we are going to protect our citizens today and protect future generations from these dangerous products. Preventing addiction and associated illnesses through accurate research on vaping is a cost-effective way of treating medical illnesses. There is still much we do not know about the effects of vaping and its direct connection with lung illnesses. “But we do know that one Juul pod contains as much nicotine as an entire pack of cigarettes, and that nicotine harms brain development.” (43) Slick advertising can deceive and entice people, especially the young. The tobacco industry and now the e-cigarette industry have perfected these marketing talents. It appears the e-cigarette industry is using false advertising, deception and possibly lying to advance their product to the American public. This fails the test of justice. Studies have shown that vaping does not protect individuals from addiction and injury, especially vulnerable children, and as a result, it is using health care resources and health care dollars that could be utilized for prevention of other diseases. In fact, it appears vaping places people directly in harm’s way. Failure to acknowledge this fact and to establish safeguards and guidelines to protect and promote the best interest of all Americans, especially children, is ethically irresponsible and morally objectionable. If proper guidelines and safeguards are not established nationally for vaping it cannot be medically, legally and ethically justified.

LEGAL IMPLICATIONS

The number of victims from the vaping epidemic grows weekly and continues to pose a serious threat to public health. Vaping and E-cigs are to be regulated and treated as tobacco products according to the law. (44) Yet the legislation intended to protect youth and public health have not been sufficient to prevent the present epidemic.

Understanding the marketing strategies, product design and other opportunities vaping companies took to gain this success can grant insights into how to prevent future generations from facing the same problems. With this knowledge, the goals of tobacco regulation can be reevaluated and implemented according to the needs of society.

Public health officials and society have already established certain goals for tobacco regulation, demonstrating it as a goal of public health. Society should make an active effort to achieve these goals at every level and not just the personal level. The FDA states three goals of tobacco regulation in the United States. To reduce smoking initiation rates, to decrease the harms posed by tobacco products, and to encourage smoking cessation among current smokers. (45) The laws and regulations in place on tobacco products and ENDS are meant to protect society. Since the current policy on E-cigs has not been helpful towards these goals, further action is needed to stop the vaping epidemic.

Tobacco laws regarding minors are very important to long-term public health goals. Advertising to minors is illegal and every safeguard possible should be taken to prevent it. First the law prevents the sale of tobacco products to minors. (46) Next, it regulates the media that tobacco advertisements can appear in to protect youth populations health. The existing law limit tobacco product advertisements to adult publications, which is determined by expected amount of youth viewers. (47) Social media was one of the main outlets for E-cig advertising from 2012-2017, and played a key role in the development of the vaping epidemic. One survey found that Instagram, one of the sites JUUL used, is the most popular youth website and is used by 72% of all teens, (48) demonstrating that teens and youth are a major target of JUUL and other E-cig companies. The E-cig industry took advantage of novel platforms like social media to spread their products popularity among youth while little was known of both E-cigs and social media.

Researches at SRITA have compiled a database of advertisements and several publications regarding the vaping epidemic and advertising. These can provide a general overview to show how many companies through years of advertising directed the public toward the vaping epidemic, followed by the specific example of JUUL. The researchers have stated that JUUL “has faithfully recapitulated the playbook of traditional cigarette marketers”. (49) Additionally, many other companies have followed suit, with E-cig advertisements that directly mimic marketing

policy of cigarettes.

The SRITA database contains over 14,000 E-cig advertisements. These advertisements are divided up into categories that show how they are imitations of traditional tobacco advertising tailored to a new target generation. The largest category is flavor advertisements with over 2,700 documented on their database, which has been confirmed as one of the reasons minors use E-cigs. There were also 651 given the label “youth appeal”. There were also 636 advertisements promoting the health benefits of E-cigs, as well as 411 for smoking cessation. (50) The remaining images could be categorized along the lines of traditional tobacco advertising or the accessibility of vaping given its futuristic design. This overview of catalogued advertisements provides a look at how companies targeted youth or intended the spread of incorrect information regarding their products. Now it is time to examine how they got away with it.

