AHA Policy Statement

Electronic Cigarettes

A Policy Statement From the American Heart Association

Aruni Bhatnagar, PhD, FAHA, Chair; Laurie P. Whitsel, PhD; Kurt M. Ribisl, PhD; Chris Bullen, MBChB, PhD; Frank Chaloupka, PhD; Mariann R. Piano, PhD; Rose Marie Robertson, MD, FAHA; Timothy McAuley, PhD; David Goff, MD, PhD, FAHA; Neal Benowitz, MD; on behalf of the American Heart Association Advocacy Coordinating Committee, Council on Cardiovascular and Stroke Nursing, Council on Clinical Cardiology, and Council on Quality of Care and Outcomes Research

For decades, advocacy for tobacco control has been a priority of the American Heart Association (AHA). In partnership with major public health organizations, the association has made major strides in tobacco use prevention and cessation by prioritizing evidence-based strategies such as increasing excise taxes; passing comprehensive smoke-free air laws; facilitating US Food and Drug Administration (FDA) authority to regulate tobacco, including comprehensive tobacco cessation treatment within healthcare plans; and supporting adequate funding of comprehensive tobacco control programs in different states. These tobacco control efforts have cut in half the youth smoking rate from 1997 to 2007 and have saved >8 million lives in the past 50 years.[1] However, the work is far from done and has stalled, especially for people living below the poverty line, those with mental illnesses,[2] and those with low educational attainment.[3] Unless current trends reverse, ≈5.6 million children alive today in the United States will die prematurely of smoking-related diseases.[1] Even now, cigarette smoking kills nearly half a million Americans each year, and an additional 16 million individuals suffer from smoking-related illness, which costs the United States $289 billion dollars annually in direct medical care and other economic costs.[1]

This statement reviews the latest science concerning one of the newest classes of products to enter the tobacco product landscape—electronic cigarettes (e-cigarettes), also called electronic nicotine delivery systems (ENDS)—and provides an overview on design, operations, constituents, toxicology, safety, user profiles, public health, youth access, impact as a cessation aid, and secondhand exposure. On the basis of the current evidence, we provide policy recommendations in key areas of tobacco control such as clean indoor air laws, taxation, regulation, preventing youth access, marketing and advertising to youth, counseling for cessation, surveillance, and defining e-cigarettes in state laws. The statement concludes by outlining a future research agenda to further our understanding of this emerging area of tobacco control and the impact of e-cigarettes on public health.

E-Cigarettes or ENDS

The first concept of an electric cigarette was patented in 1965 by Herbert A Gilbert.[4] Subsequently, an aerosolized, high-frequency e-cigarette was patented in China by Mr. Hon Lik and Ruyan Technology; it entered the marketplace in 2003[5] and was patented internationally in 2007.[6] Ruyan has since registered patents in >40 countries, including the United States,[7] and has already brought patent infringement lawsuits against several e-cigarette manufacturers.[8] E-cigarette design and manufacturing processes continue to evolve, and most products on the market today use a simpler, battery-powered heating element instead of the high-frequency, ultrasonic technology patented by Ruyan.[7]

As of early 2014, there were 466 brands and 7764 unique flavors of e-cigarette products.[9] These products are now widely available online[10] and in retail outlets in many countries across the world.[11,12] In contrast to combustible products, e-cigarette availability in retail outlets in the United States is currently more likely in neighborhoods with higher median household income and a lower percentage of black and

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Hispanic residents.[12] E-cigarette availability in retail outlets is also higher in states with weak or nonexistent laws for clean indoor air and low cigarette taxes.[12]

Although the sale of e-cigarettes is prohibited in some countries (Australia, Brazil, Canada, Mexico, Panama, Singapore, and Switzerland), it is allowed in most others, including the United States.[13] The number of e-cigarettes sold has increased exponentially year by year. Wells Fargo has predicted that sales margins for e-cigarettes could grow to $10 billion by 2017, surpassing conventional cigarette sales margins.[14] The big 3 major tobacco companies have been purchasing independent e-cigarette companies and may share 75% of the profit pool in 10 years.[14]

E-cigarettes are battery-powered devices that have cartridges or refillable tanks containing a liquid mixture composed primarily of propylene glycol and/or glycerol and nicotine, as well as flavorings and other chemicals.[5] During use, inhalation activates a pressure-sensitive circuit that heats the atomizer and turns the liquid into an aerosol that is inhaled by the user through the mouthpiece and exhaled as a fine mist.[5] Some e-cigarettes have buttons that allow the user to manually activate the heating element. The exhaled aerosol does not contain smoke, tar, or carbon monoxide. Studies of specific types of e-cigarettes have shown that compared with conventional cigarettes, the byproducts from their aerosols produce very low levels of air toxins.[15–17] Proponents of e-cigarettes maintain that these products emulate smoking behavior without exposing the user to the toxic smoke constituents of conventional cigarettes that are deleterious to health, so there would be a public health benefit if individual smokers completely switched or substantially reduced their cigarette smoking habit.[18–20] However, the use of e-cigarettes could be a problem at the population level. For instance, e-cigarettes could fuel and promote nicotine addiction, especially in children, and their acceptance has the potential to renormalize smoking behavior. E-cigarette use could also potentially serve as a gateway to other drugs and harmful substances.[21]

E-Cigarettes: Design and Operation

Since their initial manufacturing in 2003, there has been a rapid growth and evolution in the types, design, and overall engineering characteristics of e-cigarettes.[22,23] This has resulted in a large degree of product variability in size, potential nicotine concentrations, and e-liquid formulations. There have also been changes in electrical circuitry (eg, heating element or atomizer) and battery life that allow for more e-liquid delivery, adjustments in flavor, and longer device use.

Different types of e-cigarettes are being developed continuously. Table 1 lists some of the different e-cigarette types and name brands on the market today. Newer second- and third-generation devices allow for multiple types of user customization. This has resulted in cross-product and within-product differences in aerosol production, nicotine delivery, and product use risk.[22] These developments significantly complicate the ability to assess the impact of e-cigarettes on individual and population health.[22,23]

Regardless of type, there are 3 basic e-cigarette components: a battery, an e-liquid–containing cartridge, and an atomizer (ie, a vaporization chamber with heating element).[21] Other components include an airflow sensor (sensing inhalation), a microchip for controlling the heating element, and a light-emitting diode light at the tip that simulates a burning cigarette tip.[21] All devices have air holes, which control the pressure drop and facilitate the flow of air required for puffing.[22] E-cigarettes are available with automatic or manual button–activated batteries. The battery in an automatic device is activated by inhalation or the drag, whereas manual devices require the depression of a button for battery activation.[22] The smokelike aerosol produced by these devices is not because of the combustion of organic material; rather, it is an aerosol of the e-liquid. As noted, the "atomizers" contain the heating elements that convert the fluid into an aerosol. Such atomizers are an essential component of all vaporizers, and they consist of a small heating element that evaporates the fluid and a wicking device that draws in the fluid. Since the inception of e-cigarettes, the atomizers have undergone dramatic engineering changes. Developments include the evolution of the atomizer into "cartomizers" (cartridge plus atomizer), which is a combination of an e-liquid distribution system and a wick/fiber and heating element.[23]

Second- and third-generation e-cigarettes models, which are larger than the first "cigarette-like" e-cigarettes (cigalikes), are referred to as "clearomizers," "tankomizers," or "carotanks" because they can hold several milliliters of fluid in refillable reservoirs. Some second- and third-generation e-cigarette batteries are available in different voltages (3.0 to 7.0 V) and with greater battery life (greater milliampere-hour) than earlier models. Within the atomizer, a resistance wire is encircled around the wicking device that draws the fluid in. When activated by the sensing device, the resistance wire rapidly heats up, turning the fluid into an aerosol, which is then inhaled by the user. The resistance and voltage applied to the heating element, as well as the material from which the heating element is made, are important determinants of the temperature achieved, which determines in part the amount and quality of the aerosol produced by the atomizer.

Some second- and third-generation e-cigarettes have programmed pumps, diaphragms, or micropumps on microelectromechanical systems. These allow for a specific programmed amount or a combination of e-liquid delivery to the aerosol generator.[22] Some e-cigarettes contain programmable logic units, integrated circuits, and other electronic components that are used to display average use cycle and safety warnings.[22] Ongoing product development and evolution are likely to continue, and therefore, new regulatory policies will be important to ensure appropriate quality control.

Profile of Users

The number and duration of surveys are increasing and variably include current, former, and nonsmoker categories.[24,25] These surveys are difficult to consolidate because they have been undertaken in different populations and jurisdictions, using different sampling methods and definitions, over a number of years while e-cigarette types, visibility, and use have increased dramatically. Generally, non-Hispanic whites, current smokers, young adults, and those with a higher education and higher income perceive e-cigarettes as less harmful than combustible tobacco products and are more likely to use

Table 1. Types of E-Cigarettes

Generation	Examples
First generation	
First generation e-cigarettes were designed to look and feel like tobacco cigarettes. Although there is some variation in size, most resemble cigarettes and therefore have also been referred to as "cigalikes." These battery-operated devices were initially composed of 3 pieces: a battery, atomizer, and cartridge. Now, the atomizer and cartridge have been replaced by a combined "cartomizer," which screws into and connects with a battery, some of which are rechargeable. The disposable e-cigarettes are designed for 1-time use and are discarded after use. These cigalike devices are all available in various nicotine concentrations and with different flavorings.	Halo White Cloud Green Smoke Apollo Blu South Beach V2 Cigs Atlantic
Second generation	
These e-cigarette devices are larger and typically do not resemble a cigarette. These medium-battery (rechargeable)–style e-cigarettes are also referred to as "tank-styled" e-cigarettes. Sizes, shapes, and colors can resemble pens, small screwdrivers, or the tip of a hookah pipe. These larger e-cigarette devices have the basic e-cigarette components: the battery, the atomizer, and the cartridge. However, there are some key differences between these devices and the first-generation e-cigarette devices: second-generation e-cigarette devices have larger-capacity batteries (greater milliampere-hours) and therefore stay charged longer, have larger atomizers and electronic circuits that deliver greater energy (which enhances nicotine delivery to the user), and have large, separate cartridges ("tanks") that the user can fill up using different purchased e-liquids and flavorings. Some also have a manual switch that allows modulation of both puff length and frequency.	eGo Riva Tornado KGo
Third generation	
These devices are similar to the second generation but are larger and allow for more personal and custom modifications; therefore, they are sometimes referred to as "personalized vapors" or aerosols. Similar to the second-generation devices, these devices come with a range of different cartridge and atomizer options (eg, cartomizer, clearomizer, tankomizer) and batteries (greater milliampere-hours coupled with a certain voltage [3.0–6.0 V]). Some e-cigarettes devices allow the user to adjust the resistance on the atomizer/cartomizer. A low-resistance cartomizer produces higher heating element temperatures, thus generating more heat and affecting the amount and quantity of the aerosol. Users of these devices can pair different atomizers (that allow different resistances) with high-capacity batteries to maximize both aerosol production and battery life.	Companies with personal vapors: Apollo Henly Vapor Zone Volcano
E-cigars could either be classified as a second- or third-generation e-cigarette device. Available in disposable and rechargeable forms. Designed to simulate a cigar in terms of size. Some e-cigars have an LED tip that is partially hidden behind some type of screen to mimic a real cigar's ash.	E-cigar: Cuvana Marcello-rechargeable Vapor Zeus Royale premium

E-cigars indicates electronic cigars; e-cigarettes, electronic cigarettes; LED, light-emitting diode.

them.[24,26–29] European and North American surveys conducted in 2012 and 2013 report that most e-cigarette users are current or former smokers[30]; 40% to 70% of all adults have heard about them, with awareness highest in smokers and growing.[26,31–33] Such surveys also report that ≈3% to 7% of the adult population has ever used e-cigarettes[26,34] Among smokers in the United States and Great Britain, ≈11% report ever having used e-cigarettes, whereas the use of e-cigarettes is significantly lower (0.5%–1.0%) in nonsmokers.[25,26,35] A study conducted in the Czech Republic in 2012 revealed that almost 20% of smokers who try e-cigarettes go on to become regular users.[36]

It is uncertain how many e-cigarette users are smokers who really want to stop cigarette smoking or ex-smokers but persistent e-cigarette users, or who want to be dual users. At present, there are few longitudinal studies to assess how many smokers are able to completely quit cigarette use, whether they continue e-cigarette use after quitting or whether they continue dual use, that is, using them concurrently with combustible products.[36] Epidemiological studies and population surveys also indicate that although many e-cigarette users plan to use the devices to quit or reduce their smoking, they are usually using them in a dual-use capacity, especially in places where smoking is restricted.[35–40] A survey conducted in 2012 showed that >80% of current e-cigarette users do not use them on a daily basis, and almost half of all smokers indicated they may use e-cigarettes in the future.[35] Finally, among college students, another e-cigarette user group, e-cigarette use may not be motivated by the desire to quit smoking, nor may it lead to quitting.[41] In conclusion, the overall use patterns are unclear and constantly changing, which makes it difficult to draw firm conclusions about the prevalence, preference, and purpose of e-cigarette use.

Youth

Concerned public health advocates see e-cigarettes as a route to nicotine addiction and possibly as a potential gateway to tobacco use in youth or nonsmokers and to reinitiation of tobacco product use by former users.[42] Data from the 2011 to 2012 National Youth Tobacco Survey[43] showed that among students in grades 6 through 12, current e-cigarette use (≥1 day in the past 30 days) increased from 1.1% in 2011 to 2.1% in 2012 and any use of e-cigarettes (ever use) increased from 3.3% to 6.8% in the same corresponding years. Overall, by 2012, 1.78 million high school and middle school students nationwide had tried e-cigarettes. For those students who had ever used e-cigarettes, 9.3% reported never smoking conventional cigarettes, whereas 76.3% of current e-cigarette users responded that they also smoke conventional cigarettes. Among never-smokers, 0.7% were currently users (past 30 days), which indicates that few never-smokers who try e-cigarettes continue their use.[44] A survey of 40 000 middle school and high school students from ≈200 schools has shown that e-cigarette use is higher in current smokers and ever-smokers

and among those intending to quit.[43] This surveillance does not address whether adolescents are using e-cigarettes as a gateway to smoking cigarettes, but adolescents do consider e-cigarettes as high-tech, accessible, and convenient, especially in places where smoking cigarettes is not allowed.[45] Increasingly, there is robust marketing and advertising using celebrities and appealing flavors (eg, chocolate, strawberry, and vanilla) to make e-cigarettes especially more attractive and appealing to children and adolescents.[45] Much of the marketing for e-cigarettes has been through the Internet and social media outlets such as YouTube,[46] but increasingly, e-cigarettes are advertised on television, radio, and in the print media, where broadcast cigarette ads have been banned since 1971.[47] Data from a US population survey indicated that for those reporting they have heard about e-cigarettes, the majority (48%) reported television as their primary source, followed by "in-person conversation" and the Internet.[35] Another study found that youth exposure to television advertisements for e-cigarettes increased 256% between 2011 and 2013, with 24 million youth reached.[48] Online searches for e-cigarettes have surpassed those for nicotine replacement therapies (NRTs) and snus, products that have been on the market much longer.[49]

E-Cigarettes and Public Health

The major public health issues regarding e-cigarettes include whether or not they may contribute to reducing overall tobacco-related harm through complete cessation or possibly through reduction of the number of cigarettes smoked, denormalization of smoking, reduction in prevalence of use of combustible products (especially cigarettes), reduction of second-hand smoke exposure, and diminishing the influence of the tobacco industry. Although some believe that acceptance of e-cigarettes has the potential to reverse the social norm for prohibiting smoking in public places achieved over decades of advocacy work, others see these products as a way to denormalize smoking because they are a potential mechanism for quitting.[20] It is not known whether the emerging e-cigarette technology will shift people from combustible products to the exclusive use of e-cigarettes or whether dual use will persist.[50]

E-Cigarettes as a Cessation Aid

Current evidence evaluating the efficacy of these products as a cessation aid is sparse, confined to 2 randomized controlled trials and 1 large cross-sectional study, anecdotal reports, and Internet-based surveys. A large cross-sectional study showed that smokers who wanted to quit without professional help were significantly more likely to report abstinence using e-cigarettes than with traditional cessation aids or going "cold turkey."[51] The adjusted odds ratio for self-reported cigarette abstinence in e-cigarette users was 1.63 (95% confidence interval 1.17–2.27) higher than with NRT use and 1.61 (95% confidence interval 1.19–2.18) higher than for those using no aid. In a survey in the United Kingdom, 67.8% of e-cigarette users "completely replaced tobacco cigarettes with electronic cigarettes"; however, these reports are confounded by a self-selection bias in that the respondents are often e-cigarette enthusiasts.[39] In contrast, other surveys suggest that compared with never-users, e-cigarette users are less likely to be tobacco abstinent[52] and that e-cigarette users were no more likely than cigarette smokers to have quit permanently despite having reduced their cigarette consumption.[24]

The largest randomized controlled trial conducted to date, which used e-cigarettes available on the market in 2010 that are now obsolete, had cartridges labeled as containing 16 mg of nicotine and showed that the study e-cigarettes were modestly effective with or without nicotine at helping smokers quit, on par with the abstinence achieved with nicotine patches.[53] At 6 months, the verified quit rates were 7.3% with nicotine e-cigarettes, 5.8% with nicotine patch, and 4.1% with placebo e-cigarette treatment. This study also found that dual use persisted at 6 months at moderately high levels (approximately one third of participants); dual use also occurred with patch users but at much lower levels (7%).

Health Effects and Safety

The overall health effects of e-cigarettes should be considered both in the context of the intrinsic toxicity of e-cigarettes and with regard to their relative toxicity compared with the well-known injurious effects of smoking conventional cigarettes. Even if there are some intrinsic adverse health effects of e-cigarettes, there would be a public health benefit if e-cigarettes proved to be much less hazardous than combustible cigarettes and if smokers could switch entirely from conventional cigarettes to e-cigarettes. However, in general, the health effects of e-cigarettes have not been well studied, and the potential harm incurred by long-term use of these devices remains completely unknown. Nevertheless, some studies have examined the health effects of e-cigarettes by considering the constituents of their aerosol and their known toxicities and through toxicological evaluation of e-cigarette liquids and aerosols. Current data from human exposures, including experimental studies, and surveys of adverse effects and accidental exposure are discussed below. Available data on the safety and health effects of e-cigarettes have been reviewed elsewhere.[54–56]

The constituent and toxicant levels within the e-liquid and aerosol vary depending on the type of e-liquid (or e-juice) formulation and the specific design of the device.[57] Typically, e-liquid formulations contain nicotine, flavors, water, glycerin, and propylene glycol.[57] Exposure to levels and types of metals or other materials within the aerosol depends on the material and other engineering features of the heating coils.[57] Potential metallic and nanoparticles derived from the heating coils can include tin, iron, nickel, and chromium.[22,58] Other materials in e-cigarettes could include ceramics, plastics, rubber, filament fibers, and foams. Some of these materials can be aerosolized and inhaled. Importantly, low levels of harmful or potentially harmful metals such as lead, nickel, and chromium are listed as having been detected.[22,59] The e-liquids typically contain many flavorings, including tobacco flavoring. In tobacco-flavored products, other tobacco "contaminants" may be present. Trace levels of tobacco-specific *N*-nitrosamines, polycyclic aromatic hydrocarbons, and volatile organic compounds in the e-liquid and vapor have been reported; however, the amounts are deemed too low to cause human risk.[57,60] Other flavorings include fruit and spices (eg, strawberry, black cherry, and Ceylon cinnamon) or flavorings such as "bubble gum" or "chocolate truffle."

Propylene glycol is a major ingredient in e-cigarettes. It is approved by the FDA as a solubilizing agent for different types of medications and is considered generally nontoxic.[59] However, in 1 product, small amounts of diethylene glycol, a potential byproduct of nonpharmaceutical grade propylene glycol, have been detected.[61] Other contaminants found in particular products have included the weight-loss chemical rimonabant (Zimulti) and the erectile dysfunction medication tadalafil (the active ingredient in Cialis). As a result, the FDA has issued warnings to several e-cigarette companies for selling e-cartridges with these contaminants.[61]

Nicotine

Nicotine is delivered by most but not all e-cigarette products. Most e-liquids contain 24 mg/mL, 18 mg/mL, 12 mg/mL, or 6 mg/mL nicotine and are qualified by the manufacturers as high, medium, or low nicotine strength.[62] Some e-liquids are available in 36 mg/mL concentrations.[62] Nicotine solutions of 100 mg/mL for use in making e-cigarette refill liquids are available over the Internet. As a point of context, 1 regular cigarette contains ≈10 to 15 mg of nicotine and delivers a systemic dose of ≈1 mg of nicotine. Testing has revealed that the nicotine content noted in some e-cigarette products and refill solutions has been incorrect and either overestimates or underestimates the amount of nicotine,[61] which indicates a need for regulatory oversight.[61] The overall total amount of nicotine in the e-liquid depends on the size of the refill vial; for example, a 10-mL bottle of 24 mg/mL contains a total of 240 mg of nicotine.

Blood levels of nicotine are generally lower from e-cigarette use than from conventional cigarettes, but users of some e-cigarette tank systems with more powerful batteries that heat liquids to higher temperatures may achieve blood nicotine levels comparable to those of cigarette smokers.[63,64] The extent to which nicotine inhaled from an e-cigarette is absorbed through the lungs or via the throat and upper airway has not been determined. The size distribution of particles generated by e-cigarettes, discussed later in this report, suggests that at least some pulmonary absorption is likely. In 1 study,[58] it was found that absorption of nicotine from e-cigarettes was lower than from tobacco cigarettes even with the new-generation cartomizers, which suggests that most absorption from the devices occurs in the buccal mucosa or upper airways. Compared with smoking 1 tobacco cigarette, the electronic devices and liquid used in this study delivered one third to one fourth the amount of nicotine after 5 minutes of use. New-generation e-cigarette devices were more efficient in nicotine delivery but still delivered nicotine much more slowly than tobacco cigarettes.

The main health concern for nicotine in cigarette smokers is maintenance of addiction. Most of the adverse health effects of smoking are caused by tobacco combustion products,[65] but there are some health concerns that are related to nicotine per se. Many of these concerns are related to the ability of nicotine to release catecholamines, including hemodynamic effects (increase in heart rate, a transient increase in blood pressure, vasoconstriction of coronary and other vascular beds), adverse effects on lipids, and induction of insulin resistance.[65] Nicotine has also been reported to produce endothelial dysfunction and to cause fetal teratogenicity, operating by different mechanisms.[66] Nicotine in vitro and in animals can inhibit apoptosis and enhance angiogenesis, effects that raise concerns about a role of nicotine in promoting the development and spread of cancer and in the acceleration of atherosclerotic disease.[67]

Because most people use nicotine in the form of tobacco products, there are relatively few data on the health effects of prolonged exposure to pure nicotine. There are some studies of prolonged NRT in smokers who have quit smoking.[68,69] In these studies, no adverse effects have been found when nicotine medication was administered for months to several years. Other studies indicate that patients with known cardiovascular disease tolerate NRT well for periods up to 12 weeks.[65]

Because most of the toxicity from cigarette smoking derives from combustion products, the health effects of smokeless tobacco could be examined to assess potential long-term adverse effects of nicotine without exposure to combustion products. Smokeless tobacco users take in as much nicotine as cigarette smokers, although not by the pulmonary route.[70] The most extensive and rigorous epidemiological studies on smokeless tobacco use come from Scandinavia, where a large percentage of men use snus, a smokeless tobacco product that contains nicotine but relatively low levels of carcinogens and other toxins. These studies report only a very small cardiovascular disease risk in snus users compared with tobacco smokers.[71] However, discontinuation of snus use after MI has been found to be associated with nearly halved mortality risk, which is similar in magnitude to the benefit associated with smoking cessation.[72] Thus, although the adverse health effects of e-cigarettes are not known, they are likely to be much less than those of cigarette smoking, but could be significant in individuals with heart disease.

Acute nicotine toxicity is a concern if e-cigarette liquids are ingested, which may occur accidentally by children or intentionally by adults as a suicidal overdose, or with dermal exposure. Nicotine is well absorbed through the skin when in an alkaline solution, and e-cigarette liquids are alkaline. Nicotine intoxication commonly causes dizziness, nausea, vomiting, pallor, tachycardia, and sweating. Abdominal pain, salivation, lacrimation, and diarrhea have also been noted. Confusion, agitation, lethargy, convulsions, and possibly death are seen in cases of severe poisonings that cause hypotension and respiratory muscle weakness.[73] In such cases, respiratory arrest is the most likely the cause of death.[73] Symptoms usually begin within 15 minutes of acute liquid nicotine exposure and resolve within 1 to 2 hours.[73] Cutaneous exposure may lead to delayed onset and prolonged symptoms. A number of cases of accidental exposure in children and adults have been reported by poison control centers.[74,75] The concentrations of nicotine in e-cigarette liquids are high enough to be fatal to a child if even a few milliliters is ingested.[76,77] There are isolated reports of severe toxicity, including death, in children who ingested e-cigarette liquids. Nationally, calls to poison control centers attributable to accidental exposure to e-cigarettes have increased dramatically (161%–333%), mostly involving children who were exposed to the replacement cartridges and liquids containing nicotine.[78,79]

Minor Tobacco Alkaloids and Tobacco-Specific Nitrosamines

Some but not all e-cigarette liquids contain minor tobacco alkaloids (such as nornicotine, anabasine, or anatabine) and tobacco-specific nitrosamines, such as *N′*-nitrosonornicotine and 4-(methylnitrosamine)-1-(3-pyridyl)-1-butanone (NNK).[76] These may be present in the liquids because nicotine is extracted from tobacco, and these compounds are present in tobacco. Several minor tobacco alkaloids have nicotine-like actions, although they are less potent than nicotine. Extensive evidence has shown that tobacco-specific nitrosamines are highly carcinogenic[80]; however, the levels of both minor alkaloids and nitrosamines present in most e-cigarette products are low and are unlikely to pose a significant human health risk.[81] Minor alkaloids and tobacco-specific nitrosamine are undetectable in nicotine medications.[82]

Carbonyls and Other Volatile Chemicals

Thermal degradation of propylene glycol can generate propylene oxide, which is classified by the International Agency for Research on Cancer as a class 2B carcinogen. The heating of glycerol can form acrolein, which is an irritant and oxidizing agent thought to contribute to adverse pulmonary and cardiovascular effects of cigarette smoking.[83–85] Analyses of emissions from cigarettes have found primarily formaldehyde, acetaldehyde, and acrolein, along with low levels of toluene, xylene, benzene, and butadiene.[86] Although these compounds are potentially toxic, the levels in e-cigarette emissions are many-fold lower than those found in cigarette smoke and in some cases similar to those found in the mist of medicinal nicotine inhalers. The risk of exposure to low levels of these compounds is unknown. With intense heating, such as from the use of tank models with large batteries, higher amounts of formaldehyde are generated, in some cases similar to levels found in cigarettes smoke.[60,87] Formaldehyde is a carcinogen and an irritant, but the risks of prolonged inhalation of formaldehyde at the levels found in e-cigarette aerosols are unknown.

Propylene glycol and glycerol are added in e-cigarette liquids to generate an aerosol that resembles cigarette smoke. Animal studies of propylene glycol inhalation for up to several months have revealed little or no toxicity.[88,89] Propylene glycol is used to generate theater fog and is used in aviation industries. It can cause eye and respiratory irritation, and there have been concerns about respiratory irritation in the theater.[90] Thus, there are concerns about potential harm from the inhalation of propylene glycol from e-cigarettes, particularly for people with asthma or chronic obstructive lung disease, although there is little research on the effects in susceptible populations.

Metals

Detectable levels of metals such as tin, silver, iron, nickel, cadmium, and copper have been detected in some but not all e-cigarettes in which they could be generated from the heating element.[58] Some e-cigarette solutions contain tin "whiskers," microscopic crystals that emanate from tin in the solder joints.[58] The nature and amount of metals generated depend on the design of the e-cigarette product, and some generate few or no metals. The levels of metals in e-cigarette emission are generally low, but little is known about the toxicity of prolonged inhalation of low levels of metals.

Particles

E-cigarettes generate an aerosol that consists of fine and ultrafine particles in a gas phase. These particles are likely generated from supersaturated 1,2-propanediol vapor. Nanoparticles present in some e-cigarette aerosols have been reported also to contain trace levels of tin, chromium, and nickel.[58] It has been reported that particle number concentration of the mainstream aerosol generated by e-cigarettes, averaged across several liquids and types of e-cigarettes, was similar to that of conventional tobacco cigarettes.[91,92] The number of particles in e-cigarette aerosol has been found to be influenced by the liquid nicotine content and puffing time, and higher levels of particles were generated by e-cigarettes that contained higher nicotine concentrations.[91] The particle size distribution from the few e-cigarette devices that have been tested has been reported to be similar to that of conventional cigarettes.[92] Particles such as those generated by e-cigarettes can reach deep into the lungs and potentially cross into the systemic circulation. Carbonaceous particles present in cigarette smoke and ambient air have been demonstrated to have adverse cardiovascular and respiratory effects in both human and animal models.[93,94] It is not known whether the type of particles generated by e-cigarettes have the same toxicity as particles present in ambient air or those generated by conventional cigarettes, but this is an important question for determining the long-term safety of e-cigarettes.

Toxicology Studies

Results of several toxicology studies with e-cigarette liquids and aerosols have been published. These studies show that e-cigarette liquids and aerosols affect the viability of established cultured cell lines, such as human or mouse fibroblasts, human embryonic stem cells, mouse neural stem cells, and cardiomyoblasts.[95–97] For example, using 3 different cell types (ie, human embryonic stem cells, mouse-derived neural stem cells, and human pulmonary fibroblasts), Bahl et al[95] examined the cytotoxicity of several flavored e-cigarette refill extracts from 4 different manufacturers. They reported that extract flavorings such as Ceylon cinnamon were toxic to all 3 cell types tested. In addition, 1 butterscotch sample was highly toxic, whereas 2 other butterscotch samples from the same company had low toxicity, which shows the within-product and between- product variability.[95] Overall, the human embryonic and neonatal mouse–derived stem cells were more sensitive than adult lung fibroblasts to the cytotoxic effects of the extracts. Cytotoxicity was not caused by nicotine but was correlated with the number and concentrations of flavoring chemicals. In general, cytotoxicity appeared to be related to the concentrations and numbers of flavorings used and unrelated to nicotine. Of particular concern with respect to cytotoxicity of flavorings are the effects of cinnamaldehyde, a flavoring that is approved for use in food but can be dangerous when inhaled.[98] Aerosols of some but not all e-cigarettes have also been reported to be mildly cytoxic.[98]

Although the nature, concentration, and time course of exposure to e-cigarette constituents are likely to be quite different from those present in tobacco cigarette smoke, in

general, the few studies conducted so far suggest that e-cigarette emissions are much less toxic than cigarette smoke in cytotoxicity tests. The significance of these findings to the in vivo toxicity of e-cigarette liquid constituents is not clear, and additional research is needed to establish the potential toxicity of flavors and other e-cigarette constituents.

Human Health Effects

To date, relatively little research has been conducted on the human health effects of e-cigarettes. Spontaneous reports and clinical trial data have reported common minor side effects of throat and mouth irritation, dry cough, nausea, and vomiting. No serious adverse effects have been reported in clinical trials with >6 months of use compared with nicotine patches, with no difference between groups.[53,99] Because propylene glycol as a constituent of theater fog is known to cause respiratory irritation, pulmonary toxicity has been a reasonable concern. One study of 10 healthy smokers using 1 brand of e-cigarette (Nobacco, 11 mg of nicotine, >60% propylene glycol) as desired for 5 minutes found no significant effect on conventional spirometry measures but did find a small but significant increase in dynamic airway resistance (18%) and a significant decrease in exhaled nitric oxide (16%).[100] Smokers in this study had abstained from cigarette smoking for only 4 hours before using e-cigarettes, and there was no comparison with the effects of a conventional cigarette. Another study examined pulmonary function in 15 cigarette smokers and 15 never-smokers who used the same brand of e-cigarette (60% propylene glycol, 11 mg of nicotine).[101] Cigarette smoking caused a significant decrease in forced expiratory volume in the first second of expiration/forced vital capacity (FEV_1/FVC), which was not seen with e-cigarette use. This study also reported that cigarette smoking increased white blood cell count, which reflects an inflammatory response, whereas there was no significant change with the use of e-cigarettes.[101] A small retrospective study of pulmonary function and symptoms in smokers with asthma who switched to e-cigarettes found no adverse effects of e-cigarettes, but rather, the e-cigarette users had improved pulmonary function and reduced severity of asthma symptoms.[102] Eighteen heavy smokers with mild to moderate asthma who were taking a stable dose of inhaled corticosteroids and long-acting β-agonists had pulmonary function tests before and 6 and 12 months after beginning e-cigarette use. These individuals mostly started with e-cigarettes that were cigarette-like, but most switched later to tank-type devices. Ten individuals quit smoking entirely, whereas 8 continued dual use. Dual users decreased their number of cigarettes smoked per day from an average of 22.4 at baseline to 3.9 per day at 12 months. These subjects showed a small but significant improvement in FEV_1 and forced mid-expiratory flow (25%–75%) and reduced airway responsiveness to inhaled methacholine, as well as an improved score on an asthma control questionnaire. The authors comment that the improvement in asthma symptoms may be related to stopping smoking or smoking fewer cigarettes, which could have led to less severe inflammation or a reduction in corticosteroid insensitivity. Although it was small, retrospective, and not controlled, this study does provide evidence that e-cigarette use is not harmful to people with mild to moderate asthma, but more extensive studies are required to establish the safety of e-cigarette use in this population.

Few studies have reported the cardiovascular effects of e-cigarettes. The results of these studies suggest that e-cigarettes can increase heart rate and blood pressure, as expected with systemic absorption in nicotine. The use of e-cigarettes for 7 minutes did not cause diastolic dysfunction, which was seen with conventional cigarette smoking.[55] Another study found that e-cigarette use had no effect on flow velocity reserve of the left anterior descending coronary artery assessed by echocardiography, whereas cigarette smoking caused a decline in flow reserve (16%) and an increase in coronary vascular resistance (19%).[55] A case of atrial fibrillation in an elderly person after e-cigarette use has been reported, an effect that could have been caused by the autonomic nervous system effects of nicotine.[103] One case of lipoid pneumonia has been reported in an e-cigarette user, but the causation is questionable because there is no clear biological plausibility.[102]

In summary, the data on health effects to date, studied primarily in healthy people with short-term exposure, reveal little or no evidence of severe adverse events. Respiratory irritation and the bronchial constriction from a propylene glycol aerosol raise concerns about harm to people with asthma and chronic obstructive pulmonary disease, but 1 small study reports no harm but rather benefit when users quit smoking or smoke fewer cigarettes per day. There are no reports of e-cigarette safety in patients with known cardiovascular disease.

Secondhand E-Cigarette Aerosol Exposure

Passive cigarette smoke exposure is hazardous. It is associated with an increased risk of respiratory disease, including asthma; a variety of infectious diseases; lung cancer; acute coronary events; and stroke.[104] Acute exposure to secondhand smoke produces endothelial dysfunction and platelet activation. Most or all of the acute adverse effects of secondhand smoke are thought to result from exposure to the combustion products of tobacco, including many oxidants and other reactive chemicals.

Most of the secondhand smoke generated from conventional cigarettes results from sidestream smoke, which accounts for 75% of the burning cigarette mass. E-cigarettes do not generate sidestream aerosol. The secondhand emissions from e-cigarettes consist entirely of what is exhaled after inhalation by the user. We focus on data from studies in which aerosol generated by e-cigarette users was evaluated.

Schripp et al[105] studied secondhand emissions by asking a volunteer to use e-cigarettes in a closed chamber. Analysis of the air revealed the presence of formaldehyde, acrolein, isoprene, acetaldehyde, and acetic acid, but at levels 5 to 40 times lower than those generated by a combusted cigarette. Schober et al[106] conducted 6 sessions, each of which consisted of 3 subjects using e-cigarettes as desired for 2 hours in a 45-m^3 ventilated room. The e-cigarettes were refillable tank devices with a liquid that contained both propylene glycol and glycerin and either 22 mg of nicotine per milliliter or zero nicotine. E-cigarette use significantly increased $PM_{2.5}$ (particulate matter <2.5 μm in size), propylene glycol, glycerin, and nicotine, but not formaldehyde, benzene, acrolein, or acetone. There was a 30% to 90% increase in the sum of 16 measured polycyclic aromatic hydrocarbons

and a 2.4-fold increase in ambient aluminum concentration. No comparisons were made to secondhand cigarette smoke. Czogala et al[17] compared ambient levels of nicotine in a ventilated room in which people had either smoked conventional cigarettes or used e-cigarettes. Five subjects generated the aerosol over 1 hour using either pen or tank-type e-cigarettes. With e-cigarette use, the ambient level of nicotine was ≈10% of that seen with smoking conventional cigarettes (3.3 versus 31.6 μg/m^3). The ambient $PM_{2.5}$ concentration after e-cigarette use was ≈18% of that seen with cigarette smoking. In another study by Flouris et al,[101] 15 nonsmokers were exposed in a 60-m^3 ventilated chamber to 1 hour of secondhand cigarette smoke (at a concentration simulating that of a smoky bar) or to e-cigarette aerosol generated by a smoking machine. The study found that serum cotinine was similar in nonsmokers after secondhand tobacco smoke and e-cigarette aerosol exposure (2.6 versus 2.4 ng/mL). Exposure to e-cigarette aerosol had no effect on pulmonary function or white blood cell count. Thus, secondhand exposure to e-cigarette aerosol exposes a nonsmoker to nicotine, particulates, and several potentially toxic organic chemicals, but at much lower levels than from conventional cigarette smoke. The biological effects of such an exposure are expected to be much less than that of secondhand smoke, but nonsmokers are exposed to some nicotine, and the regular use of e-cigarettes has the potential to substantially contaminate the environment with nicotine.

Policy Guidance

Summary Position

The AHA recognizes the increase in e-cigarette use and the need to develop a clear policy position on their use and their impact on the tobacco control movement. E-cigarettes either do not contain or have lower levels of several tobacco-derived harmful and potentially harmful constituents compared with cigarettes and smokeless tobacco. In comparison with NRTs, e-cigarette use has increased at an unprecedented rate, which presents an opportunity for harm reduction if smokers use them as substitutes for cigarettes. However, although firm evidence is lacking, there are concerns that e-cigarette use and acceptance of e-cigarettes has the potential to renormalize smoking behavior, sustain dual use, and initiate or maintain nicotine addiction. Their use also could serve as a gateway to reinitiation of smoking by ex-smokers. Unregulated e-cigarette use also has the potential to erode gains in smoking cessation and smoke-free laws. The AHA considers e-cigarettes that contain nicotine to be tobacco products and therefore supports their regulation under existing laws relating to the use and marketing of tobacco products. To prevent the potential negative public health impact of e-cigarettes, we strongly support laws and regulation that prohibit the sale and marketing of e-cigarettes to youth. We support effective regulation that addresses marketing, labeling, quality control of manufacturing, and standards for contaminants. We also support the inclusion of e-cigarettes in smoke-free air laws. Moreover, we consider it important to monitor and prevent these products from serving as gateway products or as an initiation to nicotine addiction in nonsmokers and reinitiation in smokers. We will continue to assess the scientific evidence relating to their long-term health effects and their efficacy as a smoking cessation aid and encourage the development of a robust research agenda to understand the public health impact of e-cigarettes, especially in at-risk populations.

Below, we summarize the association's current policy guidance on specific issues related to tobacco control, as well as the rationale underlying the policy recommendation. This policy guidance was developed by an expert advisory group and leading researchers in the field of tobacco control and prevention and e-cigarettes, in tandem with a comprehensive review of the literature. The association's policy guidance will continue to be updated as rapidly evolving evidence emerges.

Inclusion of E-Cigarettes in Smoke-Free Air Laws

The AHA supports the inclusion of e-cigarettes in smoke-free air laws.

Although the levels of toxic constituents in e-cigarette aerosol are much lower than those in cigarette smoke,[15] there is still some level of passive exposure to organic compounds, nicotine, and fine particles.[58,105,107] To date, there is insufficient evidence to support the notion that exposure to exhaled aerosol has a deleterious impact on bystanders.[26] Some studies have found very low concentrations of air pollutants across different types, liquids, puff durations, and nicotine concentrations.[15,105] The levels of particle and nicotine exposure vary with the composition of the liquids, the type of e-cigarette, size of the room, puff duration, interval between puffs, and the number of users.[105] Nevertheless, there is concern that nonsmokers will be involuntarily exposed to nicotine, which could be substantial where there is heavy e-cigarette use in confined spaces. Moreover, unregulated e-cigarette use has the potential to recreate a social norm around tobacco product use in public places,[108–110] unraveling decades of work on comprehensive smoke-free air laws. It is not always easy to identify that a person is using an e-cigarette, because there is not the large plume of smoke or the strong detectable odor that comes from conventional cigarettes. Therefore, the use of e-cigarettes creates enforcement issues for employees in restaurants, bars, airport terminals, planes, and other smoke-free public places. E-cigarette companies are marketing their products to be used in all the places where smoking is banned, including bars, restaurants, hotels, offices, and airplanes, which promotes unregulated use.

Although the AHA supports the inclusion of e-cigarettes in new smoke-free laws, the AHA only supports changing existing smoke-free laws to include e-cigarettes when it can be ensured there will be no amendments attached to the legislation that would weaken existing laws.

Preventing Youth Access

The AHA supports the inclusion of e-cigarettes in state and federal laws and regulations that prohibit the sale of e-cigarettes to minors.

There is concern among public health advocates that e-cigarettes could increase nicotine addiction and serve as a gateway for the use of tobacco products, particularly among youth. As discussed above, adolescents view e-cigarettes as safer than conventional cigarettes, more convenient to use, and more readily accessible.[45] Their attraction to these "high-tech" devices is

fueled further by the marketing practices of the tobacco industry, which is manufacturing flavored e-cigarettes that are likely to be more appealing to a younger population. To reduce the availability of e-cigarettes among youth, 22 states have enacted e-cigarette youth access laws and 6 states have youth access laws for tobacco-derived or nicotine-containing products without explicitly using "e-cigarette" or similar terms in their law.[111] For instance, Arizona, California, New Jersey, and New Hampshire have now banned e-cigarette sales to minors. In its proposed rule on "Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act" the FDA proposed to ban the sales of e-cigarettes to consumers under the age of 18, which is similar to the existing federal ban on the sale of cigarettes and smokeless tobacco products to minors under the Family Smoking Prevention and Tobacco Control Act. Given that e-cigarettes are actively sold via Websites across state lines,[10] it is essential to develop a comprehensive federal law or regulation banning e-cigarette sales to minors because state laws are a temporary patchwork approach[112] and only the federal government can regulate interstate commerce.[113–115]

Marketing and Advertising to Youth

The AHA supports the inclusion of e-cigarettes in laws that restrict the marketing and advertising of e-cigarettes to minors.

There is robust marketing and advertising of e-cigarettes on television and in magazines using celebrities as well as flavorings to make these products particularly attractive to children and adolescents.[10] Many of these advertisements have themes that promote rebelliousness and glamorize e-cigarette use, which conveys the message to youth that e-cigarette use is fun, socially acceptable, and desirable. Youth exposure to e-cigarette advertising increased more than 250% from 2011 to 2013, with e-cigarette advertisements reaching >24 million youths during this period.[48] Such marketing practices are likely to recruit a new generation of nicotine addicts. The public health community is unified in developing regulation and passing legislation that restricts the marketing and access of e-cigarettes to minors, similar to existing laws restricting marketing and youth access to combustible products.

Taxing E-Cigarettes

The AHA supports taxing e-cigarettes at a rate high enough to discourage youth use, while retaining or increasing differentials with combustible products by increasing taxes on combustibles. Any revenue generated through taxation ideally should support tobacco cessation and prevention programs.

The diversity of products makes it difficult to develop a uniform tax policy for various devices and refills, and it also creates opportunities for avoidance. An ad valorem tax, one levied as a percentage of price, preferably at the retail level, could include all components of e-cigarettes and related devices. However, a tax that is too high would create a barrier to switching to e-cigarettes among low-income users of combustible tobacco. Growing evidence shows that e-cigarette users are more responsive to price than cigarette use, with 1 study estimating that a 10% increase in e-cigarette prices would reduce sales of reusable e-cigarettes by ≈19% and sales of disposable e-cigarettes by ≈12%.[116] Similarly, data from a survey with adult tobacco users show that their low prices relative to other tobacco products is a key reason for use among many current e-cigarette users (F. Chaloupka, written communication, June 6, 2014).[116] The initial cost of a reusable e-cigarette is higher, although over the long-term, they are cheaper because the reusable devices can be used over and over again. Hence, although a tax on the initial product could be punitive, especially for the low-income users, it is critical that the tax be high enough to deter youth access, because it has been demonstrated repeatedly that youth are especially price sensitive.[118,119] At the same time, increasing taxes on combustible tobacco products would prevent youth uptake, encourage some adult users to quit or cut back, and likely increase interest in switching from combustible products to e-cigarettes.

FDA Regulation of E-Cigarettes

The AHA supports effective FDA regulation of e-cigarettes that addresses marketing, youth access, labeling, quality control over manufacturing, free sampling, and standards for contaminants. The regulation should allow for quality-controlled products for adults who want to transition from conventional cigarettes to e-cigarettes or to quit or reduce smoking. Bottles containing nicotine refill liquids can be toxic if swallowed, so cartridges and bottles should have proper warning labeling and child-proof packaging.[120] It is important that the relevant government agency monitor whether these devices are used for delivery of other drugs and medications. Companies should not be able to claim that e-cigarettes are a cessation aid unless they are approved by the FDA for that purpose.

The FDA has currently issued its proposed rule to give the agency oversight over e-cigarettes, addressing youth access, sampling, ingredient listing, manufacturing, and warning labels, but not addressing marketing and advertising or flavorings. Some products currently on the market are unreliable and poorly designed, and there is inadequate and inaccurate labeling of constituents.[121,122] Several companies are moving their manufacturing processes from China to the United States to prepare for the standardization and quality control that will be required under FDA oversight.[123] Adverse event reports regarding e-cigarette use are being monitored in many countries across the globe. In the United States, the Center for Tobacco Products under the FDA is developing a tobacco-specific adverse event reporting system for e-cigarettes. Consumers or healthcare providers can report adverse events for any tobacco products through the Department of Health and Human Services' Safety Reporting Portal.[124] The FDA would regulate e-cigarettes for tobacco cessation under current rules via the Center for Drug Evaluation Research, and as is the case for all other approved cessation aides, this would require rigorous safety and efficacy studies. FDA oversight is critically important to ensure that e-cigarettes and similar products are not harmful to public health.

The entry of the major US cigarette manufacturers (Altria Group, Reynolds American, and Lorillard) into the marketplace raises a number of potential public health concerns. Rather than encouraging cessation, the tobacco industry could promote e-cigarettes as a way to circumvent clean indoor air policies, thereby promoting dual use to sell more conventional cigarettes. The industry could also steer e-cigarette users to combustible products and thereby increase rather than

decrease nicotine and tobacco addiction.[125] E-cigarette manufacturers are spending millions of dollars and working with major lobbying firms to pass legislation or influence regulation to exempt e-cigarettes or carve out a special classification.[126]

In the European Union, starting in 2016, advertisements for e-cigarettes will be banned in all 28 nations, the packaging must be childproof and have graphic warning labels, and the nicotine content will be limited to 20 mg/mL.[127] The new regulations are part of a larger regulatory package that will impose even stricter rules on combustible tobacco products. The European Parliament backed off of its original proposal, which would have treated e-cigarettes as a medical or drug-delivery device, but allows member states to categorize them as a cessation aid if member states choose to do so.[127]

E-Cigarettes and the Potential to Regulate Nicotine Content of Conventional Cigarettes

The public health benefit of e-cigarettes competing with conventional cigarettes in a free marketplace is uncertain. Some potential harms, such as toxicity of unregulated products and marketing to youth, could be mitigated by effective FDA regulation. Possibly in the context of free market competition and perhaps with improved e-cigarette products, smokers would find e-cigarettes sufficiently attractive to use them to quit smoking. On the other hand, the permissive availability of e-cigarettes could result in an increase in nicotine addiction without a reduction in overall use of conventional cigarettes. A broader public health strategy could be developed that would combine regulation for combustible products, including regulation of characteristics and pricing, with the regulation of e-cigarettes or other electronic nicotine devices that appeal to smokers.[128] In 1994, the idea of reducing the nicotine content of cigarettes to make cigarettes less addictive was proposed, but the strategy was not implemented.[129] In 2009, the FDA gained regulatory authority over tobacco, which includes the authority to reduce nicotine in cigarettes to make them less addictive, as long as the nicotine level is not reduced to zero. Such a nicotine reduction regulatory policy could mandate nicotine reduction in all manufactured tobacco products so that they would not sustain addiction. Research is ongoing on the safety and the effects of smoking behavior with cigarettes with reduced nicotine content.[130,131] If a reduced nicotine content regulatory strategy becomes policy, cigarettes could become less addictive because of limited nicotine availability, and therefore, less attractive to the smoker. If at the same time, e-cigarettes are widely available, it could potentially help the cigarette smoker to transfer their nicotine addiction from tobacco to a cleaner form of nicotine delivery. This transition could be facilitated by differential taxation and could reduce the burden of cigarette-induced disease. Nevertheless, at present, it remains unclear whether society would be accepting of recreational nicotine addiction if associated with minimal health consequences. Modeling the health effects of reducing the nicotine content of cigarettes to nonaddictive levels, Tengs et al[132] concluded that "Policy makers would be hard-pressed to identify another domestic public health intervention, short of historical sanitation efforts, that has offered this magnitude of benefit to the population."

Cessation Counseling

The AHA maintains that e-cigarette use should be part of tobacco screening questions incorporated into clinical visits and worksite/community health screenings that are tied to healthcare delivery. Clinicians should be educated about e-cigarettes and should be prepared to counsel their patients regarding comprehensive tobacco cessation strategies. There is not yet enough evidence for clinicians to counsel their patients who are using combustible tobacco products to use e-cigarettes as a primary cessation aid. The association will continue to monitor the evidence concerning e-cigarettes as cessation devices to determine whether they might be integrated into comprehensive cessation strategies. For patients with existing cardiovascular disease and stroke, or at risk of a cardiovascular disease event, intensive cessation counseling should be offered as soon as possible. (See Table 2 for a summary of recommended clinical guidance.)

The efficacy of e-cigarettes as a primary smoking cessation aid has not been established as being better than other cessation modalities. Current evidence[50,53,134] suggests at best a modest effect on cessation, likely equal to or slightly better than that of nicotine patches without behavioral support. If a patient has failed initial treatment, has been intolerant to

Table 2. Summary of Current Recommendations for Clinical Guidance

E-cigarette use should be included in tobacco screening questions that are part of every health examination.
Clinicians should be educated about e-cigarettes and should be prepared to counsel their patients regarding comprehensive tobacco cessation strategies.
Patients should be separated into 3 treatment categories based on their tobacco/e-cigarette use status[133]: 1. Tobacco product users who are willing to quit should receive intervention to help them quit 2. Tobacco product users unwilling to quit at the time should receive interventions to increase their motivation to quit 3. Those who recently quit using tobacco products should be provided relapse prevention treatment
There is not yet enough evidence for clinicians to counsel their patients who are using tobacco products to use e-cigarettes as a primary cessation aid.
If a patient has failed initial treatment, has been intolerant to or refuses to use conventional smoking cessation medication, and wishes to use e-cigarettes to aid quitting, it is reasonable to support the attempt. However, patients should be informed that although e-cigarette aerosol is likely to be much less toxic than cigarette smoking, the products are unregulated, may contain low levels of toxic chemicals, and have not been proven to be effective as cessation devices.
In the absence of long-term safety studies of e-cigarette use, it may be appropriate to advise the patient to consider setting a quit date for their e-cigarette use and not to plan to use it indefinitely (unless needed to prevent relapse to cigarettes).
It is also important to stress that patients should quit smoking cigarettes entirely as soon as possible, because continued cigarette smoking, even at reduced levels, continues to impose tobacco-induced health risks.
For patients with existing CVD or stroke, or at risk of a CVD event, intensive cessation counseling and pharmacotherapy should be offered as soon as possible.

CVD indicates cardiovascular disease; e-cigarette, electronic cigarette.

or refused to use conventional smoking cessation medication, and wishes to use e-cigarettes to aid quitting, it is reasonable to support the attempt. However, subjects should be informed that although e-cigarette aerosol is likely to be much less toxic than cigarette smoking, the products are unregulated, may contain low levels of toxic chemicals, and have not been proven as cessation devices. Because there are as yet no long-term safety studies of e-cigarette use, it may be appropriate to advise the patient to consider setting a quit date for their e-cigarette use and not plan to use it indefinitely (unless needed to prevent relapse to cigarettes). It is also important to stress that patients should quit smoking cigarettes entirely as soon as possible, because continued cigarette smoking, even at reduced levels, continues to impose tobacco-induced health risks.

Employers will have to decide whether employees who use e-cigarettes exclusively will be considered tobacco users. Within the context of incentive design within healthcare plans associated with a worksite wellness programs, employers may charge tobacco users up to 50% more for their health insurance under the new Affordable Care Act regulations. There is no significant evidence that these tobacco surcharges increase quit rates, although 1 study showed that self-reported quit rates did increase more than the national average in Georgia State Health Benefit Plan employees.[135] With currently available methods, it is not possible to distinguish between a cigarette smoker and an e-cigarette user, because only the levels of cotinine are measured. Because cotinine is a metabolite of nicotine, it is likely to be present in the blood or urine of a user of e-cigarettes, combustible cigarettes, other tobacco products, and even nicotine patches. Hence, until newer methods are developed to distinguish between e-cigarettes and conventional cigarette use, employers would have to base their decisions primarily on self-report. Whether or not employers choose to penalize employees who are using e-cigarettes, employers should provide comprehensive cessation benefits to employees that include behavioral counseling and pharmacotherapy with a minimal copay or deductible for all users of tobacco products.