JUUL’s advertising history offers the best opportunity to analyze the way in which the vaping epidemic has recently spread among youth. Its marketing presence on social media and to the American public can be divided into 3 phases. The first phase was a marketing campaign entitled “vaporized”, which began in 2015. This phase was kickstarted using celebrity promoters, free sampling and product testing events, and an aggressive social media campaign with advertisements that directly appeared to youth.(49) In cities around the country over 25 sampling events of nicotine containing products were hosted by JUUL between June 4th and Dec. 8th. The free distribution of nicotine samples to the guests at these events was illegal, and after the FDA issued a direct warning, they stopped. (51)

After this the second phase of their marketing took place from 2016 to mid-2018. It consisted of what could be considered traditional tobacco advertising. These advertisements helped normalize vaping and distinguish it from smoking and its stigma. Advertisements and social media from 3rd parties still spread these messages demonstrating the cascade effect social media can have. In late 2018, after FDA and public scrutiny into JUUL, the advertising themes switched drastically and was combined in a mass erasing of previous advertisements. At this time JUUL removed around 4,000 youth-oriented ads from Instagram and Facebook. Two social media deletions took place. The first deleted all posts before June 17, 2017, removing any public record of their early advertising campaigns. The second removed any advertisements not

pertaining to their new theme of “switch”. The newest advertisements are directly targeted at adult smokers, to convince them that E-cigs are in some way more satisfying or a better product. However, the company has yet to define any benefits or state any explicit advantages of their product, while still inferring it is better or even healthier. This however can be better discussed in the context of tobacco companies and what a modified risk tobacco product is. (50)

Surveys have shown that many believe E-cigs have benefits over cigarettes. The benefits range from assumptions about how healthy they are compared to cigarettes, to how they aide in smoking cessation. Without direct FDA approval and clinically proven results, no tobacco product can claim health benefits. This violates not only false advertising laws (52) but also laws specific to tobacco. A modified risk tobacco product is a tobacco product that has an application reviewed by the FDA and has demonstrated some benefit to smokers or been proven to have reduced adverse health effects.(53) A 2014 survey of adult E-cig users demonstrates how false health benefits can affect consumers. It found that 93% of adult E-cig users still smoked cigarettes, yet 85% of users cited health/cessation as their main reason for use.(54) Many people who use E-cigs believe that they have some benefit to them and yet still smoke and vape, while the long term health risks of E-cigs are still unknown. This misinformation has led to public to believe a product safer than it is. Leading to higher amounts of reckless and recreational use and aiding in decreasing the social stigma around vaping and tobacco. Currently use of E-cigs is not helping society to achieve the goals of tobacco regulation and it must be subject to more research and changes to prevent increases in public smoking.

There are many other strategies that JUUL and other E-cig companies have taken to spread either the popularity or some information about their product. JUUL has directly targeted classrooms by paying for the privilege to present to high school students. In some cases, the teachers were not in the room and parents were not informed of the event. (51, 55) E-cig companies like JUUL, have been accused of distributing e-juice that contained nicotine with no nicotine warning label which is once a violation of tobacco regulations that the FDA failed to enforce in the case of E-cigs until recently. (49, 56) The House Subcommittee on Economics and Consumer Policy has been investigating JUUL since July 2019. They found solid evidence to support the ideas that JUUL directly advertised its products to children. It is important that the findings of this hearing be

applied to correcting the current vaping epidemic and investigating all E-cig companies suspected of illegal practices. (57)

The FDA did not act on ENDS before May 10th, 2016 when they issued the final deeming rule, while the first E-cigs were imported into the United States in 2006. (1, 44) By 2016, multiple products had been on the market for years, yet the “final deeming rule’s” compliance date for several regulations was August 10th, 2018. The example of JUUL’s historical marketing and business practice demonstrate how vaping companies were able to take advantage of this slow administrative reaction in order to addict as many consumers as possible, especially among youth populations. The “final deeming rule” also stipulates that applications for all E-cig products must apply for review before 2020 to remain eligible for the market. While this is beneficial for the consumer, it also points out that at this point the FDA does not have official information on tobacco products being sold. It is imperative that the FDA be given the tools it needs to deal with new forms of tobacco products as they emerge, not just deal with the problems that ensue following the onset of widespread use.

The FDA did not issue the “final deeming rule” early enough to prevent the vaping epidemic, which may have been due to efforts and political pressure exerted by tobacco lobbyist. Tobacco companies have had large investments riding on the success of E-cigs given companies like PM have been researching them since the 90’s. The E-cig industry generates around 7 billion dollars in sales alone, not to mention the increase in combustible tobacco sales they have helped to generate. The power and political influence this has generated has prevented regulation of E-cigs multiple times in the past. In 2009 two E-cig companies successfully sued the FDA for trying to regulate ENDS. This was followed by the president’s administration shooting down a ban on flavored E-cigs in 2016. (58) In 2017 the FDA commissioner expressed interest in E-cigs being a more effective method of smoking cessation, he wished to remove any unapproved E-cigs from the market and focus on using the remaining ones to reduce tobacco consumption in society. He then delayed this regulation for 4 years, which allowed for the great surge in E-cig use among youth that has led to the current epidemic.

The E-cig industry is just new technology being used by big tobacco in new ways. They aim to restrict useful regulation on their product and seek widespread use among youth in society. This is clear by their actions. Lobbying by tobacco

companies, as well as the revenue they generate has prevented effective public health policy from being implemented.

RECOMMENDATIONS

In order to prevent further damage to public health, especially among high school and middle school populations, this paper will provide recommendations for public health policy regarding the vaping epidemic. To this end both reactive and proactive suggestions will be made to address the vaping epidemic and its long-term implications. Appropriate punitive measures should also be imposed on the companies engaged in activities prohibited by current tobacco regulations. This would ensure that laws are taken seriously by tobacco companies, and that they become compliant with the measures deemed appropriate by Congress. Measures to effectively mitigate the public health risks posed by E-cigs and tobacco include, temporary product bans, permanent flavor bans, and modification of E-cigs to prevent youth use. These recommendations function to help stop the spread of vaping and begin to curb current use of E-cigs among youth.

In medicine and public health, prevention is often valued higher than treatment. This is because it is often cheaper to prevent a disease than it is to treat, especially ones involving addiction. Preventative measures revolving around the future of the tobacco should first consider smoother and more regulated entrances of products into the market. Regulations should also focus on emerging social media platforms and the risks of product exposure to youth they may pose. Product design implications for E-cigs and future tobacco products as well as designing programs that are aimed at helping smokers quit. Programs designed to help smokers quit using E-cigs would be beneficial for the goals of public health and provide an effective means for curbing nicotine addiction among current users.

1. Temporary ban on E-cigs

Some argue that a complete ban on E-cigs would be detrimental to public health because it will lead current users into using either street products or combustible tobacco products. This argument assumes that vaping offers some sort of clinical benefit over cigarettes. E-cigs are a relatively new technology and not many clinical studies have been done on their short and long-term health risks, therefore it is impossible to determine which tobacco product is healthier. It is also often the case that E-cig use is either coupled with or leads into traditional tobacco use. (17, 18) This argument

also ignores the fact that many vaping products on the shelves have yet to have their official FDA review and approval. This review is conducted once the product's application has been sent to the FDA by the company and will allow the FDA to run their own clinical trials with vaping technology. This will provide experts with much needed information about the products causing the vaping epidemic. This paper suggests a temporary ban to stop new youth from initiating E-cig use until the specific product has been approved by the FDA. If their products were banned from sale, then it would be in companies' best interest to provide the FDA with their information as soon as possible. This would speed up the process of research on effective regulation for E-cigs, saving time and lives in the long run. Given the number of unknown variables involving E-cig's impact on respiratory health, the best course of action is a cautious one until more details are revealed about how safe E-cigs truly are for all people.

2. Ban of E-cig Flavors appealing to youth

As shown by surveys, (6,59) flavors are one of the main contributors to youth use of E-cigs. Companies have argued that their flavors are necessary to the experience their customers have in transitioning from combustible tobacco to vaping. However, the benefits offered to these current smokers are not balanced by the risks posed to youth while still allowing for kid-oriented flavors. A ban on unnecessary flavors, all except tobacco and menthol, would be beneficial to the prevention of smoking in our society.

3. Regulation of E-cig design

Another interesting thing about E-cigs, is that their design is much more customizable and diverse than that of traditional tobacco products. This has E-cig designs to be very convenient and as a result directly conducive to minor's use of the products. E-cigs are usually scentless and very small making them easy to conceal from parents and other authority figures. To correct this, E-cigs must be designed in a way to prevent youth use of them. The next step is preventing the devices themselves from being conducive to youth use. JUULinc. themselves have proposed to give their E-cigs Bluetooth capabilities. This would provide the device with a method of connecting to a mobile phone and scanning an ID for it to work. (60) It will also enable users to track their use patterns over time. This will prevent anyone under a given age from using their E-cig and could become the standard for E-cig technology. Minor's would still be able to use an E-cig in the presence of an adult friend or relative. In

order to decrease this further, only one ID can activate one device and should be subject to time intervals of use or some method of controlling who is using the device. If implemented correctly by public health authorities and private companies, this technology could drastically restrict youth access to E-cigs.