Insurance companies may also assess the 50% penalty in the individual market, although 10 states prohibit or restrict the ability of insurance companies to do that.[136,137] Along with age, geographic location, and family size, tobacco use is 1 of 4 variables that insurers can take into account when selling plans on the individual market. The AHA is concerned that the tobacco surcharge will make it difficult for tobacco users to access the cessation services they need. At minimum, insurers in the individual marketplace, like employers, should provide comprehensive tobacco cessation benefits with minimal copays or deductibles for all e-cigarette and tobacco users.

Surveillance for E-cigarette Use and Health Impact

The AHA recognizes the need to improve and increase surveillance on e-cigarette use throughout the US and global population and establish a research agenda to elucidate the longitudinal public health impact of e-cigarette use.

There is a need to increase or maintain surveillance using high-quality longitudinal studies on the prevalence of e-cigarette use in adults, children, and adolescents; quit attempts; quit rates; e-cigarette rates versus smoking rates; dual use (with combustible tobacco or other tobacco products); and reinitiation of ex-smokers to e-cigarettes and then perhaps back to tobacco. Current surveillance should also include adequate reference to the emerging products entering the marketplace to ensure there is a thorough understanding of the true prevalence of use of these alternatives to combustible products. Surveillance should also capture how these devices are being used for delivery of other legal or illicit drugs. There must be further experimental research and surveillance on the short-, medium-, and long-term physiological effects of deep lung inhalation of not only the nicotine but also propylene glycol and glycerol, flavorings, and other ingredients. Experimental research and surveillance also needs to capture the long-term population health impact, effect on fetal development, and physiological and behavioral effects of these ingredients, as well as the health impact of secondhand and thirdhand exposure.

Defining E-Cigarettes in State Law

The AHA supports including e-cigarettes in the definition of tobacco products (or tobacco-derived products) and smoking, not by creating a separate definition for e-cigarettes, because a separate definition can create a risk of e-cigarettes being exempted from other tobacco control laws, including smoke-free laws. E-cigarettes defined as tobacco products could still be treated differently within taxation legislation and regulation.

Bringing e-cigarettes within a general definition of "tobacco products" in state or local law is also entirely consistent with their treatment under federal law. In *Sottera, Inc. (dba NJOY) v FDA* (627 F2d 891 [DC Cir 2010]), an e-cigarette manufacturer argued that its products could only be regulated by the FDA as tobacco products under the Family Smoking Prevention and Tobacco Control Act of 2009, not under the drug/device provisions of the Food, Drug, and Cosmetic Act.[138] The court agreed with the manufacturer, holding that e-cigarettes fit within the broad definition of *tobacco product* in the Tobacco Control Act ("any product made or derived from tobacco that is intended for human consumption"). The court further held that e-cigarettes could be regulated only under the Food, Drug, and Cosmetic Act if marketed with therapeutic claims. Thus, in *Sottera,* an e-cigarette manufacturer sought to be regulated by the FDA as a manufacturer of a "tobacco product," and the court agreed that such regulation was within the FDA's authority as a matter of federal law.[138,139] These decisions were made although e-cigarettes do not actually contain tobacco, only nicotine derived from tobacco. The AHA agrees with the courts' rulings in defining e-cigarettes as tobacco products in legislation and regulation and has worked with public health partners to develop a consensus definition of tobacco products that includes e-cigarettes (Table 3). This definition includes e-cigarettes even if they do not contain nicotine, that is, any electronic device that delivers nicotine or other substances. The inclusion of all e-cigarettes in the definition facilitates implementation of laws and regulation. For example, when enforcing a clean indoor air policy, it would be impossible to determine whether someone who is "vaping" is using an e-cigarette that does or does not contain nicotine

Future Research Agenda

Because e-cigarettes are relatively new products, little is known about their use, their characteristics, or their long-term health effects on individual users and public health. Extensive

research is required to address these questions. This will help in developing more robust policies to regulate e-cigarette use, marketing, and distribution. In view of the paucity of evidence, current guidelines must be regarded as provisional and should be revised in light of future research. However, e-cigarette research faces major challenges. E-cigarettes are not a well-defined entity but a collection of rapidly changing devices that deliver nicotine and contain a variety of additives that are also changing constantly. As a result, it is possible that research on specific e-cigarettes would become obsolete as product characteristics, design features, constituents, and additives change and new products appear on the market. Therefore, research will have to keep pace with the rapidly evolving market. Nonetheless, several invariant areas of future research could be identified, which are listed below.

Physicochemical Studies

Extensive work is required to develop a better understanding of the types of e-cigarettes currently in use and the ingredients they contain. To understand the nature of e-cigarette exposure, it is important to determine how heating time and duration of puffing alter exposure and the composition and characteristics of the vapor, as well as how each of these factors is affected by the design features of different devices. It will be important to evaluate how smoking e-cigarettes deposits nicotine and other chemicals in the environment and how these emissions and depositions affect secondhand and thirdhand exposures. Additional research is needed to evaluate the efficacy of vaping devices in delivering chemicals, drugs, and pharmaceuticals other than nicotine and to document manufacturing practices and quality control issues, so that the listed ingredients correspond to the actual composition of the device.

Perception

Profiles and perceptions of e-cigarette users have been documented in the literature; however, most of these data are derived from informal surveys from the Internet and other sources. New research is needed to determine the use and spread of e-cigarettes in different population subgroups and communities and to identify demographic factors that contribute to e-cigarette use in the general population. Additional research is also required to examine use trajectories, harm perception, and user expectations, as well as to determine how flavors affect perception and how future regulations might affect user profile and perception.

Use Pattern

Although extant data provide some indication of how e-cigarettes are currently being used, additional work is required to determine typical e-cigarette usage, with special emphasis on understanding brand/type preference and loyalty, frequency of use, brand switching, flavor preference, and the effects of puff duration. These issues also relate to questions about optimal dosing, such as the optimal dose (or use) for cessation by product type and the dose and use patterns that sustain nicotine addiction or satisfy nicotine craving over time. It would be important to know whether and how these devices are being used to deliver other drugs and medication and whether their use is particularly widespread in vulnerable populations, such as youth, trendsetters, populations with low socioeconomic status, current smokers, ex-smokers, veterans, the mentally ill, those with substance use disorders, and the lesbian/gay/bisexual/transgender community.

Health Effects and Toxicity

Preclinical studies, preferably in animal models, are required to evaluate e-cigarette toxicity. Although animal models have obvious limitations, and their relevance to human exposures is often uncertain, these models could be useful in assessing the pharmacokinetic, pharmacodynamic, and toxicokinetic properties of e-cigarette exposures. Data from these studies will be useful in assessing acute and chronic toxicity, as well as the respiratory, carcinogenic, teratogenic, metabolic, immunological, and cardiovascular effects of e-cigarettes. The pathophysiological outcomes and biomarkers, identified in animal studies, should also be evaluated in controlled human exposure studies to develop validated concordance between animal and human data.

Data from in vitro and animal studies could inform the design of studies to evaluate the acute and chronic health effects of e-cigarettes. Acute effects could be evaluated in cross-sectional or cross-over studies examining the respiratory, metabolic, neurological, and cardiovascular effects, as well as the effects on insulin resistance, appetite, and weight loss. These data would be particularly informative and interesting if the health effects of e-cigarettes are compared directly with conventional cigarettes or other tobacco products. Such comparisons will help in identifying not only e-cigarette–specific health effects but also the effects common to e-cigarettes and other tobacco products. Because cross-sectionals studies cannot establish directionality, progression, or causality, long-term longitudinal cohort studies are needed to assess how e-cigarette use affects the progression of subclinical disease. The results of well-powered, multicenter, prospective cohort studies with significant follow-up will provide important data for further refining policy recommendations.

Environmental Effects

Environmental research is needed to characterize e-cigarette emissions and to determine the chemical nature, size, and abundance of particulate matter generated in e-cigarette emission. In this research, it will be important to address the relative distribution of fine and ultrafine particles and to identify the chemical composition of these particles. Such studies are required to determine how changes in design features, additives, and constituents affect the direct toxicity of e-cigarette emissions. A particularly important issue that has direct bearing on regulation is the extent of secondhand and thirdhand exposure. Although e-cigarette emissions contain fewer chemicals and lower concentrations of toxicants than conventional cigarettes, the health effects of secondhand e-cigarette aerosol exposure are not known. Currently, most communities advocate the inclusion of e-cigarettes in smoking bans. This is justified because public use of e-cigarettes leads to involuntary exposure to a psychoactive drug (nicotine) in bystanders. However, additional work is required to identify constituents of e-cigarette emissions, how these emissions are dispersed in the environment, and how the

characteristics of the environment affect the dispersal and the health effects of such emissions.

Psychological Effects

Evaluation of the psychological effects of e-cigarettes is of utmost importance in understanding how the use of these devices supports or promotes nicotine addiction and whether they aid nicotine cessation or abstinence. Although the results of some studies suggest that as a cessation aid, e-cigarettes can be at least as effective as other NRTs, further work with larger cohorts is required to establish not only their efficacy as cessation aids but also how these devices affect nicotine addiction and withdrawal, as well as how they compare with other NRTs in user satisfaction and dependence. An important question is whether e-cigarette use merely facilitates abstinence from smoking conventional cigarettes or results in complete independence from nicotine addiction. In studying the use of these devices for cessation, it is important to determine whether counseling or behavioral support would enhance efficacy, and if so, what are the most effective instructions required for the proper use of these devices as a cessation aid? And should physicians and health providers counsel for or against e-cigarette use? Research findings addressing these questions are likely to have a major impact on our understanding of the nature of nicotine addiction and how it is supported by conventional cigarettes versus e-cigarettes. Again, prospective cohort studies with long-term follow-up will be most useful in assessing how e-cigarette use affects nicotine addiction.

Marketing and Communications

Marketing and communications research is needed to determine how e-cigarettes are being marketed and how information about them is being communicated to their target audience. Research is needed to identify how specific marketing techniques are used to target specific groups, which specific groups are being targeted, and what effects labeling, product placement, advertisements, free sample distribution, location in stores, and celebrity endorsement have on e-cigarette sales, preference, and use. Additional research is needed to identify effective communication techniques for conveying health information, potential hazard or benefit, and regulatory information. By establishing a partnership with consumers, it may be possible to identify consumer perceptions and expectations and to identify cultural, social, and economic factors that impact e-cigarette use.

Surveillance

Surveillance of e-cigarette use is just beginning at the national level in the United States and is generally lacking at the state and local level. At the national level, several surveys have been collecting information, including the National Youth Tobacco Survey in 2011 and 2012 (http://www.cdc.gov/tobacco/data_statistics/surveys/NYTS/), the National Health and Nutrition Examination Survey beginning in 2013 (http://www.cdc.gov/nchs/data/nhanes/nhanes_13_14/SMQ_ACASI_H.pdf), and the National Health Interview Survey beginning in 2014 (ftp://ftp.cdc.gov/pub/Health_Statistics/NCHS/Survey_Questionnaires/NHIS/2014/english/qadult.pdf). The Behavioral Risk Factor Surveillance System, a major source of information regarding health behaviors at the state level, did not collect information about use of e-cigarettes as of 2013 (http://www.cdc.gov/brfss/questionnaires/pdf-ques/2013%20BRFSS_English.pdf).

The questions included in these surveys differ somewhat, primarily in the breadth of information collected. E-cigarette questions in the surveys above should use a similar format so the data can be pooled. Efforts to understand the public health impact of e-cigarettes require improved monitoring of awareness of the availability of e-cigarettes, beliefs about their health effects, and attitudes and behaviors regarding their use. Additional information is needed across the life span, especially in vulnerable groups, including children, and at the appropriate level to guide policy development, implementation, and evaluation; for these purposes, local and state-level data will be particularly important.

Postmarket surveillance is essential to understand and evaluate the public health impact of e-cigarettes. Such surveillance could include monitoring sales data, following the development and changes in the role of big tobacco companies and small entrepreneurs. Continuous pharmacovigilance is required to assess the safety and efficacy of these devices, changes in sales and marketing strategies, design features, and constituents. Such activities will be significantly facilitated by future regulation, which could define parameters for evaluating safety and regulatory compliance.

Economic Studies

Future research in economic issues relating to e-cigarettes is needed to evaluate the effect of taxation on e-cigarette sales and to assess the impact of e-cigarettes on healthcare costs and insurance premiums. Evaluation of the effect of taxation would be particularly important because this could have a significant impact on e-cigarette use across different populations. This type of research can be accomplished by both empirical research and observational studies, which will take longer and will require continuous analysis of sales data and purchasing behavior. Modeling work can be performed more quickly to predict what might happen with different approaches to taxation. Research in this area could be extended to include the cost of different devices and the contribution of e-cigarette sales to local and federal economies.

Legal and Regulatory Issues

Research is required to monitor and assess the effect of regulation on use, safety, and quality control and to determine the impact of legislation and regulation on industry and user responses.

Conclusions

E-cigarettes represent a major change in the tobacco control landscape. This policy guidance is developed from the current international evidence base and tobacco control environment in the United States. The AHA will continue to monitor the impact of these new technologies on population health, cardiovascular disease, and stroke and will give special attention to the effect on youth and adolescents. The association's policy position and clinical guidance will evolve over time with the rapidly emerging research and evidence base for this field.

Appendix: Definitions*

"Tobacco product" means:

(a) Any product containing, made, or derived from tobacco or containing nicotine, whether synthetically produced or derived from other sources that is intended for human consumption (and not marketed for cessation), whether smoked, heated, chewed, absorbed, dissolved, inhaled, snorted, sniffed, or ingested by any other means, including but not limited to cigarettes, cigars, little cigars, chewing tobacco, pipe tobacco, snuff†; and

(b) Any electronic device that delivers nicotine or other substances to the person inhaling from the device, including but not limited to an electronic cigarette (e-cigarette), cigar, pipe, or hookah.

(c) Notwithstanding any provision of subsections (a) and (b) to the contrary, "tobacco product" includes any component, part, or accessory of a tobacco product, whether or not sold separately. "Tobacco product" does not include any product that has been approved by the US Food and Drug Administration for sale as a tobacco cessation product or for other therapeutic purposes where such product is marketed and sold solely for such an approved purpose.

It is important to note that this definition would include e-cigarettes, even if they do not contain nicotine. Thus, subsection (b) refers to "any electronic device that **delivers nicotine or other substances"** to cover devices (and components) regardless of whether they actually have nicotine or are being used to deliver nicotine. It was also recognized that there are alternative phrases that could be used to similarly expand coverage to non-nicotine products. For instance, the definition could refer to devices that "can be used to deliver nicotine."

"Simulate Smoking" Language

It is not desirable to include language describing e-cigarettes as devices that are, or can be, used to "simulate smoking." The vagueness of this phrase may give certain companies the opportunity to argue that their particular products are not covered because users are "vaping" instead of "smoking." Given the wide variety of e-cigarette designs emerging in the exploding marketplace for these products, there is some potential for companies to argue that their particular design looks nothing like a cigarette and that its use cannot be said to "simulate smoking." Because the phrase could have a limiting effect on the products covered and does not appear to be needed to effectively regulate e-cigarettes, it would be best to avoid including it.

Separate Definition of "E-Cigarette"

Generally speaking, use of this "tobacco product" definition or similar language would obviate the need to include a definition of "e-cigarette" that is separate and distinct from the definition of "tobacco product." However, in some states, it may not be possible to include the full description of e-cigarettes in the tobacco product definition. Also, if special circumstances arise in a state that suggests the desirability of both including e-cigarettes as "tobacco products" while also including a definition of e-cigarettes apart from the definition of "tobacco product," a separate definition of e-cigarette could be adapted from subparts (b) and (c) of the consensus "tobacco product" definition:

E-cigarette‡ means:

> *Any electronic device that delivers nicotine or other substances to the person inhaling from the device, including but not limited to an electronic cigarette, cigar, pipe, or hookah, including any component, part, or accessory of such a device, whether or not sold separately. E-cigarette shall not include any product that has been approved by the US States Food and Drug Administration for sale as a tobacco cessation product or for other therapeutic purposes where such product is marketed and sold solely for such an approved purpose.*

Finally, if a definition of "e-cigarettes" separate from the definition of "tobacco product" is desirable, then the definition of "tobacco product" will need to list "e-cigarettes" as one of the products to be considered "tobacco products."

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*These definitions were developed by an expert advisory group convened by the Campaign for Tobacco-Free Kids in April 2014. Participants were Chris Sherwin of the American Heart Association, Thomas Carr of the American Lung Association, Cathy Calloway of the American Cancer Society Cancer Action Network, and Nichole Veatch, Denny Henigan, and Ann Boonn of the Campaign for Tobacco-Free Kids.

†This list of products is subject to adjustment to conform to terms used in specific state or local laws.

‡Terms such as "electronic smoking device" or "electronic nicotine delivery systems" could be used interchangeably with "e-cigarettes."

Disclosures

Writing Group Disclosures

Writing Group Member	Employment	Research Grant	Other Research Support	Speakers' Bureau/ Honoraria	Expert Witness	Ownership Interest	Consultant/ Advisory Board	Other
Aruni Bhatnagar	Director, Diabetes and Obesity Center, Smith and Lucille Gibson Professor, Division of Cardiovascular Medicine, University of Louisville, Co-Director, American Heart Association Tobacco Regulation and Addiction Center	None	None	None	None	None	None	None
Neal Benowitz	Professor of Medicine and Bioengineering & Therapeutic Sciences Chief, Division of Clinical Pharmacology University of California San Francisco	NIH grant: California Tobacco Related Disease Research Program†; Flight Attendant Medics Inst†	None	None	2014: Plaintiff, litigation against tobacco companies	None	Pfizer*	None
Chris Bullen	Director of the National Institute for Health Innovation and Associate Professor, School of Population Health, The University of Auckland, Auckland, New Zealand	In 2007, my group received funding from HealthNZ Ltd to conduct a small trial on Ruyan e-cigarettes; the product used in the trial was supplied by Ruyan Ltd.	Principal Investigator of the ASCEND e-cigarette efficacy trial, in which the e-cigarettes were provided by PGM International Ltd, a supplier of e-cigarettes (the trial was funded by the Health Research Council of NZ)*	None	None	None	Consultant on a USFDA/ NIH cofunded TCORS grant on e-cigarettes	None
Frank Chaloupka	Distinguished Professor, University of Illinois–Chicago	None	None	None	None	None	None	None
David Goff	Dean, Colorado School of Public Health	None	None	None	None	None	None	None
Timothy McAuley	Founder and Chief Executive Manager of Consulting for Health, Air, Nature, & a Greener Environment, LLC (CHANGE)	None	None	None	None	None	None	None
Mariann R. Piano	Professor of Nursing and Interim Head of the Department of Biobehavioral Health Science at the University of Illinois at Chicago College of Nursing	None	None	None	None	None	None	None
Rose Marie Robertson	American Heart Association Co-Director, American Heart Association Tobacco Regulation and Addiction Center	None	None	None	None	None	None	None
Kurt M. Ribisl	Professor, Health Behavior, University of North Carolina	None	None	None	None	None	None	None
Laurie P. Whitsel	Director of Policy Research, American Heart Association	None	None	None	None	None	None	None

This table represents the relationships of writing group members that may be perceived as actual or reasonably perceived conflicts of interest as reported on the Disclosure Questionnaire, which all members of the writing group are required to complete and submit. A relationship is considered to be "significant" if (a) the person receives $10 000 or more during any 12-month period, or 5% or more of the person's gross income; or (b) the person owns 5% or more of the voting stock or share of the entity, or owns $10 000 or more of the fair market value of the entity. A relationship is considered to be "modest" if it is less than "significant" under the preceding definition.

*Modest.

†Significant.

Reviewer Disclosures

Reviewer	Employment	Research Grant	Other Research Support	Speakers' Bureau/Honoraria	Expert Witness	Ownership Interest	Consultant/ Advisory Board	Other
Maciej Goniewicz	Roswell Park Cancer Institute	Pfizer-Global Research Awards for Nicotine Dependence (GRAND) 2011*	None	None	None	None	None	None
Steve A. Schroeder	UCSF	Robert Wood Johnson Foundation†	American Legacy Foundation†	None	None	None	None	None
Kenneth Warner	University of Michigan	Robert Wood Johnson Foundation (finishing grant on the tobacco endgame)*; Robert Wood Johnson Foundation (finishing grant on Tobacco Regulation Economics that relates to FDA's economic analysis of its graphic warning proposal)*	None	None	None	None	None	None
Rachel Widome	University of Minnesota	None	None	None	None	None	Association for Non-Smokers Minnesota*	None

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*Modest.

†Significant.

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KEY WORDS: AHA Scientific Statements ■ cardiovascular disease ■ e-cigarettes ■ nicotine ■ public health ■ smoking ■ tobacco ■ tobacco smoke pollution

Electronic Cigarettes: A Policy Statement From the American Heart Association

Aruni Bhatnagar, Laurie P. Whitsel, Kurt M. Ribisl, Chris Bullen, Frank Chaloupka, Mariann R. Piano, Rose Marie Robertson, Timothy McAuley, David Goff and Neal Benowitz
on behalf of the American Heart Association Advocacy Coordinating Committee, Council on Cardiovascular and Stroke Nursing, Council on Clinical Cardiology, and Council on Quality of Care and Outcomes Research

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Oversight lags e-cig boom in China

With few safety regulations, nation produces 90% of world's electronic cigarettes

By DAVID BARBOZA

NEW YORK TIMES

SHENZHEN, China — In a grimy workshop, among boiling vats of chemicals, factory workers are busy turning stainless-steel rods into slender tube casings, a crucial component of electronic cigarettes. Not long ago, Skorite Electronics was a tiny firm struggling to produce pen parts. Today, it is part of an enormous — and virtually unregulated — supply chain centered here that produces about 90 percent of the world's e-cigarettes.

This year, Chinese manufacturers are expected to ship more than 300 million e-cigarettes to the United States and Europe, where they will reach the shelves of Wal-Marts, 7-Eleven stores, gas station outlets and vaping shops.

The devices have become increasingly popular, particularly among young adults, and yet hundreds of e-cigarette manufacturers in China operate with little oversight. Experts say flawed or sloppy manufacturing could account for some of the heavy metals, carcinogens and other dangerous compounds, such as lead, tin and zinc, that have been detected in some e-cigarettes.

One study found e-cigarette vapor that contained hazardous nickel and chromium at four

TURN TO**E-CIG,** PAGE A12

Reports of explosions from overheating

CONTINUED FROM PAGE A1

times the level they appear in traditional cigarette smoke; another found that half the e-cigarettes sampled malfunctioned and some released vapor tainted with silicon fibers.

There have also been reports in the U.S. of e-cigarettes that exploded after a lithium ion battery or electric charger overheated, causing burns.

"We need to understand what e-cigarettes are made of," says Avrum Spira, a lung specialist at the Boston University School of Medicine, "and the manufacturing process is a critical part of that understanding."

A review by the New York Times of manufacturing operations in Shenzhen found that many factories were legitimate and made efforts at quality control, but some were lower-end operations that either had no safety testing equipment or specialized in counterfeiting, often with cheaper parts. The Times visited several such workshops in Shenzhen, including a counterfeitingshop set up in a garage and another that displayed a knockoff of an e-cigarette brand called "Russian 91%," which the factory boss said was destined for the United States.

The e-cigarette industry in China has developed differently from other industries, like toys, apparel and smartphones, where global brands outsource their manufacturing here but monitor and enforce quality control standards.

Chinese companies were the first to develop e-cigarettes, and that happened in a regulatory void. In the U.S., the Food and Drug Administration has just begun to move toward regulating e-cigarettes, working on rules that would force global producers, in China and elsewhere, to provide the agency with a list of ingredients and details about the manufacturing process.

But analysts say setting those rules and new manufacturing guidelines could take years. In the meantime, Chinese factories are quickening the pace, hoping to build profits and market share before regulatory scrutiny arrives and most likely forces many e-cigarette makers to close.

"This is really a chaotic industry," says Jackie Zhuang, deputy general manager of Huabao International, a Chinese tobacco flavoring company in Shanghai and an expert on China's e-cigarette market. "I hope it will soon be well regulated."

In a 5-square-mile area in the northwestern part of Shenzhen called Bao'an, in a district packed with industrial parks, there are believed to be more than 600 e-cigarette producers and many more component suppliers selling bulk orders of tube casings, integrated circuit boards, heating coils and lithium ion batteries, the essential components of the ecigarette. If you are a manufacturer in Shenzhen and need 50,000 baked-metal casings, a local manufacturer can supply them for about $25,000 and have them delivered within hours.

Unlike the counterfeiters' shops, the largest Shenzhen e-cigarette manufacturing operations are relatively clean, with rows of workers seated on plastic stools along a fastmoving assembly line.

In 2004, a Chinese pharmacist named Han Li helped develop the e-cigarette, which was then sold through his company, Beijing Ruyan. Other manufacturers soon followed, and by 2009, as e-cigarettes became more popular in the U.S. and Europe, more factories opened.

The boom has made China the breeding ground for a new, and some would say innovative, product. And yet the Chinese government has played no role in the development of the industry or in regulating

TURN TO **E-CIG,** PAGE A13

A worker at the Skorite factory prepares metal parts used in e-cigarettes for export in Shenzhen, China, last month. Chinese manufacturers, who operate with virtually no regulatory oversight, are expected to export more than 300 million e-cigarettes this year.

THEODORE KAYE / New York Times

Study suggests poor manufacturing lets metals like nickel, chromium enter e-liquids

CONTINUED FROM PAGE A12

it. As in the West, China's tobacco authority — which acts as both regulator and dominant, state-controlled producer of cigarettes and tobacco products — has been caught off guard by a product that is neither a food nor a drug and perhaps not necessarily even a tobacco product.

Some Chinese companies, however, are trying to get ahead of the anticipated FDA rules. First Union is one of the biggest, operating several manufacturing complexes here in Shenzhen with about 6,000 employees. Its plants have glass-enclosed, dustfree rooms that the company says are as clean and sophisticated as pharmaceutical labs.

First Union and Kimree, a rival based in nearby Huizhou, say they manufacture for many of the best-selling e-cigarette brands. Neither Chinese company, however, has a long history. The founders of Kimree got their start making consumer electronics, like cordless telephones. And before turning to e-cigarettes in 2006, the founders of First Union made silica gel brassieres and weight loss belts. Company executives say they can deliver high-quality goods.

"We have the same qualitycontrol standards as medical device makers," said Sunny Xu, the chairman at First Union.

Global tobacco giants that have entered the e-cigarette market also are manufacturing in China, and they insist they are doing so with stringent controls.

Altria, formerly known as Philip Morris, sells the e-cigarette brand MarkTen. In a statement, Altria said: "MarkTen is manufactured in China for Nu Mark" — Altria's e-cigarette subsidiary — "by an established manufacturer of e-cigarettes, which is following Nu Mark's design specifications and quality-control requirements" with "detailed quality-control measures."

Smaller manufacturers, though, are more representative of the ethos here. Tiny startup factories buy components from suppliers, set up assembly lines and hire low-skilled migrant workers to snap, stamp, glue and solder the e-cigarette components together.

"In the e-cigarette market, you don't need big capital — that's why there are now so many manufacturers here," said Qiu Weihua, the founder of Joyetech, a large Chinese firm that is trying to distinguish itself as a high-quality producer of e-cigarettes. The firm, for example, employs testers who vape and check for flaws. "The big challenge is how to make a quality product."

The e-cigarette makers, many run by young entrepreneurs, have found markets overseas,using online platforms like Alibaba.com. But occasionally, a U.S. businessman like Yaniv Nahon simply shows up at the factory gate. In 2010, Nahon, then 29, grew tired of selling e-cigarettes at a mall kiosk in South Florida and decided to produce his own line called Vapor 123.

"A lot of our products come in smaller orders using express mail service, no questions asked," Nahon said in an interview at a factory called Jomo in Shenzhen. "Importing this into the U.S. isn't difficult."

Scientific studies hint at a host of problems related to poor manufacturing standards. A study published last year in the open access online journal PLoS One found the

presence of tin particles and other metals in e-cigarette vapors and said they appeared to come from the "solder joints" of e-cigarette devices.

Another study of nearly two dozen e-cigarettes bought in the U.S. found large amounts of nickel and chromium, which probably came from the heating element, another suggestion that poorly manufactured e-cigarettes may allow the metals to enter into the e-liquids.

"We've found on the order of 25 or 26 different elements, including metals, in the e-cigarette aerosols," says Prue Talbot, a professor of cell biology at UCRiverside and co-author of several of the studies. "Some of the metal particles are less than 100 nanometers in diameter, and those are a concern because they can penetrate deep into the lungs."

Health advocates say they are troubled by a history of food and drug safety scandals in China, such as when manufacturers substituted diethylene glycol, an industrial solvent, for the sweetener glycerin when making toothpastes and cough medicine. That led to reports of more than 350 deaths in Panama, China and other countries in 2006 alone.

The risk of diethylene glycol showing up in e-cigarettes is real. In 2009, the FDA issued a warning about the potential health risks associated with e-cigarettes, saying laboratory studies of some samples had found the presence of toxic chemicals, including diethylene glycol, which is used in antifreeze.

Eventually, analysts say, the FDA could be compelled to certify e-cigarette factories and the manufacturing standards. But that could be months, if not years, away.

The agency, however, is under pressure from public health advocates and medical experts.

"What if someone in China buys nicotine, solvents and flavorings, but the source ofthese ingredients is unknown and they're manufactured with impurities?" says Maciej Goniewicz, a toxicologist at the Roswell Park Cancer Institute in Buffalo, N.Y. "That could put consumers at risk."

Keenlyawarethattighterregulations are on the horizon, Shenzhen e-cigarette makers are beginning to establish overseas branches to make e-liquids — the substance that is heated, then turned into vapor and inhaled. The FDA does not yet have standards for e-liquids, but many of the Chinese companies say they make them in labs in the U.S. that have passed FDA quality-control standards.

"I can tell you that all of our e-liquid is manufactured, bottled and filled here in the United States," the chief executive at Mistic e-cigarettes, John Wiesehan Jr., said in an email. "Our liquid never leaves the U.S. We get no e-liquid from China."

Big American e-cigarette makers have begun to move manufacturing to the U.S. or Europe. Global tobacco companies are doing likewise. And some Chinese manufacturers, including Joyetech, are also moving their production facilities to the West.

"A lot of people don't trust the air or water in China," says Qiu, the boss at Joyetech e-cigarettes, "so why would they trust our e-liquid?"

Morris, Erin

From: Erick Beall <e.beal@digitalciggz.com>
Sent: Sunday, December 14, 2014 1:43 PM
To: Morris, Erin
Subject: SUPPORTING EVIDENCE IN FAVOR OF VAPOR PRODUCTS
Attachments: 16 Cancer Causing Foods You Probably Eat Every Day.pdf; A New Approach to Tobacco Harm Reduction in the LGBT Community.pdf; Adult Smoking Rate in Wisconsin at Record Low.pdf; American Heart Association is over-cautious but supportive of e-cigarette use as a substitute for sm.pdf; American Heart Association Study Finds Vaping More Effective Than NRTs - The American Vaping Associa.pdf; AVA Comments on Defeat of NM State Rep. Liz Thomson - The American Vaping Association.pdf; Clearing The Air Stanton Glantz's $400,000 funding from Nicoderm manufacturer Johnson & Johnson's p.pdf; Comment Safer smoking — the future of e-cigarettes - Op-Ed - Times Colonist.pdf; Comparative In Vitro Toxicity Profile of Electronic and Tobacco Cigarettes, Smokeless Tobacco and Nicotine Replacement Therapy Products-E-Liquids, Extracts and Collected Aerosols.pdf; Comparison of select analytes in aerosol from e-cigarettes with smoke from conventional cigarettes a.pdf; Comparison of Select Analytes in Exhaled Aerosol from E-Cigarettes with Exhaled Smoke from a Conventional Cigarette and Exhaled Breaths.pdf; Creative thinking trying to find methodology problems when we don't like the results of research.pdf; E-Cig Allows Smoker Of 40 Years The Ability To Breathe - KFBB.com News, Sports and Weather.pdf; E-cigarette aerosol contains 6 times LESS formaldehyde than tobacco cigarette smoke.pdf; E-Cigarette Summit - Clive Bates Vaping.com.pdf; E-cigarette use rare in non-smokers, UK survey finds Reuters.pdf; E-Cigarettes a Gateway to Smoking Not Likely, Suggests New UK Study - The American Vaping Associati.pdf; E-cigarettes a positive alternative; fostering religious study UTSanDiego.com Mobile.pdf; E-Cigarettes Could Stub Out Tobacco Bonds Sooner Than Thought.pdf; E-cigarettes less addictive than cigarettes Penn State University.pdf; E-cigarettes Provide a New Lease on Life Health Aim.pdf; E-cigarettes significantly reduce tobacco cravings – KU Leuven.pdf; E-Cigs Get More Advanced as Regulation Looms.pdf; EPA & FDA Vapor Harmless to Children - Minnesota Vapers AdvocacyMinnesota Vapers Advocacy.pdf; Evaluation of Toxicant and Carcinogen Metabolites in the Urine of e-Cigarette Users Versus Cigarette.pdf; Experts Say E-Cigarettes Could Save Tens Of Thousands Of Lives Every Year - Business Insider.pdf; Farsalinos defuses "media frenzy" over formaldehyde Vaping.com.pdf; House Leaders Rush to Defend E-Cigarettes From Possible FDA Bans - US News.pdf; IMG_0087.JPG; Maker of 'Camel' cigarettes bans smoking in workplaces, but will allow e-cigarettes CTV News.pdf; Nicotine absorbed from "passive vaping" is minimal and with no health implications.pdf; No gateway, says statistics group Vaping.com.pdf; Public Health Officials Should Embrace E-Cigarettes The Daily Caller.pdf; Report Laundry 'pods' sent 1 child a day to hospitals.pdf; Studies E-cigarette regulations hinder public health goals Human Events.pdf; Study finds e-cigarettes help people quit smoking.pdf; Study finds nicotine safe, helps in Alzheimer's, Parkinson's Tampa Bay Times.pdf; The beef against electronic cigarettes is based on false evidence Opinion , Commentary THE DAILY.pdf; The Oxford Dictionaries Word of the Year is… vape OxfordWords blog.pdf; The Rest of the Story Tobacco News Analysis and Commentary IN MY VIEW American Lung Association U.pdf; Tobacco Stocks Time to Kick the Habit Fox Business.pdf; Want to help smokers quit Stop lying about e-cigs WashingtonExaminer.com.pdf; e_beal.vcf

Good Afternoon Erin-

Hopefully you're reading this Monday morning and I'm not interrupting your weekend.....

Here are all the documents, studies, articles, researches, etc. in support of vaping and vapor products. I understand if you're not able to get these through to the council members in time for Tuesday, or if they'll have the chance to comb through them before that time.

So to ensure that they will have all the necessary materials, I have created individual folders for each of the council members containing their own copies of these so that they will be able to review them at their leisure between Tuesday and the actual hearing tentatively set for February.

I will also be bringing an additional 400ish signed petitions to drop off Tuesday afternoon as well, so that will bring us right around 1000 petitioners in opposition to the proposal.

I look forward to the discussion.

Very Truly Yours,

Erick C. Beall
Director of Sales / Store Manager (Mendocino)
Digital Ciggz
2750 Mendocino Avenue
Santa Rosa, CA 95403
e.beal@digitalciggz.com
(707) 843-3047 Main
(707) 889-7139 Cell

Note: I attempted to attach 42 documents at 19 mb. If this doesn't go through please advise the best way for me to transmit these to you electronically ie dropbox, we transfer.....

16 Cancer Causing Foods You Probably Eat Every Day

Mar 9, 2014

16. Soda Pop

Perhaps you heard about the recent study that was published in May in the American Journal of Nutrition? It found that people who consumed more than one soda per day had a higher risk of stroke than people who did not drink sodas.

Loaded with **sugar**, sodas are an empty source of calories that cause weight gain and contribute to the nationwide epidemic of obesity. Drinking large amounts of this rapidly digested sugar causes your blood sugar to spike which can lead to both **inflammation and insulin resistance**. Soda is often the root cause of gastro-esophageal reflux disease, which is when the contents of the stomach leak into the esophagus causing not only pain but an actual burning of the esophagus from stomach acid.

Although sodas are not a direct cause of ulcers, they are known to irritate and make those with ulcers have more pain. Sodas also contain **artificial colorings and food chemicals like derivative**

4-methylimidazole (4-MI); no wonder soda pop has been shown to cause cancer.

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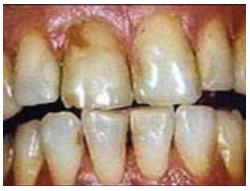
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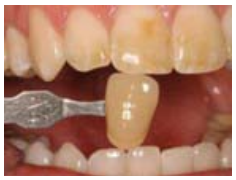
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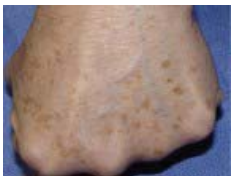
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A New Approach to Tobacco Harm Reduction in the LGBT Community

December 12, 2014 Gregory Angelo 0 Comments

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The push to blunt tobacco use across the country is nothing new, but after years of increased restrictions on tobacco use and sales, the number of cigarette smokers in the United States has hovered stubbornly around 20% for the better part of the past decade—with LGBT Americans more than twice as likely to take up smoking than our heterosexual peers. A new approach to tobacco harm reduction isn't just important; it's necessary.

Before moving to Washington, D.C. to head the Log Cabin Republicans, I was a resident of Manhattan, living in the City that Never Sleeps from day one of the tenure of Mayor Michael Bloomberg, who made smoking cessation a public health priority of his administration.

I saw it all: the implementation of smoking bans in restaurants, bars, and nightclubs all the way to a ban on smoking *outside!* (The latter, a law against smoking in public parks, was eventually knocked down by the courts, but shows that Hizzoner was serious about snuffing out smoking.)

Considering the tremendous amount of time, energy, and public resources devoted to preventing puffing, it's frustrating to see the smoking rate in the Big Apple has actually *risen* in the last year. Given statistics from the Center for Disease Control (CDC) that show minority groups have far higher smoking rates than other groups, it's not a leap to assume the LGBT community comprised a fair part of that uptick.

What's to be done—not only in New York, but across the country? Last month CVS put an end to all sales of tobacco products in their stores—a move that will likely do more to improve the drugstore's image than lower national smoking rates. A federal ban on smoking? Hardly—if government intrusion failed in New York City, there's little reason to believe federal action would be any more effective.

On the other hand, the burgeoning popularity of so-called "e-cigarettes" seems to offer a promising step-down from old-fashioned combustible tobacco products. While the efficacy of e-cigs in smoking cessation has yet to be conclusively proven, even the American Heart Association has acknowledged that medical doctors should consider encouraging e-cig use when gums, patches, and other alternatives fail.

It's an alternative form of nicotine consumption that, while imperfect, is far less harmful than tobacco. Even Stanton Glantz, an e-cig critic and director of the Center for Tobacco Control Research and Education at the University of California, declared: "There's no question that a puff on an e-cigarette is less toxic than a puff on a regular cigarette."

These are words lawmakers and e-cig opponents should keep in mind. While not smoking at all is the best course of action, a healthier alternative is better than no alternative.

And even if science concludes that e-cigarettes are not particularly effective at aiding in ending smoking entirely, it could be years before such data is accumulated—years that someone who smokes cigarettes today could be vaping "less toxic" e-cigarettes instead.

So instead of telling smokers they can't use e-cigs, lawmakers should kick their habit of encroaching in areas of commerce where their actions make the perfect the enemy of the good. We're better off reducing tobacco consumption any way we can than blowing smoke about imperfect solutions to complex problems.

Gregory T. Angelo is the Executive Director of Log Cabin Republicans.

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Adult Smoking Rate in Wisconsin at Record Low

By: Kevin Carr - Email
Updated: Mon 10:52 PM, Dec 08, 2014

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More adults in Wisconsin are kicking the smoking habit.

That's according to a study from the Wisconsin Department of Health, which shows the state's adult smoking rate at 18 percent. That's 2 percent less than in 2012, and about on par with the national average.

Paul White is just one of those adults. He says he used tobacco for most of his life, and but broke the habit through vaping-inhaling and exhaling the vapor produced by an electronic cigarette or similar device. He started out with e-cigarettes, and now uses vaporizer pens.

"I was still craving the Nicotene," White explained. "I was more concerned with my lungs, and the carcinogens that you get from combustible tobacco."

Health experts say the current adult smoking rate is proof that prevention programs and efforts are making a difference, while tobacco stores say more people like White are switching to alternatives like vaping.

"Since we've opened a year ago, the volume of customers has increased all the time," Rib Mountain Tobacco and Liquor employee Alyson Schalow said. "As long as people want to make the switch to an alternative like vaping, it's been successful."

Many users see vaping as a cheaper, healthier alternative to cigarette use. But Marathon County Department of Health Public Health Educator Destinee Coenan says they may be doing more harm than good.

"What we know is that there are risks associated with them," Coenan said. "And we know there are 10 known carcinogens found in e-cigarettes. However, we don't know the long-term effective use of these, so we really don't know in 10 years what the health effects are."

She recommends talking to a health care provider about a quitting plan, or even counseling.

"Quitting is one of the hardest things for people who smoke. We know it can take many attempts, but if they have a quit plan and some counseling or anything else that they might need, they'll be more successful," Coenan said.

White says he plans on slowly decreasing his vaping to eventually quit Nicotene altogether.

"These are giving me the satisfaction that I require to make the steps," White said. "I like to think that I'm doing it as a step-down method for my health."

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Details

Created on Monday, 25 August 2014 20:36

American Heart Association is over-cautious but supportive of e-cigarette use as a substitute for smoking

By Dr Farsalinos

The American Heart Association released today a policy statement for e-cigarettes. The main difference from other (mostly respiratory) associations is that in reality they support the use of e-cigarettes as a smoking substitute in smokers who cannot or do not want to quit smoking with other methods. They specifically mention: "*If a patient has failed initial treatment, has been intolerant to or refuses to use conventional smoking cessation medication, and wishes to use e-cigarettes to aid quitting, it is reasonable to support the attempt*."

They start the report by describing the health consequences of smoking, while they acknowledge that the reduction in smoking prevalence has been stalled in recent years, showing a much lower rate of decline compared to previous years. Among other information presented to the statement, they mention the lack of smoke, tar and carbon dioxide (due to lack of combustion) in e-cigarettes, and they acknowledge that very low levels of air toxins are produced. Importantly, they address the issue of particle size **and composition,** with the latter being significantly different from tobacco cigarette smoke. They admit that it is not known whether the type of particles emitted from e-cigarettes have the same toxicity as environmental pollution or cigarette smoke.

Although cautious in expressing themselves (using a lot of "could", "may" etc), they reproduce the statements about potential adoption by youth and being a gateway to smoking or other harmful substances, However, they accept the evidence showing that consumers are mostly current or former smokers. They propose taxation for e-cigarettes (at levels lower than smoking), in the context of preventing use by youngsters. Moreover, they propose the inclusion of e-cigarettes in smoke-free air laws, although they mentioned that in reality there is second-hand exposure to nicotine only (which has never been a reason for concern even for environmental tobacco exposure). They address the issue of use by youth by supporting the ban of access to minors.

The recommendations by AHA are quite different from the review by Grana et al. and closer to the recent reviews by Hajek et al. and by Farsalinos and Polosa. Most importantly, they seem to understand and endorse the view of many of us: **the use of e-cigarettes in those unable or unwilling to quit should be supported rather than discouraged**. This is a very important message, and I

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hope more scientific associations will follow this path.

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WorldTop Ecigs

American Heart Association Study Finds Vaping More Effective Than NRTs

admin December 10, 2014 No Comments

FOR IMMEDIATE RELEASE
December 10, 2014 at 2:45 pm EDT

American Heart Association Study Finds Vaping More Effective for Quitting Smoking than FDA-Approved Products

New study shows need for reasonable regulation, says American Vaping Association

WASHINGTON, D.C. – Today, the American Vaping Association, a leading advocate for the benefits of vapor products such as electronic cigarettes, reacted to the release of a new study published in the American Heart Association's Circulation Journal. The meta-analysis of six previously published studies found an 18% smoking cessation rate (224/1,242) after 6 months for smokers who used vapor products containing nicotine. This compares to an average cessation rate of 7% at six months for FDA-approved nicotine replacement therapy products like the nicotine gum, patch, and lozenge.

Gregory Conley, president of the American Vaping Association, issued the following statement:

"This study demonstrates exactly why e-cigarettes and vapor products have become so popular among smokers looking to quit. For smokers looking to quit, vaping is undeniably a viable option. Additionally, research continues to show that vaping is especially helpful for smokers who have tried and failed to quit multiple times with government-approved methods like the nicotine patch, gum, and lozenge. Genuine public health advocates should cheer this new study.

"We remain very concerned that the public health benefits of vaping could be squashed by improper and excessive FDA regulation. If approved, the FDA's proposed deeming regulation would act as a de facto ban on over 99% of e-cigarette products currently available on the market. Dramatically decreasing product variety will hinder, not help, the FDA's goal of reducing tobacco-related disease and death.

"We continue to call on House and Senate leadership to introduce a bill in 2015 that would substantially alter the FDA's authority over e-cigarette products already on the market."

You can learn more about AVA and vaping by visiting the AVA website. You can also find us on Facebook and Twitter.

For more information on how the proposed FDA regulations would crush the e-cigarette market, please visit these sources (1, 2, 3, 4).

# # #

About the American Vaping Association:

The American Vaping Association is a nonprofit organization that advocates for small- and medium-sized businesses in the rapidly growing vaping and electronic cigarette industry. We are dedicated to educating the public and government officials about financial and public health benefits offered by vapor products, which are battery-powered devices that heat a liquid nicotine or nicotine-free solution and create an inhalable vapor.

Contact: Gregory Conley
Tel: 609-947-8059
Email: gconley@vaping.info

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clearing the air

Private pharmaceutical nicotine entities (RWJF / Johnson & Johnson Co.) fund the smoking ban movement in order to promote their financial interests...

Tuesday, January 01, 2008

Stanton Glantz's $400,000 funding from Nicoderm manufacturer Johnson & Johnson's private foundation RWJF

Stanton Glantz has been the recipient of massive amounts of money from Nicoderm maker Johnson & Johnson Company's partner RWJF.....gee I wonder why Glantz is pro-smoking ban?

Taking on Tobacco:
The Robert Wood Johnson Foundation's Assault on Smoking

THE ROBERT WOOD JOHNSON FOUNDATION

BY JAMES BORNEMEIER

Active Grants
Tobacco Use & Exposure

Project:
Educational campaign for restaurant owners on smoke-free restaurants

Grant Detail:

$399,000, (awarded on Aug 11, 2005, starting Aug 15, 2005 ending Aug 14, 2007) ID# 052810

Grantee:
University of California, San Francisco,
School of Medicine513 Parnassus Avenue
San Francisco, CA 94143-0410

Fighting the smoking ban agenda by exposing the lies and the pharmaceutical nicotine interests that fund them....Robert Wood Johnson Foundation, Johnson & Johnson Company (ALZA) - manufacturer of Nicoderm.

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Summary:

Efforts to adopt clean indoor air ordinances in states and communities are often derailed or substantially weakened by tobacco industry lobbying and media campaigns. The tobacco industry and its allies engage in disinformation strategies targeted to restaurant owners and associations about the effect of smoke-free policies on business. Lack of support among restaurateurs for strong smoke-free policies can present major barriers to their adoption at the state and/or local level. This grant provides renewal support for the continuation of the TobaccoScam restaurant educational campaign for two years. Funds will support the placement of 32 high-quality print advertisements in major restaurant trade publications. The renewal also funds targeted outreach to media and opinion leaders, with particular emphasis on restaurant industry leaders, and an enhanced Web site to promote smoke-free workplaces within the hospitality industry as the wave of the future, reframing the discussion from one of something to fear to something to emulate.

Contact Information:
Stanton A. Glantz Ph.D.
(Project Director)glantz@medicine.ucsf.edu
Phone: (415) 476-3893

Meanwhile, the facts are that smoking bans destroy businesses and jobs in the hospitality industry at an alarming rate, despite the fact that Nicoderm, Nicotrol, Nicorette interests above, such as RWJF and its grantees, attempted to spin the message that smoking bans "are good for business."

http://cleanairquality.blogspot.com/2007/01/100-bars-and-restaurants-put-out-of.html

http://cleanairquality.blogspot.com/2010/10/minnesota-releases-revenue-numbers-that.html

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posted by marcus aurelius @ **8:39 PM**

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TIMES COLONIST

Comment: Safer smoking — the future of e-cigarettes

Corey Whelen / Times Colonist
December 3, 2014 02:54 PM

It's safe to say everyone knows that smoking is bad for your health. We've all watched the emotionally charged commercials and seen the gruesome images attached to every cigarette package.

Despite these measures, smoking persists in our society and lobbyists on both sides of the argument still spend millions of dollars a year attempting to change legislation regarding tobacco and related products.

So what's the end game?

Tobacco will never be completely outlawed. Furthermore, past attempts at prohibition tell us this strategy would be completely ineffective.

So, if smoking is dangerous, and we've determined it's an unavoidable part of life, isn't the only logical solution to attempt to minimize the health risks? When humans started dying from automobile crashes, we didn't make the car illegal. We regulated car production, installed life-saving features and offered safer alternatives to protect the lives of people who decide driving is an acceptable risk. Isn't it time we started doing the same for cigarettes?

E-cigarettes might very well be the future of smoking. They share few similarities with their analog namesake; in fact, an e-cigarette is actually a powerful vapourizer, with no actual combustion involved, so many of the harsher elements of cigarette smoke are already absent from the vapour that e-cigarette users exhale.

Furthermore, the "e-liquid" consumed by e-cigarettes is offered in many varieties, including ones without addictive nicotine, meaning people are able to try smoking without the spectre of addiction hanging over them.

Additionally, the e-cigarette potential as an anti-smoking aid is uncharted. Not only have people been using other forms of nicotine-consumption to wean themselves off cigarettes for years, the nicotine-free options provided by e-cigarettes make this process easier than ever.

E-cigarettes are already facing opposition from anti-tobacco lobbyists, despite being a legitimate alternative to smoking with significantly reduced risk of throat cancer. New laws in Ontario already prohibit the sale of e-cigarettes to minors, which is admirable, but they also prohibit stores from selling e-cigarettes, and prevent people from smoking them in public.

Wouldn't the better, long-term solution be to eliminate the health risk and the addictive nature of smoking? Kids will always experiment, but perhaps if the government regulated the companies, as opposed to the people, smoking could one day be safe enough that this experimentation could be worry-free. Or at least, the risk could be minimized.

Admittedly, as with any new technology, more research needs to be done to document the exact effects of e-cigarette smoking. It's certainly not without risk, but with the knowledge gained through the widespread adoption of e-cigarette technology, it could be possible to make even safer versions of cigarettes.

Every death caused by smoking is a tragedy, but maybe we're worrying too much about the gunshot wound, when e-cigarettes could simply take the bullets out of the gun.

Perhaps in an ideal world, tobacco would be completely undesirable. In reality, however, people have been smoking for thousands of years, so it seems unlikely they're going to stop now.

I'm not a smoker, and I probably never will be, but I'm a university student. I walk past a dozen smokers a day, and interact with more than that regularly. I might be removed from the issue, but my objectivity is unquestionable.

If we can't stop smoking for good, the least we can do is try to make it safer for everybody.

Corey Whelen is a student at the University of Victoria, majoring in English.

Int. J. Environ. Res. Public Health **2014**, *11*, 11325-11347; doi:10.3390/ijerph111111325

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Article

Comparative *In Vitro* Toxicity Profile of Electronic and Tobacco Cigarettes, Smokeless Tobacco and Nicotine Replacement Therapy Products: E-Liquids, Extracts and Collected Aerosols

Manoj Misra *, Robert D. Leverette, Bethany T. Cooper, Melanee B. Bennett and Steven E. Brown

Lorillard Tobacco Company, A.W. Spears Research Center, 420 North English Street, Greensboro, North Carolina 27405, USA; E-Mails: rleverette@lortobco.com (R.D.L.); bethanycooper@lortobco.com (B.T.C.); mbennett@lortobco.com (M.B.B.); sbrown@lortobco.com (S.E.B.)

* Author to whom correspondence should be addressed; E-Mail: mmisra@lortobco.com; Tel.: +1-336-335-6679; Fax: +1-336-335-6640.

External Editor: Konstantinos Farsalinos

Received: 1 August 2014; in revised form: 16 October 2014 / Accepted: 24 October 2014 / Published: 30 October 2014

Abstract: The use of electronic cigarettes (e-cigs) continues to increase worldwide in parallel with accumulating information on their potential toxicity and safety. In this study, an *in vitro* battery of established assays was used to examine the cytotoxicity, mutagenicity, genotoxicity and inflammatory responses of certain commercial e-cigs and compared to tobacco burning cigarettes, smokeless tobacco (SLT) products and a nicotine replacement therapy (NRT) product. The toxicity evaluation was performed on e-liquids and pad-collected aerosols of e-cigs, pad-collected smoke condensates of tobacco cigarettes and extracts of SLT and NRT products. In all assays, exposures with e-cig liquids and collected aerosols, at the doses tested, showed no significant activity when compared to tobacco burning cigarettes. Results for the e-cigs, with and without nicotine in two evaluated flavor variants, were very similar in all assays, indicating that the presence of nicotine and flavors, at the levels tested, did not induce any cytotoxic, genotoxic or inflammatory effects. The present findings indicate that neither the e-cig liquids and collected aerosols, nor the extracts of the SLT and NRT products produce any meaningful toxic effects in four widely-applied *in vitro* test systems, in which the conventional cigarette smoke preparations, at comparable exposures, are markedly cytotoxic and genotoxic.