4. Stricter guidelines for emerging tobacco products

To avoid a situation in which unapproved products enter the tobacco market from happening again in the future, steps should be taken by public health advocates and regulatory organizations like the FDA. No new tobacco product, or any product containing nicotine, should be available for public consumption until its application to the FDA is approved. This would prevent the spread of a dangerous product such as E-cigs over the nation before the risks were known to the public. This will also allow the FDA to begin standardizing commercial nicotine solutions by regulating the various brands' contents. Not only will this help to screen the products for potentially unnecessary and harmful chemicals, it will also ensure consumers are using the products and nicotine concentrations they intend to.

5. Direct approval for tobacco advertising in medias

To compliment this all tobacco products should be approved for the media they seek advertisement. This will prevent future problems of direct advertising to underage populations in media forms that have not previously been considered. These recommendations aim to decrease the prevalence of smoking among younger generations and those not yet exposed to tobacco.

6. Development of E-cigs as a smoking cessation device

E-cigs effectiveness as a smoking cessation device has been one of the most debated topics revolving around the products. As of now The FDA has not approved any ENDS as smoking cessation devices and it will not be until a product can prove clinical benefit. (61) With new technology there is always the possibility of improvement, however how E-cigs affect different populations smoking habits is very understudied. Studies seem to indicate that among general populations E-cigs lead into tobacco initiation or at least do not significantly help in smoking cessation. This is most likely due to the fact that many people use e-cigarettes recreationally and not as a means of cessation alone. This is in comparison to other nicotine containing products regulated by the FDA called nicotine replacement therapies (NRT). These products' nicotine concentrations are tightly

regulated, have helped smokers to decrease nicotine dependence for years. (62) With research and development of E-cigs they could potentially become a highly effective NRT. However, this could only be done if the products and programs created for this end were supervised by experts in addiction.

One way in which E-cigs could be implemented as effective smoking cessation devices would be to develop a therapeutic program or process that follows a chronic smoker and is overseen by a certified physician. The first step would be to design an official medical E-cig that has the Bluetooth capabilities E-cigs may soon have. The contents of the E-cig will also be regulated to mitigate health risks to the patient in their cessation process. This will allow the physician to monitor baseline use and dependency levels to develop a plan tailored to help that individual quit. As the individual progresses the physician will provide them with lower and lower nicotine concentrations to use until they are able to quit vaping altogether.

CONCLUSION

The vaping epidemic rapidly has caught public attention now that multiple deaths have resulted from it. The amount of E-cig and tobacco use among teens must be addressed as quickly and as effectively as possible. This however comes down to enforcing the current laws in place, as well as educating and reaching out to effected students. By offering counseling and addiction services to these teens chronic addiction may be prevented, or at the least they can begin to start the process of recovery. Second it is the utmost importance to learn from the vaping epidemic and to prevent something like it from ever happening again. This can only be done by making monumental changes in the way tobacco policy is implemented in society.

References

1. "Historical Timeline of Electronic Cigarettes." CASAA, 18 Oct. 2018, www.casaa.org/historical-timeline-of-electronic-cigarettes/.
2. Ruthless Vapor Corporation. "Beginner's Guide to Vaping Nicotine Salt." Ruthless Vapor Corporation, www.ruthlessvapor.com/blogs/ruthless-e-liquid/beginners-guide-to-vaping-nicotine-salt.
3. "JUUL LABS, INC." JUUL LABS, INC. (P065739), www.wdfl.org/apps/CorpSearch/Details.aspx?entityID=P065739&hash=2104944145&searchFunctionID=3f8cb1fd-2fec-4980-9102-e8fe7e16a986&type=Simple&q=Juul.
4. Center for Tobacco Control. "Vaporizers, E-Cigarettes, and Other ENDS." U.S. Food and Drug Administration, FDA, www.fda.gov/tobacco-products/products-ingredients-components/vaporizers-e-cigarettes-and-other-electronic-nicotine-delivery-systems-ends.
5. Tsai J, Walton K, Coleman BN, et al. Reasons for Electronic Cigarette Use Among Middle and High School Students — National Youth Tobacco Survey, United States, 2016. *MMWR Morb Mortal Wkly Rep* 2018; 67:196–200. DOI: <http://dx.doi.org/10.15585/mmwr.mm6706a5externalicon>.
6. "Progress Erased: Youth Tobacco Use Increased During 2017-2018 | CDC Online Newsroom | CDC." Centers for Disease Control and Prevention, Centers for Disease Control and Prevention, www.cdc.gov/media/releases/2019/p0211-youth-tobacco-use-increased.html.
7. Kasza, K. A., B. K. Ambrose, K. P. Conway, N. Borek, K. Taylor, M. L. Goniewicz, K. M. Cummings, E. Sharma, J. L. Pearson, V. R. Green, A. R. Kaufman, M. Bansal-Travers, M. J. Travers, J. Kwan, C. Tworek, Y. C. Cheng, L. Yang, N. Pharris-Ciurej, D. M. van Bommel, C. L. Backinger, W. M. Compton, and A. J. Hyland. 2017. Tobacco-product use by adults and youths in the United States in 2013 and 2014. *New England Journal of Medicine* 376(4):342–353.
8. Prevalence and Distribution of E-Cigarette Use Among U.S. Adults: Behavioral Risk Factor Surveillance System, 2016
9. Grady, Denise. "Lung Damage from Vaping Resembles Chemical Burns, Report Says." *The New York Times*, *The New York Times*, 2 Oct. 2019, www.nytimes.com/2019/10/02/health/vaping-illnesses.html.
10. "Outbreak of Lung Injury Associated with E-Cigarette Use, or Vaping." Centers for Disease Control and Prevention, Centers for Disease Control and Prevention, www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html.
11. Dutra LM, Grana R, Glantz SA. Philip Morris research on precursors to the modern e-cigarette since 1990. *Tob Control* 2017; 26: 97–105
12. Philip Morris. Philip Morris USA 92–96 operations. Philip Morris; Jul 27, 1992. [3 Aug 2016].
13. Glantz SA, Bareham DW. E-Cigarettes: use, effects on smoking, risks, and policy implications. *Annu Rev Public Health*. 2018; 39:215–235.
14. JUUL Labs, Inc. (August 10, 2018). JUULpod Basics. Retrieved from <https://support.juul.com/home/learn/faqs/juulpod-basics>
15. Nicotine. *Clinical Pharmacology* [Internet]. Tampa (FL): Elsevier. c2016- [cited 2018 August 10]. Available from: <http://www.clinicalpharmacology.com>
16. Nicotine. *Clinical Pharmacology* [Internet]. Tampa (FL): Elsevier. c2016- [cited 2018 August 10]. Available from: <http://www.clinicalpharmacology.com>
17. Primack BA, Soneji S, Stoolmiller M, et al. Progression to traditional cigarette smoking after electronic cigarette use among US adolescents and young adults. *JAMA Pediatr* 2015;169: 1018-23
18. Leventhal A. M., Strong D. R., Kirkpatrick M. G., Unger J. B., Sussman S., Riggs N. R., et al. (2015). Association of electronic cigarette use with initiation of combustible tobacco product smoking in early adolescence. *JAMA* 314, 700–707. 10.1001/jama.2015.8950
19. Barrington-Trimis, J. L., R. Urman, A. M. Leventhal, W. J. Gauderman, T. B. Cruz, T. D. Gilreath, S. Howland, J. B. Unger, K. Berhane, J. M. Samet, and R. McConnell. 2016b. E-cigarettes, cigarettes, and the prevalence of adolescent tobacco use. *Pediatrics* 138(2). 10.1542/peds.2015-3983
20. Stefanie Scheffler, 1 Hauke Dieken, 1 Olaf Krischenowski, 1 Christine Förster, 2 Detlev Branscheid, 3 and Michaela Aufderheide 1 et al. Evaluation of E-Cigarette Liquid Vapor and Mainstream Cigarette Smoke after Direct Exposure of Primary Human Bronchial Epithelial Cells.