Keywords: e-cigarette; snus; snuff; e-liquid; aerosol; cytotoxicity; mutagenicity; inflammation; condensate; *in vitro*

1. Introduction

The typical commercial electronic cigarette (e-cig) is comprised of three major components: a rechargeable or disposable battery, a heating element that generates an inhalable aerosol, and an associated switch or puff-activated circuitry. The circuitry serves to produce the aerosol only during the active puffing cycle, essentially eliminating sidestream emissions from the device during usage. The typical commercial e-cig also contains a liquid solution containing aerosol-forming excipients such as glycerol and/or propylene glycol, flavoring materials and, optionally, nicotine. This solution is usually delivered from a small reservoir by capillary wicking to the heating zone to affect the generation of an aerosol that superficially resembles cigarette smoke in appearance. A great variety of e-cig sizes, configurations, liquid formulations and designs are emerging on a continual basis in this rapidly-developing worldwide marketplace in response to users' evolving personal preferences.

As such, the popularity and sales volume of e-cigs continue to increase worldwide [1,2], and there is a need for a fuller scientific understanding of the potential benefits or risks that e-cigs may have, both to individual users as well as the general smoking and nonsmoking populations. A contemporary framework for assessing the relative risks and benefits to both individuals and populations must necessarily include the characterization of any potential toxicological hazard inherent to a product, and a consideration of those properties against those of other available alternative products. The individual risks to smokers and the harm to populations resulting from conventional cigarette smoking are very well understood and extensively documented [3]; however, the use of alternative products, such as electronic cigarettes, holds potential as an effective approach to advancing the public health amongst adult smokers in the near term [4–6].

It is well understood that tobacco cigarettes produce a multitude of harmful and toxic constituents that together induce deleterious health effects including chronic obstructive pulmonary disease (COPD), cardiovascular disease (CVD) and cancer [3]. Conversely, e-cigs do not burn tobacco and do not deliver harmful constituents in the numbers or in nearly the quantities that are found in the smoke of conventional tobacco cigarettes [7]. A recent review reporting on chemical, toxicological (mostly cytotoxicity studies on established cell lines) and clinical studies clearly indicates that e-cig liquids and aerosols contain far less and fewer chemicals, induce significantly less cytotoxicity or adverse effects, and result in considerably reduced cardiovascular and respiratory functional effects than are reported for tobacco cigarettes [8]. In prior investigations of aqueous extract of e-cig aerosols in mammalian fibroblast cells [9] and myocardial cells [10], some moderate cytotoxicity was observed for certain flavoring compounds found in the tested products. However, all such studies, to date, have reported the tested e-cig liquids and aerosols to be markedly less toxic than extracts prepared from the smoke of conventional cigarettes.

This study utilized an *in vitro* battery of established assays to examine the cytotoxicity (Neutral Red Uptake; NRU), mutagenicity (reverse bacterial mutagenicity test; Ames), genotoxicity (micronucleus

formation; MN) and inflammatory effect (cytokine IL-8 release: IL-8) in cells exposed to preparations of various tobacco cigarettes, smokeless tobacco (SLT), nicotine replacement therapy (NRT) products, and commercial electronic cigarettes. Pre-incubation and in-media exposure methods were adopted for e-liquids, aqueous extracts of SLT, NRT products, and pad-collected aerosols from e-cigs as well as pad-collected smoke from tobacco cigarettes.

To date, no systematic toxicity studies have been reported that directly compared e-cig with SLT, NRT, and tobacco cigarettes. Therefore, the present comprehensive multi-endpoint study of a variety of tobacco and nicotine delivery products that have been previously assigned different positions on a risk continuum [11,12] was designed to address the following:

1. Toxicity of e-cig liquids;
2. Toxicity of SLT products;
3. Toxicity of a NRT lozenge product;
4. Toxicity of pad-collected particulate matter from freshly-generated smoke and aerosols from tobacco cigarettes and e-cigs, respectively.

2. Materials and Methods

2.1. Chemicals and Methods

All chemicals were purchased from Sigma-Aldrich (St. Louis, MO, USA) unless otherwise stated. Recommendations from Cooperation Centre for Scientific Research Relative to Tobacco (CORESTA) were followed for the selection of toxicological assays used in this study [13].

2.2. Product Characterization

Commercial blu e-cigs containing glycerol-based e-liquids, with and without nicotine and two market leader flavors (Classic Tobacco and Magnificent Menthol), were used in this study. For comparative purposes, tobacco burning cigarettes (Kentucky Reference 3R4F, 1R5F and Marlboro Gold), SLT products (Marlboro Snus, Copenhagen Snuff) and a NRT product (Nicorette Lozenge) were also tested. The products used in the study, their general specifications and the level of nicotine measured in test samples are detailed in Table 1.

2.3. E-Liquid Extraction

The e-liquids were extracted from the wicking material located inside the cartomizer for both rechargeable and disposable e-cigs under aseptic conditions. The mouth-end plug of e-cigs was removed and the polyester wicking material was removed with sterilized stainless steel forceps. The wet wicking material was then placed in a sterile 20 mL plastic syringe tipped with a sterile 0.45 μm pore size syringe filter. The e-liquids from the wet wicking material were extracted by pushing the syringe plunger and collected in a sterilized test tube. About 1.0 mL of e-liquid was extracted from each e-cig. Subsequently, the e-liquids were diluted and delivered to the respective test systems.

Table 1. Product Characterization.

Product Class	Name/Description	Abbreviation	Lot #	Product Label Nicotine (mg)	Nicotine Measured in Samples (mg/mL)
Tobacco Cigarettes	Kentucky Reference Cigarettes	3R4F	--	0.8	2.08 *
		1R5F	--	0.2	1.27 ± 0.10
	Marlboro Gold, 72 mm	Marlboro Gold	V128Z33B4	0.68	1.96 ± 0.08
Electronic Cigarettes (e-cig)	Control e-cig	N/A	--	0	0 ± 0
	blu™ e-cigs Classic Tobacco No Nicotine (Rechargeable)	blu CT-Ø	0248	0	0 ± 0
	blu™ e-cigs Classic Tobacco High Nicotine (Cigalike)	blu CT-High	270/404	24.0	17.93 ± 0.34
	blu™ e-cigs Magnificent Menthol No Nicotine (Rechargeable)	blu MM-Ø	237	0	0 ± 0
	blu™ e-cigs Magnificent Menthol High Nicotine (Cigalike)	blu MM-High	404	24.0	20.43 ± 0.41
Smokeless Tobacco (SLT)	Marlboro® Snus	N/A	N335X0X50	15.7	0.42 ± 0.14
	Copenhagen® Snuff	N/A	NEI31755H	10.6	0.46 ± 0.03
Nicotine Replacement Therapy (NRT)	Nicorette® Lozenge	N/A	13780	4.0	0.10 ± 0.03

* Only one sample value.

2.4. Pad-Collected Aerosols for Tobacco Cigarettes and E-Cigs

All tobacco cigarettes were conditioned at 60% relative humidity at 24°C for at least 18 h prior to machine smoking. E-Cig batteries were charged immediately prior to use (rechargeable only). The e-liquid from the control e-cig contained a glycerol/water mixture, without flavors or nicotine, similar to the tested commercial products.

It has been suggested that realistic tobacco cigarette smoking, as well as the e-cig vaping profile, are more intense than the ISO machine smoking profile (35 mL puff volume, 2 s draw, 60 s puff interval). In the absence of a standardized vaping profile for e-cigs and our intention to compare e-cig toxicity with conventional cigarette toxicity, this study employed the Canadian Intense (CI) puffing conditions. Both tobacco and e-cigs were smoked on a VITROCELL® VC10 smoking robot (VITROCELL Systems, Waldkirch, Germany) under the CI puffing conditions: 55 mL puff volume, 2 s draw, 30 s puff interval, and 100% blocked air dilution in the case of tobacco cigarettes [14]. Wet Total Particulate Matter (WTPM) and e-cig aerosols were collected on Cambridge glass fiber filter pads, which capture in excess of 99% of cigarette smoke particulate matter. The filters were extracted into either dimethylsulfoxide (DMSO) for tobacco smoke or phosphate buffered saline (PBS) for e-cig aerosols, both to a final concentration of 40 mg/mL (*w/v*) and stored at −80 °C prior to analysis.

2.5. Aqueous Extract of Smokeless Tobacco (*SLT*) *and Nicotine Replacement Therapy* (*NRT*) *Products*

Aqueous extracts from commercially available products obtained at retail outlets were prepared based on previously reported methods [15]. Products were suspended in PBS at 80 mg/mL (Dulbecco's PBS, #14040, +$MgCl_2$ +$CaCl_2$, Gibco, Grand Island, NY, USA). The suspension was incubated at 37 °C for 21–24 h, shaking at 150 rpm on a shaker incubator. The final suspension was then centrifuged at 12,000 g for 10 min to remove particulates, filter sterilized, aliquoted and stored at −80 °C prior to analysis.

2.6. Nicotine Measurement

The level of nicotine in e-liquids and pad-collected smoke and aerosols was quantified using Gas Chromatography-Flame Ionization Detection (GC-FID) instrumentation with a six point calibration utilizing a nicotine standard concentration range [16]. The method precision "variability" was 0.3%–0.7%, method accuracy was 97.4%–98.6%, method LOD was 0.0524 mg/g and method LOQ was 0.1040 mg/g.

2.7. Cell Culture

Human lung epithelial carcinoma cells A549 (ATCC# CCL-185) were plated in 96-well plates in 200 µL per well of complete medium (Ham's F-12K medium with 10% heat-inactivated fetal bovine serum (FBS), 2 mM L-glutamine and 0.01 mg/mL gentamicin) at a seeding density of 75,000 cells/mL and allowed to attach and grow overnight at 37 °C in an atmosphere of 5% CO_2 prior to exposures.

Chinese hamster ovary cells CHO-K1 (ATCC# CCL-61) were seeded in 96-well plates at 2500 cells/well in complete growth medium (Ham's F-12K medium with 10% FBS and 0.01 mg/mL gentamicin) and allowed to attach and grow overnight (37 °C, 5% CO_2) prior to exposures.

2.8. Cell Treatment

Cells were treated for approximately 24 h with increasing levels of e-liquids, aqueous extracts, WTPM or pad-collected e-cig aerosols in fresh complete cell media prior to any toxicological evaluations. The cellular treatment dose range used for e-cigs (e-liquids and pad-collected aerosols) was 0–20 mg/mL and for tobacco cigarettes 0–0.5 mg/mL. The doses utilized for tobacco burning cigarette samples were based on dose range finding experiments that demonstrated high cytotoxicity occurring at or above 0.5 mg/mL. Solubility limitations of e-liquids were observed at doses beyond 20 mg/mL; therefore, doses above 20 mg/mL were not utilized in this study. The cellular treatment dose range used for SLT and NRT samples was 0–27 mg/mL, which incorporated the dose range previously utilized for smokeless tobacco products [15]. The toxicological responses were normalized with their respective vehicle controls, either DMSO for tobacco burning cigarettes or culture medium for all other samples.

2.9. Cytotoxicity and IL-8 Assay

Following cellular treatment with samples, a 200 µL aliquot of the exposure medium was taken from each well and processed for IL-8 analysis, and the cells adhered to the wells were processed for the cytotoxicity assay.

Cytotoxicity was measured in A549 cells by the NRU method [17,18]. In brief, the cell treatment medium was replaced with 1.5% (*v/v*) neutral red dye in fresh serum-free complete medium and incubated for 2.5 h. The plates were then washed and the cell-incorporated neutral red dye was released and quantified by measuring absorbance at 540 nm on an Infinite M200 Pro spectrophotometer (TECAN, Morrisville, NC, USA). The EC_{50} for NRU (mg/mL) was calculated and compared using GraphPad Prism v. 5.02 (two tailed; for comparisons, statistical significance @ $p < 0.05$).

The release of cytokine IL-8 was quantified [19] in cellular medium with an ELISA detection kit (Abazyme, Inc., MA, USA) by measuring absorbance at 450 on an Infinite M200 Pro spectrophotometer (TECAN). Results for the IL-8 release are reported as % vehicle control and compared using GraphPad Prism v. 5.02 (two tailed; for comparisons, statistical significance @ $p < 0.05$).

2.10. Bacterial Mutagenesis Assay

Ames reverse bacterial mutagenicity assays were conducted with the pre-incubation modification [20,21] in strains TA98 and TA100 with S9 activation. Aroclor-induced Sprague-Dawley rat liver S9 post-mitochondrial supernatant (Moltox, Inc., Boone, NC, USA), in 0.154 M KCl, was used for the S9-cocktail (0.1 M phosphate buffer, pH 7.4; 8 mM $MgCl_2$, 33 mM KCl, 5 mM glucose-6-phosphate (G-6-P), 4 mM nicotinamide adenine diphosphate (NADP), 5% (*v/v*) S9-fraction).

The e-cig and SLT/NRT sample dose ranges utilized for the Ames reverse bacterial mutagenicity assay were 0–48 mg/mL and 0–3.2 mg/mL, respectively, due to the sample solubility and sample volume limits of the Ames exposure system. This SLT/NRT dose range is similar to the dose range previously reported for smokeless tobacco product extracts tested in the Ames assay [15]. The control sample for e-cig liquids, e-cig pad-collected aerosols, SLTs and NRT was PBS and the control sample for WTPM from tobacco burning cigarettes was DMSO.

Exposures of *Salmonella* tester strains were performed as follows: 100 µL of an overnight culture, 500 µL of the S9-mix, plus 25 µL sample were combined in a sterile tube, capped and shaken at 250 rpm for 20 min at 37 °C prior to the addition of 2.5 mL of histidine/biotin top agar and plated onto minimal glucose agar plates. Revertant colonies were counted after 48 hours of incubation at 37 °C. All exposures were conducted in triplicate in a minimum of two independent experiments. All colonies were counted with an automated colony counter, Synbiosis ProtoCOL3 (Frederick, MD, USA). Activity reported as revertants per mg was calculated from the linear portion of the dose response curve and compared using GraphPad Prism v. 5.02 (slope analysis, two tailed; for comparisons, statistical significance @ $p < 0.05$).

2.11. Micronucleus Assay

The *in vitro* MN assay was performed in CHO-K1cells as previously described [22], utilizing the MN HitKit-K11-0001-1 (Thermo Fisher Scientific, Pittsburgh, PA, USA). Cells were exposed to samples in the absence of S9 for 20 ± 2 h followed by treatment with the cytokinesis blocking agent, cytochalasin B. Cell viability was determined by the cytokinesis-block proliferation index (CBPI). MN frequency (%MN) was determined on a Cellomics® ArrayScan® VTi (Pittsburg, PA, USA) using the Micronucleus Bioapplication, V.4 software. Activity is reported as % Control and compared using GraphPad Prism v. 5.02 (two tailed; for comparisons, statistical significance @ $p < 0.05$).

3. Results and Discussion

This *in vitro* comparative toxicological study was designed to evaluate e-liquids extracted from commercial e-cig products and pad-collected aerosols and smoke delivered by laboratory machine smoking of e-cigs and combustible tobacco cigarettes. Although several *in vitro* tests are routinely used and accepted by regulatory authorities, there are inherent limitations which affect the usefulness of the assays to predict toxicity potential of a substance *in vivo*, and especially in humans. Given that no single *in vitro* test can fully replicate *in vivo* test results, a battery of *in vitro* tests with a high concordance to *in vivo* models has the potential to establish a weight-of-evidence approach for evaluating the biological impact associated with e-cigs. In addition, the *in vitro* toxicological analysis of appropriate comparative product types further provides context for results that otherwise may be misleading or lack relevancy to the determination of biological activity.

A battery of toxicological endpoints that have been amply demonstrated to appropriately characterize the responses to cigarette smoke preparations was selected to provide points of reference in terms of the cytotoxicity, mutagenicity, genotoxicity, and inflammatory responses elicited by the tested e-cigs.

Genotoxicity (Ames and MN formation) testing is an important part of the hazard assessment of a chemical for regulatory purposes and has been demonstrated to have very high concordance with rodent carcinogenicity or *in vivo* genotoxicity when tested together [23]. Additionally, inadequate resolution of inflammation and uncontrolled inflammatory reactions can evoke a state of chronic inflammation, which is a common etiologic factor for various human respiratory lesions, including cancer [24,25].

A list of all products evaluated in this study is detailed in Table 1. This study utilized the CI smoking profile to smoke both e-cigs as well as tobacco cigarettes. As a basis for comparative analysis, this study evaluated the toxicological impact of traditional tobacco products, commercial Marlboro Gold and two Kentucky reference cigarettes, four blu e-cigs, Copenhagen Snuff, Marlboro Snus, and Nicorette Lozenge. In addition to comparing products in different classes (tobacco cigarette, e-cig, SLT and NRT), the toxicological impact of nicotine using e-cigs with and without nicotine was also investigated.

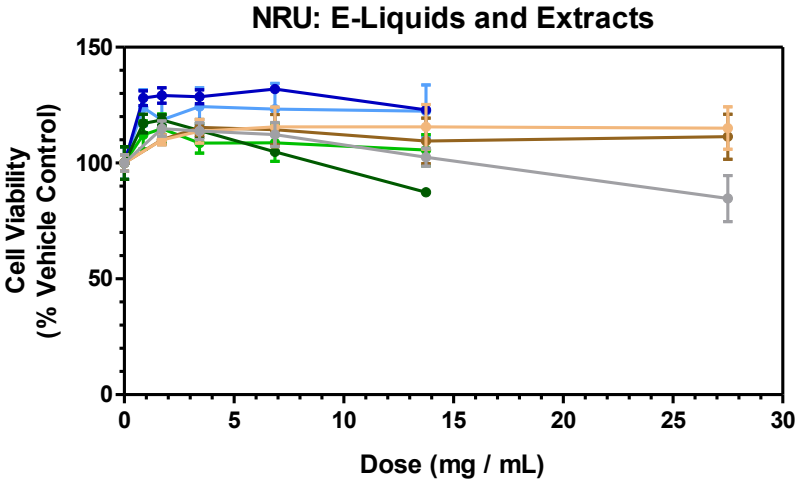
3.1. E-Liquids, Smokeless Tobaccos (SLTs) and Nicotine Replacement Therapy (NRT): Cytotoxicity

The toxicological response of e-liquids and aqueous extracts of SLT and NRT products was evaluated in A549 cells and is shown in Figures 1 A–E. No cytotoxicity was observed for any of the e-liquids, as well as for all SLT and NRT products tested up to their respective highest sample doses (Figure 1A).

Similarly, Bahl *et al*. reported little or no cytotoxicity for most of the 35 commercial refill liquids for e-cigs previously tested in human lung fibroblast cells [26]. This study utilized two blu e-cig market leading flavors, classic tobacco and magnificent menthol. To compare the dose levels, the maximum e-liquid dose utilized by Bahl *et al*. [26] was 12.6 mg/mL, equivalent to the highest dose of 1% (*v/v*), assuming a 100 µL MTT assay volume and an e-liquid density of about 1.22 g/mL. Additionally, Bahl *et al*. [26] also reported toxicity to adjacent wells at 10% (*v/v*) e-liquid dilutions, equivalent to approximately 126 mg/mL; however, the present study did not reveal any vapor toxicity

from e-liquids at doses as high as 27 mg/mL to adjacent wells. The observed cytotoxicity in adjacent wells [26] may be a result of higher e-liquid concentrations used by Bahl *et al*. or the volatility of specific e-liquid ingredients or flavors released while incubating at 37 ºC, or the possibility of differential susceptibility of the lung fibroblasts used by Bahl *et al.* and the A549 cells used in this study.

Figure 1. *In vitro* activity of e-cig liquids, smokeless tobacco and lozenge aqueous extracts in NRU (**A**), Ames (**B**), MN (**C** and **D**) and IL-8 (**E**). NRU, MN and IL-8 data reported as % vehicle control, PBS in the case of e-liquids, SLT and NRT aqueous extracts. Data points in each plot represent the mean values ± SD from a minimum of two (2) independent experiments. MN cell viability (**D**) shown to verify lack of MN induction is not due to cytotoxicity at higher doses. (—●—) blu CT-Ø; (—●—) blu CT-High; (—●—) blu MM-Ø; (—●—) blu MM-High; (—●—) Marlboro Snus; (—●—) Copenhagen Snuff; (—●—) Nicorette Lozenge; (—●—) Control e-cig.



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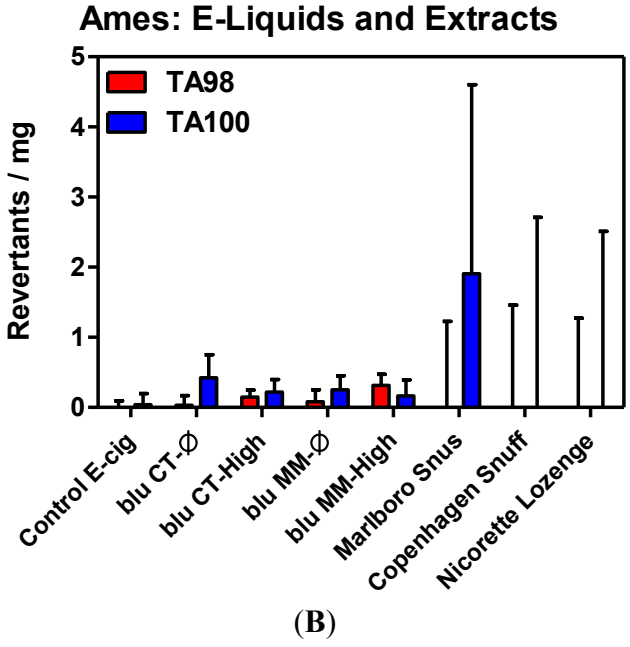

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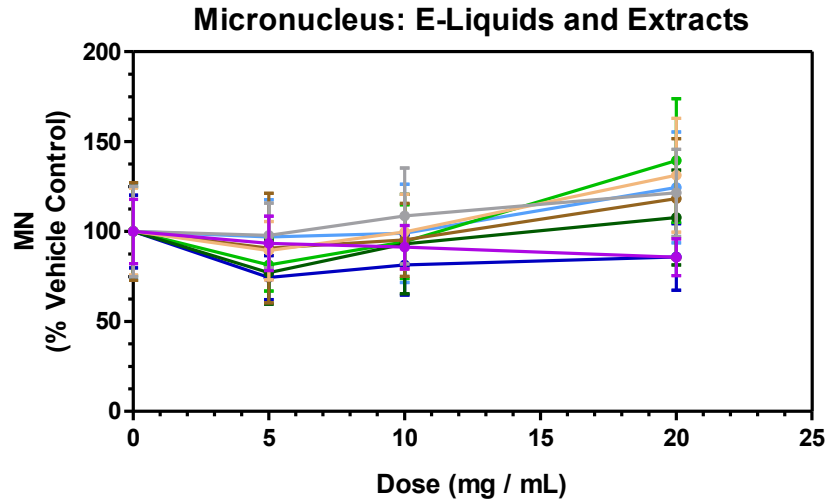

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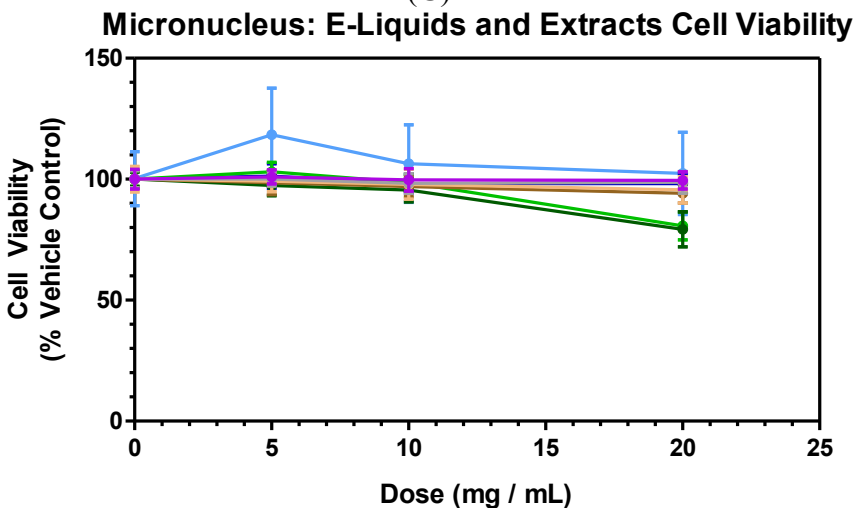

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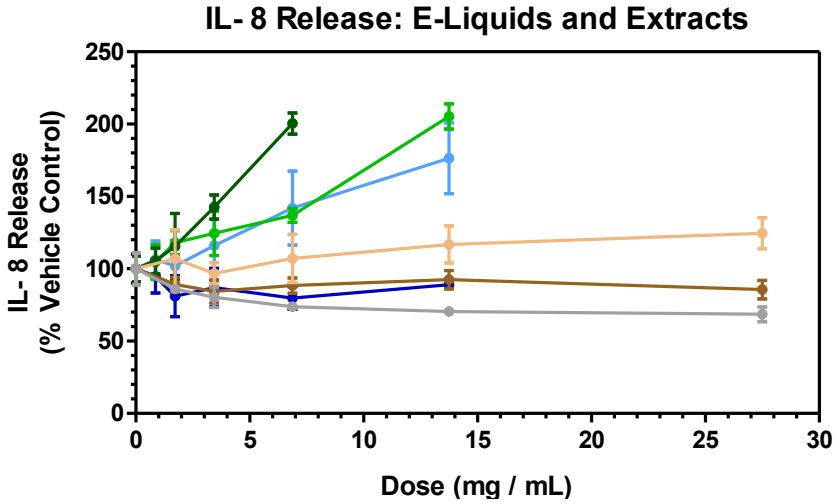
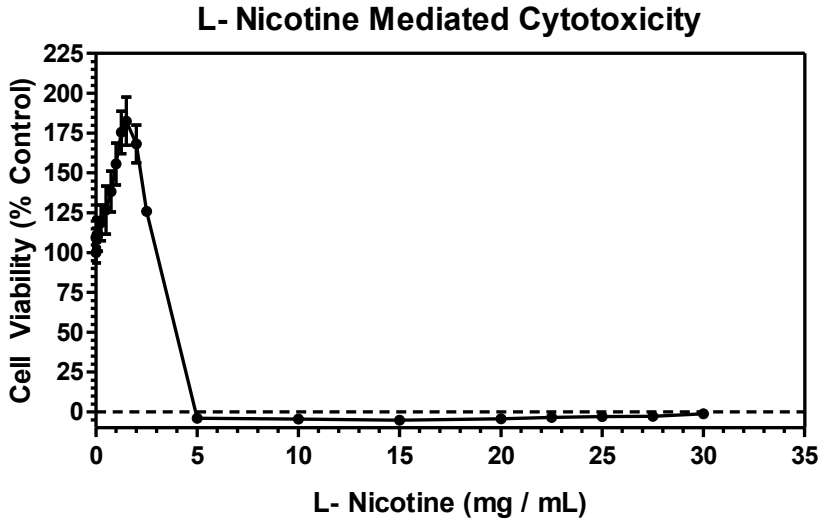


(**E**)

At the lower doses of e-liquids utilized in this study, an increase in cell viability was observed (Figure 1A) which was also evident with cells treated with lower doses of pure nicotine (Figure 2A). This increase in cellular viability was primarily associated with higher cellular proliferation and

cellular protection mediated by the low level of nicotine exposure [27]. Therefore, there may be an association between the lower nicotine present in e-cig liquids and increased cellular viability, thus cellular protection.

Figure 2. Effects of L-nicotine on cytotoxicity (**A**) NRU and inflammation (**B**) IL-8 in A549 cells. Data points in each plot represent the mean values ± SD from a minimum of two (2) independent experiments.



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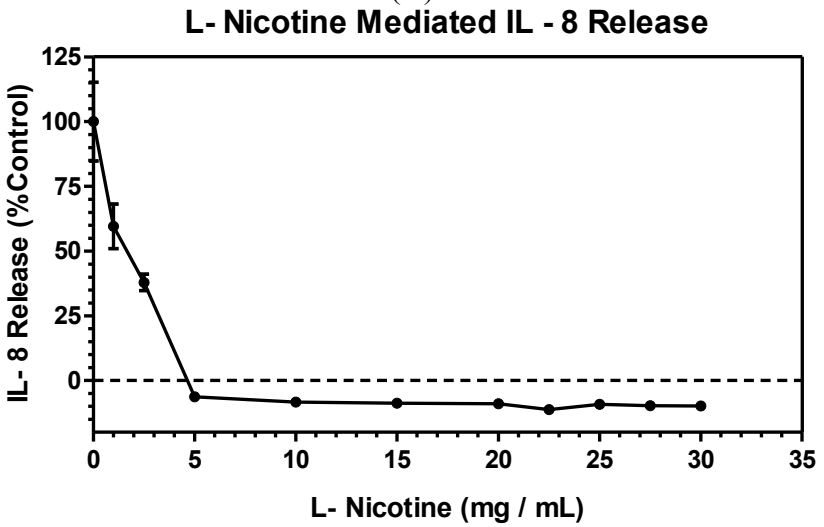


(**B**)

3.2. E-Liquids, Smokeless Tobaccos (*SLTs*) *and Nicotine Replacement Therapy* (*NRT*)*: Mutagenicity*

The Ames test, also known as the bacterial reverse mutation assay, is widely used for the determination of a compound's ability to induce mutations and has been shown to have a high predictive value with rodent carcinogenicity tests [28].

The activity of e-liquids, SLT and NRT extracts in the Ames assay is shown in Figure 1B. The control e-cig sample containing water/glycerol and the PBS control sample (SLT and NRT) did not induce any revertants above baseline and were within the variability range of this assay. No significant induction in the activity over respective controls was observed for all e-liquids and extracts (Figure 1B). The level of

e-liquids as high as 15-fold higher than SLTs and NRT extracts did not induce any activity. No evidence of cytotoxicity, as determined by the background bacterial lawn, was observed for all e-liquid, SLT and NRT samples at all doses tested.

3.3. E-Liquids, Smokeless Tobaccos (*SLTs*) *and Nicotine Replacement Therapy* (*NRT*)*: Genotoxicity*

The results of *in vitro* MN formation assay are shown in Figure 1C,D). The MN assay conducted in CHO-K1 cells, identifies clastogenic and aneugenic chemicals which essentially cause a DNA-damaging event that leads to the disruption or breakage of chromosomes and ultimately results in sections of the chromosome being deleted, added, or rearranged upon cell division (mitosis) [29].

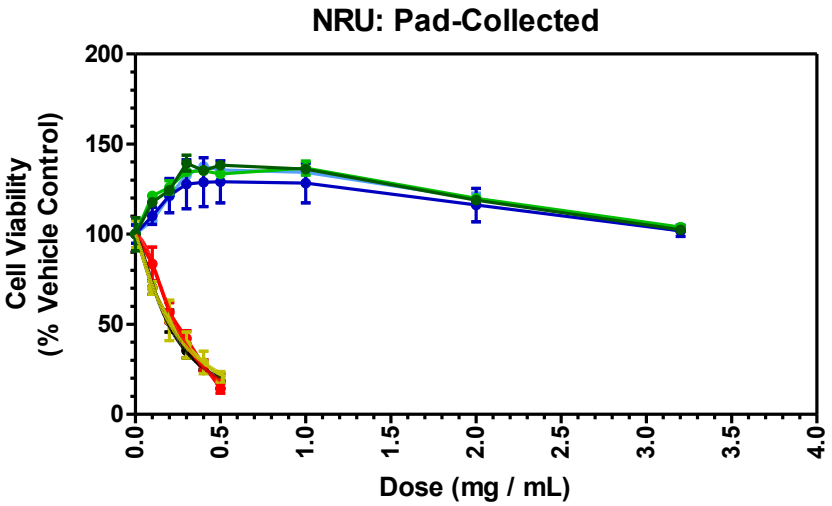
A sample dose range which does not produce cytotoxicity of more than 55 ± 5% (compared to control) was utilized in the MN formation assay [24]. The control e-cig, e-liquids, SLT and NRT extracts did not induce any significant cytotoxicity at all dose levels tested since cell-viability remained around 100% of control at all concentrations (Figure 1D). No significant induction in the MN formation over respective controls was observed for all e-liquids and SLT and NRT extracts (Figure 1C).

3.4. E-Liquids, Smokeless Tobaccos (*SLTs*) *and Nicotine Replacement Therapy* (*NRT*)*: Inflammation*

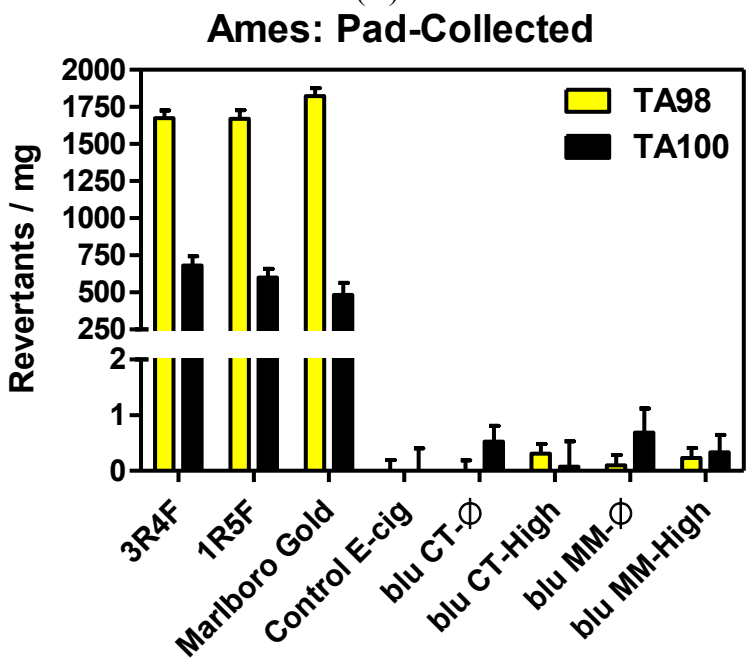
Airway epithelial cells are the first line of defense in the airways to respond to any external stimuli and secrete specific chemo-attractants and pro-inflammatory cytokines, for example IL-8, monocyte chemotactic protein-1, and IL-1ß, in order to activate the secondary response for neutrophils and macrophage infiltration [30,31]. Instead of measuring downstream acute or chronic phase inflammation specific cytokines, this study measured an upstream pro-inflammatory cytokine, IL-8.

The effects of 24 h exposures of e-liquids and SLT and NRT extracts on IL-8 release in A549 cells are shown in Figure 1E. The control samples for e-cig, SLTs and NRT did not induce any significant IL-8 release. No significant IL-8 release was observed for most of the products, with the exception of the blu MM-Ø, blu MM-High and blu CT-Ø treatments which resulted in higher IL-8 release only at extremely high doses of 6.9–13.8 mg/mL. When compared to the IL-8 release induced by conventional cigarette samples (Figure 3E), any significant IL-8 release as a result of the blu MM e-liquid treatments occurred at doses approximately 42-fold higher than the conventional tobacco cigarettes. It has been suggested that the toxicity of e-liquids may change when the same e-liquids are heated to produce the inhaled aerosol [26]. The evaluation of e-cig aerosol toxicity is essential since the intended use of e-cigarettes is through aerosol inhalation. Additionally, it is proposed that different e-liquid formulation ingredients may evaporate differently, leading to changes in concentrations in the generated aerosols as well as the possibility that components may undergo modification when subjected to the heat used to generate the aerosol; therefore, the final composition of the aerosol may be different when compared to the e-liquid [9]. In the light of that, the purpose of the study was to also characterize the aerosol toxicity as delivered by heating the e-liquid.

Figure 3. *In vitro* activity of pad-collected WTPM from tobacco cigarettes and pad-collected e-cig aerosols in NRU (**A**), Ames (**B**), MN (**C** and **D**), and IL-8 (**E**). NRU, MN and IL-8 data is reported as % vehicle control; PBS in the case of e-cigarette pad-collected aerosols, DMSO for tobacco-burning cigarette pad-collected WTPM. Control e-cig exposures in NRU and IL-8 were at the highest deliverable dose, resulting in no observable cytotoxicity or IL-8 release above background levels (data not shown). Data points in each plot represent the mean values ± SD from a minimum of two (2) independent experiments. MN cell viability (**D**) shown to verify lack of MN induction is not due to cytotoxicity at the higher doses. (—●—) 3R4F; (—●—) 1R5F; (—●—) Marlboro Gold; (—●—) blu CT-Ø; (—●—) blu CT-High; (—●—) blu MM-Ø; (—●—) blu MM-High; (—●—) Control e-cig.



(**A**)



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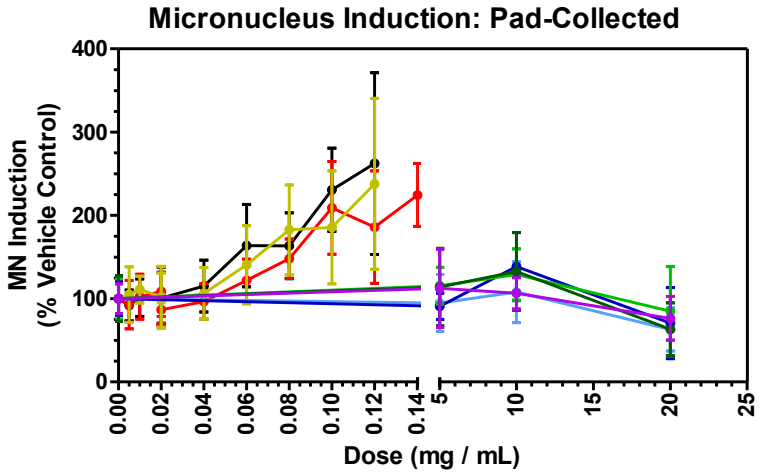

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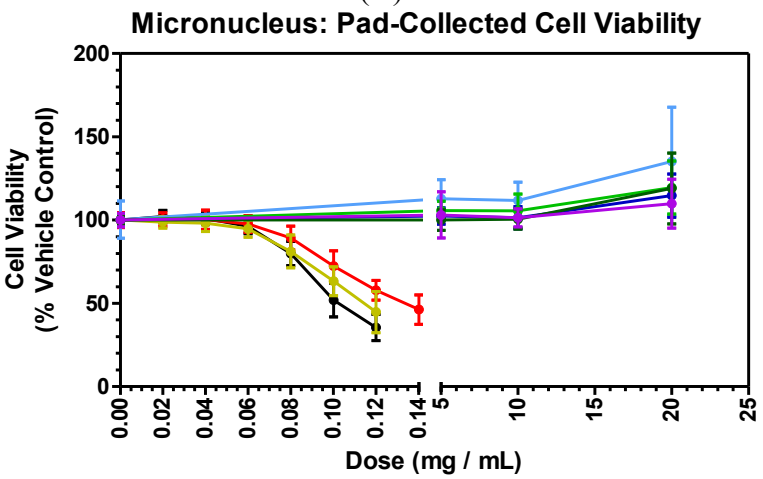

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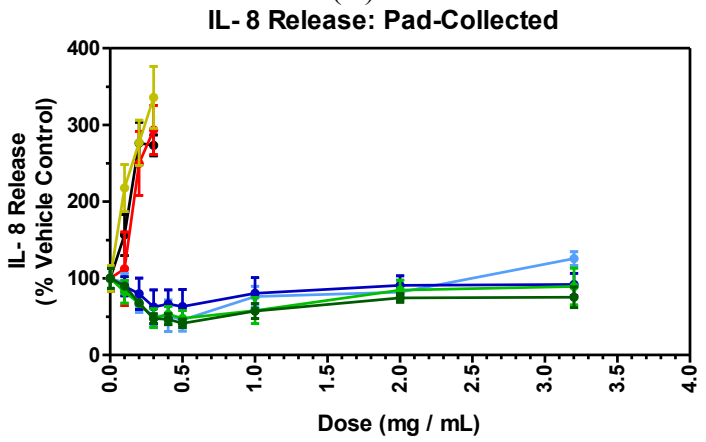

(**E**)

3.5. E-Cigarettes and Conventional Cigarettes

In order to study the comparative toxicities of the e-cig aerosols and tobacco smoke, all products were smoked by the standardized CI profile with the aerosols or smoke from each product being collected on a pad as described in the Experimental Section. The pad-collected tobacco smoke matter was extracted in DMSO because it has been widely applied as a vehicle for *in vitro* assays of test

articles of limited water solubility due to its excellent solvent properties for both polar and non-polar compounds and its moderate toxicity to test organisms [32,33]. The reasoning for the concentration ranges utilized in this study was to limit the level of DMSO in order to avoid any solvent specific effects on the assays [32]. The toxicological responses of the pad-collected e-cig aerosols and cigarette smoke are shown in Figure 3A–E.

3.6. E-Cigarettes and Conventional Cigarettes: Cytotoxicity

The cytotoxicity of e-cig pad-collected aerosol is shown in Figure 3A. The e-cig pad-collected aerosol was not cytotoxic at all tested levels. For comparative purposes, different levels of WTPM from tobacco cigarettes were also tested. A dose-dependent increase in cell death was observed for 3R4F, 1R5F and Marlboro Gold cigarettes with up to 90% cell death at the 0.5 mg/mL maximum applied dose. The WTPM mediated cytotoxicity results are in agreement with previously reported studies [12,34]. It was not possible to quantify the comparative cytotoxicity in terms of traditional EC_{50} values (a dose which induces 50% cell death) since no cell death was observed at any concentration used for all e-cig samples (Table 2 and Figure 3A).

There was an observed increase in cellular viability in cells treated with e-liquids (Figure 1A) and lower doses of pure nicotine (Figure 2A). Also treatment with e-cig aerosols resulted in a similar increase in cellular viability (Figure 3A). This observed increase in cellular viability for pure nicotine and both e-cig liquids and pad-collected aerosols could be related to nicotine's effect on cellular proliferation and protection [27].

Table 2. NRU EC_{50} values for WTPM only (mean ± SE). EC_{50} expressed in mg/mL to correct for differences in dose volumes between exposure methods. † ND: e-cig pad-collected aerosols EC_{50} not determined since cytotoxicity was not detected at doses tested.

Pad-Collected Matter: Smoke and Aerosols		
Sample	**NRU EC_{50} (mg/mL)**	**S.E.**
3R4F	0.196	0.010
1R5F	0.237	0.014
Marlboro Gold	0.204	0.009
Control e-cig	ND †	--
blu CT-Ø	ND †	--
blu CT-High	ND †	--
blu MM- Ø	ND †	--
blu MM-High	ND †	--

Similar findings were reported for aqueous extracts of aerosols from various commercial e-cigs studied in cultured mammalian fibroblast and myocardial cells [9,10]. Both studies also reported that some aqueous extracts of e-cig aerosols showed cytotoxicity related to flavors, but were significantly less cytotoxic than cigarette smoke extracts. This study evaluated two flavored e-cigs, with and without nicotine (Table 1).

With e-liquids and pad-collected aerosols, no nicotine or flavor specific cytotoxic effects were evident with e-cigs without nicotine, blu MM-Ø, and blu CT-Ø, and with nicotine as high as

24 mg/mL, blu MM-High and blu CT-High (Figures 1A and 3A). The cytotoxicity and inflammatory response of L-nicotine in this cell culture system (Figure 2) was also tested. No cytotoxicity and inflammation (IL-8 release) were observed below 2.5 mg/mL and 1.0 mg/mL nicotine, respectively (Figure 2A,B). The highest level of nicotine in e-liquids tested was about 0.5 mg/mL (Table 1), which was below the concentrations of L-nicotine required to induce cytotoxicity and IL-8 release in this experimental method. In addition, the WTPM from tobacco cigarettes at 0.5 mg/mL was extremely cytotoxic (Figure 3A), corresponding to a nicotine concentration of approximately 0.04 mg/mL, which was well below nicotine mediated toxic levels, demonstrating that WTPM induced cytotoxicity was not mediated by nicotine.

3.7. E-Cigarettes and Conventional Cigarettes: Mutagenicity

The mutagenicity of pad-collected smoke and aerosols of tobacco cigarettes and e-cigs, respectively, is shown in Figure 3B. No activity was observed for control e-cig samples in the Ames assay. The specific activity for all tobacco cigarettes was in the range of 1600–1850 and 500–750 revertants/mg WTPM for TA98 and TA100, respectively (Figure 3B). Historically, WTPM prepared under the same smoking conditions has been shown to have similar levels of specific activity (revertants/mg) [35].

No increase in Ames activity was observed for any e-cigs used in this study and the revertants/mg was extremely low and within assay background measurements (< 2 revertants/mg). It was not possible to quantify the specific activities for e-cig aerosols since no increase in revertant counts was observed with increasing doses for all tested e-cig samples (Figure 3B).

3.8. E-Cigarettes and Conventional Cigarettes: Genotoxicity

The cell viability and clastogenic effects of WTPM and e-cig pad-collected aerosols are presented in Figure 3C,D. The pad-collected aerosol from the control e-cig containing glycerol/water and the solvent (DMSO) control did not induce any MN formation. A significant dose-dependent WTPM mediated induction in MN formation was observed with all tobacco cigarettes (3R4F, 1R5F and Marlboro Gold). No increase in the MN formation was observed for pad-collected aerosols from e-cigs at all doses tested (Figure 3C). The maximum induction in the MN formation with tobacco cigarettes was about 2.5 to 3-fold over background at about 0.12 mg/mL WTPM. A sharp decrease in the WTPM-induced MN formation was observed at dose levels higher than 0.12 mg/mL WTPM due to the decrease in cell viability (Figure 3D). Similar MN findings have been reported [31]. The dose at which tobacco cigarette WTPM induced maximum MN formation is approximately 166-fold lower than the maximum e-cig pad-collected aerosol dose (20 mg/mL) tested, which had no observed induced MN formation.

3.9. E-Cigarettes and Conventional Cigarettes: Inflammation

The inflammatory responses, as measured by IL-8 release from cells treated with tobacco WTPM and e-cig aerosols are presented in Figure 3E. No IL-8 release was observed for control samples. The pad-collected aerosols from all e-cigs did not induce any IL-8 release at all doses tested (Figure 3E). In contrast, a WTPM mediated dose-dependent increase in IL-8 release was observed for all tobacco

cigarettes. A sharp decrease in the IL-8 level at WTPM levels over 0.3 mg/mL was noticed (data not shown) since significant cytotoxicity was observed at those doses (Figure 3A).

The WTPM dose at which a significant IL-8 release was observed (0.15 mg/mL) was about 20-fold lower than the maximum e-cig pad-collected aerosol tested dose (3.2 mg/mL), at which no inflammatory effect was observed. The release of IL-8 in cultured cells by different cigarette smoke preparations has been reported [36] and this inflammatory response has been associated with oxidative stress due to the free radicals present in cigarette smoke [37].

At the lower doses of e-cig pad-collected aerosols utilized in this study, compared to the control, a lower release of IL-8 was observed (Figure 3E). That effect was also evident in cells treated with lower doses of pure nicotine (Figure 2B). This phenomenon of a lower release of an inflammatory cytokine (IL-8) is associated with the anti-inflammatory effects of nicotine [38]. There may be an association between the lower nicotine present in e-cig pad-collected aerosols and anti-inflammatory effects.

3.10. Nicotine Equivalence

Assessment of *in vitro* responses observed in this study was also calculated based on the level of nicotine present in the test samples. The level of nicotine concentrations measured in the prepared samples are shown in Table 1 but varied depending on sample volume and toxicity endpoint measured in this study. The upper limit of nicotine measured in tobacco cigarette WTPM was about 0.025 mg/mL, e-cig pad-collected aerosol was about 0.223 mg/mL and e-liquid was about 0.522 mg/mL. Thus, the nicotine concentration was about 10 to 20-fold higher in e-cig samples as compared to conventional cigarette samples. No nicotine mediated cellular toxicity was observed at 2.5 mg nicotine/mL (Figure 2A). At low doses up to 2.0 mg/mL, L-nicotine in fact increased the cellular proliferation as indicated by the higher cell viability than the control (Figure 2A) indicating a cellular protective response [27] as well as lower release of IL-8 in the media than control (Figure 2B) suggesting the anti-inflammatory properties of nicotine [38].

The average human exposure to nicotine on a 10-puff basis from a typical tobacco cigarette (tar 11.4 ± 0.1 mg/cig) is about 2.0 mg and from an e-cig product (labeled 24 mg nicotine) is about 0.23 mg under the similar CI smoking profile used for this study [39]. Therefore, it was evident that the nicotine levels in e-cig treatments were well below the toxic level of L-nicotine and represent comparative nicotine levels present in the tested e-cig and conventional cigarette samples. In addition, based on literature on the beneficial role of nicotine, relative to e-liquids and pad-collected aerosols used in this study and pure nicotine effects, there may be an association between lower levels of nicotine present in samples used in this study and cellular protection as well as anti-inflammatory effects [27,38].

Under the experimental conditions used to evaluate traditional tobacco burning cigarettes, e-cigs did not produce any meaningful toxic effects as measured by four *in vitro* endpoints. These results demonstrate the potential for e-cigs to significantly reduce the toxicological impact when compared to traditional tobacco burning cigarettes.

3.11. Comparable Human Exposure: Conventional and E-Cig

The comparative human exposure to tobacco cigarette smoke and e-cig aerosol is important in order to assess e-cig mediated reduced exposure and reduced harm. It has been reported that a smoker with one pack-a-day tobacco cigarette consumption inhales on average about 261 mg/m^3 cigarette tar [40], equivalent to about 271 μg/mL or 0.271 mg/mL [40]. Internal study indicated the range of e-cig aerosol delivery to be in the range of 0.5–1.5 mg/puff under Canadian Intense conditions (39). Assuming similar e-cig use as a conventional tobacco cigarette (200 puffs), the upper limit of human exposure to e-cig aerosol is approximately 300 mg or approximately 250 μg/mL or 0.25 mg/mL. The range of e-cig pad-collected aerosol used in the present study was 3.2–20 mg/mL. No adverse toxicological events were observed in this study even when the e-cig aerosol levels used were about 12–78 times higher than expected with normal e-cig use.

3.12. Contribution of Findings to Tobacco Harm Reduction and E-Cigs

The concept of Tobacco Harm Reduction (THR) has been advanced as a pragmatic approach to achieving reductions in the adverse public health impacts of cigarette smoking in the near term; in parallel with social, educational, and regulatory strategies intended to reduce and discourage cigarette smoking, particularly among adolescents [4,41–43].

The use of non-combustible SLT products such as Swedish-style snus and traditional moist snuff are demonstrably on the order of 98% less harmful in terms of risks for lung cancer, COPD, CVD, and other cancers, (including oral cancers) as compared to cigarette smoking [11,41,44,45].

Similarly, NRT products such as dermal patches and chewing gums have been shown to be safe and efficacious in clinically-managed and over-the-counter consumer usage. Therapeutic nicotine vapor inhaler devices and aerosol sprays for nasal and oral use have to date demonstrated similar benefits and low risks in facilitating smoking cessation [46]. The efficacy of such conventional NRT cessation aids has, however, proven in practice to fall short (~7% cessation success) of what is needed by a considerable number of smokers [47]. These smokers consistently report that taste, sensory and behavioral components experienced in the act of cigarette smoking are substantial motivators of the smoking behavior and may well comprise a population that could achieve substantially higher success in quitting through use of products that mimic the behavior element of smoking as well as the delivery of nicotine. Therefore, the use of e-cigs that provide some of the taste, sensory and behavioral components of conventional tobacco cigarette smoking may hold substantial promise in defining the potential benefits of the THR paradigm [48].

Despite the absence of long-term epidemiologic data on any chronic disease risk, a growing body of recent literature is consistent with an expectation that the use of e-cigs is unlikely to raise serious health concerns [49,50], particularly in comparison to those that result from the smoking of conventional cigarettes [7]. This conclusion is currently based, and further supported by this study and on a growing number of independent analyses of commercially-available e-cig liquids and product aerosols from markets around the world, that have consistently reported very low or undetectable levels of most tobacco smoke constituents that are known or suspected to play a prominent role in the etiology of serious tobacco-related diseases. [7,51–59].

There are various essential and contributory components to the THR framework, including product use and behavior, taste, nicotine delivery, product chemistry, toxicity and clinical safety. This study shows that neither the e-cig liquids nor collected aerosols produced any meaningful toxic effects in widely used *in vitro* test systems. These findings add additional value to the increasing body of scientific weight-of-evidence supporting the potential inclusion of e-cigs into THR paradigm.

4. Conclusions

In summary, this comparative *in vitro* toxicity study of e-cigs, SLT, NRT and tobacco cigarette products demonstrates the following:

(1) E-cigs *vs*. Tobacco WTPM: At doses up to approximately 100-fold higher than typical cigarette smoke exposures, blu e-cig liquids and pad-collected aerosols had no-to-extremely low *in vitro* activity (NRU, Ames, MN and IL-8) when compared to WTPM from tobacco burning cigarettes. WTPM activity was up to approximately 6,000 times higher than e-cigs.

(2) E-cigs *vs*. SLT and NRT: blu e-cig liquids demonstrated similar no-to-extremely low *in vitro* activity as aqueous extracts from a commercial nicotine lozenge (NRT) and commercial SLT products (snus and snuff).

(3) Effect of Nicotine: *In vitro* activities (NRU, Ames, MN and IL-8) measured for blu e-cig exposures, with and without nicotine, were similar for all sample types, indicating that the presence of nicotine, at the levels tested, did not contribute to any toxicological effects, confirmed by the lack of cytotoxicity and inflammation response of L-nicotine at comparative levels.

(4) Effect of Flavors: *In vitro* activities (NRU, Ames and MN) for the commercial blu e-cigs were indistinguishable from control (glycerol/water); indicating these flavors (CT and MM), at the levels tested, had no detectable impact on the cytotoxicity and genotoxicity endpoints utilized in this study. There was some observed IL-8 induction for some e-liquids, albeit at the highest doses tested.

(5) Liquid *vs*. Pad-Collected Aerosol: *In vitro* results for blu e-cigs, in this study, were similar for the different exposure methods (e-liquids and pad-collected aerosol); demonstrating no detectable impact on the *in vitro* toxicological responses when the e-liquids were aerosolized.

(6) SLT *vs*. Tobacco WTPM: SLT extracts added to the test systems at levels up to 54-fold higher than those used for Tobacco-WTPM generated by burning cigarettes was markedly less cytotoxic and mutagenic, and evoked a significantly lower IL-8 response at all dose levels evaluated. The effects of the SLT extracts in the assays were statistically indistinguishable from those of the e-cig and NRT preparations.