- 2015 Apr; 12(4): 3915–3925
21. Layden JE, Ghinai I, Pray I, et al. Pulmonary illness related to e-cigarette use in Illinois and Wisconsin — preliminary report. *N Engl J Med*. DOI: 10.1056/NEJMoa1911614.
22. Maddock SD, Cirulis MM, Callahan SJ, et al. Pulmonary lipid-laden macrophages and vaping. *N Engl J Med*. DOI: 10.1056/NEJMc1912038.
23. Henry TS, Kanne JP, Kligerman SJ. Imaging of vaping-associated lung disease. *N Engl J Med*. DOI: 10.1056/NEJMc1911995.
24. Centers for Disease Control and Prevention. Outbreak of severe pulmonary disease associated with using e-cigarette products: investigation notice. August 30, 2019
25. Cohen A, George O. Animal models of nicotine exposure: relevance to second-hand smoking, electronic cigarette use, and compulsive smoking. *Front Psychiatry*. 2013; 4:41. Published 2013 Jun 4. doi:10.3389/fpsy.2013.00041
26. Temperance R, Rowell and Robert Tarran. Will chronic e-cigarette use cause lung disease? *American Journal of Physiology-Lung Cellular and Molecular Physiology* 2015 309:12, L1398-L1409
27. Joseph G. Allen, Skye S. Flanigan, Mallory LeBlanc, Jose Vallarino, Piers MacNaughton, James H. Stewart, and David C. Christiani 2016 Flavoring Chemicals in E-Cigarettes: Diacetyl, 2,3-Pentanedione, and Acetoin in a Sample of 51 Products, Including Fruit-, Candy-, and Cocktail-Flavored E-Cigarettes *Environmental Health Perspectives* 124:6 CID: https://doi.org/10.1289/ehp.1510185
28. Viswam D, Trotter S, Burge PS, et al. Respiratory failure caused by lipoid pneumonia from vaping e-cigarettes *Case Reports* 2018;2018: bcr-2018-224350.
29. Hureaux J, Drouet M, Urban T A case report of subacute bronchial toxicity induced by an electronic cigarette *Thorax* 2014;69:596-597.
30. Flouris AD, Chorti MS, Poulaniiti KP, et al. Acute impact of active and passive electronic cigarette smoking on serum cotinine and lung function. *Inhal Toxicol* 2013; 25:91–101.
31. Vardavas CI, Anagnostopoulos N, Kougias M, et al. Short-term pulmonary effects of using an electronic cigarette: impact on respiratory flow resistance, impedance, and exhaled nitric oxide. *Chest* 2012; 141:1400–6.
32. Ingebrethsen BJ, Cole SK, Alderman SL. Electronic cigarette aerosol particle size distribution measurements. *Inhal Toxicol* 2012; 24:976–84
33. Cullen KA, Ambrose BK, Gentzke AS, Apelberg BJ, Jamal A, King BA. Notes from the Field: Increase in use of electronic cigarettes and any tobacco product among middle and high school students — United States, 2011–2018. *MMWR Morbid Mortal Wkly Rep*. 2018;67(45):1276–1277.
34. Hannah Knowles, “As Vaping-Linked Deaths Rise to 33, Officials Are Still Seeking Answers,” *Washington Post*, October 17, 2019. <http://www.washingtonpost.com/health/2019/10/17/vaping-linked-deaths-rise-to-33>
35. Sheila Kaplan & Matt Richtel, “Juul Illegally Marketed E-Cigarettes, FDA says,” *New York Times* September 9, 2019, <http://www.nytimes.com/2019/09/09/health/vaping-juul-e-cigarette-fda.html>.
36. U. S. Food and Drug Administration, “Vaping Illness Update: FDA Warns Public to Stop Using Tetrahydrocannabinol (THC)-Containing Vaping Products and Any Vaping Products Obtained Off the Street,” October 2019. <http://www.fda.gov/consumers/consumer-updates/vaping-illness-update...>
37. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, U. S. Government Printing Office, Washington, D.C., 1979: B-1.
38. Office of U.S. Surgeon General “Get the Facts on E-Cigarettes: Know the Risks: E-Cigarettes & Young People: U.S. Surgeon General’s Report.” [Get the Facts, e-cigarettes.surgeongeneral.gov/getthefacts.html](http://www.e-cigarettes.surgeongeneral.gov/getthefacts.html).
39. Committee on Bioethics, Informed Consent, Parental Permission, and Assent in Pediatric Practice, *Pediatrics* 95 (2), (February 1995): 314-317.
40. Hannah Knowles, “Here’s What We Know About the Mysterious Outbreak of Vaping-Linked Illnesses and Deaths,” *Washington Post*, September 9, 2019. <https://www.sciencealert.com/here-s-what-we-know-about-the-mysterious-outbreak-of-vaping-linked-illnesses-and-deaths>.
41. Kaplan & Richtel, p. 2.
42. Shelia Kaplan, “Scientists Wanted: Recruited by Juul, Many Reserachers Say No,” *New York Times*, May 27, 2019. <http://www.nytimes.com/2019/05/27/health/juul-cigarettes-science>.
43. Michael Bloomberg & Matt Myers, “Ban Flavored E-Cigarettes to Protect Our Children,” *New York Times*, September 10, 2019. <http://www.nytimes.com/2019/09/10/opinions/vape-deaths-children>
44. Tobacco Control Act “Final Deeming Rule” 21 CFR 1110,1140, 1143 (2016)
45. Food and Drug Administration (2018) *Fy 2018 FDA Budget Tobacco Control Act* Retrieved from <https://www.fda.gov/media/106472/download>
46. Tobacco Control Act 21 CFR sec 1140.14 (1)
47. Tobacco Control Act 21 CFR sec 1140.32 (2)
48. Anderson M, Jaing J. Teens, Social Media & Technology. *Pew Research Center*. May 31, 2018. <http://www.pewinternet.org/2018/05/31/teens-social-media-chnology-2018/>
49. Jackler RK, Chau C, Getachew BD, Whitcomb MM, Lee-Heidenreich J, Bhatt AM, Kim-O’Sullivan SHS, Hoffman ZA, Jackler LM, Ramamurthi D. *JUUL Advertising Over its First Three Years on the Market. SRITA White Paper*
50. Jackler, Robert. “Stanford University Research into the Impact of Tobacco Advertising.” *Stanford Research into the Impact of Tobacco Advertising*, tobacco.stanford.edu/tobacco_main/index.php.
51. Tobacco Control Act 21 CFR sec 102 (d)(1)
52. Federal Lanham Act 115 U.S.C. §1125 (a)
53. Products, Center for Tobacco. “Section 911 of the Federal Food, Drug, and Cosmetic Act.” U.S. Food and Drug Administration, FDA, www.fda.gov/tobacco-products/rules-regulations-and-guidance/section-911-federal-food-drug-and-cosmetic-act-modified-risk-tobacco-products.
54. D Patel, KC Davis, S Cox, et al. Reasons for current e-cigarette use among U.S. adults *Prev Med*, 93 (2016), pp. 14-20 <https://doi.org/10.1016/j.ypmed.2016.09.011>E-cigarette knowledge, attitudes, and use in opioid dependent smokers. Stein MD
55. Liu, B. Halpern-Felsher. The juul curriculum is not the jewel of tobacco prevention education *The Journal of Adolescent Health*, 63 (5) (2018), pp. 527-528