With respect to the study, lack of any meaningful *in vitro* acute toxicity for blu e-cigs and extremely low levels of chemical constituents measured in blu [39] and the analysis of known reduced risk products such as NRT and SLT has the potential to demonstrate a decreased human health impact as compared to conventional tobacco-burning cigarettes.

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Author Contributions

Manoj Misra: Participated in study design and execution of the study, conducted cytotoxicity (NRU) and IL-8 release measurements (e-liquids and pad-collected matter from e-cigs and tobacco cigarettes, aqueous extracts of SLTs and NRT) and related data collection and interpretation, and constructed manuscript as principal writer.

Robert D. Leverette: Participated in study design and execution of the study, coordinated sample preparation (e-liquids, pad-collected aerosols and smoke condensates, SLT and NRT aqueous extracts), conducted mutagenesis Ames test measurements (e-liquids and pad-collected matter from e-cigs and tobacco cigarettes, aqueous extracts of SLTs and NRT) and related data collection, compilation and interpretation and presentation of data (graphs and tables).

Bethany T. Cooper: Conducted MN formation measurements (e-liquids and pad-collected matter from e-cigs and tobacco cigarettes, aqueous extracts of SLTs and NRT) and related data collection.

Melanee B. Bennett: Maintained and provided cultured cells, A549 and CHO cells, for the study and assisted in conducting cytotoxicity (NRU) measurements (e-liquids and pad-collected matter from e-cigs and tobacco cigarettes, aqueous extracts of SLTs and NRT).

Steven E. Brown: Participated in study design and critical review of the manuscript.

Conflicts of Interest

The authors are Lorillard Tobacco Company employees and declare no conflict of interest with respect to the research, authorship, and/or publication of this article.

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In Press, Corrected Proof — Note to users

Comparison of select analytes in aerosol from e-cigarettes with smoke from conventional cigarettes and with ambient air

Rana Tayyarah, Gerald A. Long

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Highlights

- The e-cigarettes contained and delivered mostly glycerin and/or PG and water.
- Aerosol nicotine content was 85% lower than the cigarette smoke nicotine.
- The levels of HPHCs in aerosol were consistent with the air blanks (<2 μg/puff).
- Mainstream cigarette smoke HPHCs (~3000 μg/puff) were 1500 times higher than e-cigarette HPHCs.
- No significant contribution of tested HPHC classes was found for the e-cigarettes.

Abstract

Leading commercial electronic cigarettes were tested to determine bulk composition. The e-cigarettes and conventional cigarettes were evaluated using machine-puffing to compare nicotine delivery and relative yields of chemical constituents. The e-liquids tested were found to contain humectants, glycerin and/or propylene glycol, (⩾75% content); water (<20%); nicotine (approximately 2%); and flavor (<10%). The aerosol collected mass (ACM) of the e-cigarette samples was similar in composition to the e-liquids. Aerosol nicotine for the e-cigarette samples was 85% lower than nicotine yield for the conventional cigarettes. Analysis of the smoke from conventional cigarettes showed that the mainstream cigarette smoke delivered approximately 1500 times more harmful and potentially harmful constituents (HPHCs) tested when compared to e-cigarette aerosol or to puffing room air. The deliveries of HPHCs tested for these e-cigarette products were similar to the study air blanks rather than to deliveries from conventional cigarettes; no significant contribution of cigarette smoke HPHCs from any of the compound classes tested was found for the e-cigarettes. Thus, the results of this study support previous researchers' discussion of e-cigarette products' potential for reduced exposure compared to cigarette smoke.

Graphical abstract

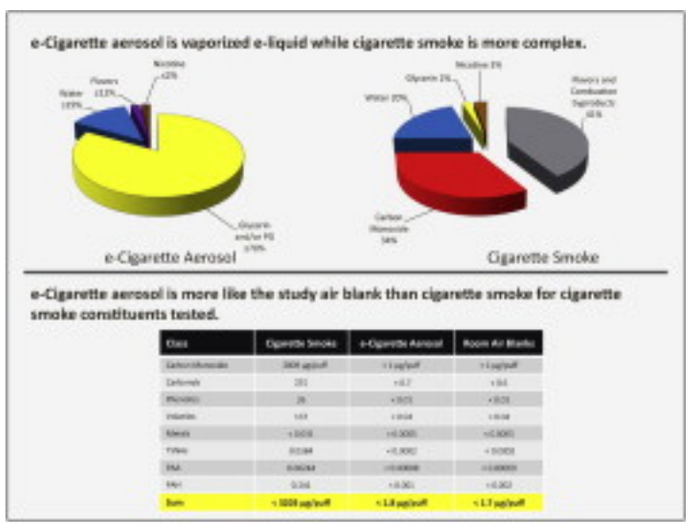

Figure options

Abbreviations

ACM, aerosol collected mass; HPHC, harmful and potentially harmful constituents; CO, carbon monoxide; TSNA, tobacco-specific nitrosamines; PAA, polyaromatic amines; PAH, polyaromatic hydrocarbons; LOQ, limit of quantitation; LOD, limit of detection; CAN, Health Canada Test Method T-115; blu CTD, Classic Tobacco Disposable; blu MMD, Magnificent Menthol Disposable; blu CCH, Cherry Crush, Premium, High Strength; SKYCIG CTB, Classic Tobacco Bold; SKYCIG CMB, Crown Menthol Bold; MGB, Marlboro Gold Box; L&B O, Lambert & Butler Original; L&B M, Lambert & Butler Menthol; TPM, total particulate matter; PG, propylene glycol

Keywords

Electronic cigarette; Smoking; Tobacco; Nicotine; Harmful and potentially harmful constituents (HPHC)

1. Introduction

Electronic cigarettes (e-cigarettes) are a relatively new consumer product. Unlike conventional cigarettes, e-cigarettes do not burn tobacco to deliver flavor. Instead, they contain a liquid-based flavorant (typically referred to as e-liquid or e-juice) that is thermally vaporized by an electric element. This liquid typically consists of a mixture of water, glycerin, and/or propylene glycol. The liquid also contains nicotine and flavor, although nicotine-free products are available.

While there are decades of characterization studies and numerous standardized analytical procedures for conventional cigarettes, relatively little published analytical data exists for commercial e-cigarette products. Furthermore, no standardized test methods or reference products exist for e-cigarettes.

Electronic cigarettes are generally purported to provide reduced exposure to conventional cigarettes' chemical constituents because they deliver flavors and nicotine through vaporization rather than by burning tobacco. Goniewicz et al. (2014) reported low levels of select chemical constituents in select e-cigarette brands commercially available in Poland. A recent review of analyses from diverse e-cigarettes shows comparatively simple chemical composition relative to conventional cigarette smoke (Burstyn, 2014). However, limited published results exist for commercial products that represent a significant presence in the marketplace (Cheng, 2014).

The purpose of this study was to evaluate e-cigarette products with a significant presence in the marketplace for bulk composition, including nicotine, and for select constituents for comparison with conventional cigarette products. Three blu eCigs products (approximately 50% of the US market) and two SKYCIG products (approximately 30% of the UK market) were chosen for evaluation. Marlboro Gold Box (US), and Lambert & Butler Original and Menthol products (UK), with significant market share in their respective geographical areas, were included in the study for conventional cigarette comparisons.

The products used in the study were evaluated for content and delivery of major ingredients (glycerin, propylene glycol, water, and nicotine) and for select constituents (carbon monoxide (CO), carbonyls, phenolics, volatile organic compounds (volatiles), metals, tobacco-specific nitrosamines (TSNAs), polyaromatic amines (PAAs), and polyaromatic hydrocarbons (PAHs)). Many of these constituents are included in cigarette industry guidance issued by the FDA that includes reporting obligations for harmful and potentially harmful constituents (HPHCs) in cigarette filler and smoke under section 904(a)(3) of the 2009 Family Smoking Prevention and Tobacco Control Act (FDA, 2012). For delivery studies, the conventional cigarettes were smoked under an intense puffing regime published by Health Canada (1999). The e-cigarettes were tested using minimal modifications to this smoking regime. Ninety-nine puffs were used to collect approximately the same aerosol mass as obtained from conventional cigarette testing. Ambient 'air' samples, empty port collections, were included as a negative control of aerosol testing for cigarette constituents (i.e. HPHC).

2. Materials and methods

2.1. Test products

Two disposable e-cigarette products and three rechargeable e-cigarette products were obtained from the manufacturers. Three conventional cigarette products were purchased through wholesale or retail sources for testing. Information for each of the products is listed in Table 1.

Table 1.

List of cigarette and e-cigarette products tested.

Product	Manufacturer	Product type	Nicotine information provided on packaging
Classic Tobacco Disposable (blu CTD)	blu eCigs	Disposable e-	Content: 24 mg/unit

		cigarette	
Magnificent Menthol Disposable (blu MMD)	blu eCigs	Disposable e-cigarette	Content: 24 mg/unit
Cherry Crush, Premium, High Strength (blu CCH)	blu eCigs	Rechargeable e-cigarette	Content: 16 mg/unit
Classic Tobacco Bold (SKYCIG CTB)	SKYCIG	Rechargeable e-cigarette	Content: 18 mg/unit
Crown Menthol Bold (SKYCIG CMB)	SKYCIG	Rechargeable e-cigarette	Content: 18 mg/unit
Marlboro Gold Box (MGB)	Philip Morris USA	Conventional cigarette	–
Lambert & Butler Original (L&B O)	Imperial Tobacco	Conventional cigarette	Yield: 0.9 mg/cig (ISO)
Lambert & Butler Menthol (L&B M)	Imperial Tobacco	Conventional cigarette	Yield: 0.5 mg/cig (ISO)

Table options

2.2. Methods overview

ISO 17025 accredited analytical methods were used to evaluate the cigarette samples for select HPHCs in mainstream smoke. Official methods are cited and other, internally validated, methods are briefly described for general understanding. Furthermore, because no standardized methods exist for e-cigarette analysis, the methods used to evaluate the conventional cigarettes were adapted to evaluate the e-cigarette products and the study blanks (room air). In an effort to maximize signal and lower methods' limits of quantitation, aerosol collection amounts were maximized (but maintained below breakthrough) and extraction solvent volumes were minimized. In some cases, alternative instrumentation was employed to improve detection. For example, mainstream smoke TSNAs were analyzed by GC–TEA while aerosol and air blank samples were analyzed by LC–MS/MS. Accuracy, precision, and method limits of quantitation and detection (LOQ and LOD) were verified for each method. On average, accuracy and method variability for the analytes tested were determined to be 98% and 3%, respectively. Analyte LOD and LOQ information is listed in Supplemental Appendix A Tables 1 and 2. Method resolution for low levels of analytes was influenced by background levels of select analytes in air control samples. These background levels are attributed to instrument or smoking machine carry-over as evidenced in solvent or air blanks. In addition, the high concentration of glycerin and water in e-cigarette aerosol present challenges for volatile-based measurement systems (i.e. GC). Additional method refinements and dedicated e-cigarette puffing machines are two areas for consideration to improve e-cigarette aerosol method sensitivities. Method development and verification details for e-cigarette liquids and aerosols are the subject of a future publication.

2.3. Smoke and aerosol collection

Cigarette preparation and machine smoking for conventional cigarettes are described in Health Canada Test Method T-115 (CAN) (1999). Two to three cigarettes were smoked per replicate for conventional cigarettes and 99 puffs were taken from single e-cigarettes for no more than approximately 200 mg of particulates collected per pad. Three to five replicates were tested for each measurement. Prior to analysis, filter pads from cigarette smoke collection were visually inspected for overloading of particulates, as evidenced by brown spotting on the back of the filter pad. To ensure no overloading of particulates for aerosol collection, e-cigarette units were weighed before and after collection to verify that product weight change and filter pad weight change were comparable. Air blanks were prepared by puffing room air (99 puffs) through an empty smoking machine port to the indicated trapping media for an analysis method. These air blank samples were prepared and analyzed in the same manner and at the same time as the e-cigarette aerosol samples. Smoke and aerosol collection sections were conducted separately. Smoke and aerosol particulate was collected onto 44 mm glass fiber filter pads with >99% particulate trapping efficiency for each replicate analysis. For carbonyls, smoke/aerosol was collected directly by two impingers, in series. For smoke metals analysis, electrostatic precipitation was used. For volatiles and PAH determinations, single chilled impingers were placed in-line with the filter pads. e-Liquid glycerin and nicotine were quantitated using GC–FID and/or GC–MS using a method equivalent to ISO 10315 (ISO, 2000a). e-Liquid water was quantitated using Karl Fischer analysis. A reference e-liquid was developed and used as a testing monitor for ingredient determinations in the e-liquid samples. The reference e-liquid is composed primarily of glycerin, propylene glycol, and water with low levels of nicotine, menthol, and Tween 80. The Tween 80 is added to improve solubility of menthol in the solution. The reference is not meant to directly mimic an e-liquid used for consumption but merely used for analytical control charts. Three replicates were tested for each sample and the reference.

2.4. Analytical assays

Carbon monoxide was determined concurrently with aerosol and smoke collection for nicotine and water and analyzed by NDIR using ISO method 8454:2007 (ISO, 2007). Carbonyls were trapped using 2,4-dinitrophenylhydrazine as a derivatizing agent with subsequent analysis by UPLC–UV using CORESTA method 74 (CORESTA, 2013). For phenolics determination, filter pads were extracted with 20 mL of 1% acetic acid/2.5% methanol (MEOH) in water using 30 min of agitation. Extracts were analyzed by UPLC-fluorescence detection using a C18 column for separation. For volatiles analysis, filter pads and impinger solutions (20 mL MEOH) were combined. Extracts were analyzed by GC–MS in SIM mode using a WAX capillary column. For metals analysis, cigarette smoke was collected using an electrostatic precipitator while e-cigarette aerosol was collected on glass fiber filter pads. After smoking, the cigarette smoke condensate was rinsed from the electrostatic precipitation tube using methanol. The dried condensates were digested using hydrochloric (10% v/v), nitric acids (80% v/v), and heat and were diluted prior to analysis by ICP-MS. For aerosol samples, filter pads were extracted using 20 mL of a mixture of nitric (2% v/v) and hydrochloric acids (0.5% v/v) using wrist action shaker (20 min). Resultant extracts were analyzed by ICP-MS equipped with an octapole reaction cell.

For TSNA analysis of smoke, samples were extracted in nonpolar solvent, treated to an SPE clean-up, concentrated and analyzed by GC–TEA following CORESTA method 63 (CORESTA, 2005). For TSNA analysis of aerosol samples, filter pads were extracted with 20 mL of 5 mM aqueous ammonium with 15 min of shaking. Extracts were analyzed by LC–MS/MS with a C18 column. For PAA determinations, filter pads were extracted using 25 mL of 5% HCl (aq) and shaking (30 min) followed by solvent exchange and derivatization with pentafluoropropionic acid anhydride and trimethylamine. After an SPE clean-up step (Florisil® SEP-PAK), samples were analyzed by GC–MS in SIM mode using negative chemical ionization. PAH analysis was conducted by extraction in MEOH followed by SPE clean-up and analysis by GC–MS in SIM mode (Tarrant et al., 2009).

The results obtained from these analyses were tabulated as mean ± one standard deviation for levels of selected compounds in Supplementary Appendix A. In cases where quantifiable amounts of analyte were present in an e-cigarette aerosol sample above that of the associated air blanks, an Analysis of Variance (ANOVA) was used to compare the means for the cigarette smoke data with respective aerosol data. Statistical analyses were performed using JMP 10.0.0 (SAS Institute, Inc. Cary, NC, USA). The significance level was established as $p < 0.05$ for all comparisons.

3. Results and discussion

3.1. Collection of aerosol

Machine smoking of cigarettes under standardized regimes is for comparative purposes and is not intended to represent the range of consumer smoking behaviors. Thus, standardized equipment, cigarette reference products, and methodology have been established to allow comparison of different products under a common set of controlled conditions. ISO 3308:2000E and Health Canada (CAN) methods are frequently used for standardized smoking of conventional cigarettes for the purposes of laboratory comparisons among products (ISO, 2000b and Health Canada, 1999). Following each of these methods, conventional cigarettes are smoked to a specified butt length using a fixed and specified puffing volume, duration, and interval.

Regarding e-cigarette experimentation, there is no generally accepted standard e-cigarette puffing regime at this time. Topography studies are limited but anecdotal information indicates e-cigarette usage depends greatly on the individual consumer and product design and capabilities. For the purposes of this study, our objective was to collect sufficient aerosol to be able to detect, if present, select HPHCs. A wide range of parameters would be adequate to accomplish this. Given the objectives of this study, use of collection parameters which are compatible with conventional and electronic cigarettes was essential for facilitating comparisons between cigarette smoke and e-cigarette aerosol. The more intense of the standard regimes used with cigarettes, CAN, which requires 55 mL puffs taken twice a minute, was adapted for this investigation. The key difference required for testing e-cigarettes with the CAN method is that a fixed puff count (rather than ‘butt length’) is necessary for aerosol collection. A standard of 99 puffs was adopted for all e-cigarette and air blank analyses. This puff count provides similar total particulate collection per pad between the e-cigarette samples and the conventional cigarette testing. This also represents approximately 11 times more puffs than are typically observed for a conventional cigarette. Marlboro Gold Box, L&B O, and L&B M averaged 9.1, 8.2, and 7.2 puffs per cigarette, respectively, when machine-smoked to the standard butt length. If more aggressive puffing parameters had been chosen for the study, the puff count specification would have been lowered to maintain the target level of ACM collected. Note that the range of puffs collected in-use may vary widely depending on product design, battery strength, and user puffing preferences. Thus, the 99 puffs collection in this study is not intended to represent a life time use yield for any of the analytes tested.

3.2. Aerosol and smoke characterization – reference information

Traditional cigarette testing incorporates the use of monitor or reference cigarettes that serve as positive

controls and provide quality metrics for standardized analytical methods. Key examples are Kentucky Reference cigarettes and CORESTA monitor cigarettes (CORESTA, 2009, ISO, 2003 and University of Kentucky, 2014). Each of these reference cigarettes can serve as a single positive control and an indicator of method variability within and among laboratories for all analytes of interest. The manufacture, design, and function of these reference products are similar to those of commercial cigarettes. Currently reference products are not available for e-cigarette testing. Given the range of e-cigarette designs, development of a consensus strategy to produce positive controls or monitors for e-cigarette testing is needed.

In the absence of standardized e-cigarette references, measures were taken to ensure experimental robustness. For example, aerosol collected mass (ACM) results for the e-cigarette samples were compared across methods as an indicator of puffing consistency for a given product among the machine-puffing sessions required to conduct the battery of tests. Thus, if a sample set yielded ACM outside of a specified ranged deemed typical for a given product, the sample set was repeated. This range was determined for each product based on collection of 20 or more replicates across the product lot using CAN parameters.

Also, because results from initial analyses indicated low or no measurable levels of many of the analytes, blank samples were included to verify any contribution of analyte from the laboratory environment, sample preparation, and/or analyses for each HPHC test method. The air blank results are listed with the samples' results in Table 4 and Table 5. There were instances for which solvent blank and air blank samples had measurable levels of an analyte. This is due to the ubiquitous nature of some of the analytes, such as formaldehyde, or to carry-over. Laugesen reported similar findings (2009). These observations serve as a cautionary note regarding the measurement of extremely low levels of constituents with highly sensitive instrumentation.

3.3. Main ingredients

e-Liquid expressed from the individual products was tested for reported e-cigarette ingredients to compare the percent compositions of the e-liquids and the aerosols. Percent composition calculations of the ingredients are shown in Table 2 for each sample and in Fig. 1 for blu CTD, as this product's comparative results were exemplary of the samples. The primary ingredients in the e-cigarette samples were glycerin and/or propylene glycol (⩾75%). Water (⩽18%) and nicotine (~2%) were also present. Based on a mass balance, other ingredients, presumed to be flavorants, were present at less than 7%. Note that this calculation would also include method uncertainty and any possible HPHCs, if present. The composition of the aerosol was calculated based on the ACM delivery as analyte yield (mg)/ACM (mg) × 100. The bulk composition of the delivered aerosol was similar to the bulk composition of the e-liquid.

Table 2.

Percent composition of e-liquid and aerosol.

	Glycerin (%)	Propylene glycol (%)	Water (%)	Nicotine (%)	Flavor[a] (%)
e-Liquid composition					
blu Classic Tobacco Disposable	82	–	9	2	7
blu Magnificent Menthol Disposable	75	–	18	2	5
blu Cherry Crush High Premium	77	–	14	2	7
SKYCIG Classic Tobacco Bold	24	67	6	2	1
SKYCIG Crown Menthol Bold	21	66	7	2	4
e-Cigarette aerosol composition [b]					
blu Classic Tobacco Disposable	73	–	15	1	11
blu Magnificent Menthol Disposable	80	–	18	2	–
blu Cherry Crush High Premium	70	–	19	1	10
SKYCIG Classic Tobacco Bold	24	61	10.4	1.4	3
SKYCIG Crown Menthol Bold	21	59	12	2	6

a Flavor content is estimated by difference.

b Aerosol % composition calculated based on the ACM delivery as analyte yield (mg)/ACM (mg) × 100.

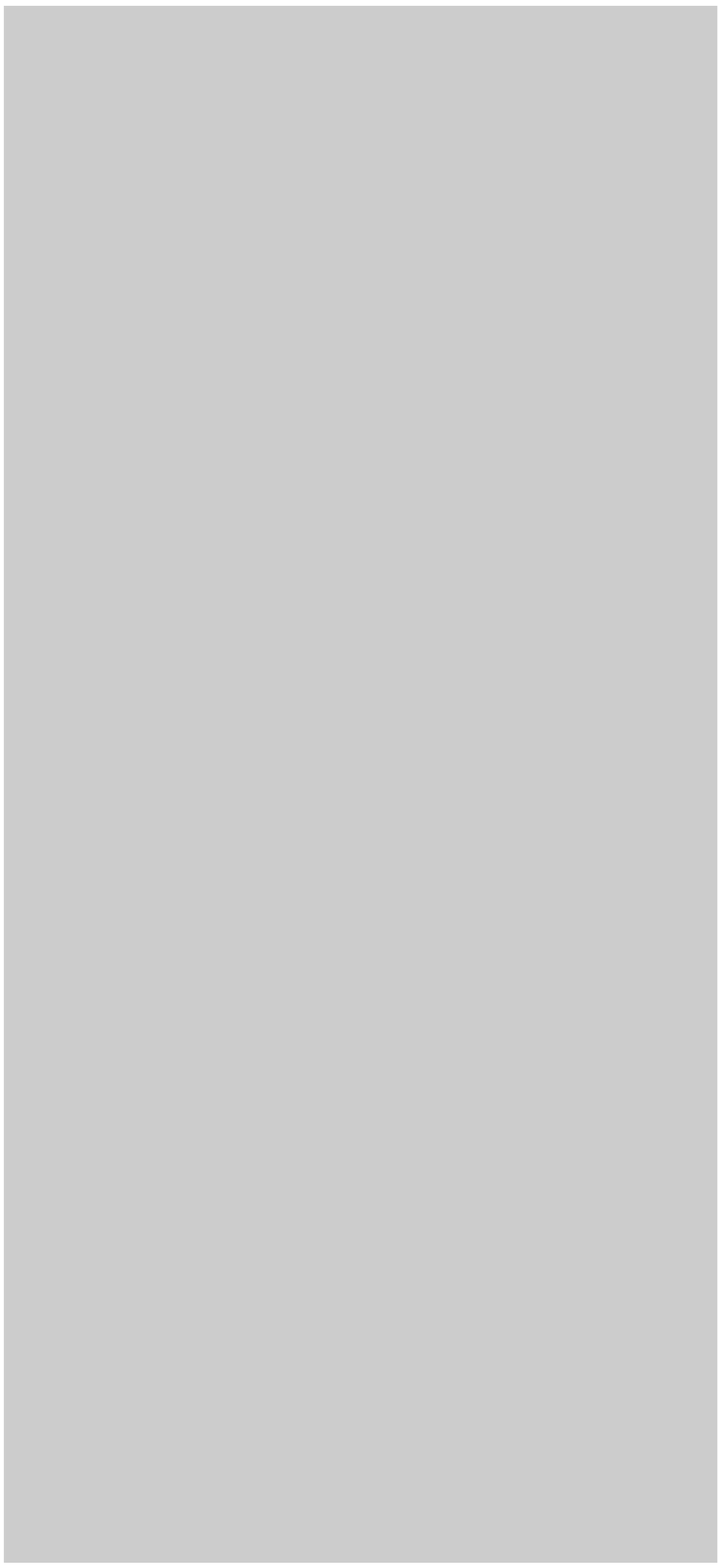

Fig. 1.

Percent composition comparison for e-liquid, e-cigarette aerosol, and cigarette smoke: (a) Classic Tobacco Disposable e-liquid Composition. (b) Classic Tobacco Disposable Aerosol Composition (99 puffs, CAN). (c) Marlboro Gold Box Smoke Composition (9 puffs, CAN).

Figure options

By comparison, the total particulate matter (TPM) of the conventional cigarettes tested is 30% water and <5% nicotine. The essential difference between the ACM composition of the e-cigarettes tested and the TPM of the conventional cigarettes is that the remaining 65% of the TPM of the conventional cigarette is predominantly combustion byproducts. There was no detectable carbon monoxide in the emitted aerosol of the e-cigarette samples. The conventional cigarettes, on the other hand, delivered more than 20 mg/cig of CO. Smoke composition for Marlboro Gold Box, exemplary of the conventional cigarettes tested, is shown in Fig. 1 in contrast to the e-liquid and aerosol results for blu CTD.

While the percent composition of the nicotine in the ACM and TPM are relatively similar, it should be noted that the actual deliveries of nicotine are markedly lower for the e-cigarettes tested than the conventional cigarettes. The nicotine yields ranged from 8 μg/puff to 33 μg/puff for the e-cigarette samples which was 85% lower than the 194–232 μg/puff for the conventional cigarettes. These results are presented in Table 3.

Table 3.

Nicotine content and yield comparison between e-cigarettes and conventional cigarettes (mean ± standard deviation).

	Nicotine content (μg/unit)	Nicotine yield (μg/puff)
blu Classic Tobacco Disposable	20,600 ± 1500	33 ± 12
blu Magnificent Menthol Disposable	20,000 ± 300	25 ± 4
blu Cherry Crush High Premium	11,700 ± 300	8 ± 3

SKYCIG Classic Tobacco Bold	12,750 ± 295	29 ± 4
SKYCIG Crown Menthol Bold	13,027 ± 280	33 ± 6
Marlboro Gold Box	11,431 ± 80	226 ± 2
L&B Original	12,941 ± 26	232 ± 5
L&B Menthol	12,131 ± 24	194 ± 10

Number of replicates = 3–5.

Table options

3.4. Aerosol and smoke HPHC testing

For cigarette smoke analysis, the conventional cigarettes were machine smoked by established cigarette smoking procedures. Approximately 7–9 puffs per cigarette were collected. For the e-cigarette samples and air blanks, 99 puffs were collected. Results were compared on an 'as tested' basis; i.e. yields for a single cigarette of 7–9 puffs compared to yields from 99 puffs of an e-cigarette as displayed in Table 4. Additionally, in order to simplify making comparisons between the cigarette and e-cigarette samples, all values were converted to yield per puff. These results are summarized by class in Table 5. Results for individual analytes are tabulated as mean ± one standard deviation in Supplemental Appendix A Tables 1 and 2.

Table 4.

Analytical characterization of commercial e-cigarettes and conventional cigarettes collected using CAN parameters – select cigarette HPHC methodology (mg/total puffs collected) summary by analyte classes.

	CO	Carbonyls[a]	Phenolics[b]	Volatiles[c]	Metals[d]	TSNAs[e]	PAA[f]	PAH[g]	Sum
Marlboro Gold Box (mg/cig)	27	1.92	0.204	1.430	<0.00020	0.000550	0.000024	0.00222	<30.6 mg
L&B Original (mg/cig)	22	1.89	0.26	1.02	<0.0002	0.000238	0.000019	0.00219	<25.2
L&B Menthol (mg/cig)	20	1.81	0.17	0.94	<0.0003	0.000185	0.000017	0.00153	<22.9
blu CTD (mg/99 puffs)	<0.1	<0.07	<0.001	<0.001	<0.00004	<0.00002	<0.000004	<0.00016	<0.17
blu MMD (mg/99 puffs)	<0.1	<0.08	<0.001	<0.001	<0.00004	<0.00002	<0.000004	<0.00016	<0.18
blu CCHP (mg/99 puffs)	<0.1	<0.05	<0.003	<0.0004	<0.00004	<0.00002	<0.000004	<0.00014	<0.15
SKYCIG CTB (mg/99 puffs)	<0.1	<0.06	<0.0010	<0.008	<0.00006	<0.000013	<0.000014	<0.00004	<0.17
SKYCIG CMB (mg/99 puffs)	<0.1	<0.09	<0.0014	<0.008	<0.00006	<0.000030	<0.000014	<0.00004	<0.20
Air Blank (blu Set) (mg/99 puffs)	<0.1	<0.06	<0.001	<0.0004	<0.00004	<0.00002	<0.000004	<0.00015	<0.16
Air Blank (SKYCIG Set) (mg/99 puffs)	<0.1	<0.05	<0.0009	<0.008	<0.00006	<0.000013	<0.000014	<0.00006	<0.16

< Indicates some or all values were below method limits of quantitation or detection, number of replicates = 3–5.

a Formaldehyde, acetaldehyde, acrolein propionaldehyde, crotonaldehyde, MEK, butyraldehyde.

b Hydroquinone, resorcinol, catechol, phenol, m-+p-cresol, o-cresol.

c 1,3-Butadiene, isoprene, acrylonitrile, benzene, toluene, styrene.

d Beryllium, cadmium, chromium, cobalt, lead, manganese, mercury, nickel, selenium, tin.

e NNN, NAT, NAB, NNK.

f 1-Aminonaphthalene, 2-aminonaphthalene, 3-aminobiphenyl, 4-aminobiphenyl.

g Naphthalene, acenaphthylene, acenaphthene, fluorine, phenanthrene, anthracene, fluoranthene, pyrene, benzanthracene, chrysene, benzo(b)fluoranthene, benzo(k)fluoranthene, B(a)P, indeno[1,2,3-cd]pyrene, benzo(g,h,i)perylene.

Table options

Table 5.

Analytical characterization of commercial e-cigarettes and conventional cigarettes collected using CAN parameters – select cigarette HPHC methodology (µg/puff) summary by analyte classes.

	CO	Carbonyls[a]	Phenolics[b]	Volatiles[c]	Metals[d]	TSNAs[e]	PAA[f]	PAH[g]	Sum
Marlboro Gold Box	2967	211	22	157	<0.026	0.0604	0.00264	0.244	<3357 µg
L&B Original	2683	230	32	124	<0.024	0.0290	0.00232	0.267	<3069
L&B Menthol	2778	251	24	130	<0.042	0.0257	0.00236	0.213	<3183
blu Classic Tobacco Disposable	<1.0	<0.7	<0.01	<0.01	<0.0004	<0.0002	<0.00004	<0.002	<1.7
blu Magnificent Menthol Disposable	<1.0	<0.8	<0.01	<0.01	<0.0004	<0.0002	<0.00004	<0.002	<1.8
blu Cherry Crush High Premium	<1.0	<0.5	<0.03	<0.004	<0.0004	<0.0002	<0.00004	<0.001	<1.5
SKYCIG Classic Tobacco Bold	<1.0	<0.6	<0.01	<0.08	<0.0006	<0.0001	<0.00014	<0.0004	<1.7
SKYCIG Crown Menthol Bold	<1.0	<0.9	<0.01	<0.08	<0.0006	<0.0003	<0.00014	<0.0004	<2.0
Air Blank (blu Set)	<1.0	<0.6	<0.01	<0.004	<0.0004	<0.0002	<0.00004	<0.002	<1.6
Air Blank (SKYCIG Set)	<1.0	<0.5	<0.01	<0.08	<0.0006	<0.0001	<0.00014	<0.001	<1.6

< Indicates some or all values were below method limits of quantitation or detection, number of replicates = 3–5.

a Formaldehyde, acetaldehyde, acrolein propionaldehyde, crotonaldehyde, MEK, butyraldehyde.

b Hydroquinone, resorcinol, catechol, phenol, m-+p-cresol, o-cresol.

c 1,3-Butadiene, isoprene, acrylonitrile, benzene, toluene, styrene.

d Beryllium, cadmium, chromium, cobalt, lead, manganese, mercury, nickel, selenium, tin.

e NNN, NAT, NAB, NNK.

f 1-Aminonaphthalene, 2-aminonaphthalene, 3-aminobiphenyl, 4-aminobiphenyl.

g Naphthalene, acenaphthylene, acenaphthene, fluorine, phenanthrene, anthracene, fluoranthene, pyrene, benzanthracene, chrysene, benzo(b)fluoranthene, benzo(k)fluoranthene, B(a)P, indeno[1,2,3-cd]pyrene, benzo(g,h,i)perylene.

Table options

All analytes tested were present in the cigarette smoke at quantifiable levels except for select metals. These results are consistent with internal historical results for commercial cigarettes tested under the CAN smoking regime. For the cigarette samples, the total yield range was 3069–3350 µg/puff of HPHCs tested.

Of the 55 HPHCs tested in aerosol, 5 were quantifiable in an e-cigarette sample but not the associated air blank. The quantifiable results for aerosol are listed in Table 6 and Table 7 in contrast with the conventional cigarettes from the same geographical region. The five analytes which were quantifiable were statistically different ($p < 0.05$) at levels 50–900 times lower than the cigarette smoke samples. Phenol was quantified in one e-cigarette product at 900 times lower than cigarette smoke. N-Nitrosoanatabine was quantified in one product at 50 times lower than cigarette smoke. Three carbonyls (acrolein, acetaldehyde, and propionaldehyde) were quantified at 86–544 times lower than cigarette smoke.

Table 6.

Per puff comparisons of quantifiable analytes for blu eCigs products from CAN puffing – yields and ratios to conventional product yields.

	Marlboro Gold Box µg/puff	blu MMD µg/puff	MGB/blu MMD

Acrolein	16.4 ± 0.2	0.19 ± 0.06	86
Phenol	1.53 ± 0.16	0.0017[a]	900

a Fewer than three replicates were quantifiable; no standard deviation is listed.

Table options

Table 7.

Per puff comparisons of quantifiable analytes for SKYCIG products from CAN puffing – yields and ratios to conventional product yields.

	L&B average µg/puff	SKYCIG CTB µg/puff	SKYCIG CMB µg/puff	L&B average/SKYCIG CTB	L&B average/SKYCIG CMB
Acetaldehyde	174	–	0.32[a]	–	544
Acrolein	17	0.15 ± 0.02	–	113	–
Propionaldehyde	12	–	0.11 ± 0.05	–	109
N-Nitrosoanatabine	0.010	–	0.0002 ± 0.0001	–	50

a Fewer than three replicates were quantifiable; no standard deviation is listed.

Table options

All other analytes were not quantifiable above the air blanks in aerosol samples. The e-cigarettes and air blanks total yields for analytes were <2 µg/puff which is 99% less than the approximately 3000 µg/puff quantified for the cigarette smoke samples. Thus, the results support the premise of potentially reduced exposure to HPHCs for the e-cigarette products compared to conventional cigarette smoke.

4. Conclusions

The purpose of this study was to determine content and delivery of e-cigarette ingredients and to compare e-cigarette aerosol to conventional cigarettes with respect to select HPHCs for which conventional cigarette smoke is routinely tested. Routine analytical methods were adapted and verified for e-cigarette testing. Aerosol collection was conducted using conventional smoking machines and an intense puffing regime. As machine puffing cannot, and is not intended to, mimic human puffing, results of this study are limited to the scope of the comparisons made between the e-cigarette and conventional cigarette products tested.

The main ingredients for the e-cigarettes tested were consistent with disclosed ingredients: glycerin and/or propylene glycol (⩾75%), water (⩽18%), and nicotine (∼2%). Machine-puffing of these products under a standardized intense regime indicated a direct transfer of these ingredients to the aerosol while maintaining an aerosol composition similar to the e-liquid. Nicotine yields to the aerosol were approximately 30 µg/puff or less for the e-cigarette samples and were 85% lower than the approximately 200 µg/puff from the conventional cigarettes tested.

Testing of the e-cigarette aerosol indicates little or no detectable levels of the HPHC constituents tested. Overall the cigarettes yielded approximately 3000 µg/puff of the HPHCs tested while the e-cigarettes and the air blanks yielded <2 µg. Small but measurable quantities of 5 of the 55 HPHCs tested were found in three of the e-cigarette aerosol samples at 50–900 times lower levels than measurable in the cigarette smoke samples. Overall, the deliveries of HPHCs tested for the e-cigarette products tested were more like the study air blanks than the deliveries for the conventional cigarettes tested. Though products tested, collection parameters, and analytical methods are not in common between this study and others, the results are very consistent. Researchers have reported that most or all of the HPHCs tested were not detected or were at trace levels. Burstyn (2014) used data from approximately 50 studies to estimate e-cigarette exposures compared to workplace threshold limit values (TLV) based on 150 puffs taken over 8 h. The vast majority of the analytes were estimated as ≪1% of TLV and select carbonyls were estimated as <5% of TLV. Cheng (2014) reviewed 29 publications reporting no to very low levels of select HPHCs relative to combustible cigarettes, while noting that some of the tested products exhibited considerable variability in their composition and yield. Goniewicz et al. (2014) tested a range of commercial products and reported quantifiable levels for select HPHCs in e-cigarette aerosols at 9- to 450-fold lower levels than those in cigarette smoke that in some instances were on the order of levels determined for the study reference (a medicinal nicotine inhaler). Laugesen, 2009 and Theophilus et al., 2014 have presented results for commercial e-cigarette product liquids and aerosols having no quantifiable levels of tested HPHCs, or extremely low levels of measurable constituents relative to cigarette smoke. Additionally, findings from several recent studies indicate that short-term use of e-cigarettes by adult smokers is generally well-tolerated, with significant adverse events reported relatively rarely (Etter, 2010, Polosa et al., 2011, Polosa et al., 2014, Caponnetto et al., 2013, Dawkins and

Corcoran, 2014 and Hajek et al., 2014). Thus, the results obtained in the aforementioned studies and in the present work broadly support the potential for e-cigarette products to provide markedly reduced exposures to hazardous and potentially hazardous smoke constituents in smokers who use such products as an alternative to cigarettes.

Additional research related to e-cigarette aerosol characterization is warranted. For example, continued characterization of major components and flavors is needed. Establishment of standardized puffing regimes and reference products would greatly aid sharing of knowledge between researchers. Continued methods' refinement may be necessary for improved accuracy for quantitation of analytes at the low levels determined in this study. To that end, it is critical that negative controls and steps to avoid sample contamination be included when characterizing e-cigarette aerosol since analytes are on the order of what has been measured in the background levels of a laboratory setting. Though researchers have reported quantification of select analytes, great care must be taken when interpreting results at such trace levels.

Conflicts of interest

The company for which the study authors work and the companies that manufacture the e-cigarettes tested for this study are owned by the same parent company.

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Appendix A. Supplementary data

Supplementary data.

This document contains supplementary tables

Help with DOCX files

Options

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Article

Comparison of Select Analytes in Exhaled Aerosol from E-Cigarettes with Exhaled Smoke from a Conventional Cigarette and Exhaled Breaths

Gerald A. Long

Lorillard Tobacco Company, P.O. Box 21688, Greensboro, NC 27420, USA;
E-Mail: glong@lortobco.com; Tel.: +1-336-335-6607; Fax: +1-336-335-6640

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Abstract: Exhaled aerosols were collected following the use of two leading U.S. commercial electronic cigarettes (e-cigarettes) and a conventional cigarette by human subjects and analyzed for phenolics, carbonyls, water, glycerin and nicotine using a vacuum-assisted filter pad capture system. Exhaled breath blanks were determined for each subject prior to each product use and aerosol collection session. Distribution and mass balance of exhaled e-cigarette aerosol composition was greater than 99.9% water and glycerin, and a small amount (<0.06%) of nicotine. Total phenolic content in exhaled e-cigarette aerosol was not distinguishable from exhaled breath blanks, while total phenolics in exhaled cigarette smoke were significantly greater than in exhaled e-cigarette aerosol and exhaled breaths, averaging 66 µg/session (range 36 to 117 µg/session). The total carbonyls in exhaled e-cigarette aerosols were also not distinguishable from exhaled breaths or room air blanks. Total carbonyls in exhaled cigarette smoke was significantly greater than in exhaled e-cigarette aerosols, exhaled breath and room air blanks, averaging 242 µg/session (range 136 to 352 µg/session). These results indicate that exhaled e-cigarette aerosol does not increase bystander exposure for phenolics and carbonyls above the levels observed in exhaled breaths of air.

Keywords: smoking; vaping; electronic cigarette; e-cigarette; aerosol; carbonyl; phenolic; hydroxybenzene; combustion; nicotine; emission; passive vaping

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1. Introduction

Electronic cigarettes (e-cigarettes) are products that became available to United States consumers in about 2007 [1]. Unlike conventional cigarettes that burn tobacco at high temperatures, e-cigarettes contain a liquid flavor solution (e-liquid) that is thermally vaporized by a battery powered heating element. The e-liquids typically contain a mixture of aerosol forming components such as glycerin and propylene glycol, various flavors and, optionally, nicotine. Recently published studies have reported on the constituents of e-liquids and e-cigarette aerosols [2–8]. Some of these constituents are among those listed as Harmful and Potentially Harmful Constituents (HPHC) for tobacco products by the United States Food and Drug Administration (FDA) [9]. Constituents that have been identified in machine-generated e-cigarette aerosols and emissions in enclosed spaces [3,4,6,10], include the carbonyl compounds acetaldehyde, acrolein and formaldehyde [3,6,11,12]. The reported levels of these carbonyl compounds were lower than those of conventional cigarettes smoked under comparable conditions by one to two orders of magnitude.

Riker, *et al*. have advanced the notion that exhaled e-cigarette aerosol may pose an exposure risk to bystanders similar to that of environmental tobacco smoke (ETS) from conventional cigarettes through "passive vaping" [13]. However, the majority (~85%) of ETS aerosol arises from side stream smoke generated during static cigarette smolder in between puffs [14], which is absent for e-cigarettes. Several investigators have reported machine generated e-cigarette aerosol contributions to particulates/droplets and chemical constituents in test chambers [13,15] and indoor environments [5]. All of these studies suggest that exposure to constituents in machine-generated mainstream e-cigarette aerosols would not exceed background, although such studies did not actually use exhaled e-cigarette aerosol from human subjects.

Recent investigations have reported emissions of constituents in closed air chambers or in rooms having minimal ventilation with human subjects using e-cigarettes [15–18]. A study by Romanga, *et al*. in an unventilated room using human subjects failed to detect a number of analytes including nicotine [16], consistent with the sampling and analytical challenges posed by the baseline levels of many of the constituents in e-cigarette aerosols.

A 2013 study by Schripp, *et al*. reported aerosol droplet counts and chemical constituents generated by e-cigarette users, under prescribed puffing parameters, in a room with air exchange [17]. Several compounds, including carbonyls, were detected. However, the authors attributed these levels to the test subjects' normal metabolic processes and not to the exhaled e-cigarette aerosols.

A recent study with nine e-cigarette users puffing *ad libitum* in a room with air exchange found propylene glycol, glycerin and nicotine in the room air [18]. No increases above background were noted for formaldehyde, acetone or acrolein.

These studies have explored the potential for bystander exposure from e-cigarettes, but that have not adequately addressed the chemical composition of exhaled e-cigarette aerosol. A simple mass balance and distribution of known constituents such as water, glycerin and nicotine has not been reported for exhaled e-cigarette aerosol. The quantities of constituents such as phenolics and carbonyls in exhaled cigarette smoke relative to exhaled e-cigarette aerosol, and to a suitable blank of exhaled breaths of air is also lacking in the scientific literature. The present study addressed these gaps with direct analyses of the quantities of phenolic and carbonyl compounds in the exhaled aerosols from human subjects using cigarettes and e-cigarettes without any dilution effects due to room volume or air exchange and determined

mass balance and distribution of water, glycerin and nicotine in exhaled e-cigarette aerosols. These data were compared with baseline levels in exhaled breath blanks to place the findings in the context of the known and common presence of some chemical constituents in indoor environments [19–22]. The analytical methodologies used in this study have been applied to collection and measurement of constituents in exhaled cigarette aerosols [23–27] and have been adapted to measure levels of phenolics and carbonyls in exhaled e-cigarette aerosols.

2. Experimental Section

2.1. Materials

The conventional cigarette and the two e-cigarettes used in this study were all products with significant U.S. market shares in their respective categories. The products used in this study are shown in Figure 1.

Figure 1. The three study products: (**a**) Marlboro Gold Box, 85 mm conventional cigarette (MGB); (**b**) blu Classic Tobacco Disposabe (blu CTD); (**c**) blu Magnificent Menthol Disposable (blu MMD).

The Marlboro Gold King Box filtered cigarette (MGB), which is the largest-selling brand in the U.S. was selected to represent the conventional cigarette category (Philip Morris USA, Miami, FL, USA) [28]. The blu eCigs Classic Tobacco Disposable (blu CTD) and blu eCigs Magnificent Menthol Disposable (blu MMD) electronic cigarettes were selected to represent the e-cigarette category (Charlotte, NC, USA), representing the U.S. market leaders for this product category. The MGB sample was obtained from a commercial wholesaler (Reidsville Grocery Company, 1624 Freeway Dr., Reidsville, NC, USA). The e-cigarette products were obtained directly from the manufacturer.

Both of the disposable e-cigarette products utilize a flow activation design whereby the heating circuit is activated only during puffing. Both e-cigarette products utilize glycerin as the aerosolizing agent and are labeled as containing nicotine (20–24 mg/e-cigarette). Compositions of the e-liquids were 82% glycerin, 9% water, 2% nicotine and 7% flavor for blu CTD; 75% glycerin, 18% water, 2% nicotine and 5% flavor for blu MMD [29]. The e-liquid loadings were 1.03 g and 1.00 g for blu CTD and blu MMD,respectively. Both e-cigarettes utilize 3.7 V batteries, 3.0 Ω atomizers, and both products are designed to deliver approximately 400 puffs.

All three samples were representative of commercially available consumer products at the time of the study. Exhaled aerosols from each of the products were captured on glass fiber filter pads. In addition to the exhaled aerosol from products, exhaled breath blanks were used to establish baseline values for the exhaled cigarette smoke and exhaled e-cigarette aerosol comparisons. Blanks were obtained from each subject prior to the exhaled aerosol sessions by collecting their exhaled breaths.

2.2. Experimental Design

This study involved collection of exhaled aerosol from human subjects using conventional cigarettes and e-cigarettes. The experiments were conducted under an IRB-approved protocol (Quorum IRB, 1501 Fourth Ave., Suite 800, Seattle, WA, USA). Subject recruiting was performed by Eastcoast Research (Eastcoast Research, 1118 Grecade St., Greensboro, NC, USA). All sessions were conducted in a 40 m^3 conference room at the Eastcoast Research facility. Subjects were screened for age ($21 \leq$ age ≤ 54), product use (e-cigarette subject puffs ≥30 puffs/day; conventional cigarettes >20 cigarettes/day), product preference (MGB, blu CTD or blu MMD) and for a stable preference for the specified products (≥6 months). All subjects were required to abstain from any tobacco product use for a minimum of one hour prior to the collection sessions. Exhaled carbon monoxide levels were verified for the subjects prior to each session with a piCO+ Smokerlyzer (Bedfont Scientific Ltd., Station Road, Harrietsham, Maidstone, Kent ME17 IJA, England) and were required to be less than 10 ppm to participate in the sessions. A total of thirty subjects were recruited for the study—ten subjects for each of the three products.

The three analyte classes (major components, phenolics and carbonyls) studied in this work are listed in Table 1 along with the individual analytes. The major components were selected to provide a mass balance distribution of water, glycerin and nicotine in exhalants from the three products. Some carbonyls have been reported in machine deliveries from e-cigarettes although at levels ten to hundreds of times less than in mainstream cigarette smoke [3,6,11,12]. A recent literature summary of e-cigarette chemical analysis also suggested the presence of *o*,*m*,*p*-cresols in the headspace of a single product [30]. Therefore, this work will also establish the levels of carbonyls and phenolics in exhaled aerosols from the cigarette, e-cigarettes and exhaled breaths.

Table 1. A listing of the three classes of analytes—major components, phenolic and carbonyl and individual analytes measured in this study.

Analyte Class	Analyte
Major Components	Water
	Glycerin
	Nicotine
Phenolics	Hydroquinone
	Resorcinol
	Catechol
	Phenol
	m,*p*-Cresol
	o-Cresol

Table 1. *Cont.*

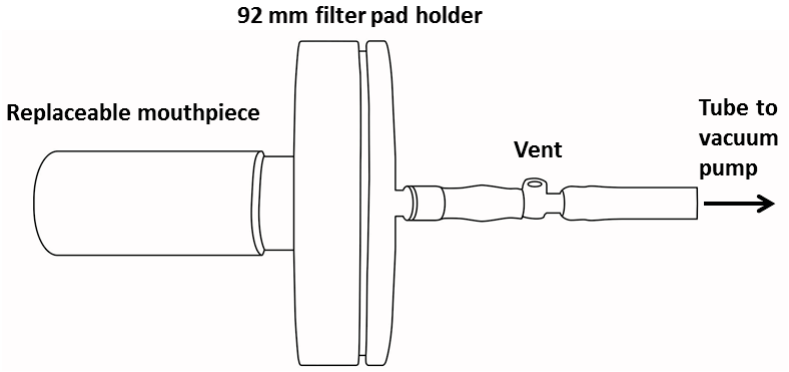
Analyte Class	Analyte
Carbonyls	Formaldehyde
	Acetaldehyde
	Acetone
	Acrolein
	Propionaldehyde
	Crotonaldehyde
	Methylethylketone
	Butyraldehyde

Total particulate matter, TPM, for three MGB cigarettes and 99 puffs from the two e-cigarettes were all approximately 150 mg under an intense puffing regime [29] and served as the basis for the puffing arrangement in this study. Cigarette subjects used three cigarettes per session and e-cigarette subjects used a maximum of 99 puffs per session. Each subject used their preferred product in a total of nine sessions which provided three replicates per subject in the three analyte classes. Sessions were limited to a maximum of two hours in duration.

2.3. Exhaled Collection Method Summary

This research utilizes modified ISO 17025 accredited conventional cigarette smoke analysis methods to quantitate select analytes in the exhaled aerosols from cigarettes and e-cigarettes. The vacuum-assisted collection system employed in the present work has been previously described [23–26] and used to quantify a number of different analytes in the exhaled smoke from conventional cigarettes. The system utilizes 92 mm glass fiber filter pads that have greater than 99% efficiency in retaining aerosols in the size range of cigarette smoke, with calibrated vacuum assistance to permit collection of exhaled samples in a manner that is perceived by subjects as neutral in terms of the effort required to deliver exhalate into the collection system. A schematic of the collection system is shown in Figure 2.

Figure 2. Schematic of the vacuum-assisted collection system for exhaled samples. The single pad collection was used for analysis of phenolics and major components. The apparatus used for the collection of carbonyls included a second filter holder of identical dimensions in series with the first.



The system incorporates a replaceable mouthpiece into which subjects exhale aerosol or breaths. The vacuum pumps were calibrated daily to aspirate 200 mL/min. The tube connecting the pad holder to the vacuum pump was vented to prevent aspiration through the pads when the subjects were not exhaling into the collection system. Subjects covered the vent with a finger when exhaling into the system and then uncovered the vent between exhaled puffs or breaths. A variation of the collection system in Figure 1 was used in carbonyl sessions. Two filter pads arranged in series and treated with a 2,4-dinitrophenylhydrazine (DNPH) solution were used for carbonyl collection sessions to increase sensitivity for these compounds.

2.3.1. Exhaled Breath Blank Collections

Blanks for each participant were collected at the beginning of each session prior to collection of exhaled aerosol from the products. These blanks were performed to obtain baseline levels of analytes in their exhaled breath prior to collection of exhalates from the products. Blanks were collected by instructing the subjects to exhale normal breaths into the vacuum assisted collection system over a twenty-minute period—a maximum of 30 exhaled breaths for cigarette sessions and a maximum of 99 exhaled breaths for e-cigarette sessions.

2.3.2. Carbonyl Room Air Blank Collections

In addition to exhaled breath blanks, a single replicate of room air was sampled with the collection system during each carbonyl session. Carbonyls have been observed in indoor air at levels in excess of 100 $\mu g/m^3$ [19–22]. Room air background levels of carbonyls were collected in the occupied conference room prior to carbonyl exhaled cigarette and e-cigarette usage sessions. Room air blanks were generated by pulling room air through DNPH treated pads with the vacuum-assisted collection system for 30 simulated exhaled puffs during cigarette sessions and 99 simulated exhaled puffs during e-cigarette sessions. The simulated exhaled puff duration for room air blanks was 2–3 sec.

After completion of the exhaled breath collections, pad holders with new pads were inserted into the collection system and the respective products presented to the subjects. Cigarette smokers were presented with an unopened pack at the beginning of each session and instructed to light their cigarettes, puff normally and exhale their smoke into the collection systems. Similarly, after e-cigarette subjects completing their exhaled breath collections, each subject received a new e-cigarette for the session. Subjects were instructed to take one test puff to verify nominal operation of their test products, puff normally and exhale their aerosol into the collection systems. Pad holders were capped upon completion of the collections and subjected to work-up within 40–60 min.

2.3.3. Analytical Method Capabilities Summary

ISO 17025 methods for cigarette mainstream smoke were verified for use with exhaled aerosol matrices from cigarettes and e-cigarettes. Cartridge-based collections were investigated for carbonyls, but were not suitable for exhaled aerosol collections due to their high resistance to air flow and observed break though during method development. Exhaled aerosol method verification involved spiking and

recovery experiments over the response ranges with an emphasis on accuracy and precision at the method limits of quantitation.

A summary of capabilities for the exhaled aerosol methods for e-cigarettes is provided in Table 2 as detection limits, quantitation limits, accuracy and precision. The limit of detection (LOD), is defined as the lowest quantity of an analyte that can be distinguished from the background matrix. The limit of quantitation (LOQ), is the level above which quantitative results may be obtained for an analyte with 99% confidence. Instrument parameters and additional method information for phenolics, carbonyls, glycerin, nicotine and water analyses are available as supplementary materials (Supplemental Files).

Table 2. Exhaled aerosol analysis capabilities for major components, phenolics and carbonyls in e-cigarette samples.

Analyte		LOD	LOQ	Accuracy (%)	Precision (%)
Major Components	Nicotine	0.69	4.86	108	2
	Glycerin	0.0059	1.51	101	2
	Water	ND	31	99	0
Phenolics	Hydroquinone	0.37	2.00	113	2
	Resorcinol	0.06	0.40	109	2
	Catechol	0.47	2.00	114	2
	Phenol	0.09	0.32	108	2
	m,*p*-Cresol	0.60	4.00	110	2
	o-Cresol	0.16	1.00	113	1
Carbonyls	Formaldehyde	0.10	12.45	97	0
	Acetaldehyde	0.39	5.20	96	1
	Acetone	0.61	13.64	96	3
	Acrolein	0.13	12.34	97	0
	Propionaldehyde	0.21	1.89	98	2
	Crotonaldehyde	0.21	2.17	95	1
	Methylethylketone	0.24	2.06	97	2
	Butyraldehyde	0.18	5.30	95	1

Notes: All units are μg/session except glycerin and water (mg/session). ND—LOD for water was not determined.

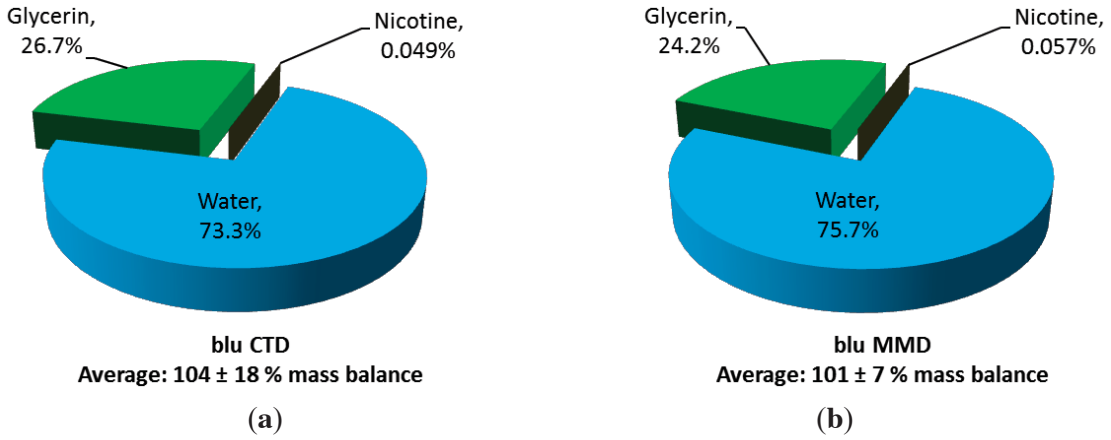
3. Results and Discussion

3.1. Exhaled Aerosol Mass Balance Distribution of Water, Glycerin and Nicotine

The average number of exhaled puffs collected during the water, glycerin and nicotine, phenolic and carbonyl collection sessions were not significantly different between methods as determined by an ANOVA analysis. The average number of exhaled puffs was 30 for three cigarettes and 95 for e-cigarettes during the water, glycerin and nicotine collection sessions.

Nicotine, glycerin and water analysis were used to compare distribution and mass balance of these analytes in exhaled aerosols. Distribution is determined by measuring the amounts of these compounds in exhalate collection sessions for the three products and then dividing by the sum total of the three constituents. The average distributions of exhaled e-cigarette aerosols are shown in Figure 3.

Figure 3. Average distributions and mass balances of water, glycerin and nicotine in exhaled e-cigarette aerosols for (**a**) blu Classic Tobacco Disposable (blu CTD) and (**b**) blu Magnificent Menthol Disposable (blu MMD).



The exhaled aerosol mass from the two e-cigarettes is primarily water and glycerin, which together comprise greater than 99.9% of the collected aerosol distribution. Average mass balances for water, glycerin and nicotine were fully accounted for in the e-cigarette aerosols at 104% and 101%. Machine-generated mainstream from e-cigarettes contain approximately 86% glycerin and 8% water [29], which is similar to the e-liquid composition itself. The high concentration of water in the exhaled e-cigarette aerosol has been attributed to water accretion from the respiratory tract by the hydrophilic glycerin aerosol [31].

Average mass balance for nicotine, glycerin and water in exhaled aerosol from the conventional cigarette was (83% ± 21%). The remaining exhaled aerosol mass for cigarettes samples are attributed to particulates from combustion processes known to comprise more than 70% of mainstream conventional cigarette smoke [32,33]. The concentration of nicotine observed in exhaled cigarette smoke was approximately an order of magnitude higher than in the exhaled e-cigarette aerosols (~0.40% *vs*. ~0.05%, respectively). Furthermore, the great majority (~85%) of real-world bystander exposures to nicotine and other smoke constituents in smoking environments is derived from the sidestream smoke emitted from the smoldering cigarette rather than from smokers' exhaled breaths [14]. Since e-cigarettes do not produce such sidestream emissions, the reductions in most potential bystander chemical exposures that accompany indoor e-cigarette usage as opposed to smoking may be anticipated to be even greater than the differences in exhaled nicotine concentrations of the very different aerosols. The public health impacts of environmental tobacco smoke have been overwhelmingly attributed to chemical constituents other than nicotine, so the simple presence of some nicotine in the exhalate of e-cigarette users does not suggest a basis for concern about bystander exposures.

3.2. Exhaled Phenolics and Carbonyls

The majority of phenolic and carbonyl measurements in exhaled e-cigarette aerosols were either not detectable, below the detection limits or below the quantitation limits. However, these analytes were consistently observed in exhaled cigarette smoke at quantifiable levels. Example data are shown in Table 3 for hydroquinone and acetaldehyde.

Table 3. Hydroquinone and acetaldehyde in exhaled aerosol (μg/session) for Marlboro Gold Box (MGB), blu Classic Tobacco Disposable (blu CTD) and blu Magnificent Menthol Disposable (blu MMD).

MGB			Blu CTD			Blu MMD		
Subject	**Acetaldehyde**	**Hydroquinone**	**Subject**	**Acetaldehyde**	**Hydroquinone**	**Subject**	**Acetaldehyde**	**Hydroquinone**
	227.6	70.6	11	<LOQ	<LOD	21	16.7	<LOD
1	186.0	60.0		<LOQ	<LOD		35.3	<LOD
	221.0	69.1		<LOQ	<LOD		38.9	<LOD
	134.7	41.3	12	<LOQ	<LOD	22	<LOQ	<LOD
2	129.8	33.2		<LOQ	<LOD		<LOQ	<LOD
	107.7	31.9		<LOQ	<LOD		<LOQ	<LOD
	131.2	32.2	13	<LOQ	<LOD	23	<LOQ	<LOD
3	169.0	47.4		86.4	<LOD		<LOQ	<LOD
	128.1	52.5		44.2	<LOD		<LOQ	<LOD
	115.6	48.5	14	<LOQ	<LOD	24	5.4	<LOD
4	119.3	47.3		<LOQ	<LOD		7.2	<LOD
	124.1	42.5		<LOQ	<LOD		9.9	<LOD
	195.4	18.4	15	<LOQ	<LOD	25	<LOQ	<LOD
5	122.0	13.3		<LOQ	<LOD		<LOQ	<LOD
	196.3	20.0		<LOQ	<LOD		<LOQ	<LOD
	208.0	99.5	16	<LOQ	<LOD	26	<LOQ	<LOD
6	116.9	103.5		<LOQ	<LOD		<LOQ	<LOD
	116.0	83.9		<LOQ	<LOD		<LOQ	<LOD
	<LOQ	22.8	17	<LOQ	<LOD	27	<LOQ	<LOD
7	88.1	8.79		<LOQ	<LOD		<LOQ	<LOD
	48.1	25.9		<LOQ	<LOD		6.2	<LOD
	380.2	29.1	18	<LOD	<LOD	28	<LOQ	<LOD
8	193.7	37.7		24.2	<LOD		<LOQ	<LOD
	189.7	30.9		<LOQ	<LOD		7.1	<LOD
	285.2	73.0	19	<LOQ	<LOD	29	6.5	<LOD
9	126.6	26.8		<LOQ	<LOD		8.9	<LOD
	104.6	81.6		<LOQ	<LOD		7.6	<LOD
	217.6	43.0	20	6.9	<LOD	30	<LOQ	<LOD
10	162.7	46.2		<LOQ	<LOD		<LOQ	<LOD
	114.1	64.0		<LOQ	<LOQ		5.4	<LOD
Avg *	156.7	46.8		<9.73 *	<0.421 *		<8.29 *	<0.367 *
SD	68.8	24.7		16.5	0.3		8.2	0.0
LOQ	41.6	2.00		5.20	2.00		5.20	2.00
LOD	0.390	0.367		0.390	0.367		0.390	0.367

Note: * LOD and LOQ values were averaged to provide upper limit estimates in exhalates from the two e-cigarette samples.

To simplify data reporting, total phenolic compounds and total carbonyl compounds in exhaled aerosols are presented for each product, along with exhaled breath blanks for comparison. Upper-limit estimates for exhaled aerosol compositions are accomplished by using the method limits for observations below the limits of detection and quantitation. In cases where individual measurements

were less than the limits of quantitation, the limit of quantitation values were used and in cases where the measurements were non-detects or less than the limits of detection, the limit of detection values were used to compare analytes in exhaled aerosol between products. ANOVA comparisons were performed to test for differences between exhaled aerosol samples, breath blanks and room air ($\alpha = 0.05$).

Total exhaled phenolics are shown in Figure 4 for exhaled aerosol and breaths collected following use of each product. The average number of exhaled puffs was 29 for three cigarettes and 98 for e-cigarettes during the phenolics collection sessions. Phenolics in exhaled breath blanks were all below limits of quantitation or limits of detection for the three products tested. The average total phenolics in exhaled e-cigarette aerosols were not statistically different than in exhaled breaths. In contrast, the average total phenolic compounds in exhaled smoke for cigarette subjects averaged 66 µg/session and ranged from 36 to 117 µg/session, significantly greater than in exhaled e-cigarette aerosol or exhaled breaths. The total phenolics for the ten MGB subjects is comparable, although higher, than data reported by Moldoveanu [23] for the phenolic compounds reported here, (12.3 µg/3 cigs, range 6–25 µg/3 cigs).

Figure 4. Total exhaled phenolics for exhaled aerosol and breaths for Marlboro Gold Box (MGB), blu Classic Tobacco Disposable (blu CTD) and blu Magnificent Menthol Disposable (blu MMD).

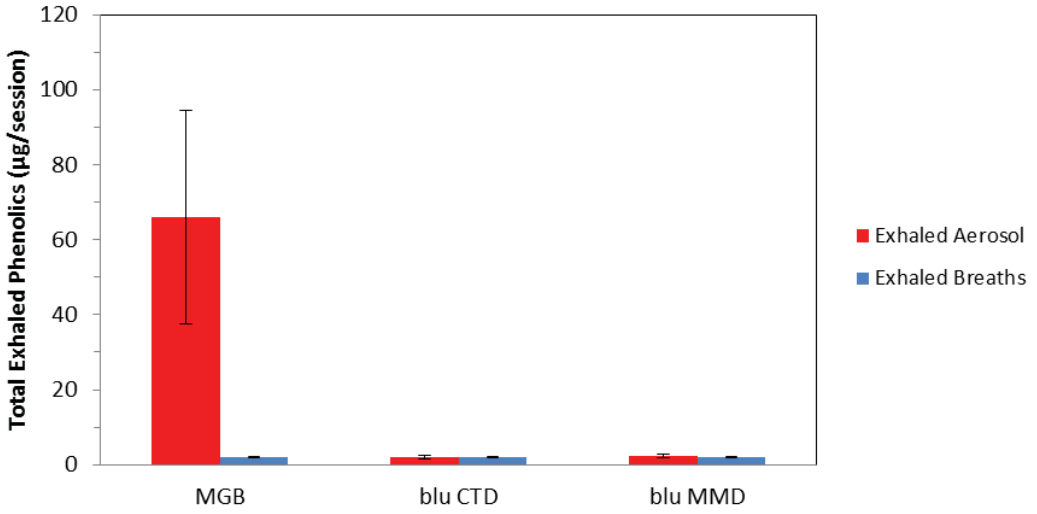


Figure 5 summarizes total carbonyl compounds exhaled from each product, exhaled breaths and room blanks. The average number of exhaled puffs was 27 for three cigarettes and 98 for e-cigarettes during the carbonyl collection sessions. Carbonyls in room air blanks and exhaled breath blanks were observed at the levels of quantitation due to the pervasive nature of carbonyls in indoor environments [20–23]. Room air blanks, exhaled breath blanks and exhalates from the two e-cigarettes were not statistically different. And as a result, total carbonyls in exhalates from the two e-cigarettes were not distinguishable from exhaled breaths or room air blanks. However, total carbonyls in exhaled smoke from cigarettes were significantly greater than the total carbonyls in exhaled e-cigarette aerosols, exhaled breaths and room blanks (average 242 µg/session, range 136–352 µg/session). The total carbonyls for the ten MGB subjects is comparable to historical data from Moldoveanu [24], for the carbonyls reported here, (average 183 µg/3 cigs, range 122–309 µg/3 cigs).

The absence of carbonyls and phenolics at quantifiable levels in exhaled e-cigarette aerosols is also demonstrated by comparing acetaldehyde and hydroquinone, as examples, for exhaled aerosol from products, breath blanks and room air as shown in Table 4. The sample aerosol values for the e-cigarettes are not statistically different than breath blanks, or room blanks.

Figure 5. Total carbonyls in exhaled aerosol, breaths and room blanks for Marlboro Gold Box (MGB), blu Classic Tobacco Disposable (blu CTD) and blu Magnificent Menthol Disposable (blu MMD).

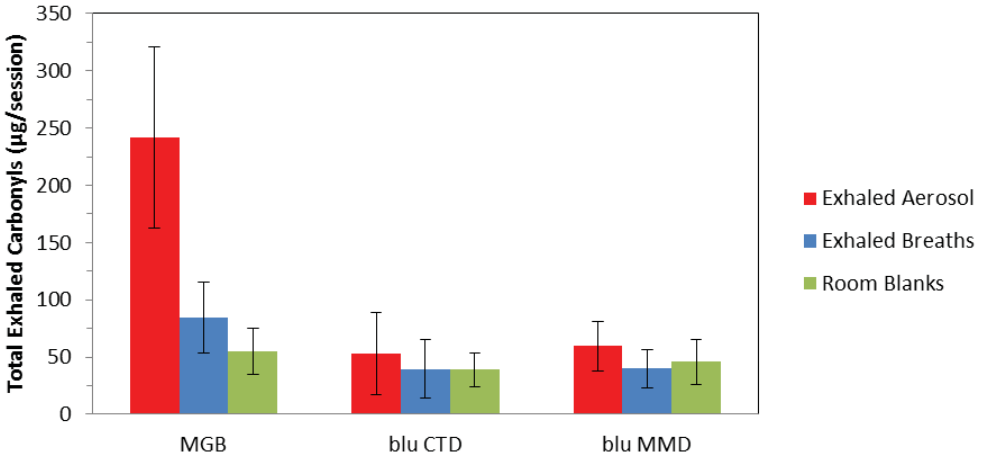


Table 4. Hydroquinone and acetaldehyde in exhaled aerosol, breaths and room air (µg/session) for blu Classic Tobacco Disposable (blu CTD) and blu Magnificent Menthol Disposable (blu MMD).

Analyte		Blu CTD			Blu MMD		
		Aerosol	Breaths	Air	Aerosol	Breaths	Air
Hydroquinone	Mean	<0.421 *	<0.367 *	ND	<0.367 *	<0.367 *	ND
	SD	0.3	0.0	ND	0.0	0.0	ND
Acetaldehyde	Mean	<9.73 *	<9.58 *	<3.60 *	<8.29 *	<5.20 *	<5.20 *
	SD	16.5	16.0	2.3	8.2	0.0	0.0

Note: * LOD and LOQ values were averaged to provide upper limit estimates in the aerosol, breath and air samples. ND—Room air blanks were not determined for phenolics.

Recent work by Robinson, *et al*. characterized the potential for second-hand e-cigarette exposure in indoor air from human subjects using validated air sampling methods (ASTM, EPA, NIOSH and OSHA) for 34 HPHC analytes [34]. Carbonyls and phenolics were no different than background levels in the room when the study subjects used e-cigarettes. Carbonyls were significantly greater than background when conventional cigarettes were smoked. Phenolics were no different than background for conventional cigarettes. Combustion byproducts were not observed above background for e-cigarettes but were present during conventional cigarette use.

The findings of this study establish the substantial reduction in the complexity and quantities of select chemical constituents in exhaled aerosols from e-cigarettes relative to exhaled smoke from conventional cigarettes. These constituents are expected in mainstream and exhaled conventional cigarette smoke as

demonstrated in this study and in extant literature since their formation is a result of combustion and pyrolysis processes. However, the thermal vaporization mode of operation common to e-cigarette designs does not provide a combustion formation pathway for those analytes. Whereas the present work has focused on the smaller, cigarette-like devices that have historically been market leaders in the U.S., the operation of these devices is fundamentally very similar to that of the larger, tank-style products that are increasingly favored by vapers in the U.S. and elsewhere around the world. The emerging technical literature in this area is consistent with an expectation that similarities in emitted and exhaled aerosols across the spectrum of innovative new e-cigarette designs will continue to demonstrate markedly reduced exposures to both users and bystanders relative to those that occur from conventional cigarette smoking.

4. Conclusions

This study was designed to measure phenolics and carbonyls in exhaled cigarette smoke, exhaled e-cigarette aerosols and exhaled breaths using a vacuum-assisted, pad collection system. This collection system was also used to determine a mass balance and distribution for water, glycerin and nicotine in exhaled e-cigarette aerosol. Distribution of exhaled e-cigarette aerosol showed the composition was greater than 99.9% water and glycerin, a small amount of nicotine (<0.06%) and gave a quantitative mass balance for these analytes in the exhaled aerosol mass, (101%–104%). Exhaled aerosol collections from e-cigarettes averaged over three times more exhaled puffs than from the conventional cigarettes. Total phenolics in exhaled e-cigarette aerosol were not significantly different than the amounts observed in exhaled breaths. Total phenolics in exhaled cigarette smoke were greater than in exhaled breaths and averaged 66 μg/session for the test subjects. Similar results were observed for carbonyl compounds in exhaled aerosols. Total carbonyls in exhaled e-cigarette aerosol were not significantly different than those in exhaled breaths and room air blanks. Carbonyls in exhaled cigarette smoke were greater than in exhaled breaths, room air blanks and exhaled e-cigarette aerosols, with an average total carbonyl content of 242 μg/session for the cigarette test subjects. Exhaled phenolics and carbonyls in cigarette smoke were comparable to historical data, although higher for the phenolics class in the present study than in prior work. The findings of this work suggest that exhaled e-cigarette aerosol does not increase bystander exposure for phenolics and carbonyls above the levels observed in exhaled breaths of air, in contrast to the quantifiable levels of these analytes in exhaled conventional cigarette smoke.

Acknowledgments

The author would like to thank the analytical testing laboratories at Lorillard Tobacco Company for methods development and testing, Eastcoast Research for support during the recruiting and data collection phases of the project and Phil Stern, Carl D'Ruiz; and Steven Brown, Dan Heck, Edward Robinson, and Robert Stevens for technical discussions.

Conflicts of Interest

The author is employed by Lorillard, a manufacturer of conventional cigarettes and the parent company of the manufacturer of the e-cigarette products used in this study.

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Details

Created on Friday, 28 November 2014 18:13

Creative thinking: trying to find methodology problems when we don't like the results of research

By Dr Farsalinos

I was just informed about a comment posted by Prof Glantz on his blog, concerning the study: "*Impact of Flavour Variability on Electronic Cigarette Use Experience: An Internet Survey*" published in International Journal of Environmental Research and Public Health on December 2013. The study evaluated the patterns of flavours use and their impact on pleasure, satisfaction and smoking reduction or cessation in a group of dedicated e-cigarette users (more than 4,000 participants).

Prof Glantz discovered a problem in the methodology, saying that: "*The problem with this study is that the sample was recruited from the e-cigarette advocacy site www.ecigarette-research.com, which is hardly a random sample of e-cigarette users or potential users (including kids)*".

First of all, the study recruited participants from major e-cigarette forums and websites. Obviously, we wanted to assess the experience of e-cigarette users, and that was the best way to recruit as many vapers as possible. Secondly, there is no such thing as a random sample because, in every case of surveys, participants are those who accept to participate, unless someone has a way to force a random sample to participate irrespective of their will. Thirdly, I am certain that less than 1% of e-cigarette consumers use flavourless liquids and I supose Prof Glantz has never met a single vaper using unflavoured liquid. Finally, it seems that Prof Glantz is "breaking through an open door". In the study results, we specifically mentioned: "*There are some limitations applicable to this study. The survey was announced and promoted in popular EC websites. Therefore, it is expected that dedicated users with positive experience with ECs would mainly participate, and the high proportion of former smokers confirms this. However, it is important to evaluate the patterns of use in smokers who have successfully quit smoking, since this can provide health officials with information on how to educate smokers into using ECs, especially during the initial period of use*".

I think the last sentence is creating the most problems to those with a pre-determined ideology against e-cigarettes. They do not want us to explore why e-cigarettes are successful in substituting smoking. Undoubtedly, dedicated vapers are the most successful users, with most of them being heavy ex-smokers who managed to quit smoking through e-cigarette use. It is of outmost importance to explore why and how these people got rid of tobacco cigarettes. Therefore, I consider the selection of participants as a strong point (rather than a limitation) of that study, and this is exactly the population group we wanted to assess. Such a selection would create problems only if we wanted to assess smoking cessation rates. However, in no such survey did we ever support (or even imply) that the success rate of e-cigarettes in smoking cessation could be examined. On the contrary, we specifically mentioned in our worldwide survey: "*It should be emphasized that participants in these surveys are mostly dedicated users... The 81% of participants reporting complete smoking*

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Letter to New York Councilman concerning a proposal to ban flavored electronic cigarette liquids

substitution cannot be interpreted as the true potential of ECs in smoking cessation in the general population; controlled studies have found much lower cessation rates".

Our methodologies and approach of clearly presenting all information in its true context is in contrast to what other groups have done. For example, Grana et al. published a longitudinal analysis of e-cigarette use and smoking cessation in JAMA Internal Medicine. They appear to have recruited a national sample of US smokers: "*We conducted a longitudinal analysis of a national sample of current US smokers to determine whether ecigarette use predicted successful quitting or reduced cigarette consumption*". The trick was that the comparison was between e-cigarette users and non-users based on **BASELINE** use. So, the "representative sample" was e-cigarette users who had failed to quit smoking at baseline (because they were all current smokers)! No surprise, they found that e-cigarette use did not predict quitting at 1 year.

In conclusion, in every study we have published, we made sure that the methodology was described clearly, the results were presented in detail, and the interpretation was made with strictly scientific criteria.

E-Cig Allows Smoker Of 40 Years The Ability To Breathe

Posted: Sep 24, 2014 6:02 PM PDT Sep 24, 2014 6:02 PM PDT

Updated: Sep 24, 2014 6:11 PM PDT Sep 24, 2014 6:11 PM PDT

By Justin Campbell - email

E-cigarettes have been banned in some cities, but one local e-cig store owner supports the trend and say's it's best option for the fight against smoking. ABC Fox Montana' Justin Campbell met one man who is trying to switch after 40 years of smoking.

What's looks like smoking is not, but just an e-cigarette, which is only water vapor and pharmaceutical nicotine. Paul Sibert just switched a month ago to an e-cig after smoking for a very long time.

“Oh yeah 40-45 years smoking,” said Paul Sibert.

His voice is still raspy from years of smoking along with health problems.

“I got COPD the doctors really want me to quit,” said Sibert.

Benefis did not get back to ABC Fox Montana on what their stance is on recommending e-cigarettes, but Paul said his doctor says his lungs sound better and he can feel the benefits from every step he takes.

“I can breathe now, it's an amazing,” said Sibert.

E-cigarette store owner Joseph Aluaces is like a doctor to his clients and got into the business after cigarettes took away his family.

“I have a father that died of lung cancer at 55, I have a twin sister, that just three and half years ago that died of lung cancer,” said Montanajo Owner Joseph Aluaces.

Joseph used to be a smoker himself and said the reason using patches to quit don't work is because they don't address the lifestyle changes of a long time smoker.

“Relax after a good meal at a restaurant with a cigarette; these are things, things that have been in me for over 30 years,” said Aluaces.

But an e-cigarette allows smokers to still have something to hold on to and use.

“The cigarette doesn't go with you so there is a void and e-cigarettes fill that void,” said Aluaces

Joseph also said e-cigarettes allow the stigma of a typical smelly cigarette smoker to disappear.

“My grand babies don't smell it; they used to yell at me for smoking " said Paul Sibert.

E-cigarettes are not regulated by the FDA, banned in some cities, and they have not been around long enough for long-term research, but Joseph said he's seen enough health and lifestyle benefits.

“Kids will hug them now, because they don't smell like cigarettes, you know these are the stories we deal with on a daily basis it changes lives,” said Aluaces

Reporting from Great Falls, Justin Campbell ABC Fox Montana News

Details

Created on Thursday, 27 November 2014 13:46

Electronic cigarette aerosol contains 6 times LESS formaldehyde than tobacco cigarette smoke

By Dr Farsalinos

Today my e-mailbox is full of messages discussing about the great issue of carcinogens being at 10 times higher levels in e-cigarettes compared to tobacco cigarettes. There is a quote from Naoki Kunugita, a researcher at the Department of Environmental Health-National Institute of Public Health in Japan, about this: "*In one brand of e-cigarette the team found more than 10 times the level of carcinogens contained in one regular cigarette*".

Interestingly, while all news-media discuss about carcinogen**s** (plural), the text mentions only formaldehyde. To tell the whole truth, this "*substance found in building materials and embalming fluids*" is in reality present everywhere in the environment, in every house, in every city, town, village, urban or rural area. So, all the noise in the newsmedia is about **one carcinogen**, not some carcinogens. Moreover, **the title is nothing but misleading** since they found the formaldehyde at "10 levels higher than cigarettes" in 1 of the 10 products tested, not in every case.

However, there is a more interesting story behind this. **I immediately contacted Prof. Kunugita to ask the results of their studies.** His response was immediate, mentioning the list of published studies from which he got the results. In fact, the results of analysis of 13 Japanese brands were presented in a table 1 in a recent review on carbonyls generated from e-cigarettes, published in International Journal of Environmental Research and Public Health. The results are shown in the table below.

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Table 1. Amounts (µg/10 puff) of major carbonyl compounds generated from 13 brands of Japanese e-cigarettes. Smoking machine was performed at 10 puffs (reproduced from [13] with permission from The Japan Society for Analytical Chemistry).

Brand	Nr of samples	Formaldehyde	Acetaldehyde	Acrolein	Propanal	Glyoxal
A	16	34 ± 35	26 ± 28	4.1 ± 3.8	8.8 ± 11	2.5 ± 3.6
	35	n.d.	n.d.	n.d.	n.d.	n.d.
B	06	13 ± 5.8	0.2 ± 0.1	6.6 ± 2.4	1.1 ± 0.7	16± 6.6
	24	1.4 ± 0.9	n.d.	1.2 ± 0.9	n.d.	n.d.
C	08	22 ± 15.4	0.9 ± 1.4	5.3 ± 5.5	3.4 ± 3.5	9.9 ± 5.2
	22	1.7 ± 1.4	n.d.	0.6 ± 0.6	n.d.	0.7 ± 0.7
D	12	15 ± 6.6	13.8 ± 6.6	20 ± 9.9	13.2 ± 10.5	4.2 ± 2.3
	37	0.8 ± 1.0	n.d.	n.d.	n.d.	n.d.
E	14	17 ± 7.7	15 ± 6.1	18 ± 6.6	15 ± 8.3	4.5 ± 2.4
	21	0.7 ± 0.8	n.d.	0.7 ± 0.9	n.d.	n.d.
F	02	6.6 ± 0.9	1.5 ± 0.1	1.1 ± 0.1	0.4 ± 0.1	1.5 ± 0.4
	3	2.0 ± 1.7	0.9 ± 0.2	0.7 ± 0.3	n.d.	n.d.
G	01	29	10	10	3.5	9.4
	25	n.d.	n.d.	n.d.	n.d.	n.d.
H	05	10 ± 4.9	4.6 ± 2.4	4.5 ± 2.2	n.d.	2.5 ± 0.5
	25	0.9 ± 1.4	n.d.	n.d.	n.d.	n.d.
I	06	3.2 ± 1.0	6.1 ± 3.2	6.1 ± 2.3	7.7 ± 2.3	n.d.
	24	1.5 ± 1.4	2.6 ± 2.9	2.8 ± 2.7	3.3 ± 3.4	n.d.
J	00	n.a.	n.a.	n.a.	n.a.	n.a.
	4	n.d.	n.d.	n.d.	n.d.	n.d.
K	00	n.a.	n.a.	n.a.	n.a.	n.a.
	30	n.d.	n.d.	n.d.	n.d.	n.d.
L	00	n.a.	n.a.	n.a.	n.a.	n.a.
	30	n.d.	n.d.	n.d.	n.d.	n.d.
M	00	n.a.	n.a.	n.a.	n.a.	n.a.
	13	n.d.	n.d.	n.d.	n.d.	n.d.

A study by Canadian researchers in 2008 evaluated the levels of formaldehyde in mainstream cigarette smoke. As shown below, the levels were on average 200µg/cigarette, which is **6 times higher than the highest value (34µg) found in e-cigarette aerosol by Kunugita**. Moreover, the study showed a much higher level of formaldehyde in sidestream smoke (>800µg/cigarette).

Table 7. Selected Carbonyl Compounds Determined in Mainstream and Sidestream Smoke from Tobacco and Marijuana under Two Smoking Conditions[a]

	ISO		extreme	
	tobacco	marijuana	tobacco	marijuana
	mainstream			
formaldehyde	200 ± 28	25.1 ± 2.7*	543 ± 91	66.5 ± 11.8*
acetaldehyde	872 ± 101	448 ± 44*	1555 ± 222	1021 ± 99*
acetone	454 ± 44	237 ± 23*	826 ± 93	514 ± 32*
acrolein	125 ± 13	54.3 ± 4.5*	251 ± 32	148 ± 13*
propionaldehyde	72.1 ± 8.1	32.3 ± 3.2*	97.8 ± 14.4	74.0 ± 6.4*
crotonaldehyde	62.9 ± 7.3	23.1 ± 1.5*	127 ± 17	56.7 ± 7.7*
methyl ethyl ketone	135 ± 16	62.4 ± 5.5*	265 ± 27	140 ± 7*
butyraldehyde	47.1 ± 5.7	46.5 ± 3.8	77.1 ± 10.0	110 ± 8*
	sidestream			
formaldehyde	886 ± 47	383 ± 27*	662 ± 29	202 ± 34*
acetaldehyde	1587 ± 45	1170 ± 69*	1383 ± 37	896 ± 112*
acetone	828 ± 22	566 ± 34*	720 ± 22	405 ± 54*
acrolein	437 ± 10	304 ± 20*	316 ± 12	179 ± 24*
propionaldehyde	121 ± 6	120 ± 6	116 ± 5	93.4 ± 11.7*
crotonaldehyde	106 ± 3	49.9 ± 3.8*	97.5 ± 8.7	42.9 ± 4.7*
methyl ethyl ketone	222 ± 9	160 ± 11*	202 ± 17	116 ± 13*
butyraldehyde	67.1 ± 2.7	173 ± 12*	60.2 ± 1.7	139 ± 13*

[a] Values are provided ± standard deviations; $n = 7$. Units are μg/cigarette. *$P < 0.05$ vs tobacco.

While we still need to see the levels of carbonyls generated from high-power e-cigarette use (using appropriate atomizers of course), the message concerning all this media frenzy is clear. **Even in the worst-case Japanese product, e-cigarette aerosol contained 6 times lower formaldehyde levels compared to tobacco cigarette smoke.** Where does the "10 times higher than smoking" statement comes from? I have no idea.

Of course, discussion about the maximum levels of a single product is scientifically inappropriate. We should examine the average levels of formaldehyde present in e-cigarette aerosol. The Japanese team of researcher present in the table (shown above) the number of samples (column 2) and the respective results. The average levels of formaldehyde found in all samples was calculated at **4.2μg/10 puffs**. Therefore, on average, the levels of formaldehyde in e-cigarettes are up to **50 times lower compared to tobacco cigarette smoke**.

Obviously, we have to realize that focusing the discussion on one of the tens of carcinogens present in tobacco cigarette smoke is misleading. Even if e-cigarettes contained similar, or higher, levels of formaldehyde, they do not contain the majority

of other toxic and carcinogenic substances present in cigarette smoke. Overall, any residual risk from e-cigarette use is orders of magnitude lower than smoking. This is exactly what smokers need (and deserve) to know.

********** UPDATE
****

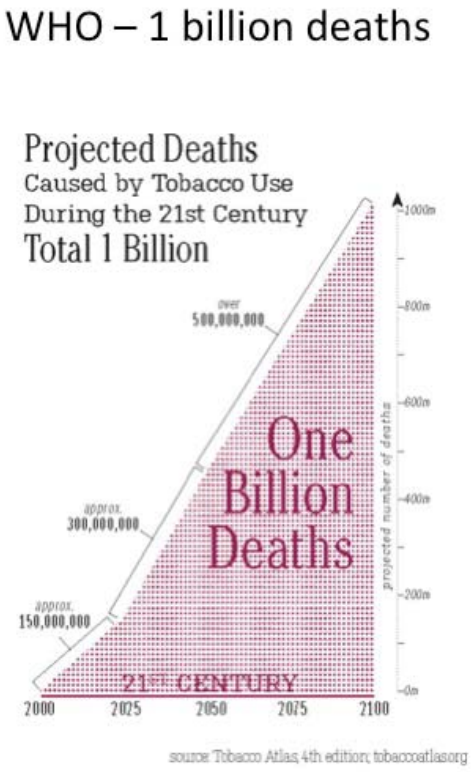
After my comment, Prof Kunugita contacted me again. He mentioned that the newsmedia reports refer to a recent evaluation of a newer-generation device, in which he found 1600μg formaldehyde per 15 puffs. It is true that this level is 10 times higher than what is present in tobacco cigarettes. However, this is an unpublished result, a single extreme case out of the many products he tested, and we do not know what went wrong in that case (e.g. high power levels, low levels of liquid inside, malfunctioning device etc). Still, the media frenzy is completely inappropriate.

This confusion shows why it is important for a new, systematic evaluation of aldehydes release, taking into consideration realistic conditions and puffing patterns together with evaluation of temperatures of evaporation. This is exactly what we are preparing to do, starting in a few days.

e-cigarette summit - clive bates

*19 Nov 2013 — By **Vaping.com (/author/5)***

Clive Bates: Disclosure - no competing interests, and particularly important to say, I of course no longer speak for ASH or for the British Government, quite the contrary in fact. **(Laughter)**
Clive Bates: Here we go. Right. Before I get stuck into the regulatory issues, let me just, a few words almost personally about why I think this is important.



(/assets/uploads/img/Slide026.jpg) I think everyone in public health, everyone involved in the smoking industry needs to keep an eye on the prize. And the prize relates to this one billion deaths that the WHO is estimating for the consequences of smoking in the 21st Century. Now, it's actually quite hard to find out where that number comes from but let's just keep it as an approximate sense of the impact of smoking in the 21st Century.

(/assets/uploads/img/Slide036.jpg) If you want to know what a billion looks like, it's five piles of pennies about the size of a bus, basically. It's a huge number of people, it's a huge number of personal storage, it's a huge amount of suffering is embodied in that number, a billion, that we toss around. And I want to go from the large-scale number just quickly to the sort of thing I get left on my blog and if you search the forums and the internet you can find

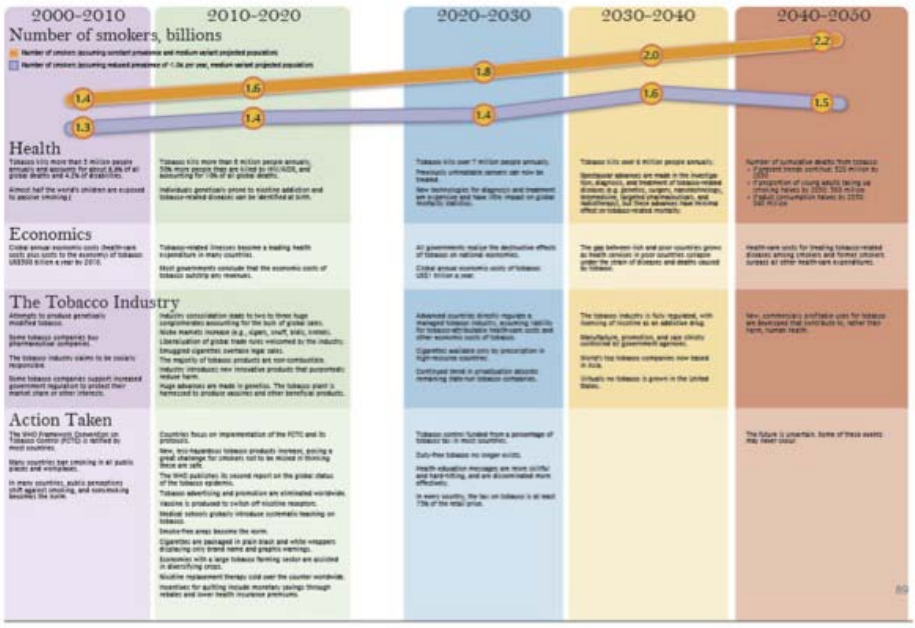
these testimonies.

> I smoked for 45 years and tried every NRT product available, none of them worked. I continued to smoke even though my health was getting worse, resulting in COPD and using oxygen daily.
>
> September 2011 I discovered e-cigarettes and they worked. It was like someone handed me a miracle. In less than a week I stopped using regular cigarettes. I haven't had a tobacco cigarette since.

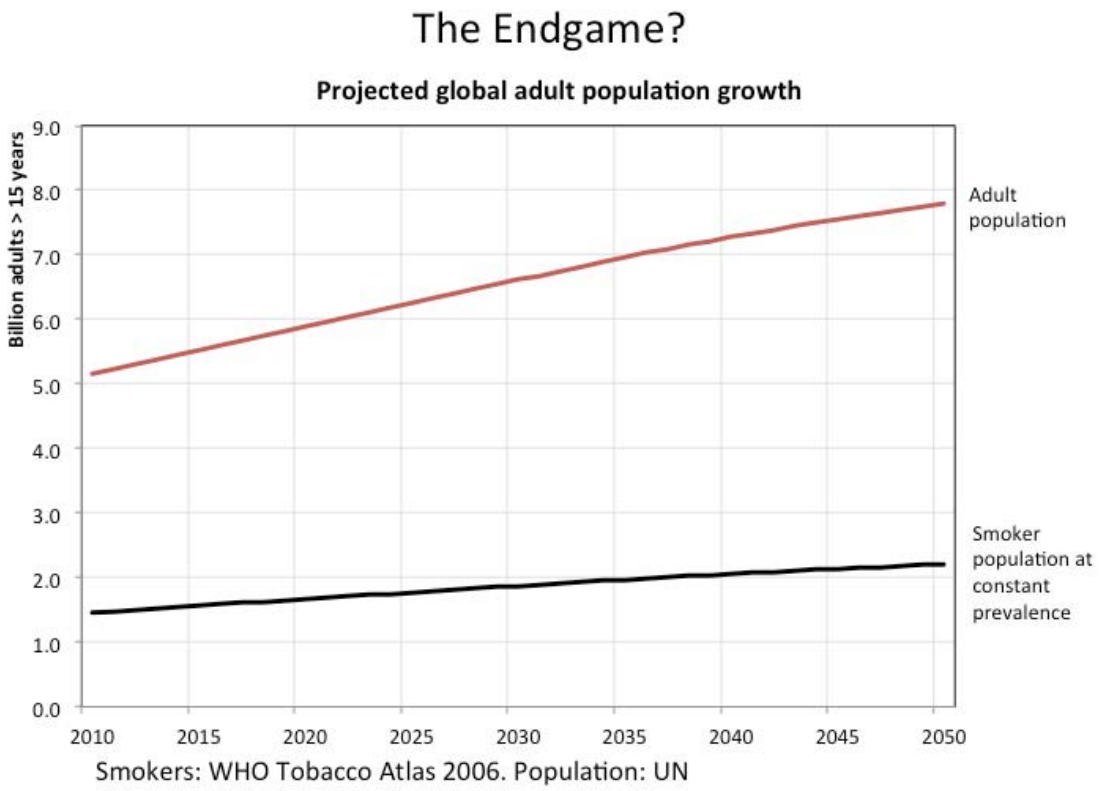
Unsolicited comment left on www.clivebates.com

(/assets/uploads/img/Slide045.jpg) Just digest that for a minute. But basically, if you're in public health, this to me is the sort of thing that ought to get you out of bed every day. I find these sort of testimonies really moving. They're people whose lives have been changed and transformed by switching from smoking to a new technology. They're empowered, they feel much better about themselves, about their lives and everything, and there are literally thousands of these all over the internet. So the question we should be asking is: how do we get more of this? How do we get fewer of the billion and more of these great personal stories?

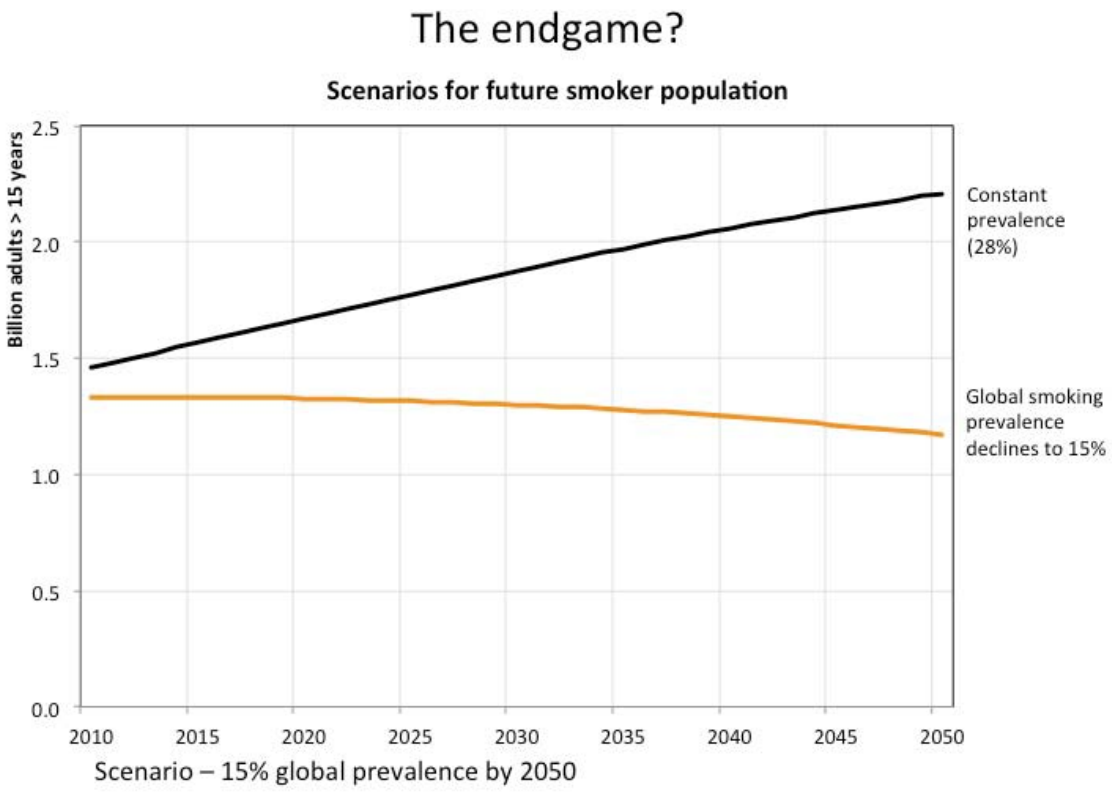
From WHO Tobacco Atlas 2006 edition



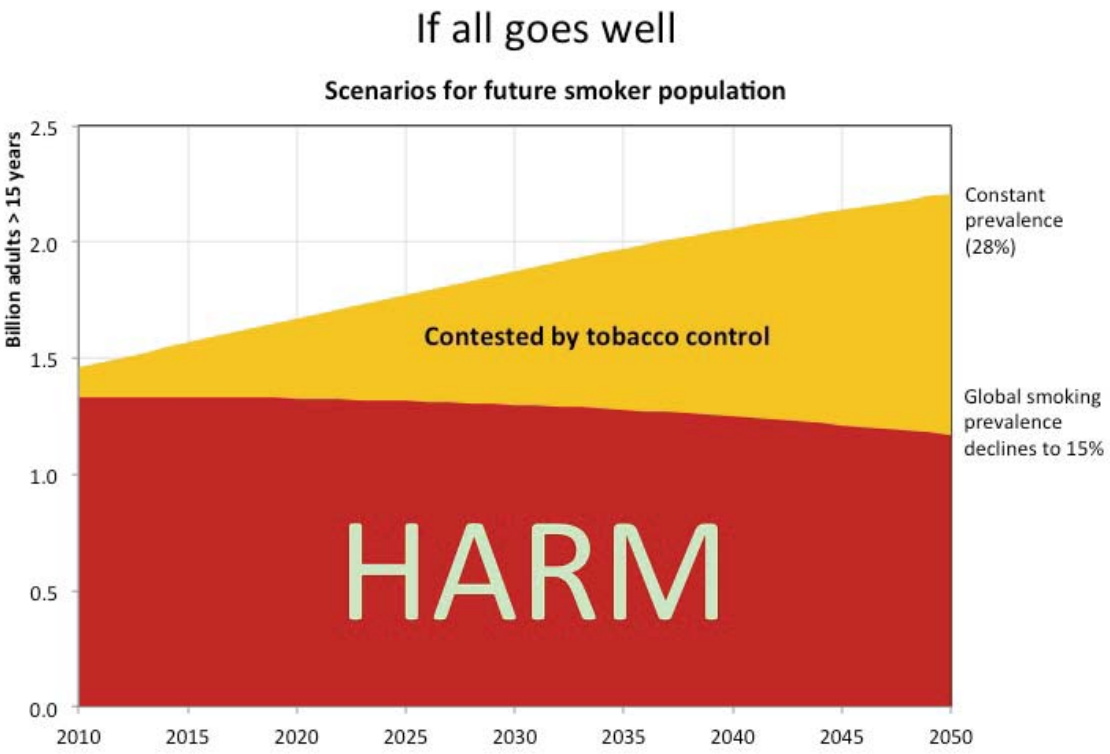
(/assets/uploads/img/Slide056.jpg) I just want to go back and investigate that billion a bit more. It's hard to find much information on this but the kind of last time anyone seems to have looked hard about what the future outlook for smoking in the world was was 2003 in a World Bank study which then got turned into these projections in the tobacco atlas which showed a number of smokers on current trends going to 2.2 billion by the middle of the decade, and then if some measures were taken dropping down to 1.5 billion in the world. Okay? And to be honest there isn't much more than that. So what I wanted to do, just to illustrate the start of this talk, was to take those numbers, use some actual data, recreate them slightly. So start with the growing adult population. This will all make sense in a minute, believe me.



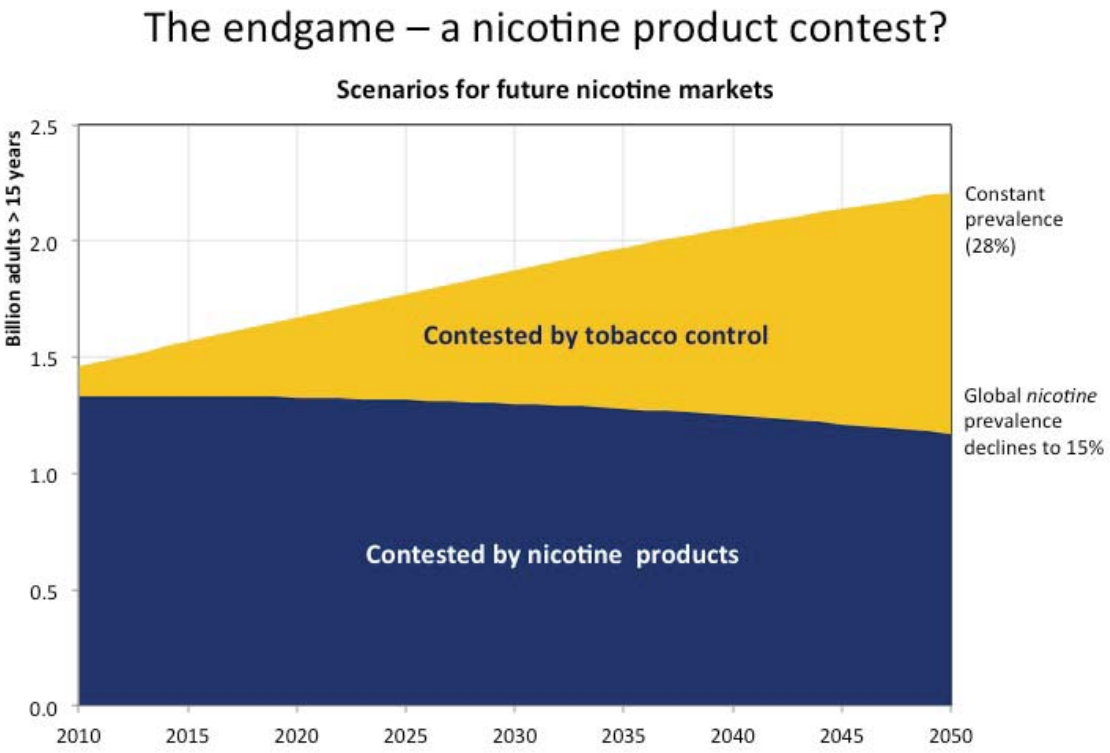
(/assets/uploads/img/Slide076.jpg) We start with the growing adult population, so these are the UN projections for people aged over 15, and it grows faster than the general population. There will be an extra 2.6 billion adults by 2050. If the current rate of smoking prevalence was to continue we'd have around 2.2 billion smokers by 2050 in the world and that's roughly the number that WHO was using.



(/assets/uploads/img/Slide096.jpg) So let's re-plot that so we're just looking at smokers, so keep your eye on the black line. Re-plotted on a different axis. That's the number of smokers that there would be on current smoking prevalence worldwide taking account of population growth. Now the WHO's numbers in the tobacco atlas implied this trajectory which is actually consistent with achieving a 15% smoking prevalence worldwide by 2050, okay? And that's what they're sort of estimating might happen worldwide. Now let's look at this in a different way. What they're sort of saying here is that they think that's the kind of performance that can be achieved by tobacco control.

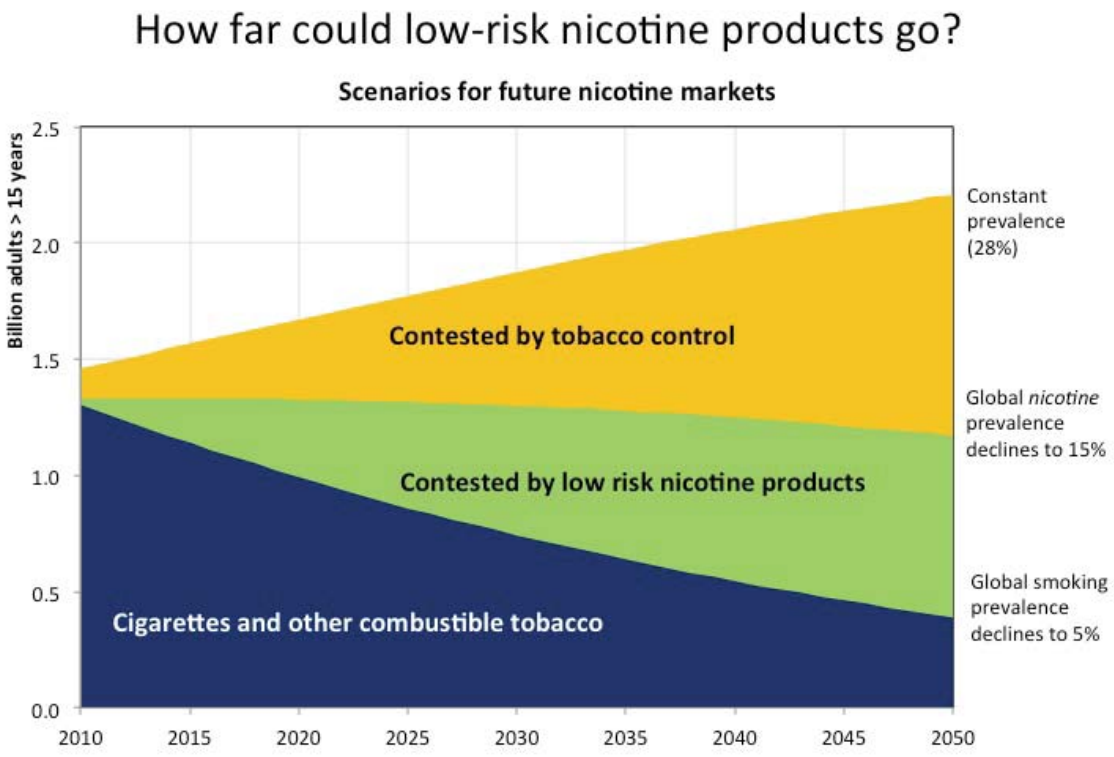


(/assets/uploads/img/Slide106.jpg) Might be more, might be less, who knows? But what they're kind of implying is that that wedge, the yellow wedge up at the top there is the sort of thing you could achieve with tobacco control, and under it is harm. This is person years of people continuing to smoke basically, billions of people continuing to smoke.