56. Tobacco Control Act 21 CFR §§ 1143.3
57. "Subcommittee Urges FDA to Evaluate JUUL Labs' False Medical Claims about E-Cigarettes." Oversight.gov, 5 Sept. 2019, oversight.house.gov/news/press-releases/subcommittee-urges-fda-to-evaluate-juul-labs-false-medical-claims-about-e.
58. Thomas, Katie, and Sheila Kaplan. "E-Cigarettes Went Unchecked in 10 Years of Federal Inaction." *The New York Times*, The New York Times, 14 Oct. 2019, www.nytimes.com/2019/10/14/health/vaping-e-cigarettes-fda.html.
59. Villanti AC, Johnson AL, Ambrose BK, et al. Use of flavored tobacco products among U.S. youth and adults; findings from the first wave of the PATH Study (2013-2014)
60. Becker, Rachel. "Juul Plans to Release New Bluetooth-Enabled Vapes Internationally." *The Verge*, The Verge, 1 Aug. 2018, www.theverge.com/2018/8/1/17640148/vape-e-cig-cigarette-juul-bluetooth-enabled-locks-israel-uk.
61. Commissioner, Office of the. "Fact or Fiction: What to Know About Smoking Cessation and Medications." U.S. Food and Drug Administration, FDA, 28 Mar. 2019, www.fda.gov/consumers/consumer-updates/fact-or-fiction-what-know-about-smoking-cessation-and-medications.
62. Food and Drug Administration (2018) Pharmacologic Product Guide: FDA-Approved Medications for Smoking Cessation Retrieved from https://www.aafp.org/dam/AAFP/documents/patient_care/tobacco/pharmacologic-guide.pdf

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