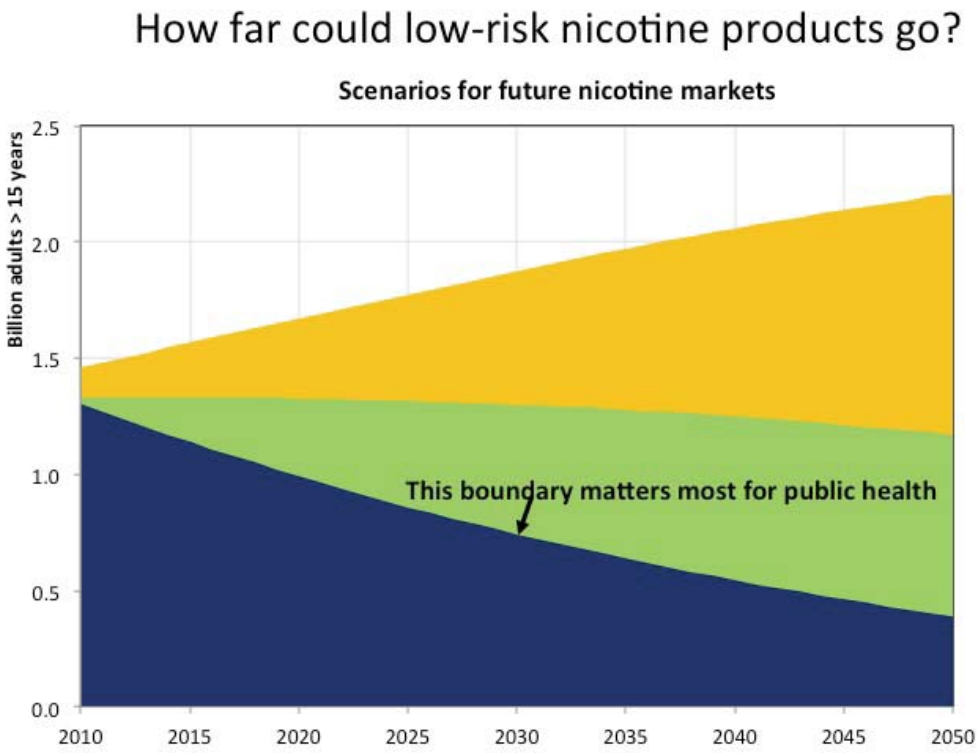


(/assets/uploads/img/Slide116.jpg) Now, the interesting thing about a supply-side response, different types of nicotine, is whether it can eat into that big, harmful area, and what I've drawn here is the idea that the top wedge is there kind of contested by tobacco

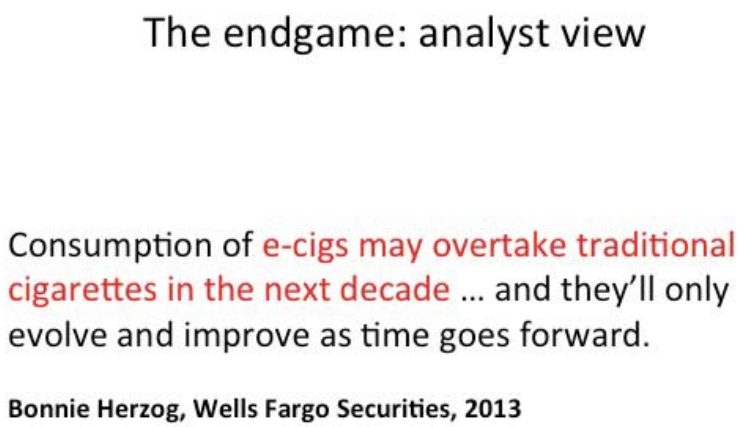
control, and that's what you kind of get from the traditional package of measures which I very strongly support. And then you've got this big rump of continuing smoking that you might be able to address with a different strategy.



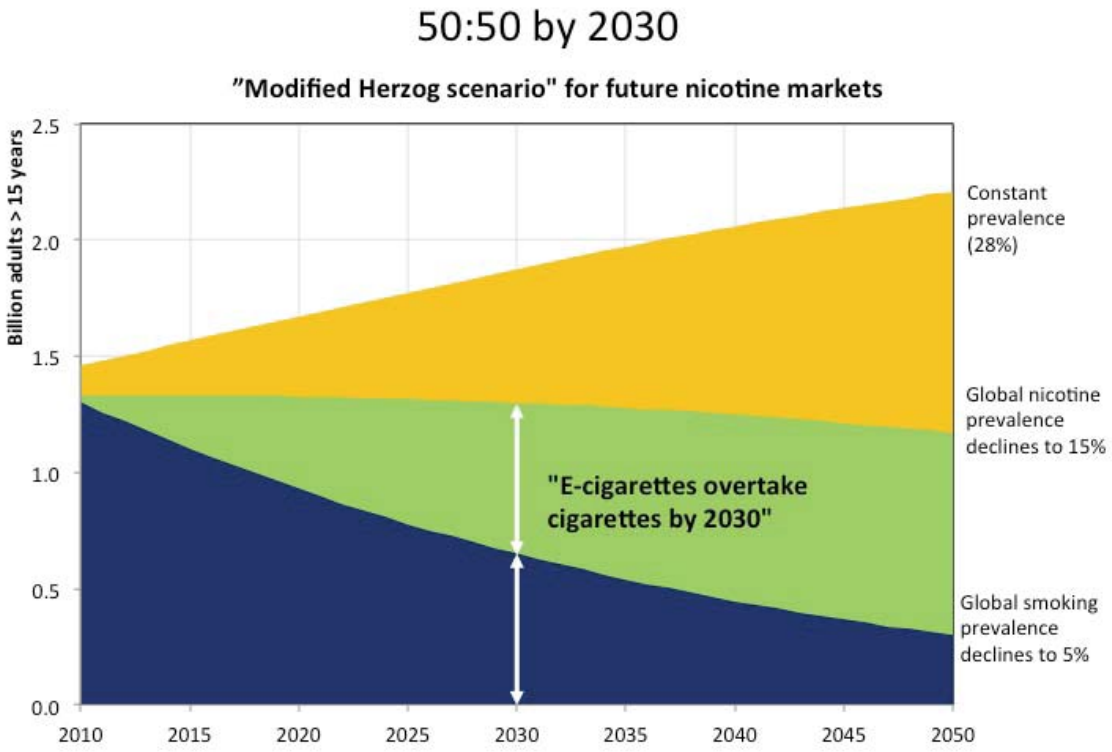
(/assets/uploads/img/Slide126.jpg) What I've done here is suggest that you might be able to get this green wedge in there, you might if you're really optimistic get a very large number of people to start to switch, and this additional strategy might reduce the area under this curve which is important for public health. Okay?



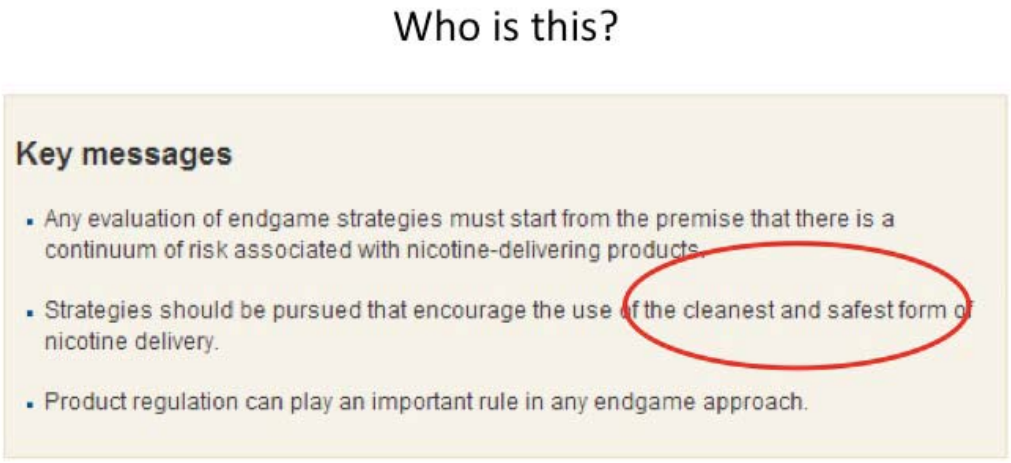
(/assets/uploads/img/Slide135.jpg) That's the boundary that matters most for public health. If you think e-cigarettes are not particularly dangerous then it's the number of people smoking, not the number of people that are using nicotine that really matters in terms of cancer, heart disease, respiratory illnesses and all the other nasties that come with smoking. Okay? Now, you might say, well these are just basically made up numbers, they're projections, they're in a model, but how realistic are they?



(/assets/uploads/img/Slide155.jpg) Well, I'm just drawing on this as quite a bullish commentator from one of the investment banks, and her view is that e-cigarettes might overtake traditional cigarettes in the next decade, and by that she means in the United States and by 2023. Okay? So there's people here in serious business who are looking at this industry think there is the possibility of a very disruptive revolution in these products, that would be an enormous impact on the cigarette market, on the tobacco industry if that did. I mean tobacco industry will be in the game, of course, but still extremely disruptive.

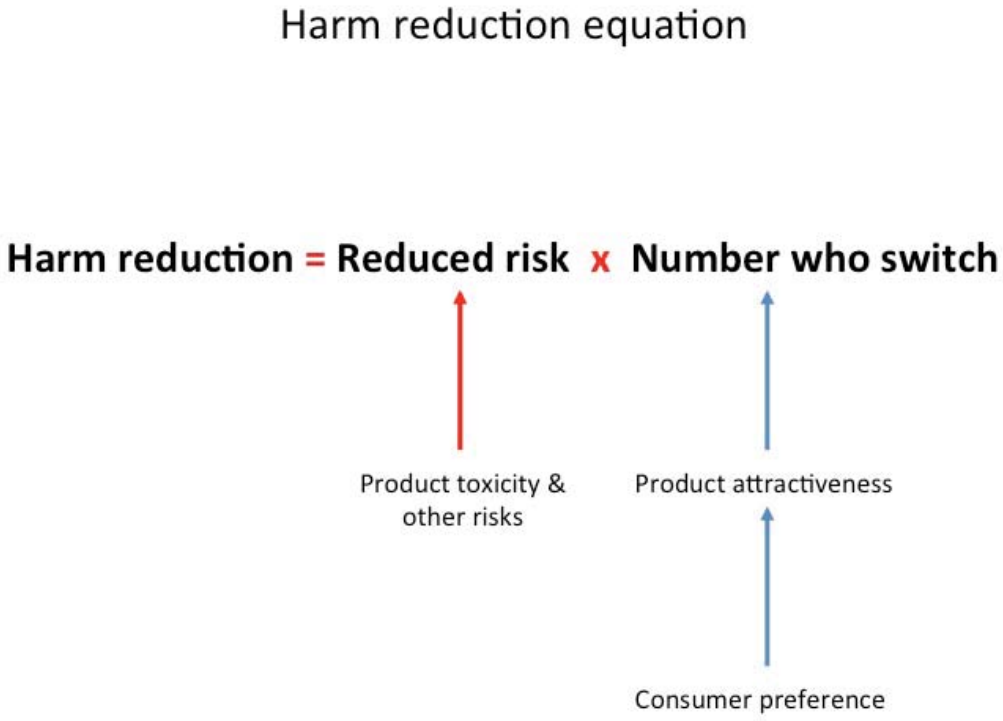


(/assets/uploads/img/Slide164.jpg) So if we just take that sort of thinking and let's say it's 2030 instead, that's the curve I showed before and that's the point at which e-cigarettes would overtake cigarette consumption, that would happen around 2030. So my whole point here is that we should be thinking really about how we get that green wedge. How do we get that green wedge to be as big and effective as possible and how do we minimise any of the unintended consequences that would come with it? And if I have a single message today it's focus on the opportunity, focus on the huge opportunity, don't become obsessed with the relatively minor risks, we'll come back to that.

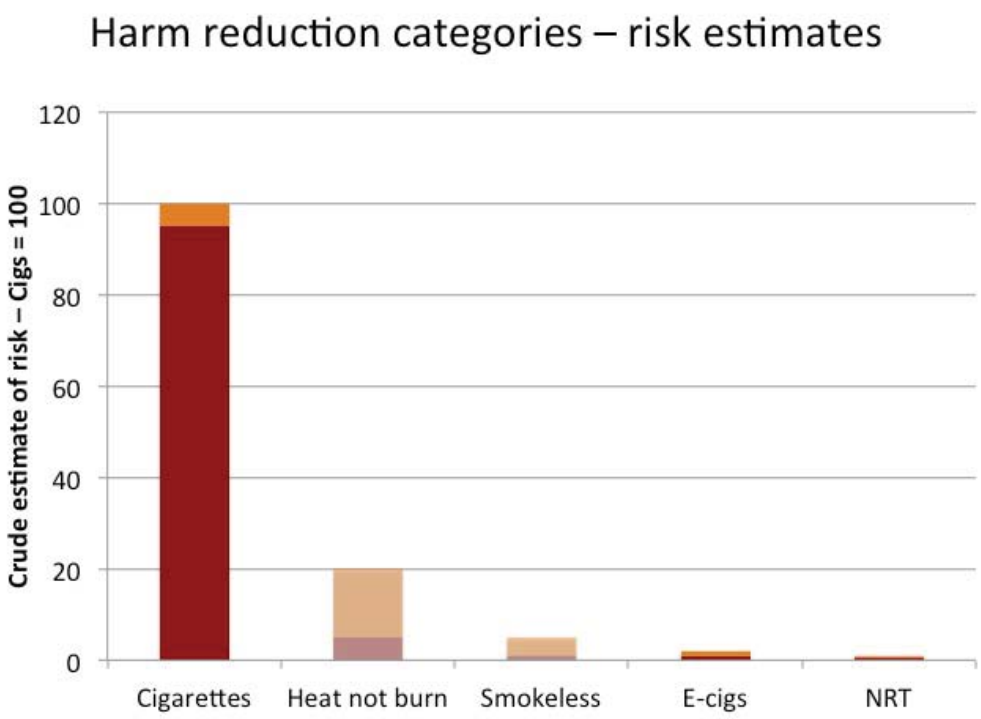


Mitch Zeller
(now) Director of the Center for Tobacco Products
FDA

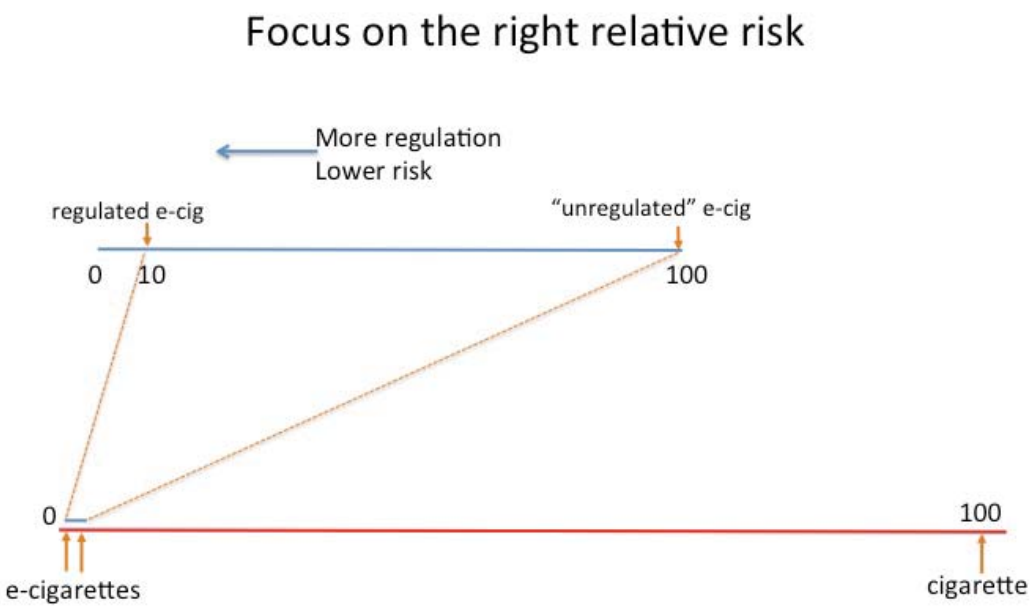
(/assets/uploads/img/Slide173.jpg) So here we go onto the regulatory piece of this. This is the sort of thing you hear people saying. "We need clean and safe nicotine delivery." And this is Mitch Zeller now of the – he didn't say this when he was there but he's now of the FDA and in charge of the tobacco booth there. Okay? "Clean and safest as form of nicotine delivery." Is that actually right? I don't think it is right, actually, that we need the cleanest and safest form of nicotine delivery. Not if we're concerned about that green wedge, the one billion, and getting as many people to switch.



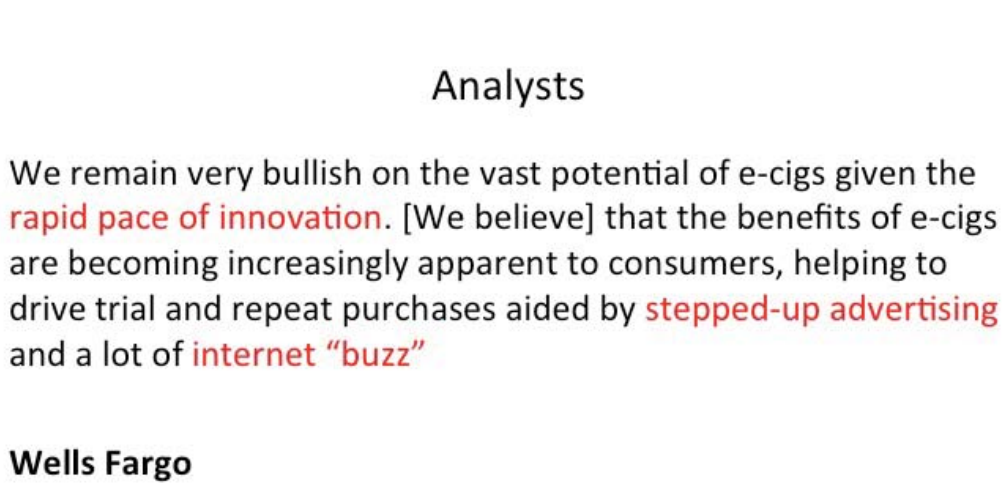
(/assets/uploads/img/Slide194.jpg) So I have created this bespoke harm-reduction equation which I'm going to use. It's a very simple thing, don't worry, to try and illustrate what I think is a really simple idea behind this. Okay? We'll do a modification on this later to take account of population effects, but basically what you're trying to do is get reduced risk products. You want the reduction in risk to be as large as possible and you want the number to switch to be as large as possible. And the actual public health impact is the product of those two things. So if you have a really, really safe product that nobody wants to use, that's no good because nobody switches. If you have something that everyone switches to but doesn't do much to reduce harm that's no good either, and that might apply to some of the combustible harm-reduction strategies. Okay? Now the elements of this, let's start on this, really are a function of the product to some extent. The number who switch is a function of how attractive the product is and what consumers actually want to buy. Okay? So people aren't going to quitting centres or getting behavioural treatment for this. Buy them in shops instead of cigarettes. So it's not about an intervention, it's about what people choose to do, it's about consumer choice here. So let's just examine the first of those arms, the reduced risk side of it. Who knows what the reduced risks? I tried to get the panel earlier to say roughly what they thought the reduced risk was.



(/assets/uploads/img/Slide202.jpg) There's some work coming out from David Nutt fairly soon, but roughly speaking we're talking about one to two orders of magnitude reduction in risk compared to continued smoking, probably 95%+ reduction, whether it's for smokeless tobacco or for e-cigarettes; very hard to imagine these things just from the physics or chemistry being more risky than that.

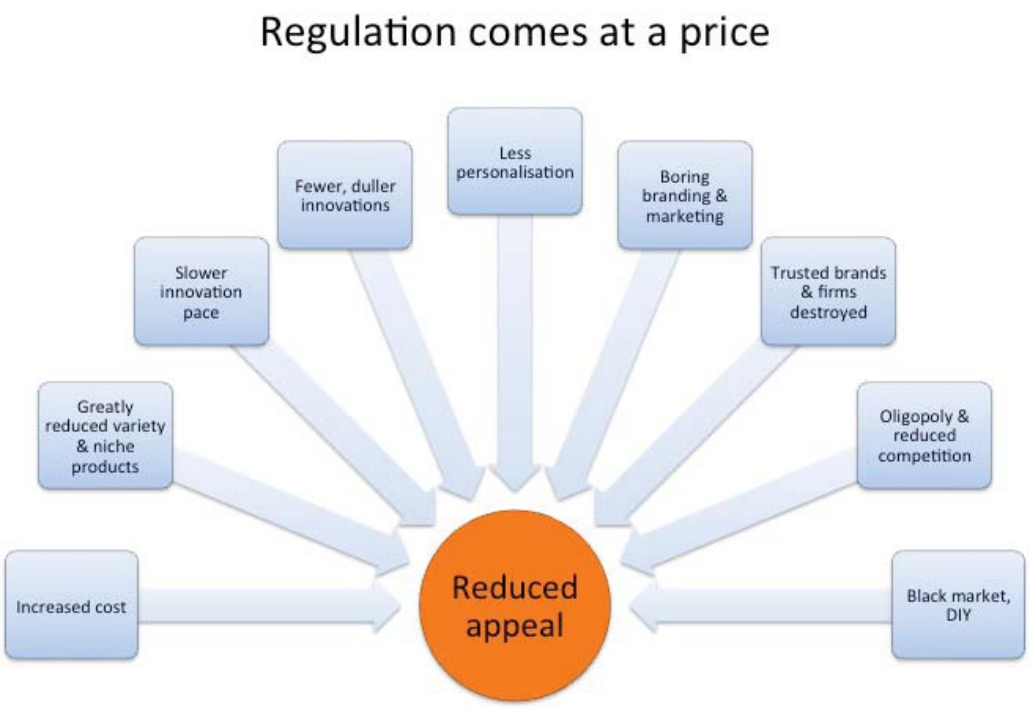


(/assets/uploads/img/Slide212.jpg) I'll try and illustrate this. Let's imagine this is a continuum of risk, and that should read 100 up there, for ecigarettes, and a regulator comes along and says, "Look, I can make these products ten times safer by regulating them, by increasing the cost, make it more difficult, and so on, but I can make them ten times safer. Is that a good thing? Is that actually a good thing? Back to Mitch Seller's comment. So an unregulated e-cigarette would be the risk of 100, and a regulated e-cigarette with a risk of ten. Sounds good, regulator's really done the job well there, but actually I don't really think it's worth doing, and this is the reason why. Because when you plot them on a risk continuum with cigarettes, basically there's almost no difference between something that's 99% and something that's 99.9% less dangerous than smoking. Okay? The whole thing here has to be about getting the risk in perspective and not spending a fortune, damaging the industry, restricting choice, making the products less attractive because you've tried to go from 99 to

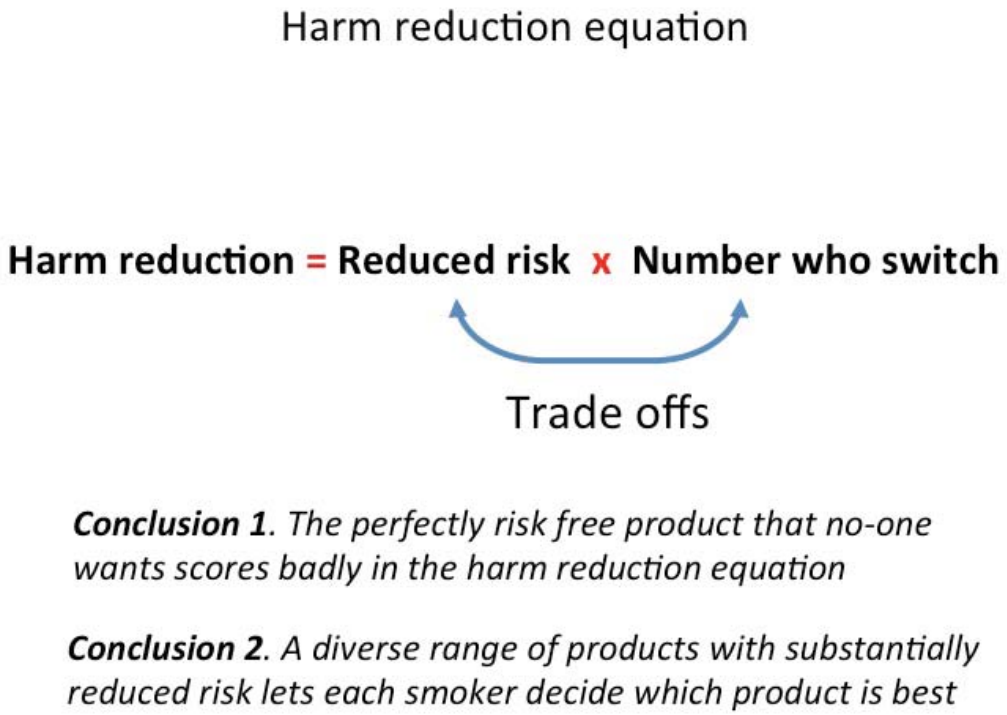


99% less risky.

(/assets/uploads/img/Slide231.jpg) Okay, let's go to the other column now, product attractiveness and consumer preference, and let us look at the unintended consequences of excessive regulation. And just remember what the analysts say about what's driving the growth of these products, and the growth of these products is largely good, it's largely an alternative to smoking and a good thing. They're talking about the rapid pace of innovation, stepped-up advertising and a lot of internet buzz. Mostly these are things that regulators suppress, by the way. They don't really do these sort of things that increase the interest and excitement around these products, and that's a Wells Fargo thing.



(/assets/uploads/img/Slide241.jpg) So regulation comes at a price and I just want to go through some of the unintended consequences of regulation that affect that second arm of my equation, the things that potentially reduce appeal. Greatly increased cost, huge investments needed in the supply chain, manufacturing regime and so on. Greatly reduced variety, it's expensive to get a product approved, niche products it won't be worth doing it, there will be only a certain number of things that will pass through a medicines regulation filter. So you would expect the cost to go up and the range of products to contract very dramatically, probably mostly towards those cigalike products that are produced by the larger companies. You would slow the pace of innovation, it isn't worth going to a regulator too often when it's expensive and very time-consuming to do it, and actually you get a bit of the censor in the head who says, "Actually it's not going to be worth it. I can't be bothered proving all this to the regulator." Fewer dollar innovations, so a lot of the buzz would go. I mean a lot of the excitement around e-cigarettes is around flavours, around mods and about special devices, again perhaps not really worth doing for the market. Less personalisation.



(/assets/uploads/img/Slide25.jpg) You might see one of the attractions of e-cigarettes as being able to configure it in a way that you seem really suits you. Now personalisation in medicine isn't actually a very common idea at all. So potentially thousands and thousands of different combinations of things making a product, how do you pass them all? The tendency to make the branding and marketing resemble the branding and marketing of haemorrhoid creams or NRT even is something that comes with the deadening hand of the regulator. A number of trusted brands and goodwill and choices would be destroyed by this, there's no question of that, and it's there in their impact assessment. We would tend to see dramatic concentration, so both at the product level and the firm level. A far smaller number of larger players who are able to clamber over the regulatory barriers to entry that they would create. And then finally, users are not stupid, they would take countervailing measures and there would be a growth and a thriving black market and DIY, all of which comes with more of the risks that you were trying to stop in the first place. So reduced appeal, the appeal is the key element in how we regulate e-cigarettes, we don't want to kill the product, we don't want to make it boring and bland. So there are trade-offs here. You could go a long way with the reduced risk, but you might reduce the number who switch, so the perfectly risk-free product that noone wants is very poor on the harm reduction equation. What you're really after is a diverse range of products, substantially reduced risk, let each smoker decide which is best.

(/assets/uploads/img/Slide26.jpg) Did I mention that medicines regulation is probably illegal? It's a disproportionate, discriminatory, it's been struck down by five courts in the European Union, so even if you think it's going to bring certainty and everything it doesn't really because somebody will challenge it and it will fail in court later.

Triple negative

Tough on harm reduction

(/assets/uploads/img/Slide271.jpg) So what should you do from a regulatory point of view? Just this sentence is quite... I was toying with this this morning. Tough on harm reduction. It's a lovely triple negative involved in this and if you think that tough regulation of harm-

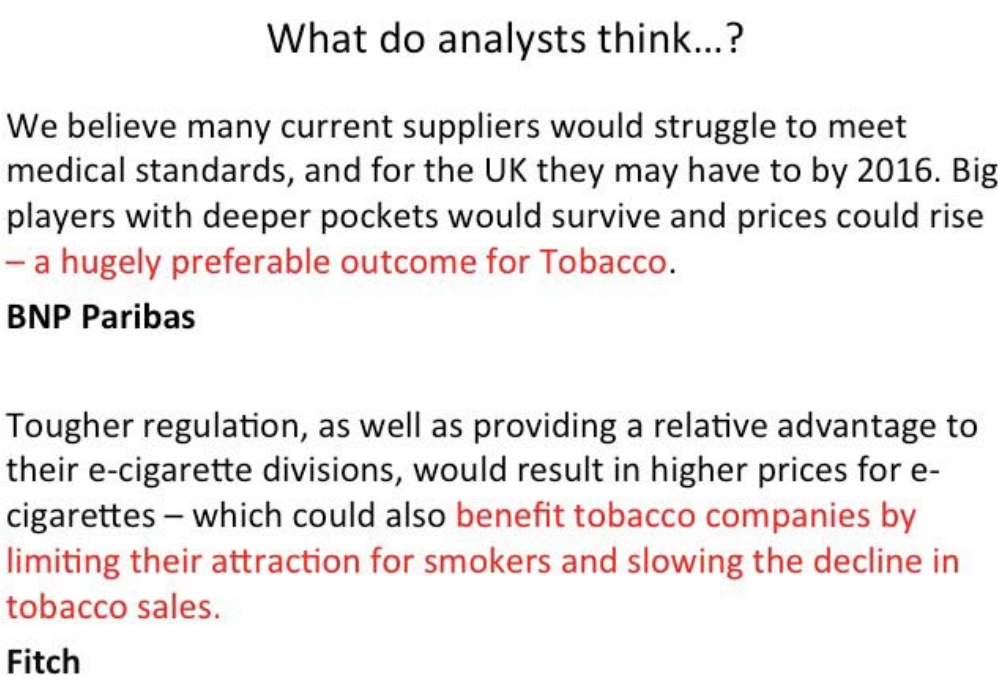
reduction ideas is a good idea you're basically being easy on harm, when you work through the triple negative that's behind this, and that's kind of the point that I really want to draw out in the next thing.

(/assets/uploads/img/Slide281.jpg) Before I do that, just people trip off the tongue, words like, you did it Linda, safety, efficacy, quality and everything. These have specialised meanings in medicines regulation, okay? They're not the way we mean it normally. So safety, is really primarily about adverse drug reactions, quality is about consistent drug dosing, and efficacy is about treating or preventing disease.

Getting tough on harm reduction?

	Counter-productive	Harm reducing
Safety	Safest possible	Safe enough
Quality	Control processes (eg. GMP)	Proportionate standards
Efficacy	Regulator decides	Consumer decides
Labelling	Warns of danger	Encourages switching
Marketing	Like medicines	Like consumer products
Bans on use	Fear of 'renormalisation'	Normalise harm reduction
Retail	Pharmacies / as tobacco	General sales
Age restrictions	Adults	Makes little real difference
Taxation	Like tobacco	Fiscal incentive to switch

(/assets/uploads/img/Slide291.jpg) Okay? Now when we're talking about e-cigarettes we're really talking about something different. So what would getting tough on harm reduction mean? Here's a few of the dimensions of regulation. On the left, I've listed the counterproductive touch on harm reduction style of regulation, on the right the harm reducing. So you want it safe enough is right. You don't want huge, expensive process controls, you want proportionate standards that the companies can meet. You don't want the regulator deciding what a good product is for goodness sake, what do they know? They don't even use the product. So you want the consumer to decide that and the trusted mechanisms of creative destruction to work out what products are actually sold. Labelling, we've got a massive problem with excessive labelling. We want to encourage switching. We want to be marketing like consumer lifestyle products. People are fretting that ecigarettes look a bit like they're marketed as cigarettes. It's not surprising, they're trying to appeal to the same people doing roughly the same thing but with vastly reduce risk. Fear of normalisation. To be honest we want to normalise harm reduction, we want these products out in the world and people switching to them. We want cigarettes to look like old technology and these to look like the new thing. Retail, we want them available everywhere. Age restrictions? If you must, doesn't make much difference, and taxation you want a fiscal incentive to switch rather than big excise duties.



(/assets/uploads/img/Slide311.jpg) Heavy regulation, what do analysts think? They think it's a big win for the tobacco industry, and those who think it's clever to raise high regulatory barriers to entry in the cigarette industry need to reconcile themselves with these kind of statements. These things advantage the big players with deep pockets that will profit from a dramatic, violent consolidation of the industry.

European Parliament – amendment 170

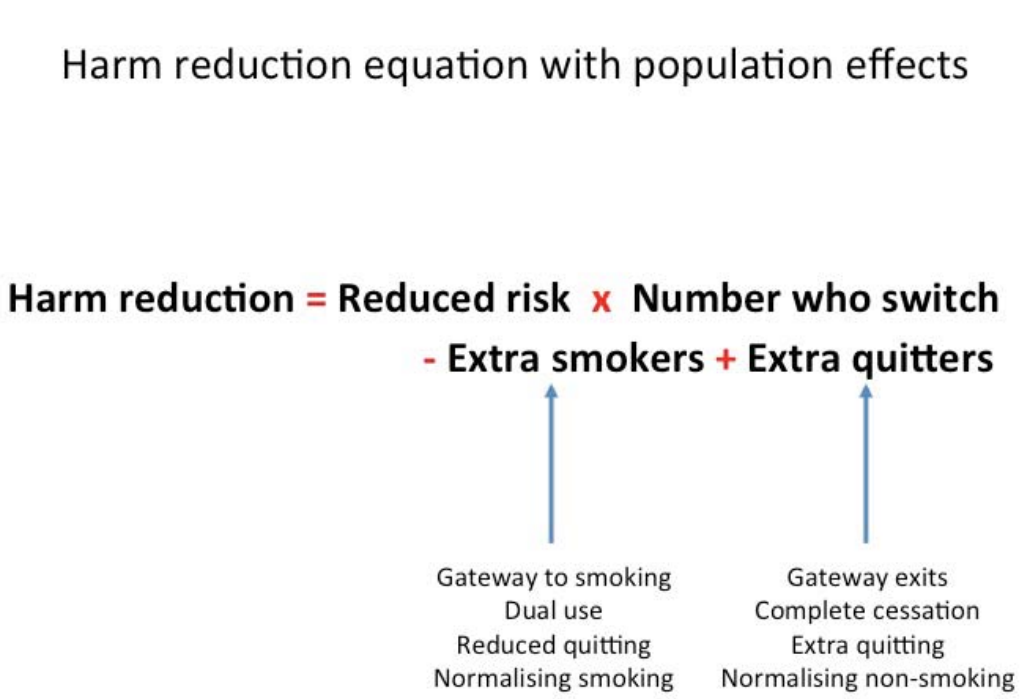
- Requires medicines regulation if claim made
- Requires Article 17 notification regime otherwise
- Emphasises general safety requirement
- Applies Article 16 – cross border distance sales
- Applies advertising directive 2003/33/EC and audiovisual services 2010/13/EU
- Information leaflet
- Warning "*this product is intended for use by existing smokers. It contains nicotine which is a highly addictive substance*"
- Warning size - 30% or 40% (Council =30%) and specification from Article 10
- 30mg/ml threshold – "are not placed on the market" (?medicine)
- Age restriction (no less than 18)
- Restriction on additives – application of Article 6.4 (vitamins etc)
- No tobacco branding
- Allows flavourings
- Requires sales allowed 'outside pharmacies'
- Review

(/assets/uploads/img/Slide321.jpg) This is the thing that parliament's created instead. I won't go into it because it makes me feel a bit like that. There's a lot of things wrong with it, it's ridiculous. It doesn't conform with my harm-reducing idea of regulation. Why would you want to prevent advertising of e-cigarettes? Ridiculous thing to do. Why would you introduce a 30mg/ml threshold? Absolutely no point to it and probably means that the products will be less attractive to heavy smokers. Why do you want to cover them with huge warnings when actually they're much better than cigarettes and so on. So I think you could learn from cosmetics regulation, and I've written a piece on this. There's a lot in common between cosmetics, they're fast-moving consumer goods, they pose risks to people, they can cause harm, they have to be high quality products and all the rest of it, and I think what we need to do now is move to purpose build regulation that is designed not to fit something that it isn't, not a medicine, not a tobacco product, not a cosmetic, not anything, but e-cigarettes and nicotine containing products.

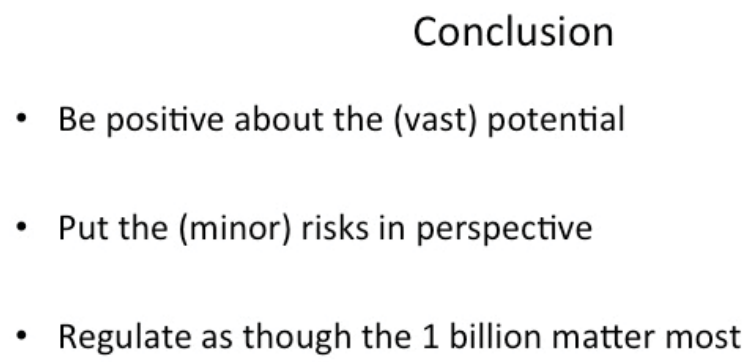
Purpose built regulation for e-cigs / NCPs

1. Accountabilities – responsible person
2. Disclosure and notification regime
3. Labeling and consumer information
4. Safety assessment and product file
5. Contaminants / purity
6. Prohibited ingredients
7. Specific standards for vaping devices CEN/ISO
8. Updating: review & technical committee
9. Marketing (like alcohol?) – mostly member state
10. Retail sales age restriction – member states
11. … public vaping?

(/assets/uploads/img/Slide351.jpg) For goodness sake, there's enough regulation produced in the world for them to do something that is specific to the actual product that they're trying to regulate. So these are the kind of elements that I think you need. Some of this is borrowed from cosmetics regulation. Down at the bottom, marketing, the idea that you have to ban advertising, you can put control on it, we have controls on alcohol advertising, nothing wrong with that. Retail sales restrictions matter for member states. Public vaping in my opinion absolutely no place for the law in this. This is a matter for the operators of spaces, etiquette to develop over time. Finally, very finally, the harm reduction equation extended for population effects, this is a big thing in the States. FDA, we're going to regulate these around population effects, which might mean you get some extra smokers or you get some extra quitters. They tend not to focus on the extra quitters by the way; they're more worried about these here.



(/assets/uploads/img/Slide361.jpg) And I can't go into this now, we'll probably come back to it in the discussion later, but basically there's a bunch of population effects that could derail this sort of idea. However, for every one of them there is another population effect which is beneficial and my contention is that the beneficial pathways through these population effects are much more likely, much, much more plausible and there are more of them, because you've introduced a much safer product into this kind of tobacco ecosystem, and we should stop the focus on them, and anyone who wants to raise those population effects shouldn't be raising it without thinking about what the consequences would be for the population effects that are actually highly desirable. And the last thing to say about this is this has all been worked through with Snus and the people who are worried about population effects say, "It's a gateway, it'll cause extra smoking." When none of those things actually happened they didn't change their mind about having a ban. So I think these things are often raised tactically rather than as a genuine concern.



(/assets/uploads/img/Slide371.jpg) Right, my final points. Be positive about the vast potential. The job of people in this room is to go after that green wedge, go after those testimonies. Keep the minor risks in perspective, don't over-regulate and therefore throw the baby out with the bathwater and make the products much less appealing and boring, and regulate really as if the one billion matter most. Thank you. **(Applause) Chair:** Okay. Thanks very much, Clive, for that very provocative talk. Those people who know Clive wouldn't be disappointed. I did you a bit of an injustice actually because you do have a few more minutes, so I can take a question of clarification from the floor. Deborah. **D Arnott:** Deborah Arnott, current chief executive of ASH. And I do wonder why you keep mentioning it, Clive, if you no longer speak on behalf of ASH, but that's another matter. **Clive Bates:** So people know who I am. **D Arnott:** But I do have a serious point which is that you talked about the costs of regulation and you came up with your alternative, but there's no attempt there to calculate what the costs would be of actually setting up a purpose-build regulatory system for e-cigarettes. Because actually it's not cost free, and I've never seen you do that calculation. **Clive Bates:** No, I mean the actual costs of the regulators themselves and the sort of regulatory interactions are really quite small in this. I mean the real costs of regulation comes from what the regulation requires the companies in the market to do. So it's costs of compliance basically, building pharmaceutical-grade factories to produce this stuff and having big IT systems, huge numbers of process controls and all the rest of it that goes with meeting the pharmaceutical, medical definitions of safety, quality and efficacy. So the way I'd look at it, Deborah, I mean these things aren't particularly… I haven't done a cost/benefit analysis on how much this would cost, but because I've been drawing on cosmetics regulation, which, it's not risk-free cosmetics by any means, I would say that we've got a very successful cosmetics industry, we've got a large number of brands, large, fast-moving

consumer goods, a lot of innovation. Actually the Commission itself when it proposed to include these in the directive back in 2010 said in its consultation that they would set standards for safety and quality, and that's what I'm advocating. It was a subsequent change where they decided that they would come back and classify these things as medicines which they plainly are not. So I think there will be costs of regulations and I think the costs should fall on the manufacturers, but the question is to keep those as low as possible consistent with the risks. I mean I don't really think that much regulation is really needed at all, but if we want regulatory red meat because that's what the European Parliament wants or the Council wants, then there are more proportionate and more modest forms of regulation than regulating these things as medicines. **Chair:** Okay. I suggest we move on. Thank you very much, Clive, thanks again for your talk.

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please consult with your doctor before using any electronic cigarette products. Please note that nicotine is addictive and toxic by direct swallowing or in contact with the skin. Nicotine is known to cause birth defects and reproductive harm. Please keep it out of reach of children or pets.

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E-cigarette use rare in non-smokers, UK survey finds

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(Reuters) - The use of electronic cigarettes in England is largely confined to smokers and ex-smokers, according to a government-backed survey, the latest report to suggest that e-cigarettes were not attracting new smokers.

The Health Survey for England found that among men who were not smokers, only 1 percent had ever tried e-cigarettes, while 29 percent of smokers and 6 percent of ex-smokers said they had.

Proportions were similar for women, said the survey, which was published on Wednesday.

E-cigarettes are metal tubes that heat nicotine-laced liquid into an inhalable vapor. Proponents see them as a healthier alternative to tobacco cigarettes, while critics fear social acceptance of them will lead to increased smoking. They also cite a lack of data on the health effects of long-term use.

The latest findings are in line with other surveys -- one published last month by Britain's Office for National Statistics and one commissioned by the health charity Action on Smoking and Health (ASH).

All seem to question a key argument that critics of the devices use in pushing for greater restrictions.

"While it is clearly important to continue to monitor both smoking rates and use of electronic cigarettes in adults and children, so far there is no evidence that use of electronic

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cigarettes is proving to be a gateway into smoking," Deborah Arnott, chief executive of ASH, said in a statement.

The Health Survey for England was carried out by the Joint Health Surveys Unit of NatCen Social Research and the Research Department of Epidemiology and Public Health at University College London. It interviewed 8,795 adults and 2,185 children.

(Reporting by Martinne Geller; Editing by Crispian Balmer)

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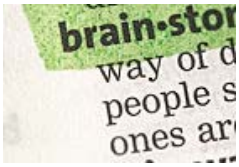

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Healthy, high-fat diet may be a pipedream

A much-hyped new study, conducted with just 150 participants, calls for us to "embrace fat" — even the saturated kind. The alleged benefits? Weight loss and, most incredibly, healthier hearts. But the truth is the jury is still out. **Commentary**

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E-Cigarettes a Gateway to Smoking? Not Likely, Suggests New UK Study

admin November 25, 2014 No Comments

Contact: Gregory Conley
Tel: 609-947-8059
Email: gconley@vaping.info

FOR IMMEDIATE RELEASE
November 25, 2014 at 12:30 pm EDT

E-Cigarettes a Gateway to Smoking? Not Likely, Suggests New UK Study

UK Office for National Statistics: Less than 1 in 300 never smokers vape

WASHINGTON, D.C. – Today, the American Vaping Association, a leading advocate for the benefits of vapor products such as electronic cigarettes, reacted to the release of new data from the UK's Office for National Statistics regarding adult smoking habits and e-cigarette usage.

Among the key findings of the report:

* Past 30 day use of e-cigarettes is almost solely confined to smokers and ex-smokers.

* E-cigarettes are being used by 12% of smokers and 5% of ex-smokers.

* E-cigarette use is negligible amongst those who have never smoked cigarettes (0.14%).

* Over half of the e-cigarette users say their main reason for using the product is to stop smoking.

* Smoking has continued to decline in the country despite (more likely because of) the rise of popularity of e-cigarettes.

This report comes on the heels of another study that found use of e-cigarettes by never smokers and young people who have never smoked is rare.

BBC coverage of the data from the Office of National Statistics can be found here.

Gregory Conley, President of the American Vaping Association, issued the following statement:

"The release of this data should be hailed by those working in public health. E-cigarettes are helping smokers quit and not leading nonsmokers to regularly use nicotine. Simply put, there is no evidence to suggest that e-cigarettes are acting as a gateway to real cigarettes.

"In the UK, many public health officials have been rational and level headed in their approach to e-cigarettes. The UK's largest anti-smoking charity, Action on Smoking & Health (ASH), has embraced e-cigarettes and warned against the unintended consequences of banning their usage where smoking is banned. Some National Health Services stop smoking clinics even actively recommend e-cigarettes to smokers looking to kick the habit. Thanks in part to this mature response, British smokers have felt comfortable switching to vaping, leading both e-cigarette usage and quit rates to consistently rise since 2013.

"Meanwhile, anti-smoking groups in the U.S. continue to defy their mission statement by attempting to scare smokers into not trying e-cigarettes. This new data should inspire these organizations to reconsider their policies towards e-cigarettes. At the least, it is time for these activists to retire their talking point that e-cigarettes may act as a gateway to cigarette smoking."

You can learn more about AVA and vaping by visiting the AVA website. You can also find us on Facebook and Twitter.

# # #

About the American Vaping Association:

The American Vaping Association is a nonprofit organization that advocates for small- and medium-sized businesses in the rapidly growing vaping and electronic cigarette industry. We are dedicated to educating the public and government officials about financial and public health benefits offered by vapor products, which are battery-powered devices that heat a liquid nicotine or nicotine-free solution and create an inhalable vapor.

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E-Cigarettes Could Stub Out Tobacco Bonds Than Thought

World | Reuters | Updated: June 24, 2014 10:43 IST

A employee works at a production line in an electronic cigarettes factory in Shenzhen, southern Chinese province of Guangdong on January 15, 2014

NEW YORK: The rapid growth of electronic cigarette sales p under-appreciated risk to holders of as much as $96 billion payments tobacco companies make to U.S. states from a settlement in 1998.

Tobacco bonds were already forecast by many analysts to beg the next 10 years. That's because Americans have given up sr rate than estimated when most of the bonds were sold in the

Cigarette consumption has dropped an annual average 3.4 pe while many bonds were structured to withstand consumption d 3 percent.

But as smokers swap traditional cigarettes for tobacco-free e-cigarettes and other vaping products, declining even faster and analysts now predict some bonds could go into default before the end

"If the decline goes to 6 or 7 percent, it will be very quick," said Tom Metzold, portfolio manager a Investment Managers. "I think that the first ones are probably five years away," he said in referen

While still a small part of the cigarette market, sales of e-cigarettes and vaporizers have already grow than $2.2 billion from next to nothing four years ago. By some estimates, they will capture more tha market within a decade, and tobacco companies are already jockeying for leading positions as tha

"We believe consumption of e-vapor will eclipse consumption of combustible cigs over the next dec improves," wrote Bonnie Herzog, analyst at Wells Fargo, who has tracked the tobacco industry for report.

Last month, Reuters reported that Reynolds American Inc. and Lorillard Inc., the second and third U.S were exploring a merger. Lorillard's leading blu e-cigarette brand, which has roughly 50 percent of t seen as one of the appeals of the deal to Reynolds.

Under the Master Settlement Agreement, or MSA, struck 16 years ago between the biggest U.S. toba 46 U.S. states, the companies make annual payments to the states using a complex formula tied shipments. The accord ended years of litigation brought by the states, which had sought to recoup h treating ailments tied to smoking.

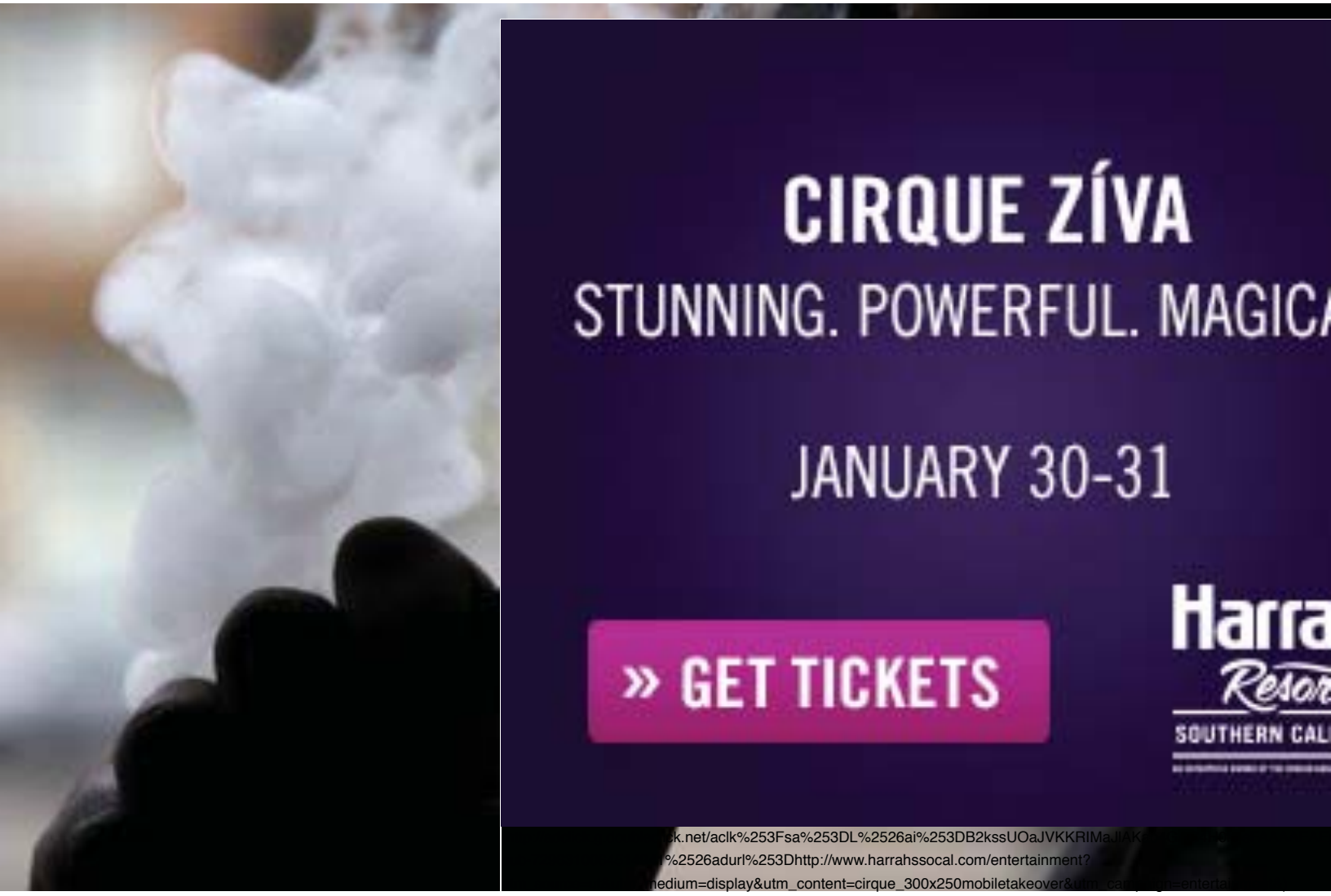
The states with the highest populations, such as California and New York, are owed the most. The arranged to get much of their money up front by selling bonds and pledging the annual payments to

The only problem is that as tobacco shipments decline, so do the payments. And sales of e-cigare appear to be helping to accelerate the tobacco-consumption decline rate, are not counted as cigare MSA.

BREAKING AMBER ALERT SUSPECT ARRESTED (/NEWS/2014/DEC/11/AMBER-ALERT-ISSUED-MISSING-MONTEBELLO-FAMILY/)

E-cigarettes a positive alternative; fostering religious study

U-T San Diego 05:00p.m. Dec 6, 2014



E-CIGARETTE USE IS A POSITIVE ALTERNATIVE

Regarding “Should a sin tax apply to e-cigarettes? (http://www.utsandiego.com/news/2014/nov/27/sin-tax-tobacco-electronic-cigarettes-california/)” (Nov. 28): First Five (like most agencies funded by “sin” taxes) does good work but prioritizes revenue over public health by proposing increased California taxes for vaporizing products, aka electronic cigarettes.

Electronic cigarettes replace tobacco as a safer option, proving more effective at helping people quit smoking than FDA approved methods.

I believe more taxation is counterproductive to improving community well-being. California cigarette sales fell 20 percent in the past five years. E-cigarettes contributed to this success.

Don’t discourage Californians from quitting smoking by taxing these products in a misguided attempt to replace declining subsidies.

Pat Meyer
Normal Heights

FOSTERING RELIGIOUS STUDY IS A POSITIVE

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"We found that e-cigarettes appear to be less addictive than tobacco cigarettes in a large sample of long-term users," said Jonathan Foulds.

Image: ©iStock Photo mauro_grigollo

E-cigarettes less addictive than cigarettes

By Jennifer Abbasi
December 9, 2014

HERSHEY, Pa. -- E-cigarettes appear to be less addictive than cigarettes for former smokers and this could help improve understanding of how various nicotine delivery devices lead to dependence, according to researchers.

"We found that e-cigarettes appear to be less addictive than tobacco cigarettes in a large sample of long-term users," said Jonathan Foulds, professor of public health sciences and psychiatry, Penn State College of Medicine.

The popularity of e-cigarettes, which typically deliver nicotine, propylene glycol, glycerin and flavorings through inhaled vapor, has increased in the past five years. There are currently more than 400 brands of "e-cigs" available. E-cigs contain far fewer cancer-causing and other toxic substances than cigarettes, however their long-term effects on health and nicotine dependence are unknown.

To study e-cigarette dependence, the researchers developed an online survey, including questions designed to assess previous dependence on cigarettes and almost identical questions to assess current dependence on e-cigs. More than 3,500 current users of e-cigs who were ex-cigarette

smokers completed the Penn State Cigarette Dependence Index and the Penn State Electronic Cigarette Dependence Index.

Higher nicotine concentration in e-cig liquid, as well as use of advanced second-generation e-cigs, which deliver nicotine more efficiently than earlier "cigalikes," predicted dependence. Consumers who had used e-cigs longer also appeared to be more addicted.

"However, people with all the characteristics of a more dependent e-cig user still had a lower e-cig dependence score than their cigarette dependence score," Foulds said. "We think this is because they're getting less nicotine from the e-cigs than they were getting from cigarettes."

Although many regular users on e-cigarettes are trying to quit smoking, the Food and Drug Administration has not approved them for this use, and they cannot be marketed as a smoking cessation product.

"This is a new class of products that's not yet regulated," Foulds said. "It has the potential to do good and help a lot of people quit, but it also has the potential to do harm. Continuing to smoke and use e-cigarettes may not reduce health risks. Kids who have never smoked might begin nicotine addiction with e-cigs. There's a need for a better understanding of these products.

"We don't have long-term health data of e-cig use yet, but any common sense analysis says that e-cigs are much less toxic. And our paper shows that they appear to be much less addictive, as well. So in both measures they seem to have advantages when you're concerned about health."

The findings, which are published in Nicotine & Tobacco Research, also have implications for developing e-cigs for smoking cessation.

"We might actually need e-cigarettes that are better at delivering nicotine because that's what's more likely to help people quit," Foulds said.

Previous research shows that nicotine replacement efficacy correlates with higher nicotine dose and faster delivery speed.

The new index used in the study is more modern than the most widely used dependence survey, the Fagerstrom Test for Nicotine Dependence. That scale was developed 25 years ago and does not reflect modern use of tobacco and nicotine products.

"People smoke fewer cigarettes today but are still clearly addicted, and the old scale -- while still reasonably effective -- was not designed to measure that," Foulds said.

The new questionnaire also allows for cross-comparisons between different nicotine and tobacco products.

"Not only are e-cigs a booming industry, but new tobacco products are set to enter the market soon," Foulds said. "Our questionnaire is designed to compare dependence across different

products simply by substituting the different product name into the questionnaire in place of cigarettes."

Additional researchers on this project are Susan Veldheer, research coordinator, Jessica Yingst, research assistant, and Shari Hrabovsky, research nurse practitioner, all at Penn State College of Medicine; Stephen J. Wilson and Travis T. Nichols, both at Penn State; and Thomas T. Eissenberg at Virginia Commonwealth University.

This work was initially funded by an internal grant from Penn State Social Science Research Institute and Cancer Institute, the National Institute on Drug Abuse of the National Institutes of Health and the Center for Tobacco Products of the U.S. Food and Drug Administration

CONTACTS:

Matthew Solovey, msolovey@hmc.psu.edu
Work Phone: 717-531-8606

Last Updated December 09, 2014

E-cigarettes Provide a New Lease on Life

By Susan Smith · Oct 9th, 2014 · 1 Comment

For almost half his life, Philip has been an active cigarette smoker. “I started when I was in my teens,” Philip said. “A lot of my friends and peers are smoking cigarettes.” Not only did he think smoking was cool. Philip thought it was just normal for people in his age take up the habit.

It was therefore not surprising that for a long time, Philip always had a pack of cigarettes in his pocket. “Everywhere I go, to my former school, to a friend’s party, I always had some cigarettes with me,” he said. “After smoking, I always checked if I still have some cigarettes left. If I used up all of them, I immediately go to the nearest store to buy another pack.”

At some point, Philip felt he was so addicted to smoking that he wanted to stop but can’t. “I know all about the health risks associated with smoking. I mean, who doesn’t?” He asks. He felt guilty every time he lights up a stick. “I told myself, this stick was going to be my last one,” he muses. But after a few minutes, and especially when he runs out of cigarettes, he finds himself going to the store buying a new pack, and swearing again that this would be his last pack.

“I felt like I was trapped in a vicious cycle,” Philip said. He felt his smoking addiction was hopeless.

Then came electronic cigarettes. E-cigs gave people like Philip the experience of smoking, but without the health risks and smell associated with smoking traditional cigarettes.

Unlike traditional cigarettes, electronic cigarettes (or E-cigarettes) do not have carcinogens, carbon monoxide, and tar that have harmful poisons to the body. There is no second-hand smoke which happens when you smoke a traditional cigarette. “With E-cigs, you do not have to worry anymore that people around you, especially those who are always near you such as your loved ones and friends, will get the harmful effects of second-hand smoking,” Philip attests.

E-cigs use a special liquid, also known as E-liquid or E-juice, which produces harmless and odorless water vapor. The E-liquid vapor being released is like the steam you get when you are boiling water. There are dozens of E-liquid available in the market today that often resemble the taste of ordinary cigarettes, menthol, and various bruits. Many E-juices offer varying nicotine concentrations. Nicotine-free ones are also widely common. Because E-cigs vaporize the E-liquid solution, many of the harmful ingredients found in the regular cigarette smoking are not present.

“At first, I was using an E-liquid that has a substantial amount of nicotine concentration for my E-cig,” Philip said. “But after a few weeks, I noticed that I can decrease the nicotine concentration and still be okay with it. Finally after three months, I am using a nicotine-free E-liquid. I’ve been using a nicotine-free E-cig since then.”

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Not only is E-cig healthier for you; it is also environmentally-friendly. If all smokers use E-cigs, the world will not have a problem anymore with cigarette butts that pose harmful effects to the environment. E-cigs are mostly reusable and powered usually by reusable batteries. You do not need a lighter to use your E-cig.

Now, after more than 10 years of being an active traditional cigarette smoker, Philip is now an E-cig user. He is now healthier and happier. “With the E-cig, I felt like I was given a chance to live life anew.”

His wife and one-year-old baby are also happy too with the result. “E-cigs have given us a way for my husband to kick off his smoking habit. My baby and I can never be thankful enough,” Philip’s wife says.

Photo by **Lindsay Fox**

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One Comment

Sandra Bamford
October 13, 2014 at 10:13 am /

I was a smoker for 37 years. I tried cold turkey, nicotine gum, pummeling my body and leading it like a slave, CHANTIX OMG, (that stuff made me crazy!) To no avail. My son and his friends quit by vaping and he helped me order a pen with accessories online. He made me promise to try it. This was the best promise I ever made. I am now the proud owner of an itaste SVD. I love the juice flavors: Butter Pecan, Butter toffee, Caramel Candy, Bannana Cream Pie and Black Cherry! I am smoke free now 3 months, NO SWEAT. I can exercise without my lungs burning. I ditched my cough with that nasty brown phlegm and I know this has added years to my life.

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E-cigarettes significantly reduce tobacco cravings

By the end of the 8-month study, 21% of study participants had stopped smoking tobacco altogether and an additional 23% cut the number of tobacco cigarettes they smoked per day by half.

19 November 2014

Electronic cigarettes offer smokers a realistic way to kick their tobacco smoking addiction. In a new study published in the *International Journal of Environmental Research and Public Health*, scientists at KU Leuven report that e-cigarettes successfully reduced cravings for tobacco cigarettes, with only minimal side effects.

Electronic cigarettes (e-cigs) were developed as a less harmful alternative to tobacco cigarettes. They contain 100 to 1,000 times less toxic substances and emulate the experience of smoking a tobacco cigarette.

In an 8-month study, the KU Leuven researchers examined the effect of using e-cigs ("vaping") in 48 participants, all of whom were smokers with no intention to quit. The researchers' goal was to evaluate whether e-cigs decreased the urge to smoke tobacco cigarettes in the short term, and whether e-cigs helped people stop smoking altogether in the long-term.

The participants were divided into three groups: two e-cig groups, which were allowed to vape and smoke tobacco cigarettes for the first two months of the study, and a control group that only had access to tobacco. In a second phase of the study, the control group was given e-cigs and all participants were monitored for a period of six months via a web tool, where they regularly logged their vaping and smoking habits.

In the lab, the e-cigs proved to be just as effective in suppressing the craving for a smoke as tobacco cigarettes were, while the amount of exhaled carbon monoxide remained at baseline levels. In the long-term analysis, results showed that the smokers were more likely to trade in their tobacco cigarettes for e-cigs and taper off their tobacco use.

At the end of the 8-month study, 21% of all participants had stopped smoking tobacco entirely (verified via a CO test), whereas an additional 23% reported cutting the number of tobacco cigarettes they smoked per day by half.

Across all three groups, the number of tobacco cigarettes smoked per day decreased by 60%.

"All the groups showed similar results after we introduced the e-cigs," concluded Professor Frank Baeyens (Faculty of Psychology and Educational Sciences, KU Leuven) and postdoctoral researcher Dinska Van Gucht (Faculty of Psychology and Educational Sciences, KU Leuven, and Thomas More University College). "With guidance on practical use, the nicotine e-cig offers many smokers a successful alternative for smoking less – or even quitting altogether. E-cig users get the experience of smoking a cigarette and inhale nicotine vapor, but do not suffer the damaging effects of a tobacco cigarette."

"By comparison: of all the smokers who quit using nothing but willpower, only 3 to 5% remain smoke-free for 6 to 12 months after quitting," says Baeyens.

Nicotine e-cigs are currently banned in Belgium. In light of their study results, the researchers are now urging for

a new legal framework for nicotine vaping in Belgium. All neighboring countries allow the sale of nicotine e-cigs.

Photo courtesy of Shutterstock

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Tags: Cancer | e-cigs | e-cigarettes | regulation | vape | smoke

E-Cig Technology Takes Off as Regulation Looms

Monday, 08 Dec 2014 07:59 AM

Just a few years ago, early adopters of e-cigarettes got their fix by clumsily screwing together a small battery and a plastic cartridge containing cotton soaked with nicotine.

Now, the battery-powered contraptions have computer chips to regulate puffs and temperature, track usage, talk to other electronic devices and even blink when "vapers" are near each other.

Federal officials say the technology race could make creating standards the devices, which heat a liquid to create vapor rather than burning tobacco, more difficult in the future.

Unlike traditional smokes that are simply chopped tobacco rolled in paper with a filter, e-cigarettes come in many shapes and sizes and the technological changes only make regulating them more of a headache.

At the same time, a rapidly growing market for e-cigarettes and the possibility that the devices could be safer than regular cigarettes have some in the industry worried that regulation that's too heavy-handed would stifle the technological innovation - and their businesses.

"I think it's fair to say that there will always be some degree of a gap between (data) and the latest innovations," Mitch Zeller, director of the U.S. Food and Drug Administration's Center for Tobacco Products, said in a recent interview with The Associated Press. "But that's the beauty of regulation because over time, regulation closes that gap. ... We will get to a point where new products have to come through us first."

It's unclear how quickly regulation will proceed, but the FDA seems to be taking a deliberate approach.

In April, the FDA for the first time proposed a set of regulations for e-cigarettes, including banning sales to minors and requiring health warning labels, as well as approving new products. The agency has said its proposal sets a foundation for regulating the products but the rules wouldn't immediately ban the wide array of flavors or styles of e-cigarettes or curb marketing on places like TV.

The agency has scheduled a two-day public meeting beginning Wednesday to discuss the

science surrounding e-cigarettes.

Late last month, House Speaker John Boehner joined House Majority Leader Kevin McCarthy and House Energy and Commerce Chairman Fred Upton in writing to federal officials raising concerns about FDA's regulation of e-cigarettes, saying the proposed rules would "impede innovation and impose unnecessary regulatory burdens" on the agency and the industry.

Smokers like e-cigarettes because the nicotine-infused vapor looks like smoke but doesn't contain the thousands of chemicals, tar or odor of regular cigarettes. Some, known as "cig-a-likes," look like traditional cigarettes and use sealed cartridges that hold liquid nicotine. Others have empty compartments or tanks that users can fill their own liquid.

Users also can buy different batteries and pieces to build their own e-cigarette. Ultimately the FDA hopes to require e-cigarette makers to apply for approval for their products before they can be sold.

That worries e-cigarette makers.

"There's a balance to be found between being protective enough and on the other hand not being too complicated for players in the market to innovate and offer new products," said Alexandre Prot, CEO of Smokio, which sells an electronic cigarette or vaporizer that connects to a smartphone via Bluetooth to track puffs, tally cost savings and possible health benefits from switching from regular cigarettes, and controls the battery power of the device, which regulates the amount of vapor produced. Smokio retails for about $80 depending on the model, and the company is closing in on selling 10,000 units by the end of the year.

The nation's biggest tobacco companies, which have also started selling e-cigarettes, boast their own technology. Reynolds American Inc.'s Vuse-brand electronic cigarette contains a microprocessor and memory chip that regulate the power to heat the liquid nicotine for what the company calls the "perfect puff." Altria Group Inc.'s MarkTen has four holes on the mouthpiece that that make the puffs more closely resemble a traditional cigarette.

Lorillard Inc.'s Blu e-cig brand offers a special carrying case that lights up when near another vaper or alerts the user when near a store that sells replacement cartridges.

Another company is marketing an e-cigarette that has a built-in Bluetooth speaker and microphone to make and receive phone calls as well as listen to music, and others are selling vaporizers that can either use liquid nicotine or ground-up tobacco or herbs. Vaporizers are also commonly used for marijuana.

Other advances foreshadowed in U.S. Patent Office filings suggest a pay-as-you-puff feature where users could buy time credits on the Internet and then sync an e-cigarette via USB to control how much they can smoke, possibly as a way to cut down. Connecting the device to the computer also would allow users to monitor how much they use, perform maintenance and automatically order additional liquid or tobacco.

And with several hundred brands in the market, technology is a way to grab vapers' attention and will continue to evolve, Cowen analyst Vivien Azer said.

"We are far from the end of the innovation life-cycle as it relates to e-cigarettes," Azer said. "Manufacturers continue to innovate, and rightly so."

While evaluating e-cigarettes is "sort of a new frontier for FDA," the agency already has the expertise to regulate more advanced technology such as pacemakers, dialysis machines and MRI machines, said Dr. Daniel Schultz, a regulatory consultant with Greenleaf Health LLC and former director of the FDA's Center for Devices and Radiological Health.

"If they can regulate all those things, I daresay that they can regulate an electronic cigarette."

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HEALTH, LEGISLATION, POLITICS, STUDIES, VAPING

EPA & FDA: Vapor Harmless to Children

APRIL 3, 2014 *matt black*

In the continued war on e-cigarettes, we hear about the "potential dangers" of e-cigarette vapor and the "unknown public health risks."

First, I find it absolutely absurd that we're attempting to pass laws based on unknowns, but what makes it even more absurd is the fact that there's very little that ***isn't*** known about e-cigarette vapor at this point. The primary ingredient of concern to those who wish to see e-cigarettes banned is the propylene glycol vapor, **which has been studied for over 70 years**.

I recently came across a document titled, "Reregistration Eligibility Decision For Propylene Glycol and Dipropylene Glycol", which was created by the United State Environmental Protection Agency (EPA).

Catchy title. I was intrigued.

This quote caught my eye:

> *Propylene glycol and dipropylene glycol were first **registered** in **1950 and 1959**, respectively, **by the FDA for use in hospitals** as air disinfectants. (page 4, paragraph 1).*

In a previous post, I had shared the summary of research that had been done in 1942 by Dr. Robertson regarding the antibacterial properties of vaporized propylene glycol, but I had never heard that the FDA wound up approving it for the purpose of an air disinfectant in hospitals.

> *Indoor Non-Food: Propylene glycol is used on the following use sites: air treatment (**eating establishments**, hospital, commercial, institutional, household, bathroom, transportational facilities); medical premises and equipment, commercial, institutional and industrial premises and equipment; (page 6, paragraph 2)*

@MNVAPERS

@Vapornaught **27 mins**

.@ClearWayMN @AlexisBylander Your entire opposition is based on "it looks like smoking" and cherry picked junk science.

@AddictionJrnl **4 hours**

Electronic cigarettes: getting the science right and communicating it accurately. Read the latest Virtual Issue free **ow.ly/Fq4L1**

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@MNVAPERS **December 10, 2014**

U Florida grad student proposing study of cessation - they only need $350 to reach funding goal. Think we can help? **experiment.com/projects/do-el…**

Continued...

> ***Method and Rates of Application***
>
> ....
>
> *Air Sanitizer*
>
> *Read the directions included with the automatic dispenser for proper installation of unit and refill. Remove cap from aerosol can and place in a sequential aerosol dispenser which automatically releases a metered amount* ***every 15 minutes****. One unit should treat 6000 ft of* ***closed air space****... For regular, non-metered applications,* ***spray room until a light fog forms****. To sanitize the air, spray 6 to 8 seconds in an average size room (10'x10'). (page 6, paragraph 6)*

A common argument used to support the public usage ban is that, "Minnesotans have become accustomed to the standard of clean indoor air." However, according to the **EPA and FDA**, so long as there's a "light fog" of propylene glycol vapor in the air, **the air is actually more clean than the standard that Minnesotans have become accustomed to.**

> ***General Toxicity Observations***
>
> *Upon reviewing the available toxicity information, the Agency has concluded that there are no endpoints of concern for oral, dermal, or inhalation exposure to propylene glycol and dipropylene glycol. This conclusion is based on the results of toxicity testing of propylene glycol and dipropylene glycol in which dose levels near or* ***above*** *testing limits (as established in the OPPTS 870 series harmonized test guidelines) were employed in experimental animal studies and no significant toxicity observed.*
>
> ***Carcinogenicity Classification***
>
> *A review of the available data has shown propylene glycol and dipropylene glycol to be* ***negative*** *for carcinogenicity in studies conducted up to the testing limit doses established by the Agency; therefore, no further carcinogenic analysis is required. (page 10, paragraphs 1 & 2)*

Ready for the bombshell? I probably should have put this at the top, as it could have made this post a lot shorter, but I figured the information above was important, too...

> ***2. FQPA Safety Factor***
>
> *The FQPA Safety Factor (as required by the Food Quality Protection Act of 1996) is intended to provide an additional 10-fold safety factor (10X), to protect for special sensitivity in* ***infants and children*** *to specific pesticide residues in food, drinking water, or residential exposures, or to compensate for an incomplete database.* ***The FQPA Safety Factor has been removed (i.e., reduced to 1X) for propylene glycol*** *and dipropylene glycol because there is* ***no pre- or post-natal evidence for increased susceptibility following exposure****. Further, the Agency has concluded that there are no endpoints of concern for oral, dermal, or* ***inhalation exposure to propylene glycol*** *and dipropylene glycol based on the* ***low toxicity observed*** *in studies conducted*

@N_Zillatron **December 10, 2014**

#ecigs reduce **#tobacco #cravings** and help people **#quit #smoking**, **dailyherald.com/article/201412…** via **@dailyherald #sensible #balanced**

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> *near or **above** testing limit doses as established in the OPPTS 870 series harmonized test guidelines. Therefore, quantitative risk assessment was not conducted for propylene glycol and dipropylene glycol.*

In a paper published in the American Journal of Public Health by Dr. Robertson in April of **1946**, Robertson cites a study published in the Edinburgh Medical Journal, which was conducted in **1944**:

> *The report of the **3 years' study** of the clinical application of the disinfection of air by glycol vapors in a children's convalescent home showed a **marked reduction** in the number of acute respiratory infections occurring in the wards treated with both propylene and triethylene glycols. **Whereas in the control wards, 132 infections occured during the course of three winters, there were only 13 such instances in the glycol wards during the same period.** The fact that children were, for the most part, chronically confined to bed presented an unusually favorable condition for the prophylactic action of the glycol vapor.*
>
> *An investigation of the effect of triethylene glycol vapor on the respiratory disease incidence in military barracks brought out the fact that, while for the first 3 weeks after new personnel entered the glycolized area the disease rate remained the same as in the control barracks, the second 3 week period showed a **65 percent reduction in acute respiratory infections** in the glycol treated barracks. Similar effects were observed in respect to airborne hemolytic streptococci and throat carriers of this microorganism.*

I don't expect the prohibitionist lawmakers to delve this deeply into this subject on their own, but I certainly hope that when presented with this data that they reevaluate their stance on the subject and consider what science has to say. If they don't, they're simply basing their judgement off of rhetoric, misinformation, and personal bias and we all know where that gets us.

URGENT – Duluth City Council Meeting 8/26/2013

URGENT: Call To Action! - Minneapolis E-cig Ban

Health Studies

children, *disinfectant*, *e-cigarettes*, *epa*, *fda approved*, *hospitals*, *propylene glycol*, *studies*, *vapor*

Matt Black's editorial for the Grand Forks Herald

UPDATE (5/1): Call to Action – Minnesota Senate Finance Committee

Comments are disabled.

58 thoughts on "EPA & FDA: Vapor Harmless to Children"

Analogs... Nope. | One Smoker's Journey to Better Health. *says:*

APRIL 3, 2014 AT 12:16 PM

[…] http://mnvapers.com/2014/04/epa-fda-vapor-harmless-children/ […]

Jaocb *says:*

APRIL 3, 2014 AT 12:45 PM

wow im actually gonna save thi article to refer people to if they have concerns about e-cigarettes. this is a very unbiased and informative article and i aplaud you for being unbiased.

matt black *says:*

APRIL 3, 2014 AT 2:59 PM

Thank you!

rich *says:*

APRIL 4, 2014 AT 8:26 AM

All this is based on experiments from the forties? Maybe that's why… Reulations and technology …awareness have come along way since then… This information inhold as obsolete

matt black *says:*

APRIL 4, 2014 AT 9:39 AM

The EPA findings were from 2006 – not

exactly old. But, how about a peer reviewed study completed in January of 2014? http://www.biomedcentral.com/1471-2458/14/18

I opt'd to utilize the older studies because it's contrary to the "no long term research" rhetoric. There's plenty of new studies that confirm the findings from the earlier studies.

rich *says:*

APRIL 4, 2014 AT 11:59 AM

Yes!!! Thanks for posting!!!

Liza *says:*

APRIL 17, 2014 AT 9:21 AM

This is great news indeed, but I wonder why vaporers continue to call our vaporizers "cigarettes". We all know that cigarettes are bad for one's health.

matt black *says:*

APRIL 17, 2014 AT 3:11 PM

Seriously – that was the dumbest name we could have come up with for vapor products. I think the name is slowly being changed, but associating vapor products with cigarettes has not done us any favors.

EPA & FDA: Vapor Harmless to Children | Mr Vape *says:*

APRIL 3, 2014 AT 12:54 PM

[…] EPA & FDA: Vapor Harmless to Children. […]

Rory Gile *says:*

APRIL 3, 2014 AT 2:59 PM

Wow…what an idiot! He doesn't even mention the nicotine…

matt black *says:*

APRIL 3, 2014 AT 3:27 PM

You mean.. the nicotine that has only been found in absolute trace levels in exhaled vapor? Such low trace levels, in fact, that it pales in comparison to your exposure to nicotine from eggplants,

soybeans, and various other vegetables? That nicotine?

Yeah, I didn't mention it because it would be idiotic to do so since it's virtually not present in the exhaled vapor. But, if you insist that I mention it, here you go: http://www.biomedcentral.com/1471-2458/14/18

Side note – it might be wise not to call people idiots when you don't know what you're talking about. It kind of makes you look like, well, an idiot.

Joseph Filemu *says:*

APRIL 3, 2014 AT 4:34 PM

Matt, great work man. Research like this is what the vape community needs with our battle to get out a life saving product. I would say you take care of the research and let the little guys handle these small fry, but that reply leads me to believe you can hold your own lol.

matt black *says:*

APRIL 3, 2014 AT 5:48 PM

Lol.. thanks, man! Yeah, dealing trolls is another one of my specialties.

Greg *says:*

APRIL 7, 2014 AT 11:38 PM

Hi Matt,

Great article as well as your response to the person calling you an idiot. Hopefully he will think twice next time.

If you have it handy, it would be ideal to include all of the ingredients in one list, simply because I think it would be forwarded all over the place. Got the pg down and a link for the nicotine. Do you have vg? I know vg (vegetable glycerin) is very good for the human body.

We actually manufacture organic flavored liquids so if someone was vaping our Green Apple, they would be vaping Organic Green Apple (so fruit), food grade vegetable glycerin, distilled water with nicotine and pg optional. Now who in their right mind would still state that "we can not determine if electronic cigarettes are better or worse than traditional cigarettes". Man everytime I hear that argument I want to slap the

commentator!!

Thanks again!

matt black *says:*

APRIL 8, 2014 AT 10:56 AM

Let me see what I can come up with.

And yes, through this whole advocacy process, I've wanted to slap many, many people. I've also discovered just how damaging the media is to common sense.

Joseph Filemu *says:*

APRIL 3, 2014 AT 4:31 PM

Wow… what an idiot! You clearly have no research to site from and make and assumption regarding an irrelevant topic to the article. Great job! You my friend, win the Idiot award… Is what I want to say. But since I can't say it, go ahead and knock yourself out reading it. Thank you for playing the internet.

zooted *says:*

APRIL 3, 2014 AT 3:13 PM

"Robertson cites a study …" This links to some kind of index/excerpt of a foreword, not to what I'm assuming you wanted to link to.

matt black *says:*

APRIL 3, 2014 AT 3:28 PM

Crap. Thank you. I'll fix that.

Ray Yeates *says:*

APRIL 3, 2014 AT 3:15 PM

Thank you Matt. Superb research. I'm posting it everywhere I go . Keep up the great work.

matt black *says:*

APRIL 3, 2014 AT 3:28 PM

Thank you!

Kimberly Biggs *says:*

APRIL 3, 2014 AT 4:10 PM

Excellent work, very well done and streamlined! This relatively short, to the point, and informative piece of work is just what vapers like me need when the whole anti-freeze and “What’s in e-juice?” topics come up. Great job!!!

matt black *says:*

APRIL 3, 2014 AT 5:49 PM

Thank you! I came across the info last night while doing some research and was like, “why wasn’t I already aware of this?” So, I’m happy others will find it useful..

Matt Novak *says:*

APRIL 3, 2014 AT 6:38 PM

So, this all focuses on PG, and vaporized in a way different from how e-cigs convert the stuff (atomization vs. vaporization via heating).

Do we know if the fact that the vapor is produced via heat, and not by being forced through a very small opening at high pressure, changes anything? I would imagine, through my fairly rudimentary understanding of chemistry, that yes, it does.

And what about the flavoring chemicals? We all know about diacetyl, and other diketones, but what about the other ingredients, of which there are many? Yes, any reputable vendor/manufacturer will only put out eliquid flavored with ingredients at least GRAS/FDA approved, but those approvals tend to focus on the ingestion of the ingredients, NOT the heating and inhalation of them (as is the case with diacetly).

So, we know that PG vapor, when atomized via physical forces, is safe, and indeed beneficial, but what about when heated and inhaled? What about VG? And the flavors?

Don’t mean to try to rain on your parade/shit in your picnic, but these are things we need to know/that need to be addressed.

matt black *says:*

APRIL 4, 2014 AT 10:01 AM

If we look at Dr. Burstyn’s findings in his peer reviewed study, “Peering through the mist”, he makes 9,000 unique observations of every component of electronic cigarette vapor. His findings confirm the little to no toxicity of PG that these earlier studies discovered, even when atomized. (his study is here: http://www.biomedcentral.com/1471-2458/14/18). Here’s a quote from his conclusions:

“Exposure of bystanders to the listed ingredients, let alone the contaminants, does not warrant a concern as the exposure is likely to be orders of magnitude lower than exposure experienced by vapers.”

Which is similar to the conclusion in McAuley's study, published by the National Institute of Health:

"The study indicates no apparent risk to human health from e-cigarette emissions based on the compounds analyzed." – http://www.ncbi.nlm.nih.gov/pubmed/23033998

So the flavorings, nicotine, diacetyl, etc. are not really relevant to this article, because my focus was addressing the "unknown public health risk" argument that vaping advocates are running into when confronting public usage bans, and because these chemicals are only present at absolute trace levels, if at all, I chose to address the primary ingredient of concern with regards to public health via second hand exposure.

Dr. Burstyn's research addresses your concerns, and I highly recommend you check it out.. it's good information and sheds a lot of light on this subject.

Greg *says:*

APRIL 8, 2014 AT 12:05 AM

Well let me help you out with that. We have a master Professor of Toxicology and Pharmacology that has almost 70 years experience. He was a chief advisor for the FDA, WHO (World Health Organization) as well as a senior global authority in approving many medications on a global scale and defining precautions with outbreaks and pandemics meaning if he makes 1 phone call and says "close the airport", he is not questioned and the airport is closed. Huge, impressive and extensive curriculum. That being said, he has extensively researched ingredients in e-liquid and he approves most ingredients. He had an issue with "Linalool " which is typically found in Chinese made e-liquids and also in the artificial flavoring in some eliquids made in the USA. He stated that he would thoroughly approve an e-liquid 100% which does not contain Linalool. We took his advice and went as Organic as possible.

Now the professor went over the typical ingredients in e-liquid which are: Food grade vegetable glycerin, food grade propylene glycol, natural or artificial flavoring, nicotine (which is optional). Every single ingredient was thoroughly approved and safe for inhalation. The nicotine also did not have issue as far as an inhalation vs consumed application. Again he only had an issue with "Linalool" but it was not anything dangerous but something to steer away from if given the choice.
So where do you get so many ingredients? In the e-liquids we manufacture, we use 3 ingredients: VG, Organic flavoring, distilled water. That's 3 ingredients!! Again nicotine is optional so that could make it 4 ingredients.

matt black *says:*

APRIL 8, 2014 AT 10:53 AM

It would be AWESOME to get his message out to the masses. We need people like him to help dispel all of the misinformation and

media hype over this crap. It gets tiring and seems absolutely ridiculous that we're fighting with government over getting people to quit smoking.

Propylene glycol vapor is safe according to FDA & EPA | The Hanging Cloud *says:*

APRIL 3, 2014 AT 9:48 PM

[…] Click HERE for more […]

Rob *says:*

APRIL 3, 2014 AT 10:08 PM

I thought everyone knew about that. PG is used by hospitals, pumped into the air system, to enhance sterility. The anti-bacterial and humectant properties of PG are well established. Further, PG is an acceptable carrier used in breathing treatments and can be found in some inhaler preparations. All this can be found on nih.gov for more info.

matt black *says:*

APRIL 4, 2014 AT 9:42 AM

I knew about Dr. Robertson's research, I just had never heard of the FDA approval of it, nor the EPA's findings of its use in closed environments.

Dragonmum *says:*

APRIL 4, 2014 AT 7:20 AM

Great article. I am so sick of defending the e-cig that I am going on the attack. In four years of vaping I have not had an asthma attack nor have I needed the antibiotics and steroids that were a steady diet; much of this I attribute to the germicidal properties of PG, and other vapers have had the same experience. May I use some of your findings in my campaign?

matt black *says:*

APRIL 4, 2014 AT 9:40 AM

Absolutely. If you could link/credit this article in someway, it would be appreciated. But I definitely want people using this info to help the fight.

Marji *says:*

APRIL 4, 2014 AT 7:53 AM

Information well done! I am very new to e-cigarettes (Jan. 8, 2014), but since then I have not had a REAL cigarette since then. I have smoked since I was 17 and am now

68. I can tell you that one of my daughters was very concerned about a cough I had. Since the change the cough is now completely gone! I also don't 'stink' from the tar and can actually 'smoke' in my home (apartment) without concern of staining walls, furniture, etc.

Thank you Matt for the wonderful confirmation of benefits! This WILL be shared!

Mike R. *says:*

APRIL 4, 2014 AT 8:42 AM

Good read. Though I think it looses some credibility by citing a study that was done in the 1940's. Science and medicine have changed significantly since then. Lots of chemicals that were considered harmless then are not. While I don't believe propylene glycol is harmless, a better argument would include reference to a paper published within the last 10-15 years.

matt black *says:*

APRIL 4, 2014 AT 9:37 AM

So… if we cite new studies, we're blasted with the "no long term research" rhetoric. And if we cite older studies, we're hit with "its age loses credibility". We can't win! lol

Anyway, the EPA document, which is where the majority of the findings that I quoted came from, is from 2006. Additionally, there's Dr. Burstyn's peer reviewed study, "Peering through the mist" which was published in the BMC Public Health Journal in January of 2014. He made 9,000 unique observations and his findings just emphasize what these earlier studies show. It's also ecig centric, so it examines all components, not just PG.

Here's the link. http://www.biomedcentral.com/1471-2458/14/18

kanor *says:*

APRIL 4, 2014 AT 11:03 AM

GREAT ARTICLE!!! now i have a concrete reference for educating people about vaping. i am from the Philippines and i will share this with all the vapers i know!

Robbie *says:*

APRIL 4, 2014 AT 2:52 PM

It's not about safety. it is about money, but wisdom kills so many things.

Doug S *says:*

APRIL 4, 2014 AT 3:42 PM

Matt black. You crack me up. Spot on post, good banter. And a thank you for the time spent in letting us know. Ta

matt black *says:*
APRIL 4, 2014 AT 4:06 PM

lol.. thank you!

Doug S *says:*
APRIL 4, 2014 AT 3:46 PM

Why also is there so many negative idiots, who leave comments without obliviously reading the article…

Dave *says:*
APRIL 4, 2014 AT 5:06 PM

I have to disagree with you on one major point of this article:

“they’re simply basing their judgement off of rhetoric, misinformation, and personal bias”

Sadly, it’s pretty apparent that what they are basing their judgement off of is none of those things. It’s based off of money paid to lawmakers to make their judgement based on the special interests of tobacco and pharmaceutical companies.

Other than that, fantastic article, and thanks for posting it!

Tatiana Castro *says:*
APRIL 5, 2014 AT 12:27 AM

I understand that propylene glycol and dipropylene glycol are not toxic. My question is, related to the nicotine. Is there a study showing the effects of the combination of nicotine with propylene glycol and dipropylene glycol? Also, is nicotine also expelled in the air when vaping an e-cigarrette?

Thank you and God bless.

EPA & FDA: Vapor Harmless to Children | Tropa de Elite Paintball Team *says:*
APRIL 5, 2014 AT 5:45 AM

[…] EPA & FDA: Vapor Harmless to Children […]

EPA & FDA: Vapor Harmless to Children | Just a Vaper's Blog *says:*
APRIL 5, 2014 AT 5:49 AM

[…] EPA & FDA: Vapor Harmless to Children […]

Those Scary Anti-e-cig Articles Are Completely Bullshit | DJ Apoc *says:*
APRIL 5, 2014 AT 5:32 PM

[…] Actually, all that was complete bullshit as well. In fact, a recent study by both the EPA and the FDA proved that the vapor is 100% harmless, even to kids. […]

Vaping - Page 9 - VolNation *says:*

APRIL 6, 2014 AT 8:52 AM

[…] For those who point to propylene glycol as a "dangerous" ingredient: EPA & FDA: Vapor Harmless to Children | Minnesota Vapers AdvocacyMinnesota Vapers Advocacy […]

The Akston Report *says:*

APRIL 7, 2014 AT 10:22 AM

[…] EPA & FDA: Vapor Harmless to Children […]

James *says:*

APRIL 8, 2014 AT 5:40 PM

I am more curious about the effects of the different extracts and flavoring used in e liquid. Any insight?

matt black *says:*

APRIL 9, 2014 AT 3:25 PM

This is one area that I will admit needs more research. This is, honestly, where the FDA should be spending their resources.

There are a few flavor additives that we know not to use. One main one is Diacetyl, which is found in some buttery type flavorings. The well known flavor vendors are, however, aware of this and are no longer including Diacetyl in their flavor additives. And any flavors that do contain it are usually labeled.

Any risk from flavorings and extracts, however, would be limited to the user.

Your Vaping News & Deals For April 4! *says:*

APRIL 9, 2014 AT 6:57 AM

[…] A fascinating article about FDA & EPA research that provides proof that vapor is harmless. Thi… […]

HeavenlyVapours Court Loss Results In Total Ban of All E-Cig Model Sales In WA - Page 136 *says:*

APRIL 17, 2014 AT 3:08 AM

[…] EPA & FDA: Vapor Harmless to Children | Minnesota Vapers AdvocacyMinnesota Vapers Advocacy […]

Dian Burnett *says:*

APRIL 17, 2014 AT 4:53 AM

I would like for people to know that I smoked since I was 13..and I quit smoking 2 years ago and have been vaping since then..I was smoking 2-3 packs a day of full flavor cigarettes. As we all know cigarettes can cost 5-7 dollars a pack. And that is not the best thing yet. I have cut the amount of how much it cost to smoke from 10 dollars a day per month..adds up to 300 bucks a month to 30 dollars with e liquid. I LOVED my cigarettes! I have not had a sinle cigarette for 2 years. I no longer get short of breath, no do I smell like a cigarette, and all you non smoking people have no secong\d hand smoke..So What is the problem?

Phil Busardo *says:*

APRIL 17, 2014 AT 11:24 AM

Although I think this in an excellent article Matt and should be shared, I feel it leaves several items out. Nicotine, VG, and even the flavorings. Not to mention the high temps that “Cloud Chasers” like to fry their liquids at. I think we can all agree that testing needs to continue, and as our vaping habits and devices change, the testing should follow suite. And when I talk about testing, I’m talking about testing everything… liquids, vapor, build materials, builds, temperatures, etc. If there are problems, let’s identify them and fix them without freaking out. If there aren’t… knowledge is power! Nice work Matt!

matt black *says:*

APRIL 17, 2014 AT 3:09 PM

Hey Phil,

Thank you! And… I agree. Since we’re all vapers, I think we all have a desire to know and understand the facts of what it is that we’re inhaling. I think Igor Burstyn’s study does a good job at summarizing it for us, but continued research is important. I just wish this whole issue weren’t so polarized, because it makes it impossible to identify & publicize potential problems & concerns without worrying about the anti’s using it as ammunition in their crusade to ban vaping. It’s incredibly frustrating. Ugh.

APA & FDA deem vapor harmless to children and infants | Vapor Cafe Blog *says:*

APRIL 17, 2014 AT 1:18 PM

[…] mnvapers.com […]

EPA & FDA: Vapor Harmless to Children - Advanced Personal Vaporizer *says:*

APRIL 17, 2014 AT 2:28 PM

[…] 3, 2014 , 47 matt […]

Ed W *says:*

APRIL 17, 2014 AT 3:03 PM

First the title hereis beyond misleading since there is no mention of nicotine. We don't absorb all the nicotine into our bodies so trace amounts will be exhaled. Compared to other toxins in the air we breathe already the effects are likely non-existent but don't use a the poor title of this article to justify blowing clouds at your toddler. My other beef is the age of the studies quoted. If I go back far enough I can find studies that say heroin is a good way to relieve migraines or women can only get pregnant during a full moon. A lot has changed since the 40s and we need new, legit, unbiased studies done to backup our argument that vaping is safe. Please, dont use articles like this to counter the fear mongering the NY Times uses, it makes us all look like idiots.

matt black *says:*

APRIL 17, 2014 AT 3:34 PM

You'll notice that the bulk of the article is citing the 2006 EPA reregistration, which was re-registering vaporized PG. It was first registered and FDA approved for air sanitization in 1950 & 1959. So, this was the EPA saying that the original findings are still valid.

Please read before offering to opine.

Alan Fletcher *says:*

APRIL 17, 2014 AT 3:37 PM

I must admit I already knew that PG was approved by the FDA as a hospital air disinfectant. I read it somewhere not long ago. As it is still approved and used, it is of no concern that earlier studies may be deemed worthless. There was no need to cover nicotine as well as it is also used in pharma NRT and deemed harmless there as well. Thanks Matt anyway for re-reminding or reminding the vaping community about PG.

Nicotine & Tobacco Research
ntr.oxfordjournals.org

Nicotine Tob Res (2014) doi: 10.1093/ntr/ntu218
First published online: October 21, 2014

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ntr.oxfordjournals.org

Nicotine Tob Res (2014) doi: 10.1093/ntr/ntu218
First published online: October 21, 2014

Evaluation of Toxicant and Carcinogen Metabolites in the Urine of e-Cigarette Users Versus Cigarette Smokers

Stephen S. Hecht, Ph.D.*, Steven G. Carmella, B.S., Delshanee Kotandeniya, Ph.D., Makenzie E. Pillsbury, B.S., Menglan Chen, M.S., Benjamin W.S. Ransom, B.A., Rachel Isaksson Vogel, M.S., Elizabeth Thompson, B.S., Sharon E. Murphy, Ph.D. and Dorothy K. Hatsukami, Ph.D.

+ Author Affiliations

+ Author Affiliations

*Corresponding author: Stephen S. Hecht Contact email: hecht002@umn.edu Masonic Cancer Center, University of Minnesota, 2231 6th Street SE – 2-148 CCRB, Minneapolis, MN 55455, USA, phone: (612) 624-7604; fax: (612) 624-3869

Received August 28, 2014.

Abstract

Introduction

e-Cigarettes are rapidly increasing in popularity but little information is available on their potential toxic or carcinogenic effects.

Methods

Twenty-eight e-cigarette smokers who had not smoked tobacco cigarettes for at least 2 months provided urine samples which were analyzed by validated methods for a suite of toxicant and carcinogen metabolites including 1-hydroxypyrene (1-HOP), 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanol and its glucuronides (total NNAL), 3-hydroxypropylmercapturic acid (3-HPMA), 2-hydroxypropylmercapturic acid (2-HPMA), 3-hydroxy-1-methylpropylmercapturic acid (HMPMA), S-phenylmercapturic acid (SPMA), nicotine, and cotinine. Levels of these compounds were compared to those found in cigarette smokers from 3 previous studies.

Results

Levels of 1-HOP, total NNAL, 3-HPMA, 2-HPMA, HMPMA, and SPMA were significantly lower in the urine of e-cigarette users compared to cigarette smokers. Levels of nicotine and cotinine were significantly lower in e-cigarette users compared to cigarette smokers in one study but not in another.

Conclusions

With respect to the compounds analyzed here, e-cigarettes have a more favorable toxicity profile than tobacco cigarettes.

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BUSINESS INSIDER

Experts Say E-Cigarettes Could Save Tens Of Thousands Of Lives Every Year

REBECCA SMITH, THE TELEGRAPH
SEP. 5, 2014, 8:03 AM

REUTERS/Mario Anzuoni

Enthusiast Brandy Tseu uses an electronic cigarette at The Vapor Spot vapor bar in Los Angeles, California March 4, 2014.

Encouraging cigarette smokers to switch to electronic versions could be a public health 'revolution' and save tens of thousands of lives a year in Britain, a coalition of experts has said.

The World Health Organisation is wrong to call for restrictions on e-cigarettes and instead should be promoting them as a way to quit smoking, it was argued.

A group of leading experts in tobacco controlled have critiqued a report by the WHO on e-cigarettes and said it contained errors and misrepresentations of the evidence.

It has been calculated that for every one million smokers who switch from cigarettes to electronic ones, which deliver nicotine but do not contain tobacco, then 6,000 premature deaths would be prevented every year.

It could mean more than 50,000 lives a year could be saved in England if every smoker switched.

The experts from the department of Epidemiology and Public Health at University College London, the National Addiction Centre at King's College London and the Tobacco Dependence Research Unit at Queen Mary University of London, have published the rebuttal of the WHO report in the journal *Addiction.*

They said the WHO report says e-cigarette use in the young is a major problem and could act as a gateway to smoking cigarettes where as in fact less than one per cent of children who have never smoked have tried them.

The WHO also said e-cigarettes contain toxins, the health effects are unknown and they should be banned indoors, but the group said the amounts are tiny and similar to that breathed in when walking down a city street.

Finally they said the WHO assertion that e-cigarettes prevent people from giving up cigarettes is not true and that they are actually as helpful as buying nicotine replacement patches from the chemist.

Prof Peter Hajek, from Queen Mary University said: "These WHO recommendations are actually detrimental to public health.

"E-cigarettes could have a revolutionary effect on public health if smokers switch from cigarettes to e-cigarettes."

He said banning them would be akin to saying everyone should keep an open fire in every room of their own in winter because central heating systems may malfunction.

He added that e-cigarettes should be made cheaper than their alternative and they should be permitted in public places where cigarettes are not.

Prof Robert West from UCL said the WHO recommendations were 'puritanical' and 'ridiculous' and did not represent the current evidence on safety or use of e-cigarettes.

He said the evidence shows that smoking rates are continuing to drop as use of e-cigarettes grew, that use of e-cigarettes amongst those who have never smoked is less than 0.2 per cent and using an e-cigarette to help stop smoking is more effective than cold turkey or buying nicotine replacement therapy over the counter, although the NHS stop smoking services still offer the best hope of quitting.

He said: "This is about smokers who are killing themselves. Every day they carry on smoking they lose six hours of life expectancy.

"England has one of the most liberal regimes in terms of e-cigarettes use in the world so if there was going to be a problem it would be here.

"I completely understand concerns about potential risks from this phenomenon but it is vital that public health experts separate opinion from evidence."

Prof Ann NcNeill from King's College London said: "The fact that in England we are not looking to ban e-cigarettes in public places is right and in line with the evidence. But I think there are still concerns about the implications of the European Tobacco Directive.

"It will restrict marketing and the strength of the products which will take off the market some products that help smokers to quit."

She said due to demand from smokers some NHS stop smoking clinics were including e-cigarettes in their quit programmes.

farsalinos defuses "media frenzy" over formaldehyde

*28 Nov 2014 — By **Gary Cox (/author/4)***

Leading nicotine scientist Konstantinos Farsalinos reports a recent discussion with Japanese researcher Naoki Kunugita, who had claimed a wildly inflated level of “carcinogens” in a single Japanese e-cig product. In an effort to curtail the “media frenzy” such claims can set in motion, Farsalinos was able to clarify the issue, writing on the website e-cigarette research.

The flaws of the study making the claim were multiple – let’s begin with the nature of the carcinogen in question. Although it claimed to find 10 times the amount of “carcinogens” (plural), only one carcinogen was actually discussed, the notorious formaldehyde. This is a naturally occurring substance found universally in the environment. It is inevitably produced by a variety of natural processes, at levels easily tolerated by the body.

Formaldehyde is “present everywhere in the environment,” notes Farsalinos, “in every house, in every city, town, village, urban or rural area.” Its industrial uses include building materials. It is used in embalming fluid. It produces that funny smell in the bio lab whenever organs or animals are preserved. One wonders if biology teachers will soon be ordered to desist from exposing students to “carcinogens” by assigning them to dissect frogs.

Next flaw: the headline cherry-picked a single fluke finding of unknown cause instead of averaging the figures. Kunugita's initial study looked at 13 brands of e-cigarette, and the average formaldehyde concentration in all samples was 4.2 mg./10 puffs, more than 50 times lower than that produced by smoking a cigarette (200 mg./cigarette, according to a Canadian research team).

A follow-up study of a newer device found 1600 mg./15 puffs, 400 times higher than the average for all the other devices, and indeed nearly 10 times the amount in a cigarette's smoke. (It is unclear what produced this fluke finding – Farsalinos suggests inappropriately high power levels or a malfunctioning unit, or perhaps inordinately low levels of liquid.)

The journalists reporting on Kunugita's research, however, picked the wildly divergent finding for their headline.
Clearly this kind of reporting serves the interests of one faction in the debate over vaping. It does not serve the aim of saving lives by maximizing smoking cessation efforts by the most effective means available.

(http://store.vaping.com)

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please consult with your doctor before using any electronic cigarette products. Please note that nicotine is addictive and toxic by direct swallowing or in contact with the skin. Nicotine is known to cause birth defects and reproductive harm. Please keep it out of reach of children or pets.

House Leaders Rush to Defend E-Cigarettes From Possible FDA Bans

Republicans call for change to FDA rules proposal on e-cigarettes.

House Speaker John Boehner, pictured smoking outside the White House in 2011, is warning Health and Human Services Secretary Sylvia Burwell, right, that new rules could snuff out the electronic cigarette industry.

By Steven Nelson | Dec. 3, 2014 | 12:52 p.m. EST

Senate Democrats harried electronic cigarette companies throughout 2014, pushing hard for new rules and restrictions on the booming multibillion-dollar industry. Now, congressional Republicans - fresh off a November election landslide - are standing up for e-cigarettes and pushing back on pending regulations critics fear may allow administrative product bans.

House Speaker John Boehner, R-Ohio, House Majority Leader Kevin McCarthy, R-Calif., and House Energy and Commerce Committee Chairman Fred Upton, R-Mich., wrote to Health and Human Services Secretary Sylvia Burwell last week requesting a change to proposed Food and Drug Administration regulations that may be enacted soon.

The proposed rules, released in April by the FDA, an HHS division, would require e-cigarette manufacturers to win “premarket” approval for their products within two years or pull the items from the market.

The new tobacco product approval process would apply to e-cigarette products released after February 2007, the proposed rules say, meaning nearly all e-cigarettes currently on the market would undergo rigorous review.

[**FLASHBACK:** E-Cigarette Advocates Relieved but Cautious After FDA Pitches Rules]

“[M]ost e-vapor products did not exist at that time,” the House Republicans wrote to Burwell. “FDA did not even consider e-vapor products to be tobacco products until 2011.”

The leaders wrote that “[a]s a practical matter, many newly deemed products could be removed from the market” if the 2007 date is not changed.

The premarket approval process - pursuant to the Tobacco Control Act of 2009 - requires significant time and expense for companies, and a favorable FDA ruling is not guaranteed. Conventional cigarettes, generally accepted as more hazardous to users’ health than e-cigarettes, were grandfathered into the regulatory framework and did not undergo premarket vetting.

Boehner, a well-known user of conventional cigarettes, and his colleagues said the proposed rules put e-cigarettes and some cigars at a disadvantage against older nicotine offerings such as cigarettes and loose tobacco.

[**SURVEY:** E-Cigarette Users Would Ignore Bans, Turn to Black Market]

The House Republican leaders ask that existing e-cigarette products be allowed to remain on the market, with a grandfathering date of either when rules are formalized or the April 2014 date the rules were proposed.

"The secretary appreciates hearing from members of Congress," a Health and Human Services spokesperson tells U.S. News. "HHS looks forward to responding to the letter."

Gregory Conley, president of the American Vaping Association industry group, says many people don’t appreciate the stakes. He notes the Tobacco Control Act is sometimes called “the Marlboro Protection Act” because it grandfathered in existing tobacco products while making it nearly impossible for small firms to introduce new items.

Conley says e-cigarette manufacturers likely would need individual applications for each e-cigarette device and each e-liquid flavor option - a burden multiplied by different nicotine concentrations.

[**RELATED:** Senator Says Adults Prefer Tobacco Flavor E-Liquid, Demands More FDA Rules]

If the rules are adopted with the 2007 date, Conley expects the FDA to use its authority to arbitrarily ban flavor options and devices.

Companies seeking premarket approval for new tobacco products must submit an application including a list of ingredients, descriptions of manufacturing and product use, and proof the product marketing is “appropriate for the protection of the public health."

The FDA predicts e-cigarette companies will spend roughly 5,016 hours per application, with an estimated compliance cost of roughly $300,000 for each submission. Consumer and industry groups say this burden disadvantages small companies who offer a diverse range of devices and e-liquid in various flavors and nicotine concentrations and may force them out of the market, benefiting brands owned by Big Tobacco that offer non-refillable devices with traditional cigarette flavors.

Conley points out if the date is moved forward to coincide with implementation, all existing flavors would be allowed. If a company wanted to introduce a new flavor, he says, they would face a much lower standard for FDA approval, a less-strenuous substantial equivalency application, showing that similar flavors are already on the market.

[**REPORT:** E-Cigarettes as Likely as Nicotine Patches to Curb Smoking]

“If you don’t move up the grandfather date, then the FDA is never going to [give premarket approval] for a flavored e-cigarette product - that will be their backdoor prohibition on almost all flavors,” he says.

“Maybe they’ll approve a scotch or whiskey, but they won’t approve the flavors I like.”

Many e-cigarette users zealously defend their preferred candy- or fruit-flavored e-liquid against claims from politicians and health advocates that these options are intended to appeal to children.

A survey conducted earlier this year by the E-Cigarette Forum website found 79 percent of 10,000 respondents would "look to the black market" if products they use are banned. E-cigarette users can already blend their own flavors using commercially available food flavoring - a practice almost certain to expand in response to restrictions.

TAGS: smoking and tobacco, FDA, Boehner, John

+ More

Steven Nelson is a reporter at U.S. News & World Report. You can follow him on Twitter or reach him at snelson@usnews.com.

San Francisco has become an unlikely national model, a kind of “urban manufacturing lab.”

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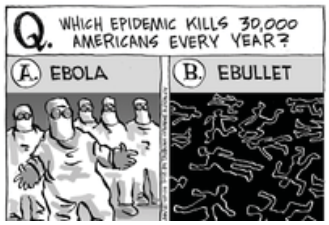

Gun Control Cartoons

Obama Cartoons

Maker of 'Camel' cigarettes bans smoking in workplaces, but will allow e-cigarettes

Camel cigarettes, a Reynolds brand, are shown here on Oct. 21, 2009. (The Associated Press / Matt Rourke)

Michael Felberbaum, The Associated Press
Published Wednesday, October 22, 2014 4:33PM EDT
Last Updated Wednesday, October 22, 2014 9:19PM EDT

RICHMOND, Va.-- Camel cigarette maker Reynolds American Inc. is snuffing out smoking in its offices and buildings.

The second-biggest tobacco company in the U.S. informed employees Wednesday that beginning next year, the use of traditional cigarettes, cigars or pipes will no longer be permitted at employee desks or offices, conference rooms, hallways and elevators. Lighting up already is prohibited on factory floors and in cafeterias and fitness centers.

The no-smoking policy will go into effect once Reynolds builds indoor smoking areas for those still wanting to light up indoors, spokesman David Howard said.

> "We believe it's the right thing to do and the right time to do it because updating our tobacco use policies will better accommodate both non-smokers and smokers who work in and visit our facilities," Howard said. "We're just better aligning our tobacco use policies with the realities of what you're seeing in society today."
>
> While Reynolds will no longer allow smoking, it will allow the use of smokeless tobacco products, including electronic cigarettes, moist snuff and pouches of finely milled tobacco called snus (pronounced "snoose").

The company also will allow the use of Eclipse, a cigarette made by Reynolds that uses a carbon tip that heats tobacco after being lit by a lighter. First released in the mid-1990s, Eclipse is in limited distribution and one of the top-selling brands in the cafeteria at the company's Winston-Salem, North Carolina, headquarters.

The percentage of Reynolds' 5,200 employees that smoke is in line with the smoking rate in the U.S. That is about 18 percent of adults, according to the federal Centers of Disease Control and Prevention.

Through its subsidiaries, Reynolds American also makes Pall Mall cigarettes, Grizzly smokeless tobacco and Vuse-branded electronic cigarettes.

Altria Group Inc., the Richmond, Virginia-based owner of the nation's biggest cigarette maker, Philip Morris USA, doesn't allow smoking on factory floors and in places like elevators or hallways, said spokesman David Sylvia. Employees with separate offices can smoke in them, but otherwise the company has designated smoking areas in office buildings, conference areas and cafeterias, he said.



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Created on Wednesday, 08 October 2014 03:23

Nicotine absorbed from "passive vaping" is minimal and with no health implications

By Dr Farsalinos

A new study evaluating passive vaping has recently been published in the journal Environmental Research. The study evaluated nicotine levels in the house of vapers and smokers (compared to non-smokers), and measured salivary and urinary cotinine levels in non-smokers who were exposed to tobacco and electronic cigarette use at their homes. The main finding of the study was that "passive vaping" results in nicotine absorption from non-smokers non-vapers, at similar levels as those exposed to smoke from tobacco cigarettes. Those exposed to more than 7 tobacco cigarettes per day had higher cotinine levels (thus, more nicotine was absorbed through passive exposure).

First of all, there is no surprise that nicotine is released to the environment. Since there is a lot of vapor exhaled, and considering that nicotine absorption is lower compared to smoking, nicotine is probably exhaled by the user (I say probably, because we need more evidence to be certain about that). However, we should assess the health implications of exposure to nicotine at such levels.

Does it mean that passive vaping may lead to nicotine dependence?

Does it mean that nicotine is absorbed to such levels that it may cause harm to bystanders?

The answer to both questions is **NO**. Passive exposure to electronic cigarette resulted in median salivary cotinine levels of 0.24ng/ml, while in the control group (no exposure to tobacco or electronic cigarette) it was 0.05ng/ml. In smokers, levels of salivary cotinine exceed 300ng/ml, especially in smokers of >20 cigarettes per day. Therefore, the level of cotinine in "passive vapers" is approximately 1200 times lower than active smokers. The same research group measured cotinine levels in smokers few years ago, finding 146ng/ml in smokers of 15 cigarettes per day. This is 610 times higher than the levels in "passive vapers". Since cotinine is directly associated with the total amount of daily nicotine intake, and assuming that smokers of 15 cigarettes per day get 15mg of nicotine and show 146ng/ml cotinine levels, we can calculate that passive vaping leads to daily nicotine intake of 0.025mg. Such a levels is not only harmless but has absolutely no biological effect, even according to the strictest regulatory definitions.

The European Food Safety Authority (EFSA) has defined the Lowest Observed Adverse Effect Level (LOAEL) of nicotine. This limit has a TOXICOLOGICAL ENDPOINT OF HEART RATE ACCELERATION, which is wrong because heart rate acceleration does not imply any long-term adverse effect. According to the definition, NOAEL (which is a much lower level compared to LOAEL) is defined as: "***"An exposure level at which there are no statistically or biologically significant increases in the frequency or severity of adverse effects between the exposed population and its appropriate control. Some effects may be produced at this level, but they are not considered as adverse, nor precursors to adverse effects"***. Thus, the definition by EFSA it is not in reality a LOAEL (or even a NOAEL), but much lower than that. The level set by EFSA was 0.008mg/kg body

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weight for ingestion, derived from calculations of intravenous nicotine injections, which found that administering 0.0035mg/kg body weight produced an acute acceleration in heart rate. For an average 75kg human, that is 0.26mg (10 times higher than the calculated 0.025mg/day intake from passive e-cigarette exposure).

In conclusion, the levels of nicotine absorbed from “passive vaping” are not only harmless but do not even produce any biological effect (not even heart rate acceleration). Considering the possibility that allowing e-cigarette use in public places may motivate smokers to switch to e-cigarette use, there is no scientific basis for any bans on e-cigarette use in public places.

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WorldTop Ecigs

no gateway, says statistics group

25 Nov 2014 — By ***Gary Cox (/author/4)***

Britain's Office for National Statistics has published figures (http://www.bbc.co.uk/news/health-30192181) suggesting that "gateway" fears – the idea that vaping could lead to smoking – are unwarranted. According to ONS statistics, vapers are almost exclusively smokers and ex-smokers, using e-cigs or more recent vaping products as a smoking cessation tool.

Says Dr. Penny Woods, Chief Executive of the British Lung Foundation, "These data should again alleviate the fears expressed by some over an e-cigarette gateway effect - people trying e-cigarettes before moving on to the much more harmful practice of smoking."

Fewer than 1 in 300 electronic cigarette users has never smoked, according to the newly published ONS data. Of the 17.14% of Brits who use e-cigs, 12% are smokers trying to quit, 5% are ex-smokers who have apparently succeeded, and 0.14% are "never smokers" who seem to just think vaping is cool.

Professor Kevin Fenton is the National Director of Health and Wellbeing at Public Health England, and Professor Fenton stresses the need for sensible regulation, to assure standards: "Balanced and effective regulation of e-cigarettes will help manage the risks and maximise the potential for these products to replace smoking."

The ONS also reports that smoking in Britain fell to 19% in 2013, the lowest figure ever. In 1946 it was 46%. Not coincidentally, it would seem, the recent period of the most dramatic drop in cigarette consumption coincides with the rising popularity of electronic cigarettes.

In its article on the subject, the BBC notes that the MHRA (Medicines and Healthcare Products Regulatory Agency) plans to regulate e-cigs as medicines beginning in 2016, with additional strictures to be placed by the European Union's Tobacco Products Directive (TPD) – unless vaping supplies company Totally Wicked succeeds in its legal challenge of that misguided document in the EU courts.

The BBC article calls e-cigs, in effect, a smoking cessation product when it states: "At present they are not available on the NHS, unlike other smoking cessation aids such as nicotine patches."

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please consult with your doctor before using any electronic cigarette products. Please note that nicotine is addictive and toxic by direct swallowing or in contact with the skin. Nicotine is known to cause birth defects and reproductive harm. Please keep it out of reach of children or pets.

Study finds e-cigarettes help people quit smoking

THURSDAY , NOVEMBER 20, 2014 - 12:08 PM

Christopher Ingraham

The Washington Post

WASHINGTON — Vaping is having a moment. The Oxford Dictionaries recently named the term, which means “to inhale and exhale the vapor produced by an electronic cigarette or similar device,” its Word of the Year for 2014. Estimates put the size of the e-cigarette market at around $2.5 billion in annual sales.

Users tout them as tar-free alternatives to traditional cigarettes that help them reduce their nicotine consumption. Others are worried about all the unknowns associated with huffing propylene glycol and concentrated nicotine.

A new study adds to a growing body of research showing that e-cigs do, in fact, help people cut back on their tobacco consumption. Over an eight-month period, Belgian researchers tracked 48 smokers who were unwilling to quit smoking. The smokers were divided in to three groups: two who were given e-cigarettes over the entirety of the period, and a third that switched from tobacco to e-cigarettes two months into the study period.

“At the end of the eight-month study, 21 percent of all participants had stopped smoking tobacco entirely, whereas an additional 23 percent reported cutting the number of tobacco cigarettes they smoked per day by half,” the authors conclude. Across all three groups, total tobacco consumption fell by 60 percent.

Nicotine from e-cigs offers many smokers a successful alternative for smoking less — or even quitting altogether, said authors Frank Baeyens and Dinska Van Gucht. “E-cig users get the experience of smoking a cigarette and inhale nicotine vapor, but do not suffer the damaging effects of a tobacco cigarette.” Altogether, 44 percent of study participants had reduced their tobacco consumption or eliminated it completely at the end of the eight months.

E-cigarettes are currently unregulated in the United States, although the FDA is currently working on it. In the meantime, government agencies have adopted an alarmist stance toward the use of e-cigarettes, based in part on claims that are demonstrably false.

The National Institutes on Drug Abuse says that “studies of the effectiveness of e-cigarettes have not shown they help with smoking cessation” -- even though numerous studies, including this one, directly contradict that statement. Similarly, the department of Health and Human Services says that “there haven’t been any scientific studies that prove e-cigs actually help people to quit smoking.”

This caution is understandable — one main source of concern is that while e-cigs may help some people quit, they may also encourage more people to take up nicotine overall. Teen use of e-cigs is another area of concern.

But even these agencies recognize that e-cigarette vapor contains far fewer toxins and dangerous contaminants than traditional tobacco smoke. From a public health standpoint, if we’re interested in promoting smoking cessation it would seem sensible to encourage studies like this one, which point to new avenues for reducing the harms of smoking and helping people quit altogether.

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OPINION

Public Health Officials Should Embrace E-Cigarettes

11:25 AM 08/20/2014

1671

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GREGORY CONLEY

It's time for public health officials to advise smokers that electronic cigarettes are a worthy alternative to smoking that can help them quit the tobacco habit.

Most e-cigarettes look like cigarettes. But people who "vape" – use e-cigarettes – are not smoking. They are instead inhaling a water-like vapor that is free of the tar and the sky high levels of carcinogens that make cigarette smoking so dangerous.

President, American Vaping Association

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Activists who have spent years seeking to extinguish smoking have allowed their hatred of tobacco to cloud their view of vaping. It's hard for them to imagine that e-cigarettes are not only smokeless, but actually are a proven way of helping people to quit smoking.

This confusion has been going on for a long time. Over five years ago, groups that have long campaigned against smoking like the Campaign for Tobacco Free Kids and American Cancer Association pressured the U.S. Food and Drug Administration to remove all e-cigarette products from the marketplace. Their campaign failed, but their anti-vaping rhetoric has only increased since then.

These groups, along with many supposed experts in the field, have been misled into thinking that the emergence of e-cigarettes is a threat to public health. In fact, it is a boon and opposition to e-cigarettes is self-defeating for public health advocates. The vast majority of the 40 million American adult who smoke cigarettes want to quit, but only 3 percent of them kick the habit each year.

Rather than being a part of the problem, e-cigarettes are a significant part of the solution. Studies have consistently shown that smokers who switch to e-cigarettes greatly reduce their health risks. Independent research has demonstrated that while e-cigarette vapor may look like smoke, it shares virtually none of the chemical characteristics.

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Indeed, while cigarette smoke contains more than 4,000 chemicals and 70 known carcinogens, e-cigarette vapor is far more comparable to the FDA-approved Nicotrol Nicotine Inhaler, which contains only trace levels of toxicants and chemicals.

Tobacco stock analysts have said the growth in vapor products accounts for the faster-than-expected decline in cigarette sales. International surveys have shown that smokers are not only using e-cigarettes to quit, but are finding more success with e-cigarettes than they are with traditional products, such as gum or patches. A recent study in the United Kingdom sponsored by Action on Smoking and Health, the country's largest anti-smoking charity, found that 700,000 ex-smokers used e-cigarettes.

Worth noting: The main reason the U.K. ex-smokers gave for using e-cigarettes was to quit or to avoid tobacco products.

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Report: Laundry 'pods' sent 1 child a day to hospitals

Kim Painter, Special for USA TODAY 12:07 a.m. EST November 10, 2014

(Photo: Center for Injury Research and Policy)

A laundry product designed for convenience has quickly turned into a serious and common hazard for small children, says a report on the dangers of liquid laundry detergent packets.

The single-use packets — often called "pods" after the popular Tide Pods brand — sent an average of one child a day to hospitals in 2012 and 2013, the first two years they were widely available in the United States, says the report out Monday in *Pediatrics*.

During those two years, poison control centers took more than 17,000 calls, roughly one an hour, about children under 6 exposed to the concentrated detergents in the packets, researchers say.

Numbers for 2014 are not yet available, but the danger persists, says lead researcher Gary Smith, director of the Center for Injury Research and Policy at Nationwide Children's Hospital in Columbus, Ohio.

Children ages 1 and 2 — old enough to be mobile but too young to recognize danger — are most at risk, he says. "These products are colorful. They can look like candy or juice to a young child."

In typical cases, children bite or poke though the thin, dissolvable packet membrane and "get this concentrated squirt of detergent down their throats" or in their eyes, he says.

The children tend to get much sicker than those exposed to traditional laundry detergent, though it is not clear why, Smith says. Vomiting and coughing are common; in rarer cases, comas, seizures and breathing problems occur. The researchers found one confirmed death and more than 100 cases in which children had to be put on breathing machines.

Since initial reports surfaced, manufacturers have added prominent warning labels and made packaging harder to open and potentially less attractive to children. For example, Procter & Gamble now puts Tide Pods in opaque tubs and bags.

Smith and colleagues found that calls to poison centers about the products started to decline in late 2013. Packaging changes and education efforts by manufacturers, pediatricians and others may have contributed, they say. But Smith says that for unknown reasons, poison centers typically get fewer calls in the later months of the year, so data from 2014 will be needed to see if there is a sustained decline.

In any case, the report says, "It is not clear that the pod containers of any brand currently on the market are truly child-resistant." The researchers call for new voluntary packaging standards. An effort to develop such standards is underway and manufacturers are involved in the process, according to a statement from the American Cleaning Institute.

The institute, which represents companies that make cleaning products, says it is important to remind parents and other caregivers to keep laundry packets and all other household cleaners away from children.

Smith goes further and advises parents of children younger than 4 to use only traditional laundry detergent. Those who use the packets should store them out of sight, out of reach and, ideally, under lock and key, he says.

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By: Rusty Weiss
9/29/2014 10:19 AM

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This article originally appeared on heartland.org.

Despite various legislative efforts to curb smoking — ranging from higher sin taxes on tobacco to public-relations campaigns intended to discourage the use of e-cigarettes — smoking rates have consistently risen in New York City.

Tobacco use in the city's population has steadily crept upward in the city for three straight years, increasing from 14 percent in 2010 to 16.1 percent in 2013. City officials are quick to cite a decrease in funding for anti-smoking programs as a root cause, but public policy researchers disagree with bureaucrats' diagnosis.

Drunken Sailors

The lack of correlation between spending on anti-tobacco programs and results is not due to a lack of effort, according to National Center for Public Policy Research Senior Fellow Jeff Stier.

Some of the government programs cited as part of the city's all-out efforts to discourage tobacco use include significant restrictions on the placement of tobacco displays, free nicotine gum and patch giveaways, and some of the highest sin-tax rates in the nation.

"New York City spends like a drunken sailor on anti-smoking ads," Stier quipped.

Although officials claim that rising tobacco-use rates are caused by insufficient government spending, an analysis of available spending data does not support this hypothesis.

For example, New York state government significantly decreased its spending on tobacco control programs significantly in 2009, yet tobacco usage rates in New York City promptly fell to record lows.

Using the Available Tools

In addition to the lack of correlation between government spending on anti-tobacco programs and actual results, such public health campaigns fail to effectively use intermediate products, such as e-cigarettes, to achieve the results intended by the programs.

Often used by smokers as a "stepping stool" to wean one's self off of tobacco dependency,

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former city Mayor Michael Bloomberg sought to ban the use of electronic cigarette devices in public places. As one of his final official acts as the city's mayor, Bloomberg signed into law an amendment to the Smoke-Free Air Act of 2002banning "e-cigs" from public use.

Stier explains that the e-cig ban is actually hindering the efforts of people trying to quit — an example of a government program's actions actually hindering fulfillment of stated intentions.

"Instead of supporting their use to help people quit smoking, the New York City public health establishment spends resources demonizing e-cigarettes and making them less appealing," he explained.

Piling upon Bloomberg's efforts to ban e-cigarettes in the Big Apple, the Federal Drug and Food Administrationis also proposing new nationwide rules regarding e-cigarettes, allowing them to further control and regulate usage of such products.

Faulty Premises

California Polytechnic State University Distinguished Scholar and Professor of Economics Michael Marlow's study of the issue also lends evidence that governments' regulation of e-cigarettes is based on faulty public policy.

Marlow's study indicates that, if government agencies became more willing to embrace the new products as a tool to advance stated public-health goals, tobacco cessation efforts would become more effective, with "between 2.4 and 6.4 million smokers" successfully ending the habit.

Marlow also analyzed the benefits of e-cigarettes from an economic standpoint, relating such smoking cessation results to a cost benefit ranging between $15.6 and $49.2 billion per year.

Ultimately, Stier says that evidence suggests that the policy conclusion is obvious: city officials, public health advocates, and politicians should choose to recognize that taxing and regulating cigarettes, while banning viable alternatives like the e-cigarette, is not an effective option.

"Public health officials should learn a lesson," Stier concludes. "Put your hands back in your pockets, stop asking for more money and more tax increases for your ineffective policies, and instead show some humility, given the new findings."

Rusty Weiss (weiss.rusty@gmail.com) writes from Troy, New York.

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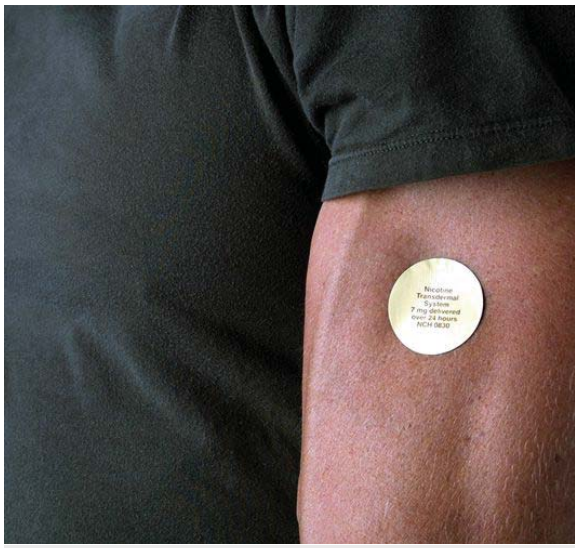
Study finds nicotine safe, helps in Alzheimer's, Parkinson's

By Tom Valeo, Times Correspondent

Wednesday, April 16, 2014 3:37pm



Los Angeles Times

Nicotine, by itself a nonaddictive drug, shows promise in a study.

Smoking, of course, damages the lungs and blood vessels, and contributes to an array of health problems, but nicotine — the calming chemical that cigarettes deliver — might actually be good for the aging brain.

Smokers, for example, are less likely to develop Alzheimer's disease — a phenomenon that has long puzzled scientists because smoking contributes to cardiovascular disease, which strongly increases the risk of Alzheimer's.

But closer investigation revealed that smoking doesn't confer the protection; nicotine does.

A study of Alzheimer's patients showed that those who wore nicotine patches were better able to remember and pay attention than those who didn't. Another study showed that nicotine boosted cognitive function in older people who didn't have Alzheimer's, but were showing signs of age-related mental decline.

Nicotine also seems to protect against Parkinson's disease, in which the death of cells in a small area of the brain results in tremors, impairing movement and as well as cognitive difficulties.

So what's going on? How does the dreaded addictive component of cigarettes produce health benefits?

For starters, nicotine by itself isn't very addictive at all, according to Dr. Paul Newhouse, the director of Vanderbilt University's Center for Cognitive Medicine. Nicotine seems to require assistance from other substances found in tobacco to get people hooked.

"People won't smoke without nicotine in cigarettes, but they won't take nicotine by itself," said Newhouse, who has done extensive research into beneficial effects of nicotine on the brain. "Nicotine is not reinforcing enough. That's why FDA agreed nicotine could be sold over the counter. No one wants to take it because it's not pleasant enough by itself. And it's hard to get animals to self-administer nicotine the way they will with cocaine."

Nicotine is chemically similar to acetylcholine, a neurotransmitter in the brain that declines in Alzheimer's disease. Drugs such as Aricept help people with Alzheimer's by boosting brain levels of acetylcholine. Apparently, nicotine binds to the receptors in the brain normally occupied by acetylcholine, which benefits people who need more, but it has no apparent effect on those who don't.

"Nicotine doesn't appear to enhance normal people," Newhouse said, "but in people who show some degree of cognitive impairment, nicotine appears to produce a modest but measurable effect on cognitive function, particularly in areas of attention and, to some extent, memory."

Newhouse and his colleagues are testing nicotine to see if it improves other cognitive problems like the mental fogginess known as "chemo brain" that afflicts cancer patients undergoing chemotherapy. They've also started a study of adults with Down syndrome, who almost always develop Alzheimer's disease by the time they reach middle age. Even people with HIV, which appears to cause accelerated cognitive decline, may benefit.

What makes nicotine especially attractive as a treatment is the fact it causes virtually no side effects, according to Newhouse.

"It seems very safe even in nonsmokers," he said. "In our studies we find it actually reduces blood pressure chronically. And there were no addiction or withdrawal problems, and nobody started smoking cigarettes. The risk of addiction to nicotine alone is virtually nil."

Tom Valeo writes on health matters. He can be reached at tom.valeo@gmail.com.

Study finds nicotine safe, helps in Alzheimer's, Parkinson's 04/16/14
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Commentary

Dec. 05, 2014 | 12:12 AM

The beef against electronic cigarettes is based on false evidence

Summary

Michael Russell and Murray Jarvik, two pioneers of smoking-cessation research in the 1970s, would probably have welcomed the development of the electronic cigarette or "personal nicotine vaporizer".

So far, none of this has

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Jacques Le Houezec | The Daily Star

Michael Russell and Murray Jarvik, two pioneers of smoking-cessation research in the 1970s, would probably have welcomed the development of the electronic cigarette or "personal nicotine vaporizer." Beyond serving as a temporary aid for people attempting to qm rightuit smoking cigarettes, such new nicotine-delivery systems could act as long-term alternatives to tobacco – making it possible to eliminate tobacco consumption almost entirely.

We have long known that people smoke for the nicotine, but die from the smoke. Indeed, the vast majority of cigarette-related diseases and deaths arise from the inhalation of tar particles and toxic gases, including carbon monoxide. Though nicotine replacement therapy has helped smokers quit, the cigarette habit remains pervasive in many countries.

The use of nicotine in noncombustible forms such as smokeless tobacco or personal nicotine vaporizers, would enable millions of current smokers to reduce considerably the harm that their nicotine consumption is doing to their health. In Sweden, the widespread use of snus – a smokeless tobacco product with a lower concentration of carcinogenic nitrosamines – has contributed to a dramatic decline in the incidence of lung cancer, to the world's lowest levels.

The benefits of phasing out tobacco consumption could not be more compelling. That is why personal nicotine vaporizers should be actively promoted as an alternative to tobacco products, aided by endorsements from health authorities, tax advantages and support from the anti-smoking movement.

But so far, none of this has occurred, largely because nicotine is viewed as a highly addictive and toxic substance, with even smokers hesitating to try nicotine replacement therapy or the personal nicotine vaporizer for this reason. In fact, nicotine has been the

LIVE NEWS VIEW ALL

primary target of anti-tobacco campaigns for more than three decades.

But nicotine is only partly responsible for tobacco dependence. Other substances from tobacco smoke – such as monoamine oxidase inhibitors, which have antidepressant effects – reinforce tobacco dependence, but are absent from vaporized nicotine. That may be why personal nicotine vaporizer user surveys suggest that nicotine is less addictive in its vaporized form.

In reality, nicotine is a relatively safe drug at dosages that a smoker or "vaper" inhales, with similar effects to caffeine. Moreover, smokers and personal nicotine vaporizer users control very precisely, on a puff-by-puff basis, the dose of nicotine they consume, virtually eliminating the risk of overdose.

In fact, a lethal dose of nicotine is a lot higher than the 30-60 milligrams that many scientific papers claim. After reviewing case reports of nicotine intoxications and suicide attempts, the pharmacologist Bernd Mayer found that the lethal dose of nicotine in humans must be somewhere between 500-1,000 mg of absorbed – not just ingested – nicotine. Given that one of the first symptoms of intoxication is vomiting, and that 70 percent of the remaining nicotine in the digestive tract is metabolized by the liver before it reaches other organs, absorbing that much nicotine is not easy.

With minimal health risks compared to tobacco smoking, personal nicotine vaporizers face only one real barrier to use: the willingness of smokers to switch. But, even on this front, the devices have had considerable success, with personal nicotine vaporizer use increasing exponentially in the last few years.

Though, in an ideal world, people would simply be able to quit using nicotine altogether, experience suggests that many smokers cannot – or do not want to – give it up, and will continue to smoke if there is no safe and acceptable alternative. If smokers are willing to accept personal nicotine vaporizers as a viable option, high-risk tobacco use could become a thing of the past.

So far, converted smokers have taken the lead in promoting the shift to personal nicotine vaporizers, sharing their experiences online, in Internet forums and on Facebook and Twitter. They are spreading the news that, for the first time in history, people can quit smoking without giving up the pleasure they derive from nicotine.

Meanwhile, health authorities and governments have adopted a fear-based approach, scrambling to regulate – or even ban – personal nicotine vaporizers. The European Union's Tobacco Products Directive and the United Kingdom's Medicines and Healthcare Products Regulatory Agency plan to introduce strict regulations of personal nicotine vaporizer sales and use, based on drug legislation, even though the devices are neither tobacco nor medical products. Even the World Health Organization has released a report expressing serious concern about the marketing and use of electronic nicotine-delivery systems.

Such opposition is not based on scientific evidence. Indeed, an increasing number of scientific publications show that personal

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nicotine vaporizer use is much safer than smoking tobacco.

In January, a group of scientists (including me) sent a letter to the European Commission imploring it to implement evidence-based, proportionate regulation that allows users of personal nicotine vaporizers to identify the product and dosage that suits them. "If wisely regulated, electronic cigarettes have the potential to make cigarettes obsolete and save millions of lives worldwide," we wrote. Excessive regulation, by contrast, "will contribute to maintaining the existing levels of smoking-related disease, death and health care costs."

Michael Russell once declared, "It is nicotine that people cannot easily do without, not tobacco." He was right. And it is tobacco smoke, not nicotine, that kills. That makes personal nicotine vaporizers the ideal solution. It is time for health authorities to get on board.

Jacques Le Houezec is a consultant in public health and tobacco dependence and honorary lecturer at the United Kingdom Center for Tobacco Control Studies at the University of Nottingham. THE DAILY STAR publishes this

commentary in collaboration with Project Syndicate © (www.project-syndicate.org).

A version of this article appeared in the print edition of The Daily Star on December 05, 2014, on page 7.

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The Oxford Dictionaries Word of the Year is… vape

As 2014 draws to a close, it's time to look back and see which words have been significant (http://www.oxforddictionaries.com/definition/english/significant) throughout the past twelve months, and to announce the Oxford Dictionaries Word of the Year (http://blog.oxforddictionaries.com/word-of-the-year-faq/). Without further ado, we can exclusively reveal that the Oxford Dictionaries Word of the Year 2014 is….

vape (http://www.oxforddictionaries.com/definition/english/vape)

Although there is a shortlist of strong contenders, as you'll see below, it was *vape* (http://www.oxforddictionaries.com/definition/english/vape) that emerged victorious as Word of the Year.

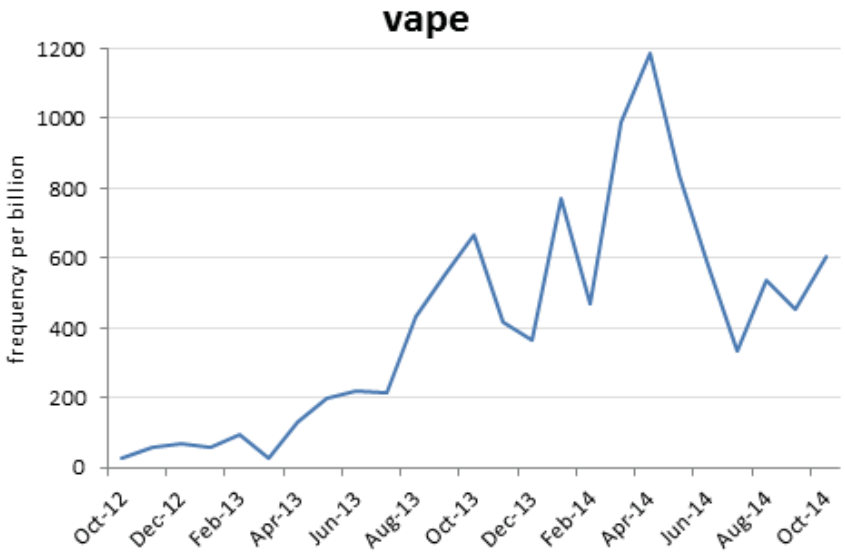
What does vape mean?

So, what does *vape* (http://www.oxforddictionaries.com/definition/english/vape)mean? It originated as an abbreviation of *vapour* (http://www.oxforddictionaries.com/definition/english/vapour)or *vaporize* (http://www.oxforddictionaries.com/definition/english/vaporize). The OxfordDictionaries.com (http://www.oxforddictionaries.com/) definition was added in August 2014 (http://blog.oxforddictionaries.com/2014/08/oxford-dictionaries-update-august-2014/): the verb means 'to inhale and exhale (http://www.oxforddictionaries.com/definition/english/exhale) the vapour produced by an electronic cigarette (http://www.oxforddictionaries.com/definition/english/electronic-cigarette) or similar device', while both the device and the action can also be known as *a vape*. The associated noun *vaping* (http://www.oxforddictionaries.com/definition/english/vape#vape__3) is also listed.

Why was vape chosen?

As e-cigarettes (http://www.oxforddictionaries.com/definition/english/e-cigarette) (or *e-cigs*) have become much more common, so *vape* (http://www.oxforddictionaries.com/definition/english/vape) has grown significantly in popularity. You are thirty times more likely to come across the word *vape* (http://www.oxforddictionaries.com/definition/english/vape) than you were two years ago, and usage has more than doubled in the past year.

Usage of *vape* (http://www.oxforddictionaries.com/definition/english/vape) peaked in April 2014 – as the graph below indicates – around the time that the UK's first 'vape café' (The Vape Lab in Shoreditch, London) opened its doors, and protests were held in response to New York City banning indoor vaping. In the same month, the issue of vaping was debated by The Washington Post (http://www.washingtonpost.com/local/dont-let-big-tobacco-hook-a-new-generation-on-nicotine-with-alluring-ads-for-e-cigarettes/2014/04/16/1acd08b2-c5a3-11e3-bf7a-be01a9b69cf1_story.html), the BBC (http://www.bbc.co.uk/news/blogs-echochambers-27082910), and the British newspaper The Telegraph (http://www.telegraph.co.uk/health/10747395/The-Great-British-Vape-off-debate.html), amongst others.



The language of vaping

Vape (http://www.oxforddictionaries.com/definition/english/vape) is also the modifier for other nouns, creating new compound nouns (http://www.oxforddictionaries.com/definition/english/compound#compound__9) which are growing in popularity. The most common of these are *vape pen* and *vape shop*, and there is also recent evidence for *vape lounge*, *vape fluid*, *vape juice*, and others. Related coinages (http://www.oxforddictionaries.com/definition/english/coinage#coinage__9) include *e-juice*, *carto*, and *vaporium* – as well as the retronym (http://www.oxforddictionaries.com/definition/english/retronym) *tobacco cigarette* for traditional cigarettes. (A *retronym* is a new term created from an existing word in order to distinguish (http://www.oxforddictionaries.com/definition/english/distinguish) the original word from a later development – for example, *acoustic guitar* (http://www.oxforddictionaries.com/definition/english/acoustic-guitar) developing after the advent of the electric guitar.)

Vape before vaping

You may be surprised to learn that the word *vaping* (http://www.oxforddictionaries.com/definition/english/vape#vape__3) existed before the phenomenon. Although e-cigarettes (http://www.oxforddictionaries.com/definition/english/e-cigarette) weren't commercially available until the 21st century, a 1983 article in *New Society* entitled 'Why do People Smoke?' contains the first known usage of the term. The author, Rob Stepney, described what was then a hypothetical (http://www.oxforddictionaries.com/definition/english/hypothetical) device:

> "an inhaler or 'non-combustible' cigarette, looking much like the real thing, but…delivering a metered dose of nicotine vapour. (The new habit, if it catches on, would be known as vaping.)"

However, despite these early beginnings, Oxford Dictionaries research shows that it wasn't until 2009 that this sense of *vape* (http://www.oxforddictionaries.com/definition/english/vape) (and *vaping*) started to appear regularly in mainstream (http://www.oxforddictionaries.com/definition/english/mainstream) sources.

The shortlist

Here are the words that came close, but didn't quite make it as Word of the Year:

bae ***n.*** *used as a term of endearment for one's romantic partner.*

budtender ***n.*** *a person whose job is to serve customers in a cannabis (http://www.oxforddictionaries.com/definition/english/cannabis) dispensary or shop.*

contactless (http://www.oxforddictionaries.com/definition/english/contactless) ***adj.*** *relating to or involving technologies that allow a smart card, mobile phone, etc. to contact wirelessly (http://www.oxforddictionaries.com/definition/english/wireless#wireless__13) to an electronic reader, typically in order to make a payment.*

indyref, ***n.*** *an abbreviation (http://www.oxforddictionaries.com/definition/english/abbreviation) of 'independence referendum', in reference to the referendum on Scottish independence, held in Scotland on 18 September 2014, in which voters were asked to answer yes or no to the question 'Should Scotland be an independent country?'*

normcore ***n.*** *a trend in which ordinary, unfashionable clothing is worn as a deliberate (http://www.oxforddictionaries.com/definition/english/deliberate) fashion statement.*

slacktivism (http://www.oxforddictionaries.com/definition/english/slacktivism), n., ***informal*** *actions performed via the Internet in support of a political or social cause but regarded as requiring little time or involvement, e.g. signing an online petition or joining a campaign group on a social media website; a blend (http://www.oxforddictionaries.com/definition/english/blend#blend__19) of slacker and activism.*

Learn more about the Word of the Year 2014 runners-up in our image gallery (http://blog.oxforddictionaries.com/2014/11/oxford-dictionaries-word-year-2014-runners-up/).

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The Rest of the Story: Tobacco News Analysis and Commentary

...Providing the whole story behind tobacco news.

Monday, May 10, 2010

IN MY VIEW: American Lung Association Urges Thousands of Ex-Smokers to Return to Smoking

The American Lung Association (ALA), through both direct statements to consumers and through its policy statements, is urging thousands of ex-smokers in the U.S. to return to cigarette smoking.

Specifically, the Lung Association is urging ex-smokers who have quit smoking by virtue of the use of electronic cigarettes to discontinue use of those devices and return instead to regular cigarettes. While the ALA might argue that it would prefer that these ex-smokers switch from electronic cigarettes to an FDA-approved nicotine replacement therapy or other smoking cessation medication, the reality is that the vast majority of vapers, if they discontinue use of e-cigarettes, will return to cigarette smoking.

In messages received by several vapers who questioned the ALA's support for a ban on electronic cigarettes, the American Lung Association states: "Until the U.S. Food and Drug Administration (FDA) determines that e-cigarettes are safe for consumers, the American Lung Association urges consumers not to use these products."

The ALA is actively working to take electronic cigarettes off the market: "the American Lung Association urges the FDA to act immediately to halt the sale and distribution of all e-cigarettes."

At the same time, the ALA states that it "is committed to helping all Americans who want to break their addiction to nicotine."

The Rest of the Story

Baloney.

The American Lung Association is clearly not committed to helping all Americans who want to break their addiction to nicotine. Obviously, it is not committed to helping the thousands

Michael Siegel

Dr. Siegel is a Professor in the Department of Community Health Sciences, Boston University School of Public Health. He has 25 years of experience in the field of tobacco control. He previously spent two years working at the Office on Smoking and Health at CDC, where he conducted research on secondhand smoke and cigarette advertising. He has published nearly 70 papers related to tobacco. He testified in the landmark Engle lawsuit against the tobacco companies, which resulted in an unprecedented $145 billion verdict against the industry. He teaches social and behavioral sciences, mass communication and public health, and public health advocacy in the Masters of Public Health program.

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of Americans who have successfully broken their smoking addiction by switching from smoking to the use of electronic cigarettes. In fact, it wants those vapers to return to cigarette smoking, rather than using a product which the FDA has not approved, but which is clearly much safer than smoking.

In fact, the American Lung Association's position is that it is better for a vaper to return to smoking than to continue to remain tobacco-free by virtue of using electronic cigarettes. Thus, the American Lung Association's actual position is that it supports smoking cessation, but only if the smoker quits by virtue of pharmaceutical products, not if the smoker quits using electronic cigarettes.

Perhaps the ALA's position is not surprising given the tremendous amount of pharmaceutical company support that it receives. In the second quarter of 2009 alone, the American Lung Association received more than $1.5 million from Pfizer, manufacturer of Chantix and Nicotrol. Moreover, Pfizer is a sponsor of the Lung Association's Freedom from Smoking program.

The financial connection is so strong that the American Lung Association goes so far as to promote Pfizer on its web site, boasting that: "Founded in 1849, Pfizer is the world's premier biopharmaceutical company taking new approaches to better health. We discover, develop, manufacture and deliver quality, safe and effective prescription medicines to treat and help prevent disease for both people and animals. We also partner with healthcare providers, governments and local communities around the world to expand access to our medicines and to provide better quality health care and health system support. At Pfizer, colleagues in more than 90 countries work every day to help people stay happier and healthier longer and to reduce the human and economic burden of disease worldwide."

In other words, the American Lung Association is allowing Pfizer to gain a huge public relations benefit out of its financial support. It is truly a partnership, not merely a charitable contribution from Pfizer. Clearly, the ALA has become beholden to Pfizer by virtue of the money it has received. No wonder the ALA finds it such a threat that thousands of smokers are quitting by virtue of a product that is not produced by Big Pharma. Electronic cigarettes are a real threat to Pfizer's profits.

Of course, no where on the site does it mention that Chantix has been linked to many serious and even fatal side effects.

Moreover, no where on its web page where it calls for the removal of electronic cigarettes from the market does the American Lung Association disclose that it has a financial conflict of interest by virtue of its receiving millions of dollars of support from Big Pharma. I view that as an unethical failure to disclose a relevant conflict of interest. Furthermore, the American Lung Association even mentions its Freedom from Smoking program on that web

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page, but fails to disclose Pfizer's financial support.

In an excellent blog post over at "*The Truth about Nicotine*," VocalEK explains: "I could understand the ALA taking the stance, “Until more is known, the American Lung Association cannot recommend the products.” However, in view of the known negative health consequences of inhaling smoke, it seems unethical to urge consumers not to use the products."

I think this is a critical point. If the American Lung Association had merely stated that it couldn't recommend electronic cigarettes, that would be one thing. But to actively encourage vapers not to use these products is tantamount to urging them to return to active smoking.

Kristin Noll-Marsh also has an excellent blog post in which she criticizes the American Lung Association for failing to recognize that switching to electronic cigarettes **is** quitting smoking and argues that the ALA is doing public health harm through its position and statements.

The rest of the story is that: (1) the American Lung Association is acting unethically in failing to disclose its financial conflict of interest with Big Pharma in its public statements lobbying for the prohibition of the sale of electronic cigarettes in the United States; and (2) the American Lung Association is no longer fighting for the best interests of the lung health of Americans; it is, instead, fighting for the financial health of the nation's pharmaceutical companies, especially those companies which provide funding to the Lung Association.

Posted by Michael Siegel at 7:35 AM 0 Comments

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Tobacco Stocks: Time to Kick the Habit?

By Lori Rothman / Published December 02, 2014 / FOXBusiness


Lori Rothman

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The centers for disease control just released a study that found fewer Americans than ever before are smoking cigarettes. The findings should be unsurprising to big tobacco companies which have been dealing with falling demand for their key product for years already. Industry analysts say U.S. cigarette sales are off around four percent this year.

So, it's quite impressive that big tobacco stocks are up 25% or more year to date and largely outperforming the broader market. Tobacco stocks also pay a handsome dividend.

Altria group (MO) pays out 4%!

How are they doing it? And can the run continue?

First, the bullish case. Asian sales are on fire. The World Health Organization reports that of China's 1.3 billion population, more than 300 million already smoke.

RELATED STOCKS

LO	63.25	
LORILLARD IN...		+0.23
CVS	91.44	
CVS CAREMARK...		+1.33
RAI	65.44	
REYNOLDS AME...		-0.23
MO	50.35	
ALTRIA GROUP...		+0.36

What's more, the industry is consolidating. Lorillard (**LO**), maker of Newport Menthols, and Reynolds American (**RAI**), maker of Camel, Pall Mall, and Natural American Spirit, announced in July a $27 billion plan to combine. The deal will allow them to streamline costs, shed assets, and ultimately boost the bottom line.

Another bright spot for big tobacco are e-cigarettes which are catching on and turning out to be a good source of revenue. Sales of e-cigs surpassed $1 billion last year and are expected to at least double this year. As part of the Lorillard/Reynolds American deal, Lorillard will divest its Blu e-cigarettes brand so that the new company can focus on Reynolds' brand called Vuse. The jury still out, however, whether 'vaping,' or sucking on a plastic device that heats nicotine is significantly more healthy than inhaling carcinogen-filled smoke. And as of right now, e-cigarette sales are still only a fraction of the $80 billion in annual U.S. tobacco sales.

The big picture here is that more people are quitting tobacco or refusing to ever start. Governments, including Chinese lawmakers, are cracking down on smokers, charging high taxes and limiting public smoking areas. Even retailers are pulling tobacco products off of store shelves. The CVS (**CVS**) drugstore chain was the first to do this in the U.S. and even though reported a decline in so-called 'front of store sales,' still reported better than expected revenue the first quarter since introducing the policy. Will others retails follow CVS?

It's likely.

There are also concerns that big tobacco stocks are expensive relative to the broader market. The price to earnings ratio – a measure of stock valuation – for both Reynolds American and Altria group are a couple of points above the S&P 500.

So, keep an eye on big tobacco. These are transitional times. It'll be fascinating to see if and how these classic sin stocks can filter in a new spark of business.

Lori Rothman joined FOX Business Network (FBN) in September 2010 as an anchor.

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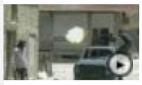

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Want to help smokers quit? Stop lying about e-cigs

GILBERT ROSS • | DECEMBER 11, 2014 | 5:00 AM

America's public health establishment, including big nonprofit organizations and many academics, is playing a shameful role in fighting our nation's most important health scourge: cigarette smoking. Without exception, our health leaders have proven reluctant to help smokers quit; although three-quarters of smokers wish to do so, only one in twenty succeed in any given year.

The reasons for the officials' dereliction in this area include a stubborn adherence to a worldview mired in the 20th century "tobacco wars." But more important is their inexcusable willful blindness to, or complicity with, the intentional manipulation of science.

The CDC trumpeted the recently-reported decline in smoking rate to 17.8 percent — a barely perceptible reduction from last year's figure. But behind this self-congratulatory façade stands the unpleasant reality: The number of American smokers stands at 42 million, about the same number as a decade ago. Worse, the latest estimates are that almost a half million of us die every year from smoking-related diseases.

While the official agencies urge smokers to use the FDA-approved methods to help them quit, they neglect to inform them that these methods — gums, nicotine patches, drugs —are not terribly effective. They actually warn smokers who want to quit against trying reduced-harm nicotine delivery devices such as e-cigarettes and vapor products ("e-cigs"). They go out of their way to alarm desperate smokers about hypothetical concerns — and their scare tactics work. More smokers are now fearful of trying these products than last year. Media comments by officials of the CDC and the big nonprofits (American Lung Association, American Cancer Society, among others) imply that the nascent, innovative e-cig industry is merely a ploy by "Big Tobacco" to lure young people into nicotine addiction.

Such assertions are mere propaganda, as their spokesmen well know. Rather than being pawns of tobacco companies, the harm-reduction "industry" consists of thousands of small businesses. Further, recent surveys — including the CDC's own— indicate that e-cigs are actually helping young smokers quit their deadly addiction by "vaping" (the term for using e-cigs) — just as their elders are doing. "Experts" based at academic centers, including especially the University of California-San Francisco, as well as highly-placed CDC officials, are widely quoted opposing the uptake of e-cigs, although millions of smokers have at last escaped their cigarette addiction by vaping.

While the long-term effects of e-cigs are unproven now, numerous published studies show that their efficacy in helping smokers quit is at least equal to the FDA-approved products, with fewer adverse effects. Those data are consistent with common sense, as e-cigs deliver only nicotine, water and a mist of safe humectants and (if preferred) flavors, as compared with the hundreds of toxins and carcinogens in cigarette smoke.

How can the drumbeat of official opprobrium directed against these miraculous, lifesaving devices be explained? One possibility: greed. The “Big Pharma” companies that market ineffective but highly lucrative nicotine-replacements are very generous donors to the same public health groups whose minions travel around the country regaling regulators and legislators to ban e-cigs. While their rationale (“protecting our children”) sounds believable to the media and politicians, in fact their agendas are antithetical to public health. They never disclose their conflicts of interest involving millions of dollars of pharmaceutical company funding, believing themselves exempt from such ethical dicta.

This unethical breach of public trust will crush the burgeoning, decentralized e-cig “industry.” It will effectively protect cigarette markets (whose excise taxes prop up many state and local budgets), and, lest we forget, it will keep smokers smoking. These officials know that addiction will eventually kill over one-half of smokers, and sicken twenty-fold that number. Isn’t it time that smokers and the public heard the truth?

Gilbert Ross, M.D., is the medical director and acting president of The American Council on Science and Health, a public health nonprofit. ACSH accepts no-strings-attached funding from many corporations, trade associations and individual donors. A small portion of ACSH's funding comes from e-cigarette makers. Thinking of submitting an op-ed to the Washington Examiner? Be sure to read our guidelines on submissions for editorials, available at this link.

A 15 YEAR TIMELINE

20 MINUTES
after quitting

The heart rate and blood pressure drop back to normal levels.

12 HOURS
after quitting

The level of carbon monoxide in the blood drops to normal.

2 WEEKS
after quitting

Circulation and lung function improve.

1-9 WEEKS
after quitting

Smoker "norms" (like a constant cough and shortness of breath) become less pronounced. The tiny

1 YEAR
after quitting

The risk of getting coronary heart disease is half as high as a smoker's.

5 YEARS
after quitting

The risk of contracting mouth, throat, esophagus, and bladder cancers is half of what it is for smokers. Risk of cervical cancer and stroke fall, too.

10 YEARS
after quitting

The risk of dying from lung cancer is half that of smokers'. Risk of getting pancreatic and larynx cancer also decreases.

15 YEARS
after quitting

The risk of heart disease is equivalent to non-smokers' risk.

The outlook for tobacco bonds is so dire that a forecast last month from Moody's Investors Service
percent were headed toward default.

ALREADY AT RISK

Tobacco bond analysts have blamed the decline in consumption of cigarettes on public smoking ba
taxes, until now.

Last year, cigarette shipments dropped by 4.9 percent, the biggest decline since the government pas
tax in 2009, a drop some blame on the rising popularity of the industry's new tobacco-free alterna
cigarettes.

"The only cause I can attribute it to is e-cigarettes," said Alan Schankel, managing director of Janne
Fixed Income Strategy team. "I think they are having an impact."

In 2013, Americans purchased 13.3 billion packs of cigarettes and 400,000 equivalent packs of e-cig
billion packs of cigarettes and 200,000 equivalent e-cigarettes in 2012.

Wells Fargo Securities predicts the pace at which consumers switch from traditional cigarettes to e
will surge in the coming years. It estimates that sales volumes for traditional cigarettes in the U.S.
percent over the next 10 years, while vapor cigarette sales will soar by more than 13-fold in the

The shift in consumer preference and the non-inclusion of e-cigarettes in the MSA "creates an ince
manufacturers to encourage their consumers to switch to vapor products," wrote Wells'

For Eaton Vance's Metzold, the recent takeover buzz in the industry confirms to him that e-cigaret
companies see their future, at least in the U.S market.

"Here's your catalyst," said Metzold, who sold all of his tobacco bonds more than a year ago. "Tobac
buying the e-cigarette companies."

Lorillard acquired blu for $135 million in 2012, and also bought the UK e-cigarette brand SKYCIG
Reynolds began distributing Vuse e-cigarettes in June and the No.1 U.S. tobacco company, Altria Gr
to roll out its e-cig brand MarkTen nationally.

NOT EVERYONE'S A BELIEVER

Still, not everyone is convinced about the e-cigarettes boom and the likelihood of early default

"E-cigarettes are not a real replacement. They are another tool for people to quit smoking, but they a
To me, it's a fad," said Dick Larkin, senior vice president and director of Credit Analysis, himself a sm
are a threat to the MSA, but I don't think they are a material threat."

And the bonds are enticing for some, largely because they're so cheap and offer juicy yields at a time
return in the fixed income market are relatively scarce.

Boston-based investment firm Loomis Sayles bought tobacco bonds several years ago when they w
discounts.

"I don't think you can say with 100 percent certainty that e-cigarettes will supplant normal cigarettes
even know that?" said Steven Bocamazo, credit research manager and senior research analyst at Lo
have a small market share and, while growing, it isn't the big threat that everyone is making i

Tobacco-settlement debt currently counts among the highest-yielding in the municipal bon

The Standard & Poor's Municipal Bond Tobacco Index sports an average yield to maturity of 6.24 pe
billion of bonds it tracks. By comparison, S&P's index for general obligation muni bonds has a yield

But, even with a rally underway this year - the S&P tobacco bond index is up more than 13 percent -
trade at distressed levels, reflecting their perceived default risk. Moody's rates around 80 percent of
at "B1" - which is four notches below investment grade - or lower.

"There are fund groups like ourselves, that said, 'We don't like what is going on here, we're getting c

SOME STATES SOFTEN THE BLOW

The softening revenue flowing to the bonds from weakening consumption trends has prompted son to support the bonds.

Earlier this month, New Jersey announced it would draw $12.5 million from reserves as a result of "i settlement revenues" in April. Ohio and Virginia made similar announcements in Ma

To further bolster payments, some Democrats in Congress want to fold e-cigarettes into the MSA, ar gives states "a powerful tool to stop e-cigarette makers from targeting youth." (Link: http://1.usa

But many states haven't spent the $100 billion received so far in tobacco settlement money on its cover healthcare costs generated by smoking. Only 14.6 percent of the funding generated by tobac state taxes are spent on causes recommended by the Centers for Disease Control and Prevention, Tobacco-Free Kids found.

Instead, states like New Jersey, New York and New Mexico have used some of the money to prop revenues or to service debt, among other things, according to the public policy group, State Buc

Among state policy makers, the rise of e-cigarettes has caught the eyes of some but has not yet reg concern.

Spokespersons for California's Department of Finance and New Jersey's Treasury Department said th the growth of e-cigarettes and both agreed it was "premature" to forecast how the new product woul payments.

Kurt Kauffman, debt manager for the State of Ohio, said the state hadn't "reached the point of concer to tap up to $31.5 million from a reserve account to cover a tobacco bond payment this year. "It's son attention to and have an interest in following," said Kauffman.

Story First Published: June 24, 2014 10:41 IST

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S
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Morris, Erin

From: Regalia, Chuck
Sent: Friday, December 12, 2014 12:53 PM
To: Morris, Erin
Subject: FW: proposed smoking ordinance update

Erin
FYI

Chuck Regalia | Assistant City Manager |
Community Development Department |100 Santa Rosa Avenue | Santa Rosa, CA 95403
Tel. (707) 543-3189 | Fax (707) 543-3269 | cregalia@srcity.org

City of Santa Rosa

From: Sheppard, Suzanne
Sent: Friday, December 12, 2014 12:09 PM
To: McGlynn, Sean; Fowler, Caroline; Regalia, Chuck
Subject: Fwd: proposed smoking ordinance update

Fyi.....this came in to Council.

-------- Original Message --------
Subject: proposed smoking ordinance update
From: Richard Comfort <rcomfort8608@gmail.com>
Sent: 10:57am, Friday, December 12, 2014
To: _CityCouncilListPublic <citycouncil@srcity.org>
CC:

Since the membership of the Council has changed since my email of September 29 on this subject, I would like to call your attention to my letter. Unlike much of the correspondence on this matter it is not a special pleading for ecigs or whatever, but takes up basic issues. I would like to stress that I strongly believe that the Council should not rush to a vote on this matter. Vital City interests are at stake, and much of the research on the subject of second-hand smoke is very complex and subject to various interpretations. In December of 2013, for example, *Forbes* magazine published an article about a huge study of second-hand smoke by the National Cancer Institute which concluded that "A large-scale study found no clear link between secondhand smoke and lung cancer…."

I would urge the Council to provide for ample opportunity for the Council members to study the research themselves rather than accepting staff interpretations as is.

My primary concerns are: timing, enforcement, cost, and less disruptive solutions to the problem.

_____
"*Intelligence is the ability to adapt to change."* Stephen Hawking
_____

Richard Comfort, PhD
Intelligent Indexing
Santa Rosa, CA
707-540-0094
mailto:rcomfort8608@gmail.com
For information concerning my services, please visit my website: comfortindexing.com